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INDIVIDUAL ASSESSMENT OF PHARMACOLOGICAL RISK IN PATIENTS RECEIVING HOME CARE SERVICES IN THE CARTAGENA CITY

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Abstract: Currently there are scales or strategies that evaluate some risks associated with the use of medications in specific population groups, but they do not consider some important variables that are found during pharmaceutical care. The Individual Pharmacological Risk Evaluation Scale (IPRES) that is used during the application of the DETI Method of Pharmaceutical care is an efficient tool to know the Individual Pharmacological Risk of a patient, facilitating its comprehensive approach and the generation of strategies for the team of care and the patient.

METHOD: A descriptive, longitudinal, prospective study was carried out that included patients from the Home Care program. For the Individual Evaluation of the Pharmacological Risk of the patients, the DETI method of Pharmaceutical Care and Pharmacotherapeutic Follow-up and its IPRES were applied.

RESULTS: The clinical and environmental conditions were identified that allowed defining the probability that a patient would present Adverse situations or Health Problems associated with their use of the Medications they received and it was found that 22% of the patients were exposed to a Very High Pharmacological Risk. High, 27% at High risk, 46% at Moderate risk and 5% at Low risk.

CONCLUSION: In the study population, the pharmacological risk to which a patient is exposed according to the IPRES is evident by the variables measured and according to its quantification, 95% of them require Pharmaceutical attention and Pharmacotherapeutic Follow-up Every 2, 3 or 6 Months or sooner depending on condition clinic due to its VERY HIGH, HIGH and MODERATE PROBABILITY of presenting Adverse situations or Health Problems associated with the use of the Medications you receive.

Keywords: Older Adult, Pharmacological Risk, Individual Evaluation of Pharmacological Risk, Cholinergic Risk, Polypharmacy, Medication Errors, PPI, Deprescription, Drug Interactions

INTRODUCTION

The Pharmaceutical Chemist is a health professional who is responsible for optimizing the use of medications and improving the health outcomes of patients (1). Their main function is to work in collaboration with the health team to ensure that patients receive appropriate and safe treatment, according to your individual needs(2).

Its importance lies in its ability to prevent and resolve drug-related problems, improve treatment effectiveness, reduce the risk of side effects, and ensure that patients receive the correct dose and duration of treatment. (1,3)

This is why this professional becomes a fundamental piece of the healthcare team, being an integrator of variables involved during care that, if not properly identified and managed, can favor the appearance of health events associated with the use of medications, affecting morbidity and mortality related to pharmacotherapy.

In Colombia, the healthcare activities of Pharmaceutical Chemists are progressing (4), however, their offer is reduced and the demand for their services in favor of the safe use of medications is increasing.

Currently, there are scales or strategies that evaluate some risks in specific population groups, related to increased mortality, greater functional and cognitive deterioration, greater hospital admissions, greater use of medical consultation and emergency services such as, Vulnerable Population Group (5 –8), Pluripathological Patients (9–12), Barthel Scale (13), Physiological Conditions that affect the pharmacokinetics of the medications received (14–19), hyperfrequent users or

Polyconsultants (20,21), Polypharmacy (22,23), Narrow-range Drugs (24), Lists of High-Risk Drugs (25–27), Haynes-Sackett Test, Morisky-Green Test, Anticholinergic Risk Scale (28–32), Drug Interactions of Clinical Relevance (33), the STOPP START criteria (34–39), Beers Criteria (40,41), DRUID Criteria (42–44), The Medication Regimen Complexity Index (45), among others; but they do not consider some important variables that are found during pharmaceutical care, which is why the Individual Pharmacological Risk Evaluation Scale (IPRES) of the DETI Method of Pharmaceutical Care and Pharmacotherapeutic Follow-up, by integrating the Sociodemographic, Clinical and Utilization Variables of Health Services and related to medication, allows an individual and comprehensive evaluation of the pharmacological risk to which a patient is exposed.

