



Health Outcomes Communicator

Information and ideas for healthcare economists

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Welcome to our December issue

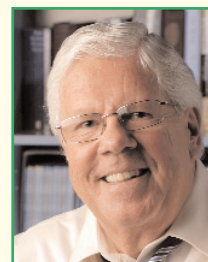
Welcome to the December *HOC*. This month Newt Gingrich, founder of the Center for Health Transformation and former US Government House Speaker, tells *HOC* of his concerns about the lack of transparency in healthcare, and his enthusiasm for new technology, particularly the huge potential of e-prescribing. Also in this issue, Julie Stauffer questions the social responsibility of pharma companies, and describes the work done by the Access to Medicine Foundation to encourage pharma to improve the help they give to poor countries.

Ruth Whittington reports on the recent European ISPOR meeting, and Mary Gabb rounds up the newsletter with a debate about the tough choices facing healthcare trusts in funding expensive drugs.

This issue of *HOC* will be my last as editor. It's been a great experience and I thank Rx Communications' CEO Ruth Whittington for inventing the newsletter and inviting me to become its editor. I'm also grateful to marketing whizz Duncan Dibble, production editor Janet Beaumont, and the writers who have made *HOC* a strong communications presence in health economics and outcomes research.

With best wishes for the new year,

David Woods, *HOC* editor (hmi3000@comcast.net)



Newt Gingrich: The need for more transparency and technology in healthcare

By Laura Goldman (laura.goldman@rxcomms.com)



Newt Gingrich

In an interview with *HOC*, former US House Speaker Newt Gingrich said he founded his Center for Health Transformation because "I wanted to have an effect; I wanted to save lives and money. America's healthcare system is becoming obsolete. The changes that are needed are complex and cannot be done bit by bit. We need an overhaul of the entire system."

Gingrich cites transparency as a major issue in healthcare. For example, a US Congressional Bill requiring hospitals to report the number of infections was challenged by hospitals because, Gingrich contends, "they don't want anyone to know the number of infections."

One of Gingrich's main goals is to secure a "21st century science and technology budget" that will allow significant research in the fields of Alzheimer's, and cancer. He wants to secure funding for scientific research and technology "not for one year but for a generation. It is the only way we will achieve significant scientific breakthroughs."

When asked about the challenge of doing all this during the current economic crisis, Gingrich said: "I don't not feel sorry for a Congress that could find \$1.2 trillion on short notice to bail out Wall Street."

Another priority for the former Speaker: "We need to study what works and adopt it all across the country. We have learned that the practice that leads to the best outcome turns out to be the least expensive in the long run," he believes.

But Gingrich's favourite cause is electronic health records, and particularly e-prescribing. To highlight the issue, the Center for Health Transformation published *Paper Kills: Transforming Health and Healthcare with Information Technology*, a book by David Merritt, a project director at the Center for Health Transformation and the Gingrich Group. Moreover, he considers that the needed infrastructure investment in electronic health records is just as vital to the country as the railroads were in the 19th century. The total devastation of the paper-based health records of the citizens of Louisiana after hurricane Katrina proves his point.

But he thinks that adopting electronic health records is meeting resistance because "Doctors have deeply ingrained habits. They are very conscious of time. For them, time literally means money. Doctors have also been against this because they are instinctively against big government and the insurance companies," who may force it on them.

Newt Gingrich dismisses privacy concerns. "When I speak in front of a group, I ask how many use an ATM in a foreign country. The hands of almost everyone in the room are raised. I tell them that the information in their accounts has travelled across borders. They were not concerned about that." But he believes that "fraud is the more insidious reason that doctors oppose electronic health records. With electronic health records, fraud will be easier to detect." Over-prescribing and over-billing will be more closely monitored. The *Wall Street Journal* estimates that 10% of all Medicare billing is fraudulent. Asked how he would propose paying for this, he says that eliminating fraud "will allow electronic records to pay for themselves. The federal government should subsidize the conversion to electronic health records."

While Gingrich acknowledges that adopting electronic health records for 100% of the population will take time but he is pressing for immediate adoption of e-prescribing. He praises the Medicare Electronic Medication and Safety Protection Act, which established bonuses for the adoption of e-prescribing technology.

