NOTE
from: the United Kingdom delegation
dated: 4 February 1994

No. prev. doc.: 4522/94 ECO 14
No. Cion prop.: 9400/92 ECO 221
Subject: Proposal for a Council Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Delegations will find attached herewith in the Annex a document presented by the United Kingdom delegation concerning costs.
DRAFT EC DIRECTIVE ON DATA PROTECTION

Analysis of costs

Prepared by the Economic and Operational Research Division of the Department of Health

Department of Health, England

January 1994
EXECUTIVE SUMMARY

Introduction

1. This note summarises the expected costs to the health services of the requirement in the EC Draft Directive on Data Protection for written consent from data subjects to the processing of data related to health. The paper which follows discusses the assumptions underlying these estimates.

2. The estimates relate only to the cost of obtaining written consent as required by Article 8. They do not include the cost of other aspects of the Directive, such as the requirement to provide detailed information (Articles 10, 11 and 12) and to ensure that records are accurate and up-to-date (Article 6). These requirements will have a substantial cost, but are difficult to cost accurately because of the variables involved.

Basis of estimates

3. In the absence of hard data, these estimates are based on the best assumptions possible. However it should be remembered that much of the analysis is based upon assumption rather than firm data. This reflects the fact that current data collection systems are not based upon the requirements of the Draft Directive, and that the implications of enforcing the Draft Directive are so considerable as to engender major structural changes in current practice.

Non-financial costs

4. These estimates are purely cost estimates - they take no account of the damage to management efficiency and patient care that are implied by the Draft Directive.

Set-up costs and recurring costs

5. The estimates of the set-up costs to the health services in England are in a range of £365.6m to £912.7m. Set-up costs are taken to include obtaining consent from all data subjects for data currently stored.

6. There would also be an annual cost over and above this set-up cost. However due to the lack of information on factors important to recurring costs it has not proved possible to estimate their size. The paper reviews the parameters relevant to estimating the recurring costs of the Draft Directive.

Variation in cost assumptions

7. The variation in estimates is due to assumptions over the response rate of individuals to requests for consent. Many data users would need to contact the entire population (by a mail-shot) and hence many individuals would be asked to provide consent by a number of data users. It is highly improbable that
a high response rate would be achieved, so data users would need to repeat their requests for consent to individuals who have not previously replied. Hence costs of £365.6m for a 100% response rate on first request for consent rise to £458m at a 80% response rate, £609m at a 60% response rate and £912.7m at a 40% response rate.

Resource costs and wage costs

8. Costs are made up of resource costs (paper, packaging, postage) and of labour costs involved in administering the system. The wage rates assumed are slightly below the national average wage. As the work involved will frequently be of a simple administrative nature, this may be an overestimate. However, low clerical wage costs will be offset by the higher costs of health professionals and supervisors. It is impossible to specify with precision where the balance will lie. Based on lower estimates of the hourly wage rate to be paid cost estimates are reduced to between £264.8m to £661m according to response rates. To be achieved the involvement of health care professionals and supervisors would need to be low.

Phasing in the Directive

9. Increasing the time allowed for the introduction of the Draft Directive to one year did not alter the costs significantly. It may however ease the managerial problems involved as these costs are then spread over a longer period.

Omissions from estimates

10. A number of omissions in the estimates need to be stressed:

   i) They refer only to England. For the UK as a whole the estimates in paragraph 4 would rise by 20% to £438.7m to £1095m.

   ii) They include no allowance for out-patients, pharmacists, Ministry of defence hospitals, non-NHS health care professionals other than those in private insurance schemes and private hospitals (e.g. they exclude most osteopaths, many chiropractors etc). Most of these groups are likely to incur substantial costs.

   iii) They exclude all costs incurred outside of the health care sector, such as private employers, Social Services, Local Authorities and Charities.

   iv) They do not cost the time lost by private individuals in providing consent.

11. These estimates cannot be taken as a replacement for a thorough costing exercise. Given the very considerable estimated costs associated with the Draft Directive, a thorough compliance cost assessment would be valuable.
1. This paper estimates the expected costs to the health services from the EC draft Directive on Data Protection.

2. The exact interpretation of the Directive is open to debate. Hence a number of scenarios are costed, each corresponding to a different set of assumptions on the implementation of the Directive.

3. The note is divided into sections as follows:-

   A. Materials costs
   B. Labour costs
   C. Implications for management efficiency
   D. Data Users and their relevant populations
   E. Set-up costs
   F. Recurrent costs
   G. Recurrent costs without set-up costs.

