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Clinical Practice Guidelines as Part of Evidence-Based Medicine and Related Legal Implications: An Analysis

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Abstract—'Evidence-based medicine (EBM)' describes the application of the best available scientific evidence in the treatment of patients. It is defined by the integration of best available research evidence with clinical expertise and patient values. A product of EBM is 'clinical practice guidelines (CPG).' Such guidelines include statements, informed by a systematic review of evidence, that outline recommendations to optimise patient care. The main focus of the present research is the use of clinical guidelines as a 'standard of care' in the context of medical malpractice litigation. Major challenges associated with the use of clinical guidelines include the multiplicity of guidelines for a given condition, and multimorbidity in patients (whereas guidelines typically address a single condition). Rigid adherence to CPG may also contribute to the erosion of professional autonomy and the development of 'cookbook medicine'. Furthermore, concerning liability, the developers of such guidelines may be held indirectly liable, alongside professional caregivers, for harm incurred by patients. This paper adopts a qualitative methodology, including descriptive and critical analysis of the literature and case laws. Its findings recognise the potential of clinical guidelines to promote uniformity provided that 'competent medical practice', based on relevance, reliability, and authenticity, can overcome the issue of multiplicity. However, strict adherence to such guidelines is associated with the erosion of professional autonomy and professional judgement.

Index Terms— Evidence-Based Medicine; Jurisprudence; Patient Rights; Personal Autonomy; Physician-Patient Relations; Practice Guidelines as Topic; Professional Competence; Professional Practice.

I. INTRODUCTION

The use of evidence-based medicine (EBM) provides the assurance that a medical professional is using the 'best available scientific evidence' in the interest of safety, effectiveness, and cost in the process of treating patients [1]. Prior to the conception of EBM, clinical practice was driven by expert advice dependent on the rationale and experience of individual clinicians [2]. This newer, evidence-based approach has helped to close the gap between evidence and real-world clinical practice [2]. Put simply, it has drawn a line between opinion-based and evidence-based medicine, demonstrating that the provision of health care is not founded solely on personal opinions, but also relies on proof.

This paper investigates the relationship between EBM and the law. What link exists between the two? In the context of EBM, the law focuses primarily on the concept of 'standard of care'. This imposes a duty on the courts to establish the yardsticks for medical liability while carefully defining 'competent medical practice'. This paper aims to provide a clear idea of the legal implications of EBM, as well as the related judicial opinions on the subject. This concerns not only the matter of 'standard of care', but also the freedom of medical professionals to exercise autonomy in clinical decision-making. The paper's qualitative methodology involves a descriptive and critical analysis of secondary sources of law, incorporating medical literature to support the legal contentions. Alongside this, it also includes analysis of landmark court judgments

II. EBM AND CLINICAL PRACTICE GUIDELINES

EBM results from the integration of the best available research evidence with clinical expertise and patient values, where such best evidence is extracted from patient-centered clinical research [3]. It can be a product of different types of evidence, including that obtained via meta-analysis of several randomised controlled research (RCR) studies OR one RCR OR one quasi experimental study; evidence from one quasi experimental study; evidence from non-experimental studies; or evidence from experts and clinical practice [4]. While the provision of patient care is now supported by scientific evidence, recently-developed technologies have altered the purpose and direction of EBM [5]. Critics

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of the adoption of EBM in clinical practice have labeled it 'cookbook medicine'; however, a number of arguments have been presented against this.

'Cookbook medicine' is simply strict adherence to clinical practice guidelines (CPG). Not withstanding arguments against slavish adherence to clinical guidelines and restricted professional autonomy, CPG have been lauded as an effective means of improving health care [6]. As expounded by Kitchener (2002), the use of clinical guidelines further ensures that professionals are aware of the most effective and cost-effective treatments, and can avoid outdated practices [6].

As discussed above, EBM is a product of research. CPG, in turn a product of EBM, are more formally defined as statements that include recommendations for the optimisation of patient care, informed by a systematic review of evidence as well as an assessment of the benefits and risks of alternative care options [7]. The emergence of CPG has introduced to the healthcare system such potential benefits as improved quality of care and improved health outcomes, while those guidelines that specifically promote interventions of proven benefit have contributed to reduced morbidity and mortality [8]. Nonetheless, there remain certain limitations of CPG, among which multiplicity, multimorbidity, conflicts of interest, patient involvement, and quality indicators are of prominent concern [9]. Of these, multiplicity and multimorbidity deserve special focus.

The field of medicine is characterised by an array of professional organisations, all centered on their own specialties and sub-specialties [10]. As endorsed by Field and Lohr (1992), CPG are the organised efforts of professional societies, which emerge as an authoritative source of communication to professionals about appropriate care. 'Multiplicity' describes the multiple information sources encountered by the medical professional who is faced with this diverse range of CPG. 'Multimorbidity', meanwhile, is the co-occurrence of two or more chronic conditions in one patient, where management focused on one condition may result in harmful consequences for another condition [11]. The issue of multimorbidity is directly related to the application of CPG, as the latter typically focus on a single condition. As propounded by Scherer (2010), multimorbidity emerges as the next frontier in EBM.

