Exploring the safety of at home powdered formula preparation

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Executive Summary

Background

Infant formula is a breastmilk substitute fed to babies when mums are unable or do not want to breastfeed. In the UK, almost three quarters of babies will have consumed infant formula by six weeks of age, and almost all will have by six months (McAndrew et al., 2012). Formula fed babies are at greater risk of gastrointestinal infections than breastfed babies because breastfeeding is protective against infections as it helps babies' immune systems develop, and because bottles of formula are at risk of bacterial contamination. Bacterial contamination is thought to occur in two ways; first, powdered infant formula (PIF) is not sterile and can contain harmful bacteria, including *Salmonella* and *Cronobacter* if not prepared properly (Crawley, Westland & Sibson, 2022), and second, bottles and teats are vulnerable to contamination during preparation (Redmond et al., 2009; Cho et al., 2019). It is estimated that in the UK over 3,000 babies end up in hospital each year, and a further 10,000 are reviewed by GPs, due to gastrointestinal infections which may be attributed to formula feeding (Renfrew et al., 2012).

NHS (2019) guidance states that PIF must be mixed with water at a temperature of 70o Celsius (oC) or greater, to kill any bacteria which may be present in the PIF. The use of boiled water from a kettle cooled to at least 70oC is recommended, which is then mixed with the PIF before allowing it to cool further before feeding. This should be repeated every time a bottle is needed to ensure the formula is safe. Bacteria can survive and multiply in formula, even if it is stored in a fridge. NHS guidance also contains steps to minimise contamination of baby feeding equipment, including washing hands, disinfecting preparation surfaces, and washing and sterilising all baby feeding equipment. However, research shows many parents do not carry out all these steps, and a third of parents do not feel confident about preparing PIF (Brown, Jones and Evans, 2020). Furthermore, there has been an increase in UK parents using formula preparation machines and their efficacy has not yet been sufficiently investigated.

Methodology

Our project aimed to explore parents' practices when preparing PIF in the home. Our study was co-designed with 78 parents of formula fed babies, recruited via social media. The study involved parents who volunteered to be 'community scientists' (i) measuring the temperature of the water they used to make PIF once and (ii) completing an online research diary which asked them about PIF preparation in relation to each aspect of the NHS guidance, using closed and open questions. Those who used a formula preparation machine were directed to measure the temperature of the hot water dispensed by the machine, to which they would usually add PIF. Only users of formula preparation machines which dispensed water (not formula) were eligible. 200 people (including some of the 78 parents who participated in co-designing the study) recruited via social media opted in to receive a thermometer, instruction sheet and a link to their online research diary, and 151 responded with either a partially or fully completed research diary. Quantitative data were analysed descriptively, whilst open text data were coded by the research team, and thematically analysed by a group of five community scientists through a series of 23 meetings. Over 150 community scientists took part in the study.

Key Findings

The average temperatures of water boiled in a kettle were compared to the average water temperature dispensed by formula preparation machines (known as the “hot shot” which the PIF is added to), which half of participants used (49%). This research found that the temperature of the “hot shot” measured by machine users was on average around 9oC lower than the temperature of the water measured by kettle users, and was significantly more likely to be below the minimum safe temperature of 70oC. Only 14.9% of machine users reported a water temperature of 70oC or greater compared with 78.3% of kettle users.

Using data from the online research diaries, we considered parents’ usual PIF preparation practices and found several areas where parents’ practices did not align with NHS guidance. For example, around 30% of parents did not always make bottles one at a time. Whilst bottles and teats were usually washed and sterilised by most parents, some commonly used items such as PIF scoops, and some less commonly used items (such as levelling equipment, portion pots or flasks) were not. It was reported that it was not always clear which items should be washed and sterilised. Similarly, many parents washed their hands (21.8%) and cleaned and disinfected bottle preparation surfaces (29.8%) only half the time or less often. Time pressures, perceived impracticality and a lack of understanding of the risks involved in preparing PIF were reported barriers to following the NHS guidance. At night and when outside of the home, the difficulties of preparing PIF intensified. While most parents (92.7%) reported feeling confident in PIF preparation, around a fifth (19.1%) did not feel they knew the NHS guidance.

Outcomes of and reflections on Community Science

Community scientists, mostly mothers, were actively involved in the study at every stage, including generating data with a genuine scientific outcome, and as collaborators in designing the research, analysing the findings and writing up the results. Some community scientists undertook multiple roles. Community scientists reported benefiting from the study through undertaking interesting and novel research which had potential relevance to their lives, and incentives and honorariums were appreciated. However, some reported increased anxiety around PIF preparation due to increased understanding of risks. Tailored feedback was provided to individual community scientists who undertook the at home experiment, highlighting areas of unsafe practice when preparing PIF. We considered the use of honorariums important for securing in-depth and long-term engagement for busy parents with young children. Our attempt at providing general science education within the study’s closed Facebook group was minimally engaged with. Those involved more intensively reported that they valued having the opportunity to contribute and collaborate, as well as being part of a non-judgemental group. They also undertook additional unguided scientific endeavours, such as testing the temperature of water stored in a flask over a period of several hours, outside of the main experiment, showing knowledge of scientific methods and increased confidence.

Conclusions

Our research shows that when compared to kettles, formula preparation machines were significantly more likely to dispense water that is below 70oC by the time PIF is added, potentially allowing any bacteria in the PIF to survive. This raises concerns about the safety of PIF made with these preparation machines which, given their widespread use, requires further investigation with a larger sample. The research also highlights a need for: (i) further investigation into regulation of formula preparation machines and better labelling of formula related products, which should contain consistent information about safer preparation of PIF and the associated risks ; (ii) Baby Friendly Initiative-based formula feeding education which enables public services to better support families with feeding (UNICEF, 2014); and (iii) increased infant feeding support for parents, with an emphasis on using hot enough water and washing/sterilising equipment. The 'at home' nature of the research meant there may have been differences in the way that the community scientists did the experiment compared to laboratory-based experiments, more accurately reflecting real-word practice. Limitations include the potential for unknown problems with the thermometers used or inaccuracies in reporting.

Background

Infant formula is a breastmilk substitute fed to babies, when mothers are unable, or do not want, to breastfeed. Around three-quarters of babies in the UK receive infant formula in the first six weeks of life, and this increases to around 99% by six months old (McAndrew et al., 2012). Most commonly the formula used comes in the form of powdered infant formula (PIF) which needs to be reconstituted into liquid form by adding water, which is then fed to the baby via a bottle with a teat. A significant number of gastrointestinal infections in infancy (at least 3000 hospitalisations and 10,000 GP visits annually) may be attributed to formula feeding in the UK (Renfrew et al., 2012). By contrast breastfed babies experience a significantly lower prevalence of gastrointestinal infections, due to both the antimicrobial and immunity supportive properties of breastmilk, and the absence of infection risk associated with formula feeding (Victora et al., 2016).

