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RESEARCH ARTICLE

Adaptation and validation of PCNE drug-related problem classification v6.2 in French-speaking Belgian community pharmacies

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Abstract

Background Many tools exist to document drug-related problems (DRP), such as the Pharmaceutical Care Network Europe (PCNE) classification. However, none have been adapted and published for French-speaking Belgian community pharmacies. *Settings* French-speaking Belgian Community pharmacies. *Objective* The objective was to translate and adapt the PCNE V6.2 classification to the Belgian pharmacy practice and legal setting and to assess the content validity, daily use and inter-rater reliability of this classification. *Main Outcome Measure* Validation of the French-language adapted PCNE v6.2 classification in Belgium. *Method* The first step translated and adapted the PCNE V6.2 classification to the Belgian setting. Thereafter academic and community pharmacists evaluated the content validity, which involved six criteria and concerned the instruction manual (clarity, helpfulness) and the registration form (representativeness, logical design, completeness and uniqueness). The next step was the DRP collection, using the PCNE tool daily. Compliance with the instructions and the time needed to solve a DRP were evaluated. Finally, the inter-rater reliability was evaluated by comparing DRP codings done by pharmacist volunteers. *Results* The classification was translated into French and adapted by adding 16 items. The classification showed a high content validity for the academics and the community pharmacists. A total of 109 DRP forms were coded, with an average resolution time of 5 min. Regarding the inter-rater reliability, 74 tool items out of the set of 83 showed high consistency in coding. *Conclusion* This study showed that the tool adaptation to a French-speaking Belgian context was reliable and has adequate validity for daily use.

Keywords Belgium · Classification system · Community pharmacy practice · Drug-related problems · French translation · PCNE · Validation

Impacts on practice

- The translated PCNE Classification V6.2 can improve DRP detection and prevention for better patient care in French speaking Belgian pharmacies.
- The Belgian validated tool may be used by pharmacists as a support tool in daily practice to classify DRPs, clinical interventions and results.
- Integration of this helpful tool into the delivery software may highlight community pharmacist skills in clinical pharmacy.
- This validated tool may create a helpful database for pharmacists' daily practice and scientific research in Belgium.

Introduction

In Belgium as well as internationally, the community pharmacist's role has evolved from drug-focused to patient-focused activities, with an increased role in counselling and follow up of chronic patients [1]. Since the publication of the "Instructions for Pharmacists" in the Royal Decree

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of 21 January 2009, Belgian pharmacists have been legally responsible for the provision of pharmaceutical care. This care includes responsibility for medication delivery and counseling for the correct use of medicines [2]. The identification, prevention and resolution of drug-related problems (DRPs) are an integral part of pharmaceutical care, and also the pharmacist's role under Belgian law [3].

Different definitions of DRP exist. The Pharmaceutical Care Network Europe (PCNE) group defined a DRP as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes" [4]. The definitions depend on the associated classification and the researcher's focus. To classify and document DRP, various tools exist, such as the PCNE classification, the Hepler and Strand classification, the PI-Doc or the Westerlund System [5–7]. These tools help to highlight the nature, incidence and prevalence of DRP, and generate a database for both researchers and practitioners [5, 8]. Van Mil et al. [9] published an overview of existing DRP classifications and proposed recommendations for choosing the best tool, depending on the study aim. The PCNE classification has several advantages. First, it includes a structured DRP classification with detailed sections and subsections, which allows each type of DRP to be coded. Second, a DRP can be classified by its type (e.g. treatment effectiveness), then its cause (e.g. patient forgets to use/take drug), the pharmacist intervention and the outcome. Third, the DRP and each category are clearly defined. Fourth, the tool has been validated through various studies in community pharmacies as well as in the hospital pharmacies context, and has been translated into different languages, such as Spanish, Turkish and Croatian [8]. However, the classification has never been validated and published in French or for the French-speaking Belgian community pharmacy setting and practice.

Objectives

The aim of this study was to translate and adapt the PCNE V6.2 classification to the Belgian pharmacy practice and legal setting, to assess the validity of its content, to evaluate its daily use practice in terms of time and instructions compliance, and to measure the inter-rater reliability of the adapted classification.

Ethics approval

This study did not require ethics approval.

Method

Translation and adaptation of the PCNE V6.2 classification

The English version of the PCNE V6.2 classification includes a registration form and an instruction manual [10]. The adapted instruction manual followed the same classification structure and was completed by adding some examples to each section and primary domains to avoid misclassification. The adaptation was conducted by the research team in collaboration with academic and community pharmacists. The changes were followed to fit better to the Belgian practise and legal context.

