

# DEVELOPING AND IMPLEMENTING CLINICAL PRACTICE TOOLS: THE LEGAL AND ETHICAL IMPLICATIONS

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## ABSTRACT

The complexity of health care is ever increasing, as is the volume of research and literature available. In response there has been a corresponding emphasis on basing clinical decisions on the best available research evidence. The development and implementation of clinical practice tools is cited as a means of ensuring research utilisation as well as moderating variations in clinical practice. It is important that nurses contribute to the development of these clinical tools in order to actively shape their own practice. Nurses therefore need to have an understanding of the terminology and processes involved, and the implications for practice. This paper outlines definitions of the various clinical tools, the development process, and the legal and ethical implications of clinical practice tools.

## INTRODUCTION

A growing interest in clinical practice tools and the process of their development and implementation has marked the past decade. This interest is usually prompted by the desire to establish best practice patterns, streamline processes and reduce health care costs. Traditionally these tools have been based on reported best practice and the consensus of expert opinions. There is now growing recognition that tools guiding clinical practice should be based, where possible, on the systematic identification and synthesis of the best available scientific evidence (National Health and Medical Research Council (NHMRC) 1998). This paper defines the terminology used in reference to clinical practice and describes the development and implementation of clinical practice tools. Finally there is a discussion of the legal and ethical implications these tools hold for nursing practice.

### Definitions and terminology

Clinical practice tools (CPT) may include guidelines, protocols, standards of care, or, critical pathways. Though sometimes used interchangeably each term has its own distinct definition. These definitions need to be considered when developing a CPT.

*Guidelines* are recommended principles and usually take the form of systematically developed statements aimed at assisting the practitioner in making decisions about health care in specific circumstances (Jaggers 1996). In general, guidelines are broad based and provide recommendations for care based on the most current research findings (Cole and Houston 1999). They allow a degree of flexibility and interpretation by the practitioner based on their clinical judgement. More rigorous methodology applied to the analysis and classification of data prior to implementation has facilitated the wider development and acceptance of guidelines in practice

(Fuss and Pasquale 1998). Guidelines may be adopted from national and speciality organisations, or developed locally following an extensive review of the relevant literature. An example of a locally developed guideline for weaning from mechanical ventilation is detailed in this paper.

*Protocols* are more formal statements, specifying in detail how a process or intervention is to be conducted. They provide a standardised approach to care with a desired outcome (Cole and Houston 1999). In contrast to guidelines, protocols do not allow for any deviation. They are intended to be followed verbatim. An example is the administration of thrombolysis therapy post myocardial infarction.

*Standards of care* are accepted principles that help to operationalise patient care processes (Cole and Houston 1999) and, in the researcher's experience, form the basis of quality assurance measurements. They are often developed from the viewpoint of one particular discipline.

*Critical pathways* provide written criteria to guide the care delivery of multiple disciplines. They delineate the optimal sequencing or timing of interventions and procedures by nurses and other staff for a specified patient population (Coffey et al 1992). Deviations or variances from the critical pathway are monitored and can form the basis for quality enhancement efforts as they provide a standard of care for comparing actual with expected patient outcomes (Burns 1998). Examples of the successful application of critical pathways include care of a patient post operatively (eg post coronary artery bypass or hip replacement surgery) and care of the patient with multi-resistant *staphylococcal aureus*.

One tool may not be sufficient to standardise practice. Guidelines and protocols often form part of a critical pathway, so a variety of tools are used to guide patient care.

## DEVELOPMENT AND IMPLEMENTATION OF CLINICAL PRACTICE TOOLS

The development of any CPT is challenging. They are without value if they are awkward, verbose and unrealistic to the practitioner in the clinical setting. CPTs need to be succinct, comprehensive, relevant and accessible at the bedside (Fuss and Pasquale 1998).

A number of leading agencies have proffered a variety of frameworks for the development CPTs (see Table 1). There are common threads running through all these suggested frameworks: defining the problem, using a (multidisciplinary) team approach, assessing scientific evidence, drafting and validating the tool, and finally implementation and evaluation (Agency for Healthcare Policy and Research 1991; NHMRC 1998; Paley 1995).

A review of the relevant literature and research is a vital part of the CPTs development process. This is essentially an extensive literature review or preferably a systematic review. Systematic reviews provide a rigorous summary of the current best evidence on a topic due to the methods used to collect, appraise and summarise research (Evans 2001). The components of a review protocol include a review question, inclusion criteria, search strategy, critical appraisal, data collection and data synthesis from which to draw conclusions and base recommendations.

