DATA NOTE

The ALSPAC fetal and neonatal resource: detailed data abstracted from the clinical records of the new-born [version 2; peer review: 2 approved, 1 approved with reservations]

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Abstract

In a previous Data Note, we outlined the data obtained from clinical obstetric records concerning many details of the pregnancies resulting in the births of the children in the Avon Longitudinal Study of Parents and Children (ALSPAC). Here we describe the data that have been abstracted from medical records concerning the fetus and neonate. Full details concerning the selection biases regarding the data abstracted are outlined in the previous Data Note.

The records that have been abstracted, and described in this Data Note, concern the health of the fetus (measured in relation to the results of fetal monitoring, presentation at various stages of pregnancy, and the method of delivery) as well as the status of the newborn immediately post-delivery. Details of signs, symptoms and treatments of this population of new-born babies, as recorded in the clinical records, are described for the time during which they were in hospital or under the care of a designated midwife.

These data add depth to the information collected from elsewhere concerning this period of the child's life: from the questionnaires completed at the time by the mother; and clinical details from neonatal intensive or special care units which will be detailed in a further Data Note.

Keywords

ALSPAC, Labour, Delivery, Fetus, Neonate

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Any reports and responses or comments on the article can be found at the end of the article.
Amendments from Version 1

REVISED

In response to the reviewers' helpful comments, the following changes have been made to the paper:

Further clarification of the ethical permissions relating to the ALSPAC data.

Change of the abbreviation NEC to NCE.

Clarification that the variables refer to the individual fetuses/neonates – not pregnancies.

Clarification of ways in which different types of CS may be distinguished.

Amendment of data relating to fetal heart rate abnormalities (Table 1d), retained placenta and manual removal of the placenta (Table 2c).

Clarification of the methods of delivery, especially relating to the use of forceps.

Any further responses from the reviewers can be found at the end of the article.

Abbreviations

ALSPAC  Avon Longitudinal Study of Parents and Children
CDS  Central delivery suite
CS  Caesarean section
CTG  Cardiotocography
DV  Derived variable
FSE  Fetal scalp electrode
IM  Intramuscular
IPPV  Intermittent positive pressure ventilation
IUGR  Intrauterine growth restriction
IV  Intravenous
LREC  Local Research Ethics Committee
NCE  Not classified elsewhere
N.O.S.  Not otherwise stated
NS  Not stated
OA  Occiput anterior
OP  Occiput posterior
SCBU  Special Care Baby Unit

Introduction

The UK’s large influential National Perinatal Mortality Survey of 1958 identified fetal asphyxia as responsible for almost half of the 35 perinatal deaths per 1000 births occurring at that time (Butler & Alberman, 1969; Butler & Bonham, 1963). By the 1990s this rate had fallen dramatically to <1 per 1000 births (Mori et al., 2008). This improvement was assumed to be largely as the result of advances in the monitoring of the fetus during late pregnancy as well as more efficient methods of resuscitation. However, the consequences of these interventions (for example, inducing or augmenting labour; delivery by caesarean section [CS]; vaginal delivery using forceps or vacuum techniques; and vigorous methods of resuscitation) may have had long-term effects on the developing child. Similar questions concerning long-term effects can be asked of other problems experienced by the newborn, including the degree of jaundice, the duration of phototherapy or the exposure to antibiotics or other medications.

One of the original aims of the Avon Longitudinal Study of Parents and Children (ALSPAC) was to determine possible effects of early exposures on later health and development in childhood, adolescence and throughout adulthood (Golding et al., 2001). The prevalence of many outcomes has changed over time, the extent of which has not been fully explained. These include increases in chronic childhood disorders such as diabetes (e.g., Patterson et al., 2012), autism spectrum disorder (e.g., Rosenberg et al., 2009) and obesity (Wang & Lim, 2012) as well as in maternal prenatal depression (e.g., Pearson et al., 2018).

Very few longitudinal studies prior to ALSPAC had collected detailed in-depth information to allow epidemiological analyses to test whether details of fetal or neonatal exposures may be associated with these and other outcomes. Therefore, we have described here the information covering the health of the fetus that has been abstracted from obstetric records and the treatment and health of the neonate that has been abstracted from paediatric records. The data described in this Data Note differ from that in a published Data Note which describes the mother during pregnancy and the puerperium (Birmingham et al., 2021a; subsequently referred to as the Obstetric Data Note). In the current Data Note we describe the individual data relating to the fetuses/births rather than pregnancies, thus allowing for different answers for different members of a multiple pregnancy. The data described here is therefore primarily child based). Examples concern the presentation of the fetus, fetal monitoring, and method of delivery.

Methods

As already indicated, ALSPAC was originally designed to determine the ways in which aspects of the environment (possibly interacting with the individual’s genes) influenced child health and development (Fraser et al., 2013). The Study enrolled pregnant women who had an expected date of delivery between 1st April 1991 and 31st December 1992. The women had to be resident in that part of the old administrative county of Avon in south-west England comprising three District Health Authorities (Southmead, Frenchay, and Bristol and Weston) (Boyd et al., 2013). Data have been collected using a variety of methods including questionnaires completed during pregnancy by the pregnant woman and her partner, abstraction of details from medical records, accurate measuring of the offspring and collection and analysis of biological samples including cord blood.

All women resident in the area at the time they were pregnant were eligible, provided that their expected date of delivery lay between 1st April 1991 and 31st December 1992. 14,541 pregnant women resident in the area were recruited into ALSPAC. From these pregnancies, there were a total of 14,676 fetuses and 14,062 live births. Of these children, 13,988 were still alive at one year of age. Mothers were considered enrolled if they had returned at least one questionnaire or attended a “Children in Focus” clinic by 19th July 1999.
Most of the deliveries took place in either Southmead Hospital (53%), Bristol Maternity Hospital (now known as St Michael’s Hospital) (38%) or Weston General Hospital (4%). A few deliveries took place at the mother’s home (2%) in a hospital out of the area due to the mother unexpectedly going into labour while, for example, on holiday or very occasionally when in transit to the hospital (2%).