A. MATERIALS COSTS

4. The Directive requires that individuals be informed of the information held about them by health services. Consent to use, or storage, or destruction of information is also required. The Directive is retrospective in that consent is required for all information currently held as well as for the future collection of information.

5. The draft Directive requires each 'data user' or 'controller' to request consent. The health service bodies which would be classified as 'controllers' are presented in Table 1. The definitions used correspond in general to discrete organisational structures - hence a provider unit (such as a hospital) must request consent, but different departments or sections within a provider unit do not need to seek separate consent, unless they are intending to use the data in a way not outlined to the individual. This also implies that it is not possible to write one wholly comprehensive document for the entire health services which an individual needs to sign once and once only to cover all possible uses of his or her personal data.

6. The size of a document sent to individuals to seek their consent may be substantial; it must explain to them all the possible uses of the data in question. It may not be easy to explain the concept of 'health needs assessment' carried out by District Health Authorities (DHAs), or why Family Health Services Authorities (FHSAs) need the data to pay contracted professions such as general medical practitioners. Clearly each 'data controller' will need its own form - though generic forms may be possible for all DHAs or all provider units as each will presumably be using the data in a fairly structured way.

7. The second area of uncertainty is how often a 'data
controller' needs to ask for consent. It is assumed that each 'data controller' needs to ask each individual only once as long as all possible uses of the data are included.

8. Materials costs are taken to include postage, paper and packaging. The cost of typing letters or forms has not been included. It is effectively assumed that they are typed once for each broad data user (hence all General Practitioners (GPs) use the same form etc), and then copied. If however, each data user individually typed their own form this would not be a acceptable assumption and the actual typing costs may be considerable.

SET-UP COSTS

9. The draft Directive requires written consent when a data controller processes health data. "Processing" includes storing or destroying data. Hence, if this Directive is enacted in its current form then all data controllers must obtain consent immediately from each person on whom they hold health data. Thus there will be substantial initial costs of securing consent for all data already collected. Effectively, for a number of controllers this will involve contacting the entire population of the country. For others, the size of the group for whom consent is required is so great that the costs of administratively sorting out the numbers for whom consent is required would be greater than seeking consent from the entire resident population.

RECURRING COSTS

10. Recurring costs will be incurred through the need to obtain consent from a number of broad groups of data subject:

i. Those newly deemed capable of giving consent (e.g. children now judged competent).

ii. Those moving between data controllers - e.g. moving to a new GP, or receiving treatment in a new provider unit.

iii. Individuals whose data is required in research projects.

iv. Those coming into contact with a wholly new data controller - e.g. using ambulance services, being referred to hospital, having an adverse drug reaction reported.

v. Individuals whose data is being processed for a new purpose, for which consent has not been obtained.

11. The level of the recurring costs will partly depend upon how far it is possible for one controller to routinely get consent for others (for example, a GP may be able to get consent on behalf of the FHSA and Prescription Pricing Authority). The recurring costs will be small in comparison to the set-up cost...

4495/94 ANNEX
as many data users will have already obtained consent from most of the population.

12. If the Directive is amended so that it is not retrospective two main alterations need to be made. Firstly, there will be direct materials savings from achieving consent via face-to-face contact with data subjects rather than having to write to them. Secondly, the costs will be spread through time. This case is dealt with in paragraphs 52-57.

FAILURE OF DATA SUBJECTS TO REPLY TO REQUESTS FOR CONSENT

13. While a number of individuals may actively refuse consent for their data to be processed, it may be conjectured that a far larger number will simply not reply. The draft Directive requires consent, and hence a nil reply cannot be interpreted as consent. In the absence of consent individual information may not be processed for essential medical, management and planning purposes. The data controller must therefore maximise the number of responses. In a number of cases, such as the registration of new patients with GPs, or attendance at hospitals etc, it should not be difficult to secure a reply as the individual and the representative of the data controller are to some extent in a face-to-face situation. However, a great many other controllers will have to rely upon getting consent by post. In order to maximise the chance of people responding, a stamped addressed envelope will need to be provided.

B LABOUR COSTS

14. There would be substantial labour costs involved in administering any such system. For many agencies the most cost-effective method of mailing people on whom it holds data would be via a mail shot to the entire population of the country. If this can be conducted centrally by automated systems then there should be few labour costs. Other agencies who will need to undertake this manually will need to isolate the relevant individuals manually.

