



Australian Government
National Health and Medical Research Council

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Clinical Ethics Capacity Building Resource Manual

Publication Details

Publication title:	Clinical Ethics Capacity Building Resource Manual
Published:	August 2015
Publisher:	National Health and Medical Research Council
NHMRC Publication reference:	E114
Online version:	www.nhmrc.gov.au/guidelines/publications/e114
ISBN Online:	978-1-925129-45-8
Suggested citation:	Clinical Ethics Capacity Building Resource Manual. National Health and Medical Research Council (2015).

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PREFACE

This manual is designed to help you plan, develop and implement a clinical ethics service in your organisation. It is intended as a resource for information on the potential forms that a clinical ethics service might take, its scope, its internal structure and place within your organisation, and the roles, operational processes and governance arrangements that it might adopt. This manual is offered by the NHMRC as a contribution to the continued development and growth of clinical ethics services across Australia.

The manual is divided into five sections:

Section One: Introduction and Background focuses on the rationale for developing and strengthening a clinical ethics service and considers issues such as:

- The importance of clinical ethics
- The status of clinical ethics services in Australia and internationally
- Alternative models for a clinical ethics service

Section Two: Building Clinical Ethics Capacity provides suggestions and resources for how to develop or strengthen clinical ethics capacity in your organisation with attention to:

- International context and Australian standards
- Clinical ethics services delivery models
- Terms of Reference, competencies and membership
- Resource requirements

Section Three: Operational Issues addresses the detail of establishing, operating and maintaining the vitality of your clinical ethics service, including advice and resources related to:

- Governance, accountability and reporting
- Evaluation
- Training
- Promoting and maintaining the profile and relevance of your service
- Standard Operating Procedures, forms and templates

Section Four: Ethics Consultation provides information on the models, processes and resources that your service might use for ethics consultation including:

- Models of case consultation and case review
- Tools for consultation and case analysis
- Documentation, confidentiality and managing expectations
- Applying ethical decision-making models

Section Five: General Resources provides links to resources on clinical ethics, health ethics and related matters drawn from Australian and international sources.

Section 1: Introduction and Background

Introduction

Healthcare is an inherently ethical activity, aimed at improving the welfare of individuals as well as protecting the health of populations. Healthcare staff are bound to act in the best interests of and respect patients, while health services must not discriminate or treat people unfairly, and must manage resources responsibly. Every decision in healthcare reflects values and principles. Much of the time the values of patients, doctors, nurses, managers and others align, so that it seems as if there are no ethical issues at stake. At other times, values conflict, leading to distress for those involved and concern about what is the right thing to do. But whether or not there is conflict, ethically sound clinical practices and organisational cultures contribute to the overall quality of health systems.¹

Clinical ethics services can support health systems by facilitating the resolution of ethical concerns, and by promoting the discussion and analysis of ethical issues arising in health care. These activities raise ethical awareness and competence across the organisation. Building ethics capacity is important for promoting a strong ethical organisational culture, which addresses 'everyday' ethical issues as well as the occasional high-profile ethical dilemma that may arise in the health care setting. An effective clinical ethics service can promote practice consistent with high standards, foster shared understanding, promote consensus, support conflict resolution in respectful ways, ensure that patients are heard and supported, and educate stakeholders to raise their ethical awareness and build competence.²

This manual is a resource for building ethics capacity in health care organisations. Clinical ethics services can be located in individual health care organisations, shared between organisations, located in a government department, or any combination of these structures. Typically, those providing clinical ethics services can be individuals, small teams, panels of experts, or committees.

Clinical ethics services are most effective when they are integrated into the systems, policies, procedures and processes of healthcare. This is ideally achieved by providing integrated support across the four key areas of:

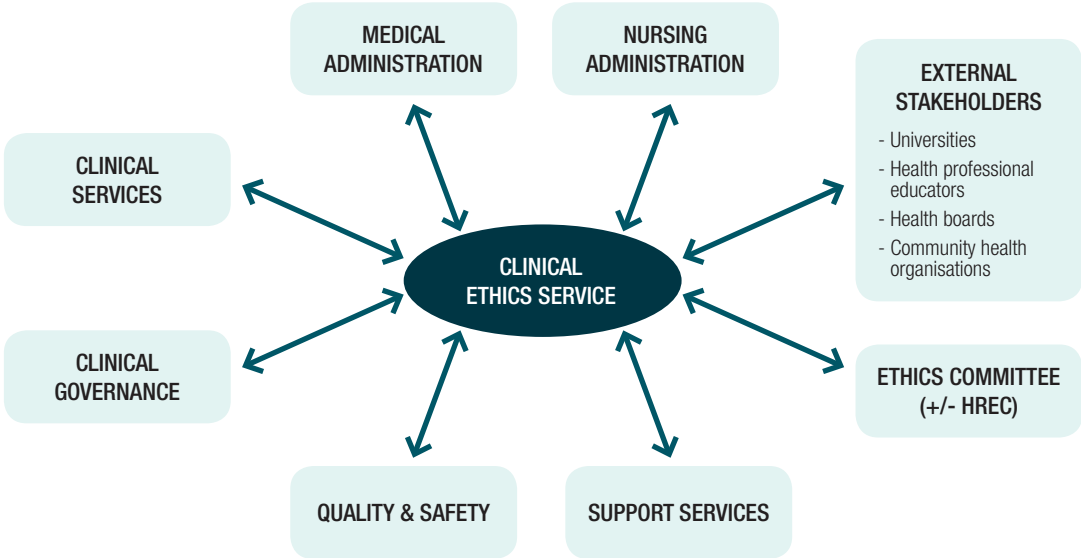
- Case consultation and/or retrospective case review
- Policy development or review
- Education
- Provision of advice regarding systems, or specific operational or administrative issues within the organisation.

Together, these promote an ethical organisational culture.

1 Doran, E., Fleming, J., Kerridge, I. & Steward, C. *Building Clinical Ethics Capacity, Final Report of the Developing Clinical Ethics Capacity in NSW Partnership project 2014*, (hereinafter cited as *VELIM NSW Report*) page 6.

2 Fox, E., Berkowitz, K., Chanko, B. & Powell, T. *Ethics Consultation: Responding to Ethics Questions in Health Care*. <http://www.ethics.va.gov/ECPrimer.pdf>, adapted from p ii.

Figure 1 shows some of the key connections that a clinical ethics service can have with other parts of the organisation and the wider community.



Background

Acting in the best interests of the patient and protecting his or her welfare by seeking to ‘do no harm’ has always been at the core of clinical practice. However, significant social and cultural changes in recent decades have changed individual, professional and community expectations with respect to what constitutes ‘harm’, how patient autonomy ought to be respected, how shared decision making can be promoted, and how communal health resources can be distributed fairly.

These changing expectations reflect a contemporary clinical environment that is technologically and ethically complex, one in which greater scrutiny and accountability is placed on patient-clinician encounters. As complexity increases and expectations rise, professional training, professional codes and organisational policies alone may not be sufficient to resolve the ethical dilemmas that arise in the care of patients.³

Interest in clinical ethics arose in the 1970s, in parallel with advances in health care that raised new ethical questions. Heart transplantation challenged traditional definitions of death. Kidney dialysis, though revolutionary, was a scarce and costly treatment. The advent of ventilators meant that the lives of ill or pre-term babies and of dying patients could be prolonged, while advances in IVF raised questions about creating life. The development of new technologies created dramatic questions of resource allocation that could be translated into attention-grabbing headlines such as “Who should live?” and “Who should die?”

The first clinical ethics committees, arising in response to these developments, were charged with making decisions in situations where conflicting values meant that no clear right or wrong decision was apparent. Sometimes, when family members challenged medical decisions through court cases, clinical ethics committees were formed to help these organisations respond. Committee members were typically selected for their particular expertise, and senior medical staff usually dominated committees. Organisations relied upon these committees to make substantive decisions regarding clinical care. While this model met the needs of the time, it was recognised that a change was needed

3 VELIM NSW report, pages 6 and 25.

away from concentrated decision making power within a small group, with limited accountability, towards a more transparent and inclusive process. For more information about the history of clinical ethics, refer to Section 5 of this manual.

Over the years, the make-up and function of clinical ethics services has evolved. Today, there are a variety of models for clinical ethics services, utilised across the world. These range from formal committees, to small 'response teams' or individual ethics consultants who can respond quickly to urgent cases. In some organisations, a combination of these approaches is used. In striking contrast to their predecessors, the individuals, teams or committees providing clinical ethics services usually act in an advisory capacity only and do not, themselves, have the authority to make clinical decisions.

In Australia there are a modest number of clinical ethics services, generally focussed on dealing with dilemmas arising out of patient care. A number of hospitals, particularly children's hospitals, have fairly long-standing clinical ethics committees or response teams and a few have individual consultants to provide ethics advice to hospital staff, patients and their families. One jurisdiction has established a state-wide clinical ethics advisory panel.⁴

However, there is now a move towards the systematic provision of clinical ethics support in Australia. This has been triggered by increasing recognition of the links between ethical considerations related to clinical care and those related to the functioning of a health care organisation or system as a whole. There is also a growing interest in ethics amongst health care professionals and the community. These changing professional and community expectations are now reflected in formal hospital accreditation processes that promote consideration of ethical issues in a more intentional and deliberate manner.⁵ In 2015, the Australian Health Ethics Committee (AHEC) released a consensus statement on clinical ethics (see Box) advocating for a national approach to the development of clinical ethics services.

This manual is part of the activities of AHEC to promote and support the development of clinical ethics services in Australia.

4 <http://www.health.nsw.gov.au/clinicaethics/Pages/clinical-ethics-advisory-panel.aspx>. This panel was established to advise the NSW Ministry of Health on clinical ethics issues of state-wide relevance, review policies that raise ethical concerns, and identify emerging clinical ethics issues relevant to the health system.

5 Equip National Guidelines. Standard 15. Criterion 2. 15.6. The Australian Council on Healthcare Standards (2012).

AHEC Consensus Statement on Clinical Ethics

The Australian Health Ethics Committee (AHEC) of NHMRC has developed this consensus statement to highlight

- the importance of clinical ethics services for the delivery of quality healthcare in Australia and
- the need to develop national resources and guidance in this area.

