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ENHANCING PATIENT SAFETY THROUGH THERAPEUTIC RECONCILIATION: LESSONS LEARNED FROM A CLINICAL IMPLEMENTATION

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ABSTRACT:

Introduction: Therapeutic reconciliation aims to mitigate medication errors and adverse events by ensuring consistency in medication regimens during care transitions, thereby enhancing patient safety. This study conducted pilot research to assess the feasibility of implementing therapeutic reconciliation at hospital admission and identify resource requirements for its clinical practice.

Materials and Procedures: The pilot study involved 100 patients over 18 admitted to an internal medicine service between October and December of the previous year and receiving at least one chronic medication. A systematic approach was employed to gather the best possible pharmacotherapeutic history, identify discrepancies, categorize them, and implement resolutions.

Results: The study sample, with an average age of 77.04 years, predominantly comprised polymedicated individuals with multiple comorbidities. Seven hundred ninety-one disparities were identified, with intentional discrepancies accounting for 50.9% of cases. Challenges encountered included limited availability and quality of therapeutic information and difficulties in interprofessional communication. Priority resources were identified across process, tools, and personnel categories.

Conclusion: The study findings underscored deficiencies in clinical records at the interface between primary care and hospitals. Opportunities for optimization include prioritizing certain patient groups, standardizing and computerizing the reconciliation process, fostering multidisciplinary collaboration, and optimizing data sources. These insights offer valuable guidance for enhancing therapeutic reconciliation practices and improving patient safety during care transitions.

KEYWORDS: Internal medicine, transition care, medication reconciliation, medication mistakes, and patient safety.

INTRODUCTION:

"A process of analyzing a patient's medication, whenever changes occur in the medication, to avoid discrepancies, that is, omissions, duplications, or inappropriate doses, promoting medication adherence and contributing to the prevention of medication-related incidents," is how the General

Directorate of Health (DGS) defines therapeutic reconciliation. Given the rise in life expectancy overall and the corresponding rise in the number of older adults utilizing health services, as well as the prevalence of numerous diseases and chronic polypharmacy, this intervention has become especially pertinent. The process of therapeutic reconciliation involves a systematic assessment of all medications introduced, altered, or removed from a patient during their care transition. This critical period is thought to be the most susceptible to errors and, as a result, the most suitable for applying preventive measures [1].

To ensure necessary services and normalize communication between health professionals, the DGS determined through the Standard that Pakistan medical institutions must encourage the adoption of therapeutic conciliation details regarding the patient's prescription regimen. The foundation of therapeutic reconciliation is that pharmacotherapeutic information is effectively conveyed in the continuity of care based on an up-to-date and trustworthy list of the present therapeutic regimen. The treatment will then be developed and optimized on this foundation. Therapy plan concurrently, as the clinical circumstance dictates. The Best Possible Drug History (BPMH) is the first list the clinical team can use to get a global therapeutic view of the patient [2]. It also helps minimize the likelihood of missing critical information while creating the hospital discharge plan. Be successfully conveyed to the patient or the following service. Inconsistencies may arise during hospitalization, at admission, or upon release from the hospital. Analysis of 15 articles covering 6,000 hospital discharges revealed a variation in the number of patients with therapy-related discrepancies from 20% to 87% in a review on therapeutic reconciliation in the patient's transition from hospital to primary health care5. This underscores the necessity of transversing this information to the entire health system. Although these interventions have strengthened patient safety practices, they necessitate excellent information communication between various individuals, technology, procedures, and services during the care transition. Because of the requirement for resources and integration into an existing workflow, hospitals continue to confront numerous problems when implementing this tool in clinical practice [3]. These challenges arise from reconciling various clinical, behavioral, and organizational factors. Initiatives in this regard are frequently developed individually and with the adaption of international models even today due to the lack of defined measurements and concept uniformity across the European Union member states. They, therefore, assessed the potential contributions of the primary information sources to the BPMH to deepen this knowledge at the national level.