The adapted registration form is structured into five sections, allowing documentation of relevant information on documented DRPs. The five sections are:

- "General information": this part was added and helps to collect data about the patient, drug(s) involved in the DRP and the context of DRP classification;
- "Problem": to specify whether DRPs were potential or manifest, and to classify the DRP into four categories: "treatment effectiveness", "adverse reactions", "treatment costs", "treatment accessibility" and "other".
- "Causes": to classify the source of the DRP in the following primary domains: "drug selection", "drug form", "dose selection", "treatment duration", "drug use process", "logistics", "patient" and "other".
- "Interventions": to record the pharmacist's initiatives to resolve the DRP;
- "Outcome": to explain the final result.

In the last part of the form, an area for comments was available to clarify a DRP description and/or DRP management.

To adapt the existing classification to the Belgian community pharmacy setting, the registration form and the instruction manual of PCNE V6.2 were translated into French and items were added or modified to fit legal and administrative regulations in Belgium. The translation was done by three investigators in the research team, each arriving at the same results. After the translation, the proposals by pharmacists were evaluated and added to the classification.

Content validity

The translated and adapted version of the tool, which includes the instruction manual and the registration form, was submitted to a group of 15 pharmacists (seven

community pharmacists; eight researchers or academics). These reviewed the format and content of each item. The evaluation was done according to six criteria: "clarity" and "helpfulness" for the manual, and "representativeness", "general structure", "uniqueness" (avoidance of two items overlapping) and "completeness" for the registration form. In total, 30 elements (Item or tool part) were evaluated and scored using a 4-point Likert scale, from 1 (strongly disagree) to 4 (strongly agree). These scores were used to calculate the content validity index (CVI); which is determined by the item content validity index (I-CVI) and the scale content validity index (S-CVI). The content validity index (CVI) is a measure that indicates the proportion of members who endorsed an element (item or part) as valid content. The I-CVI highlights the ratio of satisfied evaluators, who considered the item as valid (i.e.: evaluators who quoted the item at level 3 or 4 in their evaluations). It has been calculated for each item. The S-CVI is the mean of all I-CVI to evaluate the content validity of the entire tool. The I-CVI cut-off level was fixed at 0.8. This value, which was determined a priori from the literature, implies that the item was perceived as valid by respondents [11–13] and indicates whether an item was acceptable or not acceptable. A value under this cut-off level shows that evaluators' opinions diverged and some items need modification to be more effective. However, it does not mean that the tool is not relevant. It was for this reason that the S-CVI was also calculated. This was measured as the mean value for all items for the registration form and the manual. The S-CVI cut-off level was fixed at 0.9, above which level it is judged a relevant tool [13].

Daily use of registration form

For 3 months, 12 Belgian community pharmacists were invited to collect DRPs during their daily practice. They collected DRPs using the adapted form during their daily practice and send them back to the investigator. This registration was the first step of the inter-rater reliability evaluation. A self-completion questionnaire was then sent to these pharmacists to evaluate their experience, compliance with the instruction manual and the time needed for completion.

Inter-rater reliability

The aim of this part was to evaluate whether a DRP can be reported in one consistent way with the register form. The inter-rater reliability allows an investigator to assess the degree to which different data collectors give consistent estimates of the same phenomenon. In this study, it measured the extent to which data collectors (raters) assigned the same classification to one DRP. The method used in this study was similar to that used by Conort et al. to evaluate and validate an intervention codification tool in French clinical pharmacies [14]. The inter-rater reliability was conducted in two steps, and involved two or three pharmacists, depending on the workload at the pharmacy (X, Y and/or Z pharmacists). Following the first step, all DRPs coded by pharmacists in their daily practice (X pharmacists) were summarized by the investigator and reviewed by the research team. The 56 DRPs chosen were selected from 109 DRPs received for their clarity and comprehension. The DRPs were summarized as a case by the main investigator and reviewed by the research team. The summary included the patient description, the prescription content, the nature of the DRP and the type of intervention performed. All these DRP summaries were sent to Y and/or Z pharmacists to be coded again. All coding was then compared to calculate the inter-rater reliability (Fig. 1). The analyses and calculation were done using Excel®.

In total, 56 DRP cases were selected from X pharmacists' registrations and divided between 10 other pharmacists (Y + Z). Consistent coding between two evaluators was marked as "1" and implies identical coding. Inconsistent coding was marked as "0". When too many items were coded, it was considered as inconsistent coding. The items were then classified according to their inter-rater reliability level. A consistency level higher than 85% represented "high consistency", a level between 66 and 85% "medium consistency" and a level lower than 66% "low consistency". The different levels were taken from the literature [11, 15].