The provision of high quality health care is of utmost importance to Australians. State & Territory governments and the Commonwealth strongly support its provision. Health care should meet the needs of the community and be delivered in a just and equitable manner in accordance with accepted ethical principles.

Interactions between patients and health care professionals are at the heart of health care. These interactions have an essential ethical dimension that may at times be challenging. Supporting professionals and organisations to meet those challenges can help ensure that patient care is provided in an ethically appropriate manner.

The central role of clinical ethics services in promoting quality improvement in the delivery of health care is recognised by accreditation programs, some of which require health services to have explicit processes or structures in place for dealing with ethical issues arising in the clinical context. As such, the establishment and maintenance of clinical ethics capacity in hospital, community-based and other clinical settings is a core function of health services.

Currently, clinical ethics services exist in a small number of larger public and private hospitals. These services generally provide access to clinical ethics committees for case consultation (in real time or retrospectively), input into hospital policy and guideline development and/or the provision of staff training and education. However, their development, role, terms of reference and level of resourcing are highly variable.

AHEC recommends the development of nationally consistent guidelines for clinical ethics services. A national approach will help to ensure that clinical ethics services are effective, valued, sustainable and integrated into systems supporting the delivery of quality health care. Such guidance will:

- assist and encourage health care organisations in establishing and resourcing clinical ethics services that support clinical practice and quality improvement
- help institutions to meet accreditation requirements, and
- ensure the design and delivery of health care appropriate to the needs and values of the Australian community.

Section 2: Building Clinical Ethics Capacity

- International context and Australian standards
- Clinical ethics services delivery models
- Terms of Reference, competencies and membership
- Resource requirements

International Context

The increased emphasis on the provision of clinical ethics services is an international trend with support from international bodies such as the United Nations Educational, Scientific and Cultural Organisation [UNESCO]⁶ and a number of national governments.

In North America, it has long been a requirement for hospital accreditation that the organisation has a mechanism for addressing ethical issues arising from patient care. Both the Joint Commission on Accreditation of Health Care in the US, and the Canadian Council on Hospital Accreditation recommend the establishment of a multi-disciplinary ethics committee to meet this requirement.

As of 2014, clinical ethics services are also mandated (Belgium and Norway) or broadly supported (UK) and are reported to have an established or growing presence in Ireland, the Netherlands, France, Germany, Italy, Spain, Switzerland, Denmark, Sweden, Lithuania, Croatia, Bulgaria, Israel and Japan.⁷

In New Zealand, the Health Quality and Safety Commission promotes the introduction of a National Clinical Ethical Network within the framework of clinical governance over District Health Boards, public and private hospitals, and primary care facilities.⁸

Australian Standards

In Australia, the EQuIP National Guidelines have been developed by the Australian Council on Healthcare Standards to provide hospitals with high level benchmarks for service delivery. In the 2012 version of these accreditation guidelines, Standard 15 (directed at Corporate Systems and Safety) includes a criterion (Systems and Delegation Practices) which, in turn, includes guidelines for

“Ensuring governing body involvement throughout the ethical decision-making process ... (by providing) evidence of evaluation and improvement of the system to govern and document decision making with ethical implications, which includes: a nominated consultative body, a process to receive, monitor and assess issues, and a review of outcomes.”⁹

6 2005 Declaration on Bioethics and Human Rights, Article 19.

7 Macdonald, A. & Worthington, R. *The Role of Clinical Ethics in the Health Care System of New Zealand*. 2012 p. 42; NSW Report p. 29; Tan, A. *Clinical Ethics Committees in Western Europe: A Developmental Model for Asia*, Asia Pacific Biotech. Vol 15, No 05, May 2011.

8 Macdonald (2012) p. 4.

9 Equip National Guidelines. Standard 15. Criterion 2. 15.6. The Australian Council on Healthcare Standards (2012), pp16-17

The guidelines further describe the nature and centrality of ethical decision-making and common areas of application in the clinical context and recommend a “formal, nominated consultative entity where ethical decision-making can be referred.”¹⁰

Clinical Ethics Services Delivery Models

The ‘consultative body’ referred to in the EQuIP National Guidelines can take a number of different forms. A short list includes:

- a clinical ethics committee
- an advisory panel or response team
- an individual clinical ethicist.

What model best suits your organisation?

Clinical Ethics Committee

Clinical ethics committees can be ‘stand- alone’ committees, sub-committees or affiliates of a research ethics committee or clinical governance committee. They are generally composed of a mixture of clinical staff and staff with expertise in specialty areas, such as ethics, law, pastoral care, organisational management and issues relevant to patients and the community (see below under ‘Membership’).

Clinical Ethics Advisory Panel / Clinical Ethics Response Team

Advisory panels or response teams can be independent of a committee or affiliated with a parent body within the organisation, for example a full clinical ethics committee, a research ethics committee or a clinical governance committee that addresses quality and safety issues. These panels or teams can be available for emergency consultations and can draw upon additional internal or external expertise to address a specific set of issues when required. Typically only some members of the panel are involved in each individual consultation, depending on expertise and availability.

Clinical Ethics Consultant

An individual clinical ethics consultant can be fully independent, a staff person of the organisation, or an expert member of an organisational committee. The consultant can provide immediate advice to the staff involved in the matter-at-hand, to a committee and/or to organisational management. Individual consultants are often skilled in facilitation, mediation and other forms of conflict resolution.

The ‘hub and spokes’ model, pioneered by the Joint Centre for Bioethics in Toronto, Ontario (Canada) is a further approach to the provision of clinical ethics support. In this model, an individual clinical ethicist at the hub (e.g. at an academic centre, hospital or health service) engages with, supports and coordinates ‘ethics resource leaders’ throughout one or more organisations. This model provides a formal mechanism for spreading ethics expertise beyond a single service or centre.

The type of clinical ethics service and support preferred by an organisation will substantially depend on the type and function of the health service, the needs of the population that it serves and local capacity.

¹⁰ Equip National Guidelines. Standard 15. Criterion 2. 15.6. The Australian Council on Healthcare Standards (2012), pp16-17.

There are advantages and limitations of each model; however, whichever model is favoured, the service must have certain critical attributes, including that it is:

- visible
- accessible
- stable
- relevant
- supported by both the organisation and the clinical community that it serves.

It must also:

- have a clearly defined purpose
- be appropriately constituted and governed
- be integrated into other organisational activity and
- have adequate resources in order to both be sustainable and deliver a rigorous, high quality service.

With reference to Figure 1 above, you may wish to consider the relationship between a clinical ethics panel, team or committee and existing organisational committees or services, such as a research ethics committee. There may be overlap in member competencies, or membership of such groups. There may also be an opportunity to share resources or secretariat support; however, it is important to preserve the distinct and different functions of each committee or service.

Which functions do you want your service to have?

The main functions, or roles, that a clinical ethics service can perform are:

- Case consultation and/or retrospective case review
- Policy development or review
- Education
- Provision of advice regarding systems, or specific operational or administrative issues within the organisation.

Some clinical ethics services limit themselves to matters related to the delivery of clinical care, others also address organisational issues. The integration of a clinical ethics service into an organisational administrative structure enables consideration of the ethical aspects of administrative and operational issues. This approach also enables organisations to address the ethical aspects of systemic issues in healthcare.

Whichever functions it serves, a fundamental goal of a clinical ethics service is to foster an ethical organisational culture. To do this, a service must be committed to being:

- deliberative (seeking and being respectful of diverse perspectives)
- collaborative
- accessible and integrated
- transparent
- proactive
- oriented to and by organisational values
- effective and accountable according to measurable outcomes.

An effective clinical ethics service must also follow defined processes and, if it is a panel, team or committee, all of its members should be committed to these values, aware of the committee's remit and willing to make a constructive contribution to the effective functioning of the committee.

Thus, it is important to consider the character of the membership, the resources available and the level of support within the organisation to determine what scope of activity the service can reasonably provide and be held accountable for.

Finally, in considering which role or roles a clinical ethics service will play within your organisation, it is important to consider how the level of resourcing matches the level of service you plan to provide. Taking on all of the possible functions without adequate support, resourcing and staff may result in a poorly performing service.

Suggested steps for setting up a clinical ethics service

1. Prompt a dialogue in your organisation regarding how ethical issues are considered and resolved currently. Encourage discussion of, or formally debate, the strengths and weakness of each clinical ethics service model. Based on the discussions, formulate a proposal to your organisational executive or local health district to establish (or modify or expand) a clinical ethics service in your organisation.
2. Gather key staff who will be involved in the design or remodelling of your clinical ethics service and create a mission statement for your service. Ask them to consider which values and attributes they want for the service using some of the ideas presented in this section.
3. Identify what the service needs are (e.g. resources, support, staff time) and who will play which roles/s.
4. Identify one or more 'champions' who will promote the development of the service within your organisation.
5. Identify one or more senior executives within your organisation whose support is critical to the success of your new or re-modelled service. Plan your approach to this individual / these individuals:
 - What is your message?
 - How will you communicate this message?
 - Who will communicate this message?
 - What outcome are you seeking?
 - How will you follow up?

Terms of Reference

The development of any formal team, panel or committee requires the drafting of Terms of Reference. Terms of Reference generally include some or all of the following components:

- Purpose and scope
- Responsibilities and functions
- Membership, including terms and conditions of appointment and Chairmanship

- Induction and training
- Meeting frequency, quorum and proxy rules
- Documentation of activity (i.e. Agendas and Minutes)
- Statement on indemnification and compensation for members, if any
- Statement on access to information and confidentiality
- Accountability and reporting
- Evaluation.

Examples of clinical ethics committee Terms of Reference from within and outside of Australia are provided in section 5.

If your service takes on a case consultation role, it may choose to define certain terms in the Terms of Reference that can be ambiguous, such as ‘deliberation’, as in the example below.

Effective deliberation is characterised by:

- an openness to different perspective and values
- respect for the reasons and reasoning provided by stakeholders
- a willingness to be moved by the reasons and arguments presented by others
- preparedness to test the accuracy of assumptions and claims
- recognition of the need to attend to, and listen for perspectives that may be less vocal or marginalised in the deliberative process
- accountability for the advice provided, which may be through articulation of the reasons informing the advice, or through transparent recording of the considerations that were drawn on in coming to a determination.

