Centre de santé et de services sociaux de Laval

Université de Montréal

CRCHUM
CENTRE DE RECHERCHE

ProFiL
Programme de formation et de liaison en néphrologie

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ProFiL, a training-and-communication network program in nephrology for community pharmacists:

impact on knowledge, clinical competences, quality of medication use and clinical variables

Instituts de recherche en santé du Canada
Amgen Inc.
Léo-Pharma
Cercle du doyen

CKD a serious condition

- Prevalence of 12.5% in Canada (3.1% at stage 3-5)
- Prevalence of about 25% in patients with diabetes or hypertension
- Incidence of kidney failure doubled between 2000 and 2010

- CKD patients
  - Elderly (72 years old)
  - Numerous health problems (5-6)
  - Multiple medications (12)
  - OTC use (80%)
  - Many physicians (3.6 prescribers in 6 months)

High risk of drug-related problems (DRPs)

Management of CKD

- Objectives:
  - Prevent or control CKD complications
  - Slow the progression of kidney function decline
- Management
  - Control blood pressure, diabetes, and other CVD risk factors
  - Avoid nephrotoxic medications
  - Adjust medications based on kidney function
  - Monitor adherence to medications
- Predialysis clinic
  - Multidisciplinary team (physicians, nurses, dieticians...)
  - Pharmacists with expertise in nephrology
  - Involvement of pharmacists is limited

Community pharmacists

- Most accessible primary health care providers
  - ≥ 1 visit per month
  - Complete list of medications including OTC and natural products
  - They have the responsibility to detect DRPs and ensure appropriate medication use

BARRIERS

- Limited training in nephrology
- No access to important clinical information (eGFR)
- Undefined role within a multidisciplinary predialysis team

ProFiL Program

- Training-and-communication program designed to improve the management of CKD by community pharmacists for patients followed in predialysis clinic

Conduct a cluster randomized trial to evaluate the ProFiL Program

Objectives

Primary objective:

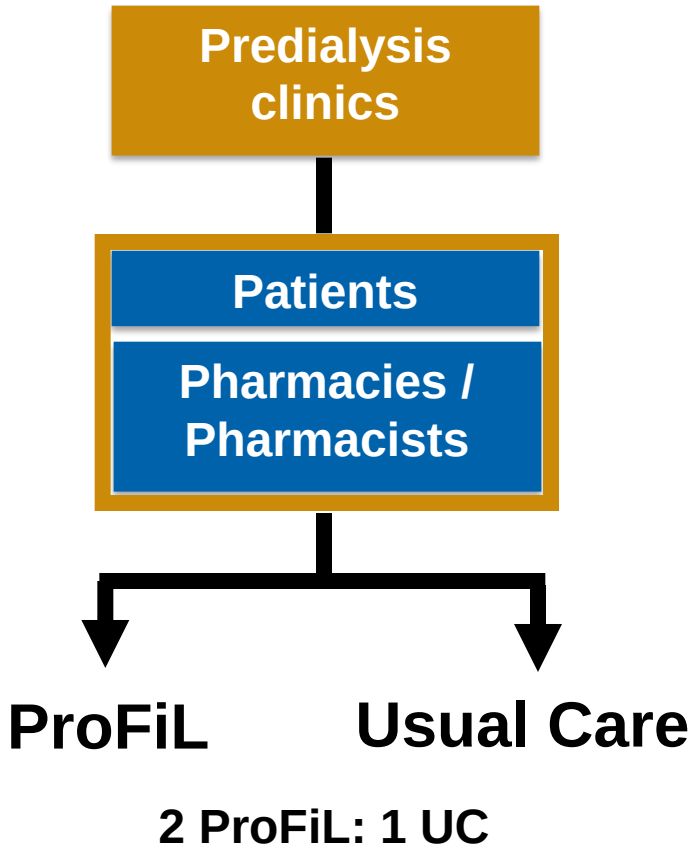
- Compare the mean change in the quality of medication use in ProFiL and UC patients

Secondary objectives:

- Knowledge/clinical competences of community pharmacists
- Progression of the clinical variables

  (eGFR, blood pressure, HbA1C, LDL-c)

