

Parents' Perspectives Towards Novel Paediatric Medication Formulations: A Qualitative Study

Andy Jeon (✉ andy.jeon@health.wa.gov.au)

The University of Western Australia Medical School <https://orcid.org/0000-0003-1708-1794>

Ellen Han

The University of Western Australia Faculty of Health and Medical Sciences

Kenneth Lee

The University of Western Australia Faculty of Health and Medical Sciences

Aine Sommerfield

Perth Children's Hospital

Lee Yong Lim

The University of Western Australia Faculty of Health and Medical Sciences

David Sommerfield

The University of Western Australia Medical School

Britta S von Ungern-Sternberg

The University of Western Australia Medical School

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Abstract

Background: The availability of age-appropriate, taste-masked oral medications for the paediatric population is currently inadequate. We have developed a novel chocolate-based drug delivery platform to taste mask bitter drugs commonly utilised in the hospital setting, but there is limited evidence regarding parent's perspectives on these medications.

Aim: To identify key themes regarding parents' perspectives on taste-masked medications that look like confectionary. Additionally, to explore and identify the various barriers and facilitators to using oral medication among the paediatric population.

Methods: Qualitative descriptive study (July to August 2020) at a single tertiary paediatric hospital (Perth Children's Hospital - PCH). Parents with at least one child (2 – 18 years) that underwent any elective operation at PCH were included in the study. Ethics approval: CAHS - RGS0000003680.

Results: The two primary themes that underpinned parent's perspectives on taste-masked medications that look like confectionary were medication safety and taste. Majority of parents supported the use of the proposed medication on the basis that the favourable taste profile will facilitate oral consumption, as opposed to their previous experiences with conventional paediatric medications that do not taste mask the bitter flavour. However, medication safety, in the forms of patient education and appropriate packaging, must be considered to minimise harmful misuse of the proposed medication.

Conclusion: Participants unanimously support the short-term use of taste-masked medications that look like confectionary, particularly in the hospital setting. However, patient education is highly sought after by parents regarding the role of these medications, to ensure medication safety with their children.

Impact Of Findings On Practice

- Short-term use of taste-masked oral medications for children should be considered, particularly in the hospital setting.
- Medication safety is highly sought after from parents through patient education and appropriate physical measures.
- Unpleasant palatability of oral medications has been identified as a common barrier to medication compliance for children, consequently taste-masking is often utilised by parents.

Introduction

Poor compliance to medications is a widespread issue among the paediatric population, approximately one-third of chronically ill children has compliance issues to their oral medication.¹ Although the underlying factors contributing to poor compliance are complex and multifaceted, the adverse taste of medication is known to be a key contributor in the paediatric population.² The variability in an individual's

sensitivity to bitter taste is attributed to the genetically diverse nature of bitter-taste receptors (TAS2R).³ Children have heightened perception to bitter taste compared with adults due to the age-dependant genotype-phenotype relationship of TAS2R38.⁴ Therefore, the importance of implementing tolerable palatability into paediatric formulations has recently received greater recognition by regulatory authorities and the pharmaceutical industry.⁵

We have developed a novel chocolate-based drug delivery platform to taste mask bitter drugs, and evaluated the platform with two medications, midazolam and tramadol. Midazolam is a commonly prescribed medication for paediatric patients in the preoperative setting due to its predictable, rapid onset and sedative effects with minimal respiratory depression.⁶ However, the bitter taste of this medication often results in poor tolerance in young children and adolescents.⁷ Therefore, attempts to mask this medication have been made, such as the formulation of oral midazolam syrups, albeit to no avail.⁸ However, a clinical trial involving paediatric patients and their carers⁸, have demonstrated the efficacy of the novel chocolate delivery platform to mask the bitter taste of midazolam.

Tramadol is a potent analgesic that is utilised in the post-operative setting to manage breakthrough pain.⁹ However, it is poorly tolerated by the paediatric population due to its bitter taste.¹⁰ A clinical trial at Perth Children's Hospital (PCH) reported improved palatability with our tramadol chocolate delivery medications over the comparator tramadol oral liquid.¹¹

Currently there is no data on parents' perspectives concerning the acceptability and safety of novel taste-masked medications that look like confectionary. This must be addressed as a carer's disposition to treatment, such as perceived efficacy and potential adverse effect, is a major determinant of medication compliance in the paediatric setting.¹²

Therefore, this study aims to identify key themes regarding parents' perspectives on emerging medicinal products that utilise confectionary to taste mask bitter drugs. Furthermore, to comprehensively understand parents' viewpoints, key barriers to oral medication compliance among the paediatric population and strategies utilised by parents to overcome these challenges will be explored as well.

