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Credentialing in surgery

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Please note that this brief report, while broad in some aspects of systematic review methodology, should not be considered a comprehensive systematic review. This report also contains non-systematic elements, such as qualitative information gathered from local surgeons.

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Executive summary

Objective

The primary objective of this systematic literature review was to assess the credentialing process at an institutional level and the governance structures required to support the credentialing process at an institutional, regional or healthcare system level. This involved the exploration of the impact that the credentialing process and the respective governance structures have on the safety and quality of healthcare services.

Three additional research areas explored the relationship between credentialing and the following issues:

- surgeon volume, technical competence and patient outcomes, especially in relation to synthesis of credentialing criteria and determination of threshold credentials
- methods of determining surgeon competence
- the role of clinical audit.

Methods

Specific search strategies were developed a priori for identifying literature relevant to the assessment of the credentialing process and governance structures; as well as for the three additional research questions. Databases searched for peer-reviewed literature included Medline, EMBASE and PubMed. Additional grey literature searches were conducted using the Google search engine. The inclusion criteria for each research question were generated a priori, and standardised extraction of the information required to inform the specific research questions was conducted systematically.

Results

A total of 38 documents were included in this systematic literature review. Thirty-three white papers were included for the assessment of the credentialing process and governance structures which support credentialing. Of these, 18 were published in Australia, one in New Zealand (NZ), 10 in the United Kingdom (UK), two in the United States of America (USA) and two in Canada. An additional four systematic literature reviews and one document were included for the additional research questions.

Credentialing process and governance structure

Credentialing process

The Australian white papers included in this systematic literature review were published by the state health departments of Queensland, New South Wales, Victoria, South Australia and Western Australia. No reports were available for the Australian Capital Territory, Northern Territory or Tasmania. Three main models for the credentialing process were identified in the Australian Commission on Safety and Quality in Health Care's (ACSQHC) *Standards for credentialing and defining the scope of clinical practice* ('ACSQHC

Standards'), and most Australian state health departments operated within the scope of these models. The process of revalidation within the National Health Service (NHS) in the UK was identified as the system of medical regulation most similar to the credentialing process within Australia, and involves the standardised re-licensure of clinicians according to local performance review results. In contrast to the credentialing system within Australia, in the UK the revalidation of a clinician's license to practice is not confined to the jurisdiction of a specific institution. One white report was available for the examination of the credentialing process within NZ, and the process outlined was similar to the process employed within Australia.

Whilst there were differences in the methods by which the credentialing process was performed, four key principles were common throughout all studies included in this systematic literature review:

- clear lines of responsibility for credentialing and supportive governance structures
- clear standards for credentialing, representing how the credentialing process should be performed and providing a standard to which credentialing processes should be measured
- a culture of continuous improvement
- evaluation of credentialing process outcomes.

Governance structure

A total of 23 documents were available to inform on governance structures, of which 13 were published in Australia, one in NZ, six in the UK, two in the USA and one in Canada. Seven of these documents were included only for the assessment of governance structures, and 16 documents that were included for assessment of the credentialing process also contained relevant information on governance structures. Information regarding institutional governance structures within the USA was available from The Joint Commission and the Veterans Health Administration (VHA). Common governance structures required for the credentialing process included a governing body, credentialing committee and senior managers. Governance structures varied between states and territories within Australia. The malpractice case of Dr Jayant Patel within Queensland Health triggered a number of reforms including governance restructuring and the formation of an independent health watchdog, namely the Health Quality and Complaints Commission (HQCC). The NZ healthcare system operates with 20 District Health Boards (DHBs), each of which is responsible for the quality of healthcare services in the institutions within their jurisdiction. In the UK, NHS Trusts are regulated by the NHS, with a number of health authorities involved in the monitoring and review of the quality of healthcare services. The implementation of the principle of clinical governance and related structures within the NHS was stimulated by the findings of the Bristol Royal Infirmary and Shipman inquiries. In contrast, the United States Federal Department of Health and Human Services contracts a Quality Improvement Organisation (QIO) in each state. These QIOs are generally private, not-for-profit companies staffed by medical

professionals, and are responsible for improving the quality of healthcare services. Canada also operates with a provincial model of governance, and the AHS operates via Boards that are responsible for a geographical zone, similar to the DHB structure of the NZ healthcare system.

Other research areas

Surgeon volume, technical competence and patient outcomes

Four systematic literature reviews were identified for assessment of the relationship between credentialing and surgeon volume, technical competence and patient outcomes. The conclusions drawn from these reviews indicated that for the purpose of credentialing, minimum surgeon volume thresholds may be necessary to indicate a minimum level of surgeon competence. However, these thresholds were not considered sufficient to indicate actual technical competence.

Methods of determining surgeon competence

One white report published by the Royal Australasian College of Surgeons was available for the examination of methods used to determine surgeon competence. Components of surgical competence identified included medical expertise, judgement and decision-making, technical expertise, professionalism, health advocacy, communication, collaboration and teamwork, management and leadership, scholarship and teaching. No information on methods of determining surgeon competence within the credentialing process was included within this document.

The role of clinical audit

Two reports published by the NHS and the New Zealand Ministry of Health included information regarding the role of clinical audit in performance review and recredentialing. Criticisms of the use of clinical audit data for performance review and recredentialing included:

- insufficient detail captured within the audit process may lead to an inaccurate portrayal of an individual clinician's performance
- senior clinicians generally provide treatments or interventions of greater technical competence, or treat patients with more complex/advanced disease, and therefore the collected data may not be appropriately risk-adjusted.

Consequently, the use of clinical audit data for performance review or for evaluating the impact of credentialing processes on the safety and quality of healthcare services may not be appropriate. This is reflected in the NHS process audit method of evaluating the credentialing process, where the performance of credentialing process activities is measured against clearly-defined standards for credentialing.

Conclusion

Credentialing processes and the governance structures which support the credentialing of clinicians were assessed within a number of healthcare systems and jurisdictions within

this systematic literature review. Whilst differences were apparent between the credentialing standards and policies across a number of jurisdictions, key common principles fundamental to the credentialing process were identified. These included ensuring that the responsibility for credentialing was clearly delegated, and that standards indicating best practice policies for credentialing were available and consulted throughout the design, implementation and monitoring of the credentialing process. The literature highlighted the need for a culture of continuous improvement within an organisation to ensure individuals are aligned to the objective of the credentialing process: the improvement of the safety and quality of healthcare services. In addition, evaluation of the credentialing process should be conducted, to ascertain its impact on patient outcomes. However, no data were available to evaluate any relationship between credentialing processes and the safety and quality of healthcare services, or patient outcomes. Consequently, this topic represents an area of further research. The only available document that evaluated credentialing processes in relation to outcomes of process audits was a preliminary analysis conducted by the NHS. This presented outcomes at the mid-point of the implementation of a number of governance structures that were introduced to support credentialing processes. Hence, the development of methods for evaluating the impact credentialing processes have on the safety and quality of healthcare services represents an area for further research.

1. Introduction

Credentialing refers to the formal process used to verify the qualifications, experience, professional standing and other relevant professional attributes of clinicians (ACSQHC 2004). The purpose of credentialing is to ensure that clinicians provide safe, high-quality healthcare services in accordance with good practice and legal requirements (Frommer et al 2005a). Defining the scope of clinical practice is commonly recognised as the process triggered following the completion of the credentialing process; and involves delineating the extent of an individual clinician's clinical practice. During this process the needs and the capability of the organisation to support the clinician's scope of clinical practice must also be assessed. Consequently, the definition of the scope of clinical practice for an individual clinician within an institution is affected by a number of complex inter-relating factors. These include competing priorities for healthcare resources, limited available data upon which to make health resource planning decisions, and the potential for healthcare services to be required on an emergency basis. Geographical factors may also be involved, including community preference for local service delivery, the availability of alternative healthcare services to a particular community, and the need for specific support services to be available to sustain core healthcare services within a particular environment (ACSQHC 2004).

Many parties are involved in the credentialing process including senior managers, the credentialing committee, the governing body, health authorities and specialist colleges. The process of defining the scope of clinical practice is organisation-specific within Australia, yet is standardised across the National Health Service (NHS) in the United Kingdom (UK).

Credentialing is one of a number of safety and quality initiatives instigated over the last decade throughout the international healthcare community. The impetuses for many initiatives, including credentialing and governance structure reforms, have been the Bristol Royal Infirmary Inquiry and the malpractice cases of Dr Harold Shipman within the UK and Dr Jayant Patel in Australia (Bristol Royal Infirmary Inquiry 2001; HQCC 2010; UK Department of Health 2006). The continued undetected malpractice of these clinicians, as well as the number of resultant victims, demonstrates the importance of formalised credentialing processes and implementation of governance structures to ensure the adequate reporting and evaluation of the safety and quality of healthcare.

1.1 Research questions

The primary objective of this systematic literature review was to assess national and international credentialing processes at an institutional level and the governance structures that are required to support these processes at an institutional, regional or healthcare system level. This involved the exploration of the impacts of the credentialing process and the respective governance structures on the safety and quality of healthcare services. Additional research questions assessed the following:

the relationship between credentialing and surgeon volume, technical competence and patient outcomes, especially in relation to synthesis of credentialing criteria and determination of threshold credentials

- the relationship between credentialing and methods of determining surgeon competence
- the role of clinical audit in relation to credentialing.

2. Methodology

2.1 Credentialing process and governance structure

To explore the impact of the credentialing process and the respective governance structures on the safety and quality of healthcare services. Secondary research areas included:

- investigation of how credentialing relates to defining the scope of clinical practice
- examination and comparison of the components of national and international credentialing process
- identification of the differences in the process for initial credentialing of clinicians versus that for recredentialing of clinicians
- exploration of any controversies surrounding the credentialing of surgeons.

2.1.1 Inclusion criteria

Study inclusion criteria are outlined in Table 1 according to publication type, intervention, comparators and outcomes.

Table 1 Inclusion criteria: credentialing process and governance structures

Selection criteria	Conditions
Publication type	Peer-reviewed literature including systematic reviews, comparative studies and case series. Grey literature including white papers and guidelines were also appropriate for inclusion.
Intervention	Implementation or development of credentialing process(es) at an institutional level. Implementation or development of governance structure(s) to support credentialing processes at an institutional, regional or healthcare system level. Literature assessing credentialing processes for rural practice was excluded on advice from the Credentialing in Surgery Advisory Committee.
Comparators	Institutions without a formalised or developed credentialing process. Absence of governance structures required for ongoing performance and support of credentialing processes at an institutional, regional or healthcare system level.
Outcomes	Evaluation or outcome data assessing changes in the safety and quality of healthcare services following implementation or development of an institution-wide credentialing system. Evaluation or outcome data assessing changes in the safety and quality of healthcare services following implementation of an institutional, regional or healthcare system level governance structure(s) to support credentialing processes.

Where appropriate, additional published material from government policy documents, fact sheets, private organisational directives, letters, conference material, commentary, editorials and abstracts were included as background information.

2.1.2 Databases searched and search terms used

The databases searched for peer-reviewed literature and guidelines are shown in Table 2.

Table 2 Databases searched

Database	Edition and date searched
Cochrane Library	Issue 8, 2011
NHS HTA	Searched 25 August 2011
NICE	Searched 25 August 2011
Ovid MEDLINE	Inception to 04 July 2011
PubMed	Inception to 04 July 2011
TRIP database	Searched 25 August 2011
York CRD	Searched 02 August 2011

NHS HTA: National Health Service Health Technology Assessment website; NICE: National Institute for Health and Clinical Excellence; TRIP: Turning Research Into Practice; York CRD: York Centre for Reviews and Dissemination.

Search terms employed in PubMed, Medline and EMBASE are outlined below in Table 3.

Table 3 Search terms used for searching PubMed, Medline and EMBASE

Search number	Search term
1	Credentialing (MeSH) OR Surgical procedure, operative (MeSH)
2	credential* (KW) AND surge* (KW) OR surg*
3	#1 AND #2

MeSH: Medical Subject Headings.

Search terms employed in the Cochrane Library, TRIP, York Centre for Reviews and Dissemination (York CRD), National Health Service Health Technology Assessment (NHS HTA), National Institute for Health and Clinical Excellence (NICE) (UK) were: credential*, credentialling, credentialing.

These search terms were also used when searching websites of Australian federal and state governments, the NHS and the New Zealand Ministry of Health for grey literature reports (Table 4).

Five additional searches with the above search terms were conducted using the Google search engine with the results confined to pages from Australia, NZ, the UK, the USA and Canada.

Table 4 Government websites searched

Website	Date searched
<i>Australian</i>	
Australian Capital Territory Department of Health	25 August 2011
Australian Commission on the Safety and Quality of Health Care	10 August 2011
Health Quality and Complaints Commission, QLD	24 August 2011
New South Wales Department of Health	24 August 2011
Northern Territory Health Department	24 August 2011
Queensland Department of Health	24 August 2011
South Australian Department of Health	10 August 2011
Tasmanian Department of Health and Human Services	24 August 2011
Victorian Department of Human Services	23 August 2011
Western Australian Health Department	24 August 2011
<i>International</i>	
National Health Service, UK	05 August 2011
New Zealand Ministry of Health	24 August 2011

QLD: Queensland; UK: United Kingdom.

2.2 Additional research areas

A number of secondary research areas related to the credentialing process were raised by the Credentialing in Surgery Advisory Committee:

- the impact of surgeon volume on technical competence, which is assessed within the processes of credentialing and defining the scope of clinical practice
- methods of assessing surgeon competence
- the role of clinical audit in relation to performance appraisal, which is a component of recredentialing and of re-defining the scope of clinical practice.

2.2.1 *Inclusion criteria*

Surgeon volume, technical competence and patients outcomes

Only systematic literature reviews that had been published between 2007 and 14 September 2011 were considered appropriate to inform on the relationship between surgeon volume, technical competence and patient outcomes. Only those reviews which contained greater than 10 studies were included.

Methods of assessing surgeon competence

Only relevant position papers and guidelines published by the Royal Australasian College of Surgeons (RACS) were included for the examination of methods for determining a surgeon's competence; as these were specific for surgical competence within Australia and NZ.

The role of clinical audit

Due to the complex nature of this topic, only identified studies that assessed the credentialing process and governance structures were used to inform on the relationship between clinical audit, performance review and recredentialing.

2.2.2 *Databases searched and search terms used*

Surgeon volume, technical competence and patients outcomes

Specific searches of the Cochrane Library and York CRD was performed to capture relevant systematic literature reviews to inform on the topic of surgeon volume, technical competence and patient outcomes.

Four search terms were used for the York CRD database:

1. surgeon volume OR centralis*
2. surgeon volume OR centraliz*
3. (surgeon volume OR centralis*) AND patient*
4. (surgeon volume OR centraliz*) AND patient*.

Three search terms were used for The Cochrane Library:

1. surgeon volume OR centralis*
1. surgeon volume OR centraliz*
2. surgeon volume.

Methods of assessing surgeon competence

The Royal Australasian College of Surgeons website was searched to identify literature. Search terms included credential*, credentialing, credentialling, competence and competenc*.

The role of clinical audit

According to inclusions criteria, only studies that assessed the credentialing process and governance structures were used to inform on the relationship between clinical audit, performance review and recredentialing. Consequently, the search strategy utilised for this research area is identical to that employed for the credentialing process and governance structures outlined earlier.

3. Studies included in the review

No peer-reviewed studies met the defined inclusion criteria for the assessment of credentialing process or the governance structures required to support the credentialing process, as none of the identified studies assessed the credentialing process from an institutional level.

A total of 38 documents were included in this systematic literature review, including 33 white papers, four systematic literature reviews and one document. Grey literature constituted the entirety of the results for examination of the credentialing process and governance structures, with a total of 33 white papers included; of which 18 were published in Australia, 10 in the UK, two in the USA, two in Canada and one in NZ.

Many of the reports included for the assessment of credentialing processes and governance structures were found via pearling of reference lists; and searching of each respective health department website as listed in Table 4.

3.1 Credentialing process

Twenty-seven studies were included for the assessment of credentialing process, with 14 published in Australia, nine in the UK, two in the USA, one in Canada and one in NZ (Table 5).

Table 5 Reports included for the assessment of credentialing processes and governance structures

Insitution (year of publication)	Credentialing	Governance structures
<i>Australian literature</i>		
Australian Council of Safety and Quality in Health Care (2005)	✓	
Australian Council of Safety and Quality in Health Care (2004)	✓	✓
Australian Council of Safety and Quality in Health Care (2002)	✓	
Frommer et al (2005a)	✓	✓
Frommer et al (2005b)	✓	✓
Health Quality and Complaints Commission (2010)	✓	
Queensland Department of Health (2011)	✓	✓
New South Wales Department of Health (2001)	✓	
South Australian Department of Health (2010)	✓	✓
South Australian Department of Health (2007)		✓
Tasmanian Department of Health (2011)		✓
Victorian Department of Human Services (2009)	✓	✓
Victorian Department of Human Services (2006)	✓	
Western Australian Department of Health (2009a)	✓	✓
Western Australian Department of Health (2009b)	✓	✓
Western Australian Department of Health (2005a)		✓
Western Australian Department of Health (2005b)		✓
Western Australian Department of Health (2005c)		✓
<i>New Zealand literature</i>		
New Zealand Ministry of Health (2001)	✓	✓
<i>United Kingdom literature</i>		
General Medical Council (2011a)	✓	✓
General Medical Council (2011b)	✓	
General Medical Council (2011c)	✓	✓
General Medical Council (2010)	✓	✓
General Medical Council (2009)	✓	
UK Department of Health (2008)	✓	
UK Department of Health (2007a)	✓	✓
UK Department of Health (2007b)	✓	
UK Department of Health (2006)	✓	✓
UK Department of Health (1999)		✓
<i>United States of America</i>		
The Joint Commission (2011)	✓	✓
Department of Veterans Affairs (2008)	✓	✓
<i>Canada</i>		
Alberta Health Services (2011a)		✓
Alberta Health Services (2011b)	✓	

UK: United Kingdom.

A summary of the documents included for the evaluation of credentialing processes within Australia is available in Table 6; and these topics were identified as the key components of the credentialing process. Studies included only for the examination of governance structures were not included in this table. Review and audit of the scope of

clinical practice and performance review were identified as key areas that ensure the ongoing quality and safety of healthcare services.

