Annexe C. Dress Rehearsal Report

DIET AND NUTRITION SURVEY OF INFANTS AND YOUNG CHILDREN

Report of the Dress Rehearsal February – June 2010

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C.1. Introduction

Following a tendering process, the Food Standards Agency (FSA) and Department of Health (DH) commissioned a collaboration comprising MRC Human Nutrition Research (HNR) based in Cambridge, the National Centre for Social Research (NatCen) based in London, the MRC Epidemiology Unit based in Cambridge and the Human Nutrition Research Centre at Newcastle University to carry out the Diet and Nutrition Survey of Infants and Young Children (DNSIYC), a survey of infants and young children aged four to 18 months in the UK. The survey field name is the National Infant Diet and Health Study. In order to develop and test the protocol for all stages of the survey, a Dress Rehearsal covering all parts of the survey was required.

The purpose of the Dress Rehearsal was to test all survey components and procedures to be undertaken in the main stage. This report describes the design and conduct of the fieldwork which took place between February and June 2010. It comprises:

Section 1.0:	Introduction to the survey
Section 2.0:	Background and aims of the Dress Rehearsal
Section 3.0:	Ethics
Section 4.0:	Methods: Stage 1
Section 5.0:	Methods: Stage 2 – Clinic Visit
Section 6.0:	Methods: Data
Section 7.0:	Methods: Providing personalised feedback to participants
Section 8.0:	Results
Section 9.0:	Recommendations

Response rates achieved are described for the two stages of the survey, a) the interviewer stage in the home where dietary information was collected and b) the clinic visit which followed the dietary component. The practicalities of using the dietary assessment portion size equipment and the feasibility of operating a mobile unit, staffing it appropriately and undertaking clinical measurements has also been evaluated. Variation in interviewer measurements of infant head circumference and length was tested and the results are summarised. Improvement measures are proposed for the mainstage, based on response rates and feedback from those who worked on the survey: interviewers, the dietary assessment team and clinic staff (including the mobile unit). The final chapter summarises these recommendations.

C.2. Background and aims of the Dress Rehearsal

The FSA obtains information on the dietary habits and nutritional status of the UK population through its dietary surveys, such as the rolling National Diet and Nutrition Survey (NDNS) programme[1], which is conducted on ages 1.5 years and over. Information about feeding practices of infants is derived from the Infant Feeding Survey (IFS)[2], which is carried out every five years by the DH. However, this survey does not collect information on actual quantities of foods consumed. The last major national survey of infants, an investigation of food and nutrient intakes of British infants aged six to 12 months[3], was commissioned by the Ministry of Agriculture, Fisheries and Food (MAFF) and carried out in 1985-86. Government advice on breastfeeding, weaning and dietary habits has changed since that time, indicating a need for more current information. DNSIYC is the only national survey providing detailed information on diet and nutrition of individuals aged four to 18 months. The data from DNSIYC will be used in conjunction with data from NDNS to provide a fuller picture of the diet and health of the nation starting from the youngest age range.

The aims of DNSIYC are to:

- provide detailed, quantitative information on the food and nutrient intakes, sources of nutrients and nutritional status of a representative sample of infants and young children aged four to 18 months from the UK population, as a basis for developing Government policy and measuring progress towards FSA Strategic Plan targets and other Government objectives;
- provide detailed information on breast and breast milk substitutes consumed by the population group under study;
- describe the characteristics of subjects with intakes and/or status of specific nutrients that are above and below national reference values;
- produce a database of food consumption to provide the basis for the calculation of likely dietary intakes of natural toxicants, contaminants, additives and other food chemicals for risk assessment;
- provide height (length), weight and other body measurements and examine their relationship to social, dietary and health data as well as data from blood analyses (if included);
- evaluate the diet of the population group under study to form a basis for establishing the extent to which it is adequately nutritious and varied;
- establish the extent of deviation of the feeding practices adopted by carers of this population group from national policy for infant health;
- act as a basis for policy development;
- roughly establish the dietary habits of the mother, and other key family members, and link to the nutrient intake and nutritional status of this population group; and
- measure blood indices that give evidence of nutritional status.

Key to DNSIYC is the combination of a number of different types of information, including data on food intake, biochemical measures of nutritional status and measures of body composition.

The specific aims of the DNSIYC Dress Rehearsal (DR) were to test:

- Sampling methodology

- Computer assisted personal interview (CAPI) programming for the interviewer questionnaires
- Question modules and protocols
- Anthropometric measurements taken by interviewers
- Food diary format and completion and the portion size equipment used
- Clinic protocol including: attendance and transport of participants, blood sampling, urine sampling and breast milk/fluid intake protocols, and estimating response rates to these various components.
- Mobile unit coverage and response rate.
- All survey procedures, including consents, tokens of appreciation, logistical arrangements for clinics, interviewer-HNR-clinic communication and data transfer.
- Coding procedures for the food diary.
- Procedures for maintaining and expanding the nutrient databank.
- Procedures for deriving nutrients from food data.
- Data preparation and processing.

References and endnotes

[1] http://www.food.gov.uk/science/dietarysurveys/ndnsdocuments 12 August 2010

[2] http://www.dh.gov.uk/en/Publicationsandstatistics/PublishedSurvey/ListOfSurveySince1990/Surveylistlifestyle/index.htm

[3] Mills A. and Tyler H. Food and Nutrient intakes of British infants Aged 6-12 months 1990. The Stationery Office

C.3. Ethics

C.3.1. Ethical approval – application and responses and Amendment 1 – applications and responses

Following approval by HNR's Research Governance Committee, the ethical application for the survey was submitted on 4th November 2009, for review at the 26th November Cambridgeshire 4 Research Ethics Committee (REC) meeting. A team of three individuals from the consortium attended the REC meeting and were invited to discuss and clarify various issues, including the sampling method, economic deprivation and ethnic status, participant burden and an opt-out option for participants. The committee also reviewed the survey documentation. A favourable provisional opinion was given on 4th December 2009, subject to further information requested from the consortium and some administrative issues. HNR responded to the points of clarification and administrative issues on 17th December 2009. A further point of clarification was requested by the REC on 7th January and a response was issued from HNR to the REC on 8th January 2010. Ethical approval for the survey was obtained from Cambridgeshire 4 Research Ethics Committee (REC) on 18th January 2010. Approval was given under the terms of the application, and approval was given to all submitted documentation. Approval was subject to gaining site-specific approval for each host organisation for the clinic visit component and Research and Development (R&D) approval where the site was an NHS site.

The first Substantial Amendment for the survey was submitted to Cambridgeshire 4 REC on 18th February 2010. The amendments requested were approved by Cambridgeshire 4 REC on 25th February 2010; these included amendments to some of the survey documentation, new documentation for the quality control day for inter-interviewer variation in anthropometric measurements and changes to the method of 'housing' and charging the mobile unit batteries at sites throughout the country.

C.3.2. Portfolio adoption – application and response

Application was made on 20th November 2009 for DNSIYC to be considered a portofolio project since many of the clinics to be used are NHS Trust sites. Adoption as a portfolio project allows access to NHS support in England, including clinicians, for research purposes via the National Institute for Health Research Clinical Research Networks (NIHR CRN). The NIHR CRN supports clinical research and helps to facilitate the conduct of trials and other well-designed studies within the NHS. The NIHR CRN in England approved DNSIYC as a portfolio adopted study on 21st April 2010.

C.3.3. Clinics: Research & Development (R&D) and site specific applications

The DNSIYC Dress Rehearsal involved four sites, Cambridge, Manchester, Newcastle and Falkirk (mobile unit). A Site-Specific application form is used for applications to local NHS R&D offices and to NHS Research Ethics Committees for site-specific assessment, where applicable. Site specific applications were approved for all four sites. Both Manchester and Newcastle were NHS clinical research facility sites. Trust R&D approval took a varying amount of time to achieve, from 22 days in Manchester to 93 days in Newcastle, from transfer of the documentation to the trust through to signed approval. Cambridgeshire 4 REC reviewed the non-NHS site applications and approval was obtained for the Cambridge site on 3rd of February

2010. The mobile unit was deemed to be exempt from site-specific approval; confirmation of this was received on 25th January 2010.

C.4. Methods: Stage 1

The methods used in the Dress Rehearsal are described in this part of the report, and are divided into a number of sections; Chapter 4: sample design and procedures and the Stage 1 procedures; Chapter 5: Stage 2 procedures; Chapter 6: the key methods of data transfer and Chapter 7: feedback to participants.

C.4.1. Overview of methodology

In order to meet the aims of the Dress Rehearsal (see section C.2.0), a sample of infants and young children aged four to 18 months was required. While it was the intention to use the Child Benefit Register for the main survey, arrangements were not sufficiently advanced to make this available in time for the Dress Rehearsal. The sample was therefore drawn from the 'Bounty' parenting club marketing database. For cost effectiveness, the sampled addresses were clustered into Primary Sampling Units (PSUs), small geographical areas based on postcode sectors, selected from three locations where discussions had already taken place so that the clinics could be set up quickly, in addition a fourth area, a rural location in Scotland, was selected, to test the feasibility of using a mobile unit. Since the Dress Rehearsal was not designed to be nationally representative, selection of the PSUs was purposive, rather than random, and based on the location of these available clinics.

An advance letter was sent by post to each address, along with a Stage 1 leaflet, introducing the survey and explaining that the interviewer would be calling. At each address, the interviewer then made a face-to-face visit to establish whether the sampled child lived at the address (from gender and date of birth information provided by Bounty). If so, the interviewer then established the parent most suitable for being interviewed about the child's feeding, i.e. the parent of the selected child who had most involvement in feeding the child. If two parents shared the feeding of the child, the interviewer selected just one to take part in the interview (on the basis of which one was most readily available) but aimed to have both present during the completion of the questionnaire, where possible.

The key elements to the Dress Rehearsal were as follows:

- Face-to-face interview conducted using CAPI (computer assisted personal interviewing);
- Dietary data collection (four-day estimated food diary);
- Anthropometric measurements (maternal height and weight; infant length, weight and head circumference); and
- A clinic visit involving further anthropometric measurements (skinfold thickness), blood sampling and stable isotopes.

The interviewer also identified the *Household Reference Person* (HRP) in each household and asked questions about housing tenure, as well as his or her employment, to determine the socio-economic classification of the household.

Participants who took part in the CAPI interview and completed a food diary for at least three days were classified as *'fully productive'* and were invited to take part in the second stage of the survey. This involved a visit to a local clinic for further physical measurements, a blood sample and fluid intake assessments using stable isotopes.

C.4.2. Sampling

The sample was drawn from the 'Bounty' marketing database. Bounty is a parenting club that holds a database of new parents from which it was possible to take a sample for the Dress Rehearsal. Child Benefit records will be used for the mainstage of the survey so using Bounty as a sample frame enabled the testing of a 'named' sample approach whilst also assessing response rates at each stage of the survey. The information on the sampled child was limited to the name of the mother, the address and the date of birth and gender of the child. The name of the child was not known (since Bounty undertake never to pass this information to third parties) so interviewers were required to identify the eligible child by their date of birth and gender. In the case of same-gender twins or triplets, the oldest child was selected.

The Dress Rehearsal covered specific areas in England and Scotland and sampled those living in private residential households only. The issued sample consisted of 315 addresses in 15 postcode sectors (points) across the two countries. The sample included infants and young children from four to 18 months. Each point (assignment) contained 21 issued addresses – hence 21 selected infants/young children. Children with a birth weight of less than 2.0kg and those with congenital abnormalities affecting feeding practices were excluded at the interview stage. The three clinics used were based in Cambridge, Manchester and Newcastle and the mobile unit was based in a rural area around the town of Falkirk in Scotland. To test the impact of distance from the clinic on clinic attendance, postcodes were at varying distances from each clinic.

C.4.3. Stage 1 – interviewer visits

C.4.3.1. Interview procedures

In this section, the fieldwork procedures carried out by interviewers are described. Details of documents used by interviewers are also provided (Appendix G).

C.4.3.1.1. Notifying the police

Interviewers were responsible for notifying the local police about the work they were to undertake in the survey. They were given a special form for this purpose which they handed in at the local police station together with a copy of the advance letter and Stage 1 leaflet.

C.4.3.1.2. Interviewer visits

The interviewer's first task was to visit each sampled address and establish whether it contained the eligible child, as identified by the age and gender information provided by Bounty. Once co-operation had been secured, interviewers made up to three main visits to the participating household. The interviewer visits covered:

- Questionnaire administration (the interview was an interviewer-administered CAPI questionnaire carried out face-to-face, with one section that could be administered either via CAPI or CASI (computer assisted self interviewing);
- Collection of dietary data for four consecutive days using an estimated (unweighed) food diary (see section C.4.3.5); and
- Taking of physical measurements, following detailed protocols: maternal height and weight (if mother resident) and infant length, weight and head circumference.

At the end of the interviewer stage, the second stage of the survey was introduced and the interviewer asked for permission for the clinic/HNR to call to discuss this stage further and to arrange an appointment.

Throughout the interview process, interviewers were allowed some degree of flexibility about the timing of various procedures in order to fit in with participant availability and maximise co-operation. However, the preferred structure and order of tasks carried out at each visit was as follows:

1st visit	CAPI questionnaire (part 1). Food diary placed with participant.
2nd visit	Food diary check up (could be done by telephone ONLY if interviewer was sure this was appropriate).
3rd visit	Food diary collected and checklist completed. CAPI questionnaire (part 2). Token of appreciation given (£30 in High Street vouchers for food diary completion). Mother and child anthropometric measurements taken. Clinic visit introduced and agreement for clinic/HNR to contact obtained. Tracer water introduced and pre-dose equipment provided if willing to take part.

An additional interviewer visit was made to those participants taking part in the stable isotope part of the clinic visit protocol. At this visit, interviewers collected urine samples and accompanying paperwork and re-weighed the child (and the mother, if taking part in the breast milk volume protocol). Full details about the stable isotope element of the survey are in section C.5.7.

C.4.3.1.2.1. Collection of dietary data: four-day food diary

Based on the day of the first individual CAPI interview, the interviewer's laptop program selected four consecutive days as the food diary recording period. Start days were randomised. The parent (hereafter referred to as 'the parent') who had most involvement in feeding the selected child was chosen for interview. If two parents shared the feeding of the child, one was selected to take part in the interview (on the basis of which one was most readily available), but ideally both were present during the completion of the questionnaire. Parents were provided with a food diary and asked to keep a record of everything their child ate and drank over these four days, both in and outside the home. Interviewers carried out a food diary check visit with participants on the second day of recording either in person or over the telephone, with the aim of improving recording for the remaining days and also providing encouragement to participants to continue recording. Interviewers then returned to collect the food diary and check the remaining days no later than three days after the final day of recording. See section C.4.3.5 for full details of the dietary data collection and processing protocols.

C.4.3.1.2.2. Anthropometry

Maternal measurements
Maternal height was measured using the portable 'Leicester' stadiometer. It is a lightweight, plastic collapsible device with a sliding head plate, a base plate and three connecting rods marked with a measuring scale.

Maternal weight was measured using calibrated Soehnle, Seca or Tanita digital scales.

Height and weight measurements were taken in metric units following a standardised protocol. Interviewers recorded the measurements for participants on a measurement record card, if the mother wished to receive them.

Infant measurements
Before any measurement was carried out, written consent was obtained from the parent of the child that was taking part in the survey.

Infant weight was measured using calibrated Soehnle, Seca or Tanita digital scales. Children were weighed whilst being held by an adult – interviewers first weighed the adult, then weighed that adult holding the child. The computer then calculated the weight of the child.

Infant length was measured using a Rollameter baby measure mat, and head circumference was measured using a disposable 'Lasso' measuring tape. All measurements were taken in metric units following a standardised protocol. Interviewers recorded the child's measurements on a measurement record card, if the participant wished to receive them.

