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Content Validity and Inter-Rater Reliability of an Instrument to Characterize Unintentional Medication Discrepancies

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Abstract

Background: Medication discrepancies are medication-related problems (MRPs) that frequently occur when patients are transferred between settings of care. Older patients are at high risk for several reasons, including high consumption of medicines, and physical and cognitive deficiencies that can impair the communication process. Most previous studies that have evaluated medication discrepancies used instruments designed for clinical practice, but a well-validated and reliable instrument for clinical research is still lacking.

Objectives: The aims of this study were to (i) develop an instrument to characterize medication discrepancies that fulfils quality requirements for classification of MRPs related to continuity of care and (ii) assess its content validity and inter-rater reliability.

Methods: The instrument was developed based on three main inputs: (i) a literature review to collect information about the quality requirements of instruments to characterize MRPs; (ii) another literature review to identify existing instruments to characterize MRPs and, more specifically, medication discrepancies; and (iii) previous experience from a pilot study on Belgian patients discharged from surgical and medical wards. Content validity was assessed using a modified Delphi technique with 11 healthcare professionals. Content validity indexes were calculated. For inter-rater reliability, three pharmacists (one experienced and two naive) were asked to identify and categorize (type and cause of) unintentional medication discrepancies for 21 patients discharged from hospital into the community. The intra-class correlation coefficient was calculated to compare the number of discrepancies identified, and a paradox-resistant index (AC1) was used to determine the inter-rater reliability for the type and cause of the discrepancy.

Results: The instrument had 54 items classified in three sections (type of discrepancy, cause and intervention), with detailed specifications on how to use it. All evaluations relative to content validity met predefined cut-off values, except for two of them. Intra-class correlation coefficients of ≥0.76 and AC1 coefficients of ≥0.89 were found for the number and the type of discrepancies, respectively. Regarding evaluation of the specific causes of medication discrepancies, final AC1 results of ≥0.86 were obtained, except for three items (which had values between 0.62 and 0.79).

Conclusion: The validity and reliability of the instrument developed to assess unintentional medication discrepancies at patient transition from the hospital to the community setting was found to be satisfactory.

Introduction

Medication-related problems (MRPs) linked to discontinuity of care frequently occur when patients are transferred across different settings of care, leading to adverse drug events, increased use of healthcare resources and increased costs.[1-4] They mainly result from unexplained differences among documented medication regimens across different sites of care. To better characterize these differences, the concept of unintentional medication discrepancies has emerged.[5] A recent literature review[4] outlined that at least one error in medication history could be found for 27–54% of patients on hospital admission and that 19–75% of the discrepancies were unintentional. Upon hospital discharge, studies reported that 14–41% of patients had at least one unintentional medication discrepancy.[5-7] Another recent study indicated that 62% of hospitalized patients had at least one unintentional medication discrepancy at the time of internal hospital transfer.[8]

Older patients are usually considered to be a population at high risk of medication discrepancies for several reasons. First, polymedication is frequent – and often needed – and the number of medications per patient has been reported as a risk factor for the occurrence of unintentional medication discrepancies.[5,9-11] In addition, impairments in physical (e.g. hearing) and cognitive functions can also complicate the communication process.

Measuring unintentional medication discrepancies is particularly well suited to evaluating continuity of care.[12] Most previous studies that evaluated medication discrepancies[4-8] used instruments designed for clinical practice, but a well-validated instrument for clinical research is still lacking. Such an instrument should fulfil the standard requirements of instruments designed to characterize MRPs.[13,14] To our knowledge, the Medication Discrepancy Tool (MDT) is the only published instrument that has been developed and validated for identifying and characterizing medication discrepancies arising when patients transfer across care settings, particularly for older patients with complex care needs.[15] However, this instrument has several shortcomings: (i) it does not fulfil all requirements raised above, for example, it lacks a section to characterize the type of discrepancy; and (ii) inter-rater reliability was found to be unsatisfactory,[15] which is probably related to the lack of specifications with respect to the use of the instrument in general as well as to specific items.[16-20] Therefore, the objectives of this study were to (i) develop an instrument to characterize unintentional medication discrepancies that fulfils quality requirements for classification of MRPs; and (ii) assess its content validity and inter-rater reliability.

Methods

Development of the Instrument

The instrument was developed on the basis of three main inputs: (i) a literature review to collect

information about important quality requirements of instruments to characterize MRPs; (ii) another literature review to identify existing instruments to characterize MRPs and, more specifically, medication discrepancies, and elements important for the completeness of the instrument (e.g. identification of causes cited in previous literature); and (iii) previous experience from a pilot study on the evaluation of medication discrepancies in Belgian patients discharged from surgical and medical wards, which used the MDT. This study highlighted the need for clarifications and additions at different levels of the instrument. Our instrument was developed in French because it was the language used in the clinical practice of the authors. When the study was completed, the instrument itself (i.e. not the instructions) was translated into English, using a forward and backward translation procedure.

