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High-Surveillance Drugs Protocol Evaluation - Management of Patient Safety

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Abstract: *Brazilian health care institutions have increased their investments in patient safety development. Public health professionals gear many of their resources towards improvements in this area. For progress to be achieved, efforts are being made focusing on research in hospitals, clinics, and health facilities. Using a protocol-verification tool called "The Appraisal of Guidelines for Research & Evaluation Instrument" (AGREE II), researchers conducted an impartial investigation of a high surveillance drug management protocol in a pediatric hospital in the city of Curitiba, Brazil. AGREE II allowed them to evaluate whether the document is adequately presented and if it adheres to the recommended standards. Following approval by the institution's IRB, researchers established a conclusion concerning the quality of the protocol by exploring each of the 25 tool-evaluation criteria. This article serves as an incentive for health services to standardize patient safety protocols and to promote research on this topic, while aiming to reduce medication errors.*

Keywords: *Patient Safety; Public Health; Medication Therapy Management; Medication Error*

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I. Introduction

The United States Institute of Medicine defines "Patient Safety," as any attitude professionals can take to avoid causing harm to patients. It also considers this to be one of six main attributes of standard care. In Brazil, Proadess (Health Systems Performance Assessment Project) considered "safety" as one of the defining characteristics of health-care quality (ANVISA, 2014).

World Health Organization has easily promoted protocols on this matter due to no major investments being needed for their implementation. Without those, errors and adverse events are significantly more frequent. The basis of this regulation is fundamented on principles of encouraging better communication, building safe care practices, improving teamwork and ameliorating risk management (Brazilian Ministry of Health Online Portal, 2016).

In 2004, the World Health Organization and the World Alliance for Patient Safety started the "Global Patient Safety Challenge" project. Currently, a challenge which focuses on medication safety is being developed. The purpose of the program is to regulate changes and to prevent or reduce the occurrence of medication-related harm - ordering, prescription, administration, and monitoring (WHO, 2017).

In the 1990s, the Institute for Safe Medicine Practice conducted a study of drugs that were most likely to cause harm to patients. Thus, drugs that would likely result in death or severe damage if they were involved in medication errors were selected to compose the High Surveillance Drug List (ENGELS et al. 2015).

It is widely recommended that each hospital develops its own selection of potentially hazardous medications. This list should be classified according to patient status: long-term hospitalized or short-term emergency room. Sub-categorizations according to therapeutic classes and other specifications should be made (ISMP, 2015).

Facing population growth, Brazil will have an increased demand for health services in hospitals, elevating counts of medical errors. To mitigate this, in addition to governmental measures that try to address the shortage of doctors, strict and specific protocols can reduce the incidence of such damage. As a positive result of these procedures, improvement of health markers would strengthen population confidence in health care services.

This research was encouraged due to the increased rates of neglection committed by professionals, generating uncertainty in health care and patient trust. Also, it is noteworthy that universities don't focus on patient safety lectures.

World Health Organization set improvement goals towards overall safety, including: correct patient identification, effective communication, increased safety measures for High Surveillance Drugs, safe surgery,

reduced risk of infections caused by care and prevention of falls. However, measures to achieve these goals are often not put in action by managers of health institutions, or even by their professionals. Furthermore, protocols that provide guidelines for professional practices are not always properly described, containing mistakes or unclear steps; necessary for the referral of practical actions.

As a result of an international collaboration, the AGREE II tool was created for clinical guideline evaluation and allows strict analysis of practice protocols. The use of AGREE II is always justified when there is the need to demonstrate the relevance of certain standardized actions and to observe the academic and scientific contribution of the subject in matter.

In this sense, the authors of this paper established as the research question: how are high surveillance medication protocols described in pediatric hospitals? To answer it, the objective of the study was to evaluate the Protocol for the Administration of High Surveillance Medicines in patient safety from AGREE II, verifying if there is adequate application of its recommendations by all professionals involved in prescribing High Surveillance Medicines.

