CONSUBSTANTIATED OPINION OF THE CEP

RESEARCH PROJECT DATA

Research Title: DEVELOPMENT OF A COMPUTERIZED SYSTEM FOR DRUG RECONCILIATION IN A HOSPITAL ENVIRONMENT

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Thematic Area:

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OPINION DATA

Número do Parecer: 4.808.651

Project Presentation:

INTRODUCTION

The World Health Organization (WHO) is concerned with ensuring patient safety in all health services1, since thousands of people worldwide suffer from errors and adverse events related to medications2. Adverse events are any unintended clinical signs or symptoms with unfavorable outcomes, any new disease, or deterioration of previously existing disease. It is a harm to the patient that is associated with health care, or more precisely, it is the event or circumstance that could have resulted, or resulted, in unnecessary harm to the patient3,4. In 2004, the WHO created the "Patient Safety Program", a program that aims to propose measures to reduce risks and reduce adverse events in all health services, especially in hospital institutions5. The events caused by the inappropriate use of medications make health agencies recommend the implementation of practices and services such as clinical pharmacy, pharmacovigilance and drug reconciliation to assist in the identification of these events and better understand the process of prescription, dispensing and administration of medications in hospitals, acting in a preventive manner6. The fact is that hospital institutions do not always have computerized support systems, financial conditions, human resources and infrastructure for the implementation of clinical pharmacy services, pharmacovigilance and drug reconciliation. Allied to this is the structural disorganization of health services, the lack of policies

public for the performance of the clinical pharmacist and scarce time for the execution of these services7. The introduction of systems to control the rational use of medicines (URM), which is one of the pillars of safety in health services, becomes a great challenge, especially for pharmacists8. In hospitals, the daily demand causes pharmaceutical professionals to move away from the clinical part, and many report lack of time to perform this function9. In an attempt to minimize these damages, and lack of time reported, computerized support systems can contribute to pharmacists optimizing their care and being able to attend with greater infallibility to a greater number of patients per period10. The economic factor can also be a differential in patient care, since rational care, with adequate costs, and scientifically proven and fulfilled, avoid unnecessary financial losses to the health system and consequent reallocation of value for new safe and effective care11. Different analyses can be performed comparing the interventions, their effectiveness and their cost, among them, the so-called "opportunity cost", which assumes that health resources are scarce and limited11 and should be optimized. Based on the above, this study aims to answer the following question: "What is the clinical contribution of the implementation of a computerized system to support pharmaceutical decision in the clinical pharmacy service and drug reconciliation?"

HYPOTHESIS

H1 – The computerized pharmaceutical decision support system contributes to optimizing the clinical pharmacy service and drug reconciliation in hospitals.

H0 – The computerized pharmaceutical decision support system does not contribute to optimizing the clinical pharmacy service and drug reconciliation in hospitals.

H2 – The computerized pharmaceutical decision support system contributes to optimizing the clinical pharmacy service, but not the drug reconciliation service in hospitals.

H0 – The computerized pharmaceutical decision support system contributes to optimizing the drug reconciliation service, but not the clinical pharmacy service in hospitals.

H3 – Determine whether a computerized pharmaceutical decision support system contributes clinically to optimizing the clinical pharmacy service and drug reconciliation in hospitals.

H0 – Determine whether a computerized pharmaceutical decision support system does not contribute clinically to optimizing the clinical pharmacy service and drug reconciliation in hospitals.

PROPOSED METHODOLOGY

Study of diagnostic accuracy. Cross-sectional design. It will be held in two hospitals located in Tubarão, SC, in the clinical hospitalization sectors. These sectors have 173 inpatient beds and an average of 411 hospitalizations/month. The population will consist of inpatients between June and December 2021. The total estimated population is 167 patients. The sample size calculation was performed using the OpenEpi® software, with (CI)=95%, frequency of 80% of inconsistency in the population and an increase of 20% for losses or refusals. All patients who fit the inclusion criteria will be invited to be part of the research. A draw will be used by means of the bed number. Contact was made with the Information Systems Course/UNISUL for the development of a pharmaceutical system for drug reconciliation/drug interaction to support data collection. Registration was made for the operation of the analyses in Excel (list of drugs, reference and generic name, active ingredients, pharmaceutical form, pharmaceutical concentrations, pharmacological class, maximum daily dose and drug interactions). The system was developed to verify and check if the method will be able to detect inconsistencies more assertively than the manual method and the time required for each of the methods (manual and computerized). After the development of this system, the project will be presented to the hospitals for the consent of the management, with the signature on the research project that contains, the cover letter, the ICF, the Declaration of Science and Agreement and the Term of Authorization of Access to Medical Records. After the signatures, the documents will be sent to the CEP with the project. After ethical approval of the study, data collection will take place by drawing lots of beds for hospitalized patients, presentation and consent by signing the ICF. A pilot study will be conducted with 10% of the sample, if it is not necessary to modify the questionnaire or the computerized support system, the patients will become part of the total sample, if modification is necessary, these patients will enter the exclusion criteria, and new patients will be selected. The patient will be interviewed by the researcher only once, and after the interview, the patient's medical record will be consulted in the Tasy system to compare the prescription of the medical record with the information given by the patient regarding the use of home medication. The researcher will record all the information in the
system developed by it and will carry out computerized analysis and analysis manually, so that
it is possible to verify the accuracy of the system. Data collection will occur in three stages: in the first stage, the researcher will collect the data through the interview with the patient, will be asked and collected data such as: use of home medications, active principles of the

medications, dosages used daily at home and if any home medication is being administered by the family/patient in the hospital, these data will be immediately entered into the computerized support system. In the second stage, the data of the medications used during hospitalization will be collected. Data such as prescribed medications and their daily dosages will be collected from the medical records that are available at the nursing stations. After collection, the data will be entered into the computerized system and manual reconciliation will also be performed. In the third step, the system will be used and compared with the manual reconciliation activity. The computerized and manual analysis will be compared verifying which points of inconsistency were detected by both methods.

