How Less Health Care Can Sometimes Be Better For You: Examples From Internal Medicine

Rita F. Redberg, MD, MSc, FACC, FAHA
University of California, San Francisco

Disclosures

- Editor, JAMA Internal Medicine
- Member, Medicare Payment Advisory Commission

Personal Influences

- Growing up in Brooklyn
- Working through college and med school
- John Eisenberg at Univ of Pennsylvania
- Living/studying in Great Britain – early 80’s
- RWJ Health Policy Fellow – 2003 - 4
Actual and Projected National Health Expenditures, Selected Years

Current Paradigms
- If some medical care is good, more care is better
- Newer technology is always better than older methods
- Getting a medical test can’t hurt
- Prevention is about getting the right test at the right time
  - Cancer screenings - PSA, colonoscopy
  - Cardiac screenings - CT, carotid ultrasound

What to do instead
- Prevention founded on lifestyle choices and public health measures
  - Diet, activity level, and not smoking
- Medical care needs to be: the right test/treatment for the right patient at the right time
- Almost all care has benefits AND risks
- If test/treatment has no known benefit, no risk is acceptable
Polypharmacy Prescriptions

- Investigating prescription practices of Central Nervous System Polypharmacy in 65+ patients
  - Using data from the 2004-2013 annual survey of office-based physicians, National Ambulatory Medical Care Survey
- Criteria for CNS polypharmacy: 3+ psychiatric medications
- Evidence of harm of polypharmacy


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Polypharmacy Results

- Central nervous system polypharmacy more than doubled in 2004-2013
- Polypharmacy increased for pain diagnosis, consistent with overall growth in opioid prescribing


Nonspecific & Inconsistent Recos

- Investigating specificity and consistency of recommendations for cancer surveillance after active treatment across guidelines
- Retrospective cross-sectional analysis
  - 41 national cancer guidelines
  - 9 cancer types

Results

- 83% (34) of guidelines contained ambiguous recommendations
  - Modality not discussed
  - No clear recommendation on modality
- 44% (18) recommended against at least 1 test
- 34% (14) guidelines included risk-based recommendations
- Fewer than 1 in 3 provided definitive stop time for surveillance testing

Improvement Recommendations

- Language should be unambiguous
- Include testing frequency with definitive start and stop times
- Tailor surveillance strategies to reduce recurrence risk
- Panels for survivorship guidelines should include all stakeholders
Intensive Care Overuse

- Intensive care unit (ICU) overuse can harm patients through costs and unnecessary care without more benefits.
- Study of 808 medical ICU admissions indicates that over 50% of patients were either too well or too sick to benefit.
- Almost 65% of total ICU days consisted of "discretionary monitoring", low benefit, or had non-ICU alternatives.

Impact of New Guidelines

- Data from National Health Interview Survey Cancer Control Module.
- Percentage of people screened for lung cancer with CT scans more than 1.5 higher in 2015 than in 2010.
- Rates of CT scans increased in never-smokers and low-risk smokers.
- Spillover raises overuse concerns.
Background & Study

- US Preventive Services Task Force recommends annual lung cancer screening with low-dose computed tomography for current and former heavy smokers aged 55-80 years

- 2106 Veterans Health Administration patients, mostly men, screened for lung cancer screening after meeting criteria

Testing Lung Cancer Screening

- Consequences of implementing proactive, population-based, comprehensive lung cancer screening program
  - Implementation is complex and challenging
  - Most patients have findings requiring follow-up
  - Few patients have early stages cancer
Pre-Study Concerns

- Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)
  - Low confidence (2.22 on a 1-5 scale) in lung cancer screening benefits weight by harms
  - Low confidence that harms of screening would be minimized and
  - High confidence (4.67) that evidence gaps remain

Study Confirms: Harms Outweigh Benefits

- For every 1000 people screened
  - 10 will be diagnosed with early-stage lung cancer (potentially curable)
  - 5 with advanced-stage lung cancer (incurable)
  - 20 will undergo unnecessary invasive procedures (bronchoscopy and thoracotomy)
  - 550 will experience unnecessary alarm and repeated CT scanning (with its associated irradiation)
Study Goal & Method

