NCD
SYMPOSIUM

Importance of complying to Clinical Practice Guidelines Legal liabilities

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CLINCAL GUIDELINES

"*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***"

(the US Institute of Medicine, 2011)

- developed based on evidence-based medicine
- influence and regulate clinical activity
- gain ascendancy in medical practice
- unfortunately tend to drive patient care to a more defensive medicine
- used more often in malpractice litigations

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CLINCAL GUIDELINES - **BENEFITS** and **LIMITATIONS**

BENEFITS

- provide a robust management strategy of care for patients
- maintain consistency and quality in healthcare
- reduce of unwarranted practice variation
- enhance translation of research into practice
- improve healthcare quality and safety
- help educate and train health care professionals
- help patients make informed decisions.

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CLINCAL GUIDELINES - **BENEFITS** and **LIMITATIONS**

LIMITATIONS

- inflexibility of guidelines and generalization in the way their recommendations are applied
  - ► care is not tailored to patients' personal circumstances and medical history
  - ► what is best for patients overall, as recommended in guidelines, may be inappropriate for individuals
  - ► can harm the patient !

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CLINCAL GUIDELINES - **BENEFITS** and **LIMITATIONS**

LIMITATIONS

- inflexibility of guidelines and generalization in the way their recommendations are applied
- low quality in the development process
  - the primary data used for developing guidelines is not evidence based, is lacking, is not updated
  - the way the guidelines recommendations are written, can mislead or can lead to misinterpretations
  - recommendations are influenced by the opinions and clinical experience and composition of the guideline development group
    - susceptibility to bias relating to the nature of evidence, misconceptions and personal recollections dependent upon the beliefs of the developers
      - ◄ may affect the validity of the guidelines.
  - lack of time, resources and skills of the development group, in the process of gathering and scrutinising every last piece of evidence
  - patients' needs may not be the only priority in the development process
    - practices, that are suboptimal from the patient's perspective, may be recommended to help control costs, serve societal needs, or protect special interests (ex.: those of doctors, of risk managers, of politics, of pharmaceutical industry etc).
    - the promotion of miss-developed guidelines by practices, payers, or healthcare systems can encourage, if not institutionalise, the delivery of ineffective, harmful, or wasteful interventions.

Those that stand to benefit from guidelines - patients, healthcare professionals, the healthcare system - may all be harmed !

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More patients are suing then ever before !

Between 1990 and 1998 in UK - the rate of new claims per thousand finished consultant episodes rose by 72%

In 1999–2000, the British National Health System (NHS) received about 10 000 new claims and cleared 9600.

At the end of March 2000 there were an estimated 23 000 claims outstanding, with an estimated net present value of £2.6 billion (up from £1.3 billion in 1996–97).

In addition, there is an estimated liability of a further £1.3 billion where negligent episodes are likely to have occurred but claims have not yet been received

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Developing of CLINICAL GUIDELINES

- look more as a reaction / as a preparedness to justify, if necessary, the clinical practice in a court of law
  - ◄ health litigation oriented environment
  - ► **MAJOR RISC** – developing a defensive medicine
- developed in such a way, that to be considered no guilty of negligence if the medical staff acts/acted in accordance with a practice accepted, as proper by a responsible body of professionals, skilled in that particular art

"... Putting it the other way round, a doctor is not negligent if is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view." (UK, Bolam test)

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Developing of CLINICAL GUIDELINES

The British Department of Health has highlighted a number of legal considerations to take into account when developing Clinical Guidelines:

(1) the objectives for the Clinical Guidelines need to be clear and clearly stated…otherwise their subsequent legal standing will be affected

(2) the intended use and applicability of Clinical Guidelines should be spelt out clearly, in the introduction

(3) the guidelines must make clear for whom they are intended / developed

(4) Clinical Guidelines should be periodically evaluated

(5) those that no longer reflect best practice might become actionable and developers need to incorporate specific statements about their validity and review procedure

(5) they should be constructed in such a way that allows deviation and does not suffocate initiative that might bring further improvements

(6) the development of Clinical Guidelines must involve all the relevant professionals, with consultation of the patient representatives

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CLINCAL GUIDELINES …to be taken in account that

- are and will be increasingly used in court
- courts are showing increasing willingness to follow national guidelines when determining the legal standard of care
  - used as examples of clinical standards across a wide range of medical practice (ex.: deciding actions in negligence)
- is an increasing tendency for claimants to argue that divergence from guidelines is *prima facie* evidence of negligence

In a recent case, the court assigned greater weight to guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) than to expert witnesses when determining whether it was acceptable to perform a vacuum extraction delivery before the cervix was fully dilated.