Table 6 Summary of Australian documents included for the assessment of credentialing processes

Study	Defs	Govern structures	Cred Process	Comm membership	Cred criteria	Def SCP	Review/audit SCP	Perf review
ACSQHC 2004	✓	✓	✓	✓	✓	✓	✓	✓
ACSQHC 2002	✓	✗	✓	✓	✓	✗	✓	✗
ACN 2005a*	✓	✓	✓	✗	✗	✓	✓	✓
ACN 2005b†	✓	✓	✓	✓	✓	✓	✓	✓
HQCC 2010	✗	✗	✗	✗	✗	✗	✗	✗
NSW Health 2001	✗	✗	✗	✗	✗	✗	✗	✗
Qld Health 2011	✓	✓	✗	✗	✗	✗	✗	✗
SA DoH 2010	✓	✓	✓	✓	✓	✓	✓	✓
Vic DHS 2006	✗	✓	✗	✗	✓	✗	✗	✗
Vic DHS 2009	✓	✓	✓	✓	✗	✓	✗	✗
WA Health 2009a	✓	✓	✓	✓	✓	✓	✓	✓
WA Health 2009b	✓	✗	✓	✗	✗	✗	✓	✗

* Frommer et al 2005a, † Frommer et al 2005b. Defs: definitions; govern structures: governance structures; cred process: credentialing process; comm membership: credentialing committee membership; cred criteria: credentialing criteria, def SCP: defining the scope of clinical practice; review/audit of SCP: review/audit of scope of clinical practice; perf review: performance review; ACSQHC: Australian Commission on Safety and Quality in Health Care; ACN: Australian Cancer Network; HQCC: Health Quality and Complaints Commission; SA DoH: South Australian Department of Health; Vic DHS: Victorian Department of Human Services. Review/audit of the scope of clinical practice is the result of recredentialing. The HQCC policy documents attracted crosses for every category as whilst a number of the above topics above were covered, they only attracted a one sentence bullet point as the document was brief.

Governance structures

A total of 23 documents were available to inform on governance structures (Table 5). Seven of these documents were included only for the assessment of governance structures, and 16 documents that were included for assessment of the credentialing process also contained relevant information on governance structures. In addition to these studies, many of the guidelines and policies included for assessment of the credentialing process also contained information on governance structures.

3.1.1 Description of included studies

Australian literature

State health department reports

A number of the Australian health department reports were commissioned and published following the dissemination of the Australian Council for Safety and Quality in Health Care's (ACSQHC) Standard for credentialling and defining the scope of clinical practice (the Standard) in 2004 (ACSQHC 2004). Consequently, the content of many of the reports synthesised by the State health departments is similar, in order to meet the requirement published within the Standard. Differences are found within the governance structures that are in place to support healthcare institutions at a regional and institutional level. However, credentialing criteria, terms of reference for the credentialing committee and credentialing application processes are very similar.

Royal Australasian College of Surgeons publications

One publication was identified to inform on the credentialing process and methods of assessing surgeon competence (RACS 2008).

International literature

New Zealand

The New Zealand Ministry of Health commissioned The Medical Credentialling Project in 1999 with the Health Funding Authority; and this resulted in the publication of *Toward Clinical Excellence - A Framework for the Credentialling of Senior Medical Officers in New Zealand* in 2001 (NZ Ministry of Health 2001).

United Kingdom

The NHS introduced clinical governance in 1999 based on information from the *Bristol Royal Infirmary Inquiry*, in the white paper *Clinical governance: Quality in the new NHS* (1999) (Bristol Royal Infirmary Inquiry 2001). This report provides guidance on the implementation of clinical governance structures within an organisation and sets out a vision of clinical governance within the context of NHS reform.

The NHS *Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients* (2006) was commissioned by the Secretary of State for Health following the publication of *The Shipman inquiry: fifth report* (Smith 2004). The Chief Medical Officer was commissioned to synthesise the report also took into account an additional three inquiries into doctor's conduct and standards of practice within the NHS.

Trust, assurance and safety – the regulation of health professional in the 21st century (Department of Health (UK) 2007b) was based on consultation received during the development of *Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients* (Department of Health (UK) 2006) and was complemented

by the UK Government's response to *The Shipman inquiry: fifth report* (Smith 2004). This report sets out a programme of NHS reform to the system of regulation for health professionals.

KPMG was commissioned by the Department of Health (UK) in 2006 to undertake a review of the state of readiness of clinical governance and medical appraisal to support the implementation of medical relicensure, and outlined their findings in the *Review of the readiness of appraisal and clinical governance to support the relicensure of doctors* (2007a). Synthesis of the review involved a mixture of document review and a focused interview programme.

The NHS introduced the concept of revalidation in 2007; which resulted in the introduction of medical licences to practice from 16 November 2009. Introduction of this system involves revalidation of a medical practitioner's licence to practice at five-yearly intervals based on local performance reviews (GMC 2010). A number of publications have been synthesised by the NHS to outline the development and implementation of this process.

Firstly, *Medical revalidation – Principles and next steps* (2008), was synthesised in 2008 by an expert working group led by Professor Sir Graeme Catto, following discussions around the principles of revalidation as outlined in previous NHS reports.

Subsequently, the *Changes to registration requirements for UK doctors* was published in 2009; providing an overview for international medical regulators regarding the changes to the UK medical regulation system. This white report outlined the introduction of licences to practice by the General Medical Council (GMC).

Revalidation: The way ahead was published in 2010 and is divided into four main sections: how revalidation will work, what employers and contractors of doctors' services will need to do, patient and public involvement in revalidation, and how and when revalidation will be introduced.

Finally, in 2011 three NHS reports were released: *Preparing for the introduction of medical revalidation: a guide for NHS leaders in England*, the *Supporting information for appraisal and revalidation* and *The good medical practice framework for appraisal and revalidation* (GMC 2011a, GMC 2011b, GMC 2011c). The aim of these reports was to outline the broad areas which should be covered in the appraisal process, the information required to successfully complete the revalidation process, and who is accountable for the revalidation process and its activities with each NHS trust (GMC 2011).

United States of America

Two white papers were identified for assessment of the credentialing process within the USA, namely, *The Medical Staff Handbook: a guide to Joint Commission standards third edition* and the Department of Veteran Affairs *Veterans Health Administration (VHA) handbook* (The Joint Commission 2011; Department of Veteran Affairs 2008). The Joint Commission handbook provides a guide to The Joint Commission standards for institution accreditation.

Canada

One provincial bylaw published by the Alberta Health Service was available for the examination of the credentialing process within Canada (AHS 2011). Whilst a number of other bylaws synthesised by healthcare institutions within Canada were identified, this was the only bylaw which met inclusion criteria, due to the level of detail reported.

3.2 Additional research questions

Four systematic literature reviews were identified for the assessment of credentialing in relation to surgeon volume, technical competence and patient outcomes. One document was identified for the assessment of surgeon competence within the Australian context, and two documents reporting on the role of clinical audit were identified within the documents included for the assessment of the credentialing process and supporting governance structures (RACS 2008, UK Department of Health 2006, NZ Ministry of Health 2001).

3.2.1 Description of included studies for additional research questions

Surgeon volume, technical competence and patient outcomes

Following application of inclusion criteria, four eligible systematic literature reviews were available to inform the examination of surgeon volume, technical competence and patient outcomes (Archampong et al 2010, Gooiker et al 2010, Marlow et al 2007, Post et al 2009).

Description of systematic reviews

Table 7 Description of systematic reviews included for surgeon volume

Author	Number of included studies	Country of publication
Archampong 2010	11	United Kingdom
Gooiker 2010	12	The Netherlands
Marlow 2007	76	Australia
Post 2009	22	The Netherlands

Methods of assessing surgeon competence

One document was identified that investigated methods of assessing surgeon competence, namely, the *Surgical competence and performance guide 1st edition* (2008) published by the RACS. Notably, this guide is currently being updated by RACS and the second edition is expected to be publicly available in November 2011.

The role of clinical audit

Two of the documents included for assessment of the credentialing process and governance structures to support credentialing assessed the relationship and role of national clinical audit, performance review and recredentialing. These were: *Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients* (UK Department of Health 2006) and *Toward clinical excellence - a framework for the credentialing of Senior Medical Officers in New Zealand* (NZ Ministry of Health 2001).

4. Results

4.1 Definitions of credentialing

A number of accepted definitions for credentialing were identified in the literature and are outlined in Table 8.

Table 8 Definitions of credentialing

Study	Definition
ACSQHC 2004	‘Credentialing refers to the formal process used to verify the qualifications, experience professional standing and other relevant professional attributes of medical practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high quality health care services within specific organisational environments’.
Frommer et al 2005b	‘Credentialing is a formal process for: <ul style="list-style-type: none"> • defining the clinical responsibilities of medical practitioners and other clinicians within a particular health-care institution, • verifying that they are qualified and competent and • working with them to review and improve or sustain their performance in fulfilling those responsibilities’.
ACSQHC 2002	‘Credentialing is the formal process of assessing a health care professional’s credentials in relation to that professional role within a specific facility’.
The Joint Commission 2011	‘Credentialing is the process of obtaining, verifying and assessing the qualifications of a health care practitioner who seeks to provide patient care services in or for a hospital’.

Sources: ACSQHC (2004) p 3; Frommer et al (2005b) p 2; ACSQHC (2002) p 3; The Joint Commission (2011) p 27.

4.1.1 Defining the scope of clinical practice

Defining of the scope of clinical practice is commonly recognised as the process triggered following the completion of the credentialing process. A number of definitions for defining the scope of clinical practice are outlined in Table 9. Defining the scope of clinical practice is known as ‘clinical privileging’ within the USA and Canada.

Table 9 Definitions of defining the scope of clinical practice

Study	Definition
ACSQHC 2004	‘Defining the scope of clinical practice follows on from credentialing and involves delineating the extent of an individual medical practitioner’s clinical practice within a professional suitability, and the needs and the capability of the organisation to support the medical practitioner’s scope of clinical practice’.
Frommer et al 2005b	‘Credentialing includes defining the scope of clinical practice for individual clinicians. This means delineating what an individual clinician may or may not do

	<p>within a particular health-care institution?. There are three factors that must be considered when defining the scope of clinical practice:</p> <ul style="list-style-type: none"> • the clinician’s qualifications, competence, experience and performance, • the needs of the institution, and • the capability of the institution to support the clinician’s scope of clinical practice (Frommer et al 2005b)’.
ACSQHC 2002	<p>Defining the scope of clinical practice ‘results from a process in which the governing body or its delegate grants a health care professional the authority to provide health care services within defined limits in a health care facility. They represent the range and scope of clinical responsibility that a professional may exercise in the facility. The scope of practice is specific to the individual, usually within a single health care facility (or group of facilities within a rural district/region) and relate to the resources, equipment and staff available’.</p>
The Joint Commission	<p>Clinical privileging (defining the scope of clinical practice) ‘is the process that the medical staff and governing body of the hospital or critical access hospital use to recommend and grant clinical privileges to a practitioner’.</p>

Sources: ACSQHC (2004) p 4; Frommer et al (2005b) p 2; ACSQHC (2002) p 3; The Joint Commission (2011) p 63.

Definition of the scope of clinical practice for an individual clinician within an institution is affected by a number of complex inter-relating factors. These include competing priorities for healthcare resources, limited available data upon which to make health resource planning decisions, and the potential for healthcare services to be required on an emergency basis. Geographical factors may include community preference for local service delivery, the availability of alternative healthcare services to a particular community, and the need for specific support services to be available to sustain core healthcare services within a particular environment. Therefore the main question to be addressed when defining an individual clinician’s scope of practice is: ‘Is it reasonable in the circumstances for this clinician to provide this service in this organisational setting, and has the organisation identified a need for this service within this organisation?’ (ACSQHC 2004).

The process of defining the scope of clinical practice is organisation-specific within Australia. Hence, there may be circumstances in which an appropriately credentialed clinician is unable to perform a specific procedure within the organisation due to a lack of organisational capability. In contrast, the opposite may be observed in rural settings, where there are adequate organisational resources and infrastructures but a shortage of accredited or endorsed clinicians. This situation may justify the performance of a specific procedure within an institution by a non-accredited clinician (ACSQHC 2004).

4.2 Safety and quality initiatives - credentialing

4.2.1 Australian initiatives

A number of the identified Australian reports (Table 5) were commissioned and published following the dissemination of the Australian Council for Safety and Quality in Health Care's (ACSQHC) Standard for credentialling and defining the scope of clinical practice ('ACSQHC Standard').

Two Australian Cancer Network (ACN) reports were the first examples of customisation of the ACSQHC Standard in order to focus on a particular, complex segment of the health system (cancer services). The first report, released in 2005, was developed in accordance with the ACSQHC Standard (2004) as a guide for Australian health-care organisations in the development and implementation of systems for the credentialling of clinicians involved in the care of cancer patients (Frommer et al 2005a). The second report was also released in 2005, and is essentially a guide and template providing a sixteen step process to follow when developing and implementing a local cancer credentialing system (Frommer et al 2005b).

The Victorian Department of Human Services (VIC DHS) commissioned a literature review in order to develop a standard approach to the credentialing and defining the scope of clinical practice in [Victorian] community health. Subsequent VIC DHS reports included *Credentialling and defining the scope of clinical practice for medical practitioners in Victorian health services – a policy handbook*, which was first released in 2007 and then updated in 2009 (VIC DHS 2009).

Additional credentialing policy documents released following dissemination of the ACSQHC Standard include SA Health's *The policy for credentialling and defining the scope of clinical practice for medical and dental practitioners* (2010), Queensland Department of Health's *Credentialling and defining the scope of clinical practice for medical practitioners and dentists in Queensland – Health policy* (2010) and Western Australian Department of Health's *The policy for credentialling and defining the scope of clinical practice for medical practitioners, 2nd edition* (2009a) and *Guidelines: Medical practitioner recruitment selection, appointment, credentialling, reappointment, and recredentialling processes within WA Health* (2009b).

Australian health safety and quality initiatives, particularly in Queensland, were stimulated following the malpractice case of Dr Jayant Patel, which was arguably the most publicised incident of medical malpractice within Australia. Dr Patel was the Director of Surgery at Bundaberg Public Hospital, Queensland, between 2003 and 2005. Dr Patel was recruited by Queensland Health and in 2005 was convicted of three counts of manslaughter and one count of grievous bodily harm; however, subsequent inquiries indicate he may be responsible for between 15 and 17 deaths (Bundaberg Hospital Commission of Inquiry 2005). The uncovering of Dr Patel's malpractice and clinical incompetence resulted in three inquiries within Queensland Health, namely the Morris (Bundaberg Hospital Commission of Inquiry), Davies (the Queensland Public Hospitals

Inquiry) and Forster (Health Systems Review) inquiries; and stimulated a number of structural reforms with regard to patient safety and health service quality within Queensland Health (Bundaberg Hospital Commission of Inquiry 2005, Queensland Public Hospitals Commission of Inquiry 2005, Queensland Health Systems Review 2005). The three inquiries discovered that Dr Patel's credentials and previous clinical performance were not confirmed at the time of recruitment. Queensland Health performance review, complaints and malpractice incident reporting processes failed to adequately feed into the credentialing and defining the scope of clinical practice processes. Consequently, there was no review of Dr Patel's approved scope of clinical practice or medical registration. The findings of the Morris, Davies and Forster inquiries indicated that no-one properly verified Dr Patel's credentials at the time of appointment (Bundaberg Hospital Commission of Inquiry 2005, Queensland Public Hospitals Commission of Inquiry 2005, Queensland Health Systems Review 2005). This malpractice case may provide other Australian state health departments with insight into the importance of clinical governance, sound credentialing and performance review systems, and verification of an applicant's credentials.

The Health Quality and Complaints Commission (HQCC), based within Brisbane, Queensland, was established in 2006 following the Morris (Bundaberg Hospital Commission of Inquiry), Davies (the Queensland Public Hospitals Inquiry) and Forster (Health Systems Review) inquiries (Bundaberg Hospital Commission of Inquiry 2005, Queensland Public Hospitals Commission of Inquiry 2005, Queensland Health Systems Review 2005). The HQCC, Queensland's independent statutory body, is funded by the Queensland Government and was formed under the *Health Quality and Complaints Commission Act 2006* (HQCC 2011). The HQCC reports to Queensland Parliament through the Deputy Premier and Minister for Health and to the Health and Disabilities Committee (a bipartisan parliamentary committee) (HQCC 2011). In 2010, the HQCC synthesised and disseminated the second version of its standard for credentialing and scope of clinical practice (HQCC 2010).

4.2.2 International initiatives

Several initiatives to improve the quality and safety of healthcare have been created and implemented in a number of countries worldwide (UK Department of Health 2006). NZ, the UK, the USA and Canada were identified as countries of particular interest when comparing and contrasting quality healthcare initiatives, by the Credentialing in Surgery Advisory Committee.

New Zealand

The Medical Credentialling Project was commissioned in 1999 by the New Zealand Ministry of Health in cooperation with the Health Funding Authority, to assist clinical leaders to develop a common approach to the credentialing of senior medical officers. This project focused on framework development and implementation issues, and on collecting the available 'best practice' information (NZ Ministry of Health 2001). This project resulted in the publication of *Toward clinical excellence - a framework for the credentialling of Senior Medical Officers in New Zealand* in 2001 (NZ Ministry of Health 2001).

United Kingdom

In the last decade the NHS has placed a greater emphasis on the quality and safety of healthcare. Reform of the NHS has involved the synthesis and implementation of best practice policies and the creation of tools and governing structures in order to measure the results of implementation; such as clinical and process audit tools and the formation of the National Clinical Assessment Service (NCAS). Other key changes within this reform have included:

- the creation of a legal duty of quality for all NHS organisations
- clear national standards
- the introduction of comprehensive local clinical governance arrangements
- a system of independent inspection against standards in hospitals and primary care services
- the establishment of a national patient safety programme (including adverse event and near-miss reporting)
- a range of initiatives to empower patients and their representatives
- establishment of a specific service, the NCAS, to support the NHS in assessing and dealing with concerns about the performance of doctors.

In 1999 the NHS introduced clinical governance based on information from the Bristol Royal Infirmary Inquiry (2001). This inquiry found that a root cause of the investigated issues was the lack of a system of accountability for standards of care and for dealing with related problems and incidences (UK Department of Health 2001; Bristol Royal

Infirmity Inquiry 2001). Clinical governance was developed to address this issue by assigning clear roles and responsibilities for improvement throughout an organisation, delegated by the governing body. The resulting document, *Clinical governance: quality in the new NHS*, provides guidance on the implementation of clinical governance structures within an organisation and sets out a vision of clinical governance within the context of NHS reform (UK Department of Health 1999).

The document: *Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients* was commissioned by the Secretary of State for Health following the publication of *The Shipman inquiry: fifth report* (UK Department of Health 2006; Smith 2004). Harold Shipman was a general practitioner (GP) who was responsible for the deaths of approximately 250 patients between 1972 and 1998, usually using narcotic drugs that he had stockpiled illicitly (UK Department of Health 2006). The Chief Medical Officer commissioned to synthesise the document *Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients* also took into account an additional three inquiries into doctors' conduct and standards of practice within the NHS.

