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Health Practitioner Regulation Systems

A large-scale rapid review of the design, operation and strengthening of health practitioner regulation systems

RCPS
Réseau canadien des personnels de santé

CHWN
Canadian Health Workforce Network

Health Practitioner Regulation Systems

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Executive Summary

Health systems worldwide face considerable challenges in recruiting, training, distributing and retaining a sufficiently skilled and competent workforce when and where it is needed. Brought into sharp focus by the COVID-19 pandemic, these challenges are compounded by the myriad of changes to health systems and workforces – increasing volume and privatization of health practitioner education; accelerating health workforce international mobility and cross-border service delivery; more team-based models of care; and the growing importance of unregulated health workers, such as in community support and traditional and complementary medicine (T&CM).

In response to these complex demands, some governments have reformed health practitioner regulation (HPR) systems to better serve the public interest.[8,47,118,119,128,189] Strengthening the way health practitioners are regulated can help to assure the safety and effectiveness of the health workforce and foster the flexibility and innovation needed to better meet population needs. There is increasing recognition that HPR systems have an essential role to play in supporting health workforce availability, accessibility, acceptability, quality, and sustainability that is fundamental to achieving Universal Health Coverage (UHC) and the Sustainable Development Goals (SDGs).[541,541] HPR can optimize the capability of the existing health workforce and assist in better aligning health workforce investments with health system needs.[128,189,541]

There are significant gaps in our knowledge about leading HPR policy and practice, such as which regulatory models, institutional governance and core regulatory functions work best in different contexts, particularly in low and lower-middle income economies (LMIEs).

This large-scale rapid review examines the diversity of regulatory principles, elements, and approaches to developing, implementing, and strengthening HPR. The aim is to identify the evidence base around HPR design and delivery, to help governments, regulators and other stakeholders better achieve health workforce and health system goals. The World Health Organization (WHO) commissioned this review to assist in the preparation of new global guidance on HPR.

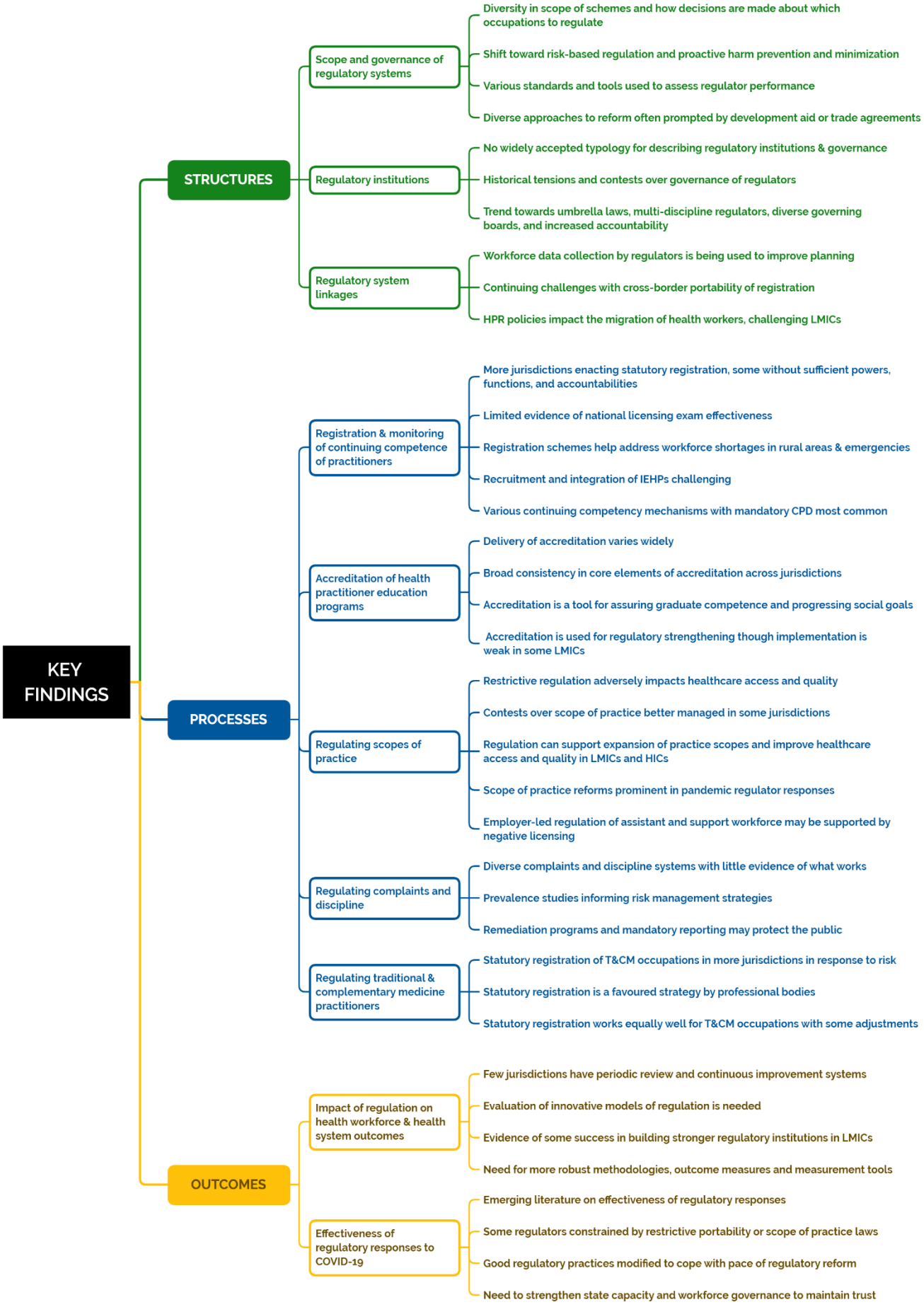
We addressed the overarching review question: *What key considerations, common principles, and core elements (models, approaches, tools) assist jurisdictions to design and deliver more effective health practitioner regulatory systems, to improve the safety, quality, quantity, capability, and effectiveness of their health workforces and achieve health system goals?*

We used rapid review methods for this large-scale systematic review because they are an efficient way of synthesizing evidence to strengthen health policy-making and health systems, by providing high-quality evidence in a timely and cost-effective manner.[514] Our research

team collaborated with the WHO and its HPR Technical Expert Group to guide the systematic search strategy and selection criteria. We also worked with an experienced health services librarian and drew on the backgrounds of team members with expertise in health policy, sociology, economics, law and public health.

A total of **410** articles published, between 2010 and 2021, and **426** sources of grey literature were selected for inclusion. These sources were reviewed and information was extracted about occupational groups, regulatory interventions, country context and outcomes. Data extraction was based on a predetermined set of general topics, organized according to the structures, processes and outcomes of HPR. Data were also extracted from the registration laws and websites of regulatory authorities in a sample of jurisdictions, on key elements of HPR schemes, their governance and functions. Key findings are summarized in the chart below with key themes described in more detail below, under the headings structures, processes and outcomes.

In terms of data sources, most of the available evidence referred to the United States, multi-jurisdiction or international studies, followed by Australia, Canada and the United Kingdom, with publications on nurses, midwives (including in advanced practice nursing roles) and medical personnel dominating over other health practitioners.


KEY FINDINGS
STRUCTURES
Scope and governance of regulatory systems
Diversity in scope of schemes and how decisions are made about which occupations to regulate
Shift toward risk-based regulation and proactive harm prevention and minimization
Various standards and tools used to assess regulator performance
Diverse approaches to reform often prompted by development aid or trade agreements
Regulatory institutions
No widely accepted typology for describing regulatory institutions & governance
Historical tensions and contests over governance of regulators
Trend towards umbrella laws, multi-discipline regulators, diverse governing boards, and increased accountability
Regulatory system linkages
Workforce data collection by regulators is being used to improve planning
Continuing challenges with cross-border portability of registration
HPR policies impact the migration of health workers, challenging LMICs
PROCESSES
Registration & monitoring of continuing competence of practitioners
More jurisdictions enacting statutory registration, some without sufficient powers, functions, and accountabilities
Limited evidence of national licensing exam effectiveness
Registration schemes help address workforce shortages in rural areas & emergencies
Recruitment and integration of IEHPs challenging
Various continuing competency mechanisms with mandatory CPD most common
Accreditation of health practitioner education programs
Delivery of accreditation varies widely
Broad consistency in core elements of accreditation across jurisdictions
Accreditation is a tool for assuring graduate competence and progressing social goals
Accreditation is used for regulatory strengthening though implementation is weak in some LMICs
Regulating scopes of practice
Restrictive regulation adversely impacts healthcare access and quality
Contests over scope of practice better managed in some jurisdictions
Regulation can support expansion of practice scopes and improve healthcare access and quality in LMICs and HICs
Scope of practice reforms prominent in pandemic regulator responses
Employer-led regulation of assistant and support workforce may be supported by negative licensing
Regulating complaints and discipline
Diverse complaints and discipline systems with little evidence of what works
Prevalence studies informing risk management strategies
Remediation programs and mandatory reporting may protect the public
Regulating traditional & complementary medicine practitioners
Statutory registration of T&CM occupations in more jurisdictions in response to risk
Statutory registration is a favoured strategy by professional bodies
Statutory registration works equally well for T&CM occupations with some adjustments
OUTCOMES
Impact of regulation on health workforce & health system outcomes
Few jurisdictions have periodic review and continuous improvement systems
Evaluation of innovative models of regulation is needed
Evidence of some success in building stronger regulatory institutions in LMICs
Need for more robust methodologies, outcome measures and measurement tools
Effectiveness of regulatory responses to COVID-19
Emerging literature on effectiveness of regulatory responses
Some regulators constrained by restrictive portability or scope of practice laws
Good regulatory practices modified to cope with pace of regulatory reform
Need to strengthen state capacity and workforce governance to maintain trust

STRUCTURES

Scope and governance of regulatory systems

Four themes were identified from the integrated synthesis of 134 published articles and 203 grey literature sources on this topic:

- First, there is diversity in the purpose, scope and features of regulatory systems and how decisions are made about which health occupations should be regulated.
- Second, the principles and tools of risk-based regulation adopted by some regulators signal a shift to more proactive strategies for harm prevention and minimization.
- Third, various generic and HPR-specific standards and tools are being used to assess HPR performance, with some adaptable for use in lower-resource environments.
- Fourth, there are diverse approaches to regulatory reform, with new regulation or regulatory strengthening activities in LMIEs, sometimes prompted by development aid or mutual recognition agreements.

Regulatory institutions

Three themes were identified from the integrated synthesis of 42 published articles and 64 grey literature sources on this topic:

- First, there is no widely accepted typology for describing HPR institutional and governance arrangements.
- Second, the historically contested nature of HPR governance continues to play out in tension over the 'profession-led' governance model and increasing government oversight and control of regulators.
- Third, HPR governance reforms show a trend toward umbrella laws and multi-profession regulators, more diverse governing board membership and increasing accountability.

Regulatory system linkages

Three themes were identified from the integrated synthesis of 110 published articles and 83 grey literature sources on this topic:

- First, routine collection by regulators of comprehensive and robust workforce data is being used to improve health workforce planning, development, supply and distribution.
- Second, despite continuing efforts for harmonization and mutual recognition, challenges remain with cross-border recognition of qualifications and portability of registration.
- Third, HPR policies impact the migration of health workers, with little evidence the WHO Global Code of Practice is protecting LMIEs from outward migration of healthcare workers.

PROCESSES

Registration and monitoring of continuing competence of practitioners

Five themes were identified from the integrated synthesis of 132 published articles and 73 grey literature sources on this topic:

- First, while there are signs of regulatory convergence as more jurisdictions establish statutory registration schemes, some schemes lack a comprehensive set of registration powers, functions, and accountabilities.
- Second, there is limited evidence of the effectiveness of the national licensing examination (NLEs) for assuring graduate capability and the complexities of running a robust and reliable NLE can be underestimated.
- Third, statutory registration schemes can assist governments to address workforce shortages in rural areas and during emergencies.
- Fourth, the recruitment and integration of internationally educated health practitioners into a workforce presents particular challenges, with some evidence of effective integration programs.
- Fifth, while regulator mandated continuing professional development (CPD) is common and can be effective, various continuing competency mechanisms are found in high income countries (HICs), with limited evidence of comparative effectiveness.

Accreditation of health practitioner education (HPE) programs

Four themes were identified from the integrated synthesis of 35 published articles and 43 grey literature sources on this topic:

- First, arrangements for delivering HPE accreditation for entry-to-practice education programs vary widely across jurisdictions and occupational groups.
- Second, despite the diversity in governance, core elements of HPE accreditation appear broadly consistent across jurisdictions and there is a growing presence of international accreditation agencies and standards.
- Third, while there is limited evidence of the effectiveness of HPE accreditation, it is considered an important tool for assuring graduate competence for entry to practice while also progressing broader social goals.
- Fourth, HPE accreditation is a focus for regulatory strengthening, although implementation is weak in some LMIEs.

Regulation of scopes of practice

Five themes were identified from the integrated synthesis of 119 published articles and 57 grey literature documents on this topic:

- First, restrictive and unresponsive scope of practice regulation inhibits workforce reform and adversely impacts healthcare access and quality.

- Second, conflicts over scope of practice reflect the tensions and competing interests between and within health occupations and some jurisdictions manage these better than others to secure reform.
- Third, using HPR to support expanded scopes of practice, such as the use of restricted medicines, is improving healthcare access and quality in both LMIEs and HIEs.
- Fourth, scope of practice reform has been a prominent strategy in the pandemic responses of HIEs to facilitate a surge workforce.
- Fifth, with increasing reliance on unregistered assistant and support workers, quality assurance of this workforce relies primarily on employer measures, although negative licensing provides an additional layer of public protection in some jurisdictions, particularly for self-employed practitioners.

Regulation of complaints and discipline

Three themes were identified from the integrated synthesis of 67 published articles and 72 grey literature sources on this topic:

- First, there is considerable diversity in the regulatory powers, governance and processes for managing complaints and discipline, but little evidence on how best to design and deliver effective systems.
- Second, regulators in some HICs are designing risk management and prevention strategies, informed by studies of prevalence rates for disciplinary action.
- Third, remediation programs for impaired and poorly performing practitioners and mandatory reporting obligations may be effective public protection mechanisms, albeit with resourcing and implementation challenges.

Regulation of traditional and complementary medicine practitioners

Three themes were identified from the integrated synthesis of 56 published articles and 35 grey literature sources on this topic:

- First, statutory registration is being extended to more T&CM professions in more jurisdictions, in response to evidence of risk.
- Second, statutory registration is a favored strategy of many T&CM professional bodies to prevent entry of untrained practitioners, foster collaborative practice, and promote integration into the mainstream healthcare system.
- Third, studies suggest statutory registration works equally well for established and widely practiced T&CM professions, with some adjustments.

OUTCOMES

Impacts of regulation on health workforce and health system outcomes

Four themes were identified from the integrated synthesis of 310 empirical studies in the published literature and 104 grey literature sources on this topic.

- First, few jurisdictions have institutionalized arrangements for periodic review and continuous improvement of their HPR systems.
- Second, further evaluation is needed of alternative models for regulating the health workforce, such as negative licensing and quality assured voluntary registers.
- Third, regulatory strengthening initiatives in LMIEs aim to build stronger regulatory institutions, infrastructure, networks and governance, with some evidence of success.
- Fourth, studies that compare regulatory regimes across multiple jurisdictions were mostly descriptive, underscoring the need for more robust outcome measures and measurement tools.

Effectiveness of regulatory responses to the COVID-19 pandemic

Four themes were identified from the integrated synthesis of 12 published articles and 58 grey literature sources on this topic:

- First, there is an emerging understanding about the effectiveness of the pandemic responses of regulators, the actions taken, and the lessons learned.
- Second, regulatory restrictions on practitioner scopes of practice and portability of licensure have in some jurisdictions constrained the ability of regulators to respond quickly and flexibly.
- Third, some jurisdictions have endeavored to maintain good regulatory practice by making modifications to regulatory policy and regulatory assessment processes.
- Fourth, concepts of trust, resilience and innovation feature in the literature as does the need to strengthen state capacity, including in health workforce governance.

Key Lessons Learned

- Certain governance trends such as multi-occupation regulators or umbrella laws were evident, but the lack of standardized typology complicates comparison of these governance arrangements across jurisdictions and occupations.
- Most studies in this review focused on statutory registration schemes and evidence suggested this model of HPR is increasingly being enacted across various jurisdictions and practitioner groups.
- HPR generally has not kept pace with the demands for greater flexibility arising from collaborative team-based practice and a more dynamic division of labor in healthcare. Evidence in this review supports the need for a change in the way scopes of practice are regulated in some jurisdictions. The imperatives created by the COVID-19 pandemic have demonstrated how quickly scope of practice reforms can be implemented.
- There was some evidence that the health workforce functions of government are more effective when HPR is used to support strategies for workforce planning, development, supply and distribution, particularly to address areas of workforce shortage.
- The evidence suggests that widespread barriers impact the mobility of practitioners.
- Evidence supports the impact of outcomes based CPD models on continuing competence to practice and patient safety.
- There is considerable scope to use the tools of HPR to better support the achievement of broader social objectives such as reducing inequality and increasing diversity.

Key evidence gaps for future research

- There is less published literature on HPR structures, processes, and outcomes in LMIEs. Evaluations should focus on identifying the highest impact HPR structures and processes and viable alternatives to statutory registration schemes, particularly for lower risk occupational groups.
- There is also a lack of evidence on how HPR systems impact the safety, quality, capability, effectiveness, and sustainability of health systems and workforces. Different institutional and governance arrangements should be evaluated against a standardized framework to enable stronger cross-jurisdictional comparisons of HPR performance, since most comparative studies identified in this review were largely descriptive.
- Knowledge gaps remain around the relative benefits of NLEs and HPE accreditation in assuring the quality of the health workforce.
- The COVID-19 pandemic has highlighted the importance of agile HPR processes and effective linkages between HPR and other regulators, systems and stakeholders. Further research in this area would help evaluate HPR reforms and innovations to determine which changes should be maintained long-term and which would be most beneficial for future crises.

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- *Alan Rassaby* assisted with the comparative analysis of country regulatory regimes, by mapping the regulatory arrangements in the Czech Republic, assisted with screening of the published literature and commented on draft chapters.
- *Debra Gillick* assisted with screening and full text review of the English published literature and commented on draft chapters.
- *Angela Doolan* provided research materials on complaints and negative licensing and advice on draft chapters.
- *Robert Henning* assisted with screening and data extraction of websites for the search of grey literature.
- *Andrew Scanlon* provided assistance with screening of published literature, advice on advanced practice nursing and assisted with research for the chapter on regulation of scope of practice.
- *Amie Steel* provided advice on methodology and commented on the draft chapter on regulation of T&CM practitioners.
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1. INTRODUCTION

Health systems around the world face considerable challenges in recruiting, training, distributing and retaining a sufficiently skilled and competent workforce when and where it is needed. These challenges are compounded by the myriad of pressures due to factors such as the increasing volume and privatization of health practitioner education; accelerating international mobility and cross-border service delivery; heightened consumer expectations; the growth of integrated, team-based models of service delivery leading to the emergence of new occupations; and the growing importance of previously unregulated occupations such as in community support work and traditional and complementary medicine (T&CM).[541] The COVID-19 pandemic has brought into sharp focus questions about whether governments have sufficient legal, regulatory and policy levers required to meet these challenges.

Strengthening systems of health practitioner regulation (HPR) can help to assure not only the safety and effectiveness of the health workforce but also the flexibility needed to respond in novel ways to meet population needs. HPR systems are increasingly recognized as playing an important role in supporting health workforce availability, accessibility, acceptability, quality, and sustainability.[541] HPR can both optimize the capability of the existing health workforce and assist in better aligning health workforce investments with health system needs.[128,189]

Globally, there is substantial diversity in the structures, processes and outcomes of HPR systems.[541] HPR systems generally provide a range of functions: controlling entry to practice, defining competencies required for practice, maintaining a register of those fit to practice, ensuring entrants meet community standards, enforcing professional codes of conduct, monitoring continuing professional development, responding effectively to unfit practice in the public interest, investigating complaints, and disciplining misconduct or unauthorized practice.[541] It also involves a range of stakeholders along the career pathways of health practitioners across jurisdictions.

To address these challenges, reforms in both the structure and operation of HPR systems have been undertaken in many countries.[128,189] A common focus has been to reorient HPR to better serve the public interest in the context of complex and evolving health systems. There is a growing interest in more pluralist and inclusive governance models with greater public participation, thereby reducing the risk of capture of the regulator by vested professional interests.[47,118,119] Yet, there are many gaps in our knowledge of leading practices around HPR, such as which regulatory models and core regulatory functions work best in specific contexts, particularly in low and lower-middle income countries (LMIEs) that have limited regulatory capacity.

Goals and objectives

Commissioned by the WHO to assist in preparing for new global guidance, this review examines the diversity of regulatory principles, elements, and approaches to developing, implementing, and strengthening HPR to better achieve health workforce and health system goals. The specific objectives of this review were to:

- identify empirical evidence of the key considerations, common principles and core elements for the design, strengthening and implementation of HPR and its impact on a range of public, professional and health system outcomes;
- capture the diversity of HPR systems and respective challenges in ensuring the quality and sustainability of health workforce education and practice; and
- identify innovations in HPR including specific reforms related to the overall objectives, institutional framework, regulatory and operational mechanisms and regulatory capacity.

Conceptual frameworks

To guide this review, the research team developed a modified Donabedian[168] conceptual framework which teases apart the structures, processes and outcomes (see Figure 1).

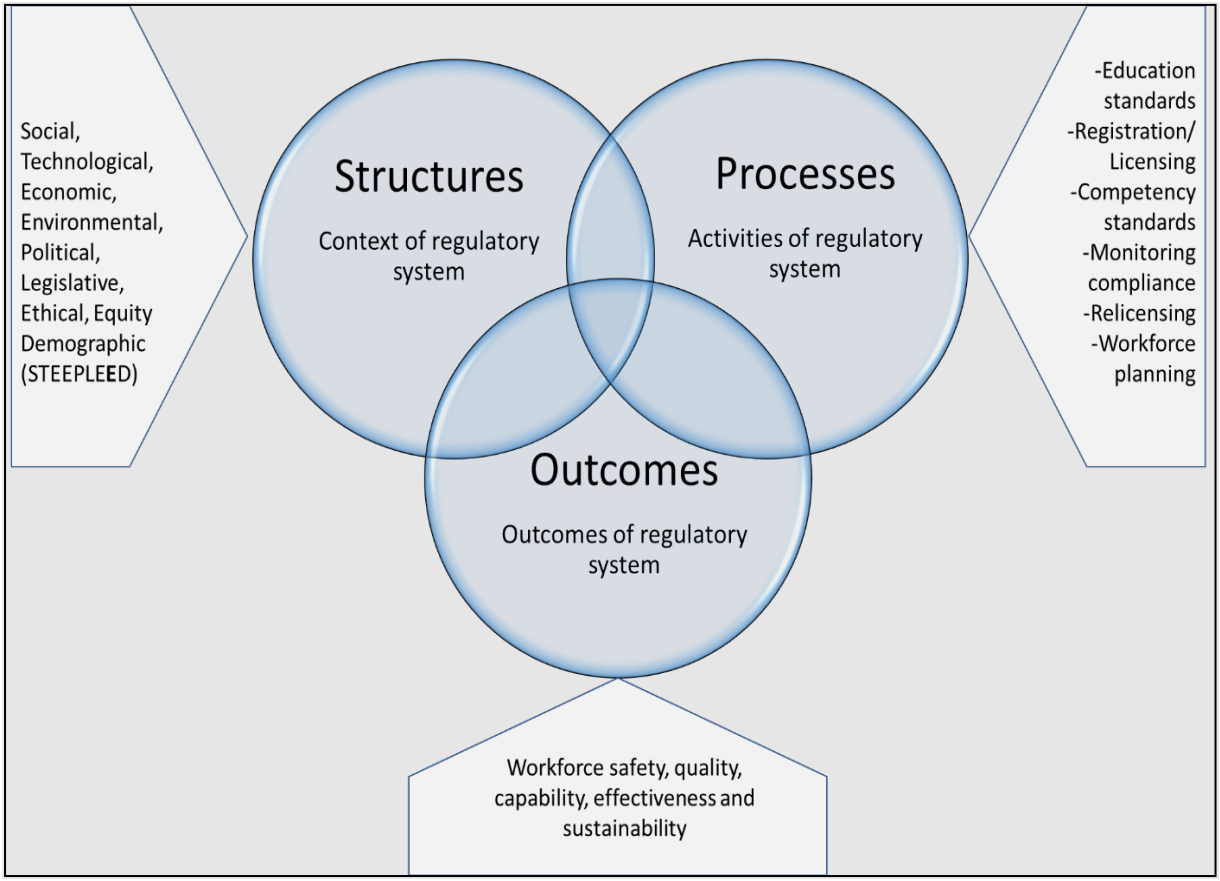


Figure 1: Modified Donabedian framework of health practitioner regulation systems

Structures represent the context of the regulatory system and include social, technological, economic, environmental, political, legislative, ethical, equity and demographic country/regional contexts (a modified STEEPLED framework adding an equity dimension). ***Processes*** include the functions and activities of the regulatory system, which may include, for example, setting qualification requirements for entry to practice, registering qualified practitioners, maintaining a publicly accessible register of practitioners, setting practice and continuing competence standards and requirements, monitoring compliance with standards, conducting fitness to practice proceedings, prosecuting offences, and supporting government health workforce planning and health system improvement. These processes are based on the analytical framework for understanding regulatory functions as set out in the WHO's *Western Pacific Regional Action Agenda on Regulatory strengthening and convergence for medicines and health workforce* (see Figure 2).[560] ***Outcomes*** encompass various parameters such as the safety, quality and effectiveness of the workforce, the efficiency and effectiveness of a regulator or regulatory system in achieving its mandate and its contribution to the achievement of broader health system goals and priorities.

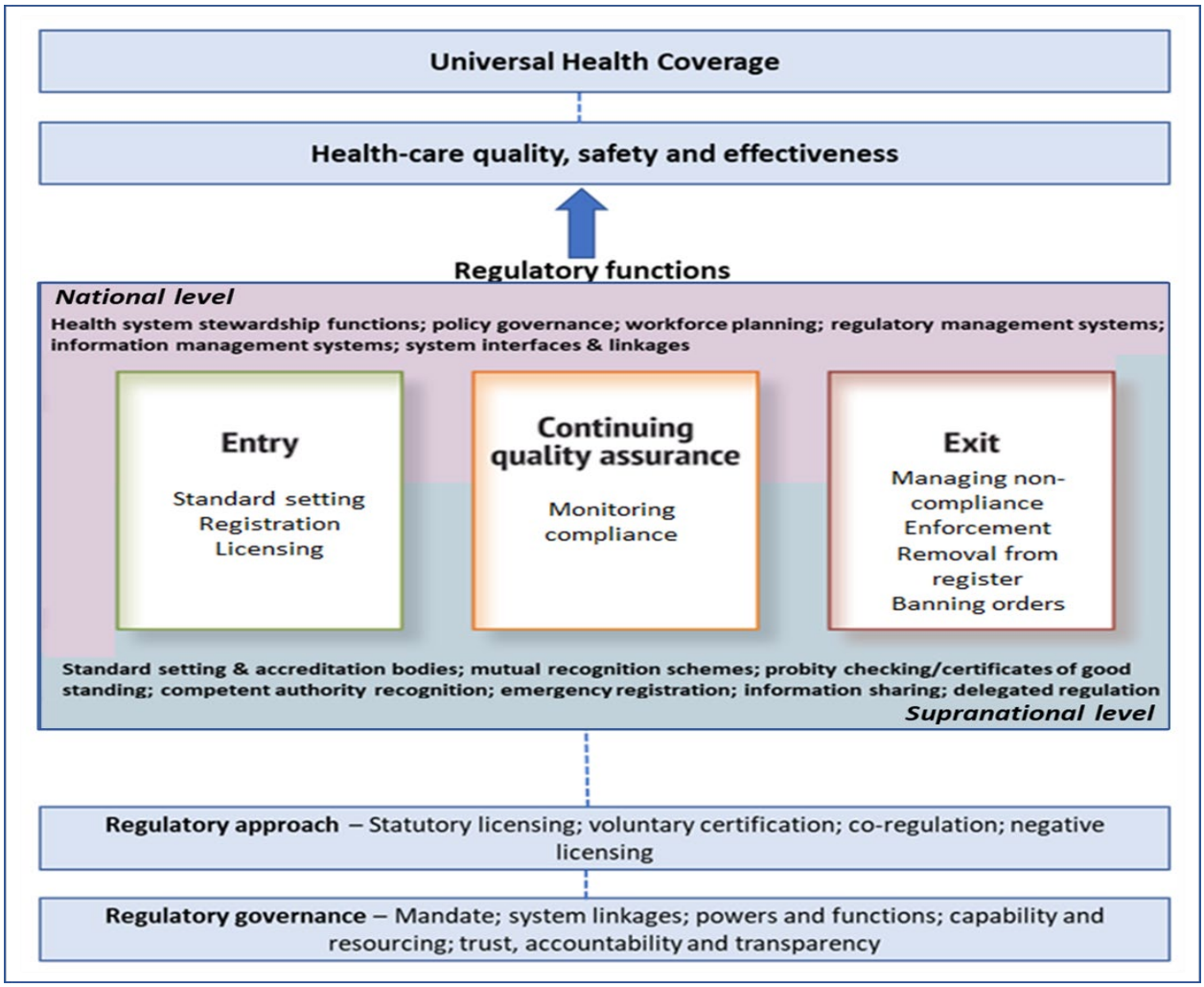


Figure 2: Analytical framework for understanding the functions of health practitioner regulatory systems (modified from WHO Western Pacific Regional Action Agenda, 2017)

2. METHODOLOGY

Review questions

This review addressed the overarching review question in Table 1. The operational questions informed the search strategy and guided the evidence synthesis across the main areas of study.

Table 1: Review and operational questions

Review question *What key considerations, common principles, and core elements (models, approaches, tools) assist jurisdictions to design and deliver more effective health practitioner regulatory systems, to improve the safety, quality, quantity, capability, and effectiveness of their health workforces and achieve health system goals?*	
Areas of study	**Operational questions**
Structural context of health practitioner regulation systems	*What contextual forces shape the design and delivery of health practitioner regulation functions and what are the key challenges faced by governments and regulators?*
Processes (functions and activities) of regulatory systems	*What are the main functions and activities of health practitioner regulation systems and what diversity of approaches, models and tools are evident in how these functions are organized and delivered?*
Outcomes of regulatory systems	*How effective are various approaches and models of health practitioner regulation in improving the safety, quality, quantity, capability, and effectiveness of the health workforce?*
Innovations in regulatory system strengthening	*What recent initiatives and innovations have been introduced to strengthen systems of health practitioner regulation, to achieve health workforce goals more effectively?*

Rapid review design

We used rapid review methods for this large-scale systematic review. Rapid reviews are an efficient way of synthesizing evidence and can strengthen health policy making and health systems by providing high-quality evidence in a timely and cost-effective manner.[514] In rapid reviews, regular components of a traditional systematic review are simplified to synthesize evidence more quickly.[513]

Applying a rapid review approach was a pragmatic choice due to the lack of common HPR terminology and the need to capture a range of evidence (both sources and types) from many disciplines and jurisdictions. The design accommodated contextual understanding and multi-

level perspectives, providing the opportunity to examine a range of evidence (both sources and types).[232,403,494] At the same time, given the breadth of the review and that over 30,000 publications were retrieved and screened for inclusion, we cannot be confident that all relevant publications have been included.

Due to the topic and the breadth of the multidisciplinary academic and grey literature reviewed, we did not conduct risk of bias or certainty of evidence assessments on the included studies – the vast majority (over 99%) of the included studies were descriptive or observational and thus would have been classified as very low or low certainty, despite the value offered by this literature. Further, the factors that can increase the certainty of evidence under GRADE (large magnitude of effect, dose-response gradient, and effect of plausible residual confounding) have little applicability when reviewing studies on HPR.

Figure 3 illustrates the integrated mixed methods review design adopted, which draws on both qualitative and quantitative evidence and accommodates literature from a range of disciplines to explain HPR at the practitioner, organizational and societal levels.[403] These approaches are appropriate for review questions that call for contextual understanding and multi-level perspectives. They provide the opportunity to combine a range of evidence arising from qualitative studies, correlation studies, economic studies, policy studies, regulatory studies and other quantitative studies.[232,403,494]

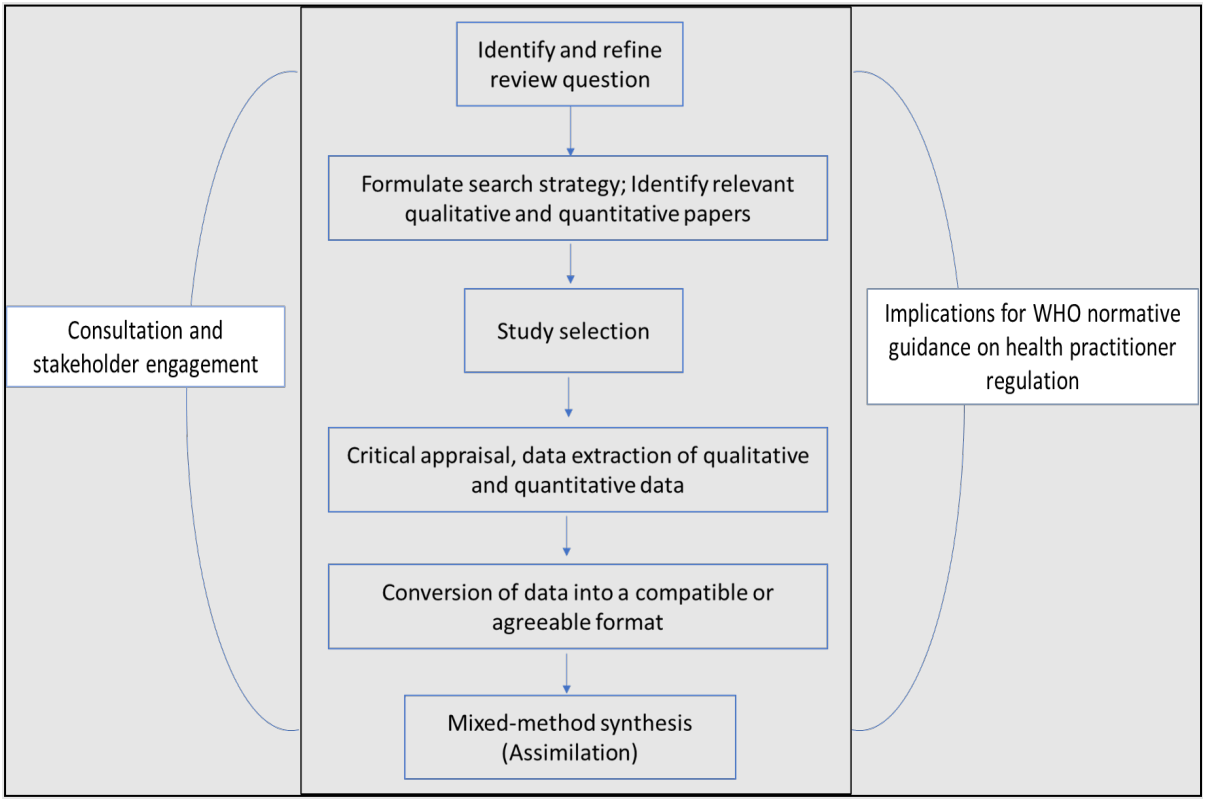


Figure 3: Modified integrated mixed methods review design

Review steps

The following steps were followed for the development of the methodology and conduct of this large-scale rapid review.

Identify and refine the review question/s

A modified PICO framework was used to determine the scope of the review and frame the operational questions – see Table 2. The framework adopts the following key elements; Population/Practitioner, Intervention/Regulatory Approach, Country/Context[a] and Outcome.[160]

Table 2: Modified PICO Framework for framing research questions

Modified PICO component	Explanation
Population	Health practitioners *(including specific classes of health practitioner, for example: medical practitioners, nurses and midwives, pharmacists, dental, allied health, traditional and complementary medicine, community health workers, epidemiologists, other registered and unregistered health workers; internationally qualified/foreign trained practitioners)*
Intervention	Approaches to health practitioner regulation *(regulatory models, powers/tools, systems – for example, self-regulation, co-regulation, statutory registration, negative licensing)*
Context	Countries/regions *(with diverse linguistic, political, social, economic and legal systems; for example common law, civil code, Islamic law, customary law, mixed or hybrid systems; basic, emerging and mature health systems)*
Outcome	Health workforce goals *(for example, safety, quality, capability, effectiveness and sustainability)*

Note: A traditional PICO framework delineates 'C' as Control, but we knew that for this review on HPR, research designs that include a control group would be highly unlikely. Thus, the research team decided to capture important contextual country information as this was deemed highly relevant.

Formulating the search strategy

An iterative three-step search strategy was employed using specific keyword searches developed in consultation with librarians and subject experts in health policy, sociology, economics, law and public health and revisited as useful search terms were discovered and employed.[404,409]

[a] A traditional PICO framework delineated C as Control, but in the case of this review, control groups will be highly unlikely.

Step 1: Initial limited search

An initial limited search was conducted in Scopus and EMBASE, followed by an analysis of text words contained in the title and abstract, and keywords/index terms used to describe the article. The use of both Scopus and EMBASE for this initial search helped to capture a range of multidisciplinary and country/region-specific databases. Search keywords were further developed based on the initial search.

Step 2: Extended search across selected multidisciplinary databases

Major academic databases searched included Medline, Embase, Web of Science, Cochrane Library, CINAHL, PsycINFO, PsychARTICLES, Scopus, Sociological Abstracts, ProQuest dissertations and theses global, Joanna Briggs Institute EBP. Hand searches were undertaken on Google and Trip clinical search engine for policies/guidelines, for keywords, titles and abstracts (Annex 1).

For legislative instruments, disciplinary cases, law reform publications and international agreements, specialist databases were searched including HeinOnline, World Legal Information Institute (WLII) and the ILO Legal Database. For a selection of countries spanning all WHO regions, national online legislation databases were searched to identify relevant extant legislation.

Step 3: Citation tracking and expert opinions

To ensure literature saturation, we employed citation tracking and forward-backward search of references in the included articles, reports, and policy documents. During the review process, the team also collaborated with WHO and the Technical Reference Group to clarify if any additional articles were missing and needed to be included.

Selection criteria

Covidence[151] review management software was employed to screen title, abstract and full texts and select published articles for extraction in duplicate with a third reviewer assessing conflicts. Lack of agreement or conflict arising in the selection of articles was resolved through group discussions.

Published articles and sources of grey literature were selected for inclusion if they described a HPR legislative instrument, regulatory system, regulator or regulatory function or intervention, or if they examined factors shaping the development, operation, or outcomes of HPR in terms of health workforce goals. Grey literature included reports from international organizations, HPR consortia, regulators and meta-regulatory bodies, and government and inter-governmental policy documents that discussed HPR systems of one or more jurisdictions. We included sources published from 2010 to 2021 in English, French, Spanish

and Portuguese. Older references (prior to 2010) identified via citation tracking or by our expert advisors were included if directly applicable to our research question.

We included both qualitative and quantitative research articles. Within the published academic literature, original research articles, narrative reviews and policy/legal/regulatory analyses were included. Commentaries, policy papers and perspectives from academic literature were included where they provided substantive content or critique of HPR related contexts, performance or reform directions. Grey literature included government reports, statutes, and policy documents, where these examined HPR systems or regulatory functions of one or more countries. See Annex 2 for the websites searched.

A separate search was undertaken of the Chinese published literature. The methods, results and thematic analysis are set out in Annex 3.

Data extraction

Data extraction from selected articles used predefined criteria either in Covidence (published literature) or Excel (grey literature). Articles obtained through other sources (citation tracking, the WHO Technical Experts Group, other advisors) were also included, subject to the same eligibility criteria.

Articles selected for full text reading and data extraction were prioritized in two steps. First, articles were classified into the following predefined topics and mapped to the structures, processes and outcomes framework – see Figure 4. Themes within these topic areas were identified and tracked.

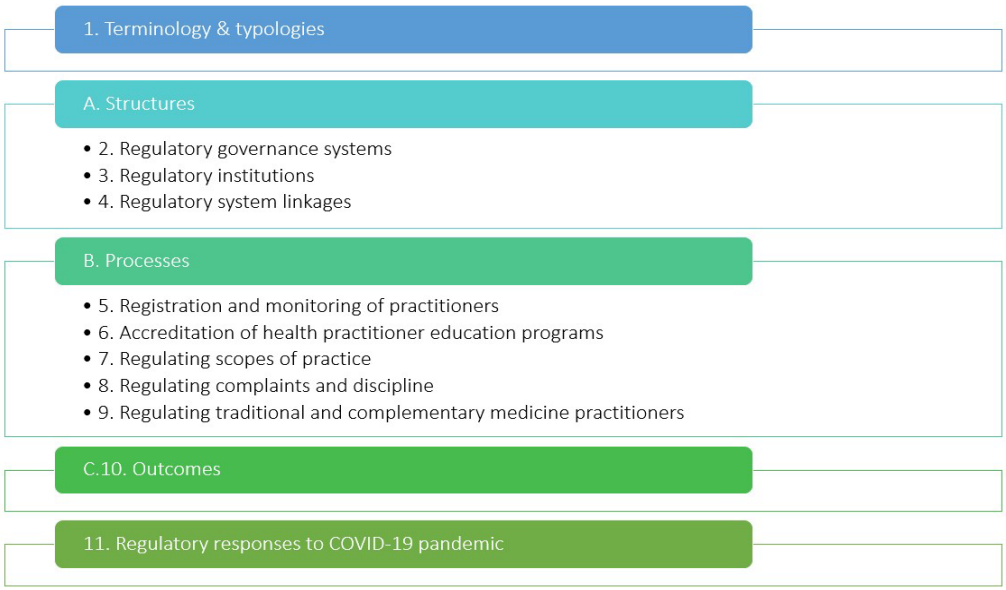


Figure 4: Topics of systematic review

Second, we prioritized for inclusion those articles that met one or more of the following criteria:

- *systematic review or scoping review or*
- *article discusses effectiveness or other 'outcomes' or*
- *key article for defining terms or regulatory models or*
- *multi-country study or*
- *comparative analysis of regulatory regimes or regulatory functions or*
- *article discusses regulatory responses to COVID-19 or*
- *LMIE single study of high relevance or*
- *article of high interest for other reason (for example, novel policy issue or finding).*

Data were extracted according to the modified PICO framework elements of Population/Practitioner, Intervention/HPR Approach, Context/Country and Outcome for synthesis in tabular format. A parallel literature extraction tool in Excel was used for the grey literature, and themes were also tracked, enabling synthesis with the information extracted from the published literature.

Selected country case studies

The search of scholarly and grey literature was supplemented with a comparative analysis of health practitioner licensing/registration laws and regulator websites from a sample of countries. We selected countries illustrative of different geographic, linguistic, and economic systems. Parliamentary and government websites were searched for statutes and subordinate legislation, to identify and compare key features of these legislative instruments. Websites of a selection of multi-profession regulators were searched, to identify and compare the type and extent of materials publicly available concerning regulatory standards, policies, procedures and activities.

For the selected regulatory regimes, we analyzed key features including:

- ***scope of regime*** – which professions are regulated; how new professions are brought into the scheme; and what regulations/restrictions apply to health workers who operate outside the scheme
- ***mandate of the regulator*** – the source of authority for the regulator to exercise its powers and functions
- ***governance of the regime and of the regulator*** – the nature of the legal entity; its constitution, membership and method of appointment; its accountability framework and relationship to government; and the roles of the Minister and the relevant department vis a vis the regulator
- ***powers and functions of the regulator in the following areas***:
    - registration of practitioners and maintenance of a public register
    - accreditation of health education providers and conduct of examinations
    - complaints handling and discipline

    - compliance monitoring and enforcement
    - data analytics capability and risk management/harm reduction programs
- ***system linkages*** – the nature of the linkages between the regulator and other regulators and entities such as in education, health service delivery, health system management and workforce planning, police, the court system.

Integrated synthesis

The framework considered most useful for conducting the integrated synthesis of qualitative and quantitative evidence is Sandelowski's 'integrated synthesis' approach.[404,475] Under this framework, both forms of data (quantitative and qualitative) are combined through a single mixed-method synthesis approach, with assimilation achieved by converting quantitative data into themes, codified, and then presented along with qualitative data in a narrative or aggregated format. The method uses both quantitative and qualitative data in the thematic exercise, and then codifies all data within a compatible system.