Formula feeding increases the risk of gastrointestinal infection because of three factors; the milk itself can contain bacteria (Crawley, Westland & Sibson, 2022), the milk feeding equipment may house bacteria if they are not thoroughly washed or sterilised (Redmond et al., 2009) and carers can contaminate equipment from handling it (Cho et al., 2019). PIF is not (and cannot be made to be) a sterile product and thus can contain *Salmonella* and *Cronobacter* (Crawley et al., 2022). These species are both gram-negative bacteria which typically cause diarrhoea, fever, vomiting and abdominal cramps. These infections can be severe, particularly for vulnerable babies, and may lead to meningitis, sepsis and even death (Center for Disease Control and Prevention (CDC), 2022). There have been several outbreaks of bacterial infections which have been linked to PIF (Strysko et al, 2020) and in February 2022 infant formula products were recalled due to a *Cronobacter* outbreak, which has been associated with the deaths of at least two infants in the United States (US) (US Food and Drug Administration, 2022).

To minimise the risk of infection, PIF must be carefully prepared to kill any harmful bacteria that may be present. To do this the World Health Organization (2007) states that PIF must be mixed with water at a temperature of 70o Celsius (oC) or greater. The NHS (2019a) advises boiling 1 litre of fresh tap water in a standard electric or stove-top kettle and using it within 30 minutes of boiling, "so that it remains at a temperature of at least 70oC". The bottle should then be allowed to cool to a drinking temperature, which can be accelerated by running the bottle under cold running water. Bottles of PIF should be made one at a time, as the baby needs them although guidance from the WHO states that reconstituted feeds may be kept in the fridge at temperatures below 5oC for up to 24 hours (WHO, 2007). Any formula left over after a feed should be discarded immediately due to the potential for rapid bacteria growth.

Research shows that parents find guidance regarding PIF preparation confusing (Fallon et al., 2017), especially with conflicting information available online (Feed UK, n.d.). Making bottles up one-at-a-time using a kettle is also time-consuming which can be challenging when dealing with a hungry baby. This may explain the increase in UK parents using formula preparation machines which may be around 50% among parents who use PIF (Brown et al., 2020). Some of these machines deliver a small volume of hot water (known as a “hot shot”) to which PIF should be added. The user then shakes the bottle to combine powder and water and returns it to the machine which dispenses cold water to the selected volume. For other machines the user pours PIF into a chamber in the machine, and the machine dispenses a bottle of made-up formula.

Concerns have been raised about the safety of formula preparation machines (e.g. Norfolk and Norwich University Hospitals NHS Foundation Trust, 2021; Food Safety Authority of Ireland, 2021; South Tees Hospitals NHS Foundation Trust, 2022) in particular in relation to the potential for small volumes of water to remain at 70oC for long enough to kill any bacteria in the PIF (Crawley et al., 2022). However, to date, there is a lack of independent research on these machines. Baby kettles are another device on the market, aimed at making formula preparation easier. There are several brands of baby kettle, but most claim to heat water to a set temperature (selected by the user) and maintain that temperature for up to 24 hours. As with formula machines, there is a paucity of research exploring their safety, though concern has been raised about whether water set to 70oC could cool rapidly after being poured (Crawley et al., 2022).

Care must also be taken by parents to minimise contamination of baby feeding equipment by washing their hands, disinfecting preparation surfaces, and washing and sterilising all baby feeding equipment. However, parents often do not fully follow this (Labiner-Wolfe et al., 2008). The NHS (2019a) advice contains 13 steps to make infant formula, yet PIF packaging labels in the UK often do not state this advice or the importance of using hot enough water to kill bacteria which may be present. Additionally, some PIF preparations, such as hypoallergenic formulas recommend using water temperatures as low as “room temperature” (Nutramigen, n.d.). Together, these issues highlight the need to understand barriers and facilitators to safer PIF preparation, as a public health priority.

Aims and Objectives

The aim of this research was to explore the usual practices of UK parents when preparing PIF in the home in comparison to NHS guidance, including measuring the temperatures of water used to prepare PIF. Our aim was divided into four objectives, to:

- engage with parents and carers who use PIF to contribute to the study design, data collection and analysis;
- generate new knowledge about how infant formula is prepared in the home;
- increase community scientists’ experience of the scientific process;
- provide insights into possible risks, benefits, and areas for investigation in relation to PIF preparation practices in the home.

Definition of citizen & community science

The ‘citizen science for food standards challenges’ required projects to “be a collaboration between researchers, a specific group of communities and, where appropriate, relevant partners from outside academia” and for communities and partners to be involved in co-creating the projects. The FSA and UKRI provided the following documents as a guide:

- ECSA’s ten principles of citizen science (ECSA, 2015)
- ECSA characteristics of citizen science (Feord, 2020)
- the recent FSA publication: Citizen science and food: a review. (Reynolds et al. 2021)

We refer to our lay co-researchers as **community scientists** following feedback in our pre-application consultation about the racialised connotations of the term “citizen” and how it could make those from marginalised ethnicities feel that opportunities to contribute to our project were not relevant to them. We were also aware of the potential for (negative) judgement to be directed towards formula feeding parents (Grant et al., 2017), and designed our research, including the language used, with sensitivity to reflect this.

Methodology

Methodology

Thirty-seven community scientists were involved in shaping the research design and data production tools. One hundred and fifty-one community scientists completed an at home experiment and online ‘research diary’. Five community scientists were involved in the analysis and write up of the project. Data on the number of community scientists engaged at each stage was collected as part of an embedded process evaluation, throughout the research period (January 2022 to March 2023).

Community Scientist profile and recruitment

Adverts were placed on social media, requesting that interested and eligible parents join a closed Facebook group called **“Finding the Formula – Community Science Group”**. This became the community science engagement platform where members shaped the study’s research design. Community scientists were parents aged over 18, with a baby aged 0-12 months old, living in the UK and who used PIF. Demographic data were not collected, although of the 78 community scientists, based on the information provided on their social media profile, only two had traditionally male names, with a further two members having gender neutral names; 74 (94.9%) had traditionally female names. Participants in the at home experiment also needed to be able to complete the research diary (on one occasion) in written English and be capable of giving informed consent.

Our Facebook group members (n=78) were initially invited to take part in the at home experiment. This was later expanded via advertisements on social media accounts held by the research team on Facebook, Twitter and Instagram, and the FSA’s internal platforms and external social media pages. Interested individuals could click on a link on the advert which led to a participant information sheet with study information, researcher’s details, an eligibility screening tool, indication of usual method of preparing infant formula (kettle or formula preparation machine), consent questions, and space to input their contact details. Only users of formula preparation machines which dispensed water (not formula) were eligible. This was so that their results could be comparable to kettle users. For hygiene and safety reasons, we also did not want parents to put a non-sterile thermometer in a bottle of formula and then feed that to their baby.

Eligible and consenting parents were sent a thermometer and hard-copy instruction sheet in the post and were contacted by email with an online link to their research diary to be completed after they undertook the at-home experiment. The thermometers used were the ‘Ashley housewares’ digital food thermometers model MT301. These were chosen over scientific or medical grade thermometers due to the budget constraints of this pilot project. The limitations of this are considered in the discussion.

