Effect of telehealth on quality of life and psychological outcomes over 12 months (Whole Systems Demonstrator telehealth questionnaire study): nested study of patient reported outcomes in a pragmatic, cluster randomised controlled trial

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- News: NHS boards see telehealth only as a means of saving money, warns expert (*BMJ* 2012;345:e4633)
- Observations: Show us the evidence for telehealth (*BMJ* 2012;344:e469)
- Feature: Does telemedicine deserve the green light? (*BMJ* 2012;345:e4622)
- News: Be wary of signing deals for telehealth technologies, conference hears (*BMJ* 2012;344:e1750)

STUDY QUESTION

Does the addition of a home based telehealth service improve health related quality of life, anxiety, and depressive symptoms over a 12 month period for patients with chronic obstructive pulmonary disorder, diabetes, or heart failure, compared with usual care only?

SUMMARY ANSWER

A series of sensitivity analyses indicated no statistically or clinically significant differences between telehealth and usual care on any of five outcome measures assessed.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Evidence for the effect of telehealth on outcomes such as health related quality of life, anxiety, and depression is uncertain, owing to poor quality studies published so far. We found no beneficial effect of telehealth over a 12 month period, but our results suggest that concerns over potential harmful effects of telehealth are largely unfounded.

Design

A study of patient reported outcomes was nested in a pragmatic, cluster randomised trial of telehealth versus usual care. Blinding was not feasible. General practice was the unit of allocation, and practices were allocated to intervention or control groups using a computer generated minimisation algorithm to ensure comparability.

Participants and setting

We recruited 1573 patients with a confirmed diagnosis of chronic obstructive pulmonary disease, diabetes, or heart failure from 154 general practices.

Primary outcome(s)

Health related quality of life was measured using two SF-12 subscales (physical component score, mental component score) and the EQ-5D. Anxiety and depressive symptoms were measured by the Brief State-Trait Anxiety Inventory and the 10 item Centre for Epidemiological Studies Depression Scale, respectively. We assessed outcomes at baseline, four months (short term), and 12 months (long term).

Main results and the role of chance

Unadjusted means showed that telehealth and usual care had relatively stable and similar patterns on the five outcome measures across the three assessment points. The confidence intervals showed that differences between trial arms were non-significant for any outcome at any assessment point (for example, SF-12 physical component scores). Adjusted inferential analyses (multilevel models) comparing outcomes at four and 12 month assessments showed no significant differences between trial arms on any outcome (all P>0.05). We calculated effect sizes (standardised mean differences) for all outcomes at four and 12 months; all comparisons between telehealth and usual care failed to reach the trial defined, minimally important clinical difference (Cohen's d=0.3). Sensitivity analyses showed that differences between trial arms were not statistically or clinically significant. These findings were robust to variations in attrition, protocol fidelity, and choice of outcome measure. The null findings are unlikely to be attributable to lack of statistical power or the role of chance.

Harms

None reported.

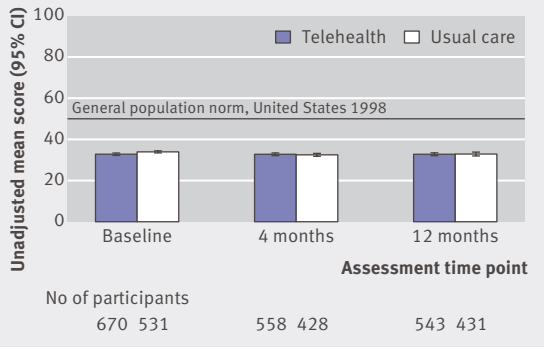
Bias, confounding, and other reasons for caution

The study had attrition bias—only 1201 (76%) participants in the questionnaire sample at baseline completed one or more follow-up assessments; only 759 (48%) completed both follow-up assessments. Non-responders at follow-up could have differed from responders in important ways that were not measured.

Generalisability to other populations

Each study site implemented variations of home based telehealth. Heterogeneity of participants, practices, and telehealth configurations was preserved in all analyses reported, thereby maximising the generalisability of the findings to other settings. It is unclear whether the findings generalise to other clinical populations.