II. Methods

This article was written via retrospective documentation and evaluation of a Protocol used for high surveillance medications of a medium and high complexity, national reference Pediatric Hospital, located in Curitiba, PR. It was developed from December 2018 to July 2019.

The Hospital provides 32 medical specialties services and allow private and public health system services (70% of total). It currently has 370 beds, of which, 60 are ICU-exclusive.

For data collection, we used the tool called "AGREE II (Appraisal of Guidelines for Research & Evaluation)", which is configured as an instrument to evaluate clinical guidelines and protocols, observing their methodological qualities (AGREE, 2009).

The document is structured in 6 domains, each covering a protocol quality criteria. Domain 1, entitled "Scope and Purpose", refers to the goal proposed by the guideline, specific health aspects, and the intended audience. The second, "Stakeholder Engagement", involves issues related to project development by practitioners and user perception. : "Development Rigor" focuses on the methodology used for data collection and defining and updating indications. Domain 4, "Clarity of Presentation", highlights important points in the structuring of the guideline. "Applicability" is evaluated by the fifth domain. Finally, domain 6 deals with "Editorial Independence": strategies to avoid conflict of interest biases (AGREE, 2009).

The collected data was analyzed using the Likert psychometric score. Each of the global assessment AGREE II items is graded on a 7-point scale, with 1 being "strongly disagree" and 7, "strongly agree". Thus, the score was defined according to the quality compliance of the information provided.

At the end, a table was prepared to show the results, presenting the grade given by 2 independent evaluators in each question.

It is worth mentioning that this study received a favorable opinion from the Ethics and Research committee of FaculdadesPequeno Príncipe in Curitiba-Pr, under number 10457718.6.0000.5580.

III. Results

AGREE II INSTRUMENT

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

DOMAIN 1. SCOPE AND PURPOSE		
The overall objective(s) of the guideline is (are) specifically described.)	**EVALUATION: 6** (E1*: 6 E2**: 6)	Criteria are present except the delimited target.
The health question(s) covered by the guideline is (are) specifically described.	**EVALUATION: 6** (E1: 6 E2: 6)	The criteria are all present except the audience specification.
The population (patients, public, etc.) to whom the guideline is meant to apply is specifically	**EVALUATION: 5,5**	Partial evaluation, because there is no mention of all professionals in the inspection process.

described.	(E1: 6 E2: 5)	

DOMAIN 2. STAKEHOLDER INVOLVEMENT		
The guideline development group includes individuals from all relevant professional groups.	**EVALUATION: 2** (E1: 2 E2: 2)	Criteria are missing except the name of the members of the protocol development group and the name of the Institution.
The views and preferences of the target population (patients, public, etc.) have been sought.	**EVALUATION: 1** (E1: 1 E2: 1)	No criteria present.
The target users of the guideline are clearly defined.	**EVALUATION: 7** (E1: 7 E2: 7)	The criteria are completely present

DOMAIN 3. RIGOUR OF DEVELOPMENT		
Systematic methods were used to search for evidence	**EVALUATION: 1** (E1: 1 E2: 1)	The required information is missing. There is only one reference from which data were collected.
The criteria for selecting the evidence are clearly described.	**EVALUATION: 1** (E1: 1 E2: 1)	No descriptions of the inclusion and exclusion criteria are present.
The strengths and limitations of the body of evidence are clearly described.	**EVALUATION: 1** (E1: 1 E2: 1)	The protocol does not contain any of the criteria.
The methods for formulating the recommendations are clearly described.	**EVALUATION: 3,5** (E1: 3 E2: 2)	Item considered partial because it does not establish a specific method for data collection (these were collected observing the hospital drug chain)
The health benefits, side effects, and risks have been considered in formulating the recommendations.	**EVALUATION: 2** (E1: 2 E2: 2)	Risks and side effects cited, the other requirements are absent.
There is an explicit link between the recommendations and the supporting evidence	**EVALUATION: 1,5** (E1: 1 E2: 2)	In this criterion, evaluator 2 partially considered the recommendations linked to the synthesis of evidence. Other items canceled.
The guideline has been externally reviewed by experts prior to its publication.	**EVALUATION: 2** (E1: 2 E2: 2)	The intention of the review, methods to conduct it, its outcomes and the description of the methodology for obtaining information did not meet expectations. External Reviewer just quoted.
A procedure for updating the guideline is provided.	**EVALUATION: 1** (E1: 1 E2: 1)	None of the requirements were present.

