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# Deprescribing in Patients on Hemodialysis: A Prospective, Controlled, Quality Improvement MedSafer Study

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| **Order of Authors:** | Émilie Bortolussi-Courval, RN |
| | Tiina Podymow, MD |
| | Marisa Battistella, PharmD |
| | Emilie Trinh, MD MSC |
| | Thomas A. Mavrakanas, MD MSc |
| | Lisa McCarthy, PharmD |
| | Joseph Moryousef, MD |
| | Ryan Hanula, MSc |
| | Jean-François Huon, PharmD |
| | Rita Suri, MD MSc |
| | Todd C. Lee, MD MPH |
| | Emily G. McDonald |

# Deprescribing in Patients on Hemodialysis: A Prospective, Controlled, Quality Improvement MedSafer Study

Émilie Bortolussi-Courval RN[1], Tiina Podymow MD[2], Marisa Battistella PharmD[3], Emilie Trinh MD MSc[2], Thomas A. Mavrakanas MD MSc[2], Lisa McCarthy PharmD[3], Joseph Moryousef MD[4], Ryan Hanula[1], Jean-François Huon PharmD[5,6], Rita Suri MD MSc[2], Todd C. Lee MD MPH[1,5,7], Emily G. McDonald MD MSc[1,8,9]

[1]Division of Experimental Medicine, Faculty of Medicine and Health Sciences, McGill University, Montreal, Quebec, Canada
[2]Division of Nephrology, Department of Medicine, McGill University Health Centre, Montreal, Quebec, Canada
[3]Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario, Canada
[4]Faculty of Medicine and Health Sciences, McGill University, Montreal, Quebec, Canada
[5]Department of Medicine, McGill University Health Centre, Montreal, Quebec, Canada
[6]Division of Pharmacy, Nantes University Health Centre, Nantes University, Nantes, France
[7]Division of Infectious Disease, Department of Medicine, McGill University Health Centre, Montreal, Quebec, Canada
[8]Clinical Practice Assessment Unit, Department of Medicine, McGill University Health Centre, Montreal, Quebec, Canada
[9]Division of General Internal Medicine, Department of Medicine, McGill University Health Centre, Montreal, Quebec, Canada

Corresponding Author:
Emily G. McDonald MD MSc
emily.mcdonald@mcgill.ca
Centre for Outcomes Research and Evaluation
Office 3E.03, 5252 De Maisonneuve Boulevard
Montréal, Québec
H4A 3S9

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**Abstract**

**Rationale:** Patients on dialysis are commonly prescribed multiple medications (polypharmacy), including some that are potentially inappropriate (PIMs). Whether clinical decision support for deprescribing is effective in this population is not known.

**Objective:** To increase deprescribing among patients receiving intermittent hemodialysis by providing clinical decision support with the software MedSafer.

**Study Design:** Prospective controlled quality improvement study with a contemporary control.

**Setting and Participants:** The study took place at a tertiary care centre in Montréal, Canada on two outpatient hemodialysis units.

**Quality Improvement Activities:** Prior to a planned biannual medication reconciliation, patient health data from the electronic medical record (Renal Insight) was input into the MedSafer web-based portal to assess for the presence of deprescribing opportunities. On the intervention unit, in addition medication reconciliation, treating nephrologists received deprescribing opportunity reports, and patients received deprescribing EMPOWER brochures for select PIMs. On the control unit, patients received medication reconciliation alone.

**Analytical approach:** The proportion of patients with ≥1 PIMs deprescribed was compared between the intervention and control units following a planned biannual medication

reconciliation. The absolute risk difference (aRD) with 95% confidence interval (CI) and number needed to treat (NNT) were calculated.

**Results:** 195 patients were included (127 control unit; 68 intervention unit); the mean age was 64.8 (SD=15.9) and 39.5% were female. The proportion of patients with ≥1 PIMs deprescribed on the control unit was 3.1% (4/127) vs. 39.7% (27/68) on the intervention unit [aRD=36.6% (95% CI=24.5-48.6; p<0.0001); NNT=3].