C.4.3.1.3. Tokens of appreciation
In acknowledgement of the amount of time and effort participants were asked to devote to the survey, tokens of appreciation were offered to those who completed a food diary for three or four days (i.e. those defined as 'fully productive'). The tokens of appreciation were £30 in High Street gift vouchers for each participant. Those who took part in the second stage of the survey were also offered tokens of appreciation. These were as follows:

- £10 in High Street vouchers for attending a clinic and taking part in the physical measurements.
- £30 for providing a blood sample.
- £50 in High Street vouchers for participating in the breast milk volume protocol of the stable isotope element of the survey.
- £30 in High Street vouchers for participating in the fluid intake and body composition protocol of the stable isotope element of the survey.

C.4.3.1.4. Consent
Oral consent was obtained by interviewers for all interviewer elements of data collection. In addition, written consent from the parent was obtained by interviewers for all infant measurements.

C.4.3.1.5. Proxy interviews
If the person selected as the parent who had most involvement in feeding the child did not speak English, the interviewer was permitted to use a translator within the household (aged 12 or over only). Interviewers could only do this if that person was present when the food diary

was placed. Interviewers were also instructed to suggest that this person should visit the clinic with the participant and parent, to help with translation there.

C.4.3.1.6. Fieldwork

Fieldwork for the Dress Rehearsal took place between February and June 2010. Stage 1 fieldwork commenced on 15th February and was completed on 6th April.

C.4.3.2. Briefings, training and de-briefings

C.4.3.2.1. Interviewer briefings

Prior to starting fieldwork, interviewers attended a two-day training course, at which they were fully briefed on the administration of the survey. The briefing sessions covered background and content, doorstep approach, questionnaire administration (including practice sessions) and placement, checking and collection of the four-day diet diaries. In addition, training sessions were included for taking height and weight measurements from mothers, as well as length, weight and head circumference measurements from children. Since interviewers had not taken infant length and head circumference measurements prior to the briefings, a certification session was included to ensure they were sufficiently trained in each of the two measurements. Interviewers were also briefed on introducing Stage 2 (the clinic visit) as well as on the background and protocols for the stable isotope elements of the survey.

C.4.3.2.2. Interviewer training in anthropometric measurements

The two-day briefings included training sessions for each of the anthropometric measurements, as well as practice sessions (on dolls) and a certification process for the infant length and head circumference measurements. These sessions were led by paediatric nurses from the MRC Epidemiology Unit. The purpose of the certification process was:

- to ensure the nurses felt confident that each interviewer could perform each measurement as accurately and confidently as possible whilst in the field; and
- to ensure the interviewers were comfortable performing each of the measurements and were confident in carrying them out in the field.

Interviewers were not permitted to work on the survey until they had passed the certification process.

C.4.3.2.3. De-briefing of interviewers

After the completion of fieldwork, all interviewers were asked to complete a feedback form covering all aspects of their work on the Dress Rehearsal. The feedback form included sections on briefings, CAPI, food diary completion and introducing the clinic visit. In addition, some interviewers were invited to attend a one-day personal debrief session in London where they could provide further feedback and where group discussions could take place about all elements of the survey.

C.4.3.3. Inter-interviewer variation quality control

Due to predicted and inevitable attrition between the interview and the clinic visit, the preference for this survey at the outset was for interviewers to carry out as many of the infant anthropometric measurements as possible during Stage 1, to maximise the amount of data obtained. Pilot work (see Addendum 3 – 'MRC HNR Interviewer Skinfold Thickness measurements, report to the Project Board (October 2009)') prior to the Dress Rehearsal

concluded that it would not be possible for interviewers to take the skinfold thickness measurements and this was therefore carried out during the clinic visit. NatCen interviewers are already skilled at taking adult height and weight measurements, as well as infant weight measurements, so these were included as part of the interviewer visit in the Dress Rehearsal and will continue into the mainstage. However, NatCen has not previously conducted any studies where infant length and occipito-frontal (head) circumference measurements have been taken by interviewers. The feasibility of this was therefore tested as part of the Dress Rehearsal. This section provides information about the number of measurements obtained by interviewers (including how accurate they felt the measurements were) and a summary of the Quality Control (QC) day that was held at the end of the Dress Rehearsal fieldwork. The conclusion of this feasibility test is that both measurements will continue to be included at the interviewer visit for the mainstage. Proposed protocol changes to be addressed are provided in section C.9.0.

C.4.3.4. CAPI

The main interview for the Dress Rehearsal was carried out using computer-assisted personal interviewing (CAPI). The CAPI questionnaire had two elements:

- 'Household Structure' interview; and
- Individual interview

The questionnaire was organised into a number of modules that could be accessed at different times at the interviewer's discretion.

The 'Household Structure' interview allowed the structure of the household to be established, with questions about:

- Those living in the household's accommodation;
- The relationship of each person in the household to everyone else;
- The 'Household Reference Person' (HRP);
- The selected child; and
- The nature of tenure of the accommodation.

The Household interview also established each person's gender, date of birth or age, work status and ethnicity and their relationship to other household members.

The individual questionnaire had two parts:

- Part 1, which was asked before the dietary data collection period; and
- Part 2, which was asked after the dietary data collection period.

The individual questionnaire was divided into a number of sections. Each section is shown in order below:

PART 1 Sections

- Breastfeeding/weaning practices

- Eating patterns
- Developmental stages
- Dietary supplements and medications currently taken by child (and by mother if breastfeeding)
- Assessment of exposure to sunlight of child over previous 12 months
- Details of childcare arrangements
- Health information
- Sleeping and minor gastrointestinal symptoms
- Smoking and drinking habits of mother (and partner, if applicable) both currently and during pregnancy
- Socio-economic details of parents/primary carers

PART 2 Section

- Parent's dietary habits and usual eating patterns

In order not to over-burden participants, a particular concern with this target group, interviewers had the option to administer some modules from Part 1 during Part 2 instead. As long as they had placed the food diary, they could exit the interview at any given point and complete it when they returned to collect the food diary.

If a participant was eligible for, and agreed to take part in, the stable isotope part of the survey, there was a separate CAPI questionnaire component, which included administrative questions. It also included re-weighing the child (and the mother, if taking part in the breast milk volume protocol).

C.4.3.5. Diaries

C.4.3.5.1. Dietary data collection – estimated (unweighed) food diary

A new food diary specifically for young children was developed at HNR, incorporating many unique features that are required for effective infant dietary data collection. The food diary was based upon the current NDNS food diary and the food diary from another study, the Cambridge Baby Growth Study[1] (CBGS) for which HNR designed the food diary and carries out the diet coding. As a result of the pilot phases (see section C.4.3.5.2) undertaken by Newcastle University, which were complete before the Dress Rehearsal began, the food diary design incorporated the following:

- Food and drink to be recorded together. Feedback from parents involved in the pilot preferred the 'food and drink together' format.
- More space for writing. The final food diary is A4 in size (traditionally diaries for parental completion are A5).

The parent was asked to keep a record of everything the participant ate or drank over four consecutive days. Parents were also asked to provide basic information on the circumstances and context in which the participant was fed, i.e. with whom, where, whether they were at the table and whether or not the television was on.

Interviewers placed the food diary with the parent and then collected it within three days of the end of the four-day dietary recording period.

Parents were asked to record portion sizes in household measures or volume by the use of graduated implements. Where the graduated implements were used, parents were asked to identify this in the food diary so that there was a clear distinction between household and graduated measures. When placing the food diary, interviewers followed written instructions in the form of a script, which gave clear instructions on how to explain the food diary and the use of the graduated implements to the parent. Interviewers went through each section of the food diary, and completed a practice day with the parent to maximise their understanding of the level of detail required. Parents were also asked to collect food label information/wrappers for any unusual foods consumed to help coders accurately code each food or drink consumed.

Parents were asked to record food and drink consumed both at home and away from home, for example at the childminder's, or at a restaurant or toddler group. Therefore, they were expected to take the food diary with them when they were away from home.

Interviewers were instructed to arrange a follow-up visit on day two of the recording period to support the parent and check for missing detail. Interviewers were instructed to review the food diary with the parent to identify and edit possible missed foods or detail. Interviewer editing of the food diary was done in green pen so the HNR coders could see where the interviewer had probed. An interviewer checklist was provided for guidance on checking.

Interviewers were asked to complete feedback on each food diary, as soon as possible after collecting it. This gave an indication of how complete or accurate they felt the information recorded by the parent was.

C.4.3.5.2. Summary of pilot phases – Newcastle University

The purpose of the pilot phases was to:

1. ensure that the use of graduated containers given out to participants did not interfere with or alter the size of portions given to the participant; and
2. determine whether parents preferred recording food and drink 'as consumed' or 'served and left over'.

Portion sizes are difficult to assess in infants and young children and hence specific methods were designed for the survey to obtain validated data on portions consumed, by providing each parent with a graduated cup, graduated storage pots and a set of measuring spoons for prepared food. The intent of the pilot was to ensure that the provision of measuring implements did not lead to an alteration in the portions fed to children.

HNR's normal practice of collecting dietary information is 'as consumed'. This means that the parent of the participant in a study has to take account of any food not consumed when the diary is completed. For young children this is more difficult than for adults and older children since much of the food offered or available to be eaten is not actually eaten, partly because appetites are small and variable, but also because much food can be wasted in the effort to feed a young child where not all goes into or stays in the mouth and can be left on the child or the eating equipment. An alternative to recording food as consumed is to record separately

that which is 'served' and that 'left over' and then have the coder calculate the amount consumed. The pilot studies included trials of each way of recording information.

The pilot phases were conducted at Newcastle University under the leadership of Prof Ashley Adamson, and were divided into three phases:

1. **Pre-Pilot** – To discuss with parents through focus groups the best and most convenient way of measuring what infants eat.

2. **Pilot Phase I** – To trial a range of designed-for-purpose diet diaries and graduated measuring implements for ease of use and accuracy.

3. **Pilot Phase II** – To trial the modified designed-for-purpose diaries for ease of use and accuracy. To examine the impact of using graduated implements on portion sizes comparing estimated intakes to weighed intakes.

During the pilot phases, the use of a food diary which required the parent to record the amount of food or drink the child consumed was compared with another food diary which required the parent to record the food or drink served and then the amount left over. Diaries were designed to incorporate both 'as consumed' and 'food served and left over' methods, and parents were asked to comment on their preferred method during all three phases of the pilot study. The results of the first two phases of the pilot studies were available prior to starting the Dress Rehearsal. The results were inconclusive regarding the preferred method of recording. The 'as consumed' style of food diary was therefore used for the Dress Rehearsal.

The full report of the Newcastle pilot is in Annexe B.

C.4.3.5.3. Portion size equipment

In order to assess more accurately infant portion sizes, parents were each provided with a set of measuring implements, namely a graduated cup, graduated storage tubs and a set of measuring scoops. To test that the use of graduated implements did not interfere with or alter the size of portions given to the participant, measured intakes (four-day unweighed food diary) and weighed intakes (four-day weighed food diary) were compared. Each parent was provided with a set of weighing scales and a set of measuring implements. Each parent completed a weighed food diary and an unweighed food diary. See Table C.8.17 for usage of graduated implements.

During the pilot phases, finger foods were highlighted on a number of occasions as being difficult to measure. These were a specific area of focus during interviewer briefings to help parents describe finger foods as precisely as possible.

References and endnotes

[1] http://www.mrc-epid.cam.ac.uk/Research/Studies/CBGS 26 July 2010

C.5. Methods: Stage 2 – Clinic visit

C.5.1. Introduction of the clinic visit

The parent of each fully productive participant was introduced to the clinic visit protocol by the interviewer, asked to read a clinic visit information sheet (clinic documents can be found in Appendix F) and then asked if he/she was prepared to receive a phone call to discuss the components of the clinic visit in detail. If agreement was given to a clinic call, the interviewer proceeded to discuss the stable isotope element of the survey.

C.5.1.1. Stable isotopes using labelled water

As part of this Dress Rehearsal, each parent was asked to allow a measurement to be made of the child's daily fluid intake, including any breast milk consumed. This involved either both the mother and the child or just the child (depending on protocol) drinking a dose of water labelled with a stable isotope tracer. There were two different protocols which varied depending on whether or not the child was still breastfeeding.

C.5.1.2. Interviewer introduction of pre-dose urine collection

For each parent agreeing to being contacted about the clinic visit, the interviewer gave a short explanation of stable isotopes and the protocol (see section C.5.7) for this component of the survey and gave out an information leaflet. If interested in taking part, the interviewer also left a pre-dose urine collection kit. Based on the two protocols, one of the following pre-dose kits was distributed:

- Protocol 1: a set for the mother choosing the breast milk intake protocol (kit contained a collection bottle for **both** the mother and child).
- Protocol 2: a set for the parent choosing the body composition protocol (kit contained a collection bottle **only** for the child).

The interviewer asked the parent to collect the urine sample prior to attending the clinic visit and advised the parent that they would be called to discuss the clinic visit within a week.

C.5.1.3. Interviewer collection of urine samples

If the participant was subsequently successfully given the stable isotope dose at the clinic visit, the interviewer then returned to that household at the end of the survey to collect the urine samples and urine collection form, and posted these to HNR for analysis.

C.5.1.4. Interviewer informs HNR of urine samples collected

The interviewers informed HNR by telephone that a completed urine sampling kit had been posted to HNR and also provided a sample tracking number. On arrival at HNR all samples and the collection form were checked for completeness and consistency. Samples were then logged into the sample tracking system and transferred to the freezer for storage at -20°C prior to analysis. Records of all distributed kits were checked regularly against the expected number of kits returned and any instances where these expected timelines had significantly been surpassed were queried.

C.5.2. Clinic call

For a parent who had agreed to a clinic call, a member of the research team called within one week at the end of Stage 1 to discuss Stage 2 and to book a clinic appointment. All elements

of the clinic visit were discussed with the parent, including the consent process, the physical measurements and skinfold thickness tests, the blood sample and the stable isotope components (called 'labelled water' for ease of understanding), and also any questions answered. The components the parent proposed to be involved in were recorded. If the stable isotope component was proposed, the parent was reminded to collect the appropriate pre-dose urine sample(s) (Protocol 1 or 2) before the clinic visit and take it to the clinic appointment. The parent was also asked to take the child's usual feeding bottle in a 'ready to use' state for stable isotope tracer water administration. Transport to and from the clinic visit and reimbursement of expenses was discussed and organised on this call.

One of the aims of the Dress Rehearsal was to consider the practicalities and logistics of the various survey elements. To consider the feasibility of each clinic making their own booking calls, and to gauge how many calls were required to gain a response, the number of calls required per participant/per site to make a clinic appointment was assessed in the Dress Rehearsal. The two NHS sites (Manchester and Newcastle) were given the option to carry out their own clinic booking calls, or to have them carried out by HNR. Both sites opted to carry out their own calls, but only the Manchester site was able to complete this arrangement. Delays in launching the Newcastle site meant that the clinic booking calls for this site were carried out by a combination of the Newcastle CRF and HNR. For the two non-NHS sites (Cambridge HNR and the mobile unit operated by HNR in Falkirk), Cambridge undertook its own clinic booking calls, and for the mobile unit, the calls were made by a combination of the mobile unit staff and HNR.

Following the clinic calls, the components proposed by the parents were entered into a database, i.e. anthropometric measurements, stable isotopes (Protocol 1 or 2) and the blood sample. This information was then transferred to the stable isotope team to indicate those involved in the stable isotope component of the survey and the relevant protocol for each participant. This prompted the stable isotope team to prepare and issue the specific doses to the relevant clinics in time for the clinic appointments.

C.5.3. Nurse procedures

The second stage of the survey, the clinic visit, was carried out by a qualified nurse or phlebotomist. All parents who completed at least three food diary days for their child were eligible for a clinic visit. Consent was taken on arrival at the clinic and a study conduct information sheet was given to the parent.