- Systematic review of studies that quantitatively assessed clinicians’ expectations of benefits & harms of treatment, test, or screening test
- Screened 8,166 articles. Reviewed 48 articles referencing 13,011 clinicians
- Studies published between 1981 and 2015 from 17 countries
- Assessed 58 outcomes

Clinicians’ Benefit & Harm Assessment

- 50+% participants overestimated benefit for 7 outcomes (32% of outcomes) and underestimated benefit for 2 outcomes (9%)
- Most participants correctly estimated harm only for 9 outcomes (13%), underestimated harm for 20 outcomes (34%), and overestimated harm for 3 outcomes (5%)

What Does This Tell Us?

- Clinicians...
  - Rarely accurately estimate harms & benefits
  - Tend to overestimate benefits and underestimate harms
  - Face challenging wealth of evidence for interventions from hundreds of journals
  - Might fall victim to “therapeutic illusion”
- Possible solutions include
  - Shared decision making
  - Up-to-date, concise, and clear summaries of intervention benefits and harms
Treating patient expectations

Patient Expectations

- 30+ studies analyzed by Hoffman and Del Mar in Less is More publication
- Assess patients’ understanding of benefits and harms of treatment
- 22 out of 34 studies (65%), patients overestimated benefits of treatment
- 10 out of 15 studies (67%) in which harms were the focus, patients underestimated the risks or harms
- Improving communication necessary for patients to understand benefits vs. harms and opt for better care

Original Investigation | Less Is More

JAMA Internal Medicine

January 2016

A Comparative Effectiveness Trial of Alternate Formats for Presenting Benefits and Harms Information for Low-Value Screening Services
A Randomized Clinical Trial

Study Design

- Randomized clinical trial of 775 individuals
  - Aged 50-85 years (mean: 65)
  - 53% women
- Benefits and harm presented to patients on one pager in four different formats

Written Intervention Has Little Effect on Patients’ Intention

- Intention-to-accept screening
  - High at baseline (at least 3.5 out of 5)
  - No significant change in intention across interventions
- Decision making process might be more influenced by emotions and cognitive biases than rational evaluation of harms & benefits

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Teachable Moment | Less Is More

February 2017

Chest Pain and Supplemental Oxygen Too Much of a Good Thing?

Maxine Corrier, MD| Todd C. Lee, MD, MPH
Patient

A man in his 60s with hypertension, dyslipidemia, and coronary artery disease presented with intractable retrosternal chest pain. The patient’s vital signs were normal, and his oxygen saturation on room air was above 95%. The paramedics started him on oxygen by nonbreathing face mask and he was transferred to our emergency department where oxygenation was continued. A 12-lead electrocardiogram revealed anterior ST-elevations and a chest radiograph showed no intrathoracic pathology. The patient underwent urgent cardiac catheterization with 2 drug-eluting stents placed in the left anterior descending artery achieving good postprocedure flow. Oxygen was stopped 2 days later. His postprocedure course was complicated by recurrent episodes of nonsustained ventricular tachycardia and atrial fibrillation requiring an amiodarone infusion. A transesophageal echocardiogram performed 24 hours after presentation revealed a left ventricular ejection fraction of 30% to 35%. The ventricular function remained decreased 6 weeks later.

The Facts

- In 1960s studies started showing potential harms of hyperoxia
- Meta-analysis of 4 trials: Possible higher risk of death in patients with MI
- Supplemental oxygen remains widely used “for comfort”
- Like this patient, “it is possible that thousands of patients are harmed by excess use of oxygen.”

