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RESEARCH ARTICLE

Translation and validation of a tool to assess the impact of clinical pharmacists' interventions

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Abstract

Background The tool CLEO in French language is designed for estimating the potential relevance of pharmacists' interventions (PIs) in three independent dimensions with regard to process-related, clinical, economic, and humanistic impact. *Objective* We aimed to translate CLEO into German ($CLEO_{de}$), to demonstrate its feasibility in daily practice, and to validate the German version. *Setting* Convenience sample of three Swiss hospitals with established clinical pharmacy services. *Method* We translated CLEO according to the ISPOR Principles of Good Practice. The potential relevance of PIs performed within a 13-day period of routine clinical pharmacy services was then estimated with $CLEO_{de}$. Ten clinical pharmacists experienced with $CLEO_{de}$ subsequently completed a 19-item questionnaire to assess user's agreement on appropriateness, acceptability, feasibility, and precision of the tool. Additionally, each pharmacist evaluated 10 model cases with $CLEO_{de}$. *Main outcome measure* User satisfaction; interrater reliability and test–retest reliability. *Results* $CLEO_{de}$ was used to estimate the potential relevance of 324 PIs. The reported time needed to complete a single estimation was less than 1 min. The use of $CLEO_{de}$ was seen as appropriate, acceptable, feasible, and precise. Interrater reliability was good for the clinical and economic dimensions and was poor for the organisational dimension; test–retest correlation was strong for all three dimensions with excellent to fair reliability. *Conclusion* We present $CLEO_{de}$ as a validated tool in German language suitable to estimate the potential relevance of PIs. After further refinement of the organisational dimension, $CLEO_{de}$ could provide a qualitative value to quantitative information on PIs.

Keywords Classification · CLEO Tool · Clinical pharmacy · Clinical relevance · Drug-related problems · Interrater reliability · Pharmacists' interventions · Translation

Impacts on practice

- $CLEO_{de}$ is a reliable and user-friendly approach estimating the potential relevance of pharmacists' interventions.
- $CLEO_{de}$ is the German language French CLEO tool which has been translated and culturally adapted.

Introduction

A drug-related problem (DRP) is defined as "an event or circumstance involving drug treatment that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care [1]." DRPs are multidimensional in that they may be preventable or not; potential or actual; and be caused by a medication error, by a deviation from current

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guidelines, or by an unpredictable reaction to an appropriate pharmacological treatment [2]. DRPs are frequent in hospitalised patients [3]. Approximately 5% of all drug applications in hospitals are medically erroneous and may lead to DRPs [3]. Due to the high number of drug applications on medical wards, medication errors are expected to affect most hospitalised patients.

A pharmacist's task in a health care team is to promote drug therapies that are appropriately indicated, effective, and safe [4], hence averting medication errors. Pharmacists' interventions (PIs), defined as discrete activities by pharmacists related to patient care [5], are shown to improve health outcomes when carried out on ward rounds, in patient interviews, medication reconciliation, and patient counselling [6]. However, pharmacists often fail to take responsibility for their interventions and tend to not adequately document, monitor, and review their services [4]. In Switzerland, the Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA) promotes the use of the GSASA classification system [7] for clinical pharmacists to appropriately report their identified DRPs and proposed PIs. This system is based on PCNE classification system V6.2 [8] and classifies DRPs in five categories.

Such classification of DRPs and their corresponding intervention ensures that the services of clinical pharmacists are adequately documented, but fails to report their relevance. Data on the relevance of PIs is necessary to publicise the value pharmacists add to health care [9]. There are three distinct approaches to assess the relevance of PIs: (1) The evaluation of actual consequences of an unresolved DRP; (2) The evaluation of actual consequences of a resolved DRP by follow-up; or (3) The estimation of potential relevance of a PI or the estimation of possible risk of a DRP for the patient [10]. The assessment of actual clinical outcomes (approaches 1 and 2) is often hindered by difficulties in follow-up, lack of resources, or the determination of causality. The estimation of potential relevance of PIs (approach 3) does not suffer from these drawbacks, but is prone to issues on subjectivity, reliability, and validity. To address some of these issues, expert panels could be consulted to report on the potential relevance of the PIs being investigated [11–13], which is a resource intensive method mainly feasible in study settings.

