Strengthening health workforce regulation

in the Western Pacific Region

World Health Organization
Western Pacific Region

AHPRA
Australian Health Practitioner Regulation Agency

Aboriginal and Torres Strait Islander Health Practice
Chinese Medicine
Chiropractic
Dental
Medical
Medical Radiation Practice
Nursing and Midwifery
Occupational Therapy
Optometry
Osteopathy
Pharmacy
Physiotherapy
Podiatry
Psychology

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Contents

Executive Summary

Health workforce regulation aims to protect the public by ensuring that only health practitioners who are suitably trained and qualified are able to practise in that profession.

Key policy principles that should underpin health workforce regulation are:

1. **Protect the public.** Always focus regulation on the public interest and public safety, not the interests of the professions being regulated.
2. **Clear basis and rationale for regulation**. Analyse the problem and assess the risks that need to be addressed. This will help in deciding if regulation is the approach that provides the greatest overall benefit to the community.
3. **Transparency.** Ensure that legislation is well designed to support the regulatory system, premised on consistent policy and purpose with transparent processes and information for the public and practitioners.
4. **Stakeholder engagement.** Engage with key stakeholders and the community and ensure transparency to build confidence, understanding and trust in the regulatory system.
5. **Well designed legislation.** Adopt consistent approaches, with clear criteria and decision-making processes, for assessing which health professions should be regulated.
6. **Clear governance.** Build a clear governance framework that covers the powers, functions and limitations of the regulator.
7. **Accountability.** Ensure explicit and clearly articulated accountability for the various functions of the regulatory system.
8. **Link education and registration.** Align the standards for education and qualification in a profession with the standards required for registration in that profession.
9. **Public register.** Maintain an up-to-date list of those practitioners who are registered and make it available to the community at no cost.
10. **Complaints management system.** Establish clear mechanisms for dealing with concerns about the professional conduct of registered health practitioners.

Well designed regulation does not create unnecessary burdens for countries (e.g. financial and administrative), is focused on risk to public safety, is proportionate to the benefit it brings, and is sufficiently flexible to respond to different health-care needs, approaches and future changes.[1]

[1] OECD best practice principles for regulatory policy: The governance of regulators. Paris: Organisation for Economic Co-operation and Development; 2014.

Although there are differences in scope and organizational arrangements between the countries in the Region, regulation of health practitioners typically involves maintaining a register or list of those who are registered, setting and assuring educational standards for entry to practice, investigating and dealing with concerns in relation to the conduct, health or performance of registered practitioners, and, increasingly, assuring continuing competence to practise.

Common regulatory frameworks include: statutory regulation, co-regulation, voluntary regulation and negative licensing and the need to tailor a regulatory system to the local circumstances, culture and context.

The key questions are: which health professions should be regulated and what legislative and governance arrangements are required? Clear criteria and transparent decision-making processes are needed to assess which health professions should be regulated and how. In developing and implementing a regulatory system, it is necessary to consider: stakeholder engagement, basic business processes, financing mechanisms, evaluation of the regulator and how to build regulatory capacity in a country.

Considerable expertise exists within the Western Pacific Region in relation to health workforce regulation. Developing more consistent approaches to the design and implementation of regulatory frameworks, along with mechanisms for sharing information, knowledge and expertise about good regulatory practice, will assist with building capacity and strengthening regulation across the Region. This includes establishing an (informal) regional regulators' network, and using existing conferences, events and regional forums to exchange ideas.

Introduction

The objective of regulation of health practitioners' education and practice is to protect individuals and communities from harm and to improve service quality, equity and access. It can also contribute to increased economic efficiency *(1)*. This policy brief aims to assist policy-makers and regulators in building and strengthening effective, appropriate and efficient systems for health workforce regulation in countries across the Western Pacific Region.

Health systems in the Region face a multitude of complex issues and challenges in moving towards universal health coverage, many of which impact the health workforce in a country and how it is managed. In many countries there are shortages and imbalances in the health workforce and concerns about the safety of health practitioners' practice, creating the need to review and strengthen health workforce regulation.

Functioning health systems are the key to effective service delivery in any country, regardless of its level of development. Health systems cannot function effectively without a competent, skilled and motivated health workforce. The issues facing the Western Pacific Region are not only challenging the traditional notions of health care for individuals, communities and service provider organizations, but are testing existing arrangements for the management of health workforce competence, capacity, safety and quality *(2)*.

Regulation of health practitioners refers to the arrangements put in place to protect the public by assuring, sustaining and improving professional standards across all regulated health professions *(1, 3)*. It is intended to ensure that the public, consumers, employers and practitioners can be confident that any concerns they raise about a health practitioner's competence and behaviour will be addressed in a way that is consistent, open and impartial.

While countries differ in their scope and organizational arrangements, regulation of health practitioners typically involves maintaining a register or list of those who are registered, setting and assuring educational standards, investigating and dealing with problems in relation to the conduct, health or performance of registered practitioners, and, increasingly, assuring continuing competence to practise.

