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

**JANUARY 2003**

### **EXAMINATION PAPERS WITH EXAMINERS' KEY POINTS AND COMMENTS**

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

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## **PAPER IA (2.5 hours)**

**1. It has been suggested that the children of teenage mothers have an increased risk of asthma in adolescence. Write short notes on how this could be studied using:**

- a) a case control study and**
- b) a cohort study.**

**Please include in your notes the advantages and disadvantages of each study design for exploring this particular hypothesis.**

### Key Points

First, need clear criteria for case definition, and explicit definitions of teenage and adolescent age ranges - "teenage" often used loosely, not just for age 13 years 0 days to 19 years 364 days. Asthma could be defined using a standard questionnaire with or without additional physiological measurements of variable obstruction to airflow.

The best approach is to take each of the two methods one by one, covering the following points:

- rationale of the study design
- selection of cases and controls
- measurement of exposure
- measurement of confounders
- statistical issues such as power, calculation of risk
- operational issues, including cost

### Case control study

Cases could have been either prevalent or incident cases of asthma in adolescents. Controls would need to have excluded those with asthma in early life but which was no longer current. Various sources of cases and controls are available, including hospitals, general practice and prevalence surveys (because the condition is quite common).

Establishment of the mother's age at the birth of the child would not be difficult and could be validated. Possible confounders include breast feeding and maternal smoking. Matching of cases and controls for age (of adolescents), sex and residence would be advisable but some confounders could be controlled for in the analysis.

### *Pros and cons*

A case control study will be quicker and cheaper to conduct, but these advantages will need to be offset against the greater risk of incomplete data and poor recall of early life events (mode of feeding, wheezy illnesses, smokers in household)

### Cohort study

This could be either prospective or retrospective. The cohort should be defined by birth in a particular area at a particular time.

### *Pros and cons*

A major advantage of the cohort approach is that exposure to confounding factors and the occurrence of asthma in early life are likely to be better assessed. Whilst cohort studies tend to be more expensive and labour intensive than case-control studies, asthma is a relatively common disease and so the number of individuals recruited would not be prohibitively large. Cohort studies are plagued with loss to follow up and as some older adolescents are relatively mobile this may impair completeness of data.

### Comments

Question 1 was not well answered. Responses did not address the stated hypothesis, and there was inability to apply knowledge or to give examples of case definitions. There was much evidence of confusion re the essential features of these study designs, e.g. some indicated that in the case control design cases or controls had to have teenage mothers. Many unnecessary or irrelevant points were made, such as that in a case control study a temporal relationship cannot be established - some candidates listed several issues then said that some of them were irrelevant here.

**2. A retrospective analysis of in-patient deaths following admission for acute myocardial infarction in Nottingham from 1982-1992 included the following results. (BMJ 1997; 315: 159-164). Using 1982 as the reference year, the crude odds ratio for such mortality in 1992 was 1.38 (95% confidence interval 1.10,1.73). Female patients were observed to have a worse prognosis than males in this series, and case-fatality increased with age. After adjustment for age and sex in a logistic regression model an odds ratio of 1.02 was obtained.**

- a) **Give brief definitions of the terms "odds ratio", "95% confidence interval" and "logistic regression", and explain why these were used in this study.**
- b) **What do you infer from the findings, and what might explain them? Which data underlying the results given above would be helpful in interpreting them?**

### Key Points

- The odds of dying in any particular year is obtained from the ratio of the number of deaths to the number of survivors. The odds ratio is obtained by dividing the odds in 1992 by the odds in 1982. It may be interpreted as a measure of relative risk and was used to represent the proportional change in mortality over the intervening 10 years. A 95% confidence interval in the long run contains the true odds ratio on 95% of such instances (from a Bayesian standpoint, with 95% probability). It was used to portray the levels of imprecision in the estimates of the odds ratios. Logistic regression is a technique which controls for potential confounding effects, used here in order to adjust for any changes in the age-sex composition of the in-patient population. Logistic used, not linear, because outcome i.e. case-fatality is binary.

- Before adjustment for age and sex, the odds ratio suggests a nearly 40% higher mortality in 1992 compared with 1982, which is statistically significant given that the confidence interval does not include one. Adjusting for age and sex reduces the odds ratio practically to the null value (unity), and it is (self-evidently) no longer statistically significant. The most likely explanation is that there were higher proportions of women and older patients in 1992 compared with 1982, since these are the groups with higher mortality rates in this context. The data which would be useful at the two time points are the age-sex distributions and the age and sex-specific mortality rates.

*The following additional points might improve the answer to 'good' or 'excellent':*

- The odds ratio approximates more closely to the relative risk for rarer outcomes - won't do so here. The confidence intervals are interval estimates of the odds ratios. Logistic regression is a technique for modelling odds ratios, allowing full flexibility for representing confounders in various ways (discrete or continuous), and also for considering interactions/effect-modification. Less flexible alternatives include Mantel-Haenszel techniques on mortality data stratified by for example age and sex, and standardisation.
- Before adjustment, even the lower confidence limit indicates an increase in mortality (10%). CI is wide - considerable uncertainty re strength of effect. Inspection of the age and sex-specific rates would indicate whether the finding of no change in mortality rates overall (from the adjusted odds ratio) is replicated across all sub-groups.
- Concomitant changes in caseload characteristics might not be confined to age and sex. Supplementary data on e.g. NYHA classification on admission might be informative - are they admitting a caseload of greater or lesser severity than earlier? Changes in diagnostic procedures may have occurred. But great caution needed in analyses adjusting for confounders - many options for which to choose to adjust for which can lead to very different conclusions.