Vo et al. [10] identified and reviewed 46 tools that estimate the potential relevance of PIs. They concluded that the majority of tools primarily focus on the clinical aspect of PIs and fail to evaluate their potential relevance more comprehensively, such as when information to other health care professionals is provided. As stated, DRPs may be multidimensional, and the PIs provided to resolve them will follow this structure. Vo and colleagues developed a new tool named CLEO to estimate the potential relevance of PIs within its three dimensions CLinical, Economic, and Organisational, hence its name. The clinical dimension focuses on impact related to the patient's well-being from the patient's perspective: averted damages, improved quality of life, and improved adherence. The economic dimension assesses the immediate impact of the PI on the current costs of therapy from the institution's perspective. The organisational dimension evaluates the impact on the process of care, focusing on the view of the health care professionals: reduced time expenditures, decreased work load, improved work place safety, and simplified collaborations. The French version of CLEO has since been validated and used within the hospital setting [14, 15].

Aim of the study

Our aims were (1) to translate the French version of CLEO into German (termed $CLEO_{de}$); (2) to demonstrate feasibility in daily practice; (3) and to validate the German version.

Ethics approval

According to the requirements of the Swiss federal law on human research this study did not need an ethics approval.

Method

Translation

The translation into German was performed according to the ten steps of the ISPOR Principles of Good Practice for the Translation and Cultural Adaption Process for Patient-Reported Outcome Measures [16]. Two independent translators with knowledge of pharmaceutical terminology simultaneously translated the original French version with focus on equality of sense/analogous meaning. We merged the two translations into a single German version with the aid of one of the translators. Discrepancies were discussed in a reconciliation meeting to ensure that semantic and conceptual equivalence between source and target language versions was achieved. We sought the second translator's approval for all changes made. Back-translation from German into French was done by a third translator unfamiliar with the original version with focus on equality of words. We sought agreement on the back-translated version from the developers of the original tool. The adapted target language version was sent to six native German-speaking and experienced clinical pharmacists, each two from Austria, Germany, and Switzerland for cognitive debriefing using a modified evaluation sheet of Breuer et al. [17]. We asked for their ratings (Likert scale; 1: poor, 6: very good) on each item of the tool with regard to comprehensiveness and linguistic style using an online questionnaire form (Flexiform version 2.7.1 g,

IT-services University of Basel). The threshold of acceptance was pre-defined to sufficient (4) for the standard deviations. All suggestions in the comments section were evaluated. We added a final back-translation as an 11th step to the ISPOR Principles of Good Practice for agreement with the original developers to possible changes due to feedback from the cognitive debriefing.

Validation

The validation process is visualised in Fig. 1.

Data collection and interpretability

We asked a convenience sample of three Swiss hospitals (capacities of 679, 337, and 290 beds) to collect performed PIs during routine clinical pharmacy services. All PIs were classified with the GSASA classification system [7] according to common practice in these hospitals. Additionally, the participating clinical pharmacists estimated the potential relevance of their PIs with $CLEO_{de}$, which was integrated into their own electronic adaption of the GSASA classification system (either Microsoft Excel spreadsheet or Microsoft Access database). Training prior to data collection consisted of written instructions on the use of $CLEO_{de}$ and two instructional videos including general information and two model cases. To demonstrate interpretability and future applications, we performed descriptive statistics on the data set obtained.

Appropriateness, acceptability, feasibility, and precision

We tested for appropriateness, acceptability, feasibility, and precision of $CLEO_{de}$ with an adapted questionnaire of Abu-Ruz et al. [18], which has been used in earlier studies [7, 19]. The questionnaire was sent as an online form to the clinical pharmacists who used $CLEO_{de}$ within routine clinical pharmacy practice during our initial data collection. The questionnaire consisted of 19 items with a 7-point Likert scale to assess the extent of their agreement (1: entirely disagree, 4: neutral, 7: entirely agree).

Reliability

The clinical pharmacists previously involved in data collection classified 10 model cases and estimated the potential relevance of the PIs described with $CLEO_{de}$. The model cases consisted of five validated cases from literature [20] which have been used previously [7], and five descriptive cases from the validation studies of the original French version of CLEO. We distributed the link to an online questionnaire form with restricted access via e-mail for data collection (Flexiform). There was a wash-out phase of seven days prior to the test–retest reliability evaluation.