**Table 1: Summary of frameworks for development of clinical practice tools**

Steps in clinical management protocol development (USA Agency for Healthcare Policy and Research 1991).	UK framework for devising a clinical protocol (nursing) (Paley 1995).	A guide to the development, implementation and evaluation of clinical practice guidelines (Australian National Health and Medical Research Council 1998).
<ol style="list-style-type: none"> <li>1. Selection of topic</li> <li>2. Selection of committee members</li> <li>3. Clarification of scope and purpose</li> <li>4. Listing of goals</li> <li>5. Assessment of scientific evidence</li> <li>6. Drafting and validation</li> <li>7. Presentation of clinical management protocol</li> <li>8. Implementation</li> <li>9. Evaluation</li> <li>10. Recommendations for research</li> </ol>	<ol style="list-style-type: none"> <li>1. Outline the area of patient care to be covered by the protocol</li> <li>2. Provide justification for using a protocol (include potential costs/benefits)</li> <li>3. Outline the involvement of the nurse in the protocol               <ul style="list-style-type: none"> <li>• Theoretical framework</li> <li>• Unique nursing interventions</li> <li>• Collaborative nursing interventions</li> </ul> </li> <li>4. Outline multidisciplinary involvement</li> <li>5. Outline the involvement of the patient of the patient in the protocol</li> <li>6. Outline the methodology and channels of communication employed</li> <li>7. Outline the expected patient outcomes from using the protocol</li> <li>8. Review and revise protocol if necessary</li> </ol>	<ol style="list-style-type: none"> <li>1. Determine need and scope of guidelines</li> <li>2. Establish multidisciplinary working party</li> <li>3. Define purpose and target audience for the guidelines</li> <li>4. Identify health outcomes</li> <li>5. Review scientific evidence</li> <li>6. Formulate guidelines</li> <li>7. Formulate dissemination and implementation strategy</li> <li>8. Formulate evaluation and revision strategy</li> </ol> <p><b>Guiding principles</b></p> <ul style="list-style-type: none"> <li>• Outcome focused</li> <li>• Evidence based</li> <li>• High quality synthesis of available evidence</li> <li>• Multidisciplinary and consumer involvement</li> <li>• Flexible and adaptable to local conditions</li> <li>• Incorporate economic appraisal</li> <li>• Guidelines accessible and 'user friendly'</li> <li>• Impact of guidelines evaluated</li> <li>• Guidelines revised regularly</li> </ul>

The development and use of CPTs can facilitate interdisciplinary collaboration. CPTs reflect joint decision making and responsibility of the health care team involved with a particular patient population (Cole and Houston 1999). For example, a clinical condition where interdisciplinary collaboration is necessary in weaning a patient from mechanical ventilation. There is no conclusive evidence supporting one weaning mode over another. However, there is evidence that the weaning process was improved by a standardised approach to a particular technique (Djunaedi et al 1997; Ely et al 1996; Kollef et al 1998; Kollef et al 1997; Wood et al 1995).

## **CASE STUDY: DEVELOPMENT OF GUIDELINES FOR WEANING PAEDIATRIC PATIENTS FROM MECHANICAL VENTILATION**

The Australian National Health and Medical Research Council's 'Guide to the development, implementation and evaluation of clinical practice guidelines' provided the framework for the development of weaning guidelines (NHMRC 1998). Ethical clearance was obtained from the relevant bodies and the guidelines were implemented only on patients from whom informed consent was obtained (either from themselves or their parent/guardian).

### **1. Determine the need and scope of guidelines**

The need and scope of the subject was gathered through reflection on current practice, a retrospective analysis of weaning outcomes and a national survey of weaning practices in Australian paediatric intensive care units (PICUs) (Keogh 2000). Historically, weaning was carried out in an empirical manner, differing according to consultant preference and driven largely by the availability of medical staff. The national survey revealed that while all seven Australian PICUs had ventilation guidelines, none had weaning guidelines in practice.

### **2. Establish a multidisciplinary working party**

In addition to the researcher, a seven member panel of PICU experts was convened to review the draft of guidelines and the evidence reviewed. The panel consisted of four medical consultants, a nurse leader, a hospital-based nurse educator and university-based nursing lecturer.

### **3. Define purpose and the target audience for the guidelines**

As a reflection of the multidisciplinary nature of the weaning process the guidelines were aimed at both medical and nursing staff. As no one particular ventilatory mode had been proven for optimal weaning, the aim was to standardise the (team) approach and keep the weaning process patient centered.