Content Validity

A modified two-round Delphi technique was conducted by email. We purposively selected different types of healthcare professionals (HCPs) with research and/or clinical experience in continuity of care related to medication management. Eleven HCPs (four hospital pharmacists – including two clinical pharmacists with experience in geriatrics; three community pharmacists; two geriatricians; one general practitioner and one ward nurse with additional research experience in home care) with research and/or clinical experience in continuity of care related to medication management were recruited for the first validation round. Experts received an email in which we explained why they had been selected, what was the instrument, what was the content validation and why it was important to assess content validity.[21] Three experts from the first round participated in the second round: one expert from each profession (a nurse, a physician and a pharmacist) and, within each profession, experts with the most contrasted judgement (i.e. who did not give ratings of 1 to all items or 4 to all items) and who gave the highest number of comments were selected.[22] The decision to have a smaller group for the second round was taken because it has been reported as acceptable[22,23] and is less time consuming.

Participants were asked to evaluate the following parameters of the instrument: (i) clarity, helpfulness and representativeness on a 4-point Likert scale (1 indicating lack of agreement and 4 indicating excellent agreement); and (ii) uniqueness and completeness on a 2-point Likert scale (1 indicating excellent agreement and 2 indicating lack of agreement). The content validity parameters assessed are defined in Appendix 1. An opportunity for open-ended commentary was also given. The content validity index for each element (I-CVI), a measure which indicates the proportion of participants who endorsed an element of the instrument as content valid, was determined at two different levels: (i) general aspects and sections of the instrument (title, definitions, instructions, examples); and (ii) individual items of the sections relative to the type of discrepancy, the cause(s), and the related intervention. For the latter level, the mean of the I-CVIs for all items for each parameter was also calculated (S-CVI).[21-23] The average deviation mean index (ADm) is an inter-rater agreement measure that was used to indicate the degree of disagreement among experts in the response option regardless whether they endorsed an element or not.[24]

Cut-off values were defined *a priori*. With regard to I-CVI values, an item was accepted if 75% of the participants considered it as valid. The cut-off value for S-CVI was set at 0.9.[22] With regard to ADm values, an item was accepted if the value was inferior or equal to the critical values at a 5% level of statistical significance for predefined numbers of participants and categories of answers and/or to the practical cut-off that reflected good inter-rater agreement relative to the number of categories of answers (high values reflecting low agreement).[24]

The two measures, I-CVI and ADm, provided very different types of information, however, and should be viewed as complementary. We firstly examined the I-CVI values to determine whether the experts endorsed an item or not and then considered the level of agreement among the experts by examining the ADm. More information on the use and interest of each of these two measures is provided in figure S1 (see Supplemental Digital Content, http://links.adisonline.com/DAZ/A19).

The index values and comments of the participants resulting from the first round were used to identify items to revise, discard or add. The second round was conducted to assess the modifications made after the first round.

Inter-Rater Reliability

Three raters were involved: the main researcher (C.C., pharmacist) and two clinical pharmacists purposively selected to reflect different levels of training and experience relative to continuity of care. The clinical pharmacists were not involved in previous development and validation but received background information on the study and the instrument.

Each rater received abstracted and standardized information on 21 patient cases. These cases were purposively selected from patients who had been included in a controlled intervention study (patients with three or more chronic medications), in order to reflect the diversity of cases. Information included age, type of hospital ward (surgical or medical), reason for admission, medication history on admission, place of discharge and medication treatment at hospital discharge (based on discharge letters and medical files), medication taken after discharge and information on initiator and reasons for changes of treatment, and patient feedback on the information received (based on semi-structured phone interviews[25] with the patient or caregiver and the general practitioner 2 weeks after discharge). Case selection and abstraction were done by the main researcher. An example of a patient case is provided in the Supplemental Digital Content (see tables S2 and S3). The mean age of the patients (± SD) was 76.8 ± 13.8 years. Patients took a mean number (± SD) of 8 ± 3 medications 2 weeks after discharge.

For each case, each rater was asked (i) to list any medication discrepancy between discharge medications and medications taken by the patient at the time of calling, and (ii) to categorize each discrepancy [type and cause(s)] using the instrument that resulted from content validation. The raters were allowed to review each case as many times as necessary. They were also invited to note comments during case coding. These were used to identify whether disagreements were due to difficulties in using the instrument or to case interpretation.

In a first round, each rater independently detected and classified discrepancies. In a second round, clinical pharmacists compared their results and discussed discrepancies. They were then allowed to change their rating. In a final round, an additional discussion was held between the clinical pharmacists and the main researcher. The clinical pharmacists could change their codification and give their feedback about the instrument. Raters were allowed to select more than one cause for each discrepancy detected.

The inter-rater reliability was calculated at each round for the number of unintentional medication discrepancies detected by case (continuous variable) and for the type and cause of each discrepancy (dichotomous variable). The units of analysis were the active substance for the type categories classification (n = 227) and medication discrepancies detected by all three raters for classification in the cause categories (Round 1: n = 87; Round 2: n = 128; Round 3: n = 136).