Competencies

Two major models have been developed to identify the competencies for clinical ethics services in the UK¹¹ and the USA¹², respectively. A synthesis of the core competencies put forward in these models is in the table below. These are competencies that the committee or group should have collectively. It is not envisaged that all members will individually have all competencies.

KNOWLEDGE CORE COMPETENCIES

Knowledge of basic concepts and analytical strategies relevant to clinical ethics (including a requirement for advanced knowledge of ethical theory and moral reasoning by at least one committee or consultation group member)

Knowledge of relevant professional codes, standards, guidelines and policies (local, national and international)

Knowledge of relevant legal and regulatory matters

Knowledge of relevant clinical practice and processes related to clinical decision making

Knowledge of the role of clinical ethics services in the management of clinical situations

11 V Larcher et al on behalf of the UK Clinical Ethics Network. *Core competencies for clinical ethics committees* 2007, 2010).

12 *Core Competencies for Health Care Ethics Consultation, 2nd Edition* (ASBH 2011).

KNOWLEDGE CORE COMPETENCIES

Knowledge of the local community, including patients, families and organisational staff

Knowledge of health care services and systems as they relate to the work of the clinical ethics service

SKILL CORE COMPETENCIES

Ability to apply the relevant knowledge (per above) to clinical and organisational issues

Ability to identify and analyse the ethical dimensions of issues considered by the clinical ethics service

Ability to facilitate effective deliberation (including eliciting the views and values of those involved)

Ability to practice and promote active listening and respectful communication

Ability to synthesise relevant considerations and formulate a range of potential responses

Ability to appropriately document and communicate the deliberations and decisions of the clinical ethics service

Ability to locate and critically use relevant academic literature

In reflecting upon these core competencies it is important to emphasise that:

- One of the strengths of a committee or group as a model of clinical ethics support is the complementary experience and expertise of individual members within the group.
- Core competencies necessary to provide clinical ethics support are founded on skills and knowledge. Different levels of skill and knowledge will be required for the undertaking of specific functions.
- Ideally, all members of a clinical ethics committee or group will have basic levels of skill and knowledge and some members will have advanced levels of knowledge and skills necessary for specific functions, e.g. leading a case consultation.
- Individuals providing case consultation services separately from the committee or group should possess all of the core skills, knowledge and personal characteristics. They require advanced skills and knowledge in some areas.
- If teams provide consultation, the full range of core competencies should be available within the team, although not all individuals will possess them initially. All members of case consultation teams should acquire at least basic competencies.
- Personal characteristics that promote and reinforce the skills and knowledge-based competencies are also necessary. Examples of such characteristics include integrity, compassion and prudence.

With respect to how these competencies might be acquired, if not already present, some options include attending ethics conferences, short courses and training modules, self-directed learning, designated topic-driven 'study days' and pursuit of full academic degrees.

Membership Considerations

Potential members of a clinical ethics committee or group may not necessarily have extensive expertise and knowledge in health ethics. In the recruitment stage, you may want to consider the following strategies.

Suggestions for finding clinical ethics service members

1. Scan your site, program or region for potential members who have experience or interest in ethics in healthcare.
2. Seek expressions of interest from all staff (and members of consumer groups and/or the community, if you plan to include them).
3. Ask heads of departments or clinical areas to nominate appropriate individuals.
4. As the committee's role and focus are determined, encourage or even require that members participate in initial and/or continuing ethics education relevant to the focus and purpose of the committee.

It is important that members be both competent and credible in their roles as ethics educators or consultants, and preparation for such roles is critical.

Members should commit to a minimum of a two year term of membership to allow for the learning curve and to promote continuity. A model of rotating membership expiration and renewal (i.e. with $\frac{1}{3}$ to $\frac{1}{2}$ of the committee reaching the end of their terms each year) is a favoured approach for the same reasons.

Membership composition will depend to a great extent on the nature of the organisation it serves; however there are broad guidelines that are used by many committees and advisory boards.

Members should be appointed for their expertise, skills and personal attributes and not to represent specific interest groups (e.g., stakeholder groups, professions, departments, etc.) per se, although, in practice, committees often end up being largely representative. It is also important that the membership includes a variety of professional groups and perspectives from within and beyond the organisation.

Membership of a clinical ethics committee may include:

- Senior organisational leadership – as full members or ex officio
- Physicians – especially those with ICU, Mental Health or Palliative Care experience
- Nurses – including general and ward nurses, nurse managers and nurse educators
- Psychologists, Behavioural Scientists
- Allied Health professionals – e.g., social workers, occupational therapists, physiotherapists, pharmacists, radiotherapists, speech language pathologists, counsellors, family therapists.
- Supportive Services personnel – e.g., Food services, Health Care Aides, Diagnostic imaging personnel
- Ethics specialists – i.e. those who have formal training in bioethics, who may also be physicians, nurses, allied health professionals, lawyers or pastoral carers
- Pastoral care specialists – including clergy and lay members of religious or spiritual groups that provide pastoral care services

- Individuals familiar with health law, regulations, codes, standards and guidelines
- Community members – including individuals who reflect the character of the populations being served, with specific attention to Aboriginal and Torres Strait Islander peoples, where appropriate¹³
- Others with relevant expertise or skills, such as (senior) Clinical Governance or Quality officers, Patient Safety representatives, etc.

In addition to bringing the relevant knowledge and skills, the criteria for membership should explicitly include reference to ‘attitudinal’ attributes and personal characteristics. Clinical ethics committees or advisory boards benefit from individuals who show high degrees of personal integrity and self-awareness, in addition to open-mindedness, respect for dialogue and process, experience in working in a multi-disciplinary environment, an interest in the field of bioethics and in continuing personal education. Diversity – of age, gender, ethnicity and values perspectives – is also an important characteristic of successful clinical ethics committees.

The Chair of the committee, advisory board or response team should be selected based on capacity to run a meeting fairly and efficiently, providing each member with an opportunity to contribute, but respecting the time constraints of busy professionals. The role of Chair is a facilitative one and not to be used as a platform to influence others. Whilst the Chair should be highly effective and respected within the organisation, it is not critical or even necessary for the Chair to be a clinician.

Your organisation should strongly consider a formal or informal mentoring program for new members to the committee. Further information regarding training and education of members is discussed in the next section.

Finally, members should be provided with letters of appointment/re-appointment that align with the Terms of Reference and include minimum attendance requirements, agreement to conduct committee/group business in accordance with shared values, etc.

Resource Requirements

It is critical to do an objective assessment of what resources will be available to your new or established clinical ethics service as you plan for it to become operational. Clinical ethics services are likely to be more successful where they are adequately resourced. If you are under-resourced, you may be unable to implement many of the creative, or even rudimentary, components of any service plan. You may also then need to consider an advocacy campaign to secure the resources that you require.

Resources that you should consider include:

- A funded position for a person with expertise in ethics
- Administrative support, including allocated time for coordination and direction of service activities and a secretary/secretariat
- Meeting space and equipment
- Budget for
 - training and education
 - recruitment of (new) members
 - sitting fees for members (optional)
 - travel expenses
 - a hard copy or electronic resource collection/library
 - ethics association membership/s (optional).

¹³ This consideration applies whether or not members of these populations are represented on any committee in a professional capacity.

Section 3: Operational Issues

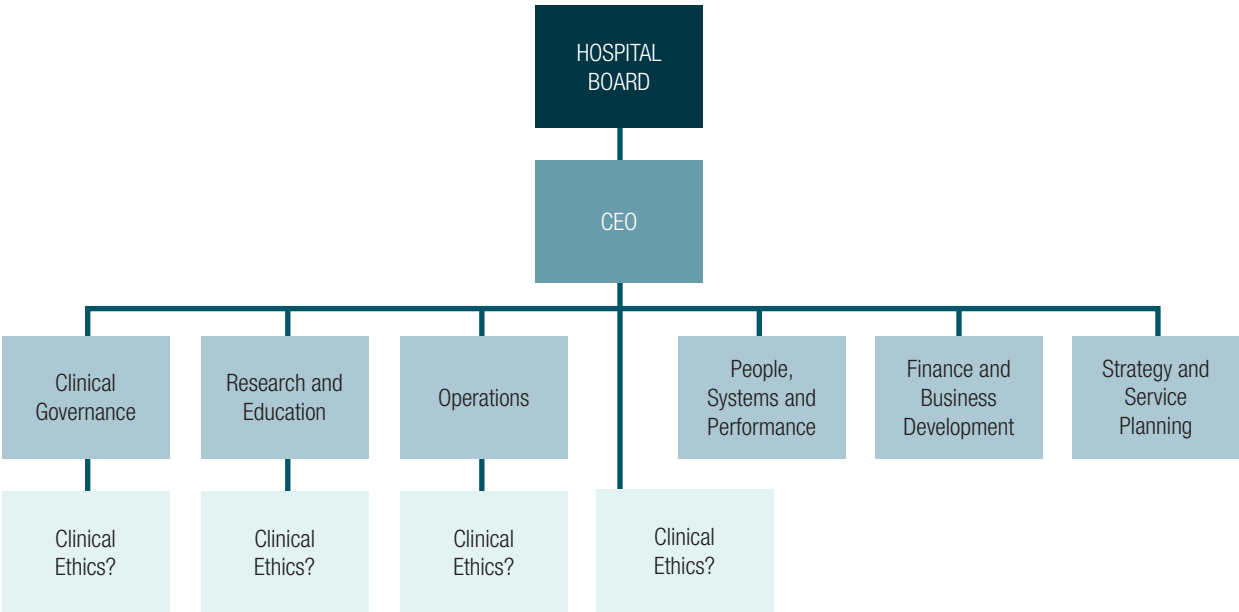
Governance, accountability and reporting

The governance and organisational ‘placement’ of a clinical ethics service is fundamental to its success. It must be sufficiently independent that it can provide impartial assessment and advice with respect to the organisation and its staff, speak for those who lack power, and be trusted and respected for the contribution that it makes to health care. It must be sufficiently embedded within the organisation so that its role and function clearly relates to existing structures, policies, processes and organisational goals and its advice and recommendations have traction.

Thus, in considering placement, it will be important to consider how the service is linked to other components of the organisation in the overall organisational structure.

The diagram below suggests potential options for placement of a clinical ethics service within an organisation.¹⁴

Example of Organisational Structure



To ensure optimal governance, the following should be clear:

- Scope and remit of the clinical ethics service
 - What sorts of matters does the service deal with?
 - To whom can the service provide advice?