In regard to the obstetric and neonatal records, a shortage of funding resulted in only slightly under two-thirds of the original Study sample having had data abstracted from medical records to date. The data abstraction form, abstraction instructions and checking instructions include data relating to the fetus, the newborn immediately after delivery and signs, symptoms and treatments during the first weeks of life (see Extended data). The choice of which records were abstracted are described in more detail in the accompanying Obstetric Data Note (Birmingham et al., 2021a). That paper includes details of the likely biases incurred in analysing the data, and the possible methods of analysis. The sample includes almost all the caesarean sections, the instrumental vaginal deliveries, the pre-term deliveries, the multiple births and the fetal and neonatal deaths. There has always been the intention to complete this data extraction to include the whole of the ALSPAC enrolled population but that awaits further funding. It should be noted that extra data are available on the infants admitted to intensive or special care within the neonatal period; the detailed records are available for analysis and will be documented in a further Data Note.

Ethics approval
An initial favourable opinion was given for ALSPAC by the three Local Research Ethics Committees (LRECs): Bristol and Weston Health Authority, (Ref E1808 28/11/1989); Southmead Health Authority, (Ref 49/89 5/04/1990); Frenchay Health Authority, (Ref 90/8 28/06/1990)]. In 1992, a general update was sent informing the LRECs of the intention to look at medical records (Birmingham, 2018). Ethical approval was less formal at that time, with the LRECs only recently established.

The data collected are governed by strict ethical criteria (see Birmingham, 2018) to ensure that no personal identifying information is revealed. Nevertheless, within these ethical strictures the Study encourages access to the data by bona fide scientists. Please note that the Study website contains details of all the data that is available through a fully searchable data dictionary and variable search tool, and a detailed proposal form for access to specified data.

The variable numbering system
The variable numbers for most of this data set start with either the letters ‘DEL_P’ or ‘DEL_B’ followed by a number. The distinction relates to whether the variable refers to the fetus up until the birth (DEL_P), or the baby after delivery (DEL_B). For simplicity these will be known as the P (pregnancy) and B (baby) numbers throughout this paper. In addition, the question number is quoted – i.e. the actual question asked on the data abstraction form (Extended data (Birmingham et al., 2021b)).

Data available
Due to funding restrictions, to date only 8369 pregnancies have had detailed data abstraction using the proforma shown in the data abstraction form (Extended data (Birmingham et al., 2021b)). Details of the case selection and the possible biases generated are detailed in the Obstetric Data Note (Birmingham et al., 2021a).

The fetus in distress prior to delivery
Monitoring the fetal heart rate. In all, there were five different types of monitoring used on the pregnant women during labour (Table 1a), the most common being the use of a cardiotocography (CTG) monitor, continuously or intermittently. Continuous CTG monitoring does not allow the mother to move freely or change position hence the common use of intermittent CTG monitoring. A small number of records (n=38) described a different type or method of monitoring. However, for about a third of the pregnancies (n=2539) the method of monitoring was not recorded. It is likely that most of these mothers would have had intermittent CTG as the hospital protocols clearly state that normal or ‘low risk’ pregnancies should have intermittent external CTG monitoring performed on admission to the Delivery Suite and for approximately 20 minutes every 2–3 hours thereafter.

Abnormalities of the fetal heart rate. Of the fetal heart rates monitored, a total of 11 different fetal heart rate patterns or abnormalities were recorded in each of the first and second stages of labour (Table 1b, Table 1c, Table 1d). There were a small number of additional fetuses for which heart rate abnormalities were recorded but it was not clear from the records as to whether they had occurred in the first or second stage of labour (data not shown); variables have been derived to indicate whether the abnormal heart rate had occurred during labour, by combining the first and second stage occurrences with those where the timing was unknown (Table 1d).

Other signs of fetal compromise. Apart from the heart rate abnormalities, other signs of fetal distress were recorded

| Table 1a. Method of monitoring the fetus. |
|-----------------------------------------|
| Method                  | P no. | Q no. | No. with information | No. (%) using the method |
|-------------------------|-------|-------|----------------------|-------------------------|
| CTG monitoring          | 1320  | C14ia | 7588                 | 4022 (53%)              |
| Continuous CTG monitoring| 1321  | C14ib | 7558                 | 4703 (62%)              |
| FSE monitoring          | 1322  | C14ic | 7557                 | 1511 (20%)              |
| Auscultation            | 1323  | C14id | 7558                 | 1368 (18%)              |
| Sonicaid                | 1324  | C14ie | 7558                 | 320 (4%)                |
| Other type*             | 1325  | C14ig | 7558                 | 38 (0.5%)               |
| Unknown type            | 1326  | C14if | 7558                 | 2539 (34%)              |

*Described as text, data not currently available. CTG = cardiotocography; FSE = fetal scalp electrode.
including whether intrauterine growth restriction (IUGR) was suspected, whether meconium was seen in the liquor (and whether this was old or new), and whether an abnormal fetal blood pH had been recorded. For those with a low pH, the level is available together with the time from that level to delivery of the baby (Table 1e).

The fetus during delivery

**Position of the fetus.** The presentation of the fetus had been recorded during pregnancy, at the start of labour and at delivery (Table 2a). During pregnancy, the presentation was recorded on several occasions often as the result of an ultrasound examination. Consequently, there are separate variables

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**Table 1b. Fetal heart rate abnormalities in first stage of labour.**

| Abnormality                  | P no. | Q no     | No. with information | No. (%) with abnormality |
|------------------------------|-------|----------|-----------------------|--------------------------|
| Any abnormality              | 1330  | C15a1    | 7187                  | 4601 (64%)               |
| Baseline tachycardia         | 1331  | C15a2b1  | 8366                  | 351 (4%)                 |
| Tachycardia n.o.s.           | 1335  | C15a2a1  | 8368                  | 371 (4%)                 |
| Baseline bradycardia         | 1339  | C15a2d1  | 8366                  | 296 (4%)                 |
| Bradycardia n.o.s.           | 1343  | C15a2c1  | 8367                  | 830 (10%)                |
| Type 1 dips/early decelerations | 1347  | C15a2e1  | 8360                  | 2130 (25%)               |
| Type 2 dips/late decelerations | 1351  | C15a2f1  | 8366                  | 847 (10%)                |
| Loss of beat-to-beat variability | 1355  | C15a2g1  | 8369                  | 73 (1%)                  |
| Reduced or poor variability  | 1359  | C15a2h1  | 8365                  | 623 (7%)                 |
| Variable decelerations       | 1363  | C15a2j1  | 8367                  | 777 (9%)                 |
| Decelerations with slow recovery | 1367  | C15a2k1  | 8367                  | 311 (4%)                 |
| Flat trace/sinusoidal pattern | 1371  | C15a2l1  | 8369                  | 119 (1%)                 |
| Other abnormality*           | 1375  | C15a2l1  | 8361                  | 1901 (23%)               |

*Described as text, data not currently available. N.o.s. = not otherwise stated.