C.5.3.1. Consent

Written consent was taken from the parent of the participant for all components of the clinic visit. To ensure informed consent the process was staged into:

- General statements;
- Physical measurements including skinfold thicknesses;
- Either measurement of breast milk intake (Protocol 1) or measurement of body composition (Protocol 2);
- Blood sample; and
- Contact details where the parent did not want results sent to them personally or to the GP so that clinically relevant results could be discussed (see section C.7.2).

C.5.3.2. Anthropometric measurements

At the clinic visit, physical measurements were undertaken, including infant length, weight and head circumference. The height and weight of the mother was also recorded. Infant skinfold thickness tests were taken at two places on the child's body: triceps and subscapular.

C.5.3.2.1. Maternal height

Height was measured using a fixed stadiometer with a sliding head plate. The parent was asked to remove shoes, stand facing forwards with feet flat on the centre of the base plate, feet together and heels against the rod. The parent was asked to stretch to maximum height with the head positioned in the Frankfort plane. A maximum of three measurements was taken, the third required if the difference between the first two measurements was greater than 0.5cm. Readings were recorded to the nearest millimetre. An average of the two closest measurements was used for analysis.

C.5.3.2.2. Maternal weight

Weight was measured using electronic scales with a digital display. The mother was asked to remove shoes and any bulky items of clothing. A single measurement was recorded to the nearest 0.1kg.

C.5.3.2.3. Infant weight

Infant weight was measured using infant electronic scales, if available. If not, having weighed the adult, the adult plus the child was measured in order to obtain the weight of the child. A single measurement was recorded to the nearest 0.1kg.

C.5.3.2.4. Infant length

Infant length was measured using a Rollameter baby measure mat. Bulky clothing was removed and the Rollameter was used on any suitable flat, firm surface. The head was moved into a suitable Frankfort plane position and the legs were held straight by applying gentle downward pressure. A maximum of three measurements was taken, the third required if the difference between the first two measurements was greater than 0.5cm. The readings were recorded to the nearest millimetre. An average of the two closest measurements was used for analysis.

C.5.3.2.5. Occipito-frontal (head) circumference

The Child Growth Foundation disposable head circumference tape[1] was placed around the child's head so that the tape lay across the frontal bones of the skull, slightly above the eyebrows, above the ears, and over the occipital prominence at the back of the head (the widest part of the child's head). The tape was tightened so that it fit snugly around the head and compressed the hair and underlying soft tissues. A maximum of three measurements was taken, the third required if the difference between the first two measurements was greater than 0.5cm. The readings were recorded to the nearest 0.1cm. An average of the two closest measurements was used for analysis.

C.5.3.2.6. Skinfold thickness measurements

Infant skinfold thicknesses were taken using the Holtain Tanner skinfold caliper[2]. The parent/carer was asked to remove the child's upper clothing, ensuring first that the room was warm and draught-free and that the child was not exposed longer than necessary. The child was held by the parent in a supine or sitting position while the measurement was taken. The jaws of the caliper were slowly and gently released to sit either side of the exact point of

measurement. The skinfold thickness was measured at the left side of the body at the tricep and the subscapular positions. The measurements were taken three times at each site to the nearest 0.1cm. Any problems in taking the measurements were recorded at the time they were taken.

C.5.4. Blood sample

A small (4ml) non-fasting blood sample was taken by venepuncture, by a nurse or phlebotomist with paediatric phlebotomy experience. Blood samples were collected using the Starstedt Monovette blood collection system with a butterfly and one attempt only was made. The parent of the participant was offered the use of anaesthetic cream on the child's arm to reduce discomfort. (see Appendix I for consent documents, section C.5.4.1 for the blood analytes measured, section C.5.5 for the methods of blood analysis and section C.5.6 for quality control).

Blood was collected in a syringe and placed into two tubes, a 1.2ml EDTA monovette and a 2.7ml Serum monovette, in that priority order. The EDTA monovette was sent to Addenbrookes Hospital in Cambridge by first class Royal Mail post on the day of sampling. Where 1ml blood was achieved for this tube, a full blood count (FBC) analysis was undertaken. Once analysed, the FBC results were sent both by post and electronically to HNR, where the results were entered into the DNSIYC database. They were later merged into feedback letters (see section C.7.0) and sent to the parent of the participant and the GP, if consent has been obtained separately.

The Serum monovette was processed at the clinic location (i.e. in the clinic laboratory or in the mobile unit). The sample obtained was centrifuged to separate the serum from the red blood cells. The serum was then aliquoted into two 500µl microtubes and placed in either a -40^{o}C or -80^{o}C freezer. Where a partial sample was achieved, this was noted at the time of blood taking on the blood tracking form (BTF). Samples in the mobile unit were transferred to a -80^{o}C freezer at the MRC Human Genetics Unit (HGU) in Edinburgh (see section C.5.12) at the end of each week, to ensure the integrity of the samples over the weekend when the mobile unit was not staffed. The samples remained stored at MRC HGU until they were transferred to HNR. Samples were couriered on dry ice from each site to HNR at the end of the Dress Rehearsal. When the samples arrived at HNR, they were checked, along with their paperwork (the BTF), against a sample reception list, and any irregularities were reported and corrected before the samples were entered into the Item Tracker software and placed in a -80^{o}C freezer for storage prior to analysis.

C.5.4.1. Blood analytes

The blood obtained from participants was analysed for full blood count (FBC), iron status markers (ferritin, serum transferrin receptors and C-reactive protein), and Vitamin D (as 25-OH Vitamin D), in that order of priority.

The FBC analysis comprised:

- Haemoglobin;
- Haematocrit;
- Mean Cell Volume;
- Mean Cell Haemoglobin;
- Red blood cell count;

- Platelet count;
- Neutrophils;
- Lymphocytes; and
- Monocytes.

C.5.5. Analytical techniques

C.5.5.1. FBC analysis

FBC was analysed on a LH700 series analyser at Addenbrookes Hospital. Red blood cells, white blood cells and platelets and their size distribution were measured using the Coulter principle; cells were counted and sized by measuring changes in electrical resistance when cells passed through a small aperture. Haemoglobin was measured spectrophotometrically. Different white cell types were characterised using laser technology. This is the same technology as is used by this laboratory for very large numbers of clinical samples; both accuracy and precision are tightly controlled.

Analysis for iron and vitamin D status was undertaken at HNR.

C.5.5.2. Iron status

Iron status was determined through concentrations of ferritin and serum transferrin receptors. CRP was used to ensure that ferritin was not raised by an acute-phase reaction.

- **Ferritin** is an iron storage protein and its concentration in serum or plasma is a good indicator of iron status in the absence of an acute-phase reaction; however, inflammation can cause a rise in circulating ferritin unrelated to iron status. Ferritin is measured in DNSIYC at HNR using a specific monoclonal antibody to ferritin coupled to very small solid particles. When this reacts with ferritin the Siemens instrument records the resulting change in the optical properties of the reaction mixture.

- **Serum transferrin receptors (sTfR)** are an independent measure of iron status, unaffected by any acute-phase reaction. The assay is an immunometric ('sandwich') enzyme-linked immunosorbent assay (ELISA) (RAMCO) quantitated by the production of a coloured product. This assay can be performed on a semi-automated system for optimum traceability or manually on very small volumes of serum or plasma when sample size is limiting.

- **C-reactive protein (CRP**) is an acute-phase protein and when raised, i.e. during infection, an acute-phase reaction is suspected indicating that the ferritin concentration may not reflect iron status. CRP is measured turbidimetrically on a Siemens automated instrument. Monoclonal antibody to CRP is coupled to very fine particles; reaction of these with CRP (in serum or plasma) results in an increase in turbidity which is measured optically.

C.5.5.3. Vitamin D Status

25-OH Vitamin D was measured on an automated platform (Diasorin Liaison) which releases 25-OH vitamin D from its binding proteins prior to immunoassay with magnetic separation and chemiluminescent detection technology. This is a competitive assay; the signal is inversely proportional to the 25-OH vitamin D concentration in the serum or plasma sample. The method

measures both D_2 (from plant-derived foods and synthetic supplements) and D_3 (produced in the skin as a result of exposure to sunshine, also present in animal-derived foods).

C.5.6. Quality Control

The Vitamin D, ferritin, CRP and sTfR assays were internally controlled to check for good within-batch and between-batch precision, by including commercial control samples and internal drift controls. To control accuracy, HNR subscribes to external quality assessment schemes administered by NEQAS (National External Quality Assessment Service).

No external scheme is available for soluble transferrin receptors; this assay was controlled internally as above and the manufacturer's recommended ranges were used as a guide to ensure accuracy of results.

For each method, if a quality control (QC) sample result was unacceptable, the assay run was repeated.

C.5.7. Stable isotope labelled water

This section describes the two stable isotope protocols, the techniques used to analyse the urine samples and the quality control procedures. The most important urine sample was the pre-dose sample, which the parent was asked to take to the clinic visit. This sample is the baseline sample and is critical in order to determine changes in concentrations of the stable isotope after taking the dose. Therefore, if the mother arrived at the clinic visit without the pre-dose urine sample for herself (if taking part in Protocol 1) or her child, then she was asked to collect a further pre-dose sample at the start of the clinic visit.

C.5.7.1. Protocol 1 – Breastfeeding mothers

Each mother who reported some degree of breastfeeding was asked whether she would be willing to participate in the breast milk intake aspect of the survey. If willing, she was asked to collect a pre-dose (baseline) spot urine sample from both herself and her child and then to attend the appropriate clinic, taking these samples with her.

At the clinic the mother was given an oral dose of 50g of approximately 10% deuterium-enriched water, and the child was given a $4gkg^{-1}$ oral dose of approximately 5% ^{18}oxygen-enriched water. The child's dose was calculated from the child's body weight obtained at Stage 1.

The mother then collected further spot urine samples from herself and her child each day for 14 consecutive days, starting the day after the clinic visit. At the end of this period the urine samples were collected by a NatCen interviewer and dispatched to HNR for analysis. At this interviewer visit, the weights of the mother and child were re-measured and recorded.

C.5.7.2. Protocol 2 – Non-breastfeeding mothers and breastfeeding mothers unwilling to collect urines for 15 days

Each parent who was not eligible for, or mother who declined to participate in, the breast milk volume assessment, was asked if they would be willing to participate in the infant fluid intake and body composition component of the survey. If willing, the parent was asked to collect a pre-dose spot urine sample from the child and take it to the arranged clinic visit.

At the clinic, the child was given a $4gkg^{-1}$ oral dose of approximately 2.5% deuterium-enriched water, based on body weight at Stage 1.

The parent had then to collect spot urine samples from the child each day for five consecutive days starting the day after the clinic visit. At the end of the survey period the urine samples were collected by a NatCen interviewer and dispatched to HNR for analysis. At this visit by the interviewer, the weight of the child was re-measured and recorded.

C.5.8. Labelled water analytical techniques

Urine sampling kits arriving at HNR were inspected for completeness and then stored at -20°C until analysis. The sample preparation and mass spectrometric methods used in DNSIYC are described in detail in Bluck 2008[3]. Briefly, the urines were placed in isotopic equilibration with a suitable light gas (hydrogen for ^{2}H and CO_2 for ^{18}O determination) and the gas was sampled and analysed by isotope ratio mass spectrometry.

For those participants who took part in the breastfeeding protocol, deuterium enrichment analyses were performed on pre-dose urine samples and on days one, two, three, five, 13 and 14 after dosing. These values were then used to calculate the levels of breast milk intake for each child. ^{18}Oxygen enrichments were also measured in pre-dose urines and urines collected on days one to five for each child in order to calculate their body composition.

For those participants who reported no degree of breastfeeding, or who declined to participate in the breast milk volume assessment, and agreed to take part in the infant water turnover protocol (body composition) instead, samples of pre-dose urine and samples from days one to five inclusive were measured for determination of deuterium enrichment.

C.5.8.1. Quality Control

The quality of the measurements was continuously monitored by including quality control standard waters in each analytical batch, which indicated that the instruments were performing to within specification.

The data obtained were interpreted in the context of established kinetic models to obtain parameters of breast milk and non-breast milk water intake in the children. In the course of modelling, the measured enrichments of each sample were checked for consistency by plotting them on the theoretical curves of enrichment and disappearance in each case, and were found to be adequate.

In summary, the analytical measurement and modelling techniques employed in the Dress Rehearsal have been successful in achieving the intended goals, and there is no reason to suggest that any changes are necessary in these areas for the mainstage survey.

C.5.9. Clinic locations

C.5.9.1. Recruitment

For the Dress Rehearsal, three locations were identified. These were:

- Manchester Wellcome Trust CRF, with which HNR had considerable experience, this having been one of the clinics used for the National Survey of Health and Development[4] (1946 British birth cohort) at age 60-65 years from 2006-2011;

- Royal Victoria Infirmary CRF in Newcastle in collaboration with Newcastle University. This contact was made through Professor Ashley Adamson who was already involved in DNSIYC through the portion size pilot work; and
- Cambridge HNR – the base for the clinic visits.

In addition, a mobile unit was established for conducting clinic visits in rural and remote areas where the distance to attend the clinic would be too great for a parent and young child. Details of setting up the mobile unit are given in section C.5.12. Mobile unit staff, comprising a van driver/research assistant and a research nurse/phlebotomist were recruited.

Each clinic was visited by the HNR team and considerable communication took place prior to R&D submission, which was carried out for each location. Applications were approved by Manchester Wellcome Trust CRF and Newcastle CRF to undertake the clinic visit within their NHS Trust and using CRF research nurses. MRC Epidemiology Unit research nurses were recruited to undertake the clinic visits at the Cambridge site at HNR.

C.5.10. Briefings and de-briefings

C.5.10.1. Nurse briefings

A one-day briefing was undertaken at each clinic location to cover the following elements:

- Background and aims of the survey;
- Overview of Stage 1;
- Review of the survey documentation;
- Review of the survey protocols;
- Training on specific protocols, i.e. skinfold thickness and stable isotope protocols;
- Blood processing protocol; and
- Data transfer requirements.

Two nurses were trained at each site to undertake the clinic visits. The nurses were given a 'sample pack' containing all the necessary equipment for one complete clinic visit. Nurses were asked to prepare packs with all the necessary documentation and equipment ready for each clinic visit.

A further day's training was necessary for the mobile unit staff to brief them on the use of the mobile unit.

C.5.10.2. De-briefing of nurses

Following completion of the clinic visits, the nurses were asked to complete a single feedback form. The feedback covered all aspects of the nurses, work on the Dress Rehearsal, and included sections on briefings, documents, data, perception of how informed parents were, clinic protocols covering each of the measurements (blood, stable isotopes, and skinfold thickness, blood processing), the management of the project and communication.

Since the de-brief it has been decided that HNR will prepare all participant packs and send them in bulk to the clinics to ensure consistency across clinic sites.

C.5.10.3 Inter-nurse variation quality control

Nurses at two sites (Cambridge and Manchester) were instructed to undertake an inter-nurse quality control exercise, assessing the quality of the infant measurements including infant

length, head circumference and tricep and subscapular skinfold thickness measurements. Manchester nurses used a variety of DNSIYC children and other study children within the four to 18 months age range and Cambridge nurses undertook the QC on children from the Cambridge Baby Growth Study[5]. Nurses at each site were asked to measure the same three or four children so that inter-nurse variation could be assessed.

C.5.11. Clinic fieldwork

The clinic fieldwork started on 16th March and continued until 1st June 2010; urine sample collection visits therefore continued for interviewers until 22nd June 2010. The sites started clinic visits at different times; the period was dictated by receipt of local R&D approval.

Table C.5.1: Fieldwork timelines by site

Site	Fieldwork commenced	Fieldwork complete
Cambridge	16 March 2010	14 May 2010
Manchester	17 March 2010	11 May 2010
Newcastle	12 May 2010	1 June 2010
Falkirk	22 April 2010	18 May 2010

Table C.5.1 shows that Cambridge and Manchester were the first two sites to undertake clinic visits. The mobile clinic started later than anticipated due to delays in purchasing and refurbishing the van (see section C.5.12) and in staff recruitment. The Newcastle clinic also started later than anticipated due to delays in R&D approval (see section C.3.3).

