

臨床指引在法庭上的地位與應用

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實例

- 2008/09/23 21:42
- 病患因車禍送至台中某醫院就醫，經X光檢查發現被害人受有左側胸部多處肋骨骨折、左側大腿骨折及顴骨骨折等之傷害。、、、同日23:54許，血壓又降為87/32毫米汞柱，胸管僅流出約500CC的血水，顯無法解釋當時偏低的血壓（74/46毫米汞柱），被告原應注意應依高級外傷救命術（ATLS）臨床指引規範，此時應再做同樣初步評估的步驟，以尋求尚未發覺之休克原因、、、
- 刑事起訴案由：業務過失致人於死罪

臨床指引是什麼？

臨床診療指引 Clinical Practice Guideline, CPG

- 以有系統的方式發展出來的陳述，用以協助醫師及病人，在特定的臨床情況下決定何為適當之醫療照護。
- Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."

Clinical Practice Guidelines

- 運用系統性回顧臨床證據以及衡量另類照護方式的好壞處，來優質化病人照護的包括建議在內的陳述。
- Statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options

Guidelines We Can Trust, Institute of Medicine 2011

Trustworthy CPGs

- Be based on a **systematic review** of the existing evidence
- Be developed by a knowledgeable, multidisciplinary **panel of experts and representatives** from key affected groups
- Consider important **patient subgroups and patient preferences**, as appropriate
- Be based on an **explicit and transparent process** that minimizes distortions, biases, and conflicts of interest
- Provide a clear explanation of the **logical relationships** between **alternative care options and health outcomes**, and provide ratings of both **the quality of evidence** and **the strength of recommendations**
- Be **reconsidered and revised as appropriate** when important new evidence warrants modifications of recommendations.

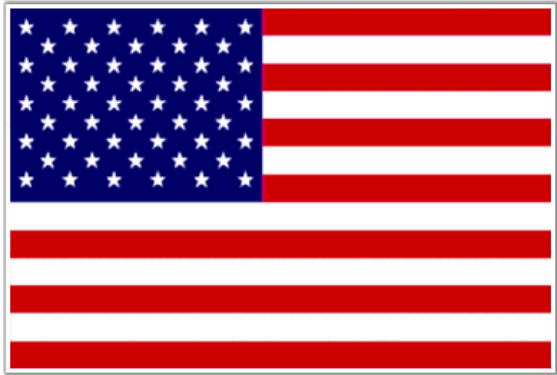
Report Brief, Institute of Medicine, 2011

Standards for Trustworthy CPGs

- Establishing **transparency**
- Management of **conflict of interest**
- Guideline **development group composition**
- Clinical practice guideline–**systematic review** intersection
- Establishing **evidence foundations** for and rating strength of recommendations
- **Articulation** of recommendations
- **External review**
- **Updating**

Report Brief, Institute of Medicine, 2011

臨床指引在法庭上的出現



The Role of Practice Guidelines in Medical Malpractice Litigation

- 1923 case Frye v. United States
- the **admissibility** of **scientific evidence** required “**general acceptance**” in the scientific community, leading to the possible use of medical treatises under this condition of admissibility.

TK Mackey and BA Liang, Virtual Mentor
(American Medical Association Journal of Ethics)
2011

Clinical guidelines and the law: advice, guidance or regulation?

- The **mandatory effects** of guidelines can be gauged, to some extent, by the **sanctions** that apply in the event of **non-compliance**.
- US courts have ruled that guideline **developers** can be held **liable** for **faulty guidelines**, and that **doctors cannot pass off** their **liability** by **claiming** that **adherence to guidelines has corrupted clinical judgement**.
- Protocols and guidelines **provide the courts** with **examples of clinical standards** across a wide range of medical practice.
- However, **adherence to guidelines** has **not automatically** been equated with **reasonable practice**, and the **courts** seem **unlikely** to **follow** the standards enunciated in clinical guidelines **without critically evaluating** their authority, flexibility and scope of application.

[Hurwitz B, J Eval Clin Pract.](#) 1995 Sep;1(1):49-60

2011 Federal Rules of Evidence, specifically Rule 702

- A **witness** who is qualified as an **expert** by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
 - **(a)** the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
 - **(b)** the testimony is based on **sufficient facts** or **data**;
 - **(c)** the testimony is the **product** of **reliable principles** and **methods**; and
 - **(d)** the expert has **reliably applied** the principles and methods to the facts of the case.

Cases U.S. (1)

- CPG admissibility as an affirmative defense in malpractice suits
- Frakes v Cardiology Consultants, PC, 1997 Tenn App 597
- A cardiologist examined a patient complaining of chest pain and ordered a chest x-ray, resting EKG, and an exercise treadmill EKG. The physician then concluded that the patient did not require hospital admission. The patient died at home 3 hours later from cardiopulmonary arrest.

