Faculty of Public Health

of the Royal Colleges of Physicians of the United Kingdom
Education Department

Working to improve the public's health

DIPLOMA & PART I EXAMINATION FOR MEMBERSHIP OF THE FACULTY OF PUBLIC HEALTH

Of the Royal Colleges of Physicians of the United Kingdom

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EXAMINATION QUESTIONS WITH EXAMINERS' KEY POINTS AND COMMENTS

N.B. Please note that these are key points, not model answers

Question 1.

Write short notes on <u>two</u> of the following:

a) The ecological fallacy
b) The use of 'funnel plots' in systematic reviews
c) Methods of controlling for confounding in case control studies

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

a) Ecological fallacy

Ecological fallacy is the misinterpretation resulting from drawing inappropriate conclusions about individuals from ecological data; the association observed between variables at the group level does not necessarily represent the association that exists at the individual level.

In ecological or correlational studies, population disease rates are correlated with factor(s) of interest that represent characteristics of entire populations e.g. food consumption, health service utilisation; the units of study are populations or groups of people rather than individuals.

Reasons for ecological fallacy:

- Cannot link exposure with disease in individuals (those with disease may not be those who are exposed)
- Data usually collected for other purposes; often proxy measures
- Use of average exposure levels may mask more complicated relationships with disease
- Inability to control for confounding.

b) Funnel plots in systematic reviews

- Define systematic review
- A statement on the role of systematic reviews and meta-analyses. A good example (e.g. streptokinase for MI)
- What a meta-analysis is (quantitative synthesis of primary data to yield an overall summary statistic)
- Possibility of publication bias (small trials with positive results more likely to be published than negative trials).
- Funnel plot: sample size of studies plotted (usually on the vertical axis) against estimates of effect size (horizontal axis). If there is no publication bias, the plot should look like a symmetrical inverted funnel, i.e. results of smaller studies more widely scattered than those of larger studies.
- Useful to detect bias in meta-analyses which may be contradicted later by large trials.
- Example (e.g. magnesium sulphate and ISIS 4)
- Apart from visual inspection, statistical tests on funnel asymmetry have been proposed.

c) Methods of controlling for confounding

At design stage: selection of controls e.g. restriction, individual or group matching. At analysis stage: stratification, adjustment, multivariate techniques e.g. logistic regression.

- Exclusion or restriction - simple to do, but loss of generalisability of results
- Matching – describe what it is, practical difficulties, loss of potential subjects, requires matched analysis, can lead to difficulties in analysis, problems of over-matching
- Stratification - relatively straightforward but if many levels can be difficult to absorb findings: investigator remains in touch with data; small numbers in individual cells may limit scope of analysis.
- Adjustment - summary figure produced, easy to absorb but figure is not 'real' and may mask patterns within data; choice of standard may distort picture, comparisons only possible if same standard used.
- Multivariate techniques - allow simultaneous adjustment for several confounders even with relatively small sample; can be difficult to interpret, investigator and reader distanced from data.
- Distinguish confounding from effect modification.
- Presence of confounding indicated if adjusted estimates of effect differ markedly from the crude estimates.

Question 2.

You are asked to design a case control study to examine the relationship between the use of mobile telephones and brain cancer. How would you go about selecting cases (not controls) and what information would you need for your sample size calculations?

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

Case definition
Need to define the condition (e.g. primary brain tumour). State whether incident or prevalent cases are to be used. Incident cases are ideal, and avoid selecting only for longest survivors, but if quick results are needed, prevalent case may be used.

<u>Selecting cases:</u>

Potential sources

- Cancer registry; convenient, large and well maintained data, but problems over delays in data incorporation and missing study-relevant data.

- Oncology/neurology specialists' patient databases; high degree of diagnostic accuracy and interested supplier, but may be skewed toward particular types of tumour or severity.

- Other sources which may be more subject to bias, e.g. patient support groups, advertising in media

Selection process

Identify all cases within a defined population (this could be an exclusive catchment area or a whole country). Section should be either all cases or a random sample, depending upon numbers, to prevent selection bias. Cases may need to be verified against explicit criteria (such as histopathological information) by an expert.

Sample size

State desired power and level of significance (e.g. '80% and 95% respectively'). State level of clinical significance sought (e.g. 'at least a two-fold increase in risk after exposure').

Then sample size will be dictated by:

- Frequency of exposure (which needs to be defined) in the control group.
- Anticipated size of effect.
- The ratio of cases to controls.

Additional factors

- If the risk is stratified then the sample must be bigger.
- If the condition is stratified (e.g. different types of brain cancer to be studied) then a larger sample is required.
- If risk (e.g. duration of mobile phone use) is used as a continuous variable (rather than binary), then the analysis will be more powerful.

Also allow for lost records, non-responders, unconfirmed cases etc. by boosting sample size accordingly.

Question 3.

Write short notes, in a named country, of the significance of TWO of the following diseases to maternal and foetal health and their associated control measures

- **rubella**
- **syphilis**
- **HIV**
- **Hepatitis B**

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

Rubella

Significance

- May produce Congenital Rubella Syndrome (CRS) if maternal infection occurs during pregnancy
- CRS causes intrauterine death, and profound multiple disabilities; congenital heart disease, cataracts, sensorineural deafness and mental retardation
- Infection in the first 8 to 10 weeks of pregnancy results in foetal damage in up to 90% of infants

- The risk of damage declines to about 10–20% by 16 weeks; and after this stage of pregnancy foetal damage is rare.
- Now fewer than 10 cases a year of congenital rubella syndrome in the UK due to the success of MMR

Control measures

- Vaccination of all children with MMR
- Prevent contact of cases with non immune pregnant women
- Screening of immune status ante-natally (or pre-natally) and (re)vaccination of women of childbearing age postpartum if found to be susceptible
- All pregnant women should be offered screening for rubella antibodies, syphilis, HIV and hepatitis B as an integral part of their antenatal care
- Women should be advised to avoid becoming pregnant for 1 month after receiving rubella containing vaccine.

