Development and Validation of the Medication Regimen Complexity Index

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BACKGROUND: Medication regimen attributes, such as the number of drugs, dosage frequency, administration instructions, and the prescribed dosage forms, have been shown to influence patient outcomes. No single tool for quantifying the complexity of general medication regimens has been published in the medical literature.

OBJECTIVE: To develop and validate a tool to quantify the complexity of prescribed medication regimens.

METHODS: Literature findings and the expertise of the authors were used for developing the tool. Eight pharmacy researchers helped in establishing the tool's face and content validity. The new tool was tested on 134 medication regimens from patients with moderate to severe chronic obstructive pulmonary disease. Six regimens with a spread of scores on the tool were presented to a 5-member expert panel that subjectively ranked these regimens to confirm the tool's criterion-related validity. The relationships between scores on the tool and various independent variables were tested to judge the tool's construct validity. Two raters scored 25 regimens using the tool to test its inter-rater and test–retest reliabilities.

RESULTS: A 65-item Medication Regimen Complexity Index (MRCI) was developed. The expert panel had strong agreement (Kendall's W = 0.8; p = 0.001) on their individual rankings of the 6 regimens. The panel's consensus ranking had perfect correlation with the MRCI ranking. The total MRCI score had significant correlation with the number of drugs in the regimen (Spearman's Rho = 0.9; $p < 0.0001$), but not with the age and gender of the patients. Inter-rater and test–retest reliabilities for the total score and scores for individual sections on the MRCI were ≥0.9.

CONCLUSIONS: The MRCI is a reliable and valid tool for quantifying drug regimen complexity with potential applications in both practice and research.

KEY WORDS: complexity, medication regimen index.

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Medication regimens are rich with interesting data for both practitioners and researchers, but information on drug regimens from cross-sectional and longitudinal studies is often confined to the medication classes and/or the total number of drugs present in the regimen.[1-6] Quantification of the various features of medication regimens is critical when evaluating the impact of regimens on outcomes of intervention studies. For example, it is logical to think that using 4 different dosage forms, each with different frequencies and complex additional instructions for their administration, would be more difficult than using 4 agents with the same dosage form, all to be taken at the same time, with no additional instructions. The lack of a reliable tool to quantify complexity results in these 2 regimens being considered as similar. No single tool for quantifying the various attributes of general medication regimens has been published in the medical literature, although an unpublished tool[7] has been used by some researchers in its original form or after modifications to suit specific patient populations or disease conditions.[8,9]

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The complexity of a medication regimen can be simply defined by the number of drugs and the dosing frequency.[10] Others have argued that regimen complexity consists of multiple characteristics of the prescribed regimen including, but not limited to, the number of medications in the regimen, the number of doses per day, the number of dosage units per dose, the total number of units per day, and food–dosing restrictions.[11] Factors such as the number of medications, the decision-making process (in terms of the time, skills, knowledge, and ability) necessary in carrying out the regimen, additional directions, and mechanical actions required for administration were taken into account in the development of the Medication Complexity Index (MCI).[7] However, the MCI failed to show satisfactory reliability with complex regimens and could not demonstrate any significant correlation with outcomes such as medication adherence,[8] warranting further work revising the index.

Number of medications,[12] dosage frequency,[13,14] administration instructions,[15] and the prescribed dosage forms[16-18] have been shown to influence patient adherence. Assuming a cause–effect relationship between these aspects of regimens and adherence, it could be argued that drug regimen–related factors influencing adherence constitute regimen complexity. Although it is recognized that other factors, such as the pharmacologic properties of the drugs in the regimen or the demographic and clinical factors of the patient, also influence adherence, the ability to measure regimen complexity could be a useful adjunct to prediction of adherence. The aim of this study was to develop and validate a reliable and comprehensive tool to quantify the complexity of prescribed medication regimens using information available on drug charts and prescriptions.

Methods

We initially tested the MCI on several hypothetical drug regimens and made changes in its design, content, and weightings. The revised MCI was applied to 134 de-identified regimens from patients with moderate to severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in 1 second <60% of predicted) participating in a randomized controlled trial. After further changes, the tool was given to 8 pharmacy researchers for their comments on its format, comprehensibility, and the weightings allotted for individual items.