**Table 1c. Fetal heart rate abnormalities in second stage of labour.**

| Abnormality                  | P no. | Q no     | No. with information | No. (%) with abnormality |
|------------------------------|-------|----------|-----------------------|--------------------------|
| Baseline tachycardia         | 1332  | C15a2b2  | 8366                  | 239 (3%)                 |
| Tachycardia n.o.s.           | 1336  | C15a2a2  | 8368                  | 270 (3%)                 |
| Baseline bradycardia         | 1340  | C15a2d2  | 8366                  | 176 (2%)                 |
| Bradycardia n.o.s.           | 1344  | C15a2c2  | 8367                  | 841 (10%)                |
| Type 1 dips/early decelerations | 1348  | C15a2e2  | 8360                  | 1061 (13%)               |
| Type 2 dips/late decelerations | 1352  | C15a2f2  | 8366                  | 810 (10%)                |
| Loss of beat-to-beat variability | 1356  | C15a2g2  | 8369                  | 12 (0.1%)                |
| Reduced or poor variability  | 1360  | C15a2h2  | 8365                  | 93 (1%)                  |
| Variable decelerations       | 1364  | C15a2j2  | 8367                  | 570 (7%)                 |
| Decelerations with slow recovery | 1368  | C15a2k2  | 8367                  | 288 (3%)                 |
| Flat trace/sinusoidal pattern | 1372  | C15a2l2  | 8369                  | 7 (0.1%)                 |
| Other abnormality*           | 1376  | C15a2l2  | 8361                  | 1089 (13%)               |

*Described as text, data not currently available. N.o.s. = not otherwise stated.
Table 1d. Fetal heart rate abnormalities during labour.

| Abnormality                          | P no. | Q no. | No. with information | No. (%) with abnormality |
|--------------------------------------|-------|-------|----------------------|--------------------------|
| Baseline tachycardia                 | 1334  | DV    | 8369                 | 591 (7%)                 |
| Tachycardia n.o.s.                   | 1338  | DV    | 8369                 | 643 (8%)                 |
| Baseline bradycardia                 | 1342  | DV    | 8369                 | 474 (6%)                 |
| Bradycardia n.o.s.                   | 1346  | DV    | 8369                 | 1679 (20%)               |
| Type 1 dips/early decelerations      | 1350  | DV    | 8369                 | 3193 (38%)               |
| Type 2 dips/late decelerations       | 1354  | DV    | 8369                 | 1658 (20%)               |
| Loss of beat-to-beat variability     | 1358  | DV    | 8369                 | 93 (1%)                  |
| Reduced or poor variability          | 1362  | DV    | 8369                 | 716 (9%)                 |
| Variable decelerations               | 1366  | DV    | 8369                 | 1351 (16%)               |
| Decelerations with slow recovery     | 1370  | DV    | 8369                 | 599 (7%)                 |
| Flat trace/sinusoidal pattern        | 1374  | DV    | 8369                 | 126 (2%)                 |
| Other abnormality*                   | 1378  | DV    | 8369                 | 3001 (36%)               |

*Described as text, data not currently available. N.o.s. = not otherwise stated; DV = derived variable.

Table 1e. Indications of fetal distress.

| Abnormality                        | P no. | Q no. | No. with information | No. (%) with abnormality |
|------------------------------------|-------|-------|----------------------|--------------------------|
| IUGR suspected                     | P1105 | B666  | 8369                 | 300 (4%)                 |
| Fresh meconium in liquor           | P1292 | C13h  | 8369                 | 279 (3%)                 |
| Old meconium in liquor             | P1293 | C13i  | 8369                 | 111 (1%)                 |
| Meconium NCE in liquor             | P1294 | C13j  | 8369                 | 1063 (13%)               |
| Abnormal fetal blood pH            | P1391 | C15b2 | 603                  | 228 (3%)                 |
| - Lowest level                     | P1392 | C15b3 | 226                  | Range 6.83-7.30          |
| - Time lowest pH to delivery       | P1393 | C15b4 | 215                  | Range 1-940 min          |

IUGR = intrauterine growth restriction; NCE = not classified elsewhere.

Table 2a. Presentation of the fetus during pregnancy.

| Presentation          | P no. | Q no. | No. with information | No. (%) involved |
|-----------------------|-------|-------|----------------------|------------------|
| During pregnancy      |       |       |                      |                  |
| Breech                | 1100  | B6f   | 8369                 | 2927 (35%)       |
| Transverse lie        | 1101  | B6ff  | 8369                 | 1725 (21%)       |
| Unstable lie          | 1102  | B6gg  | 8369                 | 65 (1%)          |
| At onset of labour    | 1200  | C5a   | 8369                 |                  |
| - vertex              |       |       | 7614                 | (91%)            |
| - breech              |       |       | 426                  | (5%)             |
| - other*              |       |       | 98                   | (1%)             |
| At delivery           | 1201  | C5b   | 8149                 |                  |
| - vertex OA           |       |       | 6603                 | (81%)            |
| - vertex OP           |       |       | 342                  | (4%)             |
| - breech              |       |       | 344                  | (4%)             |
| - other*              |       |       | 860                  | (11%)            |

*Described as text, data not currently available. OA = occiput anterior; OP = occiput posterior.
concerning whether the baby was in a potentially problematic position prior to the onset of labour (i.e., breech, transverse lie, or an unstable lie). The actual presentation at the start of labour is denoted by one variable (vertex, breech or ‘other’ – the latter being described in text). The fifth variable indicates the actual position at the time of delivery (whether vaginal or by CS).

**Method of delivery.** The method of delivery is described by one variable (DEL_P1210), distinguishing between assisted breech and breech extraction; assisted vaginal birth using forceps or vacuum extraction; CS, and spontaneous delivery. It should be remembered that the data are specific to the individual members of the pregnancy, each of which could have a different method of delivery. For example, there were 10 twin pregnancies in which one twin was delivered vaginally and the other by CS.

Further variables classify the types of forceps used and whether the CS was elective or emergency (Table 2b). In order to distinguish between cases of CS that occurred after labour had started we recommend using variable P1160 which indicates whether labour had started prior to the CS; this variable is described in more detail in the companion Data Note (Birmingham et al., 2021b).