C.5.12. Mobile unit

C.5.12.1. Set-up and operation

The purpose of the mobile unit was to reach participants in rural locations, where clinics were too far away to be reached within a reasonable amount of time (one hour) for a parent with a young child. This would then optimise response rates for blood, anthropometric measurements and stable isotope measurements. Expertise in working with young children, including taking blood, was an essential requirement for the survey and the staff within the mobile unit. However, there is a lack of paediatric phlebotomists in the UK overall and this was a consideration in the recruitment process. The mobile unit also had to have laboratory processing and storage facilities, such that blood samples could be processed immediately after collection and samples could be stored frozen prior to shipment to HNR.

C.5.12.2. Refurbishments

The mobile unit used in the DNSIYC Dress Rehearsal was purchased from Norwich and Norfolk University Hospitals NHS Foundation Trust, where it had been used on previous research studies in the Norwich area. The Mercedes Sprinter 211cdi van was refurbished by Commercial Bodies East Anglia to include the safe and secure provision of laboratory equipment including a fridge, freezer and centrifuge and appropriate power supply. The equipment had to be bolted into the van to ensure it did not move about during transit. To enable all the elements of the clinic visit to be undertaken, the following equipment was fitted and secured into the mobile unit:

- -40°C freezer

- fridge
- bench top centrifuge
- an adequate bench top to undertake infant length measurement
- an electronic scale
- a height measure
- a battery-operated two-decimal-place scale to record the weight of the stable isotope doses
- alcohol hand gel
- gloves for blood taking
- a filing cabinet for secure storage of documents and blood taking equipment, i.e. sharps
- a safe to secure any confidential data and personal effects.

The van had tinted windows to ensure confidentiality and privacy during participant visits. The mobile unit was also fitted with computer equipment, including a laptop and a printer/scanner to enable regular communication with the survey team at HNR in Cambridge.

A battery system and solar panel were adopted to ensure a constant supply of power to the fridge and freezer, even when the van was not switched on. The power supply of the van was fully powered and recharged by a 13 amp plug with a cable that fits into a normal household socket. It was necessary for the van to be fully powered overnight to ensure the batteries were fully charged each day. An arrangement was made with the MRC Human Genetics Unit in Edinburgh to operate as the mobile unit base, providing a mains power source and a base for delivery and storage of supplies and disposal of clinical waste.

C.5.12.3. Procedures

Parents of participants in an area around Falkirk, Scotland were invited to attend their clinic visit on/via the mobile unit, which was driven to their home address. All clinic visit components could be carried out on the mobile unit, including infant length, weight, head circumference, skinfold thicknesses, blood sample, and body composition, breast milk and fluid intake measured by stable isotopes. While clinic visits were carried out on the mobile unit, all doors remained closed to ensure participant confidentiality and privacy. The option was also given for the nurse/phlebotomist to carry out the clinical procedures in the participant's home where the parent might feel more comfortable and/or where there was more than one child present and hence insufficient space in the mobile unit.

References and endnotes

[1] http://www.childgrowthfoundation.org/ghd.htm 11 August 2010

[2] http://www.holtain.com/tw.php 11 August 2010

[3] Bluck LJC. Doubly labelled water for the measurement of total energy expenditure in man - progress and applications in the last decade, 2008. Nutrition Bulletin 33: 80-90.

[4] http://www.nshd.mrc.ac.uk/ 26 July 2010

[5] http://www.mrc-epid.cam.ac.uk/Research/Studies/CBGS/ 26 July 2010

C.6. Methods: Data

C.6.1. Data Processing

C.6.1.1. CAPI

Data collected by CAPI was automatically checked for valid ranges, routing and consistency. An edited version of the Blaise Dress Rehearsal interviewing instrument was developed to cater for additional office checks. Responses to 'open' questions and 'other answers' were scrutinised to inform the development of code frames for the mainstage.

C.6.1.2. Dietary assessment system – DINO (Diet In Nutrients Out)

Dietary data from diet diaries was entered into HNR's dietary assessment system DINO. DINO, written in Microsoft Access, is an all-in-one, dietary recording and analysis system which is linked to the nutrient data held in the NDNS nutrient databank. The NDNS databank is updated each year of the NDNS rolling programme. The version of the databank used for the Dress Rehearsal was year 2 of the NDNS rolling programme.

C.6.1.3. Coding of dietary data

Diet diaries were returned by interviewers and sent to HNR via NatCen's Operations Department for coding. Throughout fieldwork, the standard of each interviewer's work was monitored closely by a series of early work checks carried out by the dietary assessment team. Comments were then fed back to the interviewers from HNR via NatCen.

Each food was entered into DINO as part of a particular eating occasion. Foods were entered as discrete items or as part of a recipe. In DINO, each food code is linked to appropriate portion size descriptors for that food, which are then linked to the correct weight for the portions described for that particular food. Where portions were recorded as a number of spoons, either household or study spoons, the coder was required to obtain a weight from the database of spoon weights. This contains data on weights of food for particular spoon sizes. Where the graduated tubs were used, weights were converted from volume to weight and entered as weight (g) into DINO. Spoon weights were collated along with conversion factors on a weekly basis from the study team at Newcastle University.

C.6.1.4. Practical coding issues

The Dress Rehearsal diet diaries were difficult and time consuming to code, mainly due to the use of the graduated implements as well as the lack of information on infant foods in the NDNS databank. This resulted in a high volume of queries and lower coding rates than for other studies coded at HNR.

Low coding rates were due to a number of factors:

- Most foods in DINO are available only as weights (g) and therefore foods which were measured using the graduated tubs required conversion from volume to weight before entry into DINO. These were all recorded as queries until resolution, when they were re-entered with the updated information.

- Entries that were difficult to interpret required the coder to undertake a number of conversion factor calculations (converting weight to a volume and then back to a weight) to estimate the amount of food/drink consumed.

- The NDNS databank initially had very few infant foods and therefore a substantial amount of time was spent searching for unknown infant foods so that these could be added.

- Where portion sizes were recorded using household spoon measures or study spoons, weights for these were obtained from the team at Newcastle University. There was therefore a time delay between relaying the conversions needed to Newcastle University and waiting for weights to be returned to HNR. Coders then had to search the spoon weights database for a relevant weight before entry into DINO.

- The high volume of queries led to considerable time spent editing once they were resolved.

- Due to the novelty of coding diaries where graduated implements were used, a number of coding issues arose which required ongoing training and support which in turn took time away from actual coding.

A high volume of queries was due to:

- Food codes not being available in DINO.

- Conversion factors and spoon weights being unavailable for foods measured using the graduated implements.

- Food diary entries that were difficult to interpret and required clarification from the dietary assessment team.

C.6.1.5. Editing and dealing with missing data

Where an important detail for the coding of foods was missing, the dietary assessment team used a formally agreed default code; for example, unknown type of cow's milk consumed was coded for infants and young children as whole milk. Where a portion size was missing, an estimate was made using the same weight of the food if consumed on another food diary day, or if not, a portion size consistent with the participant's age. There were a number of eating occasions where participants had vomited after feeding. Based on data regarding gastric emptying[1] and HNR's previous experiences of coding the Cambridge Baby Growth Study[2] it was decided that where a vomit had been recorded within one hour of a liquid feed, 50% of the food consumed at the feed previous to vomiting should be coded. For a solid feed, 25% was coded if the vomiting occurred within one hour. Any vomiting at a time greater than one hour of feeding was to be coded as all consumed.

For food items not already in DINO, the dietary assessment team determined whether a new food code was needed based upon the nutritional composition of the food compared with the composition of similar existing codes; advice from the FSA assisted this decision. Where a portion was indicated in the food diary but there was no corresponding portion code on DINO, a new portion code was created using either a weight from an equivalent food, or the food item was weighed and the weight entered into DINO.

For a homemade dish where a recipe had been recorded, the ingredients were entered individually using the appropriate cooked food codes. Each individual food code that made up a recipe was allocated a recipe food group. The weight of each cooked ingredient was calculated

using the raw weight recorded by the parent, a weight loss for the entire dish (from a comparable recipe in McCance and Widdowson's The Composition of Foods series 6-16[3]) and the weight of the portion consumed. Where the food was stated as homemade but there was no recipe given, a standard homemade recipe code was chosen based on those in McCance and Widdowson's The Composition of Food Series 6-16[10]. Individual components consumed within a recipe dish were grouped together into their respective food group.

C.6.1.6. Coding error rate

Food diary coding was carried out at HNR by coders who were all trained by the HNR dietary assessment team. During the Dress Rehearsal coding period, a random 10% of diaries were 100% checked for all food and portion entries. This ensured that error rates for all the coders working on the project were below 5% and helped to highlight any coding issues.

C.6.2. Transfer of data

C.6.2.1. NatCen to HNR

NatCen transferred two files to HNR:

1) A file with the relevant dietary information including the number of completed food diary days, the child's name, date of birth, whether carer forms had been collected, whether an evaluation form had been completed and whether packaging had been collected; and
2) A file with the contact details for those willing to have a clinic call, called the 'clinic details' file. The clinic details file showed contact details, basic anthropometric data and stable isotope eligibility of participants who were willing to be contacted for the second stage.

These files were downloaded via a secure Citrix connection two or more times a week, or as necessary.

C.6.2.1.1. The 'clinic details' file

The 'clinic details' file is a file downloaded from NatCen showing contact details, basic anthropometric data and stable isotope eligibility of participants who were willing to be contacted for the second stage. The file was downloaded via secure Citrix connection two or more times a week. The secure Citrix connection was set up as follows:

- The DNSIYC 'system' is accessed externally from NatCen via two factor authentication.
- External access is made across the internet to a secure sockets layer (SSL) encrypted citrix access gateway (CAG) appliance which is located in the NatCen demilitarised zone. Access is passed from the CAG to a local area network (LAN) based server holding the data.

C.6.2.2. HNR to and from clinics

Clinics were given access to a secured MS Access database. Relevant data was extracted from the NatCen clinic details file and clinics were sent a password-encrypted zip file so that they could access contact details for the parents of participants. Each clinic database contained only the participants relevant to that clinic.

Procedure

- Each clinic un-zipped and loaded a clinic file with a built-in procedure for the secured MS Access database. The clinic file was sent from HNR twice a week initially, then daily.
- The clinic (or HNR) contacted each parent and arranged the clinic visit.
- The clinics updated the details of proposed protocols for each participant. They also recorded GP details as well as the clinic appointment date and time.
- The clinics extracted data from the database using an automated procedure and returned it to HNR on a (usually) daily basis. To ensure data security, personal identifying data were not included in this transfer.
- The clinics updated the details of the actual components undertaken following the clinic visit.
- Data from clinics were merged into the central database each time HNR received an extract from a clinic.

C.6.2.3. Internal HNR data transfers

Stable isotopes

An extract of the clinic database was produced for the stable isotope team after receipt of a file from a clinic. This showed the proposed stable isotope protocol (1 or 2) along with the dates of clinic visits, date of birth (DOB), gender, and height and weight measurements from the NatCen clinic details file. Provision was made to handle changes to clinic appointment dates and for the change from protocol 1 to 2 in the event that breastfeeding mothers were not willing to take part in protocol 1.

Barcodes

A file was used to print barcode labels for each participant where a new appointment for a clinic visit was made. This was produced following receipt of each file from the clinics. A file containing the barcode numbers that were issued was imported into the central database.

C.6.2.4. HNR to NatCen

A file was sent to NatCen following receipt of each file from the clinics showing the stable isotope protocol undertaken and the date the dose was given. This file was transferred using the secure Citrix connection. This information was used to arrange the interviewer collection of urine samples from participants.

C.6.2.5. Addenbrookes to HNR

Blood results received from Addenbrookes were imported into the central DNSIYC database upon receipt. The results were saved and then mail merged into the feedback letters that were sent to participants and GPs (see section C.7.0).

C.6.2.6. Data reconciliation

Data process monitoring was put in place at the following stages of the clinic process to check that:

- consent was held where blood was taken;
- consent was held where stable isotope was dosed;
- consent was held where skinfold thickness measurements were taken;

- the blood tracking form was received at HNR (where blood was taken or attempted);
- blood status (obtained, attempted, refused) was consistent between the blood tracking form and the data returned by the clinics; and
- date of the blood sample was held.

References and endnotes

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C.7. Methods: Providing personalised feedback to participants

Providing individualised dietary feedback and breast milk intake feedback to parents of participants was seen to be an additional incentive to participation in the survey. Feedback of clinically relevant blood results was also sent to GPs and parents (if consented) with guidance for parents on how to interpret the results.

C.7.1. Dietary feedback

The aim of the dietary feedback was to provide individual results for selected nutrients in the context of population intakes and in relation to nutrition recommendations for infants and young children. The nutrients chosen for dietary feedback in DNSIYC comprise those of particular interest for the nutritional health of young children, and which are therefore of interest to the public and are the focus of initiatives to improve the health of this population group. Nutrients included in the dietary feedback were protein, vitamin C, calcium, iron and non-milk extrinsic sugars (NMES). Total energy (kcal) was also provided. For breastfed infants additional information was provided to indicate that recommendations were designed for non-breastfed infants and that their results should be viewed accordingly.

C.7.1.1. Format of feedback

The dietary feedback information for each nutrient was presented in the form of a graph, which indicated the actual value for the intake of the nutrient by the participant in the context of the recommendation for this nutrient for this age group and usual intakes from a previous survey (NDNS of children 1.5-4.5 years for the older age group and Food and nutrient intakes of British infants aged 6-12 months (Mills and Tyler 1990) for the younger age groups). Alongside each graph, the parent was informed briefly about the importance of the nutrient for health and the types of foods that provide that nutrient. Feedback was accompanied by general healthy eating advice and direction to useful websites such as those of the FSA, the DH's 5-a-day programme, Healthy Start and Start4Life.

C.7.2. Breast milk volume feedback

The feedback of breast milk intake was sent exclusively to the parents of participants who reported some extent of breastfeeding. The feedback was issued to participants within four months of participation in the clinic visit of the Dress Rehearsal. The aim of the breast milk feedback was to provide each breastfeeding mother with an indication of the volume of breast milk consumed by the child. Three pieces of information were provided within the feedback:

1. volume of fluid taken in per day (ml);
2. volume of breast milk consumed per day (ml); and
3. percentage of the total fluid per day which was consumed as breast milk.

C.7.3. Blood analyte feedback

Feedback of blood results was issued to both the parent of the participant and the participant's GP if consent was given at the clinic visit. Feedback of blood results was reported in two letters:- The first letter, reporting the FBC results listed in Table C.7.1 was posted to participants in batches within two months of the clinic visit. The second letter contained results of the analyses for iron and vitamin D status, and was posted to participants within four months of the clinic visit (see Table C.7.2).

Table C.7.1: Full blood count analytes with ranges and units

Test	Analyte	Results[1]	Reference Range	Units
Full blood count	Haemoglobin		2-5m: 9.5-13.5 5m–3y: 10.5-13.5	g/dl
	Haematocrit		2-5m: 0.29-0.41 5m–3y: 0.33-0.39	l/l
	Mean Cell Volume		2-5m: 74-108 5m–3y: 70-86	fl
	Mean Cell Haemoglobin		2-5m: 25-34 5 m–3y: 23-31	pg
	Red blood cell count		2-5m: 3.1-4.5 5m–3y: 3.7-5.3	10^12/l
	Platelet Count		ALL: 150-450	10^9/l
	White blood cell count		2d–2y: 6.0-18.0	10^9/l
	Neutrophils		ALL: 2.0-6.0	10^9/l
	Lymphocytes		2-4m: 3.7-9.6 5-8m: 3.8-9.69 9-14m: 2.6-10.4 15m-2y: 2.7-11.9	10^9/l
	Monocytes		ALL: 0.15-1.5	10^9/l

Table C.7.2: Analytes measured to interpret iron and vitamin D status, ranges and units

Test	Analyte	Results[1]	Reference Range	Units
Iron status	Ferritin		1-6m: 8-275 6m–15y: 8-116	µg/l
	Transferrin receptors		ALL: 4.5 – 11.1	µg/l
Vitamin D	25-hydroxyvitamin D		ALL: 25-150	nm/l

[1] *Results that fall outside the reference/normal range are marked with an **

For both sets of feedback, any results that fell outside reference or normal ranges were marked with an asterisk* on the feedback letter. The survey doctor's name and telephone number were on the letter if the parent of the participant or the GP wished to follow up with the survey team about the feedback letter or the results.

