Health Practitioner Regulation Systems Key Points

EXECUTIVE SUMMARY

- 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. (pg7)
- HPR can optimise the capability of the existing health workforce and assist in better aligning health workforce investments with health system needs. (pg7)

PROCESSES

- First, restrictive and unresponsive scope of practice regulation inhibits workforce reform and adversely impacts healthcare access and quality (pg11)
- 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. (pg12)
- HPR generally has not kept pace with the demands for greater flexibility arising from collaborative team-based practice and a more dynamic division of labour in healthcare. Evidence in this review supports the need for a change in the way scopes of practice are regulated in some jurisdictions. (pg13)
- Evidence supports the impact outcomes based CPD models on continuing competence to practice and patient safety. (pg13)
- 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 standardised framework to enable stronger cross-jurisdiction comparisons of HPR performance, since most comparative studies in this review were largely descriptive. (pg14)

INTRODUCTION

- 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. (PG 17)
- 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. (PG17)

TERMINOLOGY AND TYPOLOGIES

- A good RMS serves to assess policies, analyse 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. (PG33)

- *Textbox 1: Examples of principles-based approaches to assessing what is 'good' regulation (PG33)*

Baldwin & colleagues53(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.

- 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. (PG40)

SCOPE AND GOVERNANCE OF REGULATORY SYSTEMS

- 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. (PG51)
- 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. (PG51)
- the policy-making process is often highly politicised, with vested interests lobbying government for outcomes favourable to their constituencies (PG51)
- many jurisdictions do not apply evidence-informed regulatory policy making principles to these contested decisions (PG51)
- 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. (PG52)

REGULATORY INSTITUTES

- How a regulator is directed, controlled, resourced and held to account is crucial to the overall effectiveness of regulation. (PG63)
- 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. (PG63)
- 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. (PG63)

- International professional associations promote ‘profession-led’ regulation as the preferred governance model. (PG63)
- 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. (PG64)
- with highly specialized knowledge 260(p176) and the spread of human rights values has called into question all forms of elite governance. (PG64)
- 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.). (PG64)
- 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 (PG65)

REGULATORY SYSTEM LINKAGES

- 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. (PG77)
- 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. (PG77)

Focus of part B

7. REGISTRATION OF PRACTITIONERS AND MONITORING OF CONTINUING COMPETENCE

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. (PG84)

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. (PG86)

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. (PG86)

Continuing professional development

Wenghofer & colleagues, 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. (PG89 – 90).

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 (PG90).

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. (PG92)

8. ACCREDITATION OF HEALTH PRACTITIONER EDUCATION PROGRAMS

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. (PG96)

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. (PG102)

9. REGULATION OF PRACTITIONER SCOPES OF PRACTICE

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'. Some functions within the scope of practice of an occupation may be shared with other occupational groups. (PG106)

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

Optimizing the scope of practice of health practitioners can facilitate multidisciplinary and complementary teams. 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. (PG106)

The study sought literature on how the scopes of practice of both the registered and unregistered health workforce is 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. (PG106)

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. with some legislative schemes containing a specific list of reserved professional titles as well as prohibiting other representations that might mislead the public. (PG109)

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). (PG109)

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.** *(PG110)*

- 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.
- 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.
- A prescriptive approach is often favoured 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. *(PG110)*

Leslie & colleagues
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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. *(PG111)*

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.

Scope of practice changes are among the most highly charged policy issues facing state legislators and HP regulators 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. 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. *(PG112)*

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. 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. *(PG112)*

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 some with broad scopes of practice such as some T&CM practitioners. Also, research suggests the most effective and efficient teams demonstrate a substantial amount of scope overlap and shared responsibilities and that healthcare teams with greater cohesiveness and collaboration are associated with higher levels of patient satisfaction and better clinical outcomes *(PG113)*

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. Several regulators have developed decision-making frameworks to assist this local decision-making process. 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. *(PG113)*

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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. *(PG113)*

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. Several documents propose criteria and/or processes for regulatory policy making to ensure evidence-informed changes to scopes of practice. *(PG113)*

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.

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. *(PG114)*

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. *(PG114)*

4. 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 analysed and compared The effectiveness of government and regulator responses to the pandemic. 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. (PG216).

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.

Summary *(PG119)*

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.

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 *(PG121)*

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 wilful 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.

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.

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.

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.

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 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 were warranted. *(PG128)*

'dyscompetence' (defined as poor professional performance in a limited number of crucial or expected skills).

Summary
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.