**Limitations:** This was a single center non-randomized study. Deprescribing durability was not assessed, and the study was not powered to reduce ADEs.

**Conclusions:** Clinical decision support and patient EMPOWER brochures paired with medication reconciliation could be an effective and scalable intervention to increase deprescribing for the dialysis population. A randomized controlled trial to confirm these results is needed.

**Registration:** NCT05585268.

## Introduction

The burden of polypharmacy (taking multiple medications) in patients who receive dialysis is substantial: more than 90% of patients take 5 or more medications.[1] The majority are important to modify cardiovascular risk and to assist in maintenance of calcium and phosphate balance. However, in addition to indicated and beneficial medications, many are also potentially inappropriate.[2,3] Potentially inappropriate medications (PIMs) may have limited benefit, can increase a patient's pill burden,[4] and are associated with an increased risk of adverse drug events (ADEs).[5] An ADE is an umbrella term for harm arising during medication therapy;[6] examples include falls,[7] fractures,[8] and cognitive impairment.[9] An ADE can occur from an individual PIM, or through drug-drug, or drug-condition interactions.[10] It is increasingly recognized that polypharmacy and ADEs are common, costly, and harmful to patients and the healthcare system, contributing to preventable emergency room visits, hospital admissions, premature loss of autonomy, and death.[8,11] Given that 93% of patients on dialysis are estimated to be receiving one or more PIMs,[1] pragmatic, scalable interventions to reduce medication burden in this patient population are needed.[12-14]

MedSafer is an electronic decision tool that has been shown to increase deprescribing for hospitalized older adults and for people residing in long-term care.[1,10,15,16] It is a Canadian built software that cross-references a person's usual medication list and their medical diagnoses with a curated ruleset of evidence-informed deprescribing guidelines.[17-19] Reports generated through the software provide deprescribing opportunities ordered by level of potential harm and tapering regimens for drugs considered at risk for withdrawal reactions.[17,18,20 19] In a cluster randomized controlled trial (RCT) of 5698 hospitalized older adults, when compared to usual care, the receipt of deprescribing reports increased the proportion of patients with one or more PIMs deprescribed by 22.2%, (95% CI = 16.9%-27.4%) [15]. The study included 140 patients who were receiving maintenance hemodialysis (~2.5% of the overall study population); in the dialysis subgroup, the proportion of patients with one or more PIMs deprescribed increased by 9.4% (95% CI = 1.3%-17.6%)[1] with the intervention (lower than the rate of 22.2% observed in the general

study population).[15] We hypothesized that this lower rate of deprescribing was related to the complexity of medical admissions for dialysis patients and, perhaps, to a lack of dialysis-specific deprescribing rules.

Since the RCT was published, Lefebvre et al. proposed additional dialysis-specific deprescribing algorithms as part of a quality improvement initiative.[12] We set out to integrate these algorithms into the MedSafer software and to study the efficacy of clinical decision support for deprescribing in the outpatient dialysis unit setting.

## Methods

### *Design and setting*

This prospective, controlled, quality improvement study is reported using SQUIRE guidelines.[21] The study took place between September and December 2022 in the two largest (of three) outpatient hemodialysis units at the McGill University Health Centre in Montreal, Quebec, Canada. The detailed protocol for this study was published previously.[22] The intervention unit was the Lachine Hospital dialysis unit (LCH) and the control unit was the Montreal General Hospital dialysis unit (MGH). The physician-champion randomly assigned these units. The LCH dialyzes approximately 80-90 patients per week and the MGH approximately 150-155. Patients visit the units thrice weekly on average. Both units use the electronic medical record (EMR) Renal Insight (Constellation Kidney Group, previously known as NephroCare)[23] to store clinical data. Renal Insight contains clinical data such as medical diagnoses, home medications, laboratory values, and is bi-directionally integrated with the hospital's main EMR (OACIS, Telus Health)[24]. Our *a priori* sample size calculation suggested we would have 80% power to demonstrate at least a 15% increase in the proportion of patients with 1 or more PIMs deprescribed.[22]

We paired the intervention a part of usual workflow known as "medication reconciliation." This is an interdisciplinary clinical activity performed biannually on our hemodialysis units in the Spring and Fall, and within one week following a hospital discharge. The usual reconciliation process occurs as follows: a

dialysis nurse reviews the list of usual home medications and compares this with the medication list provided by the community pharmacy noting any discrepancies. Afterwards, the treating nephrologist and nurse jointly review this data and perform necessary adjustments. This process aims to confirm appropriate dosing and avoid duplications, omissions, or errors. There is no clinical pharmacist on either unit. Deprescribing may occur, but it is not protocolized and depends on the nephrologist's clinical judgement.

