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National Clinical Standards and Cost Effectiveness

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for NSW Treasury and NSW Health

UNIVERSITY OF TECHNOLOGY SYDNEY

About CHERE

CHERE is an independent research unit affiliated with the University of Technology, Sydney. It has been established since 1991, and in that time has developed a strong reputation for excellence in research and teaching in health economics and public health and for providing timely and high quality policy advice and support. Its research program is policy-relevant and concerned with issues at the forefront of the sub-discipline.

CHERE has extensive experience in evaluating health services and programs, and in assessing the effectiveness of policy initiatives. The Centre provides policy support to all levels of the health care system, through both formal and informal involvement in working parties, committees, and by undertaking commissioned projects. For further details on our work, see www.chere.uts.edu.au.

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Executive Summary

NSW Treasury commissioned this review through the Sax Institute. The aims and specific questions to be addressed were refined after consideration of a background paper, and discussion between NSW Health, NSW Treasury and the author.

The aim of the review is to provide information about the ways in which costs and cost effectiveness are being incorporated in the approaches used by agencies within Australia, North America and Europe involved in CPG development and setting standards; and to provide recommendations for the development of the approach to be developed by the ACSQHC. The specific questions this report addresses are:

(i) Which countries/health systems have developed and implemented a systematic approach to developing clinical guidelines and/or indicators which include consideration of costs and benefits?
(ii) What approaches have been used in Australia?
(iii) What evidence is there about the effectiveness or value of these approaches?
(iv) What is known about best practice for developing clinical guidelines and/or indicators which include consideration of costs and benefits?
(v) What other aspects or issues should be considered in the development of guidelines, standards and indicators?

Over time, Clinical Practice Guidelines (CPGs) have developed from consensus of clinical opinions to recommendations developed from the use of systematic and sophisticated approaches to reviewing the scientific evidence. However, reviews of Clinical Practice Guidelines have consistently shown that most fall short of high standards of methodological rigour. Currently many if not most developed countries are attempting to develop Clinical Practice Guidelines to provide an evidence based approach to inform clinical decisions. The distinction between guidelines and standards is not clear, but standards generally imply minimum criteria which should met in delivering services; however, adherence to standards is seldom mandatory. Clinical indicators are quantifiable measures of whether standards are being met. Most of these countries are also addressing the issue of ensuring value for money in health service delivery. In many countries this challenge has been heightened by the global financial crisis.

There are a small number of countries which attempt to include economic considerations in Clinical Practice Guidelines and Clinical Standards (CS) development, but there is little detailed information on how they do this. The most detailed information available is from NICE. There is also a frequently unstated tension between the use of Clinical Standards and the increased emphasis on consumer choice and patient empowerment, which is also a feature of reforms in many countries.

In Australia, the NHMRC has provided the lead in the development of Clinical Practice Guidelines but there are now over 80 agencies producing them. A recent review identified poor documentation of the evidence base for these. Sophisticated Health Technology Assessment programs are undertaken

by PBAC and MSAC. At the local (State and hospital level) there are many different approaches with little co-ordination and consistency. This review has not identified any rigorous investigation of the value and effectiveness of the systematic approaches that have been developed.

It is possible to identify the key features of good practice in Health Technology Assessment, based on the literature review and augmented by CHERE's own experience in CPG development and in HTA at the national and local levels. These features of good practice are directly applicable to Clinical Practice Guideline and Clinical Standards development. These include integrating economic analysis into the process early, the use of rigorous methods which are applied consistently, addressing generalisability and the translation to the relevant local context, and considering the budget and resource implications as well as the cost per unit of benefit.

Clinical indicators are measures which summarise how well standards of care are being achieved. Hence indicators are required to be valid, rigorous, sensitive to clinical practice, and feasible to collect.

The Report identifies a number of issues that need to be addressed in developing guidelines, standards and indicators. These include the need for clear definitions and statements of purpose, the setting of priorities for development, consistency and reduction of duplication with other agencies with overlapping responsibilities, the need to address implementation, the need to ensure other strategies are coherent and do not impose perverse incentives, and the need to develop adequate capacity to support these new programs. Our recommendations are summarised in Table 3.

Acknowledgments

Liz Chinchen undertook the literature searches. Kees van Gool contributed the examples of Australian CPGs, and made useful comments, as have other members of CHERE. Additional information has relied on key informants and discussions at the recent Commonwealth Fund International Symposium in Health Policy and Practice.

List of Abbreviations

ACI	Agency for Clinical Innovation
ACHCS	Australian Commission on Health Care Standards
ACSQHC	Australian Council on Safety and Quality in Health Care
AHMC	Australian Health Ministers' Conference
AHRQ	Agency for Health Research and Quality
CEC	Clinical Excellence Commission
COAG	Council of Australian Governments
CPGs	Clinical Practice Guidelines
CS	Clinical Standards
GDG	Guideline Development Groups
HTA	Health Technology Assessment
IQWIG	Institute for Quality and Efficiency in Health Care
IPART	Independent Pricing and Regulatory Tribunal
MSAC	Medical Services Advisory Committee
NCC	National Collaborating Centres
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NICS	National Institute for Clinical Studies
PBAC	Pharmaceutical Benefits Advisory Committee
SIGN	Scottish Inter-Collegiate Network

Background

As part of national health care reform, the Australian Commission on Safety and Quality in Health Care (ACSQHC) will become a permanent agency with responsibility for the development of national clinical standards. These will form part of an enhanced national performance and accountability framework, and as such will provide a basis against which jurisdictional performance will be assessed. The COAG Agreement also determines that the principles for the framework (Council of Australian Governments, 2010) are:

1. where appropriate, performance measures should address access to services, quality of service delivery, financial responsibility, patient outcomes and/or patient experience; and
2. performance measures should be few in number and supported by data which is timely, comparable, administratively simple, cost effective, and accurate.

The COAG Agreement also provides that the States will "provide such de-identified clinical data to the ACSQHC and/or the National Performance Authority as is required for, respectively, development of agreed quality and safety standards, and reporting against these standards, according to a timetable determined by the ACSQHC and the National Performance Authority and agreed by Health Ministers."

The National Health and Hospitals Network Bill, 2010, will establish the ACSQHC and its functions. The focus of the ACSQHC is safety and quality. The relevant sections of the Bill are sections 9 and 10. Section 9 establishes the functions of the Commission which are:

(a) to promote, support and encourage the implementation of arrangements, programs and initiatives relating to health care safety and quality matters;
(b) to collect, analyse, interpret and disseminate information relating to health care safety and quality matters;
(c) to advise the Minister about health care safety and quality matters;
(d) to publish (whether on the internet or otherwise) reports and papers relating to health care safety and quality matters;
(e) to formulate, in writing, standards relating to health care safety and quality matters;
(f) to formulate, in writing, guidelines relating to health care safety and quality matters;
(g) to formulate, in writing, indicators relating to health care safety and quality matters;
(h) to promote, support and encourage the implementation of:
  (i) standards formulated under paragraph (e); and
  (ii) guidelines formulated under paragraph (f);
(i) to promote, support and encourage the use of indicators formulated under paragraph (g);
(j) to monitor the implementation and impact of:

(i) standards formulated under paragraph (e); and
(ii) guidelines formulated under paragraph (f);

(k) to advise:
(i) the Minister; and
(ii) each participating State/Territory Health Minister;
about which standards formulated under paragraph (e) are suitable for implementation as national clinical standards;

(l) to formulate model national schemes that:
(i) provide for the accreditation of organisations that provide health care services; and
(ii) relate to health care safety and quality matters;

(m) to consult and co-operate with other persons, organisations and governments on health care safety and quality matters;

(n) such functions (if any) as are specified in a written instrument given by the Minister to the Chair;

(o) to promote, support, encourage, conduct and evaluate training programs for purposes in connection with the performance of any of the Commission's functions;

(p) to promote, support, encourage, conduct and evaluate research for purposes in connection with the performance of any of the Commission's functions;

(q) to do anything incidental to or conducive to the performance of any of the above functions.

