Selection of tools for reconciliation, compliance and appropriateness of treatment in
patients with multiple chronic conditions

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A B S T R A C T

Background: The healthcare models developed for patients with multiple chronic diseases agree on the need
for improving drug therapy in these patients. The issues of patient compliance, appropriateness of prescrip-
tions and the reconciliation process are of vital importance for patients receiving multiple drug treatment.
Objective: To identify and select the most appropriate tools for measuring treatment compliance and appro-
priateness in multiple-disease patients, as well as the best reconciliation strategy.
Methods: The study used the Delphi methodology. We identified compliance and appropriateness question-
naires and scales, as well as functional organisation models for reconciliation that had been used in patients
with multiple chronic conditions. Based on the strength of the evidence, their usefulness in these patients
and ease of use, the panel selected the most appropriate ones.
Results: We selected 46 indications for the panel: 5 on compliance, 20 on appropriateness, and 31 on reconciliation.
The tool considered most appropriate and with a high degree of agreement was the “Adherence to Refills and
Medication Scale” questionnaire. For appropriateness, the Medication Appropriateness Index questionnaire was consid-
ered appropriate. The STOPP/START criteria were the most appropriate. The greatest degree of agreement regarding
reconciliation was on the information that needed to be collected and the variables considered as discrepancies.
Conclusions: The “Adherence to Refills and Medication Scale” questionnaire for compliance, the STOPP/START
criteria, the Medication Appropriateness Index questionnaire for appropriateness and the development of a specific
strategy for reconciliation were considered appropriate for the assessment of drug therapy in patients with multiple
chronic conditions.

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1. Introduction

The profile of patients with multiple chronic conditions (PMD) has been clearly defined in various publications [1] as those patients with
two or more chronic diseases in a list of specific clinical categories, considering severity and disability. The prevalence of this type of
patient, although low in the general population, is 38.9% of admissions to the internal medicine departments [2,3].

The care model for chronic diseases [4,5] and specific care models for patients with multiple chronic conditions agree on the need
for specific strategies for improving drug therapy in these patients.

Especially important are these three areas: compliance, appropriateness, and reconciliation.

Compliance is defined as the degree to which patients follow instructions provided to them regarding prescribed treatments [6].
Compliance rates vary considerably [7]. Moreover, compliance has been shown to be very high in short treatments and at the start of
treatments, but decreases steadily in prolonged treatments [8]. Currently, lack of compliance is a priority issue for the World Health
Organization due to its high prevalence and relationship with poorer control of the disease, increased risk of morbidity and mortality, a re-
duction in patient quality of life and increased healthcare expenditure [9]. Questionnaires are the most frequently used tools for measuring compliance, which, although subject to desirability and recall biases, are useful for their ease of administration and their applicability to clinical practice [10].

Appropriateness is a general term that includes a wide range of characteritics and behaviours related to the quality of the prescription. A prescription is considered adequate when there is clear evidence that
supports its use for the given indication, is well tolerated and has a favourable cost-effectiveness profile [11]. Additionally, in elderly patients, criteria should be considered such as prognosis, life expectancy and functional state so as to promote the use of treatments with better risk-benefit ratios [12]. Appropriateness declines with increasing numbers of drugs [13]. Results of a recent study show that the average number of daily drugs taken by PMD is 8 ± 3, which means that polymedicated patients are at high risk for inadequate medication. Moreover, the relationship between treatment inappropriateness and adverse reactions has been well established [14].

Reconciliation is defined as the formal and standardised process of obtaining the complete list of a patient’s previous medications when performing a transition between healthcare system levels or departments, comparing it to the current prescription, and analysing and resolving any discrepancies found [15]. For the first time in 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the United States [16] established that errors in reconciliation compromised the safety of medication. The National Institute for Health and Clinical Excellence (NICE), along with the National Patient Safety Agency, published a guide for solutions to medication reconciliation [17] in hospital admissions of adult patients, which concluded that studies carried out so far were insufficient to establish solid recommendations and that more research is needed on new techniques for medication reconciliation.