Key Words: Odds ratio, confidence interval, logistic regression, age and sex-specific mortality rates.

### Comments

Question 2 was also not well answered. Some candidates incorrectly inferred that the study was a case control study, in some instances stating that use of the odds ratio implied this. Few realised that the adjusted odds ratio was evidently non-significant. Few noted the role of the binary outcome as a major reason for using the odds ratio and logistic regression. Often candidates failed to interpret the data presented to them in context. There was carelessness in candidates' division of their time, so that many candidates failed to score well on the second part of the question.

### 3. Describe the principal elements of a hospital infection control service.

#### Key Points

- Aims and Functions of hospital infection control in specified hospital type e.g. acute and elective, in specified country
  - Surveillance, purpose and use of different types
  - outbreak investigation and control
  - prevention
- Staffing and other resources to support staff in the function (e.g. IT)
- Importance of hospital infection control committee and who should be on it
- Accountability structures and clinical governance
- Details about how infection is controlled in hospital, such as
  - development and implementation of policies and guidelines
  - teaching and training
  - advice to health professionals
  - hand washing
  - key advisors on cleaning and sterilisation of equipment
  - cleaning of hospital structures e.g. isolation facilities
  - role of occupational health service and OH policies
  - role in prescribing of antibiotics
  - food hygiene/kitchens
  - audit
- antimicrobial resistance
- understanding of some of the major problem organisms e.g. MRSA, MDRTB, C Diff
- Liaison with relevant agencies/personnel e.g. CCDC, PHLS, Environmental health

*The following additional points might improve the answer to 'good' or 'excellent':*

- A structured answer e.g. use of structure/process/outcome model
- Demonstrated knowledge of the local implementation of national recommendations e.g. Cooke Report, NAO report, HSC 2000/002 in the UK, relevant legislation in other countries.
- Role of PHLS
- Discussion of the role of a hospital based infection control service in relation to the continuum of communicable disease and infection control in a geographically defined population of which hospital population is a part, i.e. the relationship with community infection control services, GPs, CCDC
- Description of examples of good practice
- Recent guidance on spongiform encephalopathies and use of disposable equipment
- Use of SLA and contracts to ensure good infection control arrangements.

#### Comments

Overall the responses to this question were very poor.

There was a lack of structure to the majority of responses and very little indication of any real life experience or understanding of the workings of a hospital infection control *team* and even less understanding of the role of an infection control committee.

There was a worrying lack of mention of the role of Occupational Health and primary prevention to protect staff and patients.

There was only some mention of outbreak management and this was largely theoretical.

**4. a) Outline briefly a local strategy for promoting the health of ethnic minority groups within your local population. (40%)**

**b) How would you evaluate the effectiveness of this strategy? (60%)**

#### Key Points

Candidates would be expected to describe their population and the ethnic composition that their answer refers to. The candidate should demonstrate knowledge of the importance of ethnic monitoring.

From this starting point, they would be expected to identify the specific health needs, relating to specified ethnic groups. Health needs should be expressed as those relevant, based on evidence base, because of greater disease incidence or prevalence e.g. diabetes and hypertension, and those specific to certain ethnic groups, e.g. sickle cell disease.

The answer should then describe a strategic approach to promoting health amongst identified ethnic groups in the population. The strategy should identify aims and objectives, relevant approaches at individual and group levels, and highlight the need to understand cultural differences in attitudes to health and to health behaviours, with reference to advocacy, out-reach to local groups and accessibility of translated materials. Candidates would be expected to show that development of a strategy would need to be in partnership with other organisations and agencies, including voluntary and community groups. The strategy should include an action plan and timetable for implementation.

A structured approach to evaluation is expected, covering structures, process and outcomes. Evaluation of knowledge and attitude and use of media would be expected.

*The following additional points might improve the answer to 'good' or 'excellent':*

Development of strategy with ethnic minorities themselves taking a leading role

Use of customer/client satisfaction

Knowledge of strategies and actions that have been evaluated elsewhere and how these might be used locally.

Links with other initiatives to reduce inequalities e.g. Sure Start, community development projects

Demonstration of how a strategy covering the health of ethnic minorities might fit in with Local Strategic Partnerships, Crime Reduction Partnerships, etc.

Use of ethnic minorities themselves to monitor/evaluate effectiveness.

## Comments

This paper was in general answered in a very disorganised way. The strategy element was poorly answered in most instances while the evaluation part was answered a bit better by the candidates.

Ethnic monitoring was not really discussed and this was disappointing.