OVERVIEW OF RESULTS

In total, we included **410** published articles and **426** grey literature sources in the review. Figure 5 sets out the outcomes of the published literature screening process:

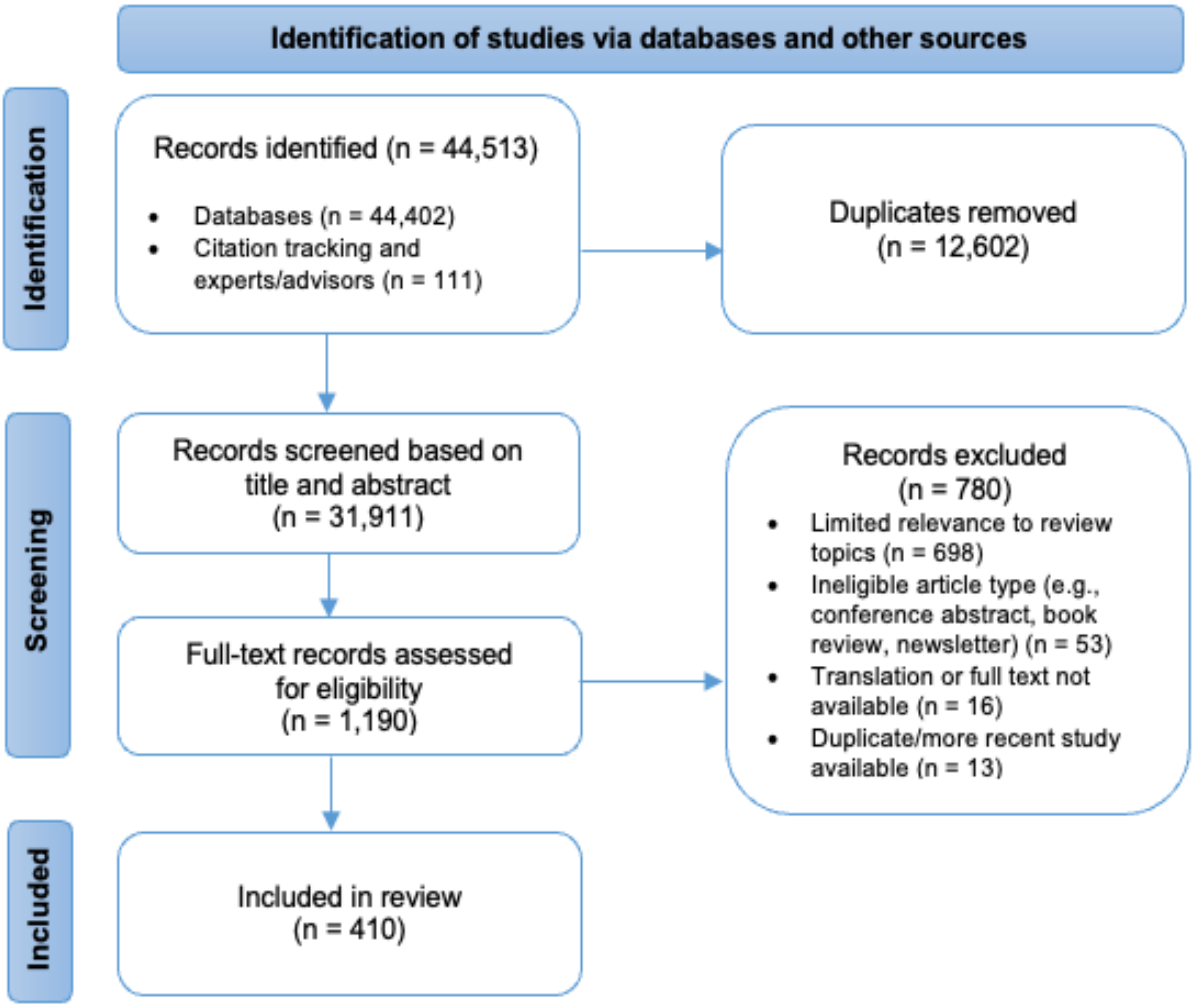


Figure 5: PRISMA diagram of published literature identified via databases and other sources

Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Figure 6 provides an overview of the number of articles addressing each of the topics under the framework of structures, processes and outcomes. A description of all these sources with reference and extraction data is included in Annex 4 (published literature) and Annex 5 (grey literature).

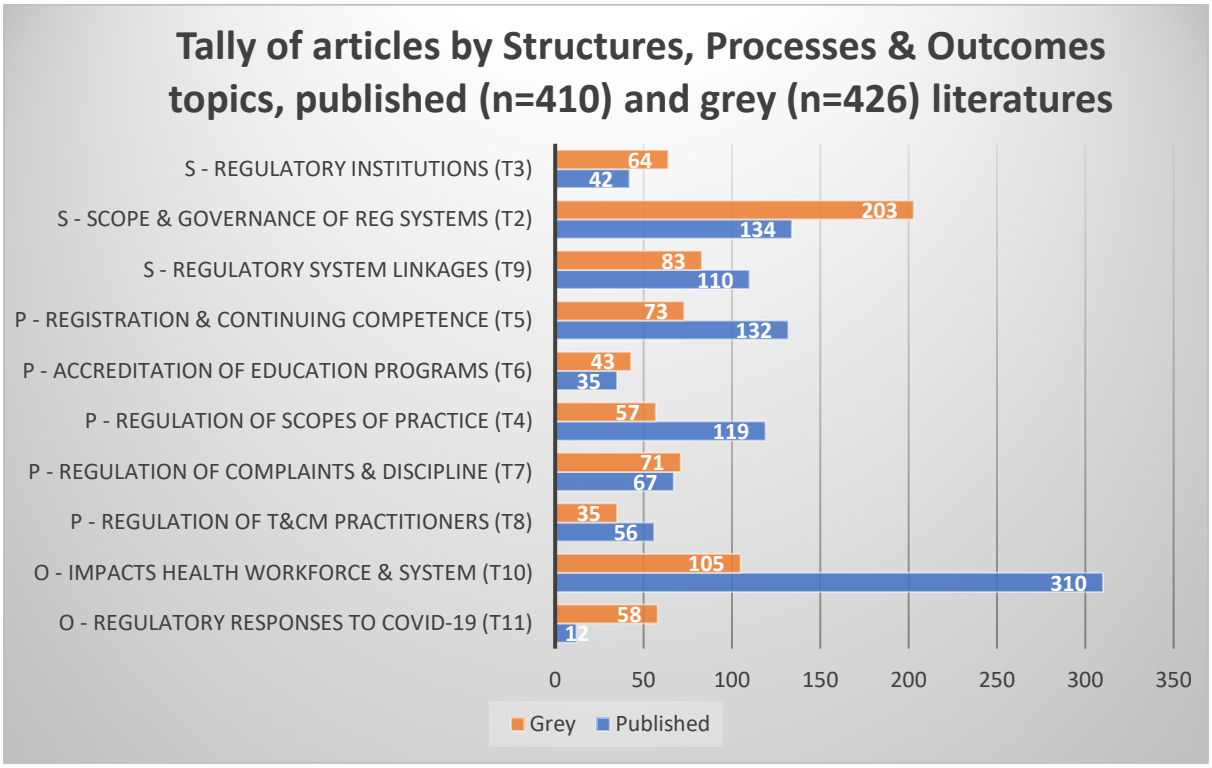


Figure 6: Distribution of published and grey literature by topic and structures, processes and outcomes

Figure 7 provides an overview of the predominant countries and health practitioners studied in the published and grey literatures. Most of the available evidence referred to the United States, internationally focused studies followed by Australia, Canada and the United Kingdom, with publications on nurses and midwives (including in advanced practice nursing roles) and medical personnel dominating over those from other health occupations.

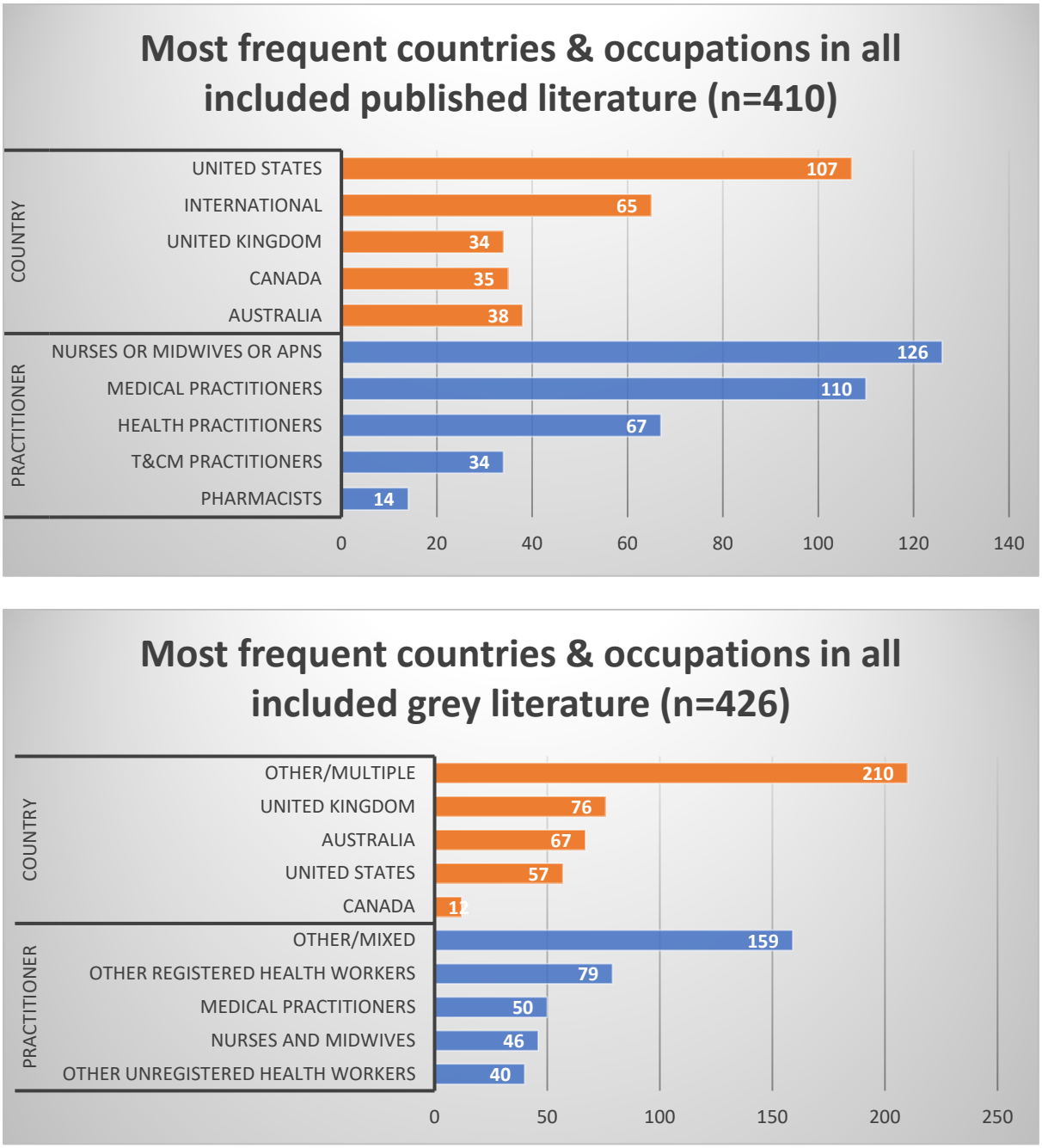


Figure 7: Most frequent countries and health occupations in all included published and grey literatures

We identified key themes in our evidence synthesis, clustered under a series of HPR topics, organized according to our structures, processes, and outcomes conceptual framework. These topics and key themes are presented in Figure 8.

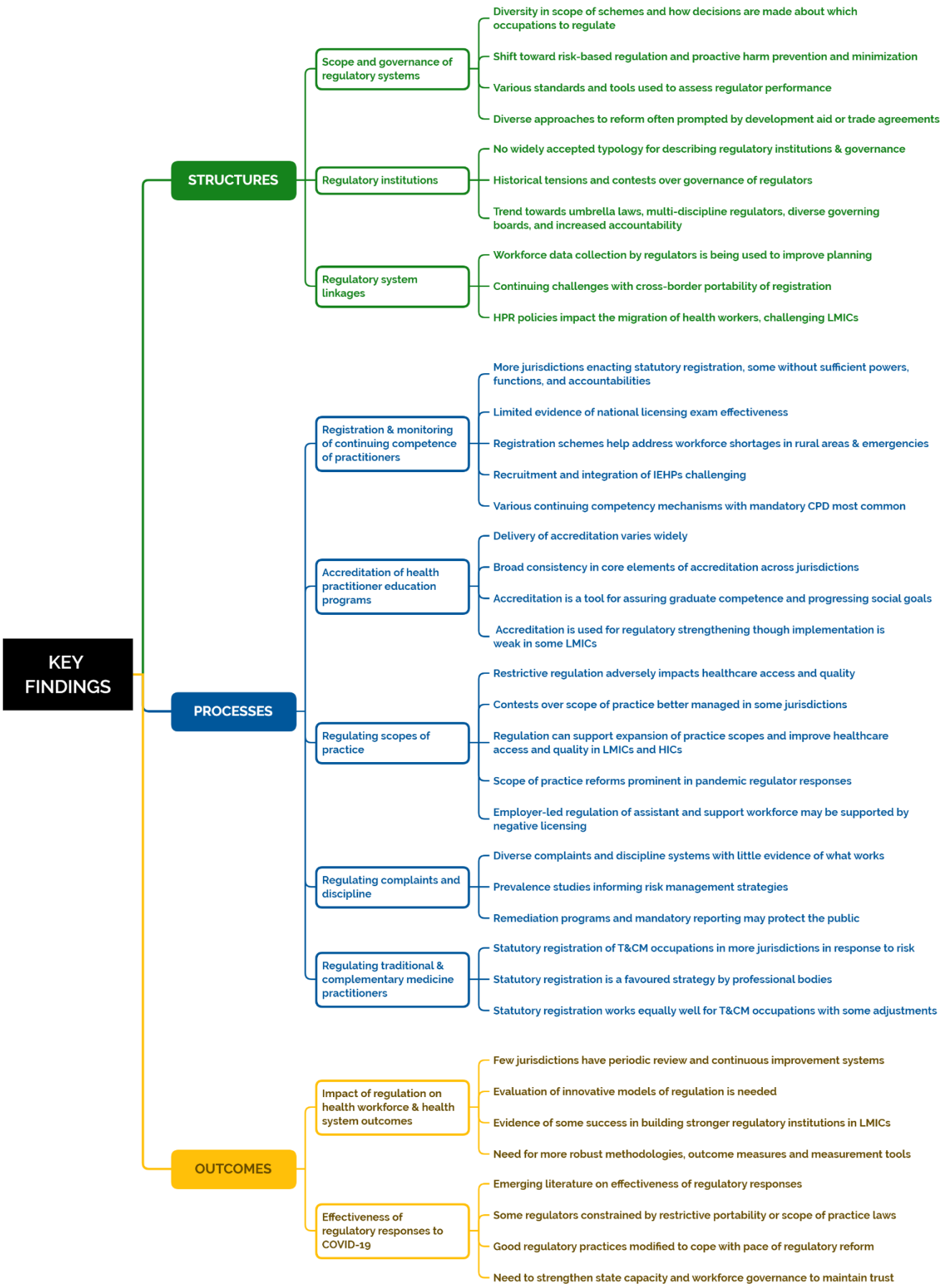


Figure 8: Overview of topics and themes by structures, processes and outcomes

3. TERMINOLOGY AND TYPOLOGIES

Overview

A common language that uses widely accepted terms and definitions fosters a shared understanding and facilitates dialogue, research and practice. Without definitional clarity, comparisons of regulatory regimes across jurisdictions and over time are cumbersome, contested and slow. This chapter presents an analysis of the terms and definitions commonly used in the literature and discusses key concepts important for understanding the scope and operation of HPR. We highlight where terms are used differently across countries and provide context for these differences. We identify some of the issues to consider when selecting and defining key terms for the Global Guidance. We also propose a typology for understanding and describing key regulatory types or models found in occupational regulation of the health workforce.

Defining key terms

The literature search identified **33 articles** that addressed matters of terminology, offered definitions of key terms or assisted in understanding definitional issues and tensions. An additional **10 sources** of grey literature were identified.[113,118,137,245(p201),380,424,425,528,557,561]

Lack of standardized terminology

Terminology is unsettled in this area and there are no broadly agreed definitions for commonly used terms. Comparative studies have highlighted the definitional ambiguity arising from how terms such as regulation, self-regulation, registration, licensing and accreditation are used differently in different countries and contexts.[74,284(p231),528] Benton & colleagues (2014) argue there is an urgent need to develop an authoritative source of definitions that can contribute to improving public safety and reducing delays in freedom of movement of health workers from one jurisdiction to another.[74(p53)]

We identified several organizations that have published glossaries containing relevant definitions. These include:

- Council on Licensing, Enforcement and Regulation (CLEAR)[137]
- International Confederation of Midwives (ICM)[248]
- The US National Council of State Boards of Nursing (NCSBN)[356]
- Professional Standards Authority for Health and Social Care (PSA)[424,425]
- World Physiotherapy (WP)[561]

Defining 'regulation' and 'good regulatory practice'

The definition of regulation is contested and its conceptualization depends on the problem or issue in focus.[84(p2)] In its everyday meaning, the term 'regulation' is defined as 'the controlling of an activity or process, usually by means of rules', and regulation is 'effective' if it 'works well and produces the results that were intended'.[144] The Organization for Economic Cooperation and Development (OECD) defines regulation as follows:

> *…the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulation includes all laws, formal and informal orders, subordinate rules, administrative formalities, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory power*.[380(p6)]

Researchers acknowledge the role of actors other than the state and how they may be harnessed in the design and delivery of regulation. For instance, Black identifies three types of regulation: the promulgation of rules by government accompanied by mechanisms for monitoring and enforcement, usually assumed to be performed through a specialist public agency; any form of direct state intervention in the economy; and all mechanisms of social control or influence affecting all aspects of behavior from whatever source, whether they are intentional.[84(p11)] Following a review of use of the term in the literature of multiple disciplines (law, economics, sociology, political science etc.), Koop and Lodge framed the following prototype definition of regulation as:

> *…the intentional intervention in the activities of a target population, where the intervention is typically direct – involving binding standard-setting, monitoring and sanctioning – and exercised by public-sector actors on the economic activities of private-sector actors*.[282(p18)]

The focus for this review is principally the rules promulgated by government, or by professional bodies under delegation from or recognized by government. The scope of the review accords largely with Koop and Lodge's prototype and with the OECD definition, except that we also included within scope those certification schemes run by professional associations (private-sector actors), where there is little or no involvement of government. Such schemes operate either alongside or in the absence of statutory registration, depending on the country context and occupation.[282]

There is extensive literature on what constitutes 'good' regulation and good regulatory governance and practice.[282,387] Also, many countries have established 'regulatory management systems' (RMSs) to manage the stock and flow of regulation, to make sure regulations are carefully designed and implemented.[36(pV),380(p6)] The Asian Productivity Organization defines a regulatory management system (RMS) as the meta structure to oversee the development and review of regulations. It has four core components: regulatory

policies; regulatory tools; regulatory institutions; and regulatory procedures. A good RMS serves to assess policies, analyze regulatory performance, and identify success factors and priority areas for reform. This leads to the institutionalization of good regulatory governance under which policies result in improvement in productivity and economic performance.[36(pV)] ASEAN defines good regulatory practices (GRPs) as internationally recognized processes, systems, tools and methods for improving the quality of regulations. The aim of GRPs is to make sure that regulations are fit for purpose and will deliver what they set out to achieve in terms of policy objectives.[42]

A range of principles, frameworks, and tools are used to evaluate the effectiveness of HPR. Principles-based approaches to assessing the effectiveness of a regulatory regime are found in the regulation literature[53] and have been applied under government regulatory management systems, by regulators and standard setting bodies.[71,73,249,251,419,427] See Textbox 1 for some examples.

Textbox 1: Examples of principles-based approaches to assessing what is 'good' regulation

Baldwin & colleagues[53(p27)] propose five criteria for measuring effectiveness of regulation:

Mandate	–	*Is the action or regime supported by legislative authority?*
Accountability	–	*Is there an appropriate scheme of accountability?*
Transparency	–	*Are procedures fair, accessible, and open?*
Expertise	–	*Is the regulator acting with sufficient expertise?*
Efficiency	–	*Is the action or regime efficient?*

The United Kingdom (UK) Government's ***Better Regulation Taskforce*** proposes five principles against which regulation may be judged: transparency, accountability, targeting, consistency, and proportionality.[77,515] The ***UK Professional Standards Authority (PSA)*** has added a sixth principle to this list – agility.[445(p4)]

The OECD publication ***The Governance of Regulators - OECD Best Practice for Regulatory Policy*** [387] offers a suite of principles of good governance for regulators, with accompanying resource materials that cover the following:

Role clarity
Preventing undue influence and maintaining trust
Decision making and governing body structure for independent regulators
Accountability and transparency
Engagement
Funding
Performance evaluation

The ***International Council of Nursing (ICN)*** [252] has published a Position Statement that sets out thirteen 'principles for professional regulation'. They are: purposefulness, definition, professional ultimacy, collaboration, representational balance, optimacy, flexibility, efficiency, universality, natural justice, transparency, accountability, effectiveness. The ICN states that policy objectives derived from these principles offer guidance in developing and evaluating regulatory systems.[71,252(p1)]

There are many frameworks for measuring the effectiveness of regulation, notably regulatory impact assessment (RIA).[42,45,351,381,382] Several frameworks have been developed specifically to measure the performance of HPR schemes and regulators – see Textbox 2.

Textbox 2: Two frameworks for measuring the effectiveness of health practitioner regulation regimes

The United Kingdom's ***Professional Standards Authority*** (PSA) has a statutory mandate to assess the performance of the UK's eight health profession regulators such as the General Medical Council. It has published its *Standards of Good Regulation*[449] and periodically carries out reviews or investigations of the regulators within its remit against these standards. It also conducts special reviews of regulators in other countries. The PSA's standards are informed by a set of principles of good regulation which state that regulators should act in a way that is proportionate, consistent, targeted, transparent, accountable, and agile.

The reports generated from the PSA's reviews, including performance reviews of UK regulators and cost-effectiveness and cost-efficiency reviews of local and international regulators, are published on the PSA website.

The ***Ontario Ministry of Health*** has enacted a new framework to assess the performance of health profession regulators annually. The *College Performance Measurement Framework (2020)* is intended to strengthen the accountability and oversight of the 26 health regulators under Ontario's *Regulated Health Professions Act* by publicly reporting on the performance of these regulators across specific performance metrics.[390] This framework sets performance benchmarks and identifies leading practices around specific functions and processes, including governance, transparency, working with system partners, information management, and regulatory policies. The first summary report from the Government of Ontario was made public in October 2021.

Reviewing the published and grey literature on this topic and the range of frameworks and tools, the following areas of definitional uncertainty are evident:

- health practitioner regulation, occupational regulation and health workforce regulation
- self-regulation, statutory self-regulation and professional self-regulation
- licensing versus registration
- accreditation
- fitness to practice

These are discussed further below.

'Health practitioner regulation', 'occupational regulation' and 'health workforce regulation'

There are differences in the literature regarding use of the term 'health practitioner regulation' (HPR). Some assume the term applies only to those who are subject to occupational licensing or statutory registration and does not include regulation of large segments of the health workforce such as those in assistant or other support worker roles. In some jurisdictions, the term 'practitioner' is defined by law to include only persons who are qualified (usually at degree level or above) and in an occupation to which licensing or registration applies (such as medicine or nursing).

Referencing the updated *International Standard Classification of Occupations*,[259] we define health practitioners to include health professionals, associate health professionals, and personal care workers in health services. This definition excludes health workforce members not directly engaged with patient care or diagnostics, such as healthcare management and support staff.

The term 'occupational regulation' is defined as 'legally defined requirements or rules that govern entry into occupations and subsequent conduct within them'.[283] The term is used in this report to describe a jurisdiction's suite of laws, regulations, bylaws, decrees, codes, directives or other rules that apply to and are targeted at an occupation or group of occupations. It also includes other non-statutory forms of regulation, such as codes, bylaws and rules of association promulgated by non-statutory standard-setting bodies such as member-based associations. Occupational regulation is considered broader than HPR in that it captures both statutory and administrative regulatory arrangements and therefore encompasses regulation of an entire health workforce, not just those 'practitioners' who are members of a registered/licensed occupation.

The term 'health workforce regulation' is found both in the grey literature[548] and in the published literature.[162] While no definition was found, its use suggests it is interchangeable with the term occupational regulation but may be broader, encompassing a variety of laws directed at occupations and a broad definition of the health workforce that encompasses support staff as well as clinical and technical health workers.

Self-regulation, statutory self-regulation, and professional self-regulation

There are conflicting perspectives in the literature about the use of the term 'self-regulation'. It is commonly used to describe certification schemes that have no statutory basis and no 'delegation of regulatory power' as described in the OECD definition of regulation above. Such schemes are generally run by non-government professional associations. On joining an association, members agree to abide by its rules and code of ethics and can be expelled for breaches.[548] Sometimes the terms 'pure self-regulation'[74(p56)] or 'voluntary self-regulation' [548,549] are used to make this meaning clear.

However, the terms 'self-regulation' and 'professional self-regulation' also are used widely but counter-intuitively to describe statute-based schemes under which health practitioners, such as in medicine, dentistry, nursing and pharmacy, are licensed to practise.[9,73,251] In this context, the terms 'professional self-regulation' or 'statutory self-regulation' are used interchangeably with 'profession-led regulation'.[251]

Using the term self-regulation to describe a statute-based scheme dates from early Anglo-American statutes where the regulators (boards or colleges) were constituted with board members who were elected by the registrants/licensees rather than appointed by

government.[119(p316),166] However, the term 'statutory self-regulation' has been described as oxymoronic,[418] not least because some jurisdictions have amended their registration laws to remove provision for direct election as a method of appointment to the governing boards of regulators and increased the diversity of membership.[9,119,143]

Levi-Faur [300] identifies three forms of self-regulation. The primary form of self-regulation is 'first party regulation,' where the regulator is also the regulatee. In second party regulation, 'there is a social, political, economic and administrative division of labour between the actors, and the regulator is independent and distinct from the regulatee'.[300(pp11-12)] Government regulation of business is an example. In third party regulation, 'the relations between the regulator and regulatee are mediated by a third party that acts as independent or semi-independent regulatory auditor'.[300(pp11-12)] For Levi-Faur, these 'hybrid' third party regulatory designs involve various types of interactions between state regulation, market-actor regulation and 'civil society regulators'. He cites 'co-regulation', 'enforced self-regulation', 'meta-regulation' and 'multi-level regulation' as examples.[300(pp13-14)]

In the governance of a HPR scheme, these distinctions are important to the extent that they shape the relationship between government and the health occupations regulated and have consequences for the accountability, transparency, and effectiveness of a regulatory scheme.

Terminology is not value-free. Multiple references found in the literature about 'the privilege of self-regulation'[143,154] suggest that it is not just a lack of standardization in terminology at issue. Some view as ideologically motivated the continued use of the term self-regulation when referring to an occupational registration regime that is underpinned by statute. For instance, Moran [348] argues that, at least in the UK, practitioner groups have defended their self-regulation, using it as a political tool to shore up their control of standard setting and market entry from incursions by the state.[348(p103)] Moran maintains that historically, the scale and reach of the medical profession's system of self-regulation was the key to insulating its interests from democratic control – the professions were able to distance an activity from politics by defining it as belonging to the domain of self-regulation.[347(p32)] Similarly, Dixon-Woods & colleagues [166] argue that UK medicine is no longer a self-regulating profession; and in Australia, Thomas has argued that for the medical profession, 'self-regulation is dead', on similar grounds.[506(p289)] For these reasons we have avoided using the term self-regulation in the typology of occupational regulation used this report.

Licensing and registration

In some countries, the terms 'licensing' and 'registration' are distinct types or models of occupational regulation. In others, no such distinctions are made and these terms are used interchangeably, or definitions are unclear.[566]

For instance, in Ross's 'inverted pyramid', he distinguishes voluntary certification, registration, state certification and licensing.[465(pp11-13)] In this typology, the distinction between registration and licensing turns on whether the scheme restricts who can provide specified services or restricted activities (i.e. reservation of practice). Under a registration scheme, the provider's name is placed on a list of persons who are considered qualified to provide a particular type of service and they are then entitled to use a reserved professional title. Under a licensing scheme as narrowly defined, only those persons who hold a license can practice or carry out specified activities and the reserved scope of practice or restricted activities are defined by law.

Despite this distinction, many international professional bodies, meta-regulators and researchers use the terms 'registration' and 'license' interchangeably and some have adopted the same definition for both terms.[75(p113),356(p65),561]

Whichever approach is adopted, in any occupational regulation scheme it is important to identify and understand:

- the entitlements conferred on persons who are within the scope of the scheme (such as the right to use a reserved title and/or carry out reserved acts or practices), and
- the types of offences or other restrictions that apply to those who operate beyond the scope of the scheme (that is, the unlicensed or unregistered).

In this report we use statutory registration as an umbrella term that encompasses legislated occupational regulation schemes based on reservation of title (sometimes referred to as "registration") and those based on reservation of practice (sometimes referred to as "licensing"). The terms registration and licensing are used interchangeably – to grant registration includes to grant a license and to be registered includes to be licensed. This reflects common usage in many countries.

When referring to statutory registration, we do not include professional association-led certification schemes (those that are non-statutory where participation is voluntary), co-regulation, negative licensing or any other type of occupational regulation.

Accreditation

The term accreditation is widely used in different contexts and for different purposes. For example, accreditation may describe the assessment and approval or recognition of a health facility or health service provider, the certification of the skills and qualifications of an individual or the assessment of an educational program and provider.[137(p1),561]

For the purposes of this review, the use of the term accreditation is limited to describe the process of assessment of programs of education, and education providers, for the purpose of

entry to practice in a health profession. In this context, a variety of bodies have offered definitions.[137(p1),244,356(p64),558(p19)]

Frank & colleagues[190] reviewed contemporary definitions of accreditation and found no universal definition, with the term variously described as a form of quality assurance (QA), an enterprise of continuous quality improvement (CQI), a form of program evaluation, and various combinations of the above.[190(p3)] After reviewing various definitions, an International Consensus Group formed for this purpose settled on the following definition:

> *Accreditation in the health professions is the process of formal evaluation of an educational program, institution, or system against defined standards by an external body for the purposes of quality assurance and continuous enhancement*.[190(p4)]

This definition is silent on who undertakes the function, apart from noting it is undertaken by an external body, presumably external to the education provider.

Fitness to practice

The term fitness to practice is used differently in different countries and contexts.[498] For instance, the NCSBN has adopted a broad definition:

> *Having the skills, knowledge, competence, health, and character to practice within the nursing profession. Evidence of moral character such as criminal background checks and references may be included*.[356(p65)]

The Council on Licensure, Enforcement and Regulation (CLEAR) defines fitness to practice proceedings more narrowly, as:

> *Proceedings to determine if a certificant/member/licensee/registrant is incapacitated, i.e., suffering from a physical or mental condition or disorder such that the member is unfit to continue to carry out his or her professional responsibilities*.[137(p10)]

Thus, in those jurisdictions that adopt a broad definition, a practitioner's fitness to practice may be compromised due to a range of reasons, not only that they are suffering from an impairment, but also where they are well intentioned but incompetent, their performance is unsatisfactory for other reasons, or they have engaged willfully in breaches of professional ethics. In other jurisdictions, the term fitness to practice is restricted to use in cases where a practitioner's performance or competence is sub-standard due to ill health or impairment. For example, the UK General Medical Council (GMC) applies a broad definition of fitness to

practice [b] and Malaysia's Allied Health Professions Council applies a narrow definition. [c] In addition to these differences, there may be complexities with use of the term 'fitness to practice' when considering matters of character, for example, where the regulator may need to take account of a practitioner's actions in their personal life that are unconnected with their work and may not have the power to do so. For these reasons, this review has used the term 'complaints and discipline' to capture the processes of receipt, assessment and investigation of complaints and the regulatory processes that may follow to deal with practitioners who face questions as to their competence, conduct or capacity (health).

Types of occupational regulation

Another complexity with analysis of HPR is the lack of a generally accepted framework for categorisation of regulatory types or models and the conceptual imprecision that accompanies this definitional variation.[72,142(p3)]

The broader regulation literature offers various typologies for categorising regulation.[49,53,59,84,194,418(p251)] For instance, Bartle & Vass view regulation as a continuum of state intervention, from no regulation to 'pure' self-regulation, 'state approved' self-regulation, statutory self-regulation, co-regulation, and statutory regulation.[59(p29)] Freiberg adds 'meta-regulation' and 'global regulation'[194(pp33-45)] to this continuum while Ross's 'Inverted Pyramid' encompasses both voluntary or non-regulatory options and government interventions, as alternatives to licensing.[465(p2)]

Benton & colleagues note the fluidity of boundaries between one category and the next and that some crossover among models exists.[72(p24)] Overlapping regulatory responsibilities are evident, for example, with the introduction of the UK revalidation procedures where there is a blurring of the line between the employer's role in performance appraisal and the regulator's role in assuring continuing competence.[72(p24)] The question of whether a regulator is practitioner-led or government/bureaucrat-led (or a hybrid) is complex.

For the purposes of this review, a simple typology is presented in Textbox 3 that encompasses four main types of occupational regulation:

- Non-statutory certification
- Negative licensing
- Co-regulation (various forms)
- Statutory registration or occupational licensing

[b] See the UK GMC's publication *The meaning of fitness to practice*, available at: https://www.gmc-uk.org/-/media/documents/DC4591_The_meaning_of_fitness_to_practise_25416562.pdf

[c] See for example, the *Malaysian Medical Council Fitness to practice declaration form*, available at: https://mmc.gov.my/wp-content/uploads/2019/11/Fitness_To_Practise_Declaration.pdf

Textbox 3: Typology for defining types of occupational regulation that apply to the health workforce

Certification (non-statutory)

Under a certification scheme, there is no underpinning statute enacted by government that confers powers on a regulator to license members of the profession or occupation. Rather, practitioners join together to establish an association with a constitution, bylaws and rules for its members. The association may be registered as a body corporate under the relevant law of a country.

On joining the association, a practitioner member agrees to abide by the rules of the association and its code of ethics, and their name and other details will generally appear on a web-based register maintained by the association. The association may also operate a consumer complaints mechanism and the rules may provide for members to be expelled for serious breaches of the code of ethics. However, the system is voluntary – practitioners can choose not to join the association and still practice, and they can continue to practice if expelled from the association for reasons of misconduct.

A variation on this model is where the entity that maintains the practitioner register may be initiated by the professional association but established as a separate legal entity, with a specific mandate to carry out regulatory functions on behalf of the profession. While there is organizational separation of the regulatory functions from the membership representation and advocacy functions, the arrangements continue to be entirely voluntary. Consumers, insurers and health service providers may rely on information provided by the register of practitioner members for trusted advice about who is qualified to practice the profession, but there is no direct involvement or recognition from government.

Co-regulation (various models)

Co-regulation is like certification. The key difference is that some of the functions of the self-regulating professional association may be either delegated from or recognized by government. This government recognition or delegation may be conditional on the certification body meeting specified standards in relation to governance and its certification standards and processes. This recognition process establishes, in effect, a partnership between government and the certifying body and the benefits that flow to practitioners from certification create incentives for practitioners to comply with the professional association's standards.

Negative licensing (statutory)

Under a negative licensing scheme, there is no legal barrier to entry to an unregistered profession – anyone can practice, no matter what their level of training or skill. However, a law is enacted that empowers a statutory regulator to receive and investigate complaints that a practitioner has engaged in 'prohibited conduct' or breached minimum standards of practice enacted under a statutory 'code of conduct'. The regulator may issue a prohibition or banning order to remove a practitioner from practice when the regulator finds the practitioner has committed an offence, breached the code or engaged in prohibited conduct AND their continued practice presents a serious risk to the public. There may be offences for breach of a prohibition order and an online searchable public register of prohibition orders issued.

Statutory registration or occupational licensing

Under a statutory registration or occupational licensing system, the purpose and functions of the system are not determined by the profession alone (as in the case of non-statutory certification schemes) but are generally set out in legislation or other instrument of authority and are subject to public scrutiny (through the responsible parliament and minister). The legislation establishes a regulatory body with powers to register or license and regulate practitioners. Entry to a regulated profession is limited only to those the regulatory body considers to be properly qualified and of good character. This gate-keeping role is underpinned by statute, with powers for the regulator to prosecute unregistered persons who pretend to be qualified to practice the profession when they are not. The statute provides an effective mechanism for restricting entry to practice in the profession and disciplinary powers to deal with practitioners whose practice falls below an acceptable standard.

There are two distinct regulatory mechanisms found in statutory registration schemes: ***reservation of title*** and ***reservation of practice***. While many registration laws contain provisions that prohibit an unregistered person from using a reserved professional title or pretending to be qualified and registered when they are not (reservation of title), some laws go further – they prohibit an unregistered person from providing certain types of clinical services (reservation of practice). Reservation of practice provisions can create an exclusive scope of practice, in effect a monopoly, for the profession or occupation concerned. Some schemes include both reservation of title and practice.

Adapted from: AHMAC (2018); Carlton (2017); WHO WPR (2016) [15,119,548]

To better understand the scope and operation of these types of occupational regulation, Table 3 compares each type against a list of features and capabilities, noting there will be local variation and not all statutory registration schemes will exhibit every feature.

Two recent studies have applied this typology to compare regulatory regimes in multiple jurisdictions at the global and regional levels.[113,557] Only statutory registration schemes provide enforceable minimum qualification and probity standards for entry to practice in a profession or occupation and powers for the regulator to actively monitor compliance with standards.[557]

Table 3 Occupational regulation types – key features and capabilities

Feature/capability	Type of occupational regulation			
	Certification	Co-regulation	Negative licensing	Statutory registration/ occupational licensing
Statutory basis	NO	Maybe	YES	YES
Enforceable minimum qualifications for entry to practice	NO	NO	NO	YES
Probity checking of persons prior to entry to practice	NO	NO	NO	YES
Accreditation of qualifying programs for entry to practice	YES	Maybe	NO	YES
Enforceable minimum standards of practice	NO	NO	YES	YES
Mandatory continuing professional development (CPD)	YES (for members only)	Maybe	NO	YES
Legal obligation to report professional misconduct by fellow practitioners	NO	NO	YES	YESs
Powers to monitor practitioner compliance with practice standards	NO	NO	NO	YES
Powers to impose conditions or limitations on a practitioner's practice	NO	NO	YES	YES
Power to issue practice guidelines/codes	YES	NO	NO	YES
Complaint and disciplinary powers	YES (for members only)	Maybe	YES	YES
Powers to remove unfit practitioners from practice	NO	NO	YES	YES
Offences and penalties for unauthorized use of professional titles	NO	NO	NO	YES
A publicly accessible register of qualified practitioners	Maybe	Maybe	No	Yes
A publicly accessible register of disqualified or barred practitioners	No	No	Yes	Yes
Publication of disciplinary decisions	No	No	Yes	Yes
Protection from civil liability for board members and staff discharging regulatory functions	No	No	Yes	Yes

Summary

The importance of conceptual and definitional clarity and consistency cannot be overstated and its absence in this literature is a critical limitation on the ability to synthesize. A note of caution is warranted in the synthesis across sources that follows because of the lack of a consistent approach to measurement.

For the purposes of this review, the following definitions have been applied:

'health practitioner' includes health professionals, associate health professionals and personal care workers in health services. This definition excludes health workforce members not directly engaged with patient care or diagnostics, such as healthcare management and support staff.[259]

'statutory registration' is an umbrella term that encompasses legislated occupational regulation schemes based on reservation of title (sometimes referred to as "registration") and those based on reservation of practice (sometimes referred to as "licensing"). The terms ***'registration'*** and ***'licensing'*** are used interchangeably – to grant registration includes to grant a license and to be registered includes to be licensed. This reflects common usage in many countries.

'***regulation***' refers to the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulation includes all laws, formal and informal orders, subordinate rules, administrative formalities and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory power.[380(p6)]

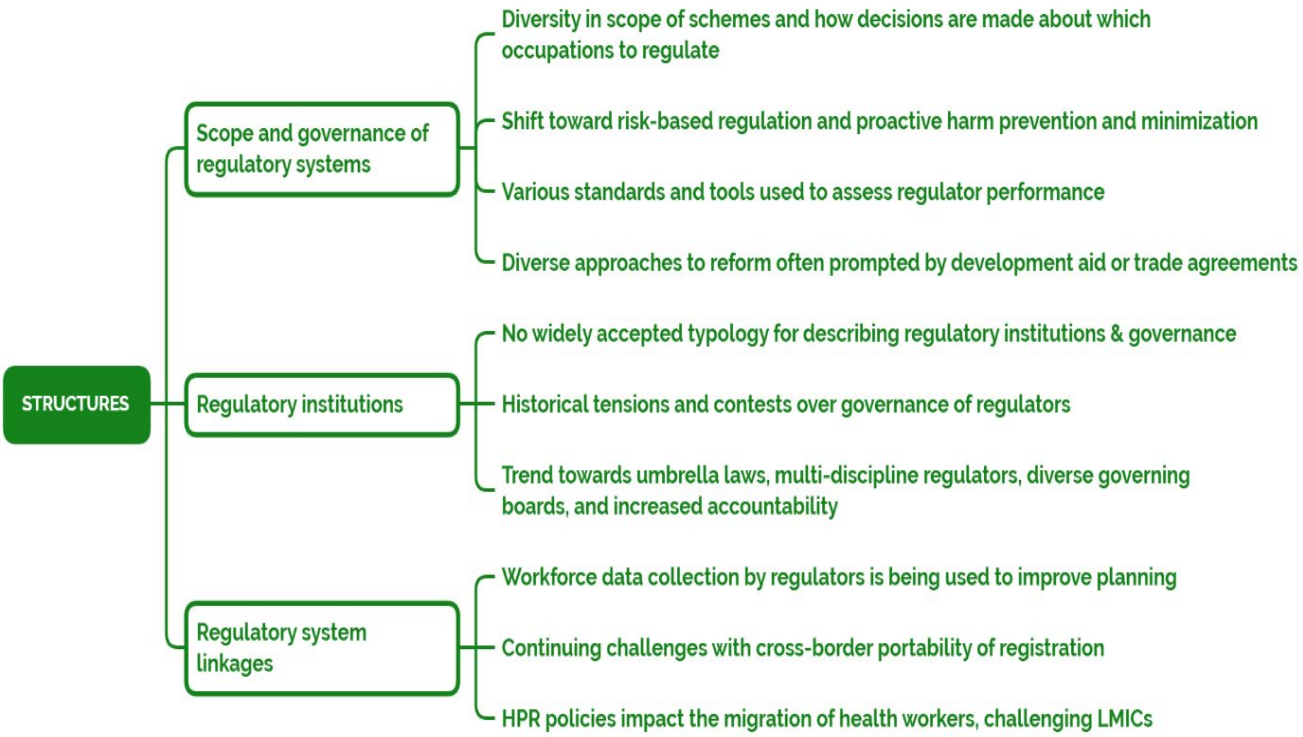
'***regulatory management tools'*** refers to the different tools available to implement regulatory policy and foster regulatory quality including regulatory impact assessment, stakeholder engagement and ex post evaluation.[380(p6)]

'*regulatory policy'* refers to the set of principles, rules, procedures and institutions introduced by government for the express purpose of developing, administering, and reviewing regulation.[380(p6)]

Occupational regulation schemes found in jurisdictions may be categorized according to four main types:

- certification
- co-regulation (various forms)
- negative licensing
- statutory registration (or occupational licensing)

PART A: STRUCTURES



4. SCOPE AND GOVERNANCE OF REGULATORY SYSTEMS

Overview

The focus of this chapter is the literature on the scope and governance of HPR systems, that is, how regulatory policy is determined concerning HPR and the regulatory management systems that apply to HPR within jurisdictions. Of particular interest is literature on:

- the scope and diversity of HPR systems and the regulatory models applied
- how jurisdictions make regulatory policy decisions about which health occupations should be regulated and how
- how jurisdictions ensure HPR is well designed and regimes are regularly reviewed to ensure they remain fit for purpose
- what oversight and accountability mechanisms apply to HPR schemes and how the performance of regulators is assessed and monitored
- the extent to which the tools of good regulatory practice (GRP) and whole of government regulatory management systems are being applied to HPR.

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **134 articles** included content related to the scope and diversity of HPR systems, regulatory policy and governance, or regulatory review and reform processes (Figure 9). For details of the publications, see Annex 4 (Table 2).

