Validation of an assessment, medical problem-oriented plan, and care plan tools for demonstrating the clinical pharmacist’s activities

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ABSTRACT

Background: Identifying, preventing, and resolving medical problems are some of the most central functions of clinical pharmacy (CP) and pharmaceutical care (PC) practitioners. Usually, the practitioners and researchers find a challenging to link the problem and the appropriate intervention to be included in the care plan. A comprehensive, well-structured, validated, simple use and standardized tool, which fulfill these requirements in daily clinical practice, are currently rare.

Purpose: To design and validate a comprehensive medical problem-oriented plan (MPOP) classification system in addition to assessment and care plan tools for use in practicing, researching, and teaching CP and PC.

Materials and methods: The methodology was composed of five steps: literature searching and classification of the problems; developing the assessment of treatments and care plan templates; implementing the tutorial; validation; completion and evaluation of the final version.

Results: The classification system (MPOP tool) is an open hierarchical structure, where higher levels are broadly defined, consisting of 5 main categories, and lower levels become more specific. In the MPOP tool’s final version, a total of 24 major subcategories were distributed to the major five categories as 4 (Indication), 5 (Effectiveness), 7 (Safety), 3 (Patient), and 5 (Miscellaneous). Different minor subcategories (subcategory 2, n = 62) and 95 plans (interventions) were determined. Each of the subcategories and plans includes a notes section that represents a specific detail. There was strong agreement on using the MPOP tool between the two authors (κ = 1.000, p < 0.0005) and between three random clinical pharmacists out of 17 (κ = 0.947, 95% CI, 0.840 to 1.055, p < 0.0005). The validity and reliability statistics demonstrate that the Alsayed_v1 tools are extremely appropriate. The majority of users expressed high satisfaction with all the assessment, MPOP, and care plan tools.

Conclusion: The Alsayed_v1 tools introduced in this paper were applied to actual patient cases and were validated. These tools include: assessment of treatments, MPOP, and care plan. Including the interventions in the classification system is important especially in PC research where the type of recommendations should be documented to assess the value and impact of the service and saves the time of practitioners in typing the appropriate interventions. By applying the steps within these Alsayed tools, the clinical pharmacists can actively provide the best practice to achieve the optimal patient outcome.

1. Introduction

Identifying, preventing, and resolving medical problems are some of the most central functions of clinical pharmacy (CP) and pharmaceutical care (PC) practitioners (Alsayed et al., 2022). The utilization of a classification system would aid in the collection of these problems and the assessment of interventions (Lampert et al., 2008).

The development of any classification system depends on the definition of the problem adopted. Several definitions for the drug-related problem (DRP) are available in the literature (Hepler 1990, van Mil et al., 2004). In the literature, several classification
2. Methods

2.1. Literature searching and classification of the problems (Step 1)

PubMed and Google scholar were used to look for published articles about medical problems and interventions categorization. The following terms were used in our search: treatment related problem (TRP), drug related problem (DRP), drug therapy problem, medication error, medication related problem, medication therapy problem, therapy related problem, and pharmaceutical care intervention. Any retrieved article discussing or studying the searching terms was then thoroughly examined by the current paper's authors (all of whom hold Ph.D. or MSC degrees in clinical practice or PharmD, and have a minimum of four years of experience teaching and/or practicing CP and PC). The categorization systems identified were reviewed, compared to one another, aggregated, and then classified into groups based on their common or shared construct to reach the first version of MPOP. The outcome of the problems section in the MPOP tool was adopted from a previously published article (Snyder and Fields 2010), and is used when applicable.

The term MPOP was selected in the current research. We defined MPOP as an interventional plan directed to a specific medical problem or event involving patient treatment to achieve the optimum outcomes for a certain patient.

2.2. Developing the assessment of treatments and care plan templates (Step 2)

The template related to the assessment of treatments was supposed to be critical since it assists in examining patient data for the presence of problems and then it helps in providing an appropriate plan (Alsayed et al., 2022). Each major group of the MPOP tool (Indication, Effectiveness, Safety, Patient, and Miscellaneous) was researched in detail, and then an appropriate assessment approach was established based on the structure of the MPOP template (as shown in the Results section). The care plan template was designed to include the identified MPOP with a free text to allow writing more details of the interventions, monitoring parameters, and follow-up. Every care plan table is designed for a specific disease/problem the patient has.

2.3. Implementing the tutorial (Step 3)

We provided the tutorial in light of a recent published study (Alsayed et al., 2022). In addition to the tools available in this study, we used two templates available in the appendix of our recent study: data collection and basic calculations (Alsayed et al., 2022).

This tutorial lasted for four weeks (a total of 10 training hours). Tutorials were provided throughout the week and incorporated problem-based learning methodologies as well as hands-on and small group activities.

This step intended to familiarize participants with the clinical problem-solving approach through didactic lectures. This step includes giving a series of didactic lectures on pharmaceutical and disease information resources via Microsoft Teams®. The following websites were discussed and used throughout the tutorial: accesspharmacy.mhmedical.com, Lexicomp’s Drug Information, UpToDate. https://online.epocrates.com, https://www.Drugs.com, and https://www.medscape.com. Participants must consult at least two of these sources in order to obtain the necessary information. In addition, participants were taught decision-making and professional communication skills over this time period.

