**BAR14-0027**

*Evaluation of a medical device to improve the security of intraspinal administration of cytotoxic drugs*

**Co-authors**

T. Bancourt¹, L. Baillet¹, M. Vasseur¹, N. Simon¹, M. Longueville¹, B. Décaudin¹, P. Odou¹.

¹Pharmacie CHRU LILLE, Nord, Lille Cedex, France.

**Background**

Intraspinal administration errors are identified in the list of ‘never events’ of the French Health Authority (ANSM). New devices with specific connectors incompatible with standard Luer-lock connectors (Univia syringe, Becton-Dickinson) could be used to secure the spinal administration of cytotoxic drugs.

**Purpose**

A feasibility study is needed regarding to its minimum capacity (2mL).

**Materials and Methods**

A comparative study between Univia (U, 2ml) and Tuberculin (T, BD) syringes was performed. Volumes of water (0.6-0.48-0.15-0.1mL) simulating usual volumes of cytotoxics were measured by an operator and weighed on a precision scale (n=30). For each volume, accuracy (%) and precision (CV%) were determined. A difference of 10% of the nominal volume was the chosen threshold.

**Results**

For U, the accuracy was 0.2%, 6.5%, 11.2% and 21.8% for 0.6, 0.48, 0.15 and 0.1mL, respectively. It was 1.2%, 2.0%, 0.1% and 6.1% for T. For U, the precision was 2.4%, 2.3%, 5.9% and 6.2% for 0.6, 0.48, 0.15 and 0.1mL, respectively whereas it was 1%, 1.0%, 7.3% and 8% for T. Accordingly, the volumes of 0.6 and 0.48 mL may be prepared with U. For both, 0.15 and 0.1mL, a transfer step with a tuberculine syringe increases both accuracy (3.9%) and precision (3.9%).

**Conclusions**

This study suggests the possibility of using U to compound cytotoxic drugs for intraspinal injection. It remains to evaluate the practical constraints related to the administration.

No conflict of interest

**Keywords**

Security; Intraspinal; Administration;

**Authors letter**

The feasibility preparation involving Univa syringe, to improve the security of intraspinal administration of cytotoxic drugs, is a step forward for future hospital pharmacy practice.

Score: 160

**Remarks all reviewers:**

Kart, Trine: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Nominee: No

please explain how "Accuracy" and "precision" differ and why both measures are necessary to consider.

Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

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**BAR14-0061**

*New opportunities for cytotoxic reconstitution*

**Co-authors**

V.N.H. Handlos¹, L. A. Knudsen².

¹Capital Region Pharmacy, R&D, Herlev, Denmark.
²Herning Sygehusapotek, QA, Herning, Denmark.

**Background**

Reconstitutions of cytotoxics are from a patient safety part of view a prominent part of European Hospital Pharmacy services to day. Quality standards for the process are not covered by common EU legislation and the quality of the process vary across Europe. Council of Europe (CE) adapted in January 2011 a quality standard for among others reconstituted products to improve the quality for these products to the
benefit of the patient safety in the member countries. Based on the CE Resolution the Danish Health and Medicines Authority issued, in May 2013, an instruction for the area opening collaboration between the Authorities and the Hospital Pharmacy (HP) profession to develop new guidelines.

Danish HP's are inspected close to the principle of EU GMP, leading to very expensive premises and complicated work procedures.

**Purpose**

First part of this project is to propose new standards for premises and procedures for product to be administered immediately (24 hours) after reconstitution.

**Materials and Methods**

The unit at Herning HP is used to study the relevant parameters for the change in processes and premises. Production capacity of the unit is approximately 10,000 doses pr. year. Plans for premises, workflow and standard operation procedures are the basic for the collaboration with the authorities.

**Results**

Instructions for:

- Organisation diagram for production, QA and QC
- Premises
- Equipment
- Standard operation procedures
- Cleaning procedures
- Microbiological monitoring
- Media fill
- Clothing
- Training of personnel
- Operator safety

**Conclusions**

A simplified reconstitution unit for cytotoxics can be built and operated according to the frame of the instructions from the Danish Authority. The CE Resolution 2011 is the basics for the instruction opening the results for other HP's in Europe.