Fifty regimens were randomly chosen from the original 134 regimens, scored using the revised tool and ranked in the order of increasing complexity. In the absence of a gold standard, an expert panel was used to establish the criterion-related validity of the tool.[19,20] The 5-member expert panel comprised an adherence expert, pharmacy practice academic, research nurse, clinical pharmacist, and a home medication review (HMR) consultant. None of the panel members had any prior exposure to the contents of the tested tool.

Six regimens (Appendix I) providing a spread of scores were chosen from the 50 regimens, randomly arranged, and presented to the expert panel by a facilitator (JG). Panel members were asked to independently rank the 6 regimens in the increasing order of complexity using their professional judgment. The facilitator instructed the panel members to rank the regimens by judging the difficulty in coping with the provided regimens without taking into account any drug-, clinical-, or patient-related factors. Once all panel members had finished ranking the regimens, the facilitator asked each member to unveil his/her individual rankings to the group and comment on the rationale for the ranking. This prompted further discussion among the panel members, resulting in changes in some of the individual rankings. The facilitator was careful not to comment on any rankings or their rationale. The new tool was given to the panel members at the end of the meeting for their comments.

From the set of 134 regimens, 25 were randomly chosen for judging the construct validity of the new tool. Correlation between complexity scores and number of medications in the regimen was used for judging the convergent validity,[20] while relationships between the complexity scores and age and gender of the patients were tested to confirm the discriminant validity. Two pharmacists (raters), who had no involvement in the design or validation of the new tool, scored the 25 regimens using the new tool twice with a gap of 2 weeks to determine inter-rater and test–retest reliability.

Agreement between the individual rankings of the experts was assessed using Kendall's coefficient of concordance (W). Spearman's rank-order correlation coefficient (Rho) was used for comparing rankings using the new tool with the panel members' individual rankings and the panel's consensus ranking. Correlations between total scores on the new tool and age and number of medications in the regimen were tested using Spearman's Rho. The relationship between total scores and gender of the patients was determined using a Wilcoxon rank sum test. The inter-rater and test–retest reliabilities of the tool were assessed by the intraclass correlation coefficient (ICC) (95% CI). A 2-sided p value of <0.05 was considered statistically significant.

Results

Several limitations of the MCI were revealed when it was tested using theoretical drug regimens.[7] It was found to be outdated in terms of dosage forms and lacked comprehensiveness to account for all the issues contributing to the complexity of regimens. Poor format, insufficient instructions, inappropriate weightings for some items, repetition of some items under different sections, and the need for users to add items and estimate weightings in certain instances limited the user-friendliness of the MCI. Clinical and research expertise of the authors and literature findings were utilized to address these limitations. Feedback from the 8 pharmacy researchers led to further changes in the design, instructions, content, and weightings in the MCI. The modified tool comprised 3 sections to account for information on the dosage forms (section A), dosing frequencies (section B), and additional directions (section C). The complexity index is the sum of scores for the 3 sections. We adopted a checklist style in the new tool to facilitate navigation.

In the absence of any reference except the MCI, we used a logical approach to allocating weightings for different items in the Medication Regimen Complexity Index (MRCI), which were finalized after scrutiny by the experts. In section A, tablets and capsules were assumed to be the most convenient dosage forms and were assigned a weighting of 1. Other dosage forms were given weightings based on the relative degree of difficulty in administering them or the number of key steps involved in their administration process (eg, inhalation devices). Patients need to familiarize themselves with each dosage form in the regimen. Administering the same dosage form more than once was considered to be easier than administering different dosage forms. Since patients are likely to combine similar dosage forms and administer them together, each dosage form present in a regimen was scored only once under this section.

In section B, "once daily" was taken as the baseline (weighting of 1) on which the other weightings were built.

An additional weighting of 0.5 was assigned for regimens to be administered at a fixed interval (eg, "twice daily" has a weighting of 2, but '"every 12 hours" has a weighting of 2.5) considering the additional burden of adhering to the recommended time interval. "As needed" (prn) regimens were assigned half the weightings of their respective daily regimens on the basis that symptoms prompting the need for medication would reduce complexity (eg, 4 times daily has a weighting of 4, while 4 times daily prn has a weighting of only 2). Weightings resulting in fractions <0.5 were rounded. From our experience piloting the tool, when the scale had items with fractions <0.5, manual application of the tool was difficult and the incidence of mathematical errors was higher compared with that after rounding. The researchers involved in the face and content validation of the tool and the expert panel agreed to the rounding. Separate dosing frequencies were introduced into the tool for oxygen therapy, based on literature findings[21] and treatment guidelines,[22] because of the nature of the study population. All dosing frequencies less than "on alternate days" were combined into one category: "on alternate days or less frequently."

