



# Risk-based approaches to regulation of health professionals

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World Health Professions Regulation  
Conference  
22 May 2016



# Canberra





# Impetus for risk-based approaches



- Cost of compliance and enforcement regimes
- Compliance and enforcement models did not prevent catastrophic events
- Using resources (time and people) to ensure the rules are followed was not efficient or effective
- Regulators expected to deliver more effective outcomes with less resources



# Moving to a risk-based approach ....



- focus on risks of non-compliance with the rules rather than enforcing the rules equally
- seek to better understand features of the risk and the “problem” to enhance mitigation strategies
- use risk assessment to tailor (innovative) decisions about regulatory responses
- monitor outcomes of regulatory initiatives and responses to inform future improvement



# An effective risk-based regulator...



- allocates resources to target risks
- reduces regulatory burden by differentiating levels of risk posed by different individuals
- seeks to achieve better regulatory outcomes by understanding the underlying problem
- uses understanding to proactively reduce risk of harm
- can evaluate the efficiency and effectiveness of regulatory actions in achieving outcomes



# Better understanding the problems they are trying to solve helps risk-based regulators to...



- prioritise their activities and resources
- design targeted initiatives
- measure effectiveness of initiatives by monitoring outcomes
- use insights from implementing initiatives to revise and strengthen understanding of problems and associated risks



# Using available data to better understanding the problem



- initial analysis showed a cluster of doctors accounted for a substantial proportion of formal complaints
- subsequent work derived a valid method to assess likelihood of subsequent formal complaints against doctors
- predictive algorithm produces Predictive Risk Of New Event (PRONE) score
- regulators might use score to identify cases that require more in-depth review

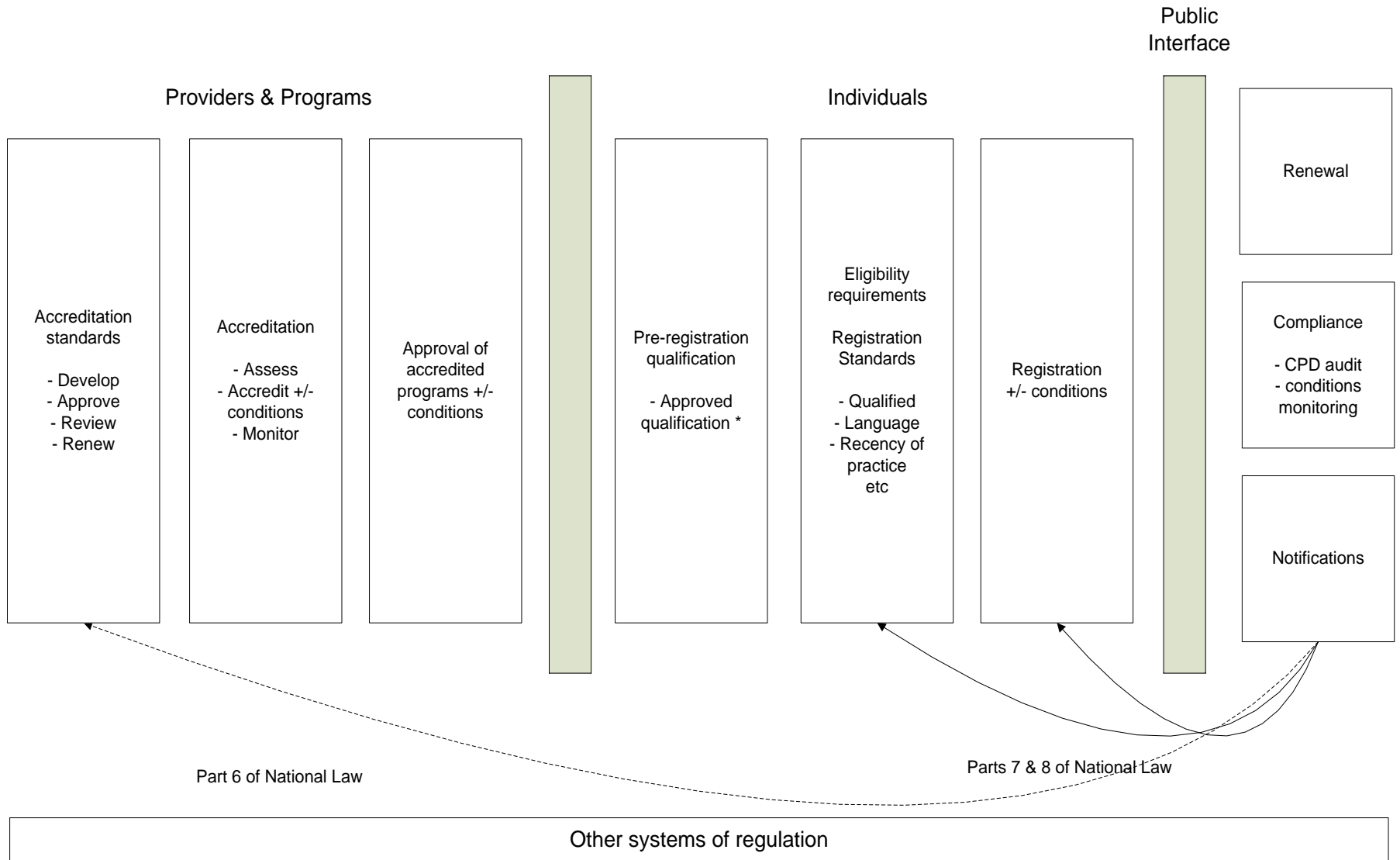
<http://qualitysafety.bmj.com/content/early/2013/02/22/bmjqs-2012-001691.full>