Study design

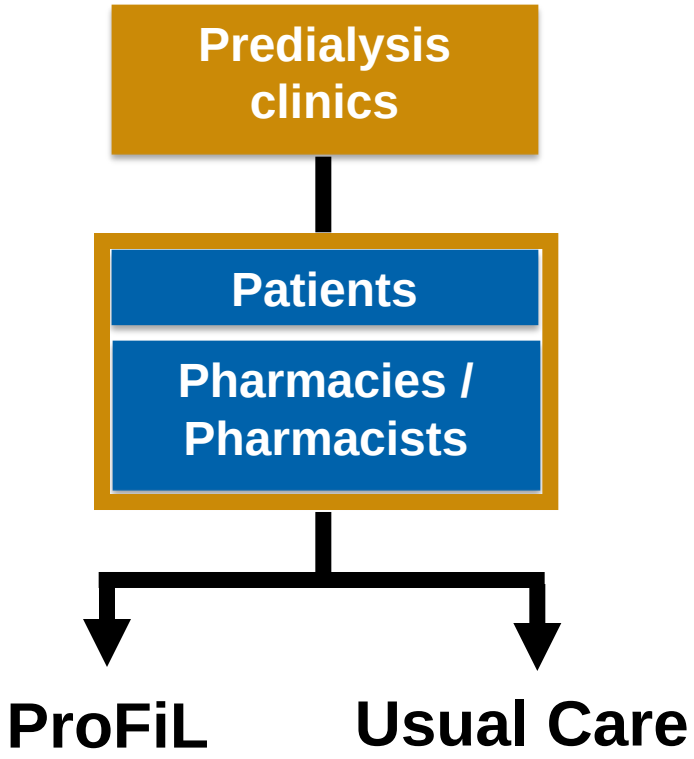


- Open-labelled, controlled, cluster-randomized clinical trial with 1 year follow-up

6 predialysis clinics

- Hôpital de la Cité-de-la-Santé
- Hôpital Maisonneuve-Rosemont
- Centre Hospitalier universitaire de Sherbrooke
- Hôpital Charles LeMoyne
- Hôpital Royal Victoria
- Jewish General Hospital

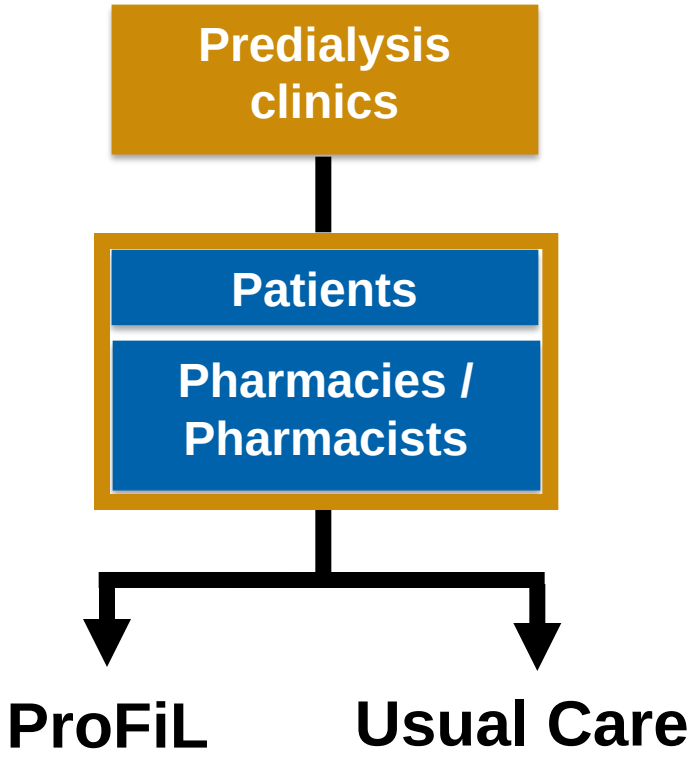
Study population - patients



Patients

- Adult
- CKD
  - moderate (30-59 mL/min/1.73m^2)
  - severe (15-29 mL/min/1.73m^2)
- Have an eligible current pharmacy that agrees to participate

Study population - Pharmacies



Pharmacies

Adequate coverage by participating pharmacists:

- >250 prescriptions/day: at least 60h/wk

OR

- ≤ 250 prescriptions/day: at least 35h/wk

OR

- Pharmacies opened <7 days/week: at least 50% of opening hours

ProFiL Program

- Web-based interactive training
- Information exchange program
  - Clinical summary
  - List of medications
- Privilege access to pharmacists with expertise in nephrology

ProFiL program – Web-based training program

❖ **Journal of Continuing Education in the Health Professions 2011; 31(3) : 140-150**

OBJECTIVES

- Familirarize pharmacists with a set of DRPs related to CKD (PAIR criteria)
- Proposed a systematic approach to detect and manage PAIR-DRPs

FORMAT

- 90 minutes
- 2 clinical vignettes (moderate/severe CKD)


Présentation du défi
ProFiL
Programme de formation et de liaison en néphrologie
OTC / NHP
Medication recorded in pharmacy chart
ProFiL clinical summary
Clinical guide
Pharmacist with expertise in nephrology
Table des matières
Terminé
Internet

Diagramme des 8 étapes

ProFiL
Programme de formation et de liaison en néphrologie

Cliquez sur « Débuter » lorsque vous êtes prêt à débuter celle-ci.

Noter que pour gérer les problèmes détectés, vous devez préalablement avoir navigué au travers de ces 8 étapes. De plus, avant de quitter la formation, veuillez vous assurez d'avoir complété l'étape dans laquelle vous êtes afin de ne pas perdre vos résultats.

1	Vérifier les doses des médicaments au dossier.	Débuter
2	Vérifier la concordance entre les listes de médicaments.	Débuter
3	Évaluer l'adhésion au traitement.	Débuter
4	Analyser les résultats de tension artérielle.	Débuter
5	Analyser les résultats de glycémies.	Débuter
6	Vérifier l'horaire d'administration réel des médicaments.	Débuter
7	Déterminer le statut tabagique.	Débuter
8	Déterminer si le patient prend des médicaments en vente libre et/ou des produits de santé naturels inadéquats.	Débuter

Table des matières

Internet

Cliquez ici pour commencer

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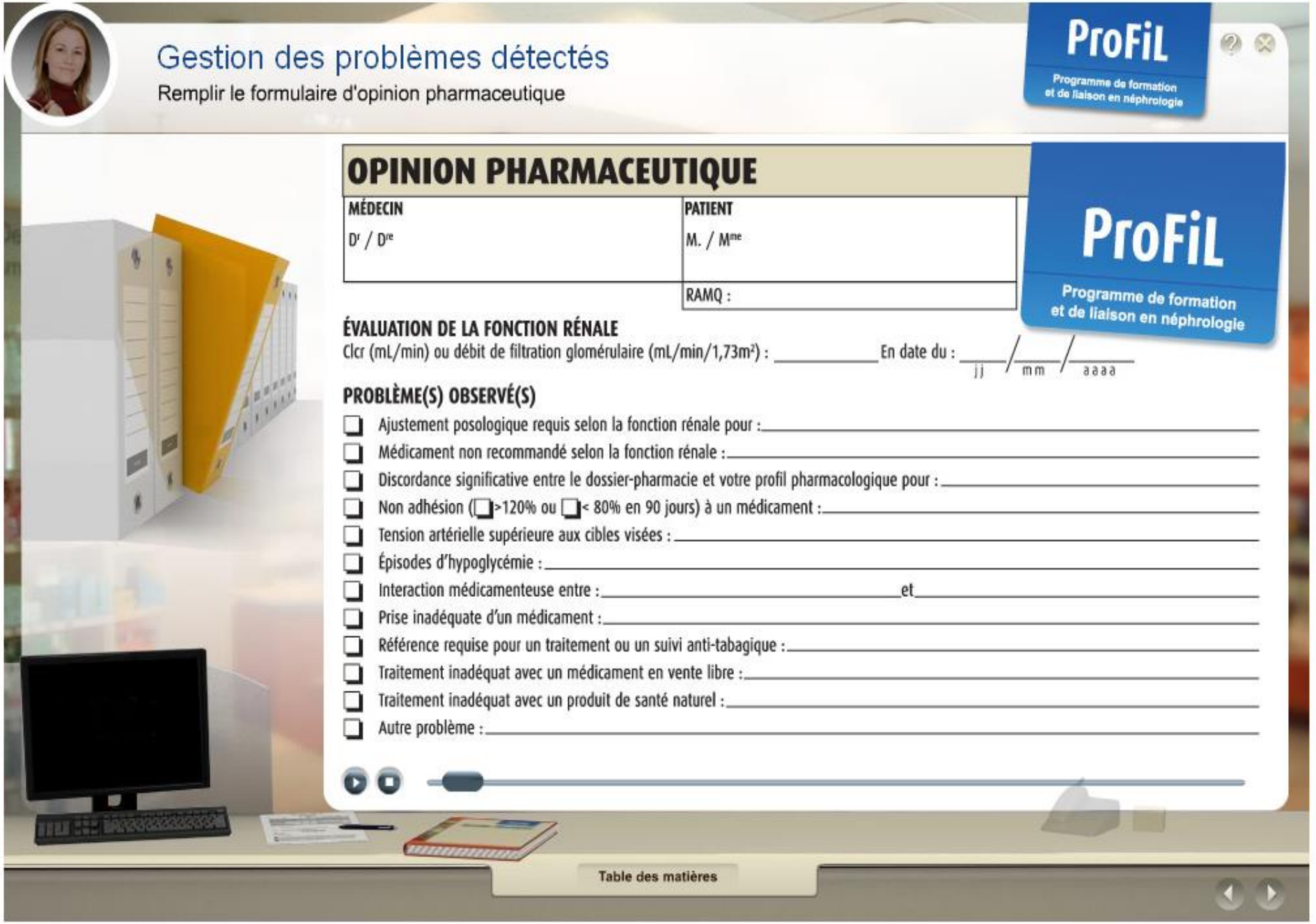


