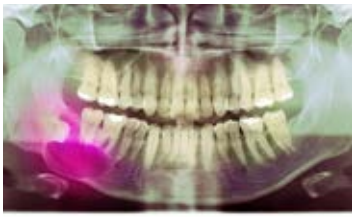
research

Doctors' political preferences do not influence intensity of patients' end of life care p 19

Cigarette price increases most benefit the health of those on the lowest incomes p 20



Analgesics after third molar extraction: first in a new series on unreported clinical trials p 22

ORIGINAL RESEARCH Retrospective observational study

Physicians' political preferences and the delivery of end of life care in the US

Jena AB, Olenski AR, Khullar D, Bonica A, Rosenthal H

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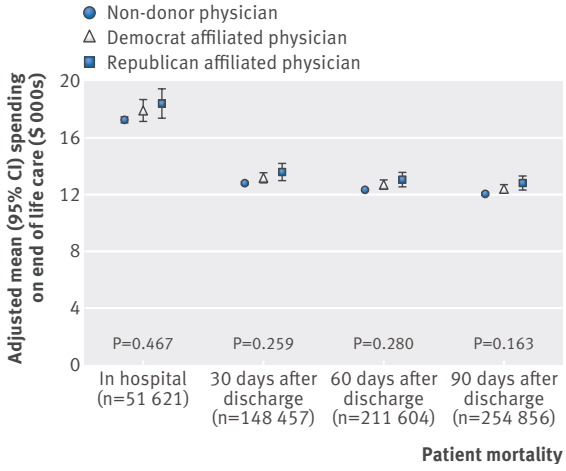
Study question Do the political affiliations of hospital physicians influence how they provide end of life care to Medicare patients in the US?

Methods For Medicare beneficiaries admitted to hospital with a general medical condition in 2008-12 and who died in hospital or shortly thereafter, data were analysed on whether end of life care varied by physician political affiliation based on financial contributions to candidates and committees identified in the Database on Ideology, Money in Politics and Elections (DIME). Measures of end of life care included total inpatient spending, intensive care unit use, intensive end of life treatments (eg, mechanical ventilation and gastrostomy tube insertion), and hospice referral among patients discharged from hospital but at high predicted risk of death shortly after discharge. Hospital physicians were categorised as Democrat, Republican, or non-donors, using federal political contribution data.

Study answer and limitations Among 1 480 808 patients, 93 976 (6.3%) were treated by 1523 Democrat physicians, 58 876 (4.0%) by 768 Republican physicians, and 1 327 956 (89.6%) by 23 627 non-donor physicians. Democrat physicians were younger, more likely to be women, and more likely to have graduated from a top 20 US medical school than Republican physicians. Mean end of life spending, after adjustment for patient covariates and hospital specific fixed effects, did not differ between Democrat and Republican physicians ($17 938 (£12 872) (95% confidence interval $17 176 to $18 700) *v* $18 409 ($17 362 to $19 456); adjusted Republican *v* Democrat difference, $472 (−$803 to $1747), P=0.47). Intensive end of life treatments for patients who died in hospital and the proportion of patients discharged from hospital to hospice did not vary with physician political affiliation. Among patients in the top 5% of predicted risk of death 30 days after hospital discharge, adjusted proportions of patients discharged to hospice were 15.8%, 15.0%, and 15.2% among Democrat, Republican, and non-donor physicians, respectively (adjusted difference in proportion between Republicans *v* Democrats, −0.8% (−2.7% to 0.9%), P=0.43). The study design was observational and therefore causal associations cannot be identified.

What this study adds This study suggests that hospital physicians' political preferences do not influence the intensity of end of life care given to Medicare patients.

Funding, competing interests, data sharing The study was unfunded. The authors have no competing interests to declare. No additional data available.



