The Standard of Care: A Very Sharp Double-edged Sword
In an era of high medical costs and technical advances, we seem to want it all...quality and cost savings...and Standards of Care are being used to achieve these dual goals...without much success...
Vocabulary

- Standards of Care and Practice Guidelines
- Cost – Effectiveness
- Normative Care and Ethical Standards
Standards of Care and Practice Guidelines

**Standards of Care** are based on the quality of the data, rigor of the methods used, and whether the finding is replicable…

- Data is ranked from the “gold standard” double blind prospective trial, the “meta-analysis”, retrospective analysis, cross-sectional data, epidemiologic data… down to anecdotal/case history and Expert Opinion

- *In the ideal*, Standards represent the best scientific evidence presented clearly and without ambiguity, devoid of moral or ethical judgment and conflict
Some argue that Standards of Care are the antithesis of modern medicine, (1) outdated by the time they are released, (2) limited in scope even with carefully done studies due to the nature of human research, (3) in conflict with the art of medicine and thus impractical and ignored, and (4) counter to the recent scientific advances in genetics, epigenetics and pharmacogenetics.

In short, an idea whose time has passed.

For Example See Willens JACC Cardiovasc Imaging 2013: 30% cardiologists to not follow ACC use-criteria for stress echocardiography.
Notable Quotes

“Like the inhabitants of Lake Wobegon, few of our patients are the “average patient” as derived by cross-sectional analysis.” Brian Mandell “From The Editor” Clevel Clin J of Med (June 2013)

“Because quality improvement efforts focus on increasing physician adherence to guidelines and reward physicians for clinical processes rather than high quality care…the message to physicians is guideline adherence rather than individualized care is best.” Lin and Matlock JAMA Intern Med (April 2013)

“Evidence based guidelines are analogous to movies based on a true story…a surrogate for quality…” Chen JAMA Intern Med (April 2013)
“Cost Effective”

Cost Effective: (1) the cost of a treatment is known; (2) treatments more than a certain amount are not cost-effective; (3) cost effectiveness should be a significant factor used to allocate care in a resource-poor or resource-limited situation.

Current Conventional Definition: $50,000 per life year saved…comes from the Medicare cost of hemodialysis in 1982 ($192,000 adjusted for inflation).

The definition is not based on clinical evidence or on normative/ethical/moral grounds…an economic term.

See Peter Ubel “What is the Price of Life and Why Doesn’t It Increase at the Rate of Inflation” Arch Intern Med 163:1637-1641 (July 28, 2003)
“Normative”

Normative has several possible meanings depending on the context in which the word is used... and is determined by moral, religious, ethical and legal norms...

What is “normal” or “agreed-upon” standards of behavior, or “public” values... community mores
Community Mores

“mores” (Webster’s 1991): “folkways of central importance accepted without question and embodying the fundamental moral views of a social group”

- Mores are values broadly held and can be a composite of religious, moral, ethical and situational values
- Notice: “…of a social group”
The Community of Medical Care

- In the social group we call Medicine, we...
- Do not practice “below the standard of care”
- Try not to waste money, to practice “cost efficiently”
- Follow professional ethical principles of practice in the way we handle the three essential areas that motivate all human behavior: money, sex and power
- In doing so, we follow professional mores within our group
Medical Ethics

- Are Standards of Care Ethical?
- Are Ethical Standards the near equivalent of Standards of Care?

Ethicist John Richard Neuhaus was highly critical of recent trends in Medical Ethics: “Thousands of medical ethicists and bioethicists, as they are called, professionally guide the unthinkable on its passage through the debatable on the way to becoming the justifiable until it is finally established as unexceptionable.”
Is the acceptance of what is legal therefore ethical?

Prior to *Roe v Wade* (1973) abortion was unethical...

Following the change in the “Code” more than 40% of physicians said the AMA was no longer their “social group”
Guidelines and Standards of Care…

What Are They Good For?
Guidelines and Standards of Care

- According to the IOM, 285 organizations have established 2400 clinical guidelines for the treatment of virtually every known disease state...
- Examples include the American Diabetes Association, American College of Cardiology, American Heart Association, American Cancer Society, American Lipid Society, American College of Obstetrics and Gynecology...
- Guidelines are written for numerous reasons based on varying levels of evidence... only 104 (4%) of Guidelines are based in large part on Level 1 evidence (prospective double blind trials)
Common Professional Uses of Standards of Care and Guidelines

- Clinical guidelines based on multiple prospective trials (the favored 104 by the IOM) and clinical practice can conflict with subsequent studies…

- For example: Ray et al Arch Intern Med, June 2010) concluded that statins do not help patients without known CAD

- On occasion, guidelines are published in the absence of evidence, based entirely on professional and expert opinion in areas where there are “gaps in the guidelines or areas where there aren’t or never will be a randomized trial.”