The intra-class correlation coefficient was computed for the continuous variable. The IBM SPSS statistics release 18.0.0. 2009 (SPSS Inc., Chicago, IL, USA) was used for calculations. The Cicchetti and Sparrow benchmark was used to interpret data: <0.40 = poor; 0.40–0.59 = fair; 0.60–0.74 = good; and ≥0.75 = excellent chance-corrected levels of agreement.[26]

For dichotomous variables, inter-rater reliability was analysed using a paradox-resistant index AC1 with 95% confidence intervals, because Cohen's Kappa is known to be influenced by prevalence and the homogeneity of results.[27] Agreestat software (Advanced Analytics, LLC, Gaithersburg, MD, USA) was used.[28] The Landis and Koch Kappa's benchmark scale was used to interpret data: slight if ≤0.2; fair if 0.21–0.40; moderate if 0.41–0.6; substantial if 0.61–0.8; and almost perfect if 0.81–1.00.[29] The proportion of positive and negative agreements was also calculated.[30]

This study was approved by the ethical committees of the hospitals (Centre Hospitalier Universitaire de Mont-Godinne, Yvoir, Belgium and Centre Hospitalier de Jolimont-Lobbes, La Louvière, Belgium) in which it was conducted.

Results

Development of the instrument

Table I describes the standard requirements identified, selected from the first literature review and applied to the instrument.[13,14,18] Among the instruments identified to characterize MRPs and medication discrepancies, the MDT[15] was used as a starting point to characterize possible causes, and the Pharmaceutical Care Network Europe Drug Related Problems classification V5.01 was used to describe interventions to solve discrepancies.[31] Additional items and specifications were identified in other references[5,31-40] and in the pilot study. The instrument had 54 items, with definitions and examples provided at instrument, section and items levels. The main elements are described in table II.

Content Validity

The I-CVI, S-CVI and ADm values related to general aspects and sections, as well as individual items, are shown in tables III and IV. After the first round, additional modifications were made, mainly concerning the following aspects: definitions of the three sections were modified; additional information relative to the aim of the instrument was provided; a second example of the use of the instrument was added; ten items were merged; two items were added; and 30 items were modified in titles, definitions or examples. The final version of the modified instrument has a total of 48 items (see Appendix 2). Full instructions for the use of this version are available from the authors upon request. Figure S1 (see Supplemental Digital Content) shows the content validity process of one item.

Table I. Standard requirements identified and selected from the literature review for the development of the instrument

✓ A clear definition of the sections, subsections and items should be provided[a]
✓ One or more examples to illustrate sections, subsections and items should be given[a]
✓ A suitable classification system consists of three parts: the classification of the medication-related problem, its cause(s) and the intervention taken to solve the problem
✓ The classification should separate the problem itself from the cause
✓ The classification system should be structured like a decision tree (main sections and subsections)
✓ The structure of the classification should be open to include new problems, preferably on subsection levels
✓ World Health Organization Anatomical Therapeutic Chemical coding system for drugs should be used to describe medications
✓ The patient's gender and age should be documented
✓ Because of the complexity of medication-related problems, the opportunity to enter free text should also be offered
✓ Problems defined should be clear and, if possible, lead to only one choice of coding; users should not be encouraged to over report (e.g. to name several problems for one)

a The literature stated that these specification have an impact on inter-rater reliability.[18]

Inter-Rater Reliability

The total number of unintentional medication discrepancies detected for the 21 examined patient cases varied from 122 to 173 depending on rater and round. The intra-class correlation coefficients were 0.76, 0.88 and 0.95 for the three successive rounds, showing excellent agreement.

Concerning the evaluation of the types of medication discrepancies, all AC1 coefficients were higher than 0.89 after each of the three rounds and agreement could be considered to be almost perfect. Regarding evaluation of the specific causes of medication discrepancies, the AC1 coefficients varied from fair to almost perfect for the first round, from moderate to almost perfect for the second round and from substantial to almost perfect for the third round. The AC1 coefficients for each individual type and cause of medication discrepancy are presented in tables V and VI, respectively.

Raters mentioned that the following items could be added to certain sections of the instrument:

- *"Type of Unintentional Medication Discrepancy":* detailed medication regimen undocumented (e.g. "chronic treatment" written in the discharge letter).
- *"Cause(s)" at the patient level:* patient's compliance with clinical pharmacist advice (e.g. a patient for whom the dosage of tetrazepam had been progressively decreased during his hospital stay discontinued this medication on his own after hospital discharge, following a suggestion made by the clinical pharmacist to

Table II. Description of the main elements composing the instrument to characterize unintentional medication discrepancies (see Appendix 2 for the version of the instrument that resulted from content validation)

