The Prudent Prescriber

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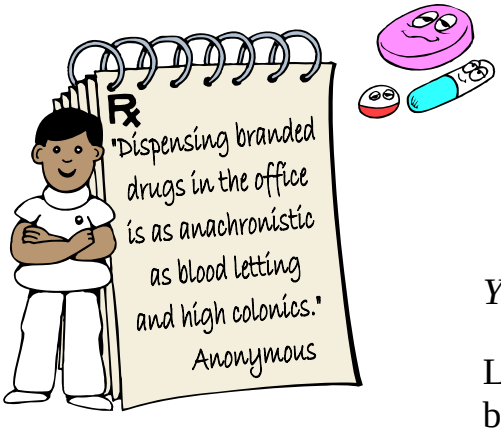

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Not ICE, Not NICE, but ICER
A Value Based Approach for Reducing Drug Costs

You can put a price on health!

Lost in the current health care debate has been any discussion of what may be one of the central issues in reducing health care costs: *comparative effectiveness research*.

Where We Are

In 2014, the Commonwealth Fund, a private foundation that aims to promote a high performing health care system reported,

> "**The U.S. ranks last of 11 developed nations overall.** Specifically, the U.S. still ranks **last** on indicators of *efficiency, equity, infant mortality and healthy life expectancy at age 60.*"

At about the same time (data 2011), **our US per capita health care expense was $8,508. That is $3000 more than the priciest of the other ten developed nations.**

CHF?

Think:
Ace
Aldactone
B-blocker
Dig
Diuretic

Avoid these expensive "me-too" drugs:

Intermezzo
Vimovo
Livalo
Pristiq
Viibyrd
Edarbi
Daliresp

Pharm Reps ≠ Rational Prescribing (PR) (RP)

Antibiotics do NOT help acute bronchitis

ß-blockers in post-MI save lives

Pill splitters save BIG

Why We Are Here

- From a pharmaceutical perspective, we are the world's most expensive place to buy drugs. The federal law passed in 2003 that prohibits Medicare from negotiating the cost of medications speaks loudly about Big Pharma's grip on Congress. (A 2015 Kaiser poll indicated that 87% of Americans favor rescinding that law.) A JAMA article in 2016 that looked at more than a decade of studies concluded, "There's little evidence of an association between research and development costs and drug prices. Rather prescription drugs are priced in United States primarily on the basis of what the market will bear."

- FDA drug approvals are based on the new product being "statistically, (not necessarily clinically) better than placebo" and "safe"; the latter decree often based on relatively small, short-term studies. The FDA does not consider either the need for new drugs (therein a recent predominance of "me-toos," 10 ARBs?) or their pricing.

- Much of the drug research is conducted or paid for by the manufacturers of the drugs being tested. This type of research is often biased toward finding that the drugs are beneficial.

- Finally, compared to the rest of the world, we Americans are relatively adverse to the concept of rationing, although we have sadly "irrationally rationed" for many years based on the patient's ability to pay.

What's Happening in the Rest of the World?

Comparative effectiveness research (CER) is the direct comparison of existing healthcare interventions to determine which works best for which patients and which pose the greatest benefits and harms. CER is alive and in play in many developed countries.

U.K.

Britain's National Institute for Health and Clinical Excellence, (NICE), is an independent, government–funded organization that advises the British National Health Service. Established in 1999, NICE has studied and recommended coverage for hundreds of medicines. NICE only carries out a small amount of CER internally. In the majority of cases, NICE commissions CER--usually in the form of evidence synthesis and economic modeling-- from other research operations.

Germany

Since 2004, the Institute for Quality and Efficiency in Health Care (IQWiG) has tendered, conducted and commissioned evaluations of health services and then provided recommendations to the Federal Joint Committee that determines coverage and pricing in the statutory health insurance benefit package. All new drugs are covered by default, but then the IQWiG may be asked to consider whether a new drug offers additional benefit compared with older treatments.

France

The National Authority for Health (HAS) was established in 2005 as an independent scientific institute, funded in large part by earmarked tax dollars. HAS performs and commissions CERs on all new drugs and issues opinions on whether they provide superior results or higher value than the current standard.

Australia

Since the early 1990s, Australia's Pharmaceutical Benefits Advisory Committee (PBAC) has been making comparative cost effective assessments on all new drugs. Following review, the PBAC makes a coverage recommendation to the ministry of health who cannot list a drug in the absence of a positive recommendation. The PBAC is an independent government committee and contracts with academic institutions for evaluation support.

US Playing Catchup

In 2009, $1.1 billion of President Barack Obama's stimulus package was earmarked for CER. The Patient Centered Outcomes Research Institute (PCORI) was established to conduct this effectiveness research, but because of fear of RATIONING, was not allowed to employ any cost or dollars per quality adjusted life years (QALY) methodologies. This political cowardice to include dollar signs in this endeavor has minimized its effect on clinical medicine and the health care bottom line.