¹⁴ It is important to reiterate that one model for a clinical ethics service is a ‘hub and spokes’ model, in which the options for placement may be meaningfully different and may be focused on placement within a health service district or collaborating organisations, rather than within a single health care organisation.

- Relationships between the service and other services and oversight bodies within the organisation
 - Does the clinical ethics service provide any reports (specific or general) to any other bodies in the hospital (e.g. Quality and Safety Committee)?
 - Should other committees or bodies be represented on a clinical ethics committee or vice versa? Which committees or bodies might this apply to?
- Expectations for accountability
 - To whom the clinical ethics service is accountable for delivering what it has undertaken to deliver?
 - Does the organisation expect Key Performance Indicators (KPIs) to be met? If yes, who determines which KPIs are relevant?
 - How will documentation be managed with respect to
 - General service activities (e.g. meeting papers, policy advice and review, systemic issues review, education activities)
 - Case Consultation (i.e. current cases and retrospective review)
 - Where are notes stored?
 - Who has access to the notes?
 - Is information stored in identified or unidentified form?
- How referrals are managed
 - Who can refer (i.e. any staff member; only medical staff; non-clinical staff; patients or families)?
 - What processes occur once a referral is received?
 - What is a realistic timeframe for responding to a referral?

As a component of accountability, particularly if your service will be a full committee and will be focusing on functions other than case consultation, a Work Plan is an effective way to document and direct the activities of a clinical ethics committee. A Work Plan should begin by describing your committee's specific goals, strategies and performance measures. It can also outline what the committee plans to achieve and by when and how it will measure what has been achieved.

Evaluation of your service

Any robust service needs to incorporate a defined process for evaluation of how it is used and its effectiveness. A good first step is to clarify with organisational leaders

- what they want the service to achieve and
- how they will gauge the success of the service.

It will also be important to start off with simple evaluation objectives in recognition of the difficulties of collecting relevant data and conducting evaluation activities. One approach is to limit evaluation to an annual survey, rather than seeking evaluation from each activity.

Other possible approaches include:

- Collating feedback from case consultation
 - Demonstrating the use of the feedback to improve the service
- Collating feedback from education sessions
 - Demonstrating the use of the feedback to improve the service

- Seeking feedback from other committees that have clinical ethics capacity (see box below).
 - Demonstrating the use of the feedback to improve the service
- Using external markers such as Best Practice Australia (BPA) Culture Surveys to track changes in organisational culture more broadly
- Engaging in research using 'before and after' measures to monitor ethics education and support. (Examples could include Ethical Climate Surveys^{15,16}, or Values clarification work¹⁷).
- Keeping records of all activities.

Training your members

Identifying and providing opportunities for training for committee members and opportunities for others who may one day choose to join the service is critical for a clinical ethics service. Training in clinical ethics comes in various forms, including:

- short courses and on-line courses offered by universities, hospitals or professional bodies
- having an ethicist provide tailored in-house training
- attending clinical ethics and bioethics conferences
- placements in other well-established clinical ethics services
- structured reading groups, such as journal clubs and
- formal or informal mentoring programs.

Promoting and maintaining the profile and relevance of your service

Strategies for training can also be used to promote and maintain the profile and relevance of your service. Training and promotion are closely linked, as it is important that members be both competent and credible in their roles as ethics educators or consultants. This requires both preparation and publicity.

Suggestions for ways to promote and maintain the profile of the service include:

- Participating in organisational structures, committees or activities (see box below)
- Creating links with existing systems and structures within the organisation that are responsible for education and training
- Collaborating in research with clinicians
- Offering sabbatical and student placements to organisational staff and affiliated personnel
- Liaising with external organisations with relevant experts, such as local universities
- Becoming a member of professional organisations (such as ethics associations)
- Placing "Who are we?" brochures in key departments and other locations
- Publishing and posting monthly newsletters and event flyers.

15 Victor, B. & Cullen, J.B. (1987). A theory and measure of ethical climate in organizations. In W.C. Frederick (Ed.), *Research in corporate social performance and policy* (pp. 51-71). Greenwich, CT: JAI Press.

16 Olson L. Ethical climate in health care organizations. *Int Nurs Rev* 1995; 42(3): 85–90.

17 Values in Action. <http://www.viacharacter.org>

Suggestions for other organisational structures, committees or activities that you/your service might link with

- Orientation for new staff (provision of information about clinical ethics support)
- Clinical department meetings
- Morbidity and mortality meetings
- Ward rounds
- Grand rounds
- Clinical governance
- Quality and safety
- Complaints processes
- New technology/innovations committee
- High cost drugs committee
- Education committees

You should consider whether participation in these committees or activities will be 'one-off' or ongoing in character and what the potential is for any cross-membership or collaborating on shared goals.

Standard Operating Procedures, forms and templates

Consideration should be given to the development of Standard Operating Procedures (SOPs) for a number of elements of a clinical ethics service. SOPs can be useful for addressing

- Meeting process (how meetings are scheduled, required attendance, structure, duration)
- How items reach the agenda, including management of referrals
- Distribution of papers
- How case consultation and/or retrospective review are conducted and documented
- How decisions are reached
- To whom the meeting deliberations and/or outcomes are communicated
 - For case consultations, whether and how documentation will be included in the patient's medical record
 - How access to the clinical ethics record will be managed.
- Whether and how follow-up will occur
- How complaints relating to the service are managed within the broader complaints process of the organisation.

Forms and templates can be valuable to ensure an appropriate standard of documentation for agendas, meeting notes, letters to referring clinicians and providing advice to other organisational staff.

Section 4: Ethics Consultation

- Models of case consultation and case review
- Tools for consultation and case analysis
- Documentation, confidentiality and managing expectations
- Applying ethical decision-making models

Models of case consultation and case review

The main purpose of offering clinical ethics consultation is to provide advice that helps patients, staff and others resolve ethical concerns in the healthcare setting. This work aims to improve the quality of health care through the identification, analysis, and resolution of ethical questions or concerns. Understanding the uncertainty or values conflict that may underlie any consultation is critical to facilitating resolution of such conflicts in a respectful atmosphere with attention to the interests, rights and responsibilities of all those involved.

Ethics consultation requires some degree of expertise in ethics – a requirement generally addressed via the membership of the consultation body or the qualifications of an individual consultant. However, whilst ethics expertise is a necessary requirement, it is not the only expertise required of a committee or consultant. Expertise in communication, mediation and conflict resolution may also be necessary. This is because, despite first impressions, the questions an ethics service may be consulted on may not be primarily ethical questions but, instead, administrative or professional questions. The range of knowledge and skills required is outlined in Section 2 of this document.

Nevertheless, for a consultation to be an ‘ethics consultation’ there must be distinctive elements of the deliberations, such as the exploration of values, the examination of arguments, the identification of assumptions or false premises, and, through a deliberative and inclusive process, an attempt to identify the most ethically appropriate action or response to the situation.

There are a series of key questions and considerations that follow a decision to include case consultation within the scope of your clinical ethics service (see box below).

Matters to consider before offering case consultations

- Who will conduct the consultation – a full committee, a sub-group, a panel, a team or an individual ethicist?
- What is the capacity of the consultant/consultation group to respond?
- Timeliness factors – how immediate can the response be to the presenting situation?
- Do other organisational processes exist that can serve as a limiting factor on or boundary for the ‘reach’ of the consultation (for example, will regulatory issues, human resource issues or conflicts of interest be considered in addition to clinical and patient-centred issues?)
- Will the treating team be part of the consultation?
- Will the family and/or the patient be involved? Depending on whether the answer is ‘yes’ or ‘no’, how can they be included, informed and supported?
- How will you handle a referral from a patient or a patient’s family (and will this differ from the management of referrals from a clinician or the organisation’s governance or management team)?
- Who will receive feedback from the consultation and how will this feedback be given and documented?
- What will the mechanism be for handling complaints?

In doing consultation as a ‘clinical ethics service’ the goal is to provide sound ethical advice where the parties involved can feel confident that all of the relevant issues and perspectives have been considered. This is the case whether the service is being performed at the request of a treating clinician, hospital management or the patient and their family.

This is achieved by a fair, impartial and comprehensive exploration of the facts and issues involved and consideration of the range of possible responses that exist. This open exploration is then qualified by weighing the strengths and weaknesses of each option and identifying which are the most ethically appropriate. It may be possible to use a variety of strategies to achieve this objective, such as a structured analysis, canvassing members’ perspectives both at the beginning and the end of the deliberative process, and working toward and testing, in an iterative fashion, the consensus, if any, that is arising during discussion.

Tools for consultation and case analysis

A number of formal ethics consultation tools have been developed and are used in Australia and overseas by professional groups or individual health care organisations and these tools vary considerably in structure. Linear approaches focus first on issues, facts, principles and conflicts between them, then on considerations of law and policy in order to lead to a defensible decision. In contrast, narrative-based approaches involve multiple re-tellings of the story to trigger reflection upon, first, one’s own attitudes, values and beliefs, then on others’ perspectives within the wider context of social and professional norms.

Each of these approaches has strengths and weaknesses. However, all are grounded in a common project: to enable those conducting ethics consultation to be aware of their own values and biases, to increase awareness of the impact of others’ values and biases in the ethical arguments that they make, to widen the sources of moral input considered, to learn from shared experiences and to increase competence in ethical decision making.

Processes or frameworks that may be used to structure the deliberative component of ethics consultation include, amongst many others:

- The Four Principles framework – Respect for autonomy / Beneficence / Non-maleficence / Justice¹⁸
- The principle-based framework¹⁹ - a systematic consideration of problems, feelings, facts, options, values and evaluation of consequences
- The IDEA Ethical Decision-making Framework²⁰ - Identify facts / Determine principles / Explore options / Act
- The Four Quadrant Approach²¹ - (medical) Indications / (patient) Preferences / Quality of life / Context
- CARE²² - Core beliefs / Actions / Reasoned opinions / Experience
- CASES²³ - Clarify / Assemble / Synthesise / Explain / Support
- A Model for Problem Solving in Clinical Ethics²⁴
- Interpersonal Ethics²⁵
- Practical Ethics for General Practice²⁶.