- See Avins “When Clinical Practice Guidelines Meet the Black Box” Arch Intern Med, June 2010; Russo et al J. Am. Coll. Cardiol (March 26, 2013) re “appropriate use criteria for implantable cardioverter defibrillator and cardiac resynchronization therapy”, developed by a consensus committee
Guidelines and Standards of Care

One of the criticisms of standards has been the level of commercial influence (e.g. from pharmaceutical companies and device manufacturers)

Members of the committees have irreconcilable conflicts of interest thru research grants and consultant fees (note the CME requirements for this program)

To a degree a desire to get the best recommendations, but is it misguided?

See “In Guidelines We Cannot Trust” Shaneyfelt Arch Intern Med 21:1633 (Nov 26, 2012)
Common Professional Uses of Practice Guidelines


- Clinical guidance
- Increasing expertise among practitioners
- Answering complex clinical questions in controversial areas without clear studies
- Quality Assurance by hospitals, larger multispecialty groups, certifying agencies
- Licensure and Board Certification examinations
- Asserting a Organization’s Professional authority
Professional Uses of Clinical Practice Guidelines

An Example:

- ADA, ACC and AHA Standards of Care for Diabetic and other high-risk patients
- “LDL cholesterol should be treated with a statin to a value of less than 100mg/dl, ideally less than 70mg/dl”
- The basis of QA standards in managed care institutions, hospitals, IHS to improve care delivery and to change physician behavior, directly or indirectly
Professional Use of Clinical Practice Guidelines:
The Flaw


But surrogate outcomes have proven to be unreliable or imprecise time and time again…as VA-DT, ACCORD and ADVANCE have recently reminded us…
Professional Uses of Clinical Practice Guidelines

- However, there is something very reassuring about a statement like: “LDL cholesterol should be treated with a statin to a value of less than 100mg/dl, ideally less than 70mg/dl”
- “[S]urrogates offer clinicians and patients a sense of understanding by implying how treatments are supposed to work thereby facilitating a sense of mastery over the disease process. The underlying assumption is that biology is predictable…” Svensson *op cit* p 611
Professional Use of Clinical Practice Guidelines

- In addition:
  - Guidelines conflict with the recognition and use of pharmo-genetics...tailored therapy based on genetic and ethnic principles of both response and actual utility (outcomes)

The FDA Director for Drug Evaluation and Research, Dr. Janet Woodcock, said at the Personalized Medicine Coalition* Conference May 23, 2013:

Targeted personal therapy would “turn the clinical trial paradigm on its head…We are going to have to change the way drugs are developed.”

Personal Therapy: Who should receive a drug, at what dose and with what expected effects and side effects, determined by genetics or clinically observable characteristic

*A group of insurers, drug manufacturers, patient groups
“In high risk patients, LDL cholesterol should be treated with a statin to a value of less than 100mg/dl, ideally less than 70mg/dl”

…except when it should not be that low or when it does not need to be that low or when a patient has genetic or ethnic risks or benefits that preclude a statin or a low cholesterol…
Clinical Practice Guidelines

Other Uses:

- The Infectious Disease Society of America (IDSA) published guidelines for the diagnosis and treatment of Lyme Disease
- Sued by The International Lyme and Associated Disease Society (ILADS) for the economic damages experienced by their members when insurance companies stopped reimbursing certain types of care
Another Example:

- American Autism Society statement was used to charge a physician in Pennsylvania with criminal negligence the death of a pediatric patient treated with chelation therapy for autism.

- This despite the fact that over 10,000 autistic children are treated annually with chelation therapy, with many high profile advocates defending and promoting the therapy.
Clinical Practice Guidelines

- Yet Another Example:

- **Chelation therapy** for ASCVD and Cancer therapy has long been opposed by traditional allopathic medicine

- So…what do you do with the recent 10 year NIH Trial Access Chelation Therapy (TACT) that was published in *JAMA* (Lamas *et al* 309:1241-1250 2013) that showed an 18% improvement in composite ASCVD outcomes?

- Or the smaller study showing addition of **naturopathic medicine** to traditional allopathic medicine improved CV risk factors, based on Framingham criteria Seely *et al* *CMAJ* (May 2013)
The Political and Legal Use of Guidelines

- A few are based on highly contentious issues (such as abortion) or cost-control measures (such as Medicare spending at the end of life)
- Increasingly used in Federal criminal prosecutions (such as Medicare Fraud and Abuse Law) and State criminal prosecutions (such as Anti-Trust) in a movement that has been called “The Criminalization of Medicine”
The **Political and Legal Use** of Guidelines

- An example in Texas: Dr. Samuel DeMaio was accused August 2010 by the Texas Medical Licensure Board of “inappropriate” stinting of patients in 2008-2009 with less than 70% occlusion...

- Based on guidelines published in 2009 by the AHA and ACC, and despite the presence of great diversity of professional opinion...

