PLYMOUTH UNIVERSITY PENINSULA
SCHOOLS OF MEDICINE & DENTISTRY

The evidence and options for medical revalidation in the Australian context

Final Report

Dr Julian Archer, Miss Rebecca Pitt, Dr Suzanne Nunn, Dr Sam Regan de Bere

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The views expressed in this report are those of the participants and the authors and do not necessarily reflect those of the Medical Board of Australia.

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Table of abbreviations and acronyms

ABMS	American Board of Medical Speciality
AHPRA	Australian Health Practitioner Regulation Agency
AMC	Australian Medical Council
CAMERA	Collaboration for the Advancement of Medical Education Research and Assessment
CME	Continuing medical education
CPD	Continuing professional development
FMRAC	Federation of Medical Regulatory Authorities of Canada
FSMB	Federation of State Medical Boards
GMC	General Medical Council
GMP	*Good Medical Practice: A code of conduct for Australian doctors*
ITS	Interrupted time series
KNMG	Royal Dutch Medical Association
MBA	Medical Board of Australia
MCNZ	Medical Council of New Zealand
MOC	Maintenance of Certification
MOL	Maintenance of Licensure
MSF	Multi source feedback
RQ	Research questions
SE	Spaced Education
SI	Supporting information
SMB	State Medical Board
SW	Stepped wedge trial design
VHHD	Very High Human Development Countries

Executive summary

1. Background

Medical regulation is a complex intervention designed to safeguard patient care, raise professional standards and promote community confidence. Responding to the evolution of doctor-patient relationships and increasing drive for accountability, medical regulators are beginning to adopt a continuous evaluative process to ensure that registered doctors are both up to date and fit to practise. Revalidation (a form of medical regulation operating in the UK) and its wider activities have been shown to demonstrate positive results across several medical related domains including the maintenance of public trust, enhanced patient care, physician behaviour and clinical outcomes. As a result, the Medical Board of Australia (MBA) has commissioned the Collaboration for the Advancement of Medical Education Research and Assessment (CAMERA) at Plymouth University Peninsula Schools of Medicine and Dentistry (UK) to explore the international processes and evidence base for revalidation in order to inform their discussions about the possible structures, design and role for medical revalidation in Australia.

2. Aims and Objectives

The aim of the study was to understand the international evidence base for revalidation, its associated activities and effective combinations in order to inform three possible models of revalidation applicable to the Australian context. The specific research objectives were to:

1. Establish the existing evidence base for the validity of revalidation or similar in countries comparable to Australia.
2. Identify best practice and any gaps in current knowledge surrounding revalidation processes.
3. Identify the underlying principles for revalidation development and implementation.
4. Develop three models for consideration including associated evaluation frameworks.

3. Methods

The research adopted a mixed method approach underpinned by a logical step wise process. The seven interrelated research steps and their corresponding methodologies were:

- Step 1: A narrative literature review of 49 very high human development countries as assessed by the United Nations Very High Human Development Country Programme (VHHD - 2013) to provide an international evidence base of revalidation or similar programmes and their accompanying activities.
- Step 2: Case study development of seven countries based on their close proximity to Australia's rank within the VHHD programme and their approaches to revalidation.
- Step 3: Tertiary review of existing literature to establish what evidence there is that revalidation activities are effective, or not, in supporting safe practice.

- Step 4: A narrative literature review exploring the evidence that combining revalidation activities supports, or not, safe practice, professional standards and community confidence.
- Step 5: Identification of underlying principles arising from steps 1-4.
- Steps 6-7: Revalidation model development; mapping of collated evidence from all previous steps *to Good Medical Practice: A code of conduct for Australian doctors (GMP)* to embed proposed models in the Australian context and development of evaluation programmes underpinned by Activity Theory as the conceptual framework to help explore the dynamic activity of revalidation, its related sub-components, communities, and interactions over time.

4. Results & Discussion

Step 1 – Literature review of 49 VHHD countries: Despite global interest in the use of revalidation, there remains a lack of unified agreement surrounding its definition, mechanisms and appropriate design. Continuing medical education (CME)/continuing professional development (CPD) is the most frequently used method to inform ongoing professional development and medical regulation. The vast majority of countries reviewed (69%) engage in mandatory CME/CPD using a credit point system (1 credit typically equating to 1 hour) that typically operates over a three or five year period requiring an average of 40-50 annual credits. The intensity, design and activities of these cycles differ substantially depending on the wider geographical and political landscape in which they reside.

Step 2 – Case study development: The majority of the case studies reviewed (UK, Canada, New Zealand, USA, Germany, the Netherlands, Belgium) use peer review and/or clinical audit as an additional form of medical regulation. All countries recognise eLearning/distance learning as a valid form of regulation. New Zealand, the Netherlands and Belgium outline a minimum number of consultation/practice hours as part of their revalidation criteria. Few countries (the UK and Canada) make a conscious effort to review patient complaints. Canada also randomly selects doctors who have been in independent (private) practice for more than five years and/or older physicians (70+) to undergo peer assessment representing a uniquely targeted approach to revalidation. The use of a high stakes examination appears to be unique to the USA. Belgium was the only case study reviewed that offers a financial incentive for revalidation engagement.

Step 3 – Tertiary review of existing revalidation activity literature: Revalidation and its associated activities have been shown to encourage beneficial professional changes to varying levels of effectiveness. CME/CPD has been shown to be effective at encouraging long term developments in physician attributes including knowledge, attitudes and communication skills. These changes are further enhanced when CME/CPD is interactive, targeted for small groups of physicians within the same discipline, utilises repetitive exposures and offers dynamic/live media use. Online CME/CPD has been shown to be equally as effective, if not more, than live CME/CPD in terms of improving physician

knowledge, skill competence and clinical decision-making offering a series of additional advantages. Appraisals are reported to be the single most important activity to encourage change in physician performance posing significant beneficial outcomes including increased motivation, career development and job satisfaction. Multi-source feedback (MSF) has also been shown to encourage substantial improvements across a range of non-clinical domains including interpersonal skills, communication and professionalism. These changes can be further enhanced if the feedback is facilitated, such as through appraisal, contains narrative comments and the facilitator is deemed credible by the physician in question. Consideration is required surrounding potential feedback bias and number of patient/colleague questionnaires required to achieve sufficient reliability. Patient complaints are an important driver in patient safety that can help identify 'at risk' physicians. Organisations and physicians alike need to value patient input in order for these to be effective. Clinical audit has been shown to be effective although this conclusion is not unanimous with organisational failings (e.g. poor management, lack of support) reported to be the most cited reason behind ineffective implementation. However, clinical audits can be effective when organisational failings are addressed; health professionals are not performing well to begin with; audits are facilitated and conducted by a respected/familiar supervisor or colleague with clear targets identified. The central location of self-directed learning and assumed ability of physicians to accurately determine their own learning needs is not well supported by the literature. There is evidence to suggest an inverse relationship between knowledge/performance and number of years since certification/registration. Interactive CME/CPD, appraisal, review of patient complaints and MSF are the most well supported revalidation activities.

Step 4 – Literature review of revalidation activity combinations: In line with established principles of adult learning theory, there is strong evidence to suggest using a multitude of educational techniques that foster interactivity and engage in facilitated feedback is most beneficial. Evidence suggests this is most effectively achieved through 'blended learning' – a hybrid model of learning where traditional methods of education (e.g. face to face CME/CPD) and more modern techniques (typically online learning) are combined. Blended learning has been shown to be both an effective and attractive form of learning across numerous populations with demonstrated abilities to enhance knowledge retention and significantly alter clinical behaviours and intentions. The literature therefore concludes that no singular approach to medical regulation works best under all circumstances. Creativity and diversity are therefore required. These conclusions strongly resonate in the Australian context and the current learning preferences of their medical professionals. More research is needed to identify which aspects of the educational activities and types of combinations are most effective for regulatory purposes as these conclusions are currently absent in the revalidation literature.

Step 5 - Principle identification: Six key principles were identified that underpin effective revalidation implementation, development, and evaluation on the basis of the evidence reviewed:

1. Clarity of purpose
2. Facilitation
3. Consideration of target groups
4. Resource provision
5. Multi-dimensional, interactive and quality controlled approach
6. Patients and the public involvement/focus

These should not be viewed as independent or exclusive but rather operating as a collaborative network in pursuit of a common goal i.e. revalidation.

Steps 6-7 - Model development and evaluation: The step-wise approach adopted throughout this research enabled the development of a robust evidence base to inform the proposal of three revalidation models. The mapping of collated evidence to the *GMP* provided a 'curriculum' for desired medical practice in the Australian context helping to secure the programmes content validity. The mapping exercise demonstrated that whilst the most commonly used revalidation activities could cover all key aspects of the Australian *GMP,* no singular activity could achieve this alone. As a result, each of the three models presented (Model A-C) varies in its intended purpose (formative, summative or mixed), number/type of activities used, intensity, and proposed exposure. Each model is designed on the basis of the international evidence base of revalidation activities, their effective combinations, identification of underlying principles and outcome of the *GMP* mapping exercise. Below is a brief synopsis of each model proposed, their limitations and advantages.

- Model A –represents a low level model of revalidation operated entirely online. Running over a period of five years, (duration typically adopted on a global scale) doctors would be required to produce an annual online portfolio/supporting information evidencing: participation in mandatory self-directed CME and MSF. These would both need to be signed off by a line manager or equivalent profession or professional body once a year with the fifth signature needed to achieve a recommendation for revalidation approval. Engagement in this model would be cost effective, potentially available nationwide provided internet access was available, easy to administer and relatively easy to assimilate into daily workloads. It would demonstrate that doctors are up to date but not necessarily fit to practise providing a single regulatory response. There is a strong reliance on internet access, limited opportunities for reflective and collaborative learning and missed opportunities to target 'at risk' physicians (e.g. 60+ or in independent practice for 5 years or more).

The heavy reliance on self-directed CME may also prevent beneficial development. In regards to conforming to the *GMP* code, model A would assess seven components offering limited levels of content validity.

- Model B –would also operate over a five year period seeking to resolve the deficiencies identified in model A. Doctors would be required to present an online portfolio/supporting information detailing: engagement in directed CME (no self-directed option), facilitated online learning, bi-annual appraisals for targeted groups (physicians aged 60+ or those in independent (private) practice for five years or more) and participation in MSF from a specified number of patients and colleagues. A revalidation appraisal would be undertaken for all doctors every fifth year. Model B has the opportunity to assess 16 components of the *GMP* framework, provide enhanced MSF opportunities and engage in bi-annual appraisals for specific groups. There remains a limited opportunity for reflective practice, a lack of regular appraisals for all Australian doctors and the development of potential hostility surrounding exclusively directed CME.

- Model C – finally model C comprises of both formative and summative components. Model C ensures doctors are both up to date and fit to practise representing a dual approach to revalidation. Doctors would be required to evidence: engagement in self-directed and directed interactive (minimum level of 25%) CME, facilitated online learning, blended learning, annual appraisals, participation in MSF with accompanying facilitated feedback and a review of patient complaints. Similar to the other models presented, model C would operate over a five year cycle with every 5th appraisal acting as a revalidation recommendation. Model C rectifies the vast majority of concerns raised in the previous two models. Possible hostility and lack of effective development arising from CME are addressed by combining both self-directed and directed CME. Doctors would therefore be required to attend a core of similar CME events providing continuity but would maintain freedom amongst their CME choices beyond this. Blended learning (where traditional methods of teaching are combined with more modern options) will help to incorporate the vast majority of learning preferences identified in the Australian context and close the current gap between evidence and practice given its demonstrated ability to improve knowledge retention and physician performance. All physicians would engage in annual appraisals providing valuable reflective practice opportunities and would therefore be in receipt of the full benefits of facilitated appraisals/feedback. A review of patient complaints would provide an additional layer of reflective practice and ensure that the patient voice was both heard and acknowledged. Although difficulties in fully implementing Model C in the Australian context are acknowledged given the high percentage of private physicians, Model C offers the best model of

revalidation informed by the current evidence base and is most likely to assure both safe, and overtime, better practice to the betterment of patients.

In terms of evaluation, Australia currently has no formal revalidation system in place and therefore presents a unique opportunity to prospectively evaluate any new revalidation model helping to develop revalidation related 'impact' evidence that may address some of the identified gaps in the current literature. Three evaluation programmes (process evaluation, outcome evaluation and trialist approaches) are discussed although several considerations including the intended purpose of revalidation (formative, summative or mixed), proposed design and piloting level will need to be made before any evaluation can begin. Whilst a trialist approach (measuring identified variables/outcomes prior to and following an intervention with a control group) could be considered, it presents numerous challenges including accurate randomisation and controlling for the many variables present in a medical profession population and intervention implementation of this size and complexity. A process or outcome evaluation may therefore be more feasible. A process evaluation that involves multiple mixed-method work streams is proposed to identify the central processes at work and address the basic question of whether the intended aims and purposes of revalidation are being effectively executed. However, a process evaluation is limited in that it cannot provide evidence of 'impact' beyond the process stage. This could be somewhat addressed by incorporating an outcome evaluation that seeks to assess the effectiveness of a specific intervention by exploring measures that change, or not, over time before, during and after the implementation of the intervention (revalidation). This approach establishes correlations but struggles to establish causation between the intervention and the chosen outcome measure(s).

In terms of delivery of revalidation, a stepped wedge design is one proposed approach given its pragmatic design capable of addressing the need for robust scientific evaluation with political, ethical and logistical constraints that often accompany any intervention implementation of this scale. Over a series of time, one randomised cluster or group of clusters move from the control to the intervention until all identified clusters have been exposed to the intervention. Data collection is therefore continuous throughout the duration of exposure so each cluster presents observations under both control and intervention conditions. This design could be used in any of the three evaluative programmes. Given the unique opportunity Australia presents, this methodology should be given serious consideration if Australia wishes to inform the revalidation evidence base whilst simultaneously developing its own robust revalidation programme. The proposed evaluations would require further development once a model or hybrid model had been selected.

5. Conclusion

In conclusion, medical revalidation is a complex intervention that requires ongoing consideration, development and evaluation. The evidence reviewed indicates that

revalidation and its associated activities should be interactive, multi-dimensional and utilise a number of learning techniques that are both relevant and attractive to its users.The intended aims, purpose and criteria of revalidation need to be clearly articulated at an early stage of development to avoid unnecessary confusion and keep revalidation activities relevant to the intended outcomes. Appraisal, blended learning, patient complaints, CME/CPD and MSF are the most well supported revalidation activities in terms of developing both safe, and over, time better practise. Beyond this, a clear line of communication between all stakeholders involved is central to the successful development, implementation and evaluation of any such complex intervention and will help to ensure that a collaborative network united in the pursuit of a common goal i.e. revalidation is both developed and maintained. Model C is presented as potentially the most effective method of revalidation although the challenges of implementing this model fully in the Australian context are acknowledged. We conclude that an outcome evaluation using a step-wedged design to support implementation is likely to be the best approach to evaluation.

It is hoped that the evidence reviewed, principles identified and proposed revalidation models/evaluations provide a robust foundation for future revalidation discussions, policy developments and implementation in Australia.

1. Introduction

Historical registers have traditionally been used as an accepted form of medical regulation designed to safeguard patient care, the medical profession and its sub-specialties. However, following a recent shift in doctor-patient relationships and an increasing drive for accountability [1-3], medical regulation is beginning to explore the ongoing medical standards of these registers through a continuous evaluative process.

Although desirable, there remains a significant lack of unified agreement surrounding the appropriate design, form and definition of medical regulation. For the purpose of this report, revalidation and its associated activities will be used to refer to an ongoing evaluative process of medical regulation.

Following its mandatory implementation in the UK (2012[4]), emerging evidence suggests revalidation (a process designed to assess '*on a regular basis whether a doctor is up to date and fit to practice* [5]') and its related activities has the potential to encourage significant beneficial changes including enhanced medical care, physician competence and patient trust [6-13].

Although discussions surrounding the possible implementation of revalidation in Australia have been ongoing since at least 1999 [14], Australian medical regulation currently requires doctors to register with the MBA on the Register of Medical Practitioners and/or the Specialist Register depending on their qualifications and necessary fellowship/relationship with a Royal Australian College. During each period of registration (12 months) doctors are required to fulfil the MBA's continuing professional development (CPD) requirements, representing a traditional approach to medical regulation that is perhaps out of date in comparison to other well developed countries e.g. UK, Canada and the USA.

Although implementing revalidation has, and will likely continue to attract some criticism [15-17] as witnessed in other countries (e.g. USA [18] and the UK [19]), the potential benefits of such an approach for all communities involved are worthy of further exploration.

As a result, the Medical Board of Australia (MBA) alongside the Australian Health Practitioner Regulation Agency (AHPRA) has commissioned the Collaboration for the Advancement of Medical Education, Research and Assessment (CAMERA) at Plymouth

University Peninsula School of Medicine and Dentistry (UK) to explore the international processes and evidence base for revalidation to inform their own deliberations about the possible introduction of revalidation. The aim of this research is to therefore:

Research aim: understand the international processes and evidence base for revalidation activities in order to inform three suggested models of revalidation applicable to the Australian context.