Some of these approaches are oriented toward structured ethics theory and principles. Others are oriented toward familiar models of evidence-based clinical decision-making or business options analysis. Others still are oriented toward an ‘interpersonal’ model which recognises the patient, family, clinical team and ethics consultants as moral agents with perspectives, assumptions and values that must be first, understood and, if possible, harmonised in the interest of finding a ‘mutually acceptable way forward’²⁷. An example of how to apply one of these models is included at the end of this section.

Documentation, confidentiality and managing expectations

Documentation of ethics case consultations presents considerations that may differ from clinical processes. Issues to consider are confidentiality, storage and access to or review of the record of the deliberation. Storage presents a special challenge, as inclusion in the patient’s chart or in the notes of the referring clinician may create confidentiality issues, depending on the nature of the issues presented. On the other hand, limiting storage to the clinical ethics service records may interfere with appropriate management of the patient and be contrary to standard governance processes. It is critical that there be transparency and consistency with respect to how the outcomes of the consultation are communicated and to whom.

18 Beauchamp, Tom L., and Childress, James F. *Principles of Biomedical Ethics*. New York: Oxford University Press 2001. & http://www.ukcen.net/index.php/ethical_issues/ethical_frameworks/the_four_principles_of_biomedical_ethics

19 <http://www.ccethics.com/framework.pdf>

20 http://www.trilliumhealthcentre.org/about/documents/TrilliumIDEA_EthicalDecisionMakingFramework.pdf

21 Jonsen AR, Siegler M, Winslade WJ. *Clinical ethics: a practical approach to ethical decisions in clinical medicine*. 6th ed. New York: McGrawHill; 2006. & http://www.turner-white.com/memberfile.php?PubCode=smp_dec08_ethical.pdf

22 Schneider GW & Snell, L. *CARE: an approach for teaching ethics in medicine*. *Social Science and Medicine*. 2000; 51:1563-7

23 <http://www.ethics.va.gov/integratedethics/ecc.asp> and http://www.ethics.va.gov/EC_Btb.asp

24 Kerridge, I., Lowe, M., Stewart, C. *Ethics & Law for the Health Professions*. (4th Edition), Sydney, The Federation Press 2013. pp140-5

25 Marian Verkerk, Hilde Lindemann et al. *Enhancing Reflection: An Interpersonal Exercise in Ethics Education*. The Hastings Center Report. Vol. 34, No. 6 (Nov. - Dec., 2004), pp. 31-38; Milligan and Winch (2015) forthcoming.

26 Rogers, Wendy and Braunack-Mayer, Annette. *Ethical reasoning and general practice*. Chapter 2 in *Practical Ethics for General Practice*, 2nd edition. Oxford University Press 2009.

27 Rogers, W (2009)

Managing the expectations of those who will rely on the outcomes of case consultations is imperative. This can be achieved by ensuring that the scope and remit of the service are clear and published well before any consultation occurs and that they are also communicated effectively to users of the service prior to each consultation. Users of the service should be aware of how to obtain access to the service, the processes that will be used, the advisory nature of any decisions or recommendations and the parameters of confidentiality that will be observed.

Finally, organisations that perform clinical ethics case consultations should ensure that all of the necessary structures, processes and resources are in place prior to beginning consultation activities.

Retrospective case review can be an important function of a clinical ethics service. A common model is for case consultations to be conducted by a sub-committee, panel or team made up of members of a full committee, while the full committee restricts itself to a later review of the case consultation process and outcome.

In conducting retrospective case review, it is imperative to clarify the purpose of the review; that is, whether the purpose is committee education, education of organisational staff, quality assurance, audit or a de-brief to facilitate either learnings for future consultations or exploration of conflicts or dilemmas or other concerns that arose during the process.

However, whatever the objective of a retrospective case review, documentation and communication of outcomes that attach to case consultations require consideration and clarity.

Applying Ethical Decision-making Models

The following example from Milligan & Winch²⁸ demonstrates the application of a framework for considering a clinical situation and developing advice in response to a request for consultation. You may prefer to explore and use one of the other models listed above.

Case

Mrs A is 49 years old. She is a single mother of 3 teenage children who has been recently diagnosed with metastases of breast cancer which was diagnosed two years earlier. During a recent consultation with the oncology team, she expressed her frustration and mistrust of conventional medicine and advised staff of her intention to cease all conventional medical treatment to begin a homeopathic treatment that she read about on the internet. The treating team have grave reservations about her proposed change in treatment and feel conventional medical care will deliver the best chance of survival. They believe that she may be depressed, which could affect her capacity to make such an important judgment. Questions about whether she may have brain metastases that might impair her capacity have also been raised. Mrs A is adamant that she intends to cease all conventional treatment.

The treating team are distressed and have requested advice from the Clinical Ethics Committee on how to resolve this situation and provide the best care for Mrs A.

The steps in this model of case consultation²⁹ are:

1. Identify the ethical problem
2. Get the facts and identify what further information is required

28 Milligan, E. & Winch, S. (2015). 'Practical ethics in clinical care'. In Fitzgerald, J., & Byrne, G (Eds.), *Psychosocial dimensions in medicine*. Melbourne: IP Communications.

29 The application of the model to the case was developed by Dr Sarah Winch.

3. Review the existing literature
4. Consider the relevant ethical principles, concepts and values
5. Identify ethical conflicts
6. Consider the law
7. Consider organisational policy
8. Come to a conclusion and document it
9. Reflection and Feedback: Are there any individual, organisational, systemic, educational or policy issues to follow up as a result?

Using this model, a methodical and comprehensive analysis can be achieved, as follows.

1. Identify the ethical problem.

Ethical problems may be considered as those arising from an imbalance or misuse of power, or from a clash of underlying values. Ethical issues can present as concern, uncertainty, disagreement or ambiguity. In this case the following points should be considered:

- Mrs A's decision to cease conventional medical treatment is in conflict with the preferred action of the treating team.
- She may die sooner as a result of her decision; hence, she may be harmed.
- The aim of the treating team is to extend her life.
- She is in a very vulnerable position. She may feel desperate about her future. The power imbalance in this context may also be contributing to her feelings of helplessness or lack of control.
- The ethical questions are:
 - Can health care staff override her autonomy and impose treatment?
 - Is the questioning of her capacity a potential misuse of power (paternalistic)? Or an attempt to advocate for her best medical interests (beneficence)?
 - How can the team respect her choice (autonomy), while believing this is not in her best long term medical interests (beneficence)?
 - How is 'beneficence' defined by the patient?

It may be helpful to pose the ethical question in this way

- Given 'the patient's decision to refuse conventional treatment that may result in a poor clinical outcome', is it ethically justifiable to 'impose treatment'?

Note: You can use this format in other cases:

- Given '_____', is it ethically justifiable to '_____'?³⁰

2. What facts are available?

- Mrs A has a life-limiting, progressive illness.
- She has expressed frustration with her treatment.
- She believes alternative therapy may extend her life
- She does not consent to further medical treatment.

³⁰ <http://www.ethics.va.gov/ECPrimer.pdf>, page 31.

- She appears to have capacity; however, her capacity is being questioned due to possible depression or potential for metastatic brain tumours.
- The treating team disagrees with her decision to try the alternative therapy of homeopathy.
- Current clinical, evidence-based research does not support the efficacy of homeopathic remedies in the treatment of cancer.

What further information is required?

- Is Mrs A competent to make these decisions?
 - She does have breast cancer, which not uncommonly metastasises to the brain, but does she actually have any secondary breast cancer brain deposits? Is further clinical information needed?
- Is Mrs A depressed? If she is, might depression interfere with her capacity to make this type of decision?
 - Even if Mrs A has clinically significant depression, this does not necessarily impair her capacity to make these types of decisions. Is further clinical assessment warranted? How might Mrs A regard any request to further assess her capacity?
- What are the beliefs and values of the patient? What are the beliefs and values of individuals in the treating team? Is there a fundamental values clash?
- What is the source of Mrs A's mistrust of conventional medicine? Could exploring this with her clarify her assumptions, and help the team understand and alleviate her fears?

3. Review the existing literature.

A quick review of the ethics and law literature confirms that, if Mrs A is competent, she has the right to refuse this treatment, and her autonomy must be respected. Doing so is ethically and legally defensible in Australia. What may be of interest is a recent study by Joseph et al. (2012) that found that women with breast cancer who refused conventional medically-based treatment had significantly worse survival time than those who accepted these treatments. This was based on a chart audit of 185 patients. This is the largest study that has been done in this area to date, and the findings may be worth sharing with Mrs A to assist her in making an informed decision. If she continues to refuse treatment, her wishes must be respected.

4. Consider the ethical principles

- Respect for the patient's autonomy requires that they be invited to participate in shared decision making with clinical staff. This means that every effort should be made to determine whether Mrs A is capable of engaging in decisions about her care. The law makes the fundamental presumption that all adults have capacity unless proven otherwise.
- Acting with 'beneficence' means seeking to do good for the patient. What 'good' means to the patient can only be known by communicating with the patient. Why is she frustrated? Are there any misunderstandings driving her opinions and expectations of the change in treatment? Does the research study referenced above alter her opinion?
- 'Non- maleficence', or not causing harming, can also only be determined by taking into account what the patient subjectively perceives as harmful. Would embarking on aggressive chemotherapy inflict significant suffering on a person who has already endured significant treatments? What is the likelihood of success? Are these probabilities acceptable to Mrs A? Does she understand all the risks and benefits of and alternatives for her care? Is it harmful to coerce (or provide information which, at worse, may frighten, or, at best, may guide) Mrs A towards the medically preferred treatment pathway?

- Consideration of justice commonly refers to issues of resource allocation and the costs associated with patient care. In a case like this, where the patient may be at the end of life, the difference in lifespan as a consequence of this intervention would not be expected to represent a significant cost of care. In our health care system, considerations of cost are not usually the primary driving factor in determining what treatments are made available to patients. While cost is not an immediate issue in this case, the judicious use of resources and the opportunity cost to others when finite resources are not used carefully makes cost an ethical issue that is a relevant consideration.

5. Identify ethical conflicts

There are a number of ethical conflicts between the patient and the treating clinician regarding the desirability of and appropriateness of imposing conventional care. In this case, the conflict could be represented as that between respecting the autonomy of the patient and the treating team's desire to do good for the patient by offering conventional treatment with a chance of extending her lifespan.

