DEVELOPMENT OF A TOOL ASSESSING MEDICINES ACCEPTABILITY IN NEONATES, INFANTS AND TODDLERS

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Introduction

Medicines are particular products due to prescriptive consumption. Nevertheless users' needs shall be considered to design accepted medicines. While medicines acceptability is crucial in paediatric population, there were no internationally harmonized testing methods developed [1]. Neonates, infants and toddlers require specific evaluation techniques as they cannot answer themselves sensory and consumer testing [2]. This abstract presents the development of an original tool allowing evaluation of medicines acceptability in children under 36 months.

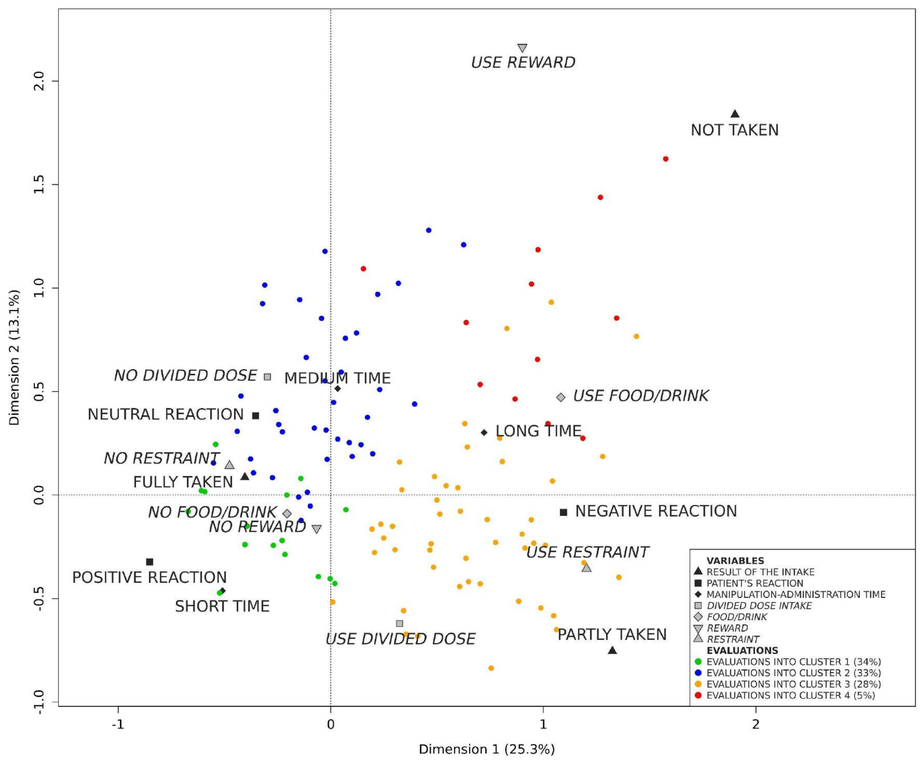
Methods

Recruitment	Recruitment was conducted throughout France, in collaboration with a network of doctors and pharmacists, into hospitals or community dispensaries. Written information (web-questionnaire content, URL and personal login password) was given to voluntary parents of children under 36 months receiving any medicine.
Data collection	Web-questionnaire focused on the first medicine's use following study inclusion. Participants had to provide information on the patient (age, gender…) and the medicine (name, dose…). Observational measures reflecting ability and willingness of patients and caregivers to use any medicine were collected: the result of the intake, the preparation and administration times, the patient's reaction and the methods used to achieve administration such as use food/drink, divided dose intake or restraint.
Statistical methods *(R software)*	A descriptive model defines an acceptability reference framework combining all the observational measures. Multiple Correspondence Analysis (MCA) summarizes dataset key information into the acceptability map. Then, Hierarchical Clustering on Principal Components (HCPC) gathers the evaluations into clusters defining acceptability profiles.

