Study Title: Non-contact infrared thermometers for measuring body temperature in acutely ill children: a method comparison study

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All investigators declare they have no conflicts of interest that could impact the integrity of the study.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

TABLE OF CONTENTS

1. SYNOPSIS

Study Title	Non-contact infrared thermometers for measuring body temperature in acutely ill children: a method comparison study	
Internal ref. no. / short title	MEasuring TemperatuRe In Children: METRIC	
Study Design	Cross-sectional method agreement study with nested qualitative study	
Study Participants	Children between 0 and 5 years with acute illness attending up to 15 GP practices and out-of-hours services in England.	
Planned Sample Size	533 for main trial & up to 30 parents for qualitative substudy (until data saturation is reached)	
Planned Study Period	1/12/2016 – 31/5/2018	
	Objectives	**Outcome Measures**
Primary	To assess the agreement between the Thermofocus non-contact infrared thermometer and electronic axillary thermometer in children aged 5 and under presenting to primary care with an acute illness	Limits of agreement
Secondary	1) To assess agreement between the Thermofocus non-contact infrared thermometer and infrared tympanic thermometer (and therefore between tympanic and axillary) in children aged 5 and under presenting to primary care with an acute illness 2) To assess agreement between the Thermofocus and a cheaper alternative brand of non-contact infrared thermometers in children aged 5 and under presenting to primary care with an acute illness 3) To assess the ability of non-contact infrared thermometers to detect fever (≥38°C) in these children 4) To assess failure rates of all thermometers due to lack of cooperation of the child (unable to obtain measurement after three attempts), mechanical issues (operational or	1) Limits of agreement 2) Limits of agreement 3) Accuracy for diagnosing fever 4) Proportion of failed measurements

	technological failure) and/or implausible results. 5) To explore acceptability of the four thermometry methods to parents and children 6) To assess the reproducibility of measurements made with the two NCITs	 5) Acceptability to parents and children if applicable 6) Intra-observer variability
Tertiary	1) To explore the association between temperature readings and medication use at the index consultation with health outcomes and healthcare usage during follow-up	1) Incidence of repeat consultations in in-hours and out-of-hours general practice, secondary care referrals and hospital admissions in the 30 days following recruitment

2. ABBREVIATIONS

GP	General practitioner
NCIT	Non-contact infrared thermometers
NICE	National Institute for Health and Care Excellence
REC	Research Ethics Committee
HRA	Health Research Authority
OOH	Out-of-hours services

3. BACKGROUND AND RATIONALE

Acute infections in children are one of the most common problems in general practice and are associated with considerable burden on NHS resources. Nearly 40% of parents with children aged 6 to 17 months consult a health care professional when their child has a high temperature.[1] In the UK, acute infections result in 4 consultations per person-year in children aged less than 1 year, and 1.3 consultations per person-year in children aged 1-15 year.[2] Febrile illness accounts for 20% of all visits to the paediatric emergency department.[3]

The National Institute for Health and Care Excellence (NICE) recommends the measurement of temperature in each child: electronic axillary thermometers should be used to measure temperature in children under 4 weeks of age, while children over 4 weeks of age may have their temperature measured using electronic axillary or infrared tympanic thermometers.[4] However, axillary thermometers require

healthcare professionals to undress the child and hold the thermometer in the axilla for at least 30 seconds.[5] Infrared tympanic thermometers are easier to use, but may be inaccurate due to ear wax or insufficient straightening of the ear canal.[6] Studies show that primary care doctors measure temperature in less than half of children,[7] despite the fact that a temperature of 40°C or higher is recognised as being a red flag for serious illness in children.[8]

Non-contact infrared thermometers (NCITs) can measure temperature rapidly and non-invasively, potentially causing less distress to children than using conventional thermometers and with minimal risk of cross-infection.[9] Non-contact infrared thermometers (NCITs) measure the intensity of infrared radiation emitted by the body using a remote sensor and convert these measurements into temperature readings. Measuring children's temperature using NCITs has several potential advantages, since no body surface contact is required.[10] Most NCITs measure temperature over the central forehead area, but temperature over other body surfaces may also be measured if the child's forehead is perspiring or if the child is moving. NCITs can also measure children's temperature while they are sleeping. In addition, the risk of cross-infection is negligible and neither disinfection nor disposable probe covers are needed.