**The cord and placenta.** Although the number of babies being born with their umbilical cord around their neck was relatively common (1933 births; 23%), the more dangerous cord prolapse only occurred on 24 occasions. The delivery of the placenta (or placentae in the case of most multiple births) often incurred problems of retained placenta, with consequent manual removal (Table 2c). However, it should be noted that retained placenta was only to be coded if stated in the notes, and it was a vaginal delivery. If manual removal was recorded, the instructions were to code retained placenta – these instructions were not always followed and the appropriate edit has now been made. The actual length of the third stage of labour ranged from immediately to 275 minutes (>4 hours) as shown in Table 15 of the Obstetric Data Note (Birmingham et al., 2021a).

Most of the placentae were retained by ALSPAC if the birth took place in either of the two Bristol-based major maternity

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**Table 2b. Method of delivery.**

| Method of Delivery | P no. | Q no. | No. with information | No. (%) | involved |
|--------------------|-------|-------|----------------------|---------|----------|
| Summary            | 1210  | C6a   | 8222                 |         |          |
| Spontaneous        |       |       | 5025 (61%)           |         |          |
| Assisted breech    |       |       | 156 (2%)             |         |          |
| Breech extraction  |       |       | 6 (0.1%)             |         |          |
| Caesarean section  |       |       | 1444 (18%)           |         |          |
| Forceps            |       |       | 713 (9%)             |         |          |
| Vacuum extraction  |       |       | 714 (9%)             |         |          |
| Other*             |       |       | 164 (2%)             |         |          |
| Type of forceps    | 1211  | C6b   | 1134                 |         |          |
| Wrigley's          |       |       | 250 (22%)            |         |          |
| Rhodes             |       |       | 443 (39%)            |         |          |
| Neville Barnes     |       |       | 166 (15%)            |         |          |
| Keilland's         |       |       | 203 (18%)            |         |          |
| Other*             |       |       | 72 (6%)              |         |          |
| Type of Caesarean section | 1212 | C6c   | 1454                 |         |          |
| Elective           |       |       | 519 (36%)            |         |          |
| Emergency          |       |       | 935 (64%)            |         |          |

*Described as text, data are available on request. This category includes methods of delivery which had failed although a different method had succeeded (e.g. failed forceps delivery. This is the explanation for the discrepancy between the number of forceps deliveries in the first part of Table 2b and the sum of the different types of forceps used in the second part.*
hospitals, provided the mother did not object. This involved placing the placenta immediately post-delivery into formalin in a container supplied especially for the purpose. There was rarely any standardisation at the time as to whether the membranes were retained, but a length of umbilical cord was cut and frozen at -20°C separately. Weight of the placenta was not standardised in any way and was available for only 3208 of the births in this sample. No analyses of these samples were undertaken without signed permission from the mother. Subsequent examinations of some of the placentae stored in formalin have produced measurements using a standard procedure (see Holroyd et al., 2016).

Condition at birth. Three different indicators of asphyxia at birth were used, including whether the baby: cried immediately; time taken before first breath (<1 minute, 1–3 minutes or >3 minutes); or was resuscitated. In addition, non-binary measurements were recorded of the time taken to establish regular respirations, and the Apgar scores at 1 and 5 minutes. Although it was relatively unusual for hospitals to record whether the baby cried immediately (26%), the other indicators were recorded in at least 85% of births (Table 3a).

Treatments at birth. Methods of resuscitation and other treatments/investigations are shown in Table 3b and Table 3c. Of the 8181 individuals with detailed information 67.5% (n=5521) had no resuscitation or other treatments or investigations at, or shortly after, delivery.

The neonatal period

Place and care of neonate. Table 4a indicates that approximately 10% of newborns were transferred immediately after delivery to a Special Care Baby Unit (SCBU) or to the transitional care ward in St Michael’s Hospital (Ward 76). This is a ward where babies can be cared for alongside their mothers who also remain in hospital. The newborns may have needed extra observations or help to feed particularly if they had been born prematurely or weighed less than 2.5 kg at birth. The duration of these admissions (if more than 24 hours) was also recorded. Those admitted to SCBU, or Neonatal Intensive Care have had detailed data collected covering their admission which will be described in a further Data Note. Nearly all the babies (98%) were discharged to their mother, with approximately 5% being re-admitted before their six-week postnatal check.

The paediatric examination of the newborns included an assessment of gestation, the mean number of weeks in this cohort is estimated to be 39.5. Abnormalities of the babies’ hips were noted in just under 5% (Table 4b).
Table 3a. Condition of baby at birth.

| Measure                                        | B no. | Q No | No. with information | No. (%) involved |
|------------------------------------------------|-------|------|----------------------|------------------|
| Baby cried immediately                        | 4000  | F1a  | 2054                 | 1428             |
| >3min before 1st breath                       | 4001  | F1b  | 7472                 | 59 (0.8%)        |
| Time until regular respirations established   | 4002  | F1b  | 7440                 | Mean 1.37 SD 1.59|
| Apgar at 1 min                                | 4003  | F1dap1 | 7954                | Mean 8.20 SD 1.59|
| Apgar at 5 min                                | 4004  | F1dap5 | 7951                | Mean 9.44 SD 0.89|
| Baby was resuscitated                         | 4005  | F1e  | 7967                 | 2409 (30%)       |

Table 3b. Methods of resuscitation.

| Method                                  | B no. | Q No | No. with information | No. (%) using method |
|-----------------------------------------|-------|------|----------------------|----------------------|
| Bag and mask                            | 4006  | F1f1 | 7967                 | 379 (5%)             |
| Bag, mask + oxygen                      | 4007  | F1f2 | 7967                 | 392 (5%)             |
| Cardiac massage                         | 4008  | F1f3 | 7967                 | 10 (0.1%)            |
| Facial oxygen                           | 4009  | F1f4 | 7966                 | 1600 (20%)           |
| Intubation                              | 4010  | F1f5 | 7967                 | 213 (3%)             |
| IPPV+intubation                          | 4011  | F1f6 | 7967                 | 226 (3%)             |
| Mouth-to-mouth+nose                     | 4012  | F1f7 | 7967                 | 0 (0%)               |
| Ventilation n.o.s.                      | 4013  | F1f8 | 7967                 | 123 (2%)             |
| Other*                                  | 4014  | F1f9 | 7967                 | 152 (2%)             |

*Described as text, data not currently available. IPPV = intermittent positive pressure ventilation; n.o.s. = not otherwise stated.