15. There will be substantial labour costs in processing replies. This will involve opening envelopes, reading replies and noting the individual's consent on his data. Where consent has been refused the appropriate action must be taken. While each individual reply is unlikely to be time consuming, the sheer weight of replies will make this an expensive operation.

FAILURE OF DATA SUBJECTS TO REPLY TO REQUESTS FOR CONSENT

16. Where no reply has been received it is unlikely that reminders can be triggered automatically. Hence each data user will have to issue reminders. It is possible that where compliance is especially low the data user may find a further population-wide mail shot is more cost effective than the laborious task of separating out the names of those who have not responded and manually issuing requests for consent.

.../...
C. IMPLICATIONS FOR MANAGEMENT EFFICIENCY

17. It is unlikely that a 100% response to requests for consent can be achieved. This will mean that only those records for which consent has been obtained may be processed. Management functions within the health services will therefore be based on incomplete information. A number of key problems are indicated below.

i) **Health needs assessment.** Purchasers will be forced to undertake health needs assessment with incomplete information. This will not allow them to make fully informed decisions as purchasers of health services for their local populations.

ii) **Research** will be prejudiced as the costs of obtaining consent and securing an adequate and representative sample become prohibitively expensive.

iii) **Payment procedures** for a wide number of services will not be able to function as at present.

18. This is not an exhaustive list. These problems will prejudice the ability of the health services to carry out their duties effectively. While there may be no direct financial cost, there will be non-financial costs in terms of poor management decisions, lost opportunities for improved services etc.

D. DATA USERS AND THEIR RELEVANT POPULATIONS

19. The EC draft Directive applies stringent controls to the uses of health data. Obviously it is the health services that are most particularly affected by this control. The key data users and the numbers of data subjects likely to be in their data systems (or filing cabinets) are presented below. The key figure is that there may be at least 360 million personal health data files held by the various parts of the NHS, each of which will require the data subject's consent.
TABLE 1

<table>
<thead>
<tr>
<th>DATA USER</th>
<th>RELEVANT POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL PRACTITIONERS</td>
<td>Resident population</td>
</tr>
<tr>
<td>DENTISTS</td>
<td>Resident population</td>
</tr>
<tr>
<td>OPTICIANS</td>
<td>Resident population</td>
</tr>
<tr>
<td>FAMILY HEALTH SERVICE AUTHORITIES</td>
<td>Resident population</td>
</tr>
<tr>
<td>DENTAL PRACTICE BOARD</td>
<td>Resident population</td>
</tr>
<tr>
<td>PRESCRIPTION PRICING AUTHORITY</td>
<td>Resident population</td>
</tr>
<tr>
<td>PROVIDERS - TRUSTS/DMUs</td>
<td>Inpatients</td>
</tr>
<tr>
<td>DISTRICT HEALTH AUTHORITIES</td>
<td>Inpatients</td>
</tr>
<tr>
<td>REGIONAL HEALTH AUTHORITIES</td>
<td>Inpatients</td>
</tr>
<tr>
<td>RESEARCH BODIES</td>
<td>2,000,000 p.a.</td>
</tr>
<tr>
<td>PRIVATE INSURERS</td>
<td>5,500,000</td>
</tr>
<tr>
<td>PRIVATE PROVIDERS</td>
<td>310,000</td>
</tr>
<tr>
<td>MEDICINES CONTROL AGENCY</td>
<td>200,000</td>
</tr>
<tr>
<td>DEPARTMENT OF HEALTH/NHS</td>
<td>1,000,000</td>
</tr>
<tr>
<td>NATIONAL MORBIDITY SURVEY</td>
<td>300,000</td>
</tr>
<tr>
<td>NHS CENTRAL REGISTER</td>
<td>Resident population</td>
</tr>
</tbody>
</table>

**Total 360,810,000**

20. For the purposes of approximation, the resident population of England is taken to be 47 million. The discussion of other numerical assumptions follows under each data user entry below.

**GENERAL PRACTITIONERS**

21. GPs will hold health data in the normal course of their duties. It is assumed that the resident population is covered by a GP. This is an approximation as firstly, some individuals may have no GP, and secondly, some individuals may be on more than one GP’s list. In general the latter outnumber the former and the number of people on GPs’ lists is greater than the total resident population.