Three skill-based workshops were conducted in order to facilitate the application of theory. Participants in the workshop were presented with simulated patient case studies and engaged in group discussions. Following the presentation of these cases, the researchers led a structured, open conversation. The primary researcher communicated with participants through video conference, providing pertinent examples, discussions, workshops, and encouraging feedback.

2.4. Validation (Step 4)

The test version was ready for validation at this step. The validation process’s objective was to identify and adjust any defects in the tools and then to produce the final version. Validation is essential for ensuring that the tools is straightforward, simple to use, and easily understood by users. Additionally, validation is required to confirm that each classification is distinct.

Following the production of the test version, the following issues were examined:

- First, content validity: two authors thoroughly examined the test version to ensure that all contents were relevant to MPOP and PC practice. The authors were continuously discussing
and reviewing the test version of the assessment, MPOP, and care plan tools for three years. The test version was used by 129 participants (17 clinical pharmacists, two general practitioners (GPs), and one family medicine specialist, as well as 109 fourth- and fifth-year pharmacy students enrolled in a CP course). The cognitive interviews were used to verify participants' comprehension of the tools and their ability to offer valid responses. Through this process, every participant submitted a report and feedback outlining their thoughts on the tools’ content, language, simplicity, and areas for improvement. We conducted semi-structured interviews consistent with cognitive interviewing guidelines and expert recommendations (Willis 2004, DeWalt et al., 2007, Patrick et al., 2011). Participants marked items they found hard to understand. An interviewer then asked about their responses to particular items (Willis 2004). If participants required assistance or clarification while completing the tools, interviewers noted this in their notes. To standardize procedures across study sites, four interviewers were trained during a three-day in-person workshop. All study investigators and interviewers participated in weekly conference calls to discuss interview experiences, findings, and ongoing progress. The authors carefully considered each feedback and, where necessary, taking measures to improve the tools. The two authors classified each item as “essential,” “useful but not essential,” or “not necessary.” Using the obtained data, the Content Validity Ratio (CVR) was determined. The CVR is the proportion obtained by dividing the agreement in the essential category by the total number of evaluations. Additionally, the Content Validity Index (CVI) was calculated. Tristán’s adaptation of the Lawshe model demonstrates that, regardless of the number of evaluators participating, a CVR score of 0.58 is sufficient to deem an item acceptable (Tristán-López 2008).

- Second, internal validity was determined by examining the tool’s uniqueness and completeness. Uniqueness is obtained when each MPOP is assigned to a specific category or subcategory. If the tool has all potential MPOPs, it is said to be complete. To ensure uniqueness, 60 cases (each with different medical conditions) were distributed to 60 participants (out of 129) who had just completed a CP course to account for every type of medical problem in these cases using the three test templates. The participants were tasked with determining whether or not there was any MPOP in the test version and classifying it. The results were thoroughly analyzed, and in cases of disagreement, the MPOP's classification, the classification's phrasing was amended, the classification itself was modified, and/or written instructions were included to prevent the MPOP's misclassification. The test version was pilot tested for over a year to more than 500 patients (internal medicine, general surgery, and emergency department) handled by seven clinical pharmacists. The patient records and clinical pharmacist assessments were evaluated to ensure that the tool addresses every possible MPOP. When a new MPOP was created, a new category or subcategory was added.

- Third, face validity was validated using three scores: comprehensiveness, clarity, and accuracy. The Fleiss' Kappa index was calculated, enabling the evaluation of observer agreement when randomness was taken into account. The results were interpreted according to Landis and Koch’s recommendation that items with scores between 0.61 and 0.80 be regarded as acceptable, showing substantial agreement (Landis and Koch 1977).

- Finally, Cronbach’s alpha was used to determine the internal consistency or reliability of the scale, with a Cronbach’s alpha of 0.70 or higher being appropriate if the scale is to be utilized in research (Tavakol and Dennick 2011).

2.5. Completion and evaluation of the final version (Step 5)

Data were analyzed using SPSS Statistics v.24 (IBM Corporation, New York, NY, USA). Cohen’s Kappa was used to assess inter-rater agreement and reproducibility between the two authors, while Fleiss’ Kappa was used to assess agreement amongst the other 17 clinical pharmacists. Two of the authors examined a collection of 60 cases, used in the previous step, that reflect the majority of the potential MPOPs subcategories in the final version. Additionally, each of these 60, was randomly assigned to three of 17 clinical pharmacists (having MSc of CP or PharmD). Three weeks later, the same set of cases was presented to the same raters to assess reproducibility. Cohen’s and Fleiss’ K values greater than 0.80 indicate strong reproducibility or agreement (Eugenio and Glass 2004, Artstein and Poeysio 2008).

To assess the tools’ satisfaction (external validity), a questionnaire was distributed to 129 individuals (as stated in step 4) who utilized the tools. The questionnaire has 12 questions in which the user is asked to rate their agreement or disagreement (on a five-point scale) with statements about the tools’ usability and usefulness, their satisfaction with the tools, and their readiness to use the tools in their practice in the future. The study was completed on November 2021.