Table 1: Definitions and Importance

No.	Aspect	Description	Reference
1	Definition of Therapeutic Reconciliation	A process of analyzing a patient's medication, whenever changes occur, to avoid discrepancies, promote medication adherence, and prevent medication-related incidents.	[1]
2	Importance due to Demographics	Given the rise in life expectancy and the corresponding rise in the number of older adults utilizing health services, as well as the prevalence of numerous diseases and chronic polypharmacy, this intervention has become especially pertinent.	[1]
3	Critical Period for Reconciliation	The process involves a systematic assessment of all medications introduced, altered, or removed during a patient's care transition, which is considered the most susceptible to errors and thus suitable for preventive measures.	[1]

Table 2: Process and Implementation

No.	Aspect	Description	Reference
1	DGS Standard for Institutions	DGS determined that Pakistan medical institutions must encourage the adoption of therapeutic conciliation details regarding the patient's prescription regimen.	[2]

2	Foundation of Therapeutic Reconciliation	Pharmacotherapeutic information must be effectively conveyed in the continuity of care based on an up-to-date and trustworthy list of the present therapeutic regimen.	[2]
3	Best Possible Drug History (BPMH)	The BPMH is the first list the clinical team can use to get a global therapeutic view of the patient, minimizing the likelihood of missing critical information.	[2]

Table 3: Challenges and Communication

No.	Aspect	Description	Reference
1	Therapy-Related Discrepancies	Analysis of 15 articles covering 6,000 hospital discharges revealed a variation in the number of patients with therapy-related discrepancies from 20% to 87%.	[3]
2	Necessity of Effective Communication	These interventions necessitate excellent communication between various individuals, technology, procedures, and services during the care transition.	[3]
3	Implementation Challenges	Hospitals continue to face challenges in implementing this tool in clinical practice due to the requirement for resources and integration into an existing workflow.	[3]

Table 4: Research and Electronic Health Records

No.	Aspect	Description	Reference
1	Variability in EU Practices	Initiatives are frequently developed individually and with the adaption of international models due to the lack of defined measurements and concept uniformity across EU member states.	[4]
2	Contribution of Primary Information Sources	Assessing the potential contributions of primary information sources in Pakistan, especially electronic health records, to improve the accuracy of therapeutic information.	[4]
3	Pilot Research Goals	Conducting pilot research at the time of hospital admission to determine the resources required for therapeutic reconciliation in clinical practice.	[4]

Table 5: Summary of Key Points

No.	Key Point	Summary	Reference
1	Definition and Importance	Therapeutic reconciliation is crucial due to demographic changes and chronic polypharmacy. It involves systematic medication assessment during care transitions.	[1]
2	Implementation Foundation	Based on the BPMH, therapeutic reconciliation ensures effective communication of pharmacotherapeutic information.	[2]
3	Discrepancies and Challenges	Significant variation in therapy-related discrepancies highlights the need for effective communication and addressing implementation challenges.	[3]
4	Research and EHRs	Pilot research emphasizes the importance of electronic health records in improving therapeutic information accuracy and identifies necessary resources for implementation.	[4]

They did this by highlighting the significance of electronic health records, particularly the platform of health department data (PDS), in improving the accuracy of therapeutic information, especially when considering a six-month look-back period until hospitalization. As a follow-up to this work, our goal was to conduct a therapeutic reconciliation pilot research at the time of hospital admission to determine what resources would be required for its application in clinical practice [4].

METHOD AND MATERIAL:

Prospective pilot research was conducted in the Internal Medicine Service of the AIMC, a public medical research university in Lahore, Punjab, Pakistan, between October and December of the

previous year. The same institution's ethics committee gave the study its approval. The study covered the first 100 individuals over the age of 18 who were admitted to the Internal Medicine service and were using at least one prescription drug at home. Situations where conducting the interview was not feasible, like patients without communication difficulties or when a family member or carer was not present (as is the case in social instances), were classified as exclusion criteria. According to the DGS, admission was selected as the transition point since it is the first crucial factor to consider when implementing therapeutic conciliation at the hospital care level [5]. The investigation was conducted in phases:

- They were gathering general information and sociodemographic data. A particular form was filled out with the patient's clinical circumstances (comorbidities, allergies, and clinical parameters), habits (smoking, alcohol, and autonomy in medication management), and sociodemographic information (sex, age, type of residence, and index of basic activities of daily life). The patient's computerized process, the computer programs Hospital Clínic (history of clinical episodes and current clinical evolution), SGCIM (integrated medication circuit management system - prescription module), and ALERT (emergency care software - admission data, clinical evolution, and prescription) were used to gather information. We refer to actual clinical records as well [6].
- They are compiling the BPMH and acquiring the prehospital pharmacotherapeutic profile. Hospital records, the Electronic Medical Record (EHR) in the Health Data Platform (PDS), seven outpatient prescriptions, lists and bags of medications brought by the patient or from long-term care facilities, as well as other prescriptions, discharge plans, and the status of prior hospitalizations, are all included in the retrospective period that lasts six months from the date of hospital admission. The list of chronic drugs, the medication dispensing history, and the availability and updating status of prescriptions for the last six months were examined during the PDS consultation [7].