**DENTISTS**

22. It is assumed that Paragraph 21 also covers Dentists.

**OPTICIANS**

23. Around 27% of the population visits an optician in any one year. However, opticians will hold records on past patients which will also need consent. While there is likely to be considerably fewer people on an optician’s list than on GPs’ or dentists’ lists, it is also likely that these lists will be less accurate as they are not used as a basis for payment and therefore individuals are more likely to be on more than one optician’s records. Hence, as a working assumption it has been taken that opticians will hold data on a population group similar to the resident population. In sensitivity analysis the number opticians must contact is reduced.
FAMILY HEALTH SERVICES AUTHORITIES

24. The FHSAs receive data from GPs and opticians (for opticians this will refer only to those claiming for NHS treatment). This data is not anonymised by GPs or opticians. While some FHSA data could not be referred to as health data, a substantial proportion is so defined and hence again, the resident population is seen as the relevant statistic. For the purposes of audit, FHSAs would in any case need access to health data.

DENTAL PRACTICE BOARD

25. The DPB hold similar information in respect to dentists as FHSAs do for GPs. Again, therefore, the relevant population group is taken to be the resident population. Sensitivity analysis of reducing the numbers the DPB should contact is undertaken.¹

PROVIDER UNITS and DISTRICT HEALTH AUTHORITIES

26. For the purposes of internal management and the contracting process, hospital providers and DHAs will need to exchange health data. The number of individuals in contact with these areas of the health services will be proxied by the statistics on the number of discharges from (and deaths in) hospital. While it is possible that an individual may be admitted twice to the same institution or paid for twice by the same purchaser, these cases of double counting will be offset by the cases where the provider also maintains records of out-patient cases and where treatment is still ongoing (hence consent is needed as data is collected but no discharge has yet occurred). Proposals exist to cover outpatients by information systems - sensitivity analysis estimates the additional cost from so doing. The number of death/discharges has been estimated from the national statistics on the number of Finished Consultant Episodes at approximately 7.5 million.

27. Clearly, it is also the case that providers and DHAs will maintain records on past cases. It is not possible to calculate how many individuals will be named on these records that do not appear as admissions in any one year. This will partly reflect local practice - both of the hospital in terms of patient record systems and the DHA in terms of both recording systems and health needs assessment. Because of this uncertainty, it has been chosen to ignore past records - this will imply that the costs

¹Essentially, these set-up costs refer to first year costs. These are a mix of the need to gain retrospective consent and the need to gain consent from new contacts. Thus the DPB may eventually need to contact the entire population as eventually most of the resident population will have some dental operation. In the longer run therefore, the assumption of population wide coverage is more reasonable. This problem occurs again in assessing the effects of altering the Directive such that it is no longer retrospective.
to providers and DHAs have been underestimated.

**PRESCRIPTION PRICING AUTHORITY**

28. The PPA is a difficult case. While it does process health data it does not do so for the entire population. However, the number of people receiving a prescription in any one year may be so great as to make it infeasible to isolate each one and request consent. Rather, it may be more cost-effective to simply mail-shot the population. In sensitivity analysis this assumption is relaxed.

**REGIONAL HEALTH AUTHORITIES**

29. RHAs process some health information. For instance the data for the HES statistics are anonymised at regional level. Hence, costs are attributed to the RHA for compliance with this Directive. The most general information the RHAs receive is the HES data in Finished Consultant Episodes - for these purposes the number of individuals involved is again proxied by the number of inpatient admissions. Other data the RHA may receive will frequently be additional information on individuals already covered in the HES data sets.

**RESEARCH BODIES**

30. The Research Division of the Department of Health estimate that 2,000,000 individual records would be investigated for the purpose of medical research in any one year.

**PRIVATE SECTOR**

31. Private sector health purchasers and providers will also be covered by the draft Directive. Private insurance firms will maintain health data - thus the number of people covered by private health insurance has been estimated. Private providers - whether at primary or secondary health care levels - will also hold health data. The number of people receiving treatment in private institutions is not known. Some will receive private care in public institutions. As a proxy, the number of people receiving treatment from private providers is assumed to be in the same proportion to the NHS admissions as is expenditure on private inpatient care is to NHS Hospital and Community Health Services expenditure. Hence this provides a figure of 310,000. This will be an underestimate as it is based only upon private medical care paid for by insurance - and does not include private care paid for directly by the patient.

**MEDICINES CONTROL AGENCY**

32. The MCA presents an unusual difficulty. While it holds personal health data it does not hold people’s addresses - hence it faces a problem of isolating the address of the individuals about whom it holds data. Generally, where other bodies do not hold addresses these may be found. The MCA data on past adverse reactions to drugs allows no such ‘easy’ access and hence the
costs to the MCA will be proportionately higher than other bodies on a ‘cost-per-consent’ basis.

