



Department  
of Health

# Matching Department of Health abortion notifications and data from the National Down's Syndrome Cytogenetic Register, 2013

June 2015

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# Matching Department of Health abortion notifications and data from the National Down's Syndrome Cytogenetic Register 2013

Prepared by:

**Department of Health, Sexual Health Team and Analytical team, June 2015**

# Contents

|  |    |
|--|----|
| Contents.....  | 4  |
| Introduction.....  | 5  |
| Summary Results From the Matching Exercise.....                          | 6  |
| Methodology.....   | 7  |
| Analysis.....  | 8  |
| Royal College of Obstetricians and Gynaecologists Commissioned Work..... | 10 |
| RCOG Recommendations at Provider Level.....                              | 13 |
| RCOG Recommendations for the Department of Health.....                   | 15 |
| Appendix A.....  | 17 |

# Introduction

Under the Abortion Act 1967, an HSA4 form must be completed by the doctor undertaking the termination of pregnancy including those undertaken on the grounds that “ there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped (section 1(1)(d) i.e. Termination of Pregnancy for Fetal Anomaly (TOPFA). The completed HSA4 form must be sent to the Chief Medical Officer (CMO) within 14 days of the abortion taking place. In addition, all cytogenetic laboratories in England and Wales collaborate with the National Down’s Syndrome Cytogenetic Register (NDSCR) and provide a notification of all prenatal and postnatal diagnoses of Down’s, Edwards and Patau syndromes. Clinicians involved in the diagnosis of these syndromes are asked to complete and send a form to the NDSCR, and to forward a copy to the local screening coordinator.

There have been two previous matching exercises using data from 2011 and 2012 notifications submitted to the Department of Health (DH) for ground E abortions related to Down’s syndrome found them to be lower than those recorded by the National Down’s Syndrome Cytogenetic Register (NDSCR). In 2014/2015, Down’s syndrome was the only anomaly for which there is a national register and therefore the only anomaly for which data matching can be carried out. This project aims to replicate the study each year to assess data quality progress. In addition, the Department of Health will investigate whether a matching exercise across all fetal abnormalities is possible following the introduction of the national congenital anomaly and rare disease register.

The national congenital anomaly and rare disease registration service will rationalise and incorporate the existing seven regional congenital anomaly registers (CAROBB, SWCAR, WANDA, NorCAS, WMCAR, EMSYCAR and YHCAR<sup>[1]</sup>), the National Down’s Syndrome and Cytogenetic Register (NDSCR) and the British Isles Network of Congenital Anomaly Registers (BINOCAR) hub. In those parts of the country where there is currently no data collection, new regional teams will be established.

From the 1 April 2015 all these components will come together as one, single comprehensive national registration service for England, managed and led by PHE. All data will be collected onto a single national secure data management system and all data release will comply fully with the information governance requirements for the use patient identifiable data collected under Section 251. This will act as a much-needed resource to support individual patients, their families, clinicians, research, service delivery, commissioning and public health.

In 2013, DH commissioned the Royal College of Obstetricians and Gynaecologists (RCOG) to undertake a thorough review of TOPFA reporting through HSA4 forms. The RCOG undertook a fact-finding exercise visiting a representative sample of provider units with the aim to understand local practices in relation to statutory compliance and the reasons for the disparity in case ascertainment. RCOG investigators also sought to identify areas of best practice and ways to improve the process to ensure maximum notification. A summary of the RCOG results can be found at the end of this report, whilst the full report is available at:

<https://www.gov.uk/government/publications/under-reporting-of-abortions-for-fetal-abnormalities>

<sup>[1]</sup> CAROBB; Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire SWCAR; South West Congenital Anomaly Register WANDA; Wessex Antenatally Detected Anomalies Register, NorCAS: Northern Congenital Abnormality Survey, WMCAR: West Midlands Congenital Anomaly Register, EMSYCAR; East Midlands and South Yorkshire Congenital Anomalies and Yorkshire and the Humber Congenital Anomalies Register

# Summary Results From the Matching Exercise

NDSCR includes 943 records stated as involving a termination of pregnancy for residents of England and Wales in 2013 (Diagram 1). A match exists in the 2013 DH abortion notifications dataset for 507 of those. That leaves 436 not in the DH dataset, of which 13 are for abortions of 24 weeks and over.

