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My brother the smoker http://bit.ly/mSOihX

Smoking cessation: big pharma butts in

MARK HENLY/PANOS

The pharmaceutical industry has a clear commercial interest in eroding public and professional confidence in unassisted smoking cessation, yet easily implemented ideas, such as graphic health warnings, are more effective than nicotine replacement therapy, says **Simon Chapman**

Tobacco control is the poster child for those now rallying behind international action to control non-communicable disease. In nations that have implemented comprehensive policies and programmes to reduce tobacco use, there have been often continuing and large scale falls in smoking prevalence over the past 20 to 40 years, in the number of cigarettes smoked per day, and—the ultimate test of effectiveness—in the incidence of index diseases like lung cancer.[1]

The World Health Organization's Framework Convention on Tobacco Control, with 174 nations having now ratified its legally binding provisions, has inspired thinking about the applicability of the tobacco control model to chronic disease at large.[2] This momentum should be profiled and boosted by the September United Nations High-level Meeting on Non-communicable Diseases.

Although preventing uptake among young people has long been a mantra for governments of all political stripes, far more lives will be saved over the next decades by promoting cessation in current smokers.[3] There is now extensive consensus on what the so called best buys in tobacco control are when reducing consumption across whole populations is the goal.

All parties—including the perennially protesting tobacco industry ("Of all the concerns . . . taxation alarms us the most"[4])—agree that tobacco tax increases are the ace in the pack. Promoting quit attempts in large numbers of smokers is the most important strategy for improving cessation rates throughout a population.[5]

Australia has seen daily smoking prevalence fall to 15.1%, with tax and well funded mass media awareness campaigns being mainly responsible.[6] Youth smoking prevalence is also the lowest on record, because youths are influenced by adult targeted campaigns[7] and the growing denormalisation of smoking.

One of the best kept secrets in tobacco control is that the great majority of ex-smokers quit without any formal assistance.[8] Between two thirds and three quarters of long term ex-smokers stop without using nicotine replacement therapy or other drugs or attending any sort of smoking cessation service.[9 10] Only 1-7% of smokers will even call a quitline.[11]

Before the advent of nicotine replacement therapy, some 37 million American smokers stopped smoking.[12] Other than the early non-specific pack warnings, there were few to none of the policies that we see today driving this exodus. Millions quit because they were exposed to years of news reports of the growing bad news on smoking and health.[13]

There is a conventional wisdom that those who have quit smoking are those who were least addicted: they were low hanging fruit who could be stimulated by anti-smoking policies to quit by themselves. But those who still smoke, the argument proceeds, are mostly those who are impervious to population health measures like tobacco excise increases, the growing denormalisation of smoking, and the messages in mass reach advertising campaigns.[14]

Against this view is evidence from 50 US states for 2006-7 that indicates that the mean number of cigarettes smoked daily, the percentage of cigarette smokers who smoke within 30 minutes of waking, and the percentage who smoke daily are all significantly lower in US states with low smoking prevalence, compelling evidence against the "hardening" hypothesis that would predict just the opposite.[15]

There is a longstanding debate between those in tobacco control with clinical perspectives who are preoccupied with smoking cessation *rates*[16] and those whose focus is on maximising cessation *numbers* throughout populations.[17] This debate seems likely to intensify in low income nations where the global tobacco epidemic is now well established, where the bulk of global tobacco caused deaths are already occurring, but where tobacco control tends to be rudimentary.

Those wanting the best possible population-wide impact to flow from the current UN momentum on non-communicable disease control will need to be vigilant against the lobbying activities of the pharmaceutical industry smoking cessation juggernaut, with its mission to medicalise smoking cessation and discredit unassisted cessation as a recipe for failure.

The industry, with its formidable promotional and public relations budgets, and an army of research consultants whose findings tend to show better outcomes than researchers not

Next month the United Nations will stage its first summit looking at the world epidemic of non-communicable diseases—in particular, cardiovascular disease, cancer, diabetes, and chronic obstructive disease (*BMJ* 2011;342:d3823). This article is part of the *BMJ*'s pre-summit coverage, looking at the risk factors linking these diseases. Future articles will look at poor diet and alcohol.

The large populations of low and middle income countries contain millions of affluent smokers who represent a goldmine to the pharmaceutical industry, but NRT remains beyond the reach of anyone but wealthy élites in the poorest nations

funded by industry,[18] has a clear commercial interest in eroding public and professional confidence in unassisted cessation.