DEPARTMENT OF HEALTH

33. While most data has been anonymised by the time it reaches the DH, the Department and the NHS does hold data on its own workforce that could be defined as health data (days off sick etc). These costs will not in essence be any different to those of any employer and are not separately costed here.

NATIONAL MORBIDITY SURVEY

34. An estimate has been made of the numbers covered in this survey.

NHS CENTRAL REGISTER

35. Holds data effectively on the resident population.

E. SET-UP COSTS

36. As mentioned, the Directive is retrospective and all data currently held will need consent. Hence the Directive has higher set-up costs than annual running costs. The set-up costs are estimated in this section.

MATERIALS COSTS

37. The materials costs are made up of two main areas,
   i) postage
   ii) paper, envelope costs

38. For the annual costs of compliance with the Directive it will frequently be possible to avoid having to write to the individual. Many data users will be in face-to-face contact with those whose consent is required. This will include GPs, dentists, opticians and providers. However at the set-up stage no-one will be in a position to rely upon face-to-face contact. This poses a question over timing:

   how long do data users have in which to get consent?

For instance, if a year was given before data users needed consent then GPs, dentists etc would be in a position to request consent on a face-to-face basis by waiting for individuals to visit them in the course of the normal round of treatment and check-ups. However, if this amount of time is not available then it will not be possible to rely upon normal consultations to request consent. This estimate assumes that the Directive will not allow sufficient time for data users to rely upon normal consultations. For sensitivity analysis, the time period for the set-up period is extended to one year. For some users this

.../...
period of grace is irrelevant as they do not in general have face-to-face contact with individuals.

39. All posted requests use second class post.

40. A second area of importance is whether the data is of such importance that data users must supply a stamped addressed envelope to encourage a reply. If so, compliance may increase but so will postage and packaging costs. If not, individual compliance is likely to be very low. It is assumed that a stamped addressed envelope will be included by all data users.

41. Where so many requests for consent are issued it becomes of importance how long the consent forms are. The Directive states that the individual must be informed of all the uses to which his or her data is put; if any new uses arise then before a data user can so use the information a further request would need to be made. Hence there is an emphasis on ensuring that the descriptions of the uses to which data is put be as comprehensive as possible. Where these uses may appear rather esoteric to the individual (such as health needs assessment, budgeting and epidemiological research), some explanation must be given. It is assumed that each letter will be two pages long. Again, this is subjected to sensitivity analysis.

42. Lastly, where consent is necessary the effects are estimated of people's failure to respond. Hence the costs are shown under varying assumptions over the response rate. Where the response rate is assumed to be 60% it is then assumed that the remaining 40% are again written to, and that 60% of that 40% reply etc.

43. All of these assumptions should be validated by discussion with the relevant data user to estimate the response rates and cut-off points. However, this is not possible within the timescale.

44. The cost of a second class stamp is taken to be 19p; a page of printed material to be 1p; a manilla envelope to be 1p.

LABOUR COSTS

45. The amount of time it will take to administer this system is an important element of costs. For some users it would be possible to issue the requests for consent centrally, for others it will involve a manual search of paper records. Given the number of data users and the variety of paper and electronic records among them a flat rate assumption is made. It is assumed that from the issuing of the request to its cataloguing on return will take an average of 5 minutes. If the data subject does not respond, the process is repeated, again assuming it will take 5 minutes of labour time. This average will conceal a wide range of labour times - those forced to manually inspect records to check compliance may take considerably longer, those with access to electronic systems may take less. Again, sensitivity analysis is made of this assumption.
46. This labour time will be costed at average UK weekly wage rates. Again, this will conceal considerable variation. It may lead to an overestimate of labour costs if the labour used to administer this system is of a lower average grade. Average weekly wage rates were £284.70 for an average of 40 hours work in 1991 (Annual Abstract of Statistics, 1993, Table 6.15). To illustrate the effects of lower wage rates all estimates include the labour costs if the average wage is equal to the lowest quartile average for women in 1991 (Annual Abstract of Statistics, 1991, Table 6.17). While wage rates have risen since 1991, the increase is not great (nor available in such detail), thus 1991 data is used.

ALTERNATIVE SYSTEMS

47. A number of alternative contact systems are used to estimate the sensitivity of cost estimates to alternative methods of acquiring consent.