Terminé

Internet

Quality of medication use -PAIR criteria

- American Journal of Kidney Disease 2011; 58 (4) : 527-535

- 51 clinically significant DRPs for CKD patients requiring the intervention of community pharmacists when detected

- RAND appropriateness process (3 rounds)
  - 4 nephrologists
  - 2 family physicians
  - 4 nephrology pharmacists
  - 2 community pharmacists

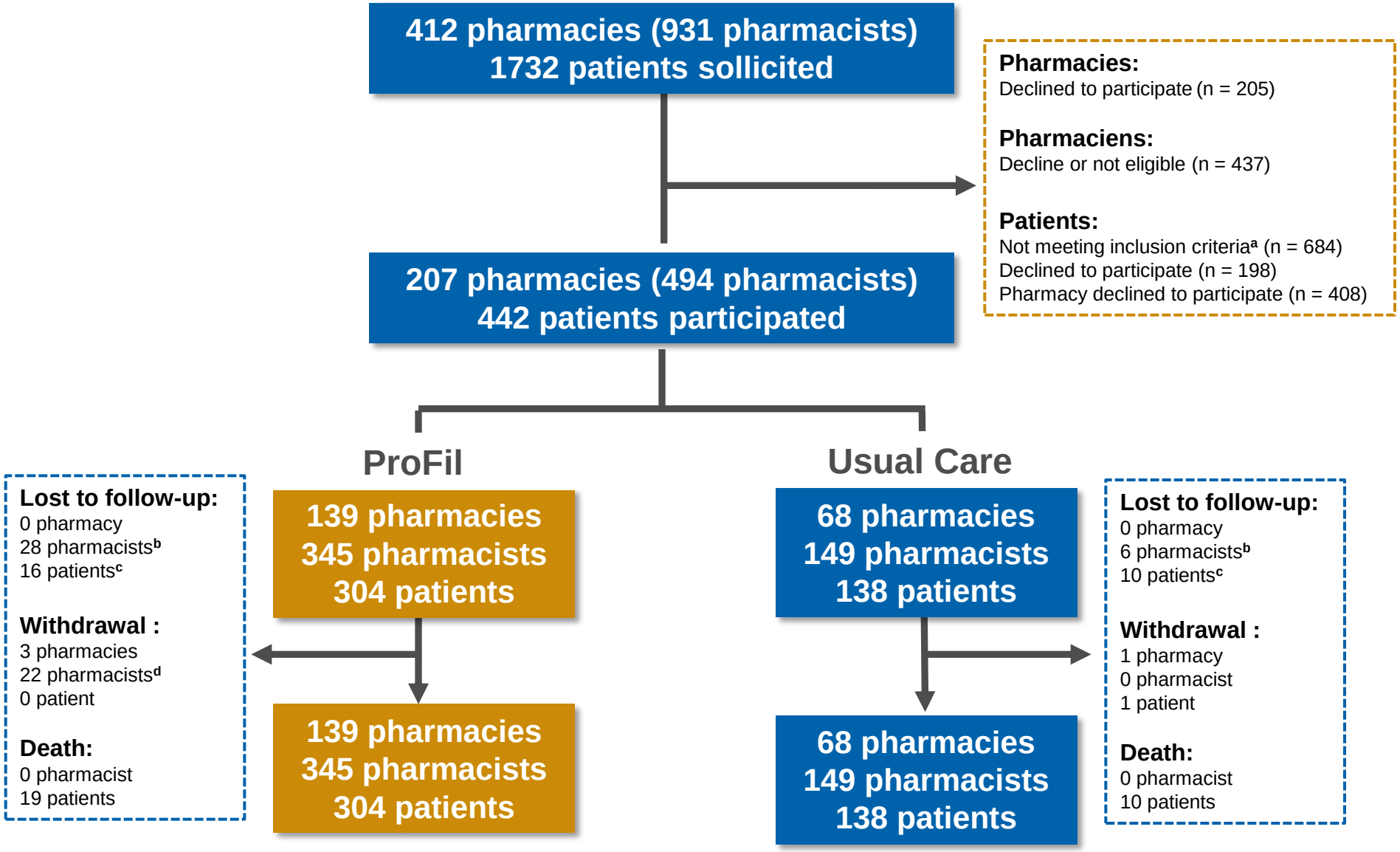
- Validation using pilot data:
  - Inter-rater reliability: Kappa: 0.82-0.96; ICC: 0.93
  - Test-retest reliability: Kappa: 0.74-1.00; ICC 0.91
  - Conceptual validity
    - Expert judgment : 3.5 DRPs/patient
    - PAIR criteria: 2.5 DRPs/patient

