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# RESEARCH

MEDICAN



## THIS WEEK'S RESEARCH QUESTIONS

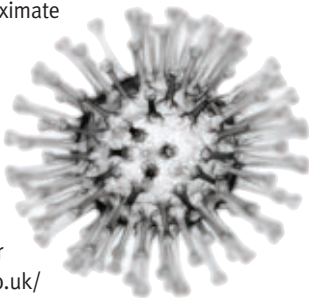
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## Mortality from pandemic A/H1N1 2009 influenza in England

Last July the Department of Health predicted between 19 000 and 65 000 deaths from swine flu in the UK. Yet this thorough surveillance study by chief medical officer Liam Donaldson and colleagues reports only 138 confirmed deaths from swine flu in England up to 8 November (p 82).

In a rapid response to the online version, Professor Donaldson expands on the problems of tracking cases and deaths ([http://www.bmj.com/cgi/eleletters/339/dec10\\_1/b5213#228219](http://www.bmj.com/cgi/eleletters/339/dec10_1/b5213#228219)). The recent official totals for influenza mortality in England and Wales include 1965 deaths in the 2004-5 winter season, none in both 2005-6 and 2006-7, 426 in 2007-8, and 10 351 in 2008-9. A total of 21 497 such deaths were recorded during the seasonal flu outbreak of 1999-2000. These routine estimates do not differentiate, however, between deaths from seasonal influenza and those from other causes of excess winter mortality or, indeed, from swine flu—and that's why this detailed surveillance study was needed.

As well as unexpectedly low total mortality, the study found that the case fatality rate was highest in the over 65s. Professor Donaldson told the BBC, "You can take a cold statistical view and look at the 300 deaths [the approximate total from swine flu in England by mid December] and throw your hat in the air. Or you can look at the families who may not have a child or a father or mother around the table this Christmas. If we can prevent those deaths then that is a reason to throw your hat in the air" (<http://www.bbc.co.uk/blogs/thereporters/ferguswalsh/>)



## Impact of negative tests during stepwise screening for diabetes in primary care



The Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (the ADDITION trial, NCT00237549) is evaluating the effectiveness and cost effectiveness of a stepwise screening strategy for type 2 diabetes and intensive diabetes treatment in 40-69 year olds in primary care. The "Anglo" trialists, based in Cambridge, have also looked at the psychological and behavioural impacts of this screening programme.

In 2007 they reported that the stepwise approach gives patients time to adjust to screening (doi:10.1136/bmj.39308.392176.BE) and does not seem to cause additional anxiety, depression, changes in self rated health, or worry about diabetes (doi:10.1136/bmj.39303.723449.55). Now Charlotte Paddison and colleagues have shown that, among patients at high risk of undiagnosed diabetes, negative results at initial screening did not falsely reassure (p 84). This finding matters because patients who believe they do not have diabetes might think they have a clean bill of health and cut back on their efforts to keep fit and well.

## Reading *BMJ* research

All research articles in the print journal are in the *BMJ* pico format, an evidence abstract prepared by the authors to inform readers and encourage them to go to the full, open access versions on [bmj.com](http://bmj.com).

We aim to publish research that can improve our readers' decision making. That's a difficult outcome to assess, but we audit *BMJ* research on a wide range of indicators including mentions by services that alert doctors to important new evidence (<http://resources.bmj.com/bmj/authors/bmj-papers-audit-1>). One of the most influential of these services is the Massachusetts Medical Society's Journal Watch (<http://www.jwatch.org/>). In its 10 most read stories about hospital medicine during 2009, and also about emergency medicine, research from the *BMJ* was mentioned more than that from any other journal, and the *BMJ* was the only general medical journal listed in its top 10 psychiatry stories.

**LATEST RESEARCH:** For these and other new research articles see <http://www.bmj.com/channels/research.dtl>

### Cost effectiveness of screening for postnatal depression in primary care

This decision modelling study concludes that routine screening for postnatal depression does not seem to represent value for money for the NHS or satisfy the National Screening Committee's criteria for a national strategy. The lack of cost effectiveness is attributable mainly to the costs of managing women with a misdiagnosis of depression at a one off screen who do not subsequently turn out to have postnatal depression (doi:10.1136/bmj.b5203).



ANGELA HAMPTON/BUBBLES/ALAMY

# Mortality from pandemic A/H1N1 2009 influenza in England: public health surveillance study

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**STUDY QUESTION** What is the pattern of death attributable to pandemic A/H1N1 2009 influenza in England?