ESTIMATES

48. Detailed calculations are presented in Annex 1.

49. Table 2 displays the estimates under varying assumptions.

<table>
<thead>
<tr>
<th>KEY ASSUMPTIONS</th>
<th>COST, £m, high wage.</th>
<th>COST, £m, low wage.</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% RESPONSE RATE</td>
<td>£365.6m</td>
<td>£264.8m</td>
</tr>
<tr>
<td>80% RESPONSE RATE</td>
<td>£458.5m</td>
<td>£331.6m</td>
</tr>
<tr>
<td>60% RESPONSE RATE</td>
<td>£608.8m</td>
<td>£440.0m</td>
</tr>
<tr>
<td>40% RESPONSE RATE</td>
<td>£912.7m</td>
<td>£661.0m</td>
</tr>
<tr>
<td>LOWER LABOUR TIME</td>
<td>£280.0m</td>
<td>£219.5m</td>
</tr>
<tr>
<td>SHORTER LETTER</td>
<td>£361.9m</td>
<td>£261.1m</td>
</tr>
<tr>
<td>ONE YEAR SET-UP</td>
<td>£334.5m</td>
<td>£233.7m</td>
</tr>
<tr>
<td>LOWER POPULATION ESTIMATE</td>
<td>£275.0m</td>
<td>£199.1m</td>
</tr>
</tbody>
</table>

Where the response rate has not been explicitly stated, the estimates are based upon an assumed 100% rate.

50. Detailed descriptions of each scenario and other sensitivity analyses are contained in Annex 1.

F. RECURRENT COSTS

51. It is clear that the major element of costs will be set-up costs. The source of the recurrent costs have been outlined in paragraph 10. The estimation of recurrent costs is extremely difficult - for instance, while it may be possible to estimate .../...
the numbers of people who move from one GP to another in any one year, it is not possible to calculate how many of these will also be moving to a new FHSA area, without accessing this information direct from the FHSA. Also, for the calculation of annual costs to DHAs/hospitals it will be necessary to calculate what proportion of cases are first contacts. This will obviously differ between health care purchasers and providers (as one DHA may pay for an individual’s attendance at different hospitals). Also it will be frequently possible for the data user to request consent on a face-to-face basis which will alter the configuration of costs. Many of the recurring costs may be quite small – hence the costs of requesting consent for the numbers of new patients joining a GP practice in any one year will not be great. Due to a lack of data no explicit figure for recurrent costs has been calculated.

52. Thus the critical factors for recurrent costs are the numbers of new contacts with each data user. These are influenced by:-

- numbers of migrants (changing GP, Dentist, FHSA, DHA)
- new contacts (those previously not in contact with a hospital; those now considered capable of giving consent).

53. The number of individuals falling in these categories is unknown. There are data on the number of people changing GP – but this will cover those moving to a different FHSA area or those not in contact with hospital providers.

G. RECURRENT COSTS WITHOUT SET-UP COSTS

54. If the EC draft Directive should be altered so that it is no longer applies to data already collected, data users will not need to gain consent for data already held, but will do so for data collected and held in the future. This is a difficult scenario to cost. One of the main difficulties is the timing of costs – for instance while most people will be in contact with their GP in their lifetime, many may have no contact in any one year. Hence the costs of requiring consent may fall in future years. We may be able to say that in the first year, some 30% visit their GP: these will then be asked for consent. In the next year some other 20% visit (thus 50% of the entire population) and request is required. Eventually the entire population will have been asked for consent. The amount of time this process takes is unknown.

55. The second major alteration to the analysis of costs is that many data users will be able to directly request consent on a face-to-face basis. Thus they will avoid postage costs. The danger is that valuable GP, dentist or nurse time may be lost in verbally requesting consent and explaining to data subjects their rights under the Directive. It is assumed below that whatever time is gained through not having to send postal requests is lost in having to verbally explain the Directive and give the data.../...
subject a form to sign. This may increase the labour costs in
that it will require a higher grade of staff to explain to data
subjects that their consent is required. Bodies such as FHSAs
and DMAs, which do not generally see patients in person, must
still rely on consent via the postal system.

56. Thus if the draft Directive is altered such that it is no
longer retrospective there will be a number of effects. The most
important are:

- a reduction in postage costs
- the costs will be spread through time.

However, eventually, the resident population will have given its
consent to the data held by GPs etc, as all visit their GP
eventually. There is no recurrent cost therefore in the normal
usage of the term. For most data users there is a slow build-up
(or not so slow) in getting consent from all those that they are
in contact with. Once achieved the recurrent costs will fall to
being those in paragraph 48-50.