Methods

Procedures and Participants

Parents' perspectives were explored with a qualitative, inductive approach and the subsequent thematic analysis was guided by the Framework Method.¹³ Semi-structured interviews were conducted face-to-face with the participants individually. The participants were not known to the research team prior to the interviews. Furthermore, no financial remuneration and reimbursement were provided to participants. Ethical approval for this study was granted by the Child and Adolescent Health Service Human Research Ethics Committee (RGS0000003680).

Purposive recruitment was conducted in July and August 2020 with the aim of maximising participant variability in terms of age and gender. Participants were included if they were at least 18 years of age, demonstrated adequate English proficiency to accurately interpret and respond to interview questions, as determined by the interviewer, and had at least one child who was a patient at the short stay surgical unit (SSSU) at PCH at time of data collection.

We recruited participants from the SSSU at PCH as children and their parents were required to stay in this monitored setting for at least several hours preoperatively and postoperatively. Therefore, this provided us with ample time to adequately recruit participants and conduct interviews while they were at bedside with their child.

An appropriate sample size for a qualitative study is difficult to quantify as it is conventionally guided by data saturation.¹⁴ This was defined by the research team as the point where no new codes were generated from the interview transcripts. Initially we planned to recruit 20 participants, however if data saturation was reached earlier then recruitment would subsequently be ceased.

Interviews

Broad, open-ended interview questions were asked regarding parents' experiences with administration of paediatric medication to their children, and parents' perspectives on novel medications that look like confectionary. These questions were developed by the research team to address the lack of current data available on parents' perspectives concerning the acceptability and safety of medications that look like confectionery. The interview guide can be seen in the appendix.

Semi-structured interviews of 15 minutes in duration were solely conducted by the first author, who received prior training in interviews for qualitative research. The audio of each interview was recorded with the PCH's Anaesthesia department's iPad and transcribed verbatim in Microsoft Word as soon as practical after each interview.

Transcript from each participant was anonymised and allocated a unique code number. The digital transcript was also supplemented with field notes written by the interviewer and corrected for any grammatical mistakes to enhance its readability. Modified transcripts were repeatedly read by the research team for data familiarisation prior to the remainder stages of the Framework Method analysis. Afterwards all transcripts were imported and coded with the NVivo software (QSR International Pty Ltd. Version 11.0).

Analysis

The Framework Method was utilised to guide a two-stage thematic analysis; manifest (descriptive) and latent (interpretive).^{13,15} Initially manifest analysis required the researcher to describe common ideas reported in the transcript.¹⁵ Subsequently, latent analysis was performed where the researcher interpreted common ideas identified in manifest stage.¹⁵

Prior to recruitment, reflexivity was discussed, and no established assumptions relevant to the study's aim were identified among the research team. Analyst triangulation was practiced as two research members (A.J and E.H) independently coded each transcript, discussed discrepancies, and reconciled as mediated by the third researcher (K.L). Furthermore, an audit trail was utilised to ensure accountability and consistency amongst the team's analytical decision-making process.

Results

Summary

Overall, 24 participants were approached at the SSSU, of whom 17 agreed to participate in the interview. Of the 7 who declined, 5 participants did not participate due to inconvenience and 2 participants did not disclose a reason for their lack of participation. Among the 17 eligible participants, there were 11 female and 6 male participants. The age of these participants ranged from 24–45 years, with the median age of 30 years. The indication for the participant's child's surgery was not recorded to maintain participant confidentiality. Finally, data saturation was observed by the 13th interview, but four more interviews were conducted to confirm data saturation.

Stage 1 Analysis: Data-Driven, Manifest Level

As identified in Table 1, commonly reported barriers to oral medication among the paediatric population were bitter taste and artificial fruit flavour. On the contrary, a common facilitator among the paediatric population was taste masking the medication in various foods, such as ice-cream and fruit juice. Nonetheless, it appears the barriers and facilitators to oral medication among the paediatric population is centred around the palatability and appearance of the medication

Table 1
Parents' perspectives on oral medication among the paediatric population

Barriers	Facilitators
Bitter taste	Mask in food (eg. Ice-cream, fruit juice)
Artificial fruit flavour <i>(Sometimes the taste is also too sweet. So she always has to take it with a drink.)</i>	Offer incentive to child (eg. Chocolate, yoghurt)
Thick texture (eg. Syrup medication)	Distract the child (eg. Watch TV, play with iPad)
Foreign appearance (eg. Round white pill)	Forceful administration (eg. Physical restraint)

As seen in Table 2, the participants who expressed positive attitudes towards the novel medication, commonly justified their position due to its positive utility in the preoperative setting. On the contrary, those expressing more negative views were concerned over the potential dangers associated with the proposed medication; psychologically and physiologically.

