Protocol for the release of confidential abortions data for bona fide research purposes

This document is intended as a guide for academic researchers requiring access to abortion data for scientific research purposes.

Contact details

For further information, or to discuss your requirements, please contact the Abortion Statistics Manager, Department of Health on 020 7972 5537 or email abortion.statistics@dh.gsi.gov.uk

Background to release of abortion data

Registered medical practitioners are legally required to notify the Chief Medical Officer (CMO) of every abortion performed. The Department of Health receives these notifications on form HSA4 and undertakes statistical processing and analysis. A statistical bulletin is published around May each year, containing tables of information derived from the notifications. Legislation relating to abortions, data protection and official statistics means that only information that does not involve a risk of identification of the individuals involved can be published in this way. A summary of current restrictions on the publication of aggregate abortion statistics can be found in Appendix B, taken from the Office of National Statistics' report : Guidance for Abortion Statistics 2005 (see link to the report below). Further tables are released into the public domain in response to ad hoc enquiries, where doing so is in line with legislation.

Office for National Statistics' Guidance on the release of abortion statistics, 2005 (link opens new window)

In addition, under regulation 5(e) of the Abortion Regulations 1991, patient level data may be released in a controlled manner "for the purposes of bona fide scientific research", subject to the Chief Medical Officer's agreement and the receipt of a completed and signed confidentiality agreement. See below and appendices A & C.

(a) Disclosure of confidential patient information:

The NHS Care Record Guarantee for England sets out the rules that govern how patient information is used in the NHS and what control the patient can have over this. It is based on professional guidelines, best practice and the law and applies to both paper and electronic records. More information can be found at:

http://www.nigb.nhs.uk/guarantee

(b) Subsequent processing by CMO:

The public interest in research which improves health and health care must be weighed against the public interest in the confidentiality of patient information. By custom and practice, the National Information Governance Board for Health and Social Care (NIGB) has become the independent body which advises Secretary of State on this balance of public interest.

Additional requirements for release of data

As noted above, patient level data may be released "for the purposes of bona fide scientific research", subject to the Chief Medical Officer's(s) agreement and a confidentiality agreement. See link below and appendices A & C for further details.

http://www.opsi.gov.uk/si/si1991/Uksi_19910499_en_1.htm

Before data are released, approval must be gained from the Research Ethics Committee (REC) and the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care (NIGB) (formerly the Patient Information Advisory Group, PIAG) using the arrangements created under S251 of the NHS Act 2006. Proof of approval from both bodies is required before an application for abortion data will be considered by the Chief Medical Officer. The Chief Medical Officer will then assess whether the information can be disclosed under the regulations of the Abortion Act 1991 and under the conditions set out in the confidentiality agreement. See appendix C.

Applications for approval can be made at the following websites. The links give comprehensive advice to researchers applying for confidential health related data.

Research Ethics Committee website.
http://www.nres.npsa.nhs.uk/

National Information Governance Board for Health and Social Care (NIGB)

http://www.nigb.nhs.uk

The Government announced at the Budget in March 2011 that it will establish a Health Research Authority this year to combine and streamline approvals for health research. This guide will be revised accordingly in due course.

In many cases, research designs can be revised so that patient identifiable data is not required and the request can be accommodated within the restrictions on data release and so avoid the need for REC, NIGB and CMO approval. For example, it might be possible to use age in place of date of birth, and PCT of residence rather than postcode. Suppressions and aggregations can also be used where small numbers of cases would otherwise prevent release.

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Appendix A

REGULATIONS 4 & 5 OF THE ABORTION REGULATIONS 1991, AS AMENDED BY THE ABORTION (AMENDMENT) (ENGLAND) REGULATIONS 2002 and THE ABORTION (AMENDMENT) REGULATIONS 2008

Notice of termination of pregnancy and information relating to the termination

4. – (1) Any practitioner who terminates a pregnancy in England or Wales shall give to the appropriate Chief Medical Officer –

(a) notice of the termination, and

(b) such other information relating to the termination as is specified in Schedule 2 to these Regulations,

and shall do so by sending them to him within 14 days of the termination either in a sealed envelope or by an electronic communication transmitted by an electronic communications system used solely for the transfer of confidential information to him.