Demographics

One hundred and fifty-one community scientists completed research diaries (either fully or almost fully). All were parents with the majority (94.7%) mothers, with eight (5.3%) fathers. The mean age of parents was 32.87 years (range: 21 to 43, SD=4.46). Parents were highly educated, with almost half (49.7%) having a postgraduate qualification. Four parents (2.6%) considered themselves to be disabled. The vast majority identified as Welsh/English/Scottish or Northern

Irish (90.1%); however, it was not possible to discern the ethnicity of these respondents due to an error in the question wording. The mean age of participants' youngest (or only) baby was 7.05 months (SD=2.74, range: 1 to 12). Over half (n=88, 58.3%) were first time parents; among those with previous children 91.8% (n=56) had experience of using PIF. All parents used PIF and 84 (55.6%) said that all their baby's daily feeds in a usual day were PIF with 29.1% (n=44) only using loose PIF. Fifty-nine parents (39.1%) were mixed feeding, giving both formula and breastmilk. Other types of formula and milk included ready to feed formula (n=91, 60.3%), cow's milk (n=12, 7.9%) and formula tablets (n=1, 0.7%),

Procedure for at home experiment

Kettle users were advised to use two bottles, first, the bottle they used to make infant formula for their baby as usual (the "formula bottle"), and second a bottle which would contain only water to test the temperature (the "test bottle"). By using two bottles we hoped to capture the real-world experience of making a bottle of formula, while avoiding contamination of formula that could potentially be fed to a baby. Parents were asked to boil the kettle (noting the time from boiling to pouring), to pour their usual volume of water into the test bottle and formula bottle, then to take the temperature of the test bottle at the same time as adding PIF to the formula bottle. By contrast, formula preparation machine users were not asked to make two bottles side-by-side as this would not be possible with only one machine. We asked parents to "immediately" record the temperature of the small volume of hot water produced by the machine (the "hot shot") before the addition of PIF or cold water, because it is the "hot shot" which first makes contact with the PIF. This water was then discarded, and the bottle cleaned and sterilised.

The instructions stated to wait 15 seconds for the thermometer reading to stabilise before recording. Community scientists were advised to have a pen to hand and to note down results on the space provided on the instruction sheet before completing their online research diary. The research diary included the experiment results and further questions about their experience preparing infant formula on the following topics:

- demographic background;
- whether PIF preparation practices aligned with NHS advice: including making bottles one at a time and washing and sterilising of bottle-feeding equipment;
- barriers and facilitators to following NHS advice;
- feelings about their involvement in the study.

Debrief emails were sent to all community scientists, with information on safer formula feeding advice including signposting to the NHS website and the First Steps Nutrition Trust parent facing webpages. Water temperatures which were lower than 70oC were highlighted to parents, and the above advice reiterated. All at home experiment participants received a £5 Amazon voucher as a thank you.

Data analysis

For the at-home experiment, temperature readings from kettle users and formula preparation machine users were compared and inferential statistics (t-tests, ANOVA, Chi Square tests, and Pearson's correlations) were performed. Extreme outliers in the experiment (temperatures <40oC) were followed up and community scientists were asked to clarify how they had prepared the water and were asked to repeat the experiment if necessary. Descriptive statistics were produced for each of the closed questions in the research diary. Only complete or almost complete responses were included in analyses. Responses remained in the sample, however, if occasional questions were not completed from the full question set. Therefore, not every table represents the full sample and missing data is reported as 'question not answered'.
For the open-ended data an inductive thematic analysis was undertaken (Braun and Clarke, 2021). Familiarisation and coding, by individual question, was undertaken by the project team and

presented to the group of five community scientists who were involved in the thematic analysis, including the writing up of results. Twenty-three one-hour group analysis sessions were undertaken. Sessions were designed following best practice for involving community members in analysis, including those aimed at affirming mental health (Jennings et al., 2018), in recognition of moral judgements associated with formula feeding and facilitating participatory theorising in relation to data (Vaccaro, 2020). A private and hidden Facebook group and email were used to share data extracts and meeting agendas at least two days prior to analysis sessions. Mothers who were not able to attend the sessions were able to comment on the private and hidden Facebook group or contribute privately by email, messenger or via one-to-one meetings. Community scientists were encouraged to feed back any issues or preferences in relation to how sessions were chaired, and the project team held sessions at regular intervals to discuss community scientists' experiences of the group so far and their recommendations for any changes.

Ethics

Ethical approval for this study was granted by the Swansea University School of Health and Social Care Research Ethics Committee. All participants gave informed consent and all aspects of this study have been performed in accordance with the ethical standards set out in the 1964 Declaration of Helsinki.

Alignment with community science principles

Community science principles were embedded into our aims, objectives, and methodology. The study was designed to meet the 10 principles of citizen science (ECSA, 2015). This included actively involving community scientists at each stage of the project, with community scientists participating in multiple stages if they wished. Furthermore, our methods of interacting with community scientists were intended to provide mutual benefit through incentives, research opportunities and providing feedback, both individually and to the group.

Community Science process evaluation

Our process evaluation focused on measuring engagement with community scientists throughout the project and capturing their views and experiences. This included:

- recruitment into our Facebook group
- engagement with shaping research design for the at home experiment
- experiences of undertaking the at home experiment
- engagement with community science education
- engagement with analysis of research diary data
- experiences of being part of the analysis sub-group.

Data included the contents of the community science closed Facebook group, research diaries for the home experiment and detailed field notes from the community science analysis group.

Research Findings

Results

Research Diary findings: feeding practices in relation to the NHS advice

Making bottles one at a time for immediate use

The NHS advises that bottles are made one at a time for immediate use. Most parents reported that they ‘always’ (n=107, 70.9%) or ‘most of the time’ (n=22, 14.6%) made bottles one at a time for immediate use. However, some (n=22, 14.6%) pre-prepared bottles half the time or more. Of these, almost all used a kettle for the experiment (n=20, 90.9%), one (4.5%) was a formula preparation machine user and one (4.5%) was an instant boiling tap user. Open text responses highlighted that when multiple bottles were prepared, the majority stored them in the fridge (n=18) and having a bottle ready for night-time feeds was a common rationale (n=11) for pre-preparing: "We prepare two for overnight, sometimes he has one in the night but most of the time they both get used in the morning". Participants who pre-made PIF noted that unused bottles were discarded within a particular time-period (n=10) with a reported range of between two hours and twenty-four hours, with twenty-four hours reported by six participants.

Washing and sterilising all bottle-feeding equipment

The bottle, teat and bottle parts were washed and sterilised by most parents most or all of the time (see Table 1). However, the scoop was not always routinely washed or sterilised. Levelling equipment, such as a knife, was recorded as ‘not applicable/not answered’ by the majority (n=112, 74.2%), which was explained by some as due to levelling tools being built into PIF boxes. Similarly portion pots and flasks were not used by many parents, although most who did use them washed them either always or most of the time but did not routinely sterilise them. Open text responses relating to washing equipment were mostly focused on why the scoop was not washed (n=46), which included believing that it was not necessary (n=28), or a belief that the use of boiling water to prepare PIF made sterilising unnecessary (n=14): "As the powder goes into hot water it seems unnecessary to wash/sterilise the scoop". Similarly, open text responses related to not sterilising items were focused on the scoop (n=44), formula pots (n=20) and flasks (n=11). Again, the rationale for not sterilising was typically not knowing that sterilising was necessary (n=30), the ability of boiling water to sterilise (n=16) and PIF itself not being sterile (n=11): "Formula pot as it gets washed in hot soapy water and then the formula is dispensed into the hot water/bottle. The tin is also not sterile so don’t see the point".