Table 3c. Treatments other than resuscitation given at, or shortly after, delivery.

| Treatment                | B no. | Q No | No. with information | No. (%) using treatment |
|--------------------------|-------|------|----------------------|-------------------------|
| Naloxone                 | 4015  | F1g  | 7967                 | 223 (3%)                |
| Other drug*              | 4015  | F1g  | 7967                 | 22 (0.3%)               |
| Suction                  | 4016  | F1h1 | 8182                 | 1555 (19%)              |
| Chest compression        | 4017  | F1h2 | 8182                 | 8 (0.1%)                |
| Other*                   | 4020  | F1h4 | 8182                 | 1284 (16%)              |
| No treatment given       | 4021  | F1h3 | 8181                 | 5521 (67%)              |

*Described as text, data not currently available.

Signs and symptoms. Signs and symptoms from minor to serious were noted in the babies’ first 14 days and are documented in Table 4c. The most common being jaundice (56%), ‘unsettled’ (38%) and pyrexia (28%). Other conditions that were noted were: apnoeic attacks, cyanotic attacks, high pitched or abnormal cry and sticky or moist eyes. The number of babies recorded as suffering from convulsions, umbilical infection or ‘twitching’ were in single figures only. Only 293 (4%) of the babies had no problems at all recorded.

Feeding and nutrition. As indicated in Table 4d, 69% of neonates were breast fed including those that were both breast and bottle fed with 11% recorded as having difficulties with feeding.

Vitamin K. Table 4e shows that Vitamin K was administered to 67% of the neonates although it is likely to have been considerably more as 2463 (32%) had no indication in the medical records that it had been administered. It is known that in one hospital, staff would document on the babies’ name cards that this vitamin had been given. These cards, which were usually attached to the mothers’ bed or babies’ cots, were...
### Table 4a. Place of care of neonate.

| Process                                | B no. | Q no  | No. with information | No. (%) involved |
|----------------------------------------|-------|-------|----------------------|------------------|
| Transferred after delivery             | 4050  | F2a   | 7982                 | 779 (10%)        |
| - SCBU                                 | 4050  | F2a   | 7982                 | 521 (7%)         |
| - Transitional care                    | 4050  | F2a   | 7982                 | 164 (2%)         |
| - Other*                               | 4050  | F2a   | 7982                 | 94 (1%)          |
| - Duration of stay 24hr+               | 4051  | F2c   | 778                  | 741              |
| Age at discharge (days)                | 4540  | F12   | 7804                 | Mean 4.24 SD 7.89|
| Place discharged to                    | 4550  | F13a  | 7816                 |                  |
| - Other hospital                       | 4551  | F13b  |                      | 154 (2%)         |
| - Mother                               | 4551  | F13b  |                      | 7656 (98%)       |
| Baby readmitted before 6-week postnatal check | 4600  | F14   | 7927                 | 363 (5%)         |
| - Age at re-admission (days)           | 4601  | F14   | 348                  | Mean 17.0; SD 12.0|

*Described as text, data not currently available.

†A further six children were either still in hospital or were discharged to others (e.g. foster parents). SCBU = Special Care Baby Unit.

### Table 4b. Procedures involving the neonate.

| Process                                | B no. | Q no  | No. with information | No. (%) involved |
|----------------------------------------|-------|-------|----------------------|------------------|
| Examined by paediatrician              | 7699  | F7    | 7699                 | 7507 (98%)       |
| Hips examined                          | 4350  | F8a   | 7618                 | 7538 (99%)       |
| - Abnormalities noted*                 | 4351  | F8b   | 7537                 | 349 (5%)         |
| Paediatric assessment of gestation     | 4400  | F10a  | 4575                 | Mean 39.5        |

*Described as text, data not currently available.

### Table 4c. Signs and symptoms in the neonatal period.

| Sign/symptom                           | B no. | Q no  | No. with information | No. (%) with symptom |
|----------------------------------------|-------|-------|----------------------|----------------------|
| Apnoeic attacks                        | 4450  | F11a  | 8135                 | 13 (0.2%)            |
| Cyanotic attacks                       | 4451  | F11b  | 8135                 | 65 (0.8%)            |
| Convulsions                            | 4452  | F5    | 7717                 | 9 (0.1%)             |
| High pitched/abnormal cry             | 4453  | F11d  | 8135                 | 10 (0.1%)            |
| Twitching                              | 4454  | F11i  | 8135                 | <5 (<0.1%)           |
| Unsettled                              | 4455  | F11k  | 8134                 | 3103 (38%)           |
Table 4d. Feeding and nutrition.

| Sign/symptom            | B no. | Q no | No. with information | No. (%) with symptom |
|-------------------------|-------|------|----------------------|----------------------|
| Sticky eyes             | 4456  | F11h | 8135                 | 1612 (20%)           |
| Moist eyes              | 4457  | F11e | 8135                 | 1221 (15%)           |
| Umbilical infection     | 4458  | F11j | 8135                 | 9 (0.1%)             |
| Mucousy                 | 4460  | F11f | 8135                 | 1769 (22%)           |
| Jaundice                | 4461  | F11n1| 7576                 | 4278 (56%)           |
| - Serum bilirubin       | 4462  | F11n2| 4265                 | 1505 (35%)           |
| - highest level (µmol)  | 4463  | 1495 | Mean 207 SD 62       |
| - age (days) at highest level | 4464 | 1481 | Mean 3.8 SD 1.9      |
| Pyrexia                 | 4465  | F11g | 8134                 | 2256 (28%)           |
| Highest temperature     | 4466  | F11grsit | 2255            | Mean 37.4 SD 0.30    |
| Lowest temperature      | 4467  | F6   | 7598                 | Mean 36.4 SD 0.32    |
| Other*                  | 4468  | F11l | 8134                 | 6711 (83%)           |
| No problems recorded    | 4469  | F11m | 8134                 | 293 (4%)             |

*Described as text, data not currently available.