The research objectives are to:

Research objectives:

- Establish the existing evidence base for the validity of revalidation or similar in countries that are comparable to Australia.
- Identify best practice and any gaps in current knowledge surrounding revalidation processes.
- Identify underlying principles that facilitate the effective implementation and development of revalidation.
- Develop three models of revalidation for consideration including their evaluation.

2. Background

Medical revalidation is a complex process built on the foundations of numerous components depending on the geographical and wider political landscape in which they reside. As a result, six research questions (RQs) and their accompanying methodologies were designed to provide a detailed picture of the current international revalidation landscape and its accompanying evidence base. It was hoped that this would provide a clear foundation for the development and possible implementation of revalidation in Australia.

Research Questions:

1. What are medical regulators doing in respect to revalidation/relicensing around the world?
2. What activities have been established within programmes to revalidate or relicense doctors internationally?
3. What evidence is there that these activities are effective or not in supporting safe practice?

4. What evidence has been established that combining these activities supports or not safe practice, professional standards, and community confidence?
5. Drawing on the evidence base what are the underlying principles for the implementation of revalidation and its activities?
6. What models could be developed and how could they be evaluated?

3. Methodology

This research adopts a mixed methods approach underpinned by a logical stepwise process designed to capture a number of related areas of interest. This will include a series of narrative literature reviews to provide an evidence base, the mapping of collected evidence to *Good Medical Practice: A code of conduct for Australian doctors (GMP)* to embed proposed models in the Australian context, the identification of underlying principles and use of Activity Theory to provide a theoretical underpinning for model evaluations.

In order to ensure that the evidence reviewed was likely to be relevant to the Australian context, we specifically focussed on countries perceived to be similar/comparable to Australia as identified by the United Nations Very High Human Development (VHHD) Country Programme (2013) [20] (Appendix 1). Australia is ranked 2nd out of 49 countries.

Conceptual framework:

The inter-related areas of research lend themselves to a logical stepwise approach that builds consecutively throughout the various work stages to present a 'thick' description of the activities involved in international regulation.

We have identified seven 'steps' outlined in Figure 1 designed to respond to each of the individual research questions identified and/or their related actions. From this we will be able to develop three potential revalidation models informed by an appropriate evidence base.

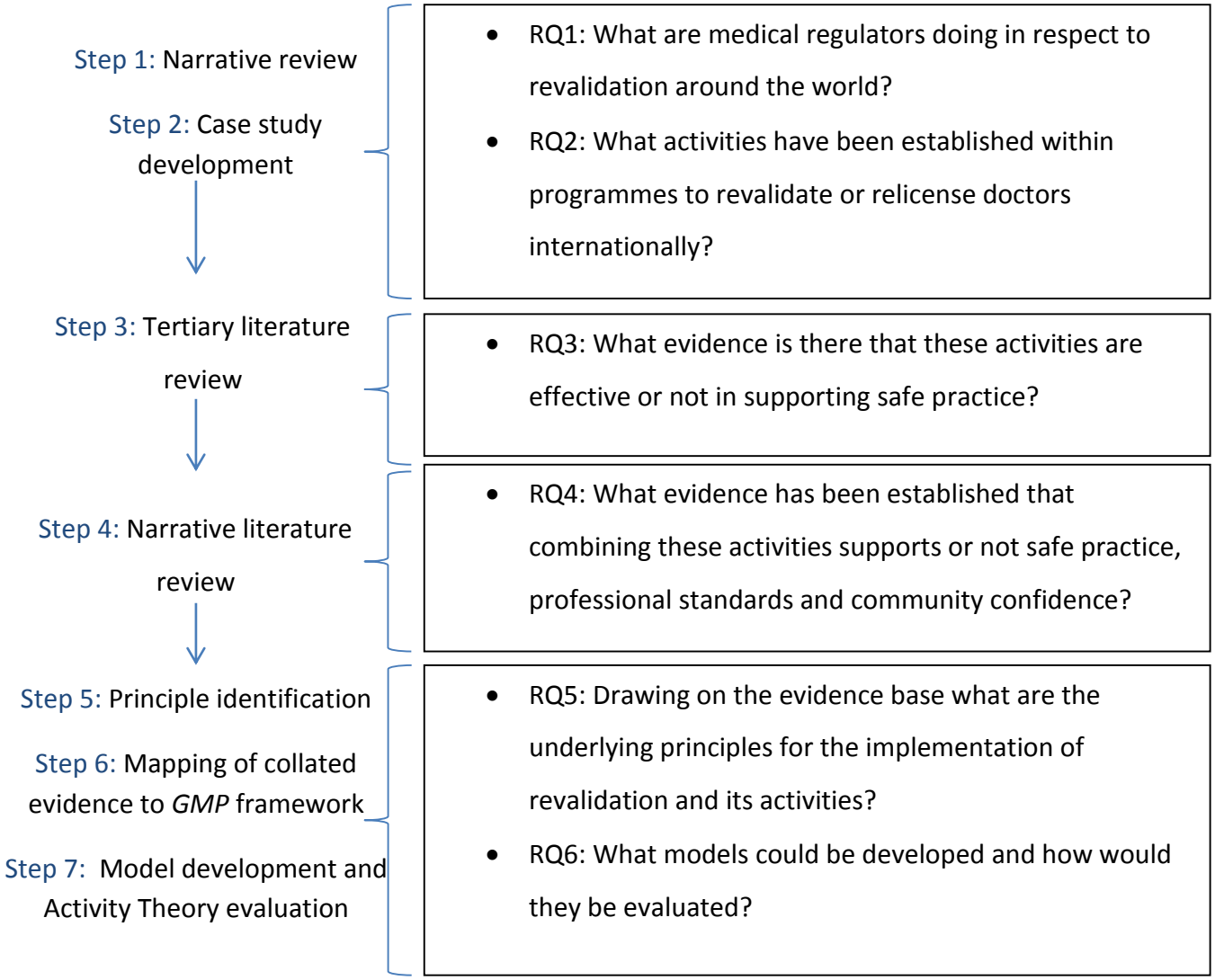


Figure 1: Stepwise approach corresponding to research questions identified and relevant actions

The final 'step' proposed in Figure 1 requires the identification of a potential evaluative model. Although there are numerous frameworks available, Activity Theory [21-23] was selected for the purpose of this research due to its acknowledgement of complexity, ability to collate numerous strands of evaluative research and accepted value in both policy implementation and evaluation[21, 23].

Activity theory (AT) is grounded in socio-cultural theory (the belief that an individual should not be seen as independent from its social and cultural environment) [22] and builds on the original work of Vygotsky[24]. Engeström[22] later developed an activity system framework (figure 2) built on the basis of five central principles (listed below) that represent the underlying structures and dynamics of activity [21, 25]:

- The unit of analysis is the activity as a whole e.g. revalidation
- *Multiple dialogues*- An activity involves populations of individuals and communities that interact and may express differing interests and opinions.
- Historicity - AT recognises that an activity system develops over time. The activities past such as previous policies/assessments need to be understood and incorporated into ongoing forms of analysis.
- Contradictions - AT recognises that possible tensions/contradictions may exist between components of the wider activity system. These can be used as opportunities for effective change and/or development[21].
- Expansive transformations - the activity in question may develop/change as a result of contradictions identified, analysis of the populations involved, and airing of differing interests/opinions over time.

AT therefore offers a conceptual framework that analyses the complexity of an activity as a whole, its interactive components, contradictions and related transformations over time. It positions both individuals and their respective communities as neither static nor independent but an important part of a wider interactive system leading to its accepted value in medical education and policy implementation/evaluation [21, 23].

Figure 2 provides a visual representation of an Activity Theory framework that shows the generic components of an activity system. The double sided arrows used in figure 2 demonstrate the dynamic relationships between the different components and it is by exploring these relationships both within (primary contradictions) and between (secondary contradictions) these components that the intended and unintended consequences of revalidation can be explored.

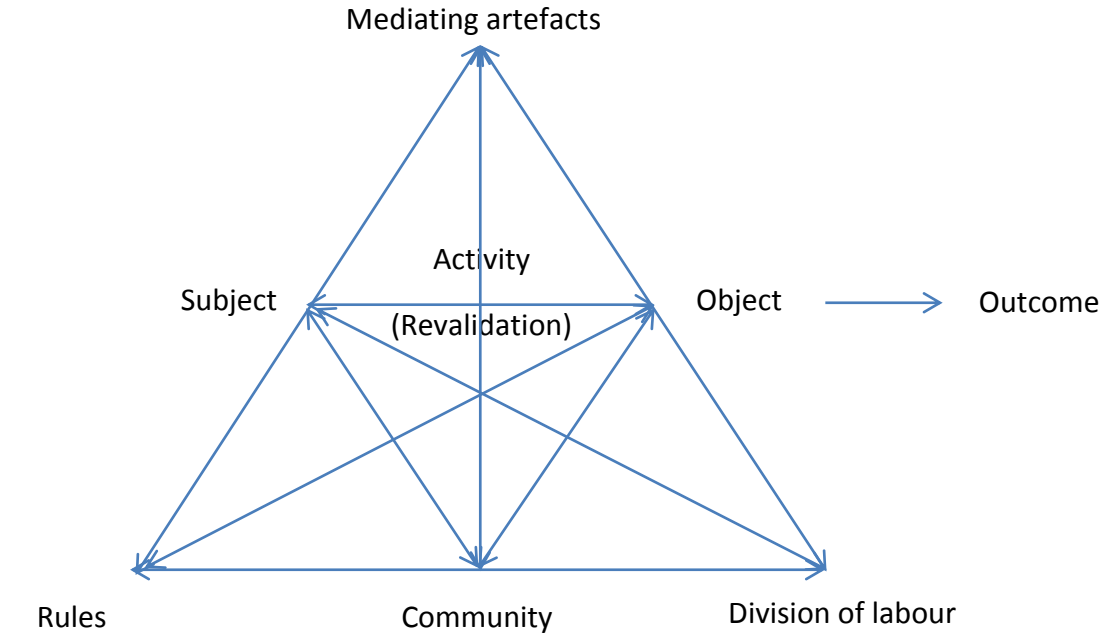


Figure 2 Activity theory model

The illustrative and dynamic nature of AT is particularly well suited for the purpose of this report and will help shape our academic approach, interpretation and evaluation. AT will also enable ourselves as researchers and the MBA to discuss the proposed revalidation models in a structured and transparent manner that may help facilitate future revalidation discussions given the developing nature of revalidation in Australia.

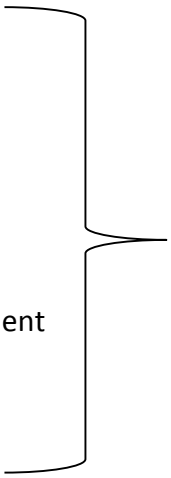
3.1 Methods

Step 1 - Narrative literature review (RQs 1 -2)

In order to address research questions (RQ) 1 & 2, electronic databases (PubMed, EMBASE, MEDLINE) and conventional search engines were explored to capture both published and grey literature - '*that which is produced on all level of governmental, academic, business and industry in print and electronic formats but which is not controlled by commercial publishers'* [26]. Key search terms (listed below) developed from previous literature searches were used in conjunction with each of the 49 VHHD countries.

Search terms used:

- Medical revalidation
- Medical relicensing
- Medical recertification
- Medical regulation
- Continuing Medical Education
- Continuing Professional Development
- Medical Chamber
- Medical Council



* And VHHD country

All 49 countries were researched in this way systematically progressing through the VHHD rank recording the presence of a medical regulation system, its related components (e.g. number of hours/CPD credits required) and regulation status (e.g. mandatory/voluntary).

Where an English translation was not available Google translate software was used. This was cross-checked with academic literature and other verified sources wherever possible to enhance levels of accuracy. Forward and ancestry searches were also used to further enrich the data collected.

Step 2 - Case study explorations.

Seven countries were selected for further exploration based on their close proximity to Australia in the VHHD programme (all within the top 22 VHHD countries); level of information available; and presence of differing/unique approaches to revalidation. These are presented as a series of in-depth case studies.

Case study countries:

- The UK
- Canada
- US
- Germany
- New Zealand
- Belgium
- The Netherlands

Step 3 - Tertiary literature review RQ3

Following this, in order to assess the evidence for effective revalidation activities, the most commonly used revalidation activities identified in steps 1 & 2 (CME/CPD, appraisal, review of patient complaints, clinical audit, feedback and eLearning/online CME/CPD) were used as key search terms to conduct a further tertiary review.

A tertiary review can be defined as a research method designed to explore literature that assembles information from a collection of both primary and secondary sources. Tertiary reviews offer a holistic way of capturing large amounts of information which can then be synthesised in the form of a narrative.

In order to produce a methodologically rigorous and insightful output, reviews should be systematic in their approach [27], focus on a single question (in this instance RQ 3), adhere to strict inclusion and exclusion criteria and pay close attention to issues of bias [28]. As a result, each revalidation activity and accompanying key word to identify levels of effectiveness (Table 1) were researched using the same databases and search engines previously discussed. Articles were selected on the basis of relevancy i.e. whether data would contribute to our understanding of the validity of revalidation and their adherence to the inclusion criteria outlined in Table 2. This criteria was used for all literature reviews conducted.

Table 1: Search terms used to conduct tertiary review

Revalidation Activity		Levels of effectiveness
CME/CPD		Medical performance
Appraisal		Clinical outcome
Review of patient complaints	*AND	Healthcare outcome
Clinical audit		Revalidation effectiveness
Feedback		Medical Impact
ELearning/Online CME/CPD		Patient care

Table 2: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Medical field only	Outside medicine
Published during and since 2005	Published prior to 2005
Comparable country to Australia	Language other than English
Written in the English Language	
Refers to medical doctors/specialists only	

Similar to step 1, forward and ancestry searches were used wherever deemed appropriate to further enrich the evidence collected. A random selection of 10% of articles were chosen and assessed/discussed by two members of the research team to ensure necessary levels of relevancy and applicability were achieved.

Step 4 - Narrative literature review RQ4

Step 4 explores '*what evidence has been established that combining 'revalidation activities' supports, or not, safe practice professional standards and community confidence?'* (RQ4) through a further narrative literature review.

The same search engines and databases were used as previously discussed. Search terms (listed below) were developed following the results of steps 1-3. The titles and abstracts of all identified papers were reviewed. Articles that fulfilled the inclusion criteria (Table 2) were included in the analysis. Articles that did not conform to the inclusion criteria were rejected helping to maintain the integrity and relevance of the review.

Search terms used in Step 4 narrative literature review:

- Online* CME/CPD
- E-learning*CME/CPD
- Self-directed learning*CME/CPD
- Audit*CME/CPD
- Feedback*CME/CPD

- Complaints*CME/CPD
- Appraisal*CME/CPD
- Peer review*CME/CPD

*And – e.g. Online and CME/CPD.

Step 5 - Principle identification/model development RQ 5

Principles that are believed to underpin both the development and effective implementation of revalidation were identified following the results of Steps 1-4. These principles alongside the collated evidence from steps 1-4 helped to inform the development of the three proposed revalidation models and their subsequent evaluation frameworks.

Step 6 - Mapping of collated evidence to Good Medical Practice: A code of conduct for Australian doctor's framework RQ6

The proposed models of assessment were then mapped against the *GMP* to embed them within the Australian context. This central document provided a form of 'curriculum' as all assessment, including medical regulation, should be blueprinted to an underlying framework/curriculum thereby helping to secure its content validity. The mapping of the proposed models to this framework was therefore a vital step in the research process to ensure sufficient levels of validity and relevancy were achieved.

Step 7 - Model development and evaluation RQ6

Each of the three models presented (Model A-C) varies in its intended purpose (formative, summative or mixed), number of activities used and target audience/groups. They are designed on the basis of the international evidence base of revalidation activities, their effective combinations, identification of underlying principles and outcome of the *GMP* mapping exercise. Three possible evaluation programmes (process evaluation, outcome evaluation, and trialist approaches) are proposed.

4. Results

Step 1: Narrative Literature Review

The results of step 1s narrative review demonstrates that despite global interest in the use of revalidation, there remains a significant lack of unified agreement surrounding the definition, mechanisms and appropriate designs of revalidation.

Despite an extensive search information was not available for Lichtenstein, Andorra, Chile, and Cuba. The results presented are therefore refined to 45 of the 49 VHHD countries. (A full report of step 1s findings can be found in Appendix 2).

The emerging evidence demonstrates that:

- All countries reviewed engage in some form of CME or CPD as a means of ongoing medical regulation.
- Few countries specifically refer to this process as 'revalidation' using other related terms such as relicensing or recertification.
- The vast majority of countries operate on a credit system with one credit typically equating to 1 hour of participation.
- 69% of countries reviewed engage in mandatory CME/CPD whilst the remaining 14 countries (31%) adopt a voluntary approach.
- The number of CME/CPD points required over a given period varies significantly between countries, e.g. Korea 12 annual hours vs. Switzerland's 80 annual hours.
- Most countries operate on a three or five year cycle with the majority requiring an average of 40-50 annual credits.
- Failure to comply with regulation requirements incurs varying penalties such as financial sanctions for medical directors depending on the country and relevant jurisdiction.
- Norway and Belgium are the only countries to offer a financial incentive for medical regulation engagement.

In summary, CME/CPD is the most frequently used method of medical regulation. The majority of countries reviewed adopt a mandatory approach incorporating a credit system that extends over a three or five year cycle typically requiring 40-50 annual credits. The intensity, mechanisms and design of these cycles differ substantially. This is further explored in the case studies below.

