Citation for published version:

DOI:
https://doi.org/10.1016/j.ijpharm.2016.03.007

Document Version:
This is the Accepted Manuscript version. The version in the University of Hertfordshire Research Archive may differ from the final published version. Users should always cite the published version of record.

Copyright and Reuse:
This Manuscript version is distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs https://creativecommons.org/licenses/by-nc-nd/3.0/

Enquiries
If you believe this document infringes copyright, please contact the Research & Scholarly Communications Team at rsc@herts.ac.uk
Acceptability of oral solid medicines in older adults with and without dysphagia: a nested pilot validation questionnaire based observational study

Fang Liu¹*, Ambreen Ghaffur¹, Jackreet Bains¹, Shaheen Hamdy²

1 Department of Pharmacy, pharmacology and postgraduate medicine, School of Life and Medical Sciences, University of Hertfordshire, Hatfield AL10 9AB, UK
2 Centre for GI Sciences, Institute of Inflammation and Repair, Faculty of Medical and Human Sciences, University of Manchester, Manchester, M6 8HD, UK

*Contact author: Fang Liu
email: f.liu3@herts.ac.uk
Tele: +44-1707284273
Fax: +44-1707288503
Abstract

Older patients (aged 65 years and over) are the major consumers of medicines and many barriers affect their ability in taking medicines orally, especially swallowing difficulties. Moreover, the characteristics of differing medicine formulations might have an impact on their acceptability in older patients. The aims of this study were to validate a Medicines Acceptability Questionnaire (MAQ) and to assess acceptability of oral solid medicines in older ambulatory patients with and without dysphagia. One hundred and fifty six older patients attending community pharmacies were recruited and attended face to face interviews. Two questionnaires were administered during the interviews, the validated Sydney Swallow Questionnaire (SSQ) assessing oral and pharyngeal swallowing function and the newly developed Medicines Acceptability Questionnaire (MAQ) evaluating patient acceptability of oral solid medicines. Seventeen (11%) participants displayed symptoms compatible with swallowing difficulties identified by the SSQ. Participants with swallowing difficulties were considered themselves more likely to have problems in swallowing tablets and capsules of large sizes (11 mm and 13 mm tablets and size #00 capsules) compared to participants without dysphagia. Dispersible/effervescent tablets and orally disintegrating tablets were considered to be the most acceptable in this cohort, followed by mini-tablets. Chewable tablets and granules were the least favoured. Consistently higher acceptability scores were seen in the dysphagic population than in the non-dysphagic population for all of the dosage forms that were easier to swallow than tablets and capsules. The development of these formulations will assist in medication taking in older patients with dysphagia and potentially their adherence to drug treatments.

Keywords: geriatric, elderly, swallow, medication, acceptance, preference
1. Introduction

Patient acceptability to a pharmaceutical dosage form is critical to ensure adherence and therapeutic outcomes, especially in children and older people (F. Liu et al., 2014). Acceptability has previously been defined as “an overall ability of the patient and caregiver (defined as ‘user’) to use a medicinal product as intended (or authorised)” (P. Kozarewicz, 2014). The European Medicines Agency has required the assessment of patient acceptability to be an integrated part of paediatric medicinal product development (E. M. A. (EMA), 2013; P. Kozarewicz, 2014). However, acceptability of medicines in older adults has been largely overlooked. Older patients (aged 65 years and over) account for 50% of the medicine prescriptions in the UK (Z. Rajaei-Dehkordi and G. McPherson, 1997). The oral route remains the most preferred mode for medicine administration; however, there are barriers for older patients to take medications orally (F. Liu et al., 2014). Swallowing difficulties (dysphagia) are common in older people which affect their ability to take oral medicines, especially tablets and capsules (C. M. Steele et al., 1997; I. Strachan and M. Greener, 2005). Consequently, medicines are often modified such as crushing tablets or capsules opened to assist administration to older patients (J. Kelly and D. Wright, 2009; D. Wright, 2002). This leads to unlicensed used of medicines and can potentially cause ineffective use or toxicity of the medicine (S. Stegemann et al., 2012).