Table 4e. Administration of vitamin K.

| Vitamin K | B no. | Q no | No. with information | No. (%) using method |
|-----------|-------|------|----------------------|----------------------|
| Given vitamin K | 4150  | F4   | 7663                 | 7629                 |
| - IM       |       |      |                      | 1535 (20%)           |
| - Oral     | 3501  | F11c |                      | 34 (0.4%)            |
| - IV       | 130   |      |                      |                      |
| - Route NS | 2463  |      |                      |                      |
| - None     | 34    |      |                      |                      |

*IM = intramuscular; IV = intravenous; NS = not stated.

Protocols from the two main hospitals state that all babies should be given the vitamin: 1mg orally for full-term normal deliveries and 0.5 mg intramuscularly for others. The hospitals differed on where the vitamin should be administered (i.e., delivery suite or ward) (see Box 2 Management Guidelines and Midwifery Operational Policies). These protocols can be found in the ALSPAC Archive in the University of Bristol Library (Special Collections Archive Box 784).
Box 2. Management guidelines and midwifery operational policies

**Southmead Hospital Delivery Suite**

KONAKION (PHYTOMENADIONE/VITAMIN K)

All infants should receive Vitamin K orally or IM after birth with maternal consent. The dose (0.5 - 1.0 mg) is determined by the baby's size and mode of delivery:

(a) Normal delivery of full term (>37w) infant - 1 mg Vit K orally

(b) Abnormal delivery and/or preterm (<37 weeks) infant - 0.5 mg Vit K, IM and infant weighing <2.5 Kg

**VITAMIN K IS NEVER ADMINISTERED ON DELIVERY SUITE (to avoid accidental confusion with other agents e.g. oxytocic [sic]) unless mother and baby are for 6 hour discharge.**

IT IS ROUTINELY GIVEN TO THE BABY ON SCBU OR ON THE POST NATAL WARDS/NURSERY AND IS INCORPORATED IN THE MIDWIVES “STANDING ORDERS”.

**Bristol Maternity Hospital Central Delivery Suite**

KONAKION (PHYTOMENADIONE/VITAMIN K)

All babies should be given Vitamin K soon after delivery. This must be recorded in the appropriate column of page 2 of the baby notes with date, time and route of administration.

All normal term infants to be given:

- **Vitamin K1 [sic]** 1 mg Orally

The following babies should be given:

- **Intramuscular Vitamin K 0.5 mg**
  1. Those unlikely to be fed orally in the first hours following birth, i.e.:
     a. Respiratory problems.
     b. Admissions to SCBU.
     c. Pre term (less than 36 weeks gestation).
     d. Intestinal obstruction (or other problems which may require surgery).
     e. Significant birth asphyxia.
     f. Convulsions.
  2. Those following traumatic birth or at high risk, i.e.:
     a. Breech delivery.
     b. Keillands forceps delivery.
     c. Caesarean section (other than uncomplicated elective sections at term).
  3. Other conditions i.e.:
     a. Moderate/severe Rhesus disease.
     b. Congenital infection.
     c. Bleeding disorders.
  4. Those requested by paediatricians.

Vitamin K is administered on CDS prior to transfer to wards (see Standing Order). Ward staff should be informed if Vitamin K not given for any reason.

**Table 4f. Treatments and procedures during the neonatal period.**

| Treatment or procedure | B no. | Q no | No. with information | No. (%) receiving treatment / procedure |
|------------------------|-------|------|----------------------|----------------------------------------|
| Antibiotics given      | 4500  | F11o1| 8135                 | 547 (7%)                               |
| Dextrose given         | 4501  | F11o2| 8135                 | 11 (0.1%)                              |
| Other drug given*      | 4502  | F11o3| 8135                 | 2512 (31%)                             |
| No drugs given to baby*| 4503  | F11o4| 8134                 | 4760 (59%)                             |
| Nursed in incubator    | 4510  | F11p3| 8135                 | 1110 (14%)                             |
| Blood sugars assessed  | 4512  | F11p1| 8135                 | 2403 (30%)                             |
| Cot shield used        | 4513  | F11p2| 8135                 | 490 (6%)                               |
| Light meter used       | 4514  | F11p4| 8135                 | 175 (2%)                               |
| Meconium observations done | 4515 | F11p5| 8135                 | 731 (9%)                               |
| Phototherapy given     | 4516  | F11p6| 8135                 | 216 (3%)                               |
| Other treatments*      | 4517  | F11p7| 8134                 | 4900 (60%)                             |
| Had treatment/investigation | 4511 | F11p8| 8134                 | 6318 (78%)                             |

*Described as text, data not currently available. *Known to have no drugs given but there are possibly more as some medical records were missing information on the administration of drugs.

The article linking IM administration of Vitamin K with childhood cancer (Golding et al., 1992) was not published until August 1992 and would not have influenced the route of Vitamin K administration for this cohort as policy change was slow due to considerable controversy. However, oral administration had long been used in some Bristol units.
or Neonatal Intensive Care will be outlined elsewhere (in preparation).

**Strengths and limitations**

There are four major strengths of these data. Firstly, each item was abstracted from the paper medical record with a strict protocol and meticulous checking; secondly, the data collected were documented at the time so that there was no element of retrospective recall; thirdly, these data can be augmented by information from the mothers’ self-completion questionnaires; and fourthly, the data provide an important baseline from which to assess the long-term benefits and possible hazards of the various facets of care.

There is one major limitation of the data - many aspects of fetal exposures, neonatal conditions and treatments are missing for over 5000 ALSPAC newborns. Admittedly, by the selection criteria used on the 8369, the majority of the more complex cases have already been abstracted, but for valid epidemiological analysis the population of all the others are also needed. It is hoped that efforts can be made in the future to fill this important gap.

**Consent**

Consent to abstract data from medical records was obtained on an ‘opt out’ basis which was acceptable to the LRECs at that time. The Study Mothers were informed in the initial information booklet that their medical records would be accessed.

**Data availability**

**Underlying data**

ALSPAC data access is through a system of managed open access. The steps below highlight how to apply for access to the data included in this Data Note and all other ALSPAC data:

1. Please read the ALSPAC access policy which describes the process of accessing the data and samples in detail, and outlines the costs associated with doing so.

2. You may also find it useful to browse our fully searchable research proposal database which lists all research projects that have been approved since April 2011.

3. Please submit your research proposal for consideration by the ALSPAC Executive Committee. You will receive a response within 10 working days to advise you whether your proposal has been approved.

If you have any questions about accessing data, please email alspac-data@bristol.ac.uk.

The Study website also contains details of all the data that is available through a fully searchable data dictionary.