Syphilis

Significance

- Rising level of STIs including syphilis
- Potential seriousness of clinical condition for mother's health
- Transplacental spread of *T. pallidum* may result in foetal death, prematurity or congenital syphilis
- Possible sequelae are foetal and neonatal infection, neurological and cardiovascular disease
- a) Facilitates HIV transmission
- b) Recent outbreaks.

Control measures

- All pregnant women should be offered screening for rubella antibodies, syphilis, HIV and hepatitis B as an integral part of their antenatal care
- Early detection of cases and active follow up of contacts through GUM and other services
- Promotion of safer sex behaviour including condom use, through education, information and other means of health promotion
- Screening of donated blood

HIV

Significance

- Rising levels of STIs including HIV
- Seriousness of clinical condition for mother; leads to a depletion of T4 cells in the peripheral blood, immunosuppression, opportunistic infections, neoplasia and full blown Acquired Immune Deficiency Syndrome
- Between 15 and 30% of infants born to untreated HIV infected mothers are infected with HIV as a result of vertical transmission either before or during birth, or afterwards due to breast feeding

Control measures

- All pregnant women should be offered screening for rubella antibodies, syphilis, HIV and hepatitis B as an integral part of their antenatal care

- HIV prevention programmes rely on public health education about the need to avoid activities that carry a risk of HIV transmission, particularly high risk sexual activity and injecting drug use
- Perinatal transmission can be reduced by counselling and testing for HIV infection in all pregnant women, as a routine part of antenatal care, combined with interventions to reduce the risk of transmission from mother to infant, including antiviral treatment, caesarean section and advice to refrain from breast feeding
- Screen all blood and blood products, and do not derive from donors at risk of infection
- Universal Precautions for the prevention of blood borne virus transmission
- Infected health care workers should be prevented from performing exposure-prone procedures

Hepatitis B

Significance
- May be transmitted from a mother to her baby before, during or after birth
- Babies born to acutely infected or carrier mothers are at increased risk
- Perinatal acquisition of Hep B more likely to lead to long term carriage of Hep B leading to cirrhosis and hepatocellular cancer

Control measures
- All pregnant women should be offered screening for rubella antibodies, syphilis, HIV and hepatitis B as an integral part of their antenatal care
- In the UK selective vaccination of high risk groups – IV drug users, homosexual and bisexual men, close family and sexual contacts of cases and carriers, babies born to acutely infected or carrier mothers
- Screen all blood and blood products, and do not derive from donors at risk of infection
- Universal Precautions for the prevention of blood borne virus transmission
- Infected health care workers should be prevented from performing exposure prone procedures
- Babies whose mothers are e antigen positive should in addition to a course of vaccine receive hepatitis B specific immunoglobulin as soon as possible after birth
- Vaccine should not be given in the buttock as efficacy may be reduced

Question 4.

Write short notes on the national public health perspective of effective methods for getting smokers to stop smoking.

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

- Stop cigarette advertising and sports sponsorship.
- Effective health education initiatives; particular focus on the proven effectiveness of TV media; National No Smoking Day; telephone helplines.
- Ensure health care premises and surroundings are smoking free.
- Facilitate other environments to become smoking free.
- Provide guidance on smoking cessation strategies and plan specialist smoking cessation services.

- Priority groups – young people and adults who want to quit, particularly the socially disadvantaged and pregnant women - high risk of MI or post MI.
- In all health care settings – Assess the smoking status of patients at every opportunity; Advise all smokers to stop; Assist smokers who wish to stop by initiation and/or advice about approaches to cessation therapies and sources of support available; arrange follow up.
- Taxation - price elasticity 0.5. Most marked effect on low income young people and social classes IV/V - the latter can be seen as repressive and may have indirect adverse effects.
- Concept of assessment and the Stepped Care approach – intensity of the patient's motivation to stop determines the extent to which increasing external efforts and support should be brought to bear in helping smoking cessation (also supportive evidence from other areas of substance dependence).
- Nicotine replacement therapy is effective whether delivered by gum, patch, nasal spray or inhaler – it is most important in the first week of smoking cessation.
- The intensity of nicotine replacement therapy should be matched to the degree of physical dependence on nicotine.
- Smoking assessment and monitoring by means of carbon monoxide in breath or biochemical assays may be helpful.
- During smoking cessation behavioural support from counsellors and appropriately trained nursing staff may be helpful.
- Prevent smuggling.
- Prevent those under16 years of age from buying cigarettes.
- Acupuncture has not been shown to be effective.
- Pharmacological agents such as buspirone, naloxone, clonidine and various tranquillisers have not proven effective.
- Recent studies suggest that the long acting antidepressant bupropion, which modulates dopaminergic activity of the brain, may increase the rate of smoking cessation even more than nicotine replacement therapy.
- Describe the disadvantages on smoking in public places
- Advantages of legislation to stop smoking in public places
- Importance of primary care in smoking cessation advice.

Question 5.

It has been suggested that local targets should be set for the reduction of deaths from colorectal cancer. Describe what information you would require to enable you to set a target. Outline ways in which you might monitor progress towards such targets and indicate any reservations you might have regarding the appropriateness of targets for this disease.

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

- A well-structured, systematic approach to the question, and demonstration of a thorough understanding of all the key sources of data
- Targets – Structure, process and/or outcome; specific; measurable; time frame.
- Identify national and local standards – NHS Cancer Plan, relevant NICE guidance etc.