(2) The appropriate Chief Medical Officer is –

(a) where the pregnancy was terminated in England, the Chief Medical Officer of the Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS; or

(b) where the pregnancy was terminated in Wales, the Chief Medical Officer of the Welsh Government, Cathays Park, Cardiff, CF1 3NQ.

Restriction on disclosure of information

5. A notice given or any information furnished to a Chief Medical Officer in pursuance of these Regulations shall not be disclosed except that disclosure may be made –

(a) for the purposes of carrying out their duties –

(i) to an officer of the Department of Health authorised by the Chief Medical Officer of that Department, or to an officer of the Welsh Government authorised by the Chief Medical Officer of that Office, as the case may be; or

(ii) to the National Statistician duly appointed under Section 5 of the Statistics and Registration Service Act 2007 or an employee of the Statistics Board (established under section 1 of that Act) authorised by the National Statistician; or

(iii) to an individual authorised by the Chief Medical Officer who is engaged in setting up, maintaining and supporting a

computer system used for the purpose of recording, processing and holding such notice or information; or

(b) for the purposes of carrying out his duties in relation to offences under the Act or the law relating to abortion, to the Director of Public Prosecutions or a member of his staff authorised by him; or
(c) for the purposes of investigating whether an offence has been committed under the Act or the law relating to abortion, to a police officer not below the rank of superintendent or a person authorised by him; or
(d) pursuant to a court order, for the purposes of proceedings which have begun; or
(e) for the purposes of bona fide scientific research; or
(f) to the practitioner who terminated the pregnancy; or
(g) to a practitioner, with the consent in writing of the woman whose pregnancy was terminated; or
(h) when requested by the President of the General Medical Council for the purpose of investigating whether the fitness to practise of the practitioner is impaired, to the President of the General Medical Council or a member of its staff authorised by him.
(i) to the woman whose pregnancy was terminated, on her supplying to the Chief Medical Officer written details of her date of birth, the date and place of the termination and a copy of the certificate of registration of her birth certified as a true copy of the original by a solicitor or a practitioner.

Appendix B

Key recommendations from the National Statistics Disclosure Review

Recommendation 1: Within a release of abortion statistics, unsafe cells are defined as being counts of abortions that are:

- zero unless no other value is logically possible
- less than 5 for Government Office Region in England, the country of Wales or any larger geography
- less than 10 for any geography below the Government Office Region in England or the country of Wales
- less than 10 for highly sensitive variables
- associated with either 1 or 2 practitioners
- associated with either 1 or 2 hospitals

The variables that are considered highly sensitive are:

- Young ages (<15)
- Late gestation (over 24 weeks)
- Procedure by gestation
- Medical conditions

Recommendation 2: Simple calculations such as rates or percentages do not necessarily make an unsafe cell safe and should not be used to protect data unless it can be demonstrated that one cannot work back to the original count. In order to keep statistical disclosure control rules clear and consistent for abortion statistics rates or percentages should only be calculated from safe cells.

Recommendation 3: In order to ensure that unsafe cells in the abortion statistics are disguised table design should be used as a preliminary protection method. Redesign should be implemented taking into account the information required by the main users of the data.

Recommendation 4: Statistics should only be constructed using area of residence rather than place of termination thus reducing the risk of disclosure from counts of events that are associated with 1 or 2 practitioners/hospitals.

Recommendation 5: If unsafe cells exist in tables after redesign these should be removed using suppression methods (primary and secondary).

Recommendation 6: In order to avoid resource intensive analysis of disclosure by differencing the abortions data should not in general be published on geographies that are non-coterminous with SHA/region/PCO/LHB or for non-standard variable categories.

Recommendation 7: In order to release more detail some data should be published aggregated over a number of years. To keep the methods for disclosure control clear, consistent and easy to implement the recommendation is made that rolling aggregates are not produced but years are aggregated independently.

Recommendation 8: The guidelines should be implemented for all published outputs of abortion data e.g. in cases where the data published can be used to make direct inferences about abortions. The guidelines should be implemented as soon as possible. The DH and ONS should work together in order to implement these guidelines for the annual bulletin release for 2003 and 2004.

Recommendation 9: Users should be made aware of what constitutes an unsafe cell within the abortion statistics. The user should also be told that the method used to protect the table is predominantly table redesign used to minimise the number of unsafe cells that require suppression. The impact on the quality of the data will be that in some cases less detail will be displayed and suppressions will mean that some information is removed from the table.