Additionally, it contributes to establishing criteria that during Pharmaceutical care allow identifying the variables present during the consultation that are susceptible to modification in order to minimize or eliminate the risks and in turn would lead to monitoring signs and symptoms suggestive of events associated with the pharmacotherapy, that is, they guide the pharmacist to define specific Pharmaceutical Care actions for patients and define the need for Pharmaceutical Care and the frequency of pharmaceutical monitoring required(46).

The DETI Method defines "**Pharmacological Risk**" as those adverse situations to which a particular patient is exposed when receiving any pharmacological treatment; said risk is conditioned by factors inherent to the treatment, the individual characteristics of the patients and their environment. (47)

The term **Pharmacological Risk** It does not necessarily imply a risk of an Adverse Event, but it gives the Pharmaceutical Chemist a clear idea of who must prioritize Pharmaceutical Care and establish frequency of Pharmacotherapeutic Follow-up.

Risk assessment attempts to characterize the potential risk of those situations that may represent a danger to human health or the environment. (48)

The IPRES of the DETI Method was validated by a committee of Experts, said validation demonstrated that the IPRES with its dimensions and subdimensions is an appropriate measurement instrument to evaluate the Individual Pharmacological Risk of patients, available for pharmaceutical chemists dedicated to Pharmaceutical Care and to pharmacotherapeutic follow-up, it is reliable to identify and classify the pharmacological risk to which a patient is exposed and allows establishing the need for Pharmaceutical Care and the frequency or not of Pharmacotherapeutic Follow-up, given the high internal consistency, obtained through the Friedman and with a good agreement of Kendall's W of the judgment results of the six experts who participated as judges.

The degree of agreement using Kendall's W coefficient was 0.837 ($\alpha < 0.05$), which indicates excellent agreement between the judges. The content validity and internal consistency of the reliability of the scale ratings by expert judges using Aiken's V Coefficient was 0.98 ($p < 0.05$) and Cronbach's alpha was 0.917. The Aiken V coefficient of the total instrument was 0.98 ($p < 0.05$).

METHOD

A descriptive, longitudinal, prospective study was carried out that included patients from the Home Care program of an IPS of a special regime in the city of Cartagena de Indias, Colombia. Home Pharmaceutical Care was provided to each of them. For the Individual Evaluation of the Pharmacological Risk of the

patients, the DETI method of Pharmaceutical Care and Pharmacotherapeutic Monitoring and its IPRES were applied during the months of January to July 2023.

PROCEDURE

For the Individual Evaluation of Pharmacological Risk and to define the action strategy, the DETI Method of Pharmaceutical Care and pharmacotherapeutic monitoring was applied with its five Phases:

Phase 0: Service Offer, Selection and Stratification of Patients.

Taking into consideration, the IPS guidelines, patients in the Home Care program were selected to receive the Pharmaceutical Care service. To define the real need for said Care, the NECAF 1.0 Scale of the DETI Method was applied. See Table 1.

Phase D: Pharmaceutical Consultation: Collection of Demographic Information, important history and Diagnosis(es) of the Patient.

A home Pharmaceutical Care Visit was carried out, the Pharmaceutical History of the DETI Method was used to collect information and identify Sociodemographic Variables and Clinical and Health Services Utilization Variables that impact the safety in the use of medications such as: Dependence Functional according to the Barthel scale, Pluripathology according to the SEFH model, Multiconsultant if the patient consults on average between general and specialized medicine 6 or more times a year or if he is treated by more than 3 different doctors in the last 3 months and if the patient had Physiological Conditions that affected the pharmacokinetics of the medications he received.

Phase E or Clinical-Pharmacological Evolution: Description of the patient's health status, health problems, concerns regarding their health, Paraclinical record, etc.

The evolution of the patients was described and their current status, their vital signs and their relationship with the drug treatment they received and any other variable or paraclinical variables related to their pathologies or clinical follow-up were identified. Are you concerned about your health? How long have you suffered from it? And if you take something to treat it?

