End-user Perceptions of Solid Oral Dosage Forms in the UK and Canada

Part 1: School Children and Adolescents

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BACKGROUND

The development of age-appropriate and acceptable paediatric pharmaceutical dosage forms should be patient-centred and take into consideration the needs of the intended users across different socio-cultural settings. Patient and consumer access to different dosage forms varies across global markets and is conditional on availability, access, licensed age for use and where appropriate, prescribing practices.

The ‘Children’s Acceptability of Oral Formulations’ (C Alf) Medicines Survey aimed to determine the views of school children and adolescents aged 6-18 years with regards to different solid oral dosage forms and their attributes. This was extended to Quebec, Canada (QC Alf) to investigate whether paediatric patients and consumers’ experiences and exposure to different dosage forms varied, and as such, whether acceptability and attitudes differed among a North American population.

METHODS

Age-adapted questionnaires had previously been developed with children and young people in line with the principles of patient and public involvement in research (PPI). Translation into French was undertaken by a fluent Montreal native and further reviewed by two other native French speakers, to ensure both versions were functionally equivalent.

Following administration of the questionnaires, participants’ perceived acceptability of tablet and capsule sizes from scaled images on paper were validated against physical models.

RESULTS

RESPONDENT DEMOGRAPHICS

Table 1: Demographics of study respondents

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<th>CALF</th>
<th>QCALF</th>
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<tr>
<td>Total N</td>
<td>110</td>
<td>101</td>
</tr>
<tr>
<td>% Male</td>
<td>41.2</td>
<td>46</td>
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<tr>
<td>% Female</td>
<td>58.8</td>
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Respondents did not differ significantly with regards to gender, presence of a chronic health condition or family exposure. The mean age of the adolescent population in Canada was younger than in the UK.

Overall, UK respondents had more self-reported experience taking tablets than those from Canada, whereas the opposite was observed for chewable dosage forms. Chewable forms in Canada were mainly taken as vitamins. Experience with other dosage forms did not differ significantly, but was slightly higher in the UK for capsules and orodispersible forms, and higher in Canada for multiparticulates (‘sprinkles’).

SIGNIFICANTLY MORE UK SCHOOL CHILDREN PERCEIVED TABLET MODELS OF 10MM OR LARGER TO BE ACCEPTABLE TO SWALLOW COMPARED TO THOSE IN CANADA. THE MAJORITY (>70%) OF RESPONDENTS WHO CHOSE SMALLER SIZES HAD LOW PRIOR EXPERIENCE, HAVING TAKEN TABLETS RARELY OR NEVER. OVER 80% OF SCHOOL CHILDREN IN BOTH SETTINGS HAD LOW EXPERIENCE TAKING CAPSULES. AMONG ADOLESCENTS, RESPONDENTS CHOOSING SIZE 3 CAPSULES OR SMALLER DID NOT NECESSARILY HAVE LOW PRIOR EXPERIENCE.

In addition to assessing capability, determining children’s willingness to take dosage forms is an important research need, and may help to identify potential barriers to acceptability. Availability and licensed age for use of paediatric medicinal products differs across global markets; for example, over the counter paracetamol/acetylsalicylic acid orodispersible tablets are licensed from the age of 2 years in Canada (Children’s Tylenol® Fastmelts®) versus 2 years in Canada (Junior Strength Children’s Tylenol® Fastmelts®). Less prior experience or knowledge of more novel dosage forms can affect end-user attitudes.

CONCLUSIONS

Canadian respondents generally showed superior acceptability of these dosage forms, in particular multiparticulates (“sprinkles”), which were not as favourable to both UK school children and adolescents. Despite differences in prior experience, chewable dosage forms were well accepted by both populations. When asked their specific preference between chewable, orodispersible and multiparticulate forms, chewable forms ranked first for UK school children (60%), while multiparticulates ranked first among Canadian school children (42%).

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Part 2: Parents and Carers

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BACKGROUND

The needs and preferences of parents and caregivers require appropriate consideration during the development of paediatric pharmaceutical dosage forms. In particular, they can strongly influence the choice and use of over-the-counter (OTC) medicines in community settings. Access to different dosage forms varies across global markets and is conditional upon availability and licensed age for use.

This study assessed the attitudes of parents and caregivers of children and adolescents aged 6-18 years to solid oral dosage forms as part of the ‘Children’s Acceptability of Oral Formulations’ Medicines Survey. The objective was to investigate whether acceptability and preferences differed among respondents in the UK (CALF) and in Quebec, Canada (QCALF).

METHODS

Children and adolescents under the age of 16 in the UK, and 18 in Canada, required caregiver consent (written or verbal respectively) to take part in the study. Caregivers were then invited to complete a corresponding adult questionnaire. For use in Canada, the questionnaires were also translated into French by a fluent Montreal native, and further reviewed by two other native French speakers.

Caregivers’ perceived acceptable tablet and capsule sizes (that their child could swallow intact) from scaled images in the questionnaire were validated against physical models.

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Caregivers’ perceived acceptable tablet and capsule sizes (that their child could swallow intact) from scaled images in the questionnaire were validated against physical models.

There was no statistically significant difference in responses among participants from the UK and Canada for both tablets and capsules.

For school aged children (6-11 years) specifically, the majority of caregivers perceived tablet model sizes of 10mm or larger to be unsuitable for their children to swallow intact (73.6% and 82.1% in the UK and Canada respectively).

In comparison with school-children and adolescents themselves (Table 2), caregivers found larger sized dosage forms significantly less acceptable.

CONCLUSIONS

Parents and caregivers perceptions of their child’s ability, or inability, to take different solid oral dosage forms may act as a barrier to end-user acceptability and the commercial and therapeutic success of paediatric medicines. However, greater exposure to and awareness of different solid oral dosage forms, including OTC medicines and vitamins, may influence attitudes in different global settings.

The authors would like to thank all of the respondents for their contribution to this study, as well as the undergraduate pharmacy students and collaborators from each of the community settings who aided in data collection.