Development and validation of the Severity Categorization for Pharmaceutical Evaluation (SCOPE) criteria to evaluate the severity of drug-related problems in chronic kidney disease: a community pharmacy perspective

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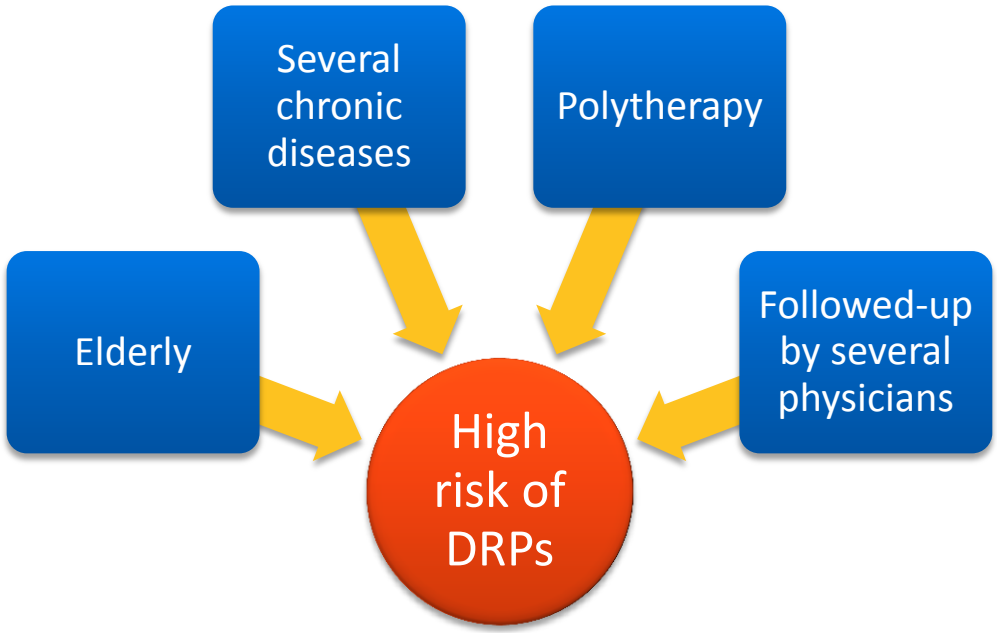
Quality of medication use in CKD



- DRPs in CKD patients
  - Hemodialysis
    - 4 to 8 DRPs /patient [1]
  - Predialysis:
    - 3.5 DRPs /patient[2]

Very little information about these DRPs' severity

1. Manley, H. J. *et al.*. *Am J Kidney Dis* **41**, 386-393, (2003).
2. Lalonde L et al. *Pharm World Sci* 2008; 30: 924-933.

Severity evaluation

- Existing tools to evaluate
  - Adverse drug reactions / events
  - Medication errors
- Evaluation of DRPs
  - Implicit evaluation (e.g. rating scale from 0 to 10)
  - Explicit evaluation (using specific criteria)
    - Schneider et al. (*Am J Health Syst Pharm* 1995; 52: 2415-2418)

Schneider's criteria

DRPs severity

- Severity of DRPs
  - Potential/real impact of DRPs on health
  - Intensity of interventions required for their management

Six levels of interventions

Schneider's criteria

SCHNEIDER CRITERIA FOR EVALUATION OF DRP SEVERITY[3]		
Severity	**Level**	**Type of intervention required**
Mild	I	Health care professional inquiry (drug information)
	II	Drug therapy modification
Moderate	III	Additional tests or treatments or non-invasive procedures
	IV	Additional tests or treatments or non-invasive procedures and increased length of stay or drug-related admission
Severe	V	Any resource utilization in level 4, long-term care admission, or required transfer to intensive care unit
	VI	Death

3. Schneider, P. J., et al. *Am J Health Syst Pharm* 52, 2415-2418 (1995).

Schneider's criteria

Hospital setting

Do not reflect current community pharmacy practice:

- Refusal / Pharmaceutical opinions
- Request laboratory tests
- Adapt a prescription
- Initiate treatment for minor/ already diagnosed condition
- Monitoring and medication dosage adjustment

3. Schneider, P. J., et al. *Am J Health Syst Pharm* 52, 2415-2418 (1995).

Objectives

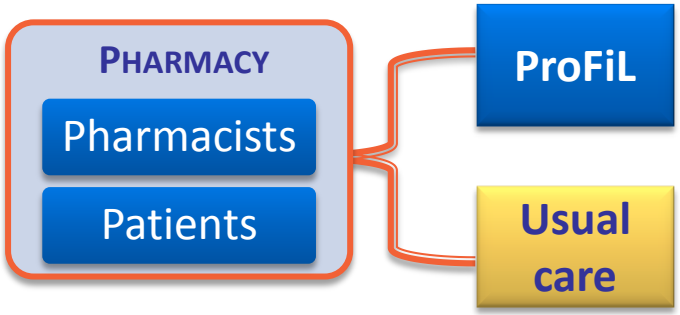
Adapt the Schneider criteria to the evaluation of the severity of DRPs in community pharmacy for patients with CKD

Evaluate their psychometric properties

- Content validation
- Test/retest and interrater reliability
- Conceptual validity

The ProFil study

- **Cluster** RCT
- **Objective**: to evaluate the impact of a training and communication program for community pharmacists to improve the quality of medication use in CKD patients



Methods

STEP 1:
« In house » adaptation (n=3) and pharmacy residents comments (n=4)

STEP 2:
Community pharmacists consultation (n=10)

STEP 3:
Modified RAND method (n=12)

STEP 4:
Evaluation of DRPs severity in the ProFiL study patients(n=2)

STEP 5:
Evaluation of DRPs severity using an implicit judgement method (n=2)

Adaptation

Content validation

Reliability

Conceptual validity

Adaptation

STEP 1:
« In house » adaptation (n=3) of Schneider's criteria and comments of pharmacy residents (n=4)

Eliminate the interventions specific to the hospital setting

Add the interventions relevant to community pharmacy

Severity Categorization for Pharmaceutical Evaluation (SCOPE) criteria

Adaptation

STEP 2:
Consultation of community pharmacists (n=10)

Pharmacists

- Participant in the ProFiL study
- Completed the ProFiL training program
- Issued at least one pharmaceutical opinion

Adaptation

STEP 2:
Consultation of community pharmacists
(n=10)

Self administered questionnaire

- **SCOPE criteria**
- 3 clinical cases with pre-identified DRPs
- Assess DRPs severity

Phone interviews

- Comments
  - Relevance for community pharmacy practice
  - Need to modify the criteria
    (e.g. to add an intervention)

Methods

STEP 1:
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Adaptation

Content validation

Reliability

Conceptual validity

Content validation

STEP 3:
Modified RAND method
Expert panel
(n=12)

Participants

- 4 community pharmacists
- 4 hospital pharmacists
- 2 family physicians
- 2 nephrologists

Content validation

STEP 3:
Expert panel

1. Individual evaluations

- Self-administered questionnaire
  - **SCOPE criteria**
  - 4 clinical vignettes with 3-4 DRPs each

2. Phone discussion

- Inter-rater discussion about disagreements in the evaluation of DRPs severity and interventions relevance

Methods

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Adaptation

Content validation

Reliability

Conceptual validity

Evaluation of psychometric properties

- DRPs identification
  - **Two** independent raters
  - 168 patients participating in the ProFiL study
    - Study entrance (**T0**)
      - Clinical summary
      - Community pharmacy chart
      - Interview OTC-natural health products