Step 2: Case study exploration

Each country studied offers a unique approach to revalidation including activities used, accreditation criteria and financial incentives. Below is a synopsis of the unique angles each country presents with full case study details available in Appendix 3.

United Kingdom

- Revalidation in the UK is unique in the sense that it is governed by a single body – the General Medical Council (GMC). Following its mandatory implementation in 2012 [4], revalidation operates on a five year cycle grounded in the GMC's *Good Medical Practice framework* [29]. Doctors are required to engage in five annual appraisals, demonstrate engagement in CME/CPD and accompanying activities whilst simultaneously developing a portfolio of supporting information (SI) populated by a multitude of sources. Six types of SI, including significant events and MSF feedback, are required to be presented at least once during each five year cycle. The SI itself is not submitted to the GMC for consideration.
- A recommendation is made to the GMC every fifth year by a 'responsible officer' (an appointed representative within each designated body typically the medical director or deputy) following the appraisal process. The GMC then make the final decision based on this recommendation.
- Revalidation and participation in its wider activities are therefore explicitly linked in the UK.

Canada

- Canadian regulation provides a number of unique approaches to revalidation including required levels of interactivity and specified target groups of revalidation.
- Participation in one of two existing CPD schemes (Maintenance of Certification [30] and/or the Maintenance of Proficiency [31]) is a mandatory requirement across all Canadian jurisdictions. The Maintenance of Certification [30] (MOC) governed by the Royal College of Physicians and Surgeons of Canada requires physicians to obtain a minimum of 40 annual credits leading to the collection of 400 credits over each five year cycle [32]. A recent update of the MOC programme sees the relevant MOC learning framework reduce the number of learning sections from six to three [32]. All Fellow and MOC participants are required to complete a minimum of 25 credits per cycle in each of the three new learning sections from the 1st of January 2014.
- CPD providers are also now required to incorporate a minimum level of 25% interactivity (activities beyond the traditional bums on seats CPD) within their CME/ CPD events to gain accreditation [33].

- Alternatively, the Maintenance of Proficiency [31] (Mainpro) scheme conducted by the College of Family Physicians of Canada requires physicians to attain a minimum of 250 Mainpro points during each five year cycle. Of these 250 points, at least 125 must be achieved through M1 (structured learning) or C points (accredited programmes). A maximum of 125 M2 points (Self-directed or non-accredited programmes) can be awarded representing a greater drive towards structured and accredited learning [31]. This approach is well supported in the literature [34]. In 2015 Mainpro is expected to become MAINPRO+ [35] with the addition of new reporting categories to earn credit for more practice activities and the development of a new smartphone application to enable efficient and accurate credit reporting.
- A further unique aspect of the Canadian revalidation system is the targeting of specific groups [36]. The College of Physicians and Surgeons of Ontario (CPSO) randomly select physicians under the age of 70 who have been in independent practice for at least five years to undergo peer assessment. All physicians over the age of 70 are subjected to a peer assessment every five years [36]. This is as a result of increasing evidence to suggest that a physicians' quality of care declines as their years in practice increase [37].

New Zealand

- New Zealand is unique in the sense that it incorporates CME under the umbrella term of CPD, most countries use these terms interchangeably. It adopts a dual approach to recertification and outlines a minimum number of peer-review hours and clinical audits as part of their revalidation criteria.
- Following the Health Practitioners Competence Assurance Act [38], all New Zealand doctors most hold a current practising certificate issued on an annual basis by the Medical Council of New Zealand (MCNZ). This will only be awarded following active participation in either the vocational or general scope pathway.
- Vocational scope recertification applies to registered specialists including GPs. Specialist recertification programmes are coordinated by respective Branch Advisory Bodies (VEAB) such as the New Zealand National Committee, Australian and New Zealand College of Anaesthesia, and Royal Australian and New Zealand College of Radiologists. Alternatively, general scope recertification is for non-specialist doctors

not in a vocational training programme and/or new registrants such as international medical graduates (IMGs). Recertification for general scope doctors can be achieved by participating in either *inpractice* a recertification programme conducted by bpac[nz] [39], or through a recertification programme provided by an accredited provider.

- Similar to the UK, both recertification pathways and their accompanying CPD schemes conform to the Council's *Good Medical Practice* guide [40], indicating that a physician's mandatory CPD should cover 5 main domains of medical practice leading to the obtainment of 50 annual CPD hours amongst other related activities. CPD and recertification are also explicitly linked in New Zealand.

USA

- The United States adoption of a high-stakes examination as a form of medical regulation remains both unique and controversial [41].
- In order to obtain an initial state medical license, doctors must pass a medical licensure examination such as the United States Medical licensing Examination (USMLE). In order to evaluate the ongoing competencies of licensed/previously licensed physicians a post licensure assessment is also in operation. This is extended to those who passed their initial licensing exams some years ago (e.g. special purpose examination provided by the Federation of State Medical Boards).
- Whilst the obtainment of a state medical license is mandatory, board certification (speciality specific) remains a voluntary process. Despite this, most primary care physicians and specialists (approximately 80-85% [42]) choose to certify with one of twenty-four American Board of Medical Speciality (ABMS) member boards following their vocational training [41]. In 2002 all 24 ABMS's agreed on comparable standards for board certification and recertification including a new evaluation of performance referred to as the ABMS Programme for Maintenance of Certification (MOC).
- However, there is an argument that current licensure renewal systems remains an 'administrative function' [43] driven by financial incentives. This concern and others raised by the Institute of Medicine (IOM) [44] are being addressed by the Federation of State Medical Boards (FSMB) (a non-profit organisation who represent the nation's 70 medical boards and collaborating organisations [45]). The FSMB wishes to incorporate a new Maintenance of Licensure (MOL) framework that would

replace the current system. This is not expected to emerge in the US for several years [46].

- The majority of SMBs require doctors to participate in 20-50 hours of CME on an annual basis with all SMBs requiring CME activities to be accredited by a legitimate organisation. The Accreditation Council for Continuing Medical Education and the American Medical Association are the two main CME accreditors for the US, both of which have strict quality assurance processes.

Germany

- In order to practise medicine or undertake specialist training, all German physicians must be in possession of a full (Approbation - which is valid across the country for an unlimited time frame) or temporary licence (Berufserlaubnis - restricted to the federal state it was issued and limited to a certain time period) issued by the state health authorities (Oberste Landesgesundheitsbehörden) of the respective state (Land).Once this has been obtained, physicians must also become a member of one of the seventeen state chambers of physicians (Landesärztekammer). Each regional chamber, which operates below the German Medical Association, approves their own CME/CPD programmes and accompanying activities. However, German CME/CPD systems remain fairly homogenous due to a regulatory framework provided by the Bundesärtzekammer (The German Medical Association) [47] .
- All physicians (except purely private physicians, where it remains voluntary) are required to fulfil CME/CPD requirements outlined by the Bundesärtzekammer over a five year cycle, acquiring a total of 250 CME points [48] across 7 categories [49] with one point typically equating to 45 minutes [50]. Specialists are required to undertake approximately 70% of their CME points in their speciality related subjects [48] offering a unique approach to revalidation. Radiologists who read mammograms are subject to additional recertification procedures.
- Germany also appears unique in their approach to medical regulation through the introduction of a barcode system. Each practising physician is given an individual 15 digit uniform CME/CPD number, identification card and set of personal barcode stickers which are then scanned following their attendance at CME/CPD events. The relevant points are then added onto their online account reducing the amount of

time needed for physicians to complete necessary paper work and potential opportunities for undesirable self-reporting bias. Each region except Baden Wurttemberg have designed a computer based registration system to facilitate this process [48].

- If an individual's CME/CPD certificate is not achieved within two years after the stated due date, accreditation can be withdrawn [48]. Similarly, medical directors face strict financial sanctions [51] if an individual fails to comply with CME/CPD requirements.
- Germany therefore provides a differing approach to revalidation including the difference in credit values (1 credit equates to 45 minutes), use of a unique barcode system, a specified percentage of specialist related CME/CPD (70%) and strict financial sanctions for medical directors following CME/CPD non-engagement.

Netherlands

- The Dutch Ministry of Public Health is responsible for the administration of medical licenses in the Netherlands [52]. In contrast to the single governed UK revalidation process, the Netherlands are coordinated by the Medical Specialist Registration Committee of the KNMG (Royal Dutch Medical Association), an umbrella organisation comprising of three registration committees (one for clinical specialists, GPs and social medicine) that have combined to create a unified agreement surrounding common requirements for registration and reregistration [53].
- In order to re-register, specialists must demonstrate on a five year cycle that they have performed a minimum of 16 hours per week in their speciality, undertaken at least 40 hours of CME a year, taken part in at least two hours of peer review every year [54] and engaged in practice audit [55]. The minimum requirement of 16 speciality related consultation/practice hours represents a unique requirement of medical revalidation.
- If doctors fail to comply with the CME/CPD criteria, it is possible for professional societies to re-register doctors for a shorter period of time e.g. one year during which the doctor is expected to complete the outstanding CME/CPD hours/credits [53]. This process is not a common feature amongst other countries reviewed.

Belgium

- Despite Belgian legislation stating that both GPs and specialists must maintain clinical competence, participation in CME/CPD programmes remains voluntary. There is therefore no system currently in place to check the professional competency of practicing physicians in Belgium [56].
- The formal CME/CPD programme was first introduced in 1994 by the central National Institute for Health and Disability insurance (INAMI/RIZIV) which continues to oversee all CME/CPD regulation. Doctors initially obtain their licence to practice from the Minister of Public Health. In order to receive further accreditation doctors must apply to the INAMI/RIZIV. Following this physicians must obtain 60 CME credits over a three year cycle (1 CME point is typically given for every hour of participation), participate in at least two peer reviews a year, and undertake at least 500 consultations a year [48, 51] to renew accreditation. There are currently 11 types of CME activities e.g. workshops, events, acting as a moderator or speaker at a CME event recognised by the GDA (Groupe de Direction l'Accreditation – a steering group responsible for CME accreditation).
- Doctors are generally free to choose which CME activities they attend but must undertake at least three credit points per year involving ethics and economics and participate in at least two medical evaluation (peer review) group meetings a year undertaken by Groupement Local d'Evaluation Medicales (GLEMs).
- Physicians are rewarded for participating in revalidation through financial incentives. Physicians can increase their earning potential/salary by around 4% [57] providing a possible explanation behind the relatively high participation rate of 80% despite revalidation being a voluntary option [56].
- Belgium therefore represents several unique approaches to revalidation including the use of a financial incentive and directed CME/CPD.

Revalidation across the globe

Table 3 provides a visual summary of the revalidation activities used in the case studies discussed.

CME/CPD appears to be the most frequently utilised method of medical regulation operating at varying degrees of intensity and duration. The majority of countries engage in

peer review and/or practice review with all countries recognising eLearning/distance learning. Some countries outline a minimum requirement for physical consultations/practice hours as part of their revalidation requirements. Few countries make a conscious effort to systematically review patient complaints. Only one country reviewed in the case study development offers a financial incentive for revalidation engagement.

Table 3: Revalidation across the globe

	UK*	Canada**	New*** Zealand	USA****	Germany*****	Netherlands******	Belgium*******
Mandatory CPD/CME	Yes - 250/5	Yes – MOC 400/4, MAINPRO 250/5 - at least 125 M1/C points up to 125 M2.	Yes – Vocational/ general scope 250/5	Yes – 62/68 SMBs 1-4 year cycles, 20-50/1	Yes – 250/5	Yes – 40/1	No – voluntary 60/3, financial incentive
Recognised distance/eLearning	X	X	X	X	X	X	X
Clinical audit/practice review	X	X	X – 1 per year	X		X	unclear
Review of complaints	X	X					
MSF	X	X		X			
Physician self-achievement	X	X		X	X	X	
Peer review		X	X-minimum of 10 hours per year		X	X – minimum of two peer reviews per year	X – minimum of two peer reviews per year
Minimum number of consultations/ practice hours						X – 16 hours in their speciality	X – 500 consultations

*UK – governed by a single body – the GMC

** Canada –targeted revalidation groups: older physicians (70+) and those in independent practice for at least five years

*** New Zealand – specify minimum number of practice hours. Separate CME and CPD as separate entities.

**** USA –use of high stakes assessment (pass/fail examination).

***** Germany – unique barcode system

****** Netherlands –minimum number of speciality related practice/consultation hours on a weekly basis

******* Belgium – requires participation in ethical and economic related CME events, offers financial incentive.

Step 3: tertiary review of revalidation activities

Despite the relatively new development of 'revalidation', its individual activities (e.g. CME/CPD, appraisal, MSF) are well supported. The following section discusses the evidence base for the most commonly used revalidation activities identified.

4.2. CME/CPD

As already established, CME/CPD is the most commonly used method of ongoing medical regulation. Whilst the evidence is not unanimous [58] with less evidence directly linking CME/CPD to improved clinical outcomes [6-8], the vast majority of evidence illustrates CME/CPD as an effective form of medical revalidation [6-13] capable of encouraging long-term changes [8, 9, 11] in physician attributes [6-8, 10, 11, 13] including:

- Physician knowledge
- Attitudes
- Skills – both surgical and non-technical
- Communication
- Practice behaviour and
- A reduction in care related complaints

For example, evidence shows that physicians who participate in accredited CME/CPD are significantly less likely to receive quality and/or care related complaints [13]. Whilst this study is restricted to a Canadian sample with the potential bias of social desirability, the study clearly demonstrates a positive relationship between participation in accredited CME/CPD activities and level of care provided [13].

This relationship can be further enhanced if the delivery, content and target of CME/CPD are also considered. These are discussed below.

4.2.1 CME/CPD delivery

Interactive CME/CPD is considered 'critical' in effective CME/CPD delivery [6, 7, 10-12]. Interactive activities including case based learning or facilitated feedback have been shown to have a greater effect size (r=0.33) on physician outcomes [7] in comparison to traditional passive methods (r = 0.30) [6, 7, 12]. Despite this, passive/didactic techniques (e.g. lectures) remain the most frequently implemented form of CME/CPD [12].

Repetitive exposures can also enhance the effectiveness of CME/CPD activities with repetitive exposures shown to be superior to single interventions [6-11, 58]. Some researchers conclude *that 'multiple exposure to information in any educational activity is necessary to affect clinical outcomes and performance*' [58] accentuating the importance of such an approach.

Similarly, activities that are delivered using multiple and/or 'live' media are more desirable [10]. Numerous reviews conclude that traditional print materials (e.g. lectures) should not be used in isolation [9-11], a more dynamic CME/CPD delivery is required.

The evidence therefore suggests that CME/CPD activities that are interactive, multi-dimensional and operate over a series of exposures are both more desirable and effective.

4.2.2 CME/CPD online delivery

Online/eLearning CME/CPD has been shown to be equally, if not more effective than live CME/CPD in terms of improved physician knowledge, levels of satisfaction, skill competence and clinical decision making [11, 59-65].

There is a strong body of research detailing numerous advantages attributed to online CME/CPD [59, 62] including:

- Improved accessibility
- Reduced travel expenses
- Easy dissemination of up to date information
- Inclusion/applicability to multiple learning styles
- Use of interactive formats
- Convenience
- Ease of access and use

In order to demonstrate the effectiveness of online CME/CPD recent research concludes that there is an increased likelihood of 48% that physicians (8,550) participating in online CME/CPD make clinically informed decisions based on the information they have learnt [61].

However, the content of online CME/CPD needs to be carefully considered. Physicians are more likely to accept and effectively engage in online CME/CPD if the activity provides: a

perceived advantage over other available alternatives; is easy to use; and is compatible with their values and norms [63]. Features that are perceived as particularly useful by physicians include assessment linkage, consistently high content quality, convenience, ease of access and ease of use [63]. Wong et al., (2010) have provided a preliminary set of questions and aids to facilitate the development of effective online CME/CPD based on this criteria [63].

4.2.3 CME/CPD target

Consideration of the target audience is also required to enhance CME/CPD outcomes. A recent meta-analysis concludes that CME activities are most effective when designed for a small group of physicians within the same discipline [7]. Numerous researchers propose that this is as a result of CME/CPD being considered as important and therefore valued by physicians [8].

Support for this conclusion stems from a recent study conducted in Ireland [66]. CME for Irish GPs is delivered in small groups (typically 8-12) by a national team of 37 tutors. Groups meet up to eight times a year to discuss cases, reflect on evidence presented and evaluate how CME may affect their practice. Results indicate that 86.3% of doctors agreed CME had positively impacted their knowledge, skills, attitudes, and application of guidelines[66]. 91.1% of doctors provided specific examples of evidential impact to support this conclusion. Targeted CME/CPD interventions can therefore offer enhanced learning outcomes [6, 8] across a variety of domains.

Similarly, support for targeted CME/CPD stems from evidence reporting an inverse relationship between knowledge and number of years since certification/registration [11, 34, 37, 67, 68]. One review demonstrates that 62 out of 63 studies reviewed saw a decline in physician performance over time [37]. More recently, the result of US recertification examinations found significantly higher failure rates for physicians more than 30 years out of training in comparison to their more recently trained colleagues [67]. Similar results have also been reported for doctors working in isolated practice [67] providing strong support for Ontario's approach to targeting older physicians (70+) and those in private (independent) practice.