Parents were asked which methods they used to sterilise and could select multiple options. The most popular method was steam sterilising (n=86, 57%), followed by cold water sterilising solution (n=52, 34.4%), and microwavable sterilising bags (n=26, 17.2%). Boiling (n=7, 4.6%) and UV sterilising (n=3, 2%) were less common. A small number of parents (n=7, 4.6%) used ‘self-sterilising bottles’ which go in the microwave. Most parents who used cold water sterilising solution (36 out of 52, 70.6%) said that they ‘always’ or ‘most of the time’ shake off excess solution from the bottle or teat or rinse them with cool boiled water (not tap water). However, two people (4%) said they only did this half the time or less, and over a quarter (n=13, 25.5%) said that they never did this.

Table 1: Washing and sterilising of bottle-feeding equipment

Equipment	Answer	How often do you wash: n	How often do you wash: %	How often do you sterilise: n	How often do you sterilise: %
the bottle?	Always/most of the time	147	97.4	142	94.1

Equipment	Answer	How oftendo you wash:n	How oftendo you wash:%	How often do you sterilise:n	How often do you sterilise:%
the bottle?	Half the time or less	2	1.3	7	4.6
the bottle?	N/A or not answered	2	1.3	2	1.3
the teat?	Always/most of the time	147	97.3	142	94.1
the teat?	Half the time or less	2	1.3	7	4.6
the teat?	N/A or not answered	2	1.3	2	1.3
the scoop?	Always/most of the time	32	21.2	11	7.3
the scoop?	Half the time or less	118	78.2	138	91.4
the scoop?	N/A or not answered	1	0.7	2	1.3
other parts of the bottle?	Always/most of the time	143	94.7	140	92.7
other parts of the bottle?	Half the time or less	5	3.3	8	5.3
other parts of the bottle?	N/A or not answered	3	2	3	2
the knife/levelling implement?	Always/most of the time	18	11.9	7	4.7

Equipment	Answer	How oftendo you wash:n	How oftendo you wash:%	How often do you sterilise:n	How often do you sterilise:%
the knife/levelling implement?	Half the time or less	21	13.9	32	21.2
the knife/levelling implement?	N/A or not answered	112	74.2	112	74.2
the portion pots?	Always/most of the time	67	44.4	24	15.8
the portion pots?	Half the time or less	17	11.3	60	39.7
the portion pots?	N/A or not answered	67	44.4	67	44.4
the flask?	Always/most of the time	46	30.5	19	12.6
the flask?	Half the time or less	18	11.9	45	29.8
the flask?	N/A or not answered	87	57.6	87	57.7

Washing hands

Parents were asked ‘How often do you wash your hands before touching any baby feeding equipment/powdered formula?’. Whilst the majority (n=118, 78.2%) of parents said that they either ‘always’ or ‘most of the time’ washed their hands, over a fifth (n=33, 21.8%) reported washing their hands half the time or less often. Often this was attributed to the view that there wasn’t a need to do so (n=20), because they only touched parts of the bottle that didn’t go into baby’s mouth (n=9) or had recently been washed (n=8) or sanitized (n=3). Additional factors included being in a rush (n=13), forgetting sometimes (n=7), trying to comfort an upset baby (n=4), or holding the baby meaning it was physically impossible to wash their hands (n=3).

Cleaning and disinfecting surfaces

Parents were asked ‘How often do you clean/disinfect surfaces where you make up the baby’s bottle?’. Over two thirds (n=105, 69.5%) of parents said that they ‘always’ or ‘most of the time’ cleaned and disinfected surfaces prior to making their baby's bottle, but over a quarter (n=45, 29.8%) said that they did this only half of the time or less often.

Water type

The NHS advises using fresh tap water to make bottles (not water that has been boiled before). Less than half of parents (n=67, 44.4%) said that they did this every time. Other common types of water used included, pre-boiled water (water already in the kettle) (n=26, 17.2%), cooled boiled water (n=37, 24.5%) and filtered water (n=22, 14.6%), with some parents selecting more than one option.

Method of heating water

Most parents (n=121, 80.1%) used a regular kettle at least some of the time, with 71 (47%) parents using this method always or most of the time. NHS advice states that to ensure boiled water is at 70oC or greater, 1 litre of water should be boiled, and it should be left for no more than 30 minutes before being used. Kettle users (n=102, 84.3%) said they usually used water within 30 minutes or less after boiling. Just over half (n=78, 51.6%) used a formula preparation machine sometimes. Instant boiling water taps (n=6; 3.9%), baby kettles (n=6; 3.9%) and microwaves (n=3, 2.0%) were less commonly used.

Parental knowledge and barriers to following NHS advice

Most parents reported feeling either 'very confident' or 'quite confident' in relation to preparing PIF (n=140, 92.7%). However, fewer reported feeling either 'very' or 'quite' knowledgeable (n=121, 80.1%). When asked about barriers for parents preparing formula in line with NHS guidelines, the major factor was the difficulty in following NHS in real world settings. This was mentioned 192 times across the dataset by 88 participants, including 70 participants who identified time pressures as a particular barrier: "Time constraints as a hungry, screaming baby can make you quite anxious to just get them fed." Alongside this, the challenging context of busy life as a parent was noted alongside a feeling that NHS guidelines were impractical to implement in real world settings (n=21). In addition, poor communication of risk associated with NHS advice was mentioned 131 times across the dataset by 75 parents, with 49 parents noting that they did not know why the advice was important: "I didn't know their (sic) were NHS guidelines to be honest. I didn't feel it was treated as a health issue particularly. Very little support from any outside professionals about feeding in general - most support and knowledge gathered from peers." In addition, conflicting (n=20) and confusing (n=14) advice reduced understandings of risk.

The experiment

Water heating method

Among the 151 community scientists who took part in this stage of the research, around half used a kettle (n=70, 46.4%) and around half used a formula preparation machine (n=75, 49%). Due to small group numbers, baby kettle (n=2, 2.4%) and instant boiling tap (n=1, 0.7%) users were excluded from group comparison analyses and only the kettle users and machine users were compared. Three people did not provide information re water heating method and were excluded from the analysis.

Experiment temperatures

Where participants reported temperatures below 60oC, research diaries were investigated to ensure that temperatures affected by factors other than preparation method were not included in the analysis. All but one kettle user's temperatures could be easily explained, for example lower temperatures relating to a delay of more than 30 minutes in boil to pour time. The kettle user with a temperature below 60 oC that could not be explained reported that she thought the thermometer was faulty, so this reading was also excluded from analysis. 11 machine temperatures were investigated, including three participants who reported water temperatures below 40oC. Two formula machine users misunderstood the experiment protocol and took the temperature after adding cold water to the “hot shot”, these participants were asked to repeat the experiment and the new readings were included in the analysis instead. A third machine user explained that she routinely dispensed a “hot shot” and then added cool water before adding PIF as the manufacturer’s guidance for the PIF she used required water to be cooler. This result was excluded from the experiment analyses. Eight machine users reporting temperatures between 40-60 oC reported that they had followed the experimental protocol, and were invited to repeat it. Four did so and three continued to have readings below 70 oC (58.5 oC, 58.8 oC and 60.3 oC), whilst one reported an initial temperature of 59.9 oC, but a second temperature of 72.7 oC, suggesting potential wide variation in temperatures or a fault with the thermometer. However the first temperature results were used in the analysis, as these four users had followed the experiment protocol. The final sample size for the experiment was 143 (n=69 kettle; n=74 machine).