6. Consider the law

- The first legal question that must be clarified is whether the patient has capacity. If she does, her wishes must be respected. Adults are assumed to have capacity until proven otherwise. On their face, there is nothing in Mrs A's comments or actions that suggest that she lacks capacity. As a legal matter, her decision to reject conventional treatment must be respected.
- If further examination indicates that she doesn't have capacity, a substitute decision maker must be identified – who this is will vary depending on state legislation. Mrs A may have an advance health directive or living will, but this will only be considered if she lacks capacity.
- The treating team have a legal duty of care to inform Mrs A of the potential consequences of her change in treatment.

7. Consider organisational policies.

In this instance, there are no specific organisational policies or procedures to guide staff where a competent patient declines treatment against the recommendations of the treating team.

8. Come to a conclusion and document it.

In this case, the conclusion would appear to be that:

- the team has a duty of care to Mrs A to inform her of the risks and benefits of recommended available treatment and alternatives to available treatment.
- given that Mrs A has capacity, her autonomous decision should be respected.

Document the conclusion and conversations with Mrs A, including that she may revisit her decision or seek further advice at a later date.

9. Reflection and Feedback- Are there any individual, systemic, educational or policy issues to follow up as a result?

In this case, there are no specific policy implications. However, the referral of such a case may highlight a need to provide education within the organisation to build understanding among staff of capacity and refusal of treatment. This can be organised within the referring team and/or for all staff in a more general ethics education forum.

On an individual level, some staff may experience moral distress as their values have been challenged and their treatment goals for the patient have not been met. Staff may require further support to understand and manage their emotional reactions to challenging cases.

This final step is critical as it allows the organisation to learn and grow from such cases, it promotes capacity building for ethical decision making among staff, and it builds an integrated ethical organisational culture that values reflection and improvement

Note on Dealing with Moral Disagreement³¹

Given the clinical, organisational and moral complexity of health care it is inevitable that disagreements will arise. Moral disagreements, in particular, can be a major source of tension and can become intractable. Nevertheless, most disagreements can be worked through and a resolution arrived at that respects the positions and values of all parties, that is acceptable to all those involved, and that enables optimisation of care.

Clinical ethics support services can use a number of strategies to resolve moral disagreement. These may include; clarification and specification of the issues involved; clarification of the understandings that people have of the terms being used – such as quality of life or consent; analysis of the validity, truth and soundness of the arguments being used in support of one position or another; and use of examples and counter-examples to assist all those involved to identify what is at stake and what resolutions may be possible.

Where resolution of moral disagreement seems difficult to achieve, clinical ethics services may sometimes also recommend adoption of an existing code or policy or development of a new code or policy to assist resolution and to ensure that future disagreements can be avoided or dealt with in a fair and transparent manner. At other times, mediation may be used to assist resolution of disagreements between health professionals or between health professionals and patients/carers and to prevent escalation of conflict. Where this fails, it may be necessary to seek legal advice or refer cases for review by relevant legal or quasi-legal tribunals. Irrespective of the strategies used to resolve moral disagreements, it is essential that health care teams and the clinical ethics services supporting them maintain on-going, respectful and open communication – something that is not always easy within healthcare contexts.

31 Beauchamp T and Childress J. Principles of Biomedical Ethics (6th Ed), New York, Oxford University Press, 2009.; Kerridge I, Lowe M, Stewart C. Ethics and Law for the Health Professions. (4th Edition), Sydney, Federation Press, 2013.

Section 5: Resources

The resources section consists of a series of appendices that include links and documents that may be useful to individuals and organisations interested in developing and strengthening a clinical ethics service. These appendices are organised loosely to mirror the sections of the manual as follows:

- Appendix A – Resources describing the history and theory of clinical ethics (Section 1)
- Appendix B – Resources for capacity building and service development (Sections 2 and 3)
 - Sample Terms of Reference
- Appendix C – Case consultation models, tools and related resources (Section 4).

Note: The resources included are limited to those published in English and/or located on English-language websites, which is not to diminish the value of resources written in other languages.

Appendix A – History and Theory of Clinical Ethics

Australia & New Zealand

Doran, E., Fleming, J., Kerridge, I. & Stewart, C. *Building Clinical Ethics Capacity, Final Report of the Developing Clinical Ethics Capacity in NSW Partnership project*, 2014. (See, especially, References).

Kerridge I., Lowe M., Stewart C. *Ethics and Law for the Health Professions*. (4th Edition), Sydney, Federation Press, 2013.

Macdonald, A. & Worthington, R. *The Role of Clinical Ethics in the Health Care System of New Zealand*. 2012.

USA & Canada

Beauchamp T. & Childress J. *Principles of Biomedical Ethics* (7th Ed), New York, Oxford University Press, 2012.

Berger, JT. *Stumbled, fumbled, bumbled, grumbled, and humbled: looking back at the future history of clinical ethics*. *J Clin Ethics*. 2014 Summer; 25(2):96-101.

Hoffmaster B., Freedman, B. & Fraser, G. *Clinical Ethics: Theory and Practice*. Clifton, New Jersey: Humana Press, 1989.

Jonsen AR., Siegler M., & Winslade WJ. *Clinical ethics: a practical approach to ethical decisions in clinical medicine*. 7th ed. New York: McGrawHill; 2010.

Appendix B – Capacity Building and Service Development

Australia & New Zealand

Doran, E., Fleming, J., Kerridge, I. & Steward, C. *Building Clinical Ethics Capacity, Final Report of the Developing Clinical Ethics Capacity in NSW Partnership project*, 2014. (See, especially, Literature Review and References).

Kerridge I., Lowe M., Stewart C. *Ethics and Law for the Health Professions*. (4th Edition). Sydney, Federation Press, 2013.

Royal Children's Hospital Melbourne Clinical Ethics Service & Bioethics Centre
http://www.rch.org.au/bioethics/clinical_ethics_service/

UK & Europe

Chevrolet, J-C. & Ricou, B. *Hospital Clinical Ethics Committees: The Geneva Experience – Switzerland*. *Diametros* No 22 (December 2009): 21 – 38.

Gaucher, N. et al. *How do national standards frame clinical ethics practice? A comparative analysis of guidelines from the US, UK, Canada and France*. *Social Science and Medicine*, 2013 85: 74-78.

Gefenas, E. *Clinical Ethics Committees and Ethics Support Infrastructure: A European Perspective*. *Asian Bioethics Review*. Volume 3, Issue 3, September 2011: 293-298.

Gillon, R. *What attributes should clinical ethics committees have?* *BMJ* 2010; 340.

Larcher, V., et al on behalf of the UK Clinical Ethics Network. *Core competencies for clinical ethics committees* 2007, 2010.

Pedersen, R., Akre, V. & Førde, R. *Barriers and Challenges in Clinical Ethics Consultations: The Experiences of Nine Clinical Ethics Committees*. *Bioethics*. Volume 23: Number 8; 2009: 460–469.

Singer, PA., & Viens, AM. (eds). *Cambridge Textbook of Bioethics*, Section VII: Using Clinical Ethics to make an impact in health care. Cambridge University Press, 2008.

Slowther, AM., et al. *A Practical Guide for Clinical Ethics Support*. The Ethox Centre, University of Oxford 2004.

Slowther, AM., et al. *Development of clinical ethics services in the UK: a national survey*. *J Med Ethics* 2012 38:210-214.

UK CEN Clinical Ethics Network <http://www.ukcen.net/index.php/main>

USA & Canada

American Society for Bioethics and Humanities: *Core Competencies for Health Care Ethics Consultation and Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants*, 2nd Edition, 2011 <http://www.asbh.org/publications/content/asbhpublications.html>

Catholic Health Association of the United States. *Striving for Excellence in Ethics: A Resource for the Catholic Health Ministry*. 2nd Edition, 2011.

Clinical Ethics Task Force of the American Society for Bioethics and Humanities: *“Improving competencies in clinical ethics consultation: an education guide”*. Glenville, IL: American Society for Bioethics and Humanities, 2009.

Kodish, E., Fins, JJ., et al. *Quality Attestation for Clinical Ethics Consultants: A Two-Step Model from the American Society for Bioethics and Humanities*. Hastings Center, Wiley Online Library, 2013.

Gaucher, N., et al. *How do national standards frame clinical ethics practice? A comparative analysis of guidelines from the US, UK, Canada and France*. *Social Science and Medicine* 2013 85: 74-78.

Godkin, D., Faith, K., et al. *Project examining effectiveness in clinical ethics (PEECE): phase 1--descriptive analysis of nine clinical ethics services*. *Journal of Medical Ethics* 2005 31(9) 505-12

Singer, PA., & Viens, AM. (eds). *Cambridge Textbook of Bioethics, Section VII: Using Clinical Ethics to make an impact in health care*. Cambridge University Press, 2008.

Tarzian, AJ. *Credentials for clinical ethics consultation – are we there yet?* HEC forum, 2009. Springer.

Winnipeg Health Region (Manitoba, Canada) <http://www.wrha.mb.ca/about/ethics/index.php>

Sample Terms of Reference

1. Royal Children’s Hospital Melbourne – Children’s Bioethics Centre (AU)

Children’s Bioethics Centre

TERMS OF REFERENCE: CLINICAL ETHICS CASE RESPONSE GROUP

1. Accountability

The Clinical Ethics Case Response Group (CERG) is an advisory group, accountable through the Clinical Ethics Service Team Leader, to the Clinical Director, Children’s Bioethics Centre (CBC).

The CERG has no independent authority.

The CERG provides monthly activity reports to the CBC Business Director and quarterly reports to the RCH Clinical Ethics Committee.

2. Roles and Procedures

(i) Roles

The CERG has been established to provide advice and support to RCH staff to promote ethically informed clinical decision making in response to clinical case requests.

It is NOT the role of the CERG to direct clinical decisions.

(ii) Procedures

- Staff may refer a case to the CERG either in person to a member of the Children’s Bioethics Centre, via email or by contacting the ethics referral paging system (x4056).
- Clinical case referrals may also be requested by parents and patients through the child’s medical consultant and/or by any member of the treating team.
- Members will be asked to meet to discuss the ethical implications of a clinical case referral. Given clinical contexts and needs, meetings may be at short notice.