57. Both effects in paragraph 56, and especially the latter,
will reduce the burden of costs. If it were possible to state
the time pattern of contact with the health services it would be
possible to estimate the costs through time and to appropriately
discount them. Unfortunately such data does not exist.
Essentially, as a base assumption, all data users in Table 1 will
need to get consent from those that they treat, though for those
only in intermittent or one-off contact with data users (a
casualty admission in hospital, or a dental record for an
individual who has since moved), there will be a direct saving.

58. In the face of this uncertainty, Case A.1 can be altered
such that all data users in face-to-face contact do not pay
postage and envelope costs. Also, it may be more reasonable to
assume that they always achieve a 100% response rate, hence, this
cost should not be pro-rated up for the differential response
rates in Section A. Rather, the lower response rates apply only
to that section of data users who cannot rely upon face-to-face
contact.
## Case A.1 revised: no-set up costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Materials cost</strong></td>
<td></td>
</tr>
<tr>
<td>Postage:</td>
<td>£89.4m</td>
</tr>
<tr>
<td>2 x 19p x 205.5m</td>
<td></td>
</tr>
<tr>
<td>Paper and Packaging:</td>
<td></td>
</tr>
<tr>
<td>2 x 1p x 205.5m</td>
<td></td>
</tr>
<tr>
<td>2 x 1p x 360.81m</td>
<td></td>
</tr>
<tr>
<td><strong>Labour cost</strong></td>
<td>£214m (£113.2m)</td>
</tr>
<tr>
<td>As A.1</td>
<td></td>
</tr>
</tbody>
</table>

Total: £303.4m (£202.6m)

59. It needs to be remembered that the costs implied in the above example will partly be incurred at future dates - and all costs incurred at future dates should be discounted. However, it is also clear that as a major part of the costs of the Directive will be labour costs these will still be eventually incurred under this system, if not this year. Such a system would however, considerably reduce the costs of administering the Directive when a 100% postal response rate is not assumed.
ANNEX 1: DETAILED CALCULATIONS

60. The cost estimates under varying assumptions are displayed below:

**CASE A.1** All Table 1 data users request consent.  
- All use postal systems  
- 100% response rate  
- 5 minute labour time to administer system per reply.  
- Two page letter plus SAE.

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postage:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 19p x 360.81m</td>
<td>360.810m x 5 = 1804m minutes</td>
</tr>
<tr>
<td></td>
<td>1804m minutes = 30,066,667 hrs</td>
</tr>
<tr>
<td><strong>Paper and packaging:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 1p x 360.81m</td>
<td>751,667 x £284.7 = £213,999.500</td>
</tr>
<tr>
<td>2 x 1p x 360.81m</td>
<td>751,667 x £150.6 = £113,201,050</td>
</tr>
</tbody>
</table>

£151.6m                  £214m (£113.2m)

Total: £365.6m (£264.8m)

**CASE A.2** All Table 1 data users request consent.  
- All use postal systems  
- 80% response rate  
- 5 minute labour time  
- Two page letter plus SAE

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postage:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 19p x 451.86m</td>
<td>451.86m x 5 = 2259.3m minutes</td>
</tr>
<tr>
<td></td>
<td>2259.3m minutes = 37,655,000 hrs</td>
</tr>
<tr>
<td><strong>Paper and packaging:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 1p x 451.86m</td>
<td>941,375 x £284.7 = £268,009,463</td>
</tr>
<tr>
<td>2 x 1p x 451.86m</td>
<td>941,375 x £150.6 = £141,771,075</td>
</tr>
</tbody>
</table>

£189.8m                  £268.7m (£141.8m)

Total: £458.5m (£331.6m)

**CASE A.3** All Table 1 data users request consent.  
- All use postal systems  
- 60% response rate  
- 5 minute labour time  
- Two page letter plus SAE

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postage:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 19p x 600.94m</td>
<td>600.94m x 5 = 3004.7 minutes</td>
</tr>
<tr>
<td></td>
<td>3004.7 minutes = 50,078,333 hrs</td>
</tr>
<tr>
<td><strong>Paper and packaging:</strong></td>
<td></td>
</tr>
<tr>
<td>2 x 1p x 600.94m</td>
<td>1,251,958 x £284.7 = £356,432,443</td>
</tr>
<tr>
<td>2 x 1p x 600.94m</td>
<td>1,251,958 x £150.6 = £188,544,875</td>
</tr>
</tbody>
</table>

£252.4m                  £356.4m (£188m)

Total: £608.8m (£440m)
CASE A. All Table 1 data users request consent
All use postal systems
40% response rate
5 minute labour time
Two page letter plus SAE

