Validation of a questionnaire to assess patients' knowledge of their medicines

García Delgado.P
Gastelurrutia Garralda. MA
Baena Parejo. MI
Martínez Martínez. F

Pharmacotherapy is the most used therapeutic choice

Fails

- Do not attain therapeutic objective
- Cause new health problem

Negative Clinical Outcome

"*Health problems, undesired changes in a patient's state of health attributable to the use (or non-use) of drugs*" *(3rdConsensus Granada)*

MRP

"Circumstances that cause or can cause a NCO" *(FORO de Atención Farmacéutica)*

Public health problem

"It doesn't matter how effective and safe a product is intrinsically, it can only fulfil its function if it is used correctly"

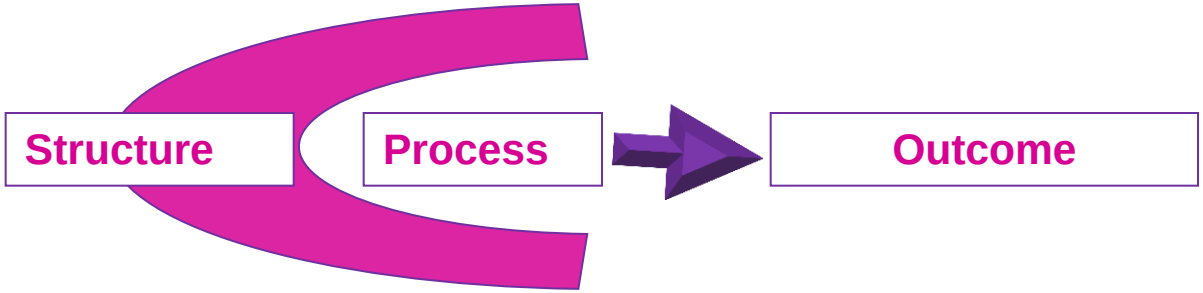
(WHO Geneva 2001.)

Rational use - Process of drug use

Patient collaboration

Quality of care process.

SPO paradigm (Donabedian -1966)



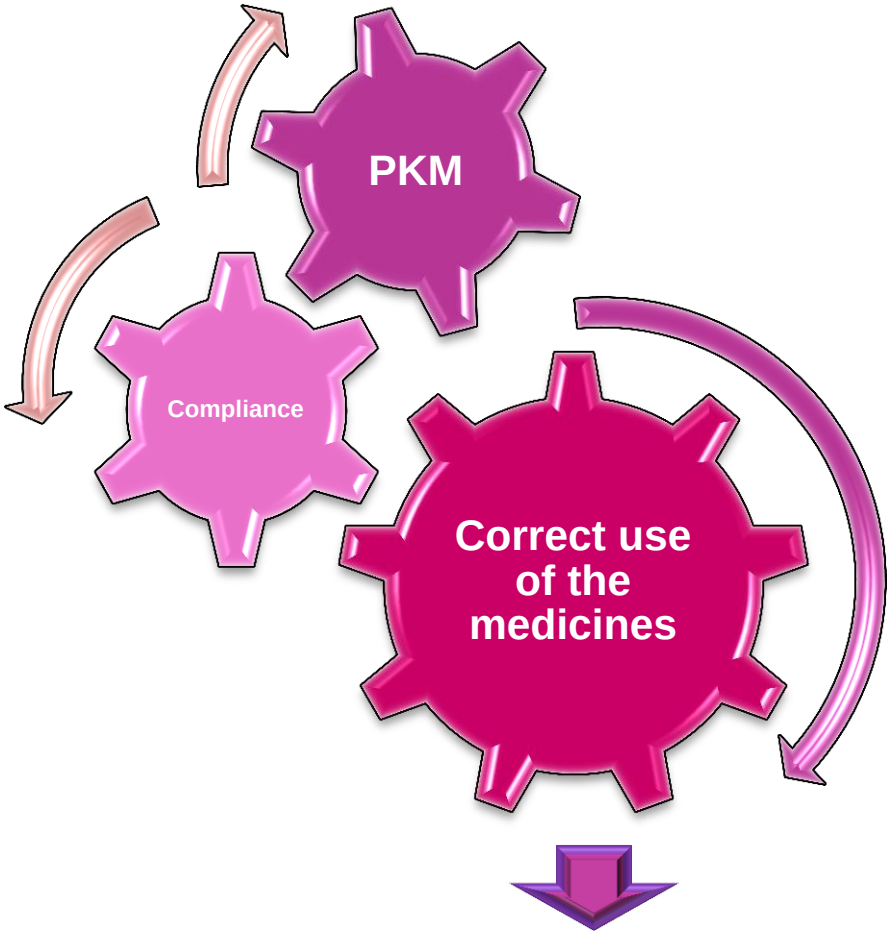
Clinical research is designed to attempt to establish relations between the process and the outcome.