There is Some Good News in USA

- The US Preventive Services Task Force conducts cost-effectiveness analyses to aid in certain decisions regarding preventive services to recommend, although they do not have specific cost-effectiveness thresholds.
- The State of Oregon and its Health Services Commission use cost-effectiveness assessments to rank order potential services for reimbursement. Services below a certain cost-effectiveness threshold are eligible for reimbursement.
- In the cancer treatment arena, the DrugAbacus tool developed at Memorial Sloan Kettering Cancer Center evaluates 54 cancer drugs to determine whether their price reflects value. In addition to the quantitative component, the DrugAbacus incorporates other value elements (disease rarity, population health burden, cost to develop the drug, novel or new mechanism of action).
- In 2014, the American College of Cardiology (ACC) and the American Heart Association (AHA) reportedly expanded their approach by adding cost and value markers to their practice guidelines. My perusal of their guidelines on syncope and management of heart failure, both published in 2017, did not reveal any cost-effectiveness data.

Enter: The Institute for Clinical and Economic Review

The Institute for Clinical and Economic Review (ICER) is emerging as a major player in the healthcare cost debate. This small Boston-based, nonprofit group assesses the values of medicines and proposes a fair price. They invite patients, clinicians, academics, pharmacy benefit managers (PBMs), drug makers and insurers to the table. ICER puts a price on the value of a particular new drug (comparing it with its older cousins) using the standardized quality adjusted life year (QALY). One QALY represents a year spent in ideal health.

ICER is gaining influence. When Medicare's government overseer announced a test last year of different ways to pay for part B drugs– like certain cancer drugs– it cited ICER reports as an example of the value based approach it was exploring.

ICER Research

The two new injectable PCSK9 inhibitors approved for treating familial hypercholesterolemia and those with heart disease who have failed statins, Repatha ($14,100 a year) and Praluent ($14,600) are prescribed forever. The final ICER report on these novel products "included value-based *price benchmarks of $5,404-$7,735 linked to long-term value to patients, and as low as $2,177* when potential short-term budget impact is considered. Given the cost of PCKS9 inhibitors, the predominant view of ICER was that these drugs at list price represent *"low" long-term value for patients."*

And on new Hepatitis C drugs, ICER found that *if* only half of the estimated hepatitis C sufferers in California sought treatment with Sovaldi, it would raise drug expenditures in the state by $22 billion in a single year. Even after 20 years, the gains from better health would offset only about three-quarters of the initial outlay. To be truly cost-effective, ICER says, *the price would have be cut by half to two-thirds.*

In a report on immune–modulating drugs for rheumatoid arthritis, ICER found that as a class, they are more effective than older therapies, but they're also overpriced. Humira came in as the most expensive at $232,644 per QALY versus Remicade at $202,824 per QALY and $168,600 per QALY for Actemra. Humira would need a 50% to 69% discount from its list price to be cost-effective.

As one might predict, the pharmaceutical industry claims that ICER is doing the bidding of insurers trying to drive down prices. "ICER cherry picks data and is cooking the numbers to get the desired outcome," claims the Center for Public Interest, a think tank that is backed by drug makers. Others are critical of the stand that would require pharmaceutical companies to compare new therapies with alternative treatments rather than placebos. They argue that such requirements would make drug research too expensive.

My Take

- The tremendous need for CER is made clear by studies showing that only a minority of medical treatments currently being used are supported by valid research. Failure to use effective treatments results in worse medical outcomes and higher medical costs. The Institute of Medicine (IOM) recently concluded, "The country needs a robust CER infrastructure." The IOM has listed the top 100 priority topics for comparative effectiveness research.
- The CER process is fraught with pitfalls, including the heterogeneity of patient populations, the threat to some physicians' clinical judgment, poorly selected surrogate endpoints, and trials that are conducted in environments that do not represent real world medical practice.
- Comparative effectiveness drug studies are useful only if the resulting recommendations are used by policymakers become enmeshed in clinical practice and support patients' access to the appropriate medications. These are huge barriers, given the length of time it takes to implement evidence-based interventions into the exam room.
- In response to Big Pharma's concerns about testing new drugs against older products rather than placebo, I would remind all that recently 80% of newly approved medications are "me-too" drugs that offer no real benefits over existing therapies.
- Might some RATIONING result from comparative effectiveness studies? Absolutely! The pot to pay for medical care is not bottomless. As a medical system and as individual clinicians, we need to quit recommending, buying and selling ineffective, futile medical care.
- Is ICER the answer? My skeptical self worries about the conflict of interest issues associated with having a majority of their governance board associated with managed care and the bulk of their advisory board, Big Pharma representatives. On the other hand, their research approach seems sound and transparent. Stay tuned!

You may access previous issues at https://www.rmhp.org/i-am-a-provider/provider-resources/publications-for-providers

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