As this information was considered the most accurate, the pharmacist-researcher finished this stage by conducting a semi-structured interview with each participant (patient/caregiver). We created the BPMH, which enables the identification of medications of chronic prehospital use (name of the drug, dosage, pharmaceutical form, frequency, and route of administration) after comparing the data from the interview with at least one of the data from the above sources. Herbal remedies and medicinal infusions were considered, as were all prehospital drugs, whether prescribed or not. Additionally taken into consideration were prescription drugs with a set duration of use for patients undergoing treatment on the day of admission. The term polypharmacy refers to the use of five or more drugs [8].

- They were examining the hospitalization prescription and finding any inconsistencies. Following acquiring the BPMH, the investigator reviewed the legitimate hospitalization prescription during the initial twenty-four hours of each patient's admission to gather information on the drugs. There were inconsistencies when comparing the medication given upon admission with the prehospital medication data in the BPMH [9].
- Discrepancy classification. Upon identification, differences were categorized based on their documentation and intentions. They were also classified according to Severity and categories, and the pharmacotherapeutic classes were noted. These include altering the dosage, frequency, pharmaceutical form, administration route, therapeutic substitution, and inclusion or exclusion of a medication. The 'conciliation' category for medication errors was also taken into consideration. This category describes circumstances where the patient's usual medication should not have been continued based on their clinical parameters at admission or where medication was started but stopped before admission [10].

Intentional discrepancies (ID) - DIs can be subdivided into 'documented' (when the justification for the change is properly recorded in the clinical record) or 'undocumented' (when the justification is

not documented). In this case, they were divided into three categories related to the rationale for the change: by changes in clinical parameters, by following therapeutic guidelines or hospital protocols, or by an additional need for confirmation of the justification by the prescribing physician [11].
Unintentional discrepancies (DNI) or medication errors - The assessment of DNI and categorization used the severity/potential to cause harm criteria. They were evaluated by a doctor specializing in clinical pharmacology regardless of the study unit, knowing only the information necessary to exercise clinical judgment. The categorization followed the severity model, which considers them "not clinically important", "clinically significant", "clinically serious" or "life-threatening" [12].
Communication of discrepancies. At the end of the process, the identified discrepancies that required evaluation were communicated to the prescribing physician in person or via computer for subsequent resolution when necessary. A quantitative descriptive analysis of the data sources used to obtain the BPMH of each patient was carried out, in addition to characterizing the age, number of medications and comorbidities, place of origin, admission method, number of discrepancies, and their classification. The information collected was entered into the Microsoft Office Excel 2019 database and analyzed using SPSS 2019 software. The analyzed variables' absolute and relative frequencies (percentages) and the means and standard deviations were calculated [13]. The therapeutic conciliation was also analyzed from a qualitative point of view to identify the resources necessary for its implementation upon hospital admission and identify opportunities to optimize existing resources [14].

RESULTS:

Population Characterization

The study population had a mean age of 77.04 ± 13.74 years (mean ± standard deviation); 80% were ≥ 65 years old, and 33% were women (Table 1). Prehospital medications were 7.72 ± 3.01 medications/patient, ranging between one and 14. Polypharmacy was identified in 85% of the participants, as well as a typical profile of multiple comorbidities (Table 2), the most prevalent being respiratory failure, high blood pressure, and type 2 diabetes mellitus. Diseases of the respiratory system (32%), mainly bacterial pneumonia (ICD J15), followed by diseases corresponding to the circulatory (16%), genitourinary (14%), and digestive (12%) systems.