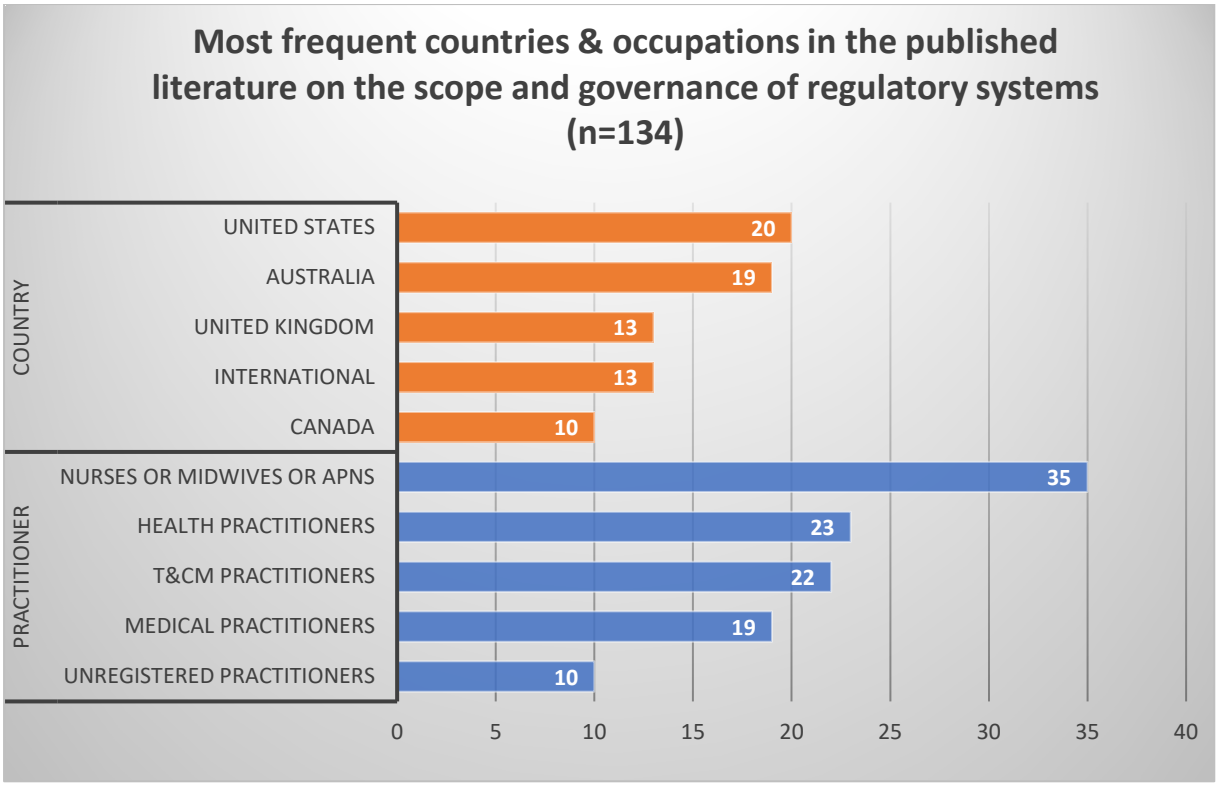


Figure 9: Most frequent countries and health occupations in published literature on the scope and governance of regulatory systems

The published literature was dominated by articles on nurses and midwives (n=35), followed by health practitioners in general (n=23) and TC&M practitioners (n=22). The United States (n=20) and Australia (n=19) dominated this literature followed by the United Kingdom (n=13). The included articles addressed an array of issues associated with the governance of regulation and regulatory systems:

- occupational regulation and unregistered or unlicensed health workers (***35 articles***)
- regulatory reform and regulatory strengthening processes (***41 articles***)
- evaluation of regulatory regimes alternative to statutory registration, such as certification (***eight articles***), negative licensing (***nine articles***) and co-regulation (***two articles***)
- regulatory policy and practice, such as regulatory principles, public interest, competition policy, regulatory burden (***10 articles***)
- risk-based regulation (***15 articles***)
- issues specific to regulation of T&CM practitioners (***12 articles***)

A total of **94 empirical studies** were identified that addressed some aspects of the effectiveness of regulation. These are discussed in Chapter 12. Only two articles compared the effectiveness of statutory registration with other occupational regulation models such as co-regulation or negative licensing.[324,532] No articles were identified that examined the impact of broader government regulatory management systems on HPR.

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **203 documents** relevant to this topic (Figure 10).

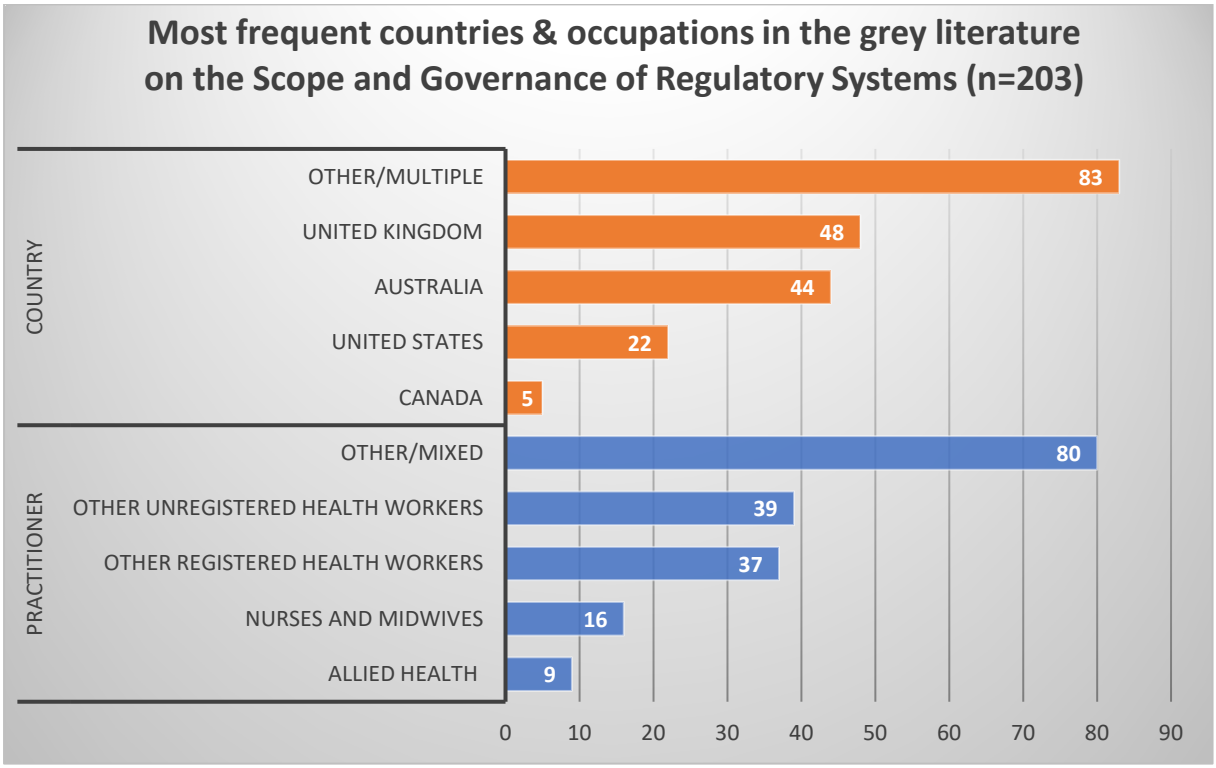


Figure 10: Most frequent countries and health occupations in the grey literature on the scope and governance of regulatory systems

Annex 2 provides a list of the websites searched. For details of the publications, see Annex 5 (Table 2). The main sources were:

- *Regulators and meta-regulators* – principally from high-income Anglophone countries of the UK, US, Canada, Australia, and New Zealand. For instance, a search of the website of the UK PSA yielded **50 policy papers and reports** within scope, including regulatory system reviews both in the UK and other countries, policy documents on specific topics such as right touch assurance methodology and public and patient perspectives on fitness to practice, and various discussion papers and position statements on good regulatory practice (***57 documents***)
- *Governments* – health departments/ministries and parliamentary committees in the UK, Canada, Australia and New Zealand where it is apparent that regulatory reform activity in HPR has been underway for several decades. These documents were of two main types – discussion papers and reports associated with regulatory impact assessment processes for expanding the scope of a registration scheme to cover additional health professions; and reports of reviews of HPR systems or regulatory functions (***49 documents***)

- *Intergovernmental agencies* – documents that relate to international and regional trade agreements such as mutual recognition arrangements that impact regulation of the health professions (***19 documents***); and policy papers and reports from the OECD that do not specifically address HPR but rather provide resources for governments about how best to introduce or strengthen regulatory governance through whole of government regulatory management systems (***10 documents***)
- *WHO and associated entities* – commissioned reports principally from two WHO regions – the African Region and the Western Pacific Region.[545,548,549] Three reports addressed regulation of nursing and midwifery,[542,545,546] two reports from the Western Pacific Region [548,549] addressed health system strengthening specifically related to HPR, and six were WHO mission reports of country HPR system reviews (***16 documents***)
- *International professional bodies* – model laws and other resource materials framed to assist countries to develop statutory registration laws, from organizations such as World Physiotherapy, World Medical Association (WMA), ICN and ICM (***11 documents***)

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of registration laws and websites of regulatory authorities in a selection of 19 jurisdictions are set out in Annex 6. Comparative data are presented on the scope of the registration schemes, including:

- the legislative instruments
- number of regulators
- list of professions or occupations regulated

The regulatory schemes selected for mapping comprised 16 national jurisdictions and three sub-national (Hong Kong SAR, China; New York State, USA; and British Columbia, Canada). The schemes sampled illustrate the variation in legislative frameworks: regulators operate under a single umbrella law in five jurisdictions (Australia, New York State, New Zealand, Somaliland and Vietnam) while the schemes in British Columbia and the Philippines each operate under an umbrella law and a suite of profession-specific laws. In other schemes, such as in the UK, Singapore, South Africa, Malaysia and Hong Kong there is a combination of profession-specific laws and umbrella laws depending on the profession. The remaining schemes operate under a suite of profession-specific laws.

The number of regulators (councils, boards, chambers or orders) in each jurisdiction also varies. Some schemes operate via a single multi-profession regulator (Australia, Qatar, Somaliland, Vietnam); others operate through multiple profession-specific regulators (British Columbia, the Czech Republic, New Zealand, Burkina Faso, Mali, Senegal). In most jurisdictions, there is a combination of multi-profession and profession-specific regulators (Malaysia, Singapore, UK). For those jurisdictions with profession-specific regulators, the numbers range from three 'chambers' in the Czech Republic to 22 'State Boards for the

professions' in New York State, 18 'colleges' in British Columbia, and 18 'responsible authorities' (a combination of boards and 'councils) in New Zealand.

There is also variability in the administrative arrangements of regulators. These range from in-house administration by the Ministry of Health (Malaysia, Qatar, Singapore, Somaliland, Vietnam) or another government agency (New York State, the Philippines), through to independently constituted statutory authorities (Australia, the Czech Republic, New Zealand, the United Kingdom, Canada). In the Philippines and New York State, the multi-profession agency has registration or licensing responsibilities that extend beyond the health portfolio to include a range of non-health professions and occupations. In Brazil and the Czech Republic, regulatory responsibilities are divided among multiple government and non-government entities including professional associations.

Comparing the number of occupations or professions regulated in each jurisdiction is somewhat complex, not least because in many schemes, several occupations are grouped together as a single profession (particularly in dental practice and medical radiation practice) and in others the workforce is differentiated by qualification level (such as in nursing) or specialty (such as in medicine and sometimes dental and podiatry). The number of occupations regulated varies from 4-6 (Burkina Faso, Mali, Senegal) through to 42 in New York State, 67 in Qatar and 87 in South Africa.

Annex 7 presents comparative data on the mechanisms used in a sample of six jurisdictions for assessing changes to the scope of a statutory registration scheme to include additional professions. Key features of the regulatory policy and practice are presented, including:

- the legislative powers available
- who undertakes the regulatory assessment
- the extent of policy documentation and website information available
- the whole of government regulatory management systems that apply (if any)

Data were located and mapped for six jurisdictions: Australia, Malaysia, New Zealand, Singapore, the United Kingdom and USA (Virginia State). The analysis illustrates the diversity of arrangements for making regulatory policy decisions. In some jurisdictions, the criteria and processes are well documented, with extensive information published, suggesting a level of transparency concerning how these decisions are made. New Zealand and the UK provide the most comprehensive suite of website materials, with Australia and Virginia State also publishing guidance on the criteria and processes that apply. All jurisdictions appear to have a whole-of-government RIA process for framing new regulations. Regulatory Impact Statements (RISs) or other regulatory assessment documentation is published in Australia, New Zealand, the UK and Virginia State.

Thematic synthesis

Four themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. There is diversity in the purpose, scope and features of regulatory systems and how decisions are made about which health occupations should be regulated.
2. The principles and tools of risk-based regulation adopted by some regulators signal a shift to more proactive strategies for harm prevention and minimisation.
3. Various generic and HPR-specific standards and tools are being used to assess HPR performance, with some adaptable for use in lower-resource environments.
4. There are diverse approaches to regulatory reform, with new regulation or regulatory strengthening activities in LMIEs, sometimes prompted by development aid or trade agreements.

These themes are expanded upon below.

First, there is diversity in the purpose, scope and features of regulatory systems and how decisions are made about which health occupations should be regulated.

In every jurisdiction where an occupational regulation scheme is enacted, policy decisions are taken about the purpose, scope and features of the scheme--which health occupations or health workers will be regulated and how. With a statutory registration scheme, these decisions include: what professional titles will be reserved; what practices, treatments or activities will be reserved or restricted (if any); which occupational groups will be authorized to carry them out; and what legislative or administrative mechanism will be used to make changes from time to time to the scope of the scheme, to add or remove health occupations.

The literature addressing these questions was of five main types:

- studies that mapped the features of statutory registration schemes across multiple jurisdictions
- regulatory impact assessments and other government/government-commissioned reports that assessed the need for statutory registration of a specific health occupation
- publications that described regulatory policy on how policy decisions are made and the criteria and processes applied in regulatory assessment
- articles and submissions to government that presented the arguments in favor of extending a statutory registration scheme to include an unregulated health occupation
- case studies, toolkits, model laws and other resources framed to assist professional associations or other stakeholders to put their case to government for registration of their profession

Statutory registration was the most common type of occupational regulation found, with schemes of some shape or form enacted in almost every country of the world.[356] For the nursing profession, the NCSBN mapped nursing regulation in 312 jurisdictions (at national and sub-national levels), finding that while nearly all jurisdictions have some form of official regulatory body that oversees nurses, eight jurisdictions have no statute or registration/licensing law.[356]

While there is some evidence of regulatory convergence as more jurisdictions enact registration laws,[69,308,549,557] the published literature shows considerable variation in the suite of occupations that are subject to statutory registration. Variability is also found within professions, for example, the types of nurses regulated (registered nurses, nurse practitioners, clinical nurse specialists, nurse anesthetists, enrolled or licensed practical/practice nurses, lady health visitors, nursing assistants etc.).

The results of mapping of a selection of registration laws reinforced the findings from the published literature. As outlined above, the number of professions/occupations ranged from over 80 in South Africa and 67 in Qatar through to 14 professions in Singapore and 13 in Hong Kong SAR, and smaller numbers in some African nations – see Annex 6.

The grey literature provided further evidence of this variability.[56,68,113,357,468,528,548,549,557]

The literature also shows that many governments have been subject to pressure from stakeholders to expand statutory registration schemes to include more health professions and occupations:

- ***35 studies*** *(out of* ***92****) including* ***three scoping reviews*** *called for statutory registration to be introduced, for various groups of unregulated health workers* [13,212,230]
- ***six studies*** *from the UK called for statutory registration for healthcare assistants and other unregulated support workers* [212,474,522]
- ***six studies****, spread across various countries (Australia, the Czech Republic, Georgia, Germany, the UK) called for stronger regulatory requirements for T&CM or CAM occupations* [285,324,355,399,413,532]
- ***three case studies*** *described 'successful' regulatory reform initiatives that resulted in the introduction of statutory registration: for Chinese medicine practitioners and paramedics in Australia* [4,119] *and physician assistants in the US*[456]

While some diversity of regulation is to be expected, due to historical differences in the division of labour, institutional legacies and population health needs, the number of regulated health professions is not necessarily indicative of the maturity of a regulatory system. As regulatory bodies in many LMIEs struggle to maintain functions with limited resources, statutory regulations are being introduced for new groups of health practitioners.[317(p14)]

WHO Western Pacific Region [549] points to the importance of the quality of the regulatory functions, such as clear criteria and transparency of decision-making processes in assessing

which professions should be registered. A well-designed regulatory system: should not create unnecessary burdens, for example, financial and administrative; should be focused on risks to public safety, proportionate to potential benefits; and should be sufficiently flexible to work effectively for different healthcare needs and approaches, and regard future changes.[549(pp40-41)]

The mapping in Annex 7 shows that some countries have established whole-of-government regulatory assessment processes that are expected to be followed before any legislation or regulations are enacted or amended.[378,380] Such processes are generally designed to strengthen evidence-informed policy making, by ensuring any new or amended law avoids unnecessary restrictions on competition, minimizes regulatory burdens and costs to business or the community and demonstrates the 'highest net benefit'.[d] Benton & colleagues [68] encourage a more structured, reliable and valid risk-based approach to determining the level of HPR needed to achieve intended outcomes.

While threshold questions about the scope of a statutory registration scheme ideally should be informed by the best available evidence and robust regulatory impact assessment, the evidence suggests that:

- the policy-making process is often highly politicised, with vested interests lobbying government for outcomes favorable to their constituencies,[119,340,445,456,517] and
- many jurisdictions do not apply evidence-informed regulatory policy making principles to these contested decisions. [18,68,118,138,196,341,382,453,548(p11)]

As a consequence, some occupational groups may be licensed when perhaps other regulatory models (such as negative licensing or co-regulation) may provide sufficient public protection.

Second, the principles and tools of risk-based regulation adopted by some regulators signal a shift to more proactive strategies for harm prevention and minimization.

Studies described how regulators are using the tools of data analytics to systematically focus (or refocus) their efforts and resources towards identifying potential concentrations or 'hot spots' of risk (due to poor practitioner conduct, competence or capacity issues) and develop targeted harm reduction programs to reduce or eliminate these.[79,307,405,411,490,507,508]

Eight articles described different approaches to risk-based regulation: in Australia,[79,507,508] Canada,[257] the UK,[307,411] the US [315,405] and an international review.[397] These studies show how regulators in HICs are refocusing their resources and strategic priorities and show some of the conceptual issues that have arisen with the application of risk-based regulatory methods. For instance, Lloyd-Bostock [307] describes the potential for the UK's General Medical Council to

[d] A 'net public benefit' is demonstrated when the benefits to the community as a whole outweigh the costs.[46]

use its electronic database to combine register and fitness to practice data to systematically identify and assess risks, predict potential harm and target regulation and inspection accordingly.[307(p585)] The capability of a single national health workforce regulator can be even greater. Bismark & colleagues [79] describe the 'unprecedented opportunities' afforded by the establishment of a single national registration scheme in Australia – the research potential of this data set, its depth and breadth of scope, that is enabling both quantitative and qualitative research, using disciplinary data calibrated accurately against relevant denominator populations.[79(p484)]

No evidence was found concerning the pros and cons of risk-based regulation and what might be the barriers and facilitators for regulators, particularly for LMIEs with limited access to infrastructure and human resource capability. Factors such as statutory mandate, resource base, policy and research capability and IT infrastructure may be pre-requisites.

Risk management has become even more important for regulators during the COVID-19 pandemic. Literature on the pandemic responses of HP regulators shows greater emphasis on trust, agility, capacity, and flexibility in HPR processes, with the adoption of policies to enable more nimble regulatory responses that balance risk to the public with access to needed health services.[41,67,358,375,385,430,472,562]

Third, various generic and HPR-specific standards and tools are being used to assess HPR performance, with some adaptable for use in lower-resource environments.

The literature offers a range of frameworks and tools that have been used by governments to design better regulation. These include the generic tools provided by the OECD and jurisdictional competition regulators (such as the UK's Better Regulation Taskforce, the Australian Office of Best Practice Regulation and the Malaysia Productivity Corporation).[46,156,350,380,381,397,405,515] There are also tools designed specifically to assist in strengthening HPR, such as the 'Right-touch Regulation' approach published by the UK PSA, the Ontario Ministry of Health's College Performance Management Framework and McCarthy & colleagues' Regulatory Function Framework developed and applied in sub-Saharan African countries.[328,329,405,419,427,448,451]

The OECD frameworks, tools and guidance encourage jurisdictions to view regulatory policy and governance as part of a whole of government system of regulation and to adopt a cycle of periodic review and revision of legislation (see the OECD *Reference Checklist for Regulatory Decision-making* 1995).[e] In acknowledging the crucial role of innovation in overcoming global

[e] The OECD Reference Checklist contains ten questions about regulatory decisions that can be applied at all levels of decision- and policy-making. These questions reflect principles of good decision making that are used in OECD countries to improve the effectiveness and efficiency of government regulation by upgrading the legal and factual basis for regulations, clarifying options,

challenges such as the COVID-19 pandemic, the OECD has recently published a conceptual framework and relevant guidance for using and adapting regulatory policy and governance.[380(p3)] It provides guidance on the basic core elements of modern regulatory frameworks to ensure they meet fundamental societal goals. It includes guidance on deciding how stakeholder engagement, impact assessment, risk assessment and institutional co-operation (including international regulatory co-operation) need to evolve in a context of rapid innovation and technological change.[380(p4)]

OECD has also acknowledged that the challenges of law-making during the pandemic have necessitated adaptation of the design and application of existing regulatory management tools to ensure their continued relevance. [383] These adaptations provide guidance on more streamlined regulatory assessment processes which may be of use in low resource environments or where policy capacity is limited.

Fourth, there are diverse approaches to regulatory reform, with studies reporting new regulation or regulatory strengthening activities in LMIEs, sometimes prompted by development aid or trade agreements.

In several jurisdictions, regulatory failures and imperatives to maintain a fit for purpose health workforce in the face of workforce shortages have prompted successive system-wide reviews and ongoing reform programs.[8,47,62,119,128,189,362,487,520] In other jurisdictions, more incremental, piecemeal or ad hoc approaches to regulatory reform are evident, particularly in the US in relation to scope of practice reforms. [196,356,491,512]

The direction of reform is not uniform.[317] While governance reforms in Anglophone countries have increased state oversight and civil society participation, with greater focus on priorities related to cost-effectiveness and health workforce management, others, including Francophone countries and former socialist countries, are strengthening the role of the professions and professional associations in the regulatory decision-making.[317(p14)]

In LMIEs, the literature shows substantial regulatory strengthening efforts, particularly in sub-Saharan African countries.[162,175,226,267,330–332,342,352] In South-East Asia, as in Europe, trade agreements that incorporate mutual recognition arrangements have created the impetus for governments to introduce or reform statutory registration schemes.[200,293,322,489]

assisting officials in reaching better decisions, establishing more orderly and predictable decision processes, identifying existing regulations that are outdated or unnecessary, and making government actions more transparent. The checklist, however, cannot stand alone -- it must be applied within a broader regulatory management system that includes elements such as information collection and analysis, consultation processes, and systematic evaluation of existing regulations.

We found a multitude of studies on the processes of regulatory reform. These were mainly descriptive studies (case studies, cross-sectional studies) and narrative reviews. The focus of research varied depending on the jurisdiction. The largest group of studies were from the US. These studies examined regulatory reform initiatives to expand scopes of practice, particularly for nurse practitioners and other advanced practice nurses (APNs), but also physician assistants, pharmacists, pharmacy technicians and dental hygienists. [7,63,99,104,125,127,136,146,163,165,197,218,294,312,323,463] Studies either mapped regulatory changes across multiple jurisdictions, described successful regulatory reform efforts or, more often, documented the problems with and efforts to reform restrictive scopes of practice and called for legislative changes to be made. [171,196,499]

Another large group of studies was from African countries (n=10). These included a single study covering Malawi, Tanzania, Uganda and Mozambique,[226] and separate studies from Eswatini,[352] Kenya,[394] Ethiopia [162] and Lesotho.[342] Seven studies addressed implementation and evaluation of the African Health Profession Regulatory Collaborative for Nursing and Midwifery (ARC) [[f]] – see Textbox 4.

Textbox 4: Studies of regulatory strengthening in LMIEs – the African Health Profession Regulatory Collaborative for Nurses and Midwives (ARC)

The ARC was a four-year regulatory strengthening program involving 17 countries in East, Central and Southern Africa that reported on a variety of successful regulatory reform initiatives.[175,267,329,331,332] It is described as an innovative, south to south partnership in which national nursing and midwifery leadership teams work together to improve professional regulation.[394(p20)]

McCarthy & colleagues [328] developed and applied a *Regulatory Function Framework*, a 'staged capability maturity model' used to evaluate progress in key regulatory functions and impact of a multi-year US government initiative to strengthen nursing and midwifery professional regulation in sub-Saharan Africa.

The framework comprised a stepwise series of performance levels that describe the sophistication of processes necessary to achieve an organization's objectives. It captured meaningful advancements in regulatory strengthening in the five supported countries and the level of regulatory capacity in participating countries. The project used the framework to assess yearly progress of supported countries, track the overall impact of the project on national and regional nursing regulation, and to identify national and regional priorities for regulatory strengthening. It was reportedly the first of its kind to document and measure progress toward sustainably strengthening nursing and midwifery regulation in Africa.

In a second ARC study by ***Dynes & colleagues*** [175] regulatory advances were measured in 11 Sub-Saharan Countries in Year 3 of the ARC. 11 country teams of nursing and midwifery leaders (''Quads'') received small grants to carry out regulatory improvement projects. The year-3

[f] In the context of addressing the burden associated with the HIV pandemic, ARC was a program to enhance the supply and use of human resources through policy and regulatory reform, to improve the quality of HIV services in this region.

evaluation highlighted limitations of the ARC evaluation strategy to capture nuanced progress and provided insight into how the RFF might be adapted for future use.

Other ARC related studies [213,267,329,331,332,342,394]

A third group of studies were from South-East Asia, particularly the Mekong countries. These generally referred to the role of the ASEAN mutual recognition agreements as the impetus for regulatory reform by member states to establish statutory registration schemes [135,200,273,293,295,322,488,489,498] – for example in Cambodia,[322] Vietnam [200] and Laos.[489]

Summary

Beyond a core suite of health occupations that are regulated in most jurisdictions (medicine, nurses and midwives, dentists and pharmacists), there is considerable variation across jurisdictions in the scope of statutory registration schemes. However, having more regulated professions is not necessarily better and instead may be an indicator of underdeveloped or lax regulatory assessment processes and/or may pre-date the implementation of effective regulatory management systems.

There is some evidence that statutory registration is being advocated or is under consideration in multiple jurisdictions, with most activity related to the following occupational groups:

- various assistant or support occupations (assistants in nursing, support workers personal care workers, community health workers)
- advanced practice occupations (such as physician assistants and surgical assistants)
- the T&CM professions (such as Chinese medicine, naturopathy and Ayurveda)

There is some evidence to suggest a trend towards regulatory convergence, to the extent that the first two decades of the 21st Century have seen statutory registration schemes implemented in both LMIEs and HIEs, including in countries with diverse institutional and governance arrangements, transitional economies and Muslim law countries.

There is evidence of regulatory review and reform effort, principally in Anglophone countries with a long history of statutory registration of health professions. There is also some evidence that the frameworks and tools developed through the ARC program with countries in sub-Saharan Africa have been effective in strengthening HPR in those countries and in some South-East Asian countries.

No evidence was found concerning the pros and cons of risk-based regulation and what might be the barriers and facilitators for regulators to adopt risk-based methods and tools.

5. REGULATORY INSTITUTIONS

Overview

The focus of this chapter is on the institutional arrangements under which the key elements of a statutory registration scheme (standard setting, compliance monitoring and enforcement) are delivered. Of particular interest is literature on:

- who does what, that is, the configuration of institutions and actors who deliver key HPR functions (registration, accreditation, complaints and discipline, compliance monitoring and enforcement) within a jurisdiction
- any distinct approaches or institutional models, their distinguishing features, similarities and differences, strengths and weaknesses
- whether HPR systems vary with the system of government (common law, civil code, Islamic, mixed systems), the socio-political context (for example, Anglo-American, Continental, transitional economies, LMIEs) or the stage of development of a health system (basic, emerging or mature health systems)
- whether the way the regulator is constituted and governed (such as the composition of regulatory entity, the accountabilities to which it is subject and its relationship with or linkages to government) has consequences for the quality and robustness of regulatory decision-making and the effectiveness of the scheme

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **42 articles** from the published literature addressed the institutional and governance arrangements through which jurisdictions deliver HPR functions (Figure 11). For details of the publications on this topic, see Annex 4 (Table 3).

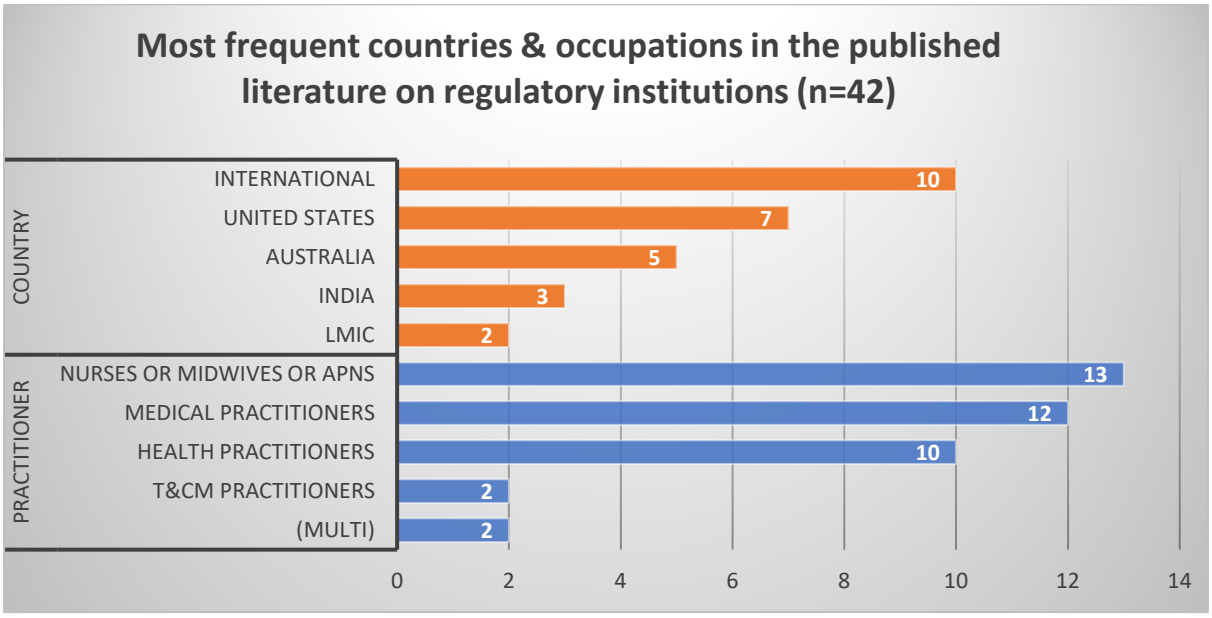


Figure 11: Most frequent countries and health occupations in the published literature on regulatory institutions

The published literature was dominated by articles on nurses and midwives (n=13), followed by medical practitioners (n=12) and health practitioners in general (n=12). International studies dominated (global and multi-country studies) (n=10), followed by the US (n=7) and Australia (n=5). A total of **30 empirical studies** were identified that addressed regulatory institutions and governance. These are discussed in Chapter 12.

The included articles addressed an array of issues associated with regulatory institutions, including:

- studies that mapped regulatory arrangements globally or in a region, to establish a profile or census for a specific occupation such as nurses, physicians, pharmacists or naturopaths, or group of occupations (***nine articles***)
- studies from LMIEs on regulatory strengthening, mostly from sub-Saharan African countries but also India and South-East Asia (***eight articles***)
- studies that included comparative analysis of sub-national regulatory institutions operating under a federated system of government, mostly from the USA but also Australia and Canada (***six articles***)

In many studies, the findings on regulatory institutions were incidental to another research focus, such as scope of practice regulation, CPD or accreditation. Two studies examined the governance features of regulatory systems across multiple jurisdictions, comparing against various parameters such as geographic region, country income level, legal tradition and government or profession-led administrations.[69,75]

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **64 documents** relevant to this topic (Figure 12).

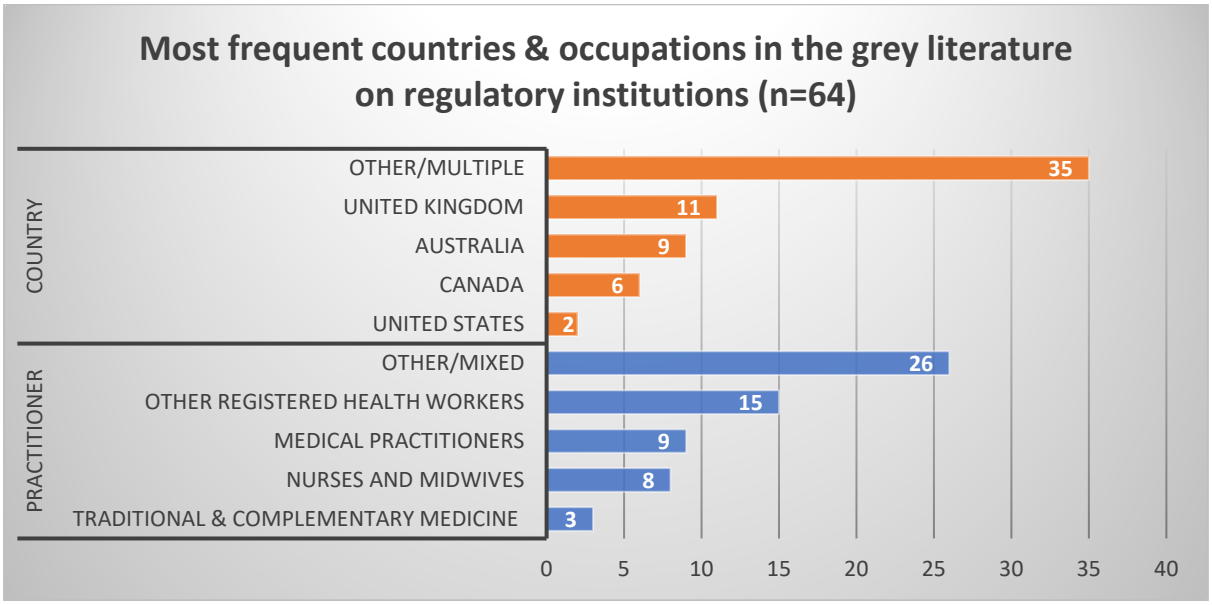


Figure 12: Most frequent countries and health occupations in the grey literature on regulatory institutions

Annex 2 provides a list of the websites searched. For details of the publications on this topic, see Annex 5 (Table 3). The main sources were:

- *Governments* – principally reports of reviews of regulators or regulatory systems, mostly from the UK, Canada and Australia (***15 documents***)
- *WHO and associated entities* – reports and policy papers issued by WHO regional offices and WHO Collaborating Centres, as well as country review reports commissioned by WHO Regional Offices and other development agencies (***13 documents***)
- *International professional associations* – policy papers, position statements and press releases that provided policy statements or guidance on matters of institutional structure and governance, from organizations such as the ICM, ICN, WMA and WNF (***11 documents***)
- *Regulators and meta-regulators* – reports from organizations that represent regulators, such as the NCSBN and IAMRA, and the meta-regulator the UK PSA (***nine documents***)

Comparative analysis of selected regulatory schemes

Data extracted from the registration laws and websites of regulatory authorities in a sample of jurisdictions are set out in Annex 8. Comparative data are presented from 17 jurisdictions, on key elements of the governance of HP regulatory institutions, including:

- the type of legal entity exercising the registration functions
- if there is a governing board, its size, mix of members and member appointment method
- the statutory role of the regulator
- the relationship of the regulator to government
- the type of information published on the websites of HP regulators

Like the scope and legislative framework of regulatory schemes, these schemes illustrate the variation in the type of legal entity responsible for registering and regulating practitioners, their statutory role and relationship to government, and the extent of information publicly available on these matters.

With respect to the type of legal entity, some jurisdictions deliver these regulatory functions directly, via staff employed within the Ministry of Health (Qatar, Vietnam) and with no statutory profession-led board, council, college or chamber.[g] In other jurisdictions the regulator is constituted as a body corporate, with power to enter into contracts, employ staff

[g] Qatar has a 'Permanent Licensing Committee', a statutory committee comprised primarily of heads of various departments within the Ministry of Health.

and own property etc. Examples include the UK and British Columbia regulators that operate as independent statutory authorities.

As outlined earlier, in some jurisdictions, multiple profession-led boards or councils are supported by a single administrative agency (for example, Ahpra in Australia and the Professional Regulation Commission in the Philippines). In others, the administrative functions of multiple statutory boards or councils are delivered by an administrative unit of Ministry of Health (Singapore, Vietnam) or Ministry of Education (New York State).

Where there is a profession-led board or council, there are also variations in the size and method of appointment of members. Some are small corporate-like boards, others are large 'representative' councils. Members may be elected from the regulated profession, nominated by specified professional associations, educational institutions and/or government agencies, or appointed by the responsible Minister. A combination of methods may be used.

The relationship between the regulator and government including the accountabilities that apply also vary, depending on what the statute or statutes dictate and whether the regulator is established as an administrative arm of government, a statutory committee or an independent statutory authority.

Thematic analysis

Three themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. There is no widely accepted typology for describing HPR institutional and governance arrangements.
2. Tensions between 'profession-led' governance models and increasing government expectations of oversight and control of regulators reflect a long history of contestation in some jurisdictions over who controls the institutions that govern health practitioners.
3. HPR governance reforms show a trend toward greater use of umbrella laws and multi-profession regulators, more diverse governing board membership and increasing accountability obligations.

These themes are expanded upon below.

First, there is no widely accepted typology for describing HPR institutional and governance arrangements.

While HPR schemes are found in most jurisdictions,[356] there is considerable diversity in the types of institutions responsible and their governance arrangements.[75,113,174,284,308,349,356,357,528]

Much of the published literature located on this topic addressed specific elements of governance, such as the challenges associated with state-based regulatory schemes under a federal system of government,[119,171,241,339] the strengths and limitations of the collegiate or peer review governance model (also known as professional self-regulation);[166,231] or the need to establish a profession-led statutory regulator in place of government operated registration.[134,349]

Eighteen sources (six from the published literature and 12 from the grey literature) compared HP regulators across multiple jurisdictions.[1,69,69,75,111–113,115–118,174,349,356,357,528,557,571] These studies show that the configuration of regulatory institutions, the division of roles and responsibilities and governance frameworks within which the institutions operate are highly variable across countries. HPR systems are shaped by the historical, legislative, political, environmental, social, cultural context in which they are developed and operate.[75,251(p9)] Comparing the structure and governance of regulatory bodies and associated systems is complex and fraught with definitional traps.[72(p23)] While systems may appear broadly similar, the devil is in the detail.[528(p146)]

For instance, organizations responsible for regulating medical practitioners range from a unitary state authorized body, to decentralized polycentric systems, with differences also in the extent to which regulation was combined with representation of the profession.[528] Besancon & colleagues attempted to identify patterns of these institutions according to region, country income level and type of government.[75] While it is unclear the extent to which the number and type of regulators vary according to such factors, it appears that as systems of regulation become more complex, the level of collaboration between governmental and regulators increases.[75(p128)]

Benton & colleagues [69] mapped nursing legislation against key attributes such as the legal tradition of the jurisdiction, the model of regulation, administrative approach, area of the world and the economic status of the jurisdiction. They provided some tentative analysis of the advantages and disadvantages of the different regulatory models.[69] However, no published literature was identified that assessed different institutional arrangements against parameters such as transparency, accountability, the safety and quality of the health workforce, effectiveness or patient outcomes.

A single study by Uys & colleagues[521] of competencies in nursing/midwifery roles in ten sub-Saharan African countries noted significantly higher role performance in Anglophone countries than in Francophone countries, with researchers identifying the presence of HP regulators in Anglophone countries as a possible contributing factor.[521(p2215)]

Analysis of the literature shows no widely accepted typology for describing the features of HPR institutions. Various terms are used, such as ‘independent’, ‘autonomous’, ‘profession-

led' and 'government-led', without clear operational definitions. There is insufficient rigor in describing the key characteristics of HP regulators, even with respect to whether a regulatory board/council/chamber/order: has separate legal identity (as a body corporate); or is a statutory committee but without separate legal identity; or is an administrative arm of a government department.

Differences in institutional configuration and governance are characterized in various ways in the literature. For instance, the ICN's Regulatory Board Governance Toolkit sees governance models as sitting along a continuum from those that are 'profession driven and organised' to those that are 'state-embedded or controlled'.[251] The ICN identifies four main models: professionally established model (which they label 'pure self-regulation'); professionally led model; state led arm's length model; part of Health Ministry model..[251(p10)] The ICN favors what it calls 'profession-led nursing regulation' which it considers promotes public protection and quality patient outcomes.[251(p9)]

Distilling from the typologies available,[72,75,118,356,357,528] there are some key dimensions, the application of which should facilitate a more robust comparison of regulators across jurisdictions – see Textbox 5.

Textbox 5: Key dimensions for comparing HPR institutional and governance arrangements across jurisdictions

Legislative instrument: omnibus law OR umbrella law OR profession-specific law OR a combination OR no legislative instrument; national OR sub-national/regional/local enactment

Type of legal entity: statutory authority (separate body corporate) OR statutory entity (established in statute but not as a separate body corporate) OR administrative committee operating within government department OR administrative unit of government department OR statutory commissioner OR non-government professional association OR hybrid entity OR a combination of differently constituted entities

Constitution of governing board/council: mix of members (professional, lay/community, ministerial/departmental nominees); method of appointment (elected, nominated, appointed by government, combination); who occupies leadership roles; gender balance

Administration: stand-alone administration with separate office OR co-location with another agency OR administrative unit within government department; single OR multi-practitioner administration

Staffing: direct employees of regulator OR public service employees/Ministry employees OR non-government agency employees OR contracted from for-profit entity OR other/combination

Financing: self-funded through registration and other fees OR funded by government OR a combination; sets own fee schedule OR fee schedule set by government/regulation; collects own revenue & approves own budget and expenditure OR fees collected by government through consolidated revenue and separate budget allocation provided OR a combination

Role of government/Minister/department: appoint/nominate members for appointment to governing board of regulator; attend board meetings as ex officio members; approve standards; issue policy directions; make/approve regulations; provide administrative staff/accommodation; provide or approve budget/provide funding; take enforcement action

Key powers and functions: set qualifications and other requirements for entry to practice; register applicants and maintain a public register; accredit and approve entry-to-practice programs; issue practice standards and guidance; monitor compliance with standards; receive and manage complaints and discipline; initiate enforcement action against registrants; prosecute offences by unregistered persons; collect and supply data for workforce planning purposes; other

Second, tensions between 'profession-led' governance models and increasing government expectations of oversight and control of regulators reflect a long history of contestation in some jurisdictions over who controls the institutions that govern health practitioners.

How a regulator is directed, controlled, resourced and held to account is crucial to the overall effectiveness of regulation. This includes the nature of the relationships between the regulatory decision-maker, Minister, Parliament, department, executive management and other regulated entities.[42,524] Good regulatory governance is linked with high-quality institutions and with sustained growth – regulatory agencies with better governance should make fewer mistakes, and have their mistakes identified and rectified more quickly and effectively, so that good regulatory practice is more readily established and maintained.[495(p53)]

We found evidence of continuing contestation over how HP regulators are or should be constituted, governed and controlled. In some jurisdictions, where the regulator is the responsible health ministry, there were calls to strengthen professional control and establish the regulator as a separate and independent entity.[12,30(pp8-9),134,242(p158),349]

In other jurisdictions (generally high-income Anglophone countries with a long history of delegating regulatory powers to profession-led bodies), there were calls to strengthen government oversight and thereby reduce the level of control exercised by members of the regulated profession, including by reconstituting governing bodies to provide a balance of professional and lay or public membership.[107,128,189,529]

International professional associations promote 'profession-led' regulation as the preferred governance model:[247,252,554]

- *The ICM Global Standards recommend legislation and regulatory authorities be midwifery specific, with membership of the regulatory authority comprising a majority of midwives, appointed through a combination of elected and appointed members nominated by the profession, and chaired by a midwife.*[247(pp15-16)] *The ICM links a midwifery-led governance model to better outcomes – protecting the health of mothers and babies by ensuring safe and competent midwifery practice.*[247(p15)]
- *The ICN Position on Nursing Regulation* [252] *states that profession-led nursing regulation contributes to public protection and quality patient outcomes, and includes as one of its principles of professional regulation 'representational balance'.*
- *The WMA states that the medical profession must play a central role in regulating the conduct and professional activities of its members.*[554] *It has published several press releases 'defending physicians' self-governance against government attacks' and critical of HPR reforms in various*

countries. The WMA states that professional self-governance facilitates professional autonomy and clinical independence and that there is 'absolutely no evidence anywhere in the world' that regulation of a profession is better done by governments'.[553]

The assumptions that inform these positions are not clear but appear to be that peer review should be the foundational principle that determines the structure and governance of a regulator – that only the professions can and should be trusted to regulate their own members and that the quality and safety of health services requires that the governance of the regulator be under the control of members of the regulated profession. Benton & colleagues [73] found a strong preference for this so-called 'delegated self-regulatory model', with little rationale or evidence presented.[73(p310)]

On the other hand, the literature raises concerns about the risk of 'regulatory capture' under governance arrangements which constitute the regulator with elected members of the regulated profession. Over several decades, successive regulatory reviews, principally from Canada, the UK and Australia, have recommended removal of 'representativeness' from the governance of regulators and greater government oversight.[47,62,128,516,520] Devolving or delegating regulatory functions to representative bodies risks the suspicion of conflict of interest.[528(p6)] Also, when key players wear multiple hats, roles and responsibilities can be blurred, important checks and balances are absent or compromised, and the risk of regulatory failure is greater.[113(p21)]

Contests over the governance of HPR institutions reflect broader shifts in the power dynamics between the professions and the state, at least in high income Anglophone countries. How a regulator is constituted determines who is engaged in the decision-making process. This in turn signals who is important and who is not, whose views are recognized as legitimate and whose are not.[260(p179)] Ordinary citizens are disenfranchised when participation is viewed as the province of those with highly specialized knowledge [260(p176)] and the spread of human rights values has called into question all forms of elite governance.[531(p20)]

An analysis by the UK PSA of evidence on the size, make up and effectiveness of governing boards of regulators recommended a shift in thinking on governance. The PSA concluded that 'representativeness' – where members of the governing boards of regulatory authorities elected from the professions they regulate – is no longer a valid organizing principle, as reflected in the move away from self-regulation and large elected councils. Boards must be credible to stakeholders and this credibility is achieved through performance rather than through specified membership.[423(p5,10)]

This principle is well established in the competition policies of many OECD countries – those who have a vested interest in a market should not alone make decisions which affect that market (such as setting standards and determining regulatory policies, entry-to-practice requirements, scopes of practice etc.). In regulatory schemes where a controlling number of

decision-makers are active participants in the market, there must be active oversight by the state.[129,149,264,379,500]

In keeping with these developments, the grey literature, primarily from HICs shows that greater expectations are being placed on regulators to be more transparent and accountable in their operations, to better manage conflicts of interest and to ensure registrants are afforded procedural fairness in regulatory decisions that affect them. This is reflected in reforms designed to provide greater 'separation of powers', particularly functional separation of those responsible for investigation/prosecution of disciplinary matters from those responsible for sitting in judgement and imposing sanctions.[17,47,113,119,128,139,189]

A recent review of British Columbia Canada's *Health Professions Act* found that the current model of regulation is inefficient; has enabled cultures that can sometimes promote the interests of professions over those of the public; is not keeping up with the changing health service delivery environment, particularly in relation to interprofessional team-based care; nor meeting changing patient and family expectations regarding transparency and accountability.[62(p4)] The deficiencies in the governance of professional colleges and a lack of transparency have allowed for the promotion of interests of the professions over those of the public, compromising public trust.[62(p4)]

Several researchers use the term 'frameworks of accountability' to describe the raft of accountability measures or oversight mechanisms that apply to regulators, such as: independent review processes, whole of government regulatory management systems and scrutiny by multiple integrity agencies (judicial review of regulator decisions, ombudsman laws, anti-corruption and whistle-blower protection laws).[62,70,189(p9),400,523] Examples include the progressive strengthening of the oversight powers of the UK PSA; the establishment of the Kenya Health Professions Oversight Authority; the establishment of the Ontario Ministry of Health's *College Performance Measurement Framework* and the establishment of tribunals external to the HP regulator to hear disciplinary matters.[189(p10),270,390,445,451,523]

Third, HPR governance reforms show a trend toward greater use of umbrella laws and multi-profession regulators, more diverse governing board membership and increasing accountability obligations.