Ethical approval was obtained from the Applied Science Private University ethics committee, number 2021-PHA-39, and from a medical center and hospital located in Amman, Jordan (2021-IRB-1-1 and 2021-P-O-925693, respectively). Patients’ informed consent was not required since this research was performed retrospectively.

3. Results

The Alsayed_v1 tools used in this study are the result of more than seven years of CP practice, research, and teaching and was applied to more than 4,000 patients during the development process. The development of these tools is part of the medical informatics and PC project, managed by the primary author, in Jordan.

All problems reported in the initial step that passed the authors’ evaluation were pooled and then classified according to their common or shared components, which are: Indication, Effectiveness, Safety, Patient, and Miscellaneous.

The assessment of treatments is depicted in Table 1 (The original word version allows a flexible space for typing, and the user will need copies depending on the total number of treatments). The user needs to find the recommended data from the appropriate references, document the data related to the patient and assess the different parts with documentation and evaluate the agreement between the recommended and medication indication in a specific patient. Effectiveness is evaluated by comparing patients’ treatment with the most updated clinical practice evidence-based guideline recommendations and achievements of the goals of treatment. Safety is assessed by conducting a review of symptoms and by investigating patients’ data for any possible adverse reaction, contraindication, or precaution related to patients’ medications. Possible medication safety-related problems are also checked by identifying if the patient is at risk but is not receiving prophylaxis. Appropriateness of dosing regimen is checked by comparing doses with evidence-based guidelines recommendations or using drug information references such as Lexicomp’s Drug Information. Patients’ clinical characteristics are taken into account when deciding about the appropriateness of the dosage regimen. UpToDate drug interactions tool is used for identifying clinically important drug-drug interactions. Patient knowledge and adherence are assessed and documented. Knowledge regarding the disease, non-pharmacological, and pharmacological treatments are
documented as either poor, average, or appropriate. Adherence to non-pharmacological and pharmacological treatments should be assessed and documented. Non-adherence to pharmacological therapies can be divided into two categories: primary and secondary. Primary non-adherence happens when a patient is prescribed a new treatment but fails to receive the treatment (or its appropriate alternative) within a reasonable amount of time after the initial prescription. Secondary non-adherence is described as when a patient fills a prescription but does not take the drug as intended or as prescribed. Non-adherence can also be characterized based on the patient’s intent to take treatment; this distinction is known as intentional versus unintentional non-adherence. Due to the multiplicity of underlying circumstances, several types of non-adherence must be treated individually. Reasons for poor knowledge and non-adherence can be recorded. Cost-effectiveness including asking the patient about affordability is also documented. After performing this analysis step for one drug, all drugs taken by the patient are required to be analyzed before performing the synthesis step (MPOP tool). Details with a medical case example will be provided in another paper.

Regarding reliability, the instrument generated a Cronbach’s alpha coefficient of 0.74, indicating that the instrument’s reliability is adequate (Streiner 2003).

The following subcategory 2 was added to III-F: “a. The patient is at high risk to develop a safety problem”
- To address the non-pharmacological and pharmacological treatments of the allergic reaction plans number 8 and 9 were added to the III-G subcategory.
- Self-care activities term was deleted and combined with the non-pharmacological treatment throughout the whole tool.

In terms of face validity and scale accuracy, the agreement index - as determined by Fleiss’ Kappa - suggested that the instrument was generally in substantial agreement, as demonstrated by understanding 0.79, clarity 0.78, and accuracy 0.68. The participants’ evaluation revealed a 98 percent agreement rate, a 96 percent clarity agreement rate, and a 96 percent accuracy agreement rate. On the basis of these findings, modifications were made to the item wording, taking into consideration both the experts’ and participants’ comments.

Cohen’s κ was run to determine if there was an agreement between the two authors on using the MPOP tool in classifying the medical problems in the 60 cases. There was extremely strong agreement between them, κ = 1.00, p < 0.005. Fleiss’ kappa was run to determine if there was an agreement between three random clinical pharmacists out of 17 on using the MPOP tool in classifying the problems in the same 60 cases. Also, there was strong agreement between them, κ = 0.947 (95% CI, 0.840 to 1.055). Fleiss’ kappa was statistically significant, p < 0.005. Individual kappa as well as statistically significant.

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The documents of the assessment and care plan templates that were filled by participants were compared and were almost similar and received favorable feedback from them during the cognitive interview. The mean (SD) of the number of minutes spent from receiving the case until submitting the three templates was 43.84 (20.80). The tools also received favorable response from users as the majority of them expressed a high satisfaction with all the assessment, MPOP, and care plan tools (Table 2). The treatment assessment template helped the participants to be able to identify MPOPs; 41.9% provided a score of 5/5, with mean (SD) of 4.15 (0.93). The MPOPs template was reported to be comprehensive (M = 4.26, SD = 0.80). Also, the care plan part was reported to be beneficial with an average score of 4.26 (0.80). More than 80% of participants stated that they will use the MPOP and care plan templates in their practice (Table 2).