What do we know about health workforce regulation in the Region?

The 37 countries and areas that constitute the World Health Organization (WHO) Western Pacific Region are diverse with respect to their culture, sociopolitical histories, population size and demography, geography, economic prosperity, resources and health status. There is further diversity in equitable access to health care across the countries and areas; in the number, type and distribution of workforces that provide health services; and in the development and implementation of legislation that regulates the education and practice of practitioners *(4)*.

A desktop review of regulation of the health workforce in the Region found significant variation between countries in the systems and approaches used, and in the maturity of these systems. This includes differences in relation to the relative maturity of regulatory systems: whether regulation is government-led or profession-led, which influences the type of institutional arrangements made, and whether other professions (e.g. the legal profession) and the general public or community are involved.

This is particularly evident in terms of:

- the governance, organizational and structural arrangements in place;
- the number and range of health professions that are regulated, and the extent of that regulation;
- the degree to which education and accreditation of programmes link to setting and ensuring adherence to standards of practice;
- requirements for registration and/or licensure (e.g. passing a national exam, evidence of qualifications from an approved course), requirements for ongoing licensure and ensuring adherence by practitioners;
- processes for credentialling or approving registration of foreign-trained health practitioners; and
- the extent to which countries and areas rely on health practitioners from other countries, and the existence of intergovernmental agreements for this purpose *(5)*.

While difference in itself is not a risk, weak regulation can negatively affect access to health services as well as health service quality and efficiency. Equitable access to sufficient numbers of appropriately trained and skilled health workforce that can deliver safe, consistent, good-quality health services remains a priority for the Region.

Some countries and areas, including Australia, China, Hong Kong (SAR), New Zealand and Singapore, feature strong, well established regulatory systems characterized by the enactment of recent or recently amended legislation, and the establishment of boards or councils with defined responsibilities for registration; setting and ensuring adherence to standards; notifications and complaints; and discipline. These systems appear to be clearly linked to education, signalling roles and responsibilities that link accreditation of programmes and/or providers to practise.

A second cluster of countries and areas, that includes China, Fiji, Japan and the Philippines, have legislation, acts, decrees or codes in place that establish a regulatory system, primarily for medicine, dentistry, nursing and midwifery and sometimes pharmacy. This group also appears to have weaker links between education standards and accreditation, as well as the mechanisms that ensure ongoing adherence to standards in practice.

A third cluster includes countries and areas that appear to have limited systems in place. An act or decree may have been enacted, but implementation is at a preliminary stage and the challenges faced are significant; examples include Lao People's Democratic Republic, Mongolia and Viet Nam.

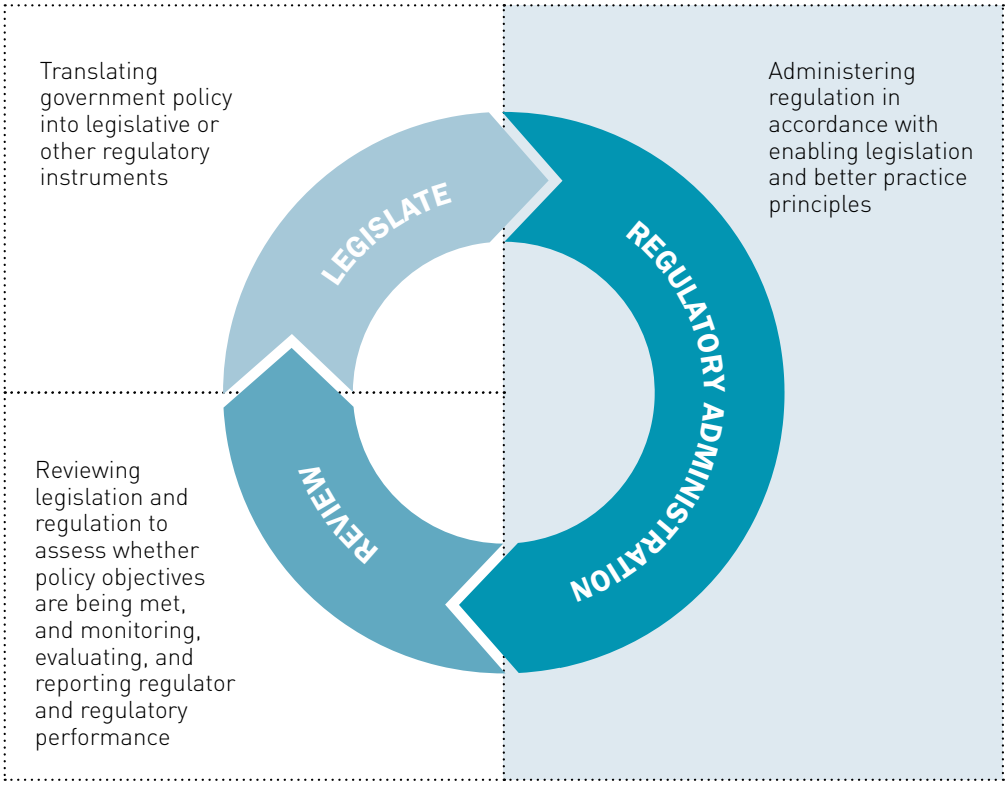
Weaknesses within the regulatory systems of some countries and areas in the Region may impact their ability to ensure effective, efficient, accessible, safe, good-quality and viable health services. Strengths in other systems are likely to play a major role in developing and retaining a skilled and motivated health workforce that can competently meet existing and projected population health needs, within the limits of the available resources.