Of the 226 records in the NDSCR dataset with a pregnancy outcome of 'not known', 76 are in the DH dataset (Diagram 1). There were also outcomes recorded as two live births, one stillbirth and nine miscarriages in the NDSCR dataset with a matching record in the DH abortions dataset.

The total number of matched records was therefore 583 (Diagram 1). That includes 99 abortions that did not contribute to the DH published figure of 613 for all abortions carried out under Ground E where there was a mention of Down's. These were 6 late notifications, 84 recorded as ground C and 15 recorded as ground E but with no mention of Down's syndrome.

The HSA4 Abortion Notification form collects method of diagnosis for cases where 'there is a 'substantial risk' of a fetal anomaly. Not all abortions recorded as Down's syndrome have confirmed diagnoses, for example, diagnosis by ultrasound scan are not confirmed cases, whereas those diagnosed by chorionic villus sampling or amniocentesis are confirmed cases. It follows therefore that some unconfirmed abortions counted as Down's in the DH dataset may not, and should not, appear in the NDSCR dataset. A total of 116 records referring to Down's Syndrome in the DH abortion notifications dataset did not have a matching record in the NDSCR (Diagram 1). 68 of these were Down's confirmed by either CVS or Amniocentesis and 48 were unconfirmed.

Around half (46.2%) the DH Abortion Notifications for Down's Syndrome are missing. However, between 2011 and 2013, there has been a 17.8% improvement in the submission of HSA4 Abortion Notifications for Down's syndrome. More detail about these calculations can be found in the analysis section.

# Methodology

## Data Used – Department of Health (DH) abortions data,

The DH abortions data is collected through HSA4 forms. DH data used in the matching exercise consisted of 185,959 complete abortion records for residents of England and Wales from:

- the 2013 frozen dataset for England and Wales (185,331 records)
- late received 2013 records not included in the frozen dataset (628 records)

## Data Used - National Down's Syndrome Cytogenetic Register (NDSCR)

The National Down's Syndrome Cytogenetic Register (NDSCR) data consisted of 2,039 records and included all prenatal Down's syndrome diagnoses for January – December 2013 together with a recorded pregnancy outcome of either: termination of pregnancy (TOP), miscarriage, live birth, stillbirth or pregnancy outcome 'not known'. About 10% of the 2,039 records had missing information, but the majority could still be used in the matching.

## Matching Methods

The DH and NDSCR datasets outlined above were compared to find data relating to the same abortion in both datasets: a 'match' is therefore two records, one from the DH dataset and one from the NDSCR dataset. The two records were said to match if there was:

- An exact postcode and exact date of birth match plus gestation +/- 2 weeks.
- A part postcode and exact date of birth match plus gestation +/- 2 weeks and date of termination match +/- 1 week. A 'part postcode' match is one that differs only in the last two letters or in the case of a 'part-complete postcode' (e.g. SE11) in the NDSCR dataset, the last 3 characters.
- An exact postcode and 'part date of birth' match plus gestation +/- 2 weeks and date of termination match +/- 1 week. A 'part date of birth' is defined as differing only in one digit of a date. e.g. 10/07/1969 and 10/01/1969 or 10/07/1968 would be counted as a match but 10/07/1969 and 10/01/1968 would not be counted as a match
- Fuzzy matching, i.e. matching a partly different postcode to a complete date of birth or a partly different date of birth to complete postcode, was used to maximise matching where there may have been slight errors in recording the information at both DH and NDSCR. For example - for a postcode such as SE123AB, matches were sought where any one of the characters was different and where both the last letters were different, eg SE12\$AB or \$E123AB or S\$123AB for one different character and SE123\$\$ for differing two letters at the end. For a date of birth such as 12/03/1995, matches were sought where any one of the numbers was different, e.g. 12/0/1995 or 12/03/199\$ or 1\$/03/1995.