In explaining his decision, the judge said…

> "***protocols such as these appear to me to give valuable guidance as to what is and what is not acceptable practice***"

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CLINCAL GUIDELINES …to be taken in account that

- are not accorded unchallengeable status - the importance the law attaches mainly to customary practice means that atypical or bizarre guidelines are unlikely to be accepted as embodying a legally required standard of clinical care

- there are situations when their use in court has been limited in setting the standard of care in cases of medical litigation

  …in UK, the traditional test in law for the standard of care is the Bolam test, which measures the standard of care against what is done, rather than what ought to be done in medical practice, sustained by a expert witness testimony in court

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CLINCAL GUIDELINES limited use in court - example

In 2022, a case was brought to the court - the improper dosage Gentamicin administration, in ICU, to an old patient with complex pathology *(Gentamicin is known to have several serious side effects so it has to be monitored in terms of dosage levels and periods)*

It was not argued that using Gentamicin was negligent, the issue was whether the dose given (400mg) was appropriate.

At the trial, various guidelines on the prescription of Gentamicin were discussed including those from:

- the National Institute for Health and Care Excellence (NICE)
- the British National Formulary (BNF) and
- the in-house developed protocol for its ICU team.

The dose given, that did not comply with NICE or BNF guidance, was given in accordance with the internal protocol for ICU patients.

The claimant's case was that the internal protocol was not in line with the NICE guidelines and therefore …

(1)the physician was negligent, not for following the internal protocol, but in failing to follow the NICE guidelines, and

(2)the hospital was negligent in operating its current guidelines.

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CLINCAL GUIDELINES limited use in court - example

Court concluded that:

- the clinician, although he had not complied with national guidelines, **had not been negligent** and **neither had the hospital**, even though national guidelines had not been followed
  - ◄ this did not mean that reliance on a local trust / hospital / department guideline or protocol, that did not accord with national guidance, would be a defense to a claim of negligence.

- the **departure from a national guideline was not *prima facie** evidence of negligence**

  but there <u>needed to be a good reason in the particular circumstances</u>… and the court felt that was the case here.

**based on the first impression; accepted as correct until proved otherwise*

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CLINCAL GUIDELINES limited use in court - example

Summary of the key points from the court judgment:

- the clinician had not blindly applied the hospital's own protocols but had deployed a 'mixed clinical strategy' and made a clinical judgment, when balancing the need to manage a potentially life-threatening infection with patient's renal function
- the clinical decision he made was supported by a responsible body of ICU clinicians, even though it did not follow the broader national guidelines
- was the clinical judgment exercised and reasonable in all the circumstances ?

◄ ARGUMENT used in court = the previous lower dose had failed and the clinician needed to take urgent action to try and control the rising infection – the risk from that infection outweighed the uncertain risk of ototoxicity from the Gentamicin

◄ **ESSENTIAL** is that clinical judgment, made in such circumstances, would be supported by a responsible body of clinicians

Importance of complying to Clinical Practice Guidelines
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Compliance with **CLINCAL GUIDELINES** can protect health care workers from liability in such circumstances?

- **Do physicians who deviate from guidelines place themselves at increased risk of being found liable in negligence ?**

NO and **YES**

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Compliance with **CLINCAL GUIDELINES** can protect health care workers from liability in such circumstances ?