Section 10 requires the ACSQHC to consult widely, unless there is a case for urgent development and promulgation of guidelines, and nominates the following;

(a) clinicians; and

(b) bodies known as lead clinician groups; and

(c) each head (however described) of a Department of State of:
(i) a State; or
(ii) the Australian Capital Territory; or
(iii) the Northern Territory;
where the Department:
(iv) deals with matters relating to health; and
(v) is administered by a participating State/Territory Health Minister; and

(d) any other persons or bodies who, in the Commission's opinion, are stakeholders in relation to the formulation of the standards, guidelines or indicators; and

(e) the public.

The Commission is required to collect, analyse and interpret such information as it considers relevant, and may incorporate any other material in its standards, guidelines and indicators. The Minister may make rules for the formulation of standards, guidelines and indicators; and in doing so must consult with participating State and Territory Ministers. Compliance with a standard or guideline is voluntary, but compliance with a standard or guideline may be required under a grant or a contract. A standard or guideline may be adopted by law in States, Territories, or the Commonwealth. Standards, guidelines and indicators as specified under the Bill are not legislative instruments.

The Bill does not provide a definition of standards, guidelines, indicators or national clinical standards.

Thus the Act will specify the formulation of standards, guidelines and indicators, plus advising the Minister which standards are suitable to be used as national clinical standards. The Bill does not mention efficiency or cost consequences in describing the formulation, and the CEO of the current Commission does not include cost-effectiveness in his description of safe and high quality health care delivery (Baggoley, 2009). However, as the (Commonwealth) Minister may make rules, ie determine the approach to formulating standards and guidelines, in consultation with State and Territory Ministers, there is the opportunity to ensure that some economic analysis is mandated.

The ACQSHC has already undertaken substantial work around standards and accreditation. The Australian Health Ministers' Conference commissioned an independent Review of Future Governance Arrangements for Safety and Quality in Health Care (Paterson, 2005) which reported in mid 2005 that: there are various bodies involved in setting standards for accreditation which has led to duplication and gaps; the standards themselves are not publicly available or accessible; and the process of setting standards is not clear and transparent. The Review recommended a transformation of accreditation arrangements. In 2006, Australian Health Ministers' Conference (AHMC) requested that the ACQSHC review national safety and quality accreditation standards. In 2008, AHMC endorsed the recommendations of the ACQSHC for new national arrangements, and the AC commenced implementation. Ten National Safety and Quality Health Service Standards have been developed, five of which have been piloted and subsequently amended, and another five which have been released for consultation. The ACQSHC has not yet released a final report following the consultation phase. It should be noted that these accreditation standards are focussed on structures and processes, rather than outcomes.

Meanwhile there are other agencies, both existing and proposed which have some overlap with the remit of the AQSHC. The NHMRC has led the development of clinical practice guidelines (CPGs), though multiple bodies have developed CPGs. The Australian Council on Health Care Standards (ACHCS) is the established body which accredits health care facilities, and has developed a set of clinical standards. The National Pricing Authority will implicitly set standards in determining efficient prices. Within NSW, reorganisation of health services structures and governance is being driven by both the national reform agenda, and the implementation of the Garling Report recommendations. The Clinical Excellence Commission (CEC) has been established to improve safety and quality of care; the new Agency for Clinical Innovation (ACI) has as its functions identifying high quality, safe and

cost-effective ways to care for patients within the NSW public health system. The CEC and ACI have jointly established a very small health economics capacity to support these functions. There is the potential for considerable overlap between the ACI and the CEC, and the NSW agencies and the AQSHC.

Aims and review questions

The Treasury has commissioned, through the Sax Institute, a review of approaches used to incorporate costs and cost-effectiveness into clinical standards and guidelines. Specifically, the review questions as stated in the brief were:

(i) What methods exist and where have they been used?

(ii) How have these methods of standard development demonstrated clinical and cost effectiveness value?

(iii) What are the strengths and weaknesses of different methods?

(iv) What criteria would be applied for judging the appropriateness of different methods for use in national safety and quality clinical standards to be set by the ACSQHC?

(v) What method is most likely to be suitable for use in national safety and quality clinical standards to be set by the ACSQHC?

The first stage of this project was the preparation of a background paper to address these objectives:

- Identify all relevant systems for including economic costs and benefits in safety and quality clinical standards
- Indicate for each method the demonstrated outcomes, strengths, weaknesses and any lessons learned
- Summarise any relevant papers in peer reviewed journals or the grey literature about the value of the methods and the practicality of their use.

The background paper provided the basis for a discussion with NSW Health and NSW Treasury and the author. The outcome of this was to refine the aims and questions of the review as follows.

The **aim** of the review is to provide information about the ways in which costs and cost effectiveness analyses are being incorporated in the approaches used by agencies within Australia, North America and Europe involved in CPG development and setting standards; and to provide recommendations

for the development of the approach to be developed by the ACSQHC. The **specific questions** this report addresses are:

(i) Which countries/health systems have developed and implemented a systematic approach to developing clinical guidelines and/or indicators which include consideration of costs and benefits?

(ii) What approaches have been used in Australia?

(iii) What evidence is there about the effectiveness or value of these approaches?

(iv) What is known about best practice for developing clinical guidelines and/or indicators which include consideration of costs and benefits?

(v) What other aspects or issues should be considered in the development of guidelines, standards and indicators?

Thus the starting point for this review is **how** to incorporate these considerations and the arguments as to whether or not they **should** be incorporated are not revisited.

This report does not address the details of the various approaches to formulating guidelines, which have variously been termed guidelines for guidelines, or methods for developing guidelines, or under the Bill are termed rules. As noted, the Bill does not define clinical guidelines (CPGs), clinical standards (CSs) or clinical indicators (CIs). For the purpose of this report we use the terms as follows:

Guidelines are recommendations to inform clinical practice and adherence to them is voluntary;

Standards are minimal acceptable criteria of treatment for a specified indication or condition and adherence to them is a marker of good quality care;

Indicators are readily quantifiable measures of the extent to which standards have been met.

In the report, the terms 'guidelines' and 'standards' are often used together, though this does not imply substitutability but rather the lack of clear demarcation between them. 'Indicators' has a distinct and separate meaning.

In comparison, the recent ACQSHC consultation paper has framed its work on standards around accreditation. The definition of a standard is "a statement of controls that must be in place to assure, or provide the best possible chance that health services will deliver the expected level of safety and quality and patient outcomes." These standards are to be both minimum levels of

achievement (quality assurance) and 'aspirational criteria' (quality improvement). The ten standards developed to date comprise:

Governance for Safety and Quality in Health Service Organisations, which provides the framework for Health Service Organisations as they implement safe systems;

Healthcare-Associated Infection, which describes the standard expected to prevent infection of patients within the healthcare system and to manage infections effectively when they occur, to minimise their consequences;

Medication Safety, which describes the standard expected to ensure clinicians prescribe, dispense and administer appropriate and safe medication to informed patients;

Patient Identification and Procedure Matching, which specifies the expected processes for identification of patients and correctly matching their identity with the correct treatment.

Clinical Handover, which describes the requirement for effective clinical communication whenever accountability and responsibility for a patient's care is transferred.