As recommended for more than two raters, we used a two-way mixed, agreement, single-measures intra-class correlation ($ICC_{A,1}$) to assess the inter-rater reliability of each dimension [21]. To assess test–retest reliability, we compared both ratings of each rater individually and calculated $ICC_{A,1}$ means ($\overline{ICC}_{A,1}$) and Spearman's rank correlation coefficient means ($\bar{\rho}$) [22]. We performed all calculations using RStudio [23] (version 0.99.903) running R version 3.3.1 [24] with the package irr [25] (version 0.84). We interpreted the $ICC_{A,1}$ and $\overline{ICC}_{A,1}$ results according to Cicchetti [26]: $ICC_{A,1} < .40$ as poor, .40 to .59 as fair, .60 to .74 as good, and .75 to 1.0 as excellent. $\bar{\rho}$ values were interpreted as follows: $\bar{\rho} = .1$ as weak, .3 as intermediate, and .5 as strong.

Results

Translation

The translation process was completed within 10 weeks and produced 10 different German versions. For the cognitive debriefing, we received responses from five of six clinical pharmacy experts (Austria: 1, Germany: 2, Switzerland: 2). The means of each of the 21 items were at least sufficient (4) for both, linguistic style and comprehensiveness. The standard deviations of 11 items exceeded our threshold of sufficient (4) in comprehensiveness or linguistic style. We reviewed all 11 items and changed 12 words according to the suggestions in the comments section of the questionnaire. The changes focused on the cultural adaption process (e.g., "Medikamententreue" was changed to "Therapietreue

	Part 1: Translation	**Part 2**: Validation		
		Interpretability	Appropriateness, Acceptability, Precision, Feasability	Interrater reliability, test-retest reliability
Methods	ISPOR Principles of Good Practice for the Translation and Cultural Adaption Process for Patient Reported Outcome Measures	Performed pharmacists' interventions during 13 days in three Swiss hospitals Classification with GSASA Evaluation with $CLEO_{de}$	User's agreement 10 clinical pharmacists 19-items questionnaire 7-point Likert scale	10 model cases 10 clinical pharmacists Wash-out: 7 days

Fig. 1 Translation and validation process

[Adhärenz]"). Proofreading of the final version resulted in one last change of wording in the organisational dimension. Our final back-translated version was accepted by the original developers. The finalised German version $CLEO_{de}$ is shown in Fig. 2.

Validation

Data collection, interpretability

$CLEO_{de}$ was used for 13 working days within routine clinical pharmacy practice in April and May 2016 in three Swiss hospitals. A total of 324 PIs were performed by ten clinical pharmacists. Twenty-one PIs (6.5%) were evaluated as 'not determined' in all three dimensions. Frequencies of all PI evaluations by $CLEO_{de}$ are presented in Fig. 3. Most PIs (n = 138, 42.7%) were evaluated to have a minor clinical relevance = 'effect on patient in regard to clinical situation, knowledge, satisfaction, adherence, or quality of life OR damage, which does not necessitate surveillance or treatment' (starting/restarting or stopping a therapy, 37.0%; dose adjustment, 21.7%; optimisation of dosing modalities, 15.2%; substitution/replacement, 9.4%; others, 16.7%), whereas 9.9% were evaluated to have a major = 'damage, which leads to hospitalisation, or prolongation thereof OR damage, which leads to disablement or impairment' or vital clinical relevance = 'damage which leads to intensive care treatment or death.' The levels 'moderate', 'major' and 'vital' all describe the avoidance of potential damages, which at least need an additional test or treatment to be resolved, i.e., they describe actions needed to be taken to prevent patient harm. PIs which were evaluated to decrease costs (n = 116, 36.0%) were classified as stopping a therapy (44.0%), dose adjustment (25.9%), substitution/replacement (10.3%), optimisation of dosing modalities (7.8%), or others (12.1%). Almost half of the PIs that were evaluated to increase costs (n = 66, 20.5%) were starting/restarting a therapy (48.5%), followed by therapy monitoring (15.0%), dose adjustment (12.2%), information to health care professionals (10.6%), and others (13.6%). The PIs were judged to have a positive (39.4%), a negative (16.0%), or no relevance (35.7%) within the organisational dimension of $CLEO_{de}$. Examples of PIs for all possible evaluations with $CLEO_{de}$ are presented in Table 1.

