

When is it ethically defensible for a medical practitioner to deviate from clinical practice guidelines?

Darius Lim Xiang Wen¹, Thirumoorthy Thamotharampillai^{2,3,4} *FRCP*

ABSTRACT

In modern medical practice, clinical practice guidelines (CPGs) have supported physicians with the development of treatment plans through concise recommendations based on evidence from medical research. Yet, the growing demographics of older patients with complexities and comorbidities mean that there is a group of real-world patients which CPGs may not adequately cover. These guidelines, which are primarily based on randomised controlled trials (RCTs), often have restrictive inclusion criteria and hence exclude such patients in their studies, resulting in recommendations that may not be in the patient's best interests. Hence, when treating such patients, physicians may be required to deviate from CPGs' recommendation to ensure the best patient outcome. This puts doctors in a difficult ethical dilemma: whether to follow the CPGs, deviate and risk being complained of, or not treat and refer the patient for palliative care. This article explores the ethical principles and considerations involved when physicians choose to deviate from CPGs in the interest of individualised patient care. The guiding philosophy when using CPGs should be that CPGs can guide the development of treatment plans, but are not meant to direct, dictate or restrict doctors in clinical decision-making.

Keywords: clinical practice guidelines, deviation from guidelines, ethics, evidence-based medicine, medical education, physician

INTRODUCTION

In today's world of rising average life expectancy, the world is populated by a significant number of older patients with complex illnesses and multiple comorbidities, such as chronic conditions like hypertension, diabetes, and cardiac and pulmonary diseases.¹ In a 2019 US study, the Agency for Healthcare Research and Quality found that 84.1% of all inpatient stays were complicated by 1 or more comorbidities, and half of these stays included 3 or more comorbidities.²

These growing demographics of older patients, individuals with comorbidities and persons with complex illnesses present a significant challenge to the use of clinical protocols based on clinical practice guidelines (CPGs). CPGs are heavily reliant on randomised controlled trials (RCTs), which tend to exclude individuals over a specified age and those with comorbidities.³ Hence, for these groups of patients who are left out of RCTs, adherence to CPGs' recommendations may not be in their best interests. This puts doctors in a difficult dilemma when facing such patients: whether to follow the CPGs, deviate and risk being complained of, or not treat and refer the patient for palliative care.

When doctors do deviate from CPGs, they may be called upon to justify the deviation before disciplinary tribunals or the courts, because society expects them to be accountable for their actions and decisions.⁴ In such situations, the justification for deviation may be grounded in well-established ethical principles that support the primacy of patient welfare in the face of guideline limitations.

At the same time, medical practitioners and users of CPGs must recognise the guiding principles of using CPGs. CPGs are defined as clinical recommendations derived from a systematic review of research evidence to assist clinical decision-making.⁵ While they serve as valuable tools to support the development of treatment plans, they are intended to guide, and not dictate, restrict or mandate clinical decision-making. When applying recommendations derived from CPGs, doctors are expected to exercise clinical judgement to tailor treatment modalities to the specific needs and circumstances of each patient.⁶ Hence, in complex or atypical clinical scenarios not adequately covered by CPGs, it is ethically permissible for doctors to deviate from CPGs, provided it is grounded in ethical principles, and supported by sound clinical reasoning and contextual factors beyond mere adherence to standardised protocols. Let us first understand the

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¹Yong Loo Lin School of Medicine, National University of Singapore, Singapore

²Office of Academic Development, Duke-NUS Medical School, Singapore

³Centre for Medical Ethics and Professionalism, Singapore Medical Association, Singapore

⁴Woodlands Health Clinical Ethics Committee, Singapore

Correspondence: Mr Darius Lim Xiang Wen, Yong Loo Lin School of Medicine, National University of Singapore, 10 Medical Dr, Singapore 117597.

Email: E1522323@u.nus.edu

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ethical principles and reasoning supporting deviation from CPGs.

Ethical principles to apply when considering deviation

(1) Principle of medical beneficence

The principle of medical beneficence refers to the physician's obligation to act in the patient's best interests, and this may at times require deviation from CPGs. This is particularly relevant for categories of patients for whom CPGs may not adequately cover: older patients, patients with comorbidities and persons with complex illnesses.⁶ The patient may not be responding to the recommended treatment, or has developed adverse reactions, allergies or hypersensitivity to the treatment.⁷ The patient may also have a comorbidity that does not support the use of recommended treatment, or have an uncommon variant of the condition such that there is a lack of experience with and expertise on the variant to be included in CPGs.⁸ In these situations, beneficence is compromised if the physician chooses to persist in following the CPG's recommendations when it is not clinically indicated to do so.

At the same time, a good physician who recommends a deviation needs to have balanced the potential benefit and risk of deviations through a careful risk-benefit analysis. Doctors can make use of clinical experience, evidence of benefit from anecdotal reports, or specific deviations that are accepted and practised by clinical colleagues with good evolving evidence of benefit to minimise risks and enable early mitigation. Consulting a colleague also precludes the possibility of personal bias. In other words, deviation from CPGs should be made in the patient's best interests.

(2) Respect for patient autonomy

Respecting the patient's autonomy involves prioritising the patient's wishes, preferences, specific needs and any special considerations. When a patient's wishes cannot be adequately fulfilled by CPGs, it becomes ethically justifiable to deviate from CPGs. Tailoring treatment plans to accommodate patient-specific factors not only upholds their right to participate meaningfully in healthcare decisions but also promotes patient-centred care.