No conflict of interest

**Keywords**

Cytotoxics; Reconstitution; European Standard;

**Authors letter**

Reconstitutions of cytotoxics are from a patient safety point of view a prominent part of European Hospital Pharmacy services to day. Uniform standards, as presented in the abstract, used across Europe are one way of improving the outcome of the process. The abstract describe the innovation of a common European way of developing standards. Hospital Pharmacists across Europe could after having seen the abstract/post be inspired to use the process and results described.

Score: 120

**Remarks all reviewers:**

Kart, Trine:

Rejected

9.

Reason for reject: ; Gouveia, Antonio Melo: Conclusion warranted

Conflict of interest clear

Accepted

Nominee: No

though it's a story, it is a very relevant one as an example.
Commercialized methotrexate syringes are available in limited dosages. There is evidence of health risks from reconstitution and handling of methotrexate vials at the specialist office or at Primary Health Care clinics.

**Purpose**
A collaboration program between the Hospital Pharmacy Department and Primary Health Care to guarantee a safe procedure, suitability of prescriptions, adherence to treatment, an appropriate waste management and a saving opportunity.

**Materials and Methods**
From February 2011 to August 2013, all the medical charts of rheumatologic patients with subcutaneous methotrexate were reviewed and prescriptions were validated. The Pharmacy Department carried out the preparation and labelling of the syringes in a cytostatic safety cabinet and the department courier service distributed them to all Primary Health Care clinics. Every office was provided with cytostatic waste bins.

**Results**
The hospital pharmacist validated the prescriptions of 147 different patients (medium: 68.4 patients by month). During the study period, 8434 syringes were prepared, but 918 doses (10.8 %) were individualized doses that didn’t have a commercial presentation. With an average cost of 26.6 Euros per commercialized syringe, the theoretical cost was calculated at 227420 Euros, considerably more than 4898 Euros which was the cost of the 3655 vials of methotrexate used. The cost for preparing was 2508 Euros of technician pharmacy. Thus, this program will offer an estimated budget saving for the Health Department of approximately 220014 Euros.

**Conclusions**
An important saving can be obtained with a central program of elaboration of methotrexate syringes for all the patients of Health Department.

Conflict of interest:
Enter Yes or No: No

**Keywords**
methotrexate;cost control;elaboration;

**Authors letter**
The authors thought that this abstract is relevance because we can control the health risks from reconstitution and handling of methotrexate vials at the specialist office or at Primary Health Care clinics. So we decided to develop a coordinated program between Primary Care Pharmacy and Hospital Pharmacy in order to improve the security of the sanitary team and for controlling cost of that therapy for our Health Department. We think this collaboration is a good way for working together Primary Care Pharmacy and Hospital Pharmacy and an interesting way of controlling cost.

Score: 140

**Remarks all reviewers:**
Kart, Trine: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Nominee: No
New category: T5
Please add references to literature that document your sentence “There is evidence of health risks from reconstitution and handling of methotrexate vials at the specialist office or at Primary Health Care clinics Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

**BARI4-0163**
Development of a sotalol hydrochloride oral solution for cardiologic paediatric patients

**Co-authors**
S. Klovrzova ¹, P. Horak ¹, Z. Sklubalova ², T. Kriz ², L. Zahaika ², L. Matysova ³.
¹University Hospital Motol, Hospital Pharmacy, Prague, Czech Republic.
²Faculty of Pharmacy, Pharmaceutical Technology, Hradec Kralove, Czech Republic.
³Faculty of Pharmacy, Analytical Chemistry, Hradec Kralove, Czech Republic.

**Background**
Antiarrhythmic betablocker sotalol is highly effective in the treatment of supraventricular tachycardia in children; approximately 14,000 capsules containing various doses of sotalol-hydrochloride were prepared in our pharmacy in the year 2012. No licensed paediatric dosage form with sotalol is available in Europe now.

**Purpose**
To replace extemporaneous preparation of sotalol-containing capsules with oral liquid for children in hospital pharmacy conditions. To ensure safe formulation from substance in terms of minimum excipients, suitable flavor, chemical and microbiological stability. To design and verify the method for routine quality control of the final product.
Materials and Methods

Development of 5 mg/ml sotalol hydrochloride solution was consulted with paediatric cardiologist. Potassium sorbate was used as a preservative, sucrose syrup as a sweetener, and citric acid to stabilise pH value. The stability of solution was evaluated over 6 months at refrigerated and room temperatures using validated HPLC method, pH was measured.