Dame Janet Smith, who chaired the Shipman Inquiry from 2000 to 2005, condemned a number of weaknesses within the NHS that resulted in the failure to protect patients. Dame Smith questioned the effectiveness of five-yearly revalidation of a doctor's licence to practice, and criticised the General Medical Council (GMC) culture, membership, methods of working and governance structures, which were deemed likely to support the interests of doctors rather than protecting patients. Dame Smith also criticised the proposed reliance on annual appraisal of NHS doctors, judging that this did not constitute a true evaluation of the full range of doctors' performance and delivery of care as the process is variable and largely formative in nature across institutions (UK Department of Health 2006). Consequently, Dame Smith concluded that this method of performance review was ineffective at detecting doctors who are incompetent, dysfunctional or delivering care to a poor standard.

These issues provided the stimulus for change, and the NHS developed the concept of revalidation and the introduction of medical licences to practice on 16 November 2009. This system involves revalidation of a clinician's licence to practice at five-yearly intervals based on local performance reviews (GMC 2010).

Revalidation

The concept of revalidation was first introduced following the Bristol Royal Infirmity Inquiry; and was a proposed method by which the GMC could ensure better patient safety, incorporating regular checks on the performance and practice of doctors and local performance appraisals. Between 1999 and 2004 the model for revalidation was developed and a number of pilots were undertaken. However, in 2004 the further development and implementation of revalidation was postponed pending the results of the fifth report of the Shipman Inquiry (Smith 2004). This inquiry criticised the original model of revalidation, noting that local appraisal systems were inconsistent and an

insufficient basis for revalidation. Consequently, the implementation of revalidation was further postponed.

Three subsequent reports by the UK Department of Health outlined a number of changes to the medical regulation of clinicians in order to support the introduction of revalidation, including the introduction of a licence to practice (UK Department of Health 2006; UK Department of Health 2007a; UK Department of Health 2008). Despite the findings of the Shipman Inquiry, all three reports supported locally-based performance appraisal as the best basis for the revalidation of doctors.

The next development and implementation stages of the revalidation process involved extensive consultations and the execution of a number of pilots across the UK; which were carried out between 2009 and 2010. In 2011, Responsible Officer regulations were introduced, which outlined the responsibility for the local appraisal process and the information required to support the revalidation process (GMC 2011). Following the publication of the *Preparing for the introduction of medical revalidation: a guide for NHS leaders in England* in 2011, the final deadline for the implementation of the revalidation system throughout the NHS was set for late 2012 (GMC 2011).

United States of America

The United States Federal Department of Health and Human Services contracts 51 Quality Improvement Organisations (QIOs) across the country whose mission is to improve the effectiveness, efficiency, economy and quality of healthcare services delivered to Medicare beneficiaries. The core functions of the QIO program are:

- improving the quality of healthcare services
- protecting the integrity of the Medicare Trust Fund by ensuring that Medicare only pays for services and goods that are reasonable, necessary and provided in the most appropriate setting
- protecting beneficiaries by expeditiously addressing complaints and violations of the Emergency Medical Treatment and Labor Act and other QOI-related law.

The majority of QIOs are private, not-for-profit organisations that are staffed by professionals, mostly doctors and other healthcare professionals who are trained to review medical care.

No safety and quality initiatives specifically addressing the credentialing process or governance structures were identified at a national level within the USA.

Canada

Canada has a provincial healthcare system, with regulation of clinicians and standards for credentialing varying according to provincial regulations and requirements. No safety and quality initiatives specifically addressing the credentialing process or governance structures at a national level within Canada were identified.

4.3 Governance

4.3.1 Australian governance models

The development, implementation and review of credentialing processes conducted within the Australian healthcare system are the responsibility of each institution (ACSQHC 2004).

Organisational governance structures required for a successful credentialing process, as outlined in the ACSQHC Standard, include:

- a governing body that is responsible for establishing a system of organisational governance which will ensure strong strategic leadership and control of all aspects of the organisation's performance
- a medical practitioners appointments committee
- a credentialing committee
- a senior manager who provides clinical leadership (ACSQHC 2004).

The governing body

The governing body should be responsible for and have the authority to:

- develop, modify and endorse credentialing policies
- lead and oversee processes for credentialing and defining the scope of services provided within the institution
- update standards of care
- monitor data on the performance of individual clinicians
- manage variations from expected performance and other problems
- prepare reports on aggregated data for the executive of the institution (Frommer et al 2005a).

The credentialing committee

The authority of the governing body may be delegated to a credentialing committee, which is discrete from and appointed by the governing body for the purpose of credentialing. Requirements for a credentialing committee include:

- a formal constitution and explicit terms of reference
- sufficient independence to review clinicians' performance objectively, and respond appropriately to the findings
- a membership that has expert capacity to assess clinical services
- sufficient support to function effectively

- linkage to both the organisation's executive and to its safety and quality-improvement mechanisms.

To ensure the impartiality of the committee, clinicians who have scope of clinical practice within the institution in which the applying clinician proposes to work, should not form part of the credentialing committee for review of the applicant. This would avoid criticism of the determination reached by the committee with regard to:

- reference to service levels or needs of the hospital rather than the clinical competencies of the applicant
- whether the decision-maker is in competition with the applicant under review and stands to benefit from any negative outcome for the applicant
- whether the decision-maker is related to a person in competition with the applicant and whether that related person stands to benefit from any negative outcome for the applicant
- whether the decision-maker stands to benefit from a positive outcome for the applicant, either because they hope to obtain a similar positive outcome if their practice is under review, or because they will gain some benefit from the work of the applicant (SA Health 2010).

In some states and jurisdictions, and particularly within small healthcare institutions, the governing body acts as the credentialing committee. Additional members of the speciality to which the applicant belongs may sit on the committee as requested.

Clinical governance

Clinical governance (also known as clinical leadership) is the term referring collectively to all the activities that promote, review, measure and monitor the quality of patient care into a unified and coherent whole (WA Department of Health 2011). Clinical governance provides a systematic and integrated approach to assurance and review of clinical responsibility and accountability that improves quality and safety, resulting in optimal patient outcomes (WA Department of Health 2011). Clinical governance has a number of similarities to corporate governance in that it "...must be rigorous in its application, organisation-wide in its emphasis, accountable in its delivery, developmental in its thrust, and positive in its connotations" (WA Department of Health 2005b, p 2). The history of clinical governance is further explored under 'International governance models'. This model of governance, incorporating clinical directorates headed by a Clinical Director, has been implemented within the Australian healthcare system.

The role of specialist colleges

Currently, the role of specialist colleges as outlined by the ACSQHC Standard entails providing advice to the credentialing committee, and/or senior managers within an institution, regarding the synthesis of essential criteria for a position. This involves providing advice regarding the nature and period of training and experience required to develop the competencies and performance required for specific positions (ACSQHC

2004). This topic is further explored under 'Initial credentialing'.

4.3.2 International governance models

New Zealand

Credentialing in the NZ context is defined as: "...a process used to assign specific clinical responsibility (scope of practice) to health professionals on the basis of their training, qualifications, experience and current practice, within an organisational context. This context includes the facilities and support services available and the service the organisation is funded to provide. Credentialing is part of a wider organisational quality and risk management system designed primarily to protect the patient" (NZ Ministry of Health 2001, p 2).

District Health Boards (DHBs) comprise the governance structure within the New Zealand Ministry of Health and each is responsible for providing or funding the provision of health and disability services in their district (NZ Ministry of Health 2011). Currently, there are 20 DHBs in NZ, which were created on 1 January 2001 upon commencement of the New Zealand Public Health and Disability Act 2000 (New Zealand Public Health and Disability Act 2000). The objective of the DHBs is to:

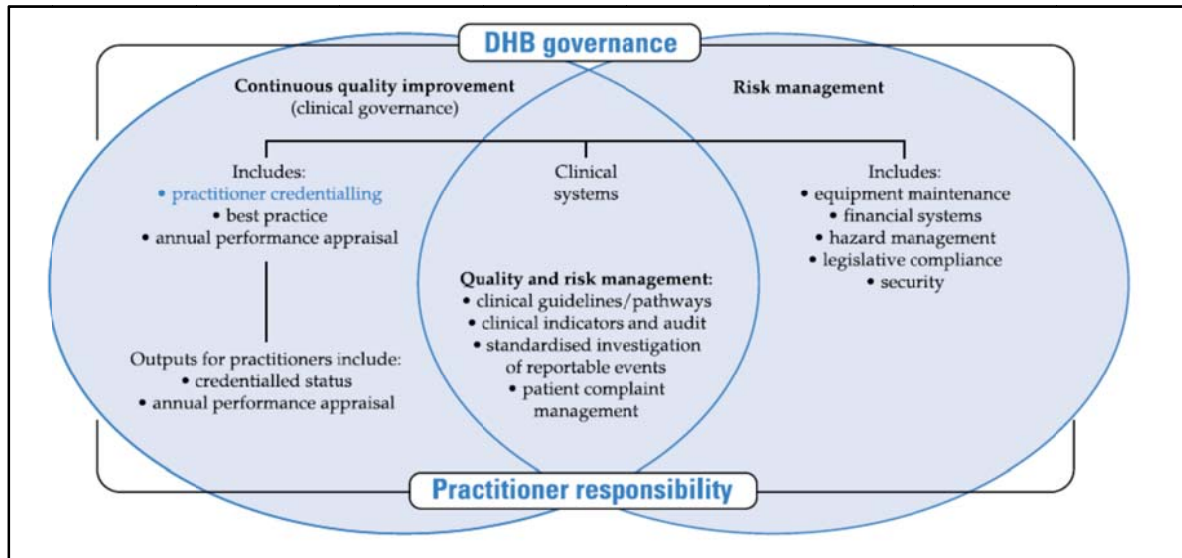
- improve, promote and protect the health of communities
- promote the integration of health services, especially primary and secondary care services
- promote effective care or support for those in need of personal health services or disability support.

Credentialing in the context of a wider organisational quality and risk management system

Within NZ, credentialing is the responsibility of the Chief Executive of the DHB, and is a requirement of clinical governance (Figure 1). The tasks of credentialing are delegated to senior medical staff, on the basis that "...judgements of practitioner competence require peer-review" (NZ Ministry of Health 2001, p 6).

The NZ governance model of DHBs is similar, in some cases, to regional boards within rural Australia. However, within metropolitan Australia the responsibility for the credentialing process is delegated by an institution's governing body and the resultant scope of clinical practice is restricted to within the jurisdiction of the institution.

Figure 1 Credentialing as part of a wider District Health Board governance responsibility in New Zealand



DHB: District Health Board.
 Source: NZ Ministry of Health (2009) p 6.

United Kingdom

The NHS model of governance differs slightly from that within Australia, with specific similarities and differences explored in Table 11. Particular reforms within the NHS over the last decade include the creation of a number of Health Authorities, clinical governance ('clinical leadership') reform and modification of funding structures for NHS Trusts (institutions) for the provision of healthcare services.

Clinical governance

Clinical governance has been defined by the NHS as the "...framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (UK Department of Health 1999, p 6). It is the role of senior clinicians within clinical governance structures to provide clinical leadership to clinicians, and in the past decade there have been a number of NHS reforms surrounding this governance structure. In 1999, the NHS moved to restructure the governance model through which all health services were provided. This involved the abolition of district management teams (also known as DHBs) from within the NHS and the creation of NHS Trusts. Each NHS Trust is a group responsible for the management of different health services within an area; for example, a number of local hospitals are managed by an NHS Acute Trust, ambulance services are managed by an NHS Ambulance Trust and dentists, doctors, opticians and chemists are managed by an NHS Primary Care Trust. As a result, each NHS Trust can focus on delivering a specific service to a defined geographical area (Bristol Royal Infirmary Inquiry 2001; GMC 2011a).

Clinical governance within a healthcare institution was further refined through the introduction of clinical directorates—a concept first championed by the John Hopkins Hospital (Baltimore, USA) in 1972. This governance model involves the division of hospital services into clinical directorates, with each managed by a clinical director (who is a consultant) and by a general manager. The objective is for the clinical director to provide clinical leadership to the clinicians within his/her directorate and for the general manager to manage all other personnel (Bristol Royal Infirmary Inquiry 2001).

Quality assurance

The creation of NHS Trusts in 1999 also allowed units within an institution, or even whole institutions, to apply to become independent trusts, and thereby no longer be encompassed within the NHS system. These independent trusts are subject to less regulations regarding institutional processes and funding, but are still regulated by the Healthcare Commission. Independent trusts have the ability to compete with NHS Trusts for NHS funding for the provision of healthcare services. The aim of this initiative was to introduce competition for NHS funding, to stimulate improvement of the quality of services provided by hospitals. Through this system the funds obtained from service delivery would follow the patient and thereby go more directly to the trust

in which the service was delivered. This would provide trusts with greater control over the quality of services delivered, through better use of available funds.

For NHS Trusts the Chief Executive carries the ultimate responsibility for ensuring the quality of services provided by the Trust.

NHS Health Authorities

A number of NHS Health Authorities have been created or have had their existing roles modified within the NHS over the past decade. A list of the current NHS Health Authorities responsible for monitoring NHS Trusts is provided in Table 10.

Table 10 NHS Health Authorities

NHS Health Authority	Role/responsibility
Healthcare Commission	Inspects healthcare organisations in order to form a judgement, in the form of an annual rating, of their performance. The Healthcare Commission has developed a new system of assessment, aligned to the core and developmental standards in <i>Standards for better health</i> (UK Department of Health 2004).
National Audit Office	Scrutinises public spending on behalf of Parliament, and aims to help public service managers improve performance and service delivery.
National Patient Safety Agency (NPSA)	A Special Health Authority that was created in July 2001 to co-ordinate the efforts of the entire country to report and learn from mistakes and problems that affect patient safety.
National Clinical Assessment Service (NCAS)	Works to resolve concerns about the practice of doctors, dentists and pharmacists by providing case management services to healthcare organisations and to individual practitioners. Its aim is to work with all parties to clarify the concerns and their origins, and to make recommendations to help practitioners return to safe practice. NCAS is a division of the NPSA.
National Clinical Governance Support Team	Offers appropriate access to centralised knowledge, expertise and project and coaching support; and to tools and techniques that support the organisation in realising each of the elements required for good clinical governance.
National Reporting and Learning Service	A division of the NPSA, and works in association with the UK Department of Health. It was established in 2001 with a mandate to identify patient safety issues and find appropriate solutions.
Care Quality Commission (CQC)	The independent regulator of health and adult social care in England. It registers, and therefore licenses, providers of care services if they meet essential standards of quality and safety. CQC also monitors these providers to ensure they continue to meet these standards.

NHS: National Health Service; UK: United Kingdom.

Progress of clinical governance implementation within the NHS

Reviews and inquiries conducted by the Department of Health (2006, 2007a) outlined the progress the NHS has made since the 1999 implementation of the new clinical governance structure to support credentialing, performance review, audit and recredentialing processes. Their findings were as follows:

- Clinical issues have become more mainstream.

- There is greater and more explicit accountability for clinical performance within NHS trusts.
- There has been a change in professional culture, towards more open and collaborative working.
- There has been positive change within institutions that have had to respond to serious incidents and external inspection.
- Progress has been made where clinical performance and outcomes are easily assessed.
- Where there is perceived competition, there has been an increase in the uptake and development of good clinical governance to improve the quality of healthcare delivered.

Areas identified as still requiring improvement included:

- significant clinical failures could continue to occur even in the presence of the introduced clinical governance model, principally because individual and collective behaviour is poorly aligned to its purpose
- patient and public involvement in improving healthcare service delivery is still poorly developed
- identification of local, natural leaders in the organisation, irrespective of their current managerial or leadership role, or lack of it
- the incorporation of authentic patient feedback into planning and prioritising service developments
- the innovative and widespread communication of patient feedback to all levels of the organisation.

Comparison of the NHS governance model to the current Australian governance model

The similarities and differences between the NHS and Australian governance models are explored in Table 11.

Table 11 NHS governance: similarities and differences to the Australian model

Similarities	Differences
Clinical directorates contain Clinical Directors, who are consultants, who provide clinical leadership within their directorate.	NHS institutions can apply to become NHS independent Trusts, allowing greater control over funds obtained through provision of healthcare services.
There is a clinical governance structure within each institution.	NHS has greater involvement of the specialist colleges in the assessment of competence for the purpose of defining the scope of clinical practice, both with initial credentialing and recredentialing (known as revalidation within the NHS system).
Participation in national clinical audits encouraged.	NHS focuses on internal and external process audit, as many complex factors confound the relationship between improved credentialing and/or governance structures and patient outcomes.

NHS: National Health Service.

United States of America

Five key governance structures are recommended by The Joint Commission handbook for accredited institutions throughout the USA (The Joint Commission 2011). The Joint Commission handbook provides a guide to The Joint Commission standards. In the USA healthcare system the approved scope of clinical practice for an individual clinician is institution-specific, and is therefore confined to provision of services within the jurisdiction of the institution.

The Joint Commission standards

The five governance structures involved in the administration of institutional policies for credentialing and granting of clinical privileges (delineation of the scope of clinical practice) within healthcare institutions accredited by The Joint Commission are:

- the governing body, "...which has the ultimate authority and responsibility for the oversight and delivery of health care rendered by licensed independent practitioners, and other practitioners credentialed and privileged through the medical staff process or any equivalent process" (The Joint Commission 2011, p 155)
- the Medical Staff Executive Committee (MEC) which reports to the governing body and provides representation for the organised medical staff
- the organised medical staff (OMS) which reports to the MEC and is responsible for providing oversight regarding the quality of care, treatment and services delivered by practitioners who are credentialed and privileged within the institution (The Joint Commission 2011). This includes responsibility for the ongoing evaluation of the competency of practitioners, delineating the scope of privileges (scope of clinical practice) and providing leadership for the performance improvement activities conducted within the institution
- the credentialing committee is responsible for providing a recommendation to the MEC following the verification of an applicant's credentials and subsequent interview, as well as all other the relevant information provided to make a recommendation
- the Chair of each clinical department, who in some institutions is responsible for interviewing the applicant and providing a recommendation to the either the credentialing committee, or directly to the MEC in cases where there is not a credentialing committee within an institution.

The Medical Staff Executive Committee

The MEC has the ability to make recommendations directly to the governing body regarding:

- medical staff membership
- the structure of the OMS

- the processes used to review credentials and delineate the scope of clinical practice.

The MEC may also notify the OMS regarding proposed amendments to rules and regulations (The Joint Commission 2011).