Characteristics of a pharmaceutical dosage form, such as the size, shape, and surface texture of a tablet, have an impact on how easily a solid oral medicine can be swallowed and pass through the pharynx and oesophagus (K. S. Channer and J. P. Virjee, 1985; K. T. Evans and G.
M. Roberts, 1981; H. Hey et al., 1982; A. B. Overgaard et al., 2001). Previous knowledge on these effects has been demonstrated in healthy young subjects; however, this remains unclear in older people especially those with existing swallowing difficulties. The type of formulation might be another factor affecting the ability and willingness of older patients to take their medicines. A number of solid oral dosage forms that are “easier to swallow” than tablets and capsules have been made available in recent years including orally disintegrating tablets (ODTs), dispersible tablets, mini-tablets and multi-particulates (granules). As most of these formulations are designed and developed for paediatric use, acceptability of some of these dosage forms in children has been reported (I. T. Cohen et al., 2005; J. Motte et al., 2005; D. Nasrin et al., 2005). For older patients who cannot swallow tablets, the availability of these formulations could be beneficial. The use of dispersible/effervescent tablets and ODTs has been demonstrated in older patients (A. J. Bayer et al., 1988; J. C. Nelson et al., 2006). Especially, ODTs have been proven to be easier to swallow than conventional tablets for patients with dysphagia (G. Carnaby-Mann and M. Crary, 2005). However, evidence in the acceptability of these solid dosage forms in older patients is still sparse. This research is a pilot study where a Medicines Acceptability Questionnaire (MAQ) was initially developed and validated before assessing the acceptability of a range of solid oral medicine dosage forms in older ambulatory patients attending community pharmacies and investigating the association between patient acceptability and the presence of swallowing difficulties.

2. Materials and Methods

2.1 Study population and setting
The study was approved by the Ethics Committee of University of Hertfordshire (LMS/SF/UH/00081) and was conducted at community pharmacies in the South East England area in the UK during October to November 2014. A convenient sample of pharmacies was recruited to participate in the study. The pharmacist in charge in each pharmacy was informed the purpose of the study and approached consecutive patients attending the pharmacy during week-day (Monday to Friday) opening hours who were eligible for the study. The eligibility criteria include patients aged 65 years or over and prescribed at least one oral medicine. No financial incentive was received by the pharmacies for participating in the study.

Given the stated aims, the primary endpoint of the study was the proportion of primary care older patients having swallowing difficulties. Based on the literature, prevalence of swallowing difficulties in community dwelling older adults was estimated as 11% (G. Holland et al., 2011). Approximately 150 participants would need to be enrolled to ensure a desired precision of at least 5%.

2.2 Administration of the Sydney Swallow Questionnaire (SSQ)

The SSQ is a validated questionnaire and composed of 17 questions assessing oral and pharyngeal swallowing function with responses entered onto a 101 mm visual analog scale except for question 12 (R. C. Dwivedi et al., 2010; K. L. Wallace et al., 2000). The SSQ was administered to the participants during an interview which took place in the private consultation room in the pharmacy. The participant placed a mark on the horizontal line of the visual analog scale. The first millimeter of the line was disregarded and a score of 0-100 was calculated by measuring the distance from the center of the mark to the first millimeter of the line for each question. A mark placed within the first millimeter of the line was scored
as zero. Question 12 contains 6 categorical responses each representing a score of 0, 20, 40, 60, 80 or 100. The maximum possible total score for the SSQ was 1700, with higher score indicating greater severity of swallowing dysfunction. Analogous to the description of Holland et al. (G. Holland et al., 2011), a score greater than 200 was considered indicating symptomatic dysphagia.

2.3 Pilot of the Medicines Acceptability Questionnaire (MAQ)

The MAQ comprised 15 questions evaluating patient acceptability of oral solid medicines. The questions were developed around three major topics. The first topic (3 items) covers general health status of the participant, number of oral medicines currently taking and any difficulties in taking solid oral medicines. The health status of the participant was measured using a 5-point Likert scale. Excellence in general health was ranked as a score of 1 and a score of 5 represented the health perception being poor. The second topic (5 items) evaluates participants’ perception on the size and shape of tablets and capsules in relation to difficulties in swallowing. The participants were shown a printed diagram of tablets of varying sizes and shapes (Appendix). Samples of 9 mm tablets (the middle size of all sizes presented) of each shape were taped onto the diagram to provide visual representatives of the size and shape. Participants were also shown samples of hard gelatin capsules (HGC) of different sizes (4#, 3#, 2#, 1#, 0# and 00#). They were then asked from what size they will start to have difficulty to swallow the tablets and capsules.