The MPOP tool’s final version is shown in Table 3. A total of 24 major subcategories were distributed to the major five categories as 4 (Indication), 5 (Effectiveness), 7 (Safety), 3 (Patient), and 5 (Miscellaneous). Different minor subcategories (subcategory 2, n = 62) and 95 plans (interventions) were determined (Table 3). Each of the subcategories and plans includes a notes section that represents a specific detail. One point to consider that the user can select more than one plan for a specific main problem (for example, non-pharmacological and pharmacological therapy).

After choosing the appropriate MPOPs for each disease, the care plan template (Table 4), for each disease or medical problem, is used to include the identified MPOPs with a free text to allow writing more details of the interventions, monitoring parameters, and follow-up. To evaluate the achieved therapeutic outcome during the follow-up period, the terms shown in Fig. 1 are used in the care plan-specific section. Fig. 2 represents a summary of the suggested clinical pharmacist activity concluded from this study, which is similar to the Pharmacists’ Patient Care Process (PPCP) with some modifications https://jcpp.net/patient-care-process/.
4. Discussion

The current research aimed to design and validate a comprehensive medical problem-oriented plan (MPOP) classification system in addition to assessment and care plan tools for use in practicing, researching, and teaching CP and PC. This classification system is connecting the identified medical problem with the required intervention(s) according to each category of medical problems.

Internationally published classification systems were reviewed, clinical experience was reflected, and healthcare system characteristics and needs were taken into consideration. The developed classification system was meant to be simple for use, applicable, and useful in different healthcare settings (general practice, hospitals, community pharmacy, and so forth), and for research and teaching purposes as well. The classification system is an open hierarchical structure, where higher levels are broadly defined, consisting of 5 main categories, and lower levels become more specific. Including the interventions in the classification system is important especially in PC research where the type of recommendations should be documented to assess the value and impact of the service and saves the time of practitioners in typing the appropriate interventions. However, the user of this MPOP tool has to provide some details in the free text part.

The development of any classification system depends on the definition of the problem adopted. Several definitions for the DRP are available in the literature (Hepler 1990, van Mil et al., 2004), Llimos and Faus (Fernandez-Llimos and Faus 2005) have suggested dropping the term DRP and using the term ‘negative clinical outcome’ instead. The Granada Consensus (Pharm 2002) suggests that poor compliance and drug interactions should not be categorized as DRPs. But this is not advantageous for the patients who are our main concern when providing PC. By using the term ‘negative clinical outcome’ we may neglect a major issue which is prevention. The ‘negative clinical outcomes’ term indicates a current issue or illness, and it neglects prevention and a problem that is a result of improper use of medications (like non-adherence to lifestyle modifications, poor knowledge about medications/disease, or drug interactions). Moreover, Van Mil et al. (van Mil et al., 2004) has questioned the issue of classifying untreated condition as DRP. Therefore, the term TRP has been used for the last 15 years (AbuRuz et al., 2006) to expand the scope of PC practice and becomes more preferred in some literature to avoid limiting the scope of PC to medication-related care.

We choose to use the term “Medical Problem-Oriented Plan, MPOP” rather than TRP or DRP the most widely used in the literature. The later terminology limits the scope of PC to medication-related care. Although the documentation of problems is important in the research, teaching, practicing, and it helps to go further into the plan, incorporating the medical plan with the problem classification is supposed to improve using such classifications in real practice. Therefore, the term MPOP was selected in the current research, and we suggest that it can replace the other terms. We defined MPOP as an interventional plan directed to a specific medical problem or event involving patient treatment to achieve the optimum outcomes for a certain patient.

We examined MPOPs for inclusion in the tool during the development process and ensured that no repetition or crossover occurred between the various classifications (uniqueness). All identified problems were then grouped into five main categories (Indication, Effectiveness, Safety, Patient, and Miscellaneous), each of which represents an issue that must be addressed in order to achieve the intended therapeutic outcomes. To practice the CP, the healthcare professional must match between the medications and the patients’ diseases to ensure the appropriate indication of every medication and disease condition and also to make sure that the patient is receiving the most effective and safest cost-effective medication. The patient on the other hand must have good knowledge about his medication(s) and disease(s) and has to adhere to the recommendations that were agreed on with his physician or pharmacist. Other issues that are important for patient management are included in the miscellaneous category.

The part specific for the assessments of treatments is designed to summarize patient information in a way that helps in identifying the MPOPs. A major disadvantage of many of the available classification systems is the lack of assessment part. The Abu Ruz classification system (AbuRuz et al., 2006) used seven templates for the assessment compared to one template in our tool, as well as the design of this study tools supposed to be easier than dealing with different columns with limited space for text in the former tool.

Validation of a classification system is important not only to confirm that each code corresponds to a unique MPOP, but also to ensure that the coding is understood by the user. According to the literature, the following criteria for validating DRP classification systems are necessary: appropriateness, acceptability, feasibility, interpretability, reliability (the results are reproducible and internally consistent), validity, responsiveness (ability to follow up interventions and monitor outcomes of interventions) (Fitzpatrick et al., 1998). The validation process was very useful as the classification system includes a comprehensive MPOPs and that each subcategory is unique. The uniqueness of the classifications is a major problem in all developed systems. The most practical way to avoid duplication of documentation or miss classification is to instruct users to report the major issue in the problem which is usually the cause. In the comment section of the tool, the user should add more details about the classification. We must also remember that identifying rather than classifying MPOPs is the most important issue.