- The charges focused on a handful of patients rather than his overall practice, which *was within reported common practice*
The Political and Legal Use of Guidelines

- For example: Data from The Canadian Cardiovascular Congress 2011 showed 4/10 Interventional Cardiologist in Canada used a “50% occlusion without symptoms” criteria for stints;
- Based on the AHA/ACC guidelines, in 2011, 12% of stints in the US were “inappropriate,” with an additional 38% “uncertain”...
The Political and Legal Use of Guidelines

- Dr. DeMaio’s care was settled by Mediation in December 2011... Without a finding of unnecessary or excessive care, and requiring a total of 30 hours of CME, most of which was outside his specialty

- The ACC and AHA changed the 2009 guidelines in September 2013 to replace the word “inappropriate” with “unusually appropriate” and “uncertain” with “may be appropriate”, adding an “extenuating circumstances” justification when anything other than “appropriate” criteria were used
The Political and Legal Use of Guidelines

“The term inappropriate caused such a visceral response...[the guidelines] were intended as recommendations to inform doctors decisions, not decrees...insurers and regulators misused the guidelines to challenge physician discretion.” Dr. Robert Hendel, Chairman ACC Guidelines Committee Bloomberg Report Oct 30, 2013
An Article…

Political/Legal Reasons

- Medicare and Medicaid reimbursement
- Medicare Fraud and Abuse enforcement
- DEA (Narcotic diversion) prosecution
- Medical Licensure supervision/discipline
- “Safe Harbors” for compliance (MI, MA, VE)
- Felony prosecution
- Tort law/Common Law (malpractice, family law)
- Federal/State funding
- Political debate (abortion, child abuse, vaccination policy, medical fertility, embryo adoption)
- Political Advocacy and Legislation
Medicare/Medicaid Reimbursement

- Non-Reimbursed “Preventable Complications” include:
  - Catheter associated Urinary Tract Infections
  - Falls and Trauma
  - Stage III and IV stasis ulcers
  - Manifestations of poor glycemic control
  - Pulmonary embolism or venous thrombosis associated with orthopedic procedures
  - Surgical site infections after CABG, orthopedic or bariatric surgery
  - Readmissions within two weeks for same or related problems
Medicare/Medicaid Reimbursement

- **Pulmonary embolism or venous thrombosis associated with orthopedic procedures:**
  Dr. Scott Flanders presented data on 20,794 patients in *Hospital Medicine* May 18, 2013 that hospitals with high rates of pharmacologic prophylaxis were more likely to have patients develop VTE than those with low rates: Low performance (55.5% use) = 0.99%, high performance (85.8% use) = 1.13%. Note also the disparity between guidelines by the American College of Chest Physicians and Centers for Medicare Services, the Agency for Healthcare Research and Quality, and the Joint Commission.

- **Readmissions within two weeks for same or related problems**

- **A major hospital complex on the Eastern seaboard is limiting admissions for certain high-risk patients to recoup losses for the across-the-board reductions in CMS payments due to higher than expected readmission rates**
Legal Uses of Guidelines

Additional Examples:

- ACOG (American College of Obstetrics and Gynecology) has developed a statement on Cerebral Palsy designed to both counter malpractice suits and to discipline physicians who testify against member physicians…

- ACOG also has a statement on abortion that requires abortion referral to meet the standard of care…used to sue physicians who did not refer for “wrongful life” in malpractice suits, leading to…
Political Uses

“Freedom of Conscience” …

- Bush Administration issued an Executive Order protecting physicians and hospitals who have “normative” reasons not to refer or provide abortion…

- Obama Administration overturned these Orders in March 2011 leaving the profession vulnerable

- Now, ObamaCare is forcing Catholic hospitals, physicians and Christian businesses to provide insurance that furthers abortion and contraception against First Amendment Protections, based in part on ACOG Standards of Care…nearly 40 pending cases…
Medicare Fraud and Abuse

A number of recent federal Medicare Fraud and Abuse cases have been based on internal DOJ Standards of Care developed with professional assistance . . .

“Providers should take heed that the days of simple medical malpractice claims as the sole recourse for substandard care are long gone . . . [C]hallenging the system on behalf of a patient is not worth the effort and the providers will just do what the system has chosen not to penalize . . . [T]he art of medicine is lost in the desire to force strict bureaucratic standards to reduce costs.” Hoffman and Schwartz “Penalizing Substandard Care: The Next Step in Combating Healthcare Fraud and Abuse” *The Health Lawyer* 22:1(April 2010
The Future Use of Standard of Care

- Maintenance of Licensure
- Socialized Medicine: A Federal and Private system based on payment and licensure
- Insurance/Federal payments will dictate care
- Beginning and End of Life issues will be impacted first… with cost a major driver
Standards of Care

- Do you recall the statement we began with?
- “In the ideal, Standards represent the best scientific evidence presented clearly and without ambiguity, devoid of moral or ethical judgment.”
- So… “How is that working for you?” Dr. Phil
Ending on a positive note…

- "Choosing Wisely" choosingwisely.com is a program funded and organized by the American Board of Internal Medicine (ABIM) Foundation
- Developed by 17 medical groups, recently published the 2013 version of a list of 140 tests and procedures that are overdone or misused
- Publicized by AARP, Consumer Reports, Leapfrog Group, Wikipedia and The National Partnership for Women and Families
QUESTIONS?