

Can it be ethical to apply limited resources in low income countries to ineffective, low reach smoking cessation strategies? A reply to Bitton & Eyal

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Public Health Ethics

Published on-line (Advance access 9 Jan 2012).

<http://phe.oxfordjournals.org/content/early/recent>

Abstract

Bitton & Eyal (2011)'s lengthy critique of our paper on unassisted cessation was premised on several straw-man arguments. These are corrected in our reply. It also confused the key concepts of efficacy and effectiveness in assessing the impact of cessation interventions and policies in real world settings; ignored any consideration of factors limiting the reach of interventions (cost, consumer acceptability and accessibility); and failed to consider that clinical cessation interventions which fail far more than they succeed also may "harm" smokers by reducing agency. Our paper addresses each of these problems, concluding that any consideration of the ethics of promoting smoking cessation in low income nations should begin and end with the question of whether the strategies to be adopted have any prospect of influencing significant numbers of smokers to quit

The publication of our recent papers on unassisted smoking cessation (Chapman, 2009, Chapman and MacKenzie, 2010) has created high levels of interest and consternation. The PLoS Med paper (Chapman and MacKenzie, 2010) has been accessed over 14,200 times and a critical editorial in *Addiction* (West et al., 2010) was translated into French, Spanish and Chinese and displayed prominently for months on the home page of the pharmaceutical industry sponsored website, www.treatobacco.net. There has also been criticism of our papers, much of which is based on misrepresentations of our key arguments (Chapman S and Mackenzie R, 2010). This attention suggests a raw nerve has been exposed in sections of the smoking cessation professional community.

Bitton & Eyal (Bitton and Eyal, 2011) have written by far the most detailed critique of our papers, in a lengthy essay of two parts. The first builds a ten point argument against one paragraph in the PLoS Med paper in which we argued that because of the high cost of nicotine replacement therapy (NRT) in low income nations, it is inaccessible to all but the wealthy and is therefore irrelevant in achieving population-wide cessation goals in such nations.

The second part, which strangely never refers to low income nations nor to the 10 arguments in part 1, is an ethical critique of two population strategies that promote smoking cessation. The central argument advanced is that raising price through tax and legislating what the authors call “stigmatizing” policies -- are “moderately harmful” to smokers. By contrast, clinical approaches to smoking cessation are said to be “benign”. This leads the authors to conclude that public health has an ethical duty to provide assistance to all smokers wanting to quit.

Straw men assumptions Bitton & Eyal speculate about what we mean by the “assisted cessation” they repeatedly claim we oppose. Unfortunately, they contribute to previous misrepresentations of our argument. It would have been sensible if they had contacted us so we could have clarified this, or referred to our publications which make this clear. But since they did not, we will first summarise our position and douse several bonfires they have set under straw men assumptions before responding to several of their arguments which we believe are ill-informed or ill-conceived.

The most frequently repeated of their straw man assumptions is the claim that we oppose all forms of assistance to smokers and that we “continue to oppose public funding for tobacco treatment and cessation”. They add that we “denounce the provision of NRT medication in FCTC guidelines”, but provide no reference for this incorrect claim. Finally, they say that we oppose “stepwise” approaches to smoking cessation, whereby population-wide policies and programs are complemented by the provision of assisted cessation.

Our principal message The main intent of our papers was to highlight and criticize the unabating neglect and denigration of unassisted smoking cessation in both the research literature on smoking cessation and more importantly, in communications with smokers about

the ways that most smokers actually quit. Our PLoS Med paper(Chapman and MacKenzie, 2010) quantified the research neglect of unassisted cessation described briefly in the earlier Lancet paper(Chapman, 2009), proposed several reasons for it and concluded with a plea for restoring balance in communications with smokers about smoking cessation: “public sector communicators should be encouraged to redress the overwhelming dominance of assisted cessation in public awareness, so that some balance can be restored in smokers’ minds regarding the contribution that assisted and unassisted smoking cessation approaches can make to helping them quit.” We also provided a summary of messages that should be given to smokers. These included: “A serious attempt at stopping need not involve using NRT or other drugs or getting professional support.” (note we did not say that it *must not* involve pharmacotherapy) and that “NRT, other prescribed pharmaceuticals, and professional counseling or support also help many smokers, but are certainly not necessary for quitting.”(Chapman and MacKenzie, 2010) Plainly, these statements acknowledge a role for assisted cessation, and that it can be helpful.