Franco et al (2020) report that multiplicity causes despair among professionals, with different guidelines from various sources issued by government agencies, scientific societies, and other internationally recognised institutions. These give rise to multiple different recommendations, causing confusion among professionals as to which should guide their clinical decision-making [9]. The same authors also identified multimorbidity as a limitation of CPG. In contrast to reality, where patients often suffer a number of disease conditions simultaneously, a CPG generally addresses a single condition. In this context, the professional must apply different guidelines covering an array of recommendations, which ultimately may have negative repercussions for the patient's health.

III. CAN CLINICAL PRACTICE GUIDELINES SERVE AS A STANDARD OF CARE?

'Standard of care' is essentially a legal term referring to the 'degree of care a prudent or a reasonable person would exercise under the circumstances' [12]. 'Duty of care', meanwhile, is the responsibility vested in a healthcare provider to deliver treatment meeting established standards while ensuring patient safety and well-being [13]. It functions to empower patients, foster trust in the healthcare system, and engender legal and ethical foundations [13]. A breach of 'standard of care' may be established with evidence of a duty of care, negligent conduct, and a causal link between the act and the injury. The focus of this paper is whether CPG can serve as standard of care.

Well-developed, medically appropriate guidelines are considered best sources, with potentially compelling benefits. Finder (2002) identified two such benefits [14], the first being the potential of scientifically reliable guidelines to improve medical practice by reducing misdiagnosis and inappropriate treatment decisions. In addition, guidelines can aid in maintaining consistency, thereby improving clinical outcomes while promoting efficiency in the healthcare system. The second benefit, as identified by Finder, relates to the process of medical malpractice litigation, whereby plaintiffs can rely on guidelines to establish the negligence of defendants. Nonetheless, in the absence of correct and sensible interpretation of guidelines, facilitating their practical use, any such benefits become irrelevant. In this context, it is worth considering the judicial opinions of the courts in different states, as

they relate to the role of clinical guidelines. The view held by common law is that it is the responsibility of the doctor to be aware of the guidelines embodying the minimum standard of care as required by law [15].

The Australian case, Gould v. South Western Sydney Local Health District [16], considered the negligent treatment of an injured boy that led to the amputation of the boy's finger. The hospital, in this case, argued on the basis that the provider had acted in accordance with the 'therapeutic guidelines'. However, the court did not find in favour of the hospital's argument, instead deciding the case based on expert opinion. Gould's case is a clear example that the courts do not rely completely on guidelines to determine the standard of care to be exercised by medical professionals. In this case, the hospital's defence was based on Section 50 of the Civil Liability Act 2002 (NSW). Section 50(1) of that Act specifically addresses the standard of care for professionals and states that a 'person practising a profession does not incur a liability in negligence arising from the provision of a professional service, if it is established that the professional acted in a manner that was widely accepted in Australia by peer professional opinion as competent practice'. The hospital argued that the treatment was 'widely accepted in Australia by peer professional opinion as competent professional practice'. However, the court denied the argument and relied on section 50(2) of the Act, which provides for the 'irrational exception'. Under this exception, the court held that the peer professional opinion in this instance was irrational and could be interpreted as illogical, unreasonable, or based on irrelevant considerations.

In the Australian case Ellis v. East Metropolitan Health Service [17], the court considered the negligent performance, by an obstetrician, of a traumatic vacuum extraction. As a consequence of the procedure, the child was left neurologically and physically impaired. In this case, the court upheld the validity of guidelines and opined that the standard of care should be in accord with the guidelines issued by the Royal College of Obstetricians and Gynaecologists, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and King Edward Memorial Hospital. It was the opinion of the court that the obstetrician's conduct amounted to negligence, as he had attempted an instrumental delivery in the ward in contravention of the relevant guidelines. Thus, the court's approach towards CPG in this case was more prescriptive, taking the view that the Obstetrics & Gynaecology guidelines set the conditions under which an instrumental delivery should be performed or abandoned. Furthermore, this decision demonstrated to medical professionals that appropriate adherence to accepted guidelines serves as persuasive evidence that a provider's actions are in conformity with 'widely held professional opinion'.

IV. MULTIPLICITY OF GUIDELINES AND 'WIDELY ACCEPTED PRACTICE'

To eliminate controversy arising from the issue of multiplicity, the concept of 'widely accepted practice' has been argued and analysed in courts. This implies the existence of different professional opinions, and the 'widely accepted' professional opinion is not necessarily universally accepted [18]. In the Ellis case, 'widely accepted practice' was defined as that 'representing competent medical practice', which precludes practice that is 'eccentric or idiosyncratic or experimental or alternative'. The ruling of this case emphasised the possible coexistence of two or more schools of thought or treatment options, all of which represent competent medical practice.

