

Health or wealth?

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J Thorac Dis 2012;4(5):548-550. DOI: 10.3978/j.issn.2072-1439.2012.09.06

Respiratory patients, like all people, want health. Their purpose in seeking health care through physicians and other health care practitioners is to secure their health. However, in many parts of the developed world the business of health care with its goal of profitability has replaced the art of medicine with its goal of improving patients' health (1). Patient advocates believe that this focus on profit and neglect of patient outcomes is the reason for the plummeting public health of the US (2). The cost of health care services in the US is approaching 20% of the country's gross domestic product (GDP), and most European countries are also experiencing dangerous increases in health care costs.

At their May 2012 meeting, ICC leaders attempted to identify ways in which the cost of COPD patient care could be reduced while maintaining or improving beneficial patient outcomes. Three factors emerged from this discussion: the need for conflict-of-interest-free clinical practice guidelines; the need for better research on the cost effectiveness of polypharmacy in advanced COPD; and the need for new methods that will permit earlier COPD diagnosis.

An underappreciated but important factor fueling health care cost increases are specialist-produced clinical practice guidelines that recommend excessive use of expensive, unnecessary health care services that do not improve patient outcomes. ICC has taken the position that it will only endorse evidence-based clinical practice guidelines (CPG) developed through the WHO-approved GRADE process. The GRADE process includes considerations of patient acceptability and cost as well as the requirement that final clinical recommendations will be decided by epidemiologists who are without any financial conflicts-of-interest related to the products or companies under review. This process has been shown to improve the practicality and acceptability of guidelines and to reduce the effects of financial

conflicts of interest.

ICC's position traces back to a joint ICC and ARIA (Allergic Rhinitis and its Impact on Asthma; www.whiar.org) meeting held at the European Respiratory Society (ERS) meeting on Sept. 18, 2010 in Barcelona. At that meeting, representatives from the World Organization of Family Doctors (Wonca), the IPCRG, ICC and ARIA all voiced the view that the guideline process must be thorough and uncontaminated by commercial interests. It is clear that respiratory specialists have scientific and medical expertise that is valuable for commercial organizations, and physician experts should be able to consult with industry; however, the representatives believed that experts receiving substantial payments from proprietary interests should not be in the position of making guideline decisions about the products of these proprietary interests. They emphasized the importance of transparency in the guideline process and the necessity of validating guideline decisions based on a final review by epidemiologic experts who do not have financial conflicts of interest.

ICC leaders, Profs. Chen Rongchang and Lin Jiangtao (representing Prof. Zhong Nanshan) emphasized the importance of patient outcomes and cost-effective therapy for COPD and other respiratory patients. Prof. Jean Bousquet, the Chair of the WHO's Global Alliance against Chronic Respiratory Diseases (GARD), discussed the use of the GRADE guideline process to create the first conflict-of-interest-free clinical practice guideline (3) and warned against the acceptance of clinical recommendations that are not developed in an unbiased process. All the representatives agreed that the conflict-of-interest-free approach was desirable, and the ICC leaders decided that ICC's Evidence-Based Resource Center should have GRADE assessments performed for key recommendations. Unfortunately, no clinical practice guideline for COPD has been developed using the GRADE process.

However, even if the GRADE process is not employed in CPG development, a way for physicians to assess the validity of a guideline has been developed by the US Institute of Medicine (IOM). The IOM, which is the major organization the US government commissions to conduct health policy research to advise them concerning health care legislation, has developed standards for developing trustworthy CPGs (4).

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Submitted Aug 18, 2012. Accepted for publication Sep 20, 2012.
Available at www.jthoracdis.com

ISSN: 2072-1439

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They recommend that guidelines that do not follow appropriate procedures should not be considered valid. The US government Agency for Healthcare Research and Quality, which established the list of recommended CPGs, has decided to exclude guidelines from its approved list that do not follow the IOM procedures.