Appendix C

DEPARTMENT OF HEALTH CONFIDENTIALITY DECLARATION AND NON-DISCLOSURE AGREEMENT FORM

ABORTION STATISTICS

Date of request:	
Research/Project Title:	

(A) **Details of Data Custodian:**			
Name (please type or print):			
Status/position:			
Organisation:			
Address:		Address where data to be held (if different):	
Telephone:		Mobile:	
Fax:		Email:	

Declaration:

I, the Data Custodian named above, understand that the information is released to me with permission from the Chief Medical Officer under regulation 5(e) of the Abortion Regulations 1991 (bona fide scientific research) and will be used only for the purposes of the approved research or project identified above. I will ensure that the publication any results using these abortion data are agreed by the Department of Health. I have read, understood, and will follow the guidelines listed at the end of this document.

Signature:	Date:

(B) Please sign and date for **confirmation of REC and ECC/S251 approval.** (A copy of the confirmation documentation should be attached to this form)	
Signature	
Date	

(C) Details of Contact Person (if not Data Custodian)				
Name:		Address (if different)	Signature	Date
Tel:				
Fax:				
Email:				

(D) Names of additional assistants	Organisation (if different)	Signature	Date

(E) How long do you wish to retain the data? **If longer than 12 months**, please justify your reasons below (the maximum data retention period is **3 years and then a review** is required).	……Months/years

(F) The data supplied will be used only for the following purpose(s) **– Please include details of your research/work:**

Notes and Guidelines

1. Please keep a copy of all the documents for your own records.

2. A copy of the documentation confirming approval from the Research Ethics Committee (REC) and the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care (NIGB) (formerly the Patient Information Advisory Group, PIAG) using the arrangements created under S251 of the NHS Act 2006 should be attached when submitting this form.

3. Assistants of the Data Custodian who wish to access the abortion data supplied must sign and date box C/D to acknowledge acceptance of the terms and conditions prior to being allowed access to the data. The Department of Health may request a copy of the up-to-date list at any time. The Data Custodian should take disciplinary action against any assistant breaching the common law duty of confidence with regard to this data.

4. After the work outlined in box F has been completed, the data must be destroyed You will be sent a letter approximately one month before the end of the data retention period. This letter will give you the opportunity to either extend the data retention period or confirm that the data is destroyed.

5. The data must not be copied or transferred to any third party. If requested under the Freedom of Information Act the data are protected by the Exemptions in sections 40 and 44 of the FOI Act and must not be released.

6. Prior notice of intention to publish abortion data should be given to the Department of Health and where feasible, a copy of the published work should be provided.

7. All outputs resulting from access to these data must meet the guarantee contained in the principles of the National Statistics Code of Practice and the Protocol on Data Access and Confidentiality.

8. The Department of Health has the right to refuse permission to publish information arising from abortion data.

9. The data must be stored with proper safeguards to prevent unauthorised access.
Please note; This condition is subject to unannounced site inspections by Department of Health staff to ensure that measures are satisfactory.

10. The Department of Health must be informed as soon as possible if custodianship of the data should change. The new Data Custodian must give assurances in writing that the terms of this document will continue to be followed. The Data Custodian must also report to the Department of Health any changes in the organisation, personnel having access to the data, or systems on which the data would be held.

11. The Data Custodian must report immediately to the Department of Health any instances of breach of any of the terms of this agreement.

12. Low Cell Values. Values between 0 and 9 must be suppressed. Note that zeros must also be suppressed. If only one cell requires cell suppression, at least one other component cell (the next smallest) must be suppressed so as to avoid calculation of suppressed value from the totals. In addition, DH must agree any tables of data published so that small numbers cannot inadvertently be derived by using a combination of published data.

13. No contact will be made with any individual(s) identified in the information supplied except as agreed in the protocol and associated letters.

Enquiries regarding completion of this form can be made on

Tel. 020 7972 5537 or by email to Abortion.Statistics@dh.gsi.gov.uk

Please return this form signed and completed to:
Abortion Statistics,
Room 5A Skipton House,
80 London Road,
London SE1 6LH

DH INFORMATION READER BOX	
Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

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