11. REGULATION OF TRADITIONAL AND COMPLEMENTARY MEDICINE PRACTITIONERS

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. *(PG134).*

Palatchie & colleagues 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 point to the important role of the state in acting as a 'broker' to recast relationships and overcome these barriers *(PG134).*

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.

Part C

Outcomes

- Impact of regulation on health workforce and health system outcomes
- Effectiveness of regulatory responses to covid-19

Few studies that evaluate the effectiveness of occupational registration laws, the performance of regulators or the effectiveness of entire occupational regulation systems

Extent of information available to the public on websites of HP regulators – one indicator of the stage of development or a scheme and level of transparency/accountability

Most websites sampled provided a range of information about the governance of the scheme, links to legislation and information on members of the governing body.

Most regulators publish a list of qualifications approved for registration purposes but few details about the accreditation of the programmes or the performance of the accreditation functions

Themes – thematic synthesis

Theme 1: Few jurisdictions have institutionalised arrangements for periodic review and continuous improvement of their HPR systems

- Few studies have evaluated the effectiveness of occupational registration law or overall performance of a regulator/regulatory system
- Common theme in studies was accountability of regulator, concept/definition of accountability, to deliver against objectives of a scheme, operate in public interest and accountability to those regulated
- 19/310 studies had researchers questioning the cope of statutory regulation schemes and called for governments to institute stronger regulation or extend registration to an additional occupational group.
- Grey literature – anglophone high income countries – some reports of unscheduled one-off regulatory reviews often in response to crisis or regulatory failure
- NZ, UK, Canada – only jurisdictions where evidence was found of periodic review of the performance of HP regulators

Theme 2: further evaluation is needed of alternative models for regulating the health workforce such as negative licencing and quality assured voluntary registers.

- Researchers critical of non-statutory certification schemes and advocated for the level of public protection afforded by statutory registration
- There is scope for further independent research of the effectiveness of alternatives to statutory regulation for some health occupations

Theme 3: Regulatory strengthening activities in LMIEs aim to build stronger regulatory institutions, infrastructure, network and governance with some evidence of success

- Sheikh & Colleagues et. Al., 2015 highlighted the following as main causes for regulatory failure
    - lack of capacity and financial resources and inadequate organisational frameworks for regulation
    - corruption and lack of transparency and accountability of regulatory organisations,
    - disparities between putative functions of regulatory organisations and the role they actually perform
    - low political will for regulation and capture of regulatory institutions by vested interests
    - information asymmetries and unequal power relationships between providers and users in LMIEs

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

- Some studies examined the impacts of scope of practice differences on patient access to services but was not explored further. Majority of studies were descriptive in nature

- No studies identified that compared the performance of multiple regulatory regimes across jurisdictions against parameters such as proportionality, accountability, transparency, efficiency and consistency etc

Chapter 13 effectiveness of regulatory responses to covid-19

Few empirical studies have evaluated the effectiveness of regulatory responses to covid-19 pandemic. Governments were found to act swiftly an made processes more streamlined, increased portability of licences, enabled more flexible scopes of pracrice and reduced regulatory burdens.

Four themes identified

Theme 1: There is an emerging understanding about the effectiveness of the pandemic responses to regulators, the actions taken and lessons learned

- Some scopes of practice changes were considered long overdue, while others carried risks that researchers concluded would require subsequent assessment of the impacts
- Several reports from grey literature – "the need for greater flexibility in scopes of practice was a recurring theme. Pandemic responses were seen as breaking up sclerotic government structures that had hampered past health workforce development and reform, nothing the unprescidented speed of implementation of certain scope of practice changes that had previously been resisted. New competnecies and training programmes were rapidly developed, supervision requreiemtsn were relaxed, and practice authorities were expanded.
- Various reports highlighted the vital role of migrants during the pandemic and the need for better recognition processes for foreign qualifications and easier access to key worker occupations

Theme 2: regulatory resitctions on practitioner scopes of practice and portability of registration have in some jurisdictions constrained the ability of regulators to respond quickly and flexibily.

- Researchers critical of regulatory responses and called for changes to strengthen systems to better deal with future crises.
- Rx to standardise competency based assessment of the qualifications of intenationall educated health providers to streamline portability of registration.
- Adopt more flexible mechanisms for recognition of specialisations
- Evaluate the effectiveness of alert systems that flag to other regulators those practitioners who are subject to temporary or permanent bans or restricted practice.
- Grey literature focused on scopes of practice changes more about the pressures and challenges faced by governments and regulators and their responsiveness in dealing with public health crises.
- Flexibility in legistration was considered key – flexible rather than directive and stakeholder engagement very important to manage shifts and practice

Theme 3: some jurisidctions have endeavoured to maintain good regulatory practice by making modifications to regulatory policy and regulatory assessment processes.

