Appendix M The spot urine sample: collecting and processing for urinary iodine measurement

M.1 Introduction

Spot urine samples were collected from participants aged 4 years and over for measurement of urinary iodine concentration in order to estimate population iodine status. Iodine concentration in a single spot urine sample does not provide any information about the individual's iodine intake because the iodine concentration fluctuates widely depending on liquid intake and therefore how dilute the urine is, as well as being influenced by the individual's recent iodine intake. However the median concentration of iodine in spot urine samples collected for a population group is used to estimate population iodine status and thresholds for interpretation have been defined by the World Health Organization (WHO).[1,a]

M.2 Ethical approval

As described in appendix B ethical approval was granted by a Multi-centre Research Ethics Committee (MREC)[b] for all aspects of the survey protocol, including collection of the spot urine sample, measurement of iodine in the spot sample and for storing spot urine sample residues for potential use in future analyses related to nutrition and health (where consent was given).

[a] The population urinary iodine median has been determined from spot urine samples. The proportion of the population with insufficient iodine intake cannot be determined from these data.

[b] Ethical approval for Years 6 to 9 was obtained from Cambridge South NRES Committee (Ref. No. 13/EE/0016).

M.3 Consent

Information leaflets were provided for participants, including an appropriate version for children. Eligible participants aged 16 years and over were asked to give written consent. For children aged under 16 years, written consent was sought from a parent or legal guardian, with written assent from the child where possible.

M.4 Exclusion from participation in providing a spot urine sample

Participants were asked a series of screening questions to assess their eligibility for providing a spot urine sample. Participants under the age of 4 years, those using a urinary catheter, and those who were incontinent were not asked to provide a spot urine sample. Women and girls were requested not to provide a urine sample if they were menstruating.

M.5 Interviewer training, procedures and instructions

Information about the recruitment and training of interviewers is provided in appendix B.

At the first interviewer visit,[c] interviewers were instructed to:

- check the participant's eligibility for providing a spot urine sample. If the participant did not meet the eligibility criteria they were not asked to provide a sample
- ensure that the participant understood the spot urine collection procedures
- confirm and obtain the appropriate written consents
- ask the participant to pass urine (not from the first urine pass after waking) directly into a labelled 30mL "universal" tube without touching the inside surface.

[c] If the urine sample could not be collected at the first visit, interviewers re-established eligibility and sought consent at visit 3 (see appendix B for more information on interviewer visits).

Participants were asked to avoid using sources of iodine contamination such as antiseptic sprays and wipes

- (after obtaining the spot urine sample) label the universal tube and the rigid outer packaging with the participant's serial ID, date of birth, sex and collection date
- record the details of the collection in the CAPI program
- leave the £5 spot urine sample promissory note with the participant

Immediately after the visit the interviewers were instructed to send the universal tube (inside the rigid outer packaging) to the Medical Research Council Elsie Widdowson Laboratory (MRC EWL) in the pre-addressed postal pack by first class post at ambient temperature and to post the associated consent form to NatCen.

M.6 Sample tracking, reception and storage

On receipt of samples at MRC EWL, associated details (serial ID, date of birth and sample collection date) were recorded and cross checked with the database, to confirm the correct data. Urine samples were refrigerated at 5-8^{o}C for up to 2 weeks before being aliquoted (after reaching room temperature) into 3 1.7mL aliquots of urine; this was modified if the spot urine sample was smaller than 5mL.The aliquots were then entered into ItemTracker and stored frozen at -20^{o}C.

The collection and aliquot tubes were always new (and unwashed) and were of manufacturing types which had been spot checked for iodine content at MRC EWL, to avoid any inadvertent iodine contamination arising from the containers.

M.6.1 Assay auditing at MRC EWL

Samples were analysed in approximate order of receipt. Internal quality control samples were included to monitor precision and external quality assurance schemes were included where available in order to confirm the accuracy of the assays.

[1] World Health Organization (WHO), Assessment of iodine deficiency disorders and monitoring their elimination. [Internet]. Available from: http://whqlibdoc.who.int/publications/2007/9789241595827_eng.pdf.