4.3 Self-directed learning

A problematic area of CME/CPD is the central position of self-directed learning [6, 69]. Most CME/CPD activities assume physicians are able to accurately determine their own learning needs [69]. However, this assumption is not well supported by the literature [69, 70], with less skilled and over confident physicians identified as particularly high risk [70, 71].

Several researchers have therefore called for the adoption of an external assessment approach [9, 70] or facilitated decision making process that extends beyond the reliance of a physician's ability to identify their own learning needs.

4.4 Audit and feedback

Clinical audit and feedback have both been shown to be effective in changing physician care and patient outcomes [6, 12], although this conclusion is not unanimous [72, 73].

Several researchers argue the ambiguity in published research is as a result of organisational failings [73-75] - the most commonly cited source of ineffective implementation. The most common barriers identified are:

- Poor management
- Lack of audit/organizational support
- Excessive workload and
- Time constraints

However, when such issues are addressed, clinical audits have been shown to be effective particularly when: health professionals are not performing well to begin with; the audit includes clear targets and an action plan; the audit is effectively facilitated by the relevant organisation and conducted by a respected and/or familiar supervisor/colleague with relevant knowledge [73].

Audit therefore has the potential to be a beneficial form of medical regulation providing organisational support and sufficient resources are in place. It remains unclear whether clinical audit is more effective when combined with other interventions [73]. This is a common gap in the revalidation literature.

4.5 Multi Source Feedback (MSF)

MSF has been shown to encourage significant improvements across a range of domains including clinical competence, skills and communication [76, 77].

A systematic review identifies the presentation of MSF feedback as the most influential factor surrounding MSF acceptance [76]. More specifically, higher levels of behaviour change are achieved if feedback is facilitated e.g. through appraisal and accompanied with narrative comments [78]. There is evidence to suggest facilitated feedback influences how a physician responds to their feedback, the level of reflection achieved, and handling of negative comments, all of which have been shown to significantly influence the level of change achieved [76, 79].

However, caution should be aired regarding the credibility of the feedback source and potential feedback bias[76]. Research reveals that MSF is most effective when feedback is presented from a source the physician deems to be credible, knowledgeable, and familiar with their work [76]. Research also indicates that personal characteristics and feedback context can affect a physician's feedback score [80]. For example, white ethnic patients over the age of 40 who rate the reason for visiting their doctor as 'very important' are more likely to provide a favourable assessment. Similarly, colleagues from non-medical professional groups who have more contact with the doctor in question are also more likely to provide favourable feedback [80].

It is therefore advisable not to utilise patient and colleague feedback as a standalone measure of physician's performance [80], a notion strongly supported by the GMC in the UK [81].

Despite this, several systematic reviews conclude that MSF demonstrates high reliability, validity and feasibility [82, 83] capable of assessing non-technical competencies such as communication, interpersonal skills, collegiality, humanism and professionalism [83].

Research suggests MSF instruments must be completed by a minimum of 8 medical colleagues, 8 co-workers and 25 patients to achieve adequate reliability and generalizability (coefficients of $\alpha \geqslant 0.90$ and $Ep2 \geqslant 0.80$, respectively) [82, 83] although some contradiction arises surrounding the minimum number of patient questionnaires required to achieve sufficient validity with suggested numbers ranging from 23 [83] to 34 [80, 84]. This is a further gap identified in current research.

4.6 Appraisal

The NHS Institute for Innovation and Improvement in the UK [85] states that appraisals are the single most important activity to encourage change in physician performance, supporting previous conclusions about the role of appraisals in reducing patient mortality [86].

One key piece of literature concludes that out of several management processes, having an appraisal system in place was found to have the strongest effect on healthcare outcomes [85]. The research concludes that appraising 20% more staff and training 20% new appraisers would result in 1,090 fewer deaths per 100,000 admissions posing significant beneficial outcomes [85].

Appraisals have also been shown to increase motivation scores across several areas including, career development, job satisfaction and commitment [87], highlighting further beneficial outcomes. Such research provides strong evidence for the adoption of appraisal as a form of medical regulation.

4.7 Review of Complaints

Patient satisfaction is often described as a complex phenomenon [88]. However, complaints can be used to accurately identify physicians at increased risk providing an important driver in patient safety [89]. Despite this, many organisations do not appear to utilise patient complaints to their full potential [90].

Research demonstrates that physician related patient complaints are associated with subsequent malpractice risk [89]. A regression analysis shows that physicians in the lowest predicted risk group (49%) averaged fewer than five unsolicited complaints during a six year period. In contrast, 8% of physicians in the highest predicted risk scored on average more than ten times this number [89].

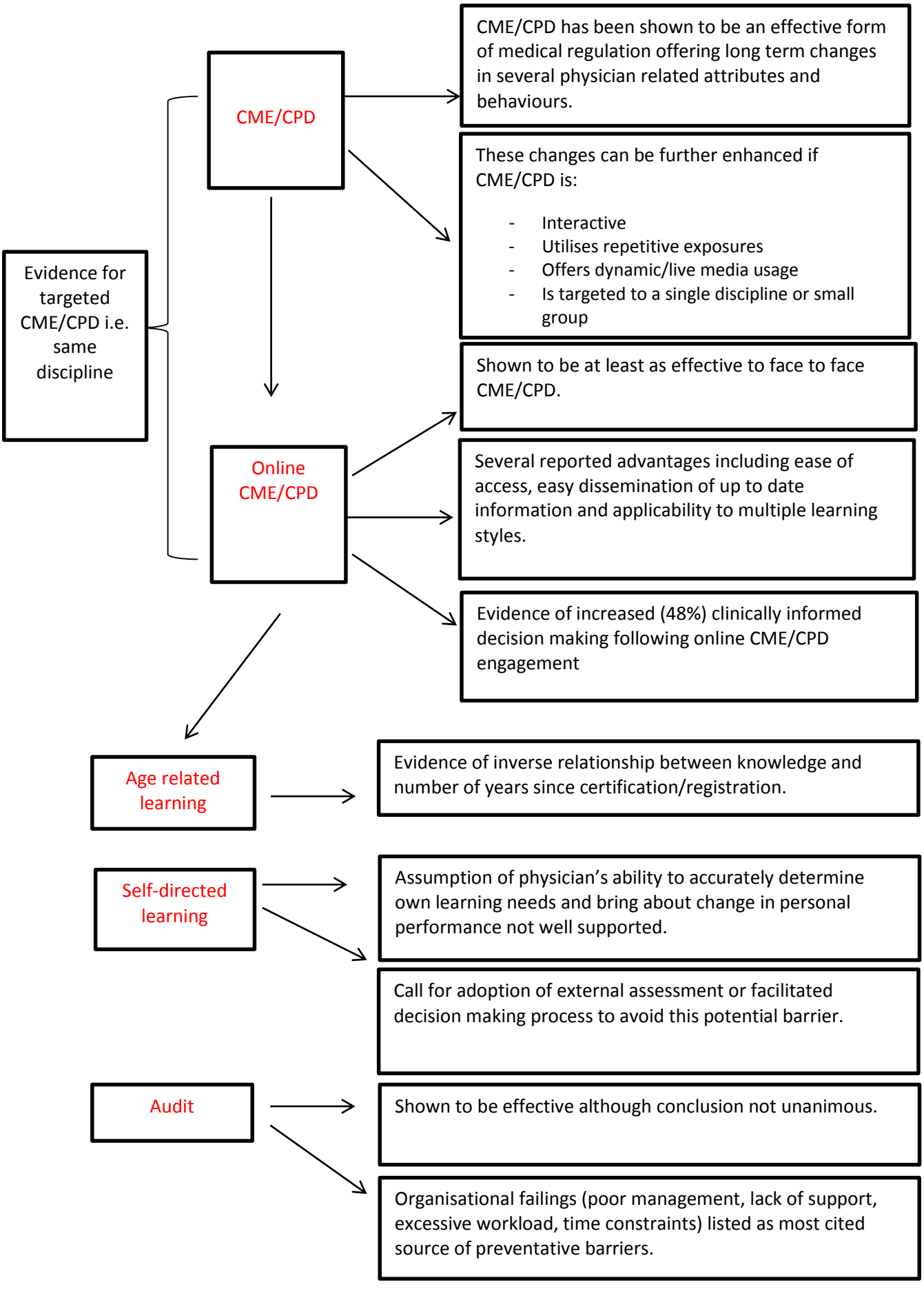
From a financial perspective (risk management related expenses) in one study the 49% low risk physicians were responsible for 4% of complaint related expenses. In contrast, the 8% of high risk physicians were solely responsible for 50% of expenses, leading to an average pay out 73 times greater than their low risk physician colleagues [91]. These findings have been replicated in other physician communities [92] including the Australian culture [93, 94] demonstrating generalisability.

Bismark and colleagues in an analysis of 18,907 complaints filed against doctors in Australia over an 11 year period demonstrated that 3% of Australia's medical professions accounted for nearly half (49%) of all related complaints whilst 1% accounted for a quarter of complaints [93]. The researchers conclude that it is feasible to predict which doctors are at 'high risk' of receiving multiple complaints in the near future [93, 94] mirroring the conclusion that the relationship between malpractice risk and patient complaints provides a strong foundation for alerting 'at risk' physicians who may benefit from targeted CME activities or further interventions [89, 91, 92].

Furthermore, in order for behaviour change to occur, feedback must be evidence based, contain comparable data, and be repeated over time [89]. Patient complaints' meets many of these requirements including evidence based and comparable data. A review of patient complaints can therefore provide a powerful tool for identifying 'at risk' physicians and facilitate behaviour change [89]. However, in order to maximise their potential, organisations and physicians alike must value and support patient involvement [95].

Summary of Step 3 findings

Figure 3 provides a visual summary of the key review findings reported.


Evidence for targeted CME/CPD i.e. same discipline
CME/CPD
CME/CPD has been shown to be an effective form of medical regulation offering long term changes in several physician related attributes and behaviours.
These changes can be further enhanced if CME/CPD is:
- Interactive
- Utilises repetitive exposures
- Offers dynamic/live media usage
- Is targeted to a single discipline or small group
Online CME/CPD
Shown to be at least as effective to face to face CME/CPD.
Several reported advantages including ease of access, easy dissemination of up to date information and applicability to multiple learning styles.
Evidence of increased (48%) clinically informed decision making following online CME/CPD engagement
Age related learning
Evidence of inverse relationship between knowledge and number of years since certification/registration.
Self-directed learning
Assumption of physician's ability to accurately determine own learning needs and bring about change in personal performance not well supported.
Call for adoption of external assessment or facilitated decision making process to avoid this potential barrier.
Audit
Shown to be effective although conclusion not unanimous.
Organisational failings (poor management, lack of support, excessive workload, time constraints) listed as most cited source of preventative barriers.

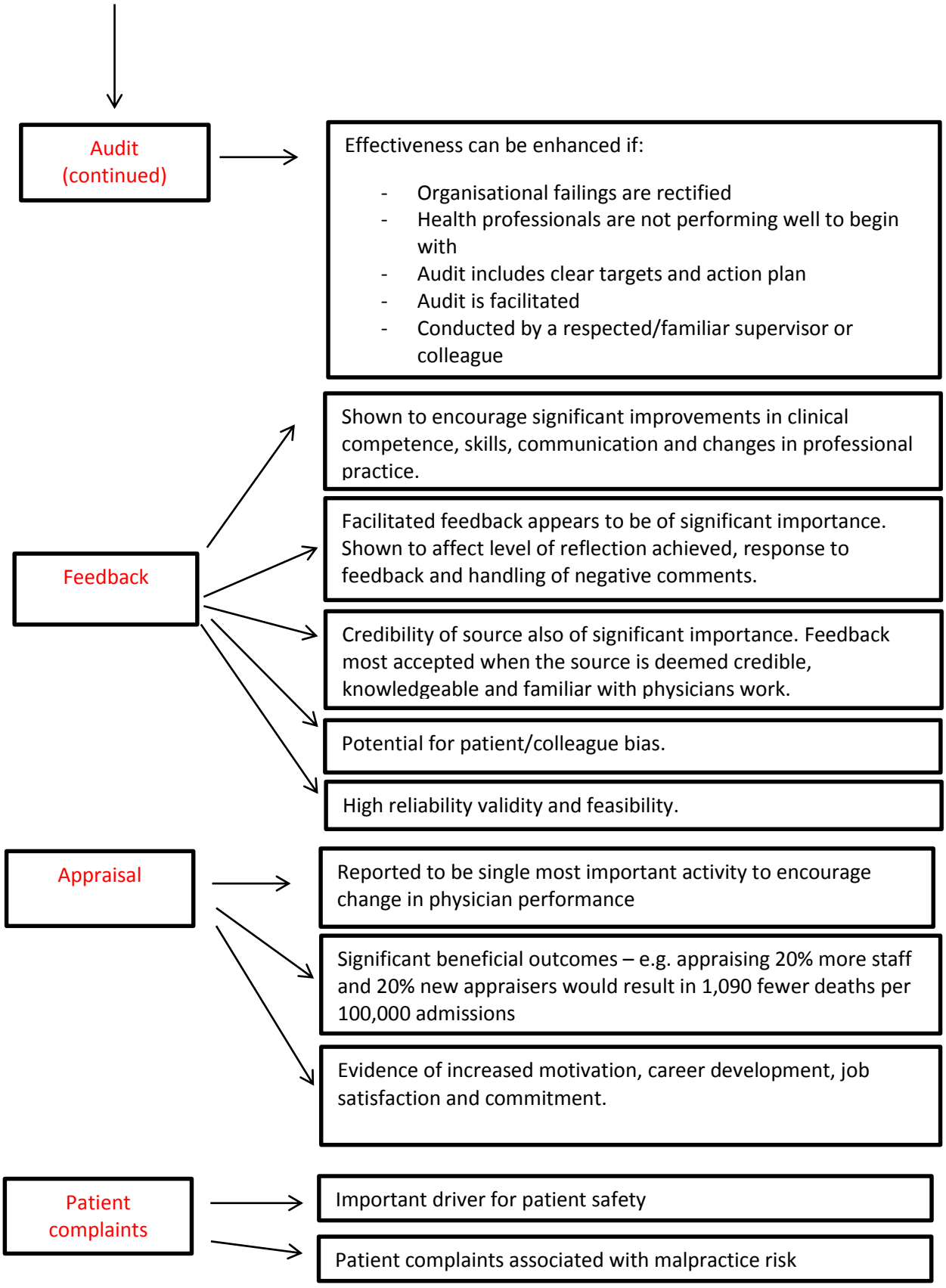


Figure 3: Summary of tertiary review findings.

In summary, there is strong evidence to support the individual components of revalidation with varying degrees of intensity. Interactive CME/CPD, clinical audit, appraisal, review of patient complaints and multi-source feedback appear to have the best supporting evidence for achieving positive change in physician behaviour. These effects can be enhanced if organisational support, interactivity, targeted interventions, repetitive exposures and a multi-dimensional approach are present. Links beyond this to any direct impact on patient outcomes, including patient safety, are lacking in the literature but these will always be hard to achieve.

Step 4: Narrative literature review (RQ4)

In order to establish existing evidence surrounding the effective combination of revalidation activities a further literature review was conducted. Using the research terms previously reported a total of 3892 articles were identified. Forty articles were selected based on their compliance to the inclusion criteria and relevance.

In line with logical thinking and principles of adult learning theory [9], there is strong evidence to suggest using a multitude of educational techniques can be highly beneficial in terms of fostering safe practice, driving professional standards and enhancing community confidence [6-9, 11, 12, 58, 96, 97].

Evidence demonstrates that techniques typically low in levels of efficacy (e.g. 'live' didactic lectures) can be enhanced when used in conjunction with more interactive means of education [9, 12]. Multiple educational techniques have also been shown to exceed levels of efficiency than either activity could achieve in isolation. Following this, researchers have called for the development of a common understanding that no singular approach to medical regulation works best under all circumstances [98]. Creativity and diversity is therefore required.

As a result, the literature has recently begun to explore the effectiveness of combining traditional face to face CME/CPD with facilitated online opportunities (blended learning) [97, 99-107]. 'Blended learning' can be defined as a hybrid model where traditional and more modern methods of teaching (typically electronic methods) are combined [101]. Whilst effective 'blending' may be difficult to achieve during the initial stages of development, results indicate a strong level of success [101-105, 107] with over 90% of

participants in one study reporting some level of improvement following the completion of a blended learning course [102]. Similar levels of success have also been achieved in an Australian nursing sample [105].

For example, following the completion of a breast cancer trainee workshop in 2010, some Australian participants were subjected to an additional online spaced education (SE) intervention. Participants received three case scenarios and accompanying questions by email every 2 days. If participants answered the questions correctly, the questions were recirculated over a 20 day period until 80% of the questions had been answered correctly on two consecutive occasions. Evidence revealed that SE participants performed significantly better than the control group [105], with 92% of participants agreeing that SE would improve their practice and a further 96% reporting that SE had effectively reinforced key components of the workshop [105].

Similar results have been replicated in other countries including the US where 97% of individuals asked to participate in future SE supplements [107]. Blended learning has therefore been repeatedly shown to be both an effective and attractive form of learning with demonstrated abilities to enhance knowledge retention and significantly alter clinical behaviours and intentions [102, 105, 107].

