International Journal of Clinical Pharmacy
https://doi.org/10.1007/s11096-020-01150-w

SHORT RESEARCH REPORT

Pharmaceutical Care Network Europe (PCNE) drug-related problem classification version 9.00: German translation and validation

Elisabeth Schindler[1] · Ina Richling[2] · Olaf Rose[3,4]

Received: 22 June 2020 / Accepted: 9 September 2020

Abstract

Background The drug-related problem classification system of the Pharmaceutical Care Network Europe (PCNE) is well established and continuously updated. A translated version of the drug-related problem classification system can facilitate research and implementation of clinical pharmacy services in the corresponding countries. *Aim* This study aimed to translate and validate the current version 9.00 into German language. *Method* The forward–backward translation method was used to translate the English version 9.00 into German language. Validation was done with 20 patient cases. Consistency was calculated in percentage and compared to international results. *Results* Translation of the classification system yielded in a German version. Validation was done with 32 pharmacists and 20 patient cases. In the five primary domains, average consistencies of 77.3% (problem), 57.8% (cause), 57.4% (intervention), 74.5% (acceptance) and 74.9% (status) were achieved. Ambiguities were found in some patient cases, as raters came to differing but plausible codes. *Conclusions* This study provides a German translation of the PCNE classification for drug related problems of approximately similar consistency as the international version. It hence can be considered to classify drug-related problems in German speaking countries. Patient cases need to be more specific in future validations, feasibility and layout of the classification system need to improve.

Keywords Classification · Clinical pharmacy service · Drug-related problem · Medication management · Medication review · Pharmacy

Impacts on practice

- A classification of drug-related problems can facilitate research and implementation of clinical pharmacy services.
- The classification system of the Pharmaceutical Care Network Europe is well established.
- To receive reproducible results, a classification should be validated.

Introduction

Drug-related problems (DRPs) usually cover aspects on therapy safety as well as on optimizing medication regimens. DRP classification systems are used for documentation in clinical research to standardize and compare the results of medication review. In clinical practice they are used for documentation and reimbursement. DRP classification systems have evolved from a simple eight item classification system, as introduced by Hepler and Strand in 1990 at the University of Florida [1], to more detailed classification systems, such as the DOCUMENT or Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA) classification systems [2, 3]. The DRP classification system of the Pharmaceutical Care Network Europe (PCNE) is internationally established and frequently engaged in medication review studies [4]. It was initiated in 1999 and

✉ Olaf Rose
rose@elefantenapo.de

[1] Institute of Pharmacology and Clinical Pharmacy, Faculty of Pharmacy, Marburg University, Marburg, Germany

[2] Department of Pharmacy, Katholische Kliniken im Märkischen Kreis, Hochstr. 63, 58638 Iserlohn, Germany

[3] Department of Pharmacotherapy and Translational Research, College of Pharmacy, University of Florida, 1225 Center Drive, Gainesville, FL 32610-0486, USA

[4] impac2t research, Maximilianstr. 31-33, 48147 Münster, Germany

Published online: 06 October 2020

has been continuously meliorated and updated. The PCNE classification comprises of the five primary domains of problem, cause, planned intervention, intervention acceptance and status of the DRP. It hence allows to classify several aspects in the process of handling a DRP from detection till implementation of a resolution. The PCNE classification has constantly adopted new aspects of medication review, has been translated into several languages and has been modified to specific demands [5–7]. Version 9.00 was released in June 2019. As a novelty, this update features causes for DRPs at the transition of care [8]. With increasing implementation of clinical pharmacy services in the German speaking countries, there is growing demand for a German classification system.

Aim

The aim of this study was to translate version 9.00 into German language and to validate the resulting translation.

Ethics approval

Approval by an ethics committee was not required, as no patient sensitive data were engaged in this research. Patient cases used for validation were fictive.

Methods

The classification and the patient cases, were developed during several meetings of the PCNE DRP working group [8, 9]. A two-phased translation process with forward and backward translation was combined with a validation study. The study flow is depicted in Fig. 1.