SC’s first paper on this subject “Stop smoking clinics: a case for their abandonment”(Chapman, 1985) was published 26 years ago in 1985. It focused on the insignificant role of smoking cessation *clinics* in contributing to reducing smoking in whole populations, not the contribution of all assisted cessation. In that paper, SC concluded that smoking cessation initiatives remain inconsequential “if they are incapable of being incorporated into a delivery system involving significant numbers of the smoking community.” The paper was a critique of the nascent emergence of dedicated quit smoking clinics in the UK when at the time, that nation had poorly developed tobacco control policies and only small mass reach campaigns. While SC did not elaborate on what such a delivery system would look like, routine interactions between primary health care professionals and smokers plainly qualify. Indeed, SC later wrote about their importance in cessation(Chapman, 1990, Chapman, 1993a). As recently as 2008 he was a non-dissenting member of a peak national Australian committee which recommended that NRT be subsidized in Australia for low income groups(Scollo S et al., 2008), and in 2010, was co-signatory on a letter to the Australian government re-emphasising the importance of subsidizing NRT. The accusation that we are opposed to all efforts to assist smokers to quit is demonstrably wrong.

One of the reasons discussed in our PLoS Med paper for the neglect of unassisted cessation was that the pharmaceutical industry, with its formidable promotional, public relations and research budgets, has a clear interest in eroding public and professional confidence in unassisted smoking cessation despite its enduring superiority across decades in delivering far more ex-smokers than all other approaches to cessation combined(Fiore et al., 1990, Shiffman et al., 2008). It is in the interests of that industry to persuade as many smokers as possible to use pharmaceutical aids for as long as possible. Smokers are now recommended to use NRT before they quit (“pre-quit”)(Lindson and Aveyard, 2011), while attempting to quit, in different combinations, to prevent relapse(Coleman et al., 2010) and according to one industry supported cessation specialist in Australia, some should use it for life. Recently, one study examined the effect on cessation of varenicline when used by smokers with no immediate

intention of quitting(Hughes JR et al., 2011), suggesting that thinking may now be circling the challenge of promoting pharmacotherapy to those unmotivated to quit.

In arguing for the restoration of balance, we felt it necessary to challenge some of the hyperbole in claims for the real-world contribution of assisted cessation(Walsh, 2008). We do not oppose efforts by clinicians to motivate quit attempts and assist smokers to quit, nor steps to facilitate greater accessibility to cessation drugs. What we oppose is the way that unassisted cessation is mostly ignored and frequently denigrated by the professional smoking cessation community, many of whom also have occupationally vested interests in maintaining the fiction that unassisted cessation is not a sensible or “evidence-based” way to quit.

We support stepwise approaches to triaging assistance to smokers, but note that many smokers can quit unassisted and that the primary message to smokers ought not to overstate the difficulty of quitting by constantly characterizing cessation as something that has virtually no chance of success when the experience of most ex-smokers shows otherwise. Smoking cessation today has become deliberately over-medicalised. For example, on this GlaxoSmithKline consumer website for Nicobate (<http://www.path2quit.com.au/>), it is impossible for any smoker to click through the various questions and not arrive at a recommendation that they should use NRT. Even those who answer that they have never attempted to quit before, smoke less than ten cigarettes per day and do not smoke their first cigarette until 30 minutes after waking are recommended to use NRT, despite the Cochrane NRT review stating that “Most of the studies were performed in people smoking more than 15 cigarettes a day.”(Stead LF et al., 2008)

Smokers are inundated with industry marketing that constantly megaphones the message “It’s very hard to quit. You will almost certainly fail if you try alone. You’ve probably tried before and failed, so you know we are right. You can double your chances of success by medicating yourself.” Each part of that message can be contested, particularly if we accept that many “attempts” are trivial, barely recalled and unworthy of being called serious attempts(Gilpin and Pierce, 1994, Shiffman et al., 1997). We believe smokers should be told that there was a great deal of successful cessation in the three decades before medications became available and that unassisted cessation still remains the way that most people quit. If people are constantly told they cannot quit alone, and hear a loud chorus of professionals uncritically singing the same tune we should expect that many will come to believe it. Our concern is with the push to turn as many smokers as possible into treatment seekers when we know that for many this is quite unnecessary. Erroneous beliefs that medication is necessary reduces human agency and may have serious iatrogenic consequences(Singh S et al., 2011).