Partnering for Consumer Engagement, which creates a consumer-centred health system by including consumers in the design and delivery of quality health care;

Blood and Blood-product Safety, which sets the standard to ensure that the patients who receive blood and blood products are safe;

Prevention and Management of Pressure Ulcers, which specifies the expected standard to prevent patients developing pressure ulcers and best practice management when pressure ulcers occur;

Recognising and Responding to Clinical Deterioration in Acute Health Care, which describes the systems required by health services responding to patients when their clinical condition deteriorates;

Preventing Falls and Harm from Falls, which describes the standards for reducing the incidence of patient falls in Health Service Organisations.

These standards are very much concerned with how the organisation works and the structure and processes that support that. The general pattern is that the standard is compliance with accepted

(Clinical Practice) Guidelines and the measure (indicator) is evidence that compliance is monitored and action taken when required. For example, under “healthcare associated infections: managing patients with infections”, the standard is compliance with current NHMRC Guidelines; but for the “prevention and management of pressure ulcers: governance and systems for the prevention and management of pressure ulcers” the standard is current agreed best practice guidelines.

Search Strategy

The literature search was conducted using Medline, Premedline, Embase and the Ovid Nursing databases via the Ovid interface. The following search terms were used:

"clinical standards" or "clinical guidelines" or "standards of care" or "standards of practice’ or “clinical adj1 standards” or “clinical adj1 guidelines". These terms were then combined with the MESH subject headings: “economic evaluation” or “cost effectiveness” or “cost benefit” or “cost utility” or “cost analysis” or “health care costs”. We limited the results to English language articles and to the years 2000 to the present.

Econlit via the EBSCO interface was also used to search the literature, using the terms "clinical standards" or "clinical guidelines" or "standards of care" or "standards of practice”.

Articles identified were scrutinised to identify those that addressed methods of incorporating economic evaluation in guideline development, guideline best practice or evaluation.

A Google search was also conducted to identify grey literature from various agencies’ websites that produce Clinical Guidelines. We commenced with those countries which we knew produced clinical guidelines, and INAHTA and the Guidelines International Network websites (though many details from the latter are limited to members only). We followed up further references and citations by hand searching.

What systems exist for developing clinical guidelines which include consideration of costs and benefits?

Clinical Practice Guidelines (CPGs) were originally a method for developing a consensus of clinical opinion. However, with the increased emphasis on the scientific evidence base of medical practice, CPGs now incorporate a rigorous systematic review of the evidence as a basis for formulating their recommendations. Thus CPGs have become much closer to the approach of Health Technology

Assessment (HTA). Indeed, some commentators consider CPG development to be a part of HTA (Jacobson, 2007). While the methods used are the same, there are some differences in emphasis which need to be considered:

- HTA often deals with a discrete procedure or intervention whereas CPGs deal with an episode of care, the investigation of a set of signs and symptoms, or the ongoing treatment of a disease or condition;
- HTA generally incorporates economic evaluation, whereas there are markedly different views on the appropriateness of including economic evaluation in formulating CPGs;
- HTA is often linked to or used to inform reimbursement decisions whereas CPGs are intended to improve clinical decision making, and have not generally been used to inform reimbursement decisions.

Clinical standards (CS) imply a norm or desired approach to diagnosis and practice. CS appear to have been adopted within health care organisations as a means of reducing clinical variation and improving patient outcomes. The distinction between CPGs and CSs is not very clear. Clinical indicators (CI) are objective and quantifiable and measure the extent to which desired standards have been met (Mainz, 2003). The Australian Council on Health Care Standards provides the following definition:

> A clinical indicator is simply a measure of the clinical management and/or outcome of care. A well-designed indicator should 'screen', 'flag' or 'draw attention' to a specific clinical issue. Usually rate based, indicators identify the rate of occurrence of an event. Indicators do not provide definitive answers; rather they are designed to indicate potential problems that might need addressing, usually demonstrated by statistical outliers or variations within data results. They are used to assess, compare and determine the potential to improve care. Indicators are therefore, tools to assist in assessing whether or not a standard in patient care is being met (Australian Council on Healthcare Standards, 2010).

CIs are the basis for monitoring and evaluating quality of care, and hence their development and collection raise issues of clarity of definition, availability of valid and reliable data, rigour (including appropriate risk adjustment), cost of data collection and analysis, and subsequent corrective action.

Table 1 provides a summary of countries which have a national approach to the development of CPGs and include some economic analysis in their development. There is much less information available on CSs and CIs, with only the National Institute for Health and Clinical Excellence (NICE) providing a major program.

The US is not included in this summary for several reasons. The Agency for Healthcare Research and Quality (AHRQ) has had a national role in promoting safety and quality, improving the effectiveness and efficiency of care, but there are a myriad of agencies across the US involved in similar activities. AHRQ provides a national clearinghouse of CPGs, but has not provided detailed guidelines for their development, in the past, though to some extent this has been taken over by the Comparative Effectiveness Research (CER) Program which was established as a component of the fiscal stimulus response to the global financial crisis of 2008. Following recent debates (Institute of Medicine, 2008), and in large part driven by the US health system reforms, a new over-arching, public-private, co-ordinating agency, the Patient Outcomes Research Institute (PORI), has been established. To date, economic evaluation has been incorporated in some HTA and CPGs in the US; however, in the current political climate there is a great deal of concern about the rationing of health care and the use of costs and cost-effectiveness to set priorities (Academy Health, 2009, Jacobson, 2007). The Charter of the PORI specifically excludes any consideration of economic implications. This approach, though, will not prevent others from taking CER results and adding an economic analysis. Within the US, several health care providers have used CSs and CIs as a strategy in improving health care quality; for example, the Veterans Administration, Inter-Mountain Health Care (Leonhardt, 2009). In short, the US approach to CPG and CS development reflects the complexity, diversity and duplication of the US health system, and the divisions within US health politics.

Table 1 shows several features in the approach taken in Canada and countries of Europe. Perhaps most strikingly, and most disappointing for the purpose of this review, there is remarkably little information available through published sources about the detail of the processes that have been implemented. The development of CPGs and CSs are generally considered part of safety and quality initiatives, but are often housed within or in close proximity to HTA programs. Approaches to the inclusion of any economic analysis vary from mandatory inclusion as in England and Wales (NICE), to an optional extra in the report such as in New Zealand. The type of economic analysis also varies, from a full economic evaluation with complex decision analytical modelling as can be found in many NICE reports, to a budget impact statement, such as in Scotland (SIGN). For the most part, CPGs , are guidelines, meeting an advisory function. It might be considered that standards and indicators imply some mandatory adoption, but this is not common. For example, in Switzerland hospitals chose to participate in the quality indicators program. In England and Wales health authorities are required to implement NICE guidance, but quality standards are not mandatory.

