

PURPOSE

The constant progress in medical and pharmaceutical sciences contributing to longevity comes along with an increasing use of medicinal products. Patients play an important role in achieving the desired therapeutic outcome, as they are frequently responsible for their own medication management. It is well documented that a major contributor for limited therapy efficacy in real world settings is related with poor adherence to prescribed medicines. In order to enhance drug administration, the drug product design should consider the targeted patient characteristics and needs.

A literature review was performed to identify clinical evidence for appropriateness, acceptability, or preference of pharmaceutical preparations, dosage forms and product designs in all age population groups. The quality of the methodology used in performing such research was also assessed.

Definitions for important terms used in this literature search were established according to Stegemann et al.¹ and EMA². The search included other terms that are currently being used by the scientific community but do not have an common agreed definition. Hence, such terms might be used in publications with different interpretations and meanings. As they are being used in relevant literature, these terms have been included in the list of keywords, with definitions being proposed by the authors and considered as such during the publication review process (Table 1).

DEFINITIONS

Table 1: Proposed definitions for terms addressed in the literature research.

Term	Definition
Appropriateness	A set of pharmaceutical design characteristics of a drug product that determines the specific target patient population if a patient and/or its caregivers can use the pharmaceutical drug product as intended.
Acceptability	Sum of positive and negative experiences of a patient and/or caregiver providing administration support with a pharmaceutical drug product before, during and after the intended use, which results in an ultimate decision to take or use the drug product.
Usability	The product characteristics and attributes of a pharmaceutical product that enables the patient and/or caregiver in its personal environment and life situation to use the pharmaceutical drug product as intended.
Preference	The personal favored selection of a product attribute over others that is perceived as an advantage whereby all choices are appropriate for the intended patient purpose.

METHODS

An independent and experienced librarian, using suitable methodology^{3,4} conducted a literature research starting in February 2016. Medline, Scifinder, Web of Science and AdisInsight databases were searched electronically for relevant publications. All searches employed three search categories, each with a list of keywords to capture all relevant aspects related to product appropriateness, acceptability or preference. Additionally, a complementary search profile was performed in April 2016 with PubMed database. Combinations of keywords with their relevant truncations were used to obtain broader searches.

RESULTS

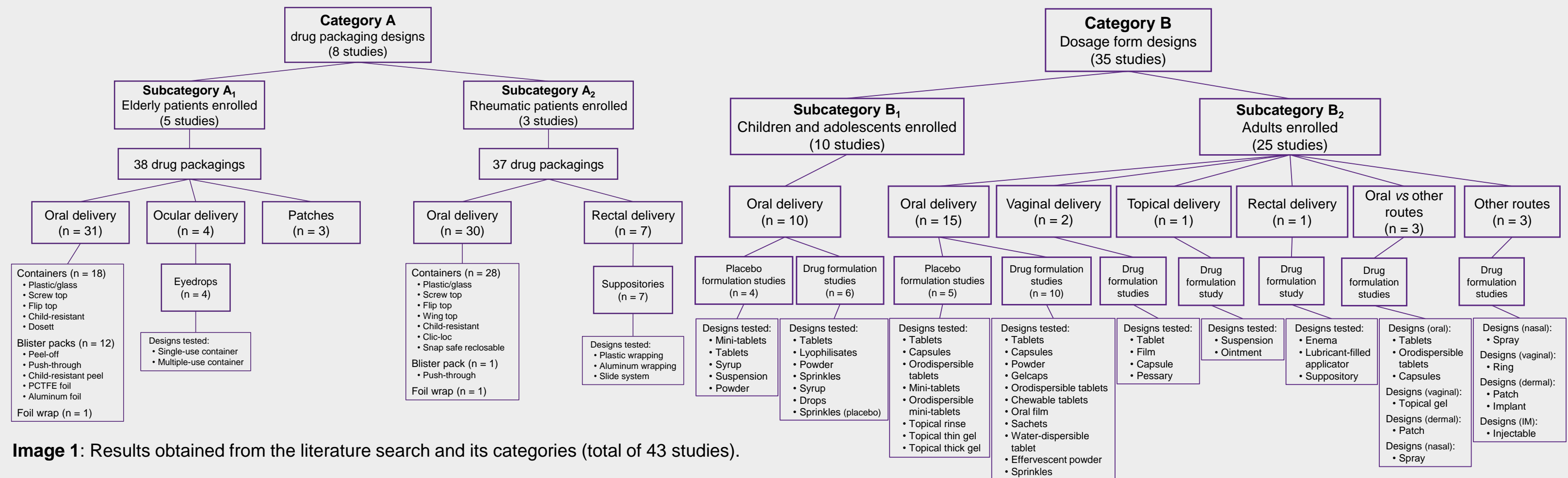


Image 1: Results obtained from the literature search and its categories (total of 43 studies).

CONCLUSIONS

- Clear definitions and the use of an agreed taxonomy in patient centric research are urgently required.
- Type of assessment is dependent on the population studied:
 - ✓ adolescents/adults: questionnaires based on quantitative (e.g. 1-5) or qualitative scales (e.g. good, bad).
 - ✓ very young children: observational studies (e.g. parents, physicians).
- Appropriateness of drug product designs is dependent on patients' geographical and cultural experiences (e.g. African sites).
- Only 10 studies used scientific methodology that could provide quality data on user's appropriateness.
- Majority of studies were problem descriptive rather than comparative for product design appropriateness.
- Little attention is being given to the development of methodologies for evaluation of drug products appropriateness.



REFERENCES

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- (4) Moher D, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Phys Ther 2009;89:873-80.