Comparative studies of HPR schemes across jurisdictions [69,76,113,118,174,200,349,356,528,557,571] and the mapping data set out in Annex 8 show the diversity of legislative mechanisms and governance models employed by jurisdictions in HPR.

While umbrella laws and multi-profession regulators remain unpopular with some professional bodies, we found evidence of a trend towards use of these multi-profession mechanisms. Some jurisdictions have enacted umbrella legislation and multi-profession regulatory regimes from inception, operating their statutory registration scheme as an

administrative function of the responsible government department (usually the Ministry of Health or equivalent). These include the Philippines, Vietnam, Somaliland and Qatar. Other jurisdictions are consolidating and rationalizing their registration laws to achieve greater consistency of standards and regulation across the professions; make it easier to keep laws up to date and responsive to emerging challenges; and facilitate more streamlined international collaborations.[h]

There is some evidence from both LMIEs and HIEs that umbrella legislation and multi-profession regulators are increasingly preferred and that the benefits are considered to outweigh the costs.[47,62,112,113,117,119,128,487] An umbrella law encourages greater consistency of standards between regulated occupations and enables a government to streamline its statute book to better maintain an up-to-date legislative framework.[113(p50)] In Vietnam and Cambodia, Fujita & colleagues found this legislative mechanism has led to a more coherent and comprehensive approach compared with the schemes of near neighbors that have separately legislated for each specific cadre of health professional.[200(p9)]

Evidence from some HICs suggests that a multi-profession administrative agency provides greater economies of scale in the regulation of health occupations than many smaller profession-specific agencies.[140,484,487,518(p26)] A larger multi-profession regulator has more shared resources available and greater capacity to resource a risk-based regulation function than multiple smaller regulators[118(p163)], or where the regulatory functions are dispersed across multiple government and non-government entities. A single study commissioned by the UK Department of Health and Social Care suggested that the 'sweet spot' where the greatest economies of scale are achieved is a minimum registrant base of 300,000 registrants. This study found that as a regulator's size increases, unit operating costs (defined as operating costs per registrant) fall, then plateauing above 300,000 registrants. No significant diseconomies of scale in large regulators were identified.[518(p26)]

Also, various WHO publications and government reviews have encouraged a multi-profession governance model to address perceived disadvantages (for standard setting and discipline) of profession-specific regulatory 'silos'.[62(p10),189(p58,64,68),548,549] The adoption of the multi-profession governance model as a solution to the problems of coordination and integration reflects a broader trend towards 'network governance' as an organizing paradigm. For instance, Lewis [301] points to a trend towards a form of organization in which clients, suppliers,

[h] Jurisdictions where multi-profession 'umbrella' statutes have been enacted covering some or all regulated health professions include Australia, Hong Kong, Malaysia, New Zealand, Singapore and UK. Examples of multi-profession administrative agencies include the UK Health and Care Professions Council, the Philippines Professional Regulation Commission (PRC), the Health Professions Council of South Africa, the Australian Health Practitioner Regulation Agency and most recently, Singapore's Secretariat of healthcare Professional Boards (SPB).

and producers are linked together as co-producers, with collaboration and partnership the dominant organizing principles.[301(p51)] Such networked governance arrangements aim to redress some of the complex coordination problems posed by multi-actor systems.[301(p44)]

Multi-profession governance models can reduce the costs of cross-profession and cross-jurisdiction policy coordination. By blurring the boundaries between institutions and sometimes between levels of government, some of the inter-professional and inter-jurisdictional tensions that previously played out externally to profession-specific regulators are dealt with internally.[119(p357)] These models are considered to facilitate a more coordinated approach to regulation with the range of interests involved in sharing regulatory authority with governments; and to enable a single national focus for international collaboration, in response to an increasingly globalized environment.[119(p357),184] However, studies of the effectiveness in practice of these governance models compared with profession-specific models are yet to be conducted.

Another development worthy of note is the concept of 'distributed regulation', a term coined to describe a model for regulating an increasingly multi-disciplinary workforce engaged in interprofessional team-based practice.[431] Such a model has been implemented in the Australian HPR system, using the mechanism of an endorsement on registration.[i]

[i] See section 97 of the *Health Practitioner Regulation National Law* under which multiple National Boards may endorse the registration of a health practitioner to confer the right to use the title 'acupuncturist' if the Board decides the health practitioner holds qualifications relevant to the endorsement. See also section 94 endorsement for scheduled medicines and section 98 endorsement for approved areas of practice.

Summary

There is considerable diversity across jurisdictions in the institutional and governance arrangements for delivery of HPR functions. Comparative studies are mostly descriptive and have identified several main governance models – in-house government operated, independent statutory authority, shared government/non-government multi-institution, and hybrid. In the absence of studies that employ a robust typology and methodology, conclusions about the effectiveness of different governance models in different contexts are necessarily limited.

The evidence suggests that in jurisdictions where there is no registration law underpinning the HPR system or where core HPR functions are dispersed across multiple government and non-government profession-led entities, there is less transparency in how standards of practice are set, monitored and enforced and less publicly available information about the performance of these core functions.

There is evidence of continuing contestation over how regulators are best constituted and controlled, with professional bodies favoring 'profession-led' regulation and some governments seeking increased accountability, oversight and control. In some HICs, there is evidence of a shift away from governing boards whose members are elected by and representative of the regulated profession/s, to smaller appointed boards with a more diverse membership and stronger reporting to, and oversight by, government.

There is some evidence of a trend towards use of the umbrella law as a more efficient legislative mechanism to ensure the HPR legislative framework is maintained up to date and fit for purpose. There is some evidence of a trend towards the adoption of a single multi-profession administrative agency, with various structural and administrative arrangements for ensuing profession-specific input into regulatory decision-making.

6. REGULATORY SYSTEM LINKAGES

Overview

The focus of this chapter is on the nature and effectiveness of the linkages and interfaces between a HPR system and other parts of the health system, particularly the systems of quality assurance.

The effectiveness of HPR relies in part on how well it operates within the broader institutional framework of a jurisdiction's health system and beyond. WHO's framework of health system building blocks assists in understanding the health system and the place of HPR within it. WHO describes an overall health system architecture that has six sub-systems: service delivery, health workforce, health information, medical technologies, health financing, and leadership and governance.[477(p31)]

A HPR scheme is a set of highly complex governance interventions aimed at the population level. It influences multiple building blocks of the health system, not just the health workforce but also information, medical products and service delivery. To design and deliver an effective HPR system to better target health system strengthening requires an understanding of the multiple relationships, interactions and synergies between these building blocks and the full range of effects, both intended and unintended, of any intervention.[477(p32)] For instance, the HPR system has key linkages with:

- licensing and/or accreditation of health services and facilities
- regulation of medicines and therapeutic goods
- regulation of public health risks for example, infection prevention and control
- employers and their representative bodies
- health consumer representative bodies
- health practitioner representative bodies – unions and professional associations
- education ministry stewardship functions of planning and oversight of the education system and qualification framework
- health ministry stewardship functions of health workforce planning and development
- law enforcement, public prosecutors and the courts
- medical error compensation systems
- public and private health insurers, pharmaceutical benefits schemes, accident compensation schemes etc.
- local government and other provider agencies
- international standard setting bodies and intergovernmental organizations

Articles included in this synthesis offer insight about the nature and effectiveness of these system linkages and relationships. Of particular interest is literature on:

- the relationship between the regulator and other entities within and beyond the health system (such as those listed above)

- the extent to which these relationships and partnerships facilitate the quality, safety, capability or effectiveness of the health workforce and the achievement of health system goals
- international or cross-border interfaces and/or cooperative arrangements involving mutual recognition arrangements, regional or international standard setting bodies and accreditation/certification bodies, networks of regulators and professional representative bodies

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **110 articles** contained content relevant to understanding regulatory system interfaces, linkages and stakeholder relationships (Figure 13). For details of the publications on this topic, see Annex 4 (Table 9).

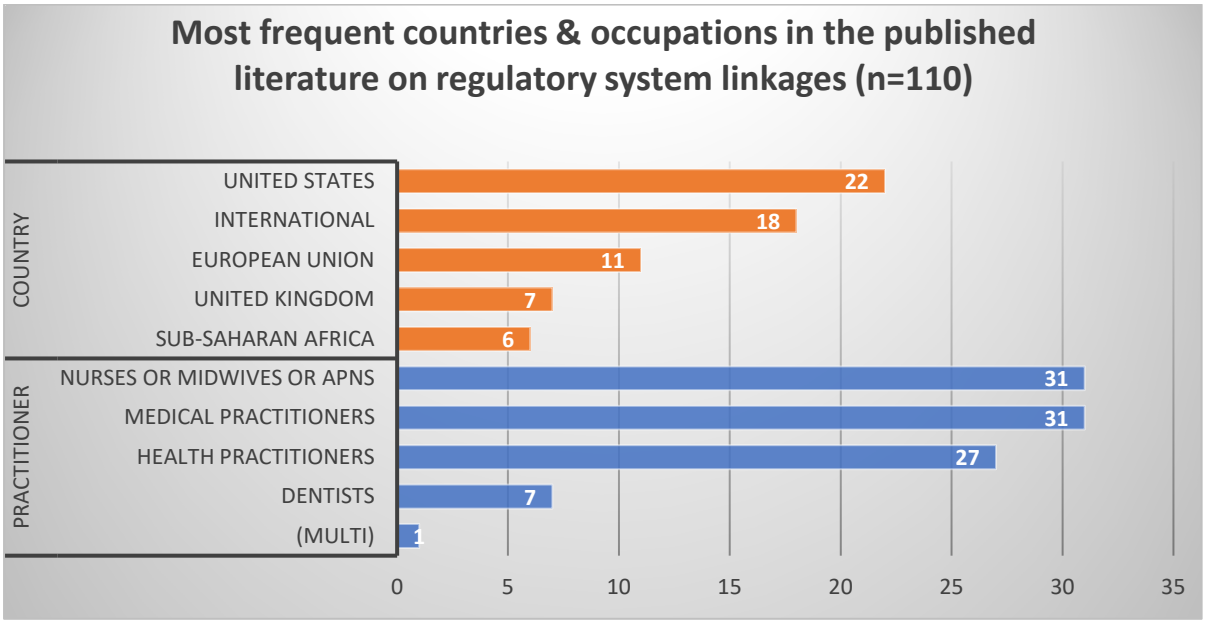


Figure 13: Most frequent countries and health occupations in the published literature on regulatory system linkages

The published articles focused primarily on nurses and midwives (n=31) and medical practitioners (n=31), followed by health practitioners generally (n=27) (Figure 13). Articles were primarily from the US (n=22), followed by articles with a global or international focus (n=18) and from Europe (n=11). A total of **83 empirical studies** were identified that addressed some aspect of regulatory system linkages. These are discussed in Chapter 12. The included articles addressed a variety of linkages and interfaces:

- interfaces between the regulator/s and broader workforce governance functions such as workforce planning, development and supply, monitoring of workforce shortages and the use of workforce data, and the design and implementation of workforce reform (***40 articles***)

- mutual recognition of qualifications for entry to practice, portability of registration and harmonization of regulatory requirements across nation or sub-national jurisdictions (***26 articles***)
- international and regional interfaces and relationships (***16 articles***)
- operational interfaces between the regulator and other entities that have a quality assurance role such as employers, facilities regulators, the court system etc ***(four articles)***

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **83 documents** that contained content relevant to regulatory system linkages and interfaces (Figure 14).

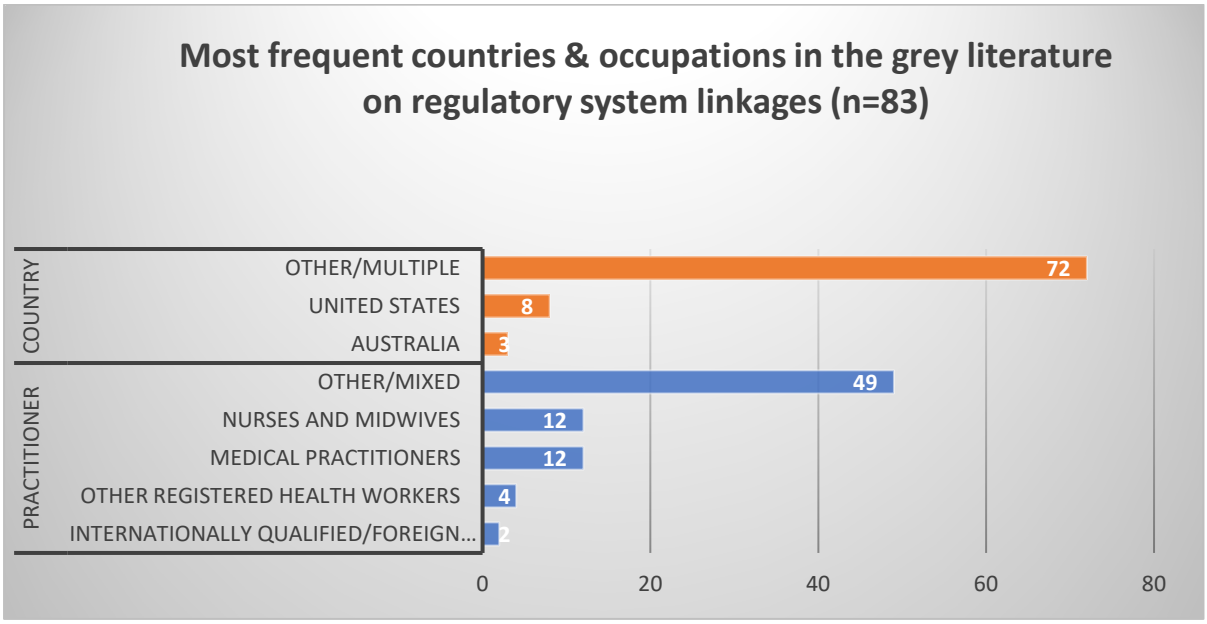


Figure 14: Most frequent countries and health occupations in the grey literature on regulatory system linkages

Annex 2 provides the list of websites searched. For details of the publications on this topic, see Annex 5 (Table 9). The main sources were:

- *Intergovernmental agencies* – reports from the OECD and the World Bank Group, ASEAN and various trade agreements that address issues such as mutual recognition of entry-to-practice qualifications and mobility of workers (***31 documents***)
- *WHO and associated bodies* – global and regional WHO reports, research and policy papers, some about health workforce regulation specifically, others about health workforce and health system strengthening, that included comments on HPR (***16 documents***)
- *Governments, regulators and meta-regulators* – policy papers, consultation papers and reports of systemwide reviews of HPR regimes, primarily from the UK, Canada, Australia and New Zealand (***11 documents***)

- *International professional bodies* – policy papers and reports from organizations such as the ICN, ICM, the World Federation of Medical Education (WFME) and World Physiotherapy (***six documents***)

Thematic synthesis

Three themes were identified from the integrated synthesis of the published and grey literature on this topic:

1. Routine collection by regulators of comprehensive and robust workforce data are being used to improve health workforce planning, development, supply and distribution.
2. Despite continuing efforts in harmonization and mutual recognition of entry-to-practice qualifications, challenges remain with cross-border recognition of qualifications and portability of registration.
3. HPR policies impact the migration of health workers, with little evidence the WHO Global Code of Practice is working to protect LMIEs from outward migration of healthcare workers.

These themes are expanded upon below.

First, routine collection by regulators of comprehensive and robust workforce data is being used to improve health workforce planning, development, supply and distribution.

Workforce shortages, skill mix imbalances and maldistribution of health workers present ongoing challenges for the delivery of health services around the globe.

The published and grey literature yielded studies and reports that highlighted how the design of HPR schemes, and the decisions of HP regulators can directly impact workforce supply and facilitate or hinder a flexible, responsive and sustainable health workforce.[47,119,393,541,548]

For many governments, the capacity to carry out accurate and effective workforce planning is limited by a lack of timely, reliable and comprehensive health workforce data. Registrant data can be used, amongst other things, to:

- develop targeted evidence-based strategies to address workforce shortages
- plan, implement and evaluate the impact of these strategies over time
- enable cross profession, national and international comparisons
- align training numbers and curriculum with health system needs[114(p62)]

The literature reveals increasing recognition of how the registration renewal systems may be used effectively to collect and supply to government a minimum set of registrant data for use in health workforce planning, including in LMIEs such as Kenya.[5,68,219,269] Benton & colleagues [68] point to how the accuracy of workforce data has improved since regulators have introduced annual renewal, pointing to work in Kenya to modernize information technology systems to provide invaluable data for improvements to pre-service training capacity and production.

Several recent reports have highlighted how the pandemic created an imperative for more effective registrant data collection to support workforce planning and mobility.[180,358,509]

The WHO report *Global Strategy on Human Resources for Health: Workforce 2030* [540] included a milestone that by 2020, all countries make progress on health workforce registries to track health workforce stock, education, distribution, flows, demand, capacity and remuneration. The capacity of a HPR system to do this depends on the design of the underpinning legislation and resourcing of the regulator. The regulator needs certain powers, capabilities and obligations: to require registration/practicing certificates be renewed periodically; to require each applicant for renewal to complete a workforce survey; to supply to government this non-identifying registrant data for workforce planning purposes; and good IT systems that support a streamlined online annual or periodic renewal process. [5,68,113,534]

The potential to use HPR systems to facilitate health workforce and health system reform may be unrealised without an explicit requirement by the government for the regulator to collect and supply registrant data for workforce planning and system improvement purposes, and to direct the regulator on policy matters that may impact workforce supply and distribution.

Second, despite continuing efforts for harmonization and mutual recognition, challenges remain with cross-border recognition of qualifications and portability of registration.

The general aim of mutual recognition schemes is to enable the mobility of health workers across jurisdictions by standardizing, harmonizing and/or streamlining entry-to-practice qualification requirements, to recognize and accept a license and related credentials granted in one jurisdiction for practice in another. In this context, enabling the mobility of the workforce is seen as a good thing to the extent that it can address workforce shortages and improve access to services, including telehealth and virtual services.

We found **24 articles** in the scholarly literature that addressed the challenges facing regulatory authorities in responding to the demand for greater mobility of registered health workers across state or national borders, and the need to streamline portability of registration. The following mutual recognition schemes featured in both the published and grey literature:

- *South-East Asia – mutual recognition agreements signed by ASEAN countries for the medical, nursing and dental professions.*[273,286,293]
- *Europe – EU Directives to standardize and harmonize regulatory requirements and recognize professional qualifications for various health occupations, such as such as Directive 2005/36/EC on recognition of professional qualifications*[105,150,159,290,295,478]
- *US – developments with the roll-out of the NCSBN's Enhanced Nurse Licensure Compact and the FSMB's efforts to establish Interstate Medical Licensure Compact*[368,574]

Some articles highlighted continuing barriers to practitioner mobility. A recurring theme was that while some progress has been made, there are continuing difficulties due to factors such as variability in the standards set for registration (qualifications, examinations);[150,273,286] the diversity of requirements for renewal of registration (CPD, revalidation);[105,290,478] and the need to assure the probity and competence of practitioners seeking registration or providing telehealth services.[295] For instance, Risso-Gill & colleagues [461] found little consistency across EU countries in how disciplinary matters are dealt with by regulators, with significant implications they argue, for professional mobility, patient safety and quality of care.

The grey literature provided more granular information about the operation of mutual recognition schemes. For instance, the WHO report *State of the World's Nursing 2020* found that mutual recognition agreements and harmonized education requirements are increasing standardization and the safe and efficient mobility of practitioners, listing the following examples (see Textbox 6):

- United States Nurse Licensure Compact [368]
- Caribbean Regional Examination for Nurse Registration [542]
- European Union Professional Directive [181]
- Association of Southeast Asian Nations (ASEAN) agreement,[43] and
- Trans-Tasman agreement (Australia and New Zealand)[542(p32)]

Textbox 6: WHO State of the World's Nursing 2020 examples of harmonization of education standards and licensure examination

In 1972, the territories of the *Caribbean Community* created the Regional Nursing Body with the initial task of establishing a shared pool of qualified educators to alleviate bottlenecks in holding competency assessments for graduate nurses. When analyses indicated that nursing education curricula objectives, content and methods of teaching were similar throughout the subregion, countries agreed to a singular and shared examination for nurses, which began in 1990. The Regional Nursing Body coordinates the examination, which is based on mutually agreed competencies for a registered nurse to practice; governance is shared between the chief or principal nursing officers, nurse tutors, and nursing council of each country, as well as educators from the universities of the subregion. The examination allows for standardization and improvement of nursing education, as well as reciprocity and ease of movement for registered nurses among the countries of the subregion.

In the *European Union*, efforts to harmonize the diversity and complexity in nursing degree structures and curricular programs started with the introduction of the sectoral directives in the late 1970s and has accelerated with revisions in 2005 (Directive 36) and subsequent updates that introduced a standard set of competencies (Directive 55). These changes, coupled with the Bologna Agreement (1999), resulted in a three-cycle educational structure of bachelor's, master's and doctoral qualifications, with harmonized academic qualifications across all disciplines.

Source: WHO *State of the World's Nursing 2020* [542]

Mutual recognition of qualifications for entry to practice seems to be viewed positively, at least in nursing and midwifery, even for those countries that are vulnerable to the 'brain drain'. For instance, a 2021 UTS WHO Collaborative Centre Scoping Study on nursing and midwifery in Pacific Island countries (PIC) suggests that the development of a regional framework along with mutual recognition of qualifications and standards may assist in ameliorating the problems associated with migration of nurses and midwives across the region.[470(p11)] The authors see benefits in mutual recognition, with seamless movement between countries expected to provide nurses across the region with opportunities to work for short periods elsewhere and enable countries to more readily increase surge capacity in times of crisis.[470(p11)]

While some reports are positive, a note of caution is also evident. The OECD has published several policy papers on mechanisms for regulatory cooperation,[2,2,147,377] with mutual recognition as one of 11 mechanisms used by countries to support their international regulatory cooperation objectives.[147(p13)j] One OECD policy paper identified various 'modalities' and investigated the potential of mutual recognition to reconcile the mission of national regulatory authorities to protect safety, health, environment and consumers (SHEC) and the imperative to facilitate or accommodate trade to support the dynamism of economies.[147(p14)] This study found a paucity of evidence on the benefits, costs and success factors of these and other regulatory co-operation mechanisms.[147(p13)] The authors suggest that greater understanding is needed of the benefits and pitfalls of using these mechanisms and the opportunities to improve existing experiences and extend them to new fields of cooperation.[147(p14)]

Third, HPR policies impact the migration of health workers, with little evidence the WHO Global Code of Practice is working to protect LMIEs from outward migration of healthcare workers.

A third group of studies addressed a diverse range of issues associated with health workforce migration, particularly the flow of health workers from LMIEs to HIEs. Chapter 7 outlines those studies that addressed the effectiveness of programs to integrate internationally educated practitioners into the health systems of destination countries.

One of the major contributing factors to an inequitable distribution of health workers is the so-called 'brain drain' that sees talented and skilled personnel leave their own countries or communities to pursue better paying work opportunities elsewhere. The escalating shortage of health workers in some middle- to high income countries is increasingly being met by

[j] The OECD typology of international regulatory cooperation mechanisms includes: integration/harmonization through supra-national organizations; specific negotiated agreements (treaties, conventions); formal regulatory cooperation partnerships (Canada-US RCC); international governmental organizations (OECD, WTO); trans-governmental networks of regulators; formal requirements to consider relevant frameworks in other jurisdictions in the same field; recognition and incorporation of international standards (ISO, IEC); soft law – principles, guidelines, codes of conduct; dialogue/informal exchange of information (OECD, 2016: 13).

recruitment of foreign health workers, often from LMIEs. This can leave already vulnerable health systems in poorer countries even more vulnerable, particularly in times of medical emergency.[145,470,542]

Several studies noted the challenges with implementation of the *WHO Code of Practice on International Recruitment of Health Personnel* and the complex range of push and pull factors.[3,126,406,459] A few studies were tentatively positive about the impact of the Code.[3,504] A Cochrane Review by Penaloza & colleagues [406] examined interventions to reduce emigration of health practitioners from LMIEs, finding only one study dating back to 1990. They noted important gaps in knowledge of effectiveness of policy interventions in either HIEs or LMIEs that might regulate positively the movement of health practitioners from LMIEs. A study of implementation of the Code in four ASEAN member states found most of the out-migrating professionals leave voluntarily, that is, outside government-to-government agreements; and while registration and employment regulations apply equally to domestic and foreign trained professionals, local language requirements were a barrier to movement.[504]

Summary

There is little empirical evidence concerning the use of HPR in health system governance. No studies were identified that addressed:

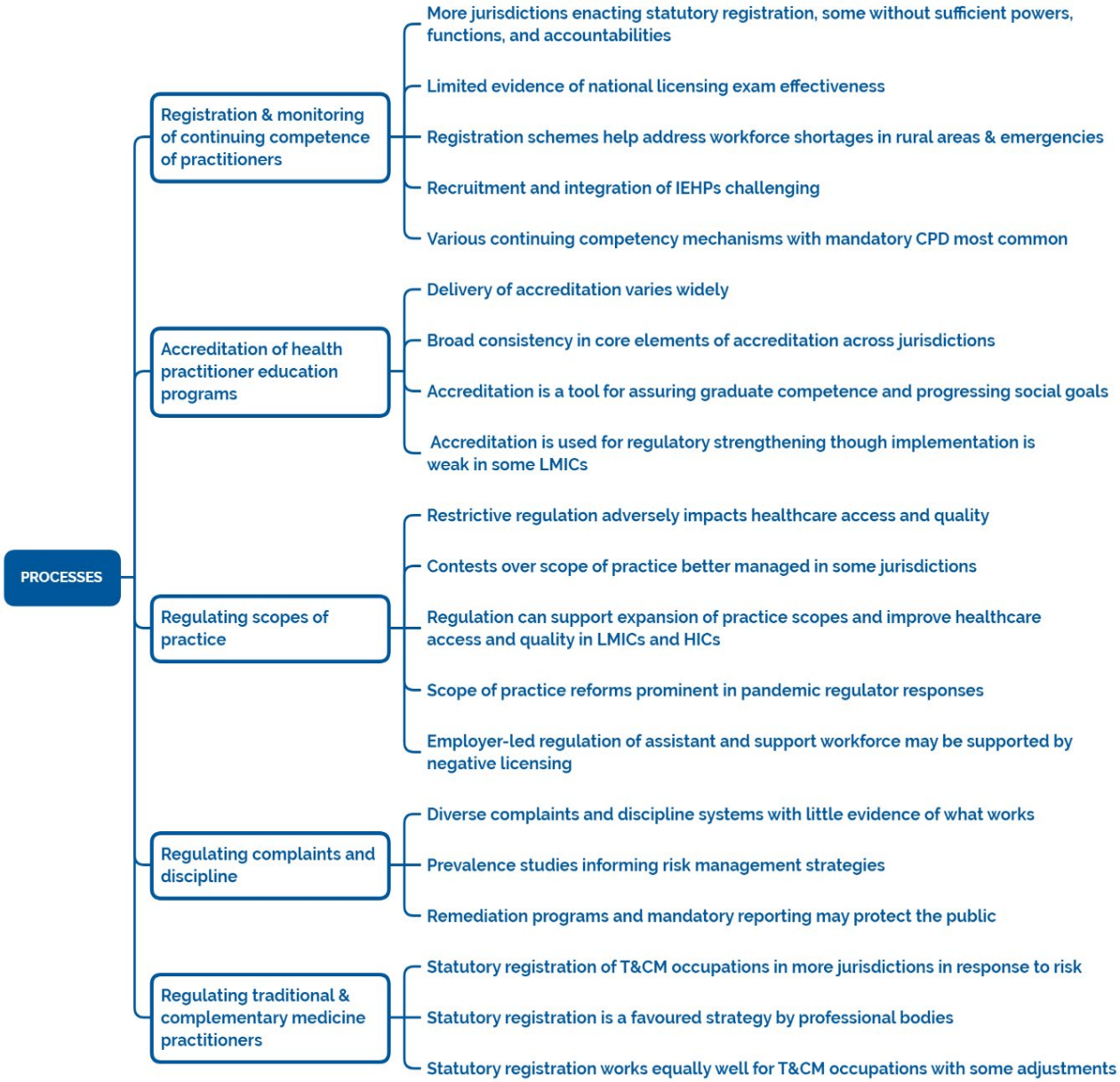
- the system linkages within a regulatory regime and how these impact the effectiveness of the regime, or
- the effectiveness of a regulator's relationships with other actors within the health system and beyond.

There is some evidence, from both LMIEs and HIEs, that the health workforce functions of government are more effective when they harness the tools of regulation to support strategies for workforce planning, development, supply and distribution, particularly to address rural workforce shortages. For instance, there is some evidence of the use of registration renewal systems to generate data for government use in workforce planning. This generally requires a clear legislative basis that authorizes the regulator to collect and supply such data as well as good IT systems that support streamlined and efficient online periodic renewal of registration.

The evidence suggests that despite considerable efforts to standardize and harmonize entry-to-practice qualifications across jurisdictions, through mutual recognition schemes, widespread barriers to the mobility of practitioners continue to apply.

Apart from the data presented in Chapter 13 on regulator responses to the COVID-19 pandemic, no evidence was identified that addressed the effectiveness of regulators in facilitating or supporting mobilization of a surge workforce for international emergency responses in outbreaks/pandemics and natural disasters.

PART B: PROCESSES



7. REGISTRATION OF PRACTITIONERS AND MONITORING OF CONTINUING COMPETENCE

Overview

The focus of this chapter is on the registration functions of regulators. This includes powers of HP regulators to:

- set qualification standards and probity (character) requirements for entry to practice in a regulated health occupation
- receive and decide applications for registration
- set practice standards, including requirements for continuing competence, and provide guidance about what constitutes good practice
- monitor the compliance of registrants with practice standards
- set and apply standards for renewal of registration
- maintain a publicly accessible register of qualified and registered practitioners as a trusted source of information for multiple users

Of particular interest is the literature on the effectiveness of a registration scheme in assuring the qualifications, probity and continuing competence of registered practitioners, including the assessment of internationally educated health practitioners (IEHPs) for registration and the transparency with which these registration functions operate.

Articles were included in this synthesis if they discussed the role of a regulator in setting standards for registration, evaluated processes for registering practitioners or monitoring continuing competence and compliance with other practice standards, or examined the operation of a publicly accessible register of practitioners. Articles were excluded if they focused solely on credentialing of postgraduate programs administered by profession-led non-government bodies, such as specialist medical colleges or professional associations.

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **132 articles** included content related to the function of registering practitioners (Figure 15) For details of the publications on this topic, see Annex 4 (Table 5).

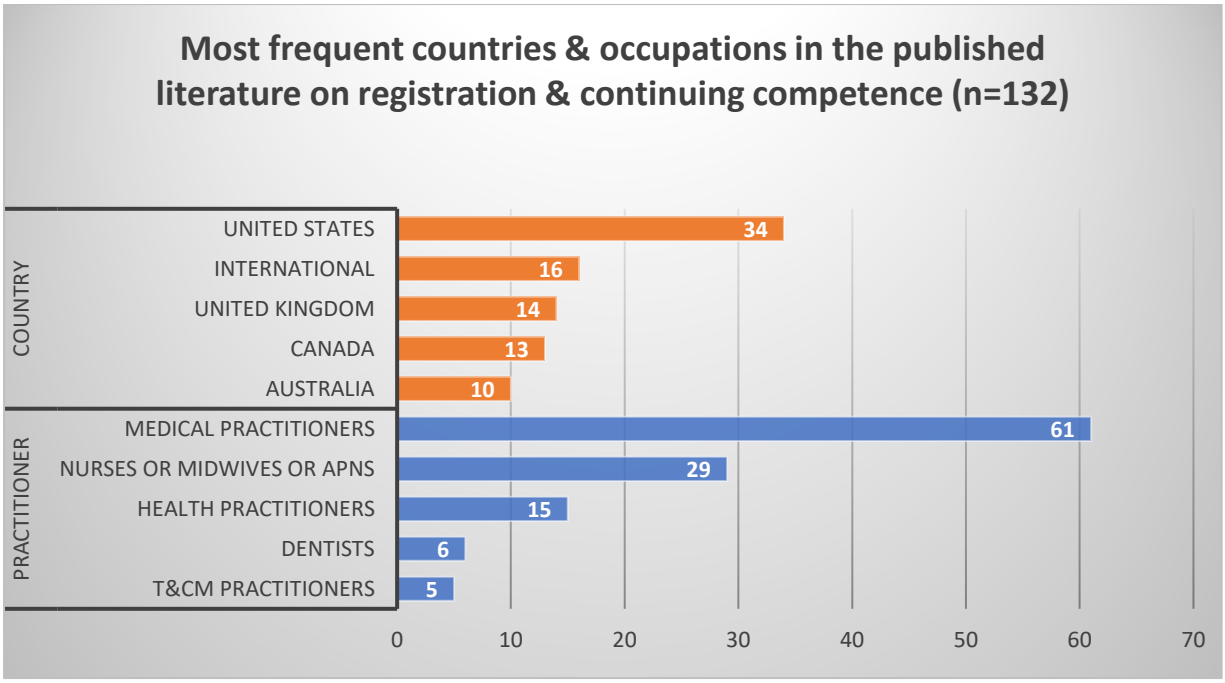


Figure 15: Most frequent countries and health occupations in the published literature on registration and monitoring of continuing competence of practitioners

The published literature was dominated by articles on medical practitioners (n=61), followed by nurses and midwives (n=29), and health practitioners generally (n=15). The US (n=34) dominated this literature followed by studies with an international focus (n=16) and the UK (n=14). This literature included **98 empirical studies** on aspects of registration and monitoring of continuing competence.

The included articles addressed an array of issues associated with the registration functions of regulators:

- the mechanisms for ensuring continuing competence of registrants (***42 articles***), such as articles on continuing professional development (CPD) (***28 articles***), certification and recertification/maintenance of certification programs (***15 articles***), and revalidation (***nine articles***)
- registration of internationally qualified practitioners (***22 articles***)
- national examinations for entry to practice in a regulated health occupation (***18 articles***)
- registration and the rural workforce (***10 articles***)

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **73 documents** relevant to the registration function (Figure 16).

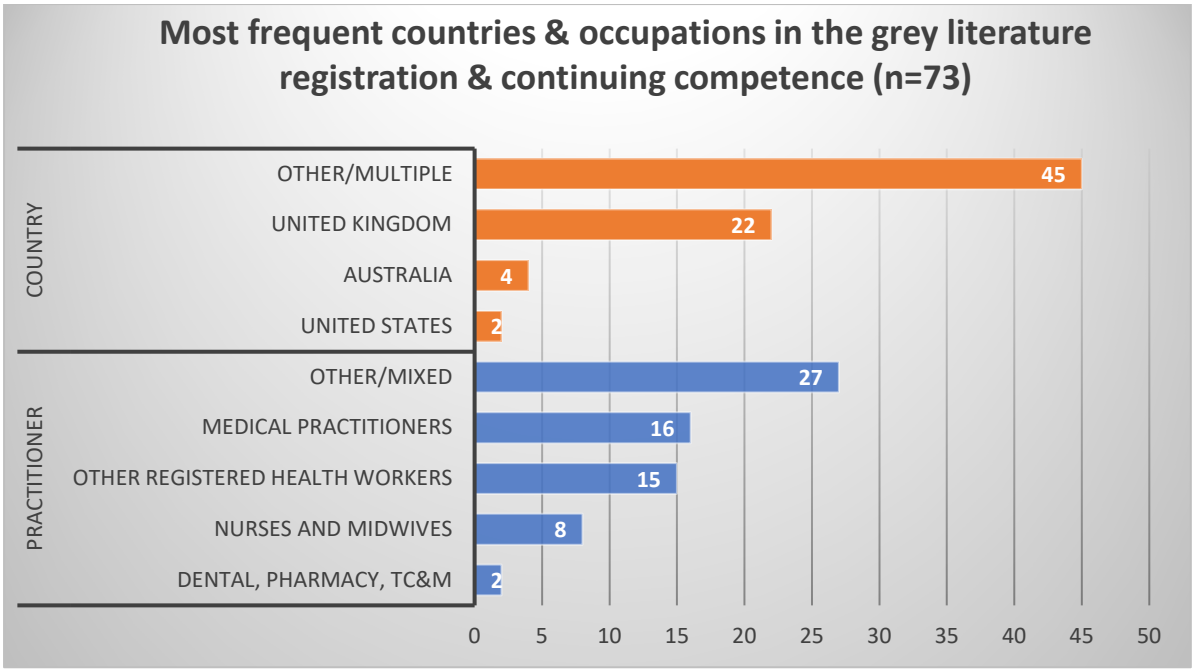


Figure 16: Most frequent countries and health occupations in grey the literature on registration and monitoring of continuing competence of practitioners

Annex 2 provides a list of the websites searched. For details of the publications on this topic, see Annex 5 (Table 5). The main sources were:

- *Intergovernmental agencies* – international conventions, trade agreements, international standards and other publications issued by a range of intergovernmental agencies such as the European Commission, the World Trade Organization (WTO), UNESCO, ASEAN, International Labour Organization (ILO), and the OECD (***20 documents***)
- *Regulators and meta-regulators* – reports by the PSA of performance reviews of UK regulators with assessments against the PSA's standards on the register and the registration functions, and reports of the US NCSBN on its national examination process (***14 documents***)
- *WHO and associated entities* – reports and policy papers issued by bodies sponsored by WHO (such as POLHN and ECSA-HN), WHO Collaborating Centres and country review reports commissioned by WHO Regional Offices and other development agencies (***13 documents***)
- *International professional and other non-government bodies* – guidance documents on standards for entry to practise in the health professions, from organizations such as the International Standards Organization (ISO), World Physiotherapy, WMA, WONCA, ICN and ICM (***seven documents***)

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of laws and regulator websites of a sample of 16 jurisdictions are set out in Annex 9. Comparative data are presented on key elements of the registration and continuing competence functions of regulators, including:

- types of registration granted
- who makes registration decisions
- whether a registration or practising certificate is subject to renewal and how often
- if renewal applies, whether it is conditional on completion of CPD activities or other requirements
- whether the regulator has specific powers to grant registration subject to conditions or restrictions
- whether a person whose application for registration is refused has a right of review of this decision and to whom
- whether there is a publicly accessible online searchable register of qualified practitioners and what information it contains

The schemes sampled illustrate the variation in how the types of registration granted by the regulators are described and categorized, with some schemes providing greater differentiation and specificity than others. In some schemes there is no provision for the regulator to grant different types of registration (Czech Republic). However, most regulators have the power to grant multiple types of registration (typically between 4-10 types), with the medical regulator in British Columbia an outlier, having the power to grant 28 different types of registration. In some schemes (Qatar, Burkina Faso, Mali, Senegal and South Africa) registration types are used to differentiate public sector and private sector employees (and their entitlements) and some to regulate dual practice (Brazil).

The entity empowered to make registration decisions also varies depending on the governance arrangements of the scheme. In most schemes, a statutory body makes registration decisions although in some schemes a registrar or committee is responsible and in others there is power for the regulator to delegate these decisions to staff.

A majority of schemes sampled have provision for periodic renewal of registration although the length of the registration period varies. In a majority of jurisdictions sampled renewal is required annually (Australia, British Columbia, Hong Kong, Burkina Faso, Senegal, Somaliland, South Africa); in others, the term is two years (Malaysia, Singapore), three years (the Philippines) or 4-5 years depending on the profession (Pakistan). In a few jurisdictions sampled, registration is for an indefinite period with no requirement to renew (Brazil, Czech Republic). In most schemes sampled, renewal of registration is subject to mandatory completion of CPD, except for those jurisdictions where there is no registration renewal. In a few jurisdictions (Hong Kong, Czech Republic) participation in CPD is voluntary.

In most jurisdictions, the regulator has the power to grant registration subject to conditions, although in a few jurisdictions, no clear head of power was identified (Malaysia, Senegal, Somaliland). In all schemes, there is a power for the applicant to appeal the regulator's decision to refuse their application for registration.

All 16 schemes sampled have an online searchable register although the range of information published varies as does the user friendliness and the currency of some of the information published.

Thematic synthesis

Five themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. While there are signs of regulatory convergence as more jurisdictions establish statutory registration schemes, some schemes lack a comprehensive set of registration powers, functions and accountabilities.
2. The evidence on the effectiveness of the national licensing examination (NLE) for assuring graduate capability is limited and the complexities of running a robust and reliable NLE can be underestimated.
3. Statutory registration schemes can help governments address workforce shortages in rural areas and during emergencies.
4. Recruiting and integrating internationally educated practitioners into the local workforce presents particular challenges, with some evidence of effective integration programs.
5. While regulator-mandated CPD is common and can be effective, various continuing competency mechanisms are found in HICs, with limited evidence of comparative effectiveness.

These themes are expanded upon below.

First, while there are signs of regulatory convergence as more jurisdictions establish statutory registration schemes, some schemes lack a comprehensive set of registration powers, functions and accountabilities.

There is evidence that both LMIEs and HIEs with differing legal traditions are enacting statutory registration schemes for key cadres of health practitioner. [k] However, the review of statutes and other grey and published literature suggests that in some jurisdictions, the enabling laws do not confer on regulators the suite of powers, functions and obligations

[k] Annex 5 shows that since 2010, statute-based registration schemes have been established, revised or extended in Australia, Brazil, Burkina Faso, Cambodia, Canada, Cook Islands, Czech Republic, Fiji, India, Malaysia, Mali, New Zealand, Pakistan, Samoa, Senegal, Singapore, the Philippines, Uganda, United Kingdom, USA and Vietnam. Note that this is not an exhaustive list.

generally found in jurisdictions where regulatory reform activity has been prioritized and laws have been periodically updated. For instance, many schemes lack a comprehensive set of registration powers, functions and accountabilities. Examples include:

- *Types of registration* – In some jurisdictions there is little or no differentiation of registration types granted. This lack of granularity in registration types has consequences for the usefulness of data collected and reported by the registration system – a lost opportunity to generate a registrant data set sufficient to support risk-based regulation, effective workforce planning and system improvement.[64,79,111,112,115,116,263,460,460,534]
- *Renewal of registration* – In some jurisdictions, registration is granted for life and there is no provision for annual or periodic renewal.[284] In others, renewal occurs every two, three or five years. Without periodic renewal, the regulator has limited tools to set expectations of registrants or to monitor compliance with practice standards, such as requirements for continuing competence and mandatory CPD. Also, without renewal fee revenue, the regulator's financial viability and capacity to regulate can be compromised.[68,528,557]
- *Procedural fairness* – In some jurisdictions, procedural fairness provisions that require the regulator's registration decisions to be made fairly and free from bias are inadequate or absent and there may be no right of an applicant for registration to seek a review of a refusal decision to a fresh decision-maker.[118(p58),284]

Second, the evidence on the effectiveness of the national licensing examination (NLE) for assuring graduate capability is limited and the complexities of running a robust and reliable NLE can be underestimated.