Table 2

Parents' perspectives on novel confectionary medication for the paediatric population

Positive	Negative
Utility for short-term use (eg. Preoperative)	Long-term psychological impact (eg. Negative association with candy and medicine)
Education of child and parent regarding role of confectionary medication (eg. Doctor, nurse or pharmacist explaining to child that this is a medicine)	Concerns over potential overdose administration at home

Stage 2 Analysis: Data-Driven, Latent Level

As seen with Tables 3 and 4, our latent-level analysis revealed two themes that underpinned parents' perspectives on oral medication and medications that look like confectionary for the paediatric population: taste and medication safety. Specifically, these two themes appear to explain the potential reasons why parents have outlined certain barriers and facilitators to oral medication for their children and more importantly why they have undertaken a specific stance on novel medications that look like confectionary. Ultimately, these themes have highlighted the unique issues that regularly occur in the paediatric setting regarding medication administration.

Table 3
Latent-level analysis: taste

Hiding in food, like cakes. My friend's kid loves lamington, so she injected the medicine into lamington. It was syrup medicine and she put it in lamington. This helps to hide the bitter taste of the medicine. [P1]

With the antibiotic, the taste was the biggest issue. Even the orange flavour of antibiotic was not helpful. My child was too young (18 months) to complain of a particular taste. However, I think bitterness and chemically/weird flavour makes it too hard. [P3]

If the kid has to take it, anything that makes it easier for them. Less stress for me and for them. Also it's better for them because if they need then they can take their medicine easily. [P3]

Short-term use before an operation I would definitely be more than fine. But if you had to take it on a daily basis for a long period of time then I think that would potentially an issue...However if it's anything longer than that, then you might have to think twice about that. But hey if it's easy to administer and the kids are happy with that I think it should be fine. [P5]

Table 4
Latent-level analysis: medication safety

<i>Sometimes I think we should just view medicine as medicine. Yeah you're getting it into them. But I'll be thinking more of the psychological element of that. What are the long term effects of that when they're adults? If we are not recognising and acknowledging this is medicine. If a child is always given medicine that looks like chocolate. Then what point then, will they acknowledge that this is medicine. [P1]</i>
<i>I suppose I don't want him to get used to having sweet stuff all the time. However as long as he understands that its medicine and it's not something he can have all the time then I'd be fine with him regularly. [P12]</i>
Electronic Supplementary Material
Interview Guide

Taste

During the interviews with participants, the importance of taste was evident as their responses were universally centred around this theme. It appears that taste was both a barrier and a facilitator to participants, depending on how they manipulated the medication for their child. However, the negative impact of bitter taste was apparent as this specific flavour was repeatedly reported as a prominent barrier among most parents (Table 3).

The critical role of palatable medication was also seen with most participants despite their differing stances towards the proposed novel medication. Many participants identified the utility of the taste-masked medication that look like confectionary in the preoperative setting, as a familiar taste and appearance will help relax their child during the unfamiliar stage of their hospital stay (Table 3).

Medication Safety

Medication safety was another theme that seemed to underlie the participants' responses in the interview. It is important to note that the notion of 'medication safety' is multi-faceted as it includes preventing an event that may lead to patient harm associated with medication.¹⁶ Therefore, this concept extends beyond physical means as several participants were also concerned of the intangible dangers associated with taste-masked medications that look like confectionary, such as long-term psychological consequences seen with lack of patient understanding. These sentiments were reflected by several different participants throughout the interviews (Table 4).

Conclusion

This study explores parents' perspectives on taste-masked medications that look like confectionary and identifies common barriers and facilitators to oral medication among the paediatric population. The findings reveal that parents prioritise medication safety and palatability when considering the use of oral

medications for their child. Therefore, our study reveals unique information that various stakeholders can benefit from and ultimately, it aims to accelerate the implementation of novel medications that look like confectionary among the paediatric population.

Declarations

Ethics approval: Child and Adolescent Health Service Human Research Ethics Committee (RGS0000003680)

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