The organised medical staff

The OMS is structured to provide governance and guidance for its members. The structure of the OMS varies between institutions according to hospital bylaws, with some hospitals only allowing physicians to be part of the OMS. The primary function of the OMS is to approve and amend medical staff bylaws and policies. Within the OMS structure there are designated members who are licensed independent practitioners (consultants) whose role is to provide clinical leadership via oversight of the care, treatment and services provided by all credentialed clinicians. The OMS is also responsible for:

- determining the mechanism for establishing and enforcing the criteria and standards for OMS membership
- engaging in performance activities
- creating, implementing and ensuring the effectiveness of hospital policy (The Joint Commission 2011).

The credentialing committee

The terms of reference for the governing body were not outlined within The Joint Commission handbook (2011). However, The Joint Commission handbook indicated that the credentialing committee, in addition to reviewing the credentials of applicants applying for a specific scope of clinical practice, has the ability to review adverse event information reported on any physician within the institution. This may include litigations, judgements, settlements, sanctions, restrictions or revocation of a physician's license and exclusion from any state or health program. Membership of the committee varies across different institutions, yet is most commonly made up of physicians. Some institutions also include a voting non-physician member of the board of directors of the hospital as a representative during the review of an application. Legal counsel and members of the risk management department may also be members of the credentialing committee, even in a non-voting capacity (The Joint Commission 2011). Veterans Health Administration

Governing structures outlined in the Veterans Health Administration (VHA) handbook for credentialing and privileging include:

- the Facility Director
- facility Chiefs of Staff (COS)
- service chiefs (Department of Veterans Affairs 2008).

Facility Directors hold the ultimate responsibility for the credentialing and privileging process. The Facility Director is appointed by the Secretary for Health and acts as the governing body of the facility.

Facility COS have the following functions:

- responsibility for maintaining the credentialing and privileging system and ensuring all healthcare professionals applying for delineation of scope of practice agree to provide continuous care to the patients assigned to them
- are supplied with a copy of and agree to abide by the medical staff bylaws and regulations
- ensuring the medical staff bylaws are consistent with the VHA handbook and any other VHA policy related to Medical Staff bylaws.

Service Chiefs are responsible for recommending the criteria for credentialing and definition of the scope of clinical practice relevant to the care provided within the service/department. Service Chiefs are also responsible for reviewing all credentials and requested scope of practices and for making recommendations regarding appointment and definition of scope of practice actions. Finally, it is the role of Service Chiefs to monitor the professional performance of those who provide patient care service with delineated scope of practice within their service (Department of Veterans Affairs 2008).

Canada

Canada has a provincial healthcare system, with the regulation of clinicians and standards for credentialing varying according to provincial regulation and requirements.

Credentialing policies are specific to each healthcare institution, and are outlined in the hospital bylaws. Some institutions within Canada voluntarily synthesise hospital bylaws based on The Joint Commission standards (The Joint Commission 2011).

Alberta Health Service

The key components of clinical governance, as defined by the AHS, "...encompass quality care and patient safety, and focus on a systematic and integrated approach to ensure a high standard of patient care" (Alberta Health Services 2011a, p 5). Professional self-regulation and individual accountability for clinical judgement are an integral part of healthcare.

The AHS is comprised of a number of zones, and operates in a similar manner to the DHB structure of the NZ healthcare system. Some differences in the medical organisational structure are apparent between zones, with each having their own zone-based committees and governance structures.

There are four governance structures involved in the credentialing process within the AHS:

- the Zone Department Head, who is a practitioner
- the Zone Application Review Committee, which acts in a manner similar to a credentialing committee, by providing a recommendation regarding the scope of clinical practice for an applying practitioner to the Chief Medical Officer
- the Chief Medical Officer, who is the most senior medical administrative leader of AHS, appointed by the Chief Executive Officer (CEO)
- the Medical Affairs Office, which is an operational and organisational office of the Executive Vice President and Chief Medical Officer portfolio.

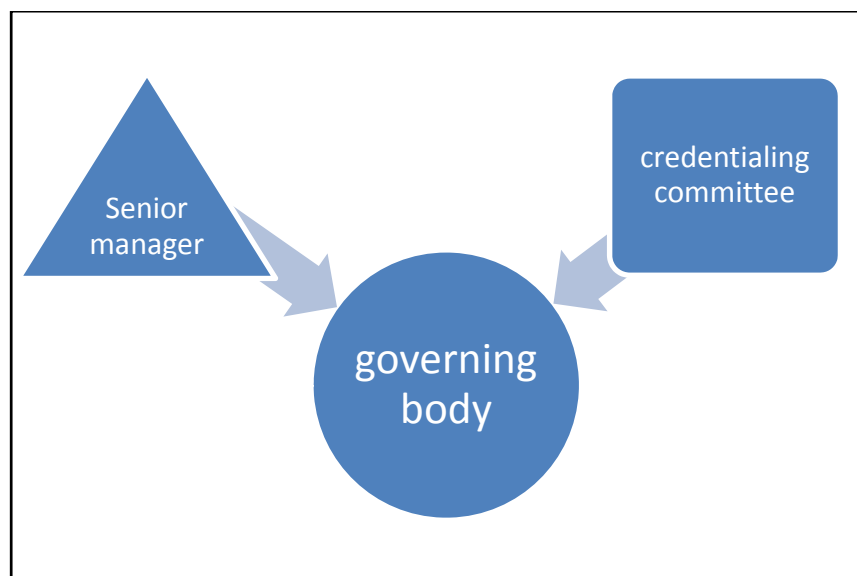
4.4 The credentialing process

Credentials reflect an individual practitioner's professional capacity within the context of specific healthcare environments; and encompass the factors that contribute to a clinician's performance, as represented in relevant documentation and reference to professional experience. However, credentials do not include any assessment of actual performance. In contrast, the credentialing process moves beyond documentation to assessment of a clinician's actual performance (Frommer et al 2005a).

4.4.1 Australian credentialing models

Three different structures for the credentialing process are outlined below according to the ACSQHC Standard (ACSQHC 2004). A number of State health departments utilise one of the credentialing processes depicted (Figure 2, Figure 3 and Figure 4). For those State health departments that use a different model, or do not provide sufficient detail to ascertain which model they employ, a narrative description of their credentialing process is included.

Figure 2 Structural approach to the credentialing process: model 1



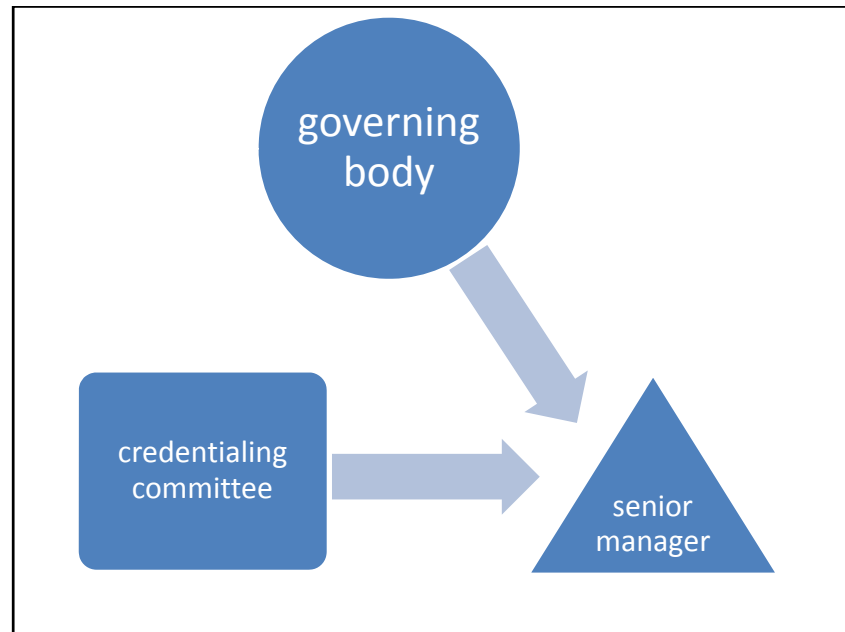
Adapted from: ACSQHC (2004) p 17.

In the first credentialing model (Figure 2) the authority to appoint clinicians is retained *in toto* by the governing body, which may be advised by a credentialing committee (or medical practitioner's appointments committee) or a senior manager (ACSQHC 2004, p 17). The VIC DHS utilises this model for credentialing, where the medical manager (senior manager) chairs the credentialing committee (separate to the governing body) and advises members of the credentialing committee. VIC DHS acknowledges that some institutions may have a slightly different credentialing process depending on the needs of

the institution, particularly in rural areas, but follow the guidelines of the ACSQHC Standard (ACSQHC 2004).

The VIC DHS credentialing and defining the scope of clinical practice flowchart is included in Figure 14, Appendix 3 on page 90.

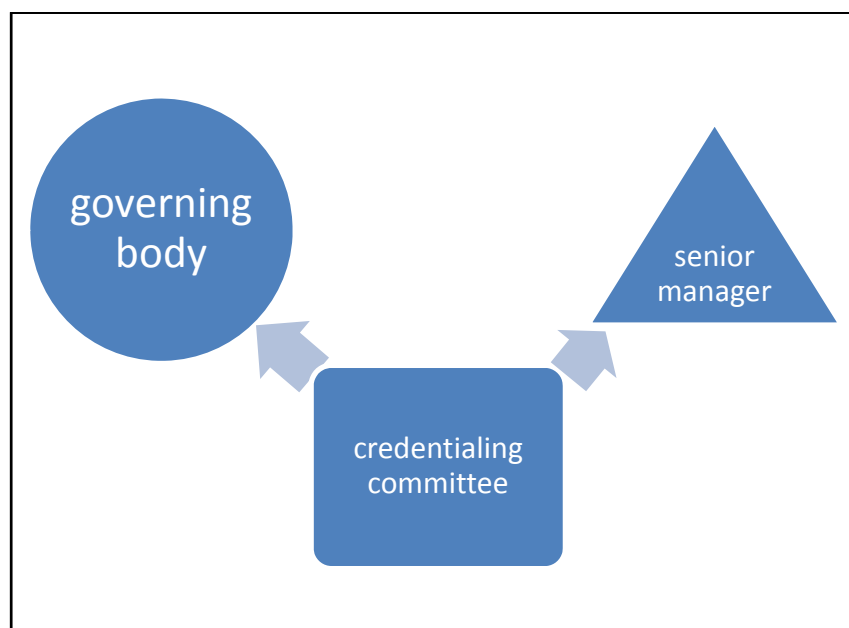
Figure 3 Structural approach to the credentialing process: model 2



Adapted from: ACSQHC (2004) p 17.

The second credentialing model (Figure 3) requires the authority for the appointment of clinicians to be formally delegated by the governing body to a senior manager, who may be advised by a credentialing committee (or medical practitioner appointments committee) (ACSQHC 2004, pp 17). QLD Health employs this credentialing model, where the CEO of the district/division acts in the role of senior manager, and is the final decision maker as to whether the scope of clinical practice suggested by the credentialing committee is appropriate. QLD Health policy dictates that the CEO cannot sit on the credentialing committee.

Figure 4 Structural approach to the credentialing process: model 3



Adapted from: ACSQHC (2004) p 17.

Within the third credentialing model (Figure 4) the authority to appoint clinicians is formally delegated to a credentialing committee (or medical practitioner appointments committee) that reports to the governing body or senior manager (ACSQHC 2004, p 17).

Additional credentialing models

The New South Wales Department of Health (NSW Health) outlines within the first edition of *The clinician's toolkit for improved patient care* that each hospital or Area health service should have a properly-constituted credentialing committee as well as a Board of clinical privileges (NSW Department of Health 2001). The credentialing committee is responsible for the comprehensive review of the competence of a clinician, and then provides a recommendation to the Board of Clinical Privileges (NSW Health 2001). This Board reviews the recommendation provided by the credentialing committee and conducts the delineation of the scope of clinical practice for the clinician. This approach differs from credentialing systems in which the function of credentialing (verification of credentials and peer-review) and delineation of the scope of clinical practice are conducted by the one credentialing committee.

The South Australian Department of Health (SA Health) policy for credentialing and defining the scope of clinical practice is outlined in the report: *The policy for credentialling and defining the scope of clinical practice for medical and dental practitioners* (2010). SA Health has a region-based credentialing system, and in some cases a number of institutions may fall within the same region. The credentialing committee reports to the Region CEO and is chaired by the Region CMO. The credentialing committee also contains three medical practitioners appointed to the committee by the CEO, a clinician in the area of specialty of the applicant, and a human resources officer of the region. The credentialing

committee verifies the applicant's credentials and defines the scope of clinical practice, and then communicates their determination to the Head of the Unit/department within the region in which the applicant will be practising.

Within the Western Australian healthcare system the credentialing committee reports to the Area/State-wide Health Service Board and to the Appointing Officer, who is a delegate of the Area/State-wide Health Service Board (WA Department of Health 2005c). The chairperson of the credentialing committee is elected by the core members of the credentialing committee and acts as the authorised channel of communication for the committee. The credentialing committee's recommendation regarding the scope of practice of a clinician is forwarded to the Appointing Officer for approval. The Appointing Officer is also accountable for the implementation and management of the organisation's clinical governance program. The clinical governance model employed within Western Australia is outlined in Figure 13 (Appendix), and a flowchart outlining the steps within the credentialing process is available in Figure 15 (Appendix 3).

4.4.2 Initial credentialing

The credentialing process involves determining a clinician's competence, performance and professional suitability. In relation to credentialing, competence can be defined as the minimum level of skill, knowledge and expertise, derived through training and experience, that is required to perform a task or procedure safely and proficiently (ACSQHC 2002). This includes the interpretation and management of initial clinical results and the management of complications, in addition to the technical aptitude needed to complete a procedure safely (ACSQHC 2002).

Information required from an applicant for the process of initial credentialing and recredentialing is outlined in Table 12.

Table 12 Information required from an applicant for credentialing or recredentialing

Initial credentialing	Recredentialing
Details of lifetime professional registration history including evidence of current professional registration	Evidence of current registration
Details of lifetime education and training history, with certified copies of all qualifications	Details of education and training undertaken, and any endorsement or accreditation awarded by a professional college, association or society since the previous declaration
Details of accreditation by professional colleges, associations or societies for the provision of clinical services, procedures or other interventions	Details of all healthcare-related employment undertaken since the previous declaration, including current employment
Details of all past and continuing healthcare-related employment	Details of current involvement in clinical audits, peer-review activities and CME since the previous declaration
Details of current involvement in clinical audits, peer-review activities and CME	Whether an activity log book is maintained
Details of experience in teaching in research, where applicable	A summary of clinical activity undertaken over the past 12 months in all locations, including approximate number, type and location of clinical services, patients procedures or interventions, diagnoses treated and consultations rendered
Whether an activity log book is maintained	Where available, objective data on the outcomes of that clinical activity. This may be obtained via performance review
A summary of clinical activity undertaken over the past 12 months in all locations, including approximate number, type and location of clinical services, patients procedures or interventions, diagnoses treated and consultations rendered	Details of the specific scope of clinical practice requested
Where available, objective data on the outcomes of that clinical activity	The precise information required to fulfil the criteria necessary for the scope of clinical practice requested
Details of the specific scope of clinical practice requested	Evidence of the type and scope of current professional indemnity insurance
The precise information required to fulfil the criteria necessary for the scope of clinical practice requested	<i>Either:</i> a declaration that there has been no change to the previous information provided regarding: any change to the defined scope of clinical practice or denial, or suspension, termination or withdrawal of the right to practise in any other organisation; any disciplinary action or professional sanctions imposed by any registration board; any criminal investigation or conviction; and the presence of any physical or mental condition or
Evidence of the type and scope of current professional indemnity insurance	
A declaration regarding any prior change to the defined scope of clinical practice or denial, suspension, termination or withdrawal of the right to practise in any other organisation	
A declaration regarding any prior disciplinary action or professional sanctions imposed by any	

registration board	substance abuse problem that could affect the clinician's ability to exercise the requested scope of clinical practice or that would require any special assistance in order to enable the clinician to exercise that scope of clinical practice safely and competently
A declaration regarding any criminal investigation or conviction	
A declaration regarding the presence of any physical or mental condition or substance abuse problem that could affect the clinician's ability to exercise the requested scope of clinical practice or that would require any special assistance in order to enable the clinician to exercise that scope of clinical practice safely and competently	<i>or:</i> a declaration describing the specific changes to the information provided relating to these aspects of professional status and performance.
Written consent for the committee responsible for credentialing and defining the scope of clinical practice and/or the organisation to verify with relevant individuals, external organisations and nominated referees the validity of all claims made, including explicit consent for the organisation to verify the clinicians declaration regarding health status, professional registration history and criminal record	Written consent for the committee responsible for credentialing and defining the scope of clinical practice and/or the organisation to verify with relevant individuals, external organisations and nominated referees the validity of all claims made, including explicit consent for the organisation to verify the clinicians declaration regarding health status, professional registration history and criminal record

CME: continuing medical education.

Source: ACSQHC (2004).

Establishing essential criteria for a clinical position

Establishing essential criteria for a clinical position is an important step in the credentialing process (ACSQHC 2004). This involves:

- consideration of the local environment, including organisational need and capacity, in which the proposed clinical services will be provided
- consideration of the available objective, evidence-based criteria relevant to competence and performance in specific positions
- consideration of the recommendations of the relevant professional/specialist college, association or society in relation to the period and nature of the training and experience necessary to develop competence and high-level performance in specific positions
- consideration of available information regarding the relationship between volume of clinical services performed and their safety and quality, and the likely impact of service volume on clinical outcomes in the local environment
- establishment of minimum credentials (threshold credentials) in consultation with the relevant clinical leader (clinical director) for each specific position and service for which applications for credentialing and defining the scope of clinical practice are expected to be received
- ensuring that threshold credentials address the minimum education, formal training, clinical experience, leadership experience, teaching and training experience, research

experience and communication and teamwork skills required for the specific position

- ensuring that threshold credentials are based on objective criteria about the necessary period and character of training and experience, rather than the possession of specific endorsement or accreditation by named colleges, associations or societies
- determining the precise education, training, experience and clinical outcome
- consideration of information that will assist with the process of credentialing and defining the scope of clinical practice and that should therefore be submitted by the applicant
- determining the threshold credentials and relevant forms and content of information that should be requested from each clinician who applies for appointment for a specific scope of clinical practice (ACSQHC 2004).

Notably, the healthcare institution should advise applicants regarding:

- the threshold credentials required before any application will be processed
- the specific forms and content of information required for submission in order to be considered by the credentialing committee (which also defines the scope of clinical practice) (ACSQHC 2004).

Establishing a policy on verification of credentials

The healthcare institution should develop an appropriate policy for the designation of responsibility to the relevant body/department/manager for the verification of credentials. This policy should cover applicants who apply for appointment in an institution, applicants who apply for any change to their current scope of practice; and applicants whose scope of practice is under review for any reason (ACSQHC 2004).