Finally, Mr Gingrich had this to say about the cost of adoption: "Would we tolerate it if the airline industry said, 'we would like to be safer but we can't afford it'?"

Access to medicines: Ranking the social responsibility of pharmaceutical companies

By Julie Stauffer (julie.stauffer@rxcomms.com)

Pharmaceutical companies produce hundreds of life-saving drugs every year. Yet each year, millions of people in developing countries die from preventable and treatable illnesses – diseases such as HIV/AIDS, malaria and tuberculosis – because they can't afford to buy the drugs they need.

In an era when businesses are scrambling to prove their corporate citizenship credentials, big pharma could be playing a key role in bridging that gap. Indeed, one of the United Nation's Millennium Development Goals specifically calls on the cooperation of drug companies to ensure that developing countries have access to essential drugs at an affordable price.

But how well do pharmaceutical companies actually measure up when it comes to helping the world's poorest citizens? Thanks to the Netherlands-based Access to Medicine Index, that information is now just a click away.

Launched in June 2008 by the Access to Medicine Foundation, an independently-funded non-profit organisation, the index assesses 20 of the world's largest drug companies based on criteria ranging from equitable pricing to research and development into neglected diseases. Its goals: to engage the pharmaceutical industry in improving global access to medicine and to give socially conscious investors an impartial assessment of how well individual companies currently perform.

According to the inaugural index, their efforts vary widely. While GlaxoSmithKline topped the list with 4.5 out of a possible score of 5.0, followed closely by Novo Nordisk, Merck & Co., Novartis, and Sanofi-Aventis, the lowest-ranked company garnered a mere 1.3.

As well as scoring companies, the index highlighted a number of best practices, such as Sanofi-Aventis's decision not to patent the anti-malarial ASAQ, Merck & Co.'s tiered pricing policy for HIV drugs based on the UN Human Development Index and HIV/AIDS infection rates, and the Wyeth/WHO collaboration on river blindness drugs.

"The Access to Medicine Index finds good practices within individual companies and holds them up as a shining example to others," says Index founder Wim Leereveld.

The foundation consulted extensively with government, researchers, NGOs, and the pharmaceutical industry to develop assessment protocols. Drawing on a variety of data, it ranked companies on a total of 28 indicators, grouped into 8 main criteria:

- Access to medicines management
- Public policy influence and lobbying
- Research and development into neglected diseases
- Patents and licencing
- Drug manufacturing, distribution, and capability advancement
- Equitable pricing
- Drug donations
- Philanthropic activities



Companies had an opportunity to verify the accuracy of the information, and a draft of the report was reviewed by independent experts.

To date, the index has attracted substantial media attention along with kudos from Microsoft Chairman Bill Gates, World Bank Executive Director Herman Wijffels, and UN High Commissioner for Human Rights Mary Robinson.

Perhaps most significantly, 12 major global investors, together representing more than \$US 1.2 trillion in assets, have formally acknowledged the index as a tool to improve transparency and assess the long-term value of pharmaceutical companies.

The Access to Medicine Foundation plans to issue the rankings annually and expand them to include more companies in 2009.

"Always note and record the unusual. Keep and compare your observations. Communicate or publish short notes on anything that is striking or new"

Sir William Osler (1849–1919) Canadian physician and author.

“Moving and Improving Concepts and Evidence for Healthcare Decisions” – the latest ISPOR congress

By Ruth Whittington (ruth.whittington@rxcomms.com)

Rx Communications has just returned triumphant from the 11th annual European Congress of ISPOR. ISPOR is a great place to meet old friends, find new ones, and discuss current issues with competitors, clients and collaborators. This year's venue (Athens) provided an interesting reminder of how far we have moved in some respects from the beginnings of the civilised world, and yet how there is “nothing new under the sun” Indeed, the ISPOR chairmen Uwe Siebert and John Yfantopolous quoted Pericles in 450 BC saying “We Athenians, as individuals, take our own decisions on policy and submit them to proper discussions; for we do not think that there is an incompatibility between words and deeds; the worse thing is to rush into action before the consequences have been properly debated. “

And debate there was. A recurring theme was the harmonisation or standardisation of HTA evaluations from agency to agency. One plenary session provoked a lively discussion of international guidelines for the evaluation of health care interventions, with the lead protagonists advocating the QALY (Mike Drummond) or the efficiency frontier (Jaime Caro), and with Milton Weinstein and Uwe Seibert inserting provocative questions regarding the applicability of standard approaches and the flaws in methodology.