Appropriateness, acceptability, feasibility, and precision

All ten clinical pharmacists completed our 19-items questionnaire on user's agreement. $CLEO_{de}$ was seen as appropriate (mean = 5.45; SD = 0.76), acceptable (4.43; 1.28), feasible (5.27; 1.44), and precise (5.90; 1.16) to evaluate the potential relevance of PIs. One item received a mean rating of below neutral (3.70; 1.3): six out of ten clinical pharmacists stated that they had issues to estimate the potential relevance of PIs with $CLEO_{de}$. The results are reported in Fig. 4. Five clinical pharmacists reported an evaluation time of 'less than 30 s' per PI; none reported an evaluation time of 'more than 1 min'.

Reliability

Each of the ten clinical pharmacists classified all ten model cases and estimated the potential relevance of the PIs twice with a washout phase of 7 days in between. Clinical experience of the participating pharmacists ranged from < 6 months (n = 3) to > 5 years (n = 1); the median was 1 year of clinical experience.

The interrater reliability for $CLEO_{de}$ was good for the dimensions clinical (intra-class correlation $ICC_{A,1} = .63$) and economic ($ICC_{A,1} = .65$) and poor for organisational ($ICC_{A,1} = .30$). Test–retest correlation was strong for all three dimensions (clinical: mean Spearman's rank correlation coefficient $\bar{\rho} = .77$; economic: $\bar{\rho} = .85$; organisational: $\bar{\rho} = .58$), yielding in excellent test–retest reliability for the dimensions clinical (mean intra-class correlation $\overline{ICC}_{A,1} = .76$) and economic ($\overline{ICC}_{A,1} = .85$) and fair for organisational ($\overline{ICC}_{A,1} = .53$).

Discussion

We successfully translated and culturally adapted the French evaluation system for PIs CLEO into the German version $CLEO_{de}$. In a time period of 13 days we collected 324 PIs routinely performed by 10 clinical pharmacists at three Swiss hospitals.

Data collection, interpretability

The 324 PIs were estimated to mainly (42.7%) have a minor clinical relevance. In CLEO, this level of clinical relevance is assigned to improvements in humanistic outcomes (better knowledge, satisfaction, adherence, quality of life) or avoided potential physical or psychological damages which would not require additional surveillance or treatments. The clinical pharmacists may have evaluated their PI as minor instead of the next higher level (i.e. moderate) because the surveillance (i.e. laboratory measurements) was routinely planned, skewing the data on clinical relevance. As previously mentioned, the levels 'moderate', 'major' and 'vital' all describe the avoidance of potential damages, which at least need an additional test or treatment to be resolved, i.e., they describe actions needed to be taken to prevent patient harm. Levels moderate to vital combined amounted to 26.3% of all 324 evaluated PIs. Dean et al. [13] collected data on 538 prescribing errors identified by clinical pharmacists

Evaluation der Auswirkung einer pharmazeutischen Intervention (PI) durch die $CLEO_{de}$ Skala

Klinische Auswirkung

Grundsatz: Die klinische Auswirkung wird nach einem wahrscheinlichem Szenario und nicht nach schlimmstem/bestem Szenario bewertet.
Die klinische Auswirkung wird aus Sicht des Patienten bewertet.

Erläuterung:
Schaden: Körperlicher Schaden - Beeinträchtigung der physischen und/oder psychischen Fähigkeiten des Patienten.
Lebensqualität: Physische Aspekte (Autonomie, körperliche Fähigkeiten, Fähigkeit tägliche Aufgaben zu erledigen, etc.), psychologische Aspekte (Ängste, Depression, Emotionalität, etc.), soziale Aspekte (bezogen auf das familiäre oder professionelle Umfeld, Freundeskreis, Pflege persönlicher Beziehungen, Teilnahme an Sozial- und Freizeitaktivitäten, etc.) und somatische Aspekte (Symptome der Krankheit).
Überwachung: Nachkontrollen, labormedizinische Kontrollen.
Behandlung: Änderung der Therapie oder zusätzliche medizinische/chirurgische Behandlung.