Results

Translation and adaptation of PCNE drug-related problem classification v6.2

The PCNE classification tool was adapted by adding one item to the "Problem" section and 12 to the "Causes" section. These new items were related to Belgian context, the dispensing process and patient behaviour. Two items were added to the "Interventions" section and one to the results section.

The details of these modifications are summarized in Table 1.

Content validity

Most evaluators gave a score of 3 or 4 on the 4-level Likert scale, for both the instruction manual and the registration form. The I-CVI and the S-CVI also showed results between 0.9 and 1, indicating a high content validity (Table 2 and supplementary material 1).

The items related to the instruction manual had an I-CVI between 0.8 and 1 (Table 2). The S-CVI was calculated at

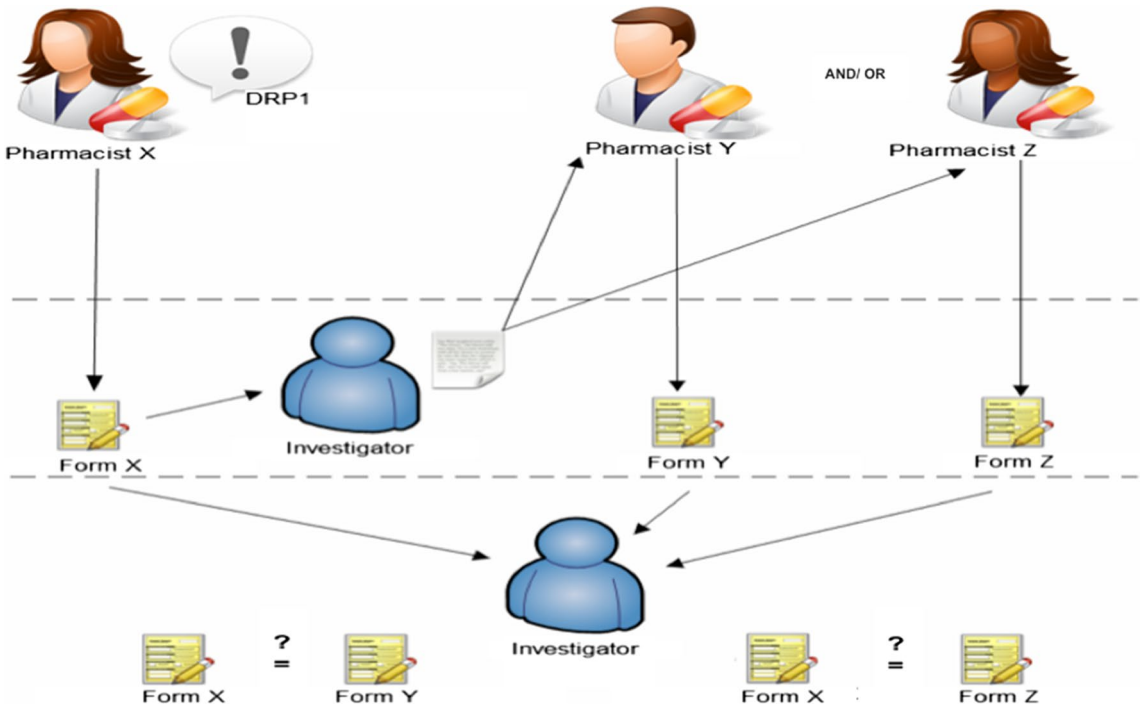

Fig. 1 The process to test the inter-rater reliability of the adapted classification tool

Table 1 Belgian adaptation of the PCNE tool V6.2

Part	Section	Item(s)	Modifications	Other information
General information	–	–	Added	To collect patient descriptive information
The problem	Treatment efficacy	Wrong drug effect	Removed	
	Adverse event	Toxic adverse event	Removed	
	Other problem	Non-classifiable DRP	Added	
The causes	Drug choice	No available alternative	Added	
	Drug use	Drug abuse/addiction	Added	
	Logistic and administrative causes	Medical device not available	Added	
		Reimbursement criteria not met	Added	
		Illegible prescription	Added	
		Incomplete prescription	Added	
		Forged prescription	Added	
		Drug to the wrong patient	Added	
	Cause linked to patient	Doubt, fear about the medication	Added	
		Drug intake influenced by perception and religion	Added	
		Life style conflicting with drug intake	Added	
		Many physicians consulted	Added	
Intervention	Prescriber level	An intervention was proposed and refused by the prescriber	Divided into two items	1: with a justification 2: without a justification
Results	Not solved	Not solved because no intervention	Added	