Although some researchers argue older physicians will not engage in this form of teaching[102], a study examining a wide age range of doctors concluded that doctors are willing to take part in such an approach if a course is deemed to be relevant irrespective of their age [102]. In this cohort, 70% had never undertaken any form of distance learning and 89% had never undertaken an online interactive course. Despite this, all participants showed an improvement across all measured categories including patient [102].

However, blended learning is not without its potential problems. For example, feelings of isolation can be common when using online media [108, 109]. Despite this, email tools, online chat forums, and occasional face to face sessions can be used to help to overcome these concerns [102, 109, 110] warranting its potential adoption in medical regulation/education [102-104].

This conclusion is further supported when reviewing the learning preferences of Australian doctors. In 2012 a stratified sample of 2500 GPs provided a valuable snapshot of the current learning preferences of Australian GPs [97]. Evidence reveals most GPs (95%) preferred learning in a group setting, 83% preferred face to face lecture based formats, 70% preferred interactive group discussions and 55% preferred online self-education [97]. Traditional face to face lecture formats therefore remain preferential within the Australian medical culture despite strong evidence to suggest this is the least effective form of medical education [7]. However, blended learning has the capacity to potentially encompass all of the Australian preferences identified in an effective manner.

Traditional 'live' CME events could be facilitated using online follow ups (e.g. spaced education) incorporating the vast majority of Australian preferences (e.g. interactive group discussions, face to face lecture based formats and online self-education). This would in turn help to bridge the current gap between evidence and practice [97] whilst simultaneously providing a well-supported form of learning that is both engaging and effective.

In conclusion, there is strong evidence surrounding the importance of utilising multiple educational techniques. More specifically, there is evidence provided from a multitude of populations to suggest that this is most effectively achieved through the adoption of blended learning. These conclusions strongly resonate in the Australian context and the current learning preferences of their medical professionals. More research is needed to identify which aspects of the educational techniques and types of combinations are most effective for regulatory purposes as these conclusions are currently absent in the revalidation literature.

Step 5: Principle identification

Stemming from the extensive literature reviews conducted in steps 1-4, we have identified the following underlying principles involved in both the development and continuing implementation of revalidation:

1. Clarity of purpose
2. Facilitation
3. Consideration of target groups
4. Resource provision

5. Adoption of a multi-dimensional and quality controlled approach
6. Patients and the public as the focus

These principles should not be viewed as independent or exclusive but as a collaborative network working towards a common goal i.e. revalidation. This is demonstrated in Figure 4.

Figure 4 Identified revalidation principle network

Clarity of purpose: A central principle for the successful implementation of any new policy initiative is clarity of purpose. It is of vital importance for medical regulators to clearly articulate what the purpose, drivers, and definition of revalidation implementation are. It is also of equal importance to consider who revalidation will target and who it will benefit.

Medical regulators and consumers alike therefore need to understand whether revalidation will act as a purely formative (to support individual learning), summative (minimum standards of performance) or mixed method form of assessment. Furthermore, medical education experts have argued in any mixed approach that there should be a 'firewalling' of regulatory procedures from developmental processes [111]. This is so that

regulatory/summative decisions do not undermine the prospect of learning from the formative components [111].

Explicitly stating the reasons and intended purposes behind the introduction of revalidation will eliminate some of the potential reluctance to engage in such an approach witnessed in other countries that failed to clearly do this e.g. the UK [112]. It will also enable organisations/communities (e.g. MBA, AHPRA, Royal Australian Colleges, lay representatives) to engage in valuable discussions surrounding how they can contribute to the desired goal of revalidation leading to the second identified principle of facilitation.

Facilitation: As concluded in our previous reviews, it is clear that physicians and members of the public alike do not learn or change their behaviour based on evidence simply presented to them [113]. For example, it is widely understood that smoking is detrimental to your health. However people continue to smoke. As a result, smoking cessation programmes use facilitation of data through mentoring and coaching to effectively bring about change and then maintain it [114]. Any model that seeks to bring about performance change (and not simply regulatory/summative decisions) would therefore greatly benefit from a facilitated approach through activities such as regular performance review procedures, appraisals, mentoring, facilitated feedback etc.

Consideration of target groups: Some countries choose to target certain groups of identified 'high risk' doctors (i.e. 70+, working in independent practice for 5 years or more or having previous complaints/identified issues). Evidence reveals that physicians practicing 30 years post certification perform significantly worse than their more recently qualified colleagues [67]. Given the data provided by the Health Workforce Australia, it takes on average 7 years to gain full medical registration with the Medical Board of Australia following the satisfactory completion of an intern year [115] (it is acknowledged that course lengths vary between 4 – 6 years in accredited Australian medical schools). Although full medical registration may be achieved at this stage, many doctors continue their educational training beyond this point to gain specialist status by around the age of 30. By the age of sixty most doctors would have therefore been in practice for thirty years since their initial certification/specialist certification. Sixty is therefore a well-informed evidence based age to consider as 'high risk' in the Australian context. The intended target groups of revalidation

(e.g. medical doctors only, all healthcare professionals, 60+, independent practice for five years or more) should be clearly articulated from the start of revalidation discussions and born in mind when interventions are designed.

Resource provision: Similar to facilitation, resource provision is also a key principle with organisational failings often reported as the most responsible factor for revalidation failure/hostility. Sufficiently resourced policies must be in place in order to support both individuals and organisations involved in the revalidation processes. This will include effective training of all individuals involved, necessary 'protected' time to complete required tasks, provision of the necessary online systems including mobile applications, and a clear line of communication between all stakeholders involved.

Adoption of a multi-dimensional and quality controlled approach: Similarly, medical regulators need to embrace the conclusion that no one method of medical regulation/assessment works best under all circumstances. A multi-dimensional approach that incorporates interactive educational techniques is required. Evidence suggests this is most effectively achieved through the adoption of blended learning that could be further enhanced when quality controlled – e.g. CME events are only provided by accredited bodies that present a minimum amount of interactivity.

Patients and the public as the focus:
Finally and most importantly, the fundamental purpose of medical regulation is to assure the public that doctors are both up to date and fit to practise and that patients remain at the heart of medical care. The central location of patient and public involvement should therefore resonate throughout all aspects of medical regulation including its development, shaping and ongoing evaluation.

Clear channels of communication therefore need to be present between the profession and members of the public. This will help to create transparency between the medical profession, their methods of regulation and public expectations. This has arguably not happened well in other countries [116].

Without it, the purpose, intentions and reasons behind revalidation are not clearly articulated or understood by members of the public preventing their potentially invaluable

involvement. Evidence of public engagement therefore needs to be present to ensure the patient voice is both heard and acknowledged.

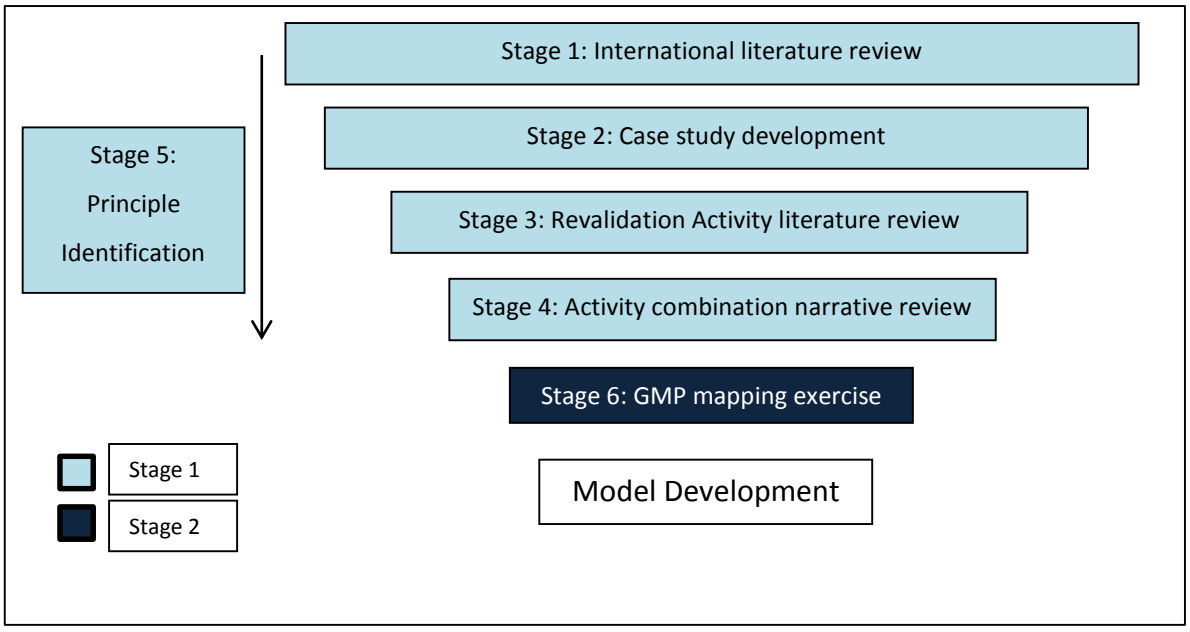
Step 6: Model development

Following the identified principles, one way in which clarity of purpose, in particular, could be achieved is to clearly establish the reasoning behind the revalidation activities chosen.

We have adopted a dual step approach to achieving this as demonstrated in Figure 5. The first step emerged from the literature reviews conducted in Steps 1-4 and the collating of all evidence reviewed presented in Figure 6. The second step required the mapping of collated evidence to the *GMP* to embed the proposed models within the Australian context.

As previously discussed, regardless of the underlying purpose(s) of revalidation in Australia any assessment programme, formative and or summative, must be blueprinted to the desired content. In this case we have taken the *GMP* as the desired 'curriculum' for medical practice. Appendix 4 demonstrates the mapping of possible revalidation activities to this document.

Figure 5: Dual approach to model development



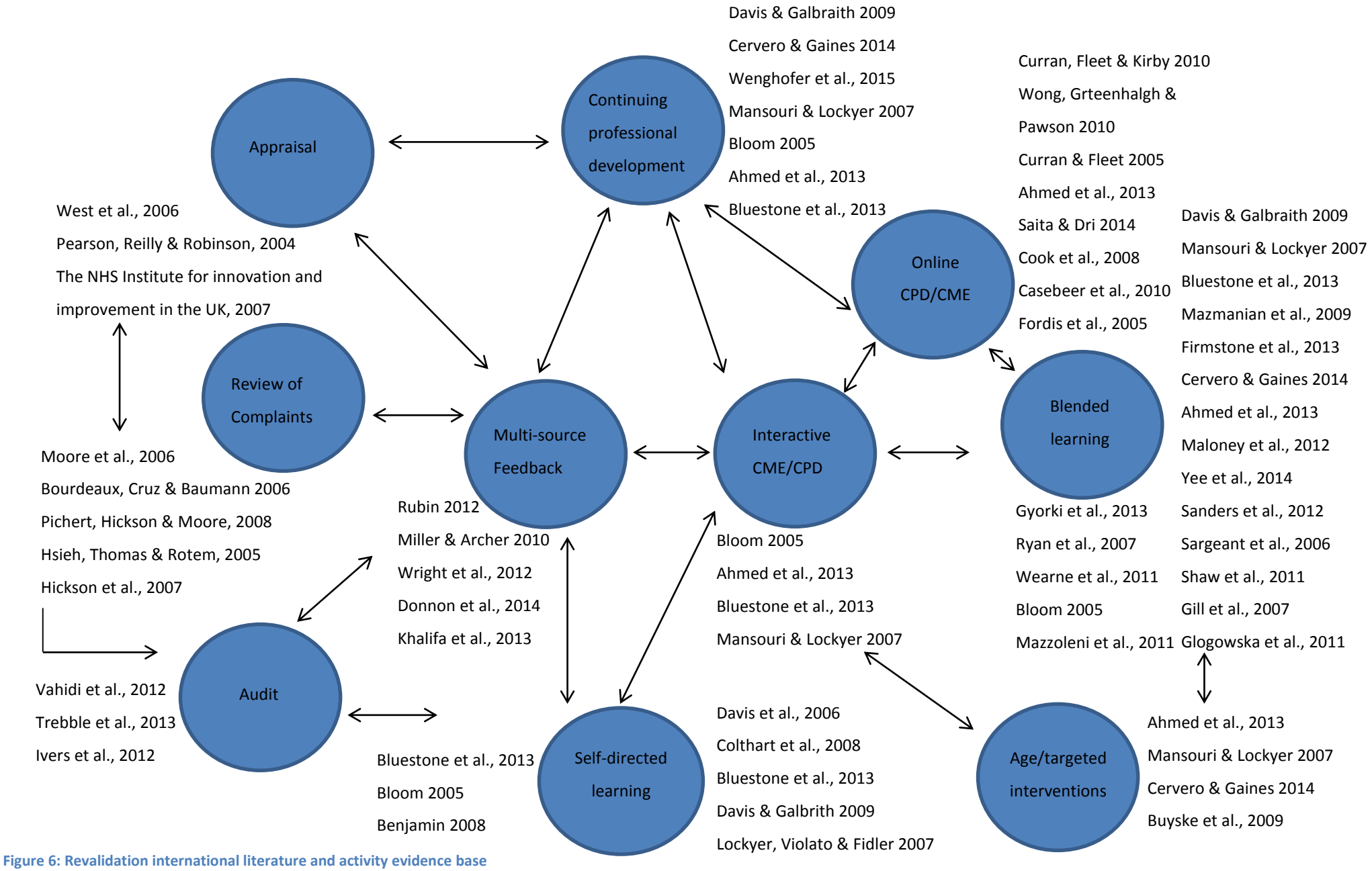


Figure 6: Revalidation international literature and activity evidence base

As Appendix 4 clearly demonstrates, the most commonly utilised revalidation activities (e.g. CME/CPD, appraisal) can cover all key aspects of the Australian *GMP* framework. However, perhaps more importantly it also demonstrates that one form of medical regulation activity e.g. CPD cannot achieve this alone. Diversity is therefore required.

As a result, the proposed revalidation models are designed on the basis of:

1) The different purposes of revalidation – summative, formative or mixed

2) The international evidence base of effective revalidation activities and their effective combinations

3) The identification of underlying principles and

4) The outcome of the *GMP* mapping exercise

Model A

Model A represents a low level model of revalidation operated entirely online. Running over a period of five years (duration typically adopted on a global scale), doctors would be required to produce an annual online portfolio (supporting information document) evidencing:

- participation in mandatory but self-directed CME and
- multi-source feedback (MSF).

Mandatory CME requirements (e.g. 50 annual hours of CME) would need to be outlined by the MBA or relevant body with the understanding that this criteria could be approached in a self-directed manner. The annual portfolio and MSF would need to be signed off by a line manager or equivalent professional or professional body once a year with the fifth signature needed to achieve a recommendation for revalidation approval. The revalidation decision would ultimately sit with the MBA.

Advantages: Due to the model operating entirely online, model A would be relatively cheap to develop and administer. Previous break-even analyses (an analysis designed to identify the point at which the revenue received equals the costs associated with receiving that revenue) in the literature reports a robustly superior advantage for online administration in

terms of participation levels and corresponding break-even points [99]. Model A also has the potential to accommodate remote/very remote doctors. In the Australian context this would translate to approximately 257 full time equivalent medical practitioners per 100,000 people in remote locations and 426 full time equivalent medical practitioners in major cities [117] offering a more accessible process providing internet access was available. Patients would also be involved through MSF activities although this would be at a minimal level.

Limitations: However, there is limited quality assurance built into model A (e.g. a simple sign off at a senior level). Whilst CME events could continue to be accredited following current Australian practice, self-directed CME does not ensure that the most appropriate CME/CPD is being undertaken. Doctors may simply follow interests they are already familiar with or activities that hold little resemblance to their daily practice preventing beneficial development. Whilst this model develops current performance reviews in Australian public hospitals with the addition of MSF, it arguably fails to develop the opportunities much further.

Model A also lacks 'impact' evidence. Whilst engagement in MSF will provide a minimal amount of information surrounding interactions with colleagues and patients, this will be significantly restricted due to the absence of facilitated feedback and online delivery. There are limited opportunities for reflective practice and collaborative learning where doctors are able to discuss, reflect and evaluate how their engagement in CME/CPD and MSF has/will change their practice, behaviours and intentions. Engagement in both of these processes has been identified as critical components of effective medical regulation and professional development [78, 79]. Model A also lacks the opportunity to target high risk doctors (i.e. over 60, working in independent practice etc.) as previously discussed.

In regards to conforming to the *GMP*, Model A would assess seven components offering limited levels of content validity (Appendix 5).

In conclusion, engagement in this model would be cost effective, potentially available nationwide, easy to administer with the administrative infrastructure already largely in place and relatively easy to assimilate into daily workloads. It will demonstrate that doctors are 'up to date' but not necessarily 'fit to practise' providing a single regulatory response.

However, there is a strong reliance on internet access, limited opportunities for reflective and collaborative learning and missed opportunities to target high risk physicians.

Model B

Also operating over a five year period, model B would require doctors to present an online portfolio detailing:

- Engagement in exclusively directed mandatory CME
- Facilitated online learning
- Bi-annual appraisals for targeted groups (i.e. 60+ and doctors in independent practice for five years or more) and
- Participation in MSF from a specified number of patients and peers.