For the purposes of this analysis, a national licensing examination (NLE)[[l]] is a large-scale examination either provided or commissioned by a HP regulator and used to determine whether applicants are qualified to be granted registration to practise.[38,417(p782)] It is usually undertaken by students who are close to the point of graduation from an entry-to-practice education program, and/or IEHPs seeking to enter and practice in a jurisdiction other than where they completed their initial training.

The NLE is seen as a strategy to ensure the quality of graduates, sometimes in response to an upsurge in private education providers, and/or to facilitate mobility of health workers across countries.[11,182,273,293,352,573]

We found **18 articles** (among the **132 articles** included for this topic) that addressed issues associated with the conduct of NLEs, for various occupations including: medical practitioners, nurses, dentists, dental hygienists and osteopaths. **Nine articles** from HICs addressed the use of a national examination to assess readiness for practice and grant registration.

[l] This term is also intended to encompass examinations conducted by regulators at the sub-national level such at the state or provincial level in countries with federated systems of government.

Four systematic reviews were found on the role and effectiveness of NLEs, including three arising from research commissioned by the UK General Medical Council where introduction of a NLE is under consideration.[38,417,480] Price & colleagues [417] developed a typology of NLEs based on candidacy, to facilitate comparison across jurisdictions and to explore the implications of different examination types for workforce planning. Some jurisdictions have no NLE, while others require either local or international candidates to sit a NLE, or both. Price & colleagues noted the trade-off in registration schemes between cost and quality – due to workforce shortages, some jurisdictions operate an alternate pathway using local assessment processes to grant temporary licenses for IEHPs who have not sat the NLE. They concluded that the usefulness of a NLE cannot be viewed in isolation from the workforce planning decisions taken by health authorities in response to workforce shortages.[417(p782)]

Archer [38] observed there is little validity evidence concerning whether licensure examinations improve patient safety and practitioner competence and disagreement about the strengths and challenges of the NLE.[38(p1)]While there is evidence that testing is important, the benefit of large-scale testing is still debated, with lack of unequivocal evidence found to either support or refute their use.[38(p13)] Archer also notes a divide between North America ,which has a long history of large-scale testing and NLEs, and Europe, where the history is one of locally developed and delivered assessment decisions and quality assurance of training programs based on peer review and inspection.[38(p11)] This debate, Archer suggests, reflects a wider ideological battle between standardization and contextualized reality construction – the two 'sides' of validity.[38(p11)]

Six studies from LMIEs addressed issues associated with NLEs.[11,182,273,293,352,573] Several studies highlight factors contributing to the pressure to introduce a NLE, such as the rise in private sector education providers leading to a surplus of graduates and uncertain standards; the need to standardize training and entry to the public service; and to improve quality of care. [182,293(p6)]

Studies illustrate some of the complexities of introducing a NLE, including in the context of mutual recognition arrangements. For instance, Kittrakulrat & colleagues [273] analyzed the arrangements for medical licensing examinations (MLEs) across ten ASEAN member countries, to facilitate efforts to harmonize education and qualification systems and enable free movement of doctors, as part of the momentum toward the ASEAN Economic Community. They found that while MLE systems exist in almost all ASEAN member states, these systems differ in some important respects that may be of concern from a fairness viewpoint. They suggest this variation will need to be addressed to progress harmonization, freedom of movement of doctors and the common market. Silva & Cabral (2018) found adverse consequences of the NLE for Brazilian nurses with respect to social injustice and inequality.[483]

Third, statutory registration schemes can help governments address workforce shortages in rural areas and during emergencies.

We found **10 articles** (among the **132** articles included for this topic) that addressed issues concerning the role of HPR and rural health.

Five articles addressed the challenges in LMIEs of supplying and upskilling healthcare workers in rural areas.[158,302,337,455,489] These studies touched on the role of the regulator, for example, in giving effect to workforce policies on compulsory rural service periods, [455,489] facilitating targeted CPD to upskill cadres of healthcare workers,[302] or dealing with disciplinary issues that may arise in relation to dual practice that breaches mandatory limits set on practice locations.[337]

A scoping review of literature from the Asia-Pacific found studies reporting that compulsory rural service periods, whether implemented as a stand-alone strategy, combined with scholarships only, or combined with scholarships and recruiting students from rural areas, were associated with higher rural preference or actual work.[455(p6)] In a systematic review of the literature on key interventions used in the Asia Pacific region to attract and retain health workers in remote and rural areas, Lui & colleagues [306] found 39 interventions of which nine (the second most reported intervention type) were regulatory. These included mandatory rural bonded scholarships and compulsory rural services. The researchers found that 'bundles' of linked or coordinated interventions were more likely to be effective than single or uncoordinated interventions and this bundling was more likely to be found in HICs such as Japan.[306(p2)] They also found a lack of rigorous evaluation of the effectiveness of interventions.[306(p3)]

The remaining **five articles** addressed the challenges for HICs in securing sufficient rural workforce capability.[319,373,486,563,567] Several studies from Australia [319,486,563] addressed different strategies for improving rural workforce capability of medical practitioners and nurse practitioners. Several studies pointed to the important role that NPs and other APNs play in serving rural communities and the need to ensure these practitioners have the legal authority to practice to their full capability. There is strong evidence that jurisdictions with more flexible scope of practice regulation that enables autonomous NP practice achieve higher NP supply, improved access and better healthcare outcomes for patients, especially in rural and underserved areas.[373(p659),486,567(p5)]

One of the challenges in this area is achieving clarity about the respective roles and responsibilities of the HP regulator vis à vis the broader government health workforce governance or stewardship responsibilities for workforce planning, supply and distribution. Role clarity is important, to ensure accountability and to evaluate the effectiveness of various workforce development interventions. The respective roles and responsibilities can be

difficult to disentangle when the HP regulator is an administrative arm of the government's health ministry.[111,112,117,118]

Fourth, recruiting and integrating internationally educated health practitioners into the local workforce presents particular challenges, with some evidence of effective integration programs.

We found **22 articles** (among the **132** articles on this topic) that examined registration and regulation of IEHPs--of these, **10 articles** on international medical graduates (IMGs), **six articles** on internationally educated nurses (IENs), **four articles** on internationally educated health practitioners in general, and **two articles** on internationally educated dental graduates. These articles were a mix of retrospective studies, case studies, quantitative studies and narrative reviews. They addressed various issues concerning IEHPs including:

- *the relationship between assessed competencies of IENs and subsequent successful completion of registration assessments for Canadian nurses [370]*
- *procedural reforms by the regulator to streamline registration and assessment processes for IENs in Canada [289]*
- *the extent to which 'discriminatory tendencies' are affecting the transition and integration of IMGs in Germany [277]*
- *the rate of disciplinary actions or fitness to practice censures against IMGs compared with locally educated practitioners in Canada and the UK [26,510]*
- *the design, implementation, and effectiveness of transition programs for IMGs in Germany [78] and Australia [563] and for IENs in the US [566]*
- *the role of the ASEAN mutual recognition agreements as the impetus for member countries to amend their regulations to facilitate practice by IEHPs [273,293]*
- *the impact of the 'culture of migration' of nurses trained in the Philippines and its contribution to the declining quality of nursing education, misuse of scarce resources, corruption, and health workforce shortages [321]*
- *the challenges faced by internationally trained dental graduates in navigating the Australian assessment and examination systems and in social and professional integration[52]*

Most articles discussed issues concerning IEHPs from the point of view of destination countries and few paid even lip service to the impact of their recruitment strategies on source countries. Two articles discussed issues of equity and strategies for reducing the adverse impacts of emigration on LMIEs [240,406] and only one article made mention of the *WHO Global Code of Practice on International Recruitment of Health Personnel* promulgated in 2010 and to which many destination countries are signatories – Tangcharoensathien & colleagues [504] assessed the extent to which the WHO Global Code of Practice has been implemented in Bhutan, Maldives, Indonesia and Thailand.

The grey literature review identified various international conventions, treaties and intergovernmental trade agreements that appear to be driving regulatory convergence. A

particular focus for these instruments is on requiring participating governments to remove or reduce barriers that prevent the recognition and portability of professional qualifications and facilitate the movement of health practitioners or services across state borders. Some of these agreements incorporate specific expectations that the criteria and processes to be applied by HP regulators to assess IEHPs be transparent, objective, impartial, fair and/or non-discriminatory. Examples include:

- *Convention on the Recognition of Qualifications concerning Higher Education in the European Region 1997* (the Lisbon Convention). UNESCO-COE (Council of Europe) [m]
- *Global Convention on the Recognition of Qualifications concerning Higher Education 2020.* UNESCO.[n]
- *Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications,* 2005. European Union.[o]
- *Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU), 2017.*[p]
- *ASEAN Mutual Recognition Arrangement on Nursing Services 2006; ASEAN Mutual Recognition Arrangement on Medical Practitioners 2008; ASEAN Mutual Recognition Arrangement on Dental Practitioners 2008.*[q]
- *Trans-Tasman Mutual Recognition Arrangement (TTMRA).* Australia and New Zealand.[r]

Unlike some other mutual recognition arrangements, the directives issued by the EU have the force of law. The European Commission's decision to initiate legal action against 18 member states for failing to adequately implement EU directives on qualifications and mutual recognition may accelerate processes of mutual recognition, harmonization and regulatory convergence. [[s]] For others, such as the mutual recognition arrangements agreed by ASEAN members in 2009, progress in improving portability and mobility appears to be slow. [[t]]

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[m] This is the main legal instrument on the recognition of qualifications in Europe and has been ratified by more than 50 states including some outside Europe. See the Council of Europe website: https://www.coe.int/en/web/higher-education-and-research/lisbon-recognition-convention

[n] See https://unesdoc.unesco.org/ark:/48223/pf0000373602.locale=en

[o] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0036&qid=1647743375411

[p] See https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/11.aspx?lang=eng

[q] See https://asean.org/our-communities/economic-community/services/

[r] See https://www.mbie.govt.nz/business-and-employment/business/trade-and-tariffs/trade-agreements-and-partnerships/closer-economic-relations-with-australia-and-the-trans-tasman-mutual-recognition-arrangement/#:~:text=The%20Trans%2DTasman%20Mutual%20Recognition%20Arrangement%20(TTMRA)%20is%20a,regulatory%20co%2Dordination%20and%20integration.

[s] See https://ec.europa.eu/commission/presscorner/detail/en/IP_21_6389

[t] See recent mapping of full and temporary registration requirements across ASEAN member states: https://asean.org/wp-content/uploads/2021/12/4.-Full-Registration-for-Foreign-Medical-Practitioners-10AMS_v.pdf

In some regions, initiatives are in train across LMIEs to encourage cooperation and joint work on the delivery of registration functions. The evidence suggests that while there is considerable scope for economies of scale for LMIEs to deliver registration functions on a regional scale, without stable governance, country ownership, a strong secretariat and ongoing financing, these initiatives often struggle for continuity and to embed institutional capability.[545,550]

Fifth, while regulator-mandated CPD is common and can be effective, various continuing competency mechanisms are found in HICs, with limited evidence of comparative effectiveness.

A range of terms are used in the literature to describe the mechanisms through which regulators (or a professional body recognized by and delegated quality assurance functions by government or a regulator) assure the continuing competence of registered practitioners. Examples include:

- *continuous professional competence framework* [278–280]
- *certification and recertification programs*[414,415,478,493,539]
- *maintenance of certification programs* [131,272,290,333,361,402]
- *maintenance of licensure programs* [233]
- *national physician validation systems* [233]
- *revalidation programs.*[37,39,101]

This diversity extends beyond terminology, to differences in scope, coverage, and content, [488(pp634-637)] with competing discourses,[40,233] underpinned by different views that have strong historical roots about the legitimate role of the state in regulating the professions.[488(p639)]

The extensive literature on continuing competence mechanisms included **10 systematic or scoping reviews**.[38,39,106,131,141,215,233,354,414,415,539] Much of this literature is 'process oriented' with few studies addressing the 'how and why' of national systems for assuring competence.[233(p8)]

Sole & colleagues distinguish 'implicit systems' (such as in Austria, Finland, Estonia, Spain) that are based on an expectation that the practitioner will maintain competence without the need to comply with explicit standards, from 'explicit systems' (such as in Belgium, Germany, Hungary, the Netherlands, Slovenia and the UK) that require continuing competence to be demonstrated formally, in a defined time period, with monitoring, and where failure to fulfill requirements has consequences for the right to practice.[488(p637)]

Five systematic reviews explored the relationship between certification programs for physicians or nurses and patient outcomes, practitioner outcomes and/or organizational outcomes.[141,215,233,415,539] Findings were generally tentative with a common conclusion being that further research is needed. Several studies cautioned about the proliferation of specialty

certifications and certifying organizations in nursing, questioning their quality, goals and methodological rigour.[131(p484),539(p1)]

There was evidence of the effectiveness of CPD in terms of increased knowledge, confidence, skills and improved attitudes, for nurses working in psychiatric care.[215] A single case control study was identified: Wenghofer & colleagues [537] investigated the relationship between participation in different types of CPD and incidences and types of public complaints to the Ontario regulator of physicians. They found a positive relationship between participation in the national CPD programs (operated by the regulator or the specialist medical college) and lower numbers of public complaints to the regulator. These findings suggest that outcome-based models that support registrants' engagement in relevant, meaningful CPD holds greater potential to positively impact on practice and strengthen patient safety.

The most studied regulatory mechanism was **mandatory CPD**. The literature suggests widespread adoption of mandatory CPD for maintenance of registration as a core regulatory tool for assuring the continuing competence of the health workforce in HICs and for uplifting the knowledge, skills and competence of cadres of healthcare workers in LMIEs. One study mapped the continuing education (CE) mandates of psychology regulators in the US (comparing regulators with a general CE mandate, a specific ethics mandate or no mandate) and their respective disciplinary action rates. They found neither the presence of CE mandates nor the number of CE credits that were mandated were associated with disciplinary action rates, although they did not measure compliance with or enforcement of mandates. They concluded that associations between participation in CE and a range of indicators of professional competence are largely correlational and that a causal relationship between aspects of CE participation and indicators of professional functioning is yet to be proven.[360(p103)]

The grey literature search yielded some regulator commissioned comprehensive reviews of the effectiveness of CPD. For instance, Murgatroyd [353] reviewed the CPD systems of regulators in 47 countries in a report for the UK General Medical Council. He found that half of the 22 countries whose regulators mandated CPD had introduced such systems since 2001.[353(p7)]

Several trends are evident in HICs as to how CPD is delivered: a shift in expectation from simple attendance or a time-based metric (credit) to a measurement that infers competence in performance; an increased focus on interprofessional education to augment profession-specific CE; the integration of CPD with quality improvement; the expansion of CPD to address population and public health issues; and identification and standardization of CE professional competencies.[55(p171)]

Bullock & colleagues [106] undertook a rapid evidence synthesis on CPD requirements for registered practitioners. Similar to other researchers, they reported a global cross-profession shift away from counting hours and limited evidence that the accumulation of hours of

educational activity enhances practice.[106(p1)] Evidence of changed practice and improved patient care is uncommon in studies of CPD and what evidence there is suggests that activities are more likely to have impact if a combination of methods is used and if the CPD activities are aligned with the practitioner's learning needs.[106(p1)] The impact is also affected by the learner and their work environment, with a clear shift from quantitative, timeserving, input-models to outcome-focused models which emphasize the identification of learning needs, selection of educational activity relevant to practice, and reflection on practice improvement.[106(p1)]

These findings are supported by Archer & colleagues [39] who reviewed the evidence base for regulator mandated CPD for medical practitioners. They found CPD has been shown to be an effective form of medical regulation, offering long term changes in physician-related attributes and behaviors. These changes are enhanced if the CPD is interactive, utilizes repetitive exposures, offers dynamic/live media usage, and is targeted to a single discipline or small group.[39(p40)] Online CPD has been shown to be at least as effective as face-to-face CPD and has reported advantages such as ease of access, easy dissemination of up-to-date information and applicability to multiple learning styles.[39(p40)] There is some evidence of increased clinically informed decision-making following online CPD and evidence of an inverse relationship between knowledge and number of years since certification/registration. Finally, Archer & colleagues found that the assumption that physicians are able to accurately determine their own learning needs and bring about change in personal performance was not well supported, suggesting the need for an external assessment or facilitated decision making process.[39(p40)]

Several studies addressed the views and experiences of practitioners concerning regulator mandated CPD, for pharmacists in Singapore;[35] clinical psychologists in Canada;[96] medical doctors in Ireland;[204] paramedics and advanced paramedics in Ireland;[278] emergency medical technicians in Ireland;[279] dental technicians in the UK;[466] nurses in China;[565] and medical doctors in Hong Kong.[570] These studies suggest widespread acknowledgement by registered practitioners of the importance of CPD in maintenance of professional competence but resistance in some cohorts in some countries to the introduction of regulator mandated CPD. Criticisms from practitioners are generally around the cost, relevance, accessibility and flexibility of CPD mandates.

Several studies pointed to where CPD is failing to be effective. Davis and McMahon [161] reported a failure to translate best evidence into practice, due to several factors: within health systems, a lack of recognition of the importance of ongoing, system linked professional education; among CPD providers, an adherence to old but easy-to-deliver "one-and-done" methods CPD; and clinicians choosing less engaging learning activities, uninformed by objective performance data.[161(p892)]

In LMIEs, particularly in countries of sub-Saharan Africa, the literature suggests CPD is a central strategy being used to lift the skills of various cadres of healthcare worker both licensed and unlicensed. See for example: Couper & colleagues [148] – mid-level health workers in Kenya, Nigeria, South Africa and Uganda; Feldacker & colleagues [186] – nurses, midwives and doctors in Malawi, Tanzania and South Africa; Gawagah & colleagues [205] – radiographers in Ghana; Hosey & colleagues [234] – nurses and midwives in 12 countries in East, Central and Southern Africa; Moetsana-Poka & colleagues [342] – nurses in Lesotho; Law & colleagues [293] – nurses, medical practitioners and dentists in Cambodia.

These and other studies have documented some of the challenges and barriers to realizing the benefits of regulator mandated CPD in LMIEs as a condition of registration, such as lack of sustainable financial resources; limitations in coordination of CPD resulting in poor accountability for CPD oversight and reduced CPD quality assurance; healthcare worker shortages limiting CPD opportunities, creating disparities in access; CPD irrelevance and imbalance between HCW-identified CPD needs and available programs, thereby reducing the enthusiasm for CPD; facility-level constraints, including poor infrastructure and weak supply chains restrict implementation of CPD skills and knowledge; and more severe challenges in rural settings.[186(pp1-2),293] While CPD has been used strategically as a positive reinforcer to encourage registration, some regulators have limited enforcement capability.[293(p5)] Several researchers highlighted contextual factors [564] and underlying structural issues [565] such as (for nurses) inaccessibility of learning programs, undervaluation of workplace-based learning and inequality of the allocation of resources especially impacting rural areas.[565(p214,218)]

Fewer studies were found on **revalidation**. While revalidation schemes have been implemented several jurisdictions (Belgium, Canada, German, the Netherlands, New Zealand, the UK and US), there is lack of agreement on its definition, mechanisms and appropriate design.[39(p8)] Sole & colleagues [488] also point to a lack of clear evidence of cost effectiveness of extremely detailed models for continuing competence such as the UK revalidation arrangements, and they question whether such models would pick up practitioners such as Harold Shipman.[488(p639)] There is, however, strong evidence to support the individual components of revalidation with varying degrees of intensity – interactive CME/CPD, clinical audit, appraisal, review of patient complaints and multi-source feedback appear to have the best supporting evidence for achieving positive change in physician behavior.[39(p42)] These effects can be enhanced if organizational support, interactivity, targeted interventions, repetitive exposures and a multi-dimensional approach are present.[39(p42)] However, links beyond this to any direct impact on patient outcomes, including patient safety, are lacking in the literature although Archer & colleagues note these will always be hard to achieve.[39(p42)] As for CPD, there is strong evidence of the importance of using multiple educational techniques and evidence from various populations, suggesting that this is most effectively achieved through the adoption of blended learning.[39(p44)]

Archer & colleagues [39] suggest that one mechanism (for example, CPD) cannot cover all key aspects of good practice and that diversity is required. Revalidation is more effective when activities are multi-dimensional, interactive and use several learning techniques that are relevant and attractive to users; and intended aims and criteria are clearly articulated early, with clear lines of communication and a collaborative network of support.[39(p66)]

Summary

There is evidence that many LMIEs and HIEs with differing legal traditions are enacting statutory registration schemes for key occupational groups, however some schemes lack a comprehensive suite of necessary powers, functions and accountabilities.

There is some evidence that regulatory tools available through statutory registration schemes can support the implementation of broader rural workforce recruitment, retention and development strategies in both LMIEs and HIEs.

No empirical evidence was found on the cost-effectiveness of the NLE for determining competence of practitioners for entry to practice, compared with other quality control mechanisms such as the accreditation of education programs.

There is some evidence of the effectiveness of programs in HIEs designed to assist internationally educated health practitioners to successfully transition to practice in their destination country.

There is some evidence to suggest a trend towards adoption of regulator mandated CPD as a condition of registration, as a core tool for assuring the continuing competence of regulated health practitioners in HIEs and in uplifting the knowledge, skills and competence of various cadres of healthcare worker in LMIEs, both registered and non-registered. However, the implementation and enforcement challenges are significant.

With respect to continuing competence mechanisms in HIEs:

- there is some evidence of the effectiveness of CPD in improving skills and knowledge, however this appears dependent on the context, the learner and the style of delivery
- there is some evidence to suggest most registered practitioners acknowledge the importance of CPD in maintenance of competence, with resistance from some cadres in some countries to regulator mandated CPD, particularly where a mandate does not already apply or when it is newly introduced
- there is reasonable evidence to justify regulators making completion of CPD an expectation for registration renewal, as long as issues of access, equity and cost are addressed for practitioners in rural, remote and low resource environments
- there is some evidence that physicians who participate in a formal maintenance of certification program are less likely to be the subject of disciplinary action by their regulator, although the nature of this relationship is not clear
- the evidence is mixed on the benefits of participation in nurse certification programs
- formal revalidation programs are relatively resource intensive and have been adopted in only a handful of countries, with no evidence of the effectiveness of these programs compared with other mechanisms

With respect to LMIEs:

- the evidence is limited but suggests CPD can play an important role in upskilling specific cadres of healthcare worker in LMIEs if it is well designed and delivered as part of a broader workforce development strategy
- given the resource intensive nature of revalidation schemes, for LMIEs a more targeted approach may be preferable, but this relies on risk-based regulation capability (strong data analytics to identify practitioners at risk of poor performance and implementation of targeted strategies to address these risks)

8. ACCREDITATION OF HEALTH PRACTITIONER EDUCATION PROGRAMS

Overview

The focus of this chapter is on the regulator function of accreditation of pre-service or entry-to-practice education programs for health practitioners. Of particular interest is literature on the effectiveness of arrangements for accreditation of health professions education programs (HPE accreditation) in assuring the competence of graduates and how this function is organized and delivered.

For the purposes of this review, 'accreditation' is defined as 'the process of formal evaluation of an educational program, institution, or system against defined standards by an external body for the purposes of quality assurance and enhancement'.[190(p1)] Accreditation of programs of study, along with examination of graduates prior to entry to practice are key tools for assuring the quality of the health workforce. Accreditation of programs of study may be undertaken under a variety of governance arrangements and for a range of purposes – for entry to practice in a profession, for specialist practice or for authorizing expanded scopes of practice. In addition to quality assurance, the objectives may include supporting continuous quality improvement of practitioner education and training, to ensure its responsiveness to evolving community need and professional practice.

Articles included in this synthesis discussed the role of a regulator in accrediting pre-service or entry-to-practice education programs. Articles were excluded if the focus was primarily the design and delivery of HPE programs, curricula etc., and did not mention the role of a regulator or discuss how the accreditation functions were organized and delivered. Articles on accreditation of post-graduate medical programs, specialist certification and recertification programs or CPD programs were also excluded.

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **35 articles** included material related to the accreditation of HPE (Figure 17). For details of the publications on this topic, see Annex 4 (Table 6).

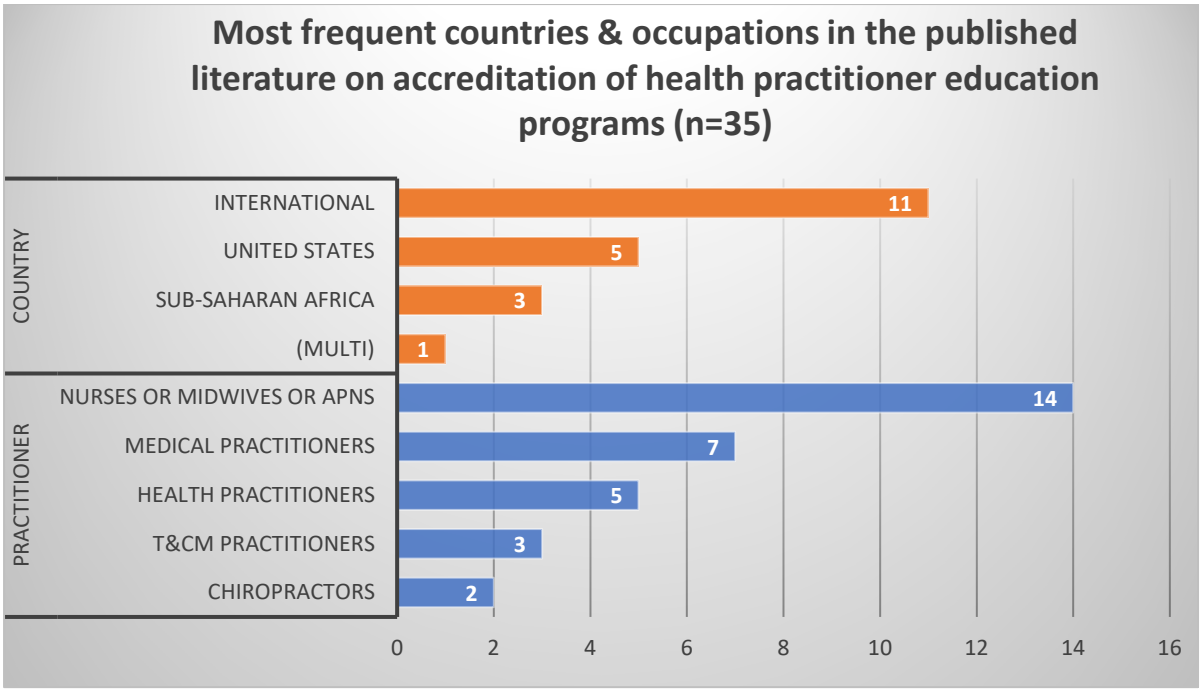


Figure 17: Most frequent countries and occupations in the published literature on accreditation of health practitioner education programs

The published articles focused primarily on nurses and midwives (n=14) followed by medical practitioners (n=7) and by health practitioners generally (n=5). Articles were primarily studies with an international focus (n=11), followed by articles from the US (n=5) and sub-Saharan Africa (n=3). This literature included **29 empirical studies** on accreditation.

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **43 documents** related to accreditation (Figure 18).

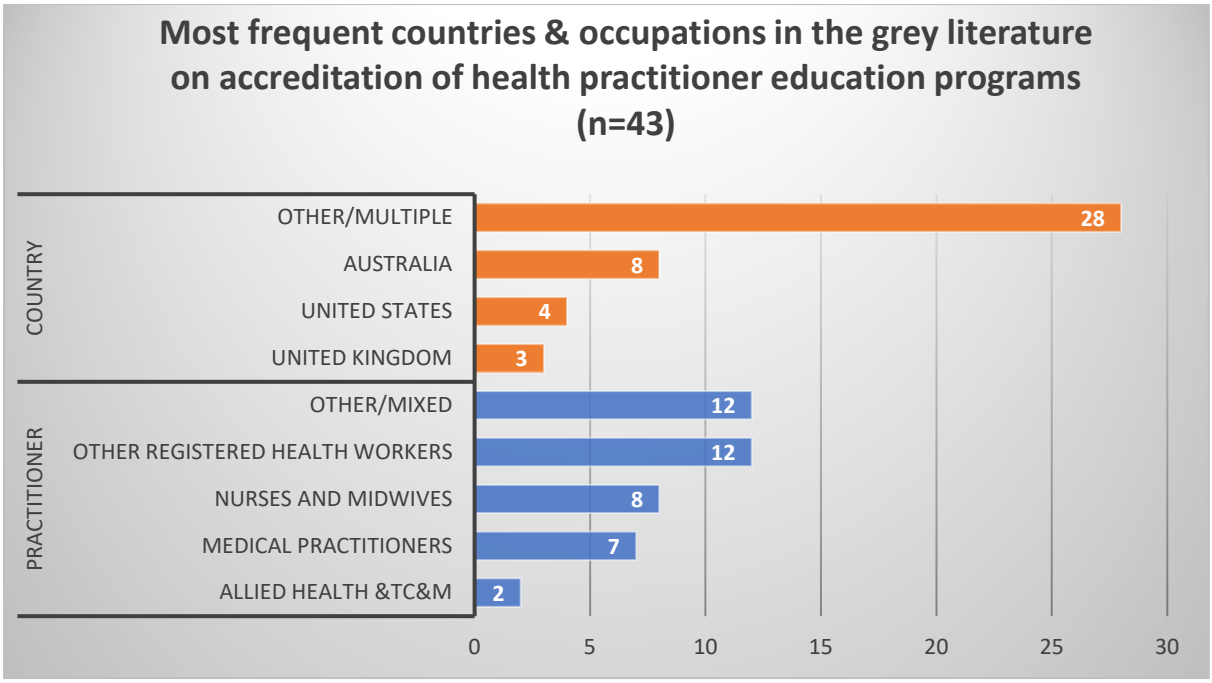


Figure 18: Most frequent countries and occupations in the grey literature on accreditation of health practitioner education programs

Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 6). The main sources were:

- *Development agencies* – WHO global and regional reports and published and unpublished country and regional reports commissioned by WHO and other development agencies such as the World Bank Group and the Asian Development Bank, with country reports mostly relating to LMIEs (***16 documents***)
- *Governments and regulators* – reports, policy papers and consultation papers issued by governments, regulators and meta-regulators. They included reports of systemwide reviews of HPR systems (mostly from the UK, Canada and Australia) that included analysis and recommendations on the role of the regulator in assuring the quality of entry-to-practice education programs, as well as several documents that focussed specifically on delivery of accreditation functions (***11 documents***)
- *International and regional professional bodies* – position statements and policy documents setting out recommended accreditation standards and processes for specific professions such as medical practitioners, nurses and midwives (***six documents***).

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of registration laws and websites of regulatory authorities in a sample of eight jurisdictions are set out in Annex 10. Comparative data are presented on key elements of the accreditation function for entry-to-practice education programs, including:

- who assures the quality of training programs
- whether a list of approved, recognised or accredited qualifications is published
- how internationally trained applicants for registration are dealt with
- whether examinations are available as a pathway to registration and for whom

The schemes sampled illustrate the variation in governance arrangements for assessing and assuring the quality of entry to practice qualifications and the training institutions that deliver them. Often the division of responsibilities between agencies (the ministry of education, the ministry of health and the HP regulator) is not clear from the legislation or the website. In some schemes (Malaysia, the Philippines, Somaliland and New York State), while the lead agency varies, there is provision for joint oversight, for example through the formation of joint 'technical committees'. In Australia there are parallel accreditation processes under separate governance, one led by the responsible National Board (or its delegated authority) and one by the state or territory education ministry. In others (UK, Singapore, South Africa), while it is clear that the regulator conducts an accreditation process, it is not clear how this intersects with any quality assurance role of the education ministry.

In just over half the schemes sampled, it is easy to find on the website of the regulator a list of the qualifications that have been approved for registration purposes.

The schemes sampled illustrate the variation in arrangements for assessment and registration of IEHPs, with some jurisdictions providing more detailed information on the available pathways and mechanisms than others. In some cases, there are multiple pathways available which combine assessment of the equivalence of qualifications with other assessment methods such as examinations and clinical rotations. Some schemes mention links with international bodies for primary source verification of qualifications. In some cases there is provision for temporary permits to be granted. It is evident that some schemes have codified and resourced assessment pathways and others do not. In most schemes sampled there is provision for examination as a pathway to registration of IEHPs, at least for some health professions.

Thematic analysis

Four themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. Arrangements for delivering HPE accreditation for entry-to-practice education programs vary widely across jurisdictions and occupational groups.
2. Despite the diversity in governance, the core elements of HPE accreditation appear broadly consistent across jurisdictions and there appears to be a growing involvement of international accreditation agencies and standards.

3. While there is limited evidence of the effectiveness of HPE accreditation, it is considered an important tool for assuring graduate competence for entry to practice and also progressing broader social goals.
4. HPE accreditation is being used as a tool for regulatory strengthening, although implementation is weak in some LMIEs.

These themes are expanded upon below.

First, arrangements for delivering HPE accreditation for entry-to-practice education programs vary widely across jurisdictions and occupational groups.

Synthesis of the published and grey literature shows considerable diversity across jurisdictions concerning who is responsible for assessing and assuring the quality of HPE, the extent of coverage of accreditation of public and private sector institutions and programs and the standards applied, and the system linkages (or lack of) within jurisdictions between the health and education sector HPE quality assurance processes.
[57,87,108,113,117,118,150,174,195(p1938),200,327,557,559]

Mapping key features of the HPE accreditation arrangements in selected jurisdictions (see Annex 10) illustrates this diversity in institutions and processes, in areas such as:

- *governance and administration* – who assures the quality of HPE and the division of responsibility between HP regulators and education authorities;
- *transparency and accountability* – what information is published on regulators' websites about the operation and performance of the accreditation system; and
- *outcomes* – whether graduates of an accredited program are considered qualified and therefore eligible for registration or must also sit a national examination to qualify.

In many HICs, HPE accreditation systems are well established and many LMIEs are proceeding to implement the WHO's *Workforce 2030* goal with respect to HPE accreditation – to have established accreditation mechanisms for health training institutions by 2020.[540(p9)] In others, the legislative framework required to support accreditation and monitoring of education providers and programs is missing and reform is challenging.[470(p14)] There is some evidence that HPE accreditation systems are also being implemented for the non-registered health professions, with these developments driven largely, it appears, by professional associations.
[87,89,98,148,150,174]

Government health and education authorities have a shared interest and responsibility to assure the quality of HPE programs.[15(p54),148(p9),195(p1928)] Studies show there are differences in how this interface operates across jurisdictions and occupational groups.[118,140,150,174,175] For instance, some jurisdictions have no HP regulator led accreditation and instead rely on their education authority (government ministry or department) to conduct HPE accreditation.[174,182] Other jurisdictions report two parallel but separate HPE accreditation processes, one led or overseen by the education authority and the other by the responsible HP regulator.[14,140] A

few jurisdictions have a single, integrated HPE accreditation process that is jointly governed and administered by the education authority and HP regulator, although this is usually for a single occupation such as medicine.[112,118]

Some jurisdictions administer their HPE accreditation functions via a multi-profession HP regulator. For example, the UK Health and Care Professions Council administers the accreditation functions for 15 regulated health professions and Ahpra (Australia's national regulator) directly administers accreditation functions for five of its 16 regulated professions. No studies were identified that examined the impacts of the various administrative arrangements, such as whether they are efficient, have greater consistency of accreditation standards and processes across professions, or achieve better outcomes such as better training for students, for example in collaborative, team-based care and inter-professional practice.

In some jurisdictions, graduation from a program of study that has been accredited by the HP regulator is sufficient to qualify for registration.[20,220,417,528] In others, graduates of accredited programs must sit a national examination to qualify for registration.[112,113,118,273,417,501] No studies were identified that examined the cost-effectiveness of these alternative models.

The structure of an accreditation system, including the respective roles and responsibilities of health and education regulators, may have consequences for the level of transparency and accountability of the system, its cost-effectiveness and whether it provides sufficient levers for governments to set priorities for and shape the production of the health workforce. Comparative studies would be needed to address these questions.

Second, despite the diversity in governance, the core elements of HPE accreditation appear broadly consistent across jurisdictions and there appears to be a growing involvement of international accreditation agencies and standards.

While there is a lack of evidence of the effectiveness of different governance arrangements for delivering accreditation functions, the literature suggests a degree of consistency across health occupations and jurisdictions, at least in HICs, concerning the key components or core elements of health education accreditation and how it is carried out.

Frank & colleagues [190] present ten 'core elements' of accreditation systems.[190(p6)] These are broadly similar to those offered by other organizations and researchers.[24,207,220,244,371,502]

There is also evidence of a shift to outcome-based measures and competency-based training.[190(p7),261,358(p14)] This is reflected in the various education, accreditation and competency standards documents published by international standard setting bodies such as the ICN, the IMC and the WFME.[246,538] Several studies document the shift in accreditation standards documents from use of process-oriented measures to outcome-oriented measures,

that is, from measuring student contact hours and other input-based measures to measuring the achievement of professional competencies.[190(p7)]

Some studies reported the involvement of and support from international and regional standard setting bodies, usually in LMIEs and often as part of broader regulatory strengthening initiatives. Institutionalization of HPE accreditation functions is evident at the international level, with these international bodies offering HPE accreditation frameworks, standards and tools for various professions. This is promoting standardization and suggests a level of acceptance globally of the role of HPE accreditation in assuring the quality of the health workforce.

Multi-country collaborations, particularly in the African Region, suggest there may be value in these professional interactions across borders and the supporting role that international bodies can play. Examples include the World Federation of Medical Education's *Programme for Recognition of Accreditation Agencies* and the Foundation for Advancement of International Medical Education and Research (FAIMER) *Directory of Organizations that Recognize/Accredit Medical Schools* (DORA).

Regional authorities such as the Western African Health Organization (WAHO), the Caribbean Accreditation Authority for Education in Medicine and other Health Professions (CAAM-HP) are playing a role in supporting regulators to establish accreditation functions.[90(p79)]

Some studies report promising results from development financed regulatory strengthening programs, to embed HPE accreditation functions within the operations of health profession regulators in LMIEs.[175,200,201,327] On a cautionary note, the grey literature has also identified accreditation documentation from international professional bodies that suggests conceptual biases or blind spots about the governance arrangements necessary to deliver these functions. Examples included promoting or preferencing profession-led and/or siloed single profession governance as the preferred model for delivering HPE accreditation functions and promoting the use of HPR powers to define and control practitioner scopes of practice.

Third, while there is limited evidence of the effectiveness of HPE accreditation, it is considered an important tool for assuring graduate competence for entry to practice and also progressing broader social goals.

We found little published literature that assessed the effectiveness of HPE accreditation in producing health practitioners who are sufficiently skilled and competent to provide effective patient care:[90(p78)]

- No studies were found in the published literature that evaluated the performance of an accreditation body or the effectiveness of an accreditation regime in improving educational outcomes.

- No studies were found that compared HPE accreditation with other quality assurance mechanisms such as national examinations.
- One study [190] discussed the role of accreditation in contributing to the production of skilled and competent health practitioners and subsequent impacts on the quality of patient care.

In a scoping review of accreditation of undergraduate medical education, Tackett & colleagues [503] noted the lack of research evidence on the effectiveness of accreditation as a tool to improve health outcomes. While they identified over 100 articles on accreditation of undergraduate medical education (UME) (including 30 cross-sectional or retrospective studies), mostly from the US or Canada, only five studies addressed whether accreditation of medical schools improved educational outcomes. They concluded that limited evidence exists to support current UME accreditation practices or guide accreditation system creation or enhancement and that more research is required to optimize UME accreditation systems' value for students, programs, and society.[503(p1995)]

The grey literature search identified several government commissioned reports from Australia that evaluated HPE accreditation functions, including their governance, cost-efficiency and efficiency.[15,487] While some comparative analysis was undertaken with UK accreditation systems,[14] it is difficult to draw conclusions from these studies given the country specific institutional context.

In a report from the International Health Professions Accreditation Outcomes Consortium (an international consensus group), Frank & colleagues [190] acknowledge the limited evidence base but see accreditation as an essential ingredient in an effective healthcare system. They maintain that there is now an evidence base that supports accreditation as 'links in a quality chain' – that by improving each of the links in the chain (admissions and student selection, the learning environment, curriculum and assessment and graduate competencies), accreditation can decrease variation in education and practice, promote adoption of accepted innovations and (eventually) improve health outcomes.[190(p5)]

Despite the limited evidence based, there seems to be a growing acknowledgement of potential for tools of accreditation to be employed to progress the achievement of social goals. For instance, a 2010 report published by the Lancet Commissions identifies accreditation as one of four key drivers of institutional improvement.[195(p1934)] Frenk & colleagues propose greater social accountability for accreditation, suggesting it could be

instrumental in production of a professional workforce that is well aligned with societal goals, including equity, quality and efficiency. [u][195(p1938)]

Fourth, accreditation is being used as a tool for regulatory strengthening, although implementation is weak in some LMIEs.

There is evidence that the establishment of HPE has been and continues to be a focus for aid agency regulatory strengthening programs in LMIEs. Of the **35 articles** on accreditation, **12 articles** reported on studies from LMIEs. The largest group of studies were associated with regulatory strengthening programs in sub-Saharan African countries.[108,148,175,201,327,352,511] There were also studies from Cambodia, India, Nepal and Vietnam.[88,200,325]

Most studies from LMIEs were on accreditation of education programs for nurses and midwives. The stated rationale for use of accreditation was to standardize training and to lift the quality of the workforce. In some cases, particularly in sub-Saharan Africa, initiatives to introduce or strengthen accreditation were embedded within broader regulatory reform programs designed to strengthen the quality of the health workforce. For instance, Toure & colleagues [511] reported on a USAID-funded regulatory strengthening program that worked with Mali's Ministry of Health and Social Development, leveraging WAHO's accreditation system to support 10 private nursing schools to introduce WAHO's regionally accepted, competency-based curriculum in reproductive, maternal, newborn and child health. The study concluded that with the rapid expansion of private nursing schools, private institutions can play a crucial role in revitalizing outdated universities.[511(p1)]

We found some evidence in the grey literature that implementation of accreditation standards in some LMIEs is problematic.[111,112,117,559] A report by the World Bank Group [559] on education and labor markets for nurses in the East, Central and Southern African region found that mechanisms to ensure compliance with accreditation are weak or do not exist in every country and lack of resources (both financial and technical) are major barriers to strengthening regulation. Key informants reported 'mushrooming growth' of 'illegal schools, and regulatory challenges including: lack of compliance reporting by schools, suggesting that the reporting data may not be routinely collected; lack of regulatory capacity and the slow process of accreditation (delays of up to two years); lack of standardized curricula in some countries; and conflicts of interest between regulators and schools (public and private) for instance where regulatory bodies are fully managed by government such that public

[u] Frenk & colleagues suggest several vehicles for this including expanding the social scope of the scheme to include upstream criteria such as social equity in admissions, scholarships for disadvantaged students and curricular exposure to work in disadvantaged communities; and downstream criteria such as policies that encourage graduates to serve in marginalized areas.[195(p1938)]

educational institutions are not inspected as closely or rigorously as private sector institutions.[559(pp38-39)]

The World Bank report noted recent global reports calling for regulatory bodies to be independent from ministries of education and ministries of health and in the event countries cannot support an independent regulatory authority, countries might consider linking with regional or international accreditation bodies.[559(p39)]

Summary

There is limited empirical evidence that HPE accreditation is effective in assuring the quality and capability of the health workforce.

There is some evidence that the use of accreditation is spreading in LMIEs, in conjunction with development programs and with assistance from international standard setting bodies. This is despite the limited evidence of the cost-effectiveness of accreditation in improving educational outcomes compared with other strategies (such as national examinations).

There is some evidence of considerable challenges in some LMIEs with implementation of accreditation standards, due to financial and technical resource constraints.

There is some evidence of growing expectations that the tools of accreditation be employed in the achievement of social goals as well as assuring the quality of HPE.

There is a fair degree of consistency, at least in HIEs, in the frameworks and approaches applied in accreditation systems both within and across professions. This consistency is evident in the adoption of competency-based curricula and assessment methods and the standardization in the steps in the accreditation process.

There is some evidence that international standard setting bodies are taking an increasingly active role in facilitating the spread of accreditation as a tool for quality assuring HPE and are contributing to regulatory convergence in this area.