### Table 2

Users’ Satisfaction with the Alsayed_v1 tools (N = 129).

| Statements                                                                 | 5 | 4 | 3 | 2 | 1 | Mean (SD) |
|---------------------------------------------------------------------------|---|---|---|---|---|-----------|
| The tutorial stimulated my interest in the PC process.                    | 37 (28.7) | 75 (58.1) | 13 (10.1) | 3 (2.3) | 1 (0.8) | 4.12 (0.74) |
| The tutorial helped me understand the concept and importance of the PC process. | 45 (34.9) | 52 (40.3) | 20 (15.5) | 3 (2.3) | 0 | 4.09 (0.80) |
| The medication’s assessment template is clear.                            | 42 (32.6) | 51 (39.5) | 24 (18.6) | 10 (7.8) | 2 (1.6) | 3.94 (0.98) |
| The medication assessment template helped me to be able to identify MPOPs. | 54 (41.9) | 49 (38.0) | 20 (15.5) | 3 (2.3) | 3 (2.3) | 4.15 (0.93) |
| MPOPs template is clear.                                                  | 46 (35.7) | 50 (38.8) | 22 (17.1) | 9 (7.0) | 2 (1.6) | 4.00 (0.98) |
| MPOPs template is comprehensive.                                          | 57 (44.2) | 53 (41.1) | 14 (10.9) | 5 (3.9) | 0 | 4.26 (0.80) |
| The care plan part is clear.                                              | 46 (35.7) | 50 (38.8) | 22 (17.1) | 9 (7.0) | 2 (1.6) | 4.00 (0.98) |
| The care plan part is beneficial.                                         | 57 (44.2) | 53 (41.1) | 14 (10.9) | 5 (3.9) | 0 | 4.26 (0.80) |
| I will use the assessment template in my practice                         | 28 (21.7) | 42 (32.6) | 34 (26.4) | 23 (17.8) | 2 (1.6) | 3.55 (1.07) |
| I will use the MPOP template in my practice                               | 45 (34.9) | 60 (46.5) | 21 (16.3) | 3 (2.3) | 0 | 4.14 (0.77) |
| I will use the care plan template in my practice                          | 43 (33.3) | 54 (41.9) | 26 (20.2) | 3 (2.3) | 2 (1.6) | 4.02 (0.92) |
| Overall, the tutorial enhanced my learning.                               | 50 (38.8) | 60 (46.5) | 16 (12.4) | 3 (2.3) | 0 | 4.22 (0.75) |

5: strongly agree; 4: agree; 3: neutral; 2: disagree; 1: strongly disagree.
### Table 3
Medical Problems Oriented Plan (MPOP) classification tool.