Sample characteristics

Patients		**n = 363**
Girl		172 (48%)
Age (months)	[0;11]	144 (39%)
	[12;23]	97 (27%)
	[24;36[	122 (34%)
Medicines (particular dosage form)		**n = 113**
Route of administration	Oral	88 (79%)
	Other [10%;2%[: rectal, pulmonary, parenteral, ocular.	20 (18%)
Formulation type	Powder for oral suspension	32 (29%)
	Other [10%;2%[: oral susp., syrup, oral sol., suppository, granules for oral susp., powder for oral sol., susp. for inhalation, drops for oral sol., sol. for injection, ocular sol.	63 (56%)
Therapeutic group (ATC2)	Antibacterials (J01)	51 (32%)
	Other [10%;2%[: Analgesics (N02), Drugs for obstructive airway diseases (R03), Corticosteroids (H02), Antihistamines (R06), Drugs for functional gastrointestinal disorders (A03), Antidiarrheals (A07), Vitamins (A11), Ophthalmologicals (S01), Cough and cold (R05), Anti-inflammatory (M01)	77 (48%)

Acceptability evaluation

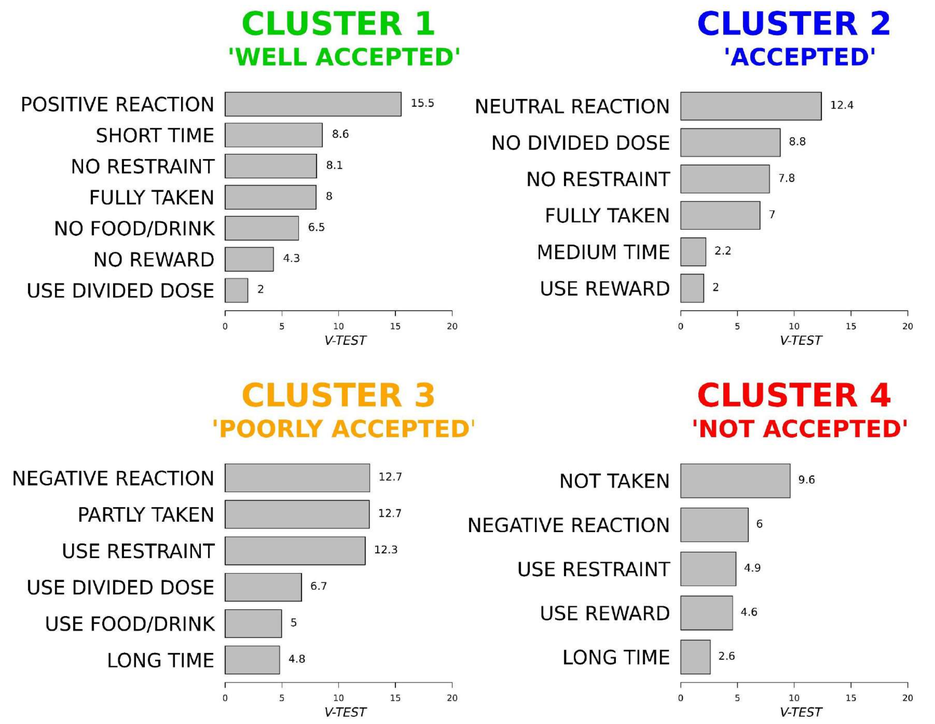


Acceptability map

The 3D acceptability map summarizes the major information of the evaluations set (50% of the total inertia). Categories of variables are close on the map if they were often selected together in the questionnaires. They characterize the closest evaluations.

Acceptability profiles

The evaluations were gathered into 4 clusters defining acceptability profiles. The profiles are described by the categories significantly over-represented into the clusters.



Categories significantly over-represented in the clusters (V-TEST>1.96)