Section C included only additional instructions relevant to the administration of the drug that could be identified from drug charts or prescriptions. Ancillary label information related to restrictions on activities during the administration of drugs (eg, "do not drive or operate machinery," or "grapefruit and grapefruit juice to be avoided while being treated") was therefore not included.

Data from 134 patients with COPD with an average ± SD age of 69.0 ± 9.8 years, comprising 65% males and on 8.2 ± 4.0 prescribed medications, were used for validating the tool.

The panel members considered the number of drugs, number of drug administration events per day, dosage forms, and mechanical actions involved in the administration process when ranking the 6 regimens. From the outset, the panel had full agreement on the rankings for regimens with extreme complexities. The overall agreement between the 5 experts was significant (Kendall's W = 0.8; p = 0.001), and the consensus ranking was easily reached following discussion. The correlations of ranking using the new tool with the consensus ranking of the panel and individual rankings of the panel members are given in Table 1.

Based on feedback from the panel, weightings of 2 items were changed and one item ("alter dose after monitoring") was deleted. The expert panel made these recommendations based on their clinical experience and logic, which were in line with the criteria they used for ranking the regimens. The final version of the tool, Medication Regimen Complexity Index (MRCI) comprises 3 sections: A (dosage forms), B (dosing frequency), and C (additional directions), with 32, 23, and 10 items, respectively (Appendix II). Rescoring of the 6 regimens using the final version of the MRCI did not change the rankings.

The significant correlation (Spearman's Rho = 0.9; p < 0.0001) between the number of medications and the investigators' total score confirmed convergent validity of the MRCI. Four patients, each with 8 medications in their regimens, had MRCI scores of 25.5, 30, 32, and 41, while 3 patients with 9 medications in their regimens had MRCI scores of 23.5, 26.5, and 36.5. Total scores on the MRCI did not have any significant correlation with age (Spearman's Rho = 0.34; p = 0.1) or gender (p = 0.487) of the patients, which confirmed the discriminant validity of the MRCI.

The raters required 2–8 minutes to apply the MRCI to each regimen, depending on its complexity. The inter-rater reliability (ICC) for the total score on the MRCI between the 2 raters was 0.991. Sections A, B, and C gave ICCs of 0.978, 0.979, and 0.977, respectively. The test–retest reliabilities for the total scores on the MRCI for the raters were 0.995 and 0.996. Sections A, B, and C showed test–retest reliabilities of 0.991 and 0.979, 0.985 and 0.997, and 0.994 and 0.994, respectively.

Discussion

Complexity of medication regimens is a theoretical concept independent of clinical, pharmacologic, and demographic factors. In the development of the MRCI, the nature of dosage forms, dosing frequencies, and the additional instructions that guide administration were assumed as the key factors contributing to complexity. The MRCI has 3 sections, with each representing a different facet of complexity. This allows the identification of the specific component of regimen complexity that predicts a particular

Table 1. Correlation Between Expert Rankings and Rankings Using the New Tool

Regimen	Rankings Using MRCI	Experts' Consensus Ranking	Expert				
			Academic	Research Nurse	Adherence Expert	Clinical Pharmacist	HMR Consultant
A	1	1	1	1	1	1	1
B	2	2	3	2	5	2	3
C	3	3	2	3	2	3	4
D	4	4	4	4	3	5	5
E	5	5	5	5	4	4	2
F	6	6	6	6	6	6	6
Spearman's Rho		1.000	0.943	1.000	0.657	0.943	0.657
p Value		<0.0001	0.005	<0.0001	0.156	0.005	0.156

HMR = home medication review; MRCI = Medication Regimen Complexity Index.

outcome of interest. The MRCI has been designed as an open index, since there is no upper limit for the number of drugs that could be prescribed for a patient or the number of additional instructions possible in a particular regimen.