Needs assessment while discussed by most was not addressed in any great detail. Information sources, utilisation and interpretation of the data was not paid sufficient attention.

There was little evidence of any sense of reality and a sense of over ambition in many responses.

Responses were very theoretical.

There was scant attention to timetabling and milestone achievement.

## **5. For a geographically defined population, what information is available to investigate inequalities (disparities) in health? How could this information be used for the benefit of this population?**

### Key Points

- a) Identification of an appropriate geographically defined population e.g. country, region, local authority or health authority, primary care trust.
- b) Identification of appropriate measures of health from readily available data at local or small area level. This should include vital statistics, avoidable causes of death, morbidity data from hospitals, infectious diseases, primary care, data on uptake of services by age and sex and where possible linked to socio-economic classifiers
- c) Methods of measuring social status or disadvantage at the small area level - census variables used as a proxy for standard of living and indicators of social disadvantage such as receipt of benefits, children at risk and in care, indices of social deprivation used in the context of the country involved (e.g. for UK Jarman, Townsend, Carstairs etc), income, educational status, housing status.
- d) Describe methods by which measures of social status or disadvantage at an area level can be related to information about health at the level of the same geographical area.
- e) Description of the way in which this information can be used to identify areas of unmet need, particular ill health, or under-utilisation of services, so that services can be targeted towards addressing inequalities in health using a multi-sectoral multi-agency collaborative approach.

*The following additional points might improve the answer to 'good' or 'excellent':*

- a) A good answer would elaborate on the quality of data available, the methodology for comparison at small area or other defining groupings,

including the appropriate application of different indices of deprivation, and would refer critically to the literature.

- b) Advanced approaches such as the application of geographical information systems and record linkage might be discussed.
- c) Issues such as ecological fallacy (application of area-based measures to individuals) might be discussed.

### Comments

Very few candidates defined the population to which their answer referred. Although most candidates were able to cite a wide range of sources of data on health, ill health, healthcare and socio-economic information, poorer candidates in general failed to:

- Elicit the main features of these sources and what they can tell us about health inequalities
- Emphasise the value of census data as denominator data, as well as its use in construction of deprivation indices
- Talk about inequalities *other* than socio-economic inequalities (e.g. age, sex, ethnicity, occupation)
- Bring in non-health service sources of data such as local authority data, police data, environmental data.

Most candidates discussed deprivation indices, some of them very well indeed. However in general there was little discussion about how the data could be analysed or used, including methods of linking or combining data from various sources to investigate inequalities. Better candidates discussed equity audits and referred to the literature.

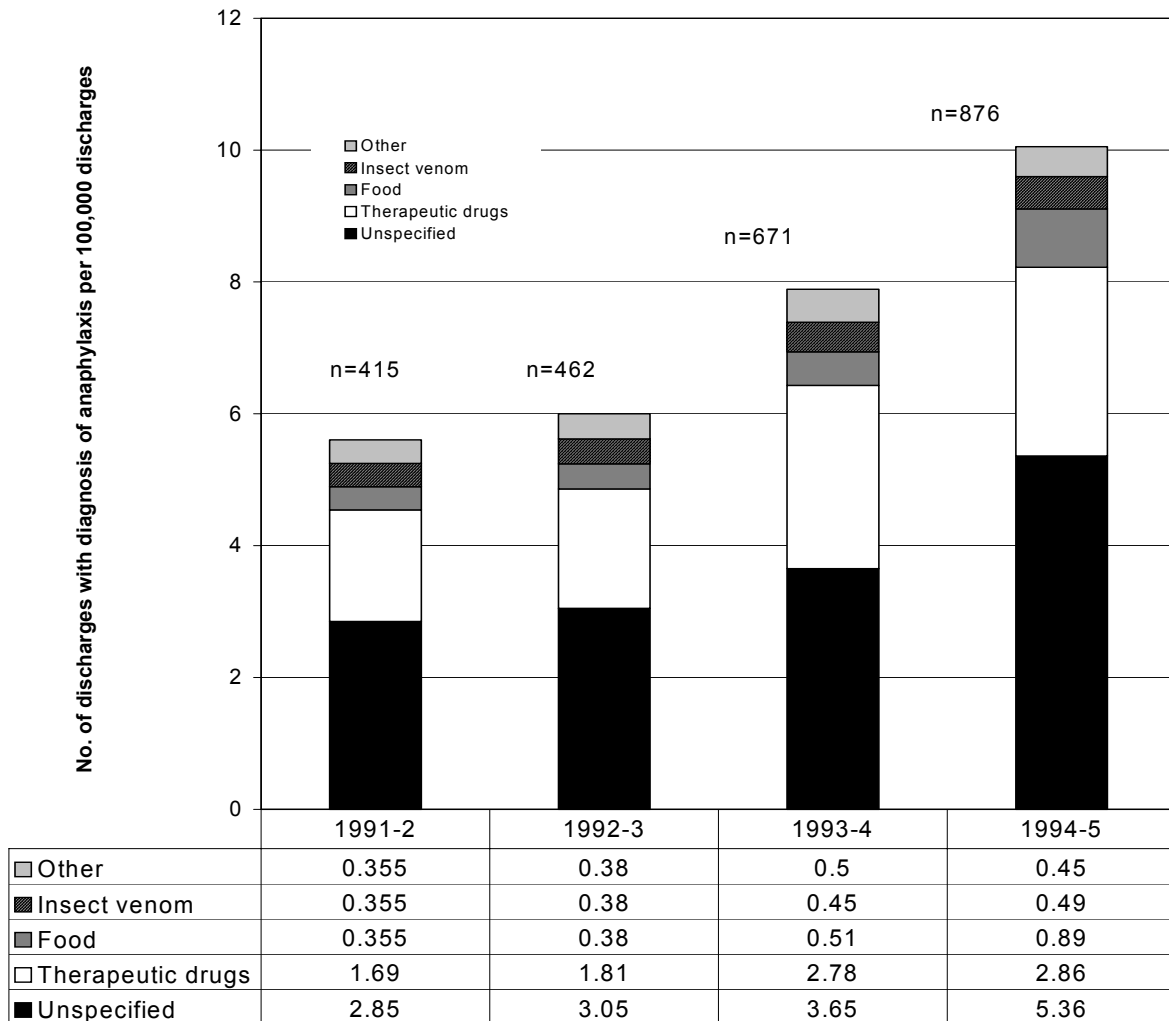
Very few candidates attempted to deal with statistical methods to link socioeconomic and health data. Very few candidates also mentioned GIS and record linkage, which suggests that they are not familiar with these techniques. No candidates mentioned ecological fallacy.