**SUMMARY ANSWER** The lowest case fatality rates are in children, while older people, who are much less susceptible, are more likely to die when affected. Two thirds of deaths have occurred in people with recognised risk factors. The overall case fatality rate so far is 26 per 100 000 (range 11-66/100 000).

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Early reports of case fatality rates for the present pandemic have been in the range 0.1-0.9%. These have tended to use laboratory confirmed cases as the denominator, which probably grossly underestimates the true incidence. Our estimated case fatality rate uses an estimate of symptomatic cases in the community by age as the denominator.

## Participants and setting

All patients dying from pandemic A/H1N1 (with either a positive laboratory test result or mention on any part of the death certificate) in England up to 8 November 2009.

## Design

All deaths were reported through a mandatory reporting system instigated in all primary care trusts and acute care trusts in England. Deaths were investigated by direct contact with the physicians responsible for the patient during their terminal illness. The Health Protection Agency estimate the total number of symptomatic cases of pandemic A/H1N1, based on primary care consultation rates by age (both general practice and use of the National Pandemic Flu Service), laboratory positivity rates by age, and the proportion of symptomatic people who consult services.

To allow for the delay between symptom onset and death, we used the total number of cases two weeks before 8 November to calculate case fatality rates.

## Main results and the role of chance

By 8 November, 138 people were confirmed to have died from pandemic A/H1N1 infection. Those aged 65 and over had the lowest estimated incidence rate but the highest case fatality rate. Conversely, those aged 5-14 and 15-24 had the highest estimated incidence rates and low estimated case fatality rates. Overall, the population risk of death was similar across all age groups. Two thirds of deaths (67%, 92/138) occurred in the population eligible for phase 1 of the pandemic vaccination campaign. The risk of death for this group was nine times greater than in the rest of the population (9.9 deaths v 1.1 deaths per million people, Pearson  $\chi^2=217$ , df=1,  $P<0.001$ ). Most patients (78%, 108/138) had been prescribed antiviral drugs, but of these, most (76%, 82/108) did not receive them within the first 48 hours of illness.

## Bias, confounding, and other reasons for caution

Under-reporting of deaths is possible because cases are either not recognised or not reported. There is considerable uncertainty in estimating true incidence of symptomatic cases in the population. It is particularly difficult to estimate the proportion who did not seek medical attention. This uncertainty is reflected in large estimate ranges. Comparisons with surviving patients or patients in hospital will be important in allowing the risks associated with particular underlying conditions to be further quantified.

## Generalisability to other populations

England has adopted an aggressive approach to managing this pandemic. Antiviral medication has been universally and readily available. Intensive care is more sophisticated than in previous pandemics and in many countries today. The impact of these factors on mortality is not yet clear. Nonetheless, a lower population impact than previous pandemics is not a justification for public health inaction when death, serious illness, and admissions to hospital can be prevented.

## Study funding/potential competing interests

This work was conducted as part of the public health response to pandemic influenza in England. No additional funding was sought. LJD is the chief medical officer for England.

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## AGE SPECIFIC INDICES OF PANDEMIC A/H1N1 2009 INFLUENZA: INCIDENCE AND MORTALITY

Age group (years)	Estimated No (range) of cases (1000s)	No of deaths	Case fatality rate (deaths per 100 000 cases (range))	Population risk of death (deaths per 1 000 000 population (exact 95% CI))
<1	7 (3-13)	2	30 (2-260)	3.1 (0.3 to 11.3)
1-4	26 (12-53)	7	27 (3-120)	2.9 (1.1 to 6.1)
5-14	187 (86-381)	20	11 (3-36)	3.4 (2.0 to 5.2)
15-24	144 (67-297)	17	12 (3-40)	2.5 (1.4 to 4.0)
25-44	125 (58-297)	37	30 (10-88)	2.6 (1.8 to 3.5)
45-64	45 (21-92)	29	65 (21-200)	2.3 (1.5 to 3.3)
≥65	3 (1-5)	26	980 (300-3200)	3.2 (2.0 to 4.7)
All ages	536 (247-1097)	138	26 (11-66)	2.7 (2.2 to 3.2)

# Topical intranasal corticosteroids in 4-11 year old children with persistent bilateral otitis media with effusion in primary care: double blind randomised placebo controlled trial

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**STUDY QUESTION** To determine if topical intranasal corticosteroids are effective in clearing effusions in children with bilateral otitis media with effusion.