The aim of this study was to identify and select the most appropriate tools for measuring treatment compliance and appropriateness in patients with multiple chronic conditions, as well as the best reconciliation strategy.

2. Participants and methods

The study was performed between May and December 2010 using Delphi methodology [18]. The first step in this method consists of identifying the list of indications, which are subsequently assessed individually and anonymously by an expert panel in two successive rounds. In our case, the indications consisted of the possible tools available for assessing treatment compliance and appropriateness in PMD, and the best possible strategy for performing treatment reconciliation in these patients.

To identify the indications, we carried out a literature review (December 2009) in the PubMed, CINAHL, EMBASE, PsycINFO and IME (Spanish medical index) databases with no date limit. We identified articles that contained information on a) measurement questionnaires and scales used for assessing compliance; b) tools for assessing appropriateness of drug treatments, such as lists of prohibited or contraindicated drugs and c) functional organisation models and procedures for performing treatment reconciliation.

We included qualitative and quantitative studies, theoretical and field studies, original studies, and reviews. We excluded case reports, studies performed on patients with acute diseases, those in languages other than Spanish and English, and those where the entire text could not be recovered. Duplicate articles were removed and a selection was made by title and abstract (MDVC, ERAL and MGB), reviewing the entire text in case of doubt. Discrepancies were resolved by a third researcher (BSR).

We completed the search with grey literature. The references of the selected documents were reviewed manually.

From all identified indications for compliance and appropriateness, the researchers selected those of possible use for PMD, based on the following criteria:

a) They were developed for PMD or very similar patients (chronic, elderly with comorbidities, polymedicated, etc.);

b) They were validated or, alternatively, widely used in clinical practice, and had at least a quality fieldwork study.

An additional criterion was added for compliance: that the questionnaire allowed for a quantitative or semiquantitative estimate or that it had a design that permitted the assessment of various items according to a Likert scale.

The group of experts consisted of 11 members from 5 different autonomous communities (see Acknowledgements), and 6 of them were women. Participants included 4 specialists in hospital pharmacy, 4 in internal medicine, 2 in family medicine and 1 in primary care pharmacy. The panel was also composed of 8 experts in PMD and 7 experts on compliance, or reconciliation and appropriateness. For recruitment, members were contacted by telephone and provided with information on the study objective, possible workload and schedule. Once they accepted, they were sent a communication agreement.

The panel members were asked to consider the following aspects: strength of evidence supporting the tool, usefulness in PMD, and feasibility of its application in clinical practice. In addition, the compliance questionnaires asked about the usefulness in detecting the cause of low compliance. For appropriateness tools, the last question was split into two: feasibility of administration by clinician in the patient interview and the feasibility of application by others based on medical records.

In the second round, each panel member received a personalised sheet with their previous vote, the results of the panel assessment and all comments and/or suggestions made anonymously during the first round. Upon completion of the panel work, the research team performed the critical assessment of the result for the definitive selection of indications, as indicated by the methodology used.

3. Results

3.1. Results of the literature search and selection of indications

Table 1 shows the 46 indications that were selected for the panel from the 116 indications identified.

None of the compliance questionnaires from the 61 identified were designed, validated or at least used in PMD, although 18 of them were designed and used in the context of chronically ill and elderly patients. Only 5 met the inclusion criteria. Table 2A shows a summary of their characteristics. The remaining 13 questionnaires were rejected for the following reasons: they did not allow for quantitative or semiquantitative estimates of compliance rates, they did not have an answer system designed according to the Likert scale (5), they were insufficiently validated or lacked quality studies (3), we were unable to recover the questionnaire (4), or the assessment measured self-efficacy for compliance and not compliance itself (1).