A revalidation appraisal would be undertaken for all doctors every fifth year. Whilst some of these elements are similar to model A, they resolve some of the deficiencies identified.

Advantages: For example, in contrast to model A, model B does not operate entirely online. This allows for the addition of bi-annual appraisals for identified 'high risk' doctors encouraging the development of reflective practice. Data provided by the Medical Board of Australia in May 2015 [118] indicates that there are approximately 19,476 registered medical practitioners over the age of 60 (Table 4). Bi annual appraisals for this group would therefore result in approximately 9.5% of Australian medical practitioners being appraised every year (approximately 1,850).

Table 4: Medical Practitioners registrant data MBA

Age group	General	General (Teaching and assessing)	General and specialist	Specialist	Provisional	Limited	Non-practising	Total
60 - 64	697	5	5,914	543	7	58	218	7,442
65 - 69	462	5	4,549	278	2	25	248	5,569
70 - 74	372	6	2,634	86		4	263	3,365
75 - 79	271	4	1,230	32		1	241	1,779
80+	278	7	689	9			338	1,321
Total	2,080	27	15,016	948	9	88	1308	19,476

Such appraisals could be conducted face to face or remotely (e.g. Skype) helping to address the diverse location of Australian doctors. Bi-annual appraisals are also a more cost effective option in comparison to annual appraisals or annual appraisals for all doctors.

Model B also asks for the development of directed CME and facilitated online learning. Directed CME overcomes the potential barrier of doctors choosing CME events that may prevent beneficial development as the literature identifies a significant weakness in the central location of self-directed learning. Some countries engage in directed CME such as Canada (M1 or C points) and Belgium where doctors are required to obtain three credit points for ethical-related CME each year [48]. Such an approach would help to assure the MBA and patients alike that all doctors were in recipient of similar core knowledge/topic information on an annual basis. Developing targeted CME could see an active role for the Royal Australian Colleges.

The addition of facilitated learning would help to address issues of isolation (a potential limitation of remotely located doctors) whilst simultaneously encouraging collaborative learning adhering to the identified learning preferences of Australian doctors.

In order to provide some form of quality assurance, completed online portfolios could be signed off by the relevant Royal Australian Colleges. This is a further development of model A where a simple signature of a line manager or equivalent would be required.

Similarly, model B provides more comprehensive MSF signed off at employer level or where this is not possible (e.g. small practices) a nominee could be appointed. This ensures patients have a voice in the continued development of revalidation in a standardised manner.

Limitations: Whilst targeting 'high risk' doctors and providing these groups with the benefits of bi-annual appraisals, doctors could potentially have a 30 year career without the advantage of a full appraisal. Issues could remain unidentified and lead to significant implications in terms of patient care and clinical outcomes. Similarly, whilst directed CME would assure both the MBA and patients alike that all doctors were attending similar events, this may be met with a certain level of aversion by doctors adversely affecting its effectiveness.

Furthermore, there is still limited evidence of 'impact' built into this model. Whilst bi-annual appraisals may allow for reflective practice, 80% of Australian doctors will not receive this opportunity until every fifth year due to their age falling below the 60+ target. Reflective practice would therefore still be operating at a fairly restricted level despite its importance reported in the revalidation literature [78, 79].

In conclusion, model B provides some significant improvements on model A. Model B has the opportunity to assess 16 components of the *GMP* (Appendix 5), provide enhanced MSF and bi-annual appraisals for targeted groups. However, there are still some limitations including a lack of regular appraisals for all Australian doctors, a lack of patient complaints review, limited reflective practice opportunities and potential hostility surrounding exclusively directed CME.

Model C

As a result, model C seeks to rectify the issues identified in both model A and B. Comprising of both formative and summative components, model C seeks to assure that doctors are both 'up to date' and 'fit to practise' representing a dual approach to revalidation. This could be achieved by:

- Doctors providing an online portfolio evidencing engagement in self-directed and directed interactive CME

- Facilitated online learning,
- Blended learning/spaced education
- Annual appraisals
- Participation in MSF with accompanying facilitated feedback and
- Review of patient complaints

Similar to the other models, model C could operate over a five year cycle with every 5th appraisal acting as a revalidation recommendation. This final appraisal would ideally be conducted face to face.

Advantages: Model C rectifies the vast majority of concerns raised in the previous two models. Possible hostility and lack of effective development arising from CME are addressed by combining both self-directed and directed CME. (Directed and self-directed topics would of course need to be developed by the MBA, Australian Medical Council, Royal Australian Colleges and other medical institutions). Doctors would therefore all attend the same type of events providing continuity amongst doctors but will also enable doctors to continue a sense of freedom amongst their CME choices. However, following the literature reviewed, the assessment of individual learning needs should be a collaborative decision wherever possible.

Blended learning/spaced education would also be incorporated having demonstrated a significant improvement in knowledge retention and physician performance [97, 99-107, 119] with evidence to suggest blended learning is both an attractive and effective method of medical education. This would also help to incorporate the vast majority of learning preferences in the Australian context [97] and close the current gap between evidence and practice.

Forums and online support communities could be in place to disseminate best practice and prevent feelings of isolation. Participation in these would form part of the appraisal process and allow the identification of impact on doctors' practice – an important component lacking in the first two models.

Quality assurance could be further enhanced with CME providers needing to be quality assured in terms of interactivity (similar to the approach in Canada– where 25% interactivity

is required [33]). CME events should demonstrate a certain amount of interactivity, provide blended learning opportunities and be approved by either the MBA, Australian Medical Council or Royal Australian Colleges. A hierarchy of sign off would also need to be developed with appraisers and a facilitator/overseer at a local level; similar to the responsible officer role in the UK [120].

Reflective practice would be further enhanced through facilitated feedback – a component deemed to be important by practicing physicians [78] largely responsible for the level of reflection and subsequent change achieved. Facilitated feedback would provide the opportunity for reflective practice for all doctors on an annual and systematic basis. Similarly, in order to ensure all areas of the *GMP* are discussed and evaluated against individual practice, all doctors would also undergo annual appraisals. All doctors would therefore be in receipt of the full benefits of appraisal offering numerous advantages over and above both model A and B including a conscious review of patient complaints. The importance of both appraisals [85, 86] and patient complaints[92-94] are well supported in the literature.

Limitations: As previously discussed it is important for regulators to establish a 'firewall' between formative and summative forms of assessment. As model C seeks to incorporate both forms of assessment it is important to use the activities and their corresponding data for their originally intended purpose – i.e. formative assessments/data does not become summative. If this is not established during the early stages of revalidation, this could become a potential concern. The key feature would be that appraisal should be confidential and only informed by 'data' that also informs the regulatory process. An outcome of appraisal therefore would be to additionally and directly inform regulatory decisions such as revalidation recommendations (other than if the doctors did not engage with appraisal).

A possible limitation of model C is the potential financial cost and difficulties of implementation in the Australian context given the high percentage of privately practising physicians and therefore less governed environments already in existence. However, based on the evidence reviewed and mapping activities undertaken, it is believed Model C offers the best model of revalidation which is most likely to assure safe, and overtime, better practice through reflective learning to the betterment of patient care. Although significant

infrastructure would be required for Model C, some of it is already in place e.g. the Victoria partner inter-performance review.

Figure 7 provides a visual summary of the proposed models

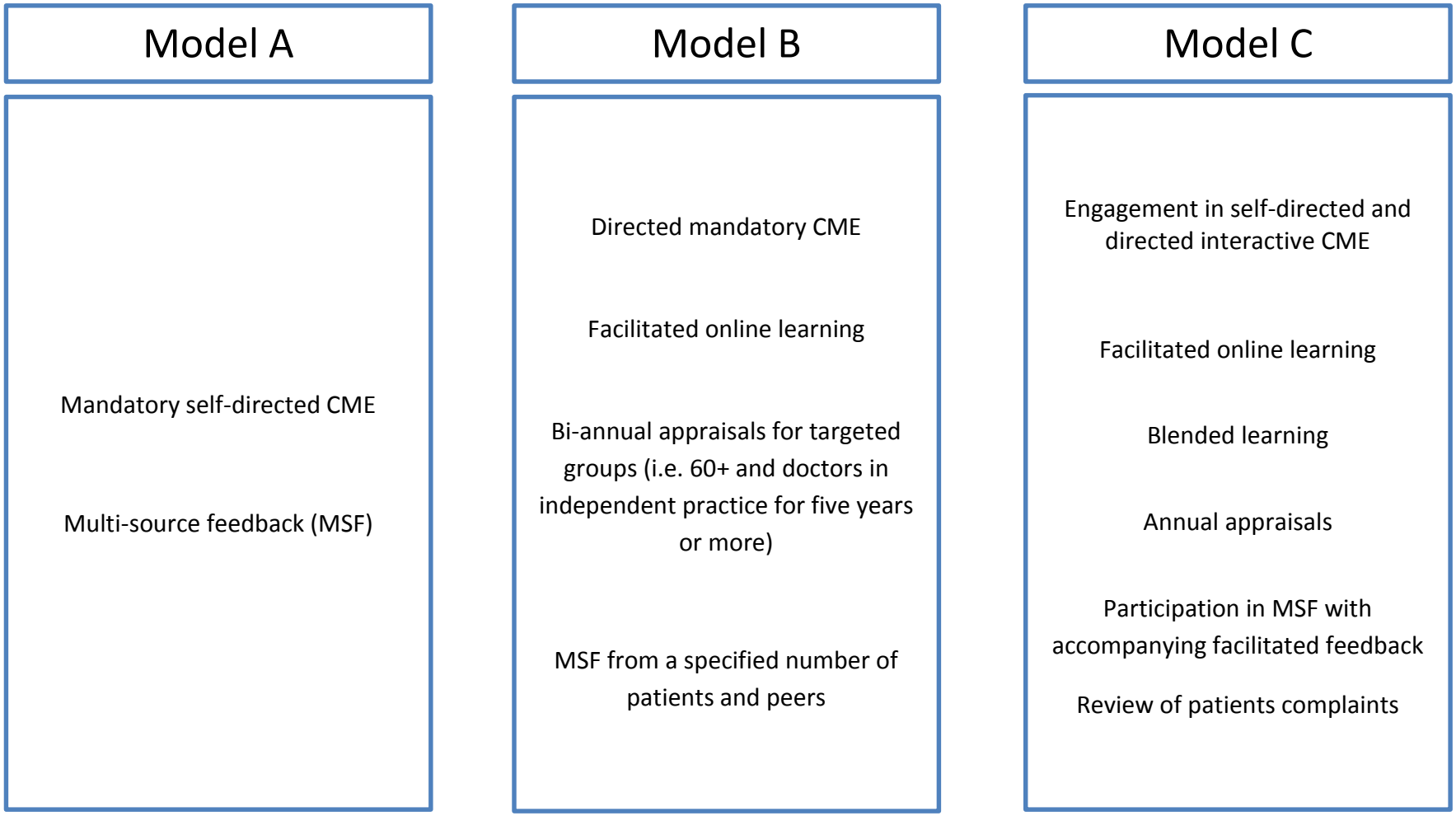


Figure 7: Visual summary of proposed models

Step 7: Evaluation of revalidation operationalisation

As with any form of assessment it is important to evaluate its operationalisation in order to ensure its proposed aims and purposes are being effectively executed in daily practice and that validity can be assured. Since Australia currently has no formal revalidation system in place, there is an opportunity to effectively evaluate a new model at both the pilot and implementation stage. This has not yet been achieved in other countries due the nature of revalidation implementation, where evaluation has typically followed implementation rather than run alongside it. Australia therefore has the opportunity to become leaders in the development of revalidation related 'impact' evidence, helping to address the identified gaps in the current literature and build a robust revalidation programme.

Several considerations will need to be made before any form of evaluation can be conducted. This will include whether one proposed model, a hybrid model, or all three proposed models will be piloted; whether this pilot will occur at either a local or national level; and where/how it will be piloted. Similarly, the purpose of revalidation (e.g. formative, summative or mixed) will need to be assured prior to the design of any evaluative programme as this will be an important factor in deciding which evaluation method is most appropriate. As a result, three key evaluation approaches (process evaluation, outcome evaluation and a trialist approach) and their corresponding limitations are discussed although these would require further development once a model or hybrid model had been selected.

If the main purpose of revalidation is formative, then a process evaluation is most likely desirable seeking to capture the views and evidence around successful implementation. If the desire is for revalidation to be mainly summative then the approach should seek a more trialist approach attempting to measure impact such as on complaints and fitness-to-practise referrals. To evaluate a hybrid model or one where the purpose of revalidation is mixed, a combined trialist and process evaluation would need to be specifically developed. This is most likely to emerge in the form of an outcome evaluation.

Process evaluation

An effective process evaluation should identify the central practices at work following the implementation of an intervention, in this case revalidation. Activity Theory (AT) could be

used to underpin such an evaluation, helping to provide rigour to the transferability of findings to future policy developments and provide a strong conceptual framework. AT could be used to explore the activity of revalidation as a whole, identify its sub-components, their populations, beliefs and contradictions over time which may be beneficial given the developing nature of revalidation in Australia. The use of AT as a conceptual framework could be extended to all the evaluation programmes suggested in this report.

In order to evaluate the process of revalidation we propose a number of multi-method work streams (please see Figure 8) designed to capture the perspectives of the different stakeholders involved. Depending on the final model selected we would include all or some of the types of information and data listed below.

Work stream 1. Supporting information

In all of the proposed revalidation models, doctors will need to provide supporting information towards their revalidation. This work stream aims to find out how guidance from the MBA and others is being applied and used, the varying types, volume and scope of supporting information put forward and how/if doctors are using this information to develop their practice over time. Importantly this work stream would capture the attitudes of doctors towards the perceived value that supporting information may bring. In order to achieve this, methods could include a review of the literature (including guidance and policy documents), a survey and/or semi structured interviews for all those actively involved in the appraisal process in model B and C: potentially this would include appraisees, appraisers and facilitators (or equivalent), and analysis of recorded appraisal meetings/or forms.

Work stream 2. Appraisal

Appraisal is also a core component of revalidation in two of the three proposed models. In order to understand how appraisals are conducted and identify any variations in standards across the country and/or relevant specialisms, a sample could be video/audio recorded. A survey of those involved in the appraisal process would provide broad data but the addition of semi-structured interviews would help granulate these findings and provide a detailed qualitative dimension. Quantitative data analysis of appraisal rates could also be conducted to understand the progress of adoption of revalidation nationally.

Work stream 3. Complaints

In model C we have proposed the implementation of an ongoing review of complaints given their reported ability to identify at risk doctors. This would primarily be a quantitative analysis of complaint data supplemented with some qualitative analysis of complaints to provide contextual information. However, as outlined by several researchers [93, 94, 121] without a control group it would be difficult to extract the impact of revalidation; for example, complaints might still rise after revalidation is implemented but one could hypothesise that they might rise less quickly.

Work stream 4. Patient and public involvement (PPI)

PPI is a universal element across all of the proposed revalidation models. PPI can appear in a number of forms i.e. individual patient feedback, lay representation on panels and boards and patient groups as representative of the 'public'. It is not only important that all these layers are incorporated but that equity and inclusivity is demonstrated throughout. We propose that a PPI group is established to advise on these three aspects of involvement (individual, lay and patient advocates). A series of round table/skype discussions to capture the public perspective followed by individual interviews to capture the patient voice could be undertaken. These will contribute to the evaluation and ongoing development of revalidation by identifying current levels of PPI, the desired level, facilitators and potential barriers to PPI involvement.

Work stream 5. Stakeholder interviews

Finally, there will be a number of stakeholders involved in revalidation including the Royal Australian Colleges, the MBA and the AMC. Representatives of these various groups should be identified and interviewed in order to provide a more collective perspective that extends beyond the individual doctor. This would help to provide a more holistic view of revalidation at both an individual and organisational level.

