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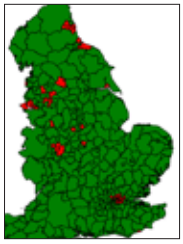

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ORIGINAL RESEARCH Time trend analysis

Investigating the impact of the English health inequalities strategy

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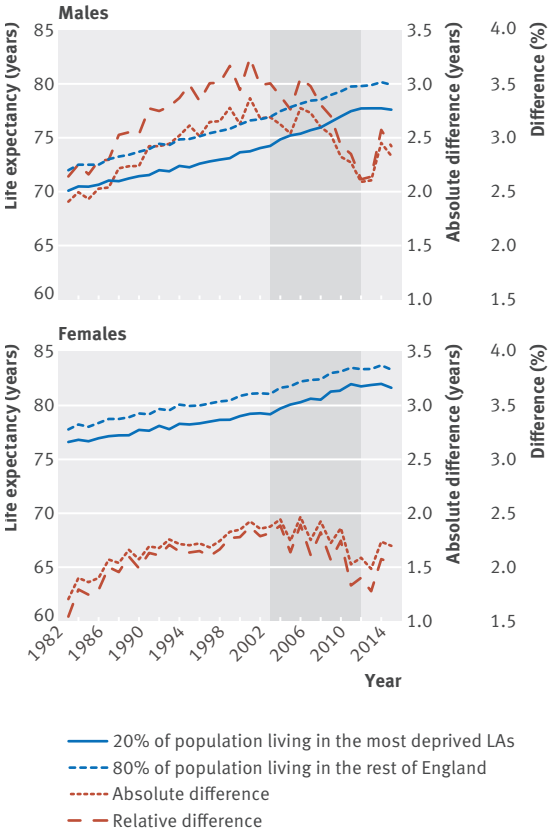
Study question Was the English health inequalities strategy (1997-2010) associated with a decline in geographical health inequalities, compared with trends before and after the strategy?

Methods Analysis of the gap in male and female life expectancy between the most deprived fifth of local authorities and the rest of the country between 1983 and 2015 using segmented linear regression.

Study answer and limitations The gap in life expectancy increased before the health inequalities strategy, declined during the strategy period, and increased since the strategy came to an end. Between 1983 and 2003 the gap increased at a rate of 0.57 months each year (95% confidence interval 0.40 to 0.74 months) for men and 0.30 months each year (0.12 to 0.48 months) for women. From 2004 to 2012 this trend reversed and the gap in life expectancy for men reduced by 0.91 months each year (0.54 to 1.27 months) and for women by 0.50 months each year (0.15 to 0.86 months). Since 2012 there has been a statistically significant change in the trend (P<0.05), with the gap increasing again at a rate of 0.68 months each year (−0.20 to 1.56 months) for men and 0.31 months each year (−0.26 to 0.88 months) for women. By 2012 the gap in male and female life expectancy was 1.2 years and 0.6 years smaller than it would have been if the trend in the gap before the strategy had continued.

What this study adds Trends in geographical health inequalities before, during, and after the strategy, show that it may have reduced these inequalities, reversing a previously increasing trend. The findings suggest that a cross government strategy that focuses increased social investment at more deprived areas and population groups can reduce health inequalities. Current government policies are potentially reversing these gains and future approaches should learn from the experience of the 1997-2010 strategy.



Trends in life expectancy in most deprived local authorities (LAs) and rest of England, and relative and absolute differences 1983-2015. Shaded area represents strategy period

Data sharing, funding, competing interests This study was funded by the Commission of the European Communities and the National Institute for Health Research. The views expressed are those of the authors and not the funding bodies. The authors have no competing interests.

E-cigarette use linked to higher smoking cessation rates

ORIGINAL RESEARCH Evidence from US current population surveys

E-cigarette use and associated changes in population smoking cessation

Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ

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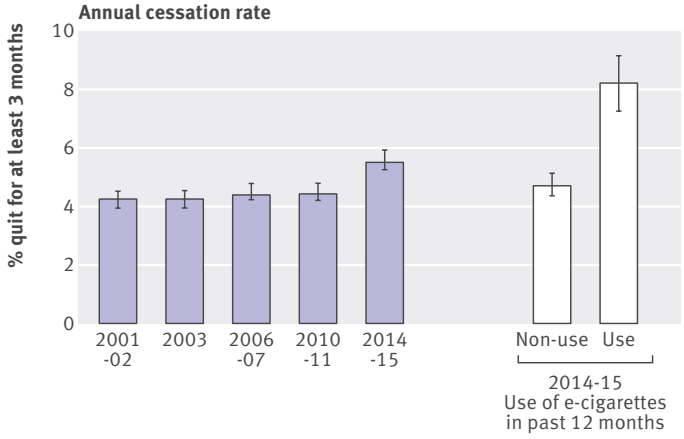
Study question Was the increase in use of electronic cigarettes in the US between 2010 and 2015 associated with a change in overall smoking cessation rate at the population level?