Evaluation

- One year prior and after the recruitment
- Quality of medication use (PAIR criteria)
  - Documentation:
    - Pharmacy chart
    - ProFiL clinical summary
    - Patient interview (OTC and NHP)
  - Two evaluators + consensus if needed
- Clinical variables
  - Results available in predialysis clinic chart
- Knowledge/clinical competences
  - 10 questions (knowledge) and 2 clinical vignettes

Analyses

- Intent-to-treat approach
- Missing data at T12 were replaced by baseline scores/group mean
- Multivariate linear mixed effects model to take into account the clustering of data within pharmacy and patient-level intra-correlation induced by repeated measures
- To adjust for confounders, all variables statistically significant ($p < 0.2$) in a bivariate model including the study group were included in the final multivariate model if they remained statistically significant ($p < 0.1$).



a Patient not meeting inclusion criteria: eGFR < 15mL/min/1,73m2 (n=325); eGFR ≥ 90mL/min/1,73m2 (n=97); doesn't have Quebec health insurance plan (n=91); unable to manage their medication (n=55); unable to speak English or French (n=49); withdrawal before entering the study (n=26); client of more than one pharmacy (n=19); unable to understand the study (n=18); and hospitalized (n=4).

b Changed pharmacy (n=34).

c Changed pharmacy (n=10); withdrawal of their pharmacy (n=9); and dialysis (n=7).

d Lack of time (n=17); withdrawal of pharmacy (n=3); and unsatisfied (n=2).