*The intervention*

MedSafer stratifies deprescribing opportunities for PIMs into categories of high risk, intermediate risk, or medications of little added value, informed by indications based on patient comorbidities and past medical history.[15] High risk equates to an elevated risk of developing an ADE; intermediate risk medications have harms that must be weighed against the benefits; and drugs of little added value superfluously increase the pill burden of a patient or have evidence demonstrating no effect.[16] Examples of a typical deprescribing report can be found in the Supplement. Patients also received deprescribing EMPOWER brochures for select classes of PIMs (e.g., opioids, gabapentinoids, sedative hypnotics).[25] These brochures contain non-pharmacologic alternatives and information about the potential harms of the medication class.

*Planning the Intervention*

Both units had a scheduled medication reconciliation planned for Fall 2022. The physicians taking part in the study attended solely on one of the two units and did not cross over between sites. The control unit (MGH) performed medication reconciliation as usual care, without the provision of deprescribing reports to nephrologists, nor brochures to patients. On the intervention unit (LCH), an introductory email was sent to the attending nephrologists containing the overview of the study and how the MedSafer reports and deprescribing brochures would integrate with the existing medication reconciliation workflow of 10-15 medication reconciliations per week. Nephrologists were also provided with a sample MedSafer report

to familiarize themselves with the output. A nephrologist champion (TP) was available to answer inquiries.

Reports were generated in advance prior to the patient's scheduled medication reconciliation and were alphabetically stored in a binder on the intervention unit (LCH) to be used as part of the exercise. The nephrologist would notify the study team of upcoming medication reconciliations and they would be provided the patient's documentation package from the binder to review. Five sequential Plan-Do-Study-Act (PDSA) cycles were subsequently used as an implementation strategy to achieve the aims of the project on the intervention unit (LCH) (Figure 1). [26,27] Each PDSA cycle was preceded by a system analysis that identified specific barriers inhibiting the success of the workflow.[26]

*Outcomes*

At the end of the intervention period for both units (December 2022) the medication reconciliation notes were reviewed to identify any deprescribing of PIMs (medications flagged by the MedSafer deprescribing report).

The primary outcome was a process measure: the proportion of patients with one or more PIMs deprescribed. Subgroup analyses by age category (<65 vs >65) were prespecified. Deprescribing was defined as any PIM that was either stopped, deliberately reduced, or tapered.[15,16]

Key secondary outcomes included: the reduction in the mean number of prescribed drugs and PIMs from baseline. Two counterbalancing indicators of harm were collected: gastrointestinal bleeds (GIB) within 3 months following the intervention and death following the intervention (see Supplemental methods). No other ADEs were collected, as this study was not powered to capture a change in incidence of ADEs after deprescribing. Implementation barriers and facilitators were collected from semi-structured interviews with nephrologists (to be reported in a separate manuscript).

*Recruitment of patients*

For the purposes of analysis, only the initial closed cohort was included in the study. This cohort was comprised of patients on maintenance hemodialysis (>3 months). New patients initiated on maintenance hemodialysis during the study, transplanted patients, and those hospitalized, transferred to another dialysis unit, or who died prior to their regularly scheduled medication reconciliation were excluded from the final analysis.

*Ethics*

The McGill University Health Centre Director of Professional Services granted access to medical charts and a waiver of consent for this quality improvement intervention.

*Data Collection*

From Renal Insight, the study lead extracted (for all patients in the study) medical conditions, usual home medications (from the best possible medication history informed by the community pharmacy's list and the EMR's list of medications), and recent glycated hemoglobin (HbA1c). This data was input into the MedSafer web-based portal and opportunities for deprescribing were assessed. Reports were only provided to nephrologists for patients on the intervention unit.