If the institution accepts verification of credentials by a third party it should clearly document the criteria by which third party organisations will be approved to undertake this role. Additionally, the institution should ensure that its performance requirements are rigorous and complete, and appropriately documented in an agreement with each relevant third party organisation (ACSQHC 2004).

The role of specialist colleges

Within Australia, the role of specialist colleges in the process of credentialing and defining the scope of clinical practice involves providing advice to institutions regarding the nature of training, education and experience required to develop the necessary competence and to perform a specific role within a specific institutional context (ACSQHC 2004). Other activities linked to the ongoing competence of clinicians, which are not directly related to the credentialing process, include standard setting in vocational

registration, continuing medical education (CME), maintenance of professional standards, and practice definition. Specialist colleges can also have a direct advisory role to individual practitioners.

4.4.3 Recredentialing

Recredentialing may be defined as “the formal process used to re-confirm the qualifications, experience and professional standing (including history of and current status with respect to professional registration, disciplinary actions, indemnity insurance and criminal record) of clinicians, for the purpose of forming a view about their ongoing competence, performance and professional suitability to provide safe, high-quality health care services within specific organisation environments” (ASCSQHC 2004, p 6).

Performance management should form a part of the recredentialing process as outlined in Table 12 (ACSQHC 2004). Increasingly, objective performance data is being collected and analysed in order to improve the quality of healthcare delivered (ACSQHC 2004).

The following areas of practice should be assessed during performance review, for the purpose of recredentialing.

Caseload

The institution’s credentialing committee should obtain data regarding the caseload of the clinician under consideration since the last credentialing review. This should comprise

- a listing of patients, diagnosis given and procedures undertaken
- summary data on numbers of patients with each diagnosis
- summary data on numbers of each type of procedure performed or each type of treatment administered (Frommer et al 2005b).

A clinician may wish to provide equivalent data from another institution in order to demonstrate total caseload. Whilst informative, this data should be reported and considered separately, as activity in another institution is outside the jurisdiction of an institution’s credentialing system (Frommer et al 2005b).

Clinical behaviour

Assessment of the clinical behaviour of a clinician can be divided into four categories:

- Assurance of organisational capability: the performance review manager should ascertain that the clinician has not performed any procedures or interventions in a situation in which they believed that there would be insufficient organisational capability or facilities to successfully achieve positive patient outcomes. For example a clinician should demonstrate that they have not performed an invasive procedure in a situation in which they were unsure whether there were adequate postoperative care facilities to cope with any post-procedural complications.
- Patient-centred care: a clinician should demonstrate adequate evidence of patient-centred care in their clinical behaviour(s). To determine this, performance reviewer managers ask a number of questions regarding:
 - patient accessibility to their services

- provision of information to patients and other members of multi-disciplinary teams
- ensuring patients make informed treatment decisions
- navigation through the treatment process
- invitation and interaction with family and social context
- communication with office staff
- documentation of complaints.
- Appropriate engagement in multi-disciplinary management: the clinician should record and report any involvement in multi-disciplinary case conferences.
- Appropriate *referral activities including*:
 - referral to specialist clinicians within their profession, who have a greater scope of clinical practice than that of the clinician under review
 - referral to clinicians from alternative specialties
 - appropriate communication with the referring practitioner (Frommer et al 2005b).

Safety and quality

Indicators for safety and quality included for performance review should be selected according to specialty, and should be provided by the credentialing committee (Frommer et al 2005b). In addition, the volume of clinical activity undertaken by the clinician over the past 12 months should also be reviewed, and conclusions drawn regarding the clinician's ongoing competence and performance. Review of available sources of objective data regarding the clinician's competence and performance, including available registry or audit data, should be analysed where available under the following considerations:

- the validity of measures of the safety and quality of the healthcare services delivered by the clinician under review, including whether they are appropriately stratified and risk-adjusted
- whether these measures contribute to a reliable assessment of the clinician's competence and performance according to the requested scope of clinical practice (ACSQHC 2004).

Recredentialing frequency

The frequency of recredentialing was examined across the white papers published by Australian state health departments.

Table 13 Recredentialing frequency reported in the included studies

Government/jurisdiction	Frequency
NSW Health (2001)	Upon appointment/re-appointment (performance appraisal frequency NR)
QLD Health (HQCC 2010)	Maximum of 5 years or when circumstances change affecting the medical practitioner (performance appraisal frequency NR)
SA Health (2010)	Maximum once every three years (experienced clinicians) Overseas or clinicians with limited experience within the scope of clinical practice applied for should have a review of performance within first three months (with a supervisory report) (performance appraisal frequency NR) New appointments: three month probationary period for scope of clinical practice; with end of probationary period performance report given to credentialing committee.
TAS Department of Health and Human Services(2011)	NR (performance appraisal frequency NR)
VIC DHS (2009)	Once every 5 years or unplanned as requested by the individual practitioner or an authorised person within the health service. Performance appraisal should be conducted annually.
WA Department of Health (2009)	Every three years, maximum every 5 years (performance appraisal frequency NR)

NR: not reported; NSW: New South Wales; QLD: Queensland; SA: South Australia; TAS: Tasmania; VIC DHS: Victoria Department of Human Services; WA: Western Australia.

4.4.4 International credentialing models

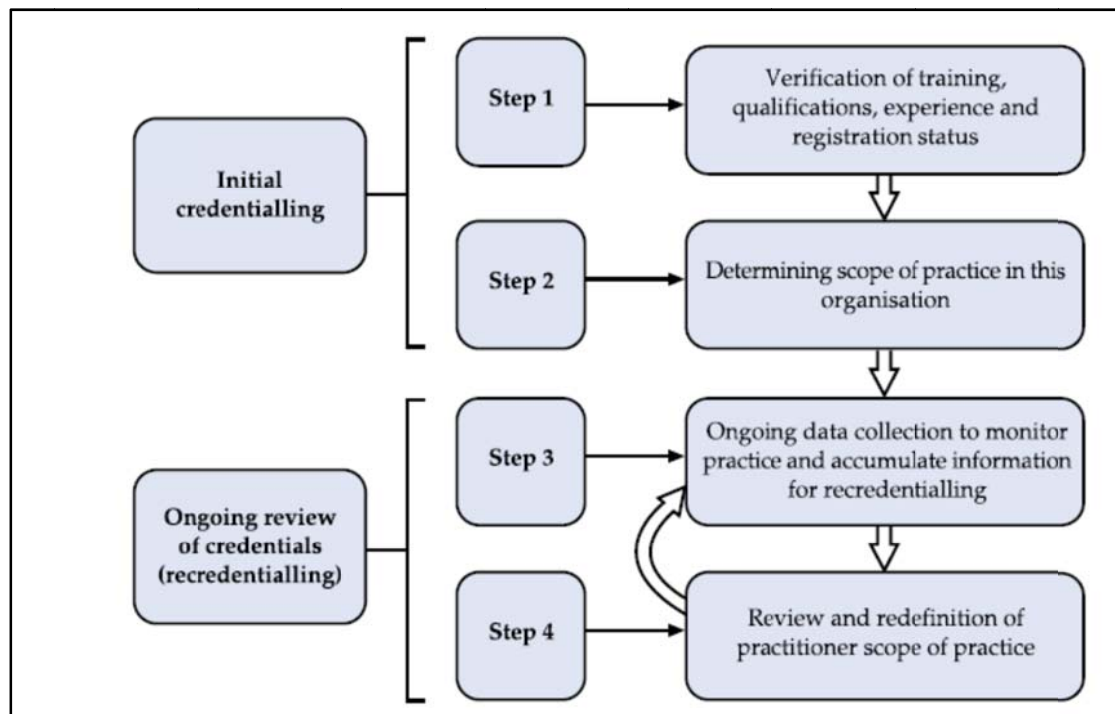
New Zealand

The definition of credentialing provided by the New Zealand Ministry of Health is as follows: "...credentialling [is] a process used to assign specific clinical responsibilities (scope of practice) to health professionals on the basis of their training, qualifications, experience and current practice, within an organisational context. This context includes the facilities and support services available and the service the organisation is funded to provide. Credentialling is part of a wider organisational quality and risk management system designed primarily to protect the patient" (NZ Ministry of Health 2001, p 2).

The NZ credentialing system is similar to that of many Australian state health departments in terms of credentialing committee structure, establishment of credentialing policies and development of essential criteria for positions.

Credentialing within the NZ healthcare system is the responsibility of the Chief Executive of the DHB as a requirement of clinical governance. The tasks within credentialing processes are delegated to senior medical staff, on the basis that judgements of practitioner competence require peer review (NZ Ministry of Health 2001). NZ has a four-step credentialing process which is outlined in Figure 5.

Figure 5 New Zealand four-step credentialing process

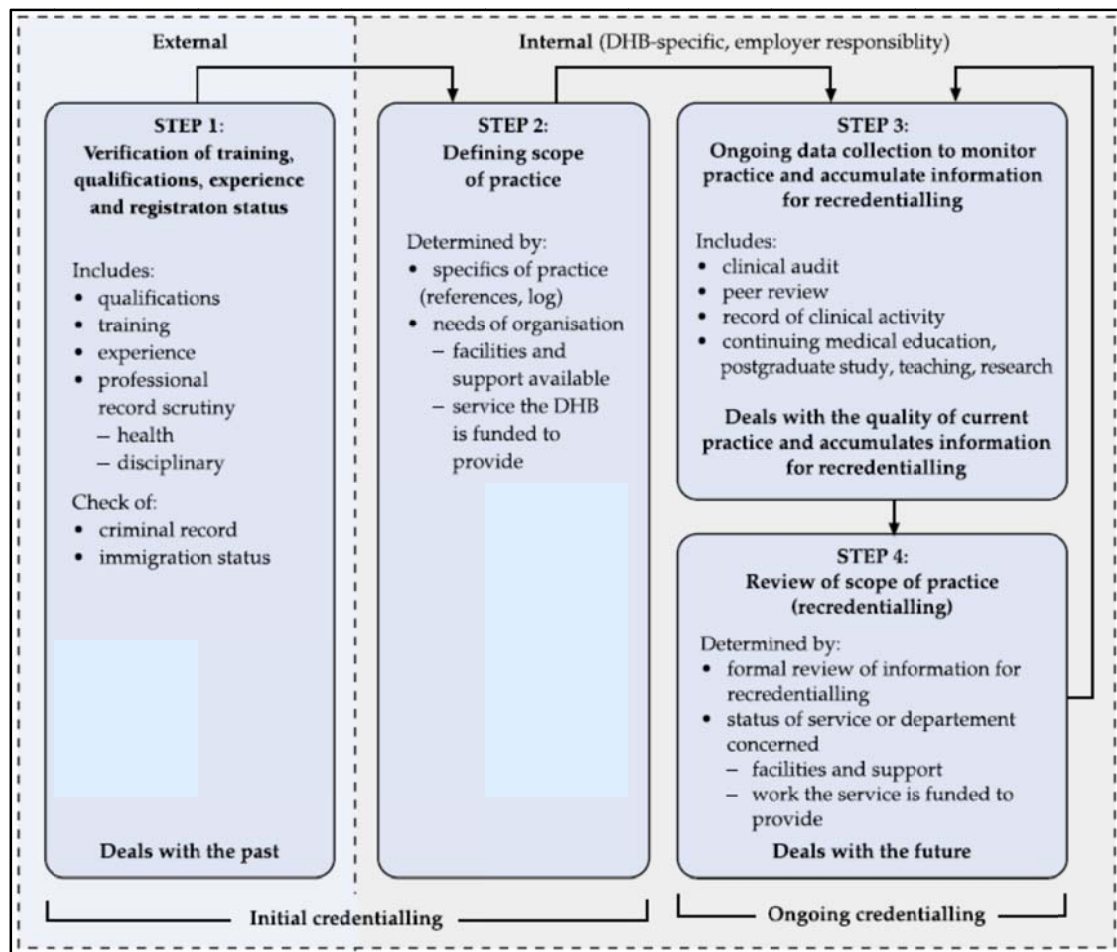


Source: NZ Ministry of Health (2001) p 7.

The first step within this credentialing process is the responsibility of, and undertaken by, the Medical Council of New Zealand, whilst the other three steps are conducted within the organisation in which the applicant is applying to practice. Step three represents the greatest demand on organisational resources, in the form of ongoing clinical quality monitoring and improvement.

The tasks and information required as part of the credentialing process within NZ are also represented in Figure 6. In addition, a more detailed summary of the four-step credentialing process is available in Appendix 4.

Figure 6 Detailed summary of the tasks within the four-step credentialing process



Source: NZ Ministry of Health (2001) p 16.

Role of specialist colleges

The roles of specialist colleges can be summarised into three categories, namely, mechanisms of providing protection to the community, communication responsibilities and process responsibilities (NZ Ministry of Health 2001).

Protection of the community and participation in the quality assurance of healthcare services can be achieved by specialist colleges through:

- involvement in standard setting in vocational registration, CME, maintenance of professional standards and practice definition
- providing an advisory role to individual practitioners, the Medical Council of New Zealand and DHBs (NZ Ministry of Health 2001).

Communication responsibilities assigned to specialist colleges within the NZ credentialing system include the provision of timely advice and expertise to hospitals, provision of external assessors upon request; and specific advice on competence issues (NZ Ministry of Health 2001).

Finally, process responsibilities of specialist colleges include collaboration with hospitals regarding:

- the development of innovative ways to achieve credentialing requirements in small/highly specialised services
- the improvement of practitioner competence (NZ Ministry of Health 2001).

United Kingdom

Over the last decade, the NHS has moved towards a standardised process of medical regulation. Following the introduction of licences to practice in 2009, revalidation now constitutes the NHS' standardised system that is most similar to credentialing, as it is based on local-level performance appraisal. However, at this stage of development, revalidation of a clinician's licence to practice does not appear to be tied to a specific institution.

Regulation of clinicians within the NHS requires that clinicians hold both a registered certificate and a licence to practice from the GMC. Medical practitioners holding registration with the GMC are listed on the GMC's Register of Medical Practitioners and those possessing a license to practice are subject to revalidation every five years.

Table 14 Regulation of clinicians in the NHS

Doctors registered <i>with</i> a licence to practice	Doctors registered <i>without</i> a licence to practice
Are able to legally practise medicine in the UK	Are not legally able to practise medicine in the UK
Are able to legally undertake any of the activities restricted by law to doctors holding a licence, such as writing prescriptions or signing of death certificates	Are not legally able to write prescriptions, sign death certificates or undertake any of the activities restricted by law to doctors holding a licence
Will be subject to the requirements of revalidation, when introduced	Will not be required to participate in revalidation when this begins (as they do not have a licence to renew)
Are required to follow the GMC's guide contained in <i>Good Medical Practice (cite)</i>	Are required to follow the GMC's guide contained in <i>Good Medical Practice (cite)</i>
Are subject to GMC fitness to practice actions	Are subject to GMC fitness to practice actions

GMC: General Medical Council; NHS: National Health Service.
Adapted from: GMC 2009.

The GMC introduced licences to practice for clinicians on 16 November 2009, to facilitate the ongoing regulation and monitoring of clinicians and to ensure the safety and quality of the healthcare services they deliver (GMC 2009). Revalidation is the process by which a clinician's license to practice is re-evaluated, and is anticipated to be introduced in late 2012 (GMC 2011a; GMC 2010).

Revalidation

Nine white reports were available for assessment of the revalidation process within the NHS (Table 15).

Table 15 Studies included for assessment of the revalidation process

Report title	Institution	Year
Preparing for the introduction of medical revalidation: a guide for NHS leaders in England	GMC	2011a
Supporting information for revalidation and appraisal	GMC	2011b
The good medical practice framework for appraisal and revalidation	GMC	2011c
Revalidation: the way ahead	GMC	2010
Changes to registration requirements for UK doctors	GMC	2010
Medical revalidation – principles and next steps	UK Department of Health	2008
Review of the readiness of appraisal and clinical governance to support the relicensure of doctors	UK Department of Health	2007a
Trust, assurance and safety – the regulation of health professional in the 21 st century	UK Department of Health	2007b
Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients	UK Department of Health	2006

GMC, General Medical Council; NHS: National Health Service; UK:United Kingdom.

The purpose of revalidation is to ensure that licensed doctors remain up to date and continue to be fit to practice (UK Department of Health 2008). Revalidation has two elements:

- to confirm that licensed doctors practise in accordance with the standards appropriate to their speciality, which are built upon the GMC generic standards
- to identify for further investigation, and remediation, poor practice where local systems are either not robust enough to do this or do not exist (UK Department of Health 2008).

When the proposed system for revalidation was first introduced in 2007 it was comprised of two processes:

- re-licensing: confirming that doctors practise in accordance with the GMC's generic standards
- recertification: confirming that doctors on the specialist and GP registers confirm with the standards appropriate for their specialty.