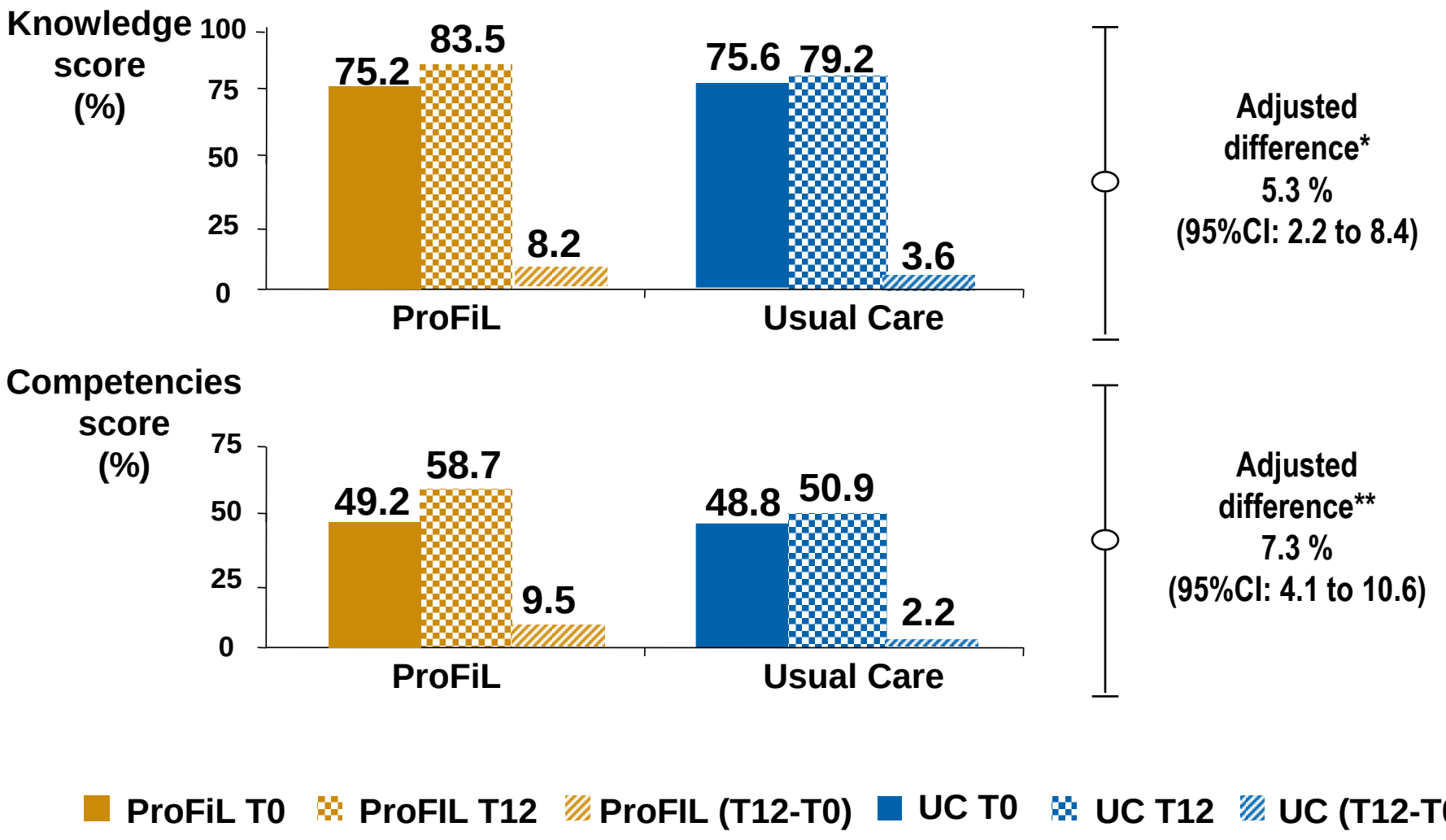
Participants characteristics

Patients	ProFiL n=304	Usual Care n=138
Age (years): mean (SD)	72 (12)	71 (13)
Men: n (%)	179 (59)	83 (60)
Severity of renal disease (Grade 4): n (%)	202 (67)	85 (62)
eGFR (mL/min/1.73m^2): mean (SD)	27 (9)	28 (11)
Comorbidities: n (%)		
Hypertension	283 (95)	130 (95)
Dyslipidemia	223 (75)	100 (74)
Type I diabetes	11 (4)	4 (3)
Type II diabetes	160 (54)	65 (48)
Anemia	160 (55)	77 (58)
Phosphocalcic metabolism disorder	138 (48)	60 (46)

Participants characteristics

Pharmacies	ProFiL n = 139	Usual care n = 68
Number of prescriptions per day: mean (SD)	440 (236)	458 (246)
Pharmacy size (>5000 ft^2) : n (%)	75 (61)	37 (62)
Pharmacists	**n = 345**	**n = 149**
Women: n (%)	236 (68)	100 (67)
Salaried pharmacist: n (%)	250 (73)	110 (74)