Table 1: Countries, guidelines and economic analysis

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
Canada	CADTH -Canadian Agency for Drugs and Technologies in Health. Independent body funded by national, territorial and provincial governments.	To provide impartial and evidence based information on health systems and technologies, including drugs. HTA program and COMPUS provides guidance of use of medications, though not termed CPGs. Also a clearinghouse for other Canadian HTA agencies. Also specialised provincial agencies.	No information Available	Likely to be broad given focus on efficiency	Not clear	Economic evaluation	No information Available
Finland	FINOHTA - an independent, publicly funded health technology assessment agency.	To produce, support and co-ordinate HTA; assess cost-effectiveness of guidelines produced by Finnish Medical Society	No – economic analysis is an add-on	Only applied to selected guidelines	NA	NA	NA

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
France	HAS - Haute Autorité de Santé – publicly funded, independent agency.	To produce CPGs, disease management programs, provide continuing profession education, accredit health care organisations	NA	Separate health economics assessments issued on some topics	NA	NA	NA
Germany	IQWIG - Institute for Quality and Efficiency in Health Care. Independent institute funded by a levy on payments from Social Health Insurance Funds. Supports the Federal Joint Committee, G-BA, which formulates coverage and quality measures	Review evidence, prepare reports on quality and efficiency of health services, appraise CPGs, recommend disease management programs, as referred. Determine reimbursable price	IQWIG has a health economics division	Mandatory if additional benefit established	Internal project group Usually with external experts, some contracting.	Full economic evaluation with measure of benefit selected as appropriate to alternatives under consideration, can be clinical outcome or quality adjusted. Detailed guidance manual.	Not indicated
Italy	Age.Na.S- The Agency for Regional Healthcare	Very broad including safety and quality, HTA and guidelines	NA	Remit includes analysis of costs but not clear if this is applied to CPGs.	NA	NA	NA

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
Netherlands	Council for the Quality of Care Although many agencies have been involved in CPG development. A new national Institute for Health Care Quality to be established, but how this will function is not yet clear.	To coordinate guideline development, facilitate national collaboration to avoid duplication, improve consideration of safety, patient centeredness, and cost-effectiveness.	NA	NA	NA	NA	NA
New Zealand	New Zealand Guidelines Group autonomous and independent organisation funded by Accident Compensation Corporation (ACC) and the Ministry of Health, and others. A new Quality and Safety Commission is being established in 2010, replacing the Quality Improvement Committee.	To promote effective delivery of health and disability services, based on evidence.	no	Partial but not if infeasible or too complex	Not necessarily a health economist	Balance sheet – financial costs and savings Manual offers advice	

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
Northern Ireland	GAIN - Guidelines and Audit Implementation Network	NA	NA	NA	NA	NA	NA
Norway	Norwegian Knowledge Centre for the Health Services. Independent agency	Provides evidence synthesis but does not formulate guidelines; these are produced by specialist groups. Performance and quality measures being developed but as yet insufficient data.	NA	NA	NA	NA	NA
Scotland	SIGN - Scottish Intercollegiate Guidelines Network Part of NHS Scotland but with 'editorial independence'	To produce evidence based clinical guidelines	Typically included in GDG but not necessary	Partial	SIGN staff	Published economic evaluations included in literature review. Cost analysis if resource implications are significant Manual chapter on resource implications not yet available	Not indicated
Spain	GuíaSalud, a national project managed by IC+S - Aragon Health Sciences Institute	To provide an information and recording system; and to implement and update guidelines.	NA	NA	Co-ordinates the work of other regional agencies	NA	NA

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
Sweden	SBU – Swedish Council on Health Technology Assessment Independent public authority	Role is HTA, prepare systematic reviews which include consideration of international guidelines. No national guidelines, but regional guidelines are produced by local level programs.	Staff and network of experts include health economists	Yes	External project groups	NA	NA
Switzerland		Legislative requirement that health services be cost-effective. However, insurance determined at canton level. Quality indicators produced for hospitals under the Quality Strategy					

Country	National Agency	Role	Economist in Guidelines Development Group	Inclusion of any economic analysis	By whom	Type of analysis	Peer review
United Kingdom	NICE – National Institute for Health and Clinical Excellence Independent NHS Agency But functions to be reviewed within context of new NHS reforms.	Wide responsibility including HTA and public health. Produces CPGs. The QOF and the quality contracts negotiated with CQUI also provide some standards and indicators.	Yes, as part of technical team from National Collaborating Centre	Mandatory	Academic groups in nominated centres	Favours cost-utility with QALYs as measure of benefit Subsequent cost analysis to support implementation Detailed guidance manuals	Yes

The most thorough and well documented approach is that of NICE. NICE offers the following descriptions for its programs:

Clinical guidelines – guidance on the treatment and care of people with specific diseases and conditions (National Institute for Health and Clinical Excellence (NICE), 2009a).

Technology appraisal guidance – guidance on the use of new and existing health technologies (including drugs, medical devices, diagnostic techniques and surgical procedures) (National Institute for Health and Clinical Excellence (NICE), 2009a). *Interventional procedures guidance* – guidance on the efficacy and safety of surgical, endoscopic and endovascular procedures and related techniques (National Institute for Health and Clinical Excellence (NICE), 2009a).

Quality standards – a set of specific, concise statements that act as markers of high-quality, cost-effective care across a clinical area (National Institute for Health and Clinical Excellence (NICE), 2009b).

Quality indicators – quantitative measures of quality that set the expected degree of achievement, where possible derived from routinely collected data (National Institute for Health and Clinical Excellence (NICE), 2009b).

Under NICE, the CPG development program is separate to technology appraisal, the review of interventional procedures, and the development of public health advice. CPG development is supported by a series of National Collaborating Centres (NCC); these groups undertake the tasks of searching, assessing and synthesising the evidence under a Guideline Development Group (GDG). The NCC project group includes a health economist from the beginning of the assessment; and the plan for the economic analysis is prepared early. Detailed guidance is available with the most recent methods guide published in January 2009 (National Institute for Health and Clinical Excellence (NICE), 2009a).

The development of quality standards is more recent, with a pilot program established in 2009-10, and the findings of a process evaluation published earlier this year (National Institute for Health and Clinical Excellence (NICE), 2010). Quality standards have been developed to date in 4 clinical areas, based on CPGs, but a further 25 topics are now underway. Topics are referred to NICE by the National Quality Board, based on priority. There are two components to a quality standard: five to ten statements which describe quality and although some individual statements may describe essential aspects of care, the statements in totality define high quality care; and measures which

define the expected achievement and can be used as high level quality indicators which may be taken up and used as national quality indicators. High priority standards will be mandated as part of the NHS Operating Framework, but others will not be mandatory and may be described as aspirational. The evaluation found that the existing expertise in NICE and the existing CPGs were strengths, but among recommendations pointed to the need for greater clarity in how standards will be used, and more consideration given to the development of indicators. Quality standards address safety, effectiveness and patient experience. To date, the inclusion of cost-effectiveness has not been explicit in QS, but to the extent they are based on CPGs considerations of cost-effectiveness have already been incorporated. Clearly there is considerable overlap between QS and other NICE guidance programs, CPG development, the Quality and Outcomes Framework, NHS Evidence, and commissioning.

Under the next round of NHS reforms, there is much greater devolution of decision making autonomy to general practice consortia which will take responsibility for all English NHS commissioning; and a greater emphasis on achieving health outcomes, comparable to the best in the world. The NHS Outcomes Framework, released in December 2010, provides a basis for accountability for the NHS Commissioning Board which has oversight of all commissioning. The first Outcomes Framework has five broad domains. These are very broad statements, eg preventing people from dying prematurely. Under these broad 'headline statements there are high level indicators (eg mortality from causes considered amenable to health care), and specified improvement areas (eg reducing under 75 mortality form cardiovascular disease). A set of NICE Quality Standards will then be developed (or are under development) to support improvement (eg standards for management of acute myocardial infarction); these in turn are expected to be supported by NICE CPGs. The Commissioning Board will commission NICE to develop Quality Standards, and must develop a process for identifying new topics which builds on the current process for selecting topics for CPG development. In the recent document, consideration of the cost-effectiveness of recommended improvements is explicitly stated as one of the principles on which QS levels will be determined.

In contrast, Scotland has taken a separate and different approach to CPG development. The emphasis is on the assessment of clinical effectiveness and appraising the clinical evidence. However, the typical GDG is expected to include a health economist, and the literature search is expected to include published economic analyses. An independent cost-effectiveness analysis is not required, but the report should include a statement of the resource implications and budget impact.