### **4. Identify health outcomes**

Specific health outcomes measured included total-ventilation-time (TVT), weaning-duration (WD), and length-of-stay (LOS) in the PICU. In addition, weaning failure and reintubation rates were monitored. The aim was to standardise and expedite the weaning process without sacrificing quality.

### **5. Review scientific evidence - literature review**

An extensive literature search of the CINAHL and MEDLINE databases for studies since 1990 examining weaning, (particularly in the paediatric population), was conducted. A total of 30 studies were found. Only 10 of these studies specifically examined ventilation, weaning or extubation in the paediatric population. Each study examined a different aspect using a variety of research methods so it was not possible to conduct a meta-analysis of the findings. There was conflicting evidence between studies about the optimal weaning mode (Brochard et al 1994; Ely et al 1996; Esteban et al 1995; Farias et al 1998; Manczur et al 2000), however, there was an overall consensus that a standardised approach to the weaning process could improve patient outcomes. A number of studies in the adult population had demonstrated this (Djunaedi et al 1997; Ely et al 1996; Kollef et al 1998; Kollef et al 1997; Wood et al 1995). One paediatric study had successfully piloted weaning guidelines in a cardiothoracic setting (Webster 2000).

### **6. Formulate guidelines**

A draft of the guidelines, including a weaning algorithm, was drawn up. The overall belief was that guideline development and refinement is an evolutionary process. To this end the panel met three times over a six-week period and the guidelines were redrafted twice before the final agreed format was ready for piloting on the study unit.

### **7. Formulate dissemination and implementation strategy**

Prior to piloting, all medical and nursing staff were sent an information letter informing them about the study and the guidelines. Education sessions were scheduled over a four week period to inform staff about the weaning guidelines and process in detail and provide them with the opportunity to ask questions. There was concern amongst some members of the nursing staff that playing a more active role in the weaning process was not within their scope of nursing practice. Consultation of the state nursing registering body's 'Scope of practice decision making framework' and the national critical care college's competencies guide supported any nurse in a role that they had the education, authorisation and competency to perform (Australian Confederation of Critical Care Nurses

(ACCCN) 1996); Queensland Nursing Council (QNC) 1998). The clinical setting also influences the scope for individual practitioners. Care of the ventilated patient is part of the responsibility of the intensive care nurse and assisting the weaning of ventilation is subsequently part of that process. The majority of nurses and doctors welcomed the guidelines. They stated that they merely formalised what many nurses had been doing for years. It seemed that for some staff this was an educational tool 'expanding' their role while for others it affirmed their role.

### 8. Pilot study

The guidelines were piloted on 10 patients over a one-month period. Outcomes measured included total ventilation time, weaning duration, length of stay as well as quality indicators (weaning failure, reintubation and reventilation rates). Results from the pilot sample were compared to the retrospective analysis and the outcome measures were comparable. The pilot sample was too small to conduct a statistical analysis, however the pilot test demonstrated that multidisciplinary weaning guidelines were a safe clinical practice tool. Minor revisions were made to the guidelines in response to feedback from staff and the guidelines fully implemented for a 12-month period.

### 9. Formulate evaluation and revision strategy

The main study continues with a preliminary six-month analysis due to be completed. Health outcomes will be compared to the retrospective analysis of the historical control to detect any clinical and/or statistical differences. In addition to the quantitative analysis focus group interviews will be undertaken to discover how the staff on the study unit perceived the guidelines from weaning from ventilation and what effect these had on their practice. The wider legal and ethical issues that need to be considered are discussed below.

## LEGAL ISSUES WITH CLINICAL PRACTICE TOOLS

With the concept of managed care on the increase, the legal and ethical implications of clinical practice tools need to be considered. Practice guidelines may not change the litigation system per se, but guidelines could be used as evidence to determine the case for negligence (Brennan 1991). A previous two-part study was conducted to determine how practice guidelines were being used in malpractice litigation in the United States of America (USA) (Hyams et al 1995). From the 259 claims of medical malpractice received at two major insurance companies, only 17 involved the use of practice guidelines. In their survey of 560 responding medical malpractice attorneys, 75% were aware of the concept of practice guidelines. A comparable proportion of attorneys (26% versus 30%) reported the use of guidelines influenced their decision whether to take a case or not, and

27% reported that guidelines influenced their decision to settle a case (Hyams et al 1995). Hyams and colleagues concluded the findings suggested that the concept of guidelines in litigation was spreading through the profession. Further study of USA court cases reported between 1980 and 1994 found 28 cases in which guidelines were used successfully (Hyams et al 1996). In the majority of the cases (78%) the guidelines were used for inculpatory purposes (ie implicating the defendant). Plaintiffs tended to use guidelines more than defendants did.