Table 2 Pharmacists' evaluation of the instruction manual

Criteria	Elements	Level 1	Level 2	Level 3	Level 4	Total %	ICV-I
Clarity	Aim of the classification	6.5 (1)	0	54 (8)	39.5 (6)	100 (15)	0.9
	DRP definition	0	0	39.5 (6)	60.5 (9)	100 (15)	1
	DRP registration formulary description	0	0	20 (16)	80 (12)	100 (15)	1
	Definition of "manifest problem"	0	20 (16)	33 (5)	46.7 (7)	100 (15)	0.8
	Definition of "potential problem"	0	6.5 (1)	46.7 (7)	46.7 (7)	100 (15)	0.8
	Elements in the chapter "DRP classification"	0	0	85.7 (13)	14.3 (2)	100 (15)	1
	Elements in the section "DRP cause(s)"	0	0	46.7 (7)	54 (8)	100 (15)	0.9
HelpfulnesHs	Elements in the section "intervention classification"	0	0	39.5 (6)	60.5 (9)	100 (15)	1
	Examples in the section "DRP classification"	0	0	39.5 (6)	60.5 (9)	100 (15)	1
	Examples in the section "DRP cause(s)"	0	6.5 (1)	26.5 (4)	67 (10)	100 (15)	0.9
	Examples in the section "intervention classification"	0	0	39.5 (6)	60.5 (9)	100 (15)	1
	Examples in the section "DRP classification"	0	0	33 (5)	67 (10)	100 (15)	1
	Examples in the "DRP cause(s)"	0	0	33 (5)	67 (10)	100 (15)	0.9
	Examples in the section "intervention classification"	0	6.5 (1)	33 (5)	60.5 (9)	100 (15)	0.9
S-CVI							0.9

0.9. The lowest score was observed for the "clarity" criterion and concerned the definition of a "manifest problem" and "potential problem". Following this step, the definitions were made more detailed and some examples were added.

Concerning the registration form, the I-CVI varied between 0.9 and 1 and the S-CVI was at 0.99 (supplementary material 1).

All these modifications are summarized in supplementary material 2.

The final adapted tool included 83 items, classified in five sections (General information, Problem, Causes, Interventions and Outcome), and a modified definition of "potential problem" and "manifest problem".

Daily use of registration form

A total of 109 daily DRPs were returned to the research team from the X pharmacists. After their reception, each form was analyzed and 56 were summarized. Items judged as essential or unnecessary were respectively added or removed.

The instructions related to the coding step were not completely effective and some pharmacists did not follow these. For example, pharmacists ticked more than one item in the "Problem" section, which was not allowed. In the "Causes" section, a maximum of three causes could be ticked but only 6% of pharmacists followed this instruction. Most pharmacists ticked more. Finally, 18% of DRP codings did not classify patients as a "regular" or "occasional" patient, while 9% of DRPs were not classified at all. This added part in the French-language adapted classification seems to have been overlooked by pharmacists.

Times to code and solve a DRP ranged between less than 1 min to 2 h, with 62% of DRPs in 5 min or less and 28% between 7 and 15 min. A long solving time for DRPs happened mostly when the prescriber was unreachable or when a drug was missing. Pharmacists then had to find a solution for a better resolution.

Inter-rater reliability

The 56 DRP cases were coded with the adapted tool. This tool includes 83 items, distributed in the five sections of the French-language adapted tool. The new items were added after daily experience evaluation and pharmacists' proposals.

The evaluation of these items showed 2 low-consistency items (with an inter-rater reliability under 65%), 7 with

Table 3 Consistency results for the chapter "DRP classification"

DRP classification	Total of agreeing responses[a]	% of consistency
Potential problem	41	59
Manifest problem	43	61
Inefficacy	69	99
Non-optimal efficacy	48	69
Allergic adverse effects	69	99
Non-allergic adverse effect	59	84
Treatment too expensive	70	100
Undeliverable treatment	62	89
Unsatisfied patient	62	89
Treatment did not work	67	96
Known disease but untreated	69	99
Non-classifiable DRP	56	80

[a]Total number of comparisons: 70 for 56 DRPs: (56 from Y pharmacists and 14 from Z pharmacists)

medium consistency (between 65 and 85% inter-rater reliability) and 74 with high consistency (over 85%) (Table 3). The items with low consistency were modified and the definitions of "potential" and "manifest" problem were adjusted a second time to avoid misclassification during tool use. The medium-consistency items were identified in three sections. The first is "Problem", with the items "Non-optimal efficacy" (insufficient or excessive drug effect), "Non-allergic adverse effect" and "Non-classifiable DRP" (unidentified or non-classifiable problem). The second section, "Interventions", concerned the items "Patient counselling" (provide oral information, advice or warning), "Patient referred to prescriber" and "Other intervention" (intervention made by the pharmacist was not included in the items list). The last was the "Results" section, with the item "Problem completely solved" (pharmacist's intervention was successful or could prevent a potential DRP).