Score	Auswirkung	Definition
-1C	schädlich/ negativ	Die pharmazeutische Intervention (PI) kann zu negativen Ergebnissen hinsichtlich des klinischen Zustandes, des Wissenstandes, der Zufriedenheit, der Therapietreue (Adhärenz) und/oder der Lebensqualität des Patienten führen.
0C	ohne	Die PI hat keine Auswirkung auf den Patienten hinsichtlich des klinischen Zustandes, des Wissenstandes, der Zufriedenheit, der Therapietreue (Adhärenz) und/oder der Lebensqualität des Patienten.
1C	gering	Die PI kann den Wissensstand, die Zufriedenheit, die Therapietreue (Adhärenz) und/oder die Lebensqualität des Patienten verbessern. ODER Die PI kann einen Schaden beim Patienten verhindern, der keine Überwachung/Behandlung erfordert.
2C	mittel	Die PI kann einen Schaden beim Patienten verhindern, der eine Überwachung oder Behandlung erfordert, aber keine Hospitalisierung herbeiführt oder einen bestehenden Spitalaufenthalt verlängert.
3C	erheblich	Die PI kann einen Schaden verhindern, welcher einen Spitalaufenthalt des Patienten verursacht oder verlängert. ODER Die PI kann einen Schaden beim Patienten verhindern, der eine dauerhafte Invalidität oder Beeinträchtigung verursacht.
4C	lebensnotwendig	Die PI kann einen Schaden beim Patienten verhindern, der eine intensiv-medizinische Behandlung nach sich zieht oder zum Tod des Patienten führt.
NB	nicht beurteilbar	Die verfügbaren Informationen erlauben es nicht, die klinische Auswirkung zu beurteilen.

Wirtschaftliche Auswirkung

Grundsatz: Die Kosten der medikamentösen Behandlung beziehen sich auf die finanziellen Kosten des Krankenhauses.

Erläuterung:
Die Kosten der **medikamentösen Behandlung** beinhalten zwei prinzipielle Aspekte:
- Arzneimittelkosten
- Die Kosten der Überwachung der medikamentösen Behandlung (z.B. Folgeuntersuchungen, Labor, etc)

Score	Auswirkung	Definition
-1E	höhere Kosten	Die PI erhöht die Kosten der medikamentösen Behandlung des Patienten.
0E	keine Veränderung	Die PI verändert die Kosten der medikamentösen Behandlung nicht.
1E	geringere Kosten	Die PI reduziert Kosten bei der medikamentösen Behandlung des Patienten.
NB	nicht beurteilbar	Die verfügbaren Informationen erlauben es nicht, die wirtschaftliche Auswirkung zu beurteilen.

Organisatorische Auswirkung

Grundsatz: Die organisatorische Auswirkung beschreibt den Einfluss auf die Qualität des Behandlungsprozesses aus Sicht des medizinischen Personals.

Erläuterung:
Folgende **Aspekte** sind insbesondere zu berücksichtigen:
- Zeitersparnis
- Verbesserte Kenntnisse
- Vereinfachung der professionellen Tätigkeit
- Vereinfachte Zusammenarbeit
- Erhöhte Sicherheit für das Personal
- Kontinuität der Behandlung

Score	Auswirkung	Definition
-1O	verringert	Die PI reduziert die Qualität des Behandlungsprozesses.
0O	ohne	Die PI hat keinen Einfluss auf die Qualität des Behandlungsprozesses.
1O	erhöht	Die PI erhöht die Qualität des Behandlungsprozesses.
NB	nicht beurteilbar	Die verfügbaren Informationen erlauben es nicht, die organisatorische Auswirkung zu beurteilen.