## Analysis

Of the 943 TOPs in the NDSCR dataset, DH had an HSA4 form for 507, leaving 436 for which a match was not found in the DH dataset (Diagram 1). 13 of these unmatched records are for abortions of 24 weeks and over. See Appendix A for a breakdown by region and gestation for these additional 436 NDSCR records.

A possible explanation for some of the unmatched cases might be that some doctors completing an official Down's syndrome Register form to record the TOP think they do not need to complete an HSA4. It is also possible that some women may not be giving their correct postcode at abortion clinics, which would limit the potential of the data matching exercise even if a HSA4 form was submitted.

Of the 226 records in the NDSCR dataset with a pregnancy outcome of 'not known', 76 are in the DH dataset (Diagram 1). It is likely that most or all of the remaining 150 led to a live birth, still birth or miscarriage.

The total number of matched records was therefore 583 (Diagram 1). That includes 99 abortions that did not contribute to the DH published figure of 613 for all abortions carried out under Ground E where there was a mention of Down's. These were 6 late notifications, 84 recorded as ground C and 15 recorded as ground E but with no mention of Down's syndrome.

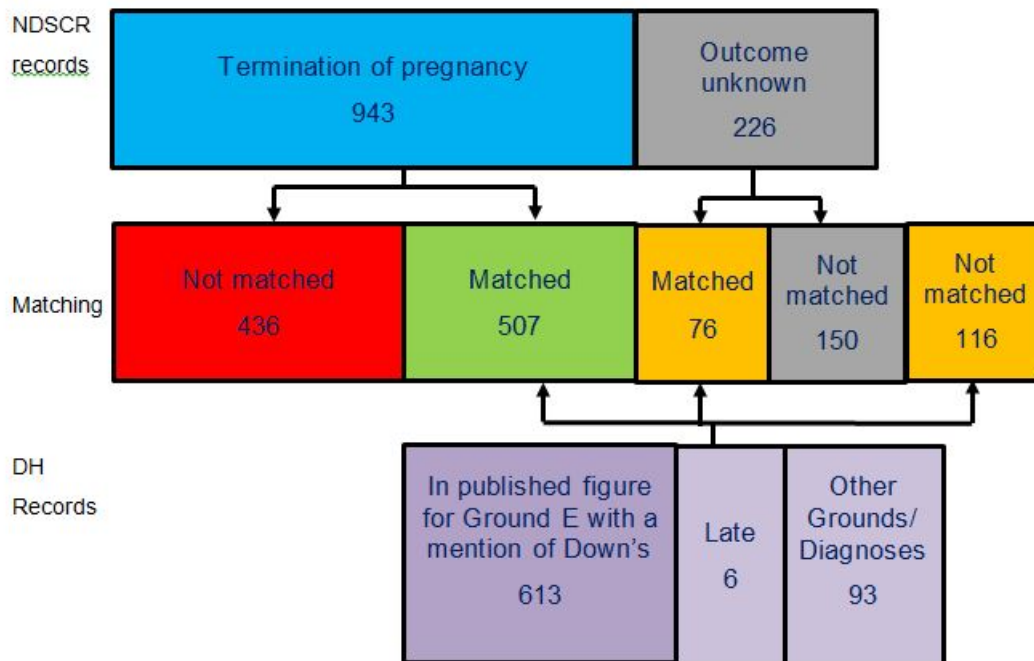
A total of 116 records in the DH abortion notifications dataset did not have a matching record in the NDSCR (Diagram 1). 68 of these were Down's confirmed by either CVS or Amniocentesis and 48 were unconfirmed.