The third topic (7 items) assesses participants’ acceptability of other alternative solid medicine dosage forms to tablets and capsules, including mini-tablets, granules in a sachet, dispersible/effervescent tablets, orally disintegrating tablets (ODTs) and chewable tablets.
These dosage forms are referred to as “alternative solid oral dosage forms” throughout this article. The participants were shown samples of all formulation types and were given an explanation of how the formulation should be administered. Mini-tablets were shown to participants as mini-tablets filled in HGCs. Granules were presented as sprinkles onto food. Dispersible tablets were presented as a drink with a minimum amount of 60 ml (or half a glass) water required to dissolve the tablet. ODTs were described as melting/dissolving on the tongue and chewable tablets were explained as needing to be chewed before swallowing. They then provided their opinion on the formulation including past experience in using the formulation, giving a score of 0-10 indicating their acceptance with 10 being the most acceptable. Open-ended questions were also used to obtain opinions of the participants on good and bad points of each formulation. The open-ended questions were analysed by reporting the percentages of participants stating the same comments on a formulation.

The content-face validity of the MAQ was assessed by two experts in the field acting as respondents. Cronbach’s alpha test was conducted to evaluate the level of reliability and internal consistency using the Statistical Package of the Social Sciences (SPSS) version 22.0 (IBM Corp., Armonk, NY, USA). Cronbach’s alpha scores of 0.7 or above were deemed as acceptable according to Nunnally and Bernstein (J. Nunnally and L. Bernstein, 1994). The MAQ was administered to the participants during the interview together with the SSQ. The interviews were conducted by two of the authors (AG and JB). Three pilot interviews were conducted in the presence of both interviewers to reach a consensus on how to conduct the interview and the subsequent interviews were conducted by one interviewer per participant.

2.4 Data analysis
Data analysis was performed using the Statistical Package of the Social Sciences (SPSS) version 22.0 (IBM Corp., Armonk, NY, USA). The results are reported as mean ± standard deviation (SD). Spearman’s nonparametric correlation was used to identify the presence of significant correlations between total SSQ score and age of participants or number of solid oral medicines taken daily. The Mann-Whitney U test was conducted to assess links between gender of participants and total SSQ score, and comparing the means of participants’ self-perceived health status between the dysphagia and non-dysphagia group. Chi-Square test was conducted to evaluate the relationship between dysphagic status of the participant and difficulty in swallowing tablets and capsules. The Kruskal Wallis test was used to assess significant relationship between total SSQ score and participants’ self-perceived health status.

2.5 Materials used to conduct the interviews

Samples of tablets, capsules and other solid dosage forms that were presented to the participants during interviews are listed in Tables 1 and 2. Samples of formulations were purchased as commercial products where possible to represent medicines used in real life. When a suitable commercial product was not identified to represent a formulation, placebo samples were used (9 mm arched round tablets).

3. Results

3.1 Validation of the Medicines Acceptability Questionnaire (MAQ)

The content/face validity of MAQ was established by experts. Any items where questions were raised were modified and the revised versions were tested again until there were no further questions. The total Cronbach’s alpha score was calculated as 0.940 and scores after
eliminating any items from the questionnaire were in the range of 0.928 – 0.945, indicating good reliability and internal consistency of the questions.

3.2 Participant demographics and the Sydney Swallow Questionnaire (SSQ) scores

Fifteen pharmacies were approached and of these 10 (including both chain-pharmacies and independent pharmacies) agreed to participate in the study. The main reason given by the pharmacies for refusing to participate was that the pharmacist had limited time available to help recruiting participants. A total of 165 patients were approached by the pharmacists and 156 (94.5%) were recruited to participate in the study. The average age of the participants is 74.0 ± 5.7 (mean ± SD) years and 80 (51.3%) participants were females. All participants completed both the SSQ and the MAQ successfully.