| Medical Problem or Healthcare Need | Date Category of Medical Problem | Subcategory 1 | Subcategory 2 | Plan | Notes | Outcome of the Problem |
|-----------------------------------|---------------------------------|--------------|--------------|------|-------|------------------------|
| **I. Indication**                 |                                 |              |              |      |       |                        |
| A. Untreated condition            |                                 |              |              |      |       |                        |
| a. Acute disease                  |                                 |              |              |      |       |                        |
| b. Chronic disease                |                                 |              |              |      |       |                        |
| c. Lifestyle problem              |                                 |              |              |      |       |                        |
| B. Unnecessary drug / substance / intervention |             |              |              |      |       |                        |
| a. Drug / substance / intervention use without a recommended indication |             |              |              |      |       |                        |
| b. Duplicate therapies for a simple indication |             |              |              |      |       |                        |
| c. A need for (additional) diagnostic or lab test or investigation |             |              |              |      |       |                        |
| **C. Diagnosis issue**            |                                 |              |              |      |       |                        |
| a. A need for (additional) diagnostic or lab test or investigation |             |              |              |      |       |                        |
| b. A need for repeated diagnostic or lab test or investigation |             |              |              |      |       |                        |
| c. A need for consultation or failure to act on results of diagnostic or lab test or investigation |             |              |              |      |       |                        |
| **D. Prophylaxis / Prevention**   |                                 |              |              |      |       |                        |
| a. The patient needs vaccination  |                                 |              |              |      |       |                        |
| b. The patient is at high risk to develop a problem |             |              |              |      |       |                        |
| **II. Effectiveness**             |                                 |              |              |      |       |                        |
| A. Replace                        |                                 |              |              |      |       |                        |
| 0 Actual uncontrolled condition   |                                 |              |              |      |       |                        |
| 0 Potential uncontrolled condition |                                 |              |              |      |       |                        |
| **B. Add**                        |                                 |              |              |      |       |                        |
| 1. Newly add the non-pharmacological treatment |             |              |              |      |       |                        |
| 2. Newly add the pharmacological treatment |             |              |              |      |       |                        |
| 3. Reserve the non-pharmacological treatment |             |              |              |      |       |                        |
| 4. Reserve the pharmacological treatment |             |              |              |      |       |                        |
| **C. Dosing**                     |                                 |              |              |      |       |                        |
| a. Under-dose (low strength or concentration) |             |              |              |      |       |                        |
| b. Incorrect route of administration |             |              |              |      |       |                        |
| c. Incorrect dosage form (e.g., ER, IR) |             |              |              |      |       |                        |
| d. Incorrect preparation method (e.g., splitting tablets, reconstitution, compounding of various intravenous admixtures and other products) |             |              |              |      |       |                        |
| e. Incorrect rate of administration - for injections (too fast, too slow, unknown) |             |              |              |      |       |                        |
| f. Incorrect timing of administration (too early, too late - more than 60 minutes outside the correct interval, unknown, morning or evening, before or after meal) |             |              |              |      |       |                        |
| g. Incorrect frequency             |                                 |              |              |      |       |                        |
| h. Incorrect duration (shorter or longer period than recommended) |             |              |              |      |       |                        |
| i. Product stability - expired product |             |              |              |      |       |                        |
| j. Product stability - deteriorated product |             |              |              |      |       |                        |
| D. Drug interaction                |                                 |              |              |      |       |                        |
| a. Drug-drug interaction           |                                 |              |              |      |       |                        |
| b. Drug-food interaction           |                                 |              |              |      |       |                        |
| **III. Safety**                   |                                 |              |              |      |       |                        |
| A. Replace                        |                                 |              |              |      |       |                        |
| 0 Actual safety problem           |                                 |              |              |      |       |                        |
| 0 Potential safety problem        |                                 |              |              |      |       |                        |
| **B. Discontinue**                |                                 |              |              |      |       |                        |
| 1. Abruptly discontinue            |                                 |              |              |      |       |                        |
| 2. Gradually discontinue           |                                 |              |              |      |       |                        |
| 3. Temporarily hold                |                                 |              |              |      |       |                        |
| **C. Dosing**                     |                                 |              |              |      |       |                        |
| a. Over-dose (high strength or concentration) |             |              |              |      |       |                        |
| b. Incorrect route of administration |             |              |              |      |       |                        |
| c. Incorrect dosage form (e.g., ER, IR) |             |              |              |      |       |                        |
| d. Incorrect preparation method (e.g., splitting tablets, reconstitution, compounding of various intravenous admixtures) |             |              |              |      |       |                        |
| **Notes**                         |                                 |              |              |      |       |                        |
| **Outcome of the problem**        |                                 |              |              |      |       |                        |
| 1- No error                       | Category A: Circumstances or events that can cause an error (potential for error only). |             |              |      |       |                        |
| 2- Error, no harm                 | Category B: An error occurred, but the patient did not receive the intervention. |             |              |      |       |                        |
| 3- Error, harm                    | Category C: An error occurred, reached the patient, without causing any patient harm. |             |              |      |       |                        |
| 4- Error, death                   | Category D: An error occurred and affected the patient and required monitoring and/or action by the provider to prevent harm. |             |              |      |       |                        |
| 5- Error, harm and caused temporary patient harm | Category E: An error occurred that resulted in the need for treatment or intervention and caused temporary patient harm. |             |              |      |       |                        |
| 6- Error, death and caused permanent patient harm | Category F: An error occurred that resulted in initial or prolonged hospitalization caused temporary patient harm. |             |              |      |       |                        |
| 7- Error, death and caused permanent patient harm | Category G: An error occurred and caused permanent harm to the patient. |             |              |      |       |                        |
| 8- Error, death and caused near-death event (e.g., drug reaction and cardiac arrest) | Category H: An error occurred that resulted in a near-death event (e.g., anaphylaxis and cardiac arrest). |             |              |      |       |                        |
| 9- Error, death and caused patient death | Category I: An error occurred resulting in patient death. |             |              |      |       |                        |
| Medical Problem or Healthcare Need | Date | Category of Medical Problem | Subcategory 1 | Subcategory 2 | Plan | Notes | Outcome of the problem |
|-----------------------------------|------|----------------------------|---------------|---------------|------|-------|------------------------|
| and other products)               |      | e. Incorrect rate of administration - for injections (too fast, too slow, unknown) |               |               | 6. Change the timing of administration |       |                        |