Reports of agreement between NCITs and conventional thermometers have been variable. A study which compared the Thermofocus 0800 with a mercury-in-glass axillary thermometer reported a mean difference of only +0.07°C (95% confidence interval [CI] -0.62°C to +0.76°C).[11] However, comparisons with infrared tympanic thermometers reported larger mean differences of -0.38°C (95% CI -1.47 to 0.70)[12] and +2.34°C (95% CI 0.26 to 4.42).[13] One study reported close agreement between NCIT and rectal thermometry, with a mean difference of 0.029°C ± 0.01°C.[14] However, the mean difference reported in another study was around ten times higher (0.34°C, 95% CI -0.92°C to 1.60°C).[15] Variation in agreement has also been demonstrated with different NCIT devices. Closer agreement is reported with the Thermofocus 0700A2 (mean difference -0.264°C ± 0.395°C) than with the Beurer FT40 (mean difference -0.767°C ± 0.681°C).[16] Additionally, whilst NCITs are mostly reported to have high sensitivity and specificity in detecting fever of 38°C or higher using conventional thermometry,[11 13 14 17] sensitivity was only estimated as 27%[15] and 12%[16] in two studies.

However, the clinical utility of NCITs in primary care settings is still unclear, since most previous studies were conducted in paediatric inpatient populations[13 15 16] or mixed hospital ambulatory care and ward settings.[14 18] Additionally, previous studies have only evaluated a limited range of NCITs, mainly from the Thermofocus range,[10 11 14 16-18] and have reported widely varying levels of agreement between temperature measurements obtained using different models of NCIT versus axillary, tympanic, or rectal thermometers.

Most studies evaluating the accuracy of NCITs recruited children from hospital inpatient,[12 13 15 16] or a combination of inpatient and ambulatory care settings[14 18] and compared NCITs with thermometers which are not currently recommended for use in children, including rectal[10 14-16] and mercury-in-glass axillary thermometers.[11]

Understanding the performance of NCITs compared to tympanic and axillary thermometers will be highly relevant to primary care clinicians. Use of tympanic thermometers is widespread in primary care, while digital axillary thermometers are least expensive and the only method recommended for the youngest children. The proposed study will examine the agreement between two NCIT models (Thermofocus and a cheaper NCIT model) versus electronic axillary and infrared tympanic thermometers in children who present with acute illness in primary care. If suitable agreement is established, particularly around the

key decision-making threshold of 38°C, use of NCITs in primary care will facilitate more efficient and equally accurate assessment of children who present with acute febrile illness. The findings of the proposed research will therefore have strong potential to inform future clinical guidelines for measuring and interpreting temperature in children who present with acute febrile illness in primary care. They will also allow parents to make more informed choices about accurate home thermometry.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To assess the agreement between the Thermofocus NCIT and electronic axillary thermometer in children aged 5 and under presenting to primary care with an acute illness	Limits of agreement	First measurement at first and only study visit
Secondary Objectives		
1) To assess agreement between the Thermofocus NCIT and infrared tympanic thermometer (and therefore between tympanic and axillary) in children aged 5 and under presenting to primary care with an acute illness	1) Limits of agreement	First measurement at first and only study visit
2) To assess agreement between the Thermofocus and a cheaper alternative brand of NCIT in children aged 5 and under presenting to primary care with an acute illness	2) Limits of agreement	First measurement at first and only study visit
3) To assess the ability of NCIT to detect fever (≥38°C) in these children	3) Diagnostic accuracy	First measurement at first and only study visit

4) To assess failure rates due to lack of cooperation of the child (unable to obtain measurement after three attempts), mechanical issues (operational or technological failure) and/or implausible results.	4) Proportion of failed measurements	Measurements at first and only study visit
5) To explore acceptability of the four thermometry methods to parents and children	5) Acceptability to parents, acceptability to children if applicable	Telephone interview within one month of the study visit
6) To assess the reproducibility of measurements made with the two NCITs	6) Intra-observer variability	Two measurements at first and only study visit
Tertiary Objectives		
1) To explore the association between temperature readings and medication use at the index consultation with health outcomes and healthcare usage during follow-up	1) Incidence of repeat consultations in in-hours and out-of-hours general practice, secondary care referrals and hospital admissions in the 30 days following recruitment	Notes review on study completion

5. STUDY DESIGN

The design is a cross-sectional method agreement study with a nested qualitative study.