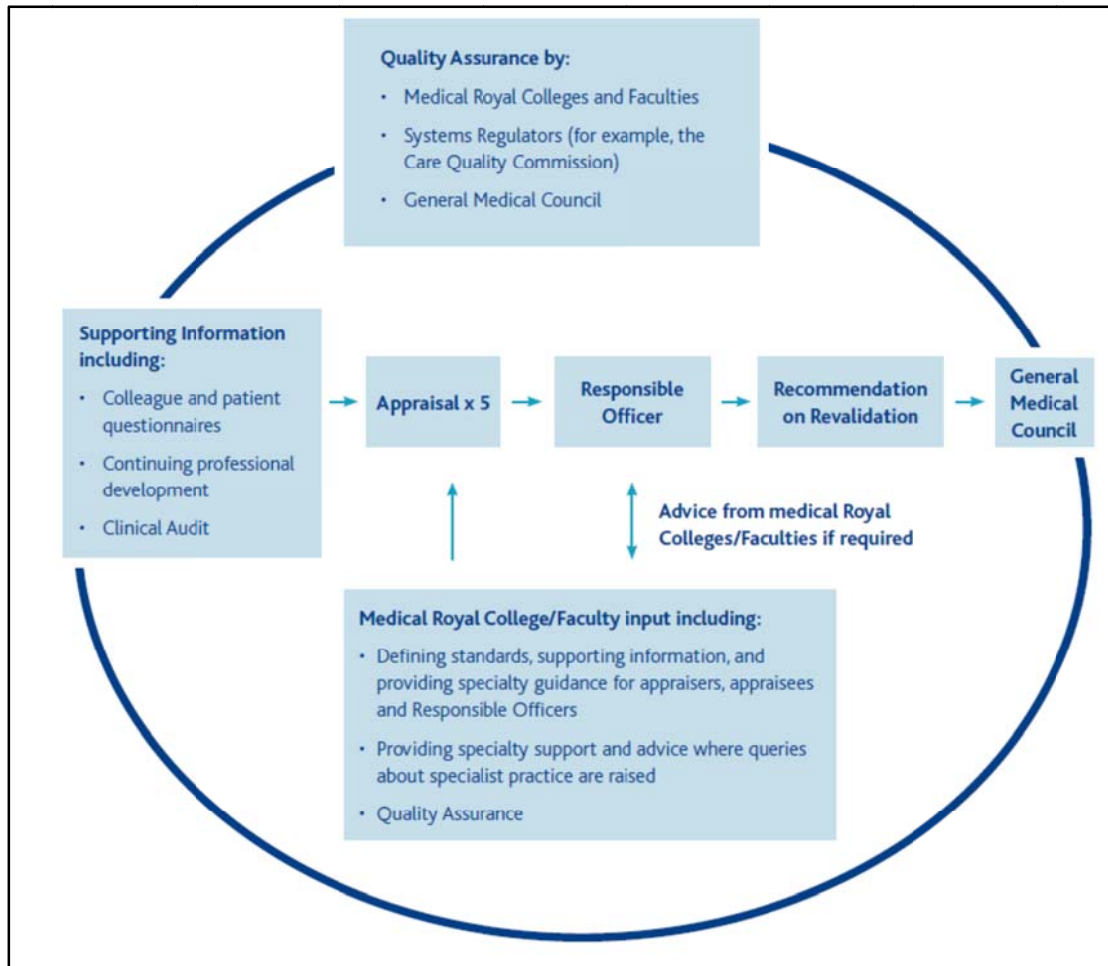
In 2010, after comprehensive consultation with specialist colleges, the NHS moved to consolidate these two processes into one process of re-licensure, known as 'revalidation'. Reasons cited included the complexity and confusion that could arise from having two separate yet concurrent processes for revalidation; and the fact that requirements of specialist colleges for re-certification of their respective clinicians were founded on the GMC's generic standards, and are adapted to add specific additional requirements

relevant to their specialty (GMC 2010).

The revalidation process

Revalidation will be based on the compiled results of local annual performance appraisal over the past five years. At a local level, the Officer responsible ('Responsible Officer') for conducting performance appraisal (usually the medical director or equivalent). This person is responsible for ensuring that the appraisal is carried out according to the standards outlined by the specialist colleges (and approved by the GMC), and is also responsible for working with doctors to address any shortfalls in performance. The Responsible Officer will also be required to collate all relevant information required to support a recommendation on the revalidation of individual doctors to the GMC. Based on the recommendation, provided by the Responsible Officer, the GMC will come to a final decision as to whether the clinician's licence to practice is revalidated (Figure 7).

Figure 7 The NHS process of revalidation



Source: General Medical Council (2010) p 37

Supporting information for revalidation

The supporting information required by the GMC for revalidation of clinicians is outlined in Table 16.

Table 16 Matrix of relevant supporting documentation for revalidation

General information	CPD	Quality improvement activity	Feedback on clinician's practice
Personal details	Personal learning	Clinical audit	Colleague feedback
Scope of work	Scope of practice (CPD should cover scope of practice)	Review of clinical outcomes via national or local morbidity or mortality audits	Patient feedback
Record of annual appraisals	Reflection (to standards)	Case review or discussion	Review of complaints and compliments
Personal development plans and their review	Outcomes (of CPD training)	Audit and monitor the effectiveness of a teaching programme	<ul style="list-style-type: none"> • awareness • participation in investigation and response
Probity	Needs-based (as assessed by the individual clinician)	Evaluate the impact and effectiveness of a health policy or management practice	<ul style="list-style-type: none"> • actions taken in response to complaint • Identify opportunities for professional development
Health	Appraisal and clinical governance	Significant events	
Personal details			

CPD: continuing professional development.

Adapted from: GMC 2010.

Revalidation and the role of specialist colleges

Revalidation must involve the specification of a clear set of standards formulated by each medical specialist college working in collaboration with specialist associations and others; and be approved by the GMC, in order to measure a clinician's performance (GMC 2010; UK Department of Health 2008). Methodologies for evaluating specialist practice will vary but must be based on actual clinical performance and assessed within the environment and clinical context. Principal responsibilities of the specialist colleges can be summarised as follows:

- defining the relevant specialty and general practice standards
- validating specialty tools for the evaluation of clinicians' practice
- describing the types of supporting information required to meet the relevant specialty standards
- providing specialty guidance for appraisees, appraisers and Responsible Officers (GMC 2010).

In addition to these principal responsibilities, the specialist college have suggested a

number of proposed methods of their input into the local performance appraisal and GMC final determination of revalidation. The NHS is continuing the discussions with specialist colleges in relation to their role in these processes. One proposal suggests that the role of specialist colleges in local appraisal would entail provision of guidance and advice to appraisers and Responsible Officers on the specialty standards and supporting information (GMC 2010). Additionally, some colleges propose their provision of direct input into the recommendation synthesised by the Responsible Officer. This may involve quality assurance of the revalidation process and/or auditing or sampling of some of the supporting documentation included in the synthesis of the recommendation. Another alternative is that each of the doctors within their specialty has direct involvement in the recommendation, by way of a local panel that would involve the Responsible Officer, college or faculty representative and possibly a non-medical representative (GMC 2010). Once assembled, a panel with this composition would be similar to those for credentialing committees within Australia, which are responsible for both initial and recredentialing.

United States of America

The process utilised for the credentialing of clinicians within institutions in the USA depends upon whether a practitioner holds an independent license to practice, provided by State Medical Boards. The requirements for obtaining a licence to practice vary across the many States and jurisdictions within the USA.

In addition to verifying the validity of a clinician's license to practice, institutions must also determine, according to state law, whether a clinician is considered independent.

The Joint Commission standards

The Joint Commission (2011) defines a licensed independent practitioner as "...any individual permitted by law and by the hospital to provide care, treatment and services without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges" (The Joint Commission 2011, p 28). The Joint Commission does not determine whether a practitioner is a licensed independent practitioner as this is determined by state law and hospital bylaws (The Joint Commission 2011). Consequently, the OMS and governing body must together ascertain and establish a policy to determine which healthcare professionals will be permitted to practice independently based on state law. The best example of a licensed independent practitioner is a physician, as state laws and hospital policies grant physicians the ability to practice without direction or supervision.

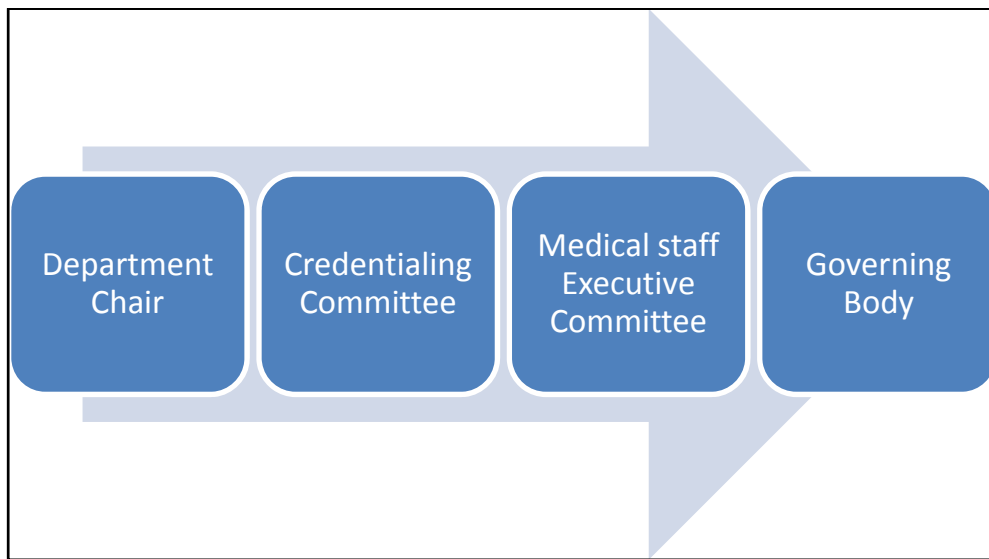
The second factor which affects the credentialing process within the USA healthcare system is whether a licensed independent practitioner is a hospital employee. If so, then hospital human resources policies also apply. In contrast, if the licensed independent practitioner is an external contractor then human resources policies do not apply, but the clinician must still complete the credentialing and clinical privileging process (defining the scope of clinical practice) according to the OMS policies.

Similarly, the scope of clinical practice determined via the credentialing processes is institution-specific within the USA healthcare system.

Credentialing process models

Two credentialing models proposed by The Joint Commission standards were identified (Figure 8, Figure 9).

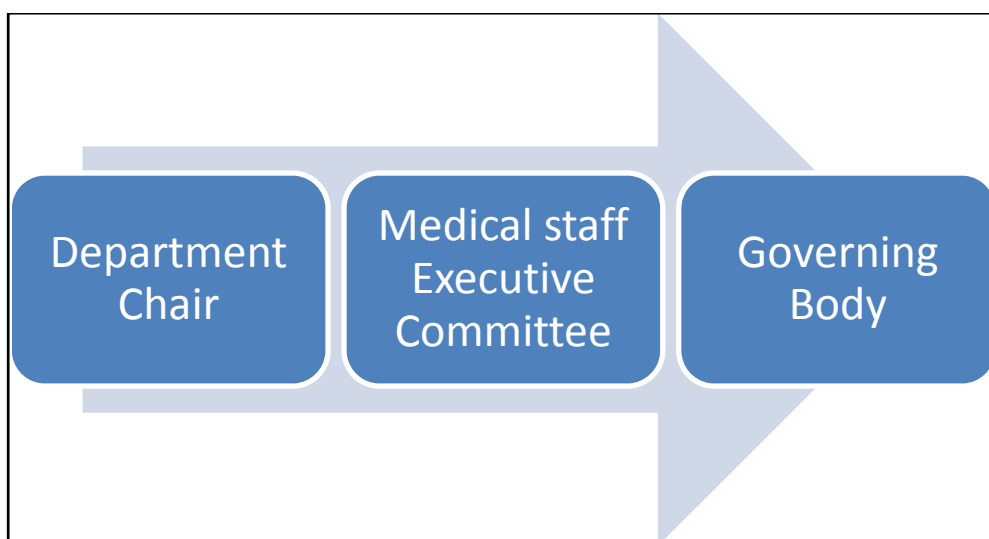
Figure 8 USA credentialing process: model 1



Adapted from: The Joint Commission (2011) p 113.

In the first model the Department Chair conducts the review of the information supplied by the applicant, interviews the applicant (if required by hospital policy) and provides a recommendation to the credentialing committee regarding the definition of the scope of clinical practice (clinical privileges). The credentialing committee then reviews the Department Chair's recommendation in the context of the information supplied by the applicant and provides a recommendation to the MEC. Finally, the MEC reviews the recommendation made by the credentialing committee and forwards the recommendation to the governing body for approval.

Figure 9 USA credentialing process: model 2



Adapted from: The Joint Commission (2011) p 113.

The second model outlines the process employed if an institution does not have a credentialing committee, which The Joint Commission standards indicates it is not a requirement for accreditation. The Department Chair conducts the interview and reviews the applicant's information and provides a recommendation directly to the MEC. The MEC then reviews the recommendation provided by the Department Chair and forwards this to the governing body for final approval.

Information required for the credentialing process

The content of the applications submitted for the credentialing process will depend upon the characteristics of the applicant, as well as the size of the hospital and the scope of services provided. Information typically included within applications includes:

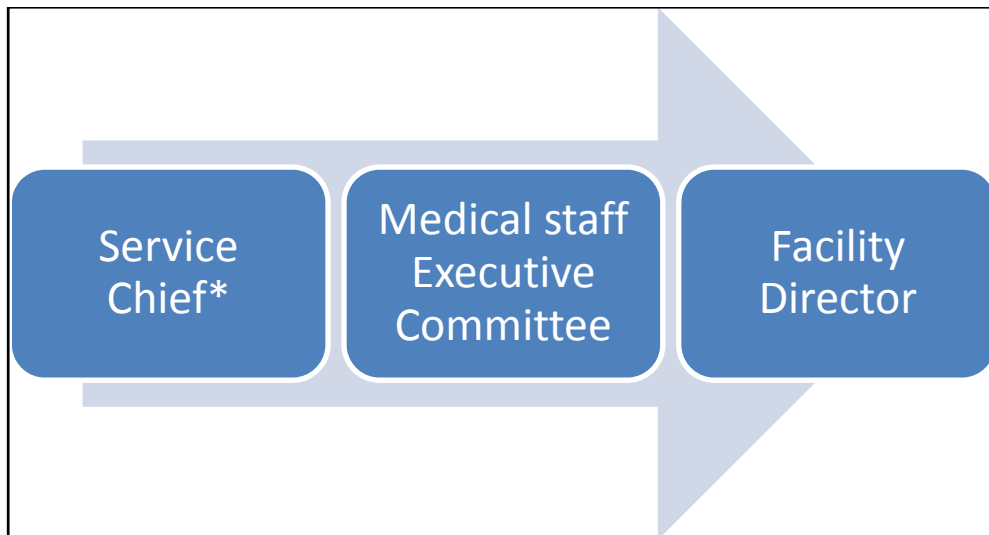
- personal information and demographics including name, date of birth, social security number and contact details
- education and training, including medical education, internships, residencies and fellowships
- military service, if applicable
- licensure including past and present certificates
- board certification from specialities or sub-specialities
- hospital affiliations, both current and past, as well as names of the department chairs and reasons for leaving if no longer affiliated
- work experience
- professional references (not including current or prospective partners in practice)
- professional liability carriers (medical insurance) including the name of the company, address, policy number, dates of coverage and amounts of coverage
- letter of health status
- delineated list of requested privileges (scope of clinical practice)
- teaching and faculty appointments, research and publications
- voluntary and involuntary termination of medical staff membership or voluntary or involuntary limitation, reduction or loss of clinical privileges (scope of clinical practice) at another hospital
- previously successful or pending challenges to any licensure or registration or the voluntary relinquishment of such licensure or registration
- involvement in professional liability action and final judgements or settlements involving the practitioner submitting the application (The Joint Commission 2011).

Veterans Health Administration

The credentialing process outlined within the VHA handbook was similar to that found in The Medical Staff Handbook compiled by The Joint Commission; as The Joint Commission represents the leading organisation for health accreditation and standards within North America (The Joint Commission 2011). Scope of practice (clinical privileges) granted by the VHA is specific to the institution in which they were applied for, and the VHA only credentials licensed independent practitioners (see definition in the previous section “The Joint Commission standards”).

The process for initial definition of the scope of clinical practice (privileging) is outlined in Figure 10.

Figure 10 Credentialing process within the Veterans Health Administration



* Chief of the specialty in which the applicant is applying for scope of clinical practice (privileges).
Adapted from: Department of Veterans Affairs (2008).

Information required for the credentialing process

The information required from an applicant depends upon the department and/or specialty in which the clinician’s services will be provided. Consequently, the criteria for the delineation of the scope of clinical practice should be recommended by the MEC and approved by the Facility Director. The general categories of information required for credentialing and definition of scope of clinical practice are similar to The Joint Commission standards outlined earlier.

Recredentialing

The process of recredentialing and re-definition of scope of clinical practice is known as reappraisal and repriviling within the VHA.

Reappraisal “...is the process of re-evaluating the professional credentials, clinical

competence and health status of practitioners who hold clinical privileges within a facility: (Department of Veterans Affairs 2008 p 40). The reappraisal process must include information regarding:

- any successful or pending challenges to any licensure or registration
- voluntary or involuntary relinquishment of licensure or registration
- limitation, reduction or loss (voluntary or involuntary) of privileges at another hospital
- loss of medical staff membership
- pending malpractice claims or malpractice claims closed since last reappraisal or initial appointment
- mental and physical status
- any other reasonable indicators of continuing qualifications.

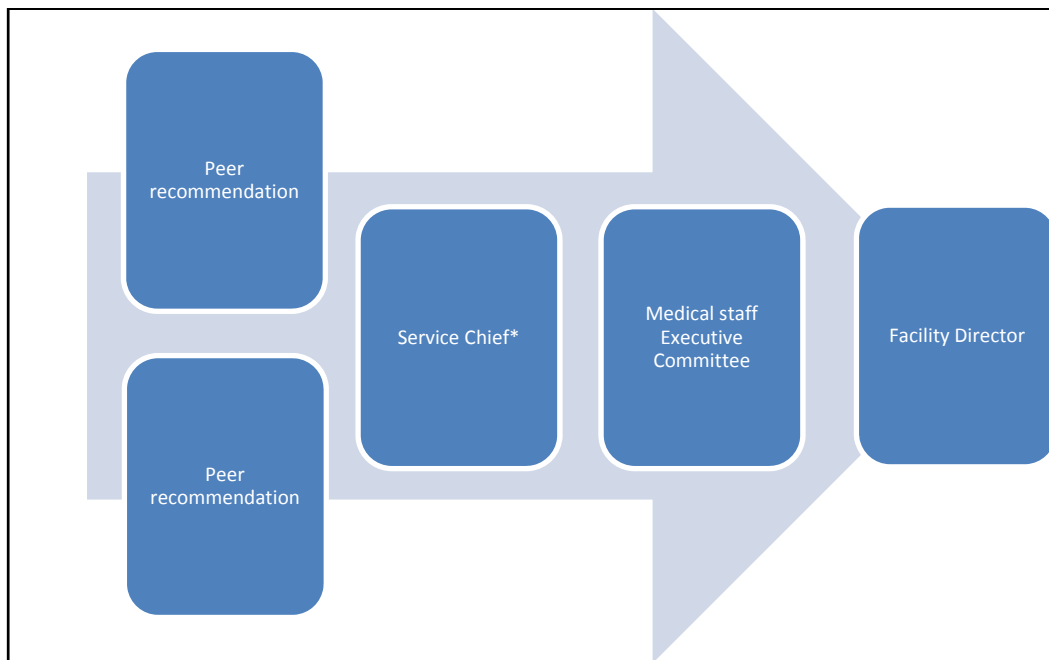
Information regarding the number of procedures performed, major diagnoses treated, rates of complications compared with others performing the same procedures; and adverse events indicating patterns or trends in a practitioner's clinical practice are also useful for the reappraisal process. However, these must be compared to the aggregate data of other credentialed practitioners conducting the same procedures within the institution.

Review of the scope of clinical practice (re-privileging)

The VHA defines re-privileging as "...the process of granting privileges to a practitioner who currently hold privileges within the facility" (Department of Veterans Affairs 2008 p 42). According the VHA policy, this process must be conducted every two years. The process for redefinition of the scope of clinical practice is outlined in Figure 11.