Reliabilty evaluation

Inter-rater reliability

- n= 168 patients
- Baseline data(T0)
- Comparison:
  - **Rater A vs. Rater B**

Test-retest reliability

- n= 84 patients
- Two months after the 1st evaluation
- Comparison:
  - **Rater A (1) vs. Rater A (2)**

STATISTICAL ANALYSES

Computed for severity <u>category</u> AND <u>level</u>:

•Correlation κ coefficients (CI95%)

• % Concordance of evaluations

Methods

STEP 1:
« In house » adaptation (n=3) and pharmacy residents comments (n=4)

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Adaptation

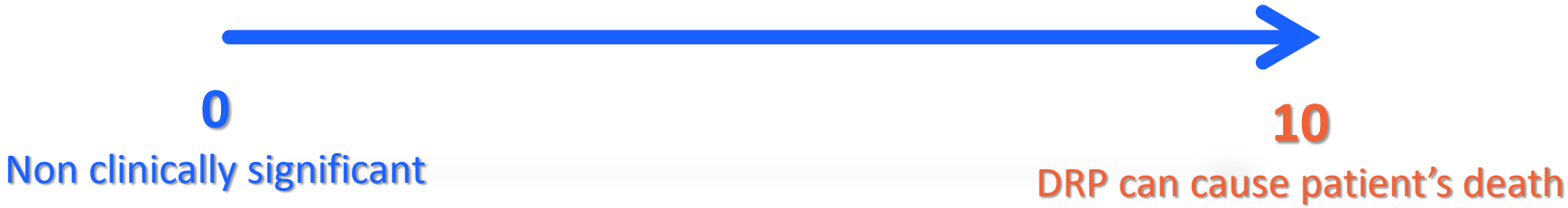
Content validation

Reliability

Conceptual validity

Conceptual validity

- n= 84 patients
- Two independent raters
- Two months after the 1st evaluation using the SCOPE criteria
  - Visual analog scale (VAS) of Dean and Barber



  - Correlation between SCOPE criteria and the score on Dean and Barber's VAS

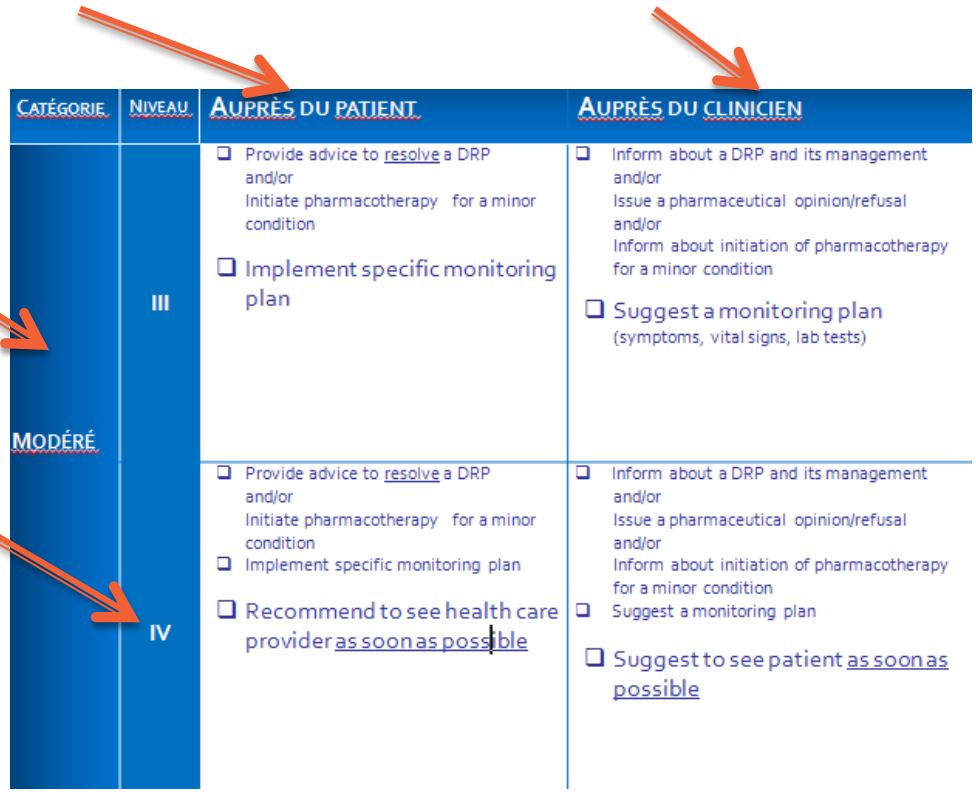
Dean BS, Barber ND. Am J Health Syst Pharm 1999;56:57-62.