The second section of the question was answered less well with a high proportion of candidates not recognising that the question was really about addressing unmet needs. The answers of weaker candidates tended to consist of *ad hoc* lists of good ideas, rather than having a basis in recognised policy frameworks, or literature.

**6. Health service researchers carried out an investigation into trends in anaphylaxis (life threatening allergic reaction) between 1<sup>st</sup> April 1991 and 31<sup>st</sup> March 1995 and published the chart over page (BMJ 2000;320:1441 (27 May).**

- i) **Describe what the chart shows and explain what conclusions may be drawn from the data.**
- ii) **List possible factors that may explain the changes between 1991 and 1995.**

## Cause of anaphylaxis



### Key Points

- The chart shows a steady rise in both the number of hospital discharges for anaphylactic reactions (from 415 to 876 cases - a 2 fold rise), as well as in the proportion of all hospital discharges accounted for by anaphylaxis (from 5.6 per 100,000 discharges to just over 10 - just under a 2 fold rise) between 1991 and 1995.
- The rise is accounted for mainly by an increase in cases due to a miscellaneous category ('unspecified') and anaphylaxis due to therapeutic drugs.
- A smaller increase is noticeable due to food allergies but the other two categories show only small rises the significance of which we cannot comment on.
- It would be a reasonable first conclusion to infer from these data that there has been an increase in anaphylactic reactions between 1991 and 1995
- Factors that may explain the apparent increase: Changes in the completeness and accuracy of clinical coding may be at least in part responsible for the apparent rise. The threshold for admission may have altered between 1991 and 1995 leading to a greater tendency to admit cases which, earlier may have been managed in A&E units or in general practice. Completeness and accuracy of clinical coding could be better, leading to fewer deaths and more discharges.

*The following additional points might improve the answer to 'good' or 'excellent':*

- Anaphylaxis is not a specific disease, rather it is a common pathway for the clinical manifestation of allergy to many possible antigenic substances. This is shown by the largest group of cases being unclassified - i.e. no incriminating antigenic substance was identified. This could also call into question the accuracy of the diagnosis.
- A lower threshold as a possible explanation of the apparent rise could be examined by studying the age and sex distribution of the cases and whether there was any geographical clustering.

### Comments

In the first part of the question, good answers were clear, precise and concise. Almost all candidates recognised that there was an increased in diagnosed cases of anaphylaxis among hospital discharges during the period. However a lot of candidates did not discuss the differential rates of increase between different causes, and some candidates appeared to get confused between rates and numbers of cases. A minority of candidates simply copied out the figures with a minimum of interpretation. Very few candidates worked out (as was very simple to do) the number of discharges per 2-year period upon which the data were based. This led to erroneous conclusions that these data were from a single hospital. Weaker candidates were vague in description and interpretation of the data.

In the second part of the question, answers varied widely in quality. Some candidates gave consideration to a wide range of explanations, including stating how each possible explanation might have affected the data obtained. Others provided either an unqualified or undefined list, or locked onto one explanation. For example, some candidates cited "data ascertainment" without explanation, or "changes in coding" without explanation of how this could affect the data. A lot of candidates took an epidemiological approach to the question, whereas in reality this is not an epidemiological study – for example, they cited "confounding" as a cause for the increase, but there is no reason to cite this, since confounding occurs primarily when an association is between cause and effect is being sought in an analytical study. Weaker candidates could not distinguish between numbers and rates, and so cited changes in the denominator as an explanation for the increase in rates – this is unlikely given the concurrent increase in absolute number of cases also.