**SUMMARY ANSWER** Intranasal corticosteroids are not likely to be an effective treatment for otitis media with effusion.

**WHAT IS KNOWN AND WHAT THIS PAPER ADDS** Otitis media with effusion is the most common reason for surgery in children, but no non-surgical intervention is of proven effectiveness. Active monitoring in primary care is feasible and acceptable and associated with high natural cure rates by as soon as one month.

## Design

We used a double blind randomised placebo controlled design. The intervention was either mometasone furoate 50 µg or placebo spray given once daily into each nostril for three months as an adjunct to usual care.

## Participants and setting

Participants were 217 children aged 4-11 years with at least one recorded episode of otitis media or related ear problem in the previous 12 months and bilateral otitis media with effusion confirmed by otoscopy plus micro-tympanometry (B/B or B/C2, modified Jerger types). The study took place in 76 practices in the UK MRC General Practice Research Network between 2004 and 2007.

## Primary outcome(s)

The primary outcome was the proportion of children cured of bilateral otitis media with effusion according to tympanometric criteria (A or C1 in at least one ear) at one month.

## Main results and the role of chance

The absolute risk of cure favoured placebo at one month and nine months. These findings indicate that topical steroids are not likely to be an effective treatment for otitis media with effusion in this setting.

## Harms

Forty-eight adverse events were noted in the steroid group and 33 in the control group. No significant differences existed between groups for individual symptoms.

## Bias, confounding, and other reasons for caution

Potential confounders were equally distributed between groups, and blinding worked well. Reported adherence was 96% in the steroid group and 90% in controls. The retention was high at one month (93%), and we used intention to treat analysis without imputation. We used tympanogram types, a more objective measure of otitis media with effusion than history or clinical examination, with full training of research nurses and independent verification of tympanograms. We evaluated clinical severity at baseline and as an outcome by using the validated OM8-30 questionnaire, and noted high baseline clinical severity. The trial under-recruited and found a higher than anticipated placebo cure rate at one month, which reduced the power to detect differences. None of the diary and questionnaire outcome measures was significantly different. Adherence may have been worse than reported, so effects may be underestimated.

## Generalisability to other populations

We selected the sample by applying tympanometric screening procedures to at risk children identified by audit of notes and by opportunistic case finding in practices (total screened 2185). The standardised symptom impact scores were not significantly different from those in an unpublished UK secondary care study of otitis media with effusion. The sample should thus be generalisable to UK primary care, and even some secondary care, populations.

## Study funding/potential competing interests

The study was funded by the NIHR Health Technology Assessment programme.

## Trial registration numbers

Current Controlled Trials ISRCTN38988331; National Research Register NO575123823; MREC 03/11/073.

## CHILDREN CURED OF OTITIS MEDIA WITH EFFUSION ACCORDING TO TYMPANOMETRIC CRITERIA\*

Time of cure	No (%)		Risk difference (%) (95% CI)	Unadjusted analysis		Adjusted analysis	
	Active	Placebo		Relative risk (95% CI)	P value	Relative risk (95% CI)	P value
1 month	39/96 (41)	44/98 (45)	4.3 (−9.3 to 18.1)	0.91 (0.65 to 1.25)	0.55	0.97 (0.74 to 1.26)	0.81
3 months	50/86 (58)	45/86 (52)	−5.8 (−20.2 to 8.9)	1.11 (0.85 to 1.46)	0.44	1.23 (0.84 to 1.80)	0.29
9 months	40/72 (56)	47/72 (65)	9.7 (−5.5 to 25.6)	0.85 (0.65 to 1.11)	0.23	0.90 (0.58 to 1.41)	0.65

\*Proportion of children with either A or C1 tympanogram in at least one ear

This is a summary of a paper that was published on *bmj.com* as *BMJ* 2009;339:4984

# Are people with negative diabetes screening tests falsely reassured? Parallel group cohort study embedded in the ADDITION (Cambridge) randomised controlled trial

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**STUDY QUESTION** Are people with negative diabetes screening tests falsely reassured?

**SUMMARY ANSWER** A negative test result at diabetes screening does not seem to promote false reassurance expressed as lower perceived risk, lower intentions for health related behavioural change, or higher self rated health.