Introduction

- A patient's knowledge of their medicine (PKM) is a frequently used term in health sciences.
- No definition of PKM has been found.
- PKM is a characteristic relating the patient and the medicine
- Only a few studies have measured PKM and these have not used a validated tool.

A tool is needed with the following characteristics:

1. Generic.
2. Dynamic.
3. Cheap.
4. Easy to use.
5. Valid.
6. Reliable.
7. Provides an immediate and clear result.
8. Applicable in any health care setting; for both general practice and research



Increase Positive Clinical Outcome

Objective

Objective

The objective of this study was to design and validate a questionnaire to assess the degree of a patient's knowledge about their medicines.

Methods

I. Questionnaire design.

"content validity"

1. Concept.

Literature search.

2.Operation.

a) **Theoretical representation of the concept**

b) **Specification of the concept**

c) **Selection of indicators**

d) **Calculation of indexes.**

Expert panel "dimension the concept" "identify minimum awareness criteria"

3. Choice of type of questions and answers on the questionnaire.

Research team

4. Drafting the items of the questionnaire.

Brain storm. “obtaining the questionnaire questions”

5. Selection of the questionnaire items.

Delphi method. “Consensus in the choice of questions”

6. Prior verification of the questionnaire. Pilot studies.

Examining the research team:

- Language used.
- Order in drafting, sense, and extension of the questions.
- Characteristics of the interviewer.

First Pre-test. With the first draft of the questionnaire, a structured interview given to 40 patients in a community pharmacy.

Then, add, delete or modify questions and identify limitations.

7. Redraft the questionnaire and specifications for its use.

Second pre-test. Second draft given to 20 patients. The same structured interview.

Final review by the research team.

The definitive questionnaire obtained.

II. Validation questionnaire.

Study population.

Patients who attended the chosen community pharmacy, requesting a drug for their own use or for somebody they are looking after (care giver).

One questionnaire to be completed per patient, excluding persons who had already participated. If patient required more than one medicine, one medicine chosen at random

Sample size.

For a 95% confidence interval and a precision of ± 5%,the optimal sample size needed was 100 persons. Participant selection done by consecutive sampling.

Field work.

The questionnaires were completed from personal interviews in a community pharmacy in Malaga over one month, with the same interviewer.

Statistical analysis.

A. **Discriminating ability of the items**.
   - Endorsement frequency.
   - Pearson's correlation coefficient.

B. **Validity of the construct**.
   - Spearman-Brown Rho coefficient.
   - PCFA

C. **Reliability.**
   -Internal consistency: Cronbach's alpha
   -Equivalence. Interobserver concordance: Kappa coefficient
   -Stability. Test-retest. CCI

Results

I. Results obtained for Objective 1: design of the PKM questionnaire.

After the qualitative techniques, the two pilot studies, the interviewer's experience using the tool and the final evaluation by the research team, the questions were rewritten and the **definitive questionnaire** was produced, with the following structure:

- **Title**.
- **Brief introduction**.
- **11 specific items** to measure the degree of PKM:

Item	Question chosen
P.1. Indication	Why do you have to take / use this medicine?
P.2. Dose	How much/many do you have to take / use of this medicine per day ?
P.3. Schedule	How often do you have to take /use this medicine?
P.4. Duration of treatment	Until when do you have to take / use this medicine?
P.5. Form of administration	How should you take /use this medicine?
P.6. Precautions	Should you take any precaution when you take / use this medicine?
P.7. Side effects	What side effects of this medicine do you know?
P.8. Contraindications	What health problems or special situation impede you taking /using this medicine?
P.9. Indicators of effectiveness	How do you know if the medicine is having an effect?
P.10. Interactions	What other medicines or food should you avoid while using this medicine?
P.11. Conservation	How should you store the medicine?

- **12 items** designed to collect **the predictive variables**:

- Age
- Gender
- User
- Number of medicines
- Name of medicine
- Importance of health problem
- Profession
- Country of origin
- Education
- Therapeutic group
- Duration of treatment
- Prescriber

II. Results obtained for Objective 2: Validation of the PKM questionnaire.

Of the 107 persons selected, 102 participated in the study:

Response rate 95.3%.

General summary of the characteristics of the participants in the pilot study.

Variable		N patients (%)
Gender	Men	36 (35.3)
	Women	66 (64.7)
Mean age	46.86 ± 16.70 years	
Profession	Not working (unemployed, retired, housewife)	7 (6.9)
	Intellectual	60 (58.8)
	Physical	35 (34.3)
Level of education	No studies	17 (6.7)
	Primary	33 (32.4)
	Secondary	22 (21.6)
	University	30 (29.4)
Number of medicines taken	One	50 (49)
	2 to 4	36 (35.3)
	5 or more	16 (15.7)
User of the medicine	Care giver	8 (7.5)
	Self	94 (92.2)
Prescriber of the drug	Physician	82 (80.4)
	Pharmacist	1 (0.98)
	Other	19 (18.6)
Time using the drug	First prescription	32 (31.4)
	0.5 to 6 months	22 (21.06)
	7 to 12 months	10 (9.8)
	13 to 24 months	23 (22.5)
	More than 24 months	15 (14.7)
Importance of the disease to the patient	Little	40 (39.2)
	Somewhat	17 (16.7)
	A lot	45 (44.1)

The mean time needed to complete the questionnaire was 4.9 minutes (SD: 2.2). Max: 12 m. Min: 2 m.