Adjusted mean spending (95% confidence interval) on end of life care, by patient mortality and physician political affiliation. Mean adjusted estimates were calculated by the marginal standardisation form of predictive margins, a standard approach that computes adjusted estimates by averaging over the entire covariate distribution in the data. P values indicate comparison between Democratic and Republican physicians

The benefits of taxing cigarettes

ORIGINAL RESEARCH Compartmental model study

The health, poverty, and financial consequences of a cigarette price increase among 500 million male smokers in 13 middle income countries

Global Tobacco Economics Consortium

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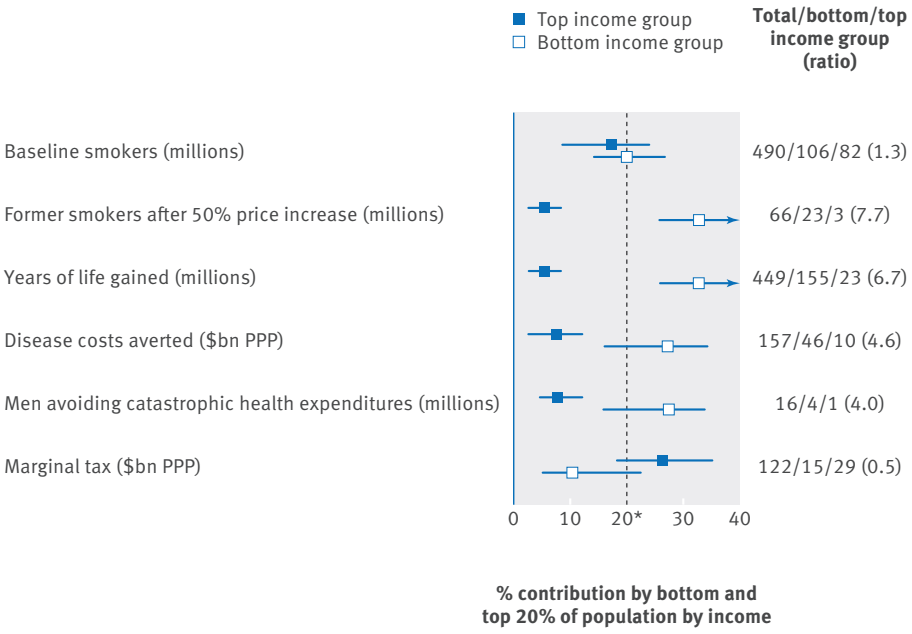
Study question How do higher cigarette taxes influence the health and finances of smokers of low and high incomes?

Methods The authors use a compartmental model to examine the effect of an increase in cigarette price on life years gained, averted treatment cost, those avoiding catastrophic health expenditures and poverty, and additional tax revenue, by income groups (contrasting the poorest 20% and richest 20% of the population), in 13 middle income countries covering 500 million male smokers.



Share of health and financial benefits accruing to bottom and top income groups of population. *Expected value if no differences exist across bottom and top income groups

COMMENTARY People on low incomes have the most to gain

In the paper above, the Global Tobacco Economics Consortium provides a detailed analysis of the effects of a substantial (50%) increase in the tobacco excise tax in 13 middle income countries.[2] In their model of half a billion male smokers, estimates of the responsiveness of demand to cigarette tax increases suggest that tax increases will result in substantial smoking cessation (particularly among people on low incomes), reduce tobacco attributable years of life lost, and decrease the risks of catastrophic medical costs in these countries.

Many economists, including former US treasury secretary Lawrence Summers, argue that taxes could be more effectively applied to slow the global epidemic of non-communicable diseases, especially in low and middle income countries. Not only do such fiscal policies reduce tobacco consumption, they also denormalise tobacco use and can support funding for public health programmes.[3]

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Economists and public health advocates agree that a substantial price increase in tobacco will result in decreased tobacco consumption and resulting illness

Here, we review some economic arguments for cigarette taxation. Firstly, smokers generate costs for non-smokers, such as from diseases due to secondhand smoke or environmental pollution from discarded cigarette butts. Although most economists would agree that such environmental externalities justify some form of government intervention, direct regulation of exposure to secondhand smoke is likely a more effective policy instrument than taxation to deal with them.

Secondly, smokers impose future costs on publicly financed health systems. This argument has been muddied (and subsequently exploited by the tobacco industry) because expenditures for smoking related illness can be offset by decreased public benefits due to shorter lifespans of smokers.[5] However, this accounting often fails to incorporate the economic and social contributions of those who live to older ages in good health.