JAMA Internal Medicine

Research Letter | Less Is More
October 2016

Low-Value Health Care Services in a Commerially Insured Population

Rachel O. Rits, MD, MS²; Brendan Rosanoff, BS; Newsg Scosl, PhD³
US Health Care System

- U.S. health care spending
  - $750 billion wasted annually
  - $200 billion in overtreatment
- Choosing Wisely waste assessment focuses on Medicare
- Current study looks at large, national, commercially insured population

Low-Value Services in 2013

- $32.8 million were spent on low-value services (0.5% of total spending)
- Most common:
  - Triiodothyronine measure in hypothyroidism
    - 1.5% of procedures
    - 2.51% of spending ($8.2 million)
  - Imaging for nonspecific low back pain
    - 1.3% of procedures
    - 9.4% of spending ($12.1 million)
  - Imaging for uncomplicated headache
    - 1.0% of procedures
    - 11.0% of spending ($3.6 million)
  - Spinal injection for lower-back pain
    - 0.4% of procedures
    - 37.0% of spending ($12.1 million)
Low Value Care

- Is low value care associated with insurance type?
- Low value care provides little benefit to patient and might even cause harm
- Cross-sectional study of Oregon claims data from 2013
  - 286,769 Medicaid and 1,376,308 commercial enrollees in 2013

Low-Value Care and Insurance Type not Consistently Associated

Moderate proportions of patients received low-value care
- 14.9% of Medicaid patients
- 11.4% of commercial insurance patients
- Low-value care driven more by local practice style than insurance type

Results & Discussion
Chronic Pain Treatment not Studied Well

- Chronic pain is most common condition affecting older adults
- Limited evidence base biggest barrier to effective treatment
- Paucity of high quality RCT
  - Too short
  - Not diverse enough
  - Sampling population younger than patients

Reid MC, Ong AD, Henderson CR. Why We Need Nonpharmacologic Approaches to Manage Chronic Low Back Pain in Older Adults. *JAMA Internal Medicine*. 2016.

RCT Design

- Randomized clinical trial
  - Mind-body program: n=140
  - Health education program: n=142

Table 1: Participant Characteristics by Randomization Status

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<thead>
<tr>
<th>Characteristics</th>
<th>Participant Group</th>
<th>Control</th>
<th>p Value</th>
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<td>Age, years (SD)</td>
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<td>71.5 (1.3)</td>
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<tr>
<td>Male, No. (%)</td>
<td>43 (31)</td>
<td>43 (31)</td>
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<td>Race, No. (%)</td>
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<tr>
<td>Other</td>
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<td>7 (5)</td>
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</tr>
</tbody>
</table>

Mindful of Meditation

- RCT using mindfulness meditation approach to management of chronic lower back pain
- Initial functional improvement (at 8 weeks)
- Primary outcome: Roland Morris Disability Questionnaire score
  - Although participants perceived a change, physical function did not improve compared to control, both groups reported ~50% improvement in score

Reid M.C., Ong A.G., Henderson C.R. Why We Need Nonpharmacologic Approaches to Manage Chronic Low Back Pain in Older Adults. JAMA Internal Medicine. 2016.

Low value Care

Early Start of Hemodialysis May Be Harmful

- Underuse of Evidence
  - US registry data from 1996-2006
  - Healthiest pts, ages 20-64 yrs
  - Compared with pts who start dialysis at eGFR <5mL/min/1.73m², pts who start earlier have a graded increase in mortality
    - HR - 1.74 for eGFR 15mL/min/1.73m²

Overuse of intervention – early dialysis

- From 1995 to 2007 the Cr level at which dialysis initiated has dropped from 8.7 to 6.3 mg/dl
- 50% of pts start dialysis at a GFR over 10mL/min/1.73m²

Johansen K. Time to Rethink the Timing of Dialysis Initiation, Arch Int Med 2010
Mechanical Support of Circulatory System

- Commentary on two JAMA IM articles that showed increases in usage of
  - Percutaneous ventricular assist devices (PVADs)
  - Intra-aortic balloon pump (IABP)
- Use of mechanical circulatory support devices is associated with increased mortality

Evidence and Guidelines have little Impact on Practice

- IABPs still used frequently despite
  - Little evidence of benefit
  - Revised guidelines against their usage by European Society of Cardiology
- Newer PVADs met with enthusiasm even though
  - No evidence they improve survival
  - Higher risk of bleeding and limb ischemia
Factors impacting Reluctance for Abandonment