Translation

The original PCNE classification of DRPs version 9.00 was translated from English into German language independently by two researchers who were native speakers of German language (ES, IR). The two translations into German language were compared and differences were discussed until an agreement was reached. Two other researchers independently translated the whole document back from German into English language (OR, OG). Similar to the forward-translation, the two versions translated back into English language were compared and differences were resolved by discussion. The final backward-translated document was discussed by all researchers (ES, IR, OR, OG). In a final phase, differences between the retrieved English version and the original English version were examined and resolved by trimming the German translation (ES, IR, OR, OG).

Validation

Validation engaged 20 patient cases provided by the PCNE (as part of a validation set), which were continuously updated during the meetings of the PCNE DRP working group for this purpose [9]. The 20 cases were translated into German language by the authors. Pharmacists were recruited and asked to classify the DRPs of the 20 German patient cases according to the German DRP classification system. The only inclusion criteria for participation was being a registered pharmacist. Recruitment of the participants was done as a convenience sample, mainly relying on the personal networks of the authors. Consistency was defined as percentage of raters opting for similar codes at the primary domains of problem, cause, planned intervention, intervention acceptance and status of the DRP. A consistency benchmark of $\geq 80\%$ was chosen in accordance with an ongoing international validation of the PCNE classification for DRPs [9]. Consistency levels were compared to the international results. Whenever one code out of the five primary domains was completely missing, the whole patient case of this rater was considered as a drop-out. Participants were also asked to fill a questionnaire form on feasibility of coding the cases with the PCNE classification for DRPs. Results were

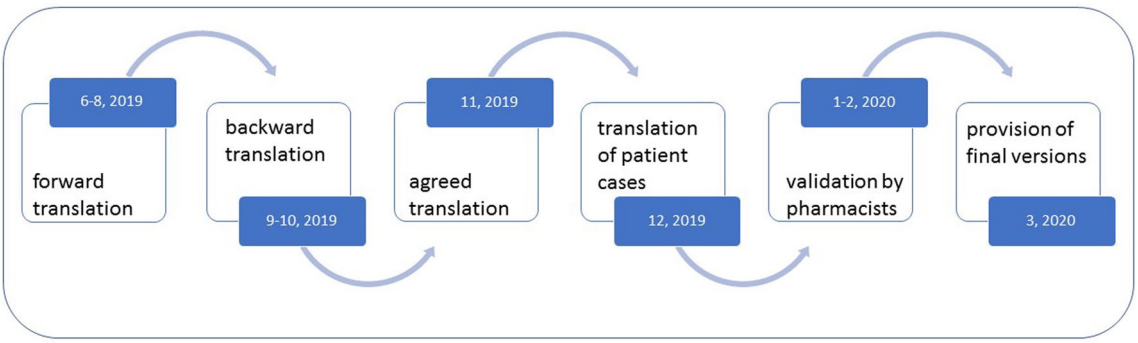

Fig. 1 Study flow of the translation and validation process

compared to the results of the international validation and are presented descriptively [9].

Results

Translation

Upon forward translation, the researchers decided to use the terminology of the German national pharmacist's board, where applicable. Most differences could be resolved by discussion of the two directly involved researchers, in very few cases the opinion of the third and fourth researcher was required. The translation is available from the PCNE website [10].

Validation

For validation of the German translation, 50 pharmacists were invited, of whom 32 responded (64.0%). Baselines were available from 30 of the 32 participants and are shown in Table 1.

Coding of the PCNE validation cases by 32 pharmacists led to a maximum of 640 rated patient cases with codes for 5 domains (minimum 3.200 codes, more than one code per problem could be chosen). The raters omitted single codes in 11 cases, which led to a drop-out for the whole case for this rater. In another 11 patient cases, two problems per patient case were identified from one or more pharmacists. This occurred most frequently in case 5 and case 17, in which 3 pharmacists found 2 problems each. A total of 3.763 codes were recorded: 648 problem codes, 854 cause codes, 971 intervention codes, 661 acceptance codes and 629 outcome codes. Consistency of ≥ 80% was given for 9/20 cases in the domain problem, for 4/20 cases in the domain cause, for 3/20 cases in the domain intervention, for 10/20 cases in the domain acceptance and for 9/20 cases in the domain status of the DRP. Table 2 shows the detailed results of the validation of the German language version in comparison to the international results [9].

