**Integrating Caregiver Perspective Towards The Next Generation Of Dispersible Tablets For The Youngest Patients**

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**Background and aims.** Neonates, infants and toddlers are the most challenging paediatric subsets to cater for when developing an acceptable dosage form (1). Previous investigation with parental involvement showed positive attitudes towards dispersible tablets (DTs) as an alternative option to oral dosage forms such as syrups. An enhanced non-proprietary DT prototype that swells as it is hydrated, to make the administration, swallowability and palatability easier is proposed in this study.

Aim: to pilot a study (*UCL Research Ethics Committee Project ID Number: 26205/002*) that will:

1. Assess dose preparation and simulated ease of administration from DTs. 2. Give caregivers hands-on experience with an ‘enhanced’ DT formulation prototype to provide a better understanding on the impact of formulation enhancement and the understanding/familiarity parents have with DTs, on the user experience and perceived acceptability.

**Methods.** *Questionnaire:* Rating, ranking and comment based questions, and information provided about the advantages of DTs. *Recruitment of n=30 participants:* Advertisements distributed via email/community groups/nursery internal to UCL (inclusion criteria: English speaking adult responsible for a child aged under 3, with/without experience administering medicines). *Data collection:* Parents/caregivers prepared a dose of syrup, regular DT (Tablet 1) and enhanced DT prototype (Tablet 2) at 3 stations, A,B,C (crossover design), before noting their experience and opinions/preferences. *Data analysis:* numerical comparison and deductive coding.

**Results.** Most participants ranked syrup above both DTs initially, but this reduced as suitability and confidence rankings for both tablets increased after information was provided about how DTs may be more optimal for dosing the youngest patients (table 1).

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| --- | --- | --- | --- | --- |
|  | **Before providing DT information** | | **After providing DT information** | |
|  | **Highest Suitability** | **Highest Confidence** | **Highest Suitability** | **Highest Confidence** |
| **Syrup** | 96.7% | 100% | 36.7% | 63.3% |
| **Tablet 1** | 0% | 0% | 26.7% | 16.7% |
| **Tablet 2** | 3.3% | 0% | 36.7% | 20% |

**Table 1.** Percentage of participants (n=30) ranking syrups, DTs and enhanced DT prototype as having the highest suitability for and confidence to dose to a child aged under 3

**Conclusion/Discussion.** This was a successful pilot study supplementing previous investigation of the challenges of preparing and administering DTs to children aged under 3. Findings showed that formulation enhancement, increasing familiarity through hands-on experience with the dosage forms as well as provision of information to foster greater understanding of DTs, can improve the user experience and their acceptability. It validates the study to be brought to a wider population of parental/caregiver groups to build a more inclusive and truer picture.

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**References:** 1. Kaneria NS, Tuleu C, Ernest T. Opportunities for enteral drug delivery for neonates, infants, and toddlers: a critical exploration. Expert Opinion on Drug Delivery. 2022;19(5):475-519.