We could start by challenging researchers to include rarely asked questions in national studies of cessation where ex-smokers rate the difficulty they experienced. From the information gained(Klingemann et al., 2010), a whole new discourse could arise that said “it can be hard for some, but here are strategies we have learned from people who have done it successfully. And

– wait for this – many ex-smokers find it surprisingly easy.”(Medbø A et al., 2011, Campling et al., 2011) These are messages that the pharmaceutical industry seeks to drown out.

There is abundant and uncontested evidence that more people quit unassisted than by any other method. It is unequivocally the “most” successful approach if you have a population rather than a clinical focus on evaluating cessation. Most recently, an Australian study of ex-smokers reported cold turkey (abrupt cessation) as being the most helpful method, ranking above any other cessation method(Hung et al., 2011). There are globally hundreds of millions of unassisted ex-smokers. Dismissing their experience as being inherently uninformative to the hundreds of millions more who will one day take steps to stop is suggestive of weapons-grade myopia.

Response to Part 1

We now turn to other arguments raised in their paper.

Efficacy, effectiveness and reach Three major problems in Bitton & Eyal’s critique are that they appear unaware of the difference between effectiveness and efficiency; appear confused about the meaning of “cost-effectiveness”; and totally ignore considerations about the *reach* of the assisted interventions they advocate. They repeatedly stress the superior “effectiveness” of assisted cessation over unassisted efforts. The concept of efficacy refers to how well interventions work in ideal or controlled situations like clinical trials, while effectiveness refers to how they work in real world settings (Revicki and Frank, 1999).

Walsh has summarized the major differences between the two in smoking cessation(Walsh, 2008, Walsh, 2011): unlike real world users, trialists get free pharmaceuticals; are contacted often by trial researchers, creating Hawthorne effects(Wolfe and Michaud, 2010); and paid travel and expenses. Trialists are also well-known to be unrepresentative of the general population(Schulz and Grimes, 2002, Rothwell, 2005) and cessation trials screen out those with mental health problems(Le Strat et al., 2011) who are heavily over-represented among smokers in the real world. NRT trials have poor blindness integrity, with over half of studies in one review showing that nicotine dependent trialists are significantly more likely than chance to accurately guess that they have been allocated to the placebo arm, meaning that their faith in the “NRT” that they are using is likely to be poor. This may translate into poorer quitting outcomes, thus exaggerating the differences between active and placebo NRT(Mooney et al., 2004). Finally, far more trialists complete the recommended drug regimen than in real world settings(Walsh, 2011, Zwan NA et al., 2002). All this combines to produce trial quit rates that are higher than those in real world settings. A recent Scottish report of 12 month cessation rates comparing an estimated annual self-quit rate of 1.5% with two multi-contact and pharmaceutical aided strategies, found 2.8% of smokers who received up to 12 weeks of individual counselling with pharmacists had quit at one year. The authors noted “This study reports much lower cessation outcomes at 1 year than those found by many other studies of behavioral support and pharmacotherapy for smoking cessation. This may in part be because this was an observational study, and outcomes are often poorer (and relapse rates higher) in population-based rather than controlled studies.”(Bauld L et al., 2011) Yet cost-effectiveness

arguments on smoking cessation drugs typically use trial-derived data, producing inflated estimates useful to the pharmaceutical industry in lobbying for government subsidies.

Moreover, in real world settings, those electing to quit unassisted have better or equivalent quit rates to those who use assisted methods(Shiffman et al., 2008). This is undoubtedly because of self-selection bias: those who choose to use assistance may be those with histories of failure to quit likely due to higher dependence and/or people who have had their confidence undermined by exposure to messages that quitting without assistance is not a sensible route to cessation.

On cost-effectiveness, Bitton & Eyal say that we claim that assisted cessation is “cost-ineffective, in comparison to the alternative of population-based tobacco-control measures” illustrating this with a reference we provided in our paper to the astronomical cost of NRT in Indonesia where 3 months of NRT can cost as much as 7 years supply of cigarettes, placing NRT totally out of the reach of all but the wealthy’. They continue “Regrettably, this is almost the only data that they cite in direct support of their concern about the cost-effectiveness of tobacco dependence treatment in the developing world.” In making this claim, Bitton & Eyal do not appear to understand the concept of cost-effectiveness: our comment on the inaccessible cost of NRT in Indonesia has nothing to do with its cost-effectiveness in cessation, but simply notes that its cost precludes it being used by anyone but the very wealthy in Indonesia.