A rational tax

A more powerful economic argument for high cigarette taxes rests on behavioural principles. Important evidence has emerged not only on the addictiveness of nicotine but also on people's hyperbolic discounting (a time inconsistent degree of patience—discounting the near term future more than the long term future—that prevents people from following through on past commitments). These behavioural features rationalise taxes as a way of aligning behaviour to long term preferences and suggest substantially higher taxes than those justified by concerns about externalities alone.[6 7]

The Global Tobacco Economics Consortium usefully counter one common argument against cigarette taxes: that they are regressive. Indeed, people on low incomes are much more likely than people on high incomes to cease smoking as prices

Study answer and limitations Higher cigarette prices provide substantially more health and financial gains to the bottom income group than to the top income group. A 50% increase in cigarette prices would lead to about 450 million years of life gained across the 13 countries from cessation. The bottom income group would gain seven times more life years than the top income group. The average life years gained for each smoker from cessation in the bottom income group would be five times that of the top income group. Of the $157bn (£113bn) in averted treatment costs, the bottom income group would avert five times more costs than the top income group. About 16 million men would avoid catastrophic health expenditures in seven countries without universal health coverage. As a result, nine million men, half of them in the bottom income group, would avoid falling below the World Bank's extreme poverty line. In contrast, the top income group would pay twice as much of the $122bn additional tax collected as the bottom income group. In the absence of epidemiological studies in each country, this modelling study used (generally robust) assumptions for some study parameters .

What this study adds In 13 countries with a range of socioeconomic levels and health finance arrangements, a 50% increase in cigarette prices strongly favours those in the bottom income group for life years saved, out-of-pocket expenses from tobacco attributable treatment costs averted, and avoidance of catastrophic health expenditures or poverty.

Funding, competing interests, data sharing This study was supported by the Fogarty International Center of the US National Institutes of Health (grant R01 TW05991-01), Dalla Lana School of Public Health, University of Toronto, Canadian Institute of Health Research (FDN 154277), the Bill & Melinda Gates Foundation, and the International Development Research Centre. The authors declare no competing interests. The analyses codes are available on written request to the authors.

rise and will therefore reap health gains large enough to neutralise concerns about regression.

Much remains to be learnt: research is required across the developing world to estimate optimal taxes according to local tobacco markets, health system costs, and people's discount rates of the future costs of smoking. Also, cigarette taxes are often part of an anti-tobacco policy package, potentially confounding the estimated effects of tax increases on demand. Finally, taxes should be designed to minimise switching to cheaper (perhaps unhealthier) types of tobacco, and to prevent illegal tax avoidance.

Tobacco use remains a leading cause of premature mortality worldwide,[8] its health consequences are disproportionally on people on low incomes,[9] and tobacco production and use creates substantial adverse global environmental impacts.[10] Public health professionals advocate for total abstinence from tobacco use and view high excise taxes primarily as a public health intervention and not a government revenue tool.[11]

All countries are committed to reducing preventable non-communicable diseases, and this stated social preference means that reduction of smoking related illness counts not only towards the "private" gain of smokers but towards broader social goals.

All together now

Both economists and public health advocates agree that a substantial price increase in tobacco will result in decreased tobacco consumption and resulting illness. The Global Tobacco Economics Consortium have done yeoman's work in its analysis, and it dispels some common misconceptions about raising tobacco taxes in middle income countries (see box 1 in the linked paper on bmj.com). Ministers of finance of signatory countries to the Framework Convention on Tobacco Control should understand the fiscal and health benefits of the tax guidelines in the framework just as clearly as the public health advocates who so vigorously support them.[12]

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Introducing unreported clinical trial of the week

Clinical trials are the gold standard in medicine, yet trial results are still routinely left unreported. This problem has been well documented and has a negative impact on patient care: we cannot make informed choices about treatments when trial results are withheld from doctors, researchers, and patients.

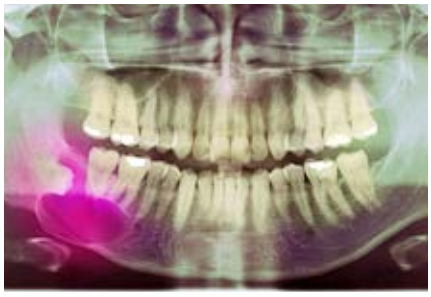
Here we describe a new regular initiative. Every week on bmj.com/blogs we will publish a brief piece describing one important, unreported trial that could be used to improve patient care. We hope that this will make the rather abstract issue of publication bias more concrete, shed light on the problem, provide a forum to discuss challenges and misunderstandings around trial reporting, and, ultimately, improve reporting rates.