Results

HPLC method verified chemical stability of the solution at +4°C for 180 days. The concentration of sotalol varied between 98,5-101,0%, potassium sorbate between 95,2-103,2%, the pH value was in a range of 4,16-4,19. In the hospital pharmacy, where the HPLC method is not available, argentometric potentiometric titration can be used to determine the sotalol hydrochloride concentration in the case of stock preparation.

Conclusions

The stable oral liquid formulation of sotalol was developed and replaced the time-consuming preparation of capsules in practice. The proposed solution has six month shelf life at refrigerator, suitable dosage flexibility and easy availability for the paediatric patients. Moreover, the safety of therapy was increased due to the formulation with declared stability and improved quality control of the final product.

Acknowledgement: Supported by MH CZ – DRO, University Hospital Motol, Prague, Czech Republic 00064203; by SVV 2013 267 001 and SVV 2013 267 002, and GAUK 1472213. The publication is co-financed by the European Social Fund and the state budget of the Czech Republic. TEAB, project no. CZ.1.07/2.3.00/20.0235.

No conflict of interest

Keywords

sotalol; paediatric; solution;

Authors letter

Prague, 11 October 2013 Dear Editor, Please find attached the abstract for S. Klovrzová, T. Krí?, Z. ? klubalová, L. Zahálka, L. Matysová, P. Horák: “Development of sotalol hydrochloride oral solution for cardiologic paediatric patients” for the poster exhibition at the annual congress of the European Association of Hospital Pharmacists (EAHP) in Barcelona in 2014. The authors’ reasons for submitting the abstract are set out below: (1) Relevance A pharmacist should provide pharmacotherapy where there is a lack of licensed medicines. The solution formulation of sotalol hydrochloride for children represents preparation with many benefits. (2) Innovation To design the preparation of a new oral liquid formulation of sotalol hydrochloride for pediatric use to replace the time-consuming preparation of capsules. (3) Implication The formulation of the oral solution brings benefits in pediatric therapy such as dosage flexibility and better compliance for patients, as well as for pharmacists (a decrease in the amount of pharmacy preparation saves time and money, and the stock preparation process increases the quality and safety of the final product).

Yours sincerely,
PharmDr. Sylva Klovrzová
Hospital Pharmacy University Hospital Motol V Uvalu 84 Prague 5 150 06 Czech Republic sylva.klovrozav@fnmotol.cz Phone: +420 224435714

Score: 260

Remarks all reviewers:
Kart, Trine: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications please reconsider the term “declared stability”. Do you maybe earn “documented stability”? TO SC: Is it good practise to document stock preparations with other methods than the one use in the stability study?
Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

BARI4-0177

Evolution of immunoglobulin prescriptions in a tertiary hospital

Co-authors
C. Pérez Diez1, V. Gimeno1, M.J. Agustín-Ferrández1, O. Pascual-Martínez1, M. Uriarte1, I. Larrodé1.
1University Hospital Miguel Servet, Farmacia Hospitalaria, Zaragoza, Spain.

Background

Intravenous immunoglobulins (IVG) are prepared in the sterile area of Pharmacy Service (PS).

Purpose

Analysis of IVG prescriptions before and after an update of IVG protocol.

Materials and Methods

Retrospective study to compare IVG prescribed in period 1 (January 2012-March 2012) with those prescribed in period 2 (January 2013-March 2013). The update of protocol was approved in January 2013. IVG indications were classified according to level of evidence and ideal weight adjusted dose was established for each indication. Type of IVG prescribed, dose (g/kg/day), total dose, medical service and
Results

122 and 88 patients were treated with IVIG in period 1 and 2 respectively (82.0% and 72.0% for each period). The hospital services that prescribed more IVIG were in both periods Hematology (74.0% in period 1 and 70.0% in second one) and Neurology (15.0% and 18.0% respectively). The main indication for IVIG was common variable immunodeficiency (CVID) (26.0% and 35.0% in period 1 and 2 respectively), followed by secondary immunodeficiency type LLC (17.0% and 16.0% respectively for both periods). Other indications were primary immune thrombocytopenia (ITP) (20.0%), chronic polyradiculoneuritis (7.0%) and Burton syndrome (7.0%) during period 1 and chronic polyradiculoneuritis (10.0%) and ITP (8.0%) during period 2. The use of IVIG has declined by a total of 16.5% (92,154 euros). It has declined in Burton Syndrome patients (80.2%); in ITP patients (67.3%) because IVIG was approved only for those with severe bleeding (WHO bleeding scale grade>2) and in CLL patients (20.4%), for which IVIG dose was adjusted according to clinical infectious to maintain the concentration of IVIG> 600mg/ml.