Data sources for obtaining BPMH

Construction of the BPMH took an average of 41.80 ± 8.40 minutes per patient. The average interview time was 11.0 ± 3.20 minutes, with the remaining time spent consulting other data sources. The interview had to be carried out accompanied by a family member in 48% of the situations; In 22%, it was possible only with the patient, and in the cases of standardized patients, in which the family member did not know how to provide the information, this was confirmed with the address. The medication list provided by the patient or home was consulted by 49% of the participants, and the medication bag was consulted by 25% [3, 16].
In 17% of the patients, accessing the PDS for any of the three items (prescription in the last six months, list of chronic medications, and medication dispensing history) was impossible. In 83% of the patients in whom access to the PDS was possible, the "dispensing history" was the element that was always available. However, 54% did not have the item 'prescription for the last six months' available, and 70%, despite having the 'list of chronic medications' available, was outdated in 59% of the situations. Compare it with the information obtained in the interview [17].

Identification and classification of discrepancies.

In total, 791 discrepancies were identified, with intentional discrepancies classified as documented (95.7%) in 50.9% of the situations. Undocumented intentional discrepancies were analyzed and divided as justified by clinical conditions and parameters (15.05%), by hospital protocols and guidelines (43.55%), and by the need for additional confirmation with the physician (41.40%). The categorization of discrepancies (DI and DNI) is described in Figures 1 and 2, respectively [18].In 22 patients, 34 DNI or medication mistakes were found. The majority of the possible harm, 55.88%,

involved omitting analgesic or antidyslipidemic drugs, which were assessed as having little clinical significance for the patient. Eight and two patients accounted for the discrepancies categorized as possibly causing clinically substantial or severe damage; these patients comprised 32.35% and 11.76% of the total IND. Conciliation and omission (90.90%) were the categories into which the discrepancies evaluated as having the potential for clinically significant harm were classified. The latter involved anxiolytic drugs (27.27%), antidepressants (18.18%), antiemetics (18.18%), anti-inflammatory medications (18.18%), vasoprotective (9.09%), and adrenergic inhalers associated with corticosteroids (9.09%). The differences assessed as clinically significant impact all medications that influence the cardiovascular system, especially diuretics (50%) and beta-blockers (50%). The categories in question were conciliation (25%), dose modification (25%), and omission (50%) [19].

Resources that are required and chances for optimization

The absence of computer tools to support the process, inconsistent therapeutic information records and their modifications, access issues to the family member or healthcare facility (time spent obtaining the interview, medication lists or bags), and the doctor's unavailability for communication, feedback, and resolving discrepancies were among the challenges noted during the therapeutic conciliation process. Six significant areas included the resources required for therapeutic reconciliation's successful and long-term application in clinical practice: process, people, management, tools, and training. When one or more of these tools are ineffective, there may be issues with how therapeutic conciliation can be applied, which automatically sets them up as intervention sites (Fig. 3). Based on the challenges found in the study, the categories of process, tools, and staff comprised the majority of the resources [20].

DISCUSSION:

Therapeutic reconciliation is offered as the first, and possibly most important, piece of the puzzle involving the management of therapeutic information in the transfer of attention, even though it cannot reduce medication errors or increase patient safety. To execute more thorough action plans, one must begin at the beginning and construct the route gradually. To do this, we conducted the pilot study presented here. This allowed us to map the required primary resources, which allowed us to identify optimization opportunities. These opportunities are tactics and measures that lower the barriers to the conciliation process and increase its applicability.

The demographic analysis supports an earlier study on the development of the internal medicine service at this same institution over the last 20 years. These factors, which are expected in internal medicine units and are risk factors in the transition of care, include a high prevalence of elderly patients, multiple pathologies, polypharmacy, and limited autonomy in medication management. As a result, therapeutic conciliation, promoted as a crucial support tool that can help identify medication errors and their subsequent prevention, becomes a viable option for these services. Of unfavorable incidents linked to a breakdown in communication between the patient and the provider and between services. 49.14% of the disparities that were determined to be deliberate were found to be undocumented, meaning that the patient's clinical history had not been changed with a valid reason.