Phase T or Patient Treatment: Record of Formulated Treatment, treatment received, Modification of Previous Treatment, Compliance with Treatment, perception of Effectiveness and Safety of Treatment, Storage Conditions (First Aid Kit Review)

Medication reconciliation was carried out by organizing the medications and other products they received taking into consideration, their ATC classification and the number of chronically used medications was calculated and it was identified if they received medications that required special handling, the presence of medications with an anticholinergic load was identified according to the ARS scale and the Anticholinergic Risk was established, the presence of drugs with a narrow therapeutic range according to the List of drugs with a narrow therapeutic range published by INVIMA and the presence of High-risk drugs according to the Spanish and American ISMP List.

Adherence to treatment was identified through the Morisky Green Test, it was verified if the patient had a history of allergies or if he had previously had adverse reactions to any drug, it was evaluated if the patient or his caregiver had limitations for the handling and administration of the medications or if there was support from a nursing assistant, if the patient had difficulty swallowing or had an enteral feeding tube and the Storage Conditions of the medications at home were reviewed.

The presence of Incidents, complications and adverse events associated with the medication and their respective causes and consequences were identified and described.

PHASE I OR ANALYSIS AND INTERVENTION (INDIVIDUAL PHARMACOLOGICAL RISK ASSESSMENT): ANALYSIS OF THE FINDINGS AND PREPARATION OF CONCLUSION AND INTERVENTIONS

Drug interactions were identified using the database of www.drugs.com, classifying them as MAJOR or MODERATE. The presence of Potentially Inappropriate Prescriptions (PPI) was evaluated taking into consideration, the Stopp/Start Criteria.

The IPRES was applied, recording the rating of each of the Items of the variables it contains: Sociodemographic Variables, Clinical Variables and Use of Health Services and Variables related to medication. See Table 2 and 3

The pharmacological risk to which each patient was exposed was calculated and the types of risks identified were described.

At the end, the conclusion of each case was described and the respective interventions were carried out by the health professionals and the patient or caregiver, taking into consideration, the results of the IPRES and the Medication-Related Incidents identified, which revolved around suggesting the evaluation of the Necessity, Effectiveness and Risk Benefit of the treatment; monitor or follow up on signs and symptoms suggestive of events associated with pharmacotherapy, Consider therapeutic or management suggestions on a case-by-case basis, especially in those patients with Physiological Conditions that affected the pharmacokinetics of the medications they received and made recommendations for proper use of medications with special emphasis on patients who had Gastrostomy Tubes or difficulty swallowing and health education related to Medication was carried out for family members and/or patients to promote the appropriate and safe use of medications according to the psychosocial conditions and of the environment in which they lived.

RESULTS

A total of 175 patients were evaluated, 71% women and 29% men; 22% presented a Very High Pharmacological Risk, 27% High, 46% Moderate and 5% Low. See Chart 1.

Taking into consideration, the IPRES variables, 95% of the patients were over 60 years of age, 71% had comorbidities, 100% had severe functional dependence, 53% had Physiological Conditions that affected the pharmacokinetics of the medications they received, 98% They were polyconsultants, 24% had a history of Allergies or having had ADRs to some medication, 97% were polypharmacy (12% received more than 16 Chronic medications, 53% between 10 and 15 and 31% between 6 and 9), 26 % Received some medication with a narrow therapeutic range, 46% received some High-risk medication, 22% suspected or demonstrated Non-adherence to treatment and/or Self-medication, 49% Received Medications with Anticholinergic Load (6% Very Strong, 14% Strong and 28% Moderate according to the ARS eschar), 89% had clinically relevant drug interactions (17% classified as MAJOR with or without MODERATE and 73% as MODERATE with or without MINOR), 75% received at least one Medication Potentially Inappropriate (PPI) and 90% received Medications that required Special Handling due to their pharmaceutical technology or because the patient could not swallow. See graph 2.