Information

- Mortality statistics (outcome)
    - identifies fatal cases
    - ready availability, legally required, up-to-date
    - can be unreliable particularly with elderly
    - can calculate specific mortality rate, direct and indirect standardised rates
    - can estimate avoidable deaths/years of life lost prematurely

- Hospital activity (mainly structure and process)
    - services available, staffing levels and training, staff experience, equipment
    - may equate to incidence of serious disease
    - routine data source, usually complete
    - may include outpatient activity and procedures

- Cancer Registry data (outcome)
    - incidence, type of tumour, spread, treatment, survival
    - trend data

Monitor progress

- Mortality, incidence, spread at diagnosis, treatment, long-term survival, inequalities

Reservations about appropriateness

    - comparisons (with national or other local data) may be difficult - e.g. variation in case definition(s), problems with age-standardisation
    - small numbers - aggregate data over several years – but this makes monitoring more difficult
- Difficult to monitor any targets about inequalities because of lack of socio-economic data and small number. Demotivation of un-realistic targets
- Deflect resources away from areas with more priority
    - Targets can lead to 'gaming'

Question 6.

In relation to population characteristics and measurement:

a) Describe the characteristics of a national population census in a named country.

(4 points)

b) Outline the main information collected in the census, and

(4 points)

c) Outline how population projections are made.

(2 points)

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

General

- Well thought out answer that is precise, clear, comprehensive and well laid out with good examples.

a) NATIONAL CENSUS (U.K.) Characteristics:

- Carried out every 10 years (except 1941 because of Second World War).
- People alive on the night of the census are counted, traditionally in the household where they spent the night.
- Organised through Enumeration Districts – each of approximately 200 households.
- Head of household completes a form giving details of every person in that household on night of census.
- An enumerator ensures that the head of household completes a form.
- Confidential.
- Co-ordinated by the Office for National Statistics.
- General Register Office for Scotland and the General Register Office for Northern Ireland carry our similar functions.
- Authority enshrined in 1920 Census Act
- Started 1801.

b) Information collected

- Post code, type of building, number of rooms, tenure, presence of amenities (bath, WC, central heating), number of cars.
- People in house - name, DOB, sex, marital status, usual address, relationship to head of household, country of birth, ethnic group (ethnic group added in 1991), whereabouts (if absent on census night), address 1 year previously, country of birth.
- Long term illness or handicap that limits daily activities.
- Employed/unemployed, occupation, higher education (if more than 18 years), higher qualification, usual means of transport to work.
- SCOTLAND/WALES - ability to speak and write Gaelic or Welsh.

c) Population projection

Population projections project the characteristics and size of populations into the future, making assumptions about fertility, mortality and migration.

Calculation process:

- Measure population at a given point in time;
- Apply expected mortality rates over a given period;
- Apply assumed future fertility rate; projected immigration and emigration rates.

Sometimes presented as a series giving alternate figures based on high, average, or low levels of fertility or migration.

Question 7.

Your local water company has agreed to add fluoride to the drinking water supply. Numerous interest groups and individuals express their opposition to this. Describe psychological and sociological factors which might contribute to differences in risk perception. Write brief bullet points on how these factors could be used to influence your risk communication strategy.

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

- People tend to overestimate uncommon risks and underestimate common risks (Lichtenstein, Fischoff)
- Some characteristics of risk are associated with increased perception of risk, e.g. involuntary exposure, uncertainty about effects, effects delayed in time, infrequent but catastrophic events etc. (Royal Society Study Group, DoH). DoH guidance calls these "fright factors"
- Media triggers identified by DoH report
- Degree to which risk is considered unknown or "dread" factors also important (psychometric approaches)
- Social class and gender differences in ranking/views of hazards, but effects variable
- Framing of risk assessment/risk information known to be important, both in affecting assessment of risk, and in affecting expert assessment of risk
- Expert assessment of risk is culture bound as well – true objectivity difficult or impossible – professionals need to accept that lay judgements may differ
- Assessment of risk is not the same as acceptance of risk – even where assessment is agreed, does not inevitably follow that people will be prepared to accept a risk
- Follows that, in relation to risk communication, it is important to: -
  - Accept that total agreement on risk is unlikely or impossible
  - Acknowledge that the process is two-way, and may need to enter a risk dialogue
  - Trust is important – once lost, hard to regain
  - May need to accept that assessment is different from acceptance of risk
- Important to listen to opposing views to ensure that framing of risk communication is appropriate
- DOH guidance argues for clear strategy, developed in advance, with clarity on how to handle professional disagreement
- Availability heuristic affects overall perception of risk
- Cultural differences in risk perception, both between countries, and between groups with different cultural orientations in the same country (e.g. work by Dake, Douglas and Wildavsky)
- Anthropologists argue that risk is a political tool used in power struggles

Question 8.

Write short notes on the key issues to be considered in undertaking an economic evaluation of a new drug treatment for a chronic disease. Illustrate your answer with examples.

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

- Two key issues;

a) Is it worth using this drug?

b) Is it affordable locally?

To pass - the candidates must examine issue a) above and the majority of the following points need to be discussed;

- Four techniques available: Cost benefit analysis (CBA)
  Cost effectiveness analysis (CEA)
  Cost utility analysis (CUA)
  Cost minimisation

- A brief discussion of the advantages and disadvantages required.
- Given the chronic nature of the disease, we need to measure quality of life of both the patient as well as that of their carers as the primary measure of outcome.

- Issues to be tackled include:
  a) Measurement of health care costs and benefits.
  b) Measurement of costs and benefits incurred by patients and carers and in particular quality of life issues
  c) Measurement of costs and benefits incurred by other services such as Social Services.

Such measurements can be facilitated if the economic appraisal goes hand in hand with studies of efficacy and effectiveness.