Mike Drummond paraphrased Winston Churchills famous quote “democracy is a lousy form of government but it's the best we have” by saying “QALY's are a lousy form of measure but they are the best we have”. He added, somewhat cynically, that incremental cost per QALY is at least flexible enough to cope with the needs of politicians.

There are both methodological and political issues arising from the use of QALYs as the fundamental decision-making approach. For example, different measurement approaches for estimating the health state preference



Abstract submission deadlines

Dates were correct at time of going to print; *HOC* cannot be responsible for any amendments made after that.

Submit abstract by	Meeting	Abbrev.	Therapeutic area	Meeting date
12 Dec 08	European Congress on Clinical and Economic Aspects of Osteoporosis and Osteoarthritis, Athens , Greece www.eceo9.org/	ECCEO	Musculoskeletal	18–21 Mar 09
1 Jan 09	Annual Meeting of Health Technology Assessment International Singapore www.htai2009.org/home.html	HTAi	Health economics	21–24 Jul 09
8 Jan 09	Meeting of the American Diabetes Association New Orleans , LA , USA www.diabetes.org	ADA	Metabolic	5–9 Jun 09
11 Jan 09	European Stroke Conference Stockholm , Sweden www.eurostroke.eu	ESC – Stroke	Cardiovascular	26–29 May 09
12 Jan 09	European Symposium on Calcified Tissues Vienna , Austria www.ectsoc.org/vienna2009/	ECTS	Musculoskeletal	23–27 May 09
14 Jan 09	European Academy of Allergology and Clinical Immunology Annual Meeting, Warsaw , Poland www.eaaci2009.com	EAACI	Immunology/ Respiratory	6–10 Jun 09
15 Jan 09	International Society of Pharmacoeconomics and Outcomes Research International Meeting, Orlando, FA , USA www.ispor.org	ISPOR (Int)	Health economics	16–20 May 09
15 Jan 09	Miami International Breast Cancer Conference Miami , Florida , USA www.cancerconf.com	IBCC	Oncology	4–7 Mar 09
16 Jan 09	National Osteoporosis Society Annual Conference Manchester , UK http://www.nos.org.uk	NOS	Musculoskeletal	28 Jun–1 Jul 09
16 Jan 09	International Congress of Parkinson's Disease and Movement Disorders, Paris , France www.movementdisorders.org	MDS	Central nervous system	7–11 Jun 09
20 Jan 09	British Society of Haematology Annual Meeting Brighton , UK http://www.bshconferences.co.uk	BSH	Cardiovascular	27–29 Apr 09
31 Jan 09	Annual Congress of the European League against Rheumatism, Copenhagen , Denmark www.eular.org	EULAR	Musculoskeletal	10–13 Jun 09

Next month

We start the new year with Obama on Healthcare and E-prescribing

Previous issues

If you missed any earlier issues of *HOC*, email duncan.dibble@rxcomms.com for a copy. Just a few of our previous articles are *Getting drugs accepted*, *Healthcare blogs* and *How to make the most of conferences*

All issues are available as an A4 4-page newsletter like this one, for you to print and keep.

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values for QALYs can give different answers, and if the concern is about the provision of social value, then equal weighting of QALYs won't necessarily give it to us. As always, the "devil is in the detail" and in the eyes of decision-makers some QALYs are more equal than others.

On the other hand, using an efficiency frontier approach where the value of the benefit is plotted against the total net cost, is a useful way of determining what role price plays in the estimation of value. A frontier is set depending on points specified by existing healthcare interventions, which enables one to plot what the current market sets as a reasonable return (benefit) for a given cost. However, this too has issues – it doesn't provide a decision rule, or address societal preferences regarding the priority of various diseases.