Methods The authors examined data from the US Current Population Survey-Tobacco Use Supplement for 2001-02, 2003, 2006-07, 2010-11, and 2014-15. The prevalence of e-cigarette use and smoking cessation rates were obtained from the 2014-15 survey (n=161 054). Smoking cessation rates from 2014-15 were compared with those from 2010-11 and with those from three other of the previous surveys. The main outcome was the rate of attempt to quit cigarette smoking and the rate of successfully quitting smoking, defined as having quit smoking for at least three months at the time of survey.

Study answer and limitations The increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. In 2014-15, e-cigarette users were more likely than non-users to



Annual cessation rate from 2001-02 to 2014-15

COMMENTARY New evidence supports a liberal approach to e-cigarette regulation

Evidence for the effectiveness of e-cigarettes as smoking cessation aids for individual smokers, still limited to just two randomised controlled trials of now obsolete e-cigarettes, suggests they are at least as effective as nicotine patches.[1]

A handful of efficacy trials currently under way with newer products will contribute much needed randomised data to this evaluation (see web extra on bmj.com). But perhaps more important to tobacco control policy makers than evidence at the level of individual efficacy is the question of whether the growing use of e-cigarettes is having a positive or negative impact at the population level.

Claim and counter claim

Since their appearance in Western countries almost a decade ago, e-cigarettes have generated considerable debate.[2] But the claims and counterclaims as to their benefits or harms, including whether they increase or decrease population quit rates, have been based more on speculation and ideology than on empirical evidence. In a linked paper Zhu and colleagues address this gap, bringing new evidence to bear on this important issue.[3]

Where permissive approaches exist, substantial numbers of smokers will make the transition away from smoking

Drawing on nationally representative samples of the US population from a series of large population surveys over a period when e-cigarette use increased dramatically, from just over 1% in 2010-11 to as high as 30% in 2014-15, the authors calculated quit attempt and quit success rates in regular smokers who used e-cigarettes and those who did not, then measured the difference in population quit rates between the two periods. The study is the largest population based study of e-cigarette use to date, with sample sizes in each included survey of more than 160 000.

The noticeable increase in e-cigarette use during 2010-15 in the United States was associated with a considerable and unprecedented increase in quit attempts, but most importantly in population quit rates, from 4.5% to 5.6%. This increase of just over one percentage point is higher than those for all other survey years since 2000 in which the surveys, using the same methods and measures, have been conducted.

But could other tobacco control interventions operating at the same time have been the key triggers to the observed step change? The authors account in meticulous detail for such alternative explanations for the associations. They mount a convincing case for why the two most likely candidates—a large federal tobacco tax increase in 2009 and a nationwide mass media campaign—could not be standalone reasons for the change in cessation rates.

Mind the gap

Some gaps need filling: Zhu and colleagues' analyses do not yet extend to investigating the distribution of effect among different population groups, particularly those with the highest smoking rates. This will be important for informing health providers and decision makers about the impact of e-cigarettes on smoking related health inequities.

Moreover, the researchers were unable to address other considerations, such as the long term safety of e-cigarettes, an important issue for clinicians and policy makers who must weigh up population harms and benefits of using e-cigarettes (but should

attempt to quit smoking, 65.1% v 40.1% (change=25.0%, 95% confidence interval 23.2% to 26.9%), and more likely to succeed in quitting for three or more months, 8.2% v 4.8% (3.5%, 2.5% to 4.5%). The overall population cessation rate for 2014-15 was significantly higher than that for 2010-11, 5.6% v 4.5% (1.1%, 0.6% to 1.5%), and higher than those for all other survey years (range 4.3-4.5%). Limitations of the study include use of self report and cross sectional data.

What this study adds E-cigarette use was associated with a statistically higher smoking cessation rate at the individual level as well as at the population level.