Seventeen (11%) participants had SSQ scores ≥ 200, indicating symptomatic dysphagia or swallowing difficulty. The mean total SSQ score across all participants was 92.2 ± 168.7 (mean ± SD, range 0.0-1026.0) and for participants with significant symptoms of dysphagia it was 497.2 ± 246.6 (mean ± SD, range 211.4-1026.0). There was no significant correlation between age and SSQ dysphagia score ($r=0.050$, $p=0.537$) and no statistically significant relationship between gender and SSQ dysphagia score ($r=-0.040$, $p=0.624$).

The mean score for the self-perceived health status of all participants was 3.2 ± 1.1 (mean ± SD, 1=excellent and 5=poor). There was a significant correlation between general health status score and SSQ dysphagia score ($r=0.250$, $p=0.002$). The mean health status scores were 3.9 ±1.0 (mean ± SD) and 3.1 ±1.1 (mean ± SD) for participants with and without dysphagia respectively. On average, the participants were prescribed 5.1 ± 3.8 (mean ± SD) oral solid
medicines on a daily basis. Sixty five (42%) participants took 5 or more solid oral medicines daily. A significant relationship was present between number of oral solid formulations taken daily by the participants and SSQ dysphagia score ($r=0.171$, $p=0.033$).

3.3 Ability to swallow tablets and capsules in patients with and without dysphagia by the MAQ

A total of 12 (7.8%) participants experienced ongoing difficulties in swallowing tablets and capsules according to the results from the MAQ. Figure 1 shows percentage of participants who has chosen the size and shape of tablets that were perceived as starting to cause difficulty in swallowing. Between 46% and 64% of the participants without swallowing difficulties (SSQ score lower than 200) reported no problem of swallowing any of the tablets sizes for the different shapes presented compared to 6%-12% of the participants with swallowing difficulties (SSQ score higher than 200; Figure 1). The majority of participants with dysphagia found that tablets of sizes 11 mm and 13 mm might started to cause difficulties in swallowing; the percentages of participants selecting 11 mm or 13 mm were 52.9%, 52.9%, 58.8% and 64.7% for flat round, arched round, oblong and oval tablets respectively.

Similar results were observed regarding difficulties in swallowing capsules of different sizes in participants with and without dysphagia (Figure 2). Around 40% participants with no dysphagia deemed themselves having no problem of swallowing any of the capsule sizes presented, compared to only 6% in participants with dysphagia. In participants with dysphagia, over a third (35%) selected size #00 as that which started to cause problems in swallowing; however, around 30% of these participants also considered size #2 to be difficult to swallow.
3.4 Acceptability of alternative solid oral dosage forms

A low proportion of participants had had experience of using the alternative solid oral dosage forms, except for dispersible/effervescent tablets which were referenced mainly to soluble paracetamol and dispersible aspirin tablets as examples (Table 3). The acceptability scores of different oral solid dosage forms are shown in Figure 3. Participants described the good/bad points they considered for each formulation as listed in Table 4.
4. Discussion