*Data Analysis*

Descriptive statistics were used to compare baseline health characteristics between patients. Chi-square and Fisher's exact tests were used to compare categorical differences. Wilcoxon rank-sum tests and t-tests were used to compare medians and means between groups. For the primary outcome, we used a two-sample test of proportions with 95% confidence intervals (CIs). For the number of drugs before and after

medication reconciliation, we used logistic regression adjusting for the presence of the intervention and the number of baseline drugs. All statistical comparisons used a two-sided alpha of 0.05 as significant with no adjustment for multiplicity of testing.

## Results

*PDSA Iterations (Figure 1)*

In *PDSA cycle 1*, to improve efficiency, the study lead prepared and ordered packages for the intervention alphabetically. In *PDSA cycle 2*, to reduce the burden on the care team, we made it explicit that only patients with select PIMs deprescribed needed to receive EMPOWER brochures. During *PDSA cycle 3*, to facilitate data extraction, the keyword "MedSafer" was entered into their progress note to document the intervention had taken place. During *PDSA cycle 4*, to improve efficiency, the study lead emailed the attending nephrologist the list of patients who were due for medication reconciliation one business day prior to the start of their rotation. During *PDSA cycle 5*, to improve efficiency, the list of PIMs for each patient was provided to the nephrologist prior to rounding.

*Population*

Initially, 240 patients were assessed for eligibility (Figure 2) and 26 (10.8%) were excluded before beginning the study: 18 from the control unit and 8 from the intervention unit. Twelve died before the beginning of the intervention, 8 were transplanted before the start of the study, 3 were transferred to another facility, 2 changed mode of dialysis, and one patient had no PIMs identified. During the study, due to competing events, a further 10 patients were excluded on the control unit, and 9 on the intervention unit; these patients were enrolled in the study but did not receive any medication reconciliation due to these events (Figure 2).

Ultimately, 195 patients were included in the final analysis (127 on the control and 68 on the intervention unit). The mean age was 64.8 (SD=15.9) and 39.5% were female (Table 1). The 3 most prevalent

comorbidities were hypertension (n = 173, 88.7%), dyslipidemia (n = 124, 63.6%) and diabetes (n = 114, 58.5%). Intervention and control unit patients were similar with respect to common medical conditions, except for diabetic neuropathy, orthostatic hypotension, and gastroesophageal reflux disorder (GERD), which were more prevalent in the intervention unit (Table 1). Patients were prescribed a mean of 15.3 medications (SD=5.3) on the control unit and 14.6 medications (SD=4.7) on the intervention unit (p=0.33) and a median of 4 PIMs (IQR=3-6) on both the control and intervention unit (p=0.5).

*Primary Outcome*

The proportion of patients with one or more PIMs deprescribed on the control unit was 3.1% (4/127) compared with 39.7% (27/68) on the intervention unit for an absolute increase of 36.6% (95% CI = 24.5-48.6-; $p < 0.0001$). The number needed to treat (NNT) for deprescribing was 3. The subgroup analysis stratified by age showed efficacy in both patients above and below 65 years of age (Figure 3).

*Secondary Outcomes*

Following medication reconciliation, the mean number of medications prescribed was 15.3 (SD=5.3) on the control unit and 14.0 (SD=4.6) on the intervention unit. The linear regression model (Table 2) showed the difference in the mean number of medications prescribed after the intervention decreased by -0.54 medications/patient (95% CI = -0.69 to -0.39, $p<0.0001$). On the intervention unit, 11/38 (29%) of the deprescribing opportunities related to the newly integrated dialysis specific rules.

*Counterbalancing outcomes*

Following medication reconciliation 2 patients died on the control unit and 1 patient died on the intervention unit. None of the deaths were related to deprescribing. Five patients on the control unit and 2 on the intervention unit had a GIB (Table 3). On the control unit, 4 of 5 patients had a GIB despite being on a proton pump inhibitor (PPI). On the intervention unit, neither GIB was related to deprescribing; at the time of the GIB, 1 patient was actively prescribed a PPI, and the other was never prescribed a PPI.