**WHAT IS KNOWN AND WHAT THIS PAPER ADDS** The potential adverse effects of false reassurance among people who test negative for diabetes at screening are unknown. Primary care based stepwise screening for diabetes is unlikely to cause an adverse shift in risk perceptions, health related behaviours, or the population distribution of plasma glucose and cardiovascular risk.

## Design

This was a parallel group cohort study embedded in a randomised controlled trial.

## Participants and setting

The 5334 participants were registered at 15 practices (10 screening, five control) in the ADDITION (Cambridge) trial; all participants were aged 40-69 years and in the top quarter of risk for having undiagnosed diabetes.

## Primary outcome(s)

The primary outcomes were perceived personal and comparative risk of diabetes, intentions for behavioural change, and self rated health. People attending screening completed questionnaires after an initial random blood glucose test and at three to six months and 12-15 months later; controls were sent questionnaires at equivalent time points.

## Main results and the role of chance

A linear mixed effects model with control for clustering by practice showed no significant differences between controls and people who screened negative in perceived personal

risk, behavioural intentions, or self rated health after the first appointment or at three to six months or 12-15 months later. After the initial test, people who screened negative reported significantly (but slightly) lower perceived comparative risk than the control group at the equivalent time point; no differences were evident at later points. Results show very limited evidence of false reassurance among those who received a negative test result after attending screening.

## Harms

A negative test result at primary care based stepwise screening for diabetes does not seem to promote false reassurance and is unlikely to cause an adverse shift in risk perceptions, health behaviours, and hence the population distribution of plasma glucose and cardiovascular risk.

## Bias, confounding, and other reasons for caution

We found little evidence of bias owing to non-response affecting comparability of the control and screening groups. However, the low relative response rates to the questionnaire survey among control participants (54%) and possible selection bias among those who chose to respond to the invitation to screening are potential limitations.

## Generalisability to other populations

Participants' interpretation of screening test results is likely to be influenced by the nature of the invitation and the specific explanation given by healthcare professionals doing the tests. Variations in the process and context of a screening programme may influence perceptions of residual risk, limiting the generalisability of our findings.

## Study funding/potential competing interests

This study was funded by a project grant from the Wellcome Trust (071200/Z/03/Z). The Cambridge ADDITION trial was funded by the Wellcome Trust (G0000753), the Medical Research Council, and NHS R&D support funding.

## Trial registration

Current controlled trials ISRCTN99175498.

**DIFFERENCES IN PSYCHOLOGICAL VARIABLES BETWEEN SCREENING ATTENDERS AND CONTROL PARTICIPANTS AT INITIAL TIME POINT\*. VALUES ARE MEANS (SD) UNLESS STATED OTHERWISE**

Psychological variables	Control group A, non-screening	Screen negative at initial (random blood glucose) test	Screen positive at initial test and referred for further testing	Difference† (95% CI); P value
Personal risk	31.5 (22.7) (n=251)	29.9 (20.8) (n=1994)	34.9 (22.2) (n=1079)	-1.58 (-4.79 to 1.65); 0.35
Comparative risk	2.92 (0.97) (n=254)	2.76 (1.02) (n=2013)	3.04 (0.95) (n=1106)	-0.16 (-0.30 to -0.02); 0.044
Intention to reduce dietary fat	3.63 (0.96) (n=260)	3.67 (0.88) (n=2065)	3.58 (0.89) (n=1140)	0.04 (-0.08 to 0.17); 0.52
Intention to reduce dietary sugar	3.54 (1.01) (n=260)	3.58 (0.92) (n=2058)	3.52 (0.91) (n=1148)	0.04 (-0.09 to 0.17); 0.54
Intention to increase exercise	3.48 (0.94) (n=261)	3.58 (0.87) (n=2065)	3.49 (0.87) (n=1138)	0.10 (-0.02 to 0.21); 0.11
Self rated health	3.14 (0.85) (n=253)	3.17 (0.87) (n=2056)	2.97 (0.89) (n=1142)	0.02 (-0.15 to 0.19); 0.83

\*Immediately after initial (random blood glucose) test for screening attenders; first contact for control participants  
†Screen negative group minus control group

This is a summary of a paper that was published on [bmj.com](http://bmj.com) as *BMJ* 2009;339:b4535



# Reflux related hospital admissions after fundoplication in children with neurological impairment: retrospective cohort study

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**STUDY QUESTION** What is the impact of fundoplication on reflux related hospital admissions for children with neurological impairment?