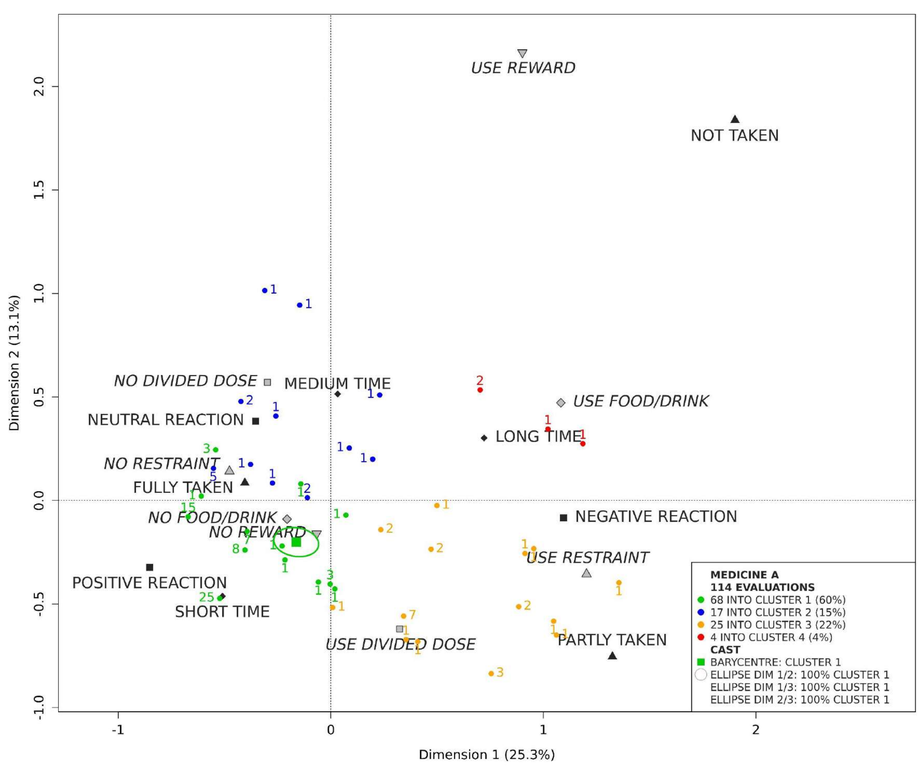
Acceptability of a medicine

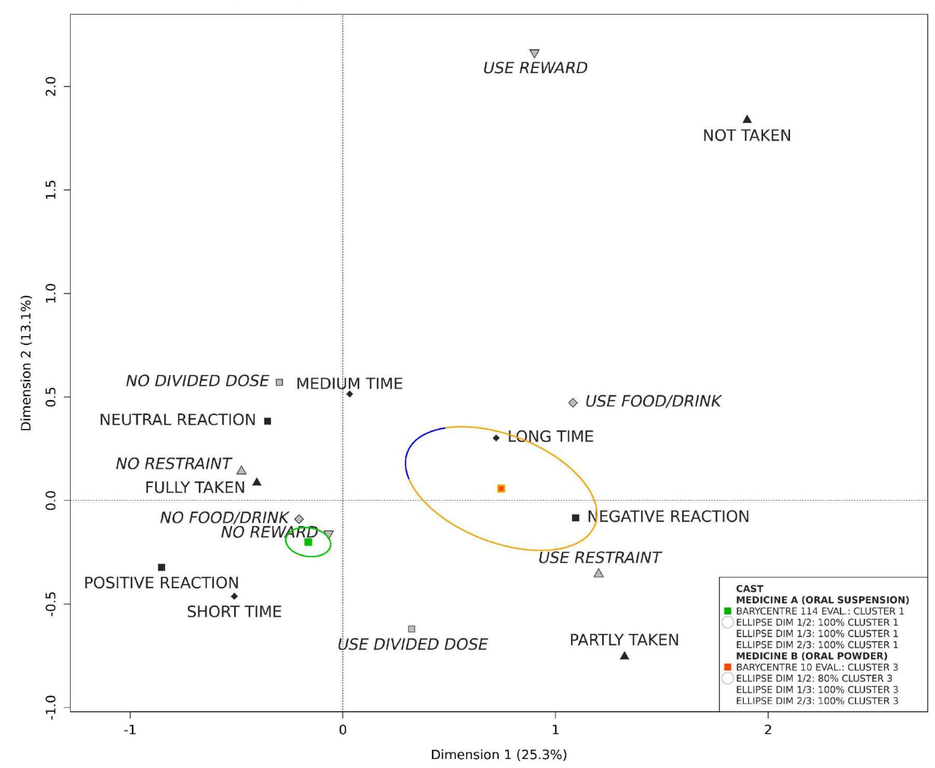
(CAST - ClinSearch Acceptability Score Test™)

A medicine is positioned on the map at the barycentre of its evaluations. The barycenter is assigned to an acceptability profile and 90% confidence ellipses for the dimensions 1-2, 1-3 and 2-3 are drawn around it.

Comparing acceptability of medicines

Acceptability of distinct medicines differs if confidence ellipses do not overlap on the map.





References

[1] EUROPEAN MEDICINE AGENCY. Guideline on pharmaceutical development of medicines for paediatric use. 2013.

[2] GUINARD JX. Sensory and consumer testing with children. Trends in Food Science & Technology. 2001;11:273–83.

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Conclusion

Using this observational approach any medicines could be positioned on the acceptability map and assigned to an acceptability profile. This acceptability reference framework provides standardized acceptability evaluations and relevant comparisons among medicines in a visual and intelligible form.

As well as for medicines, the evaluations could be gathered according to patients' features (age, sex, socio-cultural background…) or medicines' characteristics (sweetener, flavour…) to explore their impact on acceptability. The use of extracted knowledge on acceptability should improve the quality of new medicines designed.

This methodology should be appropriate to develop similar acceptability reference framework in other domains.