The mean water temperature reported was 70.4oC (SD:11.1, range: 40.1 to 99.5). As table 2 shows, the average temperatures reported by kettle users was >9oC higher than the formula preparation machine users. A t-test with a 95% confidence interval showed a significant difference was found between the groups [t(141)=5.64, p<0.001]. The Cohen’s effect size value was 0.94, suggesting a meaningful difference between the two groups.

Table 2: Experiment temperatures in degrees Celsius for different heating methods.

Heating method	n	Mean (oC)	SD	range
Kettle users	69	75.29	12.88	40.1 to 93.2
Formula preparation machine users	74	65.78	6.39	50.1 to 99.5

The data were further analysed by grouping those who reported a temperature of ?70oC compared with those who reported a lower temperature; 78.3% (n=54) of kettle users reported temperatures above 70 degrees C, compared with only 14.9% (n=11) of formula machine users. A Chi-square test showed that this difference was statistically significant [X2(1), N=143 = 57.8, p<0.001].

The 15 kettle users that reported temperatures below 70oC were examined more closely considering how long they waited from boiling the kettle to pouring the water (14 out of 15 people reported this). The average boil to pour time was 34 minutes (SD:39.7, range 3 to 157 minutes) in the <70oC group, this was compared with an average boil to pour time of 8 minutes in the ?70oC group (SD:8.16, range 0 to 33 minutes).

It was unexpected to find that some parents reported boil to pour times of less than 30 minutes, yet still reported temperatures below 70oC (n=8). However, on closer inspection of the research diaries, this appeared to be primarily due to using a mixture of hot and cool boiled water (n=4) and 4 reported temperatures in the 60oC range (68.8oC, 21 minutes; 69.9oC, 30 minutes; 66.7oC; 30 minutes, 61.8oC, 30 minutes). One person said they poured the water into a bottle and used an insulated bottle warmer to keep it warm.

In the kettle group, differences in temperature were explored based on the volume of water heated in the kettle and the volume of water poured into the bottles (data available for 67 participants). Mean temperature was greater where larger volumes of water were boiled (>1 litre n= 15 M:78oC, SD: 7.62; 1 litre exactly n=33 M:75.67oC, SD: 13.2; < 1 litre n=19 M:71.75oC, SD:15.64), however an ANOVA found that this difference was not statistically significant, [F(2, 64) 1.01, p=0.36]. Similarly, a Chi square test did not find a significant relationship between volume of water heated and likelihood of achieving a temperature ?70oC [X2(2), N=67 = 1.19, p=0.52]. However, once boil-to-pour time was controlled for an ANCOVA found a significant difference in water temperature between the three water volume groups [F(3, 60) 3.15, p=0.03]. Finally, a Pearson's correlation showed a positive correlation between the volume of water poured into the bottles and temperature recorded (greater volumes were associated with greater temperatures), but this relationship was not statistically significant [r(68)=0.69,p=0.57].

Discussion of research results

The study explored real-world experiences of infant formula preparation revealing that many parents reported practices which did not follow NHS advice. Formula preparation machines were common with around half of our community scientists using one at least sometimes. However, it was concerning to find that 85% of hot water samples produced by these machines was recorded as being lower than the recommended 70oC. One explanation for this is that hot shot volumes produced by preparation machines are typically small (as little as 1 fluid ounce, equal to 30 ml) and that these may cool rapidly in the time it takes to put the formula in the bottle. This reiterates findings of unpublished research from Crawley et al., (2022) which found that hot shot temperatures were produced at >70oC but dropped to around 60oC after around 2 minutes. In our study, hot shot temperatures were often below 70oC even though participants were instructed to take the temperature “immediately” (allowing 15 seconds for the thermometer's reading to stabilise). However, this short period of time likely reflects real life formula preparation between hot shot dispersal and adding PIF. Instructions on when to add PIF to the hot shot appear to vary across websites and sources with some suggesting that parents have two minutes to add the powder and more recent instructions that the powder is placed in the bottle before the shot is dispensed, which is contrary to NHS advice on preparing PIF (NHS, 2019). These varying and changing instructions are likely confusing for parents and combined with broader knowledge around how to prepare a bottle using a kettle (which allows for water cooling) may mean that in real life parents may delay adding PIF. Combined with the demands on caring for a hungry baby whilst preparing the feed it may be that feeds are being produced with water below recommended temperatures. This finding warrants further investigation into the temperature of the hot shot, and cooling times. Furthermore, the machine user who recorded two very varied temperatures suggests that there may be potential variation in the temperature of the water produced in each hot shot, which should be further investigated.

Our findings suggest that the NHS advice to use a kettle to boil at least one litre of water and to wait no more than 30 minutes after boiling is safest practice. However, low temperatures were also evident in the kettle group even in those who waited <30 minutes after boiling, a finding also observed in additional testing by community scientists. This shows potential for variability in the heat retaining properties of kettles made from different materials (metal, plastic or glass). Variation may also have occurred due to differences in the volumes of water boiled, as smaller volumes tended to achieve lower temperatures due to more rapid cooling. While the NHS guidance states that at least 1 litre should be boiled, the rationale for this may not be clear to parents and the cost-of-living crisis may lead parents to boil smaller volumes of water to save on energy costs.

Given the chance of discrepancies between kettles it may be safer to recommend using the water as soon after boiling as possible, rather than waiting 30 minutes, to reduce the risk of water falling below 70oC. Advising using hotter water may reduce risk given that parents are unlikely to add

PIF instantly when dealing with the demands of a hungry baby. Research has found that reconstituted formula made using water which is exactly 70oC can cool rapidly to between 57.5oC and 60oC within 120 seconds of mixing the water with the powdered infant formula. The researchers suggested that higher starting water temperatures (>85oC) would be more appropriate to ensure the water is at an adequate temperature to effectively eliminate any bacterial contamination in the powdered formula when they are combined (Losio et al., 2018).

PIF labelling in the UK typically does not match NHS advice regarding temperature or safer preparation and it is not currently required to do so. Furthermore, instructions for specialist formula (anti-reflux, probiotic and hypoallergenic formulae) state that water should be boiled and cooled to room temperature before adding PIF (First Steps Nutrition Trust, 2020; Nutramigen, n.d.). Concern about heat damaging the nutritional content of PIF has been cited by industry representatives as the reason for using cooler water (Infant Nutrition Council, 2013). However, WHO (2007) guidance has regarded this concern as insignificant when weighed against the risk of PIF associated infection.