The study will run in up to 15 GP practices and out-of-hours centres in England. We will train the practice or OOH service receptionist to hand out information leaflets to all parents who have brought in a child below the age of 5 years for a GP or nurse appointment. Subsequently, children and their parents/guardians will be approached by a research assistant from the study team while they are in the waiting room for possible recruitment to the study. Those who agree will be offered the opportunity to discuss the study further and will provide verbal informed consent.

The measurements could be conducted either prior to or after the child's GP appointment.

The child will have their temperature measured using four different thermometers:

- Electronic axillary: Welch Allyn SureTemp
- Infrared tympanic: Braun Thermoscan

- NCIT 1: Thermofocus 0800
- NCIT 2: Firhealth Forehead Thermometer

Children under 4 weeks of age will not have the tympanic thermometer measurement. Parents will be asked to score the acceptability of each thermometer on a visual analogue scale and rank the thermometers by preference. Children`s reaction to the different measurements will be recorded by the Patient Discomfort Scale.[19] We will record prior antipyretic use, parental impression of fever and fever duration, failure to perform measurements due to lack of cooperation of the child after three attempts, mechanical issues (operational or technological failure) and clinically implausible readings (based on clinician's assessment). Parents and children will be blinded to the temperature measurements until they have rated their acceptability to avoid bias.

There is only one study visit, which is at the GP practice or out-of-hours centre where the children will be recruited and all interventions will be performed.

Verbal consent will be sought for further contact regarding a qualitative telephone interview study to explore parent's views and preferences regarding the different thermometers used. A subset of parents who consent to further contact will be approached for an interview based on a purposive sampling procedure.

Verbal informed consent will also be obtained from parents to keep their contact email or telephone number securely. This would be in order that future contact could be made to obtain written informed consent to access details of their child's medical notes regarding re-attendance, secondary care referrals and admissions in the 30 days after the initial contact.

Recruitment to the study is expected to last 9 months, with each patient entering the study once.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Children between 0 and 5 years with an acute illness presenting to a GP practice or an out-of-hours service in England.

6.2. Inclusion Criteria

- Parent or guardian is willing and able to give informed consent for participation in the study.
- Male or Female, aged 0 to 5 years
- Presenting to a GP practice or out-of-hours service with an acute illness of a maximum of 14 days duration

Inclusion criteria for qualitative interviews

- Recruited to main study
- Able to conduct a telephone interview in English

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Acute trauma is the main reason for presentation
- Clinically unstable warranting immediate care
- Prior inclusion in the study
- Unable to understand trial material in English

7. STUDY PROCEDURES

7.1. Recruitment

Children will be identified and recruited at in-hours general practices and at out-of-hours services, at presentation.

7.1. Screening and Eligibility Assessment

The receptionist will hand out information sheets to parents/guardians of children aged between 0 and 5 attending a GP or nurse appointment to inform them about the study. The parents/guardians will be approached by the research assistant who will explain the study, then check eligibility and, if eligible and willing to participate, seek verbal informed consent. Parents/guardians of children aged between 0 and 5 using the computer system to check in, the research assistant will approach them and inform them about the study.

7.2. Informed Consent

Verbal informed consent will be taken by research assistants who will have completed an accredited course on Good Clinical Practice not longer than two years ago. The research assistant will record that verbal consent has been obtained in the CRF.

Written and verbal versions of the Participant Information Sheet will be presented to the parents/guardians detailing the exact nature of the study, what it will involve for the child, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the parents/guardians are free to withdraw their child from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal, and that this can be done by reply slip or email after the main study contact is complete.

The parent/guardian will be given the opportunity to question the research assistant to decide whether they will participate in the study. Considering the nature of this study and the limited risks associated with the temperature measurements, a limited time to consider the information seems warranted.

Verbal consent will also be sought for further contact by (phone or e-mail) to:

a) Ask if parents are willing to be involved in the nested qualitative telephone interview (to take place at least one week after initial recruitment)
b) Contact in the future to ask if willing to consent to their child's medical notes review

Parents who consent to further contact for the nested qualitative study will give additional Informed consent for this nested study at the point of re-contact. Consent will be obtained verbally and audio-recorded, with the researcher initialling each point to indicate that verbal consent was given.