When inconsistencies were analyzed, 49.14% of those deemed purposeful were categorized as undocumented since documentation did not support modifying the patient's clinical record. These differences are regarded as errors in the documentation. Of these, 41.40% needed further explanations from the prescriber regarding various major therapeutic classes, including antidyslipidemics and antiemetics, since they did not meet the requirements for purposeful change based on clinical characteristics or therapeutic exchange. Even when they are intentional, undocumented discrepancies affect the resources needed and the outcome of therapeutic reconciliation because they can cause confusion, necessitate further clarification, and result in future medication, even though they are not regarded as medication errors and frequently do not pose an immediate risk to patient safety, mistakes made, for instance, upon hospital discharge. The

introduction of a new medication (such as anti-infective agents), the removal of prior medicines (such as the discontinuation of oral antihypertensives), and the therapeutic substitution of one medication for another with the same therapeutic effect are some examples of the categories of intentional discrepancies that have been identified. The most common categories were objective (for example, switching from oral antidiabetics to subcutaneous insulin). When using therapeutic conciliation, it's critical to realize that deliberate modifications to the patient's treatment plan are frequently supported by the clinical condition that led to the hospitalization, the established therapeutic response plan, and the hospital's therapeutic resource pool. Even if there is intentionality in the disparities, they must be documented, accessible for consultation, and effectively communicated between the patient and the specialists so that the patient knows which prescriptions have been stopped when they return to their regular lives, adapted or included. Herein lies the significance of conciliation, both upon admission and discharge, as it facilitates the dissemination of therapeutic information during the hospital stay and aids in creating the discharge plan, thereby fortifying the patient's appropriate treatment compliance and improving the attainment of predetermined clinical goals. In turn, accidental differences allowed the most common category of medication omissions (e.g., drugs that affect the cardiovascular and central nervous systems) to be identified, consistent with findings reported in the literature.

This happens when a patient quits taking a drug they were previously taking while they are in the hospital. There could be several causes for this, including ineffective communication. However, the drug skipped, and the patient's clinical state will determine the therapeutic importance of this omission (e.g., forgetting antiepileptics or beta-agonists). Adrenergic and the potential for withdrawal symptoms, including rebound effects or withdrawal syndromes. These mistakes frequently result in a delay or even the inability to diagnose conditions brought on by using specific medications that may have directly or indirectly resulted in hospital admission. Thus, the data on therapeutic information access, acquisition, and registration, as well as its modifications, showed where documentation process breakdowns occurred and emphasized the necessity for protocols for therapeutic information registration and the creation and improvement of instruments that facilitate the conciliation process. This information is more systematically organized, facilitating transmission and communication during and after hospital stays. The average time for the therapeutic reconciliation process, which involved gathering and documenting therapeutic information in the consulted data sources, was 41.8 ± 8.4 minutes per patient. This is comparable to other studies that found an average of 47.0 ± 18.0 minutes in an Internal Medicine service in the country. Numerous factors could influence how long the therapeutic reconciliation process takes. The patient's ability to deliver information is correlated with how well-informed they are about their treatment plan or current clinical state. In these circumstances, the family member or organization with you is an information source to consider. Nonetheless, the timely or comprehensive availability of the information is frequently jeopardized by the difficulties in getting in touch with them or their ignorance of the patient's therapy. In this situation, computerized primary care records and lists, or even prescriptions carried in person to the hospital, can assist in gathering data.

These elements are contingent upon access and update availability, which establishes the required resources and impacts the completion of the reconciliation within the initial twenty-four hours of entry. As evidenced by the results (Fig. 3), therapeutic conciliation is a process that necessitates coordinated and integrated actions. As such, several resources, including national regulations, the process itself, the participants (including professionals, patients, and caregivers), local management and other services, the tools available, and the training of those involved, can have an impact. In the context of hospital admission, this combination of factors necessitates time that professionals frequently do not have. This emphasizes the significance of process mapping, critical point identification, and intervention actions based on the contribution of technology and shared actions within the health team. We separated optimization opportunities from the prioritized resources into four main categories. These could improve the applicability of therapeutic reconciliation in the

service by addressing deficiencies like the absence of reliable electronic records (PDS, for example) or by classifying omission frequency as the most common discrepancy category.
The following are the opportunities: multidisciplinary action-definition of responsibilities, integrated actions, and greater involvement of hospital pharmaceutical services; definition of priority groups, based on the mapping of the patient profile and discrepancies and the subsequent risk stratification; standardization and computerization of the process - integration of therapeutic information from admission to hospital discharge with reduction of duplications, confusing information, and standardization of records. The opportunities found or documented in the literature as enabling elements support the findings of additional analyses conducted during the transition of care, which aim to pinpoint methods for organizing safe medication practices. The success of the interventions may be jeopardized since many institutions lack the tools needed to apply conciliation widely.