In relation to PIF preparation hygiene, parents often viewed the scoop and portion pots as less in need of washing and sterilising. These items are not specified as requiring attention in the NHS advice, but Cho et al. (2019) found that harmful bacteria could be transferred from caregivers' hands to the scoop and survive in the PIF for 3 weeks and on the scoop for at least 72 hours. This also highlights the need for handwashing but over a fifth of our participants reported washing their hands half the time or less often, due to time pressures and a feeling that it was unnecessary, especially if not touching the parts of the bottle that go in the baby's mouth. The rationale for sterilisation should be clearer but the feasibility of sterilising scoops needs to be investigated. Community scientists reported concerns about the potential for plastic scoops to melt if using steam sterilising. Spare scoops would also be needed during sterilisation but as scoop sizes vary according to PIF brand this means that generic spare scoops would be unsuitable.

Sterilising methods were also explored. The NHS advises parents to either shake off excess solution or to rinse with cooled boiled water. However, over a quarter of parents in our study did not do this. Historically, rinsing off cold water sterilising solution was thought to be important because of the risk to babies from ingestion of sodium hypochlorite in the solution (Harris, 1967). Recent research suggests that ingestion of sodium hypochlorite is unlikely to cause significant toxicity (Slaughter et al., 2018), and the instructions from a popular product (Milton) state that baby's bottles soaked in the solution do not need to be rinsed but excess solution should be shaken off (Milton, n.d.). We were unable to find studies exploring the effects of ingestion of sodium hypochlorite in babies who drink from unrinsed or unshaken bottles daily over an extended period.

NHS guidance to make up bottles one at a time, for immediate use was not always followed, with around a third (mainly kettle users) reporting that they did not always do this. The guidance was viewed as impractical given the time pressures of caring for a baby and feeding outside the home. Contradictory advice to pre-make bottles and keep them in the fridge can easily be found online (Feed. UK., n.d.), which some parents favour as a source of information over health professionals (Fallon et al., 2017) despite the risk of poor-quality infant feeding advice in online sources (Taki et al., 2016). However, storing premade PIF in the fridge at 5oC for up to 24 hours is within the WHO (2007) guidance although a report for NICE raised concern about this for storage of expressed breast milk as many domestic fridges do not maintain temperatures below 5oC (Cook, 2006). Fridges may have since improved but this warrants investigation.

Considering these issues together, some parents did not perceive there to be risks associated with some aspects of PIF preparation. Broader issues surrounding perceptions of formula may play a role here such as a belief that PIF is "scientific" (Brown et al., 2020) and perhaps therefore safe. For example, some community scientists reported that they thought boiling was only necessary to sterilise the water and not the PIF, highlighting a lack of awareness that PIF is not a sterile product. If parents were aware of the rationale behind each step of safer PIF preparation advice then they may be more likely to prioritise following all aspects (Michie et al., 2014).

A key issue is that communication of guidance (and the rationale behind it) is not clear to parents. Around a fifth of parents reported that they did not know current NHS guidance. Given that our sample were motivated and had an interest in the topic, this lack of knowledge is likely to be even more prevalent in the general population highlighting the need for more support. Research has shown that mothers often feel unsupported (Fallon et al., 2017) or judged (Grant et al., 2017) when seeking advice about giving their baby formula, perceiving health professionals to be pro-breastfeeding and “not allowed” to discuss formula preparation (Lagan et al., 2014). This can be especially true for mothers who wanted to breastfeed or who are mixed feeding (Brown, 2016; Brown, 2019).

Limitations

Community scientists in our study generally reported greater knowledge and confidence in relation to preparing PIF compared with previous UK research (Brown et al., 2020). This may have been influenced by self-selection bias, as those who were motivated and interested in the topic were more likely to have chosen to take part. Similarly, the demographics of our sample were mainly older and educated to at least graduate level and this may have influenced their knowledge and PIF preparation practices, as previous research has found (Calamusa et al., 2009). The sample is therefore not likely to be fully representative of PIF preparation practices in the wider community but shows that even within this motivated and educated sample there were misperceptions or a lack of understanding around certain aspects of PIF preparation.

Furthermore, this was a pilot study, and the sample size was relatively small, and therefore the findings cannot be generalised to the wider population. The experiment was completed under real-world conditions meaning there may have been variations and human errors in data collection and reporting such as in relation to: time from pouring/ dispensing of water to inserting the thermometer into the water, not allowing the thermometer long enough to stabilise, or waiting too long to log the measurement. There is also a possibility that participants might have been influenced by social desirability bias (i.e. reporting behaviour which is seen as correct or socially acceptable), due to the status of the research team, which included health professionals.

The data may be further limited by the quality of equipment used. Participants were issued with brand new thermometers which were all the same brand, however they were basic home food thermometers (not scientific/medical grade) and had not been calibrated since purchase from the supplier. Seven participants gave feedback in their research diary that they were concerned that the thermometers were taking too long to stabilise upon a temperature reading and that this may have led to water cooling. However as noted, an approximate 15 second time period whilst a thermometer stabilises likely reflects real life home formula preparation practices. An eighth participant, when asked to repeat the experiment due to a temperature of 53oC used their own surface gun thermometer and reported a temperature of 70 oC, although the reliability of their thermometer is unknown. A kettle user was also excluded from analysis as she thought her thermometer may have been faulty. However, these limitations do not explain the significant differences between the kettle and formula preparation machine groups, as all participants were issued with the same thermometers, and all were instructed to wait 15 seconds to record the reading.

Recommendations and directions for future research

This was a pilot study and there is clear scope for future research to explore some of the limitations of the work such as parents measuring the temperature of the water used across multiple feeds and using surface temperature thermometers (guns) for greater accuracy. Further research is also warranted exploring the effect on water temperature of different volumes of water boiled and poured by kettles (of different materials), or dispensed by machines, in relation to cooling time, and how the ambient temperature impacts these. Repeating this study with a larger sample of community scientists would be beneficial to add statistical power to our analyses, including exploring practices by age of baby, and undertaken overnight and when out of the home. Further research should focus on attracting a more socio-economically and culturally diverse sample; larger incentives may have facilitated recruiting a more diverse sample.

Our findings highlight that there is a need for further research and regulation of formula preparation machines, particularly in relation to the temperature of the water produced, including if this declines with machine age. Further exploration on the impact of kettle types on water cooling would also be valuable. Increasing the recommended water temperature, especially as parents sometimes cannot add the PIF to the water immediately, may be an important change. It is also clear that parents need more consistent messaging on the rationale for following the NHS PIF preparation guidelines, which we feel should be mandatory on PIF labelling. It is also important that NICE (2021) and UNICEF UK Baby Friendly Initiative (2014) guidance is utilised to ensure all parents are given bespoke, non-judgemental support across infant feeding methods.

Where donor human milk is not available, recommending sterile ready-to-use formula instead of PIF for neonates and particularly vulnerable babies, is also likely to reduce risk, but poses further issues about when the ‘switch’ to PIF should occur and could lead to further confusion for parents. Ready-to-use formula also has a larger environmental impact and is more expensive than PIF and therefore there will be inevitable accessibility barriers for some parents which could further exacerbate health inequality.

Outcomes of and Reflections on Community Science

Our community science process evaluation focused on measuring engagement with community scientists throughout the project and capturing their views and experiences. Data included the contents of a Facebook group, home experiment research diaries, and detailed field notes from the community science analysis group. We present the outcomes of the process evaluation and reflect on their meaning for community science.