Obtaining informed consent is a fundamental aspect of respecting the patient's autonomy, because physicians must be honest with their patients and empower them to make their own informed decisions about their health. In obtaining informed consent, information that should be shared with the patient includes anything that the patient is reasonably likely to have attached significance to, when arriving at the decision to give consent. This legal principle was

also established in the landmark case of *Montgomery v Lanarkshire Health Board* [2015], which established that a physician has a duty of care to warn patients of material risks and share information that a reasonable patient would find relevant and material.⁹ Information sharing, when the patient wants to or needs to know include the proposed treatment plan, deviations from established clinical guidelines, along with an explanation of the reasons for such deviations and any associated risks.

(3) Primacy of patient welfare

The principle of primacy of patient welfare is based on a fundamental obligation of the physician to prioritise the patient's well-being and interests above all other considerations.¹⁰ This includes providing patient-centred care that prioritises specific needs and any special considerations. To uphold this principle, the physician needs to have discretionary space, time, support and resources to enable the exercise of good clinical and ethical decisions. When patients' clinical situations are not adequately covered under CPGs, the physician exercises this discretion by deviating in order to uphold the primacy of the patient's welfare. In the absence of this discretionary space, the physician may not be able to treat the patient appropriately and may be forced to abandon the patient and refer the patient elsewhere.

The principle of primacy of patient welfare also requires the physician to uphold the principle of fidelity and non-abandonment. The principle of fidelity and non-abandonment obliges the doctor to continue to care for the patient despite the difficulties and complexity of the work, and to not abandon the patient because of potential medicolegal risks. Rigidly adhering to CPGs purely to avoid legal repercussions (defensive medicine) undermines the ethical responsibility to prioritise the patient's well-being as the first and paramount consideration.

Guiding principles when using CPGs

The guiding principle when using CPGs is that CPGs are supposed to guide doctors in developing treatment plans, but they are not supposed to dictate, direct or restrict doctors in their clinical judgement, or in deciding the treatment modality. CPGs were never intended to provide comprehensive management, supersede professional judgement, or serve as legal precedents.¹¹ Rather, CPGs simply reflect the best judgement of a multidisciplinary team of expert physicians and allied health professionals who have systematically reviewed and synthesised the best available scientific evidence for a specific clinical scenario.¹¹ Hence, physicians should use their professional judgement when applying guidelines in

individualised patient care because good, evidence-based medical practice is a sum of the best research evidence, the patient's values and preferences, and the physician's clinical experience and expertise.¹² Physicians applying CPGs should remain flexible and adaptable to accommodate individual patient circumstances, comorbidities and preferences, because CPGs should be used to support patient-centred care that prioritises their needs, values and preferences.

Limitation of CPGs

The first limitation of CPGs is that recommendations may be unsuitable or erroneous, because different CPGs are developed using different methodologies and rely on evidence of differing quality. In some cases, the quality of the underlying evidence may be misrepresented, particularly since few CPGs have their full methodology published or have their guidelines submitted for external review.¹³ For example, in a US study pertaining to neurosurgical guidelines, researchers found that only 8.9% of evidence used were from well-designed RCTs or meta-analysis of RCTs, even though 24.4% of CPGs were graded as having been based on such Level 1 evidence.¹⁴ Hence, physicians may use the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument to evaluate the quality of guidelines. AGREE II characterises the quality of guidelines by evaluating the explicit scope and purpose (having clear objectives and target audience), stakeholder involvement (inclusion of individuals from all relevant professional groups), rigour of development, clarity of presentation, applicability and editorial independence (free from bias).¹⁵

Second, authors of CPGs who have financial ties to pharmaceutical companies may have undue bias due to a conflict of interest. In Japan, a study of urological guidelines found that 88.6% of authors had received financial incentives.¹⁶ Such incentives can influence guideline development and lead authors to recommend products or treatments they are affiliated with, rather than basing recommendations strictly on the best available research evidence.

Third, CPG's recommendations may be inaccurate if they are outdated and do not reflect the best current practices. To remain relevant and reliable, CPGs should be regularly reviewed and updated with new research evidence. At the same time, physicians have a professional responsibility to maintain clinical competence by staying up to date with the latest advancement in their field.¹³

CONCLUSION

Modern medical practice invariably involves elderly patients with multiple comorbidities and persons with complicated illnesses that make standard CPG recommendations unsuitable. When managing such

cases, clinicians are often required to deviate from CPGs' recommendations in order to uphold the principle of primacy of the patient's welfare. While such deviations may later be scrutinised in disciplinary proceedings or the court, they are not inherently unethical, provided that they are grounded in careful consideration of the patient's unique clinical circumstances with appropriate clinical judgement. The physician's commitment to the primacy of patient welfare is the fundamental ethical basis for all clinical decisions including deviations from standardised guidelines.

The guiding philosophy when using CPGs is that they are intended to guide, not dictate or restrict decision-making. Their primary purpose is to offer medical recommendations based on the best available research evidence. However, good medical practice must go beyond evidence and guidelines alone. It must integrate the patient's unique clinical characteristics and circumstances with the physician's professional experience, expertise and judgement to deliver patient-centred care.

Ethics statement

Not applicable given no participant involvement.

Declaration

The authors declare there are no affiliations with or involvement in any organisation or entity with any financial interest in the subject matter or materials discussed in this manuscript. The authors declare that generative AI (ChatGPT) was used to correct grammar and spelling. All sentences checked using generative AI have been edited by the authors before submission.

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