*Discussion*

In this controlled quality improvement study, we substantially increased deprescribing of PIMs for patients on hemodialysis, compared to usual care alone with a NNT of 3. We leveraged an existing workflow, medication reconciliation, as the opportunity for medication "rationalization." We noted increased rates of deprescribing in this study compared to our RCT, possibly due to the addition of hemodialysis-specific deprescribing indications. Other reasons can be attributed to the single-centre nature of this study versus the multicentred trial; to differences between the acute care setting and the dialysis unit; or to differences between nephrologists vs other subspecialists attending on the inpatient units of the RCT.

The use of technology in this study to address two key barriers to deprescribing (complexity and the time-consuming nature of the process)[1,2,10,15,28-34] was novel. These barriers are particularly true for patients with end-stage kidney disease who have multiple co-existing medical conditions and are often treated with 12-15 medications.[1,15] To our knowledge, this is the first controlled study to test newly developed dialysis-specific deprescribing guidelines by Lefebvre et al. Our results align with two small non-comparative studies that previously evaluated the efficacy of providing dialysis-specific deprescribing recommendations;[14,35] one study of 5 dialysis-specific medication class recommendations deprescribed 78% of PIMs identified.[14] Another study implemented 8 dialysis-specific deprescribing algorithms and managed to deprescribe 35 of 59 (59.3%) PIMs and 27/35 (77%) of these remained deprescribed at 16 weeks following the intervention.[35]

Where our studies differ was in our use of a contemporary control unit to observe differences with usual care. Furthermore, our reports contained both dialysis-specific and general deprescribing opportunities from multiple sources.[12,17,19,36] We also provided EMPOWER brochures to augment the intervention and engage patients. Of note, as the opportunities we flagged contained general suggestions for deprescribing (including some geared more included in this study). However, in our prespecified subgroup analysis, the

intervention was equally effective in both younger and older adults. Other strengths included leveraging Renal Insight, integrating with the existing medication reconciliation workflow, and use of a previously tested software to facilitate deprescribing decision support. We also deployed PDSA cycles to iteratively improve the process.

There are several limitations to this study worth discussing. First, we implemented two interventions simultaneously (e.g., decision support and patient brochures); consequently, it was not possible to quantify the individual impact of each intervention. Both interventions have been shown to independently increase deprescribing and we used the same approach in our multicentred RCT.[15,25] Second, this study only assessed early efficacy, and not durability; reassuringly, in our RCT, 90% of medications remained deprescribed at 30-days.[15] In the two prior studies that deployed dialysis-specific deprescribing algorithms, durability was 85% at 6 months[14] and 77% at 16 months.[35] Third, while the assignment of units was random, this was a single center study, and was not an RCT. As such, there were slight imbalances in patient comorbidities between units. However, the intervention unit had a higher prevalence of some conditions that might have made deprescribing more challenging (e.g., diabetic nephropathy, GERD, and orthostatic hypotension). If anything, we think these imbalances would have biased the intervention towards the null. Fourth, knowledge of an ongoing intervention may have led to the Hawthorne effect[37]. Nonetheless, non-research deprescribing implementation efforts also benefit from clinical champions, as do audit and feedback interventions. Finally, this study was not powered to measure an impact on ADEs, emergency department visits, or hospitalization. We sought to first study whether the process was effective for deprescribing, prior to running a larger trial. Although deprescribing PIMs is a process measure, it still reduces pill burden for patients, and decreases direct drug cost. Whether it also translates to improved outcomes and increased adherence in this population still needs to be demonstrated.

*Conclusion*

Deprescribing through clinical decision support in the hemodialysis unit can be effective when paired with the usual medication reconciliation workflow. Future studies will need to evaluate the generalizability and scalability to multiple centers and other countries. Ideally, these studies will have a large enough sample size to study the impact on ADEs and longer follow-up to evaluate the durability of the intervention.