TK Mackey and BA Liang, Virtual Mentor (American Medical Association Journal of Ethics) 2011

Cases U.S. (2)

- CPG admissibility as an affirmative defense in malpractice suits
- Moore v Baker, 989 F2d 1129 (11th Cir 1993)
- A plaintiff who was suffering from a partial blockage of her left common carotid artery underwent carotid endarterectomy and later suffered a stroke, resulting in permanent brain damage and disability. The plaintiff filed a malpractice suit, alleging that the physician had violated state informed consent law by not informing her of the availability of chelation therapy as an alternative treatment

TK Mackey and BA Liang, Virtual Mentor (American Medical Association Journal of Ethics) 2011

Maine's Medical Liability Demonstration Project

- In the 1990s
- 20 practice guidelines in four specialties (anesthesiology, emergency medicine, obstetrics and gynecology, and radiology)
- **Exculpatory ONLY, NOT inculpatory**
- **No significant reductions in defensive medicine practices or in malpractice claims**
- **Mandated CPGs** may unduly compel physicians to comply with such guidelines due to liability considerations even if they conflict with clinical judgment, potentially leading to adverse outcomes for patients

Mello MM. Univ of Penn Law Review. 2001;149(3):645- 710.



Bolam test

- ***Bolam v Friern Hospital Management Committee*** [1957] 1 WLR 582
- Muscle relaxant, restraint, warning about risks in electroconvulsive therapy.
- "If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent"
- Jury in favour of the defendant hospital.

Bolitho judgment

- ***Bolitho v. City and Hackney Health Authority*** [1996] 4 All ER 771
- Doctor not coming to intubate
- 'It is **not enough** for a defendant to **call a number of doctors** to say that what he had done or not done was in accord with accepted clinical practice. It is necessary for the judge to consider that evidence and [to] decide whether that **clinical practice** puts that patient **unnecessarily at risk**'
- Doctor would not intubate (not breach of duty) had he come to attend.

CPGs in courts in the UK

Because written guidelines cannot be cross examined they are classed as **hearsay evidence**, so British courts cannot decide what is reasonable and proper care simply by referring to them.

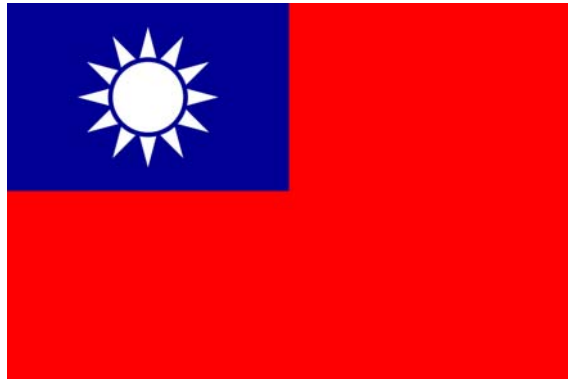
BRIAN HURWITZ, 1995 BMJ

Table 3. Lawyers' Observed Uses of Guidelines in Clinical Negligence Litigation (n = 110)[†]

In clinical negligence cases you have handled as a lawyer during the last 3 years, how often have guidelines ...	%			
	Very often	Often	Sometimes	Never
<i>Parties using</i>				
Been used in a case by you or your team?	0.9	16.5	71.6	11.0
Been used in a case by the opposing side?	0.9	7.5	71.0	20.6
<i>Purpose of use</i>				
Been used (by anyone in the case) to help prove that a doctor did <i>not</i> meet the standard of care?	0.9	10.9	75.5	12.7
Been used (by anyone in the case) to help prove that a doctor <i>did</i> meet the standard of care?	0.9	10.3	67.3	21.5
<i>Method of use</i>				
Been cited in a medical expert's report?	2.7	21.8	69.1	6.4
Been cited by a witness during his/her testimony in court?	0.9	4.7	43.0	51.4
Been cited by a lawyer in the direct examination of a witness?	1.0	1.9	46.7	50.5
Been cited by a lawyer during cross-examination of a witness?	0.9	2.8	48.6	47.7
<i>Effect of use</i>				
Influenced the court to decide in favour of the claimant?	0.9	5.0	39.0	56.0
Influenced the court to decide in favour of the defendant?	1.0	3.0	44.0	52.0

Percentages may not be rounded off to 100.

A Samanta et al,
Medical Law Review,
2006



刑事訴訟法

第 159 條

被告以外之人於審判外之言詞或書面陳述，除法律有規定者外，不得作為證據。

前項規定，於第一百六十一條第二項之情形及法院以簡式審判程序或簡易判決處刑者，不適用之。其關於羈押、搜索、鑑定留置、許可、證據保全及其他依法所為強制處分之審查，亦同。

刑事訴訟法

第 159-4 條

除前三條之情形外，下列文書亦得為證據：
一、除顯有不可信之情況外，公務員職務上製作之紀錄文書、證明文書。
二、除顯有不可信之情況外，從事業務之人於業務上或通常業務過程所須製作之紀錄文書、證明文書。
三、除前二款之情形外，其他於可信之特別情況下所製作之文書。