Level	Description
Instrument	The aim and context of use of the instrument and the medication reconciliation process are defined
	An example of use of the instrument is provided: a patient case with classification of the type, cause and resolution of the unintentional medication discrepancy
	World Health Organization Anatomical Therapeutic Chemical coding system for drugs is used to categorize medication involved in the discrepancy (14 categories)
	Patient characteristics (age and gender) can be reported
Section	The instrument has three sections: ''Type of Unintentional Medication Discrepancy Identified'', ''Cause(s)'' and ''Intervention(s) to Solve the Unintentional Medication Discrepancy''
	A definition is provided for each section
	An example to help understand the difference between intentional and unintentional medication discrepancies is provided
Subsection	The different subsections are Cause(s) at the ''Patient level'' and at the ''System level'' and Intervention(s) to Solve the Unintentional Medication Discrepancy at the ''Healthcare professional level'', ''Patient level'', ''Medication level'' and ''Other''
	The subsections are defined
	The structure of the classifications is open to include new problems, preferably on subsection levels; item ''Other'' added at the end of the list of items of each section or subsection
Items	Items are defined, e.g. definition provided for the item ''Conflicting information from different informational sources'', i.e. ''When you compare different sources of information (such as prescription order, discharge letter, verbal instruction, medication information leaflet...), there is a difference. It can be detected by the patient and/or the healthcare professional.''
	One or more examples are provided to illustrate items, e.g. for the item ''No caregiver/need for assistance not recognized'', the following example was provided: ''I would prefer that a nurse give me the injection because I can't do it alone.''
	For individual items relative to the cause of the discrepancy, in comparison to the MDT, 12 items were unchanged, four items were removed, three were slightly modified, and seven new items were added (full description and explanations available upon request)
	For individual items relative to the Intervention(s) to Solve the Unintentional Medication Discrepancy, in comparison with the Pharmaceutical Care Network Europe Drug Related Problems classification V5.01, six items were unchanged, four items were removed, eight were slightly modified, and four new items were added (full description and explanations available upon request)

MDT = Medication Discrepancy Tool.

discontinue this medication after approval by the patient's general practitioner).

- *''Cause(s)'' at the system level:* information could not be checked by the rater (e.g. the discharge letter mentions ''for analgesics see hospital prescription''); general practitioner has not seen the patient after discharge and could not help the patient in medication management; use of previous supply of medicines by the patient or the carer; and lastly, discrepancy related to hospital formulary considerations.

It took on average (± SD) 43 ± 8 minutes for the two naive raters to read and understand the use of the instrument the first time they used it. The average time taken to detect and classify each individual patient case (± SD) was 18 ± 1 minutes for a mean number (± SD) of unintentional medication discrepancies detected per case of 6.9 ± 4.9.

Discussion

The present study is one of the first to try to develop a validated instrument to identify and classify unintentional medication discrepancies after hospital discharge. The instrument developed was found to be content valid. Although direct comparison with the results obtained for the MDT[15] is impossible because of differing inter-rater reliability indexes, the results suggest that the addition of detailed specifications relative to the use of the instrument and to specific items – together with detailed descriptions of real cases – improved the inter-rater reliability.

All evaluations relative to content validity met predefined cut-off values, except two of them, namely the clarity of the definition of unintentional medication discrepancy and of the aim of the instrument (describing the medication

reconciliation process). The difficulty of understanding these two concepts might explain the results. It seems, therefore, important to provide clear and detailed explanations, especially for naive evaluators.

With regard to inter-rater reliability, an excellent agreement was found for the number of unintentional medication discrepancies detected between the three raters. As a matter of fact, it is the first time that such evaluation has been performed on patient cases that potentially included several discrepancies, as Smith et al.[15] used clinical vignettes with a single medication discrepancy.

The fact that excellent and almost perfect agreement was found for the classification of the type of discrepancy is not surprising as this classification is fully explicit and does not require personal interpretation or information other than the discrepancy itself.

Three different patterns for inter-rater reliability relative to the classification of the cause of discrepancies were observed: (i) good results after

Table III. Content validity index and average deviation mean index (ADm) results for general aspects and sections[a,b,c]

Content validity parameter assessed	Round 1		Round 2	
	I-CVI (n = 11)	ADm (n = 11)	I-CVI (n = 3)	ADm (n = 3)
Clarity of instrument title[d]	1	0.30	1	0.44
Clarity of the title of the sections of the instrument[d]	0.9	0.45	1	0
Clarity of the aim of the instrument (medication reconciliation definition)[d]	1	0.46	***0.66***	***0.89***
Clarity of unintentional medication discrepancy definition[d]	1	0.46	***0.66***	***0.89***
Clarity of cause definition[d]	1	0.17	–	–
Clarity of intervention definition[d]	0.81	***0.69***	1	0
Clarity of instructions for general use of the instrument[d]	1	0.46	–	–
Clarity of user instructions for the section ''Type of Unintentional Medication Discrepancy Identified''[d]	1	0.30	–	–
Clarity of user instructions for the section ''Cause(s)''[d]	1	0.30	–	–
Clarity of user instructions for the section ''Intervention(s) to Solve the Unintentional Medication Discrepancy''[d]	0.9	0.45	–	–
Clarity of the population targeted by the instrument[d]	0.9	0.58	1	0.44
Clarity of the example showing how to use the instrument[d]	1	0.00	–	–
Helpfulness of example showing how to use the instrument[d]	1	0.17	–	–
Clarity of the second example showing how to use the instrument[d]	–	–	1	0.44
Helpfulness of the second example showing how to use the instrument[d]	–	–	1	0
Completeness of the section ''Type of Unintentional Medication Discrepancy Identified''[e]	0.91	0.17	–	–
Completeness of the cause(s) subsection ''Patient level''[e]	***0.64***	***0.46***	1	0
Completeness of the cause(s) subsection ''System level''[e]	0.82	***0.40***	1	0
Completeness of the intervention(s) subsection ''Healthcare professional level''[e]	1.00	0.00	–	–
Completeness of the intervention(s) subsection ''Patient level''[e]	0.82	0.17	1	0
Completeness of the intervention(s) subsection ''Medication level''[e]	0.82	0.17	1	0