Table 1 Baselines of the participating pharmacists at the validation process (n = 30)

Gender female (n, % of total)	20 (66.7%)
Age (years, average)	40.5
Years in practice (years, average)	14.8
Setting (n, % of total)	
Community	15 (50.0%)
Hospital	7 (23.3%)
Administration	3 (10.0%)
Research	4 (13.3%)
Other	1 (3.3%)

Qualitative results

The raters (n = 17) described difficulties in finding an appropriate code in several cases, particularly in the domains of acceptance and status of the DRP. The average number of described vague cases was 2.1, with a minimum of 0 and a maximum of 6 cases. Patient case number 19 was rated as difficult by 8 pharmacists, case number 12 by 6 pharmacists and case number 8 by 4 pharmacists. A mistake in patient case 12 was recognized by many raters ("a statin was given" instead of "no statin was given"). One rater stated that many categories of the classification were not applicable to the cases and that the classification is not suitable for clinical practice. In contrast, a different rater expressed that the cases were realistic and covered a wide field but were limited to the outpatient setting. On a scale between 1 and 4 (with 1 meaning feasible and 4 meaning inapplicably), the classification system was rated by the participants with an average of 2.0 for feasibility in research and of 2.5 for feasibility for clinical practice.

Discussion

This study provides a translation of the PCNE DRP classification system into German language, which is available from the PCNE website [10]. The validation process was based on a quantity of patient cases and raters, which is in line with previous validation studies on DRP classification systems [5]. Consistency results found in this study do not differ profoundly from the international results for the domains of problem (77.3% vs. 76.3%) and cause (57.8% vs. 65.3%). However, for the domain of intervention, a lower consistency was given (57.4% vs. 72.9%). An interpretation of the consistency results suggests that the translation of the PCNE classification for DRPs into German language and the translation of the cases led to roughly similar results as the validation of the original version and hence can be regarded as being of approximately similar quality. Many raters expressed difficulties in finding a proper code for the cases. Yet, the study authors felt that the differing codes were mainly plausible. Cases should be revised in a way, that only one code is appropriate to allow higher consistency levels in future validations. According to the qualitative results, the feasibility of the classification system is not optimal as well. Expressions and layout should be considered for amendments in future versions.

Limitations

The translation of the PCNE DRP version 9.00 and the validation was done with great accuracy. Even though raters were instructed to code validation cases without further

Table 2 Results of coding the patient cases by the participating pharmacists (n = 32)