- During the pandemic, review of how countries have endeavoured to maintain good regulatory practies when just about every pandemic strategy involved regulatory change and regulatory oversight.
- Relevant strategies identified; modification of stakeholder engagement to rely more heavilty on expert advisory committes as good regulatory practices improve evidence based policy making and trust in the government.

Theme 3: concepts of trust, resilience and innovation featured in the literature as did the need to strengthen state capacity, including in health workforce governance.

- Grey literature included multiple references to the role and importance of trust, solidatiry, state capacity and resilience. Trust in public institutions requires transparency, through frequent and target crisis communication and by engaging stakeholds and the public in risk-related decision making, better regulation can foster integertiy of and trust in public institutions.
- Several reports pointed out that the pandemic had demonstrated an even greater need for workforce data collections, planning and mobility. 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 caaity

Grey literature – recognised the role of power relationship within and between health professionals and the government in maintaining restrictive practices and preventing or slowing down needed work reforms.

Dynamic nature of the health system, changing workforce capabilities, health technologies – requires governments to get better t work reform.

Need to avoid restrictive regulation of professionals scopes of practice that create unnecessary barriers to change

Importance of annual or periodic registration/licence renewal process to collect and provide a national mimumum data set for workforce and service planning

Chapter 14: Conclusions

- The review was commissioned by the world health organisation to assist in the preparation of new global guidance for member states on HPR.
- Most studies focused on statutory registration schemes and evidence suggested this model of HPR is increasingly enacted and some evidence suggested that this type of regulation may strengthen public protection for some currently unregulated professions.
- HPR generally has not kept pace with demands for greater flexibility arising from interprofessional team-based practice and a more dynamic division of labour in healthcare – the tension is more apparent in the literature on scopes of practice regulation. Scope of practice reforms, while necessary are among the most highly charged policy issues. There are costs to the health system, the health workforce and health consumers when practitioners are underutilised, and scopes of practice are too tightly regulated in a way that is unresponsive to reform. Evidence in the review supports the need for a change in the way scopes of practice are regulated.
- The capacity for governments to carry out accurate and effective workforce planning is limited by a lack of health workforce data, which could be addressed through better registry data.
- The evidence suggests there are widespread barriers that adversely impact the mobility of practitioners. Mutual recognition schemes are creating incentives to streamline qualifications recognition and registration.
- Evidence supports the impact of outcome based CPD models on continuing competence to practice and patient safety.
- In many countries, statutory registration schemes have been introduced to accelerate the professionalisation of indigenous and traditional medicine workforces to recruit this workforce.
- The stronger capability of a multi-professional regulator operating under an umbrella law is evident in the quality and quantity of information about scheme operations on regulator websites
- Greater attention is being paid to health system linkages and networks of quality assurance – including how regulators work in partnership with other government and non-government standard setting and regulatory agencies and stakeholders
- Many jurisdictions are applying good regulatory practices to facilitate evidence-informed regulatory policy making – a cycle of periodic review and reform of laws and regulators is necessary to maintain a fit for purpose regulatory framework
- The mandate of regulators in some countries extends beyond public protection to include broader social objectives . This requires greater accountability and transparency of regulation and regulators, government structures, practitioners, healthcare consumers and civil society.

Limitations of the review

- Lack of standardised language, ambiguity from terms such as self-regulation, registration, licencing, fitness to practice and accreditation
- Publications from the UK, UK, Australia and Canada predominate the literature

Key evidence gaps for future research

- Evaluations should focus on identifying the highest impact HPR structures and processes and viable alternatives to statutory registration schemes, such as negative licencing
- There is a lack of evidence on how HPR systems impact the safety, quality, capability, effectiveness and sustainability of the health workforce
- Despite increased research around remediation programs and mandatory reporting obligations, more evidence is needed on the effectiveness of these specific HPR complaints and discipline processes across jurisdictions, HPR models and occupational groups
- The pandemic has heightened nexus between HPR and workforce development and the importance of agile HPR processes and effective links between HPR and other regulators, systems and stakeholders

Conclusions

- Lack of strong evidence base on HPR outcomes, necessitates caution in interpretation, generalisability and applicability of these findings and makes it difficult to take a normative stance
- Complaints provide important intelligence and may be the early warning signs of a broader failure of clinical governance
- 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.
- Vigilance is needed to ensure that HPR facilitates workforce reform to have a high functioning health system – governments can take a leadership role on these issues and avoid being mired in the historical disputes and ongoing battles between and within professions over scopes of practice.
- Standardised language and better tools for measuring regulatory outcomes.