A range of medicine formulations have been made available for patients who find it difficult to swallow tablets and capsules. However, the acceptability of these formulations in targeted patient groups is often unclear. This pilot study is the first attempt to evaluate the acceptability of a range of solid oral dosage forms in older patients with and without dysphagia, using the newly developed Medicines Acceptability Questionnaire (MAQ). The content validity and reliability of the MAQ was established and the results of this study can be compared to future investigations. In our study, the prevalence of (symptoms compatible with) dysphagia in this older population attending community pharmacies was found to be 11%. This is in agreement with a study by Holland et al. in which 11.4% of participants of a community dwelling older population in England was found to have scores on the SSQ compatible with dysphagia (G. Holland et al., 2011). This also broadly agrees with or is slightly lower than other published data on prevalence of dysphagia in older primary care patients (B. R. Bloem et al., 1990; P. H. Chen et al., 2009; K. Kawashima et al., 2004). In this study, age and gender of the participant did not significantly affect dysphagia score. Studies have reported that increasing age is associated with increased severity and prevalence of dysphagia in elderly populations (G. Holland et al., 2011; K. Kawashima et al., 2004). However, Szcaesniak et al. studied SSQ score in a non-dysphagic population and found that there was no significant correlation between age and SSQ score (M. M. Szczesniak et al., 2014). The majority of the participants in the current study were non-dysphagic, which might have contributed to the non-significant relationship between age and dysphagia score. It is also possible that the size of the cohort (n=156) was not large enough to see such an effect.
Almost half of participants took 5 or more solid oral medicines daily, which qualifies as polypharmacy by definition of some published studies (D. Gnjidic et al., 2012; U. Junius-Walker et al., 2007; D. Koper et al., 2013). In addition, there was a significant relationship between dysphagia (SSQ) score and number of oral medicines taken on a daily basis. Marquis et al. did not find a significant relationship between difficulties in swallowing solid medicines and number of prescribed tablets among primary care adult patients who have at least 3 daily solid oral medications prescribed (J. Marquis et al., 2013). Marquis et al. (2013) used patients’ self-reported difficulties in swallowing solid medications instead of the validated questionnaire (SSQ) and this difference in methodology might have contributed to the deferring outcomes from the current study.

It has been documented that size and shape of tablets and capsules affect the “swallowability” and oesophageal transit in adults. Generally, difficulty in swallowing tablets increases with size (H. Hey et al., 1982; A. B. Overgaard et al., 2001). However, most of the published studies are conducted in healthy young subjects and limited information is available on the ability of older adults especially those with swallowing difficulties to swallow tablets and capsules. In the current study, participants with dysphagia (SSQ scores > 200) were more likely to have difficulties in swallowing tablets and capsules of the given sizes and shapes compared to non-dysphagic participants. Oblong and oval tablets were considered slightly easier to swallow than flat round and arched round tablets, which is in agreement with previous reports that large tablets of oblong and oval shapes are easier to swallow and pass esophagus faster than round tablets (K. S. Channer and J. P. Virjee, 1985; H. Hey et al., 1982; A. B. Overgaard et al., 2001). Schiele et al. (2013) reported that round tablets of 8 mm in diameter started to cause swallowing difficulties in patients and for oval and oblong tablets
the length of tablets reached 15 mm and 16 mm respectively to causing problem in swallowing (J. T. Schiele et al., 2013).

Amongst the alternative solid oral dosage forms, dispersible/effervescent tablets ranked highest in acceptability score. Previous use of dispersible/effervescent tablets has the highest proportion of participants giving a positive response. A national survey across the UK showed that 90% of what was prescribed or sold over the counter to older people for long-term use which were regarded as being “easy to swallow” were effervescent tablets (W. Baqir and A. Maguire, 2000). This familiarity with the type of the formulation and mode of administration might contribute to the high acceptance to these formulations.

ODTs and mini-tablets were also deemed acceptable in both the dysphagia and non-dysphagia populations, following dispersible tablets. The main advantages of ODTs reported by the participants were convenient to use and easier to swallow. Indeed, previous work has indicated that ODTs require less effort to swallow than conventional tablets in patients with dysphagia (G. Carnaby-Mann and M. Crary, 2005). The use of ODTs in older patients has been documented, especially in patients with Parkinson’s and Alzheimer’s diseases, and patients under antipsychotic treatments who might be purposely non-adherent (V. Danileviciute et al., 2009; B. J. Kinon et al., 2003; P. A. Nausieda, 2005). The mini-tablets (4 mm in diameter) were considered easier to swallow than normal tablets due to small size by the participants. Mini-tablets (3 mm) were deemed appropriate for use in patients with Parkinson’s disease, due to the potential of providing individualized dosage (S. Bredenberg et al., 2003). However, concerns were raised in respect of difficulties in handling and seeing these smaller formulations by participants in our study and the study contacted by S. Bredenberg et al.
Future research is needed in investigating acceptability of mini-tables of smaller sizes, multiple dosages and the potential of using dispensing devices in older patients.