- Candidates need to discuss affordability within the local context;
- Sensitivity analysis: effect of varying or including, discounting costs/benefits.
- Understanding the costs of the drug locally. Generalisability of study results to wider practice, numbers of patients with Alzheimer's disease who would be eligible, and modelling for different thresholds of eligibility in light of local prescribing practice.
- Natural history of the disease and needs assessment.

Question 9.

You have been given nine months in which to compile guidelines for the management of a chronic disease, for use in the catchment's area of your local hospital. These guidelines will be aimed primarily at the primary care setting and will include referral arrangements to secondary care. It is a disease of which you personally have relatively little knowledge and no well-established national guidelines exist. Describe how you would go about this task (in a named country)

KEY POINTS
(the major headings are major key points, and then the points decrease in order of importance according to the degree of indent)

- Develop background knowledge
  - Literature search, including a web search
  - Talk with experts and colleagues in other commissioning bodies
  - Liaise with relevant interest groups
  - Prevalence of the condition, burden of illness, ease of recognition of the possibility of the condition in patients presenting with symptoms in primary care, ease of diagnosis of the condition and 'receiver operating

characteristics' (ROC) of the diagnostic test, access to tests in primary and secondary care, effectiveness of interventions and category of evidence for any benefit, cost effectiveness of the interventions, availability of practitioners with appropriate expertise to manage the patients, acceptability of interventions for patients
    - Assess the quality of evidence collected
    - Make an effort to identify grey literature i.e. those that are not published in peer reviewed journals

- Primary care
    - Assess which members of the primary care team will be involved
    - Identify those interested in the topic and who can represent colleagues
    - Assess current knowledge (possible survey)

- Specialist care
    - Talk with clinicians who will be responsible for managing the patients
    - Talk about method(s) of referral e.g. development of a proforma
    - Assess capacity to review patients referred, including diagnostic procedures

- Patients
    - Talk with patients about their experiences with the health service
    - Identify and liaise with any national pressure groups for the condition or their local representatives

- Set up representative working group
    - From primary and secondary care together with patients
    - Engage clinical governance leads, specialist staff and clinicians from commissioning bodies
    - Agree terms of reference, a chair, key tasks to production of guidelines in nine months, milestones and timescales, format of resulting guideline, method of dissemination (e.g. computer template with prompts, whether any written guidelines (booklets, laminated summary, patient versions) or web based; whether one local launch or visits to primary care clinics, link of guidelines with local clinical governance procedures; list of membership and date for review in the final report
    - Make sure personal interests are declared

- Review implementation guideline
    - Make changes in light of everyday use

Question 10.

Discuss the view that, compared with other areas of public policy, health services have a relatively small impact on life expectancy.

KEY POINTS
(the major headings are major key points, and then the points decrease in order of importance according to the degree of indent)

- General comments about life expectancy
    - Used as a key determinant of health status but equally as important is the quality of life or well being – a better outcome measure is health life expectancy
    - Between and within country comparisons – e.g. Japan life expectancy in the 80s and some African states in late 30s; within country comparisons – unskilled manual v professional classes, geographical comparisons
    - Used as a key measurement of health equity and drawing attention to inequalities e.g. Acheson report
    - Used as a target to demonstrate improving health status

- Determinants of health
    - Evidence that medical care played a minor role in UK health improvement over the last 200 years – recent reports (e.g. Wanless) suggest objectives be set for major determinants and the unequal distribution of health determinants
    - Higher income correlates with higher lifer expectancy as do income differentials
        - Although a country can have a relatively low GNP per capita and a reasonably high life expectancy e.g. Cuba, or can have a high GNP per capita and a life expectancy which is not commensurate e.g. Saudi Arabia.
        - Scandinavia, Greece, Japan, Spain, Australia and Canada have less inequities and longer life expectancies
    - Income associated with other major determinants health:
        - Good nutrition
        - Quality of housing, water supply and sanitation
        - Educational attainment
        - Employment and occupation
        - Mobility and transport
        - Safe and healthy environment
    - Other factors
        - Effect of conflict
        - Natural disasters

- Health service contribution

    - Provision of access to health care and population coverage
        - 'inverse care law'; resource allocation
    - health service effectiveness and efficiency
        - evidence that over last 100 years health service interventions have led to a reduction in mortality from heart disease and cancer

- as an agent of influence in promoting health behaviours and making possible healthy choices
    - national government and statutory change e.g. on smoking; working with partners in local government, business (e.g. pharmaceutical and food industries) and voluntary agencies
- research into specific health threats to life expectancy
    - e.g. AIDS research, continuing research into cancer and circulatory disease
- NHS employees contribution to health promotion and public health
- Role of immunisation and vaccination in contributing to achieving health gain

Paper IIA.

There is national interest in the contribution fizzy drinks make to childhood obesity. Having read the accompanying paper, one of the governors of a local school in your area (who also edits the local paper) has raised the issue with you as the single-handed public health expert serving that population.

1 Write a structured abstract of the article in no more than 250 words (5 marks)

2 Write a critical appraisal of the paper (20 marks)

3 Outline the pros and cons of use of a cluster randomised trial in the context of this research. (10 marks)

4 You have a monthly opinion column in the paper. Write a 500 word column on this topic. (15 marks)

KEY POINTS IN APPROXIMATE ORDER OF IMPORTANCE

Critical appraisal of:

Janet James, Peter Thomas, David Cavan, and David Kerr
Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial
BMJ, May 2004; 328: 1237 - 1242.