9. REGULATION OF PRACTITIONER SCOPES OF PRACTICE

Overview

The focus of this chapter is on the role of HPR in regulating health practitioner scopes of practice. The term 'scope of practice' in relation to a health occupation has been defined as 'the full spectrum of roles, functions, responsibilities, activities and decision-making capacity that individuals within that profession are educated, competent and authorized to perform'.[369(p14)] Some functions within the scope of practice of an occupation may be shared with other occupational groups.[369(p14)]

An individual health practitioner's scope of practice is determined by the interplay of various factors including:

- the educational preparation of the practitioner
- conditions placed on their registration and any other legislation that governs their practice
- terms of employment and the policies and expectations of the employer
- the specific setting within which the practitioner works including the delegation and supervision arrangements
- the funding arrangements and any collaborative practice agreements
- the health needs of the patient populations or communities served[6,369]

Optimizing the scope of practice of health practitioners can facilitate multidisciplinary and complementary teams.[540] Inefficiencies occur when health practitioners are not able to work to their full capacity accorded by their education, training and competence. These inefficiencies may manifest as higher costs and more limited access to healthcare and concerns about quality and safety.[170,196,276]

Given the variability across jurisdictions in the cadres of healthcare workers that are subject to regulation, we sought literature on how the scopes of practice of both the registered and unregistered health workforce are regulated. Of particular interest is:

- what legislative mechanisms are used to regulate practitioner scopes of practice
- whether there are any differential impacts of these legislative mechanisms, in terms of health workforce capability, flexibility, access and safety and quality of services to patients
- how decisions about scope of practice and the division of labor in healthcare are, or may be, shaped by the social, political and historical context

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **119 articles** included content related to regulation of health practitioner scopes of practice (Figure 19) For details of the publications on this topic, see Annex 4 (Table 4).

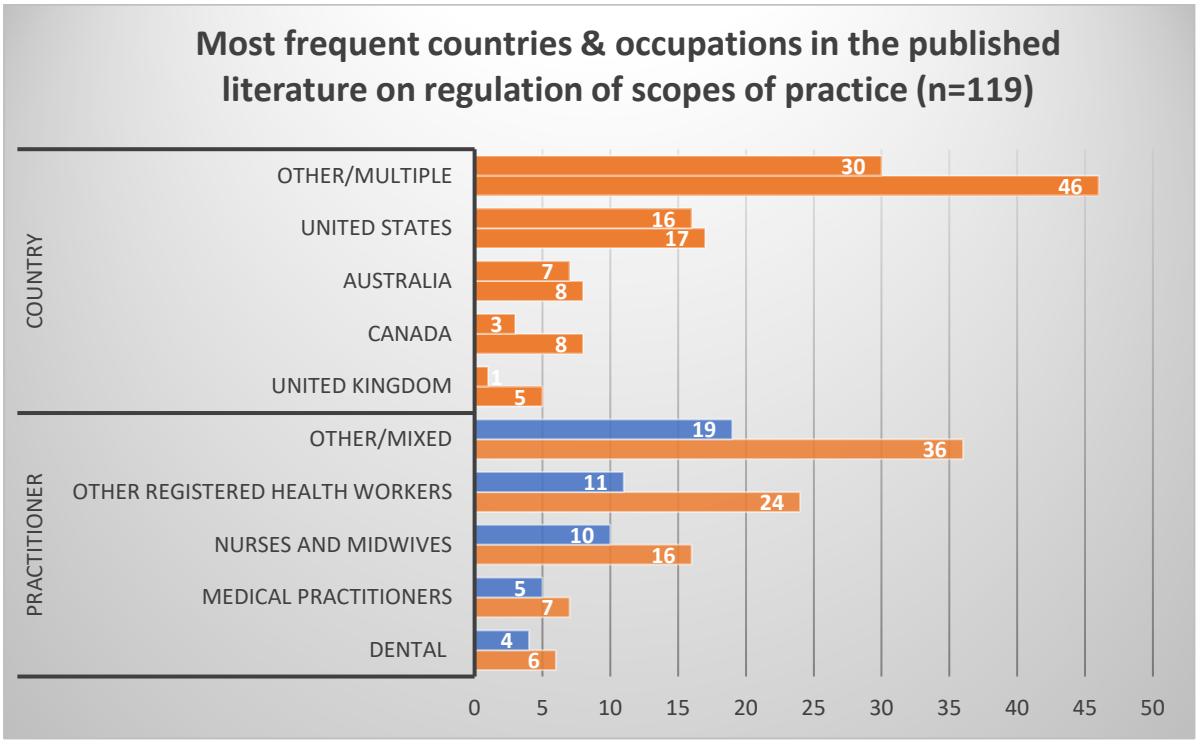


Figure 19: Most frequent countries and occupations in the published literature on regulation of scopes of practice

The published literature on this topic was predominantly focused on nurse practitioners or APN roles (n=36), nurses or midwives (n=24), followed by health practitioners generally (n=16). The US was the most studied country (n=46), followed by studies with an international focus (n=17) and Canada (n=8) and the UK (n=8). The distribution of literature by country is relevant given the different ways in which scope of practice is addressed in HPR (Leslie et al., 2021). A total of **91 empirical studies** reported on the effectiveness of scope of practice regulation.

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **57 documents** relevant to this topic (Figure 20).

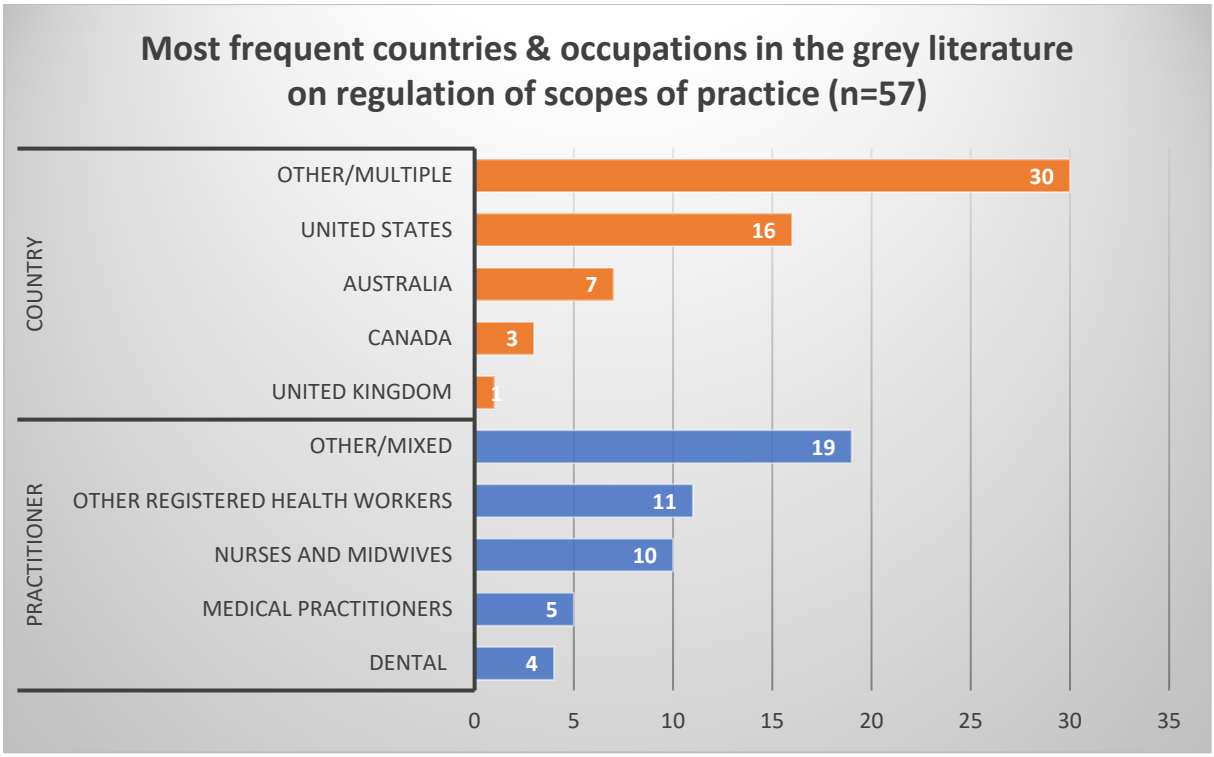


Figure 20: Most frequent countries and health occupations in the grey literature on regulation of scopes of practice

Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 4). The documents addressed an array of issues associated with regulation of scope of practice:

- *Regulation of occupation-specific scopes of practice* – these documents analyzed scope of practice regulation for individual occupations or presented the results of research comparing scopes of practice across multiple jurisdictions. Most related to nurses and dental care practitioners (dental therapists, dental hygienists). The documents issued by regulators or health workforce research bodies addressed issues such as prescribing authorities and decision-making frameworks to assist in determining individual scopes of practice (***12 documents***)
- *Regulatory policy* – these documents described or proposed criteria or frameworks to guide policy decision-making about changes to legislated scopes of practice, issued by a range of bodies including meta-regulators, international professional associations and research bodies (***nine documents***)
- *Skill mix and task sharing* – these documents primarily from LMIEs in sub-Saharan Africa generally described workforce reform initiatives and discussed regulation of scope of practice (***five documents***)
- *Pandemic related* – reports and policy papers issued by bodies such as the OECD and the European Observatory on Health Systems and Policies on how regulators have modified scopes of practice to respond to the demands of delivering health services during the pandemic

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of registration laws and websites of regulatory authorities in a sample of 18 jurisdictions are set out in Annex 11. Comparative data are presented on the mechanism/s applied by regulators, including:

- whether the registration law includes reserved or protected titles
- whether the registration law includes reserved/protected/restricted activities or legislated scopes of practice
- the mechanism of enforcement of such provisions and related offences (if any)

The HPR schemes of all jurisdictions sampled contain legislative provisions regulating the use of professional titles, with offences and penalties for unauthorized use of reserved professional titles and prohibitions on misrepresentation by the misleading use of titles. In the case of the Czech Republic, these are generic provisions in the Civil Code. The provisions are more detailed in some jurisdictions than others, with some legislative schemes containing a specific list of reserved professional titles as well as prohibiting other representations that might mislead the public.

Some schemes also include provisions that regulate professional scopes of practice, although there is variation in the scope of the provisions and the mechanism employed. For instance, some schemes contain a general prohibition on practicing the profession without a license and include offences for illegal practice (Burkina Faso, Hong Kong SAR, Mali, the Philippines, Senegal, Virginia State). In others, the regulator has the power to prescribe by regulation the professional scope of practice of the regulated profession and practitioners are prohibited from practicing outside this scope (New Zealand). In yet another variation, some schemes have legislative provisions that define a number of 'core practice restrictions' (also called 'restricted acts' or 'controlled acts') and authorize only members of specified professions to carry these out (Australia, Brazil, British Columbia). Sometimes the restricted acts are specified in law (Australia, Brazil), sometimes they must be prescribed by regulation (British Columbia, Malaysia, Singapore, South Africa).

Thematic analysis

Five themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. There is evidence that restrictive and unresponsive scope of practice regulation is stifling innovation, inhibiting workforce reform and adversely impacting healthcare access and quality.
2. Conflicts over scopes of practice reflect the tensions and competing interests between and within occupations and some jurisdictions manage these better than others to secure reform.

3. Using HPR to secure expanded scopes of practice, such as authorization to prescribe or administer restricted medicines, is improving healthcare access and quality in both LMIEs and HIEs.
4. Scope of practice reform has been a prominent strategy in the pandemic responses of HICs to facilitate a surge workforce.
5. With increasing reliance on unregistered assistant and support workers, quality assurance of this workforce relies primarily on employer measures, although negative licensing provides an additional layer of public protection in some jurisdictions, particularly for self-employed practitioners.

These themes are expanded upon below.

First, restrictive and unresponsive scope of practice regulation is stifling innovation, inhibiting workforce reform and having adverse impacts on healthcare access and quality.

Reserved practice provisions in registration laws are often used to confer the right to monopoly practice for a specific occupational group (such as the right to make a diagnosis, prescribe medicines or order tests) or to impose restrictions on practice (such as the requirement to work under supervision, only on referral or in a collaborative or shared care arrangement with another practitioner). Some registration laws contain broad scope of practice statements, while others empower the regulator to issue a detailed task-oriented scope of practice statement.[176] Some laws contain offences for unregistered persons who carry out restricted acts, and/or disciplinary powers for registered practitioners who operate beyond the specified scope of practice, while others do not (see Annex 11).

A prescriptive approach is often favored in jurisdictions where local employer or other institutional controls (such as facilities licensing, credentialing and privileging) are weak. While the rationale is usually to protect the public and improve quality of care, a registration law is a blunt instrument for regulating who can do what at the local health service level. Legislatively defined scopes of practice, particularly those that are detailed and task-oriented, inevitably become inflexible and unresponsive to change. They can impose rigidities in the health workforce that hamper team-based care, stifle innovation and militate the achievement of effective and timely scope of practice reform. Indeed, we found many studies in the published literature that documented the adverse impacts on access to and quality of care of legislated restrictions of this kind.[217,288,297,312,318,323,373,392,408,412,567,568,572]

92 empirical studies (out of **305**) from the published literature examined how professional scopes of practice are regulated under the registration laws of different jurisdictions, and the impacts of these arrangements. These studies were principally from the US (n=25), the UK (n=5), Canada (n=3), Uganda (n=2), Ireland (n=2), with single studies from a range of other countries including African countries (Eswatini, Nigeria), UAE, Thailand, Sweden, Taiwan and Australia. The occupations covered were nursing and midwifery (n= 30), the assistant

workforce (mostly unlicensed) (n=10), pharmacy (n=6) and dental hygienists (n=2). The main research interests were:

- advanced practice nursing roles including nurse practitioners (***44 studies***)
- healthcare workers in various (unlicensed) assistant roles (***18 studies***)
- delegation, supervision and task shifting (***18 studies***)
- authorities to prescribe and/or administer restricted medicines (***25 studies***)

Most of these studies examined the impacts of regulatory restrictions and the consequences for patient access to services and quality of care. Some studies assessed the effectiveness of regulatory changes that introduced extended scopes of practice (such as for nurse practitioners and other APNs) or conferred prescriptive authorities on members of various health occupations (such as nurses, nurse practitioners, pharmacists, physician assistants and psychologists). Others were case studies of successful reform efforts.[218,294,313]

We found **18 systematic reviews** on this topic of which **five** were **scoping reviews**.[13,85,110,121,131,169,185,206,226,227,235,268,281,291,401,407,539,568] Most of these studies documented how the development of both advanced practice and assistant roles are improving access to primary healthcare, in both LMIEs and HIEs.[13,110,121,169,185,226,281,407,568]

Most studies on regulation of APN scopes of practice were comparative studies from the USA, examining the impacts of restrictive state-based legislation. Practice restrictions on nurses and midwives have been linked to adverse impacts on population healthcare utilization rates, costs and health outcomes.[217,287,491,512] Conversely, several studies showed the positive impacts on workforce outcomes and primary care following scope of practice reforms.[99,163,408]

The fact that US-based research output on this topic dwarfs that of other countries may be explained in part by the way nursing scope of practice is regulated in that country. A comparative study by Leslie & colleagues [297] analyzed the differential impacts of the different approaches to regulation of scope of practice across jurisdictions (USA, Canada, UK and Australia). They highlighted the need to optimize regulation to ensure all professionals can practice to their full scope – see Textbox 7.

Textbox 7: Regulation of professional scopes of practice – a comparison across countries

Leslie & colleagues [297] compared the way professional scopes of practice are regulated in four countries: the US, Canada, Australia and the UK.

- The US was described as regulating strict scopes of practice where state-based laws and regulations define specific legal scopes of practice for health professionals including the health services that can be legally offered and the circumstances under which these services may be provided.
- Canada was described as regulating scopes of practice more flexibly through provincial/territorial laws that controlled or protected acts or tasks certain regulated professions were allowed to undertake, allowing for some overlap between practitioners.

- Australia moved from a pluralist state-based approach towards a system of national consistency in outer boundaries of scope of practice which is now primarily accomplished through title protection.
- In the UK, determining scope of practice is complex and multi-faceted where there is no common approach to determining scope of practice, nor is there any agreed definition of scope of practice among professional regulators.

Each of these approaches achieve positive outcomes for the public, but also for health professionals and the system more broadly in terms of workforce optimization.

With respect to LMIEs, **10 studies** (eight from the published literature and two from the grey literature) addressed scope of practice and workforce development in relation to both advanced practice and assistant roles. Systematic reviews addressed the effectiveness of and barriers to task shifting, for example from physicians to non-physician clinicians [226] or to nurses for antiretroviral care.[407] While there were some concerns about adverse impacts associated with task shifting,[51,157] examples of successful workforce reform were also evident, and on balance the results of systematic reviews indicated positive outcomes in improving access to primary care.[110,407]

Second, conflicts over scopes of practice reflect the tensions and competing interests between and within occupations, and some jurisdictions manage these better than others to secure reform.

Scope of practice changes are among the most highly charged policy issues facing state legislators and HP regulators [316] and these dynamics shape both the contests over scope of practice and their outcomes. The literature reflects competing views about the structure and clinical leadership of the healthcare team and the respective roles and responsibilities of its members. Position statements from medical bodies (associations, regulators, journals) suggest ongoing resistance to scope of practice reform for other professions and a desire to preserve the status quo.[28,152,199(p2),336(p130),391,552(p5),555] Some of the views of organized medicine are at odds with the literature on the imperatives driving scope of practice reform – the complexities of a dynamic and evolving division of labor in health care, the current day context of team based and interprofessional collaborative practice, and the urgency of workforce reform to improve access to care.

This review identified a body of literature that addresses change management processes. Research findings from comparative studies emphasize the need to use 'best available evidence' to inform workforce reform.[91,122,292,343,345,346] Several documents from the grey literature present policy criteria and processes to strengthen evidence-informed decision-making and better manage the politics of scope of practice reform.[15,16,118(pp32-34),198,238,363,364,445,447] The evidence suggests that physicians no longer exclusively occupy positions of leadership in clinical teams; and that members of a range of health occupations, while they may collaborate with physicians from time to time, often operate autonomously

and without physician supervision,[292,512] some with broad scopes of practice such as some T&CM practitioners.[557] Also, research suggests the most effective and efficient teams demonstrate a substantial amount of scope overlap and shared responsibilities [243] and that healthcare teams with greater cohesiveness and collaboration are associated with higher levels of patient satisfaction and better clinical outcomes.[243]

The literature also suggests a shift in understanding of how scopes of practice are or should be regulated. Decisions about individual scopes of practice are best made at the local level, via formal credentialing or negotiation between employer and employee.[54,118,297] Several regulators have developed decision-making frameworks to assist this local decision-making process.[54,369] For instance, the ICN *Position on Scope of Nursing Practice* acknowledges that the scope of nursing practice is dynamic and responsive to changing health needs, knowledge development and technical advances; is not limited to specific tasks, functions or responsibilities; includes to supervise, delegate and lead; and should be sufficiently broad and flexible to permit freedom for innovation, growth change.[253(p1)] However, much of the literature (including the ICN Position) is framed with an implicit assumption that the rightful role of an HP regulator is to define and enforce the scope of practice for regulated practitioners. Some nervousness is apparent in HICs concerning the potential loss of centralized regulatory control of scopes of practice if regulators were to vacate this space in favor of more localized scope of practice decision-making.[297,346] Also, in LMIEs where clinical governance and other institutional controls may be weak or absent, a strong HP regulator controlling scopes of practice can be appealing.

Regardless of the approach to regulating scopes of practice, the literature suggests that the workforce reform effort required to achieve and maintain an optimal skill mix in the health workforce is and should be core business for governments, with regulatory policy decisions managed within government rather than delegated to unaccountable or practitioner-led bodies.[v] Several documents propose criteria and/or processes for regulatory policy making to ensure evidence-informed changes to scopes of practice [15,118,122,199,239,365,525,526] (See Annex 7).

[v] In at least three jurisdictions, statutory bodies charged with providing regulatory policy advice to their respective governments on scope of practice matters have been or are in the process of being abolished. See the former British Columbia Health Professions Council established under the Health Professions Act (https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/professional-regulation/health-professions-council); the proposal for dissolution of the Ontario Health Professions Regulatory Advisory Council (https://www.ontariocanada.com/registry/view.do?postingId=37050&language=en), and the bill before the Queensland Parliament to amend the Health Practitioner Regulation National Law to disestablish the Australian Health Workforce Advisory Council – see https://documents.parliament.qld.gov.au/bills/2022/3093/Health-Practitioner-Regulation-National-Law-and-Other-Legislation-Amendment-Bill-2022-6e2a.pdf

Third, using HPR to support expanded scopes of practice, such as authorization to prescribe or administer restricted medicines, is improving healthcare access and quality of care in both LMIEs and HIEs.

There was a strong focus in the literature on improving access to and quality of care, particularly for rural and underserved populations, amongst other things by expanding healthcare worker scopes of practice to encompass prescribing and/or administration of restricted medicines.[7,48,83,163,165,172,208,218,274,275,281,288,291,310,313,334,464]

To support the safe use of medicines, in some jurisdictdions, HP regulators have a role in: setting the required competencies; accrediting the training programs and/or approving enhancements to accredited programs or short courses for existing registrants; and identifying on the public register those registrants who have completed the required training, have the necessary competencies and may safely be granted the authority to prescribe. In such a scheme, the regulator then monitors compliance of registrants with prescribing practice standards and deals with any complaints of poor practice, in conjunction with medicines regulators.[16,19,23,250]

We identified **45 articles** on regulation of scope of practice and extended practice and/or advanced practice roles, including:

- *extension of nursing practice* [83,97,131,185,281,539,575]
- *extension of pharmacist practice*[7,48,313]
- *comparative studies of advanced practice nursing* [100,121,222,291,454,491,512,577]
- *nurse practitioners* [99,133,136,163,167,169,287,288,310,312,326,401,408,410,568]
- *advanced practice pharmacists* [60]
- *barriers to scope of practice reform*[171,185,486]

Several retrospective cohort studies from the US found evidence of improved access to services and health outcomes, due to less restrictive regulations that enabled expanded scopes of practice for nurse practitioners and community nurse-midwives.[287,408,572]

This review found strong evidence that health practitioners in both LMIEs and HIEs can be trained, authorized and supported to safely and competently administer, supply and/or prescribe restricted medicines. **24 articles** addressed the authorization of healthcare workers to prescribe and/or administer medicines. **Two articles** (out of **24**) were about medicine administration by home care aides and other unlicensed personnel. The remaining **22 articles** were about prescribing authorities for nurses (n=16), midwives (n=1), pharmacists (n=5) and psychologists (n=2). **21 articles** (out of **24**) were empirical studies. These were generally surveys, as well as analytical pieces and quantitative analyses of large data sets to identify correlations. Several of these studies, from both HIEs and LMIEs highlighted safety concerns

where task shifting or delegated practice involving the administration of medicines occurred without adequate supervision and often beyond what was authorized by law.[13,50,51,85,153,157,211]

An international survey found that nurse prescribing occurs extensively in all six continents.[291] Ladd & Schober found the predominant model of nurse prescribing in HICs is at the advanced level role by post basic or post professional nurses and through less formal task-sharing arrangements, primarily in low- to middle-income countries. They found that nurse prescribing is evolving rapidly around the world but within highly variable roles and regulatory frameworks. They proposed that codifying these roles by strengthening educational and regulatory standards may serve to enhance the health system capacity, especially in LMIEs.[291(p40)]

Five articles addressed prescribing authorities in LMIEs.[48,158,281,291,576] Nurse-initiated and managed anti-retroviral therapy was being widely practiced and authorized in sub-Saharan African countries but was not reflected in regulation nor incorporated into preservice education.[576]

In a 2021 study, the ICN reported the results of a review of the literature on nurse prescribing, its aim being to facilitate a shared understanding of nurse prescribing. Three models of prescribing authorities are described: independent prescribing, supplementary prescribing, and prescribing via a structured prescribing arrangement or protocol.[250(p11)] The ICN study found that nurses in a range of settings are practicing with high levels of prescribing autonomy, they are prescribing safely and are as effective as other prescribers. The study also found that prescribing authorities for nurses has many benefits: it can improve effective and efficient healthcare service provision; facilitate the provision of more integrated patient care; increase professional satisfaction; and improve the overall quality of the health service.[250(p11)] Where nurses are unable to prescribe, the study found that care delivery is fragmented and negatively impacts the overall quality of health care. A strong clinical background and solid clinical knowledge are foundational to effective prescribing practice, regardless of the level of nurse.[250(p11)]

Three publications from the Australian grey literature set out national decision-making criteria and processes for assessing applications from regulators and professions to change legislated authorities to use (administer, supply or prescribe) restricted medicines, for both registered and unregistered health occupations. These guidelines are designed to facilitate workforce reform initiatives which involve extended authorities to use restricted medicines.[16,24,139]

Fourth, scope of practice reform has been a prominent strategy in the pandemic responses of HICs to facilitate a surge workforce.

Restrictive and inflexible scopes of practice have been strongly criticized during the COVID-19 pandemic, with calls for greater flexibility to strengthen responses to future crises (206–209).

We found an emerging published and grey literature from HICs that analyzed and compared the effectiveness of government and regulator responses to the pandemic. [41,102(p),103,358,374,375(p19),377,383,383,385,386,396,429(p19),430,463,472,473,499] This literature documents how many countries fast tracked reforms to scopes of practice for a variety of nursing, assistants and allied health occupations, in order to facilitate the surge workforce. For instance, in a report published by the European Observatory on Health Systems and Policies, Sagan & colleagues [473] documented how many countries made changes to skill mix and distribution of tasks among the health workforce, in response to staff shortages. The researchers documented changes in scopes of practice for paramedics, pharmacists, internists, GPs and medical specialists, physiotherapists, RNs and dentists. Changes spanned prevention, testing, tracing, monitoring and vaccinating, providing primary care, specialist outpatient care and inpatient care.[473(p52)]

The urgent actions taken by many governments underline the concerns that had been extensively documented prior to the pandemic about the restrictive way scopes of practice are regulated in some jurisdictions and the barriers this presents to team-based care and access to health services. It also highlights the need for a different approach to regulating scopes of practice, one that is more dynamic, enables greater flexibility in determining skill mix, role definition and redefinition, task sharing and task shifting, and fosters interprofessional collaboration and team-based care.

Fifth, with increasing reliance on unregistered assistant and support workers, quality assurance of this workforce relies primarily on employer measures, although negative licensing provides an additional layer of public protection in some jurisdictions, particularly for self-employed practitioners.

We found a diverse literature on the regulation of scopes of practice of the registered and unregistered assistant workforce in both HIEs and LMIEs. Of the **410 articles** that met the inclusion criteria, **18 articles** examined regulation of scopes of practice for the assistant workforce. These articles were principally concerned with task shifting and the adequacy of the educational preparation, training, delegation and supervision arrangements for unregistered healthcare workers to deliver safe and competent care, including therapy assistants, pharmacy technicians, medical assistants and community support workers. Some researchers called for registration of various cadres of assistant workers. [230,462,474]

A systematic review of the activities of unregulated nursing assistants identified 20 studies, mostly from the UK and Canada.[85] It found that the nursing assistant role is slowly (and

unofficially) expanding, with assistants performing tasks that require greater comprehension and skill for which they are not necessarily trained.[85(p1548)] A scoping review on the role of unregulated care providers in Canada [13] also found many unregulated care providers do not have a defined scope of practice and their roles have evolved to include activities previously performed by regulated practitioners, with potential implications for quality of care and patient safety. Many experience a lack of recognition and a lack of authority in decision-making in patient care; information on the role, education and employment standards of unregulated care providers is fragmented.[13(p1)]

Several US studies reported the results of comparative analyses of the extent to which states restrict by legislation the ability of licensed practitioners to delegate activities to their respective assistant cadres and the consequences of delegation (or lack of) for access to health services for underserved populations. For instance, a smaller proportion of federally funded safety net patients received dental examinations in states with restrictive state workforce policies [323] and delegated activities (from pharmacists to pharmacy technicians) were more likely in states that require technicians to be registered and certified or where accountability mechanisms (e.g., discipline authority) were in place for technicians.[197(p1194)]

Of the **18 articles** relevant to this theme, **six** related to assistant roles in LMIEs.[50,51,110,157,158,469] The findings were mixed, with some studies documenting lack of regulation and adverse impacts on quality and safety of health services [50,51,157,469] and others reporting positive impacts (or the potential for) on program efficiency and patient outcomes.[110,158]

The grey literature yielded evidence concerning the benefits of task shifting. These reports were mainly from the US, Canada and the UK, in dental care (dental hygienists and dental therapists), pharmacy technicians, and physiotherapy and occupational therapy assistants.[243,292,338,344] For instance, in oral health, researchers report that the traditional perception of the dental hygienist as a dental extender working only under the direction and supervision of a dentist is shifting. Increasingly, dental hygienists are acting as oral health specialists in autonomous roles in a variety of public health settings where they often serve as the first point of contact for patients, case managers and care coordinators.[292]

Similarly, a suite of documents on the website of the World Accelerated Medically Trained Clinicians Network (AMTC) shows the extent to which various 'mid-level cadres' of healthcare workers are contributing to health care in LMIEs and substituting for internationally mobile health practitioners – such as Clinical Officers in Kenya, Medical Clinical Officers in Uganda, and Medical Assistants in Bangladesh.[31–34] An AMTC desktop review found specialized substitutes being training in a range of medical disciplines including surgery, ophthalmology, orthopedics, radiology, anesthesiology, dentistry and dermatology, with minimal differences in patient outcomes compared with physicians.[31]

Finally, the grey literature review found evidence from five jurisdictions showing how the mechanism of negative licensing (see Textbox 3) is providing an additional layer of public protection for health service users.[221,223,224,341,372,389] Negative licensing provides assurance of the assistant workforce to the extent that prohibition orders may be issued to limit or remove from the health workforce altogether, those assistants in nursing and other personal care workers who present a serious and ongoing risk to patients due to incompetence, misconduct or impairment.[223,224,372,389]

Summary

There is a strong body of evidence which shows that the legislative and administrative mechanisms used in many countries to regulate practitioner scopes of practice centrally have significant unintended consequences in constraining local workforce flexibility and collaborative team-based care and preventing timely implementation of innovative advanced practice and assistant roles.

There is strong evidence of the costs to the health workforce, health consumers and the health system when practitioners such as nurses, midwives and other allied health practitioners are prevented by restrictive scope of practice regulation from applying the competencies for which they have been trained.

There is reasonable evidence to suggest that while the development and implementation of advanced practice roles is often contested and slow, the ingredients for effective workforce reform are well documented. Successful workforce reform requires governments to take a leadership role, to manage in a more interventionist manner the competing interests, and to remove legislative and other restrictions to accelerate the reform process. There is reasonable evidence that, at least in HICs:

- use of reserved practice provisions (restricted acts/scope of practice and associated offences) in a registration law to confer the right to monopoly practice for an occupational group can result in unnecessary rigidities in the health workforce and hamper the achievement of effective and timely scope of practice reform
- it is preferable to avoid framing provisions in registration laws that empower regulators to issue scope of practice statements that tightly define what registrants can and cannot do, particularly when combined with sanctions for registrants who practice beyond the boundaries of the approved scope of practice
- the preferred approach to the regulation of risky treatments and activities (those that are judged to be so risky that only qualified workers should be authorized to carry them out) is one which enables various cadres of healthcare workers to be authorized based on demonstrated competencies rather than which occupation they belong to
- the preferred approach to determining an individual health practitioner's scope of practice is through a local process of credentialing within the health facility, where a range of factors may be considered, including the practitioner's qualifications, skills and competence, the facilities and supports available, any upskilling they may have undertaken via CPD or on the job training and the health needs of the population served

There is strong evidence that extending prescribing rights for restricted medicines to the nursing and allied health professions improves the effectiveness and efficiency of health services and that with the necessary training, health practitioners from a range of occupations can safely and competently prescribe or administer restricted medicines.

While the evidence shows that prescribing by practitioners such as nurses, midwives and pharmacists has been implemented on every continent in both low and high-resource environments, some health occupations, particularly nursing, continue to struggle to secure prescribing authorities, often due to organized resistance from the medical profession. The evidence suggests some governments have been more effective than others in leading the design and implementation of scope of practice reform in this contested area.

There is some evidence that negative licensing provides relatively low cost and effective quality assurance for the unregistered workforce by setting minimum standards of professional conduct and providing a swift and effective mechanism to remove dangerous or incompetent workers from the health and care workforce. By removing such workers, pressure on jurisdictions to enact (or extend) more costly statutory registration schemes may be reduced.

Given the contested and often highly politicized nature of decisions about changes to scopes of practice and that practitioner-led regulators can be considered stakeholders with a vested interest in the outcome, the regulatory assessment processes of some jurisdictions afford these stakeholders greater control over, or involvement in, decision-making than is consistent with good regulatory practice. An evidence-informed assessment process conducted at arms-length from stakeholders is more likely to facilitate workforce reform.

10. REGULATION OF COMPLAINT-HANDLING AND DISCIPLINE

Overview

The focus of this chapter is on the HP regulator's powers and functions to receive and investigate complaints and manage disciplinary processes, for registrants whose practice is compromised due to impaired health, incompetence or willful misconduct.

Complaints about health practitioners serve an important purpose: they can provide essential intelligence for quality assuring health service provision and can provide early warning of broader clinical governance failures in health services. A culture that welcomes complaints, combined with efficient and effective complaint management and disciplinary processes are crucial elements of any HPR system.

First, we offer a summary of key characteristics of studies identified from the published and grey literatures and present some comparative data from selected jurisdictions on legislative powers to manage complaints and discipline, followed by the thematic synthesis of the combined literatures.

Scope of the literature on this topic

Scientific literature

Of the **410 articles** that met the inclusion criteria, **67 articles** included content related to the operation of complaints and disciplinary functions under a HPR scheme (Figure 21). For details of the publications on this topic, see Annex 4 (Table 7).

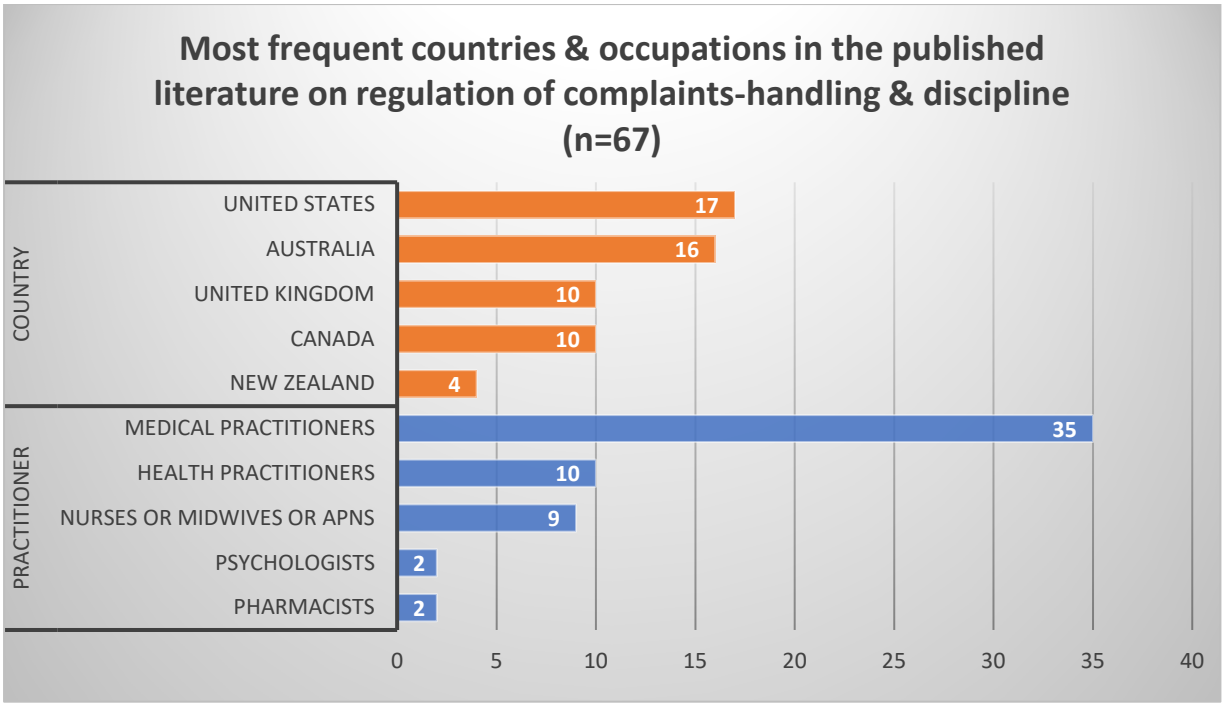


Figure 21: Most frequent countries and health occupations in the published literature on regulation of complaint-handling and discipline

The published literature focused primarily on medical practitioners (n=35), followed by health practitioners in general (n=10) and then nurses and midwives (n=9). The US was the most prominent jurisdiction (n=17), followed by Australia (n=16), Canada and the UK (n=10 each). A total of **62 empirical studies** examined some aspects of the effectiveness of the complaint handling and disciplinary functions of a regulator or regulators.

The included articles addressed a diverse array of issues associated with complaints and discipline, such as:

- analysis of data from regulators on complaints received and disciplinary actions taken, including the characteristics of complainants, types of behavior complained about, disciplinary processes followed, types of sanctions imposed
- comparative studies of disciplinary or 'fitness to practice' pathways and processes across multiple jurisdictions
- the nature of misconduct or ethical violations including elements such as: character, performance, incompetence, disengagement, disruptive behavior, boundary crossings and boundary violations (sexual harassment, exploitation and abuse)
- prevalence rates for disciplinary action in specific cohorts of practitioner (various professions including physicians, social workers, psychologists and Chinese medicine practitioners);
- the association between disciplinary action prevalence rates and other variables such as participation in CPD or maintenance of certification programs
- impaired practitioners and the effectiveness of remediation/rehabilitation programs;
- access to and use of data on malpractice cases and payments

- mandatory reporting obligations placed on practitioners or employers to report to the regulator a practitioner or a student whose practice is placing the public at risk due to impairment, incompetence or ethical breaches

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **72 documents** relevant to this topic (Figure 22).

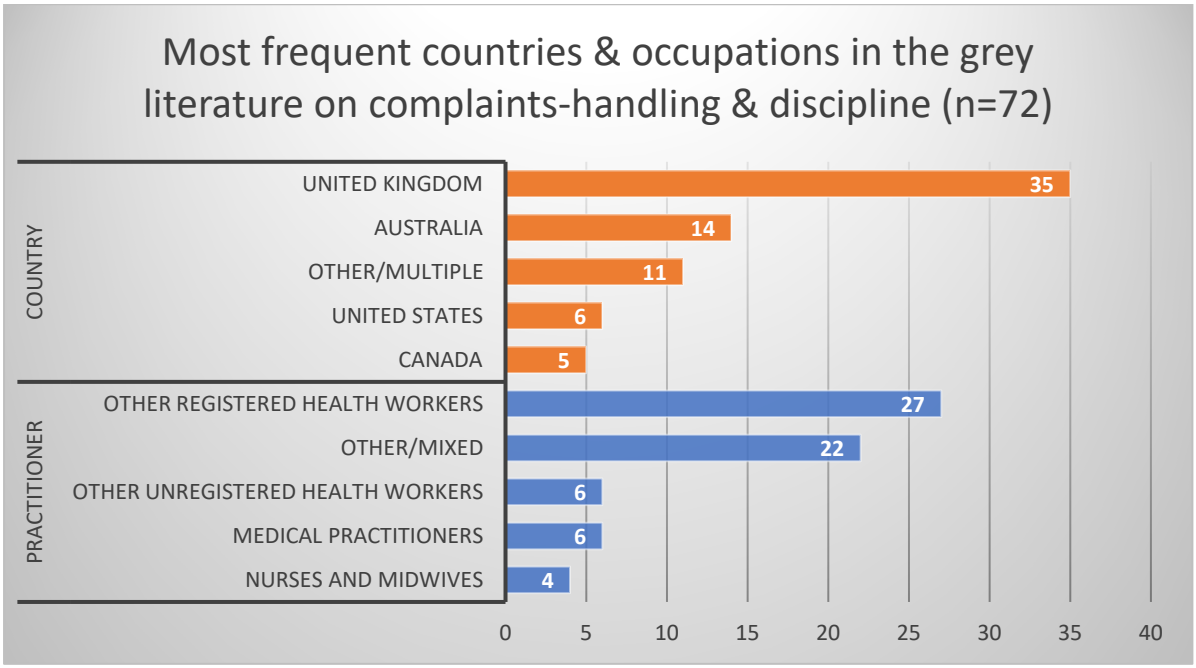


Figure 22: Most frequent countries and health occupations in the grey literature on regulation of complaint-handling and discipline

Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 7). The main sources were:

- *WHO and related entities* – regional reports from WPR on health workforce regulation and health system strengthening and WHO commissioned country and regional reports that include comparative analyses of HPR schemes in multiple jurisdictions (***10 documents***)
- *Meta-regulators* – reports of performance reviews of regulators and research reports on specific policy issues, primarily from the UK PSA (19 documents), the FSMB (***three documents***) and the NCSBN (***three documents***)
- *Governments* – reports primarily from health departments/ministries, regulators and parliamentary committees in the UK, Australia and Canada where regulatory reform activity in HPR has been occurring over several decades (***14 documents***)

The bulk of these documents related to HPR in HICs.

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of registration laws and websites of regulatory authorities in a sample of 12 jurisdictions are set out in Annex 12. Comparative data are presented on key elements of the complaints handling and disciplinary functions, including:

- how a health service user lodges a complaint about a registered practitioner
- what triggers the regulator's investigation and disciplinary powers
- the complaint investigation and disciplinary process
- who makes investigation and disciplinary decisions
- whether disciplinary decisions are publicly accessible on the public register
- whether there is a right of review for a practitioner of an adverse disciplinary decision
- the offences and penalties that apply to unregistered persons

Of the schemes sampled, all 12 regulators provide a clear pathway for lodgement of complaints about registered practitioners, with information on their websites for complainants. The grounds for making a complaint vary, with some regulators providing detailed advice on the types of matters accepted, and others providing very little information. In some schemes, the architecture of the complaint management system is spelt out on the regulator's website, with information both for complainants and for practitioners who may be the subject of a complaint. In other schemes, there is very little information and the pathways for dealing with complaints are not well codified. However, in most schemes it is clear who deals with complaints and what powers they have, and do not have.

Few regulators have specific powers to take immediate action, for example to immediately suspend the license or registration of a practitioner if they present a serious risk to the health and safety of the public.

Just over half the regulators sampled publish the details of disciplinary cases. All schemes sampled provide an avenue of appeal for practitioners who are subject to an adverse disciplinary outcome.

Thematic synthesis

Three themes were identified from the integrated synthesis of the scientific and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. There is considerable diversity in the regulatory powers, governance and processes for managing complaints and discipline, but little evidence on how best to design and deliver effective systems.
2. Regulators in some HICs are designing risk management and prevention strategies, informed by studies of prevalence rates for disciplinary action.

3. Remediation programs for impaired and poorly performing practitioners and mandatory reporting obligations may be effective public protection mechanisms, albeit with resourcing and implementation challenges.

These themes are expanded upon below.

First, there is considerable diversity in the regulatory powers, governance and processes for managing complaints and discipline, but little evidence on how best to design and deliver effective systems.

Despite the important role of HPR in identifying and managing practitioners with conduct, competence or capacity concerns, there is considerable diversity of arrangements for dealing with complaints and discipline and in some cases little transparency concerning the performance or effectiveness of these functions.[68,69,113,118,171,174,349,528]

A 2016 WHO WPR report titled *Health Workforce Regulation* conceptualized this diversity by categorizing member states into one of three 'clusters', depending on the 'maturity' of their regulatory systems.[548(p4)] The report found that while many jurisdictions have legislation which specifies complaint procedures, there may be little published information about the processes, or the penalties applied. Also, in some jurisdictions, the disciplinary process appears focused on fraud rather than misconduct and information gaps suggest some jurisdictions rely on employers to manage matters of discipline, with only serious matters elevated to the regulator. Some jurisdictions operate disciplinary processes at the regional rather than national level and in some jurisdictions, responsibilities reside with government departments that have other functions. Some jurisdictions have clear processes set out in legislation, but these may not be implemented.[548(p19)]

The mapping data from HPR statutes and regulator websites are consistent with these findings (see Annex 12). Schemes vary in:

- clarity of purpose or mandate
- clarity of architecture of the disciplinary system and how key terms are defined
- clarity of the grounds for the regulator to exercise disciplinary authority
- the extent of powers to assess complaints, conduct investigations and take immediate action to protect the public
- clarity of pathways for dealing separately with practitioner conduct, competence or capacity concerns
- the constitution of panels and conduct of hearings and the range of orders or sanctions available
- the duty of confidentiality and powers to share information and issue public warnings
- specification of requirements for procedural fairness, separation of powers and rights of review of disciplinary decisions
- the extent of monitoring and enforcement powers
- the level of transparency of disciplinary decisions

- the extent of focus on risk-based regulation and system improvement

Most of the published literature on this topic was from high income Anglophone countries and either analyzed rates or patterns in disciplinary cases for cohorts of practitioner, or addressed a specific element of the disciplinary system, such as remediation programs or mandatory reporting. Multiple comparative studies were identified.
177(p20),202,203,214,271,296,298,349,397,461,498

Studies that reported on regulatory strengthening activities in LMIEs focused primarily on entry-to-practice standards and education, devoting minimal attention to the establishment of complaint handling and disciplinary systems. Three studies were found that addressed how well these functions operate. Studies addressed: the effects of informal payments and 'rent seeking' behavior by health workers in Tanzania;[314] the tendency for disciplinary action to focus on character-related conduct rather than clinical quality and patient care in Indonesia;[266] and in Pakistan, the types of ethical violations and the need for changes in education curricula and socio-cultural values.[265]

Government or regulator commissioned consultation papers and reports from HICs generally provided more fulsome policy analysis that probed some of the systemic complexities and tensions, such as whether the primary purpose of HPR is punitive or public protection and remediation or complaints resolution, or some combination of these; how disciplinary processes fit within a jurisdiction's broader legal and quality assurance systems (for managing employee performance, medical negligence and compensation, professional indemnity insurance, criminal justice etc.); how to support both complainants and practitioners through the disciplinary process; and how much identifying information is published on disciplinary outcomes and the performance of the regulator.[62,128,155,189,450,476,516,518–520]

Second, regulators in some HICs are designing risk management and prevention strategies, informed by studies of prevalence rates for disciplinary action.