Results

Required pharmacist intervention to the patient or treating clinician/health care provider

3 categories of severity

2 Levels per category



Catégorie	Niveau	Auprès du patient	Auprès du clinicien
Modéré	III	❑ Provide advice to resolve a DRP and/or Initiate pharmacotherapy for a minor condition ❑ Implement specific monitoring plan	❑ Inform about a DRP and its management and/or Issue a pharmaceutical opinion/refusal and/or Inform about initiation of pharmacotherapy for a minor condition ❑ Suggest a monitoring plan (symptoms, vital signs, lab tests)
	IV	❑ Provide advice to resolve a DRP and/or Initiate pharmacotherapy for a minor condition ❑ Implement specific monitoring plan ❑ Recommend to see health care provider as soon as possible	❑ Inform about a DRP and its management and/or Issue a pharmaceutical opinion/refusal and/or Inform about initiation of pharmacotherapy for a minor condition ❑ Suggest a monitoring plan ❑ Suggest to see patient as soon as possible

Category	Level	Wih patient	With health care professionals
Mild	I	❑ The pharmacist provides specific counselling to prevent a DRP occurrence. ***and/or*** adjusts a prescription by modifying the dose, the pharmaceutical form or the dosage of a prescribed medication.	❑ The pharmacist sends a pharmaceutical profile or conveys relevant clinical information to the treating physician. ***and/or*** contacts the treating physician and/or the predialysis clinic to obtain relevant clinical information. ***and/or*** communicates the prescription adjustment to the treating physician.

Category	Level	Wih patient	With health care professionals
Mild	II	❑ The pharmacist provides specific counselling to resolve a DRP. ***and/or*** starts a pharmacotherapy for a minor condition for which the diagnosis and treatment are already known.	❑ The pharmacist informs the treating physician and/or the predialysis clinic about the presence of a DRP and the actions taken for its resolution. ***and/or*** issues a pharmaceutical opinion. ***and/or*** informs the treating physician and/or the predialysis clinic about the start of a pharmacotherapy for a minor condition.

Category	Level	Wih patient	With health care professionals
Moderate	III	❑ The pharmacist provides specific counselling to resolve a DRP ***and/or*** starts a pharmacotherapy for a minor condition. ❑ The pharmacist implements a specific patient follow-up plan (e.g., symptoms, vital signs, and laboratory tests).	❑ The pharmacist informs the treating physician about the presence of a DRP and the actions taken for its resolution. ***and/or*** issues a pharmaceutical opinion. ***and/or*** informs the treating physician and/or the predialysis clinic about the start of a pharmacotherapy for a minor condition. ❑ The pharmacist suggests a specific monitoring and follow-up plan (e.g., symptoms, vital signs, and laboratory tests).

Category	Level	Wih patient	With health care professionals
Moderate	IV	❑ The pharmacist provides specific counselling to resolve a DRP. ***and/or*** starts a pharmacotherapy for a minor condition. ❑ The pharmacist implements a specific patient follow-up plan (e.g., symptoms, vital signs, and laboratory tests). ❑ The pharmacist recommends to the patient to see his/her physician or a predialysis clinician as soon as possible.	❑ The pharmacist informs the treating physician about the presence of a DRP and the actions taken for its resolution ***and/or*** issues a pharmaceutical opinion ***and/or*** informs the treating physician and/or the predialysis clinic about the start of a pharmacotherapy for a minor condition. ❑ The pharmacists suggest to the physician or to see the patient as soon as possible in order to examine the signs (e.g., vital signs and laboratory tests) and symptoms.