SF-12 physical component score in study groups



Impact of a stepwise introduction of smoke-free legislation on the rate of preterm births: analysis of routinely collected birth data

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- News: Dutch groups appeal against "irresponsible" plan to exempt small cafés from smoking ban (*BMJ* 2010;341:c5503)
- Research: Short term impact of smoke-free legislation in England (*BMJ* 2010;340:c2161)
- Research: Changes in exposure of adult non-smokers to secondhand smoke after implementation of smoke-free legislation in Scotland (*BMJ* 2007;335:549)

STUDY QUESTION

What effect did Belgium's phased implementation of smoke-free legislation (for workplaces in January 2006, for restaurants in January 2007, and for bars serving food in January 2010) have on the incidence of preterm delivery in the population?

SUMMARY ANSWER

The risk of preterm birth declined after the introduction of each phase of the smoke-free legislation.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

There is growing evidence that secondhand smoke has a negative impact on pregnancy outcomes, but few studies have investigated the impact of smoking bans. The stepwise implementation of smoke-free legislation in Belgium showed successive reductions in preterm deliveries after each legislation phase, with the largest reductions coinciding with the smoking ban in restaurants and in bars serving food.

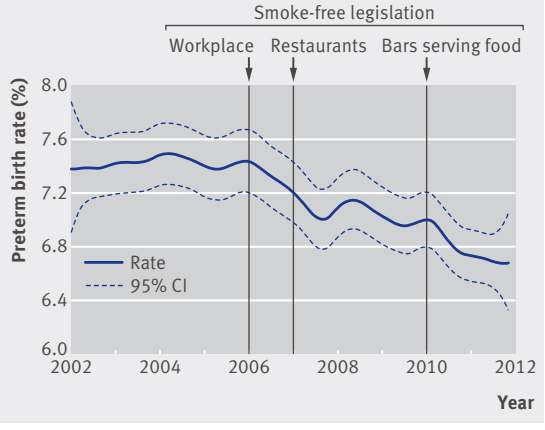
Participants and setting

We examined data for all live born singleton births delivered in Flanders (Belgium) at 24–44 weeks of gestation. In Belgium, smoke-free legislation was implemented in three separate phases: in all public places and workplaces, except for the catering industry, implemented on 1 January 2006; in restaurants, introduced on 1 January 2007; and in bars serving food, implemented on 1 January 2010.

Design, size, and duration

We conducted logistic regression analyses on routinely collected birth data from January 2002 to December 2011, with overall preterm delivery (n=606 877) and spontaneous preterm delivery (n=448 520) as the main outcome measures.

Spontaneous preterm deliveries in Flanders



Main results and the role of chance

The exploration of the time trend (figure) and the statistical model show reductions in the risk of preterm birth after the introduction of each phase of the smoke-free legislation. No decreasing trend was evident in the years or months before the bans. We found a step change in the risk of spontaneous preterm delivery of −3.13% (95% CI −4.37% to −1.87%; P<0.01) on 1 January 2007 (ban on smoking in restaurants), and an annual slope change of −2.65% (−5.11% to −0.13%; P=0.04) after 1 January 2010 (ban on smoking in bars serving food). The analysis for overall preterm delivery gave similar results. These changes could not be explained by personal factors (infant sex, maternal age, parity, socioeconomic status, national origin, level of urbanisation), time related factors (underlying trends, month of the year, day of the week), or population related factors (public holidays, influenza epidemics, and short term changes in apparent temperature and particulate air pollution).

Bias, confounding, and other reasons for caution

We adjusted for many potential confounders at the individual level and the population level. It is unlikely that our observations could be explained by abrupt changes in therapeutic strategies coinciding with the smoking bans. Data on prescriptions of atosiban and cervical cerclage (treatments for premature labour and increased risk of miscarriage) obtained from a social security organisation covering 42% of the population did not show substantial changes in the use of either treatment during the study period. The main limitation—common to most studies on population-wide smoking bans—is that we do not have data on individual smoking status, active or passive. Therefore, the observed effects may be due to reduced exposure of pregnant women to secondhand smoke, but they may also reflect an overall reduction in tobacco consumption. The birth records also did not allow us to address other known risk factors for preterm birth, such as maternal weight.