Discriminating capacity of the items.

Endorsement frequency.

Some questions had values below 20% and others above 80%.

Pearson correlation coefficient.

All the items obtained values above the reference value (0.30) except for question 11 (Conservation) (0.273); all were significant ($P<0.05$).

Construct Validity

Spearman Rho multiple correlation analysis.

		p.1.	p.2.	p.3.	p.4.	p.5.	p.6.	p.7.	p.8.	p.9.	p.10.	p.11.
p.1. Indication	Correlation	1.000										
	Significance	.										
p.2. Dose	Correlation	0.081	1.000									
	Significance	0.425	.									
p.3. Schedule	Correlation	-0.046	0.568	1.000								
	Significance	0.650	0.000	.								
p.4. Duration of treatment	Correlation	0.078	0.446	0.353	1.000							
	Significance	0.437	0.000	0.000	.							
p.5. Form of administration	Correlation	0.154	0.332	0.260	0.302	1.000						
	Significance	0.123	0.001	0.009	0.002	.						
p.6. Precautions	Correlation	0.153	0.222	0.182	0.177	0.338	1.000					
	Significance	0.124	0.027	0.069	0.075	0.001	.					
p.7. Side effects	Correlation	-0.150	-0.241	-0.002	-0.054	0.035	0.143	1.000				
	Significance	0.133	0.016	0.987	0.588	0.729	0.152	.				
p.8.Contraindication	Correlation	0.086	-0.073	-0.024	-0.163	-0.016	0.269	0.372	1.000			
	Significance	0.393	0.471	0.812	0.102	0.875	0.006	0.000	.			
p.9. Effectiveness	Correlation	0.414	0.123	0.154	0.226	0.164	0.170	0.123	-0.089	1.000		
	Significance	0.000	0.225	0.129	0.023	0.102	0.089	0.222	0.375	.		
p.10. Interactions	Correlation	-0.148	0.154	0.330	-0.042	0.082	0.158	0.455	0.423	0.110	1.000	
	Significance	0.137	0.126	0.001	.675	0.414	0.112	0.000	0.000	0.273	.	
p.11. Conservation	Correlation	0.081	-0.131	0.124	.038	0.009	0.018	0.135	0.187	-0.137	0.223	1.000
	Significance	0.420	0.193	0.221	0.704	0.925	0.860	0.177	0.059	0.172	0.024	.

Construct Validity

The Kaiser-Meyer-Olkin (KMO) coefficient and the Bartlett sphericity test were used to confirm that the sample fulfilled the **PCFA** criteria.

Dimensionality analysis showed a clear factorial structure.

Table 5. Principal Component Factor Analysis

Items	Factors			
	I	II	III	IV
p.1. Indication			0.828	
p.2. Dose	0.856			
p.3. Schedule	0.874			
p.4. Duration of treatment	0.606			
p.5. Form of administration	0.587			
p.6. Precautions		0.583		
p.7. Side effects		0.831		
p.8. Contraindications		0.657		
p.9. Effectiveness			0.833	
p.10. Interactions		0.751		
p.11. Conservation				0.870

Construct Validity

Matrix rotation produced 4 dimensions that explained 66.99% of the total variance. These dimensions were:

Dimensions	Determinants
Therapeutic aim	Indication Indicators of effectiveness
Process of use of medicines	Dose Schedule Form of administration Duration
Safety	Side effects Precautions Contraindications Interactions
Conservation	Conservation

Reliability.

- **Internal consistency**: Cronbach's alpha = 0.677.
This coefficient varied from 0.60 to 0.72 in the different dimensions of the PKM.

- **Equivalence** of the questionnaire. Measurement of the PKM showed an inter-observer degree of concordance of (Kappa) of 0.99.

- **Stability** of the questionnaire. The value obtained for the CCI was 0.745 (95% CI: 0.49-0.87).
This value ranged from 0.87 (95% CI: 0.73 – 0.94) for the dimension "Safety" to 0.72 (95% CI: 0.37- 0.87) for the dimension "Process of use".

The results show that the questionnaire has:

- ✓**Content validity.**
- ✓ **Discriminating capacity of the items.**
- ✓ **Construct validity.**
- ✓ **Internal consistency.**
- ✓ **Equivalency.**
- ✓ **Stability.**

And is reliable and valid

Conclusions

Conclusion

The designed questionnaire is agile, valid and reliable to measure the degree of patient knowledge about their medicines.

Thank you very much.