Patient case	Consistency for preferably selected code (%) and code number				
	Problem	Cause	Planned intervention	Intervention acceptance	Status of the DRP
1	P 2.1 **(100.0%)** n = 31/31	C 3.2. (57.8%) n = 26/45	I 2.3. (47.5%) n = 29/61	A 1.4. **(85.3%)** n = 29/34	O 0.1. (64.5%) n = 20/31
2	P 2.1 (79.4%) n = 27/34	C 1.4. (46.5%) n = 20/43	I 1.4. (45.2%) n = 28/62	A 1.1. **(85.7%)** n = 30/35	O 1.1. (59.4%) n = 19/32
3	P 1.2 **(90.6%)** n = 29/32	C 7.1. (50.0%) n = 24/48	I 2.1. (66.7%) n = 30/45	A 1.4. **(85.3%)** n = 29/34	O 0.1. (62.5%) n = 20/32
4	P 2.1 (78.8%) n = 26/33	C 1.5. (52.9%) n = 27/51	I 2.3. (46.8%) n = 29/62	A 2.2. (25.0%) n = 10/40	O 3.1. (54.8%) n = 17/31
5	P 1.3. (48.6%) n = 17/35	C 9.3. (55.9%) n = 19/34	I 2.3. **(91.4%)** n = 32/35	A 1.4. (51.5%) n = 17/33	O 0.1. (68.8%) n = 22/32
6	P 2.1. **(93.8%)** n = 30/32	C 2.1. (54.8%) n = 23/42	I 2.1. (50.0%) n = 28/56	A 1.4. (42.4%) n = 14/33	O 0.1. (62.5%) n = 20/32
7	P 2.1. **(84.8%)** n = 28/33	C 1.4. (43.5%) n = 20/46	I 2.1. (56.4%) n = 31/55	A 1.1. (50.0%) n = 17/34	O 1.1. (40.6%) n = 13/32
8	P 1.3. (77.8%) n = 21/27	C 1.6. (43.8%) n = 14/32	I 2.3. **(90.0%)** n = 27/30	A 3.1. (74.1%) n = 20/27	O 0.1. **(96.3%)** n = 26/27
9	P 2.1. **(93.9%)** n = 31/33	C 7.8. (75.7%) n = 28/37	I 2.1. (65.2%) n = 30/46	A 1.4. (75.8%) n = 25/33	O 0.1. (71.9%) n = 23/32
10	P 3.2. **(84.4%)** n = 27/32	C 1.3. (50.0%) n = 26/52	I 1.3. (55.9%) n = 19/34	A 2.2. (59.4%) n = 19/32	O 3.2. **(90.3%)** n = 28/31
11	P 2.1 **(100.0%)** n = 32/32	C 7.8. (75.7%) n = 28/37	I 2.1. (56.4%) n = 31/55	A 1.1. **(93.9%)** n = 31/33	O 1.1. **(96.9%)** n = 31/32
12	P 1.3. (50.0%) n = 17/34	C 8.3. (42.4%) n = 28/66	I 1.2. (45.7%) n = 21/46	A 1.1. **(90.6%)** n = 29/32	O 1.1. **(93.8%)** n = 30/32
13	P 1.2. (78.1%) n = 25/32	C 4.1. **(91.2%)** n = 31/34	I 1.3. (31.9%) n = 15/47	A 1.1. **(93.8%)** n = 30/32	O 0.1. **(81.3%)** n = 26/32
14	P 1.2. **(93.8%)** n = 30/32	C 7.7. (29.3%) n = 12/41	I 2.1. (62.0%) n = 31/50	A 1.1. **(87.9%)** n = 29/33	O 3.3. **(93.8%)** n = 30/32
15	P 1.2. (67.6%) n = 23/34	C 7.1. **(86.5%)** n = 32/37	I 2.1. (74.4%) n = 32/43	A 1.4. (72.7%) n = 24/33	O 0.1. **(90.6%)** n = 29/32
16	P 1.2. (56.3%) n = 18/32	C 1.1. **(85.3%)** n = 29/34	I 1.3. (42.0%) n = 21/50	A 1.1. **(97.0%)** n = 32/33	O 1.1. **(90.6%)** n = 29/32
17	P 1.2. (77.1%) n = 27/35	C 7.1. **(81.1%)** n = 30/37	I 2.1. **(91.2%)** n = 31/34	A 2.2. (57.6%) n = 19/33	O 3.1. (53.1%) n = 17/32
18	P 3.2. **(87.9%)** n = 29/33	C 1.3. (45.8%) n = 22/48	I 1.4. and I3.5 (39.0% each) n = 23/59	A 1.1. **(91.4%)** n = 32/35	O 1.1. (71.9%) n = 23/32
19	P 2.1. (41.9%) n = 13/31	C 2.1 (57.8%) n = 26/45	I 1.3. (35.1%) n = 20/57	A 1.1. **(90.6%)** n = 29/32	O 1.1. (71.0%) n = 22/31
20	P 1.2 (61.3%) n = 19/31	C 3.1. and C 8.1 (31.1% each) n = 14/45	I 1.2. (54.5%) n = 24/44	A 1.1. **(80.0%)** n = 24/30	O 1.1. **(83.3%)** n = 25/30
Average consistency	**77.3%**	**57.8%**	**57.4%**	74.5%	74.9%
Average consistency in international comparison	**76.3%**	**65.3%**	**72.9%**	Not available	Not available
Number of cases with consistency ≥ 80% in this domain	9 of 20 (45.0%)	4 of 20 (20.0%)	3 of 20 (15.0%)	10 of 20 (50.0%)	9 of 20 (45.0%)
Number of cases with consistency ≥ 80% in international comparison	7 of 20 (35%)	4 of 20 (20.0%)	7 of 20 (35%)	Not available	Not available