Reach refers to how well interventions can be disseminated throughout populations and involves consideration of all factors that might inhibit access and participation in any form of assisted cessation. Cost and consumer acceptability are central to access. We previously described the prohibitive cost of NRT in Indonesia(Chapman and MacKenzie, 2010). This is far from an isolated case. On a recent visit to Cambodia pack of 105 2mg gum was selling at \$58.10. Product information for 2mg Nicabate gum advises a maximum of 20 pieces per day (<http://www.nicabate.com.au/products/>). Even if we were to halve that, a 30 day supply would cost a Cambodian smoker \$166, when the average monthly income is \$170. The corresponding cost for the same product used at the same rate for a month in the Philippines is \$140.50 where the average monthly income is \$171.(World Bank, 2010) Data on the cost of NRT and Varenicline in low income nations in the Middle East and North Africa shows a similar picture(Heydari G et al., 2011). At such prices, quite obviously, NRT is utterly beyond the reach of anyone but wealthy elites in the world’s poorest nations.

Bitton& Eyal then argue that because there are examples of pharmaceutical companies occasionally lowering the cost of important drugs for impoverished nations (as happened with anti-HIV retrovirals), we should try to make the same happen for smoking cessation drugs now that NRT has been included on the WHO’s essential medications list(Kishore SP et al., 2010). They say it “is not unreasonable to propose that NRT prices may show an analogous, if not

identical, decline.” We suggest that the analogy is very poor. HIV antiretrovirals are not analogous to cessation drugs because it is perfectly possible to stop smoking without medication, whereas antiretroviral therapy is the only way to stop the progression of HIV infection to severe illness and death. The prospects of impoverished nations subsidizing NRT for whole populations anytime soon are frankly low to zero.

Those who promote assisted cessation because it is “more effective” than unassisted claim it has a higher success rate and that it is important that “every quit attempt [should have] the best possible chance of success”(West et al., 2010). But as we have argued, outside of clinical trials, this advantage is marginal. Most importantly, any relevant calculations of impact here must include the numbers of people who actually quit by various approaches and the proportion who are interested in assisted cessation. If the concern of public health is to maximise cessation throughout whole populations, it is vital that most attention is given to those factors that have realistic potential to maximise the *numbers* of people who quit.

The most elementary perspective provided by a population-wide lens is that policies and interventions with low success *rates* can be much more important than those with higher success rates when the different *reach* of those interventions is considered. The Scottish intensive quit smoking program discussed previously which saw 2.8% of participants quit after one year(Bauld L et al., 2011) may seem to be self-evidently 86% more promising than self-assisted quitting which saw only 1.5% of smokers quit. But if an intensive intervention is only ever run with small numbers of people able to afford drugs or willing to attending counseling, whereas efforts to motivate self-quitting influences 1.5% of *all* smokers to stop, the latter will be immeasurably more important than the apparently more “effective” intervention. A 2.8% success among 5000 participants yields 140 ex-smokers, but 1.5% of 10 million smokers translates to 150,000 ex-smokers.

Apart from the UK, Korea, Japan and special services provided for Maori smokers in New Zealand, we are aware of no nations where extensive networks of smoking cessation services exist with capacity to service anything but small fractions of the sheer number of smokers interested in cessation. This is particularly the case in low income nations, where such services are generally non-existent(Raw et al., 2009). Willingness to attend such services is low, with only 1-7% of smokers even being prepared to call a quitline in a year(Tzelepis et al., 2009). In 2004, the health region in the UK with the greatest participation rate of smokers in special cessation services saw just 6% utilizing these(Milne, 2005).