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only do so relative to the counterfactual of continued use of tobacco cigarettes).[4]

The study findings are not entirely novel: recent research using a different methodology published in this journal from the UK drew similar conclusions.[5] Notably, both studies analysed data from populations in countries with (currently) relatively liberal regulatory approaches towards e-cigarettes. The research by Zhu and colleagues suggests that where such permissive approaches to e-cigarettes exist—ones that enable smokers to have ready access to products that deliver nicotine effectively, at a price lower than that of tobacco cigarettes—then substantial numbers of smokers will make the transition away from smoking, and a substantial population benefit can result. In light of this evidence, policy makers in countries contemplating a more restrictive approach to the regulation of e-cigarettes should pause to consider if pursuing such a course of action is the right thing to do for population health.

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ORIGINAL RESEARCH Audit study

Pharmaceutical companies' policies on access to trial data, results, and methods

Goldacre B, Lane S, Mahtani KR, et al

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Study question What information on clinical trials do pharmaceutical companies commit to make publicly available, and do they comply with ethical and professional guidance?

Methods In this audit study, the authors downloaded all publicly accessible policy documents available at April 2016 and used these to assess each company's commitments on trial registration and access to summary results, clinical study reports, and individual patient data. The results were sent to companies for validation, and their responses were reviewed.

Study answer and limitations Policies were highly variable. Of the 23 eligible companies from the top 25 companies by revenue, 91% (21) committed to register all trials and 96% (22) to share summary results; however, policies commonly lacked timelines for disclosure; and only 26% (6) covered trials on unlicensed products. 74% (17) committed to share results from past trials: the median start date for this commitment was 2005. 96% (22) had a policy on sharing clinical study reports, mostly on request: two committed to share only synopses, and only two policies included trials on unlicensed products. 96% (22) had a policy to share individual patient data, 14 included phase IV trials, and one included unlicensed products. Policies in the exploratory group of smaller companies made fewer transparency commitments. Two companies fell short of minimal industry commitments. Companies often used contradictory and ambiguous language.

Documents were hard to find; therefore some may have been missed.

What this study adds Policies were often poorly worded and internally inconsistent. Other than journal submission for the trials within 12 months, all elements of best practice were met by at least one company, suggesting these elements are feasibly deliverable by all companies.

Funding, competing interests, data sharing BG is funded by the Laura and John Arnold Foundation to work on research integrity. BG, CH, IB, and SL help run the AllTrials.net campaign for all trial results to be reported.

Examples of companies and summary policy commitments (data are from April 2016)

Company name	Policy to share summary results?	Commit to share results within 12 months of trial completion?	Commitment from	Policy to share IPD?	Policy includes unlicensed products and phase IV trials?	Commitment from
Abbott	Unclear	No		No		
AbbVie	Yes	No	2004	Yes	No	2003
Alkermes plc	No			No		
Almirall	Yes	Yes		No		
Amgen Inc	Yes	Yes	2007	Yes	Unclear	
Astellas Pharma	Yes	No	2014	Yes	No	2008
AstraZeneca	Yes	Yes	2004	Yes	Unclear	2009
Bayer	Yes	No	2004	Yes	No	2012
Biogen	Yes	Yes	2005	Yes	No	2012
Boehringer Ingelheim	Yes	Yes	1999	Yes	Unclear	1999
Bristol-Myers Squibb	Yes	No	2007	Yes	No	2007
Celgene	Unclear	No		Yes	No	2012
Daiichi Sankyo	Yes	Yes		Yes	No	2012
Dainippon Sumitomo	No			No		
Eisai	Yes	No		Yes	No	2012
Eli Lilly	Yes	No	2003	Yes	No	2014
Esteve	No			No		
Gilead	No			No		
GlaxoSmithKline	Yes	No	2004	Yes	Yes	2014
Grünenthal	No			Yes	No	2015
Ipsen	Yes	Yes	2005	No		
Johnson & Johnson	Yes	No		Yes	No	
LEO Pharma	Yes	Yes	1990	Yes	No	2000
Lundbeck	Yes	No	2014	Yes	No	2012
Medtronic	Yes	No		No		
Menarini	Yes	Yes		No		
Merck	Yes	No	2008	Yes	No	2008
Merck KGaA / Serono	Yes	Yes	2014	Yes	No	2012
Novartis	Yes	Yes	2005	Yes	No	2012
Novo Nordisk	Yes	Yes	2005	Yes	No	2002
Orion Pharma	Yes	No		Yes	No	-
Otsuka	Yes	No		Yes	No	2012

IPD=individual patient data.