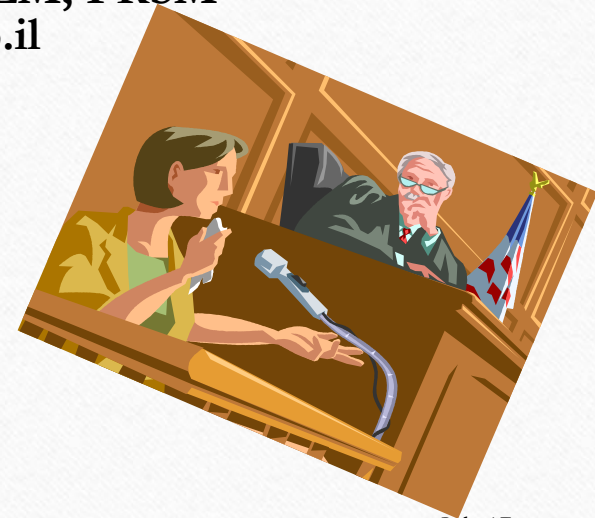


The Impact of Clinical Guidelines on Expert Testimony in Medical Malpractice Litigation



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What Are Clinical Guidelines (CG) ?

- Clinical guidelines are set as protocols that are used as a tool to indicate the standard of care at the time of treatment.
- CG are linked to evidence and are meant to facilitate good medical practice based on Evidence Based Medicine (EBM).
- Clinicians, policy makers, and patients see guidelines as a tool for improving health services and decisions about treatments.

Why Do we need Clinical Guidelines?



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ANALYSIS

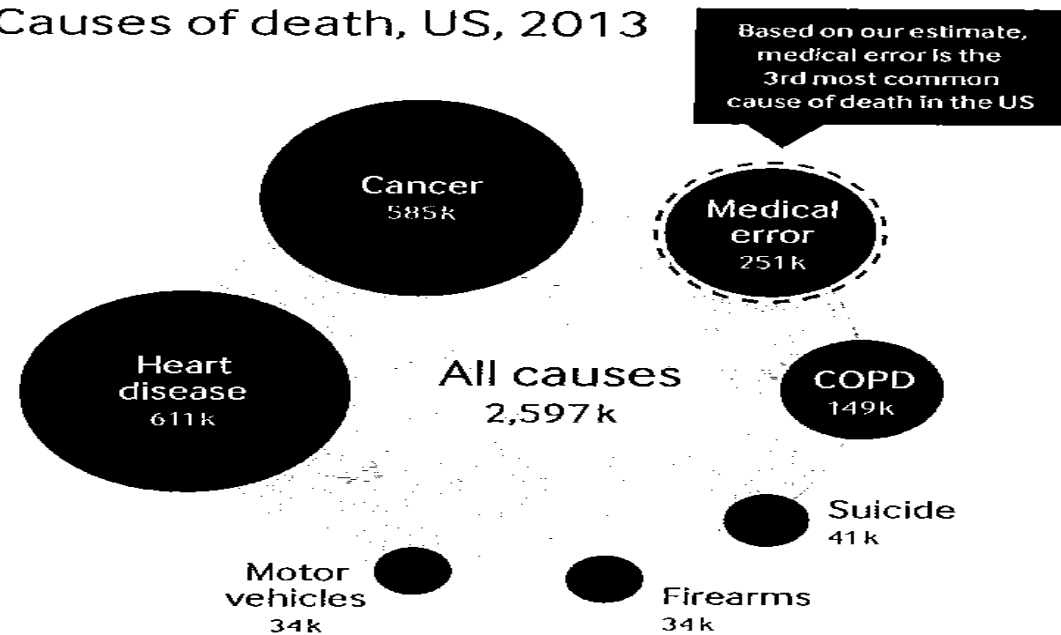


Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

Figures

Causes of death, US, 2013



However, we're not even counting this - medical error is not recorded on US death certificates

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Data source:
http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

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Fig 1 Most common causes of death in the United States, 2013²

The importance of clinical trials

- ◆ The increase of medical information has led to a flow of clinical guidelines in almost all medical fields.
- ◆ CG aim to They can be used as a tool for assessment of the questionable conduct.
- ◆ CG have legal implications that defferd from Nations and Professional bodies.
- ◆ French legislation went further – practice by guidelines was made mandatory. The 1999 UK Health act indicated a similar intent.
- ◆ The drawback too many GL of different authorities that cause confusion.