This is despite the enduring superiority of unassisted cessation across decades in delivering far more ex-smokers than all other approaches to cessation combined.[9 19] Smokers are now recommended to use NRT (nicotine replacement therapy) before they quit ("pre-quit"), while attempting to quit, in combination, and long after stopping to prevent relapse.

A large body of clinical trial evidence provides the bedrock for this advice. But there are major differences between clinical trials and real world use in smoking cessation.[20 21] Unlike real world users, those taking part in trials get free pharmaceuticals; have frequent contact with trial researchers, creating Hawthorne effects; and are paid travel and expenses.

Trial participants are unrepresentative of the general population[22] and cessation trials exclude those with mental health problems,[23] who are heavily over-represented among smokers. NRT trials have poor blindness integrity, with over half of studies in one review showing trial participants were significantly more likely than chance to accurately guess that they had been allocated to the placebo arm, meaning that their faith in the treatment they were receiving was likely to be poor.

This may translate into poorer quitting outcomes, thus exaggerating differences between active and placebo NRT outcomes.[24] Finally, far more trial participants complete the recommended drug course than in real world settings.[21 25] All this combines to produce trial quit rates that are higher than those in real world settings. A recent Glasgow study found just 2.8% of smokers using medication who received up to 12 weeks of individual counselling with pharmacists had quit at one year.[26]

However, debates about real world effectiveness of cessation pharmacotherapy are somewhat ethereal to the circumstances of the vast majority of smokers in low income nations. In late 2009 in a Phnom Penh, Cambodia, pharmacy a pack of 105 pieces of 2 mg NRT gum was selling at $58.10 (£35.44; €40.62). Product information for 2 mg Nicorette gum advises a maximum of 24 pieces per day (www.nicorette.com/quit-smoking-products/nicorette-gum.aspx).

Even if that were halved, a 30 day supply would cost a Cambodian smoker $199.20, when average monthly income is $170.[27] The cost of NRT and varenicline in low income nations in the Middle East and North Africa shows a similar picture.[28] At these prices, NRT remains beyond the reach of anyone but wealthy élites in the world's poorest nations.

Such costs mean that NRT is irrelevant to any serious talk about strategy that could make a national impact in low income nations. But the massive populations of low and middle income countries like China, India, Indonesia, Mexico, Bangladesh, and Nigeria collectively contain millions of affluent smokers who represent a goldmine to the pharmaceutical industry.

It can be expected that the industry will maximise every opportunity to surf the new UN inspired wave of interest and seek to continue to dominate public dialogue on cessation with pharmaceutical solutions. The WHO Framework Convention on Tobacco Control endorses assisted cessation but its provision is poor throughout much of the world.[29]

In the West, despite at least two decades of industry promotions, despite armies of drug retailers, and despite increasing success in the lobbying of governments to subsidise cessation pharmacotherapy, most ex-smokers continue to quit unaided. Every major tobacco control conference in the past 30 years has given major emphasis to ways of encouraging doctors and primary healthcare workers to routinely counsel and assist smokers to quit.

Yet recently, only 6.4% of 29 492 smokers in a UK health region were prescribed cessation medication in a two year study period.[30] Reviewing the potential population impacts of various smoking cessation approaches, a 2000 US National Institutes of Health monograph concluded of physician interventions, "it is not clear that additional resources would add to the number of individuals encountering these interventions . . . the promise of these interventions as established in clinical trials is not fulfilled in their real-world applications."[31]

Against this background, there ought to be a serious pause before governments in low and middle income countries embrace frontline, labour intensive, or pharmaceutical based cessation strategies, which will soak up large resources, have low consumer acceptability, particularly to the poor, and therefore make little contribution to population-wide cessation.

If smoking is to reduce in the world's poorest nations, strategies commensurate with the size of the challenge need to be adopted. Easily implemented strategies that reach every smoker, like tax, graphic pack warnings, smokefree public places, and mass reach public awareness campaigns, need to be front and centre here, with assisted cessation placed in perspective.

Great encouragement can be taken from the current support by Bloomberg Philanthropy to assist in the development of mass reach awareness campaigns now running in India, China, Vietnam, Russia, Mexico, and Bangladesh, and major investment is occurring in capacity building to ensure that such campaigns are sustained (www.worldlungfoundation.org/).

Thailand[32] and Uruguay are arguably world leaders in comprehensive tobacco control and their and other nations' successes deserve to be megaphoned at the UN summit.

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Discuss WHO reform on BMJ Group's public health forum http://bit.ly/abI1YC

Will WHO reforms open the door to private donors?