Regulation of health practitioners' education and practice sits within a broader policy and legislative context that is influenced by sociocultural and political paradigms. Each country and area in the Region has unique contextual characteristics; however, some issues appear to be priorities for all. Policy-makers and regulators have an opportunity to craft or influence policy solutions that would address many of the challenges and assist in building good regulatory practice and capacity *(6)*.

Frameworks and options for regulation

The cycle of regulatory activities is illustrated in Figure 1, and involves: the design of legislative or other instruments (based on sound policy principles), implementation of the regulatory framework, and evaluation and review. Approaches to regulation should be developed in accordance with the supporting policy and legislation, and reviewed regularly to ensure they remain appropriate and continue to meet policy objectives.

Figure 1: The regulatory cycle



Source: ANAO–adaptation of 'The cycle of regulatory activities, *Principles for the Governance of Regulators*, OECD, Paris, 2013, p.21.

Well designed regulation should not create unnecessary burdens (e.g. financial and administrative), should be focused on risk to public safety, proportionate to the benefit it brings, and should be sufficiently flexible to work effectively for different health-care needs, approaches and with respect to future changes *(7)*. It should not unduly interfere with the day-to-day duties of health practitioners and the benefits should outweigh the costs. Regulation should give consumers, patients and the public confidence that the country's health practitioners are suitably trained and qualified to practice in a competent and ethical manner *(8)*.

Regulators are more likely to succeed if they use mechanisms or frameworks that are responsive to the context, conduct and culture of those being regulated. Responsive regulation to the relationship between the regulator and the regulated entity, and the regulatory instruments that are available can vary depending on the level of risk to the public *(9)*.

Statutory regulation

Statutory regulation carries the most regulatory force. Professions that are typically regulated under statutory regulation include medicine, nursing, dentistry and pharmacy.

Under a statutory registration regime, a regulatory body is established under statute and given powers to register and regulate entry to the professionnal. Entry is limited to those who hold the required qualifications and have met other probity standards for entry to the regulated profession set by the regulator. The regulator promotes and enforces clinical (and in some countries cultural) competencies and standards of ethical conduct. The regulator has powers to deal with those whose practice falls below an acceptable standard. Sanctions may include criminal penalties, license revocation or suspension, and there may be mandatory requirements for revalidation in addition to registration renewal. The regulator operates a public register that provides a trusted source of information about who is qualified to practise.

Statutory regulation is also the most costly, particularly for professions with small numbers of members and a lower regulatory workload, and there is a risk of over-regulation for professions for which the risk of harm is low. The benefits of intervening with regulatory force must, therefore, outweigh the costs involved especially for those they regulate or, indirectly, the broader community.

Co-regulation

There are many types of co-regulation arrangements. The most common type in the health sector is when a government enters into a partnership arrangement with an industry body or a professional association to regulate enty to the profession or an activity.

The key difference between voluntary regulation and co-regulation is that some of the functions undertaken by the industry body are delegated from or recognized by the government. Practitioners who have met the standards administered by the industry body may then be recognized or accredited by the government for other purposes, such as eligibility to access government-funded health-care payment schemes or private health insurance.

This delegation of functions is generally subject to the industry body meeting specified governance and operational standards set by the government. Examples of co-regulation in the Western Pacific Region can be found in Australia, where some groups of non-regulated allied health professionals (e.g. dietitians) are given approval to access health-care benefit scheme rebates.

Voluntary regulation

Voluntary regulation has no statutory force. Under voluntary regulation, there is no occupational licensing or statutory registration law that requires a person to be registered in order to practise.

Instead, members of a profession:

- voluntarily establish an association, and
- agree to abide by the rules and standards of the association.

The association may then:

- receive and investigate complaints about members; and
- take disciplinary action, including withdrawing membership if the member's conduct breaches the association's rules.

The behaviour of health practitioners may be influenced through a range of mechanisms in the public interest, including clinical protocols and guidelines, industry standards and codes of conduct. Codes of conduct are flexible tools that can be updated without changes to regulations, and can also be "called up into" or referenced in regulations *(10)*.

Voluntary regulatory systems can only regulate members of professional associations who seek voluntary regulation or accreditation. The processes are not enforceable and may not be standardized across a profession. Voluntary regulation can be more effective when overseen by an established peak body or professional association that is also closely involved in developing criteria for entry to a regulated profession, and the programmes for professional development. Examples of self- or voluntarily regulated professions include speech pathologists, audiologists, counsellors and social workers.