The literature shows substantial research effort in HICs is being directed at measuring the prevalence rates for disciplinary action in particular cohorts of practitioner and how these data may be used to identify and address risk of harm to the public. There were many retrospective cohort studies that described patterns of disciplinary action for specific cohorts of registrants. These studies were principally from the US but also from Canada, the UK and Australia.

The largest group of studies, from the US, examined historical disciplinary data for individual medical specialties. These studies aimed to assess the nature of the relationship between maintenance of specialty certification and later disciplinary action by the responsible state medical regulator. Multiple studies found that physicians who failed certification or let their

certification lapse were significantly more likely to be subject to disciplinary action later.[272,333,361,402]

Several studies compared prevalence rates for disciplinary actions across multiple jurisdictions.[203,349,498] For instance, a US study by Harris & Byhoff [214] accessed data on the rate of medical malpractice claims by physicians in each US state (via the US National Practitioner Data Bank), combining this with disciplinary data from state medical regulators. They found a fourfold variation in the annual rate of physician disciplinary action across US states. Similar variation in rates of disciplinary action was reported in Morioka's study of medical regulators in 13 countries [349] and Struckmann & colleagues in 11 European Union countries.[498] The reasons for these variations were not clear although it suggests some regulators may be more active than others in pursuing disciplinary action.

While several studies examined the stress experienced by practitioners when subject to disciplinary action [44,94,124] it is primarily governments and regulators that have commissioned research on the complainant experience.[25,225,421,423,427,443]

A common focus in retrospective cohort studies was to identify patterns in disciplinary data concerning the characteristics of registrants who are subject to disciplinary action. The rationale is to use this information to 'take preventive action' [26] or identify 'contributory risk factors'. This information may then be used to develop professional standards and early interventions and strengthen the abilities of managers to recognize and prevent events that seldom occur but seriously threaten the safety of patients when they do.[397(p1588)] Six studies demonstrate this shift to risk-based regulation, drawing on the sizable data set available via a single national multi-profession regulator to identify the patterns and characteristics of registrants who have been subject to disciplinary action.[80–82,471,507,508]

Extensive documentation was located on the website of the UK PSA, a meta-regulator.[444] This included reports of reviews of the performance of UK HP regulators,[432,433,433–441] responses to government consultations,[420,426,452] policy and research documents and conceptual analysis of issues associated with 'fitness to practice' processes.[422] Policy issues subject to recent PSA research activity include:

- enhancing the confidence of complainants in the disciplinary process [423,450]
- the scope for 'consensual disposal' of fitness to practice matters [476]
- biases in fitness to practice decision making [155]
- the nature of dishonest behavior by practitioners [421]
- case studies of the lessons learned by regulators in responding to the COVID-19 pandemic[429,430]

Third, remediation programs for impaired and poorly performing practitioners and mandatory reporting obligations may be effective public protection mechanisms, albeit with resourcing and implementation challenges.

There was interest from regulators and researchers in the extent to which impaired, or poorly performing registrants may be 'remediated' and returned to safe and competent practice. There were, however, few studies that assessed formal remediation programs and their effectiveness. Studies have generally reported positive effects in HICs of HPR remediation processes, though such programs are resource intensive.[303,535]

Bourgeois-Law & colleagues [93] explored alternative conceptualizations of remediation as education or regulation, finding that regulators seemed to switch between the two. Some studies referenced concepts of 'therapeutic jurisprudence' and 'restorative justice'.[164]

Six studies, including one systematic review, reported on the outcomes of remediation programs for practitioners who had been identified through disciplinary processes as impaired and/or performing poorly. These studies were from the Netherlands, New Zealand, the UK and US. Lillis & colleagues [303] identified key features of a successful remediation program: the training of both assessors and educators; workplace-based nature and comprehensiveness of the assessment process (including review of clinical notes and audit of current practice); the individualized and supported educational program (with tutoring on a one-to-one basis; a program that proceeds at a pace comfortable for the physician); careful attention to indicators of progress in remediation; and formal reassessment where warranted.[303(pp100-101)]

Weenink & colleagues [535] conducted a systematic review of the evidence on the outcomes of remediation and rehabilitation programs for healthcare professionals with performance concerns and explored whether outcomes differ for specific concerns and professions. They found the literature was mostly on outcomes for physicians in North American programs and no studies were identified that specifically compared outcomes between professions. There were positive outcomes for substance use disorders (SUDs) (approximately 80-90% of participants were employed after treatment), while most studies on 'dyscompetence' (defined as poor professional performance in a limited number of crucial or expected skills) were from Canada and showed varying outcomes. They concluded that valid comparisons cannot be made in outcomes between professions and for specific performance concerns.[535(p1004)]

Studies also examined HPR schemes that include a legislative obligation for mandatory reporting, a mechanism for alerting regulators to practitioners and sometimes students with conduct, competence or capacity concerns. Identifying and investigating concerns about the practice of registered health practitioners (or students engaged in clinical training) is an important way that regulatory bodies protect the public and strengthen health systems. The

aim of mandatory reporting is to accelerate the identification of underperformance and remedy the problems identified as quickly as possible.[416] The obligation to report may be placed on employers, registered/licensed colleagues, a treating practitioner (in the case of an impaired registrant/licensee), or an education provider (in the case of students enrolled in qualifying programs).

We found **seven articles** that examined mandatory reporting as a mechanism for alerting the regulator as early as possible to an at-risk practitioner. Some studies addressed the pros and cons of mandatory reporting.[80,81,95,297,298,416]

Leslie & colleagues [296] found considerable variation in the legislative mandatory reporting frameworks across 12 Canadian jurisdictions, primarily in the scope of reportable conduct and the threshold that triggers the requirement to report. They found the most common reportable conduct was sexual misconduct or sexual abuse of a patient, with mandatory reporting requirements in six provinces extending beyond sexual abuse or misconduct to concerns about conduct, competence, and capacity.[296(p1)]

The issues associated with HPR complaint management systems where the functions are distributed amongst a range of government and non-government entities did not feature prominently in the literature. However, several studies by Weenink & colleagues [535,536] point to challenges in a system where the professional associations are principally responsible for disciplinary matters. For instance, they found at least 9% of healthcare professionals reported dealing with impaired or incompetent colleagues during the previous year [536(p56)] and that they experienced uncertainty about avenues for reporting.[535(p838)]

While there is some early evidence of the effectiveness of mandatory reporting as a public protection measure, the introduction of mandatory reporting obligations has been contentious in some jurisdictions, not least because of concerns that it may discourage practitioners from seeking treatment for fear they will be reported to the regulator by their treating physician. Bismark & colleagues conclude that mandatory reporting in the Australian HPR system reinforces the primacy of patient safety [80(p1165)] and provides additional impetus for practitioners to alert the regulator of a registrant's misconduct, in circumstances where they might be uncertain or otherwise reluctant to report. However, the researchers acknowledge the evidence of its effectiveness is limited at this stage and that some of the tensions require careful management by the regulator, including to ensure the reporting threshold is appropriately defined and clearly understood; to improve access to evidence-based health programs for practitioners; and to strengthen upstream protections to prevent and minimize impairment at its roots.[80(p1165),80,81,95,205,298,416]

Summary

There is some evidence from HICs that formal remediation programs that are designed to support return to practice for impaired registrants or those with performance concerns may be an effective tool, particularly for those with substance use disorders. Few studies were found that evaluate the features of effective remediation programs.

There is early evidence in HICs that a mandatory reporting obligation placed on registered practitioners to report a registrant who is impaired, poorly performing or engaging in misconduct is an effective public protection mechanism if reporting obligations are carefully framed and clearly communicated.

There is reasonable evidence to suggest that physicians in the US who let their specialty certification lapse or fail their recertification are significantly more likely to be subject to disciplinary action later. However, the nature of the relationship is not clear and requires further research.

There is evidence of wide disparities between jurisdictions in the rate of complaints and disciplinary action and, in the absence of comparative studies, there is lack of clarity about the reasons.

There is considerable variability across jurisdictions in the extent to which complaint handling and disciplinary powers of regulators are codified and variability in the level of transparency in operation.

11. REGULATION OF TRADITIONAL AND COMPLEMENTARY MEDICINE PRACTITIONERS

Overview

The focus of this chapter is on the literature on the regulation of T&CM practitioners and practice. Of particular interest is literature on:

- the approaches adopted in different countries to ensure T&CM practitioners are safe and competent to practice
- the types of occupational regulation that apply and the role of regulation in facilitating professionalisation of this workforce
- how different regulatory arrangements impact efforts within jurisdictions to strengthen institutions and facilitate the integration of the established T&CM professions into the wider health system

Scope of the literature on this topic

Published literature

Of the **410 articles** that met the inclusion criteria, **56 articles** included content related to T&CM practitioners and HPR (Figure 23). For details of the publications on this topic, see Annex 4 (Table 8).

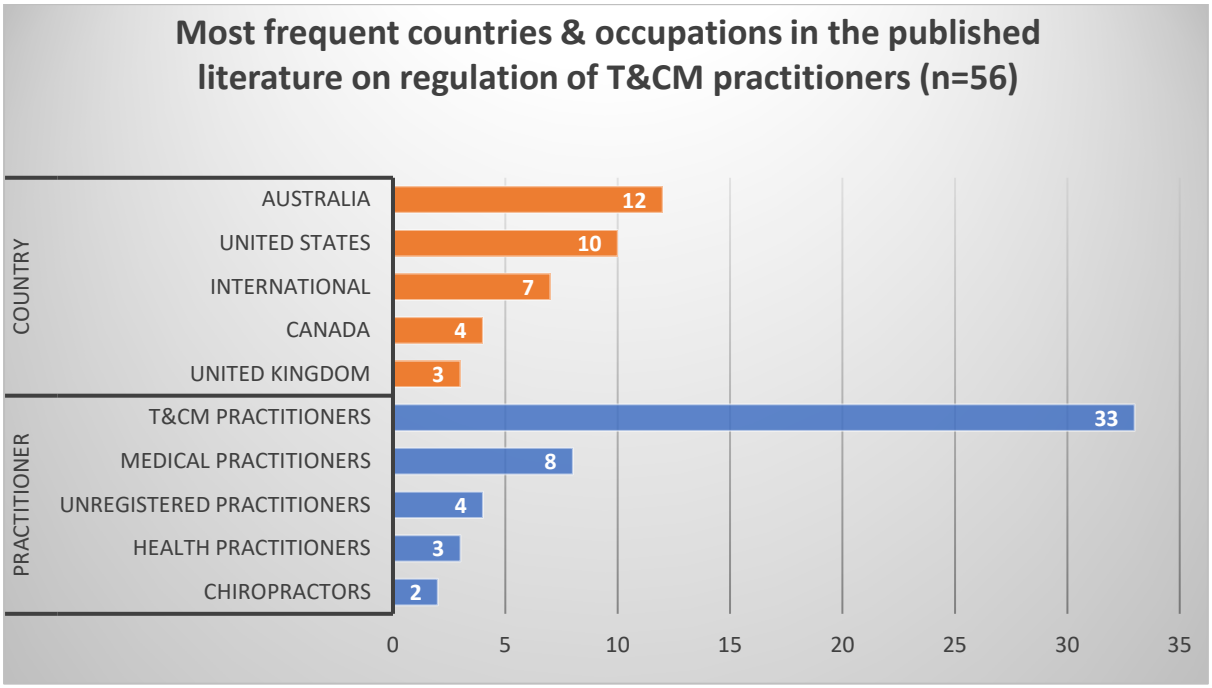


Figure 23: Most frequent countries and health occupations in the published literature on regulation of T&CM practitioners

Articles from Australia (n=12), the US (10) and international focus (n=7) were prominent. There was considerable diversity in the studies found, the main groupings being:

- studies on the adequacy or effectiveness of regulation of the T&CM professions in UMIEs and HIEs and associated issues and challenges (***14 articles***)
- studies on the adoption of T&CM modalities by other professions or the integration of T&CM providers into heath systems (***10 articles***)
- studies on the need for regulation to better integrate traditional healers into the health systems of LMIEs such as in sub-Saharan African countries and India (***seven articles***)
- studies on change management processes associated with the introduction of new regulatory schemes for T&CM professions (***six articles***)
- studies examining issues of risk associated with the practice of the T&CM professions (***four articles***)
- studies on specific regulatory functions vis a vis the T&CM professions, such as complaints and discipline, accreditation standards, competency standards and interprofessional practice (***four articles***)
- studies comparing regulatory arrangements for the T&CM professions globally or in regions (***three articles***)
- studies of stakeholder attitudes to regulation of T&CM professions (***three articles***)

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **35 documents** relevant to this topic (Figure 24).

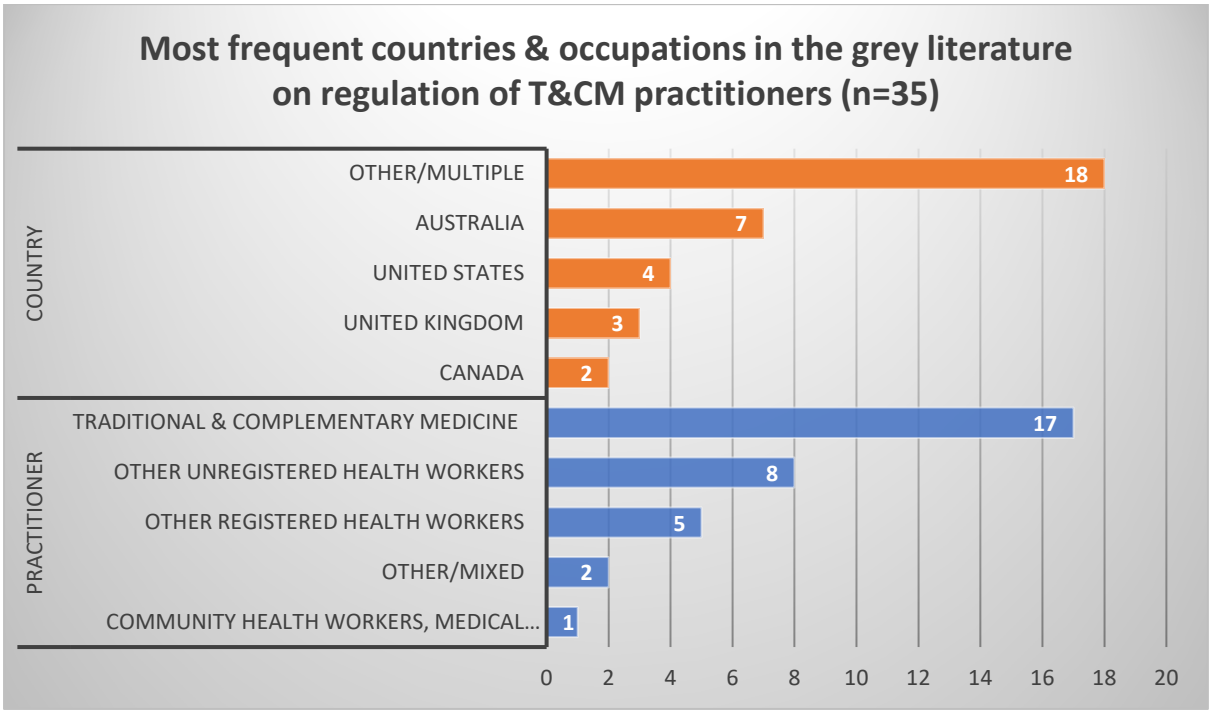


Figure 24: Most frequent countries and health occupations in the grey literature on regulation of T&CM practitioners

Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 8). The main sources were:

- *WHO and related entities* – reports and policy papers issued by WHO regional offices, as well as country review reports commissioned by WHO Regional Offices and other development agencies (***11 documents***)
- *Governments* – reports of regulatory assessments on whether to regulate a T&CM occupation, from Australia, Canada, New Zealand and the UK (***12 documents***)
- *International and national professional associations* – research reports and position statements on regulatory arrangements for T&CM professions (***four documents***)

Comparative analysis of selected regulatory schemes

Data extracted from the mapping of registration laws and websites of regulatory authorities in a sample of 15 jurisdictions from the Western Pacific Region is set out in Annex 13. Comparative data are presented on key elements of the regulatory arrangements for T&CM professions including:

- the range of quality assurance mechanisms such as national policy, accreditation of entry-to-practice education programs, national examinations, assessment of internationally qualified practitioners
- if registration or licensing applies, then:
    - legislative instrument
    - type of regulator
    - occupations regulated

The data presented illustrate the variation across jurisdictions in the types of occupational regulation applied and the extent to which registration laws have been enacted and registration schemes established for T&CM professions. Eleven jurisdictions have registration for one or more T&CM professions.

The data illustrate the range of legislative mechanisms used to establish and empower the regulator – a multi-profession umbrella law (Australia, New Zealand) and profession-specific legislation. The data also illustrate the variety of governance models for delivery of registration functions. These include:

- a statutory body that operates several voluntary registers (the Philippines)
- an administrative unit within a government department (Fiji, Japan, Vietnam)
- a 'distributed model' where regulatory functions are spread across several government departments (China, Mongolia) and sometimes including a non-government professional association (Republic of Korea)
- a statutory board with administrative functions delivered by a unit or office within the health ministry (Hong Kong SAR, Singapore, Malaysia)
- an independent statutory authority with its own staff and office, either multi-profession (Australia) or profession-specific (New Zealand)

Thematic analysis

Three themes were identified from the integrated synthesis of the published and grey literature on this topic and comparative analysis of data from HPR laws in selected jurisdictions:

1. Statutory registration is being extended to more T&CM professions in more jurisdictions, in response to evidence of risk.
2. Statutory registration is a favored strategy of many T&CM professional bodies to prevent entry of untrained practitioners, foster collaborative practice and promote integration into the mainstream healthcare system.
3. Studies suggest statutory registration works equally well for established and widely practiced T&CM professions, with some adjustments.

These themes are expanded upon below.

First, statutory registration is being extended to more T&CM professions in more jurisdictions, in response to evidence of risk.

There is evidence that pluralist health systems increase equity of access to healthcare in both urban and rural systems by harnessing all locally available human resources to improve health, and that greater regulation improves the effectiveness of practice.[130,216,236]

There is considerable diversity in occupational regulation of T&CM practitioners, both across and within jurisdictions (Annex 13).[113,557] The evidence suggests that statutory registration is the most common type of HPR applied to established and widely practiced T&CM professions and that schemes have been enacted at an accelerating rate over the past two decades.[111,113,557]

We found **six articles** (n=26) from the published literature and **six sources** from the grey literature that mapped at the regional or global level the occupational regulation arrangements that apply to the T&CM professions. These studies suggest that while statutory registration has been established in over a third of countries for one or more T&CM professions, there is considerable variability in the architecture and scope.[113,551,557] Some countries reported three or four types of occupational regulation, others none.[113,557] A WNF study found that countries are enacting licensing laws for the naturopathy profession at an accelerating rate,[557] with at least eight countries and eight sub-national governments legislating registration schemes since 2010.[557] Dunn & colleagues [174] found that standards of education were highest and consistency more apparent in those countries with statutory registration.

Multiple reports and guidance documents were aimed at encouraging jurisdictions to strengthen regulation of T&CM practitioners.[113,115,543,544,546,547,549] The WHO Global TM Strategy, *WHO Traditional Medicine Strategy 2014-2023*, identified a range of challenges

facing member states in regulating the T&CM workforce.[544(p40)] Several studies reported on country specific developments in regulation of T&CM practitioners, in Australia, Canada, Malaysia, Portugal and South Africa.[27,29,257,305,309,398,532]

In many countries, T&CM practitioners are primary care providers with a broad scope of practice and where many consumers use their services often in conjunction with conventional biomedicine.[557] Studies suggest that, at least for some established T&CM professions, particularly those working in primary care settings with a broad scope of practice that encompasses the use of ingestive therapies and/or skin penetration, the risk profile warrants the level of public protection that statutory registration affords.[134,189,223,423,443]

The grey literature review found that some jurisdictions have applied evidence-informed policy making and regulatory impact assessment processes to determine whether to regulate a T&CM profession.[281,291,313,334] In various government reports over several decades and across jurisdictions, the decision not to introduce statutory registration for a T&CM profession cited factors other than risk or cost/benefit, for instance, that the introduction of regulation would provide undue credence to these practices or that certain threshold requirements must be met before regulation can be justified, such as a credible evidence base, a voluntary national register or nationally agreed standards of education.[29(p5),119(pp188-189, 196-197),120,530]

Second, statutory registration is a favored strategy of many T&CM professional bodies, to prevent entry of untrained practitioners, foster collaborative practice and promote integration into the mainstream healthcare system.

While the literature points to continuing interest in and use of T&CM by consumers in both LMIEs [171,214,265,266] and HIEs,[29,80,155,314,450,476] studies suggest that government policy in many countries is lagging. T&CM practitioners from established professions continue to struggle for institutional recognition of their practice and to engage collaboratively with other primary care practitioners.[29,174,395] Researchers point to the benefits of statutory registration for established T&CM professions, to prevent the untrained and unqualified from entering practice.[532(pI)] Much of this literature highlighted the underlying power relations and epistemic tensions between professional groups that adversely impact the position and role of T&CM practitioners in the health system. In some jurisdictions, registration laws are being used to restrict T&CM practitioner scopes of practice and access to their tools of trade (herbal medicines).[44,81,94,124,155,471] In others, legislators have enacted provisions to protect registered

practitioners from disciplinary action where they practice a therapy that departs from prevailing medical practice.[w]

We found multiple studies in both HIEs and LMIEs that addressed the dynamics of marginalization and exclusion and the structural and other barriers to recognition and integration of T&CM practices and practitioners.[119,130,174,183,187,188,216,228,255,395,399,479,505]

In a study of complementary and alternative medicine (CAM) regulation in 39 European countries, Wiesener & colleagues [551] concluded that the variation in regulation of CAM may represent a substantial lack of common risk understandings between health policymakers in Europe and that the discrepancies in regulation are to a considerable degree also based on factors unrelated to patient risk. They propose that to address patient safety, policy makers should apply the WHO patient safety definitions and EU's policy to facilitate access to "safe and high-quality health care", and regulate CAM accordingly.[551(p1)]

Palatchie & colleagues[395] argue that in New Zealand, a multi-cultural health model remains a myth as biomedical stakeholders deploy discourses (the need for scientific evidence, public safety, qualification standards and English language fluency) as strategies to limit the scope of TCM practice. Almeida & Gabe [27] point to the important role of the state in acting as a 'broker' to recast relationships and overcome these barriers.[27(p73)]

In LMIEs, **9 studies** (n= 26) documented the widespread use of Indigenous medicines and practitioners by large segments of the population, the importance of traditional healers in community settings, particularly in rural and remote areas, and the barriers to integration. Studies addressed efforts to better harness the traditional medicine workforce to deliver primary care and assist in meeting public health goals. Researchers pointed to occupational regulation as a key vehicle to lift the status of Indigenous practitioners and facilitate their integration into mainstream healthcare systems.[25,265,266,421]

Third, studies suggest statutory registration works equally well for established and widely practiced T&CM professions, with some adjustments.

We found **14 empirical studies** (n=23) that evaluated the effectiveness of T&CM regulatory interventions, regulators or regulatory systems, or compared regulations across jurisdictions. Three main types of study were identified:

[w] See for example, section 25.4 of British Columbia's *Health Professions Act* which states "The college must not act against a registrant or an applicant for registration solely on the basis that the person practises a therapy that departs from prevailing medical practice unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice."

- studies that applied evidence-informed policy making and regulatory impact assessment processes to determine whether to regulate a T&CM profession[66,119(pp186-202),237,304,305,364,527]
- studies of the outcomes of complaints-handling and disciplinary processes conducted by statutory regulators in Australia and New Zealand[305,471]
- studies that described some of the challenges associated with regulation of T&CM professions within a dominant Western biomedical paradigm[254–258,395,399,467,505,551]

For those T&CM professions already subject to statutory registration (for example, chiropractic, osteopathy and traditional Chinese medicine in the US, Canada and Australia), the literature suggests that this model of regulation can work just as well for the T&CM professions as for other professions.[305,471,482] The literature shows a typical range of research concerns such as the content of accreditation standards,[261,262] evidence based national examinations[13,111,464,496] and the effectiveness of complaint handling and disciplinary processes.[305,471]

Lin & Gillick examined 10 years of registration, complaint and prosecution data from Chinese medicine regulators compared to other Australian regulators. They concluded that statutory registration of Chinese medicine practitioners for reasons of public health and safety was justified and that the decision to regulate was appropriate, given the need to enforce minimum standards of qualification, competence and conduct. They argued that occupations posing significant risk of harm provided sufficient cause for registration.[305(pF)]

A series of Canadian studies by Ijaz & colleagues[254–258] notes some of the policy challenges and adjustments required when applying licensing to the T&CM professions, such as when evaluating risk and applying English language requirements. Such adjustments are considered necessary to protect traditional knowledge, prevent misappropriation and address historical inequities and the delivery of care to underserved populations.[256(p307)]

Summary

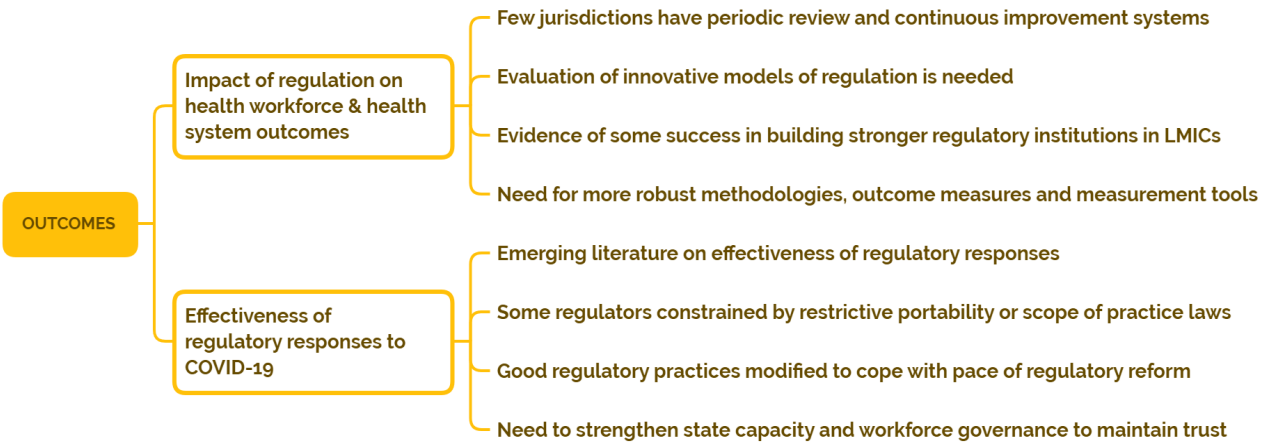
There is considerable evidence of the barriers faced by the established T&CM professions in achieving institutional recognition and collaborative practice arrangements with conventional biomedical practitioners within primary care health systems.

The evidence suggests that statutory registration schemes are being enacted for the established and widely practiced T&CM professions at a greater rate than in previous decades and that this type of regulation is justified based on risk profiles, particularly for those T&CM professions with a scope of practice that includes use of ingestive medicines.

There is evidence showing that statutory registration is an effective tool for strengthening public protection for consumers who use T&CM services, preserving Indigenous medical knowledge and strengthening health service delivery to underserved populations, in both LMIEs and HIEs.

There is some evidence to suggest that the design of occupational regulation for the established T&CM professions presents challenges and must be carefully managed to ensure traditional knowledge is preserved and institutions strengthened.

PART C: OUTCOMES



12. IMPACTS OF REGULATION ON HEALTH WORKFORCE AND HEALTH SYSTEM OUTCOMES

Overview

This chapter presents the findings from the published and grey literature on the effectiveness of HPR. Our focus here is on empirical studies that examine how well HPR works and to what extent it produces the results that are intended or sought by governments. In this context, we are interested in the operation of HPR at the micro, meso and macro levels, that is, the impacts of a specific regulatory intervention or function (micro), an occupational registration law or regulator (meso), or the performance of an entire HPR system (macro), for both the regulated and unregulated health workforces.

This chapter addresses the meso and macro levels. Of particular interest is literature on:

- the evaluation models, approaches, principles and criteria that have been applied in practice
- the outcomes of HPR that have been measured and how
- the performance of HPR regimes overall

Scope of the literature on this topic

Published literature

The review of the published literature found **310 empirical studies** which addressed one or more research questions related to the effectiveness of HPR (Figure 25). For details of the publications on this topic, see Annex 4 (Table 10).

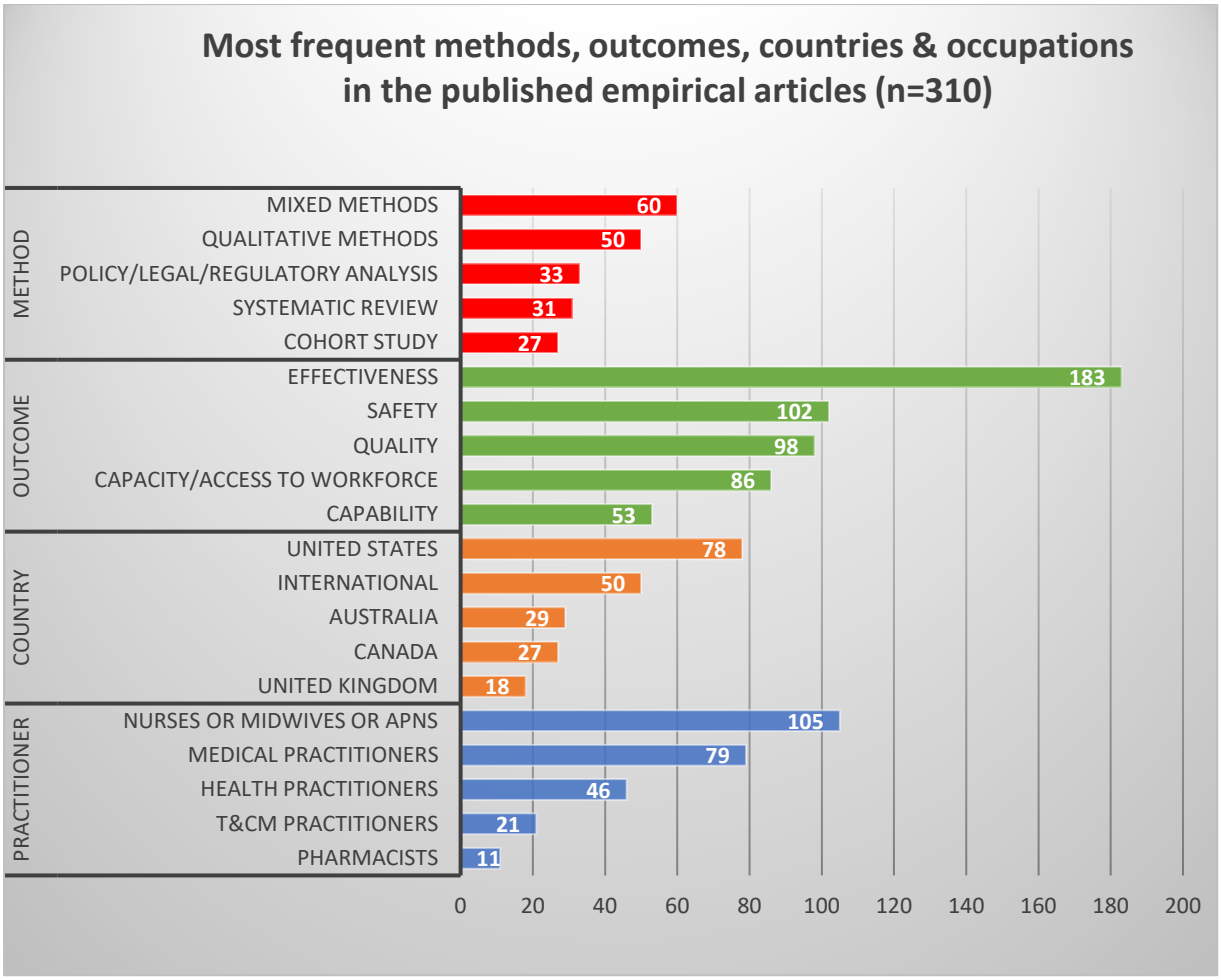


Figure 25: Most frequent methods, outcomes, countries and health occupations in the published literature on the impacts of regulation on health workforce and health system outcomes

Studies were primarily on nurses, midwives and APN roles (n=105), and medical practitioners (n=79), followed by health practitioners in general (n=46). Similar to other topics, the US was prominent (n=78), followed by international studies (n=50), Australia (n=29) and Canada (n=27).

For the purposes of analysis, the empirical studies from the published literature were grouped as follows:

- *Regulatory interventions* – studies that reported on the performance or impacts of a specific regulatory function or intervention (***101 studies***)
- *Scope of practice regulation* – studies that reported on the impacts, outcomes or effectiveness of regulation of professional scopes of practice (***78 studies***)
- *Performance of regulators/laws* – studies that reported on the effectiveness of an occupational registration law and/or the performance of a single regulator (***18 studies***)

- *Performance of regulatory systems* – studies that reported on the performance of a jurisdiction's entire health practitioner regulatory system (***36 studies***)
- *Regulatory strengthening* – studies that reported on the impacts, outcomes or effectiveness of a regulatory strengthening initiative or program (***34 studies***)
- *Multi-country studies* – studies that reported the results of comparative analysis of regulatory regimes across multiple jurisdictions (***72 studies***)

Empirical studies on the performance or impacts of a specific regulatory function or intervention are reported in Chapter 7 (registration and continuing competence), Chapter 8 (accreditation) and Chapter 10 (complaints and discipline) and studies of the impacts of scope of practice regulation are reported in Chapter 9. A breakdown of these studies by topic is in Figure 26.

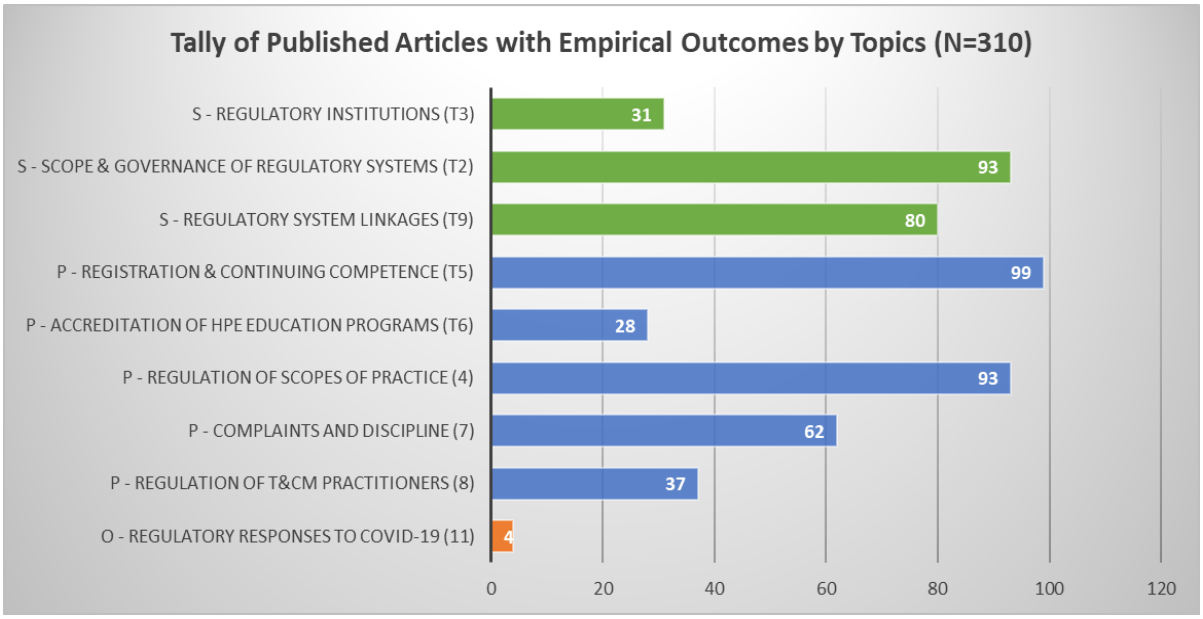


Figure 26: Tally of published articles with empirical outcomes by topic

Grey literature

The search of **102 websites** (80 English; 14 French; eight Spanish) yielded **105 documents** that contained content relevant to this topic (Figure 27).

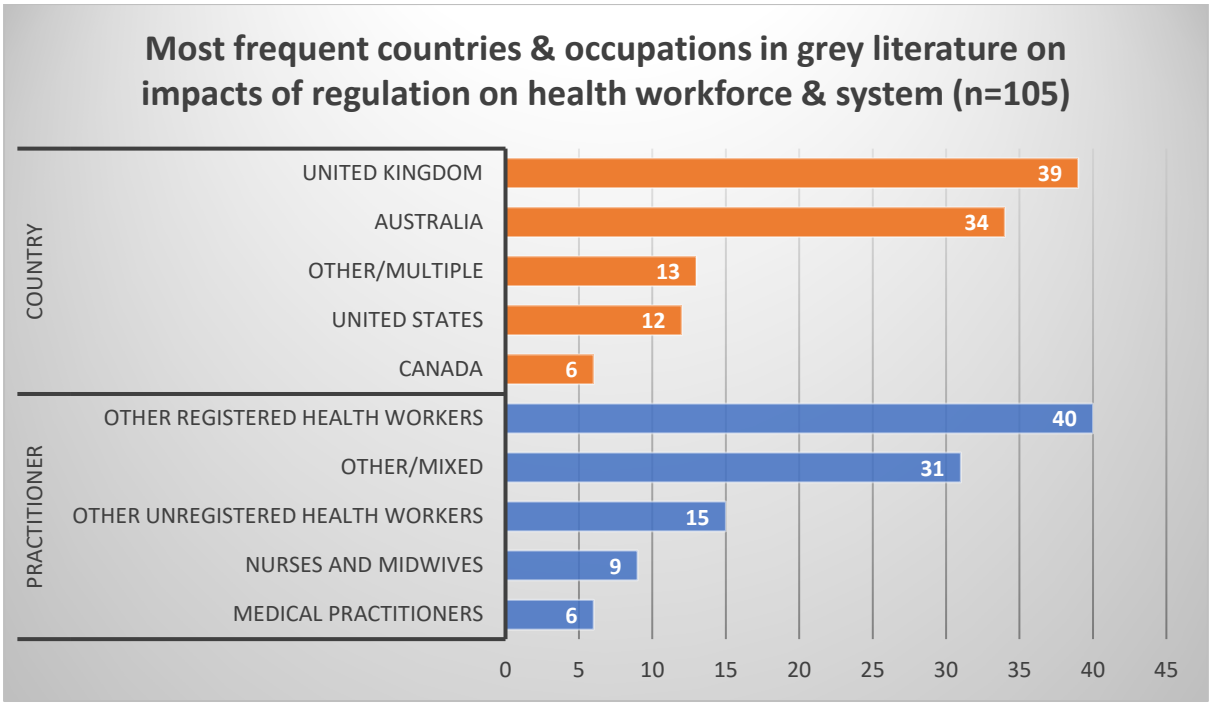


Figure 27: Most frequent countries and health occupations reported in the grey literature on impacts of regulation on health workforce and health system outcomes

Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 10). The main sources were:

- *Meta-regulators and regulators* – evaluation reports and policy papers, the largest group being publications from the UK PSA (***33 documents***) followed by the NCSBN (***seven documents***) and the FSMB (***three documents***); and
- *Governments* – reports of reviews of HPR systems, laws or regulators (***12 documents***).

Comparative analysis of selected regulatory schemes

The extent of information available to the public on the websites of HP regulators is one indicator of the stage of development of a regulatory scheme as well as the level of transparency and accountability with which it operates.

Data extracted from the mapping of websites of regulatory authorities in a sample of nine schemes are set out in Annex 14. Comparative data are presented on the type of information published on websites with respect to:

- governance arrangements of the regulator
- registration and continuing competence functions
- type and extent of information published on the register/s of practitioners
- complaint handling and disciplinary functions
- compliance monitoring and enforcement functions
- risk management and data analytics capabilities

This sample illustrates the variation in the level of information published on the operation of HPR schemes. Most websites sampled provided a range of information about the governance of the scheme, links to related legislation and regulation, and information on the members of the governing body. Few websites provide information on how the scheme is financed. Most regulators sampled publish annual reports and some also publish materials on their strategic goals or plan.

The sample illustrates the variation in the IT capabilities of regulators, with some regulators providing online applications and renewals and others not. Most regulators sampled provide an online searchable register, however the level of detail published about registrants varies as does the usefulness of the search function.

Most regulators publish very little information about how the quality of entry-to-practice education programs is assured (the assessment processes, standards, schedule of fees etc). In some cases this may be explained by differences in the division of responsibilities between the government agencies responsible for health and education. Most regulators publish a list of qualifications approved for registration purposes but few publish any details of the accreditation of these programs (schedule, conditions, adverse findings) or the performance of the accreditation functions.

Information published by regulators on their complaint handling and disciplinary functions is generally patchy with very few regulators providing user friendly guides for complainants or for registrants who are subject to a complaint. Less than half of the sampled regulators publish information on disciplinary cases and very few publish data on performance of their disciplinary functions. Few regulators provide for online lodgment of complaints.

Very few regulators publish information on their compliance monitoring and enforcement activities. Only two regulators publish information on data analytics capabilities.

Thematic synthesis

Four themes were identified from the integrated synthesis of the published and grey literature on this topic and the comparative analysis of data from HPR laws and regulator websites in selected jurisdictions:

1. Few jurisdictions have institutionalized arrangements for periodic review and continuous improvement of their HPR systems.
2. Further evaluation is needed of alternative models for regulating the health workforce, such as negative licensing and quality assured voluntary registers.
3. Regulatory strengthening activities in LMIEs aim to build stronger regulatory institutions, infrastructure, networks and governance, with some evidence of success.

4. Studies that compare regulatory regimes across multiple jurisdictions were mostly descriptive, underscoring the need for more robust outcome measures and measurement tools.

These themes are expanded upon below.

First, few jurisdictions have institutionalized arrangements for periodic review and continuous improvement of their HPR systems.

While there many are studies of the economic impacts of statutory registration in general,[86,276,457,491,492,512] this review found few empirical studies that evaluated the effectiveness of an occupational registration law or the overall performance of a regulator or regulatory system.[162,192,305,311,481,482]

A study by Dejene & colleagues[162,256] evaluated the performance of Ethiopia's national authority to regulate health professionals, following its establishment in 2010. They examined practices and gaps in registration, ethics, scope of practice and CPD. They found the regulator had limited capacity to enforce regulation due to shortages of skilled staff, budget and infrastructure.[162(p1)] **A single study** by Benton & colleagues (2020) addressed questions of the effectiveness of regulator pandemic responses.[67]

Twelve studies evaluated elements of governance or regulator performance.[61,68,73,119,162,193,305,311,482,569,571] A common theme in these studies was the accountability of the regulator, with studies examining elements such as the concept and definition of accountability;[61] accountability to deliver against the objectives of a scheme;[305] accountability to operate in the public interest;[68] and accountability to those regulated.[311]

Nineteen empirical studies (out of **310**) from the published literature addressed the effectiveness of a regulatory system. Although this was a disparate group of studies, researchers often questioned the scope of statutory registration schemes and called for governments to institute stronger regulation or extend registration to an additional occupational group. Examples included: community health workers in the US;[58] CAM providers in the Czech Republic [413] and Georgia;[355] massage therapists in Canada;[188] and unregistered health practitioners in Australia.[532,533] Freckelton [191] documented the first steps to establish a new national registration board for Indigenous health practitioners in Australia, noting it was part of a broader government strategy to address Indigenous disadvantage.

We found **five studies** (out of **310**) relating to HPR systems in LMIEs: for unlicensed medical practitioners in tribal dominated rural areas of India;[485] 'unrecognized' midwives in Nepal;[88] Indigenous medicine in Kenya;[236] ethical violations in clinical settings and Pakistani nurses;[265] and governance arrangements for health systems in low-income countries.[229] Given the diversity of topics, it is difficult to draw conclusions from these studies although again, there were calls for stronger regulation.