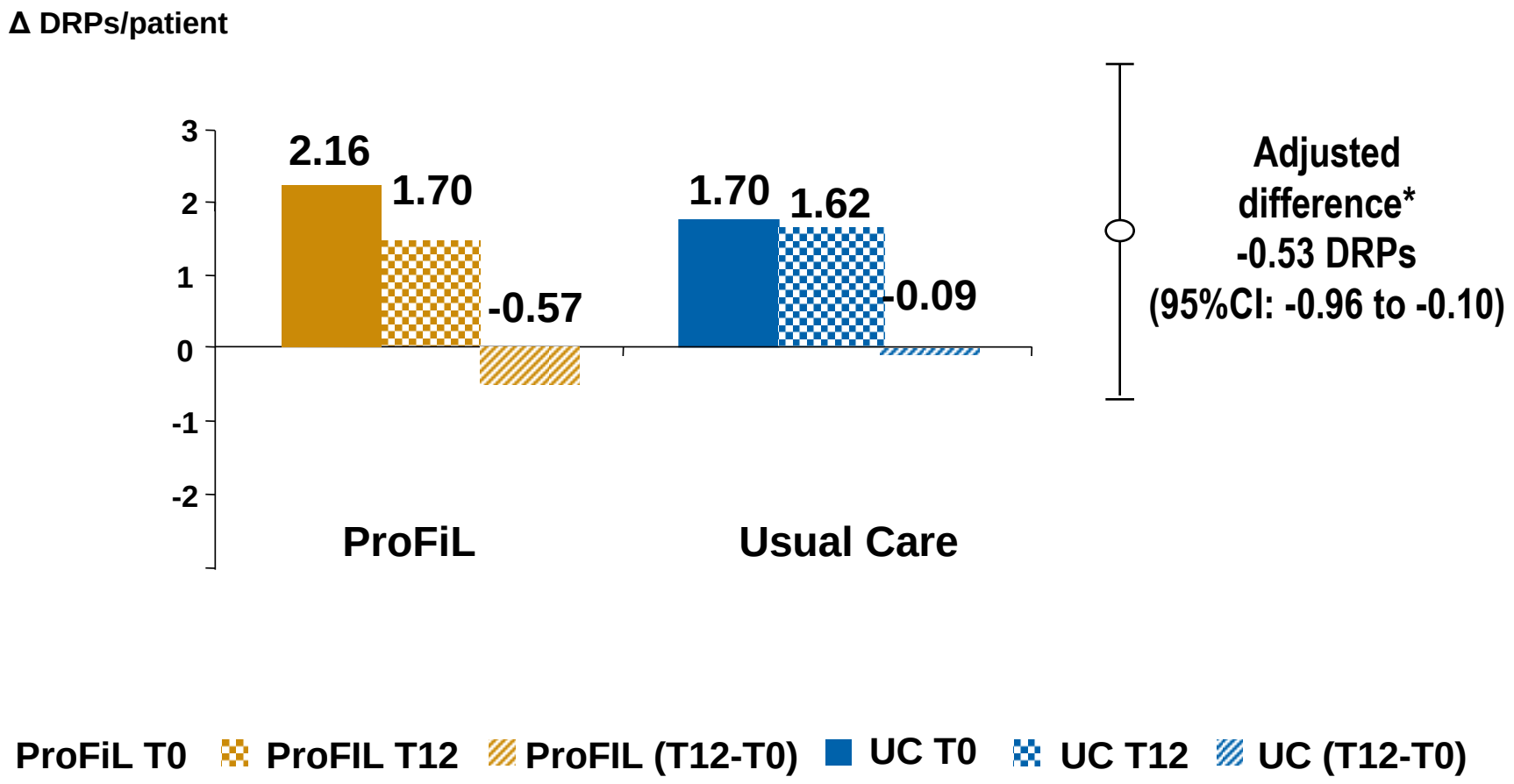
Knowledge and clinical competences



* Adjusted for having a training on pharmaceutical opinion in the last year and for being an associate clinician