A number of candidates recognised that the increase could be due to an increase in numbers surviving to get to hospital and thus be admitted, and/or due to a reduced in hospital mortality rate, resulting in fewer deaths but more discharges for the same number of patients. This is a valid and important point, and should be added to the key points.

## PAPER IB (1.5 hours)

### 7. Write short notes on two of the following:

- a) **the use of discounting in the economic appraisal of health services;**
- b) **marginal costs;**
- c) **cost benefit analysis.**

#### Key Points

- a) Costs and benefits of programmes are evaluated from the point of view of the present, whereas they may both occur at varying times between the present and the future. Conventionally they are less heavily weighted the further into the future they occur. The reasons are that individuals have a positive time preference, preferring current consumption, and regard future costs and benefits with uncertainty. Discount rates are often calculated by an official amount, such as that set by the Treasury. Evidence for individuals' positive time preferences is not strong and discounting works against preventive programmes in resource allocation. There are differences in discount rates between costs and benefits, and between countries.
- b) The distinction is made between average costs and marginal costs. The average cost of a facility is the total cost divided by the units of output. Marginal cost is the extra cost of producing one extra unit of output. Average and marginal costs are usually different. For example, the extra cost of keeping a patient in bed one day longer or of admitting one extra patient per week is unlikely to be the same as the average cost because, for example, it is unlikely that extra staff are hired or many overheads are increased.
- c) Cost benefit analysis is one method of economic appraisal that can be used to inform choices between alternative policy options. It requires the calculation of the costs and benefits that are associated with options, either from a particular perspective (say, government) or from a societal perspective where all costs and benefits are calculated. Cost benefit analysis differs from cost minimisation analysis in that the latter assumes equivalent outcomes. Cost benefit analyses are usually distinguished from cost-utility analyses in that benefits are often expressed in monetary terms rather than utilities such as QALYs. Full cost benefit analyses take account of all direct and indirect costs and consequences. Sensitivity analysis is essential, given the many assumptions required.

#### Comments

The majority of candidates did well in this question. In relation to discounting, a few answers assumed that discount rates were the same as interest rates. Most candidates recognised the differences in views on discounting costs as opposed to discounting benefits. This was noted rarely the last time this question was set, and represented a clear improvement. In some instances candidates were able to quote relevant figures, but did not seem to understand the concept.

The marginal cost question was generally well answered. Some candidates confused cost-benefit analysis with cost-efficiency analysis, and few mentioned the role of

sensitivity analysis. Some candidates were confused about the differences between average and marginal costs.

Cost benefit analysis was usually well described. Some candidates provided a full account of economic analysis, which has not required.

**8. Certain members of a local environmental pressure group are seeking your support, as a public health practitioner, to prevent the siting of a clinical waste incinerator near to their village on the grounds of the risk to their children's health. Discuss how you would respond to this group.**

Key Points

Ascertain the facts of the situation:

- Is an incinerator to be built near to the village and if so exactly what, where, when and by whom?
- What is the membership, nature and influence of the pressure group, and what are their concerns?
- Are there likely to be other agendas?
- Who is/are the responsible authority/ies and to what extent have they been or should they be involved?
- Results of any impact assessments undertaken so far, as part of the regulatory process
- Mechanisms/processes available for obtaining the facts

Decide on whether there is a need for the involvement of a public health practitioner and if so the nature and extent of that involvement:

- Personal/professional
- Any likely conflict of interest, if incinerator is for clinical waste?
- Independent advice to the pressure group/advice to the responsible authority/ies
- Expertise/resources available
- Mechanisms/processes available for deciding on the involvement
- Scoping of the problem before embarking on full health impact assessment

Assuming a professional involvement, obtain and interpret the relevant and available data and information, make recommendations and facilitate their implementation.

Answers may include need to identify:

- Past and current health risk and health data of the population in question
- Known health risks and health effects of exposure/proximity to clinical waste incinerators
- Likely health risks to and health effects in the population in question of exposure/proximity to the proposed clinical waste incinerator, including any sub-groups at risk
- Mechanisms for consultation/involvement
- Sources of data and expertise
- Mechanisms/processes available for implementation of findings/recommendations

*The following additional points might improve the answer to 'good' or 'excellent':*

Demonstrated knowledge of the health risks and health effects of exposure/proximity to clinical waste incinerators.

Demonstrated understanding of the practical and political aspects of such situations.

Demonstrated understanding of the organisational and legislative frameworks within which such situations are dealt with in candidate's area

Identification of possible conflict between NHS role in relation to clinical waste incinerator, and public health role – issues of trust involved.

Recognition of the likelihood of political involvement in any debate.

Monitoring of health impact if incinerator built

Probability that situation will not be resolved to everyone's satisfaction.

Possible conflicts on types of evidence used by different interest groups.

#### Comments

Most candidates made a good attempt at this question, and were familiar with relevant literature. Structured answers did better than poorly focused short essays.