In a small number of Anglophone high income countries, we found extensive grey literature indicative of regulatory reform effort over several decades.[47,128,189,366,487,519] There were also reports of unscheduled, one-off regulatory reviews, often in response to a crisis or regulatory failure.[21,128,189,367]

In only three jurisdictions was evidence found of a system of periodic review of the performance of HP regulators (the UK, New Zealand and Ontario, Canada), although the mechanism for sunset review of regulations that applies in some US jurisdictions may serve a similar purpose. An active continuous improvement program was evident in the UK via the operation of its meta-regulator, the PSA, and more recently in Ontario. A requirement for independent performance reviews of regulatory authorities has been legislated in New Zealand.[366,390,451] [x] Bodies such as the NCSBN and the FSMB also featured in the grey literature on regulatory system improvement, as did a range of inter-governmental bodies such as the OECD, the Asia-Pacific and European Observatories, the Asian Productivity Organization and the WHO.[56,123,147,173,178,306,380,382–384,468,548,549,559]

Second, further evaluation is needed of alternative models for regulating the health workforce, such as negative licensing and quality assured voluntary registers.

We found **11 studies** in the published literature that addressed the effectiveness of alternatives to statutory registration, such as certification, negative licensing (**8 studies**) and co-regulation.

In several of these studies, researchers were critical of non-statutory certification schemes and negative licensing, instead advocating for the level of public protection afforded by statutory registration. Researchers examined various issues such as:

- the effectiveness of a voluntary register for nutritionists, accredited under the PSA's Accredited Registers program[109]
- lack of monitoring and regulation of CAM providers and practices compared with other healthcare providers[413]
- the adequacy of the protections afforded by a negative licensing scheme: for women's birthing choices;[335] for unregistered personal care workers in residential and community care services;[320] for persons who use acupuncture and wet cupping (hijama);[324] and unregulated health practitioners in general[532,533]
- the inability to prevent sanctioned unregulated practitioners from continuing to work and the lack of public information of fitness to practice issues[324]

We found several government-commissioned studies which examined the costs and benefits of different approaches to regulation of an occupation or class of health worker.[18,138,304,446] The UK PSA evaluated the risk of harm arising from the practice of sonography, applying its

[x] Section 122A (Performance Reviews) of the New Zealand Competence Assurance Act (2003).

'right-touch assurance' methodology to assess the evidence and provide advice on the most appropriate form of assurance for the role.[420,428,442,446,453] Two Australian regulatory impact assessments examined the regulatory requirements for all unregulated healthcare workers not subject to the national registration scheme [138] and assessed the profession of paramedics for inclusion in national scheme.[18] These RIAs compared the effectiveness (costs and benefits) of various options for achieving the government objectives (public protection) including professional association certification programs, negative licensing, co-regulation (such as the UK PSA's Accredited Registers program) and statutory registration.

The UK PSA has also conducted several evaluations of its own accredited registers program and of prohibition order schemes (negative licensing). There is interest from other jurisdictions in these models, with Hong Kong Department of Health establishing an Accredited Registers Scheme. There is scope for further independent research of the effectiveness of these alternatives to statutory registration for some health occupations.[209,210]

Third, regulatory strengthening activities in LMIEs aim to build stronger regulatory institutions, infrastructure, networks and governance, with some evidence of success.

We found **19 studies** (out of **310**) from the published literature that addressed strengthening HPR systems or regulatory functions. Of these, **16 studies** were from LMIEs, mostly from sub-Saharan African (such as Uganda, Nigeria, Kenya, Eswatini, Malawi), South-East Asian countries (Cambodia and Vietnam) and India.

The largest group (**six studies**) evaluated the impacts of the *African Health Profession Regulatory Collaborative for Nurses and Midwives* (ARC). As part of a multi-year US Government initiative to strengthen nursing and midwifery regulation in sub-Saharan Africa,[328] ARC developed and applied a 'capability maturity model' (the *Regulatory Function Framework*) to evaluate progress in key regulatory functions. The model was used to assess yearly progress, track overall impact of the project and identify national and regional priorities for regulatory strengthening.[175,213,267,332] Researchers concluded the model captured meaningful advancements in regulatory strengthening, with 14 out of 17 participating countries progressing at least one stage on the capability maturity model and significant increases in all five domains of leadership and organizational capability.[213 175]

Two studies of regulatory strengthening initiatives in South-East Asian countries adapted and applied the ARC Regulatory Function Framework to strengthen nursing regulation in Cambodia and Vietnam.[200,322] Matsuoka & colleagues also applied the ICN's *Regulatory Board Governance Toolkit*.[251,251]

In a broader study of healthcare regulation in LMIEs, Sheikh & colleagues [481] examined the architecture and processes of healthcare regulation and its contribution to regulatory failure. In reviewing the literature, Sheikh & colleagues found the explanations for regulatory failure were varied. They highlighted five main causes: lack of capacity and financial resources and

inadequate organizational frameworks for regulation; corruption and lack of transparency and accountability of regulatory organizations; discrepancies between putative functions of regulatory organizations and the roles they actually perform; low political will for regulation and 'capture' of regulatory institutions by vested interests; and information asymmetries and unequal power relationships between providers and users in LMIEs.[481(p42)]

Fourth, studies that compare regulatory regimes across multiple jurisdictions were mostly descriptive, underscoring the need for more robust outcome measures and measurement tools.

We found **55 studies** (out of **304**) from the published literature which compared the operation of HPR regimes across multiple jurisdictions. **Six studies** were also found from the grey literature.[20,113,357,528,556,557]

Some of these studies looked at issues of portability of licenses and mutual recognition of entry-to-practice qualifications, and the impacts of scope of practice differences on patient access to services. For example, Ching & Mickelson [132] investigated state licensure parameters for 13 professional disciplines across all 50 US states and the District of Columbia. Their interest was to document the status of national licensure/certification requirements for professionals working in early childhood and explore the trend towards inclusive and interdisciplinary service delivery. They found historic variance in licensure requirements persists within and between disciplines involved in the delivery of services to young children with disabilities and their families.

Other studies compared the operation across jurisdictions of specific regulatory functions such as national examinations;[273] continuing professional development (CPD) schemes;[353] maintenance of certification schemes;[290] processes for dealing with misconduct;[203] mandatory reporting obligations;[298] and the application of administrative sanctions.[349]

While a diverse range of studies were found that compared HPR arrangements across multiple jurisdictions and in some cases globally, these were mostly descriptive studies. The suite of publications from Benton & colleagues (2013;2016)[68,69,74] along with publications from the NCSBN provide a variety of frameworks and methodologies for comparative studies of HPR regimes. There is scope to draw from these to strengthen the methodologies for comparing regulatory regimes and identifying and measuring outcomes.

Summary

There are few studies in the published literature that evaluate the effectiveness of occupational registration laws, the performance of regulators or the effectiveness of entire occupational regulation systems.

The evidence shows the context specific nature of HPR regimes, although comparative studies can provide insights to inform the design or reform of HPR. While a range of templates and tools have been developed to facilitate comparative analysis, methodologies are under-developed and studies are of variable quality.

Greater research focus on a broader systems approach to understanding regulatory failure in LMIEs (see for example, Sheikh et al., 2015),[481] may yield useful lessons for regulatory strengthening efforts.

There is evidence to suggest that the Regulatory Function Framework developed by McCarthy & colleagues as part of the ARC development project and applied in 17 sub-Saharan African countries between 2012 and 2018 is a useful framework to assist LMIEs with the design and implementation of HPR regulatory strengthening projects and to evaluate the outcomes of system strengthening initiatives.

There is evidence that comparative analysis of HPR systems across multiple jurisdictions is a useful tool to assist policy-makers and regulators to identify and analyze the similarities and differences, strengths and weaknesses of regulatory regimes, to inform regulatory policy development and better develop and implement regulatory strengthening initiatives. However, studies were largely descriptive – no studies were identified that compared the performance of multiple regulatory regimes across jurisdictions, against parameters such as proportionality, accountability, transparency, efficiency, consistency etc.

While there are few studies that examine the effectiveness of alternatives to statutory registration, studies from the grey literature suggest regulatory models such as negative licensing (in Australia and the USA) and accredited registers (in the UK and Hong Kong) have a role to play as part of a broader health workforce regulatory regime, to improve the quality of health services and better protect consumers.

13. EFFECTIVENESS OF REGULATORY RESPONSES TO COVID-19

Overview

The focus of this chapter is on how HP regulators have responded to the COVID-19 pandemic. Of particular interest is literature on:

- the challenges and demands faced by HP regulators in regulating and supporting the health workforce and the actions taken
- the effectiveness of different regulatory systems and regulators in responding to the demands of regulating the workforce during the pandemic

Scope of the literature on this topic

Published literature

Of the **410 articles** included in the review, **12 articles** were found that referred to HPR responses to COVID-19 of which **four** were **empirical studies.** Most articles related to medical practitioners (n=6) and nurses, midwives or APNs (n=3). The US was the focus of seven articles and an international focus in four. For details of the publications on this topic, see Annex 4 (Table 11).

Grey literature

The search of **102 websites** (80 English; 14 French; 8 Spanish) yielded **58 documents** related to HP regulator COVID-19 pandemic responses. Annex 2 provides a list of websites searched. For details of the publications on this topic, see Annex 5 (Table 11). The main sources were:

- *Meta-regulators* – reports and papers focused primarily on the regulator responses and lessons learnt, including the NCSBN's Environmental Scan for 2021 that looked at the implications of COVID-19 for US nursing regulators, 13 reports from UK PSA reviewing the performance of regulators and a discussion paper with case studies from 10 UK health professional regulators on lessons learnt from responses to the initial crisis (***22 documents***)
- *OECD* – reports and policy papers on how countries have adapted regulatory policy making to respond to the demands of making new regulations during the pandemic, the role of international regulatory cooperation and the various strategies adopted by regulators to support a surge health workforce (***8 documents***)
- *WHO and related entities* – European Observatory reports and papers focussed primarily on health system governance and promoting resilience, as well as documenting regulator responses and provision of a webpage (the COVID-19 Health System Response Monitor) that collected and organised information on changes to regulations and how countries' health systems are responding to the crisis (***7 documents***)
- *Regulators* – websites of regulators published a range of information for registrants on COVID-19, including arrangements for temporary registration, information for

registrants on waivers or streamlined arrangements for meeting requirements such as CPD and results of disciplinary actions against practitioners for breaches of COVID-19 related professional standards (***7 documents***)

Thematic analysis

Four themes were identified from the integrated synthesis of the published and grey literature regarding regulator responses to COVID-19:

1. There is an emerging understanding about the effectiveness of the pandemic responses of regulators, the actions taken and the lessons learned.
2. Regulatory restrictions on practitioner scopes of practice and portability of registration have in some jurisdictions constrained the ability of regulators to respond quickly and flexibly.
3. Some jurisdictions have endeavoured to maintain good regulatory practice by making modifications to regulatory policy and regulatory assessment processes.
4. Concepts of trust, resilience and innovation feature in the literature as does the need to strengthen state capacity, including health workforce governance.

These themes are expanded upon below.

First, there is an emerging understanding about the effectiveness of the pandemic responses of regulators, the actions taken and the lessons learned.

We found one study in the published literature that compared the pandemic responses of regulators, across multiple jurisdictions.[67] In this case, regulators used a range of legislative and administrative tools to support faster mobilization of the workforce and delivery of health care. Some scope of practice changes were considered long overdue, while others carried risks that researchers concluded would require subsequent assessment of the impacts.[67]

Other articles (principally from the US and Europe) provided commentaries or descriptions of various strategies recommended or adopted by country/HP regulator but did not assess effectiveness.[92,458,463] A single LMIE study was found,[459] arguing that US reliance on foreign trained healthcare professions has contributed to the dire situation facing India where its health system is ill-equipped to face the pandemic health needs.[459(p1)]

There was extensive grey literature describing the actions taken by regulators to support a COVID-19 surge workforce.[41,103,358,359,374,377,385,386,429,430,472,473,562] Actions included fast tracked registration, recruitment from abroad, fast tracked processing of recognition of foreign qualifications, recruitment of final year medical and nursing students, rapid retraining using online learning, and incentivizing labor mobility.[386(p10)] Many of the websites screened had

webpages (COVID-19 hubs) devoted to providing COVID-19 information.[y] These often included an extensive suite of guidance documents and links to government advice and international organizations such as WHO.

Several reports from the grey literature examined questions of effectiveness. The need for greater flexibility in scopes of practice was a recurring theme. Pandemic responses were seen as breaking up sclerotic governance structures that had hampered past health workforce development and reform, noting the unprecedented speed of implementation of certain scope of practice changes that had previously been resisted.[41,103(p47)] New competencies and training programs were rapidly developed, supervision requirements were relaxed, and practice authorities were expanded.[41,103(p46)]

Further research is in the pipeline. The NCSBN's 2021 Environmental Scan announced its launch of a series of pandemic related research studies including:

- *the Prelicensure Nursing Cohort Study – following the 2022 class of nursing students through their program and into their first 6 months of practice to determine the effects of the pandemic and the effects of the abrupt changes made in clinical and didactic teaching on their education outcomes*
- *a study examining the role of virtual simulation and whether high-fidelity simulation can be substituted for more than 50% of a traditional clinical experience*[358(p15)]

Various reports highlighted the vital role of migrants during the pandemic in filling both high and low skill health workforce roles in OECD countries and the need for better recognition processes for foreign qualifications and easier access to key worker occupations.[374,375(p14)]

The PSA's report on lessons learned highlighted some of the achievements of UK's 10 health profession regulators – guiding registrants through an unprecedented time; supporting the increase in the workforce; providing COVID specific guidance; conducting online investigation committees and virtual fitness to practice hearings; enabling students to either help or continue their studies; and switching to paperless technologies and remote working to control the spread of infection.[430(p4,7)] The PSA report also identified some issues and challenges with the pandemic responses of its 10 regulators:

- ***diminished involvement of patients, service users and the public*** *– in the rapid development of guidance and positions, some have reflected that the patient and public voice was not given sufficient influence*
- ***as yet incomplete assessment of the impact of innovations*** *– necessarily, as determined by the speed of necessary changes, but with potential negative impacts such as on the trust of the public in regulation*

[y] See for example: HW, UK HCPC, GMC, Ahpra, WP, Health Professions Council of South Africa, Philippines Professional Regulation Commission, European Observatory on Health Systems and Policies

- ***blurring of boundaries*** *– has seemed an ever-present risk in the examples of regulators working with other organizations, with a resultant potential for confusion about where responsibilities lie*
- ***limitations of technology*** *– some regulatory processes being a poor fit for online working, particularly where the supporting information or documentation is complex, and where too comprehensive adoption risks excluding some people*
- ***losses from not being able to meet in person*** *– the exact nature of which is not easy to quantify, but which requires further consideration before online working becomes enshrined as a new normal*
- ***the operational impacts in some areas*** *– such as the build-up of fitness to practice cases which it has not been possible to progress – will need to be addressed*[430(p8)]

The COVID-19 information on regulator websites suggests that in some countries, efforts to communicate and to facilitate a surge workforce were directed principally at the registered professions and occupations whose members work in publicly funded health and care sectors, thereby bypassing the T&CM professions. For instance, the PSA reported a perceived lack of recognition of the Accredited Registers (unregistered health or care practitioners) in the early stages of the pandemic response,[429] and the temporary register established by Ahpra encompassed 13 out of 16 regulated health professions, thereby excluding the regulated complementary medicine professions of osteopathy, chiropractic and Chinese medicine.[22]

Second, regulatory restrictions on practitioner scopes of practice and portability of registration have in some jurisdictions constrained the ability of regulators to respond quickly and flexibly.

In the published literature, researchers were critical of regulatory responses, calling for changes to strengthen systems to better deal with future crises.[65,299,396,459,499] Changes sought included to:

- make permanent the temporary scope of practice changes for APNs and NPs[499]
- find permanent ways of enabling portability of licensure across state borders [65]
- standardize competency-based assessment of the qualifications of IEHPs to enable more streamlined portability of registration[299]
- adopt more flexible mechanisms for recognition of specializations such as intensive or emergency care, to enable rapid identification of appropriate personnel in times of urgent need[396]
- evaluate the effectiveness of alert systems that flag to other regulators those practitioners who are subject to temporary or permanent bans or restricted practice[396]

Some of the grey literature also focused on scope of practice changes but was more measured, pointing out the extraordinary pressures and challenges faced by governments and regulators and their responsiveness and innovation in dealing with the public health crisis.

Flexibility in legislation was considered key – flexible rather than directive processes enabled some regulators to put in place emergency responses without legislative change while others faced barriers to planning.[562(p1)] The WP also cited the importance of active stakeholder engagement in securing the rapid shifts that enabled greater cross border practice and international mobility, provision of guidance that facilitated telerehabilitation services, processing of extended access licenses, modified HPE accreditation processes, modified clinical placement requirements for students, postponement of national examinations and facilitated entry to practice for student cohorts.[562(pp3-8)]

Third, some jurisdictions have endeavored to maintain good regulatory practice by making modifications to regulatory policy and regulatory assessment processes.

We identified a suite of publications from the OECD addressing how countries have endeavored to maintain good regulatory practices when just about every pandemic strategy involved regulatory change and regulatory oversight staff were being redeployed to regulatory policy making roles.[383(p19),384,385] The OECD papers noted that while maintaining regulatory discipline had been challenging, various strategies were adopted by OECD and ASEAN countries to maintain good regulatory practice processes. These included:

- *exempting some regulation making from the RIA process, or streamlining/shortening the RIA processes, for example by shifting away from estimating the costs and benefits of prospective proposals to more simplified qualitative descriptions and identification of impacted stakeholders* [383(pp5-6),385(p2,9)]
- *modification of stakeholder engagement processes to rely more heavily on expert advisory committees and virtual rather than physical consultations* [385]
- *increased leveraging of digital technologies and one stop shops* [385]
- *reducing regulatory burdens through shortened procedures, relaxed administrative rules and inspection regimes and facilitated compliance* [384(pp1-4),385]
- *new forms of government coordination structure* [384(p2)]
- *greater international regulatory cooperation through networks such as the ASEAN-OECD Good Regulatory Practices Network* [377,385]

The OECD papers suggest:

- good regulatory practices (RIA, stakeholder consultations, ex post reviews of legislation, regulatory oversight bodies) improve evidence based regulatory policy making and trust in government [385(p4)]
- there is a need to 'future proof' regulation to better cope with crises, leverage digital technologies to support stakeholder engagement and preserve good regulatory practices [385]
- abridged or simplified RIA processes can still strengthen regulatory policy to ensure efficient functioning of markets and appropriate protections for citizens [385(p9)]
- with less robust design methods, careful ex post reviews of emergency regulations become more important to assess what has worked and not worked[383]

These abridged or streamlined RIA processes developed in response to severe time and resource constraints may provide a model for LMIEs to strengthen regulatory policy making. Modifications include applying a qualitative rather than quantitative assessment of impacts and shifting away from use of expert advisory groups and virtual consultations, while ensuring a broad range of voices including traditionally marginalized groups are consulted.[385(p27)]

Fourth, concepts of trust, resilience and innovation featured in the literature, as did the need to strengthen state capacity, including in health workforce governance.

The grey literature included multiple references to the role and importance of trust, solidarity state capacity and resilience.[173(p8),388,429(p7),473(p21)] Trust in public institutions requires transparency: through frequent and targeted crisis communication and by engaging stakeholders and the public in risk-related decision making, better regulation can foster integrity of and trust in public institutions.[388(pp2-4)]

Another common theme was the opportunities the pandemic presented for regulators to work closely with governments and other stakeholders to problem solve and innovate. Examples included:

- *the development of temporary pandemic registers by regulators such as the HCPC, GMC and Ahpra; task shifting and the expansion of professional scopes of practice* [41]
- *the use of digital technologies to facilitate telehealth and regulatory waivers to allow cross-border practice;*[41,358,359,562] *shift to paperless technologies and remote working;* [429(p35),430(p100)]
- *changes to accreditation standards and processes to support modifications to the HPE pipeline, for example to adapt clinical training to make better use of simulation, develop practice-academic partnerships, ensure competencies and facilitate participation of students in the surge workforce* [67,358(pp14-15),562]
- *the use of national 'regulatory sandboxes' to trial digital technologies* [385]
- *applying existing regulatory tools to new problems such as the use of negative licensing powers to address the 'infodemic' of misinformation, with one Australian regulator issuing multiple prohibition orders to prevent non-registered practitioners from spreading misinformation or disinformation on social media about COVID-19 and vaccines*[221]

Some grey literature addressed state capacity and the need for resilience in health workforces and health systems.[41,472,473] The European Observatory suggests the pandemic has highlighted the importance of underlying state capacity and the interlinkages between health and other sectors, with calls to further build state capacity.[473(pp96-97)] Governance was described as critical – the 'mortar' that binds all the other components together and creates trust in the system.[472(p21)] Key components of effective governance were identified as adequate and effective leadership, effective coordination, effective communication systems and flows and surveillance enabling timely detection of shocks and their impacts.[472(p21)]

Several studies identified health workforce governance as an important area of state capacity, specifically, the capacity of governments to undertake effective health workforce planning, development and reform. A European Observatories publication distilled strategies [473] and

general lessons for enhancing health systems resilience. *Strategy 14* involves implementation of flexible and effective approaches to using the workforce. Task shifting featured prominently in this strategy, including: delegating tasks to non-medical staff; task shifting to draw on the full scope of skills available; expanding the roles of individual health professions; and adapting or introducing teamwork.[473(pp51-52)] The report noted that:

- *adapting and innovating skill mix was facilitated by changes to national policy or legislation* [473(p52)]
- *while changing what staff do has implications for training and medical indemnity, those countries that had well developed task shifting arrangements in place found it easier to adapt and innovate* [473(p52)]
- *the adaptability was already available in some countries that had, prior to the pandemic, overcome restrictive practices to make full use of skills of the health workforce*[473(p52)]
- *changes were often supported by close working relationships with professional associations that were traditionally wary of changes that might threaten their members' status, power and incomes* [473(p52)]
- *these changes have been enabled by changes in the balance of power among professional groups within the health system, changes in technology and greater patient empowerment*[473(p93)]

Several reports pointed out that the pandemic had demonstrated an even greater need for workforce data collection, planning and mobility.[358(p8),473] Health system resilience during the pandemic is reliant on a good understanding of health workforce availability with existing skill profiles critical to informing actions to increase surge capacity. Not all countries had access to the information needed.[473(p50),542] In future emergencies, state and national workforce databases will be expected to help deploy nurses to areas of need.[358(p8)] In the US, pressure is growing for a national health workforce repository and for regulators to add workforce data collection to the registration renewal process.[358(p8)]

Summary

While few empirical studies were found that evaluated the effectiveness of regulator responses to the COVID-19 pandemic, evidence from both the published and grey literature suggests that many governments and regulators acted swiftly in response to the need for a surge workforce and made a range of legislative and administrative changes to:

- streamline entry and re-entry to practice processes, particularly for medical practitioners, nurses and other retired practitioners
- facilitate the portability of licenses and the mobility of practitioners across sub-national and national borders
- enable more flexible scopes of practice, expand advanced practice roles and enable greater task shifting
- modify operational processes considering lockdown orders to reduce regulatory burdens on registrants and support efficient processing of registration and accreditation applications, continuing competence requirements, maintenance of certification and specialist recognition

Evidence from the review of grey literature suggests:

- the importance of flexibility in legislation to enable regulators to take swift administrative action to facilitate a surge workforce during emergencies
- an acknowledgement of the role of power relations (within and between the health professions and with government) in maintaining restrictive practices and preventing or slowing needed workforce reforms
- the dynamic nature of the health system, the changing workforce capabilities, health technologies and population need require governments to get much better at workforce reform and to embed workforce reform initiatives into core work programs
- the need to avoid restrictive regulation of professional scopes of practice that creates unnecessary barriers to change, including during emergencies;
- the importance of the annual or periodic registration/license renewal process to collect and provide a national minimum data set for workforce and service planning purposes
- learnings from the pandemic on how good regulatory practices such as RIA have been modified and streamlined in response to time and resource constraints, which may be useful to LMIEs to strengthen their regulatory policy making

14. CONCLUSIONS

Summary

This review aimed to assess the evidence base around HPR design and delivery, to help governments, regulators, and other stakeholders achieve health system goals and support health workforce availability, accessibility, quality, and sustainability. This review was commissioned by the World Health Organization to assist in the preparation of new global guidance for member states on HPR. We identified key themes around HPR structures, processes, and outcomes.

Certain governance trends such as multi-profession regulators and umbrella laws were evident. While the lack of standardized typology complicated comparisons of these governance arrangements across jurisdictions and occupations, there is some evidence that the multi-profession governance model substantially increases regulatory capacity and capability, thereby providing more and better data and more effective levers for governments to drive workforce planning, development and reform.

Some jurisdictions have whole of government regulatory management systems that embed good regulatory practices and evidence-informed regulatory policy making, such as when considering changes to the scope of a statutory registration scheme to include additional occupations, or the introduction or removal of restrictions on professional scopes of practice. These tools are designed to ensure regulation is better targeted and that legislative frameworks are regularly reviewed and maintained up to date and fit for purpose. The tools of risk-based regulation are being used by some regulators to better target regulatory interventions, weighing risk to the public with the need to improve access to health services, particularly for underserved populations.

Most studies in this review focused on statutory registration schemes, and evidence suggested this model of HPR is increasingly being enacted across various jurisdictions and practitioner groups. We found some evidence suggesting that this type of occupational regulation may strengthen public protection for some currently unregulated T&CM professions, considering their scopes of practice and risk profiles. For the assistant and support workforce, lower-cost models of quality assurance (for example, co-regulation, negative licensing or professional association certification programs) may be sufficient, but further study is required on the effectiveness of these models.

HPR generally has not kept pace with the demands for greater flexibility arising from interprofessional team-based practice and a more dynamic division of labor in healthcare. This tension is most apparent in the literature on scope of practice regulation. Scope of

practice reforms, while necessary to maintain a flexible, responsive and sustainable health workforce, are among the most highly charged policy issues facing state legislators and healthcare regulators.[199,316] There are costs to the health system, the health workforce and health consumers when practitioners are underutilized and scopes of practice are too tightly regulated in a way that is unresponsive to reform. Evidence in this review supports the need for a change in the way scopes of practice are regulated in some jurisdictions. For instance, the evidence suggests HPR regulators should be regulating individual scopes of practice only around the edges, such as in response to a disciplinary process, or when supporting the upskilling of a registrant cohort to take on authorities conferred under other laws (where not all registrants have completed the necessary training). Prescribing rights are a case in point. Some health practitioner groups, particularly nursing, have struggled to secure prescribing authorities, often due to resistance from sections of the medical profession. These tensions and barriers suggest workforce reform should be core business for governments and demarcation disputes between professions should be managed in a more interventionist way, to increase the pace of reform. The imperatives brought by the COVID-19 pandemic have demonstrated how quickly scope of practice changes can be implemented. These reforms should be evaluated and systematically built upon.

There was some evidence from both LMIEs and HIEs that the health workforce functions of government are more effective when HPR is used to support strategies for workforce planning, development, supply and distribution, particularly to address areas of workforce shortages. For many governments, the capacity to carry out accurate and effective workforce planning is limited by a lack of health workforce data, a gap that could be addressed through leveraged HPR registry data. However, this generally requires strong information technology systems that streamline annual or periodic renewal of registration, as well as a clear legislative basis that authorizes regulators to collect these data and provide it in de-identified form to stakeholders such as governments, educators and researchers.

The evidence in our review suggests there are widespread barriers that adversely impact the mobility of practitioners. This is despite considerable efforts to standardize and harmonize regulatory arrangements across jurisdictions. Mutual recognition schemes are creating incentives to streamline qualification recognition and registration processes for IEHPs but implementation has been variable. The European Commission's decision in 2021 to initiate legal action against 18 member states for failing to adequately implement EU directives on mutual recognition of qualifications may accelerate harmonization and regulatory convergence.[179]

We also found evidence supporting the impact of outcome based CPD models on continuing competence to practice and patient safety. This evidence suggests CPD may be valuable in upskilling specific cadres of healthcare workers in LMIEs, if delivered as part of a broader

workforce development strategy. While revalidation mechanisms have been considered by governments and, in a few cases, implemented, the resource-intensive nature of these schemes means the uptake has so far been limited and is unlikely in LMIEs. Beyond including participation in CPD as an expectation for renewal of registration, the application of other risk-based regulation strategies that enable regulators to better target continuing competence requirements to higher-risk groups may be a more cost-effective approach.

Innovation in HPR was evident in many places. Throughout sub-Saharan Africa, South-East Asia and in Mekong countries (Cambodia, Laos, Vietnam), the introduction of statutory registration schemes is a relatively recent development, with regulatory models, governance and institutions being adapted to local circumstances. In Africa,[90,328] the Caribbean,[90,542] and the Pacific Island countries,[470] networks of regulators are working together on standard setting for education and training, continuing professional development and to support health system strengthening. These collaborative initiatives point to potential for regional partnerships of regulators, to enhance regulatory capability by sharing regulatory functions.

In many countries, statutory registration schemes have been introduced to accelerate the professionalization of Indigenous and traditional medicine workforces, to facilitate recruitment of this workforce to address public health priorities. Also, there is evidence of the role of regulators in strategies to more actively support the upskilling of workforces, to secure changes in skill mix and measured task shifting to cadres of community support worker, nursing and allied health assistant and non-physician clinician.

A few innovative models of occupational regulation were found that target the unregistered health workforce and provide a lower cost alternative to statutory registration, for the lower risk health occupations. The accredited registers program in the UK (and more recently in Hong Kong) and codes of conduct and negative licensing/prohibition order powers of regulators in Australia and the US (Minnesota State) are notable examples. In some HIC Anglophone countries where statutory registration schemes have been operating for well over a century, innovation is also evident.

Four developments are worth noting:

First, some regulators are applying the tools of risk-based regulation, using data analytics to identify hotspots of risk and design targeted and time-limited preventive or harm minimization strategies. The stronger capability of a multi-profession regulator operating under an umbrella law is evident in the quantity and quality of information about scheme operations accessible on regulator websites.

Second, greater attention is being paid to health system linkages and networks of quality assurance - how regulators work in partnership with other government and non-government standard setting and regulatory agencies and stakeholders (employers, third party payers, professional associations, consumer groups) to assure the quality of health services.

Third, many more jurisdictions are applying good regulatory practices, to facilitate evidence-informed regulatory policy making – in decisions about which health occupations to regulate, in the design of legislative schemes and in the development and application of standards that impact practice and competition within the health market; and more jurisdictions are accepting that to foster trust in government, a cycle of periodic review and reform of laws and regulators is necessary to maintain a fit for purpose regulatory framework.

Finally, in some countries the mandate of regulators now extends beyond public protection to include a broader role in health system improvement. Some regulators are now expected to use the tools of HPR to support the achievement of broader social objectives such as reducing inequality and increasing diversity, promoting cultural safety and eliminating racism from the health system. This requires greater accountability and transparency of regulation and regulators, and governance structures that support stronger partnerships between government, practitioners, healthcare consumers and civil society.

Limitations of the review

A critical limitation of comparative HPR research and synthesizing the state of HPR evidence is the lack of a standardized language. Definitional ambiguity arises from how terms such as self-regulation, registration, licensing, fitness to practice and accreditation are used differently in different countries and contexts.[284,528] This lack of standard language makes comparative analysis difficult, given the diversity of PICO (populations, interventions, contexts, outcomes) elements in studies and the wide variety of research designs. To strengthen our review, we have used a rigorous extraction and thematic analysis process, guided by the WHO's Technical Expert Group on Regulation. Still, strict adherence to certain PRISMA elements was not feasible. More consistent definitions would not only enhance global understanding of HPR but also improve the design of regulatory regimes and the mobility of practitioners, and ultimately increase public safety and access to healthcare.[74]

Publications from the US, UK, Australia and Canada predominate in the literature. This is, in part, an artefact of funding availability and the broader research landscape. As a result, the themes and findings strongly reflect matters of interest and contention in high-income Anglophone countries. In the design of the review (the framing of the research questions, topics and inclusion criteria), and in the synthesis and presentation of the findings, we have

tried to highlight available data from LMIEs and discuss the implications of our findings for these lower resource environments.

Key evidence gaps for future research

We identified areas where critical knowledge gaps remain. There is less published literature on HPR structures, processes, and outcomes in LMIEs. Evaluations should focus on identifying the highest impact HPR structures and processes and viable alternatives to statutory registration schemes, such as negative licensing, particularly for lower risk occupational groups.

There is also a lack of evidence on how HPR systems impact the safety, quality, capability, effectiveness, and sustainability of the health workforce. Different institutional and governance arrangements should be evaluated against a standardized framework to enable stronger cross-jurisdictional comparisons of HPR performance, since most comparative studies identified in this review were largely descriptive. For instance, comparative studies of the performance of regulatory regimes against criteria such as proportionality, accountability, transparency, cost-effectiveness and agility may increase our understanding of what works. Schemes that lack basic transparency (such as an online searchable register, online lodging of patient complaints, or publication of disciplinary decisions) may not be making best use of regulatory data for health system improvement. Also, despite an increasing focus on risk-based approaches to HPR, robust evaluation of the impact of these approaches on patient safety and health workforce quality are required.

Knowledge gaps remain around the relative benefits of national licensing exams and HPE accreditation in assuring the quality of the health workforce. Despite increased research around remediation programs and mandatory reporting obligations, more evidence is required on the effectiveness of these specific HPR complaints and discipline processes across jurisdictions, HPR models, and occupational groups.

The pandemic has highlighted the nexus between HPR and workforce development and the importance of agile HPR processes and effective linkages between HPR and other regulators, systems and stakeholders. Empirical studies and intergovernmental reports of the effectiveness of HPR pandemic responses have continued to be published after our review's inclusion dates.[10,376,380,458,497] Further research in this area would help evaluate HPR reforms and innovations to determine which changes should be maintained long-term and may be most beneficial for future crises. This research should also evaluate the effectiveness of system linkages and how HPR is best placed to contribute to emergency responses that require a fit for purpose surge workforce.

Conclusion

In summary, our large-scale review synthesized evidence from a broad range of academic and grey literature sources relevant to our research question on HPR regulation. We identified key themes, findings of significance and evidence gaps in the literature around HPR structures, processes, and outcomes. More evidence was found on HPR structures and processes than outcomes, although most studies were descriptive in nature. Synthesis was limited by the lack of common terminology. The lack of a strong evidence base, particularly on HPR outcomes, necessitates caution in interpretation, generalizability, and applicability of these findings and makes it difficult to take a normative stance in most areas.

The tools of HPR are increasing in use around the world, as many governments search for better ways to ensure their health workforce is fit for purpose, able to meet population health needs and responsive to emerging challenges.

Every HPR system operates within a different context – is a product of and responsive to different legal frameworks, different socio-political forces, different health workforces with different mixes of occupations and division of labor and different scopes of practice. However, internationally, some trends are evident. Examples include the increasing use of umbrella laws, multi-profession regulatory agencies, innovative regulatory models (such as negative licensing and quality assured voluntary registers), and the increasing use of the data collected by regulators to enable better workforce planning and distribution. Innovation is also evident in the use of the tools of risk-based regulation to mine the data generated by a registration system's complaint handling and disciplinary systems. We know that complaints provide important intelligence – they may be the early warning sign of a broader failure of clinical governance within a health service.

Despite this, we are a long way from knowing what works or works best in different contexts and why, and we do not yet have a common language to support the dialogue needed. We know very little about how to measure the return on investment of different quality assurance tools – accreditation of HPE programs, national examinations, mandatory CPD, mandatory reporting etc.

We do know that regulatory systems must be managed, that legislation must be reviewed and amended from time to time to ensure it remains up to date and fit for purpose, that regulator performance must be regularly reviewed with core functions benchmarked internationally. There are whole of government GRP tools available to assist in the design, implementation and review of HPR schemes.

Vigilance is needed, to ensure that HPR innovates, that it facilitates the workforce reform required to support team-based models of care and a high functioning health system. Governments can take a leadership role on these issues and avoid being mired in the historical

demarcation disputes and ongoing battles between and within professions over scopes of practice.

Standardized language and better tools for measuring regulatory outcomes would aid comparative research and inform decisions on regulatory design and implementation. We suggest assessing the impact of HPR should be prioritized in future work and that this includes a means of systematically tracking the results of studies that evaluate health workforce outcomes.

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LIST OF ACRONYMS AND ABBREVIATIONS

AHMAC	Australian Health Ministers Advisory Council
Ahpra	Australian Health Practitioner Regulation Agency
AMTC	World Accelerated Medically Trained Clinicians Network
APN	advanced practice nurse
ARC	African Health Profession Regulatory Collaborative
ASEAN	Association of South-East Asian Nations
AYUSH	ayurveda, yoga and naturopathy, unani, siddha, homeopathy
BC	British Columbia (Canada)
CAAM-HP	Caribbean Accreditation Authority for Education in Medicine and other Health Professions
CAM	complementary and alternative medicine
CE	continuing education
CETA	Comprehensive Economic and Trade Agreement
CLEAR	Council on Licensure, Enforcement and Regulation
CM	complementary medicine
CME	continuing medical education
COAG	Council of Australian Governments
CPD	continuing professional development
CPME	Council on Podiatric Medical Education
DORA	Directory of Organizations that Recognize/Accredit Medical Schools
ECSA-HC	East, Central and Southern Africa Health Community
EU	European Union
FAIMER	Foundation for the Advancement of International Medical Education and Research
FSMB	Federation of State Medical Boards (USA)
GMC	General Medical Council (UK)
GRPs	good regulatory practices
HCPC	Health & Care Professions Council (UK)
HIE	High income economy
HIV	human immunodeficiency virus
HP	health practitioner
HPE	health professions education
HPR	health practitioner regulation
HPRAC	Health Professions Regulatory Advisory Council (Ontario, Canada)
HRH	human resources for health
HWTAC	Health Workforce Technical Assistance Centre
IAMRA	International Association of Medical Regulatory Authorities
ICM	International Confederation of Midwives
ICN	International Council of Nurses
IEN	internationally educated nurse
IEHP	internationally educated health practitioner
ILO	International Labour Organization
IM	integrative medicine
IMG	international medical graduate
ISO	International Standards Organization

LMIE	Low-income and lower-middle income economies
MLE	medical licensing examination
NCSBN	National Council of State Boards of Nursing (USA)
NLE	national licensing examination
NMBA	Nursing and Midwifery Board of Australia
NP	nurse practitioner
NRAS	National Registration and Accreditation Scheme for the health professions (Australia)
NSW HCCC	New South Wales Health Care Complaints Commission (Australia)
NZ	New Zealand
OECD	Organization for Economic Cooperation and Development
PIC	Pacific Island countries
POLHN	Pacific Open Learning Health Net
PRC	Professional Regulation Commission (Republic of the Philippines)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	Professional Standards Authority for Health and Social Care (United Kingdom)
RCC	Canada-United States Regulatory Cooperation Council
RIA	regulatory impact assessment
RN	Registered Nurse
SPB	Secretariat of healthcare Professional Boards (Singapore)
T&CM	traditional and complementary medicine
TCM	traditional Chinese medicine
TM	traditional medicine
TTMRA	Trans-Tasman Mutual Recognition Arrangement
UAE	United Arab Emirates
UHC	universal health coverage
UK	United Kingdom
UME	undergraduate medical education
UMIE	Upper-middle income economy
UNESCO-COE	United Nations Educational, Scientific and Cultural Organization – Council of Europe
US	United States of America
USA	United States of America
UTS WHO CC	University of Technology Sydney World Health Organization Collaborating Centre for Nursing Midwifery and Health Development
WAHO	Western African Health Organization
WBA	workplace-based assessment
WHO	World Health Organization
WHO WPR	World Health Organization Western Pacific Region
WFME	World Federation of Medical Education
WMA	World Medical Association
WNF	World Naturopathic Federation
WONCA	World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians
WP	World Physiotherapy
WTO	World Trade Organization

GLOSSARY OF TERMS

Accreditation – in the context of the health professions accreditation is the process of formal evaluation of an educational program, institution, or system against defined standards by an external body for the purposes of quality assurance and continuous enhancement (Frank et al., 2020: 4).

Certification – A voluntary time-limited process by which a nongovernmental organization within a profession or specialty grants recognition of competence to an individual who has met pre-established eligibility requirements and standards (WHO WPR, 2019: 75).

Complementary medicine (CM) – the terms 'complementary medicine' or '***alternative medicine'*** refer to a broad set of healthcare practices that are not part of that country's own traditional or conventional medicine and are not fully integrated into the dominant health-care system. These terms are used interchangeably with traditional medicine in some countries (WHO 2013: 15).

Continuing competence – the demonstration of specified levels of knowledge, skills, and abilities throughout a heath practitioner's professional career.

Continuing professional development – The establishment of higher levels of competence in the range of knowledge, skills and abilities needed to perform duties or support interventions, be they in clinical practice, management, education, research, regulation or policy-making (WHO WPR, 2019: 76).

Credentialing – processes used to designate that an individual, program, institution or product have met established standards set by an agent (governmental or nongovernmental) recognized as qualified to carry out this task. The standards may be minimal and mandatory or above the minimum and voluntary. Licensure, registration, accreditation, approval, certification, recognition or endorsement may be used to describe different credentialing processes (WHO WPR, 2019: 76).

Governance – the processes which define expectations, grant power and verify performance (World Bank, 1991).

Health worker – used here to describe a person who delivers preventive, curative, health promotion or rehabilitative healthcare services either directly, such as doctors and nurses, or indirectly such as aides, laboratory technicians, patient transport officers or clinical waste handlers. They work in a range of settings hospitals, healthcare centers and other service delivery settings as well as in academic training, research, and administration. They may or may not be subject to a statutory registration regime.

Health workforce – The human resources for health includes physicians, nurses and midwives, but also laboratory technicians, public health professionals, community health workers, pharmacists and all other support workers whose main function relates to delivering preventive, promotive or curative health services (WHO WPR, 2019: 77).

Jurisdiction – a country, state or other area where a particular set of laws or rules apply.

Occupational regulation – used here to describe the subset of a jurisdiction's laws, regulations and bylaws that are directed at regulation of an occupation or occupations, or a class of persons within an occupation. It includes occupational registration laws and other non-statutory forms of regulation, such as bylaws and rules of association promulgated by non-statutory standard setting bodies such as member based professional associations. The term may be used interchangeably with '***health workforce regulation'***.

Profession – used here to describe a class of practitioner that is subject to regulation under a country's occupational registration laws. Where there are multiple sub-groups regulated in a sector – for example in dentistry or pharmacy, where there are dental nurses and pharmacy assistants as well as dentists and pharmacists – then these sub-groups are referred to as ***'occupational groups'*** within a profession.

Regulator – used here to describe the entity that exercises the statutory functions to register and regulate health practitioners in a country. The regulator may be a government department, a committee or board established by government, or a statutory authority established as a separate legal entity and operating at arm's length from government. Regulators are known in various countries as boards, councils, colleges, orders and chambers (ICN, 2014: 6).

Regulatory governance – Refers to the different ways that regulatory organizations or institutions manage their affairs. Governance is the act of governing and thus involves the application of laws and regulations, but also of customs, ethical standards and norms. Good governance means that affairs are managed well, not that the laws, regulations or norms are themselves necessarily "good" (WHO WPR, 2019: 80).

Regulatory strengthening – Strategies and efforts to support national regulatory authorities to fulfil their mandate in an effective, efficient, predictable and transparent manner, which is of critical importance in ensuring the quality, safety and efficacy of health products in an increasingly complex global environment. (WHO WPR, 2019: 81)

Scope of practice – the full spectrum of roles, functions, responsibilities, activities and decision-making capacity that individuals within that profession are educated, competent and authorized to perform (NMBA, 2013: 1).

Statutory registration – used interchangeably with '***occupational licensing***' to describe a legislative scheme where the qualifications, character and other credentials of a person are assessed, their name is placed on a public register (usually web-based) and they are legally authorized to practice in a regulated occupation or profession and/or use a reserved occupational title. Under some statutory registration laws, a process of both registration (the first entry of the person's name on the public register) and licensing (issuing of an annual practicing certificate) is required. Statutory registration is distinguished from other types of licensing scheme in the health sector in that the registrant is an individual practitioner rather than a business, facility, medicine or therapeutic good and the grant of registration affords the person certain entitlements (use of title, reserved practices) which unregistered persons do not have.

Traditional medicine (TM) – traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (WHO, 2013: 15).

Traditional and complementary medicine (T&CM) – T&CM merges the terms TM and CM, encompassing products, practices and practitioners (WHO, 2013: 15).

ANNEXES

Annex 1: Key topics informing the literature search, inclusion criteria and evidence synthesis

Annex 2: Websites searched for grey literature by type of organization and search results, and list of hand-searched reference sources

Annex 3: Chinese literature search methodology, results and key themes

Annex 4: Modified PICO tables of published literature sources by topic

Annex 5: Modified PICO tables of grey literature sources by topic

Annex 6: Scope of statutory registration schemes in selected jurisdictions – legislation and occupational groups regulated

Annex 7: Regulatory assessment processes in selected jurisdictions for extending statutory registration to additional health occupations

Annex 8: Governance of regulators in selected jurisdictions

Annex 9: Registration and continuing competence functions of regulators in selected jurisdictions

Annex 10: Qualification accreditation and examination functions of regulators in selected jurisdictions

Annex 11: Mechanisms for regulating use of titles and scope of practice in selected jurisdictions

Annex 12: Complaint handling and disciplinary functions of regulators in selected jurisdictions

Annex 13: Regulatory arrangements for T&CM occupations in selected jurisdictions

Annex 14: Information publicly available on the websites of regulators in selected jurisdictions