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**Table 1: Patient Characteristics**

| | No (%) | | |
|---|---|---|---|
| **Characteristic** | **Control (n = 127)** | **Intervention (n = 68)** | **p-value** |
| Demographic information | | | |
| Age, mean (sd) | 64.8 (16.9) | 64.7 (13.8) | 0.95 |
| Female sex | 50 (39.4) | 22 (32.4) | 0.42 |
| Medications | | | |
| Number of medications, mean (sd) | 15.3 (5.3) | 14.6 (4.7) | 0.33 |
| Number of PIMs identified, median (IQR) | 4 (3-6) | 4 (3-6) | 0.5 |
| Comorbidity | | | |
| Diabetes | 79 (62.2) | 35 (51.5) | 0.15 |
| Diabetic neuropathy | 64/79 (81.0) | 35/35 (100) | 0.006 |
| Hypertension | 112 (88.2) | 61 (89.7) | 0.75 |
| Dyslipidemia | 82 (64.6) | 42 (61.8) | 0.7 |
| Ischemic heart disease | 36 (28.3) | 17 (25) | 0.62 |
| Heart failure | 35 (27.6) | 22 (32.4) | 0.48 |
| Atrial fibrillation | 16 (12.6) | 8 (11.8) | 0.87 |
| Valvular heart disease | 11 (8.7) | 8 (11.8) | 0.49 |
| History of ischemic stroke | 11 (8.7) | 9 (13.2) | 0.32 |
| History of venous thromboembolism | 10 (7.9) | 7 (10.3) | 0.57 |
| COPD | 12 (9.4) | 2 (2.9) | 0.09 |
| Asthma | 9 (7.1) | 5 (7.4) | 0.95 |
| Orthostatic hypotension | 3 (2.4) | 15 (22.1) | < 0.001 |
| Gastroesophageal reflux disease | 5 (3.9) | 13 (19.1) | < 0.001 |
| History of gastrointestinal bleed | 11 (8.7) | 7 (10.3) | 0.71 |
| Constipation | 33 (26) | 20 (29.4) | 0.61 |
| Solid organ cancer | 23 (18.1) | 20 (29.4) | 0.07 |
| Psychiatric disorder[a] | 25 (19.7) | 11 (16.2) | 0.55 |
| Parkinson's disease | 3 (2.4) | 0 (0) | 0.20 |

[a] substance use disorder, major depressive disorder, bipolar affective disorder, schizophrenia.

Abbreviations: sd, standard deviation; IQR, interquartile range; COPD, chronic obstructive pulmonary disease.

**Table 2: Proportion of Patients With 1 or More PIMs Deprescribed by Intervention Status**

| Characteristic | Control (N=127) | Intervention (N=68) | p-value |
|---|---|---|---|
| Number of patients with 1 or more PIMs deprescribed (n, %) | 4 (3.1) | 27 (39.7) | < 0.0001 |
| Absolute risk difference (RD) of deprescribing | RD 36.6 (95% CI 24.5-48.6) | | |
| Number Needed to Treat (NNT) | 3 | | |
| Mean estimated change in total drugs (95% CI) | REF | -0.54 (95%CI -0.69 to -0.39) | <0.0001 |

Abbreviations: PIM=potentially inappropriate medication, CI=confidence interval, REF=referent comparison group

**Table 3: Counterbalancing Measure of Harm: Gastrointestinal Bleeds**

| Bleeding episode[a] | Allocation | Did GIB lead to death? | Proton pump inhibitor status at time of GIB | Anticoagulants prescribed at time of GIB |
|---|---|---|---|---|
| Patient 1 | Control | Yes | Active prescription | - |
| Patient 2 | Control | No | - | - |
| Patient 3 | Control | No | Active prescription | Aspirin 80 mg daily |
| Patient 4 | Control | No | - | - |
| Patient 5 | Control | No | - | - |
| Patient 6 | Intervention | No | Active prescription | - |
| Patient 7 | Intervention | No | Active prescription | Aspirin 80 mg daily |