A direct relationship was observed between pharmacological risk and Extreme polypharmacy (more than 10 medications of chronic use) and from this derived in the presence of Medication errors, drug interactions of clinical relevance, suspicions of adverse reactions and non-Adherence. to

NECAF 1.0 (IPRES adaptation of the DETI Method of Pharmaceutical Care and Pharmacotherapeutic Monitoring)					
Surprise Question					
Do you suspect that the patient has a Medication-Related Problem (DRP) or a Negative Medication-Related Outcome (NMR)?					
YES / NO	**"+ At least 30 points on the scale"**		**YES /NO**	New patient to be evaluated	
DIMENSION TYPE	**DIMENSION**	**DEFINITION**	**Answer**	**POINTS**	**General Pharmacological Risk**
Sociodemographic Variables	**Age/Type of Population**	The patient is 60 years or older (Older adult)	YES/NO	0 ó 7	New Patient to be Evaluated
Clinical Variables and Health Services Utilization	**Comorbidity**	The patient has two or more chronic diseases with special complexity or comorbidity	YES/NO	0 ó 5	
	Dependence on a caregiver	The patient has severe functional dependence	YES/NO	0 ó 3	
	Physiological conditions that affect the pharmacokinetics of the medications you receive	The patient has Physiological Conditions that affect the pharmacokinetics of the medications he receives (Kidney, Hepatic Impairment, Obesity).	YES/NO	0 ó 7	
	Multiple consultation (more than 6 consultations per year) or Attended by different doctors (more than 3 different doctors in the last 3 months)	The patient consults on average between general and specialized medicine 6 or more times a year or is treated by more than 3 different doctors in the last 3 months	YES/NO	0 ó 5	
Variables related to medication	**History of Allergy or Adverse Reaction to Medications**	The patient has a history of allergies or has had an adverse reaction to any medication.	YES/NO	0 ó 7	
	Chronic use medications (Use for more than 3 months)	The patient receives between 6 and 9 (A), 10 and 15 (B) or C (more than 16) Chronic use medications	NO/A, B o C	0, 3, 5 or 7	
	Medicines with a narrow therapeutic range	The patient receives a medication with a narrow therapeutic range	YES/ NO	0 or 7	
	High Risk Medication	The patient takes any medication included in the Spanish ISMP list of high-risk medications in hospitals and/ or in the American ISMP list of high-risk outpatient medications.	YES /NO	0 or 7	
	Non-adherence and/or Self-medication	There is suspicion or evidence that the patient is not adhering to his treatment.	YES/NO	0 or 7	
	Medication requiring Special Handling	The patient receives medications that require special handling due to their pharmaceutical technology or because the patient cannot swallow.	YES/NO	0 or 3	
Total					
NO	**"+ At least 30 points on the scale"**		NO	NECAF NEGATIVE Does not require pharmaceutical care	
			YES	NECAF POSITIVE Requires General Pharmaceutical Care	
YES	**"+ At least 30 points on the scale"**		NO	NECAF POSITIVE Requires General Pharmaceutical Care	
			YES	NECAF POSITIVE Requires Specialized Pharmaceutical Care	

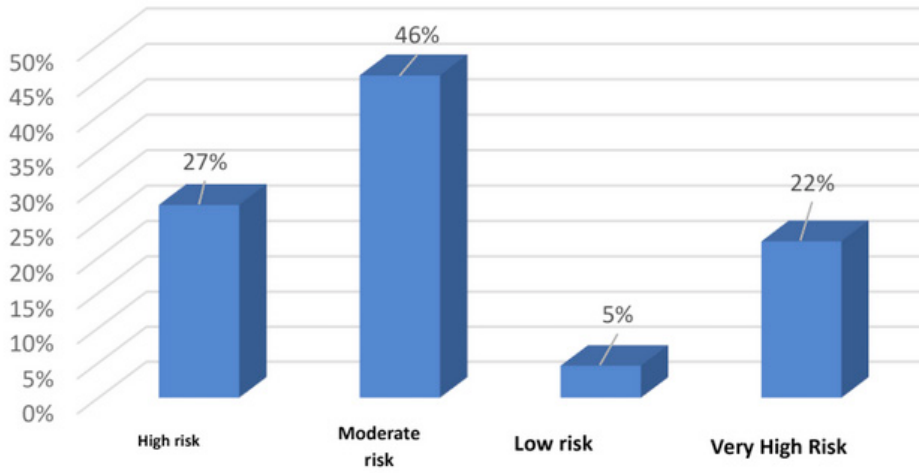
Table 1. NECAF 1.0-IPRES Adaptation of the DETI Method of Pharmaceutical Care and Pharmacotherapeutic Monitoring