Conclusions

The update of IVIG protocol enabled more efficient use of IVIG. There has been saving in treatment of ITP and the administration of IVIG for PTI, LLC and Burton syndrome has decreased.

No conflict of interest

Keywords

Immunoglobulin; Protocol; Treatment;

Authors letter

The hospital pharmacist is the professional responsible for storage, control and preparation of intravenous immunoglobulins (IVIG). It has achieved the cooperation between various hospital services to perform a protocol using IVIG. To check if the update of IVIG protocol in a third-level Spanish hospital have enabled a more efficient use of them, we have made a retrospective study comparing IVIG prescribed in two different periods. We have classified IVIG indications to the level of evidence and the ideal weight adjusted dose for each indication to develop the protocol for future hospital pharmacy practice and improve hospital pharmacist’s work in sterile area of Pharmacy Service (PS).

Score: 100

Remarks all reviewers:

Kart, Trine:
Rejected
3.
Reason for reject: ; Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No
New category: T1

BARI14-0218

DEVELOPMENT OF READY-TO-USE ADRENALINE SYRINGES FOR EMERGENCY USE

Co-authors

S. Fleury Souverain1, T. Sigrist1, L. Gschwind1, L. Bouchoud1, F. Sadeghipour2, P. Bonnabry1

1HUG, Pharmacy, Geneva, Switzerland.
2CHUV, Pharmacy, Lausanne, Switzerland.

Background

Adrenaline (epinephrine) is commonly used in cardiac arrest, bronchospasm and anaphylaxis. To secure the process and reduce the preparation time in wards in case of emergency, the availability of a ready-to-use form would be very welcome.

Purpose

To develop a ready-to-use syringe of adrenaline with a long shelf-life at room temperature stored in every resuscitation trolley of the hospital.

Materials and Methods

A capillary electrophoresis method with UV detection was developed and validated as stability-indicating method. An adrenaline tartrate solution (1 mg/mL) containing 5 mg/mL of sodium metabisulfite in 0.9% sodium chloride was filled under nitrogen flow and aseptic conditions into 5 mL polypropylene syringes. Stability was tested on syringes stored at 25°C for 1 year and analyses were performed at t = 0, 1, 3, 6, 9 and 12 months. The pH and non-visible particulate matter were measured throughout the study. Sterility was controlled at the beginning and the end of the study.

Results

A complete separation of adrenaline and main degradation products was achieved in less than 10 min. An optimal period of 9 months at 25°C was defined to stock adrenaline syringes without loss in potency. After this storage duration, adrenaline content was 94% of the initial concentration (at t=0) and the
solution was uncoloured. At t=12 months the concentration of adrenaline was still superior to 90% but the solution became yellow. The pH values did not change appreciably and the syringe content remained sterile throughout the study. Each syringe fulfilled all European pharmacopeia criteria in terms of non-visible particles.

Conclusions

Adrenaline syringes 5mg=5mL supplied by the hospital pharmacy were found to be stable for 9 months at 25°C. This ready-to-use preparation stored in resuscitation trolleys should contribute to an improved safety of adrenaline use in case of emergency.

No conflict of interest

Keywords

Adrenaline; Ready-to-use syringe; Stability testing study

Authors letter

The development of an unavailable on market of ready-to-use syringes of adrenaline with an acceptable stability at room temperature offers the opportunity to have these syringes in resuscitation trolleys and will contribute to a safer use and administration of emergency drugs.

Score: 280

Remarks all reviewers:

Kart, Trine: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
Please include information on which syringes were used. TO SC: Would you accept 94% (6% degradation) of the initial concentration as the content at the end of the stability period? IN DK is usually 5%.

Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No
maybe a nominee

BAR14-0269

Analysis of literature in galenic formulations for the treatment of pain

Co-authors

A. Pasquale1, S. Calderone2, E. Taormina1, M. Cannizzaro1, C. La Seta1.
1A.O.U.P. Paolo Giaccone, Farmacia, Palermo, Italy.
2—, —, Palermo, Italy.