Face and content validities of the new tool were achieved through feedback from 8 pharmacy researchers. The content, weightings, and instructions of the tool evolved further during the validation process. Since no gold standard exists for measuring medication regimen complexity, the consensus ranking by an expert panel was used as the reference standard for establishing the tool's criterion-related validity. Perfect correlation between the expert panel's consensus ranking and ranking using the new tool confirmed the appropriateness of the new tool in quantifying regimen complexity.

We were aware of the potential for the facilitator to introduce bias in the outcomes of the expert panel meeting. This was addressed by providing concise guidelines for the panel members and by restricting the facilitator's involvement in further discussion. Initially, the HMR consultant and adherence expert took some of the pharmacologic properties of the drugs and disease-related factors into account while ranking the regimens, contrary to the guidelines given, resulting in lesser agreement with other panel members. Once the purpose of the tool was further clarified through discussion among the panel members, consensus was reached easily. All of our expert panel members were part of one academic faculty; 4 were pharmacists. Hence, it is possible that the opinions of the panel could be different from those of other healthcare professionals and patients. However, all of the panel members were senior practitioners with affiliations to various multidisciplinary advisory panels and boards at both national and international levels. Additionally, rankings by a research nurse were in complete agreement with the consensus reached by the panel.

The correlation observed between the number of medications and total MRCI scores does not negate the significance of the MRCI. The number of medications present in a regimen contributes to complexity, but does not constitute complexity per se.[7,10,11] Although older patients and women are more prone to polypharmacy,[23] age and gender do not contribute to the complexity of regimens, whereas number of medications does.[7] Hence, it is desirable to have a good correlation between the number of drugs and the total MRCI scores, especially when the regimens have a broad spectrum of complexity. The MRCI has been shown to discriminate between regimens with equal number of medications, and higher complexity scores were obtained for some regimens with fewer drugs. These findings confirm the advantages of MRCI over a simple medication count in quantifying regimen complexity.

Disagreements among the raters resulted from lack of awareness of the available options (eg, special dosing frequency instructions for oxygen), confusion with some of the options in section C (eg, alternating dose and variable dose), and mathematical errors. The 2 raters interpreted some of the instructions and items in the MRCI differently. An electronic version of the MRCI linked to prescribing and dispensing programs could be developed to address these limitations. There were occasional instances where raters had different scores for individual sections, but the same total scores. This is apparent from the greater ICC observed for total scores in the MRCI compared with scores for individual sections and is suggestive of flexibility within the MRCI.

Multiple comorbidities are common among patients with COPD.[24] They are often prescribed complex medication regimens comprising time contingent and as-needed drugs to be administered by multiple routes, for both respiratory and nonrespiratory conditions.[25,26] Medication utilization by our subjects was greater than that reported in other studies on general elderly populations.[4,5,27] All of these justify our sample selection for the validation processes and are suggestive of the applications of the MRCI in other practice settings and disease conditions. However, for wider use of the tool, its reliability, practicability, and validity in other patient populations and practice settings need to be tested.

The MRCI could be used as a risk assessment tool to predict health outcomes or for identifying patients who would greatly benefit from additional services such as domiciliary reviews, special pharmacotherapy consultations, and home visits. This evaluation process could be easily performed at the time of discharge from hospitals or at the time of dispensing by linking the MRCI with dispensing programs. The MRCI could be useful for reporting drug regimen data and also for proving the null hypothesis in clinical and epidemiologic studies. Availability of a standard tool for quantifying the complexity of regimens would help in comparing the outcomes of various intervention studies.

Summary

Our aim was to develop and validate a tool for quantifying the complexity of prescribed medication regimens using information from drug charts or prescriptions. The MRCI quantifies complexity of regimens according to the dosage forms, dosing frequencies, and additional directions. The MRCI is a reliable and valid tool with potential applications in both clinical practice and research.