Negative licensing

Negative licensing is another mechanism that may be used to govern the practice of individuals whose conduct is otherwise unregulated or where professional misconduct under health legislation is considered extreme *(10)*. Under negative licensing, there is no requirement for a person to hold a license before starting to practise. However, entities, such as those responsible for responding to health complaints, can have powers to apply sanctions and prohibit them from practising if they breach specified standards.

A form of negative licensing known as "code regulation" has been implemented in Australia. Under code regulation, a code of conduct is enacted by law and powers are conferred on a complaints body to:

- investigate breaches of the code; and
- take enforcement action against a person if the breach is serious.

This action may include issuing a court-enforceable prohibition order to prevent the person from continuing to practise. Breach of this order is a criminal offense. Code regulation aims to protect the public from future harm where a person is not fit to provide health services.

The regime may be considered appropriate where there are small numbers of practitioners and the costs of setting up a full licensing system would not be justified, particularly as those costs would ultimately be passed on to practitioners or to the public in the form of higher registration fees.

Key features of a health workforce regulatory system

Who and what should be regulated and why?

There is wide variation across the Region in the number and type, or cadre, of health professions that are subject to statutory licensing regimes. Most countries and areas have legislation that regulates medical doctors, dentists, nurses, midwives and, often, pharmacists; a few countries and areas separately regulate some allied health professions (e.g. China, Hong Kong (SAR), New Zealand and Singapore); and a small number of countries and areas regulate some traditional medicine professions (e.g. Australia, Japan and the Republic of Korea).

Clear criteria and transparent decision-making processes are needed for assessing which health professions should be regulated. A risk profile or harm threshold is increasingly being used to make this decision. There needs to be demonstrated evidence of risk to the public, and that it is in the public interest that the particular profession be regulated. The risk must be one that exists over and above the risk of harm which is a necessary element of practice (i.e. procedures such as surgery that already carry a high degree of risk).

The risk profile for each profession is typically calculated on the basis of the number, frequency and significance of the notifications and complaints made against members of the profession, where those data exist. In some countries, it may also include consideration of the cost of adverse events. It should also include risks associated with context (e.g. non-hospital settings, degree of supervision or oversight), scopes of practice, training relevance and quality, skill retention, and clinical decision-making and treatment protocols.

Most countries regulate "by title" which means that they protect the name of a health profession by law. Title protection provides for exclusive use of a title (e.g. dentist) by those practitioners who have acquired the distinct education, special body of knowledge, and the regulatory standards and requirements for licensure in that profession. Some countries such as New Zealand also regulate by "scope of practice" whereby the regulator can define the specific area of practice the health profession may work in, including stipulating any restricted activities.

Legislative and governance arrangements

Is a legislative approach required?

Countries and areas in the Region vary with regard to the purpose of regulation, and whether the purpose is explicit, outlined in the legislation, or clarified in the regulations. The decision to pursue a policy option requiring legislation should be made by governments on the basis of evidence that legislation is the right instrument to manage risk and to give effect to policy, and that non-legislative options (e.g. service or employer-level agreements, performance contracts and voluntary protocols and guidelines) have been considered *(9)*. Well designed legislation should be premised on consistent policy and purpose. Legislative instruments may focus on a single profession, or, through umbrella legislation, apply to two or more professions.

Globally, there is increasing interest in multiprofessional regulation. This is the case in Australia, for example, which provides for greater alignment of regulatory decision-making across professions and consistent governance arrangements, operating and business structures for each of the professions covered by the overarching law, in principle allowing regulatory functions to be shared across professions that have lower regulatory workloads. This should reduce costs, enable greater flexibility with regard to qualifications and scopes of practice, and potentially, better support interdisciplinary education and practice *(8)*. However, there may be challenges in aligning common approaches and realizing such efficiencies where professions have significantly differing risk profiles and regulatory workloads.

How should governance and arrangements for accountability to government be designed?

Governance is about the rules that allocate roles and responsibilities among governments and their agencies, providers and beneficiaries and that shape the interactions between them (i.e. external governance). It is also about the regulator's organizational structures, standards of behaviour, roles and responsibilities, oversight of business processes, financial reporting and performance management (internal governance) *(11)*.

In some countries and areas in the Region, regulation of health practitioners is the direct responsibility of the ministry or department of health; examples include China, Japan and Viet Nam. Other countries have structures that are within the government or ministry of health, but also have a separate board or council for licensing or registering each profession. In the Philippines, the Professional Regulation Commission confers licensing responsibilities to profession-specific regulatory boards. Other countries, such as Australia and New Zealand, have systems that are more independent of government but where board or council members are ministerial appointments.

A governance framework covering the powers, functions and limitations of the regulator provides governments with clarity about the institutional arrangements and tools for the proper management of a regulatory agency. The framework can specify practical measures or benchmarks against which improvements in the quality of regulatory practice, and the achievement of required outcomes, can be periodically assessed and reported. Leadership from policy-makers, together with the possibility for regulators and other stakeholders to influence the policy agenda further strengthens regulatory governance and effectiveness.