The World Health Organization's critics accuse it of being bogged down in red tape and politics. But attempts at reform are raising concerns over conflicts of interest. **Nigel Hawkes** reports

For as long as many can remember, the World Health Organization has been facing a crisis. From decade to decade, the nature of that crisis might change, but it never quite goes away.

Despite its past accomplishments, WHO fits increasingly uneasily into a world with a growing number of international players who seem fleeter of foot and deeper of pocket. Set up as an agency to provide advice to governments at a time when government health departments were the prime movers in health policy and delivery, it seems passé beside such upstarts as the Global Fund to Fight Aids, Tuberculosis and Malaria, the GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunization), and private philanthropies such as the Bill and Melinda Gates Foundation.

Setting the agenda of global health?

The existence of such organisations is a reproach to WHO, whose bureaucracy and politicisation have been increasingly bypassed by governments in the interests of getting something done. Jack C Chow, a former assistant director general of WHO, claimed last year that the organisation was becoming irrelevant.[1] It was outmoded, underfunded, and overly politicised, he said. "WHO is no longer setting the agenda of global health; it's struggling to keep up." His theme was echoed this year by Barry R Bloom, professor of public health at Harvard, who pointed out that of WHO's budget of $3.9bn (£2.4bn; €2.7bn) in 2008-9, less than $1bn came from member states' mandatory contributions.[2] The rest were earmarked funds provided by countries or foundations for specific projects, indicating a lack of confidence in WHO's ability to set the right priorities if left to itself.

Financing

But as if to prove that whatever WHO does will alienate some of its stakeholders, a reform package announced in May to deal with these concerns caused outrage to several international non-governmental organisations. A report by the director general, Margaret Chan, called *The future of financing for WHO* (64th World Health Assembly, Agenda item 11, paper A64/4) admitted many of the criticisms were true. WHO was overcommitted, overextended, and in need of specific reforms, she said. "Priority setting is neither sufficiently selective nor strategically focussed. Given the large number of agencies now active in health, duplication of effort and fragmented responses abound, creating an unprecedented need for greater coherence and more effective coordination."

New ways were needed of working with other global actors, her report added. They needed to participate and have their voices heard in the shaping and making of health policy. While less than a quarter of WHO's budget came from predictable and flexible funds (national contributions) it would not be free to determine its own priorities, so member states were urged to increase their contributions. But at a time when government budgets were under pressure, WHO would also need to attract new donors and explore new avenues of funding, including "foundations and the private and commercial sector."

"We depend on WHO being a health advocate that puts health first. Without that, we wouldn't now have 60 countries banning advertising of formula milk for babies"

The first World Health Forum

To help involve such people, she said, WHO would organise the first World Health Forum, to be held in Geneva in November 2012. Along with member states, this would include representatives of non-governmental organisations, the private sector, academia, and other international organisations. To purists who believe WHO should not sup with the devil, this caused huge anxiety. To them it looked like an attempt to subvert WHO's principles of governance and cosy up to private industry. Their suspicions were heightened by the late appearance of the plan, just days before the World Health Assembly—WHO's governing body—met for its 64th meeting.

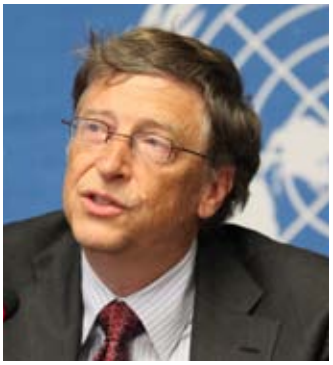
A wide range of non-governmental organisations were unhappy, and launched a protest at the assembly. Patrick Durisch, speaking on behalf of Health Action International, Knowledge Ecology International, the Third World Network, the Berne Declaration, the People's Health Movement and International Baby Food Action Network (IBFAN) said that the new policy raised conflicts of interest for WHO. Dr Chan's plan presented "an unrealistic and empirically unsupported assumption that all stakeholders will collaborate to advance the public interest." Any changes in governance structures should deal with those conflicts of interest in a realistic manner, he said, and members of WHO should guard against initiatives that would give private interests and donors a greater role in its governance.

"Nobody was being very clear" says Patti Rundall of Baby Milk Action, a long term opponent of food giant Nestlé. "Margaret Chan said, in effect, 'we want your money' and that if it was forthcoming, WHO would meet its partners' expectations, You can't do that and also meet the expectations of the member states.

"We depend on WHO being a health advocate that puts health first. Without that, we wouldn't now have 60 countries banning advertising of formula milk for babies. Involving private companies in setting priorities creates an unsurmountable conflict of interest. Margaret Chan says that she'll only deal with the 'good' companies, but how will she know?"