Study funding/potential competing interests

The Study Centre for Perinatal Epidemiology is financed and commissioned by the Flemish Centre for Care and Health. This study was supported by grants from the Flemish Scientific Fund, ERC starting grant, and Hasselt University Fund.

Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis

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- Clinical review: Narcolepsy and excessive daytime sleepiness (*BMJ* 2004;329:724)
- Clinical review: Narcolepsy mistaken for epilepsy (*BMJ* 2001;322:216)

STUDY QUESTION

Is there an increased risk of narcolepsy in children and young people who received the AS03 adjuvanted A/H1N1 pandemic influenza vaccine in England?

SUMMARY ANSWER

After vaccination with AS03 adjuvanted pandemic A/H1N1 vaccine, children and young people have a significantly increased risk of developing narcolepsy.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Studies from Finland and Sweden have reported an increased risk of narcolepsy in children who received the ASO3 adjuvanted pandemic vaccine. The current study found a similar risk in children in England, confirming that the association is not confined to Scandinavian populations.

Participants and setting

Children and young people with narcolepsy aged 4-18 with onset from January 2008 who received the diagnosis at sleep centres in England by July 2011.

Design

Retrospective analysis of records held by sleep centres in England complemented by review of cases reported by paediatric neurologists or identified in the national hospital episode statistics database. Vaccination histories were independently obtained from general practitioners. In each case, the population vaccine coverage was ascertained for children and young people in England of the same age at the time of onset of symptoms in the affected patient.

Primary outcome

The odds ratio for receipt of the AS03 adjuvanted pandemic vaccine before onset in patients with narcolepsy compared with the matched population after adjustment for the presence of high risk conditions that were an indication for vaccination.

Main results and the role of chance

Of the 23 centres in England contacted, 16 reported seeing cases in the relevant time period. A total of 245 possible cases were identified, of which 75 were retained for analysis, after we excluded patients with onset before January 2008 or an unconfirmed diagnosis. We found an increased odds ratio for receipt of the AS03 adjuvanted pandemic A/H1N1 vaccine before the onset of symptoms. The odds ratio for receipt of the AS03 adjuvanted pandemic A/H1N1 vaccine at any time before onset of narcolepsy in children and young people aged 4-18 in England was 14.4 (95% confidence interval 4.3 to 48.5). Alternative analyses with the date of first healthcare contact or date of diagnosis also gave significantly increased odds ratios. The attributable risk was estimated at between one per 57 500 to one per 52 000 doses.

Bias, confounding, and other reasons for caution

Despite attempts to minimise ascertainment bias by including only affected patients with a diagnosis before the public interest in the association, and by using two independent methods of case identification, there is potential for overestimation of risk because referral might be more rapid in vaccinated patients. Long term follow-up of the exposed cohorts is needed to properly evaluate the attributable risk.

Generalisability to other populations

Failure to identify a signal in other European countries suggested that the risk reported from Finland and Sweden might be specific to those populations. Our study indicates that the risk is not restricted to Scandinavian populations. Further studies are needed to investigate whether there is a risk with other types of pandemic strain vaccine, with or without an adjuvant.

Study funding/potential competing interests

This study was funded by the Department of Health policy research programme (grant No 039/0031) and the Health Protection Agency.

Odds ratio (95% confidence intervals) for receipt of AS03 adjuvanted vaccine before onset of narcolepsy in children and young people aged 4-18 with diagnosis by July 2011

Interval before onset	No of patients vaccinated	Total No of patients eligible for vaccination in interval before onset	Expected proportion vaccinated after matching to risk group	OR (95% CI)
12 weeks	5	10	0.098	18.4 (3.7 to 91.6)
6 months	6	10	0.151	16.2 (3.1 to 84.5)
Any time	10	17	0.160	14.4 (4.3 to 48.5)

Observational intensity bias associated with illness adjustment: cross sectional analysis of insurance claims

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bmj.com/podcasts
John Wennberg discusses the findings of this paper in a BMJ podcast

STUDY QUESTION

What is the extent of bias introduced by risk adjustment methods that depend on diagnoses recorded in administrative databases and can it be reduced?