7.3. Randomisation and blinding

Randomisation will only take place to define the order of the thermometers used to do the measurements. Children will not be randomised. We will use Random Number Generator (www.random.org) to generate a predefined list, which will be placed directly on the CRF using stickers.

Children and their parents/guardians will be blinded from the readings until they have indicated acceptability for each thermometer.

7.4. Study visit

The research assistant will record demographic information (including household composition, parental age and ethnicity) and baseline information (including prior fever medication use, parental impression of fever, fever duration) for each child. Subsequently, the research assistant will measure body temperature with four different thermometers, in a random order predetermined by the use of a random number generator.

Temperature measurements will be taken in a dedicated space either in the waiting room or in a separate room at the primary care facility. The child will be partially undressed to allow for the axillary measurement before any measurement is taken. Measurements will be performed consecutively in the shortest time frame possible, and no medication or drinks will be administered between measurements. Once the four primary measurements are complete, a second measurement will be taken with each NCIT to evaluate reproducibility. Parents will be asked to score the acceptability of the different thermometers on a separate form.

The readings of the NICE recommended thermometers (electronic axillary and tympanic) will be made available to the GP who subsequently sees the child when the child is seen by the study personnel prior to their appointment. These readings will be performed by an appropriately trained member of the research team. The GPs will be informed that measurements are taken by researchers who do not hold a medical qualification but are suitably experienced to perform this measurement. Providing these readings will reduce subsequent burden to the child of a repeated measurement being taken during the consultation and will reduce the time needed for the consultation. The GP will decide on appropriate clinical management as they see fit.

7.5. Follow up data collection

We aim to collect data on health outcomes and incidence of repeat consultations in in-hours and out-of-hours general practice, secondary care referrals and hospital admissions in the 30 days following recruitment. This will be requested by the researcher form the GP over the phone within 1 month following the study visit.

7.6. Follow up interview

After the study visit, a subset of parents who indicated they might be willing to take part in the qualitative interviews will be contacted and interviewed by telephone within one month after initial recruitment. These qualitative telephone interviews will explore their views and preferences regarding the different thermometers used. Recruitment to the nested qualitative study will be based on a purposive sampling procedure.

7.7. Discontinuation/Withdrawal of Participants from Study

Main study

Each parent/guardian has the right to withdraw their child from the study at any time. In addition, the Investigator may discontinue a child from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Withdrawal of Consent

Withdrawal from the main study will result in exclusion of the data for that child from analysis. Withdrawn participants will be replaced.

The reason for withdrawal (if given) will be recorded in the CRF.

If parents decide to withdraw their child's data from the study or withdraw their consent for further contact, they can inform the study team by e-mail or by sending the reply slip (which is included in the PIS pack) back to the study team.

Qualitative study

In our qualitative interviews each participant has the right to withdraw from the study at any time, without giving a reason by e-mailing or calling the study team. If participants do decide to leave the study, we will use the information we have collected up to that time accordingly:

If the tape recording has been transcribed (and anonymised) at the point where consent is withdrawn, then the data will still be included in the study.

If, however, the tape recording has not been transcribed at the point where consent is withdrawn, then the data will not be used.

7.8. Definition of End of Study

The end of the study is the date of the last follow-up interview, which is expected to be completed 1 month after inclusion of the last child.

8. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICES

8.1. Description of non-contact infrared thermometers

A non-contact thermometer is a no touch thermometer, designed to allow temperature measurements on the forehead without touching the body by sensing infrared emissions.

NCIT 1: Thermofocus 0800

The Thermofocus is a non-contact infrared thermometer that measures body temperature by pointing the Thermofocus thermometer at the centre of the forehead. The optimal distance between the forehead and the thermometer is determined by a LED system emitting two light beams. As the thermometer is moved closer to the forehead, at the right distance, (approx. 3 cm) the two beams converge to a single red dot. Releasing the button until the lights flash will result in a temperature reading.

A manual calibration system is provided with the thermometer to improve accurate readings. No extensive training is needed to operate the device and a comprehensive user manual is provided together with the device.

The Thermofocus 0800H5 by Thermofocus is a certified medical device, FDA approved and CE marked.