BMJ criticizes the attempt to legalize CG (UK)

"Any doctor not fulfilling the standards and quality of care in the appropriate treatment that are set out in these Clinical Guidelines, will have this taken into account if, for any reason, consideration of their performance in this clinical area is undertaken." Department of Health, 1999.

Evidence based guidance arguably offers the most trustworthy advice available to clinicians concerning medical management. Their authoritative status may explain why clinical guidelines are sometimes prefaced with vague warnings that link guideline compliance with accountability. But how authoritative can guidelines actually be, and does evidence based guidance entirely supplant clinical discretion?

The legal status of evidence based guidance is examined, including whether guidelines from the National Institute for Clinical Excellence (NICE) should be understood to carry special importance in helping courts to decide whether or not allegations of negligence should be upheld.

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Too many CG can cause confusion



The problem of Obesity

Overweight and obesity are the **fifth leading risk for global deaths**. At least 2.8 million adults die each year as a result of being overweight or obese. 44% of the diabetes burden, 23% of the ischemic heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity.

Handling the problem of Obesity

- Obesity continues to be a major public health problem in the western World.
- In the United States more than one third of adults considered obese as defined by a body mass index (BMI) $\geq 30 \text{ kg/m}^2$
- Obesity has been associated with an increased hazard ratio for all-cause mortality as well as significant medical and psychological co-morbidity.
- Obesity is not only a chronic medical condition but should be regarded as a bona fide disease state.

FDA CG for treatment of Obesity



Surgery for Obesity and Related Diseases 9 (2013) 159–191

SURGERY FOR OBESITY
AND RELATED DISEASES

AACE/TOS/ASMBS Guidelines

Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient—2013 Update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery[☆]

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[☆]These Guidelines are endorsed by the European Association for the Study of Obesity (EASO), International Association for the Study of Obesity (IASO), International Society for the Perioperative Care of the Obese Patient (ISPCOP), Society American Gastrointestinal Endoscopic Surgeons (SAGES), American College of Surgery (ACS), and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

By mutual agreement among the authors and editors of their respective journals, this work is being published jointly in *Surgery for Obesity and Related Diseases* 2013, <http://dx.doi.org/10.1016/j.soard.2012.12.010>; *Obesity* 2013, <http://dx.doi.org/10.1002/oby.20461>; and *Endocrine Practice* 2013, <http://dx.doi.org/10.4158/EP.12437.GL>.

Abbreviations: AACE, American Association of Clinical Endocrinologists; ACS, American College of Surgery; ASMBS, American Association of Metabolic and Bariatric Surgery; BAC, blood alcohol content; BED, binge eating disorder; BEL, best evidence level; BMI, body mass index; BPD-DS, biliopancreatic diversion with duodenal switch; CCS, clinical case series; CK, creatine kinase; CPAP, continuous positive airway pressure; CPG, clinical practice guidelines; CSS, cross-sectional study; CT, computerized tomography; CVD, cardiovascular disease; DCCP, diabetes comprehensive care plan; DVT, deep venous thrombosis; DXA, dual-energy x-ray absorptiometry; EL, evidence level; EN, enteral nutrition; FDA, U.S. Food and Drug Administration; GERD, gastrointestinal reflux disease; HDL, high-density lipoprotein; ICU, intensive care unit; LABS, longitudinal assessment of bariatric surgery; LAGB, laparoscopic adjustable gastric band; LDL, low-density lipoprotein; LSG, laparoscopic sleeve gastrectomy; MI, myocardial infarction; MNRCT, meta-analysis of nonrandomized controlled trials; MRCT, meta-analysis of randomized controlled trials; NAFLD, nonalcoholic fatty liver disease; NASH, nonalcoholic steatohepatitis; NE, no evidence; NIH, National Institutes of Health; OHS, obesity hypoventilation syndrome; OSA, obstructive sleep apnea; OS-MRS, obesity surgery mortality risk score; PTH, parathyroid hormone; PCOS, polycystic ovary syndrome; PCS, prospective cohort study; PE, pulmonary embolism; PN, parenteral nutrition; PPI, proton pump inhibitor; RCT, randomized controlled trial; RML, rhabdomyolysis; RYGB, Roux-en-Y gastric bypass; SCR, single case report; SG, sleeve gastrectomy; SOS, Swedish Obesity Subjects; SS, surveillance survey; T2D, type 2 diabetes mellitus; TOS, The Obesity Society; TSH, thyroid-stimulating hormone; UGI, upper gastrointestinal; VTE, venous thromboembolism.