For both sets of feedback, if any analytes could not to be measured the following codes were inserted into the results box:

- NA = not applicable
- NM = not measured
- NR = for technical reasons it was not possible to carry out this analysis

Where the child's results were at an actionable level (see Addendum 2) and immediate action might have been required, Addenbrookes alerted HNR, who contacted the survey doctor, Dr Ken Ong. The survey doctor then contacted the parent of the participant to discuss the abnormal result. In the event that the parent did not want blood feedback letters sent to either

themselves or their GP, contact details were taken for the parent, which allowed the survey doctor to contact the parent in the event of a clinically actionable analyte level.

C.8. Results

C.8.1. Response rates (overall and at each stage)

C.8.1.1. Introduction

Response rates in this report are based on 100% coverage of addresses issued to interviewers in the Dress Rehearsal. Please note that figures presented are taken from unedited data and are hence subject to change after data cleaning. The report covers:

- Summary of achieved household response rates; and
- Individual response rates:
    - to aspects of the survey;
    - to proposed and actual clinic visit, by clinic site;
    - breakdown of clinic outcome, by age group;
    - breakdown of blood and stable isotope outcomes, by age group;
    - breakdown of clinic outcome, by clinic site; and
    - breakdown of blood and stable isotope outcomes, by clinic site.

The overall response rate target for the survey was to achieve 58% of fully productive participants (three or four completed food diary days) within eligible households. Target response rates for the different stages of the survey are summarised in Table C.8.1, below.

Table C.8.1: Summary of target individual response rates

	Target:
Fully productive (at least 3 food diary days)	58% of those sampled
Visited clinic	60% of fully productive participants
Gave blood sample	50% of fully productive participants

C.8.1.2. Household response

In the Dress Rehearsal, 315 addresses were issued to interviewers. Of these, 82% were eligible to take part, 10% were ineligible for selection and 9% were screened out. In the Dress Rehearsal, ineligible addresses consisted of those addresses where the parent named on the sample file had moved (with the eligible child) to an address that was not possible to obtain or to an address that was out of the sample area. Screened out addresses included those with no child with the correct date of birth (or a similar date of birth – within one month) as specified on the sample file or where a child was ineligible due to feeding problems at birth or a birth weight less than 2.0kg. Ineligible addresses were defined as such on the doorstep by interviewers. Addresses were screened out at an early stage in the CAPI program when the interviewer found out if the child had a birth weight of less than 2.0kg, had been fed by a feeding tube or if the child had been referred to a hospital dietitian. In these situations, interviewers explained to participants that we were unable to include them further in the survey and the interview was terminated at that point.

The process of deciding the eligibility of children for the Dress Rehearsal included three CAPI questions to exclude children with a birth weight of less than 2.0kg or those with congenital abnormalities that affected feeding. The three questions were:

1) How much did 'childname' weigh when he/she was born?

2) Can I just check, has 'childname' ever needed the help of a stomach tube to help with his/her feeding - either just after birth or at any other time?
3) Have you ever been referred to or advised by a hospital dietitian about 'childname's' feeding?

A child would not be eligible to participate in the survey if the birth weight was less than 2.0kg or if they answered 'Yes' to question two or three. Each participant was asked all three screening questions. In total, 9% of households/children were screened out due to there being no child with the correct date of birth present or due to the three eligibility criteria questions.

Table C.8.2 shows that 77% (197) of individuals in eligible addresses were productive, i.e. completed a food diary to some extent in the DNSIYC Dress Rehearsal. Refusals made up the majority of the 23% of unproductive households. Of the productive households, 73% were fully productive, i.e. completed three or four food diary days.

Hence, the target for eligible participants completing at least three food diary days (58%) was met in the Dress Rehearsal (see Table C.8.2).

Table C.8.2: Summary of achieved household response rates

	N	%
Issued addresses		
Total	315	100
Ineligible addresses	31	10
Screened out[1]	27	9
<2kg birth weight	*4*	*2*
Feeding tube	*14*	*4*
Hospital dietitian	*11*	*3*
No child with correct or similar date of birth	*2*	*1*
Specified child has died	*0*	*0*
Eligible	257	82
Eligible addresses		
Non-contact	3	1
Refusal	45	18
Other unproductive	12	5
Productive households	197	77
Productive households		
Partially productive individuals (< 3 food diary days)	9	4
Fully productive individuals (≥ 3 food diary days)	188	73

[1] As all weight/feeding-related screening questions were asked for each participant, an infant may have been ineligible for more than one reason. Therefore, the total number of responses to the individual screening questions is greater than the total number of participants screened out.

C.8.1.3. Individual response rates

Table C.8.1 (see section C.8.1.1) presents a summary of the Dress Rehearsal target response rates for fully productive participants as well as participants visiting a clinic and providing a blood sample.

The target for participants attending a clinic visit was 60% of the fully productive individuals. Table C.8.3 shows that 91% of parents agreed to a clinic telephone call to discuss Stage 2, but that ultimately 41% of the fully productive participants actually visited a clinic or were visited by the mobile unit. Hence a number of parents did not take their child to a clinic visit, although they agreed to a clinic call and in many cases made an appointment. Table C.8.3 shows that every child who attended a clinic visit had skinfold thickness measurements carried out, 91% of children who attended a clinic visit took part in the stable isotope element and 35% of children gave a blood sample (of fully productive participants the results were 41%, 38% and 14% respectively of those children who took part in the skinfold thicknesses, the stable isotope component and gave a blood sample).

Table C.8.3: Summary of individual response to aspects of the survey

		Total
	N	**%**
Fully productive (≥ 3 food diary days)	188	100
Agreed clinic could call, of which:	171	91
Visited clinic	78	41
Gave blood sample	27	14
Stable isotope dose taken	71	38
Skinfold thickness measured	78	41

C.8.1.4. Individual response rates to proposed and actual clinic visit, by clinic site

Table C.8.4 shows the number of parents who booked or refused a clinic visit at the time of the clinic call and the number who were not contactable. The average number of calls per clinic site made to each participant's parent to achieve a clinic visit decision as well as to follow up non-attendance of a clinic visit was recorded.

The results in Table C.8.4 show that of those who agreed to a clinic call, 103 (60%) parents booked a clinic appointment and the remainder either refused a clinic visit (24%) or could not be contacted (18%). Of the 103 who booked an appointment, 78 in total attended a clinic and the remainder either cancelled or did not arrive for their appointment. The clinic visits that were not attended were followed up by further phone calls with the aim of re-scheduling the appointments. Table C.8.5 shows the reasons given where it was not possible to re-schedule the clinic visit.

Table C.8.4 shows the average number of call attempts required to book an appointment across all sites was four calls. The number of calls made before finally coding as 'no contact' increased to an average of six calls per participant. Calls were also made following non-attendance at a booked visit, in order to find out the reason for non-attendance and, where possible, to re-schedule the clinic visit.

The average number of calls attempted varied among clinic sites, as shown in Table C.8.4. The methods to improve the clinic response at the booking call stage and the resourcing of the clinic booking calls are discussed in the recommendations in section C.9.0.

Table C.8.4 also shows the average length of time between the first interview and the clinic visit (54 days). The average length of time was 42 days for the Manchester and Cambridge clinics where there were no delays in starting.

C.8.1.5. Individual clinic outcome, by age group

Table C.8.5 shows the clinic visit outcome by age of the child and describes the reasons for refusal of the clinic stage. Of the parents who booked an appointment 76% attended the clinic visit with their child, while 23% either cancelled or did not attend the booked appointment. The target response for the clinic visit of 60% of fully productive participants was therefore not achieved because of the cancellation/non-attendance rates. The reasons for non-attendance of the clinic visits are also provided in Table C.8.5. Some of the reasons given by parents 'not wanting to re-arrange' a clinic visit included being too busy and changing their mind about being involved in the clinic stage of the survey. The reasons for 'wanting to re-arrange, but unable to' were primarily due to being unable to re-contact the parent and reaching the end of the survey period (largely Newcastle).

C.8.1.6. Individual blood and stable isotope outcomes, by age group

At the time of the clinic booking call parents of the participants indicated the components of Stage 2 that they were willing to undertake. Table C.8.6 shows which components those participants (by age) proposed and then went on to take part in. So that a review could be undertaken of how many parents changed their mind at the clinic visit, the proposed and undertaken components are only shown for those participants who attended the clinic visit. Of those parents who originally agreed or were unsure about their child giving a blood sample, 18% refused the blood component at the clinic visit. Some of the reasons for this included: the baby's temperament on the day, parents' uncertainty/fear about providing a blood sample or the parent feeling that the child was too young. Of the 12 who, at the time of the clinic booking call, were unsure about giving a blood sample, four went on to consent to give blood and sampling was attempted at the visit. A sample was obtained from one of the four participants.

There were very few parents who refused the stable isotope component on the day;- 96% of participants whose parents had proposed to undertake this component did so. Table C.8.6 also shows whether or not the stable isotope protocol was fully adhered to, in that viable urine samples were provided such that analysis could be conducted. Some of the issues leading to unsuccessful analysis were: less than 50% of the dose being consumed (see Addendum 1), the weight of the dose not being recorded or being recorded incorrectly, documented contamination of the pre-dose urine sample, inconsistency between the weighing of the isotope dose and equipment (such as bottle/cup/straw) before and after the dose was taken, urine samples being collected on the wrong day, insufficient number of urine samples collected and the mixing of different urine samples.

It should be noted that although the optimum protocol requires that most of the dose be taken in by the child and that the time of administration and the amount given be precisely known, the consequence of not achieving these ends is not complete failure in the measurement objective. Provided no other non-compliance occurs it is possible to augment the estimate of infant body water obtained from the isotope data with a prediction based on infant weight and height. The weighted average of the two estimates can then be used along with other isotope-derived kinetic parameters to obtain estimates of breast milk and/or other fluid intake, which although less accurate are nevertheless still useful.

C.8.1.7 Individual clinic, blood and stable isotope outcomes by clinic site

Tables C.8.7 and C.8.8 show the same information as in Tables C.8.5 and C.8.6, subdivided by clinic site rather than by age of child. These differences were important to assess in order to identify improvements for the mainstage. The Newcastle clinic successfully obtained blood from 73% of the total blood attempts (i.e. 'attempted, not obtained' plus 'obtained'),

compared with 29% at Cambridge and 36% at Manchester. This was a result of effective paediatric blood support from the paediatric registrars of the Newcastle upon Tyne NHS Foundation Trust, a collaboration set up by the local Principal Investigator. This is discussed further in the recommendations in section C.9.0. The percentage of stable isotope samples that could be successfully analysed was particularly high in Cambridge and Falkirk (see Addendum 1). It should be acknowledged that as the protocol was set up in Cambridge, the staff members in these two locations benefited from additional hints and tips from the stable isotope team and had a greater opportunity to ask questions and refer queries than those at external sites. This is also discussed further in the recommendations.

Table C.8.4: Individual response to proposed and actual clinic visit, by site

Response rate	Cambridge	Manchester	Newcastle	Falkirk*	Total
	N	N	N	N	
Fully productive (≥ 3 food diary days)	49	45	55	39	188
Agreed to clinic call	45	39	51	36	171
Clinic call outcome[1]:					
Booked	29	27	20	27	103
% of agreed clinic call	*64%*	*69%*	*39%*	*75%*	*60%*
Refused	9	8	15	7	39
No contact	7	4	16	2	29
Average number of call attempts to achieve clinic outcome					
Booked	7	2	4	4	4.25
Refused	3	2	4	4	3.25
No contact	10	3	7	5	6.25
Clinic visit outcome[2]					
Clinic attended	22	19	13	24	78
Clinic not attended	7	8	7	3	25
% attended of fully productive	45%	42%	24%	62%	*41%*
Follow-up of clinic non-attendance[3]					
Re-arranged[a]	5	4	4	2	15
Refused	0	1	4	1	6
No contact	4	7	1	1	13
Other	2	0	1	0	3
Average number of call attempts to achieve outcome of non-attendance[3]					
Re-arranged	11	1	4	5	5.25
Refused	n/a	1	8	5	4.7
No contact	11	1	5	7	6
Other	8	n/a	4	n/a	6
Average length of time (days) between agreeing to and attendance of the clinic visit	41	43	75	57	n/a

[1] of those participants who agreed to a clinic call
[2] of those participants who booked an appointment
[3] those who did not attend a booked clinic appointment
* Mobile unit
[a] the re-arranged appointments may have either subsequently attended or not attended and are already included in the clinic visit outcome numbers

Table C.8.5: Individual clinic outcome, by age group

Clinic outcomes	4-6m	7-9m	10-11m	12-18m	Total
	N	N	N	N	
Fully productive (≥ 3 food diary days)	23	32	28	105	**188**
Agreed to clinic call	19	30	26	96	**171**
Clinic call outcome[1]:					
Booked	13	20	16	54	**103**
% Booked	*68%*	*67%*	*62%*	*56%*	***60%***
Refused	3	7	4	25	**39**
No contact	3	3	6	17	**29**
Reasons for refusal:					
Too busy	0	2	0	7	**9**
No real interest, could not tell interviewer	2	4	3	11	**20**
End of survey period	1	1	1	2	**5**
Other reason	1	1	0	3	**5**
Clinic visit outcome[2]					
Attended 1st appointment	9	16	11	32	**68**
Attended a rearranged appointment	2	1	1	6	**10**
% attended	*85%*	*85%*	*75%*	*70%*	***76%***
Did not attend 1st appointment	2	2	5	11	**20**
Did not attend rearranged appointment	0	1	0	4	**5**
Outcome of non-attendance[3]					
Cancel – did not want to rearrange	0	0	0	2	**2**
Cancel – wanted to rearrange, but unable	0	0	0	1	**1**
No show – unable to contact	2	2	4	12	**20**
Contacted and refused	0	1	0	1	**2**

[1] of those participants who agreed to a clinic call
[2] of those participants who booked an appointment
[3] those who did not attend a booked clinic appointment

Table C.8.6: Individual blood and stable isotope outcomes, by age group

Blood and Stable Isotope outcomes	4-6m	7-9m	10-11m	12-18m	Total	*% who attended clinic*
	N	**N**	**N**	**N**	**N**	
Clinic attended	11	17	12	38	**78**	*n/a*
Proposed blood[1]						
Agreed	10	14	7	26	**57**	*73%*
Unsure	0	2	2	8	**12**	*15%*
Refused	1	1	3	4	**9**	*12%*
Blood sample outcome[2]						
Attempted, not obtained[2]	8	6	4	10	**28**	*36%*
Obtained[2]	2	7	3	15	**27**	*35%*
% obtained rate	*20%*	*54%*	*43%*	*60%*	***49%***	*n/a*
Refused on the day	0	3	2	9	**14**	*18%*
Proposed stable isotope[1]						
Protocol 1[a]						
Agreed to take dose	4	7	0	1	**12**	*15%*
Refused	0	0	0	0	**0**	*0*
Protocol 2[b]						
Agreed to take dose	6	9	12	35	**62**	*80%*
Refused	1	1	0	2	**4**	*5%*
Stable isotope placement[3]						
Protocol 1[a]						
Dose taken	4	7	0	1	**12**	*15%*
Dose not taken	0	0	0	0	**0**	*0*
Protocol 2[b]						
Dose taken	5	9	12	33	**59**	*76%*
Dose not taken	1	0	0	2	**3**	*4%*
Reasons for non-placement of stable isotope:						
Refused on the day	0	0	0	2	**2**	*n/a*
Other	1	0	0	0	**1**	*n/a*
Stable isotope outcome: ability to analyse[4]						
Successful	7	9	9	18	**43**	*55%*
Unsuccessful	2	7	3	16	**28**	*36%*
Reasons for unsuccessful stable isotope outcome[5]						
<50% of dose drunk	1	5	2	8	**16**	*n/a*
Other clinic non-compliance‡	0	2	2	3	**7**	*n/a*
Participant non-compliance‡	1	1	1	5	**8**	*n/a*