**SUMMARY ANSWER** Children with neurological impairment who had a fundoplication had reduced short term reflux related hospital admissions for aspiration pneumonia, gastro-oesophageal reflux disease, and mechanical ventilation, but admissions for pneumonia remained constant and those for asthma increased after fundoplication.

**WHAT IS KNOWN AND WHAT THIS PAPER ADDS** Studies of the effectiveness of fundoplication in children with neurological impairment report conflicting results. This study shows that fundoplication was associated with a reduction in reflux related hospital admissions at one year.

## Participants and setting

We included children with neurological impairment born between 2000 and 2005 who had at least one admission at a study hospital before their fundoplication. Participants were selected from 42 children's hospitals in the United States.

## Design, size, and duration

This was a retrospective, observational cohort study derived from an administrative database. Of the 955 285 children born during the study period, we included 3721 with neurological impairment who had a fundoplication and followed them for one year. The main outcome measure was the incident rate ratio for reflux related hospital admissions, defined as the post-fundoplication admission rate divided by the pre-fundoplication admission rate. Reflux related hospital admissions examined included aspiration pneumonia, gastro-oesophageal reflux disease, mechanical ventilation, pneumonia, and asthma.

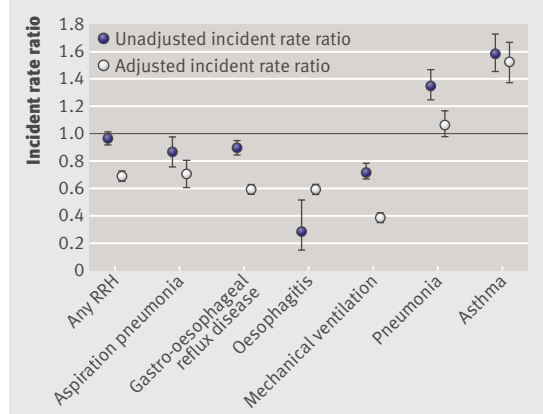
## Main results and the role of chance

After fundoplication, hospital admissions decreased for any reflux related cause (incident rate ratio 0.69, 95% confidence interval 0.67 to 0.72;  $P<0.01$ ), aspiration pneumonia (0.71, 0.62 to 0.81;  $P<0.01$ ), gastro-oesophageal reflux disease (0.60, 0.57 to 0.63;  $P<0.01$ ), and mechanical ventilation (0.40, 0.37 to 0.43;  $P<0.01$ ), after adjustment for other patient and hospital related factors that may influence reflux related hospital admissions. Hospital admissions increased for asthma (incident rate ratio 1.52, 1.38 to 1.67;  $P<0.01$ ) and remained constant for pneumonia (1.07, 0.98 to 1.17;  $P=0.16$ ).

## Bias, confounding, and other reasons for caution

We adjusted our analyses for sex, ethnicity, payer, discharge

## UNADJUSTED AND ADJUSTED INCIDENT RATE RATIOS, WITH 95% CIs, FOR REFLUX RELATED HOSPITAL ADMISSIONS (RRH)



disposition, chronic conditions, gastrostomy tube, tracheostomy, upper airway anomalies, and region of country, as well as for volume and percentage of fundoplication in the study hospitals. Potential sources of bias include coding reflecting physicians' unwillingness to label a post-fundoplication admission as related to gastro-oesophageal reflux disease or aspiration pneumonia, but the reduction in admissions for mechanical ventilation is less subject to this bias. Our study may have overestimated the effectiveness of fundoplication in very young children, but a subanalysis of children who had at least one year of pre-fundoplication data gave similar results. Many of the diagnoses and outcomes rely on clinical data that were unavailable in the database, but we have no reason to suspect systematic bias. Future studies should include comparative effectiveness (such as for gastrojejun feeding tubes) to better contextualise the impact of fundoplication.

## Generalisability to other populations

Our findings may not be generalisable to fundoplication in older children with neurological impairment and gastro-oesophageal reflux disease or to the neonatal population. Other studies will need to examine the effectiveness of fundoplication in these populations.

## Study funding/potential competing interests

RS and JGB are recipients of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health awards K23 HD052553 and K23 HD058092. Additional funding came from the Children's Health Research Center, University of Utah and Primary Children's Medical Center Foundation.