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Appendix I. Drug Regimens Evaluated by Expert Panel

Regimen A
- albuterol MDI 100 μg 2 puffs each morning

Regimen B
- albuterol MDI 100 μg 2 puffs as needed
- flunitrazepam 1 mg 1/2 tablet each night
- fluticasone MDI 125 μg 2 puffs twice daily
- ipratropium MDI 42 μg 2 puffs 3 times daily

Regimen C
- aspirin 100 mg 1 tablet daily
- budesonide Turbuhaler 400 μg 2 puffs at midday
- eformoterol Aerolizer 12 μg 2 puffs twice daily
- ipratropium MDI 42 μg 2 puffs twice daily
- simvastatin 20 mg 1 tablet each night
- zolpidem 10 mg 1 tablet at night as needed

Regimen D
- albuterol MDI 100 μg 1 puff as needed
- albuterol nebules 2.5 mg/2.5 mL 1 each morning and afternoon
- alendronate sodium 5 mg 1 tablet weekly
- fluticasone MDI 125 μg 1 puff twice daily
- furosemide 40 mg 1 tablet twice daily
- ibuprofen 400 mg 1 tablet twice daily
- ipratropium nebules 250 μg/mL 1 each morning and afternoon
- perindopril 4 mg 1 tablet each morning
- potassium chloride 600 mg SR 1 tablet twice daily
- theophylline 300 mg SR 1 tablet twice daily

Regimen E
- albuterol MDI 100 μg 1–2 puffs every 4–6 hours
- albuterol nebules 2.5 mg/2.5 mL 1 twice daily
- doxycycline 50 mg 1 tablet daily after food
- fluticasone plus salmeterol Accuhaler 500/50 μg 1 puff twice daily
- ipratropium MDI 42 μg 1–2 puffs every 4–6 hours
- ipratropium nebules 500 μg/mL 1 twice daily
- medroxyprogesterone 10 mg tablets, use as directed
- estradiol 50 μg 1 patch each week
- pantoprazole 40 mg 1 tablet daily
- piroxicam 10 mg 1 capsule as needed

Regimen F
- acetaminophen 500 mg 2 tablets 4 times daily
- albuterol MDI 100 μg 2 puffs as needed
- albuterol nebules 2.5 mg/2.5 mL 1 puff 4 times daily
- alendronate sodium 70 mg 1 tablet weekly
- amitriptyline 50 mg 1 tablet each night
- atorvastatin 10 mg 1 tablet each night
- colchicine 0.5 mg 1 tablet daily
- digoxin 250 μg 1 tablet daily
- doxycycline 100 mg 1 tablet each morning
- ergocalciferol 25 μg 1 capsule daily
- ferrous sulfate plus folic acid 1 tablet daily
- fluticasone MDI 250 μg 2 puffs twice daily plus salmeterol MDI 25 μg 2 puffs twice daily (separate inhalers) or fluticasone plus salmeterol MDI 250/25 μg 2 puffs twice daily (1 inhaler)
- furosemide 40 mg 2 tablets twice daily
- gliclazide 80 mg 3 tablets each morning
- human insulin injection 3 mL, use as directed
- ipratropium MDI 42 μg 1 puff 4 times daily
- ipratropium nebules 250 μg/mL 1 puff 4 times daily
- levodopa plus benserazide 100/25 mg 1 tablet each morning and 2 tablets at midday
- metformin 500 mg 2 tablets twice daily
- pantoprazole 40 mg 1 tablet daily
- prednisolone 5 mg 1 tablet twice daily
- sertraline 50 mg 1 tablet each morning
- spironolactone 25 mg 1 tablet at lunch
- warfarin tablets, use as directed

MDI = metered-dose inhaler; SR = sustained release.

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Appendix II. Medication Regimen Complexity Index (MRCI)