Yet Bitton & Eyal argue that labour-intensive strategies should command a high portion of a nation’s smoking cessation budget (“usually, a high portion of [tobacco control] funds ought to serve clinical treatment.”) They also argue that we are mistaken in being concerned that the costs of providing widespread access to treatment (free or subsidized drugs and counselling) will be at the expense of greater outlays for population health measures (principally the costs of mass reach public awareness campaigns, as legislation like health warnings and advertising bans cost governments virtually nothing). They claim “budgets for treatment approaches often

come from existing general health services budgets, while the budgets for legislation and campaigns often derive from funds appropriated from general or tobacco taxes. It is rarely politically realistic to transfer clinical care funds into funding legislative efforts.” In fact, what *is* rare is for population-health strategies to be funded from some explicit hypothecation of general or tobacco tax. Health departments in wealthy nations may well be capable of funding both robust population cessation measures and assisted cessation for all smokers who are interested. But poorer nations typically have little to none of either. In such circumstances the “best buys” are undoubtedly population-wide measures which promote quit attempts (Levy DT et al., 2010).

Bitton & Eyal’s fourth argument is particularly odd. They state that our “recurrent claim that ‘unassisted cessation remains the . . . most successful method used by most ex-smokers’ is misleading”. “When someone quits cold turkey” they continue, “not as an effect of clinical cessation programs, it is not necessarily accurate to accredit population-based measures for their successful quit: some such quits are the effect of neither clinical programs nor population-based measures.” We do not pretend to understand what this argument is proposing, but suspect they might be acknowledging that some smokers who quit do so “spontaneously” without conscious attribution of their decision to any policy or intervention. To us, this is saying little more than that the “cause” of people’s decisions are often unclear to them (Chapman, 1993b) but not that the decision to quit in such people is inherently inscrutable.

Their fifth argument is that there is a “large segment of smokers (30%? 50%?) who cannot quit on their own because of high nicotine or psychological dependency” and that they are “often wholly unresponsive to population-based measures - even less responsive than it is to medications.” They offer no support for these two assertions, instead recycling the conventional wisdom inherent in the hardening hypothesis (Warner and Burns, 2003, Hughes, 2011). The argument here is that those who have quit to date were “low hanging fruit”: they quit because they were not particularly addicted, and responded to population measures that stimulated quit attempts, while those still smoking today are more than ever before intransigent, heavily addicted smokers, untouched by population strategies. There are major problems with this argument. Before the advent of NRT and other pharmacotherapies, some 37 million Americans stopped smoking (American Cancer Society, 1986). No one has ever suggested that this massive social phenomenon comprised only light, non-addicted smokers and that there were not many hundreds of thousands, probably millions, of very heavy smokers who quit unaided in these pre-NRT decades. Next, data on smoking in 50 US states for 2006–2007 indicate 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. This is compelling evidence against the hardening hypothesis which would predict the opposite (Giovino et al., 2009).

Response to Part 2 (“Beyond sheer cost-effectiveness”)

The central argument of the second half of their paper is that population-oriented tobacco control is “moderately” or “somewhat” harmful while clinical cessation is benign. We stand accused of having “entirely side-stepped” consideration of a “battery of ethical considerations” which Bitton & Eyal claim justify the provision of assistance to smokers.

Their case for the harmfulness of population-focussed smoking cessation consists of a few apparently self-evident assertions that because raising tobacco prices through tax fails to stop all smokers from continuing, that this price slug harms those who continue to smoke. They summarize the problem thus: “Admittedly, even measures that harm all smokers moderately in economic and psychosocial terms benefit many smokers more than they harm them. Smokers who successfully quit because of these measures usually gain much more than they lose. But for the smokers who do not quit, taxes and stigmatizing regulations represent net harm.”

First, consider the harm from a tax rise. When tobacco tax rises, some of those who fail to stop smoking reduce their consumption, possibly reducing their risk and spending the same each week as before. Others may adjust other expenditures in their lives to accommodate their decision to keep smoking at the same rate. Those who point to rising tobacco prices harming the poor typically assume that it is only essential expenditures which are thus impacted. We have very poor detailed information on how continuing smokers adjust their consumption of other goods and services when the price of tobacco rises. Some may indeed reduce their expenditure on “positive” outlays like food, health care, children’s clothing and education or savings. But others may reduce their consumption of discretionary negative “sin” outlays such as gambling or excessive alcohol consumption or expenditures such as frivolous use of mobile phones. For Bitton & Eyal though, the harm caused by raising tobacco tax is self-evident, and requires no evidence.