Two appropriateness questionnaires were identified: the Medication Appropriateness Index (MAI) [19] and the Handy questionnaire [20]. Only the first was included as an indication for the panel; the second was rejected for being targeted mainly at the reduction of multiple drug treatments and for not being sufficiently validated in subsequent studies (Table 2B).

Of the 6 objective evaluation criteria identified in the search (ACOVE [21], Beers [22], CRIME [23], IPET [24], NORGEP [25] and STOPP/START [26]), 3 of them were added as indications to the panel (Beers, IPET and STOPP/START). The ACOVE, NORGEP and CRIME methods were excluded from the panel for the following reasons:

- ACOVE (Assessing Care of the Vulnerable Elders) is considered an assessment method of the quality of comprehensive care for the elderly and not just for medication (only 29% of the indicators were on treatment);

- CRIME and NORGEP criteria were specifically developed for Italian and Norwegian populations, respectively, and were published very recently (with little available evidence).
We found 14 studies that developed specific instruments, of which 6 were included in the panel.

In the search, we identified 34 variables or characteristics to consider in the organisation of a reconciliation procedure, grouping them in 31 for the panel (Table 2C).

The tools that were ultimately selected are shown in Table 3.

### 3.2. Results on compliance

The only tool considered appropriate as a whole and that had a high degree of agreement in all assessed aspects was the “Adherence to Refills and Medication Scale” (ARMS) questionnaire (Table 3).

We also considered the usefulness of the “A14-Scale” for detecting causes of non-compliance and the feasibility of its implementation in clinical practice. Agreement was not reached on the “ASK20 Adherence Barrier Questionnaire” and its feasibility of implementation in clinical practice. This was because it was considered to be excessively long, and it was determined that it was designed and validated for much younger and less complex patients. As for the “General Adherence Scale” (GAS), it was considered due to its feasibility of implementation in clinical practice, but not for other aspects. The GAS scale included more than just drug compliance, which, on one hand may be considered interesting, but on the other, may induce errors.

In the case of the Brief Medication Questionnaire (BMQ), there were doubts about its appropriateness for all evaluated aspects, with consensus between panel members in most cases. With the BMQ scale, there was special consideration given to the fact that it had been tested on few patients and on patients who were also younger and undergoing treatment with ACEIs, which made it unsuitable for the multiple disease scenario.

### 3.3. Results on the appropriateness of the treatment

Regarding the MAI questionnaire, the panel members considered it appropriate for patients with multiple chronic conditions, although it lacked strength of evidence. However, most of the items contained in the MAI questionnaire were considered appropriate, with fair agreement, except for the relatively ambiguous question on practical instructions given to the patients. Similarly, there was significant agreement on the appropriateness of other items not contained in the MAI but that were identified in field studies on appropriateness. These items are shown in Table 3.

<table>
<thead>
<tr>
<th>Articles identified</th>
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<th>Tools identified</th>
<th>Tools included in the panel</th>
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<tbody>
<tr>
<td>Compliance</td>
<td>509</td>
<td>106</td>
<td>61</td>
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<td>A14 Scale</td>
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<td>Appropriateness</td>
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<td>Medication Appropriateness Index (MAI) questionnaire (complete)</td>
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<td>5 on healthcare transitions that need reconciliation</td>
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<td>3 on reporting the reconciliation</td>
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</table>

| Total               | 830              | 220             | 116                        |

The second questionnaire (Hamdy) [25] was not selected as an indication since it was mainly targeted at reducing multiple drug treatments, and because it had not been used in any subsequent publication.

The adaptation to the Pharmaceutical Guidelines of the SEMFYC (Spanish Society of Family and Community Medicine) continues to be a point of discrepancy, lacking agreement among the panel members.

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</tbody>
</table>

| Total               | 830              | 220             | 116                        |
4. Discussion

Regarding external validation lists of treatments, there was considerable agreement that the STOPP/START criteria were the most ideal for patients with multiple chronic conditions. The Beers and IPET criteria were rejected by clear consensus due to their lack of usefulness. They were thoroughly debated by the panel members without reaching a consensus, which resulted in the criteria being rejected as useful tools for this project.