The term 'practice' is evolutionary in nature, and the weight given to clinical guidelines depends on several factors. As expounded by Rosoff (2001), for a CPG to be accepted as a legal standard in medical malpractice litigation, evidence of customary practice should be established [19]. This is the 'professional community standard'. Accordingly, adherence to certain professional standards is considered a defence in medical malpractice litigation, and a medical professional who fails to conform to a guideline risks the inference that their performance does not meet the accepted standards.

The acceptance of guidelines as standard of care is interpreted differently in different jurisdictions around the world. In the USA, a moderate stance is taken on the subject; however, certain evidentiary obstacles remain in this regard. Thus, for a guideline to be accepted as evidence in a trial, the proponent must be able to prove its 'relevance', 'reliability' and 'authenticity' [20]. Relevance is confirmed if the guideline in question can be shown to address the particular medical procedure at the center of the litigation [20, p.512]. This must be established through medical expert testimony to facilitate the proof of relevance of a pre-established standard to the case. In parallel to this, reliability presupposes the admissibility of the guideline as evidence in a

court of law [20, p.512]. Alongside relevance and reliability, authenticity also plays a prominent role, requiring the party offering the evidence to demonstrate that such evidence is what they claim it to be [20, p.515].

V. PROFESSIONAL AUTONOMY AND SLAVISH ADHERENCE

The existence of CPG generally establishes a link between medicine and law. Correct adherence to guidelines reduces malpractice litigation, leaving professionals less susceptible to liability [21]. Clinical guidelines are positively recognised as a mode of implementing science to improve the quality and effectiveness of health services [22]; however, their recognition as an aspect of 'standard of care' creates a requirement for sufficient justification in the event of deviation from such guidelines [23]. Damen et al. (2003), in discussing the benefits of clinical guidelines, caution that they are not a substitute for sound medical judgement. This points to the fact that CPG cannot be considered the 'sole determinant' of 'standard of care'. However, does adherence to guidelines curtail professional autonomy?

Salvatore et al. (2018) recognise three main dimensions of 'autonomy' for a medical professional; namely, clinical freedom, social and economic freedom, and influence on organisational decisions [24]. Chief of these, clinical autonomy can be further elaborated as the freedom to provide patient care without being restricted or limited by organisational procedures and other controls [24]. A conflict arises between autonomy and guidelines, due to the latter's 'inflexibility'. It is the inflexible rules and guidelines applied in the scope of medical practice that contribute to the concept of 'cookbook medicine' [25]. The extent to which medical professionals must adhere to guidelines remains controversial, with proponents and opponents on both sides. One of the arguments against clinicians' use of guidelines is the risk of over-dependence [26]. Proponents of this argument view unnecessary dependence on guidelines as a negative clinical practice that creates a generation of professionals who lack confidence to make clinical decisions [26]. It has been said that the use of clinical guidelines in the process of treating patients creates two distinctive groups: wise men and fools. Although guidelines are considered a part of medical life, there is a difference between a professional who lacks a comprehensive understanding of a particular area of medicine but follows the guidelines, and a knowledgeable professional who does not follow guidelines slavishly [27].

Rigid adherence to clinical guidelines has been criticised from several angles. It can be considered an erosion of clinical judgment, converting medical practice to a task of 'mechanistic rule-following activity' [15]. Case law has clearly established the power of courts to reverse a guideline that is mechanistically applied. In the UK case, McFarlane v. Secretary of State for Scotland [28], a guideline issued by the Royal College of Ophthalmologists was taken into consideration, which empowered the Secretary of State for Transport in enforcing a minimum field of vision safe for driving. The case concerned the decision of the Secretary to revoke the plaintiff's driving license upon uncontested findings that the plaintiff's vision did not equate to the minimum recommended by the Royal College of Ophthalmologists. The sheriff contended that the authorities had 'simply followed the recommendation in the guidelines.' After hearing expert testimony, the court found that the plaintiff's vision defect was not of a nature that would not affect his driving ability, and reinstated his driving license. This view underscores the leeway provided by law for the development and application of flexible guidelines for the exercise of discretionary powers. However, the court held that the exercise of discretionary powers should not be tainted with 'rigidity'.

Concerns surrounding CPG are not limited to the matter of slavish adherence; they extend also to those instances where professionals feel that adherence would not support the best outcomes. The legal liability imposed on a professional for not adhering to guidelines is a matter of ethical concern, as is adherence to a guideline known by the professional to be sub-optimal [29]. Professional integrity is compromised when a practitioner's actions are contrary to what they determine to be the patient's best interest.