The medium- and high-consistency items were considered as "consistent" and were not modified.

Discussion

The aim of this study was to adapt and validate the PCNE DRP classification tool (V6.2) for the Belgian community pharmacy setting. The adaptation of the PCNE V6.2 classification tool allowed it to be better understood by Belgian pharmacists. The validation of this adapted classification highlighted a good content validity and a high inter-rater reliability. In daily use, 62% of DRPs were coded in 5 min or less. However, for the inter-rater reliability, items such as "manifest problem" or "potential problem" were modified twice as they remained unclear despite the previous modifications. The medium consistency in the "Problem" section might be related to its multiple classification possibilities. For the "Interventions", the consistency could be related to an omission by pharmacists. For example, counseling is a common practice and may have been forgotten in coding when any other intervention was applied, e.g. a change of drug. Clearer instructions on the number of items to tick in each section could be added to avoid a large number of items being ticked. This should be done in the manual as well as in the classification tool to decrease these discrepancies and make the tool more usable in daily practice.

The PCNE group tried to improve their classification and update it regularly. The last update was V8.02, in which different changes were noted. Many items were modified to be more understandable, with clearer items or sections, and easier to complete, by reducing the number of items. For example, "non allergic, allergic and toxic adverse events" were grouped together in one item: "adverse drug event (possibly) occurring". Compared to our translated and validated tool, this change will avoid some discrepancies [10]. However, the new classification does not give more information about how to differentiate a manifest and a potential problem, which will result in the same kind of discrepancies [10]. A Swiss classification, the PharmDISC tool, was set up and helps to decrease this risk by defining a manifest problem as "reactive" and a potential problem as "preventive" in the registration tool [16]. This change could be added to the PCNE tool to improve its inter-rater reliability.

During this validation study, the adapted classification tool seemed to be suitable for community pharmacists to classify and document DRPs. Its validation has the advantage of ensuring that each encountered DRP can be correctly described by pharmacists through the proposed items.

However, the main limitation of this classification tool was the time needed to code each DRP. As presented in the results, some sections were not completed at all, which might be due to a lack of time or the large number of items. In 18% of cases, the patient information section was not completed and for 9% of DPRs, the problem was not classified at all. These sections might have been considered as unnecessary for classifying a DRP and therefore not completed to save time. Most pharmacists took 5 min or less to code and solve a DRP but some DRPs might be more time consuming, according to their complexity. In Germany, a study evaluated the coding and resolution time for a DRP. DRPs were classified using a modified version of the problem-intervention-documentation (PI-Doc) classification system. The median time needed to solve a DRP was about 5 min [17], which is similar to our results. This limitation was also discussed by Krähenbühl et al., who proposed that the time barrier was the main limitation to the documentation process for pharmacists. They also highlighted the persistence of this limitation as pharmacies received no incentive programme, such as financial or human aid in documentation. This limitation can lead to the proportion of DRPs being underestimated, as the time needed to collect and code DRPs could discourage pharmacists in daily practice. However, this time might become shorter with more frequent use by pharmacists.

A backward–forward translation was missing in this study, which could be seen as a limitation.

The inter-rater reliability evaluation was influenced by the DRP cases and description and could also be a limitation.

Although the time was a limitation, the integration of this tool into regular dispensing software might be informative for an optimal medication review, for better patient follow-up by pharmacists. Such as review could highlight pharmacists' knowledge, or improve research by creating a large database in Belgium for epidemiologic studies, as we can find in Sweden or Denmark [18, 19]. Some classifications are more appropriate for community pharmacy daily practice, such as the PharmDISC. Others are more suitable for research, such as the PCNE classification [5, 7, 10, 20–23]. The French version of the latest adaptations of the PCNE 8.2

and PharmDISC tools could be considered for wider use in pharmacy practice and research. In addition, the introduction of an incentive programme could be evaluated as a strategy to increase DRP coding. Finally, the combination of this classification tool with patient health data collection could increase the relevance of the coded information and result in better DRP management.

Conclusion

This study allowed an international DRP classification to be adapted and validated for the Belgian community pharmacy setting. The results showed that the tool was reliable and had an adequate content validity to measure the frequency and nature of DRPs. However, some adaptations were still required to decrease the time needed to code a DRP in daily pharmacy practice and to include it in pharmacy workflows.

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