Stronger answers considered the information required when making a decision on involvement, rather than assuming that public health input would be useful. . Most candidates took a Health Impact Assessment approach, involving a scoping of the problem in advance of a decision on commitment. Some answers saw public health in an adversarial role, and automatically on the 'side' of the pressure group, even in advance of assessment of evidence. Better answers commented on the value of information on the existing health status of the population. Some answers related local concerns to relevant risk theory.

Weaknesses in some responses lay in limited acknowledgement of the potential for conflict, and for potential media and political involvement. Few answers demonstrated a clear view of how any conclusions would be fed in to the regulatory process.

### **9. Outline the steps and key themes necessary to reduce the risk of errors in clinical care, illustrating your answer with reference to a named health system with which you are familiar.**

#### Key Points

Reasons why systems are necessary for:

- Patients (e.g. outcomes)
- Individual practitioners (e.g. self esteem)
- Teams (e.g. poor morale)

- Organisations and the health system (litigation costs, poor performance in league tables, loss of confidence in the system)

Mechanisms to reduce clinical error:

- Good education systems
- Recognition of error:
  - monitoring by individuals, teams and organisations
  - systems of reporting
  - no blame culture where excellence can flourish
  - methods:
    - audit, clinical governance procedures, risk assessment, complaints monitoring
- Examples of specific methods to prevent clinical errors:
  - provision guidelines, integrated care pathways, protocols and policies – including a whistle-blowing policy, redesign of services
  - within protocols acknowledge importance of workload, work patterns e.g. circadian rhythm and clinical supervision in relation to local patterns of clinical errors

*The following additional points might improve the answer to 'good' or 'excellent':*

Use of examples e.g. Bristol and quotes guidance e.g. An Organisation with Memory  
Use of examples from other risk areas e.g. airline pilots.

### Comments

Most candidates had an understanding of the methods available to reduce risks in clinical care. Good answers took a holistic approach to the whole system of care and were inclusive of all the elements necessary. Many poor answers missed out key components such as Risk Managements, dealing with poor performance, the components of being a learning organisation. There was a poor understanding of the relationship between systems of assessing risk within a procedure or care pathway and relating this to adverse event monitoring. Some candidates interpreted the question as relating to a specific service rather than a 'named health system'. Where their answer showed knowledge of the general principles this was acknowledged.

**10. Managers of the main hospital in your area have sought your advice as a public health practitioner on how to understand and manage the increasing demand for its accident and emergency department (emergency room) services. Outline your approach to investigating the situation, with reference to a named country, and discuss how any ensuing organisational changes might be managed and implemented.**

### Key Points

Understand the nature of the demand in relation to pre and post increase

- Age and gender
- Geographical origin
- Temporal patterns of attendance and change
- Case mix

- Appropriateness - investigations undertaken and outcome attendance e.g. admission

#### Context of increasing demand

- With regard to population change
- Changes in the local health system
  - e.g. closure of local hospitals, introduction of new services e.g. telephone advice lines, changes in protocols e.g. emergency services, changes in primary care

#### Managing organisational change

- Alternative ways of managing demand
  - primary care changes
  - changes within the A and E department e.g. triage
  - take into account cost effectiveness
- Reference to change management techniques

*The following additional points might improve the answer to 'good' or 'excellent':*

Examples from the international literature concerning the management of a specific example of increase in accident and emergency demand together with the evidence base for demand management in general.

#### Comments

Most candidates had knowledge of several change management theories. Good answers were those that showed an ability to interpret these in a practical way to address the question. Poor answers to this question failed to include details of an epidemiological assessment of the problem including demographic changes in the population, alterations in population size, changes in primary care services and changes in morbidity patterns etc. Change management was better covered on the whole. Again some candidates failed to identify the country they were answering from.

## **PAPER IIA (2.5 hours)**

**You are taking part in a review of mental health services in your health district and have been asked to look at the role of counselling for depressive illness in a primary care setting. In response you are to appraise the accompanying article by Chilvers C *et al.* "Antidepressant drugs and generic counselling for treatment of major depression in primary care: randomised trial with patient preference arms". BMJ 2001;322:772-5.**

- 1. Write a structured abstract of no more than 400 words. (15%)**
- 2. Critically appraise the paper, paying particular attention to:**
  - the methods used including statistics
  - choice of outcomes
  - results
  - conclusions drawn (40%)
- 3. The review group is being pressed to fund the expansion of counselling services. What would be your response; what additional information is needed? (15%)**
- 4. What are the ethical and clinical issues involved in patient choice (and its denial)? (15%)**
- 5. Suggest a design for a study (use diagrams) that could identify any benefits of responding to patient preference. (15%)**