DOMAIN 4. CLARITY OF PRESENTATION		
The recommendations are specific and unambiguous.	**EVALUATION: 7** (E1: 7 E2: 7)	Criteria meet expectations. Regarding the "possibility of specific qualifications", the evaluators considered it not relevant.
The different options for management of the condition or health issue are clearly presented.	**EVALUATION: 7** (OR 0*) (E1: 7 E2: 7)	Not applicable.
Key recommendations are easily identifiable.	**EVALUATION: 7** (E1: 7 E2: 7)	The statement of recommendations is explicitly stated correctly.

DOMAIN 5. APPLICABILITY		
The guideline describes facilitators and barriers to its application.	**EVALUATION: 1,5** (E1: 2 E2: 1)	In item 18, the only topic positively evaluated by evaluator 1 was the description of how the information served to elaborate the recommendations.
The guideline provides advice and/or tools on how the recommendations can be put into practice.	**EVALUATION: 6,5** (E1: 6 E2: 5)	The specification for the implementation sector and document synthesizers and manual algorithms with step by step are present. The rest of the requirements are missing.
The potential resource implications of applying the recommendations have been considered.	**EVALUATION: 1** (E1: 1 E2: 1)	The first three cost analysis criteria were disregarded by the authors, as it does not apply. No information on other requirements.
The guideline presents monitoring and/or auditing criteria.	**EVALUATION: 1** (E1: 1 E2: 1)	No items are present in the guideline.

DOMAIN 6. EDITORIAL INDEPENDENCE		
The views of the funding body have not influenced the content of the guideline.	**EVALUATION: 7** (OR 0*) (E1: 7 E2: 7)	Not applicable.
Competing interests of guideline development group members have been recorded and addressed.	**EVALUATION: 7** (OR 0*) (E1: 7 E2: 7)	Not applicable.

OVERALL GUIDELINE ASSESSMENT		
Rate the overall quality of this guideline.	**EVALUATION: 3,5**	1: Lowest possible quality 2 3 X (E1) 4 X (E2) revisor 5 6 7: Highest possible quality
I would recommend this guideline for use.	- Yes. - Yes, with modifications - No	Yes, with modifications

SUBTITLE: E1: Evaluator 1; E2: Evaluator 2;

IV. Discussion And Analysis

In the first AGREE II Domain, regarding scope and purpose, three issues defined the final assessment. The examiners agreed that in the High Surveillance Protocol, the objectives were expressed clearly and briefly, as were the health purposes. The document mentions the expected benefits, but there was not a specific place for this purpose. The targeted group was not found. The goals of the protocol was easily identified and was present in a uniquely demarcated sector below the introduction. Due to this, the final score was 6 (on the Likert Scale). According to the evaluators, the interventions were properly described: in order to guide the use of each particular drug, and outcome as expected. Regarding the environment or context of health care, the document subsections them according to each level of care (score 6 on the Likert Scale). In addition, the professionals to whom certain actions were intended could be found in the text, but there was no mention of key employees for some items of this inspection. Gender, age, clinical condition, disease severity, comorbidities, and excluded populations were not considered by the evaluators, because they were irrelevant in the protocol. (score 5 on the Likert Scale).