Category	Level	Wih patient	With health care professionals
Severe	V	❑ The pharmacist recommends to the patient to see his/her physician or to go to the emergency room immediately.	❑ The pharmacist informs the treating physician and/or the predialysis clinic about the presence of a DRP and the actions taken for its resolution. ***and/or*** The pharmacist issues a pharmaceutical opinion. ❑ The pharmacist suggests to the treating physician to see the patient immediately.

Category	Level	With patient	With health care professionals
Severe	VI	❑ The pharmacist calls 911 to request immediate medical assistance for the patient.	❑ The pharmacist informs the treating physician and/or predialysis clinic that a call to 911 was made to request immediate medical assistance for the patient. ***and/or*** The pharmacist issues a pharmaceutical opinion.

Results- Evaluation of reliability

Inter-rater reliability

- 168 ProFiL patients
- 487 DRPs identified at baseline

Severity	% concordance (n)	K coefficient (CI95%)
Category	95.1% (463 PRPs)	0.90 (0.86-0.94)
Level	86.5% (421 PRPs)	0.77 (0.72-0.82)

Results- Evaluation of reliability

Test-retest reliability

- 84 ProFiL patients
- 267 DRPs identified at baseline

Severity	% concordance (n)	K coefficient (CI95%)
Category	94.8% (253 PRPs)	0.89 (0,84-0,95)
Level	91.0% (243 PRPs)	0.85 (0.79-0.90)

Results- conceptual validity

- n= 84 patients
- 220 DRPs
- The score determined using Dean and Barber's VAS increases with a higher SCOPE severity level ($p<0.0001$)

Severity level	Number of DRPs	Mean score (CI95%)
I	33	4.17 (3.60 – 4.72)
II	68	5.39 (4.96 – 5.82)
III	118	6.26 (5.99 – 6.52)
IV	1	6.50 (6.21 – 15.21)
V	NA	NA
VI	NA	NA

Strenghts

- ✓ First tool evaluating DRPs severity in the community pharmacy context
- ✓ Systematic approach considering the expertise of primary care clinicians and nephrology specialists
- ✓ Psychometric properties proven to be satisfactory
  - ✓ High reliability (inter-rater /test-retest
  - ✓ Criteria well aligned with clinical judgement

Limits

- Severity was evaluated using the information collected for an RCT
- Development and validation of the SCOPE criteria were performed within the CKD context