**Extended data**

Although the abstraction form, instructions and checking instructions are labelled “ALSPAC Mother during pregnancy and the puerperium”, these documents also cover data abstraction relating to the fetus, the new-born immediately after delivery and signs, symptoms and treatments during the first weeks of life.

Figshare: ALSPAC Mother during pregnancy and the puerperium_data abstraction form. https://doi.org/10.6084/m9.figshare.13614701 (Birmingham et al., 2021b).

Figshare: ALSPAC Mother during pregnancy and the puerperium_data abstraction instructions. https://doi.org/10.6084/m9.figshare.13621598 (Birmingham et al., 2021c).

Figshare: ALSPAC Mother during pregnancy and the puerperium_ abstraction checking instructions. https://doi.org/10.6084/m9.figshare.13621703 (Birmingham et al., 2021d).

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

**Acknowledgements**

We are extremely grateful to all the families who took part in this study, the midwives for their help in recruiting them, and the whole ALSPAC team, which includes interviewers, computer and laboratory technicians, clerical workers, research scientists, volunteers, managers, receptionists and nurses.

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Open Peer Review

Current Peer Review Status: ✔️ ❓ ✔️

Version 2

Reviewer Report 12 June 2024

https://doi.org/10.21956/wellcomeopenres.23494.r78444

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Wojciech Hanke
Nofer Institute of Occupational Medicine, Łódź, Poland

The scope of information about the health of neonates presented is very extensive. However, the goal of the paper is not provided. The description of the results is very clear and the information seems valuable. The clear presentation of the goal of the paper will allow to identify better the target audience for the paper.

Is the rationale for creating the dataset(s) clearly described?
No

Are the protocols appropriate and is the work technically sound?
Yes

Are sufficient details of methods and materials provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Reproductive epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 12 April 2024

https://doi.org/10.21956/wellcomeopenres.23494.r76930
Gordon C. Smith
Department of Obstetrics and Gynaecology, Cambridge University, Cambridge, UK

The authors have addressed my comments and I have no further comments to add.

Is the rationale for creating the dataset(s) clearly described?
Yes

Are the protocols appropriate and is the work technically sound?
Yes

Are sufficient details of methods and materials provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 17 February 2023

https://doi.org/10.21956/wellcomeopenres.19022.r54261

Neha Sethi
Department of Obstetrics and Gynaecology, Faculty of Medicine, Universiti Malaya, Kuala Lumpur, Malaysia

A very well done presentation with details to the data abstraction and it’s use.

Some of the data abstracted from the medical records - example for the CTG abnormalities - does it specify if the CTG interpretation was done appropriately and followed a specific criteria? If so, it
might be worth mentioning as the criteria to classify CTG and fetal heart rate changes in your data shows a consistent pattern from the records.

In the method of delivery, with regards to forceps delivery and cesarean section, the types are mentioned differently and are different in numbers. What does it mean? The explanation is not very clear.

The retained placenta and manual removal of placenta are mentioned as different entities. The manual removal of placenta is a procedure to remove the retained placenta. Hence why the difference. Why is it mentioned as a separate entity?

The apgar score of baby at 5 minutes - does it only include babies who did not require any resuscitation / is there data on post resuscitative apgar scores?

What was included in the examination of the newborn - general/systemic/biometric measurements/ponderal index/ballard score? Are there details on that?

Is there any protocol of vaccination at birth (e.g., BCG)\(^1\)? If yes, it might be worth considering and including.

References
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Is the rationale for creating the dataset(s) clearly described?
Yes

Are the protocols appropriate and is the work technically sound?
Yes

Are sufficient details of methods and materials provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

*Competing Interests:* No competing interests were disclosed.

*Reviewer Expertise:* Fetal medicine

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
Yasmin Iles-Caven

A very well done presentation with details to the data abstraction and it’s use. Some of the data abstracted from the medical records - example for the CTG abnormalities - does it specify if the CTG interpretation was done appropriately and followed a specific criteria? If so, it might be worth mentioning as the criteria to classify CTG and fetal heart rate changes in your data shows a consistent pattern from the records.

Thank you for your comments. The data from the fetal heart rate monitoring has not been reviewed using standardised criteria. Instead we required the data transcribers to collect only the interpretations of the traces as written in the notes. We have now made this clearer in the revised version of the paper.

In the method of delivery, with regards to forceps delivery and cesarean section, the types are mentioned differently and are different in numbers. What does it mean? The explanation is not very clear.

Thank you for pointing this out. We have now made the point in the text referring to this table that the data are referring to individual members of the pregnancy, not to the numbers of pregnancies. We realise that this has caused confusion among our readers and hope that by reiterating this, readers will be able to comprehend. Thus a difference in numbers between the caesarean sections can result from one twin being delivered vaginally and the other by CS. There is also a problem in interpretation of the numbers of deliveries where forceps were used. The method of delivery category ‘other’ includes methods of delivery which had failed although a different method had succeeded (e.g. failed forceps delivery is coded here rather than under the forceps category). This is the explanation for the discrepancy between the number of forceps deliveries (713) in the first part of Table 2b and the sum of the different types of forceps used in the second part (1134). We have now clarified that in the text.

The retained placenta and manual removal of placenta are mentioned as different entities. The manual removal of placenta is a procedure to remove the retained placenta. Hence why the difference. Why is it mentioned as a separate entity? We apologise over this confusion. There was an instruction for all cases of manual removal of the placenta to be also recorded as a retained placenta, but the edit was not undertaken. The data have been amended in the revised version of the paper.

The apgar score of baby at 5 minutes - does it only include babies who did not require any resuscitation / is there data on post resuscitative apgar scores?

Apgar Scores at 1 and 5 minutes were recorded for almost all babies regardless of their resuscitation status: n= 7954 at 1 minute and n= 7954 at 5 minutes. We did not collect data on later Apgar scores.

What was included in the examination of the newborn - general/systemic/biometric measurements/ponderal index/ballard score? Are there details on that?

The criteria for the examination of the newborn is likely to have varied within the different hospitals and training of the clinicians. The data abstractors were asked to only record what was written in the clinical record.

Is there any protocol of vaccination at birth (e.g., BCG¹)? If yes, it might be worth considering and
If BCG immunisation is to be given in Avon that usually happens shortly after birth, but only 1.7% of babies in this study had such an immunisation. Other immunisations were not routinely given until at least 3 months after birth. Details of which immunisations were given and when have been obtained in questionnaires completed by the study mothers at various ages and are available to researchers. We have not included the data here, but are considering developing a further data note to cover all immunisations.

