# Non-contact infrared thermometers compared with current approaches in primary care for children aged 5 years and under: a method comparison study

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# Scientific summary

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# **Scientific summary**

## Background

Acute infections are very common in children, resulting in a high proportion of children seeking health care for acute infections. There is specific guidance for management of febrile illness in children aged  $\leq$  5 years, including the measurement of temperature in each child presenting with fever symptoms using either electronic axillary thermometers or infrared tympanic thermometers in children aged  $\geq$  4 weeks. However, axillary thermometers require the child to be at least partially undressed and the thermometer has to be held in place for at least 30 seconds. Infrared tympanic thermometers are easier to use but may be inaccurate when the ear drum is insufficiently exposed because of ear wax or insufficient straightening of the ear canal. Non-contact infrared thermometers could reduce both the distress of the child and the risk of cross-infection. These thermometers do not require direct contact with the child, are fast and do not require additional disposable probe covers. This means that they could result in less discomfort, while minimising the risk of cross-infection. However, our Horizon Scan of this diagnostic technology found limited evidence of comparative accuracy to standard methods.

## **Objectives**

The objectives of this study were to compare non-contact thermometers with electronic axillary and infrared tympanic thermometers in children presenting to primary care. These objectives included an assessment of agreement between different thermometer types, and exploration of the acceptability and discomfort to patients.

## Design

This was a method comparison study with a nested qualitative study.

## Setting

The study was conducted in nine general practices and one out-of-hours centre in Oxfordshire.

#### **Participants**

Children aged  $\leq$  5 years attending with an acute illness of a maximum of 14 days were eligible. Children for whom acute trauma was the main reason for presentation, who were clinically unstable, who had already been enrolled in the study or whose parents were unable to understand trial material in English were excluded from the study.

#### Interventions

Each child had their temperature measured using four different thermometers:

- 1. electronic axillary Welch Allyn SureTemp (Welch Allyn®, USA)
- 2. infrared tympanic Braun Thermoscan (Braun GmbH, Kronberg, Germany) (not in children < 4 weeks of age)
- 3. non-contact infrared thermometer 1 Thermofocus 0800 (Tecnimed Srl, Varese, Italy)
- 4. non-contact infrared thermometer 2 Firhealth Forehead Thermometer (Firhealth, Shenzhen, China).

The Thermofocus non-contact infrared thermometer was included as it was the most extensively evaluated thermometer in other settings. The Firhealth device was included as an example of a cheaper, non-contact infrared thermometer. The order in which the thermometers were used was randomised prior to the study start for each participant [using a random number generator (www.random.org)]. Measurements were performed consecutively; a second measurement with each non-contact thermometer was carried out to evaluate reproducibility. Failed measurements were recorded.

We assessed discomfort to the child using the Patient Discomfort Scale and Wong–Baker FACES<sup>®</sup> Pain Rating Scale (Wong–Baker FACES<sup>®</sup> Foundation, Oklahoma City, OK, USA). Parents were also asked to score acceptability of each thermometer on a visual analogue scale and rank thermometers by preference.

#### Analysis

The sample size calculation was based on a desired accuracy of  $\pm 0.075$  °C 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 0.5 °C. The sample size initially set at 533 participants was revised during the course of the study to 400 participants, assuming that 0.10 °C accuracy would be sufficient. Analyses of agreement were conducted based on Bland–Altman plots, which provide an indication of bias and limits of agreement between the measurements. Exact 95% confidence intervals around this estimate have been calculated. Diagnostic accuracy for detecting fever (temperature of  $\geq$  38 °C measured by the electronic axillary thermometer) was analysed by calculating sensitivity, specificity, predictive values and likelihood ratios, with 95% confidence intervals. Other analyses, such as failure rates and indeterminate readings, are reported as proportions with their corresponding estimates of precision. The scores on the visual analogue scale and the Patient Discomfort Scale have been analysed using nonparametric techniques, resulting in median acceptability (and interquartile ranges) for each thermometer.

For the nested qualitative study, parents were purposively sampled to achieve maximum variation in gender, age of parent, age of child, ethnicity and number of other children in the household. Recruitment continued until the research team agreed that data saturation had been achieved and sufficient explanation for the categories generated was reached. Interviews were semistructured and by telephone (n = 20) or face to face (n = 1) following a flexible topic guide developed by the research team and patient and public involvement panel, which evolved in response to emerging themes. Data analysis followed a thematic approach with the assistance of NVivo (version 11; QSR International, Warrington, UK). This included familiarisation with the data, open coding and subsequent inductive reasoning to identify salient categories and relationships between emerging themes derived from the data. Data and codes were then checked by two researchers (EM and MG). The codes and themes were developed and interpreted in discussion with the wider research team.

#### Main outcome measures

The primary outcome was agreement between the Thermofocus thermometer and the axillary thermometer. Secondary outcomes included agreement between all other sets of thermometers, diagnostic accuracy for detecting fever, and acceptability and discomfort.

