Serum Eye Drops - Preliminary Results of an International Survey on Manufacturing and Use

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Background: Serum eye drops (SED) are in use since more than 40 years. Manufacturing is, in contrast to other blood components, not very standardized. The therapeutic efficiency is considered to be very good but lacks data as large, randomized studies have not yet been performed. In Europe the development of substance of human origin (SoHO) guidelines as example for national regulations gives the chance for evaluation and standardization.
Aims: To collect large data sets to evaluate strategies for manufacturing, current use and experiences with SED a study was conducted.
Methods: In a standardized questionnaire data on size and regulatory structure of manufacturing, details on validation and manufacturing, delivery, and documentation of efficiency were evaluated. Also, long-term experiences of manufacturing were asked. The survey was conducted with a validated online questionnaire sent via international scientific societies for transfusion medicine, ophthalmology, and manufacturers of material for production of eye drops from human blood.
Results: The preliminary evaluation comprises 30 questionnaires completed until February 15th. Due to inconclusive data 7 anonymous answers were excluded. 23 answers from 11 countries, 21 from Europe, 2 from Asia were evaluated. As source of SED 22 used serum, one platelet lysate; one participant additionally to serum platelet lysate and platelet-rich plasma (PRP), another one PRP from apheresis.
In the year 2024 almost 4,000 autologous donations corresponding to more than 140,000 single daily doses were manufactured in closed systems (Biomed Device, https://biomeddevice.it/en/ or Meise System; https://www.meise.com/de/), more than 40,000 in eye drop bottles. In the allogeneic directed setting 377 donations corresponded to over 19,000 daily doses in closed system and over 22 respectively in 6,000 in eye drop bottles. More than 7,000 allogeneic undirected donations resulted in in over 584,000 daily doses in closed systems and over 65,000 in eye drop bottles.
Sterile filtration, which is discussed with respect to SoHO guidelines, had been validated by 6 institutions. As ”active” substance, for validations, albumin, total protein, FGF, VEGF, PDGF, EGF were named by single centers, 19 did not report an active substance. 22 centers issue SED frozen (dry ice, cooling packs), one institution delivers them to the patient thawed. Other details with respect to manufacturing, such as donor selection, validation, dilutions, bacterial safety, showed a large variety and will be reported separately. 19 participants were interested to join an international working group on preparation of serum eye drops.
Summary / Conclusions: This preliminary evaluation of our large survey showed a variety in almost all details of manufacturing eye drops from human blood. As a consequence, a study group will be constituted to evaluated possibilities for improvement and standardization of the donation, manufacturing and issuing of the SED in the context of the SoHO regulations.

Acknowledgement: We thank all colleagues, who participated in this survey, their respective donors and patients.