► **Do physicians who deviate from guidelines place themselves at increased risk of being found liable in negligence ?**

NO and **YES**

study commissioned by the Netherlands Health Council indicated that, guidelines had been followed in only 55% of clinical decisions

◄ **WHY ?** …the reason lies in the inability of guidelines to address all the uncertainties inherent in clinical practice

- non compliance would not automatically mean negligence if

  (1) there were good reasons to depart from the guidance

  (2) that course of action would be supported by other clinicians in a similar scenario

  (3) there are specific circumstances that certain clinicians regularly encounter with good reason to depart from national guidelines

  (4) what local or even specific department guidelines say may be a relevant consideration

- adherence to guidelines has not automatically been equated with reasonable practice …

  ► the courts seem unlikely to follow the standards enunciated in clinical guidelines without critically evaluating their authority, flexibility and scope of application

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Compliance with **CLINCAL GUIDELINES** can protect health care workers from liability in such circumstances ?

- if a particular clinical guideline would normally have been used in a treatment regime but was not applied in the instant case, a reasonable explanation is called for.

  ►the reasons of any diversion from the **Clinical Guideline/Procedure should be documented carefully** to show that the treatment decision was "reasonable and responsible"…. failure to do so could lead to a successful claim for negligence.

- even the most rational and carefully **documented decision** to depart from professional guidance will expose a physician to risk of litigation if patient consent is inadequate.

  ◄ **no consent / inadequate consent = risks liability of mallpractice or negligence !**

"the doctor is... under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments"

(Lords Kerr and Reid, *Montgomery case,* 2015)

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Compliance with **CLINCAL GUIDELINES** can protect health care workers from liability in such circumstances ?

- **Do physicians who respect *"ad literam"* clinical guidelines, do not deviate from holly words, are to be protected in court ?**

YES and **NO**

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Compliance with **CLINCAL GUIDELINES** can protect health care workers from liability in such circumstances ?

► **Do physicians who respect *"ad literam"* clinical guidelines, do not deviate from holly words, are to be protected in court ?**

YES and **NO**

- doctors should not be lulled into a sense of false security by following strictly the clinical guidelines

  ◄ medical practice on autopilot should never take place - in the law's view, the professional autonomy of the practitioner always remains.

- a physician could be negligent if a patient's condition contraindicated the application of the guideline but it was still applied nevertheless

  ► many guidelines carry the warning that professional judgement / clinical autonomy is not suspended when they are used

CLINCAL GUIDELINES "…are not magic bullets", "...not railway lines", "not cookbook medicine"

◄ enthusiasm for them must be tempered with clinical caution

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C O N C L U S I O N S

- the existence of a **clinical guidelines** does not mean that clinicians cannot adopt alternative strategies as long as :
  - it is in the interest of the patient
  - dose not harm the patient and
  - patient is informed
- **clinical guidelines** need to be interpreted and applied in a way that is clinically appropriate
- **clinical guidelines** represent just one option for improving the overall quality of clinical care
- clinicians must act in a way that is “reasonable and responsible” regardless of whether or not they are following clinical guidelines
  - treatment may meet the necessary standard of care even if it diverges from clinical guidelines
  - treatment may be negligent even if clinical guidelines are followed perfectly

◄ **the courts remain the final arbiter on what is “reasonable and responsible”**

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CONCLUSIONS

- adherence to guidelines may not exonerate the defendant
- any diversion from the Clinical Guideline/Procedure so should be documented carefully to show that the treatment decision was "reasonable and responsible"
- any medical decision, mainly diversions from the Clinical Guideline/Procedure, should be explained adequately to the patient, checked if patient really / fully understood them and obtain consent
- all documented variances of practice should be evaluated/analysed and used for the improvement of the practice
    - clinical guideline must be reviewed regularly, updated according reviewed/validated data
    - hospital's protocols must be reviewed by a hospital multidisciplinary committee, which would include the clinical risk manager that has to spot any possible legal issues, such as consent or capacity.
    - previous versions of clinical guidelines are to be dated, kept, and filed, to have the possibility to identify the prevailing range of opinion about acceptable practice from perhaps 10 or more years previously a malpractice suspicion case

CLINICAL GUIDELINES

will become increasingly important over the coming years

as a result of the

major developments in EU countries patient rights laws and law practice in medical cases

Thank you