# Health and disease in 85 year olds: baseline findings from the Newcastle 85+ cohort study

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**STUDY QUESTION** What is the health status among 85 year olds?

**SUMMARY ANSWER** Despite significant levels of disease and impairment, 85 year olds have good functional ability and self rated health.

**WHAT IS KNOWN AND WHAT THIS PAPER ADDS** People aged 85 and older (oldest old) are the fastest growing group in many countries but their health and factors influencing their health trajectories need better description. Among 85 year olds levels of self rated health and functional ability were good, despite substantial levels of disease and impairment.

## Participants and setting

People born in 1921 (n=1042) and registered with a participating general practice in Newcastle upon Tyne or North Tyneside, United Kingdom.

## Design

Cross sectional analysis of baseline data from a cohort study.

## Primary outcome(s)

Detailed health assessment (questionnaires, measurements, function tests, and fasting blood sample) and review of general practice medical records (disease, medication, and use of general practice services); participants could decline elements of the protocol. Baseline recruitment and assessment in 2006-7.

## Main results and the role of chance

Of the 1453 eligible people, 851 (58.6%) were recruited to health assessment plus record review, 188 (12.9%) to record review only, and 3 (0.2%) to health assessment only. Data from record review are reported on a maximum of 1030 and

from health assessment on a maximum of 853; individual denominators differ due to withdrawal and missing values. Of the health assessment sample (n=853), 62.1% (n=530) were women and 10.4% (n=89) were in institutional care. The most prevalent diseases were hypertension (57.5%, 592/1030) and osteoarthritis (51.8%, 534/1030). Moderate or severe cognitive impairment was present in 11.7% (96/824) of participants, severe or profound urinary incontinence in 21.3% (173/813), hearing impairment in 59.6% (505/848), and visual impairment in 37.2% (309/831). Health assessment identified participants with possible disease but without a previous diagnosis in their medical record for hypertension (25.1%, 206/821), ischaemic heart disease (12.6%, 99/788), depression (6.9%, 53/772), dementia (6.7%, 56/840), and atrial fibrillation (3.8%, 30/788). Undiagnosed diabetes mellitus and thyroid disease were rare (1%, 7/717 and 6/762, respectively). A median of 3 (interquartile range 1-8) activities of daily living were carried out either with difficulty or required an aid, appliance, or personal help. Overall, 77.6% (646/832) of participants rated their health compared with others of the same age as good, very good, or excellent. High contact rates in the previous year with general practitioners (93.8%, 960/1024) were recorded. Women had significantly higher disease counts (medians: women 5, men 4; P=0.033) and disability scores (medians: women 4, men 2; P=0.0006) than men, but were less likely to have attended outpatients in the previous three months (women 29% (150/524), men 37% (118/320), odds ratio 0.7, 95% confidence interval 0.5 to 0.9).

## Bias, confounding, and other reasons for caution

Most (83%) local general practices participated and, although not a random sample, they were similar to non-participating practices. The recruited sample was sociodemographically representative of the local population but with slight under-representation of women. Non-responders or refusers may have been frailer than participants, although only 30% of those who gave a reason for non-response or refusal specified poor health.

## Generalisability to other populations

The study cohort was sociodemographically representative of England and Wales except for ethnic diversity, limiting generalisability to people from ethnic minority groups. The sample was urban, which might limit application to rural settings.

## Study funding/potential competing interests

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## DISEASE AND DISABILITY IN 85 YEAR OLDS

Disease	Men	Women
Hypertension*	52.9 (195)	60.1 (397)
Atherosclerotic disease*	55.0 (203)	42.8 (283)
Osteoarthritis*	42.6 (157)	57.0 (377)
Cataract*	38.5 (142)	51.6 (341)
Cancer (ever diagnosis)*†	20.1 (74)	12.3 (81)
Dementia*	7.1 (26)	9.1 (60)
Median (interquartile range) disease count‡	4 (3-6)	5 (4-6)
Median (interquartile range) disability score§	2 (0-6)	4 (1-9)

Values are percentages (numbers) unless stated otherwise

\*Data from general practice medical record review (369 men, 661 women)

†Non-melanoma skin cancer excluded

‡Data from combination of general practice medical record review and health assessment (291 men, 438 women). Eighteen diseases included

§Data from health assessment (319 men, 523 women): number of activities of daily living undertaken with difficulty or requiring an aid, appliance, or personal help