For practice protocols to be of use in litigation, the protocol must be relevant (Brennan 1991). In the case of *Quigley v Jobe in 1992* (cited in Hyams et al 1996) a guideline was ruled not relevant as it was promulgated by a private insurance company. Therefore the impetus for the protocol or guideline development needs to be considered. Guidelines that are centrally developed by national and government agencies are too general and vague for courtroom disputes (Hall and Dadakis 1996). Research based protocols, developed to meet the local health care needs, are more likely to establish a conclusive standard of care that can be admitted into court as evidence (Hall and Dadakis 1996).

It can therefore be concluded that although the use of guidelines in medical litigation is as yet limited, it has nevertheless had an impact on the decision-making processes of the attorneys involved. In her review of the liability issues associated with practice protocols Noonan stated that protocols offered a decrease in the need to practice defence medicine as well as a method to improve quality of care (Noonan 1997). Of significance though, from the review of all the medical malpractice cases reviewed, was the finding that practice protocols and guidelines did not eliminate the use of expert witnesses. Protocols, guidelines and critical pathways incorporate, but do not replace physician orders. CPTs require practitioners to use professional judgement by making explicit the rationale for their use (Brown 1995). As always - good clinical judgement must prevail.

## ETHICAL CONSIDERATION WITH CLINICAL PRACTICE TOOLS

Ethical issues related to the use of CPTs are identical to the ethical issues surrounding the use of any therapy or intervention. Four ethical principles need to be considered: nonmaleficence (do no harm), beneficence (do good), autonomy (respect for patient self-direction), and distributive justice (be fair) (Beauchamp and Childress 1989; Jonsen et al 1992). When the decision to treat has been made, the only remaining choice is to use the most appropriate technique or process for delivering that treatment. The principles of autonomy and distributive justice become less important (Morris et al 1994). However, the importance of nonmaleficence and

beneficence remain undiminished. Striking a balance between the principles of nonmaleficence and beneficence is a challenge to the health care practitioner. In essence, a risk-benefit analysis must be undertaken, and is best done when probable estimates of outcome for treatment options are based on sound data. This statement alone mounts a convincing case for the use of research based tools for delivery of care. However, the development and implementation of CPTs in itself can give rise to ethical concerns.

The principle of autonomy requires patient participation and consent. The question then arises as to whether CPTs are considered a new and innovative non-standard therapy? Are CPTs decision support tools that merely formalise and standardise common practice? If the latter argument is used then informed consent is not mandatory. The principle of distributive justice is not an issue as long as the tool is applied to all patients without prejudice (Morris et al 1994).

When addressing the principles of nonmaleficence and beneficence in regards to CPTs, a shift is required from the traditional view that the physician is the (only) expert with the knowledge, skills and belief about what is the best available therapy for the patient. The assumption that physician belief is a reliable reflection of best information available does not acknowledge the general human limitations with information processing. (Miller 1956; Morris 1993; Morris and Gardner 1992). The forethought and consensus approach to CPT development means that more consideration and planning is behind decisions made under CPT control than by any individual practitioner (James and Eddy 1994). The intent to do good and the belief in a therapeutic decision within the increasingly complex area of critical care is not always enough. In the absence of credible data concerning outcomes from different therapy options clinicians are forced to use intent and belief to drive operational decisions rather than beneficence (Morris et al 1994). Therefore, the use and development of standardised approaches to patient care raise ethical issues that are comparable to decisions made in the conventional manner. Indeed, CPTs provide a sound basis to guide clinical decision and evaluate outcomes for ongoing assessment and quality assurance.

## CONCLUSION

Clinicians can anticipate encountering practice guidelines and protocols more in future practice (Callender 1999). Quality guidelines can aid in making health care more appropriate and effective. The impact of CPTs has already been realised in medical litigation process. However, this should not be the impetus for the CPT development on a clinical issue. CPTs encourage professionals to share and define practice and utilise research to meet common goals. The ethical issues to be

considered compare to those associated with conventional clinical decision making processes. CPTs can, in fact, assist practitioners by promoting practice patterns associated with good clinical judgement, research based interventions and improved patient outcome (Cole and Houston 1999). If appropriately prepared, implemented and reviewed CPTs offer the health care team a valuable opportunity to harness the best knowledge and practice.

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