Accountability is the cornerstone of good governance. It allows institutions and the public to track progress and adjust strategies and policies accordingly *(12)*. It involves both answerability – the obligation to provide information about decisions and actions – and enforcement, whereby the institution responsible for accountability can sanction the offending party or remedy the contravening behaviour.

Accountability for various elements of regulatory processes can lie with different agencies (e.g. government departments, ministerially appointed boards or councils, local government, provincial entities or prefectures), each applying different mechanisms and levels of transparency. Nonetheless, regulators have a civil obligation to the government and to the public to act visibly, predictably and understandably to promote participation and accountability, and to discharge their responsibilities impartially. This can be enhanced through transparent processes for the appointment of members to the regulatory board or council, whose role is to bring their particular expertise to the governance of the organization, not to represent the interests of the sector.

How should organizational arrangements for regulation of health practitioners be designed?

The governance and structural arrangements for regulation within countries and areas appear to broadly influence the degree to which initial education, qualifications and licensure to practise are linked. These arrangements also appear to influence the type and effectiveness of processes that relate to ongoing adherence to standards, managing complaints and implementing disciplinary decisions.

Regulatory agencies need to be structured in a manner that ensures that they are capable of discharging their responsibilities and fulfilling their functions effectively and efficiently. The organizational structure should be commensurate with the objectives of regulation and the nature of the activities to be regulated and relevant to the size and complexity of the regulatory workload. It should be sufficiently resourced to enable the regulator to establish operational, risk management and reporting processes *(13, 14).* Organizational arrangements should also enable stakeholders to understand where accountability lies and how decisions are made, and be flexible enough to integrate new strategies or initiatives.

Regulators should be encouraged to see themselves as part of a connected system of regulation across health professions and sectors, both within a country and across a region. The sharing of expertise and information about the approaches, challenges and processes used, can contribute to improving the quality of regulated health services, and to health workforce planning and policy development. In addition to strengthening overall regulatory capacity, this may help simplify the regulatory environment and reduce the regulatory burden, including the administrative costs *(10).*

Registration

What should the registration requirements be?

Registration requirements vary considerably between professions and across countries and areas in the Region, and include various categories from student to specialist, the duration of which may also vary. Most stipulate the educational qualifications that must be attained for eligibility to register; however, there is considerable variation as to whether standards for each profession have been developed or linked to registration.

Standards are published documents setting out specifications and procedures designed to ensure that the practice of health practitioners is safe, reliable and consistent. They establish a common set of requirements for each health profession. Most regulatory systems stipulate the standards required for entry into a profession (to become registered or licensed), and for maintaining registration. Mechanisms for dealing with people who breach the standards, for example how fitness to practise is assessed, and how notifications and complaints are managed, should also be stipulated and published.

Standards at entry should be practical, achievable, based on sound clinical or scientific experience and reflect current and predicted health-care environments. They should be regularly reviewed to ensure they keep pace with new technologies, societal expectations, and patterns of workforce utilization. The community and professional associations have a key role in advising on the standards, for example, through consultation processes during the development of standards.

How does the public know if a health practitioner is registered?

The registration status of a health practitioner is generally contained in a register or list which is publicly available. The rules defining how the register will operate are usually set out in the enabling legislation. These rules should describe the purpose of the register, how it is to be used, and what level of information will be contained in it. The rules should also outline how information in the register can be accessed and by whom.

Keeping the register up to date, accurate and publicly available without cost to the community, is the most important task of the regulator, and should be supported by an appropriately resourced organizational structure. Publication of registration data provides stakeholders with confidence that registered health practitioners have been assessed against consistent standards, in the public interest.

Registration data are also a valuable source of information for policy-makers and health-service planners about workforce trends; however, how to manage access to registration data over and above those contained in the public register is a decision for individual countries to make. It is therefore important to define the data elements to be published in the register. These include the identity of the practitioner (e.g. name, sex, date of birth, registration number), registration information (e.g. registration status, type, and date of original registration), qualifications (including any additional postgraduate qualifications gained since initial registration) and disciplinary history.

Are there ongoing requirements for registration?

Countries and areas in the Region vary with regard to the requirements for maintaining licensure or registration. These requirements range from annual renewal of registration (e.g. annual practising certificates) such as in New Zealand, to licensure for life, as for example in Japan. There is variation as to whether practitioners must demonstrate that they continue to meet standards and competencies, whether evidence of continuing professional development is required, or whether only a declaration relating to professional conduct (e.g. fraud or criminal convictions) and payment of the renewal fee is required.

For new registrants, appropriate supervision is also a critical component in ensuring support, mitigating risk and motivating and retaining newly qualified practitioners. Linking registration renewal to well planned and relevant continuing professional development and education is important in improving standards of practice, and in safeguarding the public, employers, and the health practitioner and their career. Regulators could also consider introducing regular revalidation in addition to registration renewal requirements and, over time, expanding these requirements to include clinical audit and multisource feedback *(15)*.[2]

Are there clear educational pathways to registration?