Consistency rates ≥ 80% are shown in bold

n number of selections for this particular code/total number of selections

interpretation, some cases seemed to be rather unclear. This was found to be the greatest obstacle of the project and for reaching consistency. Recruitment of the raters was limited to a convenience sample, which is another limitation of this study. However, raters were experienced in clinical pharmacy services and worked in different professional settings.

Conclusions

This study provides a German translation of the PCNE classification of DRPs of approximately similar consistency as the international version. It hence can be suggested as an instrument to classify DRPs in clinical pharmacy services in the German speaking countries. Emphasis should be placed on patient cases, which need to be more specific in future validations. Feasibility of the classification system can be improved by changes in the layout.

Acknowledgements The authors like to thank Ms. Olga Grintsova for her participation in the translation process, the members of the PCNE DRP group for the close collaboration and the participating pharmacists for their commitment and time.

Funding This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflicts of interest Elisabeth Schindler declares no conflict of interest. Ina Richling has received a speaker honorarium from Tilray, Gehe, Dr. Pöhnl, Univadis, Hexal, KWHC, Bionorica and Pfizer. Olaf Rose has received a speaker honorarium from AbbVie, MSD Sharp & Dohme, Novartis and Omnicell.

References

1. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990;47:533–43.
2. Williams M, Peterson GM, Tenni PC, Bindoff IK, Stafford AC. DOCUMENT: a system for classifying drug-related problems in community pharmacy. Int J Clin Pharm. 2012;34:43–52.
3. Maes KA, Tremp RM, Hersberger KE, Lampert ML. Demonstrating the clinical pharmacist's activity: validation of an intervention oriented classification system. Int J Clin Pharm. 2015;37:1162–71.
4. van Mil JWF, Westerlund LOT, Hersberger KE, Schaefer MA. Drug-related problem classification systems. Ann Pharmacother. 2004;38:859–67.
5. Horvat N, Kos M. Development and validation of the Slovenian drug-related problem classification system based on the PCNE classification V 6.2. Int J Clin Pharm. 2016;38:950–9.
6. Eichenberger PM, Lampert ML, Kahmann IV, van Mil JWF, Hersberger KE. Classification of drug-related problems with new prescriptions using a modified PCNE classification system. Pharm World Sci. 2010;32:362–72.
7. Koubaity M, Lelubre M, Sansterre G, Amighi K, Vriese C de. Adaptation and validation of PCNE drug-related problem classification v6.2 in French-speaking Belgian community pharmacies. Int J Clin Pharm. 2019;41:244–50.
8. Pharmaceutical Care Network Europe. Classification for drug related problems. https://www.pcne.org/upload/files/334_PCNE_classification_V9-0.pdf. Accessed 2 Sept 2020.
9. Horvat N. PCNE working group on drug-related problems. Final report. 2020. https://www.pcne.org/upload/files/411_2020-05-04_Final_Report_online_validation_PCNE_classification.pdf. Accessed 2 Sept 2020.
10. Pharmaceutical Care Network Europe Association. PCNE Klassifikation arzneimittelbezogener Probleme V9.00. https://www.pcne.org/upload/files/343_PCNE_V9.0_German_translation.pdf. Accessed 2 Sept 2020.