There is a manual available to support the preparation of guidelines, but the chapter on developing resource implications is not yet available (Scottish Intercollegiate Guidelines Network (SIGN), 2008).

The German Institute for Quality and Efficiency in Health Care, IQWiG, was established in 2004, but not until 2007 did it address the issue of economic evaluation. Currently, assessments are focussed on drugs but the same methods are intended to cover a broad range of technologies. Assessments are referred to IQWiG by the Joint Commission and, as well as providing guidance for coverage decisions, can be used to determine the maximum reimbursement amount for new drugs (and technologies). Clinical effectiveness is assessed first, and new but less effective therapies are not considered even if they are less expensive. The economic evaluation is therefore added on after the assessment of clinical effectiveness. The analysis estimates the additional benefit and costs of the new intervention compared to existing available interventions for the same disease or condition; described by the developers of the approach as the efficiency frontier. This approach does not estimate an Incremental Cost Effectiveness Ratio and determine whether that represents value for money; which requires a shadow value or social willingness to pay for a unit of health gain. Rather this approach determines the worth of the new intervention by comparing its incremental effectiveness, using if appropriate multiple measures of benefit instead of constricting benefits to QALYS or other composite measures of health gain. Cost effectiveness is assessed against other funded therapies for the same condition. Using an ICER threshold means that some conditions where treatment costs are high and gains very small can be considered poor value; the consequence of the IQWiG approach is that expensive to treat conditions are not excluded from treatment (Institute for Quality and Efficiency in Health Care (IQWiG), 2010). When used for pricing determinations the approach is akin to the reference pricing approach adopted in Australia for PBS pharmaceuticals prior to 1990 when mandatory assessment of cost-effectiveness was introduced (Caro, et al., 2010).

What approaches have been used in Australia?

The National Health and Medical Research Council (NHMRC) led the development of CPGs in Australia in the early 1990s. A review in 1993 identified 34 CPGs produced by 32 organisations (Ward and Grieco, 1996). From 1995 the NHMRC has published guidance for the development of CPGs. The current manual *A guide to the development, implementation and evaluation of clinical practice guidelines* was published in 1998, and is supported by a series of handbooks, including one on incorporating economic considerations (National Health and Medical Research Council, 2001a). This was published in 2001 (though prepared two years before that). Given the developments in this

area, this has to be regarded as out of date. The NHMRC has continued to develop CPGs (and that activity is now based in the National Institute for Clinical Studies unit of the NHMRC) but other Australian agencies also produce CPGs. A recently published review identifies over 80 CPG producing agencies and 313 CPGs produced between 2003 and 2007 in Australia (Buchan, et al., 2010).

PBAC and MSAC have well developed approaches to using evidence in HTA, including a mandatory requirement that they consider the cost-effectiveness of the drugs/procedures being assessed. Indeed, the PBS was the first agency worldwide to introduce the mandatory requirement for economic evaluation into its process. The initial evaluation is provided by a sponsor (usually the Pharmaceutical Company), and reviewed independently. Evaluations are treated as "commercial in confidence" and justifications of positive and negative recommendations are restricted to a brief statement. Although cost-effectiveness is a major consideration, other factors are taken into account such as the magnitude of clinical benefit, the availability of alternative treatments and the provision of treatment for severe conditions for which there is no other effective intervention (the so called "rule of rescue") (Pharmaceutical Benefits Advisory Committee). It is important to note that the way the PBS operates is essentially an open-ended entitlements program with few restrictions on volume.

The MSAC was established to undertake the HTA of new items, considering evidence on safety, effectiveness and cost-effectiveness of the procedure. MSAC analyses now include the budgetary impact of the decision to list the new item for MBS purposes. Although the HTA process for new MBS items is modelled on PBAC, there are some interesting differences. MSAC often deals with interventions as part of a clinical pathway (eg a new diagnostic test, a new prosthesis). Both PBAC and MSAC provide detailed guidelines for the economic analysis, which are largely consistent (Pharmaceutical Benefits Advisory Committee, Medical Services Advisory Committee`,). The evaluation of devices and other non-drug technologies present different issues and challenges to drug evaluation (Drummond, et al., 2009), so MSAC frequently has to include and disaggregate a broader range of costs than are relevant for PBAC decisions, and these considerations are included in the MSAC guidelines. However, the development of the MSAC assessment is under the direction of the Committee, with sub-contracted evaluation groups (though further revisions to the process are being considered and open for consultation at the time of writing); whereas for PBAC the assessment is prepared by the sponsor (generally the pharmaceutical company); MSAC economic analyses are only subject to review by MSAC's Economics Sub-Committee, whereas PBAC assessments are appraised by an independent evaluation group, the PBAC secretariat, and the PBAC Economics Sub-Committee. MSAC relies almost entirely on evidence in the published and peer

reviewed literature, while PBAC evidence is often produced by the sponsor from company funded clinical trials.

The strength of the PBAC/MSAC process is the national consistency in the availability of new technologies, and the linking of HTA to public funding. However, a similar process has not been nationally applied to public hospitals, nor to services covered by private health insurance. Public hospitals do not require PBS/MBS funding to introduce new technologies, teaching hospitals are often innovators in the adoption and dissemination of new technologies; and the types of technologies are largely beyond the scope of current national health technology assessment (HTA) processes (Australian Department of Health and Ageing, 2009, Haas, 2007).

There are different processes across States and across public hospitals. Victoria has implemented a state-wide approach through the Victorian Policy Advisory Committee on Technology (VPACT), established in 2004, whose role is to implement a systematic approach to the investment, introduction and use, and disinvestment in new and existing technologies. It is required to assess clinical effectiveness and cost-effectiveness. VPACT is supported by Technology/Practice Committees in metropolitan and regional health services whose remit is to assess proposals for technologies and practices new to that network, monitor their uptake, and review existing technologies and practices. In contrast, NSW has adopted a more decentralised approach, although managed under the Statewide Services Development Branch. Since 2005 Area Health Services have been required to develop policies and processes to ensure the introduction of technologies to the Area, or to facilities which have not previously used new technologies, are safe, effective and offer value for money.

The Australian Council on Health Care Standards is another agency with a mission to improve the safety and quality of health care. The Agency works through the process of accreditation whereby provider organisations are assessed against a set of standards including clinical standards. Other agencies involved in accreditation of health facilities include the Royal Australian College of General Practitioners for general practice; the Aged Care Standards and Accreditation Agency for residential aged care; and the National Pathology Accreditation Council/National Association of Testing Authorities for laboratories.

The ACQSHC has determined that its role should be the development and maintenance of standards, but that the process of accreditation should be conducted by other agencies, themselves accredited by the ACQSHC. It does not comment on which agency(ies) should develop CPGs, the standards to be used in developing CPGs, or the relationship between CPGs and standards. The recent consultative report identifies that implementation of the recommended standards will require adequate

resources; and states that the improvement of quality and safety will reduce health care costs (Australian Commission on Safety and Quality in Healthcare, 2010). However, there is no consideration of how resources and costs of implementation might be balanced against improved health outcomes and patient experience, and reduced subsequent health care costs.

What evidence is there about the effectiveness or value of these systems?

