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

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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.

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.

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

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

4 protocol parts

Expert panel
Recruited by remodeling centers approached in 2019 (ASEDs producers, non producers or did not respond)

CIRCUIT

1 Questionnaire construction
2 Mailing with link access to GoogleForms®
3 Response analyses
4 Consensus rate calculation (consensus when ≥ 80 %)
5 Anonymous referral to experts
6 Result synthesis

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