3.4. Results on reconciliation

The greatest agreement was reached in a) the selection of healthcare transitions that need reconciliation, b) information that must be collected on patient treatment and c) possible variables to consider as discrepancies. However, there were extreme scores for indications 26–29 (Table 2C) that led to an intermediate situation, and in the case of indication 28 almost led to disagreement (Table 3).

The indication evaluated with greatest controversy among the panel members concerned the most ideal practitioner to perform the reconciliation.

4. Discussion

Drug therapy is the main therapeutic tool for patients with multiple chronic conditions. This study represents a first approach to selecting tools to evaluate the quality of drug therapy in this specific patient group, thereby improving safety [21].

Although the Delphi method is generally applied to surgical and medical procedures, it has also been used in the hospital setting to evaluate healthcare organisations [27]. In our case, we met most of the recommended criteria for use of this tool, including frequent procedures that consume significant resources, have high variability and whose use is controversial [24]. The method used eliminates biases of face-to-face methods such as production blocking, cognitive interference and evaluation apprehension. We attempted to minimise the potential variability of the results, depending on the intervening experts, by balancing the group composition based on various characteristics and thus increasing the representativeness of the panel.

A significant number of methodologies and tools were identified, but only a small fraction was selected. This fact is probably due to the recent definition of the PMD concept, compared to other patient profiles that were defined long ago and have been followed up for a longer time.

4.1. Compliance

One of the most widely used tools for assessing compliance in the general population is the questionnaire developed by Morisky et al. [28]; nevertheless, this was not included because it did not meet the established selection criteria since it was structured into items with dichotomous answers, and does not allow for a quantitative or semiquantitative estimate of compliance. The purpose of applying this criterion was to obtain an estimated rate of compliance, or at least, to broaden the information obtained, compared to structured questionnaires with dichotomous responses, or specify the uncertainty resulting from open questions.

There was substantial agreement among the panel members on selecting the ARMS scale. Although this scale is not validated in patients with multiple chronic conditions, it was designed to assess compliance in patients with chronic diseases and was validated in patients with coronary heart disease, which in most cases is accompanied by other comorbidities.

Among the tool’s strengths are its ease of use and design, which includes two clearly distinct sub-scales: one related to the proper administration of medication and the other one related to the collection or acquisition thereof. This structure allows for greater understanding of the various barriers to compliance, enabling the subsequent implementation of interventions specifically aimed at the causes of non-compliance [29].

4.2. Appropriateness

There are two major approaches to measuring appropriateness. On one hand, there are the implicit methods or those based on judgments, which assess treatment itself and consider all patient characteristics. These methods intend for drugs to be properly prescribed and respond to an indication/need. On the other, there are the explicit methods or those based on criteria that attempt to measure the appropriateness of the prescription to predefined criteria, which is usually a mix of data from evidence and consensus. These systems are forced to choose only some of the available evidence [30].

Given its wide presence in the literature, we considered submitting the complete MAI questionnaire to the panel members for their consideration. However, faced with the possibility of future development of a questionnaire specifically for patients with multiple chronic conditions [32] and the clear difference in applicability of the various questions in the MAI questionnaire, we decided to submit each of the questions to the panel separately. It was later observed that this was the correct approach because the questions were assessed very differently. Of the 10 items that made up the questionnaire, 6 were agreed upon and 2 (“Are the practical instructions to the patient correct?” and “Is it the most cost-effective drug?”) were not. In terms of the feasibility of the implementation, one of the items was questionable (“Are the practical instructions to the patient correct?”). Agreement was not reached on the appropriateness of three items: “Is the drug effective for this indication?”, “Is there a lack of relevant interactions
between this and other drugs?” and “Is it the most cost-effective drug?”