- It is acknowledged that individual members will not be able to meet to discuss every case referral.
- The CERG would endeavour to meet in person with the referring health care providers and other members of the treating team.
- Where requested or relevant, the CERG or representatives there of, may also meet with the patient and/or their family or representative/advocate.
- If possible, all members shall be supplied with written clinical information prior to the meeting.
- It may be necessary to meet on more than one occasion to discuss an individual case.
- Following consultation and discussion, the CERG will
 - Provide the referring health care provider with a considered exploration of the ethical issues (including written documentation) and wherever possible recommendations regarding the best way forward.
 - Develop a plan in consultation with the referring health care provider to communicate information relevant to a patient's care with the treating team.
- It is recognised that the final clinical decision rests with the treating team in consultation with the parents/guardians and, where applicable, mature minor.
- The CERG may invite additional parties to be present for discussions and may seek advice from experts on issues as needed.

3. Committee Membership

(i) Membership

The CERG is comprised of members from a range of clinical specialties and disciplines including the following:

- Clinical Director of the CBC
- Clinical Ethics Service Team Leader
- Clinical Ethicist
- At least 2 medical staff representative from a range of clinical specialties
- At least 2 nursing staff representatives
- At least 2 allied health staff representatives
- At least 1 RCH Chaplain or representative
- 1 Medico-legal representative
- At least 1 representative with expertise in adolescent health

For each individual case referral, a smaller team of members will be drawn from the broader CERG group to respond to the case. The group that forms for a case consultation will reflect the expertise and availability of team members.

(ii) Selection of Membership

Members will be nominated to participate in the CERG based on the following:

- an established interest in paediatric ethics,
- ability to attend meetings regularly,
- skills and experience relevant to the CERG needs

All nominations for CERG membership must be endorsed by the Clinical Ethics Committee.

(iii) Terms of Membership

Membership shall be for two years. Longer appointments may be possible at the discretion of the Clinical Ethics Service Team leader.

All members are expected to participate in at least 1 ethics training program per year. These will be run by the Children's Bioethics Centre at various times throughout the year.

It is anticipated that the CERG will be asked to respond to approximately 15-20 cases per year (based on referrals received in 2009/2010). CERG members will be expected to attend at least 10 cases per year. This will ensure members maintain the necessary skills and expertise required to assist and respond to case referrals.

4. Meeting Frequency

The CERG shall meet face-to-face when required. In addition to responding to case consultations, optional opportunities for professional development and case review will be offered throughout the year.

5. Notes of the Meetings

Notes shall be taken at each meeting by the Clinical Ethicist and distributed to CERG members for review. These will then be forwarded to the referring clinician and any other nominated members of the treating team as indicated in Section 2ii.

Children's Bioethics Centre

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2. Gold Coast Hospital and Health Service (AU)

Terms of Reference

Gold Coast Hospital and Health Service Clinical Ethics Committee

Approval

The Terms of Reference of the Clinical Ethics Committee have been reviewed and accepted by:

SIGNED

Gold Coast Hospital and Health Service

Governance Intent:

1. Purpose:

1.1 Purpose:

- Promote a culture within the GCHHS whereby consideration of ethical issues is routinely embedded in the work culture.
- Facilitate the resolution of ethical issues involving individual patient care at the request of treating clinicians:
 - The term “facilitate” has been chosen intentionally to promote understanding of the CEC’s role in supporting clinical decision making and building organisational capacity.
 - The Clinical Ethics Committee will not make definitive decisions on the appropriate course of action as clinical decisions remain the province of the treating team.
- Assist in organisational policy review, to consider the ethical implications of such policies in clinical practice, where such a review is requested by staff or the Clinical Governance Committee. Promoting supportive policy frameworks is important in creating and sustaining an ethical organisational climate.
- Contribute to education on ethical issues or evolving ethical problems at staff forums.
- Provide input, if asked, into any ethical issues that may arise from the development of new procedures or treatments. These may include the impact of new technology, guiding principles of resource allocation, or other emerging issues.

2. Scope:

2.1 Scope:

To foster and lead a culture of safety and continuous quality improvement through inter-disciplinary review and practice, ensuring ethical considerations are included across the Gold Coast Hospital and Health Service.

3. Responsibilities:

3.1 Responsibilities:

- Undertake review of clinical cases when invited by Clinical Governance Committee or any individual staff member for consideration/advice. A Clinical Ethics Sub-committee may be convened to consider urgent clinical matters, and provide immediate support when requested. Instances considered by the sub-committee will be reported to the Clinical Ethics Committee at the next meeting.
- From the cases considered, identify areas of educational need for staff and collaborate with the Director of Clinical Governance and other relevant bodies to address these needs.
- Provide clinical ethics assistance to the wider Gold Coast District when requested.
- Review institutional policies and guidelines on clinical ethical issues in response to requests received from Clinical Governance Committee and/or referral from individual staff.
- Provide a clear organisational pathway and process to support clinical staff in making difficult ethical decisions.

4. Membership

Positional Membership:

- Executive Director Medical Services (or delegate)
- Executive Director of Nursing Services (or delegate)
- Director of Clinical Governance (or delegate)
- Executive Support Clinical Governance Unit

Expertise Membership:

- Consumer Advocate
- Ethicist
- Pastoral Care
- Legal

Clinical Membership:

Membership by appointment will be determined by an annual service wide expression of interest to the Director of Clinical Governance. Appointment to the committee will consider the personal attributes and expertise that the member brings to the committee as well as their influence within their respective clinical areas. It is expected that the Committee will have a diverse membership drawn from the Medical, Nursing and Allied Health professionals, however, members are appointed as individuals with interest and expertise and not as advocates or representatives of any group or area. Committee members are chosen for their individual qualities that they can bring to the group for the betterment of the whole system.

The tenure of membership is to be two years. Members may re-nominate for future tenure

The Chair may invite persons outside the membership of the Committee to attend a meeting of the Committee and participate in its deliberations. Typically these persons will have specialist knowledge for insight into a particular discussion. Invited guests do not assume membership or participate formally in the consensus process of developing a recommendation from the meeting.

5. Induction, Mentoring and Training

New members will be provided with individual induction and mentoring via the Chair and other members of the GCHHS Clinical Ethics Committee.

Throughout their tenure, members will be encouraged to attend conferences and workshops that are relevant to the roles and responsibilities of the GCHHS Clinical Ethics Committee.

6. Relationships:

This Committee reports to the CEO via the District Clinical Governance Committee.

7. Chairperson:

Nominated from the Clinical members

8. Secretariat Support:

Clinical Governance Unit

9. Frequency:

Bi - monthly, up to one (1 1/2) hour duration

10. Proxies & Quorum:

Positional members may designate a delegate to attend in their absence. Proxies for attendance by other members at meetings are not accepted.

A quorum for full meeting of the committee will be 50% of the membership plus 1.

A quorum for extraordinary meetings of the sub-committee will be determined on an individual case basis by the Chair.

11. Agenda and Minutes:

- Agenda items together with the relevant discussion papers may be submitted by any Committee member not less than 4 days before the meeting.
- The Agenda will be distributed at the least 2 days prior to the meeting.
- Minutes will be disseminated to all members at least one week prior to meetings.
- Minutes confirmed by the Committee will be forwarded to the District Clinical Governance Committee.
- The minutes will record the general discussion and agreed outcomes and actions. Minutes will not contain names of patients or staff.
- A Committee Performance report is to be forwarded to the Clinical Governance Committee as per the reporting schedule.

12. Access to Information / Confidentiality:

Members of the Committee have the right to access information and documents relevant to issues being considered within the terms of reference. It is acknowledged that certain issues being examined may be of a confidential and/or sensitive nature, which will require members of the committee and the secretariat to ensure confidential information remains as such.

13. Evaluation of Committees Performance:

The Committee will consider the function and operating principles of the Committee against which it measures its performance. It will undertake an annual self-assessment of its performance against the approved terms of reference and the operating principles.

Document Revision History

Membership 20XX – YY

3. Norfolk and Norwich University Hospitals (UK)

Norwich Clinical Ethics Group

Terms of Reference

Function

The Norwich Clinical Ethics Group (the Group) is a multidisciplinary advisory group. The objectives/purpose of the Group are:

- to promote and support an ethical approach to clinical practice;
- to offer the facility for structured and rigorous ethical discussion and advice to clinical teams, concerning individual cases or guidelines;
- to have an educational role in clinical ethics' teaching;
- to liaise with similar groups locally and through the UK Clinical Ethics Network.

Please note that this Group does not deal with research ethics.

Structure

Reporting

The Group reports to the Clinical Governance Committee and submits an annual report.

Meetings

The Group usually meets ten times a year for committee meetings. Meetings may also be held as educational meetings. Meetings may also be held on an 'as required' basis and/or short notice basis in response to a case (these are often called 'hot cases' for issues which cannot wait until the next committee meeting).

Attendance

Members are encouraged to attend a minimum of 50% of meetings (including education/hot cases etc).

Quorum

In general a meeting will be considered quorate with four members present. In the Chair's absence the chairmanship of a meeting will be agreed by those present.

Processes

Referral Pathway

This sets out details of the pathway to be followed by anyone considering referring an ethical issue or problem to the Group. It includes contact details for the Group and can be found on 'Trust Docs' (copy attached).

Documentation

Committee meetings: the agenda for each business meeting is circulated to all Group members together with the minutes of the previous business meeting. These do not contain confidential information.

Case discussions: for reasons of confidentiality notes of case discussions are not circulated but reviewed at the next Group meeting. A copy is retained for the Group's records. While these notes do not contain names or other identifiers they may be recognisable due to the unusual or contentious nature of their content.

Hot case discussions: occasionally the chair will write a clinical letter or write in the case notes following a case discussion.

Membership

Membership recruitment

This is by agreement of the Group and is usually by self-nomination or succession. Members will be recruited from across the Trust's divisions with a view to maintaining the balance, predominantly clinical, but with a mix of backgrounds and competencies. Members should have an interest in ethical matters and an enthusiasm to get involved and learn more.

Total membership of the Group is usually 20 with at least two from each division. In addition members may be drawn from the medical school, the chaplaincy, primary care and the non-executive directors.

Members will be asked to make themselves available for Group meetings, some of which may have to be at short notice. Members will be expected to evaluate their own training needs for their work with the Group and to develop and maintain their skills in clinical ethics.