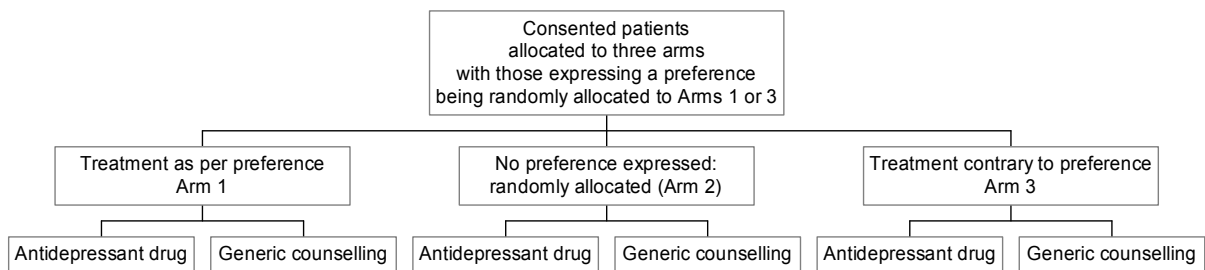
### Key Points

- Abstract: Headings should include at least objective, methods, results (key outcomes) and conclusions. Methods must include study design, patient entry criteria and outcome(s) assessed.
- CA: randomised trial of alternative treatments with patient preference arm. Entry and exclusion criteria described and done to checklist. Ethical approval obtained. Statistical methodology described (is appropriateness discussed by candidate?) Power calculation described ... but relates to just one outcome. The numbers needed according to this changed calculation were not reached in terms of numbers completing 12 month questionnaire ... study therefore not powered to test the (unstated) hypothesis (this is the major flaw in the study and mention of this should carry most marks). Use of patient preference arm data with randomised data reduces the trial quality.
- Outcomes described: Beck's depression inventory, time to remission (remission defined), global outcome (described) and research diagnostic criteria but no mention of validation of any of these scores.
- Results: baseline characteristics were missing for many patients (no telephone interview) so this data unhelpful in assessing bias/confounding. Large amounts of outcome data missing and some outcomes 'estimated' (from case notes). For research diagnostic criteria in the small randomised arm a difference in 'no longer depressed' rates came close to statistical significance at  $p=0.07$  ... if the study had been bigger? Unhelpful use of sensitivity analysis ('if we assumed') to assess

possible effects of missing data as analysis produced full range of possible results.

- Conclusions: Claims that patients choosing counselling are less depressed not supported by *all* measure of severity. *This* paper does not support the claim that both treatments are effective (and certainly not that 'remission rates are impressive with both treatments' as no controls to compare, nor that antidepressants work more quickly (no stat significant difference in median time to remission even for those randomised to antidepressant ( $p=0.1$ )). Absence of evidence is not evidence of absence (of a difference).
- Establish patient preference at trial entry then randomise to drug or counselling within each preference (6 arms in total). This has the potential to show a 'dose response': treatment of choice; no preference; treatment not preferred. Or simpler observational study with single treatment (e.g. all get counselling but establishing patient preference at entry). This latter will likely suffer confounding/bias with unequal arms.

Diagram of suggested trial design:



- Economic analysis needed. Counselling scarce resource (even if funding available) and long NHS waiting times a bar to effective delivery of counselling .. would need rapid (2 week) access.
- Complying with patient choice should in theory enhance 'placebo effect' and may be of particular importance in mental illness (patient empowerment); it should also enhance treatment compliance/concordance. If two treatments are of equal effectiveness it should be the patient who chooses, not the doctor. However what if unequal cost effectiveness and patient chooses treatment with higher cost effectiveness .. what of equity (equal resources for equal need) and opportunity costs?

*The following additional points might improve the answer to 'good' or 'excellent':*

- Abstract: setting; numbers of patients; good balance between completeness and shortness to be rewarded.
- CA: Objectives: what is the hypothesis being tested ... can a null hypothesis be proven?? Power calculation changed and study resized during course of study (rather than recruit for longer).
- One of a number of papers published on the same research = 'salami slicing': as a result this paper is difficult to fully assess with so many references to other papers in the 'series'.
- Study should have been extended to recruit sufficient patients; cessation of recruitment ethically questionable as study has not answered questions posed.
- Marginal economic analysis is needed i.e. to assess costs and benefits of treating in accordance with patient choice.

- Despite few statistically significant findings there is a general tendency to refer to a variety of differences as if they were significant (though using words such as 'suggest' and 'seemed'). Lots of presumptions not much evidence!
- Complying with patient choice is a goal of the NHS Plan; lawyers may seek to apply Human Rights Act to denial of *chosen* treatment. As complying with patient choice should in theory enhance 'placebo effect' and may be of particular importance in mental illness (patient empowerment), this may be a genuine justification for clinical freedom (though it's really patient freedom!)

### Comments

There was a tendency for candidates to adopt a "scatter-gun" approach particularly to sub-sections 3 and 4, not adapting their knowledge to the question. Sub-section 5 was generally poorly answered with inadequate thought given to answers, many candidates seemed rushed. The critical analysis elements (sub-section 2) were better. There were relatively few good answers.