|                                   |      | f. Incorrect timing of administration (too early, too late - more than 60 minutes outside the correct interval, unknown, morning or evening, before or after meal) |               |               | 7. Change the frequency |       |                        |
|                                   |      | g. Incorrect frequency |               |               | 8. Change the duration |       |                        |
|                                   |      | h. Incorrect duration (shorter or longer period than recommended) |               |               | 9. Change the product |       |                        |
|                                   |      | i. Product stability - expired product |               |               |                        |       |                        |
|                                   |      | j. Product stability - deteriorated product |               |               |                        |       |                        |
| D. Drug interaction               |      | a. Drug-drug interaction |               |               | 1. Separate |       |                        |
|                                   |      | b. Drug-food interaction |               |               | 2. Abruptly discontinue |       |                        |
|                                   |      |                           |               |               | 3. Gradually discontinue |       |                        |
|                                   |      |                           |               |               | 4. Replace with abrupt discontinuation |       |                        |
|                                   |      |                           |               |               | 5. Replace with gradual discontinuation |       |                        |
|                                   |      |                           |               |               | 6. Change the drug dosage regimen |       |                        |
|                                   |      |                           |               |               | 7. Change the diet plan |       |                        |
|                                   |      |                           |               |               | 8. Change the timing of administration |       |                        |
|                                   |      |                           |               |               | 9. Change the frequency |       |                        |
|                                   |      |                           |               |               | 10. Change the duration |      |                         |
|                                   |      |                           |               |               | 11. Change the product |      |                         |
| E. Monitoring                      |      | a. A need for additional monitoring test or investigation |               |               | 1. Perform the monitoring test or investigation |       |                        |
|                                   |      | b. A need for repeated / more frequent monitoring test or investigation |               |               | 2. Add non-pharmacological treatment (when / if) |       |                        |
|                                   |      |                           |               |               | 3. Add pharmacological treatment (when / if) |       |                        |
|                                   |      |                           |               |               | 4. Resume the intervention (when / if) |       |                        |
|                                   |      |                           |               |               | 5. Discontinue the intervention (when / if) |       |                        |
|                                   |      |                           |               |               | 6. Modify the treatment (when / if) |       |                        |
|                                   |      |                           |               |               | 7. Add non-pharmacological treatment |       |                        |
|                                   |      |                           |               |               | 8. Add pharmacological treatment |       |                        |
| F. Prophylaxis / Prevention       |      | a. The patient is at high risk to develop a safety problem |               |               | 1. Discontinue |       |                        |
|                                   |      |                           |               |               | 2. Temporarily hold |       |                        |
|                                   |      |                           |               |               | 3. Continue |       |                        |
|                                   |      |                           |               |               | 4. Patient education about avoidance and provided with a written list of the generic and brand names of the causative drug as well as possibly cross-reactive drugs |       |                        |
|                                   |      |                           |               |               | 5. Patients with potentially severe reactions should carry wallet cards, wear an identification card |       |                        |
|                                   |      |                           |               |               | 6. Start new drugs at lower-than-normal doses when feasible |       |                        |
|                                   |      |                           |               |               | 7. Administer under medical observation if necessary |       |                        |
|                                   |      |                           |               |               | 8. Add non-pharmacological treatment |       |                        |
|                                   |      |                           |               |               | 9. Add pharmacological treatment |       |                        |
|                                   |      |                           |               |               | 10. Add non-pharmacological treatment |       |                        |
|                                   |      |                           |               |               | 11. Add pharmacological treatment |       |                        |
| G. Allergic reaction              |      | o Immediate reaction (i.e., urticaria, angioedema, or anaphylaxis) |               |               |                        |       |                        |
|                                   |      | o Delayed reaction |               |               |                        |       |                        |
|                                   |      | a. First exposure |               |               |                        |       |                        |
|                                   |      | b. Subsequent exposure with no previous history of an allergic reaction |               |               |                        |       |                        |
|                                   |      | c. Subsequent exposure with a previous history of an allergic reaction |               |               |                        |       |                        |
|                                   |      | d. Unknown |               |               |                        |       |                        |
| IV. Patient                       |      | A. Knowledge |               |               | 1. Patient education |       |                        |
|                                   |      | a. Disease |               |               |                        |       |                        |
|                                   |      | b. Non-pharmacological therapy |               |               |                        |       |                        |
|                                   |      | c. Pharmacological therapy |               |               |                        |       |                        |
|                                   |      | d. Non-adherence to non-pharmacological treatment |               |               |                        |       |                        |
|                                   |      | e. Non-adherence to the monitoring plan |               |               |                        |       |                        |
|                                   |      | C. Incorrect administered medication |               |               |                        |       |                        |
|                                   |      | a. By patient |               |               |                        |       |                        |
|                                   |      | b. By caregiver |               |               |                        |       |                        |
|                                   |      | C. Incorrect administered medication |               |               |                        |       |                        |
|                                   |      | a. Disease |               |               | 1. Patient education |       |                        |
|                                   |      | b. Non-pharmacological therapy |               |               | 2. Recommend an alternative |       |                        |
|                                   |      | c. Pharmacological therapy |               |               |                        |       |                        |
|                                   |      | d. Non-adherence to non-pharmacological treatment |               |               |                        |       |                        |
|                                   |      | e. Non-adherence to the monitoring plan |               |               |                        |       |                        |
|                                   |      | F. Data |               |               | 1. Insufficient information |       |                        |
|                                   |      | a. Insufficient information |               |               | 2. Document missing data |       |                        |
|                                   |      | b. Documentation errors |               |               |                        |       |                        |