** No significant confounding variables

Quality of pharmacotherapy



* Adjusted for patient education and pharmacist working in several pharmacies

Number of DRPs per patient

PAIR DRPs	Mean change (95% CI)	
	ProFiL	Usual Care
Inappropriate prescription: Incorrect dosage Contraindicated agent	**-0.10 (-0.17 to -0.03)** **-0.15 (-0.21 to -0.08)**	0.00 (-0.08 to 0.06) -0.11 (-0.21 to 0.00)
Nonoptimal treatment adherence	-0.10 (-0.22 to 0.03)	0.12 (-0.06 to 0.29)
Nonoptimal blood pressure	**-0.09 (-0.14 to -0.04)**	-0.04 (-0.11 to 0.02)
Hypoglycemia secondary to sulfonylurea	0.04 (0.00 to 0.07)	0.04 (0.00 to 0.08)
Drug interaction	0.00 (-0.02 to 0.04)	0.01 (-0.01 to 0.04)
Drug used inappropriately	**-0.08 (-0.13 to -0.03)**	-0.01 (-0.06 to 0.03)
Smoking	0.00 (-0.02 to 0.04)	0.02 (0.00 to 0.05)
Inappropriate use of Over-the-counter medication Naturel health product	**-0.11 (-0.17 to -0.04)** 0.00 (0.00 to 0.00)	-0.11 (-0.20 to -0.02) 0.00 (0.00 to 0.00)

Progression of clinical variables

	ProFiL		Usual Care (UC)	
	Study entry (T0) Mean (SD)	Changement during study (T12-T0) Mean (95% CI)	Study entry (T0) Mean (SD)	Changement during study (T12-T0) Mean (95% CI)
eGFR (mL/min/1.73m2)	26.8 (9.3)	0.2 (-2.3 to 2.7)	28.2 (10.6)	-1.3 (-2.4 to -0.2)
Blood pressure (mmHg)				
Systolic	135.8 (19.4)	-1.4 (-3.5 to 0.8)	136.4 (20.2)	-0.3 (-3.9 to 3.3)
Diastolic	69.4 (11.6)	-0.4 (-1.7 to 0.8)	70.7 (11.5)	-1.0 (-3.0 to 0.9)
LDL cholesterol (mmol/L)	2.0 (0.7)	-0.1 (-0.2 to 0.0)	2.0 (0.7)	0.0 (-0.1 to 0.1)
Patients with dyslipidemia	1.9 (0.7)	-0.1 (-0.2 to 0.0)	2.0 (0.7)	-0.1 (-0.2 to 0.0)
Glycosylated hemoglobin (%)	6.9 (1.3)	0.0 (-0.1 to 0.1)	6.7 (1.1)	0.1 (-0.1 to 0.2)
Patients with diabetes	7.4 (1.4)	-0.1 (-0.3 to 0.1)	7.1 (1.4)	0.2 (-0.1 to 0.5)

Summary of results

- Quality of medication use improved significantly in the ProFiL group
  - Incremental reduction of 0.5 DRP/patient
  - Significant reduction of DRPs related to:
    - Inappropriate dosage adjustment
    - Drug not recommended in CKD
    - Uncontrolled blood pressure control
    - Inappropriate use
    - OTC not recommended
- After one year, persistent improvement in knowledge (5%) and clinical competencies (7%) of community pharmacists
- No significant differences on the change in eGFR, blood pressure, HbA1C, and LDL-cholesterol.

Quality of medication use

- Quality of medication use is suboptimal (2 DRPs/pt)
  - Regular follow-up in predialysis clinic
  - Multidisciplinary team
- Training/support + essential clinical information = improvement

Strengths and limits

Strengths

- Cluster-randomization → high level of internal validity
- Relatively high participation rate
  - Pharmacies' acceptance: 50%
  - Patients' refusal: 11% (of patients invited)
- DRPs were blindly evaluated using validated criteria

Limits

- Recrutement of patients after randomisation (selection biais)
- Low questionnaire response rate at T12 (65%)
- Missing values for laboratory test results
- Only few patients per pharmacy

Next step….

- Adapt and implement ProFiL to improve the management of CKD patients followed in primary care
- Take into account recent legislation changes
  - Dossier Santé Québec
  - Bill 41: adapt prescription, prescribe laboratory tests
- External facilitator/expert pharmacist to accelerate clinical practice changes

Thanks!

Nephrologists
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Thank You!