Around half (46.2%) the DH Abortion Notifications for Down's Syndrome are missing. This compares to 50.1% in 2012 and 56.2% in 2011. This shows that between 2011 and 2013, there was a 17.8% improvement in the submission of HSA4 Abortion Notifications for Down's syndrome. There are various ways of calculating the proportion of missing records as there are missing and mis-recorded records in both datasets. The table below shows the simplest calculation, that is, the proportion of NDSCR TOP records not present in the DH dataset.

| Percentage of NDSCR records<br>not in the DH dataset, 2011-2013 |      |
|---|------|
|   | %    |
| 2013  | 46.2 |
| 2012  | 50.1 |
| 2011  | 56.2 |



Diagram 1 Matched and unmatched records in the DH and NDSCR data sets



A breakdown of 84 of the 93 additional Down's syndrome-related abortions (those recorded as grounds other than E) which were found following matching, together with the 436 records found to be missing from the DH dataset, can be found in the appendix. The breakdown by region was an attempt to use the data available to assess whether doctors from particular clinics or hospitals were not submitting forms or submitting forms and choosing grounds other than ground E. The results were inconclusive however, as the missing data was spread across all regions (see appendix A). It would have been preferable to have a breakdown by clinic rather than region of residence but clinic information was not available in the NDSCR dataset. The breakdown by gestation is useful and shows expected results representative of the data as a whole.

# Royal College of Obstetricians and Gynaecologists Commissioned Work

In addition to the above work, DH commissioned the Royal College of Obstetricians and Gynaecologists (RCOG) to undertake a thorough review of TOPFA reporting through HSA4 forms. The RCOG undertook a fact-finding exercise visiting a representative sample of provider units with the aim to understand local practices in relation to statutory compliance and the reasons for the disparity in case ascertainment. RCOG investigators also sought to identify areas of best practice and ways to improve the process to ensure maximum notification. RCOG is grateful for the full co-operation of all the sample units, allowing investigators to undertake a thorough examination into the causes of this disparity. RCOG has made no attempt to evaluate the relative contribution of different causes.

## Terms of reference

1. To assess the likely reasons for the apparent discrepancy between the reporting of fetal abnormality abortions to congenital abnormality registers (CARs) and to the Chief Medical Officer (CMO), as required under the Abortion Act.
2. To suggest ways to improve the reporting of fetal abnormality abortions.

## Study

Many organisations had reviewed their processes after the CMO letter of February 2012 and could demonstrate that HSA1 forms were completed appropriately, but only some units had extended the process to manage a failsafe for the HSA4 forms.

Since HSA1 forms are retained in the hospital notes, it is easy to audit compliance. However, the process for the HSA4 form is more complicated, as the form is sent to the DH without any way of confirming receipt. Most of the healthcare organisations visited were grateful that the issues related to statutory notification had been drawn to their attention by the RCOG. As a result, several hospitals commenced in-depth audits of their HSA4 processes, and developed action plans to change and improve their documentation and notification procedures.

Different processes were observed in each unit visited. It must be emphasised that the local variations encountered had developed in response to local organisation, staffing, skills and capacity.

It became apparent during the visits that there is no consistent or accepted way to organise notification of TOPFA under Ground E. Units developed their own reporting systems. Whilst the statutory responsibility for returning Form HSA4 rests with the doctor who terminates the pregnancy, it is not always clear who this (if it is the Fetal Medical Centre or the referring District General Hospital (DGH)).

In none of the units visited was there any evidence or impression that there was wilful failure to comply with the law, but rather a lack of understanding of the statutory requirements, which in turn produced a lack of organisation and accountability.

The majority of units would welcome some guidance and help in developing a secure, workable and failsafe system to ensure accurate reporting.

### **Summary of the findings of the reasons for the under-reporting through HSA4 forms**

There are a number of possible reasons why the number of cases reported appear to be so different. The review has not attempted to apportion the relative significance of the different possible explanations.