Background

Pain is a frequent symptom in the course of a disease, often it is an important sign for the initial diagnosis. The possibility to compound medications in a galenic pharmacy lets medicine prescribers able to use doses of the same active ingredient or compounds in a more 'personalized' way for individual patients, allowing them to achieve a therapy that otherwise would not been able to with the medicines that already exist on the market. Extensive studies with reliable statistics show that pain is present in all U.O. of our hospitals with higher prevalences in orthopedics, emergency and oncology where there is a 20% of patients that present acute and chronic pain syndromes due to radiation and chemotherapy.

Purpose

The object of this study was to create a galenic handbook for the treatment of pain

Materials and Methods

The informations founded in the literature easily accesible. The compounds had to have the characteristic of being easily accessed and readyly available at the pharmacy.

Results

24 active principle were identified as useful for our purpose, many of consolidated use such as morphine, other more particular ingredients such as capsaicin (although it is available in the market as a short time painkiller sold as a patch) and Alzaopride a prokinetic pain killer used in conjunction with morphine in order to reduce vomiting, a classic collateral effect of opioids. From the galenic preparations to fit, 10 were capsules in the pharmaceutical form, 8 were liquid preparations for oral use, 6 were oromucosal preparations, 5 were for rectal use and 4 were semisolid preparations for dermal applications. The data regarding the way preparations were integrated with information relative to the modality on conservation and therapeutic activity.

Among the preparations 12 of them present simultaneously more than one active ingredient.

In a relevant number of equipments we were able to notice how many of the active ingredients evaluated also had a wide range of doses for adults when it was necessary, due to the particular pharmacokinetics of specific active ingredients, the adjustment of the doses was also due to the doses already evaluated.
or certain active ingredients, the ajustment of the dose was also due to the degree of renal or hepatic function.

Conclusions

The galenic clinic is being recognized more and more as a place to ensure the best care for individual patients. The commercial products developed in controlled conditions are good for most uses but leave unattended some age classes and subjects with specific diseases. The galenic clinic in cooperation with a careful clinical evaluation gives an answer to this need.

No conflict of interest

Keywords

galenic;pain;handbook;

Authors letter

Score: 100

Remarks all reviewers:
Kart, Trine:
Rejected
5.
Reason for reject: ;
It is difficult to read whether a handbook on pain management, an overview of available compounded analgesic medicines or something third has been developed.
Gouveia, Antonio Melo: Conclusion NOT warranted
Conflict of interest clear
Accepted, but Author modifications
1.3.
Modifications needed: ; ;
Nominee: No

BAR14-0296

Oral viscous budesonide suspension for the treatment of eosinophilic esophagitis

Co-authors

A. Menclova 1, M. Hojny 2, J. Martinek 2.
1 Institute for Clinical and Experimental Medicine, Hospital pharmacy, Prague, Czech Republic.
2 Institute for Clinical and Experimental Medicine, Hepatogastroenterology, Prague, Czech Republic.

Background

Budesonide is a frequently used glucocorticoid in the treatment of eosinophilic esophagitis and of other inflammatory gastrointestinal diseases.

In the Czech Republic the treatment of esophageal inflammation by topical corticosteroids was possible only via commercially available metered dose inhalers. The treatment by inhalers was insufficient in terms of achieving a desired concentration of the drug at the site of inflammation.

Purpose

To develop a viscous oral dosage form of budesonide with minimum amount of excipients to avoid allergen exposure. To determine stability and shelf life of oral suspension by standardized method – High-performance liquid chromatography (HPLC).

Materials and Methods

A viscous budesonide 0.2 mg/ml suspension was prepared. Substance of budesonide was dispersed in glycerol 85%. Viscosity was achieved by using aqueous methyl cellulose gel. Glycerol 85% and oil of orange (Oleum Aurantii) were used to cover the bitter taste of budesonide. Optimum stability was achieved by the preservative excipient glycerol. The stability of the suspension was assessed at room (15-25°C) and reduced (2-8°C) temperature by HPLC method.

Results

A formulation of suspension was optimized with respect to stability and taste. A HPLC method was evolved to test the stability. A viscous budesonide suspension improved the course of eosinophilic esophagitis (treatment success was verified endoscopically).