Another criticism of guidelines as standard of care points to over-reliance on expert opinion, which, according to the critics, compromises the objectivity and consistency of care. The concern is that guidelines are based on subjective expert opinions regarding the various clinical approaches to specific medical conditions [25]. Another facet of this criticism is the lack of, or variation in, transparency with regard to the development process of guidelines, which is a distinctly negative aspect [25].

The above discussion regarding slavish adherence to CPG underscores the importance of retaining professional autonomy and judgment. There is a valid argument for safeguarding the freedom of doctors to adapt treatment to the individual circumstances of patients and their medical histories. Not every option recommended by a clinical guideline is the best treatment option for all patients; an element of freedom is required for doctors to adapt a 'treatment choice'.

Further negative commentary focuses on poor-quality guidelines which often result from inadequate or conflicting evidence [30]. According to Lenzer (2013), the task of developing practice guidelines is complicated, often requiring the incorporation of conflicting opinions to promote a unified recommended approach.

VI. CLINICAL PRACTICE GUIDELINES AND CAUTION

While acknowledging the advantage of guidelines in promoting quality care, it has been recognised that CPG are still in the development stage, and scholars caution their use a foundation for litigation [31]. Furthermore, some versions of guidelines may prejudice patient expectations; accordingly, lay versions and flawed clinical guidelines are considered pernicious. Poorly structured guidelines have the effect of misleading or confusing patients and disrupting the doctor-patient relationship. They also have a significant negative effect on public policy for patients [32]. In addition, flawed clinical guidelines can compromise quality of care and pose potential harm due to inaccurate scientific information and clinical advice [32]. They are also associated with the promotion of ineffective and wasteful interventions.

VII. LIABILITY OF GUIDELINE DEVELOPERS

This section addresses the risk of indirect liability for guideline developers in the event that a guideline causes harm to a patient. For such liability to be imposed, certain criteria must be fulfilled. According to Jutras (1993), for the developer to be held liable, the guideline should recommend an unreasonable course of action or eliminate the consideration of a reasonable course of action that ought to have been considered [33]. This clearly emphasises that the developer's negligence in drafting, updating, or implementing the guideline can be invoked only if it can be proved that reasonable care has not been exercised. The second point propounded by Jutras relates to the causal link between a flawed guideline and the harm incurred: it must be proved that the guideline is necessarily the cause of harm, and that the harm would not have occurred without its involvement [33].

This paper supports Jutras' views concerning the liability of guideline developers. The recognition of such liability is essential in the current era of scientific and technological advancement in medicine. The guidance given to a medical professional regarding the selection of tools, techniques, and treatment plans should be correct, precise, and comprehensible. Nonetheless, the developers' accountability is secondary in nature, arising when negligence cannot be attributed to the professional and the erroneous conduct is a consequence of the guideline itself. Accordingly, the courts are entrusted to analyse the substance of guidelines. In the modern world, with CPG receiving greater publicity through digitisation, the possibility of varying interpretations is higher. Thus, it is the responsibility of the courts to adopt the correct and logical interpretation.

VIII. CONCLUSION

Clinical practice guidelines are a product of EBM, which promotes the use of scientific evidence in treating patients. Benefits of CPG include improved quality of care, providing health systems with positive health outcomes. Nonetheless, the limitations of such guidelines cannot be ignored, and there is significant concern around the use of clinical guidelines as standard of care. This has its advantages, such as scientific reliability and the promotion of uniform practice, or 'widely accepted practice', which denotes treatment or diagnosis supported by the consensus of the professional community but not necessarily universally accepted.

In the context of litigation, the courts' have taken varying views on the application of CPG. In the Ellis case, an obstetrician's liability was upheld on the grounds that he did not adhere to CPG. Conversely, in the case of McFarlane, the court found in favour of the doctor's discretion, rather than strict adherence to CPG. While CPG may serve as a legal standard in medical malpractice litigation, not all guidelines are considered evidentially significant. The evidentiary value of CPG is measured according to three key yardsticks, namely relevance, reliability, and authenticity. In the case of

flawed or misleading guidelines, the risk of liability extends also to guideline developers, whose liability can be established with proof of lack of reasonable care in drafting, updating, and implementing guidelines.

There remain numerous arguments for and against clinical guidelines; nonetheless, due to their inherent inflexibility, slavish adherence to guidelines results in the erosion of professional autonomy and contributes to 'cookbook medicine', 'resembling a mechanistic rule following activity'. Over-dependence on CPG curtails the professional discretion of doctors to act in the best interest of patients. Furthermore, complications such as multiplicity and multimorbidity should also be considered in association with clinical guidelines. Doctors should exercise due caution when adhering to CPG, ensuring that guidelines are not flawed or poorly constructed so as to prejudice patient-centered care.

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