With regard to the other criteria used in field studies identified in the literature, three were widely accepted, since they provided new highly relevant considerations for the appropriateness of drug treatment that were not included in the items that make up the MAI questionnaire: “Is there a diagnosis or symptom recorded in the medical history that does not have a drug treatment but could have one?”, “Is this the best administration route for the drug for this patient?” and “Is the regimen schedule correct for this drug and patient?”

New extrinsic methods have appeared in recent years, targeting elderly patients and lacking an accepted international standard. Each research group and geographical area has developed its own methods.

Regarding the Beers criteria and their amendments, although they have had much success in the literature, they have little clinical application and are very controversial [31–33]. For their part, the IPET criteria have not been used much outside Canada. These were the reasons for clear agreement among the panel members concerning the criteria’s lack of usefulness.

The STOPP/START criteria have been validated in Spain and, according to the panel, are the most appropriate for patients with multiple comorbidities [34]. However, it is possible that although they manage to detect some opportunities for improving appropriateness, they miss others. It should also be noted that the STOPP/START criteria are based on evidence of isolated diseases, and are sometimes difficult to apply to patients with multiple comorbidities.

For all of these reasons, it would be of great interest to develop a strategy that combines different tools to ensure appropriateness of treatment in this group of patients.

4.3. Reconciliation

There was consensus that any healthcare transition must be considered a critical point in the safety of patients with multiple chronic conditions, and not only just hospital admission. For example, the study of Boockvar et al. [35] found that most adverse events related to discrepancies in medication appeared after readmission to nursing homes.

The experts expressed their agreement on performing the reconciliation within 24 h, in line with the abundant evidence of the importance of reconciliation as a strategy for reducing medication errors and thereby reducing the potential risks to the patient [36,37].

There is considerable controversy as to which practitioner should be responsible for performing this process. There was divided opinion among the clinicians, both family doctors and internal medicine specialists. The majority thought that the clinician recording the medical history should perform the reconciliation and a minority believed that the help of an outside professional would be more appropriate. The pharmacists as a whole backed the suitability of performing this activity themselves. In this sense, the most appropriate professional and moment for performing reconciliation is, in theory, the actual clinician during the patient assessment. However, the literature supports quite the opposite. That is, successful reconciliation programmes have been

### Table 2C

<table>
<thead>
<tr>
<th>Chapters</th>
<th>Indications</th>
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</table>
| CHAPTER 1: Healthcare transitions that need reconciliation | 1. The process of reconciliation should be carried out only at the primary care level.¹  
2. The process of reconciliation should be carried out only at hospital admission.  
3. The process of reconciliation should be carried out only at hospital discharge.  
4. The process of reconciliation should be carried out only at hospital admission and discharge.  
5. The process of reconciliation should be carried out at hospital admission and discharge and, after discharge, after the patient visit to primary care.  |
| CHAPTER 2: Resources for obtaining home treatment in the hospital | 6. The list of drugs that comprise home treatment should be obtained only through the digital medical history used in primary care.  
7. The list of drugs that comprise home treatment should be obtained only through the clinical interview with the patient.  
8. The list of drugs that comprise home treatment should be obtained through the digital medical history programme used in primary care and through the clinical interview with the patient.  
9. The list of drugs should record all drugs, doses, regimen, administration route and last dose administered.  
10. The form should record habits of self-medication and over-the-counter medication for minor symptoms.  
11. It should indicate whether the patient is receiving phytotherapy or other products.  
12. It should include possible drug allergies and intolerances.  
13. It should record any previous treatment terminations and the causes (side effects, refractoriness, etc.).  |
| CHAPTER 3: Form for preparing the list of drugs | 14. The list of drugs that comprise home treatment should be integrated in the digital medical history using a standardised format.  
15. The list of drugs that comprise home treatment should be recorded on paper in a standardised format.  
16. The maximum time for each reconciliation will be 24 h.  
17. The maximum time for each reconciliation will be 48 h.  
18. The list of drugs that comprise home treatment should be obtained by a pharmacist.  |
| CHAPTER 4: Methodology for preparing the list of drugs | 19. The list of drugs that comprise home treatment should be obtained by a nurse.  
20. Data processing (list of drugs) should be carried out on a sheet of paper that is kept in the medical record.  
21. Data processing (list of drugs) should be stored on a computer.  
22. Data processing (list of drugs) should be carried out on paper as well as in electronic format.  
23. Omissions of drugs without clinical justification should be considered as discrepancies.  
24. Initiating drug treatment without clinical justification should be considered as discrepancies.  
25. Discrepancies in doses, route or frequency of administration without clinical justification should be considered.  
26. Incomplete prescriptions that require clarification should be considered as discrepancies.  
27. Therapeutic duplication should be considered as discrepancies.  
28. Drug interactions should be considered as discrepancies.  |
| CHAPTER 5: Data processing | 29. The communication channel must be oral.  
30. The communication channel must be written.  |
| CHAPTER 6: Variables to be considered as discrepancies in reconciliation | 31. The communication channel may be either oral or written.  
32. The list of drugs that comprise home treatment should be obtained by the doctor.  
33. The list of drugs that comprise home treatment should be obtained by the main caregiver.  
34. The list of drugs that comprise home treatment should be obtained by a pharmacist, but not exclusively.  |
| CHAPTER 7: Reporting the reconciliation | 35. Data processing (list of drugs) will depend on whether the medical history is in electronic or hard copy format.  |