Fig. 2 $CLEO_{de}$

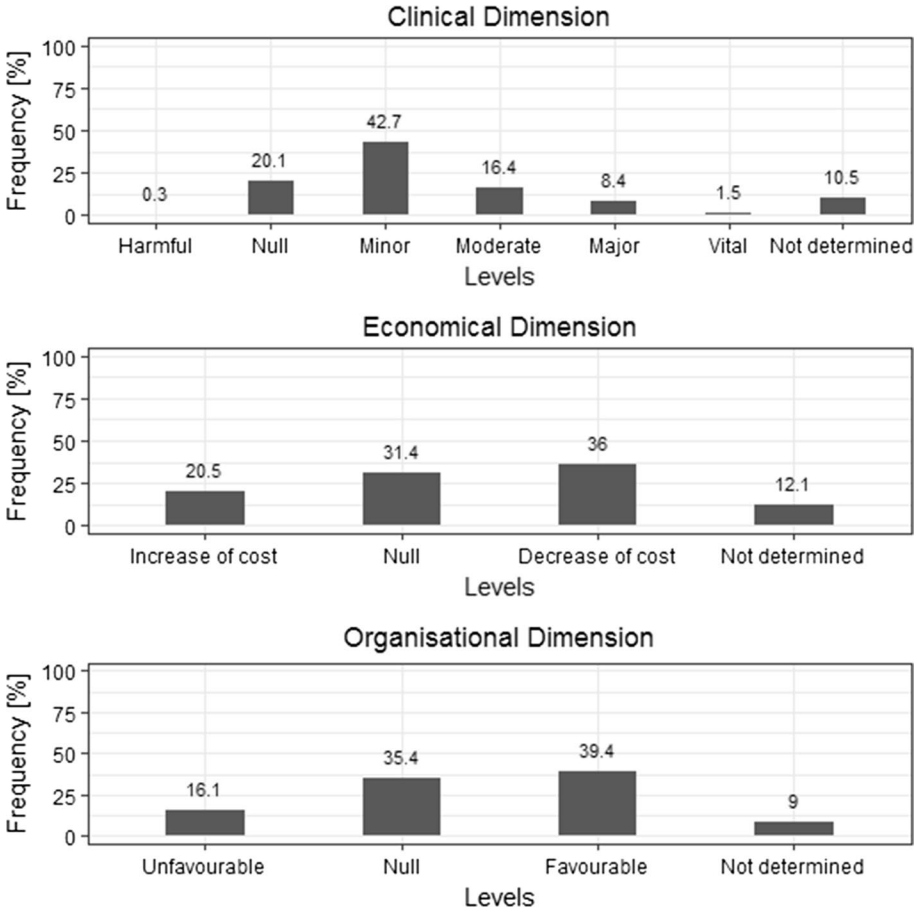

Fig. 3 Estimated potential relevance of pharmacists' interventions during 13 days in three Swiss German hospitals, sorted according to the dimensions of $CLEO_{de}$ (n = 324). Levels (translated from German): Null: No effect on patient in regard to clinical situation, knowledge, satisfaction, adherence or quality of life; Minor: Effect on patient in regard to clinical situation, knowledge, satisfaction, adherence, or quality of life OR damage, which does not necessitate surveillance or treatment; Moderate: Damage, which necessitates surveillance or treatment, but does not lead to hospitalisation or prolongation thereof; Major: Damage, which leads to hospitalisation, or prolongation thereof OR damage, which leads to disablement or impairment; Vital: Damage which leads to intensive care treatment or death

within four weeks, and similarly detected 26% (n = 142) potentially serious errors ("likely to cause patient harm") rated by one researcher and one clinical pharmacologist.

The allocation of PIs that were evaluated to increase (20.5%) or decrease (36.0%) the costs corresponds to the categorisation of the proposed PI: approximately 76% of the PIs evaluated as cost-raising were categorised as starts or restarts of therapies, dose increases, or recommended therapy monitoring, all of which generate immediate costs; Approximately 80% of the PIs evaluated as cost-lowering were categorised as termination of therapies, dose decreases, or substitutions, all of which decrease the immediate costs. This congruence of evaluation and categorisation of PIs suggests validity of the economic dimension.

The evaluation of the organisational impact, however, was inconsistent: the ten clinical pharmacists rated the same interventions (e.g. 'starting/restarting a therapy', 'terminating a therapy' 'substitution/replacement') as having a positive, having a negative, or having no impact on organisational aspects, thus preventing a clear interpretation of the findings. The evaluation of the organisational impact hence seems heavily dependent on the point of view: an intervention may cause additional workload for nurses by improving workplace safety. The current version of CLEO leaves the decision up to the rater on which indicators they focus to estimate the organisational impact of their PI.

In our study, only 21 PIs (6.5%) were evaluated as 'not determined' in all three dimensions, confirming appropriateness of $CLEO_{de}$. As these 21 PIs were heterogeneous in their underlying DRP, we were not able to define a certain intervention as not determinable by $CLEO_{de}$. However, 16 of the 21 non-determinable PIs originated from one of the hospitals, suggesting a training issue.