a Cut-off values: I-CVI (n = 11) = 0.78; I-CVI (n = 3) = 0.75; ADm (4 categories of answers, n = 11, at 5% level of statistical significance) = 0.63; ADm (2 categories of answers, n = 11, at 5% level of statistical significance) = 0.17; ADm cut-off at 5% level of significance for 3 judges: not applicable; ADm (practical cut-off for 4 categories of answers) = 0.67; ADm (practical cut-off for 2 categories of answers) = 0.33.

b I-CVI = the number of judges who choose a positive answer (3 or 4 on the 4-point Likert scale for the aspects 'clarity', 'helpfulness' and 'representativeness,' or 1 on the 2-point Likert scale for the aspect 'uniqueness' and 'completeness') divided by the total number of judges.

c Values not valid with regard to cut-off value are in italic bold.

d On a 4-point Likert scale with 1 indicating lack of agreement and 4 indicating excellent agreement with the validity of a specific item.

e On a 2-point Likert scale with 1 indicating lack of agreement and 2 indicating excellent agreement with the validity of a specific item.

n = number of participants; – indicates not assessed.

Table IV. Content validity index and average deviation mean index (ADm) range results for individual items of the three sections[a,b,c]

Content validity parameter assessed	Round 1		Round 2	
	S-CVI (n = 11)	ADm range (n = 11)	S-CVI (n = 3)	ADm range (n = 3)
Representativeness[d,e]	0.97	0–***0.66***	1.00	0–0.59
Name clarity[d,e]	0.93	0–***1.14***	0.97	0–0.59
Definition clarity[f,g]	0.95	0–***0.81***	0.97	0–0.67
Helpfulness example[h,i]	***0.85***	0–***0.99***	0.94	0–***0.92***
Uniqueness[d,e]	***0.85***	0–***0.46***	0.96	0–0.30

a Cut-off values: S-CVI cut-off value = 0.9; ADm (4 categories of answers, n = 11, at 5% level of statistical significance) = 0.63; ADm (2 categories of answers, n = 11, at 5% level of statistical significance) = 0.17; ADm cut-off at 5% level of significance for 3 participants: not applicable; ADm (practical cut-off for 4 categories of answers) = 0.67; ADm (practical cut-off for 2 categories of answers) = 0.33.

b S-CVI = total sum of all I-CVIs obtained for items divided by the total number of items of the instrument for which the parameter was assessed.

I-CVI = the number of judges who choose a positive answer (3 or 4 on the 4-point Likert scale for the aspects 'clarity', 'helpfulness' and 'representativeness,' or 1 on the 2-point Likert scale for the aspect 'uniqueness' and 'completeness') divided by the total number of judges.

c Values not valid with regard to cut-off value are in italic bold.

d 45 items in the instrument assessed at the 1st round.

e 41 items in the instrument assessed at the 2nd round.

f 32 items with a definition in the instrument at the 1st round.

g 38 items with a definition in the instrument at the 2nd round.

h 25 items with an example in the instrument at the 1st round.

i 35 items with an example in the instrument at the 2nd round.

n = number of participants.

the first round for ten items; (ii) unsatisfactory results after the first round, but an improvement and an almost perfect agreement after the second and/or third rounds (two items, i.e. medication history incomplete/inaccurate and intentional nonadherence); and (iii) items for which almost perfect agreement was not reached even after the third round (three items, namely unintentional nonadherence, instructions to patient and between prescribers incomplete/inaccurate/illegible). These results show that evaluation of the cause of the discrepancy is more difficult and subject to personal interpretation. This is especially relevant if the instrument is to be used by evaluators with limited experience or expertise in continuity of care. This problem can be minimized by providing explicit and comprehensive instructions. For example, reliability concerning the item ''Medication history incomplete/inaccurate'' was insufficient after the first round because it was not clear to the rater with the poorest experience that medication history on admission had to be taken into account. Another example relates to the item ''Instructions to patient at transfer incomplete/inaccurate/illegible''. It was unclear as to whether oral instructions without written information could be considered as sufficient or not because this was not specifically mentioned in the instructions. As discharge from hospital is a stressful period for patients and carers, it is unlikely that they will fully remember oral information.[41] For the purpose of the study, we therefore considered that oral information needed to be always reinforced with written information. These specifications could easily be added to our instrument. Finally, the discussion between raters also highlighted that new items should be added, to better fit with the clinical reality, and thereby, improve the inter-rater reliability.