最高法院案例

- 刑事訴訟
- 103,台上,142 裁判日期 1030430
- 未依高級外傷救命術（ATLS）臨床指引急救休克病患
- 二審以臨床醫師確實未依臨床指引實施急救，但就其專業能力而言，已為適當、合理之處置。
- 三審認為二審判決未違反法律，駁回檢察官上訴。

民事訴訟

- 最高法院102年度台上字第2216號判決
- 「證人就其非親身經歷或在場聞見，而係自他人之處所得知或所瞭解之事，在審判上所作之供述，即所謂之傳聞證據，民事訴訟法並無明文禁止之規定，即尚不能排除其證據能力。至其證明力（證據力或證據價值），則不妨參酌其他之佐證及是否賦予對造當事人程序保障之情形（如是否命證人具結及給予他造質問之機會等），依自由心證判斷之，以利於追求真實之發現。」

民事訴訟

- 最高法院102年度台上字第192號判決
- 「民事訴訟之傳聞證人（間接證人或徵憑證人）所為之證詞，本非絕無證據能力，其與直接證人陳述親自見聞之證言比較，祇是證據力之強弱而已，尚非不得採為證據方法之使用，法院對該傳聞證據之價值，仍可由法官憑其知識、能力、經驗等依自由心證予以認定之。」

民事訴訟

- 最高法院另於103年度台上字第2216號判決
- 「證人李王OO、李OO係分別證述聽聞被上訴人或李OO告知系爭建物為被上訴人出資興建等語，顯屬傳聞證據，應不具證據能力，原審逕採為系爭建物屬被上訴人所有之佐證，於法亦有未合。」

民事訴訟法

第 222 條

法院為判決時，應斟酌全辯論意旨及調查證據之結果，依自由心證判斷事實之真偽。但別有規定者，不在此限。

當事人已證明受有損害而不能證明其數額或證明顯有重大困難者，法院應審酌一切情況，依所得心證定其數額。

法院依自由心證判斷事實之真偽，不得違背論理及經驗法則。

得心證之理由，應記明於判決。

責任原因判定

就醫療事故中醫方**責任原因**之判定而言，不宜將實證醫學數據本身從基於該數據所發展出之**臨床指引**或醫療常規中抽離出來，單獨作為過失判斷之基礎，毋寧綜合考量**臨床指引**或醫療常規制定之合理性與目的性、以及病患受損權益之重要性等因素而為判斷。

[吳志正，國立臺灣大學法學論叢／第 40 卷 第 1 期／139-208 頁 2011.03](#)

損害範圍及責任範圍之計算

- 毋寧正視該數值之減損其實只是反映出病患身體權與健康權受損害程度之參考，於責任範圍上損害之數額算定時再予以**參酌**。
- 算定責任範圍上損害時，無論是客觀賠償範圍與單位期間賠償數額、總期間、或是履行利益賠償數額之估算上，均應參酌**實證醫學數據**為之。

[吳志正，國立臺灣大學法學論叢／第 40 卷 第 1 期／139-208 頁 2011.03](#)

因果關係判斷

以實證醫學數據作為「抽象因果關係」並藉以判定「個案因果關係」時，應**力求二者間情節變數之一致**，方能獲致正確之論證結果。

[吳志正，國立臺灣大學法學論叢／第 40 卷 第 1 期／139-208 頁 2011.03](#)

最高法院民事案例

- 民事訴訟
- 裁判字號
 - 105,台上,136
- 案由
 - 請求損害賠償
- 主文
 - 原判決關於命上訴人為給付及該訴訟費用部分廢棄，發回台灣高等法院台中分院。
- 案情
 - 未依高級外傷救命術（ATLS）臨床指引急救休克病患
- 理由
 - 是否應減輕上訴人之賠償責任，始符公平原則？

- 鑑定意見形同完全拘束承審法官之心證活動，凌駕司法審判而儼然成為主宰訴訟成敗之「證據之王」，不容忽視。

吳俊穎 實證法學：醫療糾紛的全國性實證研究 2014

結論

- 在美國及英國法庭上，臨床指引原則上被視為傳聞證據，因此不能直接成為法庭證據，僅能藉由專家證人或律師間詰問攻防而間接成為裁判依據。
- 在我國，不論刑事訴訟或民事訴訟，都沒有排除將臨床指引直接以傳聞證據適用之可能，但是實務上不論照護標準的衡量還是因果關係的鑑定，都會經由衛生福利部醫事審議委員會內的醫事鑑定小組所做成的醫療糾紛鑑定報告而成為法庭參考的一部分。由於在絕大多數的情況之下，鑑定的結果就是法院裁判的結果，因此如果鑑定報告中有引用臨床指引，則法院裁判中有將其視為傳聞證據的趨勢。

結論

- 不論國內國外，臨床指引在法庭上有越來越多被引用的趨勢。
- 不論直接或間接引用，品質良好的臨床指引才有被法庭引用的地位與價值。

Hairlines