DIMENSION TYPE	DIMENSION	DEFINITION	PUNCTUATION
Sociodemographic Variables	Age/Type of Population	The patient is 60 years or older (Older adult)	7
Clinical Variables and Health Services Utilization	Comorbidity	The patient has two or more chronic diseases with special complexity or comorbidity	5
	Dependence on a caregiver	The patient has severe functional dependence	3
	Physiological conditions that affect the pharmacokinetics of the medications you receive	The patient has Physiological Conditions that affect the pharmacokinetics of the medications he receives (Kidney, Hepatic Impairment, Obesity).	7
	Polyconsultant	The patient consults on average between general and specialized medicine 6 or more times a year or is treated by more than 3 different doctors in the last 3 months	5
Variables related to medication	History of Allergy or Adverse Reaction to Medications	The patient has a history of allergies or has had an adverse reaction to any medication.	7
	Chronic use medications (Use for more than 3 months)	The patient receives more than 16 chronic use medications	7
		The patient receives between 10 and 15 Chronic Use Medications	5
		The patient receives between 6 and 9 Chronic Use Medications	3
	Medicines with a narrow therapeutic range	The patient receives a medication with a narrow therapeutic range	7
	High Risk Medication	The patient takes any medication included in the Spanish ISMP list of high-risk medications in hospitals and/or in the American ISMP list of high-risk outpatient medications.	7
	Non-adherence and/or Self-medication	There is suspicion or evidence that the patient is not adhering to his treatment.	7
	Anticholinergic Risk ARS Scale	The patient receives medication(s) whose anticholinergic load is VERY STRONG	7
		The patient receives medication(s) whose anticholinergic load is STRONG	5
		The patient receives medication(s) whose anticholinergic load is MODERATE	3
	Drug Interactions of Clinical Relevance	In the treatment you receive, drug interactions classified as MAJOR WITH OR WITHOUT MODERATE are identified.	7
		In the treatment you receive, drug interactions classified as MODERATE WITH OR WITHOUT MINOR are identified.	5
	Potentially Inappropriate Medications (PPI) STOPP Categories	The patient receives Potentially Inappropriate Medications (PPI) STOPP Categories	7
	Medication requiring Special Handling	The patient receives medications that require special handling due to their pharmaceutical technology or because the patient cannot swallow.	3
		Maximum total score in the model:	86

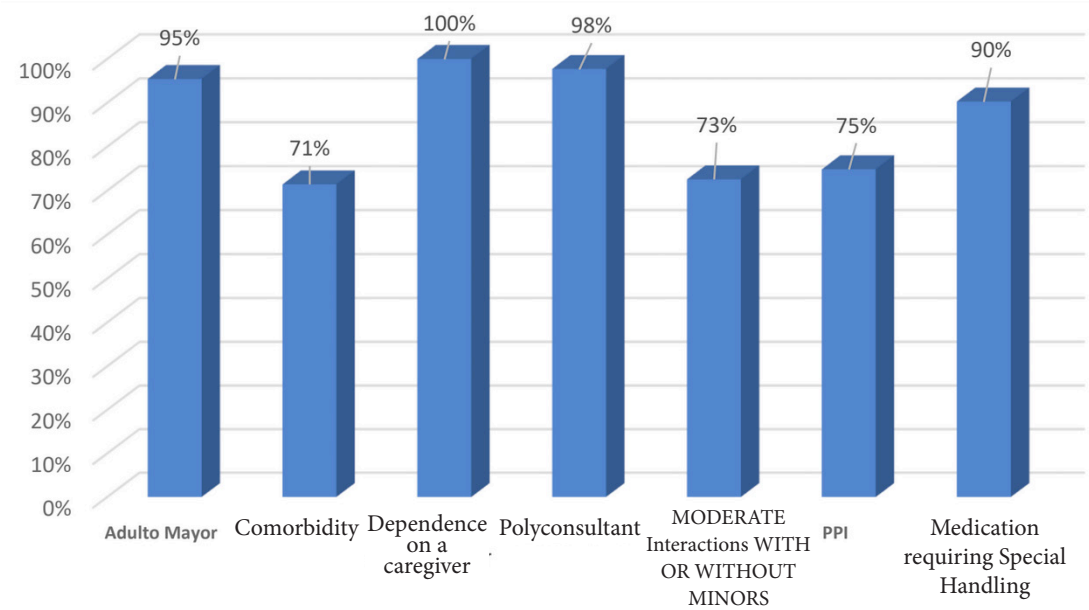
Table 2. Dimensions and subdimensions of the Validated Individual Pharmacological Risk Assessment Scale

