

A DELPHI METHOD TO STANDARDIZE THE PREPARATION OF AUTOLOGOUS SERUM EYE DROPS ?

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Abstract
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OPHTHALMOLOGICALS

BACKGROUND AND IMPORTANCE

Dry eye disease = frequent cause of ophthalmology consultation (5%–34% of population worldwide).

Severe forms, refractory to conventional treatments (artificial tears, topical corticosteroids, cyclosporine A, contact lenses, punctual occlusion, systemic diseases appropriate management), are responsible for a **significant visual impairment and disability**.

Autologous serum eye drops (ASEDs) are then proven to be an **interesting therapeutic alternative**.

First, in March 2019 we carried out a **national inventory of ASED preparations practice**

Highlights **low supply** (13 producer centers) and **production heterogeneity**.

AIM AND OBJECTIVES

General objective: to **improve** ASEDs quality, safety and supply in our country care institutions.

Specific objectives: to define the consensual items, in order to establish a **national standardized preparation protocol**.

MATERIALS AND METHODS

Delphi method

Method for consensus reaching

Local steering group

- Pharmacy resident
- Head of compounding unit
- Pharmacy methodologist

4 protocol parts

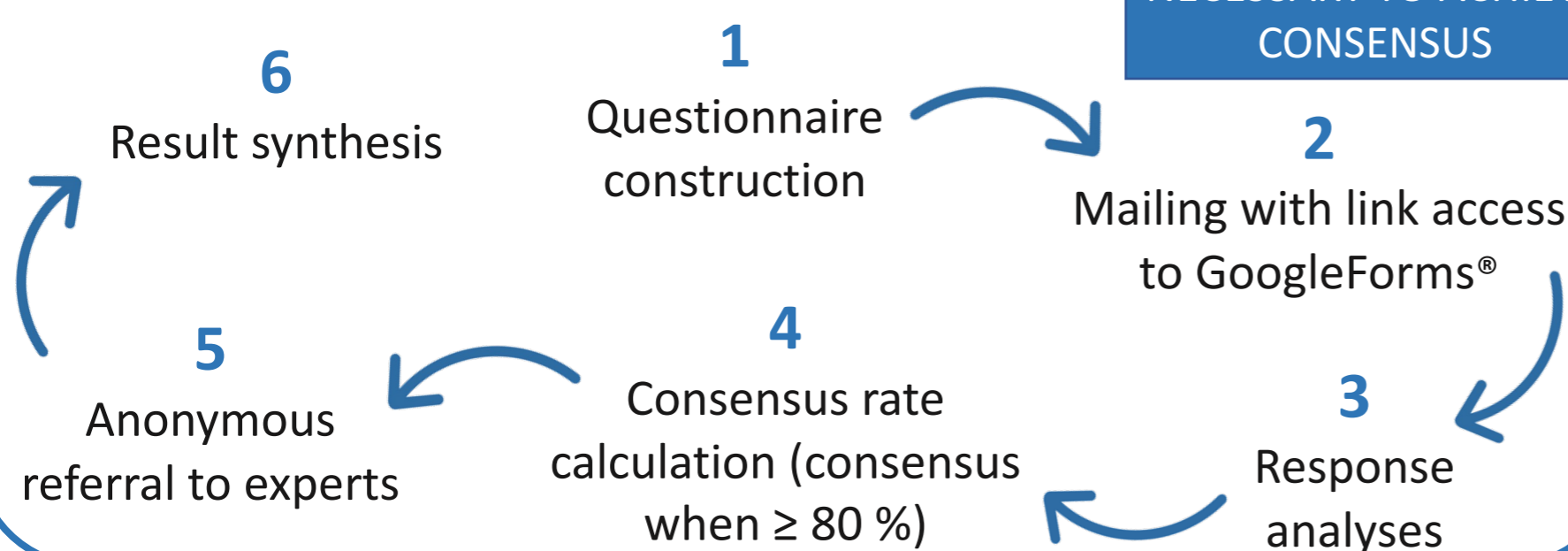
- Sampling
- Preparation
- Controls
- Conservation

Expert panel

Recruited by remobilizing **centers approached in 2019** (ASEDs producers, non producers or did not respond)

CIRCUIT

AS MANY ROUND AS NECESSARY TO ACHIEVE CONSENSUS



RESULTS

12
answering
experts

4
rounds in
86
days

39
proposals
initially
submitted

26
validated
10
abandoned

SAMPLING
15 items validated, 5 dropped.
PREPARATION
5 validated, 1 dropped.
CONTROL
3 validated, 4 dropped.
CONSERVATION
3 validated.

CONCLUSION AND RELEVANCE

A standardized protocol ASEDs preparation will be proposed. This could improve the supply of care across the country.

Method strengths: Expert opinion solicited on the initial questionnaire ; qualified experts on the topic ; no geographical limitations ; anonymity avoiding opinion leader influence ; applicability criteria.

Limitations: no ophthalmologists, biologists, patients in the panel; no participation of the largest eye drop producer (despite requests).

A clear definition of this eye drop **status** (pharmaceutical preparation or not) is also **necessary**.

Biochemical quality controls, abandoned, to be resubmitted (molecules supposed to support ASEDs efficacy). Supplementary round necessary to decide the fate of the last item (solution volume in each eye drop bottle).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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