The IOM process includes (I) transparency of guideline development, (II) management of conflicts of interest (including selection of participating experts, disclosure of conflicts of interest, divestment of properties causing conflicts of interest), (III) broad representation of the guideline group participants, (IV) systematic review of evidence, (V) assessment of evidence strength, and (VI) external review. These processes apply to all clinical guidelines. When the CPG “feathers the nest” of a specialty group, provides payoffs to specialty leaders, or promotes specific drugs or devices, most or all of these required processes will be violated. These provisions of the IOM standards are consistent with the GRADE process so if you read a CPG and the process of guideline development is not in compliance with the IOM standards or does not detail the process that was used then ICC believes you should not assume that it is valid.

IOM standards state that the majority of members of a guideline panel must have no financial conflicts of interest, the chair of the guideline committee must have no conflict of interest, and the guideline group must include a patient group advocate. The major global guideline for COPD is the Global Initiative for Chronic Obstructive Lung Disease (GOLD), but a review of the conflict-of-interest disclosures for the GOLD Board of Directors (5): the group that is responsible for approving the GOLD guidelines, show that none of these requirements is met. This does not mean that individual therapeutic recommendations made by GOLD are not valid; however, one must identify the clinical trials upon which the recommendations are based and evaluate the studies themselves to determine their merit.

A second issue that emerged from the ICC leaders’ discussion about how the cost of COPD patient care can be reduced while maintaining or improving patient outcomes, is the difficulty in comparing the effectiveness of different COPD therapies and in assessing the benefits that will result when using therapies concomitantly.

Many commonly used medications, such as ICS, acetylcysteine, LABA, LAMA, and roflumilast can reduce COPD exacerbations; however, does polypharmacy that includes several or all of these agents further reduce exacerbation beyond that provided by one or two of them? The answer to this question is not known, and yet the information is important to reduce the cost of therapy without reducing the benefit of therapy. LABA and LAMA therapy not only reduce exacerbations but also diminish COPD symptoms, which is an important patient benefit and supports the priority of their use if the addition of the other agents does not provide substantial additional benefit.

These issues relate to the management of COPD that has progressed extensively. An even more attractive approach to reducing the cost of COPD care is earlier diagnosis of COPD, since the current approach after symptoms have progressed often results in the loss of 50% of the patient’s pulmonary function prior to diagnosis. By contrast, an alternative diagnostic approach explored by Prof. Zhong Nanshan and his colleagues (6) can identify COPD when only 10% of lung function is affected and therapy is more effective. If the disease can be arrested early it may even be possible to preclude the development of exacerbations, although this has not yet been established.

Many physicians are frustrated that insurance companies, the pharmaceutical industry, for-profit hospitals, and other health care businesses adversely affect patient outcomes by their focus on profiting from health care services. In many developed countries, payments by health care corporations to politicians and government officials have enhanced the profitability of their businesses at enormous cost to patients. In addition, not all governments wish to invest in the health of their people. In a recent study of the need for access to health care among adults in the US (7), those with limited health care coverage had a 6.1% increase in all-cause mortality (19.6 deaths per 100,000 adults) compared to those who received expanded state Medicaid eligibility. However, as a result of a recent US Supreme Court ruling, states are no longer required to provide expanded Medicaid coverage, and the results of a lack of coverage on access to care and mortality may be devastating. US health care agencies have estimated that from 20,000 to 30,000 people already die unnecessarily in the US each year from treatable causes because they do not have access to care. Recent data from the US show that life expectancy among Caucasians without high school diplomas has decreased by 4 years between 1990 and 2008. Health care coverage for these people during that period decreased substantially (8).

The clear message from the ICC’s member organizations is that funds available to provide health care for COPD patients should be used to improve COPD prevention and patient outcomes, not to provide expensive, unnecessary services to enhance health care businesses! The decisions about appropriate COPD care should be made through processes that do not allow financial conflicts of interest to affect decisions and adversely influence COPD patients’ lives.

Acknowledgements

Disclosure: The author declares no conflict of interest.

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Cite this article as: Grouse L. Health or wealth?
J Thorac Dis 2012;4(5):548-550. DOI: 10.3978/
j.issn.2072-1439.2012.09.06