* Adapted from (Snyder and Fields 2010), and used when applicable.
The final version of Alsayed_v1 tools is composed of three parts: the assessment of treatments, the MPOP, and the care plan. Upon evaluating the final version, the inter-rater agreement and the reproducibility were excellent. Users were very positive regarding the tool. The majority of them indicated they were satisfied with all parts and that the three parts were comprehensive and useful. Around 19.4% indicated that they will not use the assessment part in their practice because of time limitations. This is comparable to a previous study (AbuRuz et al., 2006) and was expected as the assessment part was designed for training the beginners on the principles of identification of MPOPs. Another explanation is that we included a relatively large sample size, compared to previous studies, and some of the participants may not be interested in the field of CP practice as future work. Compared to a recently published classification system (Maes et al., 2015) which is based on a small number of clinical pharmacists (n = 6), we included a total of 129 clinical pharmacists and students to evaluate the validation and reliability, so selection bias should be very low. Also, the current study MPOP tool subcategories are mutually exclusive.

This study tools (Alsayed_v1) have several advantages, but not all new as different currently available classifications systems have many of these advantages. However, this study tools have several features that are new in the field. First; the assessment of treatments part helps the clinical pharmacist to evaluate patient data for the presence of medical problems and probably increases the likelihood of detecting problems. Second; we introduced the concept of MPOP rather than DRP or TRP. We believe this terminology would increase the scope of PC practice and gain more acceptance from other healthcare professionals. Third; in the MPOP tool, new classifications appear that have not been mentioned in other tools. These new elements include, but are not limited to, the need for ICU admission, the need for vaccination, and different subcategories of dosing problems that are related to effectiveness and safety with the appropriate interventions.

On-going project aims to evaluate the implementation and the user’s satisfaction of this first version tools (Alsayed_v1) in daily practice and to analyze the pooled data retrieved from hospitals, community pharmacies, and other primary care settings. In addition, the primary author is currently adapting the tools to be incorporated in an electronic database managed and owned by the primary author involving website and mobile application intended to provide PC (www.asami-draacare.com).

5. Conclusion

The Alsayed_v1 tools introduced in this paper were applied to actual patient cases and were validated. These tools include three main parts: assessment of treatments, MPOP, and care plan. Including the interventions in the classification system is important especially in PC research where the type of recommendations

Table 4
Patient Care Plan.

| Date | Medical problem or healthcare need | Goal(s) of Treatment | MPOP classification | Intervention(s) / Recommendation(s) | Follow-up (Monitoring and Evaluation) | Monitoring parameter(s) (therapeutic or toxic) / Endpoints / Frequency | Follow-up (timeframe) | Evaluation of the therapeutic outcome achievement | Follow-up (Monitoring and Evaluation) | Monitoring parameter(s) (therapeutic or toxic) / Endpoints / Frequency | Follow-up (timeframe) | Evaluation of the therapeutic outcome achievement | Follow-up (Monitoring and Evaluation) | Monitoring parameter(s) (therapeutic or toxic) / Endpoints / Frequency | Follow-up (timeframe) | Evaluation of the therapeutic outcome achievement | Follow-up (Monitoring and Evaluation) | Monitoring parameter(s) (therapeutic or toxic) / Endpoints / Frequency | Follow-up (timeframe) | Evaluation of the therapeutic outcome achievement |
|------|-----------------------------------|----------------------|---------------------|-------------------------------------|--------------------------------------|--------------------------------------------------------------------|-------------------------|------------------------------------------------|-----------------------------------|--------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------|-----------------------------------|--------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------|-----------------------------------|--------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------|

The appropriate time for evaluation

| Resolved (acute) / Stable (chronic) | Improved | Partially improved* | Unimproved | Failure* |
|-----------------------------------|-----------|---------------------|------------|----------|
| Worsened* | Failed to achieve goals of treatment | Goals of treatment have been achieved |

Fig. 1. Evaluation of the therapeutic outcome in the follow-up period. *Indicates a need for therapeutic modifications. Resolved: Goals of treatment have been achieved. The treatment has been completed and can now be discontinued (usually for acute diseases/problems). Stable: Goals of treatment have been achieved. The same treatment has to be continued without modifications. Partially improved: There is some observable progress being made toward reaching the desired goals of treatment. However, adjustments in treatment are required to better achieve the goals. Unimproved: At this time, no or only slight progress in reaching goals of treatment can be observed. More time is required to assess the maximum response of the treatment. Therefore, at this time, the same treatment has to be continued. Worsened: A decline in the medical status has been observed while receiving the current treatment. Some adjustments in the treatment are required. Failure: Goals of treatment have not been achieved. Gradual or abrupt discontinuation of the current treatment and replacement with different therapy is recommended.
should be documented to assess the value and impact of the service and saves the time of practitioners in typing the appropriate interventions. By applying the steps within these three parts, clinical pharmacists can actively provide the best practice to achieve optimal patient outcomes.

In addition to these tools have been validated and clinically tested, they have other advantages including the presence of assessment, medical problems, and intervention parts, presence of a coding system for the MPOP which allows easy documentation with an open hierarchical structure, where higher levels are broadly defined and lower levels become more specific, and the option to enter free text.

**CRediT authorship contribution statement**

Ahmad R. Alsayed: Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation.

Conceptualization, Data curation, Software, Writing – original draft. Writing – review & editing. Abdullah Al-Dulaimi: Formal analysis, Validation, Writing – review & editing. Dalal Alnatour: Validation, Writing – review & editing. Dima Awajan: Validation. Bushra Alshammari: Writing – review & editing.

**Declaration of Competing Interest**

The authors declare that they have no competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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