#### Results

A total of 401 children (203 boys) were recruited, with a median age of 1.6 years (interquartile range 0.79–3.38 years). Most children were of white British ethnicity (69.83%). Approximately 30% of the children were feverish at the time of inclusion. There were 396 temperature readings with the Thermofocus non-contact thermometer (first measurement), 399 with the Firhealth non-contact

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thermometer (first measurement), 376 with the electronic axillary thermometer and 390 with the tympanic thermometer. Second measurements with the Thermofocus and Firhealth non-contact thermometers resulted in 395 and 397 readings, respectively.

On average, the non-contact thermometers showed lower readings than the electronic axillary thermometer. The readings of the Thermofocus differed from those of the electronic axillary thermometer by a mean of -0.14 °C (95% confidence interval -0.21 to -0.06 °C), with the lower limit of agreement being -1.57 °C (95% confidence interval -1.69 to -1.44 °C) and the upper limit being 1.29 °C (95% confidence interval -1.69 to -1.44 °C) and the upper limit being 1.29 °C (95% confidence interval -1.69 to -1.44 °C) and the upper limit being 1.29 °C (95% confidence interval -1.69 to -1.44 °C) and the upper limit being 1.29 °C (95% confidence interval -0.23 to -0.09 °C), with the lower limit of agreement being -1.54 °C (95% confidence interval -1.66 to -1.41 °C) and the upper limit being 1.22 °C (95% confidence interval -1.66 to -1.41 °C).

Agreement between the first and second readings with each non-contact thermometer resulted in a mean difference of  $-0.04 \,^{\circ}$ C (95% confidence interval -0.07 to  $-0.01 \,^{\circ}$ C), a lower limit of agreement of  $-0.56 \,^{\circ}$ C (95% confidence interval -0.60 to  $-0.51 \,^{\circ}$ C) and an upper limit of agreement of 0.47  $\,^{\circ}$ C (95% confidence interval 0.43 to 0.52  $\,^{\circ}$ C) for the Thermofocus. There was a mean difference of 0.01  $\,^{\circ}$ C (95% confidence interval -0.02 to 0.04  $\,^{\circ}$ C), a lower limit of agreement of  $-0.60 \,^{\circ}$ C (95% confidence interval -0.65 to  $-0.54 \,^{\circ}$ C) and an upper limit of agreement of 0.61  $\,^{\circ}$ C (95% confidence interval 0.56 to 0.67  $\,^{\circ}$ C) for the Firhealth thermometer.

Sensitivity and specificity of the Thermofocus non-contact thermometer were 66.7% (95% confidence interval 38.4% to 88.2%) and 98.0% (95% confidence interval 96.0% to 99.2%), respectively. For the Firhealth thermometer, sensitivity was 12.5% (95% confidence interval 1.6% to 38.3%) and specificity was 99.4% (95% confidence interval 98.0% to 99.9%). Similarly, the sensitivity of the tympanic thermometer to detect fever defined by axillary temperature measurement was 62.5% (95% confidence interval 35.4% to 84.8%) and specificity was 96.0% (95% confidence interval 93.4% to 97.8%).

The non-contact thermometers required fewer attempts to obtain a reading than the axillary and tympanic thermometers. In addition, there were nine technical failures with the Thermofocus non-contact thermometer, one with the Firthealth non-contact thermometer, eight with the electronic axillary thermometer and 10 with the tympanic thermometer.

The majority of parents found all methods acceptable, although discomfort ratings were highest for the axillary thermometer. Median parental acceptability as assessed with a visual analogue scale was highest for the Firhealth non-contact thermometer (8.23 cm, 95% confidence interval 8.04 to 8.41 cm), followed by the Thermofocus non-contact thermometer (7.82 cm, 95% confidence interval 7.60 to 8.03 cm), the tympanic thermometer (7.12 cm, 95% confidence interval 6.89 to 7.34 cm) and, finally, the electronic axillary thermometer (5.01 cm, 95% confidence interval 4.71 to 5.31 cm).

We interviewed 21 parents. Parents' experiences with the axillary thermometers were mostly described in negative language, such as being uncomfortable and impractical, whereas experiences with the tympanic thermometer were more neutral. Parents were pleasantly surprised by the practicality and convenience of the non-contact thermometers, which they had been unfamiliar with until then.

#### Limitations

The design of a method comparison study does not compare new methods against a gold standard, which in this case would be central thermometry requiring the placement of a central line, which is not feasible in primary care. Digital and tympanic thermometers have been found to have moderate agreement themselves with central temperature measurements.

#### Conclusions

The two types of non-contact infrared thermometers evaluated in this study on average resulted in lower temperature readings than the currently recommended approaches to temperature measurement in children presenting to the general practitioner with acute illness (i.e. electronic axillary and infrared tympanic thermometers). The mean difference was -0.10 to -0.16 °C, and the lower and upper limits of agreement ranged from -1.47 to -1.57 °C and 1.22 to 1.35 °C, respectively. Sensitivity for fever was low to moderate in both cases.

#### **Future work**

Better methods for peripheral temperature measurement that agree well with central thermometry are needed.

#### **Trial registration**

This trial is registered as ISRCTN15413321.

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