Importance of Oral Drug Product Characteristics to Patients and Implications of Characteristic Changes for Missed Doses and Information Seeking

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INTRODUCTION

- Drug developers and regulators increasingly recognize the potential for drug product characteristics — size, shape, etc. — to impact patient responses, behaviors, and outcomes, such as acceptability, information seeking, and adherence, and, thereby, safety and efficacy [1].
- A previous scoping review identified several product features as important for patient acceptance and preferences for solid oral dosage forms, with some more well-studied than others [1].
- Patients taking medications to treat chronic conditions may also observe changes in drug product characteristics over time (e.g., due to formulation changes by the manufacturer), which can potentially impact behavior [1].
- Patient preferences, and patient response to changes in drug products, may vary according to patient and disease characteristics [1].

OBJECTIVE

This cross-sectional, observational, survey-based study sought to:

1. quantify the relative importance to patients of drug product characteristics and
2. evaluate the likely impact of changes in these characteristics on missed doses and likelihood to seek information.

METHODS

Adults in France (n=401) and Ireland (n=401) regularly taking ≥1 oral prescription medications completed a survey (June-July 2023) including:

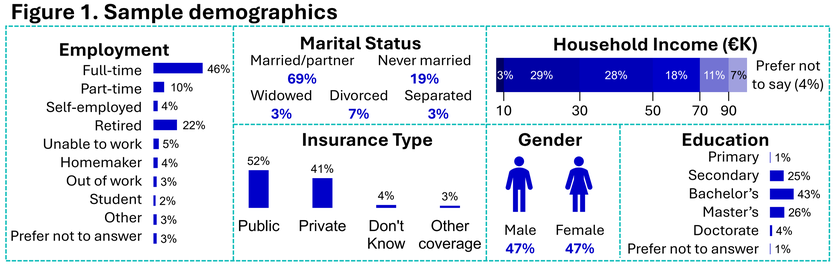
- a 27-item, object-case best-worst-scaling (BWS) exercise
- questions about self-reported frequency of missed doses with current medication, and
- expected response to changes in medication characteristics.

Table 1. Drug product characteristics for BWS

Domain	BWS items
Appearance	Small size, Large size Normal shape, Unusual shape with sharp edges Bright color, Dull color Glossy or shiny finish, Flat finish with no shine Even and uniform color on the surface, Uneven or inconsistent color on the surface Opaque exterior that you can't see inside, Transparent exterior and mix of different colored/sized particles inside Hard to read name or logo Color runs if pill is wet or damp Chipped tablet coating or dented capsules
Texture	Smooth feel, Chalky, rough or gritty feel, Waxy feel Tablet or capsule is brittle and breaks with handling
Swallowability	Dissolves in mouth before swallowing Sticks to inside of mouth Easy to swallow, Difficult to swallow Burning sensation in mouth, Burning sensation in throat
Palatability	Bitter, sour, metallic or chemical taste Has an odor

RESULTS

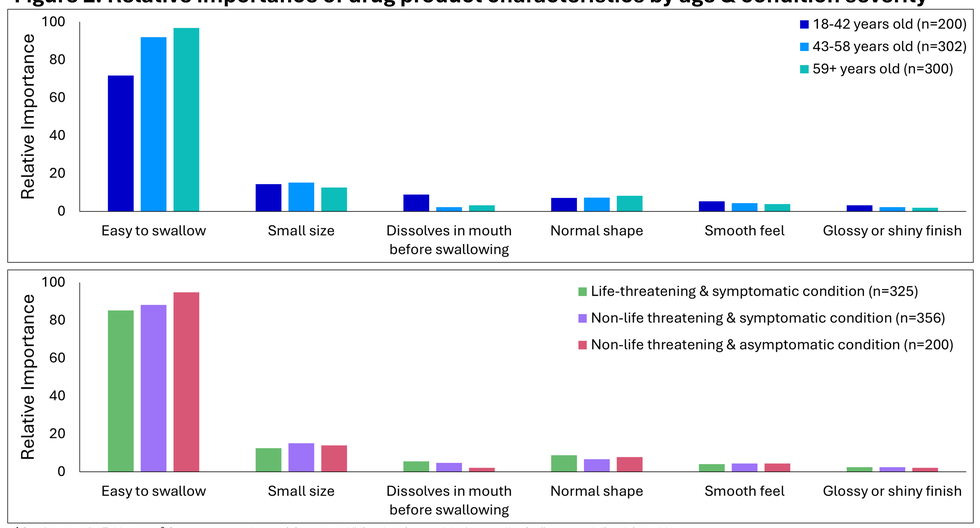
Figure 1. Sample demographics



- The sample was socio-demographically diverse (Figure 1).
- Older participants were more likely to be taking medications daily (youngest to oldest: 59%, 78%, 88%) and were more likely to have been taking medication for their chronic condition for more than 4 years (youngest to oldest: 37%, 51%, 61%).
- Patterns in daily medication use and years of treatment were less clear by condition severity; daily medications were most common among participants with non-life-threatening and asymptomatic conditions (93%) and treatment for more than 4 years was most common among participants with life-threatening and symptomatic conditions (56%).