NCIT 2: Firhealth Forehead Thermometer

The Firhealth Forehead Thermometer by Firhealth is an FDA approved CE-marked non-contact infrared thermometer that works in essentially the same way as the Thermofocus. To measure temperature, you have to point the thermometer probe to the forehead at a distance of 1 to 5 cm. After pressing the "Measure" button, the device bleeps and displays the temperature reading on the LCD screen.

Considering the relative ease-of-use of both these devices, no specific training, apart from the instructions provided above, is needed to handle these thermometers.

9. STATISTICS AND ANALYSIS

9.1. Description of Statistical Methods

Statistical methods will focus on the agreement between thermometers, the accuracy of detecting fever and the failure rates. All children will contribute data to each analysis, when available. No interim analyses will be performed, other than recruitment monitoring.

9.2. The Number of Participants

The sample size will allow estimation of both the primary outcome (agreement between Thermofocus NCIT and the electronic axillary) and secondary outcomes with sufficient precision. We anticipate that more than 2000 children will attend the GP practices and out-of-hours services during the study period of whom a minimum of 533 would have to consent to be included in the study. In previous observational studies in primary care we have consistently achieved a participation rate of 70% or higher, which makes us confident that we will be able reach the required sample size.

Our primary outcome is the agreement between the Thermofocus NICT and the electronic axillary thermometer. The sample size calculation is based on the desired accuracy of the limits of agreement.[20]. Assuming an accuracy of ±0.075C is desired for the 95% confidence intervals of the limits of agreement and the standard deviation of the agreement between temperatures measured by non-contact and electronic axillary thermometers would be 0.5C[10 11 13 14 17], a minimum sample size of 533 participants will be required.

Secondary outcomes of agreement between the other thermometer types will be estimated with the same precision.

Diagnostic accuracy for detecting fever (temperature ≥38°C) will be analysed by calculating sensitivity, specificity, predictive values, and likelihood ratios, with 95% confidence intervals. Based on our previous experience of recruiting unwell children in primary care, we expect 25% of children to have a fever, so we expect to have data from approximately 133 children for calculation of sensitivity, and 399 for calculation of specificity. Reports of both sensitivity and specificity of NCIT for detecting fever range from 75-97%.[11 13 14 17] Assuming that sensitivity and specificity are both 85%, the half-width of the confidence intervals for sensitivity would be 4.3%, and 2.5% for specificity. Even if sensitivity and specificity are 75%, we would obtain half-widths for the confidence intervals of 5.2% for sensitivity, and 3.0% for specificity.

For the qualitative interviews, we aim to interview up to 30 parents of children included in the study, continuing until saturation is reached.

9.3. Analysis of Outcome Measures

The primary endpoint, agreement between the non-contact Thermofocus 0800 and the electronic axillary thermometer, will be based on Bland and Altman plots which will provide an indication of bias and limits of agreement between the measurements. Exact 95% confidence intervals (CI) around this estimate will be calculated.

The diagnostic accuracy of the thermometers to detect fever will be expressed as sensitivity, specificity, predictive values, likelihood ratios and odds ratio using standard analysis and reported with 95% confidence intervals.

The association between antipyretic medication use and patient outcomes will be investigated using multivariate logistic regression, taking into account patient age and axillary temperature, as well as the type of antipyretic used. If comparable data can be sourced from other studies in similar patient groups, we will consider whether an analysis using combined data will be more appropriate to increase the power of this analysis.

The scores on the Visual Analogue and Patient Discomfort Scales will be analysed using non-parametric techniques resulting in median acceptability (and interquartile ranges) for each thermometer.

Failure rates and indeterminate readings will be reported as proportions with estimates of precision.

For the qualitative interviews, we will use constant comparative analysis, involving familiarisation with the data, noting initial themes, systematic and detailed coding, and exploration of relationships amongst codes. The coding schemes will incorporate emerging themes as well as topics presented a priori in the topic guide. Data collection and analysis will be concurrent so that emerging themes are explored in further interviews. Interim themes will be discussed by the research team and PPI group for consensus and validation.