All countries require some form of educational qualification in order for practitioners to be eligible for registration. There is, however, variation between countries, and between professions within some countries, as to whether a pass in a national exam is also required. There is also variation in the extent to which this exam is linked to a curriculum, and what involvement professional associations or colleges have in setting the content of the curriculum, the exam, or the standards for entry to practice.

Regulators need assurance that the qualifications awarded by an educational provider meet the educational standards for entry to practice, and align with those that are required for registration. This means that there should be a clear link between the processes and requirements for programme and provider accreditation, the standards for preregistration education and training, and the prerequisites for practitioner registration.

Education institutes and regulatory agencies need to cooperate to align the mechanisms that assure educational quality and relevance (accreditation), and the mechanisms that ensure competencies and standards are met (i.e. registration). Regulators play a key role not only in setting expectations for accreditation standards, but also in influencing compliance of education providers with these standards.

Accreditation by agencies external to the education provider is likely to be more effective than internal checks and audits, as it reduces the likelihood of subjective bias or influence on the outcome. An independent regulator or body that sets standards and accredits courses and institutions is also more likely to provide transparent mechanisms for review, and consequences for managing poor institutional performance.[3] Increasingly, mechanisms are required to ensure that education provider and programme standards are being met across both the public and private education sectors.

[2] The United Kingdom of Great Britain and Northern Ireland has recently introduced 5-yearly revalidation.

[3] WHO Regional Strategy on Human Resources for Health 2006–2015.

How are overseas-trained practitioners registered?

No country or area in the Region is entirely self-sufficient in producing enough health workers to meet the health-care demands of its population, thus all rely to some degree on graduates and practitioners who qualified elsewhere. The increasing mobility of health practitioners throughout their education, training and practice blurs the regulatory picture in an already diverse region. A health practitioner may receive training in one country, complete an internship in another and be employed in several others. Further, recognition of prior learning and determination of equivalence in regard to qualifications is increasingly complex, given the variability in educational quality and standards in the Region, and in the requirements for and institutional oversight of continuing professional development.

A competenty authority model used in some countries, such as Australia, can be useful in assessing the equivalence of the qualifications of overseas-trained health practitioners. In this model, the regulator recognizes the standards applied by another country's regulator, and accepts as equivalent the qualifications of practitioners from that country. However, regardless of the model used, consideration should be given to obtaining information from the overseas regulator on each health practitioner's professional practice, in order to identify any disciplinary history of concern.

The issues for policy-makers to consider include: the degree of reliance on overseas-trained health practitioners; the sources, pathways and supply; the mechanisms that exist to facilitate (or restrict) cross-border movement (e.g. common education or registration standards); and whether mutual recognition, bilateral, multilateral or other agreements exist. Importantly, consideration needs to be given to the ability, and capacity of the system to regulate and integrate these practitioners. Other issues include how compliance with registration standards and continuing professional development requirements, and disciplinary matters, will be managed for practitioners who are registered in another country. Developing core, common and consistent principles and approaches to regulation across the Region may mitigate some of these issues.

Dealing with concerns about the professional conduct of practitioners

Concerns about the conduct, competence or health of a health practitioner may relate to: a pattern of practice over time that does not meet accepted standards of competence; a one-off incident of performing significantly below accepted standards; recognized poor performance in spite of local interventions; a criminal offense; or health issues, with declining standards that become apparent.

Many countries and areas in the Region specify the notification and/or complaint procedures in their legislation. However, apart from countries with relatively mature and well established regulatory systems, published information on how these procedures are implemented is limited, including about the type of censure or penalty applied.

Obligations to protect the public and maintain public trust in the professions that are regulated means that procedures for notification and/or complaint management should be designed to safeguard the community. Health practitioner regulation exists alongside numerous other mechanisms for monitoring and managing performance and risk. Employers, professional associations, health ombudsmen, ministries, departments and patient advocacy groups all have an interest in, and responsibility for ensuring, a safe, competent and effective health workforce. Common judicial processes such as court and tribunal proceedings also play a role in achieving outcomes that protect the public.

Regulators should provide information to the public about what constitutes poor professional conduct, how to raise concerns or report unsafe practice and the outcomes of disciplinary procedures. Regulators, professional associations and other stakeholders can provide guidance to practitioners and employers about how to recognize and report poor performance by a colleague or employee. Consideration may also be given to include in the legislation a mandatory duty to report conduct, health or competence issues.[4]

Practitioners should receive feedback, intervention or face more serious consequences (including possible deregistration) if they breach professional standards. Effective complaint management systems also include information for practitioners about the criteria and processes for appealing decisions on disciplinary matters *(17).*

How are concerns dealt with and investigated?

Regulators should establish clear processes for investigating concerns and determining the appropriate action. The process, which should be constructive, transparent, consistent and fair, should include: lodgement, assessment, investigation, health or performance assessment, immediate action, and complaints committee/panel hearings.

[4] For example under the Australian Health Practitioner Regulation National Law 2009.