MEDICATION REGIMEN COMPLEXITY INDEX

Patient ID: ----------

Total no. of medications (including prn/sos medications): ----------

Instructions

1. MRCI applies only to prescribed medications. All entries are to be made only based on information on the label or drug chart (at the time of dispensing or discharge). No assumptions are to be made based on clinical judgement.
2. There are three sections in the scale. Complete each section before proceeding to the next. At the end, add the scores for the three sections to give the MRCI.
3. If the same medication (same brand and same dosage form) is present more than once in different strengths in a regimen (e.g. Marevan 5mg, 3mg and 1 mg mdu), it is still considered as one medication.
4. In cases where the dosage is optional, choose the dosing instruction with the smallest dose/frequency. (e.g. Ventolin MDI 1-2 puffs, 2-3 times daily will get weightings for 'metered dose inhalers', 'variable dose' and 'twice daily'; but not for 'multiple units at one time')
5. In certain cases the dosing frequency needs to be calculated (e.g. Ranitidine 1mane and 1nocte is 1twice daily)
6. It is possible that with certain 'use as directed' instructions, the regimen will not get a score under dosing frequency (e.g. Prednisolone 5mg mdu)
7. If there is more than one dosing frequency direction, they should be scored for all the dosing frequency directions (e.g. Ventolin MDI 2 puffs bd and prn, will get scores for 'metered dose inhalers', 'multiple units at one time', 'twice daily' as well as 'prn')
8. Instances where two or more medications are mutually exclusive, they need to be scored twice or more as prn with the recommended dosing frequency (e.g. Ventolin MDI or Ventolin nebuliser twice daily will get scores for both 'metered dose inhalers' and 'nebuliser' under dosage forms, but needs to be scored two times for 'twice daily prn')
9. In cases where there is no matching option, choose the closest option (e.g. six times daily could be considered as 'q4h')

A) Circle the weighting corresponding to each dosage form (ONCE ONLY) present in the regimen.

Dosage Forms		Weighting
ORAL	Capsules/Tablets	1
	Gargles/Mouthwashes	2
	Gums/Lozenges	2
	Liquids	2
	Powders/Granules	2
	Sublingual sprays/tabs	2
TOPICAL	Creams/Gels/Ointments	2
	Dressings	3
	Paints/Solutions	2
	Pastes	3
	Patches	2
	Sprays	1
EAR, EYE & NOSE	Ear drops/creams/ointments	3
	Eye drops	3
	Eye gels/ointments	3
	Nasal drops/cream/ointment	3
	Nasal spray	2
INHALATION	Accuhalers	3
	Aerolizers	3
	Metered dose inhalers	4
	Nebuliser	5
	Oxygen/Concentrator	3
	Turbuhalers	3
	Other DPIs	3
OTHERS	Dialysate	5
	Enemas	2
	Injections: Prefilled	3
	Ampoules/Vials	4
	Pessaries	3
	Patient controlled analgesia	2
	Suppositories	2
	Vaginal creams	2
	Total for Section A	

DPI = dry-powder inhaler; MDI = metered-dose inhaler.

(continued on page 1375)

Appendix II. Medication Regimen Complexity Index (MRCI) (continued)

B) For each medication in the regimen tick a box [√] corresponding to the dosing frequency. Then, add the no. of [√] in each category and multiply by the assigned weighting. In cases where there is no exact option, choose the best option.

Dosing Frequency	Medications	Total	Weighting	Weighting × No. of medications
Once daily			1	
Once daily prn			0.5	
Twice daily			2	
Twice daily prn			1	
Three times daily			3	
Three times daily prn			1.5	
Four times daily			4	
Four times daily prn			2	
q 12h			2.5	
q 12h prn			1.5	
q 8h			3.5	
q 8h prn			2	
q 6h			4.5	
q 6h prn			2.5	
q 4h			6.5	
q 4h prn			3.5	
q 2h			12.5	
q 2h prn			6.5	
prn/sos			0.5	
On alternate days or less frequently			2	
Oxygen prn			1	
Oxygen <15hrs			2	
Oxygen >15hrs			3	
			Total for Section B	

C) Tick a box [√] corresponding to the additional directions, if present in the regimen. Then, add the no. of [√] in each category and multiply by the assigned weighting.

Additional Directions	Medications	Total	Weighting	Weighting × No. of medications
Break or crush tablet			1	
Dissolve tablet/powder			1	
Multiple units at one time (e.g. 2 tabs, 2 puffs)			1	
Variable dose (e.g. 1-2 caps, 2-3 puffs)			1	
Take/use at specified time/s (e.g. mane, nocte, 8 AM)			1	
Relation to food (e.g. pc, ac, with food)			1	
Take with specific fluid			1	
Take/use as directed			2	
Tapering/increasing dose			2	
Alternating dose (e.g. one mane & two nocte, one/ two on alternate days)			2	
			Total for Section C	

Medication Regimen Complexity = Total (A) + Total (B) + Total (C)=

DPI = dry-powder inhaler; MDI = metered-dose inhaler.