10. DATA MANAGEMENT

10.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

10.2. Data Recording and Record Keeping

All study data will be recorded on paper during the study visit and subsequently entered by a member of the research team into a password protected electronic database, hosted at the Nuffield Department of Primary Care Health Sciences at the University of Oxford. Paper files will be kept in a locked filing cabinet at the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The participants will be identified by a study specific participants number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

For the qualitative study, participants will be identified by the same study specific participants number as in the main study; the name will NOT be included in the electronic file. Interviews will be audio-recorded, with the consent of the participants. Audio recordings will be transcribed by a transcription company approved by the University for this purpose with whom the University has a confidentiality agreement and who can provide secure transfer of electronic files (usually through the OxFile system) without the need for e-mail or post. When they are returned to the researcher, the transcripts will be checked against the audio recordings and any identifying information removed from the transcripts. Audio recordings will not be anonymised but will be kept securely on a password protected computer and destroyed at the end of the study. All files will be uploaded into NVivo 10 on a password-protected computer. Other anonymised study material will be kept for a minimum of 21 years after study completion.

Data relating to individual participants will be labelled with an identifier number. The identifier key will be stored separately and securely on a password-protected computer in the Nuffield Department of Primary Care Health Sciences (NDPCHS).

11. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

12.3. Approvals

The protocol, informed consent forms, participant information sheets and any proposed advertising materials will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

12.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, with the exception of the CRF. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

12.6. Other Ethical Considerations

The study will recruit children between 0 and 5 years of age. Parents or guardians will be asked for consent after being fully informed about the goal and procedures of the study. Limited time will be provided to consider participation due to constraints of measuring the temperature just before or after their GP's consultation. There is a low risk of discomfort or additional stress for the child by virtue of

having additional tests whilst potentially feeling unwell. We have attempted to reduce this by performing the procedure at the GP surgery/OOH rather than requiring a separate visit.

13. FINANCE AND INSURANCE

13.1. Funding

The study is funded by the NIHR Health Technology Assessment programme.

13.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

14. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR Health Technology Assessment programme. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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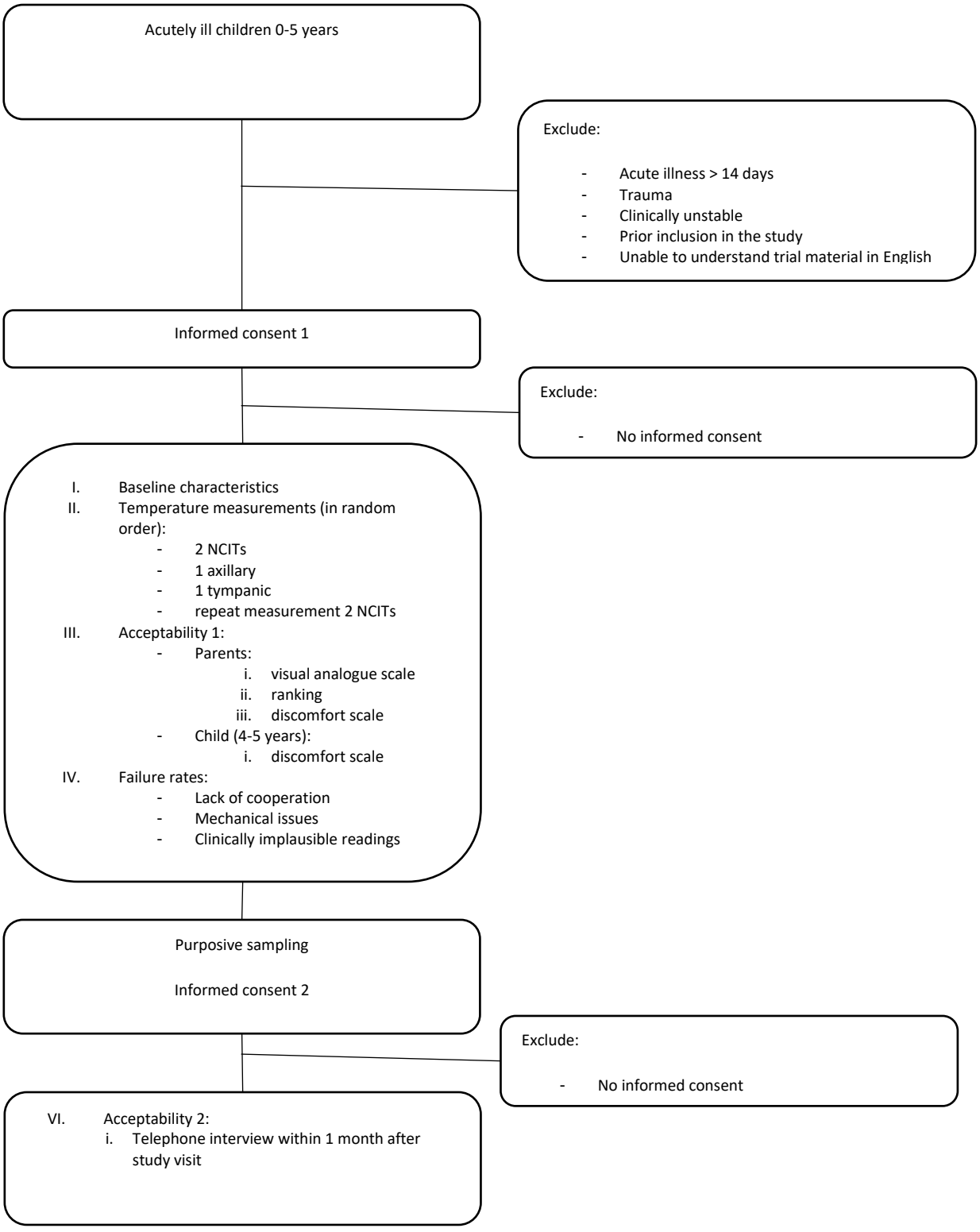
16. APPENDIX A: STUDY FLOW CHART