Important points:

- Addresses topical and important public health issue
- Appropriate methodology – randomised trial appropriate method for assessing effectiveness
- Cluster trial methodology because unit of intervention and analysis is school and intervention was at a population level
- Intervention delivered by one person – one hour health education message per class per term – 4 sessions altogether. 1st term re: natural sweetness and children shown tooth immersed in cola. Second and third, music competition. 4th session art and competition.
- Outcomes were BMI and fizzy drink consumption
- Primary schoolchildren 7-11

- Randomisation by cluster, blinded to schools/classes using a random number table (minimise ascertainment concealment bias)
- But consent obtained after randomisation although children and parents blind to which group they were in. Consent reduced sample size by 30%.
- Key issue is sample size – needs to be larger for any given expected effect size because individuals in clusters likely to have similar outcomes i.e. outcomes not independent. Need to calculate/estimate intraclass correlation coefficient (ICC) for outcomes within cluster to account for this lack of independence and inflate sample size accordingly. This study was powered to detect average reductions in fizzy drink consumption using a range of ICCs.
- Summary measures were cluster proportions compared using t-tests – entirely correct test.
- Figure 1 shows flow of both clusters and individuals
- Randomisation gave balanced groups (table 2).
- Drop out rates - no clusters, ~ 10% individuals not a threat to validity
- Analysis by intention to treat (this was not stated in the paper).
- Analysis done both at cluster and individual level (overweight and obesity)
- Main results – intervention groups significantly decreased consumption of carbonated drinks and consumed significantly less than control group. Both groups increased water consumption. Prevalence of overweight and obesity fell slightly in intervention group but increased in control group in both sexes. Biggest effect seems to be in overweight in boys and girls (small number obese) – regardless of how overweight/obesity defined
- Comments – low return of diaries potential source of bias in estimating fizzy drinks consumption if systematically different between control/intervention clusters – paper states no difference between obese/overweight but not between control/intervention. Also since increases in water consumption were found in both groups suggesting contamination by wider interventions e.g. schools introducing drinking water points.
- Overall study suggests that relatively simple intervention to classes in primary school can reduce carbonated drink consumption, promote water consumption and control weight gain.
- Generalisability – would need more detail about nature of intervention, costs etc. but potentially widely applicable. Results need replication – does it seem plausible that modest reduction in consumption of carbonated drinks in intervention group (0.6 drinks a day) can lead to the divergence in weight gain of the two groups? (authors claim it is)

Additional points

- Trial seemingly well done
- Follows good practice in reporting (CONSORT)
- More discussion of confounders and contamination e.g. what was distribution of control/ intervention clusters within schools
- Further discussion of diary recall/ low response rates.

Pros and cons of cluster randomised trials

Pros:

- Population is unit of randomisation and intervention

- Appropriate for public health interventions
- May be cheaper and quicker to conduct
- Best quality evidence
- Credibility

Cons/ issues

- More complex design – need to take account of intra-cluster correlation
- More complex analysis - there are two levels of inference rather than one: the cluster level and the individual level - it is important to indicate explicitly the level at which the interventions were targeted, how the hypotheses were generated, the outcomes were measured, and randomisation was done. May need multilevel / hierarchical models
- Power – needs greater sample size
- Skills in design and analysis
- Ethical issues – informed consent - Because a cluster randomised design increases the complexity of the research and requires many more participants than an individually randomised design (to ensure equivalent statistical power), it is particularly important that the rationale for adopting a cluster design is clear
- Post randomisation bias (consent sought *after* randomisation) – potential for selection bias is high because allocation is known for all persons in a cluster => greater care to mask cluster allocation
- Drop out rates
- Generalisability – maybe more complex to assess e.g. are results applicable to clusters/ persons or both

An adequate answer will include first three points in each section.

500 word article

A good article will:

- Be written in lay language
- Advocate – that is have a key message e.g. kids can be taught to drink less fizzy drinks and this can help prevent weight gain – crucial in the fight against obesity
- Start with the main message and get more detailed (pyramid principle)
- Describe the research in one paragraph – "a new study in schools shows that a simple set of fun lessons focussing on what primary school children drink can help them understand the importance of not taking too much sugar… X schools took part in the study which involved…
- Quote from authors "our findings are very exciting. Although they will need replicating, it does seem that some simple, fun lessons with the right message can help children reduce how much fizzy drink they take, and in turn this seems prevent weight gain…"
- Start with the particular and become more general - e.g. although more work needs to be done in this area, local schools can contact the authors for details of the content of the lessons…. to 'obesity affects 1 in 20 children and 1 in 5 children are overweight'
- Include quotes from local people e.g. local DPH or headmaster as a quote e.g. "this kind of research will help us to consult on providing healthy options in our school"…..

- Set it in context – white paper, NAO report, childhood obesity
- Try not to be a rehash of the critical appraisal

Paper IIB.

This question takes a current issue which allows the demonstration of the application of basic public health skills to a problem which is typical of the work of public health practitioners.

Organisation A is responsible for providing healthcare for a population and has requested public health advice in assessing the potential impact of recent guidance on providing *in-vitro fertilisation* (IVF). The organisation has previously maintained a very rigid policy of only supporting requests for IVF in women aged between 31 and 34 years for one course of treatment. There have been a mean number of 126 requests per year from an average population of 6384 women in the age group of women referred for treatment. The new guidance suggests that women aged 27-38 inclusive should be supported. The guidance also states that women should be offered 3 courses of treatment.

It is known that 30% of women will conceive with one course of treatment. The conception rate falls to 20% for a second course (for those women who fail to conceive on the first course) and only 40% of the remaining women wish to try a third course.