During the review process the Service Chief must assess a minimum of two peer recommendations (Figure 11). Following receipt of peer recommendations, the Service Chief of the specialty in which the clinician is being re-privileged produces a recommendation for re-privileging to the MEC. The MEC then provides a recommendation to the Facility Director, based upon the Service Chief's recommendation and review of the applicant's re-privileging information. The Facility Director provides the final approval for the privileges granted through the re-privileging process.

Figure 11 Review of definition of clinical practice process within the VHA



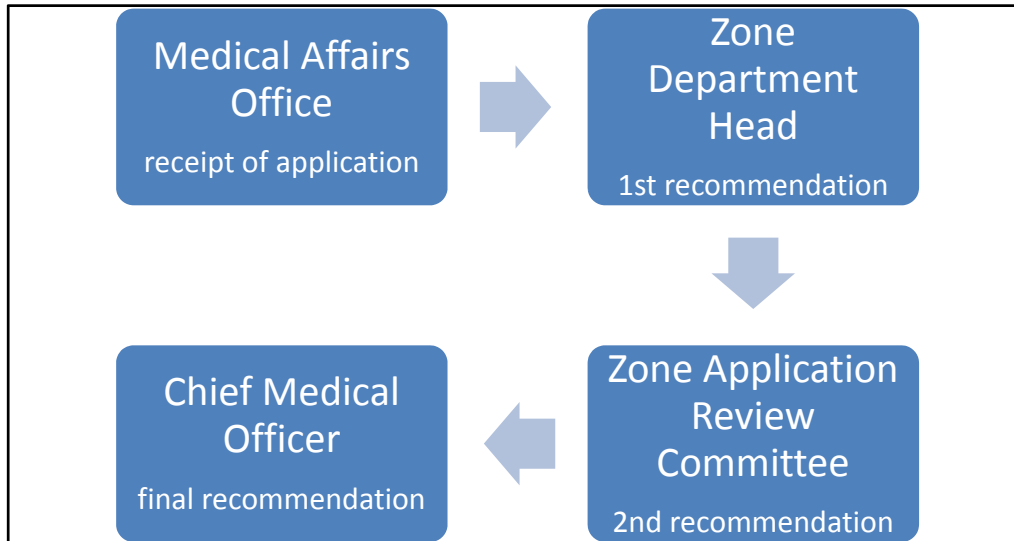
* Chief of the specialty in which the applicant is applying for scope of clinical practice (privileges).

Adapted from: Department of Veterans Affairs (2008).

Canada

One white paper published by the AHS was available for the assessment of the credentialing process within the province of Alberta, Canada (AHS 2011b). The AHS process of credentialing and defining the scope of clinical practice is comprised of four key steps (Figure 12).

Figure 12 Albert Health Service credentialing process



Adapted from: Alberta Health Service (2011b).

Firstly, the Medical Affairs Office (MAO) receives the applications from clinicians seeking to be credentialed. Once the MAO has verified the application is complete and that all supporting information is attached, it progresses to the Zone Department Head, who provides an initial recommendation to the Zone Application Review Committee (ZARC). This committee acts in a similar manner to a credentialing committee. The ZARC receives the initial recommendation from the Zone Department Head, reviews this recommendation as well as the supporting information, and forwards a second recommendation to the Chief Medical Officer regarding final approval.

Similarly to the USA, within Canada each healthcare institution operates according to medical staff bylaws. Credentialing policies and processes are synthesised in accordance with these medical staff bylaws. As each institution is responsible for producing medical staff bylaws, there is variability between institutions with regard to credentialing and defining the scope of clinical practice policy and procedures. Medical staff bylaws were identified for a number of institutions throughout Canada; however, were not included in this report as they did not meet the inclusion criteria for the examination of the credentialing process and the supporting governance structures.

4.5 Additional research questions

A number of topics of interest were identified by the Advisory Committee, including the impact of surgeon volume on technical competence as well as methods of determining surgeon competence, and the role of clinical audit in performance appraisal and recertification; which are briefly outlined in this section.

4.5.1 Surgeon volume and technical competence

The literature indicated that criteria for assessing clinician competence, including technical and cognitive skills, should be recommended by the specialist medical college to which the clinician is registered (UK Department of Health 2006). Whilst technical competence is an attribute to be assessed in the credentialing process, none of the identified literature included specifically for assessment of the credentialing process or governance structures required to support credentialing processes, provided guidelines on surgeon volume and its subsequent impact on technical competence. Consequently, a number of focused and specific literature searches were conducted to obtain high-level evidence to inform on the relationship between surgeon volume, technical competence and patient outcomes. Four systematic literature reviews were available to inform on a number of indications (Archampong et al 2010; Gooiker et al 2010; Marlow et al 2007; Post et al 2009). The findings of these reviews are outlined in Table 17.

Table 17 Findings of the systematic literature reviews for surgeon volume

Study	Indication	No. of included studies	Findings
Archampong et al 2010	Rectal cancer surgery	11	Rectal cancer patients of surgeons with higher case-loads were associated with better survival and lower risk of permanent stoma and abdominoperineal excision of the rectum. There was no significant difference between high and low case-load volume surgeons for anastomotic leak rate.
Gooiker et al 2010	Surgical treatment of breast cancer	12	A meta-analysis that survival after breast cancer surgery was significantly better with high-volume providers; however, solid evidence for a specific minimal volume standard cannot be identified in the literature.
Marlow et al 2007	Abdominal aortic aneurysm, knee arthroplasty, liver resection, oesophagectomy, prostatectomy	76	There was insufficient evidence available to definitively state that increased hospital/surgeon volume positively impacted patient morbidity, mortality or length of stay.
Post et al 2009	Rheumatoid arthritis, diabetes mellitus, cystic fibrosis	22	The available literature suggested that outcomes were not superior in specialised centres or with subspecialists compared with other forms of chronic illness care.

Post et al (2009) postulated that surgeons who possess a greater case-load volume may have superior processes for the delivery of care. Consequently, Post et al (2009) suggested that further research should be conducted to evaluate differences in processes of care between high-volume and low-volume providers in order to identify those factors that positively affect patient outcomes.

Technical competence and credentialing

The findings of these systematic reviews may indicate that for, the purpose of credentialing, minimum surgeon volume thresholds may be necessary to indicate a minimum level of surgeon competence, but are not sufficient in indicating actual technical competence.

4.5.2 Methods of assessing surgeon competence

The definition of competence, as outlined in RACS *Surgical competence and performance guide* (2008) is "...what we [as surgeons] have been trained to do and, during training, the process of developing competencies under the supervision of the RACS Education Board" (RACS 2008, p 3). In contrast, performance is about practice. "How we [as surgeons] perform is influenced by a variety of abilities, some of which are technical and others are non-technical" (RACS 2008, pp 3). There is an inter-relationship between competence and performance.

Components of surgical competence identified in the RACS guide include:

- medical expertise
- judgement and decision-making
- technical expertise
- professionalism
- health advocacy
- communication
- collaboration and teamwork
- management and leadership
- scholarship and teaching.

Defining the scope of clinical practice is a component of technical expertise (RACS 2008). For a surgeon this involves understanding the limitations of both one's competencies and of organisational factors, such as infrastructure and human resources, that may compromise the performance of certain procedures under certain conditions.

Tools for assessing surgeon performance across the nine key competencies outlined within the RACS guide include self-assessment, assessment by others, surgical audit and peer review, performance review, review of complaints and adverse events, case review

and multi-source feedback (RACS 2008).

Self-assessment

The RACS guide may be used by surgeons to assess their own performance and the status of their competencies (RACS 2008). In addition, completion of the annual RACS Continuing Professional Development (CPD) ensures that surgeons maintain a record that demonstrates their ongoing commitment to life-long learning (RACS 2008).

Assessment by others

Assessment by others may be undertaken by a number of methods, which are outlined below:

- surgical audit and peer-review: all surgeons who perform operative procedures are required by RACS to participate in an annual peer-reviewed audit;
- performance review: to be undertaken by the Director of Surgery;
- review of complaints and adverse incidents: currently the most used assessment tool, this method of assessment generally takes place following a perceived incident of poor performance by an individual surgeon;
- case review: a form of audit that is typically undertaken when a surgeon's performance is questioned, yet a specific complaint or incident appears to be absent;
- multi-source feedback: also known as 360 degree review, this is a process in which feedback can be provided by a range of colleagues. In order to be accurate and comprehensive, greater lengths of time and input are required to capture the perspective of a number of colleagues.

4.5.3 The role of clinical audit

Two documents were available for the assessment of the role of clinical audit with regard to performance review and recredentialing (NZ Ministry of Health 2001; UK Department of Health 2006). The NZ report indicated that credentialing policy should explicitly state the requirements of recredentialing and may include involvement in clinical audit (NZ Ministry of Health 2001).

The UK report indicated that national clinical data sets, which gather and analyse clinical performance and draw conclusions, are valuable in obtaining a snapshot of nation-, state- or institution-wide performance. However, the value of such data may be limited when applied to performance appraisal and recredentialing processes for an individual clinician for a number of reasons:

- insufficient detail captured within audit process may lead to an inaccurate portrayal of an individual clinician's performance
- senior clinicians generally provide treatments or interventions of greater technical competence, or treat patients with more complex/advanced disease; and

therefore data collected may not be appropriately risk-adjusted (UK Department of Health 2006).

Consequently, the use of clinical audit data for performance review or for evaluating the impact of credentialing processes on the safety and quality of healthcare services may not be appropriate. Rather, the method proposed by the NHS for evaluating the credentialing process is process audit, where the performance of credentialing process activities is measured against clearly defined standards for credentialing (UK Department of Health (UK) 2006). This proposed form of audit is championed by the NHS, which recognises that there are a number of complex factors affecting the relationship between credentialing and appropriately defining the scope of clinical practice, and the overall impact on the safety and quality of healthcare services (UK Department of Health 2006). Consequently, methods for evaluating the effectiveness of the credentialing process represent an area for further research.

5. Discussion

The objective of this systematic literature review was to examine the credentialing process at an institutional level and assess the governance structures required to support the credentialing process at the institutional, regional and healthcare system levels. This involved the exploration of the impact that the credentialing process and respective governance structures have on the safety and quality of healthcare services. Three additional research questions were identified by the Credentialing in Surgery Advisory Committee, which explored the relationship between credentialing and:

- surgeon volume, technical competence and patient outcomes
- methods of determining surgeon competence
- the role of clinical audit.

Application of systematic methodologies for the assessment of the credentialing process and supporting governance structures was challenging, given the nature of the evidence base. In order to obtain relevant literature to answer the defined research questions, the assessment of the credentialing process was restricted to those occurring at an institutional level.

Grey literature comprised the entirety of the included documents for assessment of the credentialing process, as these were the only publications reporting findings at an institutional level. Government white papers were also identified to report on the governance structures required to support the credentialing process at an institutional, regional or healthcare system levels. This review assessed the credentialing process and governance structures within a number of healthcare systems and jurisdictions within Australia, NZ, the USA, Canada and the UK.

5.1 Australasia

Credentialing white papers, including policy documents, were available from five Australian state health departments as well as other Australia-wide organisations including the ACN and the HQCC. Similarities were evident between the Australian state health department reports, as many were published following the release of the ACSQHC Standard in 2004. Parallels in credentialing process policies within Australia were evident with regard to establishing clear lines of responsibility for credentialing processes, composition of the credentialing committee responsible for defining the scope of clinical practice, and establishment of essential criteria for clinical positions.

Differences were evident between Australian state health departments regarding the delegation of responsibility for the credentialing process; however, these differences were still within the models described within the ACSQHC Standard (ACSQHC 2004).

NZ utilises a four-step credentialing process which had many similarities to the

Australian credentialing process; including credentialing committee membership, interactions with and the roles of specialist colleges, synthesis of credentialing policies, delegation of the responsibility for the credentialing process, and establishment of essential criteria for clinical positions.

5.2 International healthcare systems

The USA and Canadian healthcare systems differ greatly in structure and function to those of Australia and NZ. Safety and quality initiatives in healthcare are provided within North America mostly by private not-for-profit organisations contracted by state/provincial health departments or individual institutions. Healthcare institutions within both countries are required to develop medical bylaws, by which the institution operates. Credentialing and delineation of the scope of clinical practice policies and procedures are formulated in accordance with these bylaws; and therefore vary between institution as well as between state/province jurisdiction. No specific credentialing initiatives were identified within the USA or Canada.

The process of revalidation within the NHS in the UK was identified as the system of medical regulation most similar to the credentialing process within Australia; and involves the re-licensure of clinicians according to local performance review results. The NHS has worked to standardise this process, and additionally established numerous NHS Health Authorities to assist in the monitoring of governance structures that support health service quality initiatives. In the last decade, seven NHS Health Authorities have either been created, or had their existing roles modified, including the Healthcare Commission, NPSA, National Clinical Governance Support Team and the Care Quality Commission.

The impetuses for the creation and modification of the role of Health Authorities, implementation of governance structures and formalisation and development of the revalidation process in the UK were the Bristol Royal Infirmary Inquiry and the inquiry into the case of Harold Shipman (Bristol Royal Infirmary Inquiry 2001; UK Department of Health 2006). Failings in the NHS system identified by the Bristol Royal Infirmary Inquiry indicated that there was confusion throughout the NHS regarding who was responsible for monitoring the quality of care, and that no standards were in place for evaluating performance. Additionally, the continual and undetected malpractice of Dr Shipman, as well as the number of resultant victims demonstrates the importance of formalised revalidation and credentialing processes, the development of standards for performance evaluation, and of governance structures to ensure the adequate reporting and evaluation of the safety and quality of healthcare.

No evaluation data that measured the impact of implementation and/or development of credentialing processes on healthcare service quality, safety or patient outcomes was reported in the studies included in this systematic literature review. Therefore, this area represents a topic for further research. The only evidence identified was provided by

publications arising from a number of process audits conducted by the NHS, at the mid-point of the implementation of a number of planned structural reforms. However, these process audits did not provide any evaluation data regarding the effect these reforms had on the safety and quality of healthcare services or patient outcomes. The development of methods to evaluate the effect of implementation, modification, formalisation or development of the credentialing process or governance structures to support credentialing, would assist in determining the impact these reforms have on the safety and quality of healthcare services. However, it is likely that characterisation of this relationship and the capture of the required evaluation data would be difficult, as many factors confound the relationship between credentialing and the delineation of the scope of clinical practice, as well as the net result on patient outcomes.

6. Conclusion

Credentialing and defining the scope of clinical practice are activities performed as part of other broader initiatives to ensure the safety and quality of healthcare services. The importance of developing and implementing credentialing processes may be best demonstrated in the cases of The Bristol Royal Infirmary Hospital and of Drs Shipman and Patel and the many resultant victims. Inquiries into these malpractice cases demonstrated that weaknesses and failures in credentialing processes and the governance structures which support credentialing processes resulted in a failure to identify and prevent the malpractice (Bundaberg Hospital Commission of Inquiry 2005, Smith 2004).

Credentialing processes and governance structures that support the credentialing of clinicians were assessed within a number of healthcare systems and jurisdictions. Whilst there were differences in the methods by which the credentialing process was performed, four key principles were common throughout all documents included in this systematic review:

- clear lines of responsibility for credentialing and supportive governance structures
- clear standards for credentialing, representing how the credentialing process should be performed and providing a standard to which credentialing processes should be measured to
- a culture of continuous improvement
- evaluation of credentialing process outcomes.

Credentialing lines of responsibility and governance structures

The impact and success of credentialing processes relies on the responsibility for the credentialing process and the resultant definition of a clinician's scope of clinical practice being clearly delegated and defined. The committee, body or senior manager responsible for the credentialing process is also held accountable for the synthesis of credentialing policies, establishment of essential criteria for clinical positions and definition of credentialing criteria and verification of credentials. Governance structures support the credentialing process, as they ensure that the lines of responsibility are clear and delegated, and provide the framework in which the credentialing process operates within the context of broader safety and quality initiatives.

Credentialing standards

The literature included in this systematic literature review highlighted the need for clear and defined standards for credentialing and defining the scope of clinical practice. Credentialing standards represent the guideline for how credentialing processes should be conducted in an institution and the benchmark to which the effectiveness of credentialing processes should be measured.

Cultural factors

The experience of the NHS with regard to credentialing process and governance reform highlighted the need for individuals to be collectively aligned to the overall purpose and aim of quality initiatives within these areas of quality assurance in healthcare. Whilst implementation of credentialing standards, policies and clear definition of governance structures and lines of responsibilities may be established, if individuals are not aware of or aligned to their purpose, institutions will not reach their objective of improvement in the safety and quality of the provided healthcare services.

Evaluation of credentialing process outcomes – a future area of research

This systematic literature review did not identify any literature containing evaluation data for the assessment of the outcomes of the credentialing process. Capturing such data is difficult, due to the numerous factors which affect the relationship between credentialing, patient outcomes and the overall safety and quality of healthcare services. Methods used by the NHS for assessment of credentialing processes include process audit against the standards for credentialing. Consequently, development of methods of measuring the effectiveness of credentialing processes represents a topic of future research.

Shortened forms

ACSQHC	Australian Commission on the Safety and Quality of Health Care
ACN	Australian Cancer Network
AHS	Alberta Health Service
BOM	Board of Management
C&SOP	credentialling and scope of practice
CEO	Chief Executive Officer
CME	continuing medical education
COS	Chief of Service
CPD	continuing professional development
CQC	Care Quality Commission
CRD	Centre for Review and Dissemination
DHB	District Health Board
GMC	General Medical Council
GP	general practitioner
HA	Health Authority
HQCC	Health Quality and Complaints Commission
MAO	Medical Affairs Office
MEC	Medical staff Executive Committee
NAO	National Audit Office
NCAS	National Clinical Assessment Service
NHS	National Health Service
NHS HTA	National Health Service Health Technology Assessment
NICE	National Institute for Health and Clinical Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning Service
NSW Health	New South Wales Department of Health
NZ	New Zealand
OMS	organised medical staff
PCG	primary care group

PCT	primary care trust
PICO	patient, intervention, comparator and outcome
QIO	Quality Improvement Organisation
QLD Health	Queensland Department of Health
RACS	Royal Australasian College of Surgeons
SA	South Australia
SA Health	South Australian Department of Health
TRIP	turning research into practice
UK	United Kingdom
US	United States
VHA	Veterans Health Administration
VIC DHS	Victorian Department of Human Services
ZARC	Zone Application Review Committee

Sources of additional information

The credentialing and defining the scope of clinical practice and appointment checklist can be found in Appendix 2 (p 14) of the *Credentialling and defining the scope of clinical practice for medical practitioners in Victorian health services – a policy handbook* 2009 by the VIC DHS. This checklist should be read in conjunction with the National Standards.