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postage: 2 x 19p x 900.86m</td>
<td>900.86m x 5 = 4504.3m minutes</td>
</tr>
<tr>
<td>Paper and packaging: 2 x 1p x 900.86m</td>
<td>4504.3 minutes = 75,071,667 hrs</td>
</tr>
<tr>
<td>2 x 1p x 900.86m</td>
<td>75,071,667 hrs = 1,876,792 weeks</td>
</tr>
</tbody>
</table>

£378.4m

Total: £912.7m (£661m)

CASE B. All Table 1 data users request consent.
All use postal systems
100% response rate
3 minute labour time
Two page letter plus SAE

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>As A.1</td>
<td>360.810 x 3 = 1082.43m minutes</td>
</tr>
<tr>
<td>1082.43 minutes = 18,040,500 hrs</td>
<td></td>
</tr>
<tr>
<td>18,040,500 hrs = 451,013 weeks</td>
<td></td>
</tr>
<tr>
<td>451,013 x £284.7 = £128,403,401</td>
<td></td>
</tr>
<tr>
<td>451,013 x £150.6 = £67,922,558</td>
<td></td>
</tr>
</tbody>
</table>

£151.6m

Total: £280m (£219.5m)

CASE C. All Table 1 data users request consent.
All use postal systems
100% response rate
5 minute labour time
One page letter plus SAE

<table>
<thead>
<tr>
<th>Materials cost</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postage: 2 x 19p x 360.81m</td>
<td>As Case A.1</td>
</tr>
<tr>
<td>Paper and packaging: 2 x 1p x 360.81m</td>
<td></td>
</tr>
<tr>
<td>1 x 1p x 360.81m</td>
<td></td>
</tr>
</tbody>
</table>

£147.9m

Total: £361.9m (£261.1m)
CASE D 'Point of entry' data user requests consent.

All use postal systems
100% response rate
5 minute labour time
Two page letter plus SAE

'Point of entry' refers to the agent the patient meets on a face-to-face basis. Under this scenario, this data user would request consent for themselves and all users to whom this information (or some part of it) may be passed.

Hence, GPs: request for themselves, FHSA, PPA, Central Register

Dentists: request for themselves, PPA, DPB
Opticians: for themselves and FHSA
Providers: request for themselves, DHAs, RHAs
All others remain as Table 1.

Materials cost

<table>
<thead>
<tr>
<th>Description</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postage:</td>
<td>157.81m x 5 = 789.05m minutes</td>
</tr>
<tr>
<td>Paper and packaging:</td>
<td>13,150,833 hrs = 328,771 weeks</td>
</tr>
<tr>
<td></td>
<td>328,771 x £284.7 = £93,601,104</td>
</tr>
<tr>
<td></td>
<td>328,771 x £150.6 = £49,512,913</td>
</tr>
<tr>
<td>Total:</td>
<td>£66.28</td>
</tr>
<tr>
<td></td>
<td>£93.6m (£49.5m)</td>
</tr>
</tbody>
</table>

Total: £159.9m (£115.8m)

CASE E: One year set-up time - estimates of numbers seeing GP (60%), Dentist (60%), and Optician (30%)\(^2\) in one year and all admissions to hospitals in one year. For these categories, no postage costs are incurred for the estimated numbers of patients visiting. Time costs are the same - as there may be increased use of face-to-face contact time for those explaining the process.

Otherwise as Case A.1.

Material cost

<table>
<thead>
<tr>
<th>Description</th>
<th>Labour cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postage:</td>
<td>As A.1</td>
</tr>
<tr>
<td>Paper and packaging:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Total:</td>
<td>£120.5m</td>
</tr>
<tr>
<td></td>
<td>£214m (113.2m)</td>
</tr>
</tbody>
</table>

Total: £334.5m (233.7m)

\(^2\) Estimates taken from General Household Survey, numbers attending for regular check-up at dentist, and optician. Estimates of dentist/GP up-rated for those attending, but not for a regular check-up.
CASE F: lower estimates for population coverage of opticians, PPA, DPB. These are reduced to 50%, 30% and 30% of the resident population.

All others as case A.1

Materials costs
Postage:
2 x 19p x 271.5
114m

Paper and packaging
2 x 1p x 271.5m
52.5m

Total: £114m

Labour costs
271.5m x 5 = 1357.5m minutes
1357.5 minutes = 22,625,000 hours
22,625,000 hours = 565,625 weeks
565,625 x £284.7 = £161,033,438
565,625 x £150.6 = £85,183,125

Total: £161m (£85.1m)