Low Risk (<=29 Points)	Patient with clinical and environmental conditions with **LOW PROBABILITY** of presenting Adverse situations or Health Problems associated with your use of the Medications you receive. **May require Pharmaceutical Care. Served and discharged**
Moderate Risk (30 and 49 Points)	Patient with clinical and environmental conditions with **MODERATE PROBABILITY** of presenting Adverse situations or Health Problems associated with your use of the Medications you receive. **Requires Pharmaceutical Care and Pharmacotherapeutic Follow-up Every 6 Months or sooner depending on clinical condition**
High Risk (50 and 59 Points)	Patient with clinical and environmental conditions with **ALTA PROBABILIDAD** of presenting Adverse situations or Health Problems associated with your use of the Medications you receive. **Requires Pharmaceutical Care and Pharmacotherapeutic Follow-up Every 3 Months or sooner depending on clinical condition**
Very High Risk (>=60)	Patient with clinical and environmental conditions with **VERY HIGH PROBABILITY** of presenting Adverse situations or Health Problems associated with your use of the Medications you receive. **Requires Pharmaceutical Care and Pharmacotherapeutic Follow-up Every 2 months or sooner depending on clinical condition**

Table 3. Interpretation of IPRES Results



Graphic 1 . Distribution of Pharmacological Risk of the Home Care Population



Graph 2. Distribution of the most frequent variables of the IPRES in the study

PPI: Potentially Inappropriate Prescribing

treatment. See Table 4 and 5.

An average of 11.3 ± 3.91 medications per patient was evident. Patients who received ≤ 5 Medications presented 0.83 ± 1.17 Moderate Interactions and no Major Interactions, those who received between 6 to 9 Medications Presented 1.69 ± 1.38 Moderate Interactions and 0.07 ± 0.26 Major Interactions, those who received between 10 to 15 Medications Presented 3.92 ± 2.42 Interactions Moderate and 0.43 ± 0.65 Major Interactions, those who received between 16 to 19 Medications Presented 6.73 ± 3.37 Moderate Interactions and 0.47 ± 0.74 Major Interactions and those who received ≥ 20 Medications Presented 8.50 ± 1.22 Moderate Interactions and 0 1.50 ± 1.22 Major Interactions. The level of polypharmacy was highest within the age categories ≥80 years and 70 to 79 years, respectively. See Table 6

DISCUSSION

As described by Ospina et al. 2011(4) and the American College of Clinical P… 2008 (3), the Pharmaceutical Chemist must ensure that patients receive adequate and safe treatment, according to their individual needs, preventing and resolving drug-related problems, improving effectiveness. of the treatment, reduce the risk of side effects and guarantee that patients receive the correct dose and the appropriate duration of treatment. In this research, by carrying out the Individual Pharmacological Risk Assessment using the IPRES used in the DETI Method, it was achieved this end in an efficient and methodological manner.