Barry R Bloom, professor of public health at Harvard, says there's an urgent need for WHO to win back trust

Dr Andrew Cassels, WHO director of strategy. Critics are wrong to argue the reforms will change the organisation's decision making



Bill Gates. Plans to allow the Gates Foundation to partly fund reforms has raised concerns over conflict of interest

Dr Margaret Chan. WHO director general. The organisation needs to attract new donors and explore new avenues of funding

WHO

The proposed World Health Forum provided a target around which the non-governmental organisations circled. "We find this proposal absolutely unacceptable, especially since WHO has given member states no time to discuss and consider the implications," said Arun Gupta, regional coordinator for IBFAN Asia. Médecins Sans Frontières joined him and others in condemning the claim that the forum would not usurp the decision making prerogatives of WHO's own governance as "not credible." A joint statement asked: how can the World Health Forum meet the expectations of commercial actors without usurping the prerogatives of WHO's own governance?

Dr Chan's plan survived the World Health Assembly, but came in for further criticism at the WHO executive board that followed. She was instructed to produce three papers, on the governance of WHO, the independent evaluation of WHO, and the World Health Forum, by the end of June and to convene a special session of the executive board in November to discuss them. Although open to all, only the 34 members of the board will have a vote. Anxieties were expressed at the meeting at the WHO Secretariat's plan that the development of the reform programme be partly funded by the Gates Foundation. Germany raised the issue of WHO's financing, a key to the reforms but not one of the issues Dr Chan is required to report on. It proposed that financing be added to the governance paper, but Dr Chan responded by arguing that there was too little time to include it and Germany withdrew its amendment.

Andrew Cassels, WHO director of strategy, says that the critics of the plan are wrong to argue that it will subvert WHO's traditional governance, or dilute the voice of developing countries. The reform plan started, he says, as a means of achieving a better alignment of WHO's income and its work. "Some parts of the work are underfunded, and with greater flexibility of funding we could do a better job. Member states responded to the suggestion they should increase assessed contribution by saying yes, but only when we're clear what WHO's priorities are.

"It would be nice to increase the proportion of voluntary contributions that are less closely specified. But the key thing is not to be too concerned about total resources, but to make them predictable."

WHO's priorities

From this, he says, followed the need to discover what other global players believed WHO's priorities should be. "The director general is keen to bring greater coherence to WHO's activities. If we are going to achieve that, we need some forum to discuss the issue that isn't just governments." That would be the World Health Forum. So far, the forum has yet to gain the formal approval of the executive board, which will discuss it at its November meeting and again next January.

"The concern that some people have is that it will change WHO's decision making process, but it's not about that," says Dr Cassels. "Its conclusions would speak to all global health organisations, not just WHO. The purpose is not to influence WHO's own governance procedures, which would remain unchanged."

The three papers Dr Chan was mandated to produce are complete, but not publicly available, and are being discussed by WHO's regional committees. Different views have been expressed about the need for an independent evaluation of WHO, one of the key changes called for by Professor Bloom, who argues that the World Bank, the Global Fund, and GAVI all have extensive external review procedures, but WHO does not. However, Dr Cassels says that in the discussions so far, some have questioned whether the timing is right, some whether an independent evaluation is even necessary.

In the background, financial pressures are rising. WHO ran a deficit last year, and Dr Chan found it necessary to assert in her speech to the World Health Assembly that "we are most definitely not bankrupt." The executive board meeting was picketed by staff members protesting at cuts. To balance its books, it needs to persuade governments and others to contribute more by persuading them that it is on the right track—or to cut costs. Neither is easy.

A former staff member says: "WHO as usual tries to do too much, its priorities aren't very clear, and its power to make real executive decisions that would cut some programmes is limited, and always has been. Individual departments compete with each other for funding so there's little sense of a united front and unwillingness to make sacrifices for the common good. Staff morale is low and some people are actually losing their jobs."

Funding for global health initiatives

Yet funding for global health initiatives is not lacking. The money devoted to global health related activities by donors, including governments and foundations, has risen from $5.6bn in 1990 to $26.8bn in 2010,[3] and the third replenishment meeting of the Global Fund in 2010 raised $11.7bn for 2011-13. This is less than the fund had asked for but is still very substantial.

That WHO should be facing budget cuts is an eloquent commentary on how its performance is perceived. The urgent need is to win back trust, Professor Bloom argues. But with so many stakeholders to satisfy that remains a very tall order.

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