Organisation A is responsible for the following estimated population of women in the next year:

ORGANISATION A	27-30	31-34	35-38
Number of requests		126	
Population	5647	6384	6970

A neighbouring Organisation (B), having a population with a similar demographic and socio-economic profile, has operated a policy which includes the proposed age groups for the past three years and has found the mean number of requests per 12 months given below:

ORGANISATION B	27-30	31-34	35-38
Number of requests	46	143	96
Population	8764	7906	7230

1. List the characteristics of the population that you would consider when choosing a *comparator* healthcare provider. (5 marks)

2. Using the rates per 1000 women from the (*neighbouring Organisation B as a comparator estimate the*)[1] potential number of requests to Organisation A in the next 12 months and comment on any difference you note with the current figure. (5 marks)

[1] Question 2; the text in brackets did not appear in the question paper used during the examination

3. Using the figures derived from Organisation B, how many courses of treatment will be required for the population served by Organisation A as a result of changing to the new guidelines (10 marks)

4. Resources to support the new guidelines are to be based on an estimated demand for IVF services of 8.9 requests per 1,000 women per year. This figure has been derived from a series of studies across the country on 180,000 women aged between 27 and 38 years inclusive. Is the rate for the potential number of requests you have calculated using data from Organisation B significantly different from this nationally derived figure?
Comment on the potential impact on resource management for organisation B (15 marks). ***This was intended to read as organisation A in the paper used in the examination.***

5. Write a discussion paper for Organisation A outlining the implications of changing its policy to embrace the new guidelines. Include a summary of other factors that organisation A may wish to consider when supporting couples for in vitro-fertilisation. (15 marks).

ANSWERS / KEY POINTS:

1 (5) List the characteristics of the population served that you would consider in choosing a comparator healthcare provider:

Similarity across:

- *general health status*
- *socio-economic profile*
- *demographic (age & gender) profile*
- *biological criteria for supporting IVF*
- *social criteria for supporting IVF*
- *causes of sub-fertility / prevalence of STIs*
- *ethnic/cultural background of population*
- *use of healthcare services by population*
- *size of population, ideally larger to offer more accurate figures*

Good answers would include the importance of having similar levels of sexually transmitted infections that could lead to tubal occlusion and a similarity of primary care services to allow expression of health needs and onward referral.

2 (5) Using the rates per 1000 women from the neighbouring organisation B as a comparator estimate the potential number of requests to organisation A, in the next 12 months, and comment on any difference you note with the current figure for organisation A.

This should preferably be calculated using age-group specific request rates:

	27-30	31-34	35-38
Number of requests for organisation B	46	143	96

Population organisation B	8764	7906	7230
Rate per 1000 for organisation B	5.25	18.1	13.3
Estimated no. of requests for organisation A	5.25 × 5.647 =29.6	18.1 × 6.384 =115.5	13.3 × 6.970 =92.5

Using age-group specific rates, a total of 237.7 or 238 requests would be expected.

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An alternative method uses the overall rate for Organisation B. This is simpler, but less satisfactory as it disregards detailed age differences between the two populations, i.e. B predominantly younger, A predominantly older within this 12 year age range of eligibility.

Organisation B: 285 requests from a population of 23,900 or a gross request rate of 11.9/1,000.

Applying these rates to the population of organisation A (19,001) estimates the number of requests as 11.9 x 19.001 or 227, thus 227 requests for treatment will be expected.

2 marks for correct approach using age-specific rates. 2 marks for correct answer 238 (allow tolerance 230-250 to allow for minor errors of calculation in using age-specific rates)

Only 2 marks (max.) for second approach using only overall rate. (allow tolerance ±5 to allow for minor errors of calculation)

1 mark for noting that the estimate (115.5) is different from the actual figure recorded for age 31-34 for organisation A (126) and offering a cogent possible explanation such as:

- *some patients who would be included in the middle age-range group on Organisation A's current policy as would already have received treatment in the younger age group on Organisation B's current policy*
- *being based on small numbers this may not be a significant difference.*

As a result of some confusion over the actual question printed for the examination of May 2005 credit was given for two other answers using a different permutation of rates including: the application of the rate derived from using 126 per 6384 (or 19.74) requests per 1000, then using this rate for the specified populations of age groups 27-30 & 35-38 serviced by organisation A; a further permutation was the rate for all age groups from organisation B put into the populations serviced by organisation A. The use of these figures to derive a number of requests was not penalised in question 3 if it had been used either in answering this question or the rest of question of 3.

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3 (10) Using the figures derived from organisation B how many courses of treatment will be required for the population served by organisation A if they use the new guidelines?

The question states that 30% conceive with one course; and of the remaining 70%, 20% conceive on a second course. Only 40% of the women who do not conceive after two courses of treatment wish to try a third course. (In reality, age differences would be

expected in conception rates, but age-specific conception rates are not given, thus the question implies that they are to be taken to be the same across all age groups.)

The most straightforward approach is to work with one starting figure:

Estimated requests for organisation A		**238**
Conceptions with one course of treatment	238 × 0.3	= 71.4
Women not conceiving with one course of treatment	238 – 71.4	= 167.6
Conceptions after second course of treatment	167.6 × 0.2	= 33.5
Women not conceiving after 2nd course of treatment	167.6 – 33.5	= 134.1
Women seeking third course of treatment	134.1 × 0.4	= 53.6

Total number of courses = 238 + 167.6 + 53.6 = 459

Some candidates may perform these calculations separately for each age group and total across age groups. Here, there is no advantage whatever in doing the calculation this way as the conception rates assumed are the same for all age groups.

Marks for:
2 for correct starting figure,
3 for deriving number seeking 2nd course of treatment,
3 for deriving number seeking 3rd course of treatment
2 for correct figure 459 (450-465 accepted to allow for minor summation errors)

i.e. 6 marks still possible for method even if starting with wrong figure

4. Resources to support the new guidelines are to be based on an estimated demand for IVF services of 8.9 requests per 1,000 women per year. This figure has been derived from a series of studies across the country on 180,000 women aged between 27 and 38 years inclusive.