1. The discrepancy between NDSCR and DH figures on TOP for chromosomal abnormalities is explained by the high case ascertainment rate achieved by the NDSCR through a rigorous and robust reporting system. No similar process has been developed for the HSA4 forms for TOPFA.
2. In cases where the termination takes place before 24 weeks the doctor may lawfully be faced with a choice, if it is believed that termination on Grounds C and E are both justified – however this has been considered in the data matching exercise.
3. Some of the patients who are referred to in paragraph 2 above may refer themselves to a private abortion clinic and seek termination under Ground C –again this was considered during the cross matching exercise.
4. Some cases may not be reported on Form HSA4 because the statutory obligation is imposed on the doctor who terminates a pregnancy and it is not always clear who this may be or even which hospital is responsible. In these cases the abortifacient medication may be administered at the Fetal Medicine Centre and the patient will then return to the DGH to complete the abortion.
5. Some doctors do not appreciate the statutory obligation to complete Form HSA4.
6. Where doctors were aware of the HSA4 form, and where they may have fully completed or signed the form, there was sometimes no system or process to ensure that the form was submitted.

7. Since the Abortion Act became law, clinical practice has changed and developed. Abortion was initially a gynaecological procedure whereas now, especially with advances in prenatal screening and diagnosis, TOPFA is much more an integral part of maternity and obstetric care. This involves different staff and while there was a 'system' for managing the HSA4 forms in gynaecology departments, this needs to be translated to the maternity environment. Matters relating to the Abortion Act<sup>1</sup> are not included in the formal midwifery training programmes.
  
8. It was clear that in none of the healthcare organisations visited was there any evidence to suggest that either doctors or midwives were trying to hide or manipulate the figures relating to TOPFA. It is also important to record that there is no doubt that the care of the individual women and families was the overwhelming priority for the clinicians and healthcare workers that were interviewed.

# RCOG Recommendations at Provider Level

## In the short term

### ***Leadership***

Every maternity unit should appoint a single person to be responsible for overseeing and ensuring the record-keeping within the service relating to TOPFA, and specifically submission of the HSA4 forms once completed by the practitioner terminating the pregnancy. The statutory responsibility lies with the doctor who performs the termination of pregnancy and it must be clearly identified who this may be. We recommend that in cases where a medication is administered to induce a miscarriage; it should be the doctor who administers that medication, even if the woman may complete the abortion at another centre. This is an oral medication prescribed by a doctor but administered by a midwife.

### ***Networks and care coordination***

Where women are referred to tertiary care, there should be agreed and consistent processes between the central and peripheral units with clear understanding of:

- which doctor is responsible for signing the HSA4 form,
- how the information for completion of the form will be collected, and
- who will be responsible for sending the form to CMO.

These arrangements must be agreed with the doctor/s completing the HSA4 form in units.

### ***Documentation***

All healthcare organisations undertaking TOPFA should be encouraged to develop a single pack containing all the papers needed for the management of the whole care pathway, and the documentation of the TOP procedure from the decision to terminate the pregnancy to the post-procedure follow-up. These packs should include the copy of the HSA1 and the HSA4 forms, and an itemised checklist to include a line to confirm that the HSA4 form has been submitted to the CMO, and the name of the person responsible for doing so.

### ***Data collection***

Every maternity unit should develop a method of collecting and recording outcome data on every pregnancy where a fetal anomaly is suspected and confirmed. It would be logical for this to be done by the person responsible for the service and the HSA4 forms. Ideally, the data would be kept on an electronic database such as ViewPoint or astraia, but few DGHs have these systems. There are good examples of simple Excel spreadsheets and paper supports functioning as excellent records. Accurate records will require the healthcare professionals to have time to complete them, and professional cooperation to ease data collection.

**Annual audit**

Regular audit against specific standards should be carried out in every unit to ensure that the documentation is complete and that the HSA4 notification process is robust. It is possible that the Care Quality Commission (CQC) could include reference to HSA4 compliance in their inspections.

