Content validity and inter-rater reliability of a classification system for drug-related problems for community pharmacists in Japan

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Background and Aims

- Drug-related problems (DRPs) are associated with increased morbidity and healthcare costs.
- Validated DRP classification systems are essential for identifying and managing DRPs, and for systematically documenting pharmacists' interventions and outcomes.
- Although DRP classification systems have been developed in several countries, none has been rigorously validated for use in Japanese pharmacies.
  - This study aimed to develop and validate a DRP classification system for Japanese pharmacists, and to evaluate its inter-rater reliability.

Methods

- This study followed a three-step process. Data were collected via REDCap and analysed using Python.
- Step1: An initial DRP classification was drafted using the PCNE DRP Classification System. Additional items were identified through a literature review, and detailed descriptions were developed for each item.[1,2]
- Step2: Content validity was assessed using a modified Delphi technique involving two surveys and an expert panel discussion. Ten pharmacists rated items on a 5-point scale. Item-level (I-CVI) and scale-level (Ave-CVI) content validity indices were calculated, with thresholds of I-CVI ≥ 0.8 and Ave-CVI ≥ 0.9 indicating valid.
- Step3: Inter-rater reliability was evaluated among 10 pharmacists using 31 case scenarios curated from a national database to assess whether they could consistently classify them into the appropriate categories. Inter-rater agreement for each category was assessed using Fleiss' Kappa(κ) (Poor <0.00, Slight 0.00-0.20, Fair 0.21-0.40, Moderate 0.41-0.60, Substantial 0.61-0.80, Almost perfect 0.81-1.00).

Results

- Step 1: An initial DRP classification system was developed with 62 items under four main categories (cause 38; intervention 10; acceptance 4; outcome 10).
- Step 2: Experienced pharmacists currently working in community pharmacies were recruited with support from two pharmacist associations. In the first round, 39 of 62 items met the criteria. Through panel discussion, 27 items were accepted. Other items were revised, and 26 proceeded to a second-round rating. After the second round, a total of 52 items were included (cause 31; intervention 9; acceptance 4; outcome 8).
- Step 3: Ten pharmacists classified the 31 cases related to DRPs. Inter-rater agreement was high to almost perfect across categories (cause κ=0.97; intervention κ=0.86; acceptance κ=0.82; outcome κ=0.91).

Table 1. Content validity assessment criteria

Item	Description
Representativeness	Appropriately represents the type of DRP
Name clarity	Clear and unambiguous naming
Description clarity	Precise and easy-to-understand description
Uniqueness	Unique and non-overlapping with other items

Step 1: Development (N=62)
Review

Initial DRP classification (N=62)
(Cause 38, Intervention 10, Acceptance 4, Outcome 10)

Step 2: Consensus testing

Round 1 online survey (N=62)
- 49 Accepted (all 4 items met the threshold)
- 13 Unaccepted

Representativeness	○: 58, ×: 4
Name clarity	○: 59, ×: 3
Description clarity	○: 56, ×: 6
Uniqueness	○: 56, ×: 6

Expert panel discussion (N=62)
- 27 Included
- 12 Deleted (combined)
- 23 Moved to Round 2
- 5 Newly added and moved to Round 2

Round 2 online survey (N=28)
- 21 Accepted (all 4 items met the threshold)
- 7 Unaccepted

Representativeness	○: 28, ×: 0
Name clarity	○: 28, ×: 2
Description clarity	○: 23, ×: 5
Uniqueness	○: 26, ×: 2

Review by research team (N=28)
- 25 Modified and included
- 2 Deleted (combined)

Validated DRP classification (N=52)
Cause 31, Intervention 9, Acceptance 4, Outcome 8

Step 3: Reliability testing (N=52)
- Cause κ=0.97 (Almost perfect)
- Intervention κ=0.86 (Almost perfect)
- Acceptance κ=0.82 (Almost perfect)
- Outcome κ=0.91 (Almost perfect)
- Overall κ=0.93 (Almost perfect)

Final validated DRP classification (N=52)
Cause 31, Intervention 9, Acceptance 4, Outcome 8

Figure 1. Study flow and validation results

【Cause】

Code	Item
	Prescription
C1.1	Inappropriate combination: drug and disease/condition
C1.2	Inappropriate combination: drug and drug
C1.3	Off-label prescribing
C1.4	Duplication of therapeutic group
C1.5	Potentially unnecessary medication
C1.6	Inappropriate drug selection (Use of non-recommended medication)
C1.7	Omitted prescription
C1.8	Incomplete or incorrect prescription details
	Logistics
C2.1	Medication supply shortage
C2.2	Expired prescription
	Carers
C3.1	Caregiver forgets to administer medication
C3.2	Caregiver misunderstanding in administration
C3.3	Caregiver-initiated discontinuation, dose reduction
C3.4	Caregiver-initiated dose increase
C3.5	Caregiver incorrect administration route
C3.6	Caregiver inappropriate storage
C3.7	Caregiver-related barriers
	Patients
C4.1	Patient missed dose
C4.2	Patient misunderstanding in administration
C4.3	Patient-initiated discontinuation or dose reduction
C4.4	Patient-initiated dose increase
C4.5	Patient incorrect administration route
C4.6	Patient inappropriate storage
C4.7	Patient-related barriers
C4.8	Leftover medication problem
C4.9	Inappropriate combination: drug and food/drink
C4.10	Physical limitation in medication use
C4.11	Medication abuse
	Monitoring
C6.1	Adverse drug reaction (confirmed or suspected)
C6.1	Inappropriate monitoring frequency
	Other
C6.1	Other problems

【Intervention】

Code	Item
I1	Medication change
I2	Medication initiation
I3	Medication discontinuation
I4	Change in dose / method of administration / duration / strength
I5	Dosage form change
I6	Change in medication support method
I7	Other interventions
I8	Report only (pharmacist's recommendation not provided)

【Acceptance】

Code	Item
A1	Accepted (fully or partially)
A2	Not accepted
A3	Other
A4	Not applicable (pharmacist's recommendation not provided)

【Outcome】

Code	Item
O1	Medication change
O2	Medication initiation
O3	Medication discontinuation
O4	Change in dose / method of administration / duration / strength
O5	Dosage form change
O6	Change in medication support method
O7	Testing performed or postponed
O8	Other outcomes
O9	No change

Figure 2 Validated DRP classification with high reliability

Conclusions

- The DRP classification system for Japanese community pharmacists was established with high inter-rater reliability.
- This system supports more consistent identification, classification, and documentation of DRPs in practice, with potential benefits for patient safety and outcomes.
- It could be applied to evaluate DRP patterns and guide pharmacists to quality improvement interventions.

References: 1. Pharmaceutical Care Network Europe Association (2020). Pharmaceutical Care Network Europe Classification for Drug Related Problem V9.1. Available at: https://www.pcne.org/upload/files/417_PCNE_classification_V9-1_final.pdf.
2. Basger, B. J., Moles, R. J., & Chen, T. F. (2014). Application of drug-related problem (DRP) classification systems: a review of the literature. European journal of clinical pharmacology, 70(7), 799-815.

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