Is the rate for the potential number of requests you have calculated using data from Organisation B significantly different from this nationally derived figure?

Comment on the potential impact on organisation B. (15 marks for entire question)

Two statistical approaches are possible, using standard errors based on binomial and Poisson distributions. With small proportions as here, it makes little difference which is used.

(a) **Binomial based method**

Standard error of difference between percentages = $\sqrt{\{p_1 \times (100- p_1) / n_1 + p_2 \times (100- p_2) / n_2\}}$

(1) Convert the two rates above to percentages and use the above formula for the standard error of the difference between percentages. Reduced marks given if

candidate uses a method that takes the standard rate as given without any sampling imprecision.

(2) National figure: 8.9 per 1,000 from a population of 180,000 or 0.89% (p_1)
Organisation B: 11.9 per 1,000 from a population of 23,900 or 1.19% (p_2)

SE $= \sqrt{\{0.89 \times 99.11 / 180{,}000 + 1.19 \times 98.81/23{,}900\}}$
$= \sqrt{\{4.9 \times 10^{-4} + 4.92 \times 10^{-3}\}}$
$= \sqrt{5.41 \times 10^{-3}}$
$= 0.0736$ or 0.074

The difference between the 2 proportions = 1.19 – 0.89 = 0.30%.

(3) This is (highly) significant – about 4 times its standard error, or equivalently, calculate CI for difference as 0.30 ± 1.96 (or 2) $\times$ 0.074 and note it doesn't include zero.

(4) The figure used for resource allocation derived from the nationally aggregated populations is significantly lower than the figure derived from the neighbouring healthcare provider (organisation B).

(b) **Poisson based method**

Population B: 285 out of 23,900 women i.e. 11.9 per 1000.
Standard error of 285 is $\sqrt{285} = 16.85$
Standard error of rate per 1000 is 16.85 out of 23,900 i.e. 0.71 per 1000.

National rate 8.9 per 1000 i.e. 1602 out of 180,000 women
Standard error of 1602 is $\sqrt{1602} = 40$
Standard error of rate per 1000 is 40 out of 180,000 i.e. 0.22 per 1000.

Difference between two rates 11.9 – 8.9 = 3.0 per 1000.
Standard error is $\sqrt{\{0.71^2 + 0.22^2\}} = 0.74$
Difference is (highly) significant – about 4 times its standard error, or equivalently, calculate CI for difference as 3.0 ± 1.96 (or 2) $\times$ 0.74 and note it doesn't include zero.

Interpretation as before:
Particularly able candidates would note that results given for Organisation B are based on data for 3 years, not 1. This has the effect of reducing the standard error for Organisation B's proportion or rate by a factor $\sqrt{3}$ which is 1.73. Thus for the Poisson based method, the calculation would become:

Population B: rate is 285 out of 23,900 women i.e. 11.9 per 1000 per year, as before.
This is based on $3 \times 285 = 855$ women over the 3 year period.
Standard error of 855 is $\sqrt{855} = 29.24$
Standard error of rate per 3 years is 29.24 out of 23,900 i.e. 1.22 per 1000.
Standard error of rate per year is 1.22/3 = 0.41 per 1000.

SE of difference between Population B and the national rate is reduced commensurately.
This makes the difference even more highly significant.

These results suggest that the neighbouring PCT (organisation B) has a substantially higher demand than the populations on which the national estimates of demand are based. Nationally derived rates (8.9/1000) are not, therefore, good predictors of demand from the population for which organisations A (14/1000) or B (11.9/1000) provide healthcare.

If resource allocation in Organisation A is based on the national levels of resourcing, organisation A is unlikely to have sufficient resources to meet the demand of its population. Organisation B is, by definition, already funding its IVF service so that they are unlikely to experience a funding shortfall.
Clearly, needs of populations are different so that there are problems with resourcing local organisations on the basis of a single national figure. Even using a figure derived as an average would mean that some organisations may be over-resourced whilst others are likely to be under-resourced.

Marks were allocated in May 2005 on the basis of ten marks for a logical (ideally statistical) approach to the question including calculations. A further five marks were awarded for the implications of the national funding allocation on the local organisations.

If the calculations were performed with respect to the crude rate for Organisation A of 238 requests from a total population of 17,001;

National figure: 8.9 per 1,000 from a population of 180,000 or 0.89% (p_1)
Organisation B: 14 per 1,000 from a population of 17,001 or 1.40% (p_2)

SE $= \sqrt{\{0.89 \times 99.11 / 180{,}000 + 1.40 \times 98.60/17{,}001\}}$
$= \sqrt{\{4.9 \times 10^{-4} + 8.12 \times 10^{-3}\}}$
$= \sqrt{8.61 \times 10^{-3}}$
$= 0.09279$ or 0.093

The difference between the 2 proportions = 1.40 – 0.89 = 0.51%.
This is (highly) significant – about 6 times its standard error, or equivalently, calculating CI for difference as 0.51 ± 1.96 (or 2) $\times$ 0.093 and note that it doesn't include zero.

The figure used for resource allocation derived from the nationally aggregated populations is significantly lower than the figure derived from the neighbouring healthcare provider (organisation B).

or using the Poisson based method:

Population B: 238 out of 17,001 women i.e. 14.0 per 1000.
Standard error of 238 is $\sqrt{238} = 15.4$
Standard error of rate per 1000 is 15.4 out of 17,001 i.e. 0.091 per 1000.

National rate 8.9 per 1000 i.e. 1602 out of 180,000 women
Standard error of 1602 is $\sqrt{1602} = 40$
Standard error of rate per 1000 is 40 out of 180,000 i.e. 0.22 per 1000.