Implementation considerations

Mobility and obligations under intercountry, bilateral and mutual agreements, such as the Association of Southeast Asian Nations (ASEAN) mutual recognition arrangements, emphasize the importance of well designed, and more consistent, regulatory approaches across the Region. Effective regulation at a country level requires an integrated approach that considers policies, institutions and tools as a whole, at all levels of government, across sectors, and across the regulatory continuum. Monitoring the impact of regulations and reviewing the performance of regulators can show whether policy objectives are being met, and where changes need to be made.

Engaged and involved stakeholders

Public confidence in the regulator, its decisions and its actions is enhanced by good regulatory governance that includes acknowledging and managing the expectations, relationships, power and interests of stakeholders. A cooperative effort by government, regulators, the regulated and the broader community, together with high-level political commitment to achieving a safer health system, are all important factors in achieving good regulatory outcomes.

Regulators should clearly identify who their key stakeholders are (i.e. which groups, entities, associations and individuals), why their involvement is important, and how they can contribute to regulatory processes, including the processes for the design and review of regulatory policy. Mechanisms vary, but generally include: active and meaningful formal consultation; expanding the pool of eligible candidates for appointment to board or council positions (e.g. lay people and professionals from other sectors such as law, finance and education); and regular stakeholder meetings and public forums. The choice of mechanism will depend on the issue to be discussed and the range of stakeholders who may be affected.

Consultation

Consultation provides opportunities to understand stakeholders' views on issues (such as the introduction of new scopes of practice), their attendant risks, impacts and opportunities. It also provides a valuable opportunity to educate and inform people. Processes should be premised on a clear policy that also outlines how regulators will ensure they will balance and report on stakeholder perspectives. Processes should also be designed to maximize the quality of the information disseminated and its effectiveness.

Board/council membership

Expanding the pool of eligible candidates, for example, to include non-practitioners, lawyers or community members, for appointments to regulatory boards or councils broadens the range of skills and experience that a board can draw on to make its decisions. It can also provide assurance to the public and other stakeholders about the impartiality of decisions, and reduce the risk of professional capture and loss of objectivity.

Simple business processes

Registration

The business processes that regulators need to establish for registration should cover: receiving and considering an application, assessing compliance against requirements for registration, decision-making, maintaining a record of registrants (the register) and cancelled registrations (and the reasons for cancellation). Regulatory effectiveness is enhanced if these processes are simple, easily administered and transparent. There may be value in regulators sharing a secretariat or staff for some or all of these functions, particularly for professions with small numbers of practitioners and a lighter regulatory workload. Consolidated regulatory frameworks that span multiple (or all) regulated health professions, and are managed by a single, national regulatory agency may be one option for achieving more consistent governance, more efficient operating and business processes, better regulation and reduced costs.

Grandparenting arrangements

Changes in policy may require regulators to include previously unregulated professions on the register. Transitional provisions, commonly referred to as grandparenting, should be set out under legislation, and available for a time-limited period. Grandparenting provisions should not unduly disadvantage health practitioners who have previously been practising legitimately in the profession.

Early communication with affected health practitioners prior to the commencement and the end of the grandparenting period is essential. Information should be consistent, and should clearly outline the purpose and time frame of the transitional arrangements, the registration and decision-making processes, and the mechanisms for appealing decisions.

At the conclusion of a grandparenting period, applicants for registration are generally required to meet all the regulatory agency standards, including those for qualifications, skills and training.

Appropriate mechanisms for financing

The design of the regulatory system, including aspects such as who is regulated and how they are regulated, will impact the financing required. Options for financing include funding by the health practitioners through payment of registration fees, and subsidization or payment of wages by government departments where regulatory agency staff are government employees. It may also involve subsidization of health practitioner registration fees by employers.

Decisions need to be made about whether the financing mechanisms are relevant or appropriate, and whether they enable the regulator to discharge its duties in an impartial manner, free from undue professional or political influence.

A regulatory agency may have authority delegated to it through legislation to make regulations and/or charge fees and levies to enable it to carry out its functions under that legislation. The law may also state the rules about how fees are to be applied. Regulators need to consider the size and complexity of the regulatory workload when determining the fees. In many jurisdictions, final decisions about fees require external authorization or noting, such as by ministers or the cabinet, and this can help maintain trust in the integrity of decisions.

Consideration should also be given to hidden costs, such as those incurred by poorly implemented or managed regulation, and opportunity costs i.e. a loss of other alternatives when one is chosen. Decisions about which professions should be regulated, whether to include multiple professions in a shared register, and whether legislation should be focused on scope of practice or title protection, all require policy-makers to assess the impact of hidden and/or opportunity costs when designing legislation and regulatory frameworks.

Routine evaluation of regulatory performance

Internal review

Regulatory agencies are often small bureaucracies with heavy workloads and competing demands; however, they are not excused from fulfilling their statutory roles because of limited resources. Regulators have an ongoing obligation to monitor and review their regulatory frameworks and systems, and assess their performance to ensure that they remain effective. Performance measures can include quantitative aspects (e.g. processing times and costs for regulatory approvals or other decisions) as well as qualitative aspects of the regulator's activities (e.g. public understanding of the regulator's role). Mandatory reporting through parliament or the legislature should be a minimum requirement. Other reporting mechanisms include consultation processes, stakeholder meetings and web- or Internet-based methods.