During the synthesis of this review, however after the search execution date the Victorian Department of Human Services published an updated version of their Credentialling and defining the scope of clinical practice for medical practitioners in Victorian health services- a policy handbook:

Victorian Department of Human Services 2011, *Credentialling and defining the scope of clinical practice for medical practitioners in Victorian health services- a policy handbook*, Victorian Government Department of Human Services, Melbourne.

Available from:

[http://docs.health.vic.gov.au/docs/doc/F75634AE22D42207CA25790D001A379F/\\$FILE/Credentialling%20and%20defining%20the%20scope%20of%20clinical%20practice%20for%20medical%20practitioners%20in%20Victoria_2011%20update.pdf](http://docs.health.vic.gov.au/docs/doc/F75634AE22D42207CA25790D001A379F/$FILE/Credentialling%20and%20defining%20the%20scope%20of%20clinical%20practice%20for%20medical%20practitioners%20in%20Victoria_2011%20update.pdf).

Appendix One: international governance models

United Kingdom

Table 18 Components of clinical governance in the NHS

Main Components of Clinical Governance	Trust	HA	PCG	PCT
<p>1. Clear lines of responsibility and accountability for the overall quality of clinical care through:</p> <ul style="list-style-type: none"> • The NHS Trust Chief Executive carries the ultimate responsibility for assuring the quality of services provided by the Trust • A designated senior clinician responsible for ensuring that systems for clinical governance are in place and monitoring their continued effectiveness • Formal arrangements for NHS Trust, PCT and PCG Boards to discharge their responsibilities for clinical quality, through a clinical governance committee • Regular reports to NHS Boards on the quality of clinical care given the same importance as monthly financial reports • An annual report on clinical governance 	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>	<p></p> <p>✓</p> <p></p> <p></p> <p>✓</p>	<p></p> <p></p> <p>✓</p> <p>✓</p> <p>✓</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>

Table 18 Components of clinical governance in the NHS (continued)

Main Components of Clinical Governance	Trust	HA	PCG	PCT
2. A Comprehensive programme of quality improvement activities which includes:				
<ul style="list-style-type: none"> • Full participation by all hospital doctors in audit programmes, including speciality and sub-speciality national audit programmes endorsed by the Commission for Health Improvement 	✓	✓		
<ul style="list-style-type: none"> • Full participation in the current four National Confidential Enquiries 	✓	✓		
<ul style="list-style-type: none"> • Evidence-based practice is supported and applied routinely in everyday practice 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Ensuring the clinical standards of National Service Frameworks and NICE recommendations are implemented 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Workforce planning and development (i.e. recruitment and retention of appropriately trained workforce) is fully integrated within the NHS organisation's service planning 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Continuing Professional Development: programmes aimed at meeting the development needs of individual health professionals and the service needs of the organisation are in place and supported locally 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Appropriate safeguards to govern access to and storage of confidential patient information as recommended in the Caldicott Report on the Review of Patient-Identifiable Information 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Effective monitoring of clinical care with high quality systems for clinical record keeping and the collection of relevant information 	✓		✓	✓
<ul style="list-style-type: none"> • Processes for assuring the quality of clinical care are in place and integrated with the quality programme for the organisation as a whole 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Participation in well designed, relevant R&D activity is encouraged and supported as something, which can contribute to the development of a "evaluation culture". 	✓	✓	✓	✓

Main Components of Clinical Governance	Trust	HA	PCG	PCT
3. Clear policies aimed at managing risks:				
<ul style="list-style-type: none"> • Controls assurance which promote self-assessment to identify and manage risks 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Clinical risk systematically assessed with programmes in place to reduce risk 	✓			✓

Table 18 Components of clinical governance in the NHS (continued)

Main Components of Clinical Governance	Trust	HA	PCG	PCT
4. Procedures for all professional groups to identify and remedy poor performance, for example:				
<ul style="list-style-type: none"> • Critical incident reporting ensures that adverse events are identified, openly investigated, lessons are learned and promptly applied 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Complaints procedures, accessible to patients and their families and fair to staff. Lessons are learned and recurrence of similar problems avoided 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Professional performance procedures which take effect at an early stage before patients are harmed and which help the individual to improve their performance whenever possible, are in place and understood by all staff 	✓	✓	✓	✓
<ul style="list-style-type: none"> • Staff supported in their duty to report any concerns about colleagues' professional conduct and performance, with clear statements from the Board on what is expected of all staff. Clear procedures for reporting concerns so that early action can be taken to remedy the situation. 	✓	✓	✓	✓

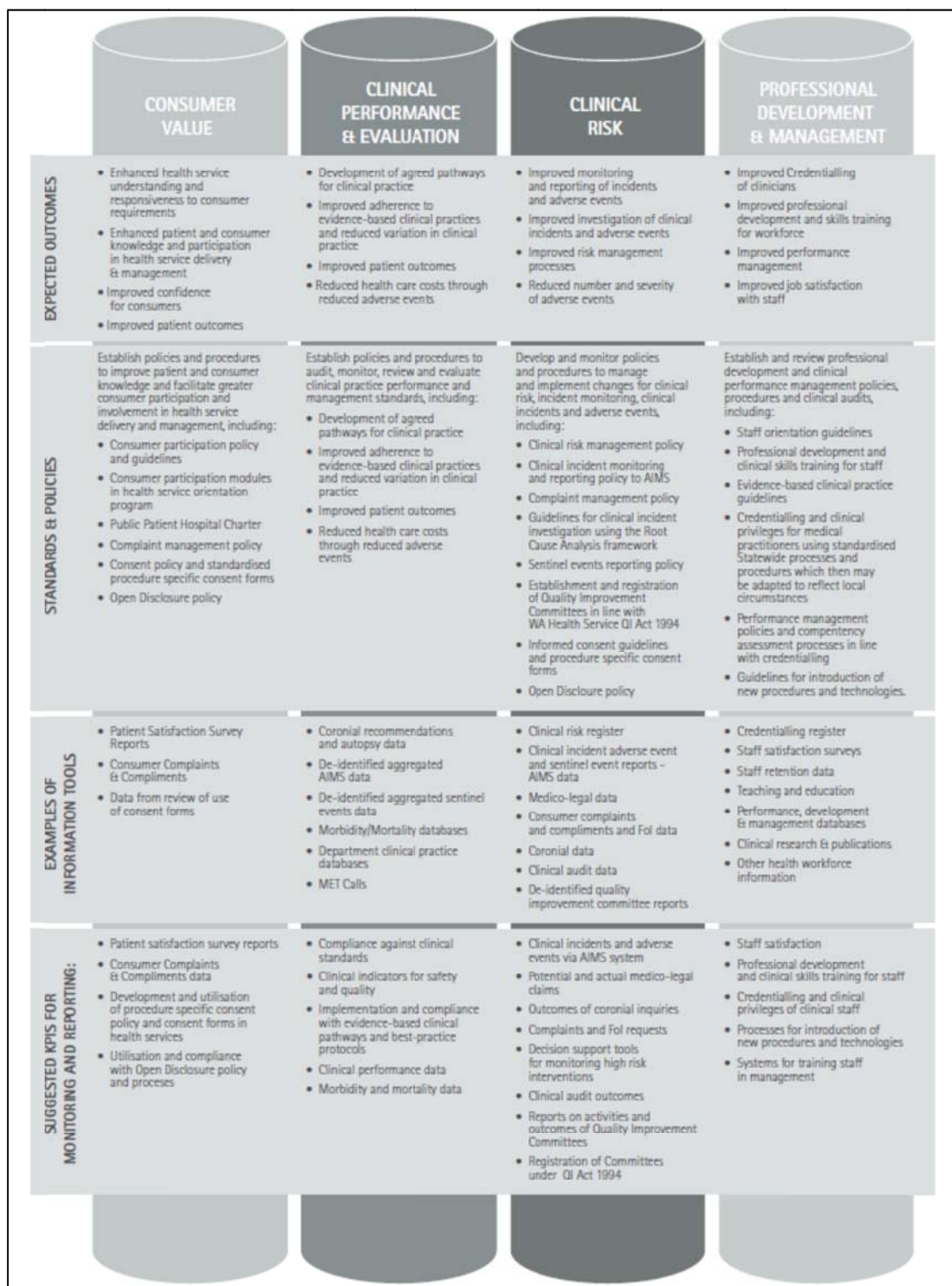
HA: health authority; NHS: National Health Service; PCG: primary care group; PCT: primary care trust.
 Source: UK Department of Health 1999, p 26.

Appendix Two: Australian clinical governance models

Western Australia

Western Australia has a 'four pillar' clinical governance system as previously described. Credentialing, recredentialing and performance review falls under the fourth pillar: professional development and management, which is depicted below in Figure 13.

Figure 13 Western Australian four pillar clinical governance model

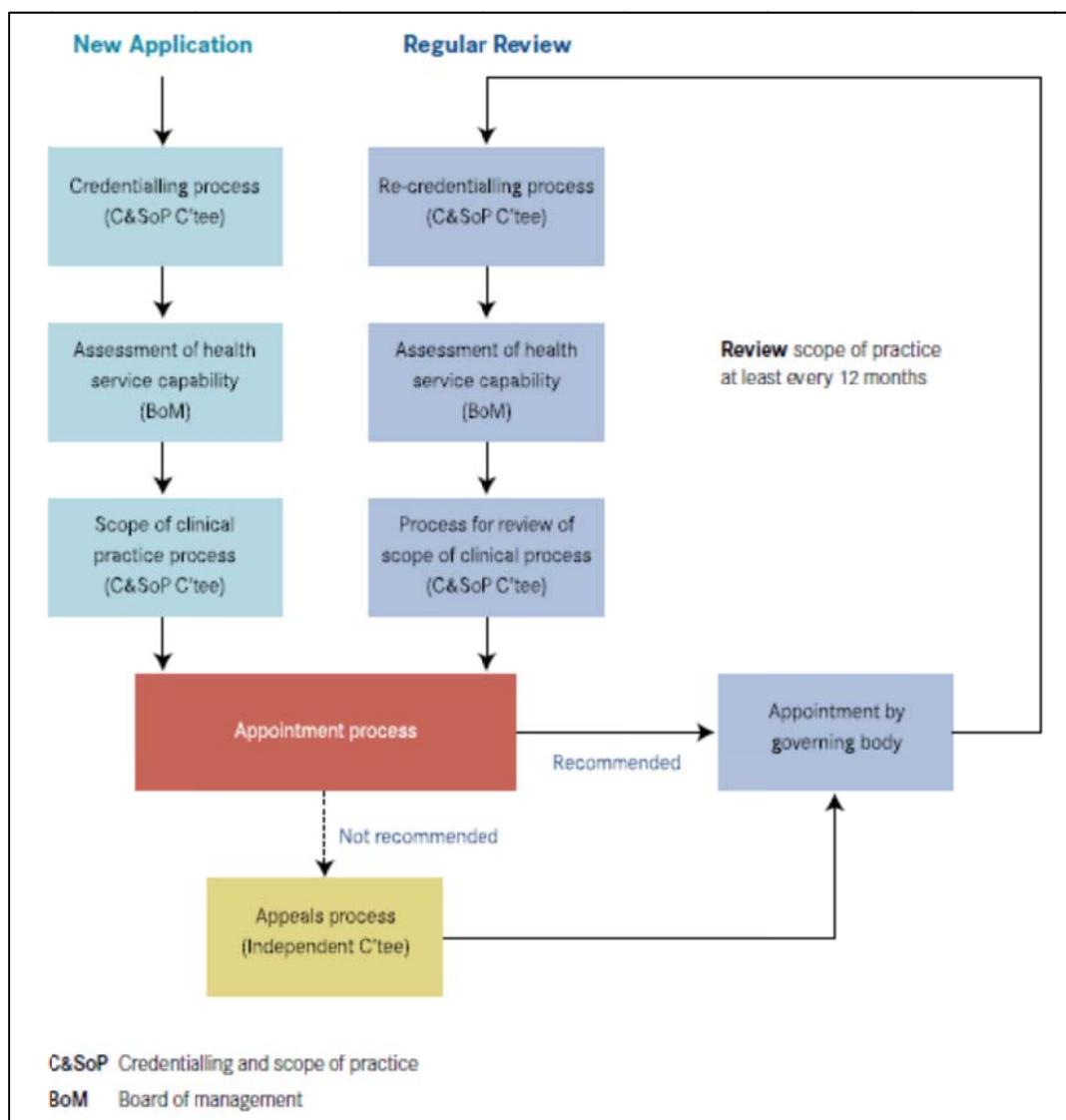


Source: Department of Health, Western Australian Government 2005c p 19.

Appendix Three: Australian credentialing process models

Victorian Department of Human Services

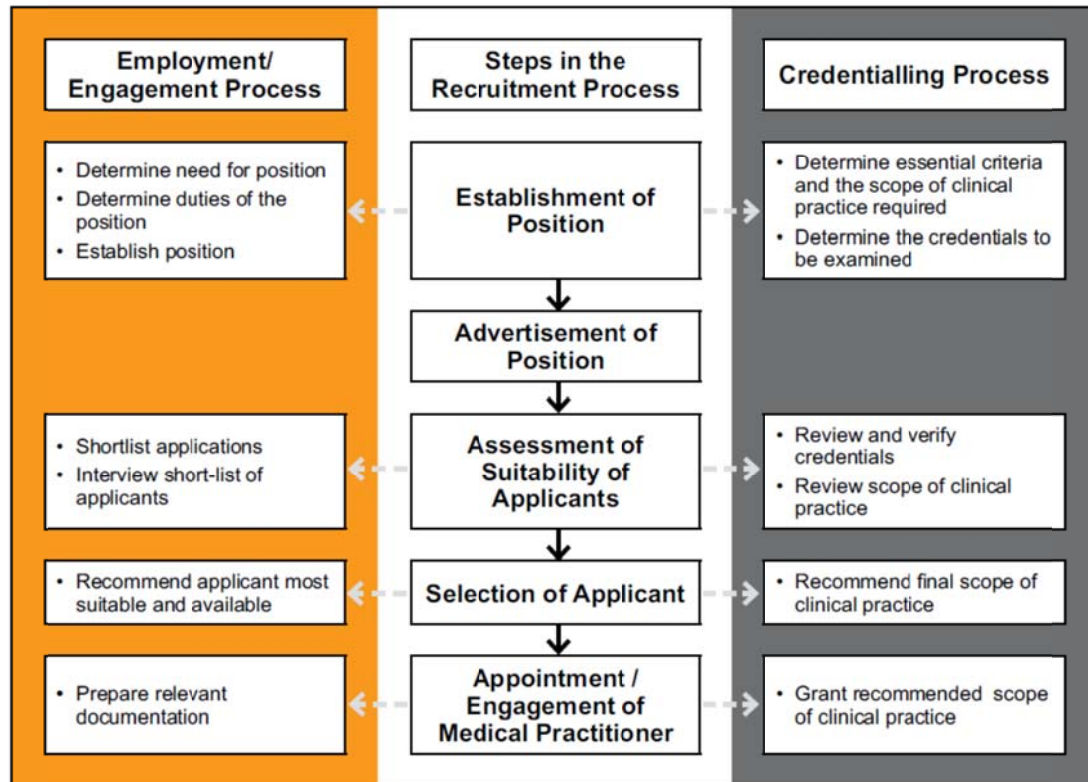
Figure 14 Victorian Department of Human Services credentialing and defining scope of clinical practice flowchart



Source: Victorian Department of Human Services 2009 p 13.

Western Australian Department of Health

Figure 15 Western Australian Department of Health flowchart for recruitment and the relationship with initial credentialing processes for Australian-trained medical practitioners



Source: Western Australian Department of Health, 2009a p15.

Appendix Four: international credentialing models

Table 19 Detailed summary of New Zealand’s four-step credentialing process

Step	Requirement of credentialing framework	Comments
1 Verification of qualifications, training, experience and registration status	<p>A clear position description is provided that identifies training, qualifications and experience required for the position offered.</p> <p>The ongoing credentialing process includes a review of training, qualifications and experience.</p>	<p>Verification at source is the ultimate guarantee of authenticity. Medical Council verification quality standard should be acceptable to employers. Once verified, qualification and training details should be held in a central database for subsequent employer access.</p> <p>Reference checking is an employer activity.</p> <p>Training, qualifications and experience and registration status are dynamic criteria.</p> <p>Central database requires regular update.</p>

Table 22 Detailed summary of New Zealand’s four-step credentialing process (continued)

<p>2 Determining the scope of practice on appointment</p>	<p>The organisational scope of practice is defined in writing.</p> <p>Preceptorship may be a requirement of appointment during the orientation period, where this is appropriate, while the practitioner establishes a clinical track record in the organisation.</p>	<p>Scope of practice decisions takes into account the competence of the practitioner; the facilities and support available, and the current needs of the organisation.</p> <p>Scope of practice in the context of credentialling is organisation-specific. For a senior medical officer it is most likely to be defined as the area of clinical practice for which the practitioner has the appropriate training, qualifications and experience, identifying any services that cannot be undertaken in this organisation.</p> <p>The scope of practice is reviewed as part of the ongoing credentialling process.</p>
<p>3 Ongoing data collection</p>	<p>Each service identifies the quality assurance data to be collected and the process of ongoing monitoring of clinical competence.</p> <p>Written policy specifies the role of the credentials committee where:</p> <ul style="list-style-type: none"> • a trend of declining performance is evident, necessitating a formal review outside planned service recredentialling • a mismatch develops between the work the service is funded to do and the adequacy of the facilities and support provided • the service or an individual practitioner is considering a new procedure/service where credentialling will be required • an interim review is requested <p>Competence monitoring of short- term appointments is specified where tenure will end before formal recredentialling occurs.</p>	<p>The appropriate medical college or specialist society recommendations and the needs of the organisation will influence information requirements. These should include ongoing monitoring and accumulation of information for recredentialling in the following areas:</p> <ul style="list-style-type: none"> • clinical audit • peer review • record of clinical activity • patient satisfaction • continuing medical education, post graduate study, teaching and research.
<p>4 Recredentialling</p>	<p>A formal review of practitioner credentials (recredentialling) within the context of the service in which the practitioner is employed should occur at least every five years.</p> <p>Membership of the credentials committee must include specialty expertise from outside the organisation.</p> <p>A documented appeal process should be managed independently of the credentials committee.</p>	<p>This includes feedback from other health professionals within the service and patients regarding the practitioner’s technical and interpersonal skill related to the scope of practice.</p> <p>This requirement assists in achieving objectivity of assessment, particularly in smaller services, and maintenance of national standards.</p>

Source: NZ Ministry of Health 2001 p 25.

Appendix Five: excluded studies

Studies which were retrieved but subsequently excluded following application of inclusion criteria are documented below with reasons for exclusion.

Did not report credentialing processes at an institutional level

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Reported on credentialing processes in rural settings

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