Outcomes

Recruitment into our Facebook group

Our Facebook group reached 84 members, 6 of whom were members of the academic/health professional research team. Demographic data were not collected, although of the 78 community scientists, based on the information provided on their social media profile, only two had traditionally male names, with a further two members having gender neutral names; 74 (94.9%) had traditionally female names.

Engagement with shaping research design for the at home experiment

The community scientists co-produced the research diary and instruction sheets through eight Facebook posts resulting in 75 unique comments, 43 of which were from community scientists, with a mean of 3.9 community scientists responding per post. To boost the limited engagement, two mothers known to the research team provided an additional review via email. Community scientist engagement resulted in additional questions and response options for closed text questions being added to the research diary, and a change from one instruction sheet for all participants, to separate instruction sheets for kettle users and formula preparation machine users, to aid clarity.

Engagement with community science education

Overall engagement was very limited with our attempts to engage community scientists in general scientific and research topics and themes. Within the Facebook group, we initially asked participants what the word "research" meant to them. Four community scientists commented, with a range of ideas, including that it included "gathering information" and "peer review" and that it was "empirical", "controlled" and "scientific".

However, when we asked community scientists what their understanding of "community science" was four group members noted that they had "not heard that term before". No response was received from further questions about knowledge of research, or the question "what would you like to know about research?". Following completion of the at home experiment, content relating to infant formula safety was posted, including infographics from First Steps Nutrition Trust, which resulted in some discussion regarding the use of "follow on formula", which is not recommended by the NHS.

Engagement with analysis of research diary data

Following the at home experiment, a single post was made in the community science group, which aimed to recruit up to five community scientists to take part in an intensive group involved in analysis. The post stated that there was funding available to pay honorariums for those who took part at £20 per hour. Five community scientists were recruited, all white women, with varied educational backgrounds and experience of research. The analysis sub-group met twenty-three times at 11.00am on a Friday via zoom for one hour, to fit around school drop offs and babies' napping and feeding times, with babies attending some sessions. In addition, a private and hidden Facebook group was set up for the analysis sub-group, data extracts and session agendas were shared in this group and by email in advance of sessions. Tasks included interpreting open text data, leading to identifying themes for the thematic analysis; reviewing this report's contents; and considering their experiences of being part of the group, including to input into methodological papers. No formal training was provided, with new tasks described and discussed during sessions.

During the course of the sessions, detailed notes were taken by McIntyre, which were expanded on by Grant and Ellis afterwards. Attendance varied between 5 and 2 people (mean after 18 of 23 sessions: 3.71 attendees), with those who could not attend often taking part via email, the private Facebook group, or through one-to-one catch ups with Grant. One member withdrew at week 8. Attendance declined during the school summer holidays, where one session was abandoned due to only one attendee. Four members of the sub-group recorded content for two videos about their experiences of the project.

Reflections

Fit with Community science principles

Community science principles were woven throughout our aims, objectives and methodology (ECSA, 2015). Adherence to principles 1-5 is shown in Table 3.

Table 3: Alignment with European Citizen Science Association principles

Principle	Element	Application
1.	Actively involve citizens	Community scientists were actively involved from the start of the study at each step of the project, including shaping the research design and in data analysis and writing up.
1.	Generate new knowledge	The study generated new knowledge relating to the preparation of infant formula in the home.
1.	Citizens are contributors, collaborators or leaders	Community scientists were able to (i) collaborate in research design and analysis of findings; (ii) contribute to data collection, or both.
2.	Projects have a genuine science outcome.	Our primary outcome measure was the temperature of water used to prepare PIF. Sufficient data was collected to allow statistically significant findings to be identified.
3.	Benefits for scientists	The project was an interdisciplinary collaboration and scientists were able to answer an important question. Three scientific articles are planned from this research.
3.	Benefits for community scientists	Community scientists collecting data noted that they found the project interesting and worthwhile. However, some noted that it reduced their confidence in preparing PIF. Members of the intensive analysis sub-group felt part of a supportive and non-judgemental community, the benefit of renumeration and valued for their knowledge.
4.	Research design	Community scientists provided 43 comments which shaped the data collection method; revised and added questions to the research diary and contributed to designing instructions for the at home experiment.
4.	Data collection	200 parents were posted a thermometer and instructions for the at home experiment; 151 completed data collection.
4.	Data analysis	Five community scientists were intensively involved in analysis, through 23 group sessions, a Facebook group and one-to-one meetings when attendance was not possible.

Principle	Element	Application
4.	Writing up	Community analysts have been involved in reviewing drafts of this report and journal articles.
5.	At home experiment feedback (individual)	Following research diary completion, Jones, a health visitor, provided tailored advice, including identifying when elements of unsafe PIF preparation had been reported.
5.	At home experiment feedback (group)	Early findings from the open text questions in the research diaries were shared via the study Facebook group to seek validation. Further findings will be shared with the group, via the Facebook group, when this report is published.

Overall, we feel that we have broadly met these aims, with considerable evidence of good practice. However, these principles were not always fully met. For example, regarding principle 1, community scientists were not truly ‘leaders’ in this short pilot project, although we anticipate that our analysis sub-group members could take leadership roles in a future study, but they will be unlikely to still be formula feeding at that point. Furthermore, relating to principle 3, our open text data from research diaries show that a minority of participants felt more aware of risks, more worried or less confident in their PIF preparation technique following their participation in the study.

In relation to principles 6-10, we have already reported on ethical issues (principle 10), quality and participant experience (principle 9) and acknowledged the limitations and biases in our results (principle 6). Furthermore, community scientists are acknowledged in this report and in other outputs, including the analysis sub-group being authors on outputs (principle 8). We did not aim to meet the data sharing principle (principle 7), due to ethical concerns about our data being exploited by infant formula companies to undermine breastfeeding.

Engagement and remuneration

Throughout the study we consistently received higher engagement from women than men, showing that community science was of interest to women in this study, likely reflecting women’s greater role in infant feeding. We took a flexible approach to running this community science project, including seeking additional input to review the research diary and instructions and reducing the extent of the planned community science education element when lower than anticipated engagement occurred. Overall, we felt that providing honorariums was important for community scientists; these were available for one community scientist (Dvorak) at the research design stage, data collection (£5 voucher) and the analysis sub-group (£20 shopping voucher per hour). On reflection, we feel that £5 per participant was too low, as the experiment and recording took around half an hour. The analysis sub-group resulted in the most engagement from community scientists, and remunerating community scientists feels important from a power sharing perspective when the research team are being paid.

To secure optimal engagement, we recommend that researchers wanting to use community science methods budget to provide an appropriate level of honorariums (as per NIHR, 2022) and provide opportunities so that community scientists can sign up for paid opportunities throughout the project. When advice was sought, the university finance team was also unclear whether those in the analysis sub-group would need to register as self-employed if they received their honorarium in cash which resulted in all sub-group members receiving supermarket vouchers, rather than cash. Guidance on how to appropriately remunerate community scientists within UK tax regulations has been provided (NIHR, 2022) and should be integrated into UK university finance teams.