External review

External evaluation of the regulator's performance by an independent and/or national or international agency can ensure that regulators are held accountable and maintain the trust and confidence of the stakeholders. Evaluation reports, which should be made public, are a vital step in the regulatory cycle, and provide information for governments on how well policy objectives are being met, and where changes may need to be made.

Building regulatory capacity

Capacity is needed across all dimensions of regulation. Governments need to develop and maintain a strategic capacity to ensure that regulatory policy remains relevant and effective and can adjust and respond to emerging challenges. Capacity is needed in a regulator's governance and operational management and to ensure an appropriately qualified and resourced secretariat and staff.

Emerging issues

The rapidly evolving health-care context, including in the way health care is delivered, is challenging existing mechanisms for effective regulation. A number of emerging issues have been noted, which include the following examples.

Interdisciplinary education and practice

Interprofessional and multidisciplinary education is emerging as an important contributor to improving links between education and practice, bridging the roles of health practitioners, and building workforce capacity. A number of agencies (e.g. governments, professional associations and educational institutes) must work together for this to be successful. For example, governments can develop and communicate policies for interprofessional practice as well as providing mechanisms, resources and structures to support it (including the regulatory and medico-legal levers); regulators, supported by professional associations or peak bodies, can develop shared competencies and standards; accreditation agencies can integrate interprofessional practice into accreditation requirements; and finally, educational institutions can foster the values, skills, opportunities and professional role-socialization necessary for interprofessional learning and practice *(18)*.

Non-technical skills

A significant amount of what good practitioners do to achieve consistently high performance involves nonclinical or non-technical skills. These skills include situation awareness, decision-making, teamwork, leadership and communication, as well as values and professional ethics. Regulators will increasingly be tasked with assessing non-technical skills when dealing with notifications and complaints, and should consider including these skills in core competencies and standards so they can be subject to regulation. International literature indicates an emerging interest in approaches for teaching and measuring such skills in health practitioners.[5]

[5] The term non-technical skills comes from European aviation and they can be defined as "the cognitive, social and personal resource skills that complement technical skills, and contribute to safe and efficient task performance". There are now methods for training and rating the non-technical skills of surgeons (NOTSS) and anaesthetists (ANTS), with applications being developed for other clinical specialists.

Advances in technology

The rapid increase in the use of technology such as virtual consultations, telehealth and Internet-based support systems, is challenging existing mechanisms for assuring competence, quality and adherence to professional and clinical standards.[6] Service-level agreements and memoranda of understanding between countries can be useful mechanisms to document expectations. However, monitoring compliance and enforcing expectations can be difficult.

Private education and health-care service providers

Together with regulatory issues arising from innovations in technology, an increase in the number of private health-care and training providers, and the rapid expansion in online learning and qualifications, is challenging existing systems for managing quality. This includes how poor performance of a provider is managed. Some countries require all private health-care service providers to be registered; others restrict the number of schools that can open. The issue remains complex, especially given shortages of health-care practitioners in many countries, and the increasing demand from the private sector for health practitioners.

[6] Reid C. Nursing Council of New Zealand. Personal correspondence, July 2014.

Moving forward

This paper presents policy principles and considerations in relation to the design and implementation of an integrated system for the regulation of health practitioners. Regulation should be tailored to local circumstances, culture and context; however, some issues are priorities for all countries and areas, regardless of their level of development.

Assessing regulatory systems and approaches against the principles and considerations outlined in this document should provide countries and areas with a snapshot of current regulatory practice, as well as identifying strengths and opportunities for change and improvement. These principles focus on:

- protection of the public,
- assessing the problem and associated risks in deciding whether to regulate,
- transparency,
- a clear basis for the decision on who to regulate,
- well designed legislation,
- a clear governance framework,
- accountability,
- forming links between education and registration,
- maintaining a public register,
- dealing with complaints about practitioners, and
- stakeholder engagement.

Determining which regulatory activities should be prioritized for review is a decision for individual countries and areas to make; however, the cycle of regulatory activities provides a solid framework and foundation for decision-making. The framework also supports countries and areas in working towards a far more consistent approach to the design and implementation of regulation across the Region.

Building regulatory capacity, and improving the effectiveness of regulation in the public interest, requires a collaborative effort at the global, regional and country levels. Considerable expertise exists within the Region that would support a regional network of regulators. Countries and areas are encouraged to share knowledge and information about good regulatory practice, as well as on the challenges and how they can be resolved. At the very least, establishing an (informal) regional regulators' network, and using existing conferences, events and regional forums to exchange ideas, will improve knowledge, build capacity, and strengthen regulation across the Region. Not ensuring a suitable, fit-for-purpose and fit-for-practice health workforce is not an option.

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Useful references

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