SUMMARY ANSWER

Patients living in regions with high rates of visits by physicians seem to be sicker and those in regions with low rates of visits seem to be healthier than they really are. This bias can be reduced by further adjustment.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Among US regions, the rate of visits by physicians is strongly correlated with the mean number of diagnoses. This study introduces a modification of the standard adjustment method to adjust comorbidity measures for the frequency of physician visits.

Participants and setting

20% sample of people enrolled in the US Medicare program's fee for service insurance plan in 2007 (n=5 153 877).

Design

A cross sectional analysis comparing the ability of the standard and the modified method of illness adjustment to explain and reduce variation in age, sex, and race adjusted mortality among 306 US hospital referral regions. The standard method adjusts for illness using comorbidity measures based on the diagnoses listed in administrative databases. Our modified method statistically corrects the comorbidity measures to remove the component associated with physician visits. We compared the methods using three conventions for measuring comorbidity: the Charlson comorbidity index, the Iezzoni chronic conditions, and the hierarchical condition categories score. Results are reported for individual regions and for regions aggregated into fifths according to the mean rate of physician visits.

Primary outcomes

Ability to explain and reduce regional variation in age, sex, and race mortality and yield plausible estimates for illness adjusted mortality rates.

Main results

The modified Charlson comorbidity index explained more of the variation in age, sex, and race adjusted mortality across the hospital referral regions than the standard index (R^2=0.21 *v* 0.11, P<0.001). Illness adjustment using the modified method reduced regional variation in mortality, whereas adjustment using the standard method increased it. Age, sex, and race adjusted and illness adjusted mortality using the modified method were similar in the fifths with the highest and lowest rates of visits. However, because those living in the highest fifth seemed to be sicker (on the basis of the number of conditions recorded in their insurance claims) their risk adjusted mortality using the standard method was 17.6% lower than it was for those living in the lowest fifth of visits (P<0.001). The standard method also resulted in implausible changes in regional spending rates. Similar results were seen when illness adjustment was made using Iezzoni chronic conditions counts and the hierarchical condition categories score.

Bias, confounding, and other reasons for caution

The study is restricted to Medicare beneficiaries in fee for service Medicare and could not look at the effect of visit rates on the frequency of diagnosis when medicine is practised under different circumstances. The analysis cannot distinguish between the effect of the intensity of observation and intentional up-coding, although to the extent that such behaviour is correlated with frequency of physician visits, our adjustment method would control for it.

Generalisability to other populations

The importance of observational intensity bias in other countries can only be answered through further study.

Study funding/potential competing interest

This study was partially supported by the National Institute on Aging (PO1-AG19783) and the Robert Wood Johnson Foundation. Neither organisation was involved in designing and conducting the study; data collection, analysis, and interpretation; or the preparation, review, and approval of the manuscript.

Age, sex, and race (ASR) mortality and illness adjusted mortality rates per 1000 Medicare beneficiaries according to standard and modified methods for adjustment using the Charlson comorbidity index*. Values are mortality rates (95% confidence intervals) unless stated otherwise

Variables	1st fifth	3rd fifth	5th fifth
Mean visit rate	18.0	26.8	43.9
Method of mortality adjustment:			
ASR mortality	51.0 (50.6 to 51.4)	53.1 (52.7 to 53.6)	50.0 (49.5 to 50.4)
Standard method	56.3 (55.9 to 56.7)	52.8 (52.4 to 53.2)	46.4 (46.0 to 46.8)
Modified method	52.6 (52.2 to 53.0)	52.1 (51.7 to 52.5)	51.5 (51.1 to 51.9)
% change in mortality rate:			
ASR adjusted to standard method	10.3	−0.6	−7.1
ASR adjusted to modified method	3.1	−1.9	3.2

*Regions are aggregated into fifths based on rate of visits by physicians.