INCLUSION AND EXCLUSION CRITERIA
Inclusion Criteria: All patients aged 18 years or older, hospitalized in the medical clinic sectors of hospitals located in the city of Tubarão (SC), who use home medications before hospitalization will be included.
Exclusion Criteria: Patients hospitalized only for examinations, patients who have prescriptions with only one drug, patients who are in contact, respiratory or aerosol isolation, by determination of the Hospital Infection Control Service (SCIH) of the hospital, patients who do not sign the free and informed consent form (ICF) or patients who are cognitively unable to answer the questions described in the form will be excluded of research.

The information listed in the fields "Project Presentation", "Research Objective" and "Risk and Benefit Assessment" were taken from the Basic Research Information, file "PB_INFORMACOES_BASICAS_DOPROJETO_1722586.pdf", posted on the Brazil Platform on 06/04/2021.

Research Objective:
PRIMARY ENDPOINT:
Develop and apply a computerized pharmaceutical decision support system for the clinical pharmacy service and drug reconciliation in a general hospital.

SECONDARY OBJECTIVE:
Assist in the development of a computerized pharmaceutical decision support system for

enable the realization of medication reconciliation and the search for drug interactions by comparing the manual and computerized means of support.

Risk and Benefit Assessment:

RISKS:

The risks of this study are considered minimal because it is a cross-sectional study. The information contained in the medical records and interviews will be kept confidential throughout the study and the analysis of the data and the publication will be through codes that will not characterize the participants. The variables of interest to be investigated do not offer any risk to the patient. Risks related to COVID-19 are anticipated and minimized. The researchers undertake to follow all the recommendations of the different health agencies of the different spheres, as well as, the determinations of the hospital unit where the research will be carried out will be adopted. No patients or caregivers will be approached in isolation wards for COVID-19 and both the researcher and the patient and companion will use masks, hand hygiene and materials with 70% alcohol gel as recommended.

BENEFITS:

The research will contribute to the study and development of a computerized pharmaceutical decision support system for the clinical pharmacy service and drug reconciliation in a general hospital. By verifying the accuracy of the system it can be applied and ensure safer treatments, and possible corrections in prescriptions so that drug treatment is carried out safely and in a timely manner.

Research Comments and Considerations:

1. Academic character: PhD project of the Graduate Program in Health Sciences (PPGCA), Campus Sul - Tubarão/SC.

2. Participants: 167 patients over 18 years of age.

3. It presents the Informed Consent Form and the Authorization Term for the accomplishment of Research in the Medical Record and Commitment of use of the data.

1. Forecast to start - 06/01/2021 and close - 12/31/2021 (data collection - after ethical approval of the study).

Considerations on the Mandatory Presentation Terms:

See field "Conclusions or Backlogs and List of Inadequacies".

Recommendations:

See field "Conclusions or Backlogs and List of Inadequacies".

Conclusions or Backlogs and List of Inadequacies:

All pending issues, as set forth in the "Letter of Response to Backlogs," were addressed. No ethical obstacles were found.

Final Considerations at the discretion of the CEP:

Research protocol in accordance with Resolution 466/12 and/or 510/16 of the National Health Council.

This opinion has been prepared on the basis of the documents listed below:

Type Document	File	Post	Author	Situation
Basic information of the project	PB_INFORMAÇÕES_BASICAS_DO_PROJETO_1722586.pdf	04/06/2021 10:12:27		Accepted
Others	Carta_resp_pend.pdf	04/06/2021 10:10:37	Alessandra de Sá Soares	Accepted
Previous opinion	Primeiro_parecer_CEP.pdf	21/05/2021 15:09:45	Alessandra de Sá Soares	Accepted
Informed consent form	TCLE_em_doc.docx	21/05/2021 15:04:18	Alessandra de Sá Soares	Accepted
Project	Projeto_19maio21.docx	21/05/2021 15:02:31	Alessandra de Sá Soares	Accepted
Others	Aut_Pront_Soci_versao2.pdf	20/05/2021 12:02:44	Alessandra de Sá Soares	Accepted
Others	Aut_Pront_HNSC_versao2.pdf	20/05/2021 12:02:12	Alessandra de Sá Soares	Accepted
Others	Decl_Con_Soci_versao2.pdf	20/05/2021 12:01:17	Alessandra de Sá Soares	Accepted

Continuação do Parecer: 4.808.651

Declaration of agreement	Decl_Con_HNSC_versao2.pdf	20/05/2021 12:00:13	Alessandra de Sá Soares	Accepted
Cover Page	Rosto.pdf	06/04/2021 13:54:41	Alessandra de Sá Soares	Accepted
Schedule	CRONOGRAMA.docx	06/04/2021 13:39:32	Alessandra de Sá Soares	Accepted

Status of the Opinion:
Approved

Needs CONEP Appreciation:
No

PALHOCA, 26 de Junho de 2021

Assinado por:
Silvana Cristina Trauthman
(Coordenador(a))