**Induction and ongoing mandatory training**

The Head of Midwifery and Clinical Director should be responsible for ensuring that the legal requirements relating to TOP as well as the necessary local processes and system for documentation are included in midwifery and medical staff induction and ongoing mandatory training, so that all healthcare professionals are aware of local arrangements. It is important that staff have an opportunity to state if they have a conscientious objection to being involved in abortion work. The education programs should include reference to the DH guidelines for completion of the HSA1 and HSA4 forms. Medical trainees should be made aware of the existing RCOG continuing professional development resources (StratOG).

**In the long term****Skills and Competencies**

Regular training and ongoing support for all aspects of antenatal screening (trisomy 21 and fetal anomaly ultrasound screening) for screening coordinators is needed.

**Data collection**

Hospitals should consider including a 'default' field or drop-down box on local hospital IT systems, or perhaps on the delivery or discharge summaries, to record and confirm completion of HSA1 and HSA4 forms. This should be possible on commonly used systems such as Meditech, Euroking etc. There could also be an additional field included on the ViewPoint and astraia databases as drop- down boxes.

**Communication and data sharing**

Increasing sophistication of electronic communication by secure email should enable confidence in data sharing between units to check on HSA4 completion/submission, where there are confirmed referral pathways and shared care between secondary and tertiary care.

Solutions need to be found to enable Fetal Medicine Units to retrieve pregnancy outcome data from the woman's booking (referring) hospital in order to assess the quality and effectiveness of the TOP documentation process.

# RCOG Recommendations for the Department of Health

## In the short term

### ***Guidance on completion of forms***

The guidance is not easy to find for those who are unfamiliar with the Government website. The DH should look at ways to increase knowledge of the legal requirements and procedures surrounding abortion. The knowledge needs to get to the healthcare professionals managing the women and involved in the whole care pathway. This should be through communication with healthcare organisations who have the responsibility for submitting the data, but also through professional bodies such as: RCOG; Royal College of Midwives (RCM); the Heads of Midwifery; Local Supervisory Authority (LSA) Midwifery Officers; Lead Midwives for Education (LME); Royal College of Nursing (RCN); Royal College of Paediatrics and Child Health (RCPCH); Royal College of General Practitioners (RCGP); Royal College of Radiologists (RCR); British Maternal and Fetal Medicine Society (BMFMS).

### ***Clarity of legal requirements***

The DH should review the guidance to ensure absolute clarity about:

- which doctor signs the HSA4 form
- when it should be signed
- when it should be submitted.

### ***Audit***

The DH should develop (or ask the RCOG to develop) a template to be made available to healthcare organisations to aid audit of compliance with TOP notification. This template could be a requirement for CQC inspections.

### ***Patient information***

DH should develop, with the help of professional and user groups, appropriate wording for information leaflets for use or adapting locally, to ensure that women are informed of the fact that details of their abortion will be sent to the CMO. The information leaflets should be designed to cause minimal anxiety.

There should be clarity on data protection and data sharing on outcomes.

DH should provide reassurance on the requirements of the Data Protection Act to enable outcome data to be shared where the woman has been treated on more than one site.

## **In the medium term**

### ***Buy-in and awareness***

The clinicians responsible for the data submission are largely unaware of how the data are used and why it is important. A feedback mechanism would help to make the health care professional feel involved and valued, and to have ownership of their contribution. Consistently the clinicians involved requested that there should be some way for the DH to acknowledge receipt of the forms, even if this was a report of the number of HSA4 forms submitted each month.

### ***System change***

The development of combined HSA1 and HSA4 forms should be explored (perhaps having the HSA1 in duplicate on the front of the HSA4) so that when the HSA1 is signed, one copy can be forwarded directly to the CMO. In this way, the intention to terminate a pregnancy would be registered with the DH, who could then have a method to follow-up and chase the HSA4 forms.

Clinicians also thought it should be possible to use a secure email system (similar to nhs.net) to submit complete details on the HSA1 forms and then confirmatory submission with additional details and signature required for the HSA4 form. This would mean that the patient is registered when the HSA1 form is signed, and then automatically linked to the HSA4 form electronically.