Next, consider their claims for the harm of “stigmatizing regulations”, none of which are either named nor the harm said to arise detailed. Perhaps they believe that pack warnings and mass public awareness campaigns highlighting the risks of smoking harming smokers are harmful to them? If so, would it follow that ethical conduct would require that such information be suppressed because it might upset some smokers who were thus exposed?(Chapman S, 1988) Would it be more virtuous to keep smokers in blissful ignorance of the risks they faced?

Or perhaps they are alluding to the often expressed alienation and stigmatization that some smokers report about having to smoke outdoors and being now unable to expose others to their secondhand smoke in public spaces? Again, if such restrictive policies harm smokers, it hardly follows that we should return to the days when smokers were able to exercise their freedom to smoke at the expense of others’ health and amenity.

Bitton & Eyal also fail to acknowledge that mass reach public awareness campaigns targeted at smokers are also known to have important collateral effects on reducing uptake among young people who see these adult-targeted campaigns and are influenced by them(White VM et al.,

2011, White et al., 2003). We are unaware that any comparable collateral preventive benefits have ever been documented following adoption of assisted cessation strategies.

There is an extensive legal-philosophical literature around the concept of harm, the the work of Feinberg being particularly important(Feinberg J, 1984, Feinberg J, 1986). It is not necessarily the case that a cost, or an adverse effect, always qualifies as a harm. Bitton & Eyal need to do much more to establish that tax increases harm smokers, especially as they agree such measures will induce some smokers to quit, thereby leaving smokers at least as well off, and probably better off. It could then be observed that even if population health measures do deliver net harms to some smokers, access to cessation services would only present adequate compensation for that harm if they were able to benefit them. As we have argued, the cessation assistance cannot be relied upon to deliver such benefits.

Is assisted cessation ethically benign? The authors argue that the provision of cessation assistance is ethically superior to population-focused tobacco control because “Treatment agencies ... impos[e] less harm through free or low-cost, non-stigmatizing cessation interventions.” Notwithstanding recommendations that smoking cessation medications should be part of all nations essential drugs programs, free or low cost assistance is far from a reality in most nations(Raw et al., 2009), where purchasing smoking cessation medication involves considerable financial outlay that economists would count as “harmful”.

Moreover, most who pay for cessation drugs or attendance at specialized cessation services fail to quit and so get no gain for their outlay. A 2003 meta-analysis of studies of over-the-counter users of NRT found that 93% had resumed smoking within six months(Hughes et al., 2003) Varenicline has been implicated in serious health risks (Singh S et al., 2011). Additionally, any smoker could not fail to have encountered on thousands of occasions messages that using assistance greatly improves the chances of successful cessation. Consider then, that in real-world settings a large majority of smokers who use varenicline, NRT or attend counseling fail to quit. Might not it be likely that such experiences would lower the self-confidence of such smokers even further than had their previous experiences of trying to quit unaided? Might not many such smokers say to themselves: “I heard experts saying that I should use drugs and professional help to quit and that trying to quit by myself is a recipe for failure. So I got help, and I still failed. Perhaps I am now beyond help?”

Compare the putative harm from such scenarios with that allegedly caused to smokers being exposed to unsettling information about health risks or being told that they cannot ignore the wishes of others to not be harmed by secondhand smoke. Bitton & Eyal ignore such considerations.

Conclusion

We believe that any consideration of the ethics of promoting smoking cessation in low income nations should begin and end with the question of whether the strategies to be adopted have any prospect of influencing significant numbers of smokers to quit across whole populations.

Promoting quit attempts in large numbers of smokers is the most important strategy for improving cessation rates throughout a population (Hyland et al., 2006, Levy DT et al., 2010). Forms of assistance that are beyond the reach of most smokers because of cost or scarcity of access are simply irrelevant to any serious discussion about increasing cessation across the populations of such nations. With few low income nations having even rudimentary mass-reach cessation promoting policies and interventions in place, the proposal that the governments of such impoverished nations would even consider investing in population-wide free or subsidized access to pharmaceutical or labour-intensive counseling services is unrealistic. Beyond mass reach media campaigns to stimulate quit attempts, incorporating minimal cessation interventions into routine primary care holds the most promise. However, even here, expectations should be realistic. As the 2000 US National Institutes of Health Monograph that reviewed population impacts of various smoking cessation approaches 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.” (National Cancer Institute)

Acknowledgement: We thank our reviewers for their helpful comments

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