In this case, service management fears resource availability because the benefits are not sufficiently conspicuous. This ultimately makes it difficult to visualize the anticipated outcomes, hinders the precise observation of the tool's impact in clinical practice, and makes its adoption challenging. Therefore, through defining priorities and subsequently improving the targeting of already available resources, pilot studies such as this one can help in this regard. Understanding the current flows and procedures is crucial to promoting consistent actions that allow progress, as the deployment of an inadequate reconciliation process can jeopardize patient safety instead of ensuring it. As a result, determining the service's profile regarding primary diseases, medications, and disparities enables more targeted and informed activities based on actual data.

CONTRIBUTIONS AND LIMITATIONS:

This study aimed to determine current practices, evaluate essential issues, and highlight tactics supporting this and other services with comparable features. Its shortcomings include the absence of a comparison group or history, as well as the absence of a pharmacist employed in clinical services on the clinical team. Future research can focus on two aspects of this project: applying the previously indicated optimizations and validating the suggested method in additional services.

Implications for clinical practice

The planning and structuring of the process, including the creation of protocols, roles, and quality indicator monitoring, as well as the reliability of databases and clinical information systems, are the primary resources needed to apply therapeutic conciliation in clinical practice. Accessible, their integration, update, and inter-service access. Lastly, we may emphasize the necessity of the multidisciplinary team's availability and cooperation and the patient's or his representative's involvement in transition care to find a less costly procedure that improves the patient's safety tolerance. Therapeutic conciliation needs to be viewed and handled with the overall goal of patient safety, not just during the hospital stay but throughout the continuity. This is more than just an accreditation requirement in and of itself, which can occasionally include a bureaucratic burden and be costly. Help, encompassing the patient's residence, social services, community pharmacies, health clinics, and other medical settings.

CONCLUSION:

The findings enabled us to conclude that the hospital's internal operations and the primary care/hospital interface have flaws in how treatment information is transmitted and registered. To optimize and use therapeutic reconciliation in this service, it is essential to consider factors like improved interdisciplinary action, improved data source accessibility, and improved techniques for recording therapeutic information and its modifications.

Appendix:

Table 1: A description of the research population's sociodemographic information (n = 100)	
Study variables	**Outcomes**
Sample size, n (%)	100 (100%)
Sex, n (% female)	33 (33%)
Age, (mean ± SD)	77,04 ± 3,74
Admission Type, n (%)	
Emergency Service	94 (94%)
Outpatient consultations	6 (6%)
Residence, n (%)	
Residence	67 (67%)
Home	28 (28%)
Continuing Care Unit (CCU)	5 (5%)
Katz index, n (%)	
0	34 (34%)
1 – 2	16 (16%)
3 – 4	9 (9%)
5	13 (13%)
6	28 (28%)

Table 2: Clinical data characteristics for the study population (n = 100)	
Study variables	**Outcomes**
Sample size, n (%)	100 (100%)
Number of prehospital medications, n (%)	
1 – 4	15 (15%)
5 – 9	56 (56%)
≥ 10	29 (29%)
Autonomy in medication management, n (%)	
Sick	26 (26%)
Family member/caregiver	38 (38%)
Home professional/UCC/Day Center	36 (36%)
Number of comorbidities, n (%)	
0 – 4	10 (10%)
5 – 9	67 (67%)
10 – 15	23 (23%)
Number of prehospital medications (mean ± SD)	7,72 ± 3,01
Number of comorbidities (mean ± SD)	7,80 ± 2,53
Allergy to medications, n (%)	
Yes	8 (8%)
No	92 (92%)