It was an interesting debate, with no clear outcome. In some ways, it reminded me of the contentions regarding the peer-review process in publications – if you think of the QALY as a means of measuring value in healthcare, the peer review process in publications is the means of measuring value in a publication. And again, there are methodological issues and political issues in the peer review process. For example, reviewers' opinions about the value of a manuscript can be strongly influenced by their own perceptions/positions in the therapeutic area, and in many cases the decision of the journal editor whether or not to accept the article is influenced by political considerations (the prestige of the lead author for example, or the likelihood of reprints) as much as they are influenced by the value of the research in the article.

So in my view both the QALY and peer review methods are deeply flawed – but they are the only ones we have for decision making. The question then becomes: do we "throw the baby out with the bathwater" as it were, and redesign the whole process of measuring value, or do we use these flawed measures as a guideline of value and apply commonsense and a little humanity in our decision-making?

The value of congresses such as ISPOR is that these issues are raised and debated, and with an open exchange of views and perceptions we gradually move forward in our thinking, and eventually find better ways of making decisions.

"In my experience' is a phrase that usually introduces a statement of rank prejudice or bias. The information that follows it cannot be checked, nor has it been subjected to any analysis other than some vague tally in the speaker's memory."

Michael Crichton (1942–2008) American physician and bestselling author

Tough choices about expensive drugs

By Mary Gabb (mary.gabb@rxcomms.com)

The UK's National Institute for Health and Clinical Excellence (NICE) has recently ruled that four drugs used to treat advanced kidney cancer are not effective enough to warrant their coverage by the National Health Service (NHS). NICE estimated that the drugs cost between £71,500 and £171,300 per QALY, far exceeding the typical NICE cut-off of £30,000 per QALY.

This isn't the first controversial decision by NICE. The *BMJ* reports on a survey of England's primary care trusts (with which patients can lodge an 'exceptional request' for drugs to be funded that are not approved by NICE), showing large differences in the policies and processes for approving such requests or appeals.

Moreover, the impact of NICE decisions does not remain solely in the UK. The US has been watching and studying NICE, as part of an effort to rein in the more than US\$2 trillion (16% of US GDP) it spends on healthcare each year. A bill was introduced into the US Senate to establish the Health Care Comparative Effectiveness Research Institute, which would review evidence and conduct studies to determine which drugs and devices provide the best clinical outcomes. Annual funding for the institute after 5 years is projected to be US\$300 million.

Another strategy used by the US to manage such high-cost medications is to incorporate co-insurance into the tiered drug co-payment system. In the tiered system, drugs are prioritised to tiers 1, 2, or 3 based on the payers' preference for the drugs, and patients are required to pay a fixed fee (a 'co-pay' based on the tier, see next page).



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Typical co-pays for tiered drugs in the US healthcare system:

Tier 1 (typically generic drugs)	\$5 to \$10
Tier 2	\$20 to \$30
Tier 3	> \$50

Co-insurance is sometimes referred to as tier 4 drugs, but instead of a fixed amount for co-payment, the consumer is charged a percentage of the overall drug cost (usually 20% to 33%). Co-insurance is applied to drugs with very high price tags, such as the latest biologic drugs developed for cancer and other chronic illnesses that require long-term therapy. For a drug that costs \$100,000 per year, the tier 4 co-payment (or co-insurance cost) could be more than \$30,000 for the patient.

Sir Michael Rawlins, who (in an interview with *The Observer*) vehemently criticised the pharmaceutical industry for 'perverse incentives' to increase the price of drugs, also pointed out that "we have a finite amount of money for healthcare, and if you spend money one way, you can't spend it in another". Nonetheless, the cost-effectiveness criteria used by NICE may be under review next year.

Another proposal under consideration by the NHS is to base drug pricing on the value a drug offers, not on the cost to develop it. Currently, the UK Department of Health negotiates with the Association of the British Pharmaceutical Industry to set price controls and profit caps for pharmaceutical manufacturers.

With rumours of co-pays being instituted in the NHS and a US presidential election in full swing (see the August 21 edition of the *New England Journal of Medicine* for a review of each candidate's health care plan), health economists will be making more of these decisions with other stakeholders.

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