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Israeli MoH CG for Bariatric Surgery for Obese Patients

- Israeli Ministry of Health followed WHO and Published CG for treating Obesity
- Obesity is a significant health concern due to high prevalence and health risk
- Obesity and overweight are defined clinically using the Body Mass Index BMI
- BMI is the most common measure for relative weight in Adults therefore CG specify the indications necessary for treating **Obesity, i.e. $40 < \text{BMI}$**
- CG also specify indications counter indications & Preparations for **Bariatric Surgery**. CG also require **psychiatric evaluation of patient before Surgery**.
- CG indicate that post Operative follow up and treatment will take place at the Medical institution that can treat and report any complications after surgery.

The case of Mrs. M.C

- Mrs. M.C was 50 yr., overweight and suffered from depression after the death of her mother. Her BMI was measured at different times was less than 40
-
- Mrs. M.C was offered a Bariatric Surgery. She had agreed believing that losing weight will solve her problem. She wasn't seen by a psychiatrist according to CG indications.
 - After the Operation M.C suffered infection that caused a complication of Splenic Abscess and was treated at a different hospital than operated her.
 - Mrs. M.C was treated in a different approach that was handled by the operating hospital as proven in 2 case reports. She died from sepsis after a long struggle.
 - Her death could have been avoided.

Case report of Bariatric Sugary Complications

59 (10) 1.77

Obesity Facts
The International Journal of Obesity

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Case Report

Splenic Abscess after Sleeve Gastrectomy: A Report of Two Cases

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Key Words
Splenic abscess • Laparoscopic sleeve gastrectomy • Morbid obesity • Splenectomy

Abstract
Objective: Partial demarcation and infarction of the upper pole of the spleen is not a rare occurrence after laparoscopic sleeve gastrectomy (LSG). However, development of an abscess in the absence of leakage is extremely rare. **Case Reports:** We present herein two unusual case reports of splenic abscess in patients following LSG. Copyright © 2012 S. Karger GmbH, Freiburg

Introduction
Laparoscopic sleeve gastrectomy (LSG) is rapidly gaining momentum in bariatric surgery. Partial demarcation and infarction of the upper pole of the spleen following LSG is not uncommon and has been previously reported [1, 2]. One of the steps in LSG is mobilization of the fundus including the division of the short gastric vessels (SGVs). In the vast majority of patients, it has no clinical relevance. On the other hand, formation of splenic abscess is an extremely rare consequence that has been never described before. Its rarity and the nonspecific clinical presentation could make the diagnosis difficult and could be easily confused with leakage and subdiaphragmatic abscess. We present herein two cases of splenic abscess after LSG managed by surgical intervention.

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Case study of Splenic Abscess

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Proving Medical Evidence in court

- The writing of an expert opinion for legal purposes is a art in which the expert tries to influence the outcome of the proceedings.
-
- The expert opinion should be supported by medical records and data collected according to Evidence Based Medicine (EBM) rules and rely on medical literature and studies published in scientific text books and journals.
 - In many jurisdictions guidelines can serve the court as a source of sound information, provided they are the product of a recognized professional body, and proven to bear no relation to a body which may have interests in the delivery of healthcare.

Bias of expert opinions in the legal process

- Any expert opinion is influenced by unconscious or cognitive bias of the expert that could influence the outcome, particularly the interests of the parties.
- Therefore, contractual relations between the interested party and an expert create a built-in conflict of interests between expert's loyalty to a party and his professional duty to maintain objectivity.
- This multiple relationship raises questions concerning the weight that should be given to CG in medical cases as an important tool and the weight given to an expert witness's testimony that don't comply with clinical trial guidelines.

How should the court measure Expert witness testimony that doesn't comply with clinical trial guidelines?

-
- ◆ The multiple relationship raises questions concerning the "standard of care" required Medical Malpractice cases.
 - ◆ Should the standard of care set by expert witness's testimony or by Clinical guidelines?
 - ◆ The clash between expert witness testimony and clinical guidelines concerning the required "standard of care" in Medical Malpractice case law raises question in all medical fields where clinical guidelines are regulated by government and institutions.