Furthermore, we experienced significant bureaucratic challenges associated with sourcing shopping vouchers through university finance procedures; McIntrye, Grant's Access to Work job aide, spent up to an hour per week procuring five £20 vouchers, due to regularly changing procurement procedures and errors. Two vouchers that were supplied, for differing shops, failed to work when community scientists tried to use them at the checkout. One was immediately replaced with a surplus voucher, and Grant reimbursed the other herself via PayPal as soon as notified, to avoid damaging trust, but waited four months to be reimbursed. Accordingly, where university processes cannot be made more favourable, it is recommended that significant administrative support is costed into larger community science projects run through universities to ensure that honorariums are promptly provided to community scientists; without this, trust in the research team will diminish and engagement may be negatively impacted.

Experiences of undertaking the at home experiment

Community scientists who undertook the at home experiment were asked to report on their experiences. Closed questions identified that the majority were either very positive (n=105, 70.9%) or quite positive (n=30, 20.5%) about taking part in the research. Open text questions identified that taking part had been positive (n=21) because it was interesting, enjoyable or empowering for participants, for example: "Interested. Formula feeding was confusing at first and there is a lot of conflicting advice around. I'm pleased to contribute to a study about this topic". Conversely, 17 participants noted that the study had had a negative impact, in that it had worried parents about their PIF use or reduced their confidence: "It made me question whether I was doing the right thing for my baby again." Three parents explicitly noted that taking part in the study had made them revise their PIF preparation practices to make them safer, such as identifying that their kettle was not remaining at 70oC for as long as they had expected.

Experiences of being part of the analysis sub-group.

On multiple occasions (meetings 5, 15 and 19-23), sub-group members were asked to reflect on their experience of being involved in the study. This group noted they valued being part of a "supportive" community where "there's no judgement" and analysis meetings could feel "cathartic" in the context of some parents urgently needing to transition to PIF following a lack of breastfeeding support. This was viewed as in contrast to "people's language around formula and how they speak about it. It's quite a negative subject and people don't think about how or the reasons why you're using formula." The use of online meetings "fit around family life," although meeting online reduced opportunities for group bonding, which could have been improved through the use of additional "ice-breaker" tasks. The option to respond in writing in the sub-group's secret Facebook group or one-to-one with Grant was appreciated when members could not attend scheduled meetings. In addition, several members contacted Grant separately via messenger or email if they were unsure of instructions or had concerns. Sub-group members preferred the oral format of meetings, making research accessible ("I process things better by talking about it"), sometimes whilst simultaneously caring for an infant.

Sub-group members' experiences of interpretation and thematic analysis of research diary answers included: wanting greater clarity about their role, additional research methods training, and additional clarity of how their work was feeding into the project, and to know "a bit more behind the answers, like knowing that person's situation". When a full (anonymised) participant research diary was shared, however, community scientists still wanted increased depth in the data, showing the enthusiasm of the community scientists, the limitations of research diaries for collecting open text data, and the potential for the use of interviews or focus groups to go alongside research diaries in a future study to gain greater understanding of issues. Homogeneity of participants, and the limitations of recruiting via Facebook and other social media were also raised as limitations: “The group of participants doesn't appear to be very diverse.”

Sub-group members noted “the incentive has been great as cost of living that’s gone up”, but also that family finances are “sensitive” and “a lot of people don’t want to talk about it.” Community scientists also reported that they felt valued for their knowledge and expertise, which they hadn’t always recognised before: “Don't worry about your knowledge level or standard of English. My responses and opinion have felt so valued at every point. It has also shown me that I do have something worth saying!”

Members of the group displayed increased confidence over the course of the meetings, including feeling less shy, and more comfortable with using Zoom meetings for the group. Scientific awareness – or confidence to voice their scientific thoughts - appeared to have increased over the course of the meetings, with community scientists independently undertaking additional experiments, reviewing policy documents and reading research evidence. This included reporting to the group on: recording the time a formula preparation machine takes to prepare a bottle and the rate at which a kettle cools the water; reviewing international policy documents for PIF preparation; and reviewing research evidence relating to the need to sterilise scoops and rinse off cold water sterilising solution. During discussion important scientific questions around practicalities when preparing PIF were raised regularly. Community scientists also felt that they knew more about research: “its’ given me a new appreciation for research.” Later meetings often contained remarks around confounding factors, reliability, and validity from multiple members, such as “but I guess you’d need to do a trial to find that out”.

Future research opportunities

We asked participants in the at home experiment their thoughts about taking part in a more in-depth PIF safety home experiment, for example, measuring the temperature of each bottle made for a period of 24 hours.137 (92.6%) said that they would, with 61 leaving open text comments to this effect. A further 21 noted that they would be interested to take part but acknowledged the inconvenience of taking part in an experiment over a longer period of time, for example: “the thank you payment would need to be worth it”. Overall, 27 people noted the importance of providing sufficient incentives. When discussed in the analysis sub-group, the requirement for a 24-hour period was considered impractical for many people, due to the busyness of family life, changes in PIF preparation methods when leaving home, or infants who were at nursery, meaning that incentives would need to be sufficiently large to outweigh the significant inconvenience. Furthermore, it was recommended that if somebody was unable to complete the experiment on one day, due to unforeseen circumstances, they could “pause” the data collection and resume it at that time on a subsequent day. To further increase completion of a longer data collection phase, the use of a digital thermometer “gun” was recommended. It is not yet clear how this would affect accuracy, particularly when smaller ‘hot shot’ volumes are being tested.

Conclusions and Implications

Our research shows that formula preparation machines were significantly more likely than kettles to dispense water which is below the 70oC required to kill any bacteria in PIF. This has serious implications for the safety of infants who are fed PIF prepared using formula preparation machines, which needs to be urgently investigated further. Barriers to safer preparation of PIF centred around time pressure alongside a lack of understanding of risk. There is a need for clear labelling of PIF to reflect safest PIF preparation practice, highlighting the importance of water temperatures and the risks associated with PIF. Parental support and education around preparing infant formula as safely as possible, particularly in relation to hand washing and washing and sterilising all equipment used is also vital. The ‘at home’ nature of the research mean our data reflect real world practice, although there may have been differences in the way that community scientists performed the experiment although all were given instructions. There may also have been unknown problems with the thermometers or inaccuracies in reporting. However, these issues should have affected both groups equally and do not fully explain the significant differences between the water temperatures recorded by parents using kettles and those using formula preparation machines.

Our approach to community science showed that women were interested in taking part in community science in greater numbers than men, which has not been found in other community science projects (Ibrahim et al., 2021), and safe feeding for babies as a research topic was seen as of considerable importance, for both the mothers involved and for future generations of parents. We did not secure in-depth engagement with areas of the study where community scientists were not remunerated (study design) and/or were not of interest (general science education). However, where incentives were utilised, engagement was high, with over three quarters of participants sent a study pack in the post completing the at home experiment, and long-term engagement was secured in the analysis sub-group. The online format of the sub-group, with options to feed in after meetings, made for a family-friendly environment, although engagement dipped due to the school summer holidays. Some members of the sub-group reported feeling awkward or unconfident at first, with recommendations made for increased training at the outset in future projects, but their confidence grew over time, with members making suggestions about scientific rigour and undertaking additional experiments around the preparation of PIF and reporting these back to the group.

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