## PAPER IIB (1.5 hours)

**A local multi-agency group set up to plan services for people with diabetes has asked for your advice on the establishment of a screening programme for sight-threatening diabetic retinopathy. In order to approach this task you undertake a literature review and obtain the following information on two different screening programmes:**

### 1. Ophthalmoscopy by local optometrists

	Number of people invited for screening	Number of people who respond and are screened	Number of people who are found to be positive on screening and are referred	Number of people who are found to be negative on screening and are <u>not</u> referred
Number of people who are subsequently diagnosed as having retinopathy			74	26
Number of people who are subsequently diagnosed as <u>not</u> having retinopathy			144	756
<b>TOTAL</b>	1300	1000	218	782

### 2. Hospital based digital retinal photography

	Number of people invited for screening	Number of people who respond and are screened	Number of people who are found to be positive on screening and are referred	Number of people who are found to be negative on screening and are <u>not</u> referred
Number of people who are subsequently diagnosed as having retinopathy			85	15
Number of people who are subsequently diagnosed as <u>not</u> having retinopathy			90	810
<b>TOTAL</b>	1700	1000	175	825

**Using the above information, and any other relevant information from your own knowledge, write a report for the group on the approach to screening**

**for diabetic retinopathy that should be adopted locally. Your report should include sections on the following (as a minimum):**

- i. An analysis of whether a screening programme should or should not be implemented; you should state your recommendation, together with your reasons. (40%)**
- ii. An assessment of the technical performance of the two screening methods (i.e. ophthalmoscopy and digital retinal photography) showing all relevant calculations. Advise upon which should be employed, giving the reasons for your choice. If you identify any other options for how the screening programme could be organised you may include these also. (40%)**
- iii. Your advice about any other aspects of the screening programme that you feel are relevant and important. (20%)**

Key Points

The answer should be written in the format of a report in an appropriate style, format and language suitable for a largely professional group, with credit given for a well-structured and logical approach.

The paper should include key points in relation to sections i. ii. and iii. as follows:

Section (i)

An analysis of whether a screening programme should be implemented with reference to the Wilson and Jungner or the National Screening Committee criteria. Key points include: retinopathy is the biggest single cause of blindness amongst working age people in the UK; social cost of blindness in working age people is considerable; diabetes is a relatively common condition (prevalence 2%); 10% of people with diabetes will have retinopathy requiring treatment; retinopathy can be detected by ophthalmoscopy or digital retinal photography; laser treatment is effective in preventing blindness if carried out at an early stage of sight threatening retinopathy; screening and treatment are acceptable to people; treatment facilities are available; screening tests are easily performed and at an acceptable cost. On the basis of current evidence and policy a screening programme should be recommended.

Section (ii)

The following analysis of the information included in the question is required in approaching this section:

Sensitivity and specificity of each screening method, i.e.

	Disease +ve	Disease -ve	
Test +ve	a	b	a + b
Test -ve	c	d	c + d
	a + c	b + d	

Sensitivity =  $a/a+c$

Specificity =  $d/b+d$

Positive predictive value =  $a/a+b$       Negative predictive value =  $d/c+d$

Uptake or response rate = number screened/number invited.

Prevalence of retinopathy in screened population = number of disease positive/total number screened.

The results are:

	Sensitivity	Specificity	Uptake
Ophthalmoscopy	74%	84%	77%
Digital retinal photography	85%	90%	59%

Prevalence = 10%

Additional marks would be available for calculation of other statistics, e.g. false positive/negative rates and/or positive/negative predictive values.

Key points should include: an explanation of sensitivity, specificity, false positive/negative rates and positive/negative predictive values of a screening test; that digital retinal photography is technically superior; that a higher uptake is achieved with ophthalmoscopy undertaken by local optometrists, the significance of this and possible explanations; other advantages and disadvantages of each screening method (e.g. cost differences, permanent record with photography). Other options for delivering the screening programme could be included and described, e.g. mobile digital retinal photography.

### Section (iii)

Other aspects of a screening programme that are important could include: the organisation and management of the programme; the need for a complete register of people with diabetes supporting a call and recall system; screening interval; quality assurance systems and service standards; the need for training of staff; follow up and treatment of people with retinopathy; the need to maintain links between the screening programme and the routine care of people with diabetes; given the higher incidence amongst some ethnic minorities the need to ensure that the screening programme and literature are culturally sensitive; the need for evaluation including monitoring of uptake rates.

### Comments

This question was on the whole answered well. In particular there was a comprehensive description of the Wilson and Jungner/National Screening Committee criteria for assessing screening programmes. The assessment of the technical performance of the screening tests (i.e. calculation of the sensitivity, specificity etc) was performed well. However, candidates lost marks for the following reasons:

The Wilson and Jungner/National Screening Committee criteria were described but not applied to assess whether the diabetes retinopathy screening programme should

be implemented; in some cases no clear recommendation was given whether the screening programme should be implemented.

The data that was included in the question regarding the performance of the screening tests were not appropriately organised into a 2 by 2 table so that incorrect calculations were undertaken.

There was insufficient explanation given about the performance of the screening tests in terms of their sensitivity, specificity etc.

No recommendation was given about which screening test should be employed or any alternatives proposed; there was no recognition of the need to consider the balance between technical performance of the screening test, uptake achieved and costs.

There was insufficient information provided about those aspects of a screening programme that contribute to its overall effectiveness, e.g. the information system, quality assurance, training of staff.

The report produced was not well structured or did not follow a logical approach that would be expected by a professional group.

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