The present investigation shows that using the developed instrument is time consuming and requires training. Moreover, as described in the Methods, the collection of the data needed to use the instrument is also time consuming. The use of the instrument is therefore appropriate for research and educational purposes but not for daily

Table V. Inter-rater reliability for evaluation of the type of unintentional medication discrepancy (n = 227)[a,b,c]

Type	Round 1							Round 2							Round 3						
	CP1/MR			CP2/MR			All	CP1/MR			CP2/MR			All	CP1/MR			CP2/MR			All
	AC1	ppos	pneg	AC1	ppos	pneg	AC1	AC1	ppos	pneg	AC1	ppos	pneg	AC1	AC1	ppos	pneg	AC1	ppos	pneg	AC1
Omission	0.96	0.83	0.98	0.97	0.88	0.99	0.96	0.98	0.91	0.99	0.98	0.93	0.99	0.98	0.98	0.93	0.99	0.97	0.87	0.99	0.98
Addition	0.90	0.75	0.96	0.89	0.74	0.95	0.90	0.94	0.86	0.97	0.93	0.83	0.97	0.95	0.95	0.89	0.98	0.93	0.84	0.97	0.95
Brand-generic substitution	0.98	0.44	0.99	0.99	0.57	0.99	0.98	0.99	0.75	1.00	0.99	0.57	0.99	0.99	1.00	0.86	1.00	1.00	0.86	1.00	1.00
Therapeutic substitution	0.98	0.44	0.99	0.98	0.44	0.99	0.98	0.98	0.60	0.99	0.98	0.60	0.99	0.99	0.99	0.77	0.99	0.98	0.60	0.99	0.98
Dosage	0.93	0.78	0.97	0.92	0.79	0.96	0.90	0.98	0.94	0.99	0.94	0.86	0.97	0.95	0.99	0.97	0.99	0.98	0.94	0.99	0.98
Frequency	0.96	0.67	0.98	0.93	0.53	0.97	0.94	0.98	0.81	0.99	0.93	0.61	0.97	0.95	0.99	0.89	0.99	0.99	0.94	1.00	0.98
Route	1.00	0.67	1.00	1.00	1.00	1.00	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Formulation	0.99	0.57	0.99	1.00	1.00	1.00	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Time	0.96	0.84	0.98	0.91	0.76	0.96	0.92	0.98	0.92	0.99	0.93	0.80	0.97	0.94	0.99	0.96	1.00	0.97	0.91	0.99	0.98
Length	0.92	0.00	0.96	0.95	0.69	0.98	0.93	0.94	0.54	0.97	0.96	0.76	0.98	0.95	0.98	0.87	0.99	0.99	0.94	1.00	0.98
Other	–	–	1.00	–	–	1.00	–	–	–	1.00	–	–	1.00	–	–	–	1.00	0.97	0.00	0.98	0.98
Mean	**0.96**	**0.60**	**0.98**	**0.95**	**0.74**	**0.98**	**0.95**	**0.98**	**0.83**	**0.99**	**0.96**	**0.80**	**0.99**	**0.97**	**0.99**	**0.91**	**0.99**	**0.98**	**0.81**	**0.99**	**0.98**

a Round 1 = each CP independently detected and classified discrepancies; Round 2 = CPs compared their results and discussed discrepancies; Round 3 = discussion between each CP and MR. Change in codification was allowed for Rounds 2 and 3.

b Missing values (as indicated by a '–' symbol) reflect a situation in which neither of the raters selected a particular item.

c Benchmark scale for AC1: slight if ≤0.2, fair if 0.21–0.40, moderate if 0.41–0.6, substantial if 0.61–0.8 and almost perfect if 0.81–1.00.

AC1 = paradox-resistant index; **CP** = clinical pharmacist; **MR** = main researcher; **n** = number of active substances for the 21 patient cases; **pneg** = proportion of negative agreement; **ppos** = proportion of positive agreement.

Table VI. Inter-rater reliability for identification of the cause(s) of the unintentional medication discrepancy[a,b,c,d]