## **In the long term**

### ***National Congenital Anomaly Register***

Inconsistency and poor reporting could be resolved if there was a national Congenital Anomaly Register.

It is imperative that when the National Register is developed, there is coordination to ensure that a single data input provides all the required national data. If organised efficiently, the information regarding TOPFA could be extracted centrally from the register rather than requiring separate registration from the provider. Implementation of this recommendation would require a change to legislation.

### ***Electronic data collection***

Coordination is required in order to ensure that electronic systems are developed so that data can be sent to CARs from Viewpoint/astraia systems. Sharing of experience and knowledge in this area will be efficient, and save time and resources.



# Appendix A

**Table a) All abortions notified to DH, 2013**

The table shows the spread of missing HSA4 forms across regions. Totals and spread of received forms by regions are also given as a comparison. For example, looking at the percentages of missing forms against received forms, it looks like the South West (14% and 7% respectively) are missing the most forms. Though not ideal, this is the best analysis from the data available.

Number and proportion of NDSCR TOPS with unmatched DH record by region compared to all abortions, 2013

| Region                   | Total missing forms | %          | Total all abortions | %          |
|--------------------------|---------------------|------------|---------------------|------------|
| East                     | 54                  | 13         | 16,254              | 9          |
| East Midlands            | 30                  | 7          | 11,824              | 6          |
| London                   | 114                 | 27         | 45,652              | 25         |
| North East               | 29                  | 7          | 6,832               | 4          |
| North West               | 20                  | 5          | 24,324              | 13         |
| South East               | 32                  | 8          | 24,711              | 13         |
| South West               | 60                  | 14         | 12,962              | 7          |
| West Midlands            | 27                  | 6          | 19,253              | 10         |
| Yorkshire and the Humber | 30                  | 7          | 16,240              | 9          |
| Wales                    | 28                  | 7          | 7,863               | 4          |
| not known                | 12                  |            |                     |            |
| <b>Grand Total</b>       | <b>436</b>          | <b>100</b> | <b>185,331</b>      | <b>100</b> |

**Table b) All abortions of 12+ weeks gestation notified to DH, 2013**

The table shows the spread of missing HSA4 forms by gestation. Totals and spread of received forms by gestation are also given as a comparison. For example, looking at the percentages of missing forms against received forms, it looks like gestations of 20-23 are the least likely to go unreported. Though not ideal, this is the best analysis from the data available

Number and proportion of NDSCR TOPS with unmatched DH record by gestation, compared with all abortions, 2012

| Gestation          | Unmatched forms | %          | Total all abortions | %          |
|--------------------|-----------------|------------|---------------------|------------|
| 12 weeks           | 9               | 4          | 4,864               | 24         |
| 13 to 19           | 305             | 84         | 12,963              | 63         |
| 20 to 23           | 35              | 10         | 2,563               | 12         |
| 24 and over        | 13              | 4          | 190                 | 1          |
| not known          | 74              | .          | 0                   | .          |
| <b>Grand Total</b> | <b>436</b>      | <b>100</b> | <b>20,580</b>       | <b>100</b> |

**Table c) Abortions notified to DH, 2013**

The table shows the regions most likely to report down's syndrome pregnancies under grounds other than ground E with London being the highest region.

DH abortions recorded as grounds other than ground E yet matched to NDSCR records, by region, 2013

| Region                   | Abortions performed under grounds other than E |            |
|--------------------------|--|------------|
|                          | Total  | %          |
| East                     | 15   | 18         |
| East Midlands            | 1  | 1          |
| London                   | 26   | 31         |
| North East               | 2  | 2          |
| North West               | 0  | 0          |
| South East               | 11   | 13         |
| South West               | 23   | 27         |
| West Midlands            | 0  | 0          |
| Yorkshire and the Humber | 5  | 6          |
| Wales                    | 1  | 1          |
| <b>Grand Total</b>       | <b>84</b>                                      | <b>100</b> |