The Expert Opinions in the Case of Mrs. M.C

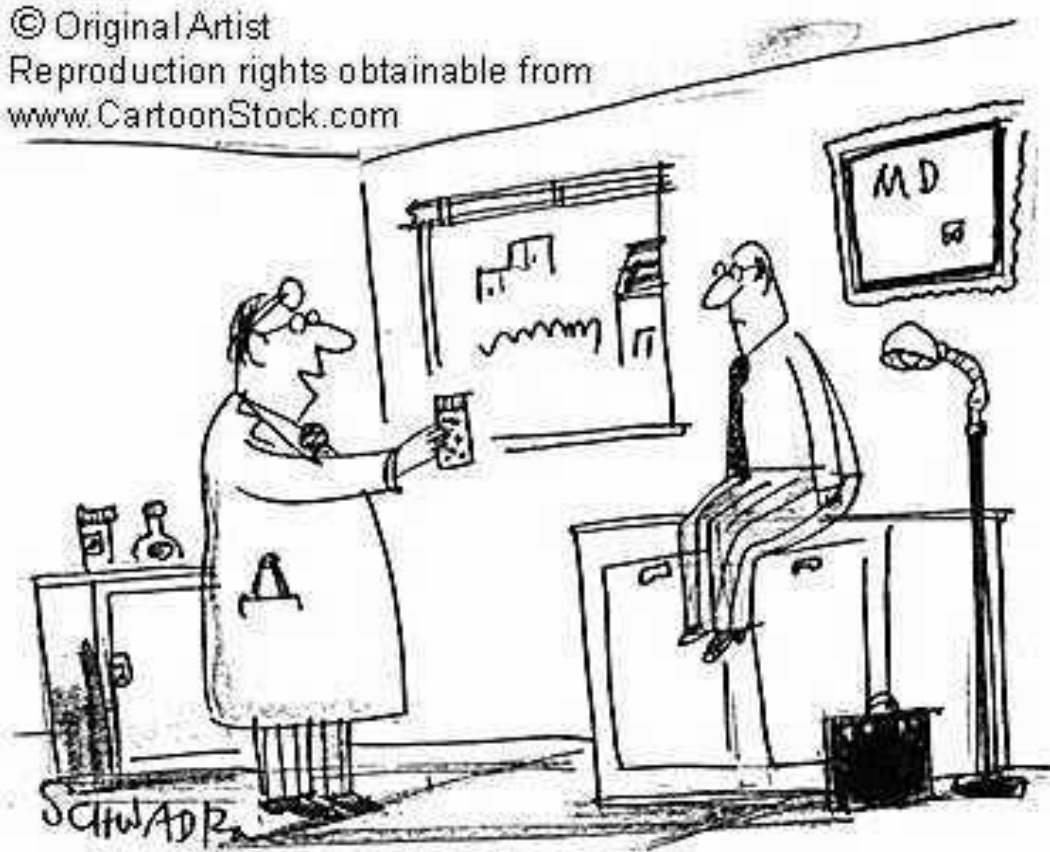
- ◆ Our office represented the estate in the case of M.C
-
- ◆ Expert on behalf of Plaintiff (the Estate) and Defendant (Hospital) argued if there was Malpractice in indications for surgery and post operative treatment. There was no dispute over causation.
 - ◆ Expert on behalf of Plaintiff argued based on CG that the post operative treatment wasn't according to reasonable standard of care.
 - ◆ We have argued that CG are used as a tool to prove standard of care and any clash between Expert opinion and CG the guidelines should prevail.

Clinical guidelines as a "golden standard"

- ◆ The content of a guideline is based on a systematic review of Clinical evidence. i.e. evidence based medicine (EBM)
- ◆ The guidelines are meant to assist the medical clinician to practice good medicine as a "golden standard" of the particular procedure.
- ◆ Courts have already accepted the introduction of practice guidelines by expert witnesses as EBM of the standard of certain traditional medical malpractice cases.
- ◆ If courts accept the introduction of CG as evidence approved by a medical authority they can substitute expert opinion.

The art of the expert witness

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"WE'VE COME UP WITH A NEW DRUG TO COMBAT 'GREED',
BUT IT'S \$90 PER PILL."

Thank You

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