Domain 2 requires critical analysis of stakeholder engagement. The first question was if the guideline development team includes professionals from all relevant groups. The name of the members of the protocol creation group and the name of the Institution in which it will be used were the only mentioned. The discipline or specialty of the authors, the city and state of the Institution, and the role of each group member in the development of the guideline were absent. It was not specified if there was an expert in protocol design methodology (score 2 on the Likert Scale). There was no exposure to the method applied to determine the viewpoint and preferences of the target audience. Likewise, the strategies by which information was collected, the outcome on patient data, and the clarification on how the information obtained were used for the elaboration of the protocol were not mentioned (note 1 on the Likert Scale). In the session called “ANNEXES”, there was a flow of receiving, storage, dispensing and administration, dedicated to nursing, pharmacy and the supply center. Both graduated the usage recommendations as "excellent". (Score 7 on the Likert Scale).

Domain 3 refers to the document's rigour of development. In the methodology, it was concluded that the following were not mentioned: electronic databases used, the research period, the study descriptors and the search method. There was only one reference from which data were collected. (Note 1 on the Likert Scale).

Due to lack of knowledge being a major cause of pharmacological, prevention strategies should be discussed in groups to promote or underpin patient safety. The prevention of pharmaceutical failures should be based on a search for causes of errors in service organization systems (PENA, M. M., et al., 2016).

There were no descriptions of the criteria for selection of evidence and, although the protocol emphasizes that conduct was based on hospital practice, it did not consider it's bias. In addition, there was no description of study design, methodology constraints, relevance of outcomes, consistency of outcomes in each study, outcome direction, risks versus benefits, and applicability (score 1 on the Likert Scale). Procedures were defined based on norms of the collaborative areas of the medication chain at the Hospital. In addition to this, drugs were chosen by a highly supervised surveillance process. For this reason, critics considered the development and its description as "satisfactory". The outcome of recommendation development process was absent (scores 2 and 3 on the Likert scale). In the analysis of "health benefits, effects and risks", only the risks related to each drug were identified.

AGREE II demands publication of support and benefit information and risk versus benefit reports, which were missing (score 2 on the Likert Scale). Regarding a clear link between what the protocol recommends and the supporting evidence for it, one of the evaluators considered partially present, justifying that the guideline exposed the correct conduct but did not explicitly relate it to any evidence. Focusing on other parameters (description of how a team's association developed the document and their usage of clinical evidence) the two evaluators consented to their absence (scores 1 and 2 on the Likert scale).

Furthermore, the use and intention to review, methods for conducting a review, outcomes and description of how information was used towards the development process met the expectation. An external review team (Therapeutic Pharmacy Commission - translated from portuguese) was the only association mentioned. (Score 2 on the Likert Scale). An evaluation tool requires an update statement, record or explanation time about a new update, and reports of the methodology for the development of the review; none of which were found. (Score 1 on the Likert Scale).

Any misconduct in preventing drug errors should be considered and viewed as an opportunity for improvement. Considering that there are several variables in each institution, the update should not be based on other studies. The researcher must identify these unique characteristics to assist him in an expected improvement (PENA, M. M., et al., 2016).

The fourth section (Clarity of Presentation) obtained a maximum grade from both. The targeted population was clearly mentioned, as well as a delimitation of the purpose of the action and the recommended conduct. However, in the item that verifies the possibility of specific qualifications, the evaluators considered it as not relevant in the this protocol (grade 7 in the Likert Scale). As the protocol was not used for conduct in the medical clinic, the "description of the clinical situation that best fits a situation" - criterion used to evaluate this questionnaire - cannot be examined. However, the evaluators consider the protocol appropriate in relation to the conducts oriented to each drug. Also, the "description of approach options" does not fit, as all high surveillance drugs require, according to the protocol, specific measures and actions (not assessed on the Likert Scale). Recommendations were explicit and organized in synthetic tables — grouped together in one section — and as a flowchart. (Note 7 on the Likert Scale).