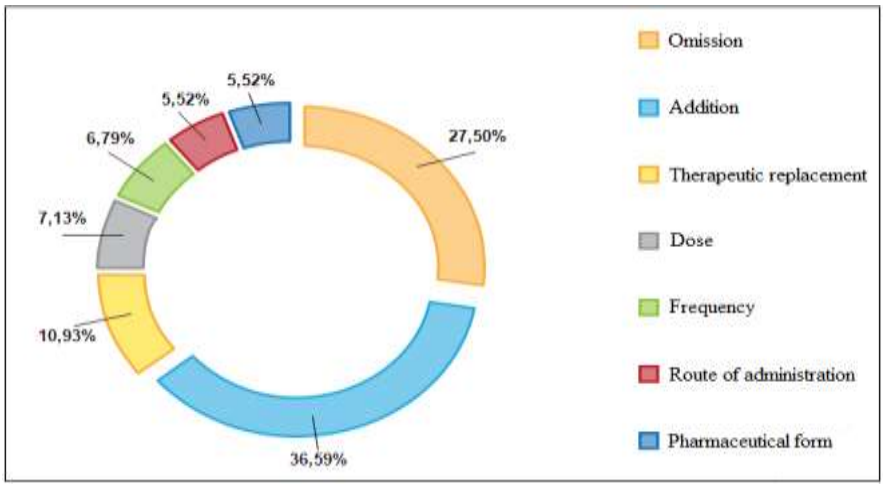

Figure 1: Intentional Discrepancies Categorized

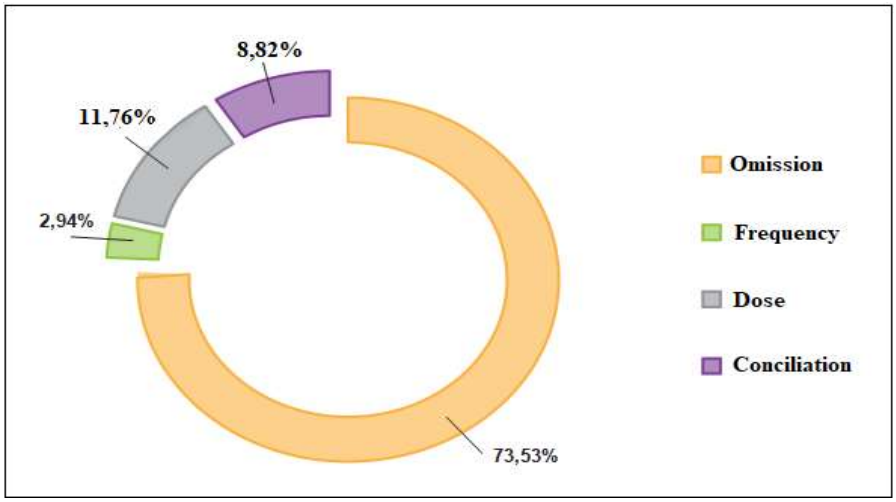

Figure 2: Unintentional Discrepancy Categorization

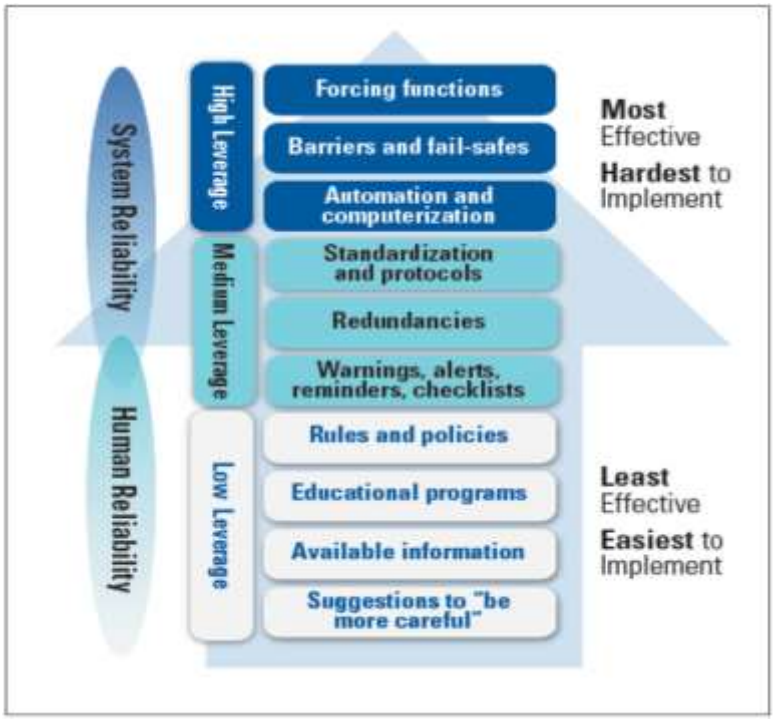

Figure 3: Resources Used in the Process of Therapeutic Reconciliation

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