Numerous reviews of CPGs demonstrate that there has been little systematic incorporation of economic considerations in their development. Eccles and Mason (2001), after reviewing the development of UK guidelines in 2001 determined that at that time there was a strong emphasis on clinical effectiveness with little explicit consideration of economic issues or costs. Wallace et al (2002) compared CPGs with the available economic analyses for five clinical conditions and found that less than 10% of available, above average quality economic analyses had been incorporated or referenced in the relevant CPGs. Similarly, only 26% of Canadian CPGs mentioned costs or economic analysis, and only 4% defined measurable outcomes (Coyle and Graham, 2003). The New Zealand Clinical Guidelines Group commissioned a review which did not address the inclusion of economic considerations, but did find that the anticipated improvements in outcomes had not been achieved (McKinlay, et al., 2001). As there has been so little contribution of economic analysis to CPGs, it is not surprising that there is little evidence of its impact.

Within Australia, the National Institute of Clinical Studies (NICS) has published a review of over 300 CPGs produced in a five year period (Buchan, et al., 2010). This too aimed at reviewing the CPGs produced, and accepted that there is intrinsic value in having CPGs. Only 29% of these guidelines provided documentation of the evidence used in development. This NICS review did not consider whether economic considerations were part of the evidence considered in producing the guidelines.

We looked at four current NHMRC guidelines related to cancer care and examined how economic considerations were incorporated.

> *Management of Advanced Breast Cancer* published by the NHMRC in 2001 and listed as a current document. This guideline does not consider the cost-effectiveness of alternative treatment options. This gap was recognised by the authors who state that the guidelines were "endorsed without inclusion of a comparative economic analysis of the costs associated with their implementation. It is the understanding of the NHMRC that an up-to-date economic analysis will be included when the *Clinical practice guidelines*….are next

updated" (National Health and Medical Research Council, 2001b). However, to our knowledge this has not been achieved

Management of Early Breast Cancer published by the NHMRC in 2001. The guideline undertook a preliminary and non-comprehensive review of the economic evaluation literature on breast cancer treatment. The review focused only on studies which considered options for treatments that were discussed in the guidelines. The guideline reports some very general cost-effectiveness information for locoregional therapy, adjuvant therapy and follow-up care. Despite the limited evidence and narrow focus of the review on cost-effectiveness it makes some very sweeping recommendations, stating that "the treatment of women with node-positive, pre-menopausal breast cancer with systemic adjuvant chemotherapy is considered to be one of the most cost effective interventions in contemporary medical practice" (National Health and Medical Research Council, 2001c). Nevertheless, the guidelines recognise that the results of the economic studies reviewed cannot be generalised to the local setting.

Clinical Practice Guidelines for the Prevention, Diagnosis and Management of Lung Cancer published by the NHMRC in 2004. This guideline has a separate section on the economic evidence. This section sets out the relevant clinical pathway of lung cancer and considers the economic evidence under the topics of prevention, screening, assessment and treatment of non-small-cell lung cancer (including surgery, chemotherapy and radiotherapy). However, in considering the evidence, the Working Party which developed the guidelines only took account of an intervention's effectiveness, rather than its cost or cost-effectiveness (National Health and Medical Research Council, 2004).

Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer published in 2005. Similar to the lung cancer guideline it contains a separate chapter on the economic evidence. However, in this guideline there is a greater emphasis on the economic evidence throughout the document and some notion that the economic evidence was, at the very least, considered in formulating the clinical recommendations (National Health and Medical Research Council, 2005).

These four examples provide a spectrum of the way economic evaluation can be incorporated into CPGs. In both breast cancer guidelines, economic considerations were virtually non-existent. In the lung cancer guideline, the economic evidence was reported separately but not considered in formulating recommendations. In the colorectal cancer guideline the economic evidence is referred

to throughout the document and seems to have been considered in the author's recommendations. In short, there are considerable inconsistencies in the way economic evidence was incorporated, and a failure to update the evidence and the CPGs.

In 2003, NICE commissioned the European Regional Office of WHO to carry out an independent review of its CPG program (de Joncheere, et al., 2006). The Review described it as "one of the largest, most productive and best organized developers of clinical guidelines in the world (p3)." However, the terms of reference were quite limited, asking the team to comment on whether the methodology had been consistently applied, the results were reproducible, there was a clear relationship between the evidence and the recommendations, and the stakeholder consultations had been effective. Thus the evaluation was limited to aspects of process, with no assessment of effectiveness or value; that the NICE approach is valuable and effective was assumed to hold. The findings pointed to the program's strengths: NICE own staff are enthusiastic about the program and highly motivated; the arms length relationship between the National Collaborating Centres and NICE itself; and the detailed manual for CPG development. Nonetheless, the team reported that the methods are not consistently applied leading to a lack of reproducibility of results, and therefore a lack of transparency in the link between evidence and recommendations. They also concluded that while stakeholder involvement in CPG development was effective, it was less effective in implementation. The Review also determined that integration of the economics and clinical perspectives was lacking. The rigorous NICE approach meant that the process was slow and expensive. They recommended the development of different types of CPGs, and an increase in the minimum size of NCCs to 20.

Currently, there is a much stronger contribution of health economics to NICE CPG development than in CPG development in other countries, as reflected in Table 1. The NICE GDG includes members of the project group from the NCC, one of whom is a health economist. GDG Chairs are given training in health economics. The Guidelines Manual provides a good discussion of the role of the review of published economic analyses, noting that studies in other health systems may not be generalisable to the NHS, and that the economic analysis has to be designed to be relevant to NHS practice.

NICE also commissioned a review of the quality standards program, as described above. This review focussed on the process of developing CSs and did not address the effectiveness or efficiency of the Program. However, at the time the evaluation was conducted only 4 CSs had been developed so this was an early assessment and any summative evaluation would have been premature. The new

Outcomes Framework commits the Minister for Health to commissioning an independent evaluation every five years.

Another UK based review investigated the use of economic evaluations in a range of health policy decision contexts (Williams, et al., 2008). This report found that economic analysis was well integrated into HTA at the national level, but that at the local level it was exceptional. Rather local authorities made decisions based on evidence of clinical benefit and cost implications. The authors also noted the lack of capacity at the local level to generate access and interpret the relevant information. The new Outcomes Framework also requires the Commissioning Board to translate national outcomes and indicators to the local context; further, it identifies the importance of continued research and the use of research at the local level.

After reviewing the Dutch experience, Niessen et al (2007), reported that CPG development incorporating economic considerations is feasible, strengthens the evidence base, and contributes to efficient health care. They also point to the value of using the same approach to evaluating CPG dissemination strategies.

In considering whether systems of CPG development are effective, it is also possible to draw on the findings of evaluations of HTA processes in Australia. The Victorian model has been formally evaluated, and reported success in establishing policies and procedures with some problems in achieving State-wide dissemination, undertaking independent assessments, establishing priorities linked to funding. The NSW Health approach lacks a formal evaluation, but anecdotally there are substantial differences across the Areas, with some undertaking formal assessments while others simply limit consideration of safety to existing clinical governance structures. More recently, in NSW IPART reported on costs, clinical practice and outcomes in NSW hospitals with the aim of providing evidence that could be used to promote clinical best practice (The Independent Pricing and Regulatory Tribunal of NSW (IPART), 2010). The findings of this investigation are that inconsistencies in hospitals' coding of morbidity and clinical costing, problems of data accuracy, and different approaches to purchasing make it difficult to make valid inter-hospital comparisons. This will present challenges for the Independent Hospital Pricing Authority as well as the ACSQHC.

A review of HTA has also been released by the Commonwealth Government this year (Australian Department of Health and Ageing, 2009). While much of that inquiry focussed on national processes, including PBAC and MSAC, it also considered HTA at State and local levels. The Review concluded that diverse approaches risk duplication of effort, inconsistency in methods, and poor sharing of information. It suggested that this also resulted in poorer quality appraisals. Furthermore, the HTA

Review highlighted a shortage of an appropriately skilled workforce able to meet the current demands for HTA, let alone expanding the range and applications of HTA, particularly the inclusion of economic considerations in CPG development.