Currently, there are scales or strategies that evaluate some risks in specific population groups, related to increased mortality, greater functional and cognitive deterioration, greater hospital admissions, greater use of medical consultation and emergency services (5–38,40–45), but they do not consider some important variables that are found during pharmaceutical care; The IPRES of the DETI method integrates relevant variables, such as: Sociodemographic, Clinical and Use of Health Services Variables and related to medication, allowing an Individual and comprehensive evaluation of the pharmacological risk to which a patient is exposed in an efficient manner, providing In addition, criteria that during Pharmaceutical care allow for the identification of variables that are susceptible to modification in order to minimize or eliminate risks and in turn would lead to monitoring of signs and symptoms suggestive of events associated with pharmacotherapy, guiding the definition of actions. Specific Pharmaceutical Care on patients and define the need for Pharmaceutical Care and the frequency of pharmaceutical follow-up required, something that is not evident in the reviewed literature.(47,49)

In the literature, there is no information related to the concept "**Pharmacological Risk**", however, it is relevant to consider the definition proposed by the DETI Method of Pharmaceutical Care and Pharmacotherapeutic Monitoring, which defines it as "those adverse situations to which a patient is exposed. particular patient when receiving any pharmacological treatment, said risk is conditioned by factors inherent to the treatment, the individual characteristics of the patients and their environment" whose variables are contained and valued in the IPRES, as an input to establish a safe and comprehensive management of the pharmacotherapy in treated patients. (47.49)

CONCLUSIONS

In the study population, the pharmacological risk to which a patient is exposed according to the IPRES is evident by the variables measured and according to its quantification, 95% of them require Pharmaceutical attention and Pharmacotherapeutic Follow-up Every 2, 3 or

AT-RISK GROUP	EP	ED	EA	EdeA	INT	MV	Suspected RAMs	Adverse Event
High risk	12	2	6	0	208	0	9	0
Moderate Risk	20	1	4	0	200	0	13	0
Low risk	1	0	1	0	5	0	1	0
Very High Risk	16	5	13	0	250	0	8	1
Grand Total	49	8	24	0	663	0	31	1

Table 5. Distribution of pharmacosafety findings 2

INT: Drug Interactions of Clinical Relevance.

		DRUG INTERACTION	
MEDICATION RANGE PER PATIENT	**Medication Per Patient**	**MODERATE**	**GREATER**
≤ 5 Medications	3.83 ± 1.31	0.83 ± 1.17	0.00 ± 0.00
6 to 9 Medications	7.85 ± 1.03	1.69 ± 1.38	0.07 ± 0.26
10 to 15 Medications	12.16 ± 1.75	3.92 ± 2.42	0.43 ± 0.65
16 to 19 Medications	17.13 ± 1.25	6.73 ± 3.37	0.47 ± 0.74
≥ 20 Medications	22.16 ± 2.40	8.50 ± 1.22	1.50 ± 1.22

Table 6. Polypharmacy and Drug Interactions

AT-RISK GROUP	Average number of chronic medications	Average INT	There is suspicion or evidence that the patient is not adhering to his treatment.
High risk	12	4	48
Moderate Risk	10	3	80
Low risk	8	2	8
Very High Risk	15	7	39
Grand Total	11	4	175

Table 4. Distribution of pharmacosafety findings 1

EP: Prescription Errors, **ED:** Dispensing Errors, **EA:** Administration Errors, **EdeA:** Storage Error, **INT:** Clinically Relevant Drug Interactions, **MV:** Expired Medications, **ADRs:** Adverse Drug Reactions,

6 Months or sooner depending on condition clinic due to its VERY HIGH, HIGH and MODERATE PROBABILITY of presenting Adverse situations or Health Problems associated with the use of the Medications you receive.

According to the indications of the DETI Method, the patients in the study are exposed to Cross Allergies, Medication Errors, Falls, to be receiving medications as part of the Therapeutic Cascade, to present clinical manifestations of Drug Interactions and PPIs, to be receiving Therapeutic duplications, to present marked anticholinergic effects, to present consequences of drug preparation error, to therapeutic failures and toxicity, to reactions and to adverse events, which is why it guides to intervene during consultations with the following Action Strategy: Deprescription, Alternatives more safe, Dose Adjustment, Risk Monitoring, Administration Schedule Adjustment, Avoid interchangeability, Monitor Efficacy and Toxicity, Health Educate about the safe use of Medications and select Alternatives with less anticholinergic load.

Clinically relevant drug interactions increase with the number of medications consumed. As polypharmacy increases, the risk of major interactions increases, with this being more prevalent in patients with more than 10 medications.

CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

FINANCING

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