<http://qualitysafety.bmj.com/content/24/6/360.long>









\* This diagram does not include elements that contribute to regulation for qualifications that are not approved



# Embedding a risk-based approach – Australian context



The Australian Health Practitioner Regulation Agency:

- published regulatory principles to foster consistent risk-based approach
- established a Risk-based Regulation Unit
- collaborates with external researchers and academics

<https://www.ahpra.gov.au/annualreport/2015/highlights.html>

# Example of Australian regulatory principles



"... our primary consideration is to protect the public.

In all areas of our work we:

- **identify the risks** that we are obliged to respond to
- **assess the likelihood and possible consequences** of the risks, and
- **respond in ways that are proportionate and manage risks** so we can adequately protect the public

When we take action about practitioners, **we use the minimum regulatory force to manage the risk** posed by their practice, to protect the public. Our **actions are designed to protect the public and not to punish practitioners.**"



# AHPRA's Risk-based Regulation Unit



- formally established in 2014
- analyses data to detect and predict risk factors
- supports provision of evidence based advice to further enhance Board's decision-making
- enhances ability to tailor specific regulatory activities to reduce risk of harm



# Elements of a risk-based regulatory framework



1. Define regulatory outcomes
2. Identify risks
3. Assess risks
4. Understand problems
5. Link work to outcomes
6. Identify measures
7. Allocate resources
8. Tailor regulatory response to address risks
9. Monitor, report and continually improve



[http://www.dpc.nsw.gov.au/programs\\_and\\_services/better\\_regulation/quality\\_regulatory\\_services\\_initiative](http://www.dpc.nsw.gov.au/programs_and_services/better_regulation/quality_regulatory_services_initiative)



# Features of a risk-based regulator



- clearly identifies the contribution of activity to regulatory outcomes (i.e. the impact), and the resources used to achieve these outcomes (i.e. the impact's efficiency)
- greater flexibility to adapt to changing circumstances
- increased transparency
- more informed and meaningful interactions with regulatory partners and other stakeholders
- more effective engagement with regulated health professionals



# Reality/challenges of risk-based approaches



- outcomes of risk-reduction activities are difficult to measure objectively - level of subjectivity is inherent
- notion of “acceptable level of risk” and “acceptable cost”
- how is value of public confidence accounted for in cost:benefit analysis
- increased transparency/accountability may expose regulator to criticism
- public safety and avoiding harm must remain the priority



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