- Myocardial infarction complicated by cardiogenic shock associated with high in-hospital mortality (40-50%)
- Mechanical circulatory support might seem reasonable in critically ill patients
- Need randomized clinical trials comparing
  - New and existing treatments
  - Existing treatment equivalence and cost
- Lack of RCTs due to
  - High cost
  - Low incentive

Cardiac Catheterization

- Rarely indicated, patients with abnormal noninvasive cardiac test results undergo elective diagnostic catheterization
- No benefit of preoperative coronary revascularization from randomized clinical trials for most patients
- Descriptive analysis of patients in National Cardiovascular Data Registry CathPCI Registry
- Study included 194,444 patients from 1046 sites
**Presence of Obstructions**

![Image](image_url)

**Patient Characteristics**

- Most are clinically stable and asymptomatic
- High prevalence of cardiac risk factors and prior CAD
- Most had positive stress test results
- Subset with preoperative PCI:
  - Higher disease burden
  - Usage of bare metal stents

**Patient Characteristics Impacting Stress Test Results**

- Poor or unknown exercise tolerance
  - Correlates with higher burden of comorbidities, including CAD risk factors
- Obesity
  - Associated with higher rate of artifact-related false-positive stress test results
- Study findings show inherent conflict between diagnostic and revascularization guideline recommendations
Telemetry Use Study

- Studying risk of missing life-threatening arrhythmias (LTAs) with reduced telemetry use
  - Retrospective review of alarm logs before and after protocol revision
  - Alarms designated as emergency prompted medical record, arrhythmia, and change in care review


Telemetry Alarms Not Clinically Important

- Even infrequent emergency alarms rarely lead to change in patient management
- Life-threatening arrhythmias exceedingly rare
- Telemetry usage can safely be reduced to Choosing Wisely guidelines

Medical Background

- Atrial fibrillation (AF) estimated prevalence of 2.7 to 6.1 million people in the United States
- Patients with AF have a 5-fold increased incidence of embolic stroke
- Pharmacological treatment comes with elevated bleeding risk
- 90% of thrombi causing AF-related strokes arise from the left atrial appendage (LAA)
- Closure of LAA might reduce stroke risk without increasing bleeding risk

Unstudied Safety & Effectiveness of Lariat Device

- No safety & effectiveness analysis for off-label usage Lariat device
  - Lariat device received FDA 510(k) clearance for soft-tissue approximation
  - Widely used off-label for left atrial appendage (LAA) exclusion
  - Similar to Watchman device
Systematic Review Results

- Formal analytic review of FDA MAUDE database to compile adverse event reports from real-world practice with Lariat
- 5 published reports of Lariat device usage in humans (n=309)
- Successful closure of the LAA during procedure: 90.3% (279 of 309 procedures)
- Potentially concerning complications
  - Urgent cardiac surgery (2.3%) (7 of 309 procedures)
  - In-hospital death (0.3%) (1 of 309 procedures)


Larger Issues with FDA Processes

- Study raises concerns about FDA new device application 510(k) clearance protocol
  - Lariat device is exclusively used for off-label
  - Safety & efficacy not assessed for that usage


National Cardiovascular Data Registry
- Fred Masoudi

Left Atrial Appendage Occlusion Registry
- Paul Varosy
Get involved!
*Teachable Moments – JAMA Internal Medicine*

High Value Care - A Better System
- Evidence of outcomes benefit prior to (permanent) regulatory approval – FDA, and widespread use - CMS, private insurers
  - Randomized clinical trial
  - Meaningful clinical outcomes
  - Blinded, if feasible
  - Valid control
  - Long term outcomes

Paradigm Changes
- Go from fee for service to pay for value
- A test is not always helpful and can hurt
- Effective reassurance can be talking to your patient
- More care is not always better
Policy Implications

- We could get much better health by doing less of certain common health care behaviors
- We could get much better value for health care spending
- More primary care
  - Gatekeeper role
- Tiered financial incentives
  - Pay less for treatments of no benefit
  - Higher copay

Final Thoughts

- Will take a culture change. The climate is more conducive now than ever before.
- Physicians should be part of the solution
- Patients need real voice
- Speak out to improve our system
- Will require multiple strategies, but fixing fee-for-service inequities must be central
- Buckle your seat belts!