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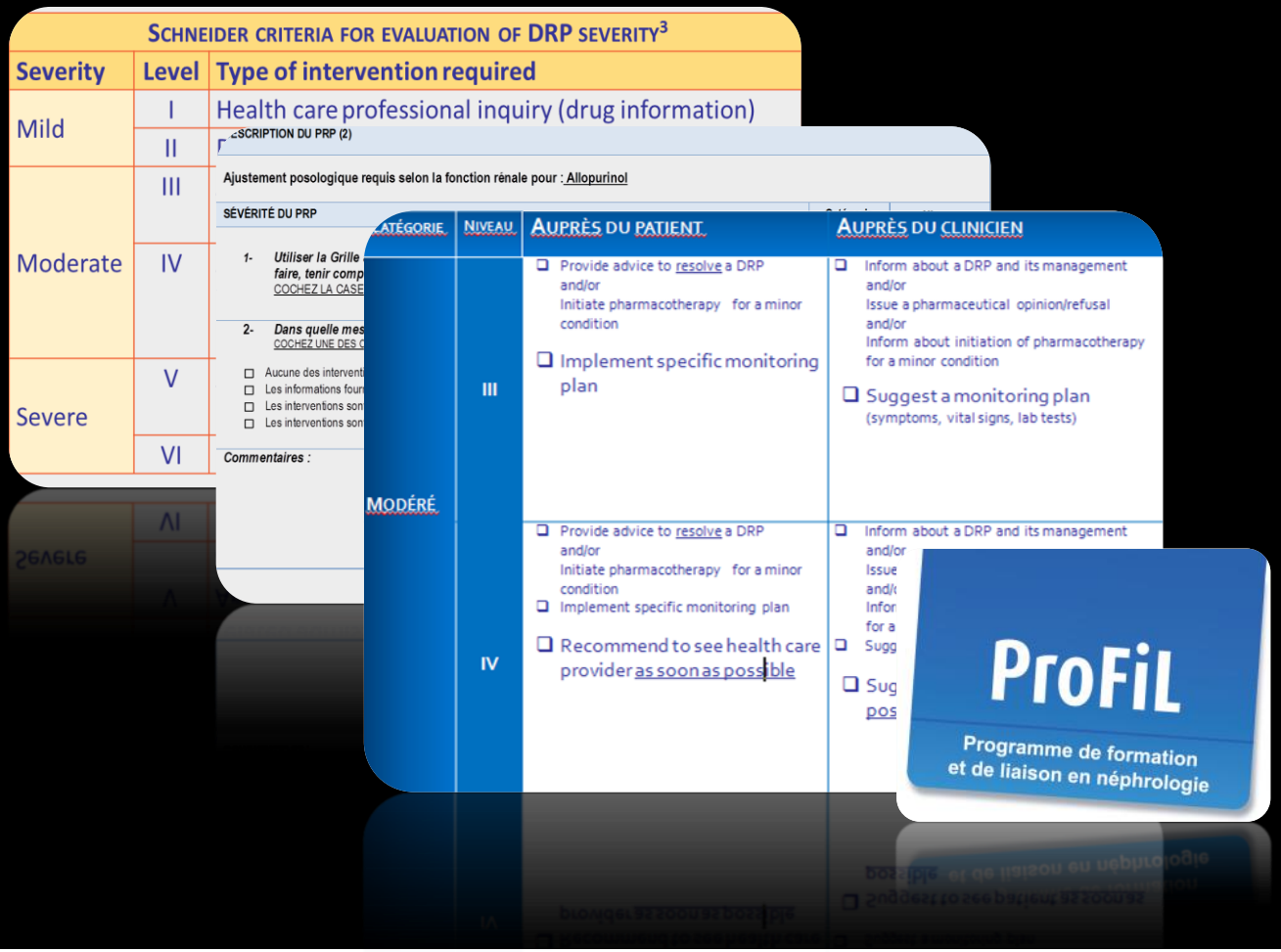
SCHNEIDER CRITERIA FOR EVALUATION OF DRP SEVERITY[3]
Severity
Level
Type of intervention required
Mild
I
Health care professional inquiry (drug information)
II
Moderate
III
IV
Severe
V
VI
Ajustement posologique requis selon la fonction rénale pour : Allopurinol
SÉVÉRITÉ DU PRP
CATÉGORIE
NIVEAU
AUPRÈS DU PATIENT
AUPRÈS DU CLINICIEN
MODÉRÉ
III
Provide advice to resolve a DRP and/or Initiate pharmacotherapy for a minor condition
Implement specific monitoring plan
Inform about a DRP and its management and/or Issue a pharmaceutical opinion/refusal and/or Inform about initiation of pharmacotherapy for a minor condition
Suggest a monitoring plan (symptoms, vital signs, lab tests)
IV
Provide advice to resolve a DRP and/or Initiate pharmacotherapy for a minor condition
Implement specific monitoring plan
Recommend to see health care provider as soon as possible
ProFiL
Programme de formation et de liaison en néphrologie

Thank you