Chewable tablets and granules were considered as the least acceptable amongst the alternative dosage forms. Chewable tablets were useful in paediatric medicines for children over 2 years old (T. M. Michele et al., 2002). However, they might not be appropriate for use in older patients, as there has been a reported decline in chewing ability in older age primarily due to tooth loss (I. A. Kida et al., 2007; P. Peltola and M. M. Vehkalahti, 2005). Granules were not favored amongst the participants mostly due to reluctance in mixing medicines with food and concerns on incomplete dosing.

For all of the alternative solid dosage forms, consistently higher acceptability scores were seen in the dysphagia population than in the non-dysphagia population. Participants with dysphagia (SSQ scores > 200) are more likely to experience problems in taking their medicines in the form of tablets and capsules. The current study shows that formulation characteristics play a role in medicine acceptability in older patients. It is therefore important to make available a variety of formulation choices for older patients who find swallowing tablets and capsule difficult. The European Union legislation in paediatric medicines has prompt the development of formulations suitable for children (P. Kozarewicz, 2014). The increasing availability of paediatric formulations could benefit older patients; however, there are distinct differences between the two populations (F. Liu et al., 2014). Consequently, explicit considerations should be given to the older population to address their unique and specific needs in drug therapy and medicine use.
The study has its limitations. The study recruited a convenient sample of community pharmacies which might introduce selection bias. The patients’ self-reported difficulties in swallowing solid medicines were not compared with the current medications prescribed to the patients which might have correlated better with the types and characteristics of formulations that the patients can or cannot take. Diagrams of tablets of different sizes and shapes (except for 9 mm tablets) were presented instead of real samples which might affect participants’ judgement in ability to swallow. The study focused on oral solid dosage forms and liquid medicines were not included. The need for liquid formulations might be higher in nursing homes and hospitals and these settings would be ideal to assess the acceptability to liquid medicines in future studies. The acceptance scores of the alternative dosage forms were not directly compared with that of tablets and capsules, which would be useful information for further investigation.

5. Conclusions

A significant proportion of older patients attending community pharmacies have symptoms compatible with dysphagia. These patients are more likely to have difficulties in swallowing tablets and capsules compared to those with no dysphagia. Healthcare professionals should identify patients with high risk of having problems swallowing their medicines and assist in selecting most appropriate medicine dosage forms. The development and availability of alternative oral formulations other than conventional tablets and capsules will likely to assist in medication administration and management in patient with dysphagia and might lead to better adherence.
**Acknowledgements:** The authors would like to thank the kind supply of capsule shells from Capsugel (Morristown, New Jersey, USA).

**Appendix: Images of tablets of different sizes and shapes**

References

Baqir, W., Maguire, A., 2000. Consumption of prescribed and over-the-counter medicines with prolonged oral clearance used by the elderly in the Northern Region of England, with special regard to generic prescribing, dose form and sugars content. Public Health 114, 367-373.


Strachan, I., Greener, M., 2005. Medication-related swallowing difficulties may be more common than we realise. Pharmacy in Practice.


Figure 1. Percentage of participants selecting the tablet size and shape that started to cause difficulty in swallowing.

**Fig 2.** Percentage of participants selecting the capsule size that might start to cause difficulty in swallowing.
Fig 3. Acceptability scores of different oral solid dosage forms (ODT: orally disintegrating tablet).

Table 1. Products used to represent 9 mm tablets in different shapes

<table>
<thead>
<tr>
<th>Tablet shape</th>
<th>Product used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat round</td>
<td>Imodium Instants tablets (McNeil Products Ltd)</td>
</tr>
<tr>
<td>Arched round</td>
<td>Placebo tablets produced at University of Hertfordshire laboratories (Ingredients: 99% lactose monohydrate, 1% magnesium stearate, compressed using a CPR-6 single punch tablet press, Isopak Limited)</td>
</tr>
<tr>
<td>Oblong</td>
<td>Zirtek 10 mg tablets (UCB Pharma Limited)</td>
</tr>
<tr>
<td>Oval</td>
<td>Finasteride 5 mg tablets (Dr Reddy’s Laboratories (UK) Ltd)</td>
</tr>
</tbody>
</table>

