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CLEO$_{de}$

Translation and Validation of a French Tool to Assess the Impact of Clinical Pharmacists' Interventions

Master Thesis in Pharmacy
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11th January-3rd June 2016

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Abstract

Background: A major competence of clinical pharmacists includes identifying, resolving, and preventing potential drug related problems (DRPs). An effective way to detect DRPs by clinical pharmacists is a medication review that may lead to a pharmacist's intervention (PI). There are several classification systems to document PIs such as GSASA, DOCUMENT, PI-DOC and PCNE. The systems are all well established and validated, but lack in evaluating the impact of PIs. On the basis of a systematic review a new multidimensional tool to assess the potential impact of a PI was developed in Grenoble. The result was the tool CLEO – a simple, multidimensional, and comprehensive evaluation system for PIs.

Objectives: To translate the French evaluation system CLEO into German and validate the German version.

Methods: The translation of the tool CLEO into the German version $CLEO_{de}$ was performed according to the ISPOR "Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO)." We tested the German version of CLEO for appropriateness, acceptability, feasibility, and precision by using a 19-item questionnaire with a 7-point Likert scale (1 = entirely disagree, 7 = entirely agree). Interrater reliability (Fleiss-Kappa coefficients κ) and test-retest reliability (Kendall tau correlation coefficient τ) were determined with 10 model cases. To assess interpretability, clinical pharmacists evaluated all PIs during 17 days with our first German version $CLEO_{de}$.

Results: The evaluation system CLEO for pharmacists' interventions was successfully translated into German. During our translation process we introduced an eleventh step to the ten steps for a good translation: A final back translation into the original language. The asked clinical pharmacists think that $CLEO_{de}$ might be an appropriate (5.8±0.6) and comprehensive instrument (5.1±0.7) for the evaluation of PIs. All clinical pharmacists were estimating the evaluation time for a PI to be less than one minute; half of them even estimated it to be fewer than 30 seconds. Concerning the interrater reliability of $CLEO_{de}$, the dimension "economic impact" (κ = 0.75 and 0.79) is reliable as the kappa values were above the set threshold of κ = 0.4. The dimension "clinical impact" is almost reliable (κ = 0.37 and 0.31), while the dimension "organizational impact" is not reliable yet (κ = 0.28 and 0.19). The test-retest reliability of the evaluation system $CLEO_{de}$ can be assumed: The correlation coefficient Kendall Tau-b is high for the dimension "economic impact" (τ = 0.87), moderate for dimension "clinical impact" (τ = 0.69) and "organizational impact" (τ = 0.59). In the test phase 324 PIs were evaluated in three hospitals with $CLEO_{de}$.

Discussion: We successfully translated the evaluation system for pharmacists' interventions CLEO. During our translation process we introduced an additional final step to the good principles of translation, which we now propose for future translations of clinical outcome assessments. The validation of $CLEO_{de}$ with six out eight criteria of Fitzpatrick suggests that $CLEO_{de}$ may be a valuable addition to the classification system GSASA.