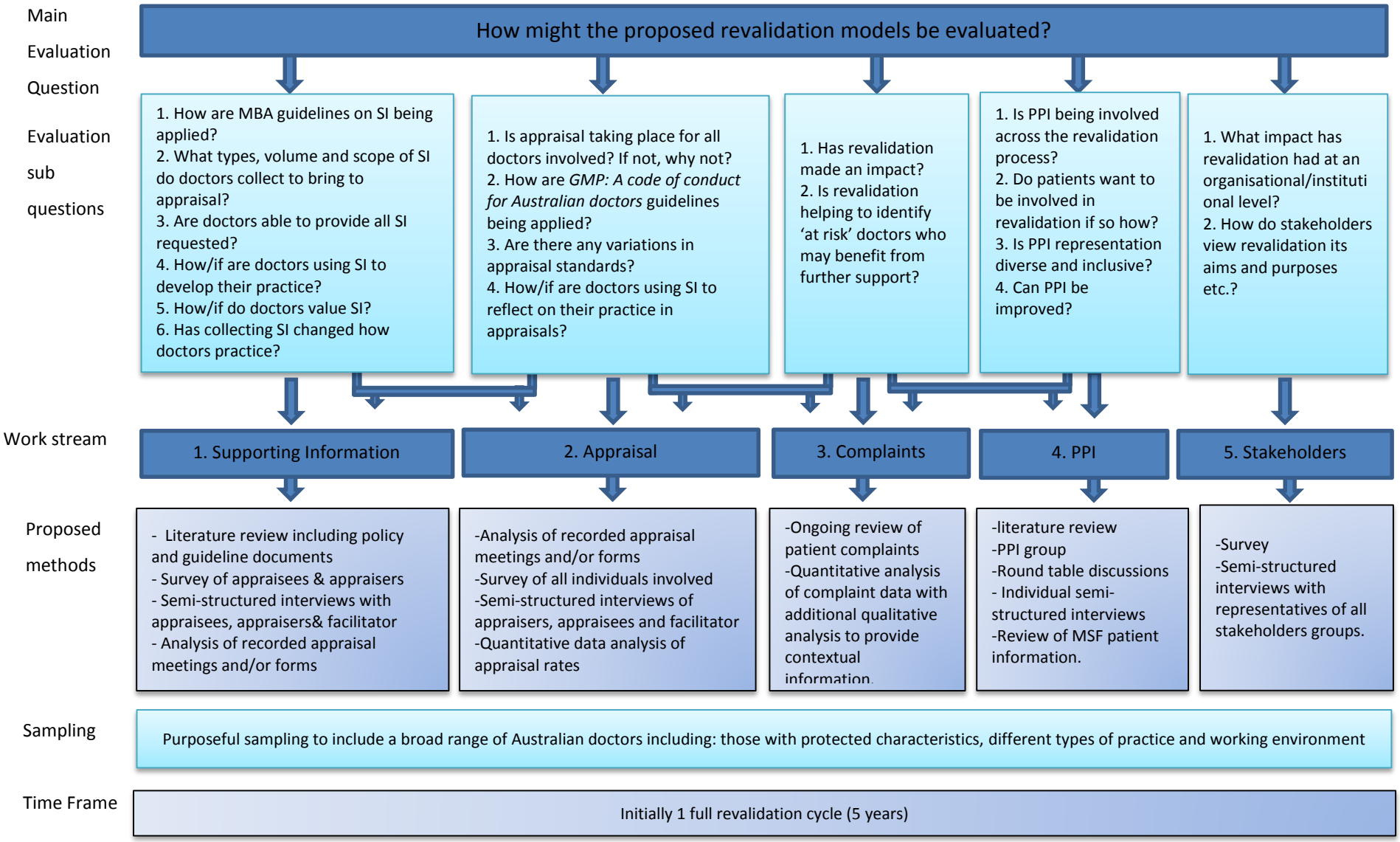


Figure 8: Visual summary of proposed evaluation work streams and accompanying process evaluation questions.

However, whilst a process evaluation would address the most basic questions of whether policy strategies/aims were being implemented as planned and some trend data (such as complaints), it is unable to measure the 'impact'/effectiveness of revalidation in achieving change.

Outcome evaluation

Building on the underlying principles of a process evaluation, an outcome evaluation seeks to assess the effectiveness of a specific intervention over time by exploring what effect, if any, the intervention has had on the individual concerned, and how much, if any, the difference observed was as a result of the intervention alone.

When developing an outcome evaluation it is of considerable importance to consider the measures one would expect to see change following the introduction of the intervention, in this case, revalidation. These are often shaped by the intention of revalidation i.e. educational, early identification of underperforming doctors etc. Once the purpose of the intervention have been established, it is important to address what can be measured and how. With revalidation, measures collected before, during, and after implementation such as complaints or fitness to practise referrals are often selected as many regulators already routinely gather these data.

The main limitation however of both a process and outcome evaluation is the lack of a control group. This means that any change seen cannot be directly attributed to the intervention. So while correlations can be found, causation cannot. Evaluation approaches are easier to implement and are often undertaken first in order to better understand what impact the intervention might be having and therefore then identify future measures that could be collected as part of a formal trial.

In summary, whilst outcome evaluations provide an additional step beyond process evaluations, causality can be hard to establish. For example, it is known that complaints are on the rise in healthcare and indeed across all consumer cultures in the developed world [121]. It is therefore likely that a rise in complaints may occur naturally despite the intervention. Measuring 'if the rise is less' is therefore not possible without a control group.

Trialist approach

Fundamentally a trial collects measures over time, as with an outcome evaluation, but it does so in both an intervention and control group. Two possible trialist approaches are discussed below.

Stepped wedge cluster randomised trial (SW)

One approach is the use of a stepped wedge cluster randomised trial (SW). SW is a relatively new research method increasing in popularity [122-124]. Offering an alternative to parallel cluster trail designs, SW trials consist of an initial period where no cluster 'populations' are exposed to the intervention in question e.g. revalidation. Over a series of time, one randomised cluster or group of clusters move from the control to the intervention until all identified clusters have been exposed to the intervention. Data collection is therefore continuous throughout the duration of exposure so each cluster presents observations under both control and intervention conditions [122-124].

SW trials have been described as a pragmatic design capable of reconciling the need for robust scientific evaluations with political, ethical and logistical constraints [122-124] that often accompany any intervention implementation of this scale. SW trials have also been described as particularly suited to the evaluation of service/policy interventions that do not rely on individual patient recruitment, involve large sized clusters, are developed on existing evidence to support the implementation of the intervention, and/or for financial, logistical or political reasons it is not possible to deliver the intervention simultaneously [122, 124]. When one or more of these factors are present, SW trials represent a more powerful methodology in comparison to parallel designs where only half of the clusters receive the intervention raising possible ethical concerns. Furthermore, the use of a SW design could potentially alleviate some concerns over causality following the analysis of data over time at both control and implementation stages.

Given the lack of a full revalidation system in place in Australia and proposed duration of five years for all revalidation models, Australian doctors would have different revalidation dates if the models are adopted. These could be used as a natural clustering technique. Alternatively, the location of Australian doctors could also be used as a form of clustering e.g. major city, small town, and rural physicians.

One limiting factor is that although 'revalidation' is not yet in place, some physicians already engage in some of the proposed activities such as appraisal. There is therefore not a clear-cut before and after scenario. However, the most plausible outcome measures such as referral rate comparisons between doctors who have been revalidated and those who are yet to go through their first full cycle and patient complaints could provide some indication surrounding the 'impact' of revalidation.

Survival analysis

Another possible method of evaluating revalidation 'impact' is to explore the possibility that revalidation has facilitated the earlier identification and addressing of underperforming physicians, and/or before they become safety concerns/fitness referrals through survival analysis.

Survival analysis relates to the study of time between entry into study and event related data [125]. In this instance the event would be defined as a doctor's referral to fitness-to-practise procedures. Using data that is typically collected by medical regulations over a period of 5-10 years it is possible to compare the 'survival' (e.g. non-referral) of doctors before revalidation implementation and after its first full cycle, then after the first full revalidation completion and five years later and so on. Comparing certain time frames may help to identify if the proposed interventions are working, i.e. one would expect a fall in referral rates since revalidation implementation in comparison to current practice as doctors are identified earlier and/or keep up to date better.

However, in order to provide robust research using this methodology, large samples of referral cases are needed to provide significant statistical power and the analysis would have to be conducted over a considerable length of time.

In conclusion, we have proposed three different approaches to revalidation evaluation (process, outcome, trialist). Whilst a process evaluation allows stakeholders to identify whether the proposed aims/purposes are being carried out as desired, it is unable to assess impact beyond process implementation. An outcome evaluation rectifies this limitation although it is unable to establish causality. Whilst a trialist approach seeks to overcome these issues, it presents numerous challenges including the highly time consuming development of accurate randomisation and matched- control groups. Implementing a

trialist approach in the Australian context therefore presents a challenging task for the reasons listed above. An outcome evaluation or more simplistic process evaluation may therefore be a more suited option.

5. Conclusion

In conclusion, revalidation is a complex intervention that requires ongoing consideration, development and evaluation. The evidence reviewed indicates that revalidation and its associated activities are most effective when they are multi-dimensional, interactive and utilise a number of learning techniques that are both relevant and attractive to its users. Following this, the intended aims, purpose and criteria of revalidation need to be clearly articulated at an early stage of development to avoid unnecessary confusion and keep revalidation activities relevant to the intended outcomes. There should be a clear line of communication between all communities involved that extends beyond the development, implementation and evaluation of revalidation. This will help to ensure that a collaborative network united in the pursuit of a common goal i.e. revalidation is both developed and maintained. These processes should be underpinned by the principles identified to ensure its robust operation becomes effectively ingrained in the Australian medical profession for the benefit of patients. Three potential models are proposed that map to *GMP* and offer opportunities to assess doctors either in a formative, summative or combined manner. Model C is presented as potentially the most effective method of revalidation although the challenges of implementing this model fully in the Australian context are acknowledged. We conclude that an outcome evaluation using a step-wedged design to support implementation over time is likely to be the best approach to evaluation. However the most applicable evaluation framework is largely dependent on the model selected and the intended purpose and outcomes of revalidation.

It is hoped that the evidence reviewed, principles identified and proposed revalidation models/evaluations provides a beneficial foundation for future revalidation discussions, policy developments and implementation in Australia.

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Appendices

Appendix 1: United Nations Very High Human Development Country Programme 2013

HDI rank	Country
1	Norway
2	Australia
3	Switzerland
4	Netherlands
5	United States
6	Germany
7	New Zealand
8	Canada
9	Singapore
10	Denmark
11	Ireland
12	Sweden
13	Iceland
14	United Kingdom
15	Hong Kong, China (SAR)
16	Korea (Republic of)
17	Japan
18	Liechtenstein
19	Israel
20	France
21	Austria
22	Belgium
23	Luxembourg
24	Finland
25	Slovenia
26	Italy
27	Spain
28	Czech Republic
29	Greece
30	Brunei Darussalam

31	Qatar
32	Cyprus
33	Estonia
34	Saudi Arabia
35	Lithuania
35	Poland
37	Andorra
38	Slovakia
39	Malta
40	United Arab Emirates
41	Chile
42	Portugal
43	Hungary
44	Bahrain
45	Cuba
46	Kuwait
47	Croatia
48	Latvia
49	Argentina

Appendix 2: Narrative literature review summary exploring medical regulation internationally

	Medical Regulation Evident	Status X – Mandatory 0 - voluntary	Points required	Point System
1.Norway	X	X – since 2001	40/1 200/5	
2.Australia	X	X – since 2010		
3.Switzerland	X	X since 2007	80/1	1 = 60 minutes
4.Netherlands	X	X – directly linked to revalidation	200/5	1 = 60 minutes
5.United States	X	X in 62 of 68 Medical states	20-50 hours	1 = 60 minutes
6.Germany	X	X legal requirement	150/3 250/5	1 = 45 minutes
7.New Zealand	X	X	50/1	1 = 60 minutes
8.Canada	X	X – MOC or Mainpro	MOC 4-/1 400/5 Mainpro 250/5	
9. Singapore	X	X – 1st Jan 2003	50/2	
10. Denmark	X	0	200/5	1 = 60 minutes
11. Ireland	X	X	250/5 50/1	1 = 60 minutes
12. Sweden	X	0	Roughly 10 days	Not based on credits or hours
13. Iceland	X	X		
14. United Kingdom	X	X	250/5 50/1	1= 60 minutes
15. Hong Kong	X	0	30/1 90/3	
16. Korea	X	X	12/1	1 = 60 minutes
17. Japan	X	0	60/ 180/3	1 = 60 minutes
18. Lichtenstein				
19. Israel	X	0		
20. France	X	X	250/5	1 = 45/60 minutes

21. Austria	X	X	250/5	1 = 45 minutes
22. Belgium	X	0	20/1 60/3	1 = 60 minutes
23. Luxembourg	X	0		
24. Finland	X	0	10 working days	Not based on credits
25. Slovenia	X	X – linked to recertification	150/7	1 = 60 minutes
26. Italy	X	X	150/3	1 = 60 minutes
27. Spain	X	0		
28. Czech Republic	X	X –legal requirement	120/5	
29. Greece	X	X		1 = 45 minutes
30. Brunei Darussalam	X	X	30/1	
31. Qatar	X	X	40/1	1 = 60 minutes
32. Cyprus	X	0	150/3	1 = 60 minutes
33. Estonia	X	0	300/5	1 = 45 minutes
34. Saudi Arabia	X	X – re-registration	200/5	1 = 60 minutes
35. Lithuania	X	X – 1998	120/5	
36. Poland	X	X- legal requirement	200/5	1 = 60 minutes
37. Andorra				
38. Slovakia	X	X	50/1 250/5	1 = 60 minutes
39. Malta	X	0		1 = 60 minutes
40. United Arab Emirates	X	X		1 = 60 minutes
41. Chile				
42. Portugal	X	0		1 = 60 minutes
43. Hungary	X	X - revalidation	250/5	1 = 60 minutes
44. Bahrain	X	0	150/2	1 = 60 minutes
45. Cuba				
46. Kuwait	X	0	250/5	1 = 60 minutes
47. Croatia	X	X- legal requirement	120/6	
48. Latvia	X	X	250/5	1 = 60 minutes
49. Argentina		X		

Appendix 3: Case Study Explorations

United Kingdom

Medical revalidation became mandatory in the UK in 2012 representing '*the biggest change in medical regulation for more than 150 years'*[127].

The UK's approach to revalidation is unique in the sense that revalidation is governed by a single body – the General Medical Council (GMC). The process of revalidation in the UK and its accompanying mechanisms is therefore largely based on the GMC's *Good Medical Practice* [29] framework composed of four domains and twelve accompanying attributes (Table 1).

Table 1: GMC's Good Medical Practice Framework – Domains and attributes.

	Accompanying Attributes
Domain 1: Knowledge, skills and performance	- Maintain your professional performance - Apply knowledge and experience to practice - Ensure that all documentation (including clinical records) formally recording your work is clear, accurate and legible
Domain 2: Safety and Quality	- Contribute to and comply with systems to protect patients - Respond to risks to safety - Protect patients and colleagues from any risk posed by your health
Domain 3: Communication, partnership and teamwork	- Communicate effectively - Work constructively with colleagues and delegate effectively - Establish and maintain partnerships with patients
Domain 4: Maintaining trust	- Show respect for patients - Treat patients and colleagues fairly and without discrimination - Act with honesty and integrity

The GMC states that doctors should use the framework to [29]:

- '*reflect on your* [their] *practice and approach to medicine'*
- '*reflect on the supporting information you* [they] *have gathered and what that information demonstrates about your practice'*
- *'identify areas of practice where you* [they] *could make improvements or undertake further development'*
- *'demonstrate that you* [they] *are up to date and fit to practise'*

In order to ensure that physicians are adhering to the suggested revalidation framework, doctors are required to engage in five annual appraisals designed to help physicians reflect and review their current practice and future developments.

One key component of this process is the presentation of supporting information (SI) collected from a multitude of sources.

The GMC's *Supporting Information for Appraisal and Revalidation* [81] indicates that SI falls under four main headings:

1- General information – providing context about what you do in all aspects of your work

2- Keeping up to date – maintaining and enhancing the quality of your professional work

3- Review of your practice – evaluating the quality of your professional work

4- Feedback on your practice – how others perceive the quality of your professional work

Doctors are expected to collect six types of SI at least once during each five year cycle[81] : under the four main headings above. The SI types are:

1. Continuing professional development (CPD) as required by relevant College or Faculty run CPD schemes,

2. Quality improvement activity e.g. clinical audit, review of clinical outcome data
3. Significant events
4. Feedback from colleagues
5. Feedback from patients

Multi-source feedback (MSF)

6. Review of complaints and compliments

The SI itself is not submitted to the GMC for consideration [80]. A recommendation regarding the renewal of the doctor's medical licence is made by a 'Responsible Officer' (an appointed representative within each designated body – typically the medical director or deputy) to the GMC following the appraisal process. The GMC then makes their final decision based on this recommendation.

Revalidation and participation in CME/CPD and wider activities are therefore explicitly linked in the UK.

Canada

Following a series of national workshops held between 1994-1996 and the subsequent development of the Maintenance and Enhancement of Professional Performance (MEPP) model [128], several significant changes have been made to Canadian medical practice.

In 2006 the Federation of Medical Regulatory Authorities of Canada (FMRAC) brought all 13 Canadian jurisdictions together leading to the unified agreement that participation in one of two existing CPD schemes (the Maintenance of Certification [30] conducted by the Royal College of Physicians Surgeons of Canada and/or the Maintenance of Proficiency [31] run by the College of Family Physicians of Canada) should become mandatory across all jurisdictions.

- The Maintenance of Certification (MOC)

The MOC programme governed by the Royal College of Physicians and Surgeons of Canada is an evidence-informed programme designed to support and enhance CME/CPD activities.

Similar to the UK, the MOC programme is based on a five year cycle with physicians required to complete a minimum of 40 annual credits. The College also states that doctors must obtain a minimum of 400 credits over each five year cycle [32].

A recent update of the MOC programme sees the relevant MOC learning framework reduce the number of learning sections from six [32]:

1- Accredited group learning activities

2- Other learning activities

3- Accredited self-assessment programmes

4- Structured learning projects

5- Personal practice review

6- Personal education development.

To three [32]:

1- Group learning e.g. conferences, courses, either face to face or web based

2- Self-learning – activities planned to address specific needs, enhance awareness of new evidence potentially relevant to practice

3- Assessment – activities that provide data and feedback to physicians or health teams that facilitate the identification of needs.