[1] of those who attended a clinic appointment
[2] of those whose proposed blood was either agreed or unsure
[3] of proposed stable isotope who agreed to placement
[4] of those stable isotopes placed (protocol 1 and 2)
[5] there may be more than one reason for the ability to analyse to be judged unsuccessful
‡ non-compliance to protocol
[a] Protocol 1: Breast milk, fluid intake and body composition
[b] Protocol 2: Fluid intake and body composition

Table C.8.7: Individual clinic outcome, by clinic site

Clinic outcomes	Cambridge	Manchester	Newcastle	Falkirk*	Total
	N	N	N	N	
Fully productive (≥3 food diary days)	49	45	55	39	**188**
Agreed to clinic call	45	39	51	36	**171**
Clinic call outcome[1]:					
Booked	29	27	20	27	**103**
% Booked	62%	69%	39%	75%	***60%***
Refused	9	8	15	7	**39**
No contact	7	4	16	2	**29**
Reasons for refusal:					
Too busy	1	1	5	2	**9**
No real interest, could not tell interviewer	5	5	4	5	**19**
End of survey period	2	0	3	0	**5**
Other reason	1	2	3	0	**6**
Clinic visit outcome[2]					
Attended 1st appointment	19	16	10	23	**68**
Attended a rearranged appointment	3	3	3	1	**10**
% attended	76%	70%	65%	88%	***75%***
Did not attended 1st appointment	5	7	6	2	**20**
Did not attended rearranged appointment	2	1	1	1	**5**
Outcome of non-attendance[3]					
Cancel – did not want to rearrange	0	1	0	1	**2**
Cancel – wanted to rearrange, but unable	0	1	0	0	**1**
No show – unable to contact	6	6	7	1	**20**
Contacted and refused	1	0	0	1	**2**

[1] of those participants who agreed to a clinic call
[2] of those participants who booked an appointment
[3] those who did not attend a booked clinic appointment
* Mobile unit

Table C.8.8: Individual blood and stable isotope outcomes, by clinic site

Blood and Stable Isotope outcomes	Cambridge	Manchester	Newcastle	Falkirk*	Total	*% of those attending clinic*
	N	**N**	**N**	**N**	**N**	
Clinic attended	22	19	13	24	**78**	*n/a*
Proposed blood[1]						
Agreed	14	16	9	18	**57**	*73%*
Unsure	8	0	2	2	**12**	*15%*
Refused	0	3	2	4	**9**	*12%*
Blood sample outcome[2]						
Attempted, not obtained	9	10	3	6	**28**	*36%*
Obtained	5	4	8	10	**27**	*35%*
% obtained rate	*36%*	*29%*	*73%*	*63%*	***49%***	*n/a*
Refused on the day	8	2	0	4	**14**	*18%*
Proposed stable isotope[1]						
Protocol 1[a]						
Agreed to take dose	5	3	0	4	**12**	*15%*
Refused	0	0	0	0	**0**	*0*
Protocol 2[b]						
Agreed to take dose	16	15	13	18	**62**	*80%*
Refused	1	1	0	2	**4**	*5%*
Stable isotope placement[3]						
Protocol 1[a]						
Dose taken	5	3	0	4	**12**	*15%*
Dose not taken	0	0	0	0	**0**	*0*
Protocol 2[b]						
Dose taken	16	15	11	17	**59**	*76%*
Dose not taken	0	0	2	1	**3**	*4%*
Reasons for non-placement of stable isotope:						
Refused on the day	0	0	1	1	**2**	*n/a*
Other	0	0	1	0	**1**	*n/a*
Stable isotope outcome: ability to analyse[4]						
Successful	16	8	5	14	**43**	*55%*
Unsuccessful	5	10	6	7	**28**	*36%*
Reasons for unsuccessful stable isotope outcome[5]:						
<50% of dose drunk	1	6	3	6	**16**	*n/a*
Clinic non-compliance‡	0	3	2	2	**7**	*n/a*
Participant non-compliance‡	5	1	1	1	**8**	*n/a*

[1] of those who attended a clinic appointment
[2] of those whose proposed blood was either agree or unsure
[3] of proposed stable isotope (protocols 1 & 2) who agreed to placement
[4] of those stable isotopes (protocols 1 & 2) placed
[5] there may be more than one reason for the ability to analyse to be judged unsuccessful
[a] Protocol 1: Breast milk, fluid intake and body composition
[b] Protocol 2: Fluid intake and body composition
‡ non compliance to protocol
* Mobile unit

Table C.8.9: Response Rate for clinic attendance by distance from clinic

Distance from home to clinic	Agreed to clinic call	Attended clinic	%
≤ 18 miles	74	36	49%
> 18 miles	61	18	30%
ALL	135	54	40%

Table C.8.9 shows the number and percentage of participants who attended a clinic visit by distance from their home to the clinic; ie. whether the home address was 18 miles or less, or more than 18 miles distance from their home address to the relevant clinic. The figures include the participants that attended Manchester, Newcastle or Cambridge clinics. The response rates show that 49% of parents attended the clinic if the distance from home to the clinic was 18 miles, or less than 18 miles whereas 30% of parents attended a clinic visit if the distance was greater than 18 miles.

C.8.2. Anthropometric Results

Tables C.8.10 and C.8.11 show the means, medians, standard deviations and lower and upper 2.5 percentiles for the anthropometric measurements undertaken in both Stage 1, taken by the interviewer and Stage 2, taken by the nurse in the clinic. Stage 2 included skinfold thickness measurements. The measurements at Stage 1 and 2 are not directly comparable because they were taken at slightly different ages, the age of the child having increased by Stage 2. Table C.8.4 shows the average length of time (d) between the last visit in Stage 1 and attendance at the clinic visit, for each clinic.

Table C.8.10: Anthropometric measurements at Stage 1

Anthropometric measure		4-6m N=11	7-9m N=17	10-11m N=12	12-18m N=38	Total N=78
Weight (kg)	Mean	7.8	8.9	10.0	11.1	10.0
	Median	7.7	8.8	10.2	10.9	10.1
	SD	1.4	1.0	1.0	1.5	1.8
	Upper 2.5 percentile	10.2	10.4	11.9	14.3	14.2
	Lower 2.5 percentile	6.1	7.4	8.1	8.6	6.1
Length (cm)	Mean	68.4	72.9	76.8	80.9	76.7
	Median	68.1	74.3	76.3	81.2	76.6
	SD	3.7	3.8	2.2	4.2	6.0
	Upper 2.5 percentile	75.8	79.5	80.1	90.1	89.6
	Lower 2.5 percentile	63.5	67.0	73.0	72.7	64.7
Head circumference (cm)	Mean	43.5	44.6	46.4	47.5	46.1
	Median	43.4	45.2	46.5	47.7	45.9
	SD	1.5	1.3	1.8	2.3	2.5
	Upper 2.5 percentile	47.0	46.5	50.9	53.2	52.1
	Lower 2.5 percentile	41.8	42.4	44.0	41.1	41.8

Table C.8.11: Anthropometric measurements at Stage 2

Anthropometric measure		4-6m N=11	7-9m N=17	10-11m N=12	12-18m N=38	Total N=78
Weight (kg)	Mean	8.2	9.3	10.3	11.4	10.3
	Median	8.2	9.0	10.2	10.9	10.4
	SD	1.3	1.1	1.5	1.4	1.8
	Upper 2.5 percentile	10.7	11.3	13.5	14.5	14.3
	Lower 2.5 percentile	6.3	7.4	8.0	9.1	7.1
Anthropometric measure		**4-6m N=11**	**7-9m N=17**	**10-11m N=12**	**12-18m N=38**	**Total N=78**
Length (cm)	Mean	69.7	78.6	78.9	81.6	78.8
	Median	68.8	76.0	77.1	81.3	78.1
	SD	6.1	8.3	6.4	5.6	7.5
	Upper 2.5 percentile	85.0	95.0	98.0	95.0	95.0
	Lower 2.5 percentile	61.8	65.5	73.1	68.0	65.0
Head circumference (cm)	Mean	44.6	45.2	46.6	47.7	46.5
	Median	44.2	45.3	46.3	47.7	46.2
	SD	1.3	1.2	1.2	2.7	2.4
	Upper 2.5 percentile	47.2	47.1	48.4	52.1	52.0
	Lower 2.5 percentile	43.0	42.9	44.9	40.2	40.7
Triceps skinfold (cm)	Mean	8.8	9.2	8.1	9.5	9.3
	Median	8.0	9.0	8.5	9.6	9.0
	SD	2.2	2.2	2.4	2.5	2.4
	Upper 2.5 percentile	13.0	15.7	13.2	16.1	15.7
	Lower 2.5 percentile	5.9	7.1	4.8	5.2	5.2
Subscapular skinfold (cm)	Mean	7.5	8.4	7.4	7.5	7.7
	Median	7.4	7.6	7.2	7.2	7.2
	SD	1.4	2.4	2.0	1.4	1.7
	Upper 2.5 percentile	9.6	14.0	10.6	11.3	13.6
	Lower 2.5 percentile	5.7	5.1	4.6	5.1	5.0

C.8.2.1. Inter-interviewer results

Table C.8.12 indicates that infant length and head circumference measurements were taken from 96% of fully productive participants. After each measurement, interviewers were asked to record whether they felt it was a reliable measurement. If they felt it was not reliable, they recorded why this was the case. Interviewers felt that the infant length measurements were reliable in 78% of cases, and that the head circumference measurements were reliable in 88% of cases, indicating greater concern about the accuracy of the infant length measurement than the head circumference measurement. For both measurements, the main reason given for feeling that it was not accurate related to the child moving too much – 'wriggling', 'fidgety', 'would not stay still'.

A Quality Control (QC) day was held at HNR in Cambridge, at the end of the Dress Rehearsal fieldwork. This was led by the same paediatric nurses who provided the training during the briefing sessions. The purpose of the QC day was to investigate the accuracy of the interviewers in measuring length and head circumference, and thus to assess the feasibility of interviewers continuing with these measurements in the mainstage. Four interviewers who worked on the Dress Rehearsal attended the QC day, and each performed each of the two

measurements on six volunteer children. Table C.8.14 shows the results of the QC day measurements.

Table C.8.12: Summary of anthropometric measurements and interviewer perception of reliability

		Total
	N	%
Fully productive (≥ 3 food diary days)	**188**	
Infant length measurement	**180**	**96**
Reliable	140	78
Unreliable	40	22
Don't know	0	0
Head circumference measurement	**181**	**96**
Reliable	159	88
Unreliable	21	12
Don't know	1	1

Table C.8.13: Group results of QC inter-interviewer measurements

	Head circumference	Infant length
Absolute TEM (Technical Error of the Measurement) (cm)	0.7	1.0
Relative TEM (%)	1.6	1.3

In DNSIYC, to reduce measurement error, interviewers were given a standard protocol, supported by training, to use on each occasion, and measurements were taken in triplicate. To assess the level of imprecision in the measurements the technical error of the measurement (TEM) was calculated from a subset of four interviewers, who each measured both the length and head circumference of six different children. The absolute TEM assesses the physical error between measurements undertaken on the same participant. This was transformed into a relative TEM in order to express the error as a percentage.

The results of the inter-interviewer relative TEMs were 1.6% and 1.3% for head circumference and infant length, respectively, and indicate acceptable levels of precision between interviewers. Target 'in training' values of TEM have previously been set by Zerfas (1985)[1] at 1% for length, height and weight. Head circumference error levels have not specifically been set. Ulijaszek and Kerr (1999)[2] state that for measurements other than length, height and weight, the error levels should be used with care when assessing the youngest age groups and particularly the smallest children within an age group. Similar studies such as the Cambridge Baby Growth Study (CBGS)[3] undergo similar quality days to assess inter-nurse variation. TEMs for infant head circumference and length on these occasions are generally about 0.4% and 0.9%, respectively.

C.8.2.2. Inter-nurse results

Quality control was undertaken in the clinics to assess the error of the nurses in the Dress Rehearsal. Nurses at the Manchester and Cambridge sites were asked to undertake infant length, head circumference and skinfold thickness measurements on three or four children to assess the measurement error. Tables C.8.14 and C.8.15 shows the inter-nurse variation results for the triceps and subscapular skinfold thickness measurements in Manchester and Cambridge, respectively.

Table C.8.14: **Manchester results of QC inter-nurse skinfold thickness measurements**

	Subscapular	Triceps	Head Circumference	Length
Absolute TEM (Technical Error of the Measurement) (cm)	0.2	0.1	0	0.2
Relative TEM (%)	3.4	1.5	0.1	0.2

Table C.8.15: **Cambridge results of QC inter-nurse skinfold thickness measurements**

	Subscapular	Triceps	Head Circumference	Length
Absolute TEM (Technical Error of the Measurement) (cm)	0.2	0.1	0.1	0.1
Relative TEM (%)	3.4	2.3	0.3	0.2

The results of the inter-nurse relative TEMs show acceptable levels of precision between nurses at the clinical sites.

C.8.3. Dietary data

C.8.3.1. Quality of data

The Dress Rehearsal diaries were coded at a rate of six diaries per week per coder compared with 12 diaries for CBGS[3] and GEMINI[4] (refer to section C.6.1.4, practical coding issues). The Dress Rehearsal diaries generated a high volume of queries (1160 in total for 188 diaries), on average six queries per food diary, compared with two queries per food diary for both GEMINI and CBGS.

Table C.8.16 shows that the highest proportion of queries related to coding of portions. This is mainly due to volume and spoon weights not being available in DINO rather than poor recording by the parent in the food diary.

Where an appropriate food code was not available for an item recorded in the food diary a process of food matching was undertaken. The nutritional information and ingredients of the unknown food were matched to existing food codes on the NDNS nutrient databank by the food composition co-ordinator and further validated by the FSA. The total number of matching sheets produced during the Dress Rehearsal coding period was 74. Most of these matches related to commercial infant and toddler foods. As a result of these unknown food matches during the Dress Rehearsal (together with pilot phase II) HNR added 84 new food codes to the nutrient databank and updated 31 of the existing food codes in line with current information.

Only 7% of all queries related to missing or insufficient detail provided by the parent compared with 20% for year 1 of NDNS. This figure highlights the overall high quality of recording by the parents; no diaries were excluded on the basis of poor quality of food diary recording.

Table C.8.16: Types of queries raised during dietary assessment

Query type	N	%
Food code not available in DINO	**350**	**28**
Portion code queries	**786**	**63**
Missing/insufficient detail to code	**82**	**7**
Recipe: missing ingredients/insufficient detail to code food	**27**	**2**

C.8.3.2. Portion size equipment

Table C.8.17: Usage of graduated implements

	N	% using implements
Total	188	100
Study spoons	128	68
Graduated tubs	91	48
Graduated drinking cup	42	22

Table C.8.17 shows that a high proportion of respondents used the portion size equipment provided to them.