**Competing Interests:** None

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**Reviewer Report 13 January 2023**

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**Gordon C. Smith**
Department of Obstetrics and Gynaecology, Cambridge University, Cambridge, UK

**Comments:**
1. Page 3. The abbreviation NEC is better avoided as this is used for necrotizing enterocolitis in neonatology. Suggest use NCE = not classified elsewhere.

2. Page 3. Sentence “Here we describe the data...” I don't really understand what they mean here.

3. Tables 1a-c. Late decelerations are thought to reflect acidosis which is quite uncommon whereas variable decelerations are thought to reflect umbilical cord compression which is relatively common. I am surprised that in all of these tables late decelerations were more common than variable decelerations. It would be good to know how this information was gleaned from the case record. Were the CTG traces reviewed and classified or were these qualities based on reading free text in the case record?

4. Table 2b. Emergency caesarean section can be further subdivided into pre-labour and intrapartum. Do they have this information?

5. Table 2c. Manual removal of placenta is only performed in the context of retained placenta. How can there be more cases of manual removal than of retained placenta? One would expect the opposite pattern as some cases of retained placenta resolve without MROP.

6. Page 8. Did the paediatric examination include basic measurements, such as head circumference and ponderal index? If so, have these data been collected?
7. Ethics and consent. I note that the study only obtained opt out consent and this was appropriate for the conduct of the study at the time. However, the data and – I assume – the biological samples are still being used now. It would be useful if they could comment more on the ethical and legal framework for sharing patient level data or storing and analysing biological samples without written consent. For example, are the biological samples held based on a Human Tissue Act license or on the basis of a current active ethics permission? Also, the offspring are now adults and it would be useful if they could explain the ethical and legal framework for storing data and samples from individuals who were infants at the time of the study but who are now adults. Alternatively, there may be other publications where these issues are covered and, if so, the authors should cite these.

Is the rationale for creating the dataset(s) clearly described?
Yes

Are the protocols appropriate and is the work technically sound?
Yes

Are sufficient details of methods and materials provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Epidemiological and translational research in adverse pregnancy outcome

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 11 Mar 2024
Yasmin Iles-Caven

We are very grateful for your helpful comments which we have used to improve the paper.

1. Page 3. The abbreviation NEC is better avoided as this is used for necrotizing enterocolitis in neonatology. Suggest use NCE = not classified elsewhere.

We have changed NEC to NCE as suggested throughout the paper.

1. Page 3. Sentence “Here we describe the data...” I don't really understand what they mean here.

Apologies for the confusion. We have reworded that and the following sentence to read: The data described in this Data Note differ from that in a published Data Note which describes the mother during pregnancy and the puerperium (Birmingham et al., 2021a; subsequently referred to as the Obstetric Data Note). In the current Data Note we describe the individual data relating to the fetuses/births rather than pregnancies, thus allowing for different answers for different members of a multiple pregnancy. The data described here is
therefore primarily child based. Examples concern the presentation of the fetus, fetal monitoring, and method of delivery.

1. Tables 1a-c. Late decelerations are thought to reflect acidosis which is quite uncommon whereas variable decelerations are thought to reflect umbilical cord compression which is relatively common. I am surprised that in all of these tables late decelerations were more common than variable decelerations. It would be good to know how this information was gleaned from the case record. Were the CTG traces reviewed and classified or were these qualities based on reading free text in the case record?

The data abstractors were expected to abstract what was recorded as free text in the clinical records and not to attempt interpretation of CTG traces. Interpretation may have been biased by the different training and skill sets among the midwives and clinicians.

1. Table 2b. Emergency caesarean section can be further subdivided into pre-labour and intra-partum. Do they have this information?

There is a way of identifying CSs occurring after the onset of labour, and this is now described in the text describing Table 2b.

5. Table 2c. Manual removal of placenta is only performed in the context of retained placenta. How can there be more cases of manual removal than of retained placenta? One would expect the opposite pattern as some cases of retained placenta resolve without MROP. Thank you for spotting this. It was due to an editing error on our part. The instructions to the data abstractors were that if a manual removal had been recorded in the clinical records, then retained placenta should automatically be coded. This had not always taken place, so a computer correction has been made. However, there was a discrepancy in 13 cases where there was a twin pregnancy – one placenta was retained, but not the other. This has now been clarified in the table and text.

1. Page 8. Did the paediatric examination include basic measurements, such as head circumference and ponderal index? If so, have these data been collected?

Details of the outcomes of pregnancy, including birth measurements (birthweight, birth length, birth head circumference), whether live or stillborn, classification of perinatal deaths, and details of any neonatal deaths are in a further Data Note (as stated in the paper)

1. Ethics and consent. I note that the study only obtained opt out consent and this was appropriate for the conduct of the study at the time. However, the data and – I assume – the biological samples are still being used now. It would be useful if they could comment more on the ethical and legal framework for sharing patient level data or storing and analysing biological samples without written consent. For example, are the biological samples held based on a Human Tissue Act license or on the basis of a current active ethics permission? Also, the offspring are now adults and it would be useful if they could explain the ethical and legal framework for storing data and samples from individuals who were infants at the time of the study but who are now adults. Alternatively, there may be other publications where these issues are covered and, if so, the authors should cite these.

We have enhanced the Ethics statement to address your queries as follows: Informed consent for the use of data collected via questionnaires and clinics was obtained from participants following the recommendations of the ALSPAC Ethics and Law Committee at
the time (Birmingham, 2018). All participants have the right to withdraw from the study, or elements of it, at any time – and permissions are obtained at various timepoints. Consent for biological samples has been collected in accordance with the Human Tissue Act (2004). Where researchers have used linked data (e.g. educational and/or health records), at the age of 18, study children were sent 'fair processing' materials describing ALSPAC's intended use of their health and administrative records and were given clear means to consent or object via a written form. Data were not extracted for participants who objected, or who were not sent fair processing materials. For linkage to their health records, ethical approval for the study was obtained from the ALSPAC Law and Ethics committee and local research ethics committees (NHS Haydock REC: 10/H1010/70). Full details of ethical approvals can be found at http://www.bristol.ac.uk/alspac/researchers/research-ethics/

Competing Interests: None