Eccles and Mason concluded “There has been no widely accepted successful way of incorporating economic considerations into guidelines.” (Eccles and Mason, 2001). Niessen et al, reviewing the Dutch pilot program in 2006, concluded “there is no international standard yet on how to incorporate economic considerations into practice guidelines” (Niessen, et al., 2007). Nonetheless, they do make several recommendations for achieving best practice which (along with other best practice recommendations) are summarised in Table 2. These sources are: NICE, accepting that as the best resourced and developed systematic approach, this can be taken as world best practice; the WHO recommendations; and the features of best practice HTA as identified in a previous CHERE report. Williams and Eddy (2008) have clearly described how CPGs based on evidence of effectiveness and then costed will differ from CPGs developed with considerations of cost effectiveness issues integrated into the work of the CPG and the retrieval and analysis of evidence. The retrieval and analysis of evidence on effectiveness which is formulated into recommendations then costed will allow the comparison of value for money across CPGs for the most effective treatments. But less effective but potentially more cost-effective options will be excluded from further consideration. The latter approach, that is integrating economic considerations, is consistent with the most efficient use of resources. Our recommendations (col 1) are supported by the review of the literature, but also draw on our experience with PBAC, MSAC, our own work in guideline development, and in HTA and CPG development at the local (Area Health Service) level.

Table 2: recommendations for best practice CPG and CS development

Our recommendation	*Supported by …*			
	NICE guidelines	WHO recommendations	Niessen et al 2007	Consistent with best practice HTA, Haas et al 2008
Independent and rigorous methods	x			x
Economic analysis integrated	x			x
CDG includes health economist	x	x	x	x
Chair involved	x		x	x
Policy focus	x	x		x
Economic evaluation in ICER	x	x		x
Budget and resources		x		x
Implementation issues				x
Literature review	x	x	x	x
Addresses generalisability	x	x		x
Standardised methods	x		x	x
Model transparency/ Peer review	x	x	x	x

The process should be independent and supported by adequate expertise and rigorous methods.

There is always concern that CPG/CS development will be overly influenced by vested interests, whether these be governments or funders aiming to reduce expenditure, manufacturers or suppliers attempting to increase volume and profits, or clinicians motivated by income, prestige or other factors. The influence may be subtle, and reflected in the choice of comparator, the form of analysis, and the range of costs and outcomes considered. The most effective response to these concerns is to ensure the independence of the agency given the responsibility for CPG development, that there

is an adequate capacity in the workforce with expertise to conduct evidence based reviews, and that the methods used are rigorous and best practice.

Economic considerations should be integrated

Integrating economic considerations at the beginning of the CPG/CS development will ensure a broader range of options are considered, including those which are less effective but less costly and so represent greater value for money than the ICER of the most effective treatment alone.

There should be a health economist as a member of the GDG or supporting project team.

The inclusion of the health economist early in the process ensures that the economic analysis is included in the planned analysis from the beginning. This enables the economics perspective to be brought to the framing of the clinical question, and the assessment of the evidence.

The GDG Chair should support the need for economic analysis.

The Chair plays an influential role in the development of the clinical questions, the plan for the analysis and the framing of the recommendations. If the Chair is neither convinced of the need for the economic perspective, nor familiar with the assessment of economic evidence and modelling, then the health economist member of the CPG generally will have limited impact. Some agencies provide training in health economics for Chairs and other CPG members.

The economic analysis should be driven by the policy decision; but it should include economic evaluation, budget impact, resource implications and any implementation issues.

The economic evaluation should be based on the comparison of the clinically relevant alternatives, including current clinical practice. Results should be expressed as an incremental cost-effectiveness ratio, or ICER. However, the ICER is an insufficient guide for decision making. The analysis should also include the impact on the health budget, disaggregated by the funders' perspectives. Any particular issues that would affect resource allocation should be canvassed; for example, a new technology may increase services for one group of patients while reducing them for another, unrelated group as providers change their patterns of practice. Implementation issues include needs for new training, accreditation, any minimum volume requirements, or implications for related services.

There should be a systematic review of the published economic analyses but the analysis must address the issues of generalisability to the relevant context.

The published economic evaluation studies are of much less relevance to the development of the CPGs than the published clinical studies. Not only can effectiveness differ in different patient groups, costs will vary over time, over country and over setting. Thus a treatment may be cost-effective in one setting but not in another for a number of reasons. The published literature may provide guidance in planning the economic analysis but cannot be generalised.

There should be detailed methods guidelines to ensure consistency.

Detailed explicit guidelines to constructing the economic analysis must be provided to ensure consistency over different CPGs. These should be consistent with accepted best practice, and subject to periodic review and revision.

The economic model should be clear and transparent. It should be subject to external peer review.

Increasing economic analysis is relying on sophisticated and complex modelling. To ensure clarity, the analyses should be subject to an independent peer review including re-running at least some aspects of the model.

Other aspects of guidelines and standards development

There is a need for clarity in defining CPGs and CSs. This requires not just a definition of the concept and desirable features but also a clear statement of their intended use and how they will be implemented. This is necessary to ensure they are fit for purpose. It is crucial that any links to funding mechanisms, including bonuses and penalties, are also clear. In our opinion, CPGs and CSs should represent achievable not aspirational goals. This is crucial in the development of CIs, and if there are any links to funding.

The role of the ACSQHC is being developed in an environment in which other agencies have already established similar or overlapping programs. Further the implementation of the health reforms also establishes other agencies which have a direct (eg the performance reporting authority) or indirect (eg the funding authority) effect on standards. Thus there is a need to ensure a minimum of overlap

and duplication (to ensure efficiency) and maximum consistency (to eliminate conflicting incentives) across these disparate agencies.

The development of CPGs is costly. In the UK, the process takes some 12-18 months, and this represents the best organised and best resourced approach. The New Zealand Guidelines Group similarly points to the cost of undertaking rigorous CPG development (McKinlay, et al., 2001). Thus there is a need to prioritise CPG development to ensure a rational allocation of the resources required for development. Studies of clinical practice variations can be useful in determining priorities for CPG and CS development, as can identifying high cost – high volume procedures.

The development of CPGs and CSs relies on the available evidence of safety, effectiveness and efficiency. The extent of available evidence depends on earlier investment decisions in medical and health research, which in turn are prompted by vested interests of manufacturers or subject to the vagaries of peer review competitive grant schemes. Thus groups developing CPGs and CSs can be frustrated by the lack of relevant evidence. Consideration should be given to how this process can be linked back to research investment, either through coverage with evidence approaches, or influencing priorities for research grants agencies.

Various reviews of CPG implementation have consistently reported poor implementation (Dowie, 1998, Grimshaw, et al., 2004). A number of explanations have been advanced, but there remains little evidence of how to ensure effective take-up, and even less on cost-effectiveness of implementation strategies. This NZ report also cites evidence that clinicians cannot manage more than two changes to their clinical practice each year (McKinlay, et al., 2001). Again, this underscores the need for prioritisation, as well as considering implementation strategies.