Our initial sample of unreported trials will be drawn from those recently breaching the Food and Drug Administration Amendments Act (FDAAA 2007). This law requires that certain clinical trials in the US report results within one year of completion, and it was initially hailed as proof that publication bias has now been tackled. Sadly, audits estimate that only one trial in five has complied. Furthermore, although the FDA can levy fines of $10 000 (£7148) per day for every overdue trial, no such fine has ever been imposed.

The "final rule" that clarified details around the implementation of FDAAA was published in 2016. This gave much needed clarity on FDAAA's numerous complex loopholes: the global ethical obligation is that all trials must report results, but FDAAA still permits various categories to be left undisclosed. Nonetheless, we have reviewed this law in detail and we have implemented all its loopholes in software form, as described in our preprint paper.

Every day our code automatically downloads the whole of ClinicalTrials.gov. Every day we identify every individual new unreported trial—the moment it goes overdue. All these data are searchable, and ranked, live online at our interactive website (FDAAA.trialstracker.net).

We think our live TrialsTracker approach is superior to a static estimate of overall reporting rates in a journal paper. The data on our TrialsTracker update daily: any sponsor who improves is rewarded, immediately, and we hope that this will help incentivise improvement. Our tool is also searchable: we don't just give overall



performance statistics for sponsors; we make it easy to find the individual unreported trials. This is by design. We believe that individual accountability is an important motivator for change.

But more than this, we have made our tool available to help those who want to comply with their obligations: we don't just publish an overall ranking; we want to help institutions and companies find unreported trials, and tackle them. This is more than a theoretical aspiration. We already have positive feedback from staff at US universities who have used our tool to find and report unreported trials that had previously been overlooked.

That is the context for this series. Every week we will cover one unreported trial; describe the interventions, population, number of participants, and outcomes measured; briefly discuss the trial's clinical relevance; and identify the sponsor and principal investigators. These pieces will be written in collaboration with some of the thousands of patients and patient organisations that are part of the AllTrials campaign. We welcome offers of wider collaboration from patients and suggestions for individual unreported trials to discuss.

It has been more than four decades since non-reporting of clinical trials was first reported. It is time for this to be fixed. We look forward to productive discussions in the responses to this series, and we hope that these will focus on getting all trials reported.

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Síle Lane, head of international campaigns and policy, Sense about Science

Richard Stephens, chair, Consumer Forum, National Cancer Research Institute

Competing interests: See online.

THIS WEEK'S UNREPORTED STUDY

Analgesics after third molar extraction

Background The US FDA Amendments Act (FDAAA 2007) requires certain clinical trials to report their results on ClinicalTrials.gov within one year of completion. Our tracker (FDAAA.trialstracker.net) shows all individual trials that breach this legal requirement.

Trial NCT02133326 This week's unreported study is: "Assessment of Preemptive Analgesic Effect of Caldolor® vs. Ofirmev® on Third Molar Surgery: A Prospective, Randomized, Double-blinded Clinical Trial." The participants were adults (n=67), each having at least two teeth removed. Participants were randomised to receive either intravenous ibuprofen or intravenous paracetamol before surgery. The primary outcome was postoperative pain, as measured on a visual analogue scale during the week after surgery. The secondary outcome was the amount of pain medication consumed. The trial was double blinded and began in March 2014. The completion date given is January 2017, and the trial's registry record was last updated by the researchers in January 2017.

Discussion This is an important trial results of which would be invaluable for clinicians and patients. The condition is common: impacted wisdom teeth are seen throughout the world, and surgical removal is common, with 10 million operations per year in the US. No one likes to be in pain, and knowing the relative merits of one drug over another in preventing postoperative pain for common procedures can have a huge impact on quality of life. This study is particularly relevant given the growing opioid crisis: dentists are proportionally the largest prescribers of opioid drugs in the US. The secondary outcome of the trial assessed reduction in use of postoperative analgesics.

Conclusion This unreported trial was sponsored by Tufts University School of Dental Medicine in Massachusetts, where it was also conducted. The primary investigator is Archana Viswanath. We hope that the investigators will share the results of this trial soon.

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