Cause	Round 1 (n = 87)							Round 2 (n = 128)							Round 3 (n = 136)						
	CP1/MR			CP2/MR			All	CP1/MR			CP2/MR			All	CP1/MR			CP2/MR			All
	AC1	ppos	pneg	AC1	ppos	pneg	AC1	AC1	ppos	pneg	AC1	ppos	pneg	AC1	AC1	ppos	pneg	AC1	ppos	pneg	AC1
Patient level																					
Adverse drug event	0.98	0.50	0.99	1.00	1.00	1.00	0.98	0.98	0.67	0.99	1.00	1.00	1.00	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Time	–	–	1.00	–	–	1.00	–	–	–	1.00	–	–	1.00	–	–	–	1.00	–	–	1.00	–
Financial barrier	–	–	1.00	–	–	1.00	–	–	–	1.00	–	–	1.00	–	–	–	1.00	–	–	1.00	–
Unintentional nonadherence	***0.46***	0.42	0.78	***0.45***	0.46	0.77	***0.58***	***0.74***	0.71	0.89	***0.66***	0.64	0.86	***0.76***	0.91	0.92	0.96	***0.79***	0.78	0.91	0.86
Self-medication	0.93	0.67	0.97	0.94	0.75	0.97	0.94	0.98	0.86	0.99	1.00	1.00	1.00	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Intentional nonadherence	0.88	0.60	0.95	***0.78***	0.29	0.90	0.81	0.94	0.75	0.97	0.95	0.78	0.98	0.95	0.98	0.92	0.99	0.98	0.92	0.99	0.98
Other	0.99	0.00	0.99	0.99	0.00	0.99	0.98	–	–	1.00	–	–	1.00	–	0.99	0.00	1.00	0.99	0.00	1.00	1.00
System level																					
Conflicting information sources	0.88	0.18	0.94	0.89	0.50	0.95	0.90	0.86	0.53	0.94	0.87	0.55	0.94	0.89	0.96	0.90	0.98	0.86	0.52	0.94	0.89
Confusion	0.98	0.00	0.99	1.00	1.00	1.00	0.98	0.98	0.00	0.99	0.99	0.67	1.00	0.99	0.99	0.00	0.99	0.99	0.67	1.00	0.99
Instruction to patient at transfer incomplete/ inaccurate/illegible	***0.65***	0.75	0.85	***0.35***	0.67	0.68	***0.44***	***0.46***	0.69	0.76	***0.53***	0.78	0.75	***0.51***	***0.79***	0.86	0.91	***0.62***	0.81	0.81	***0.64***
Instruction between prescribers at transfer incomplete/inaccurate/ illegible	***0.67***	0.59	0.86	***0.62***	0.42	0.84	***0.69***	***0.54***	0.55	0.81	***0.55***	0.54	0.81	***0.66***	***0.76***	0.85	0.89	***0.63***	0.77	0.84	***0.64***
Medication history incomplete/inaccurate	***0.74***	0.75	0.89	0.81	0.86	0.92	***0.77***	0.82	0.81	0.92	0.84	0.83	0.93	0.86	0.95	0.95	0.98	0.96	0.97	0.98	0.96
Prescribing error	0.98	0.00	0.99	0.98	0.00	0.99	0.97	0.98	0.00	0.99	0.98	0.00	0.99	0.98	0.99	0.00	1.00	–	–	1.00	1.00
Dispensing error	0.99	0.00	0.99	0.99	0.00	0.99	0.99	–	–	1.00	0.99	0.00	1.00	0.99	–	–	1.00	–	–	1.00	–
Inadequate quantity	0.95	0.00	0.98	0.98	0.67	0.99	0.97	0.98	0.67	0.99	0.98	0.67	0.99	0.99	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Patient barrier(s)	0.83	0.33	0.92	0.86	0.67	0.94	0.83	0.89	0.59	0.95	0.90	0.69	0.96	0.90	0.97	0.92	0.99	0.98	0.95	0.99	0.97
Administrative problem	–	–	1.00	–	–	1.00	–	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Other	0.91	0.00	0.96	0.91	0.22	0.96	0.93	0.93	0.00	0.97	0.94	0.36	0.97	0.95	0.92	0.29	0.96	0.92	0.38	0.96	0.94
Mean	**0.85**	**0.32**	**0.95**	**0.84**	**0.50**	**0.94**	**0.85**	**0.87**	**0.56**	**0.95**	**0.88**	**0.63**	**0.95**	**0.90**	**0.95**	**0.71**	**0.98**	**0.91**	**0.77**	**0.97**	**0.92**

a Round 1 = each CP independently detected and classified discrepancies; Round 2 = CPs compared their results and discussed discrepancies; Round 3 = discussion between each CP and MR. Change in codification was allowed for Rounds 2 and 3.

b Missing values (as indicated by a '–' symbol) reflect a situation in which none of the raters selected a particular item.

c Benchmark scale for AC1: slight if ≤0.2, fair if 0.21–0.40, moderate if 0.41–0.6, substantial if 0.61–0.8 and almost perfect if 0.81–1.00.

d Values under 0.81 for AC1 are in italic bold (if applicable).

AC1 = paradox-resistant index; **CP** = clinical pharmacist; **MR** = main researcher; **n** = number of similar discrepancies detected by the three raters; **pneg** = proportion of negative agreement; **ppos** = proportion of positive agreement.

clinical use. For research purposes, the data conveyed by the instrument are essential because they enable understanding of the process by analysing the types of medication discrepancies and their causal factors. It is only by identifying the main causes that one can design and evaluate appropriate approaches for improvement. However, depending on the objectives of each study, only some parts of the instrument could be used. For example, some studies – as is already the case – could characterize the type of discrepancy but not the cause. This would significantly decrease the amount of information needed. In descriptive studies related to an intervention, the researchers could decide to document only the intervention performed to address the discrepancy.