The next Domain was "Applicability". Regarding the description of the facilitating factors and the barriers to application, the only topic graded positively by one of the evaluators was the description of how the information served to elaborate the recommendations. The other examiner did not identify the description of how the information was used. Due to the explicit absence of facilitators and barriers to the implementation of the guideline, the following criteria received minimum score: identification, methods that guided the search for information related to them, information on the types of facilitators and barriers highlighted during the investigation (score 1 and 2 on the Likert Scale). Instructions regarding access to tools and resources were missing. The implementation sector was in line with AGREE II expectations. As for the second item, the following were absent: solutions to the barriers previously analyzed, explanations of how to benefit from facilitating aspects, lessons learned and conclusions from the pilot test. However, the synthesizing documents and step-by-step algorithm manuals were found to be adequate (scores 5 and 6 on the Likert Scale).

As the protocol was not aimed at specific individuals, but for a group of professionals, the "cost" analyzes were disregarded by the evaluators, thus judging the first 3 items of this item to be irrelevant (about cost: types of information, methods that guided the information search and information description). Both scored 1 as the last criterion for the lack of resource information used to support the document (score 1 on the Likert Scale). There was no criteria for assessing the guideline, its impact, nor its temporal and operational measurement advice. (Note 1 on the Likert Scale).

It was noted that the sixth Domain was disregarded by the analyzers. The "funding agency assessment" does not fit the type of protocol evaluated as it covers a very large amount of therapeutic measures for patient safety. The purpose of the guideline was to assist in the management of high-vigilance drugs, not to provide information about only one drug. In view of this, the records and conflicts of interest of the team members who developed the guideline should not be required. (Not evaluated)

The average quality rating was 3.5 (average grade: 3 and 4 on the Likert scale) and both agree they would recommend the protocol, but would make modifications beforehand.

Pharmaceutical care aims to prevent treatment-related morbidity and mortality. Even with such principles, 87.7% of drug-related harm is preventable. In addition, more than 6 out of 10 prescriptions are considered unnecessary (CALVO-SALAZAR, R. A. et al., 2018).

The nursing staff is critical for reducing mistakes, but should not be solely responsible for treatment-related conduct. The construction of the protocol aims to implement a standardization that is safer in certain procedures. For it to be effective, however, there must be critical collaboration between practitioner and researcher. (GUZZO, G. M. et al., 2018)

Individual action became insufficient in view of the reduction of medication errors. To be successful in these preventive measures, modifications to existing protocols and systems must be made. However, damage data are not published - save situations where a famous person is a victim and the case becomes news. (DHAWAN, I. et al., 2017)

V. Conclusion

The research proved beneficial in identifying improvement aspects and situations that still compromise patient safety outcomes. The information collected in this study can help health services standardize a patient safety protocol to avoid future errors. The resulting possible change in behavior should encourage further research and attention from the hospital's responsible sectors. Findings from these would be important for current and future studies that have the same theoretical approach and are based on similar objectives.

Researchers and experts have pointed out how the creation of algorithms can be used to achieve the most positive results based on their evidence. This practice extends to pharmacology and prescription drug. Furthermore, this study can serve as a foundation for such algorithmic elaboration, especially in the institution where it was performed.

In addition, the number of medical error cases has been consistently increasing. Whether due to misconduct or non-evidence-based decisions, professionals and hospitals have devoted some of their resources to fighting legal battles. As for the prescription, with this result, important points of the Protocol of High Surveillance Medication could be adjusted and shared in a larger scale. An effective, less chance of error and evidence-based method would be available to prevent failures and to ensure legal support.

The chance of inappropriate drug interactions may compromise health care. This becomes even more noticeable when a medication falls into the high-vigilance group; with greater potential for negative effects. The instigation of services towards improvement can be made through the results presented here, as they may lead to progress in reconciling all these drugs and thus reducing all the harm resulting from polymedication.

The data serves as a basis and incentive for the analysis of other protocols. To break the paradigm of the difficulty in developing research with this scope, the authors aim to promote this practice by demonstrating convincing results and specific points of focus that can be reversed by service providers and their guardians, promoting the pursuit of excellence in care and attention.

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