- *Easy to swallow* was the most important characteristic overall and for all subgroups considered.
- The top-6 most important characteristics were the same for all subgroups considered, with some variation in rank order and relative importance (Figure 2).
- Five additional characteristics rounded out the top 10 for age and condition severity subgroups:
  1. *even and uniform color on the surface* (all ages and condition severities)
  2. *flat finish with no shine* (all ages and condition severities)
  3. *tablet or capsule is brittle/more likely to break* (18-42 years old; life-threatening & symptomatic conditions)
  4. *bright color* (43-58 and ≥59 years old; all condition severities)
  5. *exterior you can see through* (all ages; non-life threatening & symptomatic conditions and non-life threatening & asymptomatic conditions)

Figure 2. Relative importance of drug product characteristics by age & condition severity[1]



[1] See footnote for Table 2 [2] Consumers may have misinterpreted "dissolves in mouth before swallowing" as an oral dissolving tablet

Table 2. Participant likely responses to changes in drug product characteristics by condition severity[1]

Change in Drug Product Characteristics (new state relative to prior state)	Percent who would miss a dose or stop taking their medication				Percent who would ask to switch medication or seek information			
	Life-thrt. & symp. cond.	Non-life thrt. & symp. cond.	Non-life thrt. & asymp. cond.	Cancer	Life-thrt. & symp. Cond.	Non-life thrt. & symp. cond.	Non-life thrt. & asymp. cond.	Cancer
Bottle: Contains Broken Tablets	54%	58%	62%	43%	95%	94%	95%	100%
Swallowability: More Difficult	53%	62%	56%	42%	94%	96%	96%	96%
Smell: New Noticeable Smell	50%	64%	56%	39%	95%	96%	96%	97%
Taste: New Noticeable Taste	47%	58%	52%	30%	97%	94%	94%	93%
Shape: Now Larger	34%	43%	37%	28%	89%	89%	81%	93%
Surface: Chipped More Often	31%	38%	30%	28%	87%	77%	75%	83%
Tablet Texture: Now Rough	30%	35%	29%	25%	90%	85%	86%	89%
Exterior: Now Transparent	28%	33%	30%	23%	87%	96%	89%	95%
Tablet Color: Uneven On Surface	25%	31%	30%	22%	94%	88%	89%	92%
Surface: Dented More Often	23%	29%	23%	18%	97%	85%	89%	100%
Tablet Shape: Normal To Unusual	23%	21%	21%	18%	97%	88%	83%	100%
Exterior: See Bead Size And Color	22%	19%	18%	17%	90%	85%	86%	87%
Color: Different From Before	21%	18%	15%	15%	96%	86%	77%	94%
Packaging: Changed From Before	20%	22%	16%	14%	92%	87%	90%	93%

[1] Condition severity was assigned based on the chronic condition the patient reported regularly taking a prescription oral medication for. Life-threatening & symptomatic conditions included cancer and conditions such as diabetes, asthma, some cardiovascular, etc. Life-threatening & asymptomatic conditions were defined as atrial fibrillation, chronic liver disease, or chronic kidney disease. Non-life-threatening & symptomatic conditions included allergies, dermatologic conditions, autoimmune conditions, migraine, etc.

- Changes in *swallowability*, *smell*, and *presence of crushed/broken tablets* increased the expected likelihood of missing a dose or stopping the medication for most patients (Table 2).
- People with cancer and people with life-threatening symptomatic conditions were least likely to state that they would likely miss a dose or stop a medication following changes in characteristics.
- Most patients reported they would ask to switch medication and/or seek information following changes in medication characteristics.

DISCUSSION & CONCLUSION

- *Easy to swallow* was the most important drug product characteristic to patients; this extreme relative importance may have limited our ability to distinguish other characteristics.
- Both age and condition severity impacted the relative importance of drug product characteristics.
- In our sample, strongest preferences for *easy to swallow* compared to other drug product characteristics appear positively correlated with cumulative medication use and frequency of use.
- Additional, uncaptured patient characteristics may influence preferences, such as changes in swallowing ability with age [2].
- Nevertheless, the magnitude of difference between serious and non-serious conditions was relatively small, suggesting that comfort-related characteristics remain meaningful to all patients.
- Even among patients with serious, life-threatening conditions, changes in drug product characteristics may impact adherence.
- This suggests the importance of investigating the acceptability of drug product characteristics in early product development, regardless of the therapeutic context.

REFERENCES

1. Hauber B, Hand MV, Hancock BC, Zarrella J, Harding L, Ogden-Barker M, Antipas AS, Watt SJ. Patient Acceptability and Preferences for Solid Oral Dosage Form Drug Product Attributes: A Scoping Review. Patient Prefer Adherence. 2024 Jun 21;18:1281-1297.
2. Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in Older Adults. Mayo Clin Proc. 2021 Feb;96(2):488-497.

DISCLOSURES

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