Difference between two rates 14.0 – 8.9 = 5.1 per 1000.
Standard error is $\sqrt{\{0.091^2 + 0.22^2\}} = 0.057$

Difference is (highly) significant – over 6 times its standard error, or equivalently, calculate CI for difference as 5.1 ± 1.96 (or 2) $\times$ 0.057 and note it doesn't include zero.

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5 (15) Write a discussion paper for organisation A outlining the implications of changing its policy towards the new guidelines. Include a summary of the social factors that the organisation may wish to consider when supporting couples for

in-vitro fertilisation.

Key points:

- *Expect a discussion paper around the implications of the change in guidelines rather than a re-iteration of the questions and answers above.*
- *Use of general format of Introduction, Implications of change in age criteria, Implications of change in number of courses, social factors for eligibility considered.*
- *Using data derived from earlier parts of the answer*
- *Differences between primary and secondary infertility recognised.*
- *Non-judgmental yet realistic approach to social factors.*
- *Estimating financial implications*
- *How does this issue relate to other priorities for the organisation?*

These issues would be expected to be given in the form of a short paper using standard subtitles suitable for presentation to a committee of managers.

Good answers would include:

- *Increase investment in preventative approaches to secondary infertility through early detection and treatment of chlamydia/gonorrhoea infection*
- *Preventive aspects of the tubal causes of infertility. Awareness of benefits of chlamydia screening amongst high risk groups. Possible improvements to services for STIs.*
- *Recognise the imperatives of rationing*
- *Partnership working to raise uptake of adoption*
- *Relevant comments regarding the Human Rights legislation*
- *Acknowledge differences between need and demand*
- *Ethical dimensions related to assisted conception: surrogacy.*
- *Knowledge of other techniques to assist conception; intra-cytoplasmic sperm injection (ICSI), intra-uterine sperm implantation may attract merit although not without the other aspects being considered.*
- *Use of the private sector by patients; estimating the number of couples who already use this*
- *It may be mentioned that "guidance" can be ignored*
- *A meaningful summary*

The model answer outlines the basic approach that would be expected (in 700 words).

Up to 5 marks were awarded for an appropriate approach which covered the main issues. Content attracted an additional five marks and up to 5 marks were allowed for a summary of relevant social criteria.

Planning for changes to policies to support assisted conception

Summary

New guidelines suggest that the organisation should support in vitro fertilisation (IVF) for a wider age range. Extension from the current age range viz. 31-34 to include both a younger (27-30) and older age group (36-39) would increase annual requests for IVF from 126 to 238. The new guidelines also suggest offering up to 3 courses of treatment. This would require funding an increase from 126 courses of treatment per year to 459. On a pro rata basis it is estimated that this will increase the total cost of providing this service by a factor of over 3.5.

Introduction
National guidelines supporting a change in the criteria for IVF will require greater resource use. This has been estimated (see annex) using a comparator population with a broadly similar demographic profile. The implications are explored below.

The effect of changes in age criteria
As a result of widening the age range for eligibility, the number of women requesting treatment is projected to increase from 126 to 238 per year, an increase of 112 or 89%. Two-thirds of these will arise from the 36-39 age group where the chance of conception occurring is least. This runs counter to normal decisions which support clinical effectiveness. However, with an increasing older age at conception more women do not seek assisted conception until they are in their 30s.

The effect of changes in number of courses of treatment required
The annual number of courses of treatment will increase further to 459 if women are offered up to 3 courses in line with the new guidelines. This represents a further increase of 221 courses of treatment. Thus the effect of offering multiple courses of treatment is expected to be nearly twice as great as that resulting from widening the age criterion for eligibility. However, in practice, conception rates decrease with age. Further work is required to refine these calculations accordingly.

Social factors
The organisation has to decide whether to support an increase in resource use for IVF against other competing priorities for services. Accordingly, it should use this opportunity to review the social factors used to determine whether a patient's request for IVF should be supported. This may require a broader debate involving a formal community consultation. Thus, should IVF be available for all people who request treatment, or should it be limited to those with the greatest need, viz. the childless? Some women and their partners may have children from previous relationships. Should the organisation only support those women who have no children based on a women's right to control her fertility? Conversely, does the male partner have a right to the maximum chance of getting a child if his partner has had children as would be supported by equal rights for both genders?

The organisation (or its social care counterpart) may be considered to have a duty to satisfy itself that the health and well being of any existing children is protected. Likewise it could be considered irresponsible if it did not ensure protection of the welfare of any future children conceived through IVF it provides. A case can be made for establishing assurances of the health of both parents before approval is given. Though it must be borne in mind that this also incurs costs, and limited sensitivity is inevitable.

To ensure that the organisation honours its responsibilities for child protection it should consider specifying a specific number of years to define a "partnership" for couples. Clinicians do not usually consider initiating fertility investigations until 3 years of unprotected intercourse. This period would appear sufficient to define "partnership".

Conclusions
The organisation should consider strengthening its social criteria to counterbalance the increasing costs of supporting more courses of treatment for an extended age group of patients. Changes to the social criteria could usefully involve some form of public consultation.

In order to minimise the impact on costs the organisation may consider restricting the number of courses of treatment offered. This will save more resources than not supporting the lowering of the age limit for sponsorship, and is more in line with the principle of equity.

Specific social factors to be considered in approving requests for assisted conception:

1 The existence of surviving children (as opposed to children deceased)
2 Previous criminality of either parent, especially related to child protection issues
3 Preferential support to women experiencing primary infertility

There are many subjective issues which may be considered:
Smoking. obesity amongst the applicant and her partner (which both reduce the chances of successful conception) pending the uptake of appropriate advice; ability to provide care for a child (contentious as the ability to conceive could be argued to be a right irrespective of learning or physical disabilities). Child rearing by same sex couples & organ harvesting to aid the survival of another infant.