17. APPENDIX B: QUALITATIVE INTERVIEWS TOPIC GUIDE

Parent/guardian interviews: Topic Guide

1. Introduction

Explain purpose of interview and audio recording procedures.

Answer any questions. Ensure participant has given informed consent.

Begin audio recording.

2. First thoughts about the thermometers

- What were you hoping for when you came to the GP or OOH GP?
  (Did you expect your child would have a temperature measurement? Did you want your child to have a temperature measurement?)

- What did you think when you were offered the temperature measurements?
- Was there anything that put you off any of the temperature measurements?
  (Were you worried about any of them being uncomfortable for your child/ dangerous/ anything else?)

3. Taking the test

- How do you think your child felt about having the temperature measurement with the non-contact thermometer no. 1 and no. 2; with the axillary thermometer and with the ear thermometer?
  (Was it painful? Was it annoying? Was he/she nervous? Was it as they expected? How did you feel about your child having the measurements done? How did you feel about the actual measurements?)

4. Future use of the thermometers

- Which thermometer do you think should be used in the future?
  (In what situations? Would you want your child to have it again?)
- How do you feel about measuring temperature in children more generally?
  (Do you think these measurements are offered frequently enough? Do you want your child to have more or less temperature measurements?)
- Would you consider using a non-contact thermometer in the home environment or suggesting they use one at a childcare facility? What features make you more or less likely to do this?
- What would it take to reassure you about the accuracy of any type of thermometer?

5. Any other remarks?

6. Close

Thank participant.

End audio recording.

18. Appendix C: SCHEDULE OF STUDY PROCEDURES

Procedures	**Visits (1)**
	Visit timing **Day 0**
	All procedures performed by research assistant
Eligibility assessment	X
Verbal Informed consent 1	X
Demographics	X
Baseline information	x
Randomisation	X
Assessment 1	Non-contact thermometer 1
Assessment 2	Non-contact thermometer 2
Assessment 3	Axillary digital thermometer
Assessment 4	Tympanic thermometer
Assessment 5	Non-contact thermometer 1
Assessment 6	Non-contact thermometer 2
Failure rate recording	x
Acceptability 1	Visual analogue scale and ranking by preference
	Telephone follow up within 1 month
Informed consent 2	X
Acceptability 2	Telephone semi-structured interview

19. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	2	10/03/17	Dr Gail Hayward	Changes suggested following Berkshire Ethics Committee review were made as follows: • Stated that " Children under 4 weeks of age would not have the tympanic thermometer measurement" • Written consent forms are no longer necessary. Research assistants will obtain parents/guardians verbal consent for the main study and record that verbal consent has been obtained it in the CRF • Verbal consent will also be sought for further contact by phone or e-mail to ask if parents are willing to participate in the interview study or for future contact regarding access to their child's medical notes review • Telephone number or e-mail address of parents/guardians who consent for further contact will be collected by the research assistants and stored securely