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EXTRACTO

TRASFONDO: Se ha demostrado que características del régimen de tratamiento, tales como el número de medicamentos, la frecuencia de las dosis, las instrucciones para la administración, y las formas de dosificación prescritas, influyen en los resultados de la terapia en los pacientes. No se ha publicado en la literatura médica ningún instrumento que ayude a cuantificar la complejidad de los distintos regímenes de tratamiento.

OBJETIVO: Desarrollar y validar un instrumento para cuantificar la complejidad de los distintos regímenes de tratamiento que se prescriben.

MÉTODOS: El instrumento se desarrolló usando como base hallazgos publicados en la literatura científica y la experiencia de los autores. Ocho investigadores en farmacia ayudaron a establecer la validez de contenido y el aspecto. El instrumento se aplicó a 134 regímenes de tratamiento de pacientes con enfermedad pulmonar obstructiva crónica (COPD, por sus siglas en inglés) de moderada a severa. Se presentaron 6 regímenes con una dispersión de puntuaciones en el instrumento a un panel de 5 expertos, quienes los clasificaron subjetivamente para confirmar la validez de criterio. Se examinó la relación entre las puntuaciones obtenidas mediante el instrumento y varias variables independientes para determinar la validez de construcción del instrumento. Dos evaluadores utilizaron el instrumento en 25 regímenes para probar la confiabilidad entre evaluadores y la confiabilidad de prueba–reprueba.

RESULTADOS: Se desarrolló un Índice de Complejidad del Régimen de Tratamiento de 65 pregunta (MRCI, por sus siglas en inglés). El panel de expertos concordó completamente en sus clasificaciones individuales de los 6 regímenes (W de Kendall = 0.8; p = 0.001). La clasificación por consenso del panel tuvo una correlación perfecta con la clasificación del MRCI. La puntuación total en el MRCI tuvo una correlación significativa con el número de medicamentos en el régimen (Rho de Spearman = 0.9; p < 0.0001), pero no con la edad y el género de los pacientes. La confiabilidad entre evaluadores y de prueba–reprueba para la puntuación total y las secciones individuales del MRCI fueron de 0.9 o más.

CONCLUSIONES: El MRCI es un instrumento confiable y válido para cuantificar la complejidad de los regímenes de tratamiento; puede aplicarse tanto en la práctica clínica como en la investigación.

Homero A Monsanto

RÉSUMÉ

CONTEXTE: Il a été démontré que les caractéristiques des régimes médicamenteux telles que le nombre de médicaments, la fréquence d'administration ainsi que les formes posologiques prescrites peuvent avoir un impact sur l'issue du traitement. Aucune publication ne fait mention d'un outil pouvant aider à évaluer et quantifier la complexité d'un régime médicamenteux.

OBJECTIF: Développer et valider un outil pour évaluer la complexité de régimes médicamenteux.

MÉTHODES: Une recherche de la littérature de même que l'expertise des auteurs a été utilisée pour développer l'outil. Huit chercheurs en pharmacie ont collaboré à établir l'interface et la validité du contenu. Le nouvel outil a été validé à l'aide de 134 régimes médicamenteux de patients souffrant de maladie pulmonaire obstructive chronique. Six régimes ayant des différences dans leurs scores ont été présentés à un groupe de 5 membres experts qui ont subjectivement classé ces régimes afin de confirmer la validité des critères de l'outil. Les relations entre les scores et les variables indépendantes ont été évaluées afin de bâtir la validité de l'outil. Deux individus ont évalué 25 régimes en utilisant l'outil afin de mesurer sa variabilité interindividuelle et sa répétitivité.

RÉSULTATS: L'index de complexité des régimes médicamenteux (MRCI) utilisant 65 critères a été développé. Le groupe d'experts a été fortement en accord dans la classification individuelle des 6 régimes (Kendall W = 0.8; p = 0.001). Il y a eu une corrélation parfaite entre le consensus du groupe et les scores obtenus avec le MRCI. Le score du MRCI a démontré une corrélation significative entre le nombre de médicaments (Rho Spearman: 0.9; p < 0.0001) mais non avec l'âge et le sexe des patients. La variabilité interindividuelle de même que la répétitivité des scores du MRCI étaient égales ou supérieures à 0.9.

CONCLUSIONS: Le MRCI est un outil valide et fiable pour quantifier la complexité d'un régime médicamenteux et pourrait être utilisé en pratique comme en recherche.

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