This study has several strengths. First, both content validity and inter-rater reliability were evaluated. These are essential components of the validity of any measure instrument.[13] Second, different HCPs from different practices were involved in the content validation. Third, the instrument has a separate section devoted to the characterization of the type of discrepancy. This section, together with the section describing causes and contributing factors, helps researchers and clinicians to understand where the gaps are and where resources should be assigned, and their priority, for optimization. Fourth, real patient cases were used to evaluate inter-rater reliability, and those cases were more complex and may better reflect the reality than the vignettes used by Smith et al.,[15] which, therefore, increases validity. Finally, the instrument clearly defines the key concepts of unintentional medication discrepancy and medication reconciliation.[38,39]

Our study has also several limitations. First, the three raters were pharmacists, and the results may, therefore, not be transposable to other HCPs. While the majority of studies concerning optimization of continuity of care in medication management are conducted by pharmacists, those involved in the present study had differing experiences relative to continuity of care, which increases the generalizability among this group of HCPs. However, further studies in which inter-rater reliability was independently assessed amongst pharmacists, physicians and nurses would be of interest. Second, the intra-rater reliability was not tested. Since one would expect the agreement to be higher within a rater than among raters, we felt the assessment was not necessary. Finally, we did not rerun the evaluation after inclusion of the additional modifications proposed to the instrument. However, it is likely that this would only further improve the reliability score, which was already globally very good.

Conclusion

The instrument we propose is a new, valid and reliable tool to assess unintentional medication discrepancies at patient transition from hospital to the community and home care settings. It will now be used in investigations to assess the impact of an intervention aiming at improving the continuity of care.

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Appendices

Appendix 1

Definition of the content validity parameters assessed.

- *Clarity:* The item is clearly phrased.
- *Representativeness:* The item represents the content domain as described in the theoretical definition.

Instrument to Characterize Unintentional Medication Discrepancy

The instrument was developed to facilitate reconciliation of patient medication regimens across different settings, and/or different prescribers and/or the actual, patient medication uptake.
Definitions and examples are available in appendix. COMPLETE ONE FORM FOR EACH DISCREPANCY

Patient	Name: Surname:	Age: Sex: ☐ F ☐ M	***Date :*** / / ***Transfer :***

MEDICATION NAME (INN): ……

ANATOMICAL MAIN GROUP: Tick one choice:

- o A Alimentary tract/metabolism
- o B Blood and blood forming organs
- o C Cardiovascular system
- o D Dermatologicals
- o G Genito urinary system/sex hormones
- o H Systemic hormonal preparations – excluded sex hormones/insulin
- o J Antiinfectives for systemic use
- o L Antineoplastic/immunomodulating agents
- o M Musculo-skeletal system
- o N Nervous system
- o P Antiparasitic products, insecticides and repellents
- o R Respiratory system
- o S Sensory organs
- o V Various

1. TYPE OF UNINTENTIONAL MEDICATION DISCREPANCY IDENTIFIED: Tick one choice:

- o 1. Omission
- o 2. Addition
- o 3. Generic-brand substitution
- o 4. Therapeutic substitution
- o 5. Dosage
- o 6. Frequency of administration
- o 7. Route of administration
- o 8. Formulation
- o 9. Time of administration
- o 10. Length of treatment
- o 11. Other: _____

2. CAUSE(S): Check all that apply :

1. Patient level

- o 1. Adverse drug event
- o 2. Didn't have time to fill the prescription
- o 3. Money/financial barrier
- o 4. Unintentional nonadherence
- o 5. Self-medication
- o 6. Intentional nonadherence
- o 7. Other: _____

2. System level

- o 1. Conflicting information from different informational sources
- o 2. Confusion between:
  - Brand/generic names
  - Medication hospital formulary/ Equivalent medication
- o 3. Instructions to patient at transfer incomplete/inaccurate/illegible
- o 4. Instructions between prescribers at transfer incomplete/inaccurate/illegible
- o 5. Medication history incomplete/inaccurate
- o 6. Prescription error
- o 7. Dispensing error
- o 8. Inadequate quantity
- o 9. Patient barriers not taken into account:
  - Cognitive impairment
  - Vision/hearing/dexterity impairment
  - Swallowing difficulties
  - No caregiver/need for assistance not recognized
  - Literacy/language barrier
- o 10. Administrative problems
- o 11. Other: _____

Continued next page

Fig. A1. Version of the instrument to characterize unintentional medication discrepancies (version resulting from content validation). **HCP** = healthcare professional; **INN** = International Nonproprietary Name.

3. INTERVENTION(S) TO SOLVE THE UNINTENTIONAL MEDICATION DISCREPANCY: Check all that apply :

1. Healthcare professional level - HCP (prescriber, pharmacist, nurse, …)

o 1. HCP informed only
o 2. Requested information from HCP
o 3. Intervention suggested to HCP
o 4. Other:_____

2. Patient level

o 1. Verbal patient medication counselling
o 2. Patient written information provided only
o 3. Patient referred to HCP
o 4. Other: _____

3. Medication level

o 1. Drug changed (cancelled or started)
o 2. Generic-brand substitution
o 3. Therapeutic substitution
o 4. Dosage changed
o 5. Frequency changed
o 6. Route changed
o 7. Formulation changed
o 8. Time of administration changed
o 9. Length of treatment changed
o 10. Other:_____

4. Other

o Other: _____

Details: If necessary, give details on the unintentional medication discrepancy and describe exactly cause(s) and intervention(s):

- *Uniqueness:* The item does not overlap with another item.
- *Helpfulness:* The example provided (if available) illustrates the item.
- *Completeness:* The addition of item(s) in a section is necessary.

Appendix 2

See figure A1 for the version of the instrument that was developed to characterize unintentional medication discrepancies (version resulting from content validation).

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