Table 2. Products used to represent various oral formulations

<table>
<thead>
<tr>
<th>Type of formulation</th>
<th>Products used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule</td>
<td>Hard gelatin capsule shells of sizes #00, #0, #1, #2, and #3 (supplied by Capsugel, Morristown, New Jersey, USA) filled with lactose monohydrate</td>
</tr>
</tbody>
</table>
Mini-tablet
  Round shaped mini-tablets (4 mm) was obtained as the content of Inconex XL 4 mg Prolonged-release Capsules (Sandoz Ltd)

Granules
  Fybogel sachet (Reckitt Benckiser Healthcare (UK) Ltd)

Dispersible tablet
  Boots soluble paracetamol tablets (The Boots Company PCL)

Orally disintegrating tablet (ODT)
  Imodium Instants melt (McNeil Products Ltd)

Chewable tablet
  Gaviscon double action chewable tablets (Reckitt Benckiser Healthcare (UK) Ltd)

Table 3. Number of participants who had previously used the flexible solid oral formulations.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Number (%) of participants who have previously used the formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini-tablets</td>
<td>8 (5%)</td>
</tr>
<tr>
<td>Granules</td>
<td>17 (11%)</td>
</tr>
<tr>
<td>Dispersible/effervescent tablets</td>
<td>107 (68%)</td>
</tr>
<tr>
<td>Orally disintegrating tablets</td>
<td>34 (22%)</td>
</tr>
<tr>
<td>Chewable tablets</td>
<td>47 (30%)</td>
</tr>
</tbody>
</table>
Table 4. Participants’ impression on the flexible solid oral dosage forms.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Advantages</th>
<th>Participants (%)</th>
<th>Disadvantages</th>
<th>Participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispersible/effervescent tablets</td>
<td>• Easy to swallow; less harsh than swallowing tablets</td>
<td>19</td>
<td>• Require water; takes long to dissolve</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• Good for those with swallowing difficulties</td>
<td>8</td>
<td>• Cannot use on the move – takes long to dissolve</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>• Nice to drink</td>
<td>40</td>
<td>• Concerns on taste</td>
<td>38</td>
</tr>
<tr>
<td>Mini-tablets</td>
<td>• Small, easy to swallow</td>
<td>24</td>
<td>• Difficult to see for visually impaired</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>• Good for those with swallowing difficulties</td>
<td>23</td>
<td>• Do not want to mix food with medicine</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>• Can take more than one at once</td>
<td>8</td>
<td>• If food is not completed consumed, patient does not receive full dose</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>• Can be sprinkled onto food</td>
<td>6</td>
<td>• Concerns on taste</td>
<td>28</td>
</tr>
<tr>
<td>Granules</td>
<td>Orally disintegrating tablets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Good for those with swallowing difficulties</td>
<td>• Melts itself, minimal effort and thought required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Can be sprinkled onto food</td>
<td>• Good for those with swallowing difficulties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Come in various flavours</td>
<td>• No water required: easy to take</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Convenient/quick when on the go</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not want to mix food with medicine: Presentation and flavour of food can be ruined</td>
<td>Patients can be tempted to swallow early</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opening sachet can be difficult for those with poor manual dexterity</td>
<td>Patients may remove formulation from the mouth before it is fully dispersed leading to sub-therapeutic outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need to finish meal to get whole dose</td>
<td>Can leave residual and after-taste in the mouth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns on appearance</td>
<td>Concerns on taste</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns on taste</td>
<td>Concerns on taste</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

23
### Chewable tablets

- No water required: Easy to use
- Good for tablets which are too large and cannot be swallowed
- Good for those with swallowing difficulties
- It is sweet-like so does not appear as if you are taking a medicine

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>5</td>
<td>9</td>
<td>15</td>
</tr>
</tbody>
</table>

- Patients who wear dentures cannot use.
- Can get stuck in teeth – hard for those with dentures
- Chewing time is long
- Concerns on taste

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>6</td>
<td>36</td>
<td>12</td>
</tr>
</tbody>
</table>