Chairmanship

The usual duration is four years and the chair is selected by consensus from established Group members.

At an individual level members should

1. Be willing to be informally and confidentially approached.
2. Discuss a dilemma and determine if an ethical question is posed, help frame the question and advise on the referral pathway.
3. Refer to any existing sources of information e.g. Trust or national guidelines.
4. Help liaise with existing support frameworks e.g. Team, Multidisciplinary team, PALS, Matrons, Complaints Department. (NB Unless exceptional circumstances the senior members of the care team should always be approached if the cases demand more than informal advice.)
5. Where advice is required for an ongoing HOT situation alert the chair of the CEG who will convene a small 'working group' from CEG – usually by e-mail.
6. For COLD matters (cases or themes which have reached resolution but raise important points) refer to the CEG chair. The referring person (or the member on their behalf) may present the case/theme at a routine group meeting or a unit study day could be set up.

There are therefore three types of CEG meeting

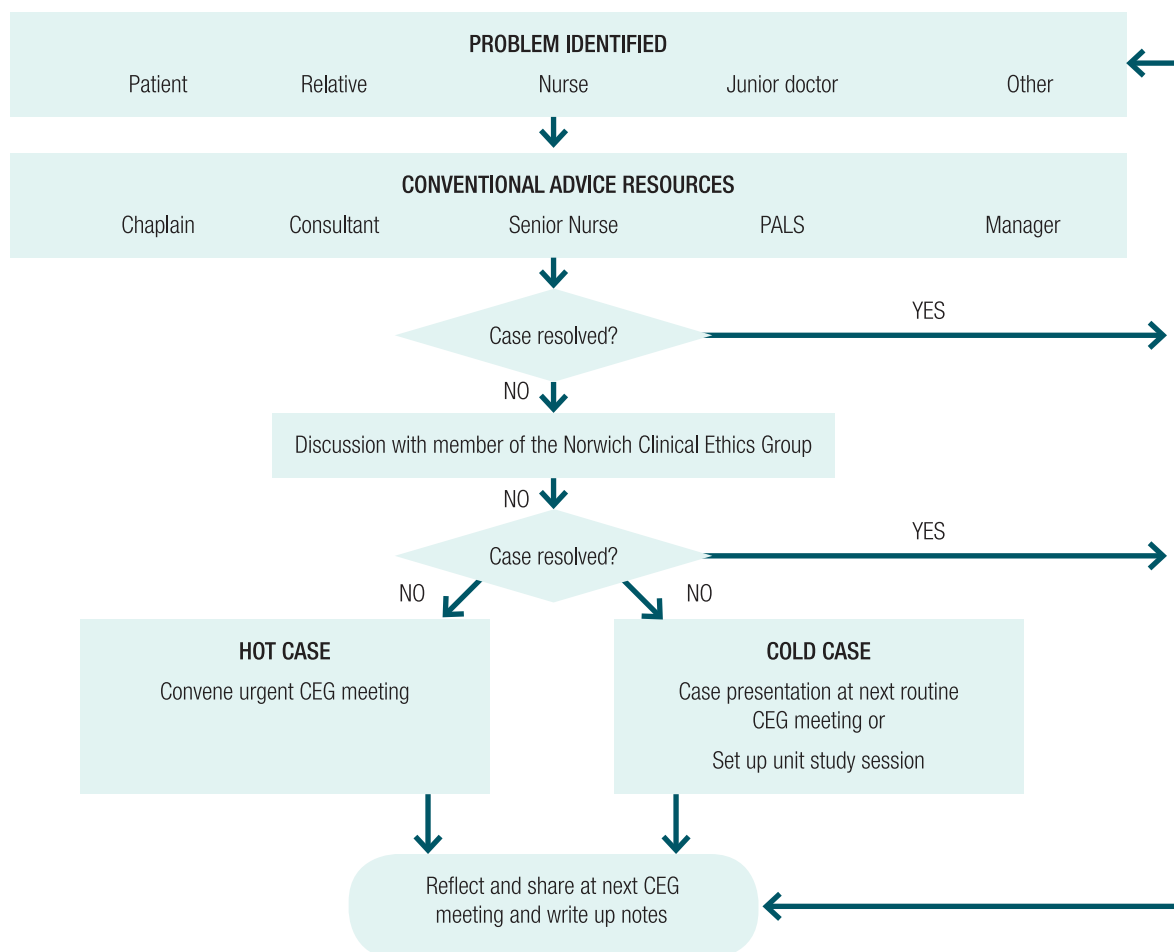
1. **A HOT case discussion.** Involves a specific challenging case where key decisions are yet to be made. Will be convened as quickly as possible (usually within a few days) and will consist of at least three CEG members who are not directly involved in the case. For example, a hot case might cover:

- Resuscitation decision making for a patient who is not competent and where there are disagreements about their best interests;
 - A patient refusing life-saving treatment where staff are uncomfortable with the likely outcome.
2. **Routine group meetings.** Monthly meetings which combine organisational business with case presentations (by an invited non-member or by the CEG member initially approached).
 3. **Unit Study Sessions.** The CEG can co-ordinate and provide speakers at study sessions covering common major ethical topics. These will usually be themed and often utilise more than one example case. They are usually open meetings and we encourage multidisciplinary attendance. They can last one hour or half a day. Examples already completed include
 - Neonatal unit problems
 - Artificial feeding in stroke
 - Renal replacement therapy

Reflection and Note Keeping

For HOT cases a summary of the discussion and any advice given are usually recorded contemporaneously in the clinical records. For all cases an anonymised standardised case description, discussion and learning points are also held by the Group administrator.

The Norwich Clinical Ethics Group (CEG) – Referral Pathway



Appendix C – Case Consultation

Australia & New Zealand

Doran, E., Fleming, J., Kerridge, I. & Steward, C. *Building Clinical Ethics Capacity, Final Report of the Developing Clinical Ethics Capacity in NSW Partnership project 2014.*

Kerridge I., Lowe M., Stewart C. *Ethics and Law for the Health Professions.* (4th Edition), Sydney, Federation Press, 2013.

NSW Health Clinical Ethics Advisory Panel <http://www.health.nsw.gov.au/clinicaethics/Pages/clinical-ethics-advisory-panel.aspx>

Rogers, W. & Braunack-Mayer, A. *Ethical reasoning and general practice. Chapter 2 in Practical Ethics for General Practice, 2nd edition.* Oxford University Press 2009.

Royal Children's Hospital Melbourne Clinical Ethics Service & Bioethics Centre
http://www.rch.org.au/bioethics/clinical_ethics_service/

UK & Europe

Slowther, A. et al. *A Practical Guide for Clinical Ethics Support.* The Ethox Centre, University of Oxford 2004.

UK CEN Clinical Ethics Network <http://www.ukcen.net/index.php/main>

USA & Canada

American Society for Bioethics and Humanities: *Core Competencies for Health Care Ethics Consultation and Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants,* 2nd Edition 2011 <http://www.asbh.org/publications/content/asbhpublications.html>

Baylis, F. ed. *The Health Care Ethics Consultant.* Totowa NJ: Humana Press, 1994.

Centre for Clinical Ethics - A Principle Based Framework/Process for Ethical Decision Making
<http://www.ccethics.com/framework.pdf>

Fox, E., Berkowitz, K., Chanko, B. & Powell, T. *Ethics Consultation: Responding to Ethics Questions in Health Care.* IntegratedEthics. National Centre for Ethics in Health Care. Veterans Health Administration. <http://www.ethics.va.gov/ECPrimer.pdf>

Georgetown University Center for Clinical Bioethics Ethics Consultation Service
<https://clinicalbioethics.georgetown.edu/consult>

IDEA1 Ethical Decision-Making Framework Guide & Worksheets: http://www.trilliumhealthcentre.org/about/documents/TrilliumIDEA_EthicalDecisionMakingFramework.pdf

Jonsen AR., Siegler M., Winslade WJ. *Clinical ethics: a practical approach to ethical decisions in clinical medicine.* (7th Ed), New York: McGrawHill; 2010.

Schneider GW. & Snell, L. *CARE: an approach for teaching ethics in medicine. Social Science and Medicine.* 2000; 51:1563-7.

Spike, J. & Greenlaw, J. Ethics consultation: High ideals or unrealistic expectations? *Ann Intern Med.* 2000; 133(1):55-57.

University of Toronto Joint Centre for Bioethics Consultation services
<http://jointcentreforbioethics.ca/services/consultation.shtml>

Verkerk, M., Lindemann, H. et al. *Enhancing Reflection: An Interpersonal Exercise in Ethics Education*.
The Hastings Center Report. Vol. 34, No. 6 (Nov - Dec, 2004); pp. 31-38.

Winnipeg Health Region (Manitoba, Canada) <http://www.wrha.mb.ca/about/ethics/framework.php>

Resources for Clinical Ethics Consultation http://en.wikipedia.org/wiki/Resources_for_clinical_ethics_consultation

Appendix D – Process Report

This Manual was developed by a working committee of the Australian Health Ethics Committee (AHEC) during the 2012-2015 triennium. Members of this committee included:

Associate Professor Eleanor Milligan (AHEC member, Chair)

Professor Susan Dodds (AHEC member)

Associate Professor Ian Kerridge (AHEC member)

Professor Wendy Rogers (AHEC member)

Professor Lynn Gillam (external member)

NHMRC project support was provided by Jeremy Kenner.

The Manual is intended as a resource for health professionals in Australia and to promote and support capacity building for clinical ethics in Australian health care institutions.

NHMRC gratefully thanks the following bodies for making available documentation related to their clinical ethics services:

Australia

Australian Council on Healthcare Standards

Gold Coast Hospital and Health Service

NSW Ministry of Health

Royal Children's Hospital Melbourne

South Eastern Sydney and Illawarra Area Health Service

Sydney South West Area Health Service

New Zealand

Capital and Coast District Health Board

United Kingdom

Birmingham Children's Hospital

Cardiff and Vale University Health Board

Lewisham and Queen Elizabeth (Greenwich) Hospitals

Luton and Dunstable University Hospital

Norfolk and Norwich University Hospitals

Oxford University Hospitals

Queen Mary's Hospital

Canada

Eastern Health

Winnipeg Regional Health Authority