New developments in health technologies are generally considered to be the major driver of increasing health care costs (Productivity Commission, 2005). The use of an ICER yields the additional health benefit per dollar, and decisions are made around what cost per QALY gained is ‘good value’. The implication of this is that diseases/conditions where ICERs are high will be accorded a lower priority than diseases/conditions where ICERs are low. The German approach has explicitly rejected this decision rule, and focussed the comparisons within disease/condition group so that expensive to treat conditions are not disadvantaged. This is not without controversy. The challenge of determining value for money is made more complex by the fact that health technologies vary considerably in their value for money. It is not just the case that one health technology represents

better value for money than another, but also that a given health technology may be good value for money in one context but bad value in another. The Productivity Commission concluded that it is virtually impossible to conclude that a particular technology will *always* be cost effective, as much will depend on the context of who is receiving it and the cost effectiveness of available alternative treatments; and the same conclusion can be equally applied to CPGs (Productivity Commission, 2005).

This means there is a need to ensure that CPG implementation is considered within a local context, an approach that seems consistent with the focus of decision making moving to Local Health and Hospital Networks. CPGs can be used to provide an evidence base for LHNs to determine priorities. However, responsibilities for capital planning and role determination will remain with the State health authority. These decisions affect the feasibility of implementing CPGs. There is also a need to link CPGs and CSs to accreditation of facilities, and to clinical privileges of medical staff.

The translation of CPGs to the local context to support greater local autonomy and flexibility will require skills in systematic reviews and economic evaluation to be available to local area decision makers. As many Australian reviews acknowledge, this expertise is already in short supply in Australia. This further reinforces the need for an investment in an adequately skilled workforce.

It is also important to ensure that payment mechanisms and incentives support CPG implementation. LHN income earned will be largely activity driven, with the efficient price set by the IPA. There are implications in this for any change in clinical treatment patterns. Where a new CPG will reduce costs, without changing the profitability of the case classification, there is an incentive for the LHN to adopt it. Where a new CPG will improve health outcomes but also increase costs, there is an incentive to delay its adoption until the efficient price is revised to incorporate the change. However, under activity based funding there is a strong incentive to shift costs from the hospital sector to the community or primary care sector, though this may not be more efficient from the broader perspective of the health system. Any implementation of CPGs must address the inherent incentives.

The developments in electronic health records can be harnessed to the developing safety and quality strategy. E-health records can be expected to facilitate adherence to CPGs and CSs, by introducing links to evidence summaries, automatic prompts, and checklists, as well as providing an efficient

means of collecting indicator data (this review did not include reviewing the evidence on implementation strategies).

There is a need to ensure that CPGs and CSs are regularly reviewed and updated to take account of new evidence, and when linked to payment schedules to reflect changes in underlying costs.

Clinical indicators development

Clinical indicators differ from CPGs and CSs, though they should be consistent and coherent. All the issues discussed in the previous section apply to the development of CIs; however there are additional issues to be addressed due to the nature of CIs. Indicators may address structures and patient outcomes, as well as processes. CIs are required to be measures, and should be high level summaries which reflect the achievement of CSs. They should also be sensitive to changes in clinical practice. Further, the development, collection and analysis of CIs will also be a cost of the program and should be included in cost estimates. Efficiency requires that, as far as possible, they be based on readily available data.

CIs require scientific rigour. That is they should be valid and reliable measures of quality. Further they must capture what is amenable to clinical practice and under the control of the provider. This means that adequate risk adjustment is required to identify provider practice from case severity, particularly when the CIs are expressed as rates. A CI may be a sentinel event, an event that is never acceptable (eg wrong side surgery) or rarely acceptable. For almost purposes, timeliness is another important feature of CIs.

CIs must capture achievable good practice, in the context of health care delivery and relevant to the local setting in which they are employed. For example, what is an achievable standard of care in a city teaching hospital may not be achievable in a remote multipurpose facility. There is a strong requirement that CIs be fit for purpose. It is also highly desirable that CIs be consistent with CPGs and CSs developed by the ACSQHC.

CIs are intended to increase quality; that requires consideration of what action follows the monitoring of CIs. CIs may be used for performance reporting with information available to the professional colleagues and the public for accountability. CIs may be used by funding or accrediting agencies to reward or penalise poor performance. CIs may be used as flags or screens which trigger investigations, such as the Variable Life Adjusted Display (VLAD) approach developed and

implemented in Queensland (Duckett, et al., 2008). Clearly the subsequent action will also affect the requirements of the CI.

The notion of patient centredness, patient responsiveness or patient experience is growing in its significance to health system governance. COAG has included 'patient experience' in its requirements for indicators. The notion of patient experience does not fit well within a clinical indicator but it is an issue to be addressed in considering the approach to developing standards and measures of quality more broadly. Similarly, another issue to be considered is access, also nominated by COAG as an important component of quality.

What recommendations can be made from reviewing these approaches?

Table 2 provided a set of recommendations for the inclusion of economic analysis in CPG and CS development. Those recommendations were supported by the literature and our own experience in HTA. In this section we present a broader set of recommendations, addressing all the issues discussed in this report. The basis for this is the analysis presented in the report, including discussions with NSW Health and NSW Treasury.

Recommendation	*Status*	*Consequence of not adopting*
Clarity in definition and purpose of CPGs, CSs, and CIs	Essential	Not fit for purpose Impossible to implement
Outcomes should be relevant to patient experience,	Essential	Will not achieve quality goals
Perspective should be whole of health system and societal impact	Essential	Inconsistency in decision making criteria across health system Sub-optimal decision making
Co-ordination with other agencies to ensure minimum duplication and maximum consistency	Essential	Waste due to duplication and overlap Inconsistent incentives with poor outcomes
Priorities for development of CPGs, CSs, CIs	Essential	Failure in program development and implementation
Adopt best practice HTA as summarised in table 2	Essential	Lack of rigour and consistency Poor decision making
Priorities should influence on evidence development (research)	Desirable	Program is limited by lack of evidence Poor decision making in the long term

Early consideration of implementation issues	Essential	Program is not implemented
Translation to local context	Essential	Poor decision making and misallocation of resources Failure to address implementation issues, including impact on other services, accreditation and clinical privileges and training
Consistency with funding and performance management	Essential	Perverse incentives
Link to developments in electronic health records	Desirable	Lost opportunities for implementation and evaluation
Regular reviews and updates	Essential	Loss of adherence over time
CIs to be valid and rigorous, easy to collect	Essential	Not feasible to implement
Investment in capacity to undertake analyses	Essential	Poor adherence to best practice Sub-optimal decision making Lack of support for local decision making

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Electronic Resources

Country	Agency Name	URL
Australia	NHMRC	http://www.nhmrc.gov.au/publications/subjects/clinical.htm
New Zealand	New Zealand Guidelines Group	http://www.nzgg.org.nz/index.cfm?
Canada	Canadian Agency for Drugs and Technologies in Health	http://www.cadth.ca/index.php/en/home
UK	NICE	http://www.nice.org.uk/Guidance/CG/Published
Scotland	Scottish Intercollegiate Guidelines Network	http://www.sign.ac.uk/index.html
Ireland	GAIN (Guidelines and Audit Implementation Network)	http://www.gain-ni.org/Library/Guidelines/index.asp
Italy	The Agency for Regional Healthcare	http://www.agenas.it
Netherlands		http://www.g-i-n.net/newsletter/country-updates/the-netherlands-february-2010 (information on Dutch guidelines)
Germany	IQWIG (Institute for Quality and Efficiency in Health Care	http://www.iqwig.de/health-economic-evaluation.736.en.html
Sweden	Swedish Council on Health Care Technology Assessment	http://www.sbu.se/en/
US	Agency for Healthcare Research and Quality	http://www.guideline.gov/browse/by-topic.aspx
Portugal		http://www.g-i-n.net/newsletter/country-updates/portugal-and-the-iberogpc-october-2009
Finland		http://www.g-i-n.net/newsletter/country-updates/finland-september-2008
Spain		http://www.g-i-n.net/newsletter/country-updates/spain-may-2008