Appropriateness, acceptability, feasibility, and precision

Clinical pharmacists familiar with the tool rated $CLEO_{de}$ as appropriate, acceptable, feasible, and precise. In addition, they reported 'less than 1 min' needed for the estimation of the potential relevance of one PI. As time expenditure is an essential element for the acceptance of a new tool, this result removes a hurdle for future implementation. However, the questionnaire on users' agreement also highlighted issues that need to be addressed prior to implementation: the issues within the organisational dimension affected user satisfaction. Some clinical pharmacists also stated that the training video with two sample cases was insufficient as preparation.

Table 1 Examples of PIs documented with the GSASA classification and evaluated with $CLEO_{de}$

Description	GSASA problem	GSASA reason	GSASA intervention	$CLEO_{de}$ clinical	$CLEO_{de}$ economic	$CLEO_{de}$ organisational
Anticoagulation is currently paused because patient is awaiting pericard puction. Preventive therapy with heparin is recommended for short hospital leave	Untreated indication	Treatment not received	Therapy started/restarted	Major	Increase of cost	Favourable
Information to the health care team: SGLT2-inhibitors may cause urinary tract infections	Safety of treatment	Adverse effect	Information to care givers	Null	Null	Favourable
Amlodipin 5 mg twice a day replaced with 10 mg once a day	Patient dissatisfaction	Inappropriate timing or frequency of administration	Optimisation of administration	Minor	Decrease of cost	Favourable
Taking of thyroid hormone changed to 30 min before a meal	Treatment effectiveness	Inappropriate timing or frequency of administration	Optimisation of administration	Moderate	Null	Unfavourable
Treatment of atrial fibrilation has been forgotten when the patient changed wards	Untreated indication	Treatment not received	Therapy started/restarted	Vital	Increase of cost	Favourable
Metamizol prescribed twice as reserve in case of pain	Safety of treatment	Drug not indicated or duplication	Clarification in the case notes	Not determined	Not determined	Not determined
Pharmacist proposed alternative first-line treatment for hypertension (currently: Beta-blocker). Patient informed care providers about his history of tachycardia	Safety of treatment	No concordance with guidelines or contraindication	Substitution	Harmful	Null	Null

We propose guidance by discussing typical examples from daily practice to achieve greater degrees of certainty and user satisfaction.

Reliability

$CLEO_{de}$ achieved good interrater and excellent test–retest reliability for the dimensions clinical and economic in a sample of 10 selected clinical pharmacists, working in three different hospitals and having different levels of clinical experience. A high degree of reliability is a key factor when considering a specific tool for the estimation of the potential relevance of a PI [10]. This aim is met for CLEO and $CLEO_{de}$ for the clinical and economic dimensions.

However, the organisational dimension achieved poor interrater and fair test–retest reliability. These issues have already been identified for the French version of CLEO: Vo et al. [14] reported fair interrater reliability. Our results again highlight the necessity to facilitate the evaluation in this dimension by reducing the number of indicators to choose from and by intensifying the training process. It may be argued that in contrast to the other two dimensions, clinical pharmacists might not be familiar with judging their PIs from the perspective of other health care professionals. Combined with the many organisational indicators to choose