All fellow and MOC participants with new MOC cycles beginning on the 1st of January 2014 are also now required to complete a minimum of 25 credits per cycle in each of the three new learning sections stated above.

CPD providers are required to incorporate a minimum of 25% interactivity (activities beyond the traditional 'bums on seats' CPD) within their events [33]. Failure to do so will prevent CME/CPD accreditation.

- Maintenance of Proficiency (Mainpro)

The second mandatory CME/CPD scheme conducted by the College of Family Physicians of Canada requires doctors to obtain a minimum of 250 MAINPRO points during each five year cycle. Of these 250 points, at least 125 must be achieved through M1 (structured learning) or C points (accredited programmes). A maximum of 125 M2 points (self-directed or non-accredited programmes) can be awarded. There is therefore a greater drive towards structured and accredited learning in comparison to self-directed/non-accredited learning [31]. This approach is supported by the literature [34].

Similar to the modified MOC, the basis of the MAINPRO programme consists of three categories:

1- Self-reflection on practice

2- Enhancing knowledge

3- Enhancing skills relevant to the practice of family medicine and self-directed learning

Doctors have to submit proof of participation by self-reporting information onto MAINPRO (an online system) and retain proof of participation for a minimum of 6 years.

In 2015 MAINPRO is expected to become MAINPRO+ (detailed in table 2) with the addition of new reporting categories to earn credit for more practice activities facilitated by the development of a new smartphone application enabling quick and easy credit reporting.

Table 2: MAINPRO+ changes as proposed on CFPC website[35].

	Certified (Formerly 'Accredited')	Uncertified (Formerly 'Unaccredited')
Group Learning	- Conferences - Hospital rounds - Journal Clubs etc.	- Non-industry Events - AAFP elective credit CPD - Uncertified Rounds etc.
Self-Learning	- Online CPD programmes	- Journal Reading - Manuscript Preparation - Podcasts, CDRoms etc.

	- Learning linked to Teaching, Research etc.	
Assessment	Simulation-based activities Practice Audits, 360^0 Reviews, Physician Achievement Review (PAR) Teaching Assessment, etc.	

One unique and important aspect of Canadian revalidation stems from the target groups for medical regulation. In Ontario, The College of Physicians and Surgeons of Ontario (CPSO) purposefully select physicians in one of two ways: 1 - Physicians under the age of 70 who have been in independent (private) practice for at least five years are randomly selected to undergo peer assessment, 2 – physicians who are over the age of 70 are subjected to a peer assessment and then every five years after that [36]. This is as a result of increasing evidence to suggest that physicians are at greater risk of providing lower quality care as their years in practice increase [37].

New Zealand

Following the Health Practitioners Competence Assurance Act (2003) [38], all New Zealand doctors must hold a current practising certificate issued by the Medical Council of New Zealand (MCNZ) on an annual basis. A practicing certificate will only be issued if the doctor can demonstrate active participation in CPD schemes.

Stemming from this, the MCNZ currently adopts a dual approach to medical recertification.

Approach 1 – Vocational Scope Recertification

Vocational scope recertification applies to registered specialists including GPs. Specialist recertification programmes are coordinated by respective Branch Advisory Bodies (VEAB).There are currently 36 accredited vocational recertification programmes provided by the VEABs [38] including the New Zealand National Committee, Australian and New Zealand College of Anaesthesia, and the Royal Australian and New Zealand College of Radiologists.

Approach 2 - General Scope Recertification

Alternatively, General Scope recertification is for non-specialist doctors not in a vocational training programme and/or new registrants such as international medical graduates (IMGs). Recertification for general scope doctors can be achieved by participating in either *inpractice* a recertification programme conducted by bpac^{nz} (Best Practice Advocacy Centre New Zealand) *[39]*, or through a recertification programme provided by an accredited provider.

In order to ensure that a doctors' declaration of active CPD participation is correct, the MCNZ audits 15% of all recertification applications [129]. Specialist colleges may also audit a small percentage of participating doctors.

Both methods of recertification and their accompanying CPD schemes conform to the Councils *Good Medical Practice* guide [40], indicating that a physician's mandatory CPD should cover 5 main domains of medical practice:

1. Medical care – e.g. providing good clinical care, keeping accurate records,
2. Communication – e.g. doctor-patient relationship, confidentiality,
3. Collaboration and management – e.g. working with colleagues
4. Scholarship – e.g. teaching, training and appraising doctors and students
5. Professionalism e.g. raising concerns about patient safety

As a general rule, the Council requires 50 hours of CPD each year incorporating:

- Collegial relationship meetings (six meeting in the first year and four meetings a year after that)
- One clinical audit of medical practice (at least one audit per year) with a statistical basis
- Peer review (a minimum of 10 hours per year)
- Continuing medical education (a minimum of 20 hours per year).

Unlike the other countries previously discussed, New Zealand outlines a minimum number of CME hours under the umbrella term of CPD. New Zealand also specifies a minimum

number of peer-review hours and clinical audits to be undertaken highlighting a unique aspect of medical revalidation in New Zealand.

USA

In order to obtain an initial state medical license, doctors must pass a medical licensure examination such as the United States Medical licensing Examination (USMLE) or similar high stake examination. In order to evaluate the ongoing competencies of licensed/previously licensed physicians a post licensure assessment system is also in operation. This is also extended to those who passed their initial licensing exams some years ago (e.g. special purpose examination provided by the Federation of State Medical Boards [130]). Doctors are expected to renew their license every 5-10 years depending on their speciality [131].

Whilst the obtainment of a state medical license is mandatory, board certification (speciality specific) remains a voluntary process. Despite this, most primary care physicians and specialists (approximately 80-85% [42]) choose to certify with one of twenty-four American Board of Medical Speciality (ABMS) member boards following their vocational training [41]. In 2002 all 24 ABMS's agreed on comparable standards for board certification and recertification including a new evaluation of performance referred to as the ABMS Programme for Maintenance of Certification (MOC).

The ABMS MOC aims to provide a structured approach for enhancing patient care and patient outcomes by involving ongoing measurements of six core competencies [132] (listed below) measured by a four part framework [133] (also listed below).

Six core competencies:

- Practice based learning and improvement
- Patient Care and Procedural Skills
- Systems-based practice
- Medical knowledge
- Interpersonal and Communication Skills

- Professionalism

Four part framework:

1. Evidence of good professional standing (usually defined as an unrestricted license to practice in a relevant state)
2. Participation in knowledge self-assessment
3. A secure examination of knowledge
4. A practice audit and improvement exercise

All MOC programmes implemented by the Medical Boards measure the same six competencies using this four-part framework helping to provide continuity.

CME/CPD remains a central part of both the MOC and medical license renewal. CME/CPD is a mandatory requirement for re-licensure within 62 of the 68 SMBs. However, given the variation in jurisdiction governance, large variations surrounding CME/CPD requirements exist. For example, re-licensure cycles are on average two years, however they can be between one and four years depending on the SMB.

Despite this, the majority of SMBs require doctors to participate in 20-50 hours of CME on an annual basis with all SMBs requiring CME activities to be accredited by a legitimate organisation. The Accreditation Council for Continuing Medical Education and the American Medical Association are the two main CME accreditors for the US, both of which have strict quality assurance processes.

In addition to CME/CPD, the US also incorporates a high-stakes examination as a form of medical regulation [41]. However, there is an argument that licensure renewal remains an ‘administrative function’ [43] driven by financial incentives. This concern and others raised by the Institute of Medicine (IOM) in 1999 indicating a greater desired level of input from State Medical Boards (SMB) to continuously assess a physician’s ability after initial license obtainment [44] are being addressed by the Federation of State Medical Boards (FSMB) (a non-profit organisation who represent the nation’s 70 medical boards and collaborating

organisations [45]). The FSMB wishes to incorporate a new Maintenance of Licensure (MOL) framework that would replace the current system.

The aim of the MOL is to provide a form of CPD that fosters lifelong learning as a condition of license renewal [45]. It would not require a mandatory high stakes examination and would operate independently of current specialised Maintenance of Certification (MOC) programmes. FSMB are looking to incorporate activities that physicians already engage in such as accredited CME to match the three components of effective life-long learning (listed below) and the MOL framework:

1. Reflective self-assessment
2. Assessment of knowledge and skills
3. Assessment of performance in practice

The new MOL system is not expected to emerge in the US for several years [46].

In summary, the US appears unique in their approach to revalidation by utilising a high stake examination as a form of medical regulation. However, this is likely to change in the future if the new MOL system is approved. The system of obtaining a state medical license (general license) with the option to certify as a specialist mirrors other approaches previously discussed.

Germany

The Social health Insurance Modernisation Act (2003) and Social Health Insurance Modernisation Act (2004) resulted in a major reform of physician quality and subsequent CME/CPD development in Germany [134].

In order to practice medicine or undertake specialist training, all physicians must be in possession of a full (Approbation - which is valid across the country for an unlimited time frame) or temporary license (Berufserlaubnis - restricted to the federal state it was issued and limited to a certain time period), both issued by the state health authorities (Oberste Landesgesundheitsbehörden) of the respective state (Land).

Once this has been obtained, physicians must also become a member of one of the seventeen state chambers of physicians (Landesärztekammer). Each regional chamber,

which operates below the German Medical Association, approves their own CME/CPD programmes and accompanying activities. However, CME/CPD systems remain fairly homogenous across Germany due to a regulatory framework provided by the Bundesärtzekammer (The German Medical Association) [47] .

All physicians (except purely private physicians, where it remains voluntary) are required to fulfil CME/CPD requirements outlined by the Bundesärtzekammer over a five year cycle, acquiring a total of 250 CME points [48] across 7 categories [49](listed below) with one point typically equating to 45 minutes [50]

- Lecture and discussion
- Congress
- Active Participation (workshops)
- Interactive education (print and online)
- Self-study of scientific literature
- Author/Referent
- Practical Training

Specialists are required to undertake approximately 70% of their CME points in their speciality related subjects [48]. Radiologists who read mammograms are subject to additional recertification procedures.

One unique aspect of the German regulation approach is the introduction of a barcode system. Each practicing physician is given their own 15 digit uniform CME/CPD number, an identification card and set of personal barcode stickers which are then scanned following their attendance at CME/CPD events. The relevant points are then added onto their online account reducing the amount of time needed for physicians to complete necessary paper work and potential opportunities for undesirable self-reporting bias. Each region except Baden Wurttemberg have designed a computer based registration system for CME/CPD to facilitate this process [48].

However, whilst a system for accrediting CME/CPD events/activities exists, the validity of this system has been called into question [56]. Organisers must currently gain recognition from the State Chamber of physicians.

If an individual's CME/CPD certificate is not achieved within two years after the stated due date, accreditation can be withdrawn [48]. Similarly, medical directors face strict financial sanctions [51] if an individual fails to comply with CME/CPD requirements.

Germany therefore provides numerous differences to previously discussed regulation processes including the difference in credit values (1 credit equates to 45 minutes), the presentation of a unique barcode system, a specified percentage of specialist related CME/CPD (70%) and strict financial sanctions for medical directors following CME/CPD non-engagement.

Netherlands

The Dutch Ministry of Public Health is responsible for the administration of medical licenses in the Netherlands [52]. In contrast to the single governed UK revalidation process, the Netherlands are coordinated by the Medical Specialist Registration Committee of the KNMG (Royal Dutch Medical Association), an umbrella organisation comprising of three registration committees (one for clinical specialists, GPs and social medicine) that have combined to create a unified agreement surrounding common requirements for registration and reregistration [53].

The KNMG's Medical Specialisms' Board (College Geneeskundig Specialismen) determines the educational and training requirements for all 33 specialisms currently operating in the Netherlands.

In order to reregister, specialists must demonstrate on a five year cycle that they have performed [54]:

- A minimum of 16 hours per week in their speciality
- Undertaken at least 40 hours of CME a year
- Taken part in at least two hours of peer review per year
- Engaged in practice audit to assess practice organisation and performance [55].

Accreditation of CME/CPD activities remains the responsibility of independent professional societies although a uniform application form and assessment framework has been used by all professional bodies to help standardise CME/CPD accreditation.

An online system (GAIA) has also been developed for doctors to record their CME/CPD activities helping to provide a further standardised approach.

If doctors fail to comply with the demands of CME/CPD, it is possible for professional societies to re-register doctors for a shorter period of time e.g. one year in which the doctor is expected to complete the outstanding CME/CPD hours/credits [53]. This process is not a common feature amongst other countries reviewed.

Belgium

Legislation in Belgium states that both GPs and specialists must maintain clinical competence. However, participation in CME/CPD programmes remains voluntary. There is therefore no system currently in place to check the professional competency of practicing physicians in Belgium [56].

The formal CME/CPD programme was first introduced in 1994 by the central National Institute for Health and Disability insurance (INAMI/RIZIV) which continues to oversee all CME/CPD regulation. Doctors initially obtain their licence to practice from the Minister of Public Health. In order to receive further accreditation doctors must further apply to the INAMI/RIZIV.

If a physician wishes to renew accreditation they must obtain 60 CME credits over a three year cycle (1 CME point is typically given for every hour of participation), participate in at least two peer reviews a year, and undertake at least 500 consultations a year [48, 51].

Various committees including the Conseil National de la Promotion de la Qualite (CNPQ) and the Groupe de Direction l'Accreditation (GDA – a steering group responsible for CME accreditation) help to ensure all CME activities are quality assured. There are currently 11 types of CME activities e.g. workshops, events, acting as a moderator or speaker at a CME event recognised by the GDA. Since 2005 the INAMI/RIZIV also recognises CME/CPD in the form of e-learning and has developed its own accreditation form for organisers of e-learning material, participating in the UEMS EACCME system [51].

Doctors are generally free to choose which CME activities they attend but must undertake at least three credit points per year involving ethics and economics as well as participate in at least two medical evaluation (peer review) group meetings a year undertaken by Groupement Local d'Evaluation Medicales (GLEMs). The requirement to engage in ethics and economic events represents a unique aspect of Belgium medical revalidation.

A further unique aspect is the use of a financial incentive for medical regulation. Physicians are rewarded for participating in revalidation by increasing their earning potential/salary of around 4% [57] providing a possible explanation behind the relatively high participation rate of 80% despite revalidation being a voluntary option [56].

Belgium therefore represents several unique approaches to revalidation including the use of a financial incentive and set requirements to engage in ethical and economic related events.

Appendix 4: Good Medical Practice: a code of conduct for doctors in Australia Mapping exercise

	Continuing professional development	Multi-source feedback	Review of complaints	Clinical Audit/Peer review	Appraisal
1 Providing good care					
1.1 Introduction					
1.2 Good patient care	X	X	X	X	X
					X
1.3 Shared decision-making	X				
1.4 Decisions about access to medical care					
1.5 Treatment in emergencies					
2 Working with patients					
2.1 Introduction					
2.2 Doctor-patient partnership		X			
2.3 Effective communication		X			
2.4 Confidentiality and privacy					
2.5 Informed consent					
2.6 Children and young people					X
2.7 Culturally safe and sensitive practice	X	X	X	X	X
2.8 Patients who may have additional needs			X		X
2.9 Relatives, carers and partners			X		X
2.10 Adverse events					

	2.11 When a complaint is made 2.12 End-of-life care 2.13 Ending of a professional relationship 2.14 Personal relationships 2.15 Closing or relocating you practice					
3	**Working with other healthcare professionals** 3.1 Introduction 3.2 Respect for medical colleagues and other healthcare professional 3.3 Delegation, referral and handover 3.4 Teamwork 3.5 Coordinating care with other doctors	X X X	X X X		X	X
4	**Working within the health care systems** 4.1 introduction 4.2 Wise use of healthcare resources 4.3 Health advocacy 4.4 Public Health				X X	
5	**Minimising Risk** 5.1 Introduction					

	5.2 Risk management 5.3 Doctors' performance – you and your colleagues	X	X X	X X	X X	X X
6	**Maintaining professional performance** 6.1 Introduction 6.2 Continuing Professional Development	X			X	X
Total		8	9	6	8	10

Appendix 5: Number of *Good Medical Practice* components fulfilled Models A-C.

Model A

Mapping to Good Medical Practice:

Providing good care:

1.2

Working with patients:

2.10, 2.11

Working with other health care professionals:

Working within the healthcare systems:

4.2

Minimising risk:

Maintaining professional performance:

6.2

Professional behaviours:

7.2, 7.4

Model B

Mapping to Good Medical Practice:

Providing good care:

1.2, 1.3,

Working with patients:

2.2, 2.3, 2.7, 2.9, 2.10, 2.11,

Working with other healthcare professionals:

3.4

Working within the healthcare systems:

4.2, 4.4

Minimising risk:

5.3

Maintaining professional performance:

6.2

Professional behaviours: 7.2, 7.4, 7.9

Model C

Mapping to Good Medical Practice:

Providing good care:

1.2, 1.3, 1.4, 1.5

Working with patients:

2.2, 2.3, 2.4, 2.6, 2.7, 2.8, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14

Working with other healthcare professionals:

3.2, 3.4, 3.5,

Working within the healthcare systems:

4.2, 4.4

Minimising risk:

5.2, 5.3

Maintaining professional performance:

6.2

Professional behaviours:

7.1, 7.2, 7.4, 7.9, 7.10, 7.11