¹ Eliminated after the first round, since the panel members considered that they excluded each other.
those performed by pharmacists with a specific methodology, although in reality these are limited to specific experiences [38-40].

In any case, professionals should have sufficient knowledge and experience in the handling of medication, and reconciliation should be established at the local level and considered a shared responsibility [41].

The computerisation of medical histories, single digital histories and thus, the possibility of immediate online access from the hospital to the patient's chronic treatments, and from the family doctor's office to hospital admissions, will facilitate or even make unnecessary treatment reconciliation in the future.

5. Conclusions, usefulness and limitations

This study represents the first attempt to identify useful tools in evaluating drug therapy for PMD, a concept that defines patients of clinical and psychosocial characteristics that may be very different from elderly or chronically ill patients with a single predominant underlying disease. The tools selected for this group of patients will need to be validated to determine their usefulness and sensitivity.

The main limitation of this study was probably the date of the literature search (December 2009). However, this search was performed using the highest number of available databases and the articles referenced in the studies found were recovered in order to review all available studies. A future literature search is therefore needed in case new tools arise that need evaluation.

Learning points

This study identified, by means of expert panel opinion, useful tools for the assessment of drug therapy in the group of patients with multiple chronic conditions for the following issues:

- **Treatment compliance**: the tool considered most appropriate was the “Adherence to Refills and Medication Scale” questionnaire.
- ** Appropriateness**: the STOPP/START criteria were the most appropriate, although the Medication Appropriateness Index questionnaire was considered appropriate too.
- **Reconciliation during healthcare transitions**: the greatest degree of agreement regarding reconciliation was on the information that needed to be collected and the variables considered as discrepancies.

Conflict of Interest

The authors state no conflict of interest.

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- Olga Delgado Sánchez, Servicio de Farmacia, Hospital Son Espases de Palma de Mallorca, Spain
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- Carmen Gallego Fernández, Servicio de Farmacia, Hospital Carlos Haya de Málaga, Spain
- Jesús Medina Asensio, Servicio de Medicina Interna, Hospital 12 de Octubre de Madrid, Spain
- María Muñoz García, Servicio de Farmacia, Hospital Ramón Cajal de Madrid, Spain
- María Dolores Nieto Martín, Servicio de Medicina Interna, Hospital Universitario Virgen del Rocío de Sevilla, Spain
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