C.8.3.3. Energy and nutrient intakes

Table C.8.18 shows the energy and nutrient intakes for selected nutrients including those reported in the dietary feedback letters. Boys and girls are reported together. Feedback nutrients (energy, protein, calcium, iron, vitamin C and non-milk extrinsic sugars (NMES)) were compared to the ranges found in the NDNS of children 1.5-4.5 years for the older age group and 'Food and nutrient intakes of British infants Aged 6-12 months'[5] for the younger age groups. All feedback nutrients were within the ranges seen in these previous surveys suggesting the current dietary method is robust and is therefore recommended for use in the mainstage of the survey. The dietary data results should be used with caution due to the sampling frame and size and so the dress rehearsal energy and nutrient intake data should not be used as a representative depiction of dietary intakes in this age group in the UK.

Table C.8.18: Mean daily energy and nutrient intakes of children aged 4 to 18 months

		4-6m	7-9m	10-11m	12-18m
		N=23	N=32	N=28	N=105
Energy (MJ)	Mean	2.7	3.0	3.5	4.1
	Median	2.6	2.9	3.5	4.1
	SD	0.7	0.6	0.6	0.8
	Upper 2.5 percentile	5.3	4.1	4.6	5.6
	Lower 2.5 percentile	1.4	2.0	2.1	2.9
Energy (kcal)	Mean	647	723	824	975
	Median	605	693	842	968
	SD	169	133	138	184
	Upper 2.5 percentile	1256	980	1095	1340
	Lower 2.5 percentile	334	485	496	680
Protein (g)	Mean	15.7	22.0	28.0	38.4
	Median	15.0	20.5	28.1	38.8
	SD	4.7	6.7	5.8	9.4
	Upper 2.5 percentile	26.2	40.1	40.7	57.1
	Lower 2.5 percentile	6.6	11.9	15.1	19.8
Protein (% food energy)	Mean	9.7	12.0	13.7	15.7
	Median	9.7	11.3	13.5	15.7
	SD	1.7	2.2	2.6	2.5
	Upper 2.5 percentile	12.8	17.4	21.1	21.2
	Lower 2.5 percentile	7.5	8.7	9.6	11.2
Fat (g)	Mean	30.5	29.8	33.5	39.5
	Median	31.6	29.5	33.9	39.3
	SD	8.8	5.5	8.3	9.6
	Upper 2.5 percentile	59.4	42.3	53.3	57.2
	Lower 2.5 percentile	17.9	19.8	21.0	22.6
Fat (% food energy)	Mean	42.6	37.5	36.4	36.3
	Median	42.6	36.6	37.0	35.9
	SD	6.2	5.2	4.6	4.6
	Upper 2.5 percentile	53.2	49.6	43.8	45.0
	Lower 2.5 percentile	32.1	28.1	24.9	27.8
Carbohydrate (g)	Mean	82.8	97.9	109.3	124.0
	Median	79.4	96.1	109.0	123.9
	SD	23.9	22.3	19.4	25.9
	Upper 2.5 percentile	164.5	140.4	144.9	178.2
	Lower 2.5 percentile	39.7	55.7	53.7	81.1

		4-6m	7-9m	10-11m	12-18m
		N=23	N=32	N=28	N=105
Carbohydrate (% food energy)	Mean	47.9	50.6	49.9	47.9
	Median	47.0	52.1	48.8	48.2
	SD	4.8	4.9	5.7	5.7
	Upper 2.5 percentile	57.4	58.4	63.3	58.1
	Lower 2.5 percentile	39.4	38.3	40.6	35.6
Non milk extrinsic sugars (% food energy)	Mean	3.2	5.1	6.5	7.6
	Median	1.4	3.9	6.0	7.3
	SD	3.9	4.2	3.0	3.7
	Upper 2.5 percentile	15.3	18.9	13.4	16.1
	Lower 2.5 percentile	0.0	0.0	1.8	1.2
Calcium (mg)	Mean	496	538	608	777
	Median	507	517	575	808
	SD	146	143	146	235
	Upper 2.5 percentile	784	911	1006	1186
	Lower 2.5 percentile	196	326	412	294
Iron (mg)	Mean	5.0	6.8	6.7	6.4
	Median	5.5	7.4	7.0	6.0
	SD	2.1	2.8	2.2	2.3
	Upper 2.5 percentile	11.1	11.2	9.7	12.1
	Lower 2.5 percentile	1.0	1.5	2.3	2.9
Vitamin C (mg)	Mean	70.6	72.2	61.3	54.3
	Median	76.0	73.6	61.2	46.6
	SD	16.3	23.9	21.4	27.9
	Upper 2.5 percentile	92.7	123.1	99.1	135.2
	Lower 2.5 percentile	36.2	25.3	12.0	20.7

Table C.8.19: Dietary Reference Values for feedback nutrients[6]

Age	Gender M/F	Estimated Average Requirement	Reference Nutrient Intakes			
		Energy kcal/d	Protein g/d	Vitamin C mg/d	Iron mg/d	Calcium mg/d
4-6 months	M	690	12.7	25	4.3	525
7-9 months	M	825	13.7	25	7.8	525
10-12 months	M	920	14.9	25	7.8	525
1-3 years	M	1230	14.5	30	6.9	350
4-6 months	F	645	12.7	25	4.3	525
7-9 months	F	765	13.7	25	7.8	525
10-12 months	F	865	14.9	25	7.8	525
1-3 years	F	1165	14.5	30	6.9	350

Energy
The results show that mean energy intake was greater with increasing age and was close to the Estimated Average Requirement (EAR) for all age groups apart from those aged 12-18 month age group. The month mean intake for this age group was below the EAR for energy. No statistical analysis has been undertaken.

Protein
For all age groups but particularly for the 12-18 months age group, mean protein intake was higher than the Reference Nutrient Intake (RNI).

Calcium
Mean calcium intake increased with age and was above the RNI for all age groups (mean intake was more than double the RNI in the 12 to 18 months age group).

Iron
Mean iron intake did not meet the RNI in all age groups with the exception of the four to six months age group.

Vitamin C
Mean vitamin C intake exceeded the RNI in all age groups.

NMES
All age groups had a mean intake of NMES that met the population average Dietary Reference Value of no more than 10% of total energy[17].

C.8.4. Blood results

Of the 27 blood samples obtained, 22 were analysed for FBC. Four samples were not analysed for FBC due to incorrect labelling and one sample had an insufficient volume of blood. Twenty-four samples were analysed for vitamin D and iron status; three samples had insufficient volume to analyse. Table C.8.20 shows the results of the vitamin D and iron status analytes.

Table C.8.20: Blood results

Analyte		Total N=24
Vitamin D (nmol/l)	Mean	61.3
	Median	63.0
	SD	23.1
	Upper 2.5 percentile	104.0
	Lower 2.5 percentile	16.8
Iron		
Ferritin (µg/l)	Mean	34.4
	Median	27.5
	SD	20.6
	Upper 2.5 percentile	87.0
	Lower 2.5 percentile	10.0
TfR (µg/l)	Mean	6.1
	Median	6.1
	SD	0.9
	Upper 2.5 percentile	7.8
	Lower 2.5 percentile	4.5
CRP* (mg/l)	Mean	2.7
	Median	2.1
	SD	1.7
	Upper 2.5 percentile	5.9
	Lower 2.5 percentile	1.1

* N = 16 for CRP

Some of the samples were below the detection level of the analyser for CRP. This is normal and not a cause for concern. CRP was measured only because a high CRP concentration would indicate an acute-phase reaction (e.g. inflammation and/or infection). Ferritin concentration in the serum is also raised as part of the acute-phase reaction and so in this situation it is not a reliable indicator of iron status. All CRP concentrations were within the reference range, indicating the absence of an acute-phase reaction; therefore the concentrations of ferritin reflect the infants' iron status.

C.9. Recommendations

C.9.1. Response Rates

C.9.1.1. General clinic recommendations

- To reduce the number of cancellations and non-attendance of parents we propose to:
    - introduce a script for interviewers to ensure parents of participants fully understand the procedures and time involved in the clinic visit;
    - modify the telephone booking call structure to allow adequate time for questions and ensure that parents are fully comfortable with the clinic visit;
    - adapt the clinic appointment letter so that it looks more friendly and less official;
    - introduce a clinic visit reminder for the day prior to the clinic visit appointment; telephone calls/text message reminders are proposed;
    - introduce a Freephone telephone number for queries and cancellations; and
    - introduce a 'missed appointment' card.

C.9.1.2. Skinfolds

There are no recommendations required for the skinfold thickness measurements. Clinic QC data will continue to be collected throughout the mainstage of the survey.

C.9.1.3. Blood

- To increase response to proposed blood samples, we propose to:
    - introduce a script for interviewers to ensure parents of participants are fully informed about the benefits of blood taking for nutrition and health research and understand the procedures and time involved in the clinic visit (see general clinic recommendations, section 9.1.1); and
    - modify the clinic call script to ensure there is adequate time and prompting of questions. The more informed parents can be, the greater chance of allowing an attempt to take blood.

- To reduce the number of blood samples parents 'refused on the day', we propose to:
    - encourage nurses to ensure parents of participants are fully informed about the benefits of blood taking for nutrition and health research; and
    - during the taking of consent, reassure the parent and to ensure he/she is entirely comfortable with the protocol, understands that the child may experience some discomfort but that this is temporary and minimal, and provide reassurance that the staff involved are skilled paediatric phlebotomists, who are accustomed to carrying out these procedures in young children who may become distressed.

- To increase the number of blood samples obtained, we propose to:
    - make efforts to ensure appropriate paediatric experience by:
        - discussing and assessing in greater depth the paediatric expertise when recruiting/screening prospective clinics; and
        - proposing a collaborative model, similar to that adopted in Newcastle whereby the local Principal Investigator/registrars offer ongoing

paediatric support to research nurses and will take the blood sample on occasions where increased experience is required;
    - subject to ethical approval, allow a second attempt to obtain the blood sample where parents are willing to increase the number of blood samples attempted. Feedback from clinic staff indicated that some parents would have been willing to allow a second attempt and that this is normal practice for paediatric research; and
    - subject to ethical approval, allow the blood sample to be taken from a 'suitable' vein, rather than stating from the arm. Feedback from clinicians was that having wider variety in the blood taking site would help to improve the success. We propose to submit for authorisation to take the sample from the hand, arm, foot or leg.

It was highlighted when producing the first feedback letters (containing FBC results) that a large number of the participants had monocyte results outside the determined ranges. It is necessary therefore to change the monocyte ranges from 0.7-1.5 to 0.15-1.5 10^9/l, in line with recent literature[7] (see Addendum 2).

C.9.1.4. Stable isotopes

- To improve the clinic non-compliance issues and thus increase the successful analysis and response rate, we propose to:
    - modify the training and instruction for clinic staff to ensure that:
        - dose weights are always recorded and are recorded accurately;
        - dosing times are always recorded;
        - there is no possibility of contamination of the pre-dose urine sample by touching the dosing bottle before a pre-dose urine sample is obtained and sealed in its container;
        - all weighing of the dose container before and after drinking is carried out correctly; and
        - forms are modified to indicate more clearly those fields that must be completed;
    - have a representative of HNR present for at least the first day of each clinic appointment when isotope is administered, to ensure the protocol is followed correctly (see general clinic recommendations section C.9.1.1);
    - actively monitor compliance issues and follow-up with clinics, providing telephone support (or extra visits if necessary); and
    - consider creation of a training video to demonstrate the correct dosing procedure.

- To ensure consumption of sufficient stable isotope dose for successful analysis and hence improve the response rate for this component, we propose to:
    - develop and offer an alternative dosing protocol to improve the problem of the child not drinking enough of the dose:
        - for younger babies this will involve taping a narrow tube to the mother's finger. The tube is connected to a syringe containing the dose and is held out of sight of the child who is encouraged to suck on the mother's finger (with the tube attached) and thereby ingest the dose.
        - in the older age groups if the child's favourite bottle/cup is not available a more suitable alternative cup will be provided.
    - modify the clinic training to impress upon the clinic staff that the dose can be administered slowly over the duration of the clinic visit:

- the record sheet will be amended to allow both 'start of dosing' and 'end of dosing' times to be entered.

- To enable use of less than optimal dose consumed (<50%) to determine ingestion rate, we propose: in such cases where less than adequate dose has been consumed, to estimate infant body water by prediction equations and to combine these with those estimated from stable isotope measurements to obtain weighted averages. These can be used with the other parameters estimated from the isotope disappearance curves to give breast milk intake and water intake from other sources.

- Since the project board meeting it has been decided to incorporate a breastfeeding food diary into the stable isotope protocol. This is due to the time delay between Stages 1 and 2 and will determine if breastfeeding practices have changed in this time. A direct comparison between the food diary and the outcome of the stable isotope analysis may be achieved with this new information.

C.9.1.5. Mobile unit

- To address the issue of lighting/heating in the winter months, we propose to:
  - fit the current mobile unit with ancillary lighting and more effective 'cab' heating systems; and
  - offer the option of home-visits as this is likely to be preferred/more attractive in very cold/wintry conditions.
- To address space issues, we propose to:
  - modify the current mobile unit to provide more space; and
  - obtain additional mobile unit(s) either through purchase or rental from mobile unit companies.
- To address the need to clean the mobile unit between visits, we propose to:
  - space out visit times to allow time between visits for cleaning, a break for staff and for the time to travel between homes.
- To address the issue of insufficient power, we propose to
  - replace the current charger.
- To address the need for locations with mains supply to process blood samples, we propose to:
  - identify a range of options, including GP surgeries (ethics already approved), ambulance services sites, UK camp sites, town/village halls, where the mobile unit can be parked safely, plugged in to mains-power supply and where processing can be undertaken. It will be necessary to locate bases where the mobile unit can be re-charged overnight.
- Taking the Stage 2 clinic visit to participants' homes via the mobile unit has proved an effective way to achieve clinic outcomes in the field with high response rates. This strategy is dependent on the availability of appropriately kitted-out mobile units, trained and experienced personnel (paediatric phlebotomists), and access to blood processing facilities. To increase mobile unit capacity for the main stage of the survey, we propose to:
  - increase the proportion of visits in the mainstage occurring via mobile units. This will mean expanding the mobile unit fleet by a further one or two mobile units (budget dependent); and launch a wide paediatric phlebotomist recruitment campaign, as staffing is a potential constraint.

C.9.2. Anthropometry

Inter-interviewer variation

Feedback from interviewers suggests there are concerns about performing the infant length and head circumference measurements during Stage 1 of the survey. Interviewers tended to feel that they were not the best qualified people to carry out these measurements and they found both difficult to perform, particularly infant length. All interviewers said that the training did not prepare them for the reality of measuring actual babies (who wriggle and fidget) since the training was carried out using dolls. Interviewers' concerns about accuracy of the measurements recorded – again, particularly for the infant length measurement - are confirmed by the figures shown in Table C.8.12 (see section C.8.2.1).

If the infant length and head circumference measurements continue to be included in Stage 1 for the mainstage, it must be considered that some interviewers may be put off working on the survey as they will not be comfortable performing the measurements. In addition, we cannot guarantee that all interviewers working on the mainstage will be as experienced as the interviewers who worked on the Dress Rehearsal – this is a particular issue now the fieldwork has been condensed and a larger number of interviewers will be needed in a shorter time period. Less experienced interviewers might not cope so well with the infant length and head circumference measurements. However, we acknowledge that delaying these measurements to the clinic stage will result in attrition and fewer participants from whom the measurements can be taken.

With the measurements continuing to be carried out during Stage 1 in the mainstage, the following changes to protocols will be made:

- Introduce a 'reassurance' program for interviewers, to increase confidence. This could include:
    - Holding regular QC days in Cambridge;
    - NatCen nurse supervisors or nurses from the MRC Epidemiology Unit accompanying interviewers and carrying out QC out in the field with the aim of providing support and feedback;
- Re-record the Dress Rehearsal measurement training DVD so it covers all relevant information and show the measurements from different angles. A copy of this DVD would be supplied to interviewers for them to re-watch at home as and when they need to; and
- Abandoning the use of the Frankfort Plane cards for the infant length measurement. Interviewers would be trained in what the appropriate head position is but they would not need to use the card every time.