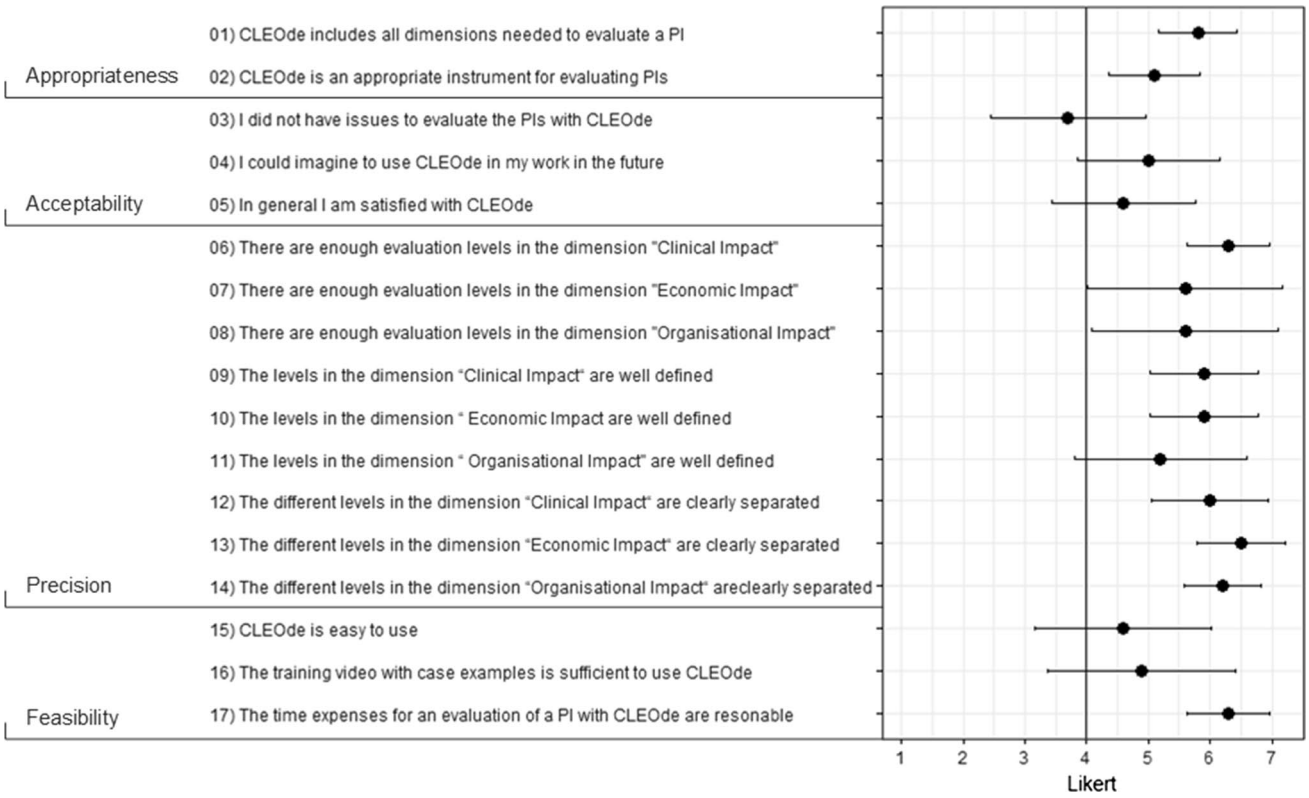

Fig. 4 User's agreement on appropriateness, acceptability, precision, and feasibility of the tool. 7-point Likert scale; 1: entirely disagree, 4: neutral, 7: entirely agree (mean ± SD). The two non-Likert additional items of the questionnaire on time requirements and further comments are not displayed

from in this dimension, the evaluation of the organisational impact with CLEO becomes difficult.

Strengths and limitations

The strengths of the work lie in the structured methodological approach of the translation process and the consecutive validation of the translated version: we minimised the risk of mistranslating or inserting our own interpretations by closely following the steps of the ISPOR Principles [16]. Cognitive debriefing with native speaking clinical pharmacy experts from all three German speaking countries ensured comprehensibility and correct linguistic style for the targeted users. We tested for appropriateness, acceptability, feasibility, interpretability, precision, and reliability, covering all criteria which might be influenced by the quality of a translation. Simultaneously we were able to demonstrate feasibility for implementation and possibilities for evaluation in daily routine clinical pharmacy services.

One limitation of this study is that only ten clinical pharmacists were involved in the validation process of $CLEO_{de}$, of which five had a clinical working experience of less than 1 year. This imposes selection bias that potentially affected our data collection. However, this composition of clinical pharmacists represents the current situation in the involved hospitals, i.e. junior clinical pharmacists are responsible for the documentation of PIs which were previously discussed with their experienced supervisors. Additionally, Vo and colleagues used 30 model cases for their initial assessment of reliability of CLEO, which ensures higher representability of the model cases. However, the results of the work of Vo and colleagues may be applied to the translated version, which allowed for a smaller re-evaluation in order to identify discrepancies between both results, which would have highlighted faulty translations.

Conclusion

We present $CLEO_{de}$ as a correctly translated and culturally adapted tool, validated with regard to reported acceptability, appropriateness, feasibility, and precision, as well as interpretability and reliability. $CLEO_{de}$ is a promising tool for research, which may in combination with existing classification systems for DRPs add qualitative value to quantitative information on PIs.

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