Conclusions

A stable viscous oral budesonide suspension which provides an effective delivery of budesonide into the esophagus was developed. Adult and pediatric patients are successfully treated by the viscous suspension in the Czech Republic.

No conflict of interest

Keywords

eosinophilic esophagitis;budesonide;oral dosage form;
Authors letter

The abstract provides a new treatment option of eosinophilic esophagitis in the Czech Republic. A viscous oral dosage form of budesonide was developed to achieve a therapeutic dose at the site of inflammation.

Score: 260

Remarks all reviewers:
Kart, Trine: Conclusion warranted
Conflict of interest clear
Accepted, but Author modifications
please change the word "evolved" to "developed" or "developed and validated" whichever covers the activity performed
Gouveia, Antonio Melo: Conclusion warranted
Conflict of interest clear
Accepted
Nominee: No

BARI4-0314
Implementation of a process optimization protocol for the elaboration of ready-to-use (RTU) intracameral cefuroxime for endophthalmitis prophylaxis (EP) after cataract surgery

Co-authors
C. FERNANDEZ LOPEZ1, C. MEDARDE CABALLERO1, R. LOPEZ SEPULVEDA2, C. VALENCIA SOTO2, S. RUIZ FUENTES1, S. BELDA RUSTARAZO1, C. GOMEZ PEÑA1, C. GARCIA FERNANDEZ1, A. CABALLERO ROMERO1, D. BLANQUEZ MARTINEZ2.

1 Hospital Universitario San Cecilio, Pharmacy, Granada, Spain.
2 Hospital Virgen de las Nieves, Pharmacy, Granada, Spain.

Background
The use of intracameral cefuroxime is becoming more widely accepted for EP. Recently, the European Medicines Agency approved a single, sterile, unit-dose of intracameral cefuroxime in a few countries in Europe.

Purpose
To describe the optimization protocol for the elaboration of RTU intracameral cefuroxime syringes from the cefuroxime 1500mg vial and to evaluate the economic saving result of its implementation.

Materials and Methods
A review of the literature was made for the development of the formula. To evaluate the economic savings we compared the consumption of cefuroxime 1500mg vials in the elaboration of syringes since the implementation of the protocol with the costs if the commercialized unit-dose of intracameral cefuroxime would have been used.

Results
In horizontal laminar flow cabinet according to good manufacturing practices:
1. Reconstitute cefuroxime 1500mg vial with 50 ml 0.9% sodium chloride.
2. Add the above solution through a 0.22 mm filter to a bag of 100 ml 0.9% sodium chloride.
3. Take 0.3 ml in 1 ml graduated polypropylene syringes. In the operating room (OR) surgeons purge to 0.1 ml to administer 1 mg of cefuroxime. In each batch 200 syringes are elaborated. 40 syringes are sent weekly to OR and the rest are stored frozen in Pharmacy. The stability of RTU syringes is: three months in freezer (-20 °C), 15 days under refrigeration and 24 hours at room temperature. 10 syringes from each batch are sent for the microbiological control.
Between January-July 2013 five vials of Cefuroxime 1500mg were used to elaborate 1000 RTU cefuroxime syringes, with a cost of 14.56 € (PVP: 145.6/50 vials). If the commercialized unit dose would have been used, for the same administrations the cost would have been 12164 € (PVP: 121.64 €/10vials); meaning a 99.8% reduction on costs.

Conclusions
The implementation of the new protocol has led to an economic saving without compromising the quality of the process and the patient’s health.
No conflict of interest

Keywords
endophthalmitis; prophylaxis; intracameral-cefuroxime;

Authors letter

The use of intracameral antibiotics, specially cefuroxime, is becoming more widely accepted for endophthalmitis prophylaxis after cataract surgery. This protocol is an easy and safety way that allows saving costs in the antibiotic prophylaxis after this surgery.

Score: 160

Remarks all reviewers:
Kart, Trine: Conclusion NOT warranted
Conflict of interest clear
Accepted, but Author modifications
3.
Modifications needed: ;
Nominee: No
New category: T1
To align your abstract you could choose only to focus on the economic impact and exclude information on the manufacturing process as it seems to be mainly the economic potential you want to demonstrate within the abstract.
Gouveia, Antonio Melo: Conclusion warranted

Accepted
Nominee: No