C.9.3. Dietary Assessment

The use of graduated implements resulted in a low coding rate and a high volume of queries, impacting on the resource required to code and edit such diaries. Based upon the expected number of participants and the compressed time of the main stage of DNSIYC, the use of graduated implements would have major resourcing consequences. For 1800 participants over January, February, April and May 2011, and with approximately seven weeks' coding allowed for each month, the dietary assessment team should aim to code and edit approximately 64 diaries in total per week to ensure feedback deadlines are met. Table C.9.1 summarises the expected coding resource required for the main stage both with the graduated implements and without.

Without implements estimates have been derived from the GEMINI[2] and CBGS[1] diaries which are currently being coded at HNR and use both estimated and household measures to record portion sizes.

Table C.9.1: Expected diet coding resource required for the main stage

	With graduated implements	Without graduated implements
Diaries coded/week/coder	6[a]	12[b]
Queries per food diary	6	2[c]
Expected queries per week[d]	384 (242 portion queries[e])	128
Coders required over 8 months	10.7	5.3
Editors/Research Assistants required	3.0	2.5
Newcastle Action required	Yes	No

[a] Based upon Dress Rehearsal coding rates for the week of 3rd May 2010.
[b] Coding rates used for CBGS and GEMINI (September and October 2009), and GEMINI (December to March 2010 inclusive) and CBGS (week of 7th June, 2010).
[c] Queries for GEMINI (December to March 2010 inclusive).
[d] Based upon coding 64 diaries per week.
[e] See Table C.8.16: Type of query raised by coders. 63% of queries related to portion size.

To enable dietary coding and editing to be completed in line with resources proposed in the DNSIYC Best and Final Offer (BAFO) document and to provide dietary feedback within four months of food diary completion, we propose to:

- abandon the use of the graduated implements. While the implements provided accurate information and they did not appear to impact on the dietary results obtained (demonstrated in the Newcastle pilot), the coding and editing of diaries was considerably more onerous as a result of their use.

C.9.4. Data

We propose to:

- host the clinic database on HNR servers, allowing remote access by clinics. This will greatly improve efficiency of data transfer between HNR and clinics and will allow for mid-survey changes to the database.
- change the clinics database to improve the monitoring and recording of phone calls to parents of participants.
- incorporate within the clinic database the facility to record a larger variety of reasons for refusal of the clinic appointment and to ensure this step cannot be by-passed.
- ensure that barcode labels include DOB and gender identifiers to guard against tubes or forms being incorrectly labelled.
- incorporate a reconciliation process:
    - to check receipt of original forms from clinic
    - to check receipt of all electronic faxes.

References and endnotes

[1] Zerfas AJ. Checking Continuous Measures: Manual for Anthropometry, 1985. Los Angeles, CA: Division of Epidemiology, School of Public Health, University of California, Los Angeles.

[2] Ulijaszek SJ and Kerr DA. Anthropometric measurement error and the assessment of nutritional status 1999. British Journal of Nutrition, 82, 165–177.

[3] http://www.mrc-epid.cam.ac.uk/Research/Studies/CBGS/ 7 August 2010

[4] http://www.geministudy.com 8 August 2010

[5] Mills A. and Tyler H. Food and Nutrient intakes of British infants Aged 6-12 months HMSO 1992.

[6] Department of Health, RHSS41- Dietary Reference Values for Food Energy and Nutrients for the United Kingdom HMSO 1991.

[7] Cranendonk et al. Compared automated ranges with manual diffs in 0–16yr olds, 1985. Journal of Clinical Chemistry and Clinical Biochemistry 23, 663 – 667.

Addendum 1. Stable isotope graphs demonstrating percentage of dose drunk

Figure 1a: Percentage of stable isotope drunk, by clinic site

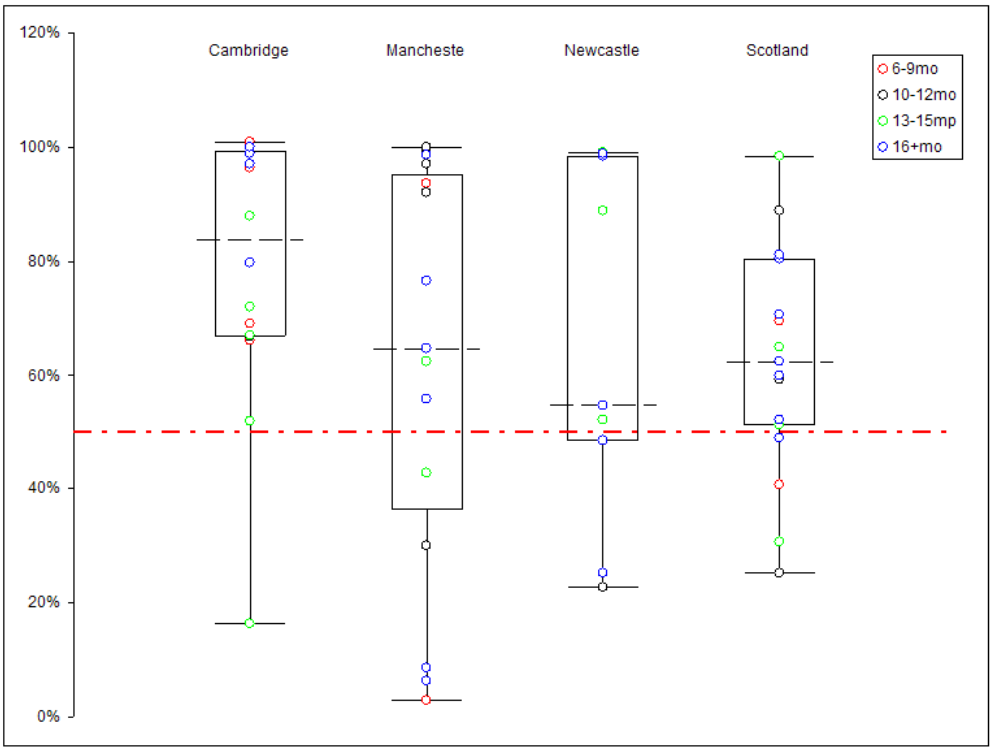
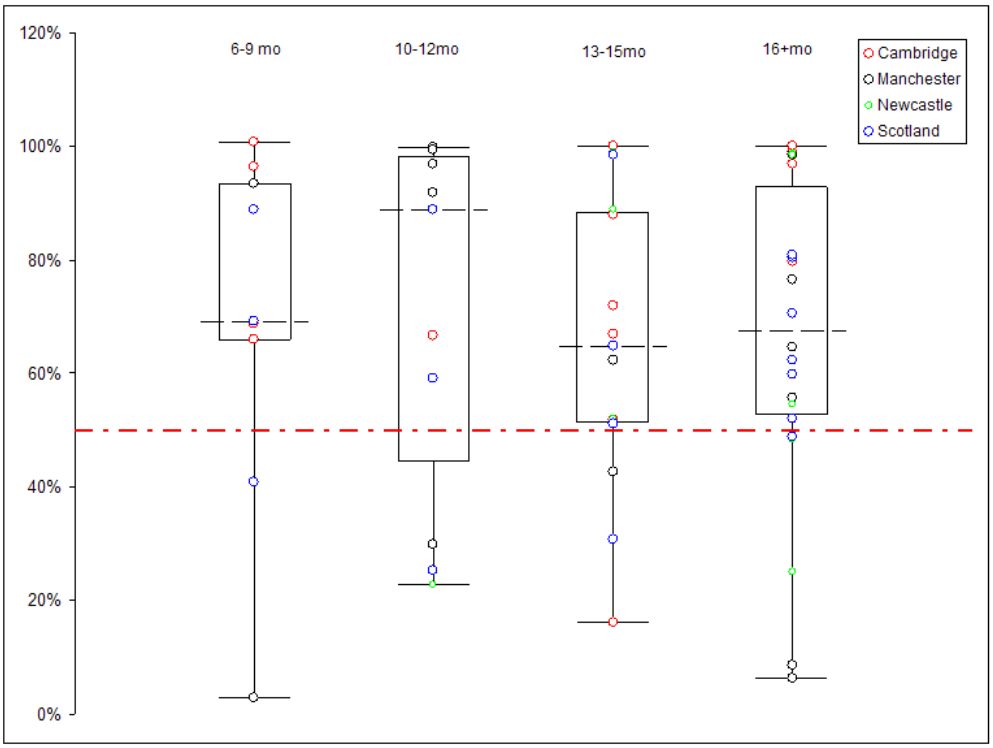


Figure 1b: Percentage of stable isotope drunk, by age group (age at clinic visit†).



†Age at clinic visit is used only for the purpose of displaying this information.

Addendum 2. Reference ranges for blood biochemistry results reported to GPs and parents of participants

Analyte	Unit	Age	Sex	Reference Range	Action level for serious conditions that need immediate action	
					Low	High
Haemoglobin[1]	g/dl	2-5mo 5mo– 3y	F&M F&M	9.5-13.5 10.5-13.5	<6.0[1]	>20.0[1]
Red Cell Count[1]	10^{12}/l	2-5mo 5mo– 3y	F&M F&M	3.1-4.5 3.7-5.3	N/A	N/A
Haematocrit[1]	l/l	2-5 mo 5mo– 3y	F&M F&M	0.29-0.41 0.33-0.39	N/A	N/A
Mean Cell Haemoglobin[1]	pg	2-5mo 5mo– 3y	F&M F&M	25-34 23-31	N/A	N/A
Mean Cell Volume[1]	fl	2-5mo 5mo– 3y	F&M F&M	74-108 70-86	N/A	N/A
Platelet Count[1]	10^9/l	All	F&M	150-450	<20[1]	>1,500[1]
White Cell Count[1]	10^9/l	2d– 2y	F&M	6.0-18.0	<1.0[1]	>50[1]
Neutrophil Count[1]	10^9/l	All	F&M	2.0-6.0	<0.5[1]	N/A

Analyte	Unit	Age	Sex	Reference Range	Action level for serious conditions that need immediate action	
					Low	High
Lymphocyte Count[1]	10^9/l	2-4mo 5-8mo 9-14mo 15mo– 2y	F&M F&M F&M F&M	3.7-9.6 3.8-9.9 2.6-10.4 2.7-11.9	N/A	N/A
Monocyte Count[4]	10^9/l	All		0.15-1.5	N/A	N/A
Plasma ferritin[1]	µg/l	1-6mo 6mo– 15y	F&M	8-275 8-116	N/A	N/A
25-hydroxyvitamin vitamin D[1]	nmol/l	All	F&M	25 – 150	12.5-25 nmol/L represents moderate Vitamin D deficiency; please make an appointment to discuss this result with your GP. <12.5 nmol/L represents severe deficiency please make an appointment to discuss this result with your GP.	N/A
Transferrin receptors (sTfR)[3]	µg/l	ALL	F&M	4.5 – 11.1	N/A	N/A

[1] Addenbrookes Department of Clinical Biochemistry & Immunology;
[2] Previous NDNS reference ranges;
[3] Virtanen et al Higher concentration of sTfR in children than in adults *Am J Clin Nutr* 69:256-260 1999
[3] Cranendonk et al J Clin Chem Clin Biochem (1985) 23, 663 – 667 compared automated ranges with manual diffs in 0 – 16yr olds

Addendum 3. MRC HNR Interviewer Skinfold Thickness Measurements

Report from HNR for DNSIYC Project Board Meeting 19th October 2009

1 AIMS

1.1 To determine if it is possible to train NatCen interviewers to measure skinfold thickness on infants with a suitable degree of accuracy to enable them to carry out skinfold measurements on all infants at the home interviews

2 METHODS

A session was organised to facilitate the training of interviewers:

2.1 A one day training day with Paediatric research nurses who:

- discussed the theory of skinfolds
- explained the use of skinfold calipers
- explained the standard operating procedure for skinfolds
- discussed the need for accuracy for these measures
- gave theoretical training on measuring subscapular and triceps thicknesses
- supervised practice on adult volunteers in the morning
- supervised practice on infant dolls in the afternoon
- organised an adult quality control session to determine accuracy of skinfold measurements by NatCen interviewers. Each research nurse (n=2) and each NatCen interviewer (n=5) recorded the subscapular and tricep thickness measurements on 5 adults volunteers
- discussed the practical differences and transition from taking skinfold thickness measurements on adults to taking them on infants

Accuracy was determined by comparing the mean bias and level of inter-observer error between research nurses and NatCen interviewers.

2.2 A separate quality control session was also planned to assess the accuracy of performing skinfold measurements on infants aged between 4-18 months, however this was cancelled due to issues regarding research governance and Ethics committee approval.

3 RESULTS

The first training session provided results for the triceps and subscapular measurements for each of the 5 volunteers who had their skinfolds measured (these were performed in triplicate and the average was taken for each measurement).

Table 1: Triceps thickness

	Mean Triceps thickness (mm)	Inter-observer Variation
Interviewer (n=5)	13.7	14%
Nurse (n=2)	12.6	5%
Mean difference	*+1.1 (+9%)*	

Table 2: Subscapular Measurements

	Mean Subscapular thickness (mm)	Inter-observer Variation
Interviewer (n=5)	11.1	6%
Nurse (n=2)	10.8	14%
Mean difference	*+0.3 (+3%)*	

Following the training session, the volunteers were asked to complete a short questionnaire regarding their experience as "test subjects" for skinfold measurements. As the infants in DNSIYC will not be of an age to communicate through words it was important to understand how volunteers 'felt' after their experience. There was a mixture of responses:

"from interviewer to interviewer the amount of skin pinched felt as though it varied considerably, with muscle often included"

"It was a shame there couldn't have been infants to practice on, but perhaps it was just as well, in order to first see the difficulties experienced by interviewers measuring adults, before looking at other issues related specially to measuring babies"

"Personally, I found the measurement ***quite uncomfortable*** *and, at times,* ***painful****."*

"In terms of carrying out a skinfold measurement, yes I do think the skills are transferable. I think a general skill of being around and handling children would be useful for measuring the skinfolds of infants".

"nurses held onto the area of skin from which they were going to apply the Calipers. The interviewers often let go of the skin once they had applied the Calipers. This was often the case when the measurements caused a ***slight discomfort****."*

"Interviewers were often too apologetic… this may cause the parents of the respondents to become more anxious about the measurements being taken"

"Some interviewers were better than others"

"Quality control would also be difficult to manage and, with children involved, I think it is best to err on the side of caution"

"I felt very little discomfort or pain, however I could feel the differences in the technique between people and think that some may struggle to apply this technique to very small, wriggly infants."

4 DISCUSSION

Previous Quality Control assessments at the MRC Epidemiology Unit (not published) have shown inter-observer variations of 4-11% for triceps and 3-4% for subscapular measurements. While variation of <10% would be ideal, skinfold measurements are notoriously difficult, possibly more-so in adults where variations of up to 15-20% are often reported.

Although the above results support the feasibility of the training schedule used, similar data would be required in infants to ensure that the technique is carried out correctly in children aged 4-18 months and to assess the accuracy of the measurements in infants. Unfortunately this assessment cannot be undertaken outside of an Ethically approved study, but could be performed during the dress-rehearsal stage of the survey.

Regardless of the supportive quantitative data for the actual measurements carried out supports the proposal that skinfolds are feasible for interviewers. However qualitative reports of the levels of discomfort and variation by interviewer suggests that there are challenges for interviewers in carrying out skinfold measurements on infants in the field.

5 CONCLUSION

We have determined that it is possible to train NatCen interviewers to measure skinfold thicknesses in adults with reasonable accuracy. However, there were concerns from some adult volunteers regarding discomfort and also variation in the proficiency of use of the equipment, and it was recognised that more appropriate training on infants of all NatCen interviewers in the survey would not be feasible.

We therefore propose that infant skinfold thickness measurements should be performed by trained paediatric research staff at the hospital-based research centres.

We raise the possibility of including arm circumference measurements by NatCen interviewers at home interviews as an alternative assessment of infant nutritional status.