[a]During the study and for 3 months post intervention

Abbreviations: GIB=gastrointestinal bleed

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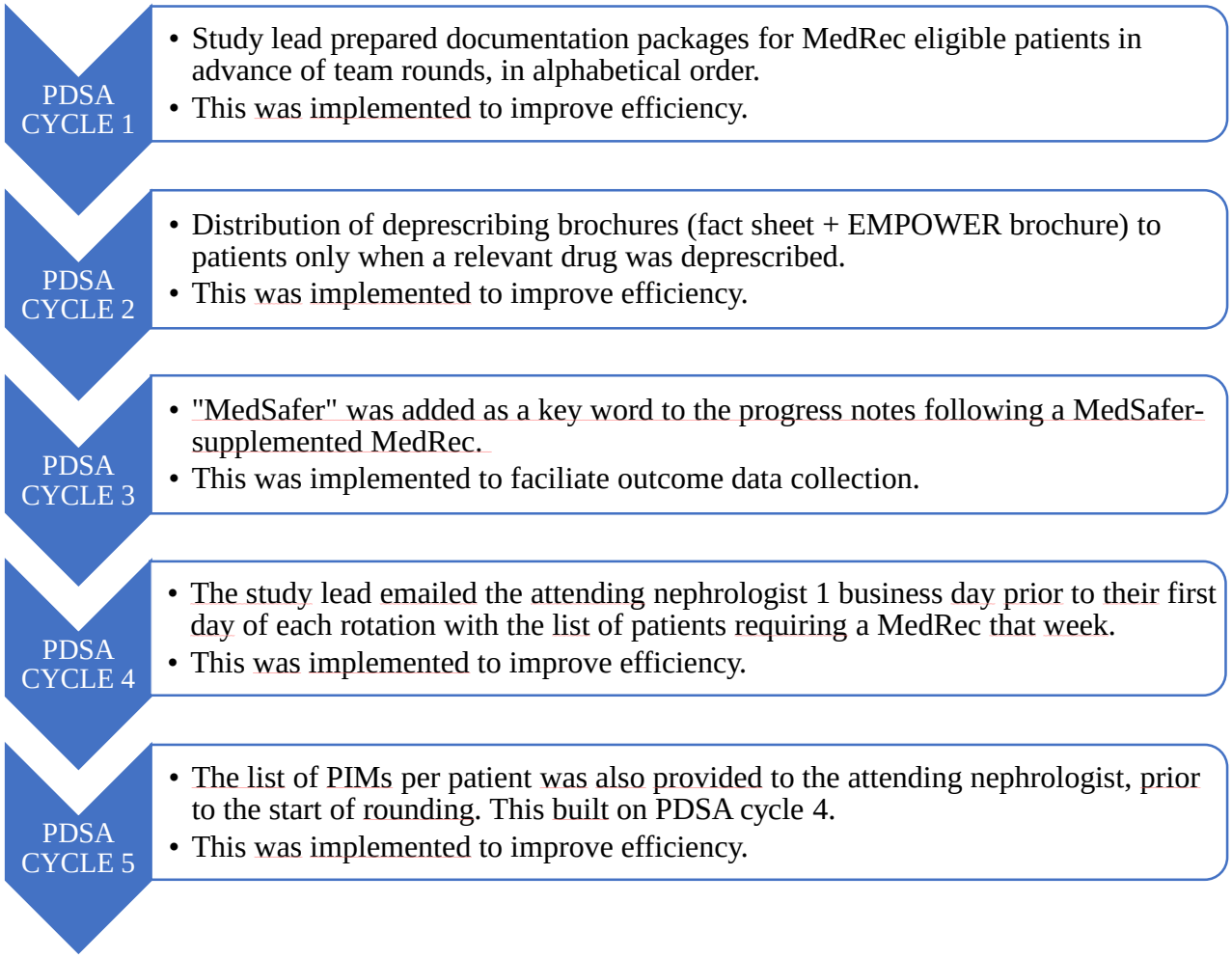
**Figure 1: Plan Do Study Act (PDSA) Cycles During the Quality Improvement Intervention**




Abbreviations: PDSA=Plan, Do, Study, Act; MedRec=medication reconciliation; PIM=potentially inappropriate medication

**Figure 2: Consort Flow Diagram of Hemodialysis Patients Assessed for Study Inclusion**

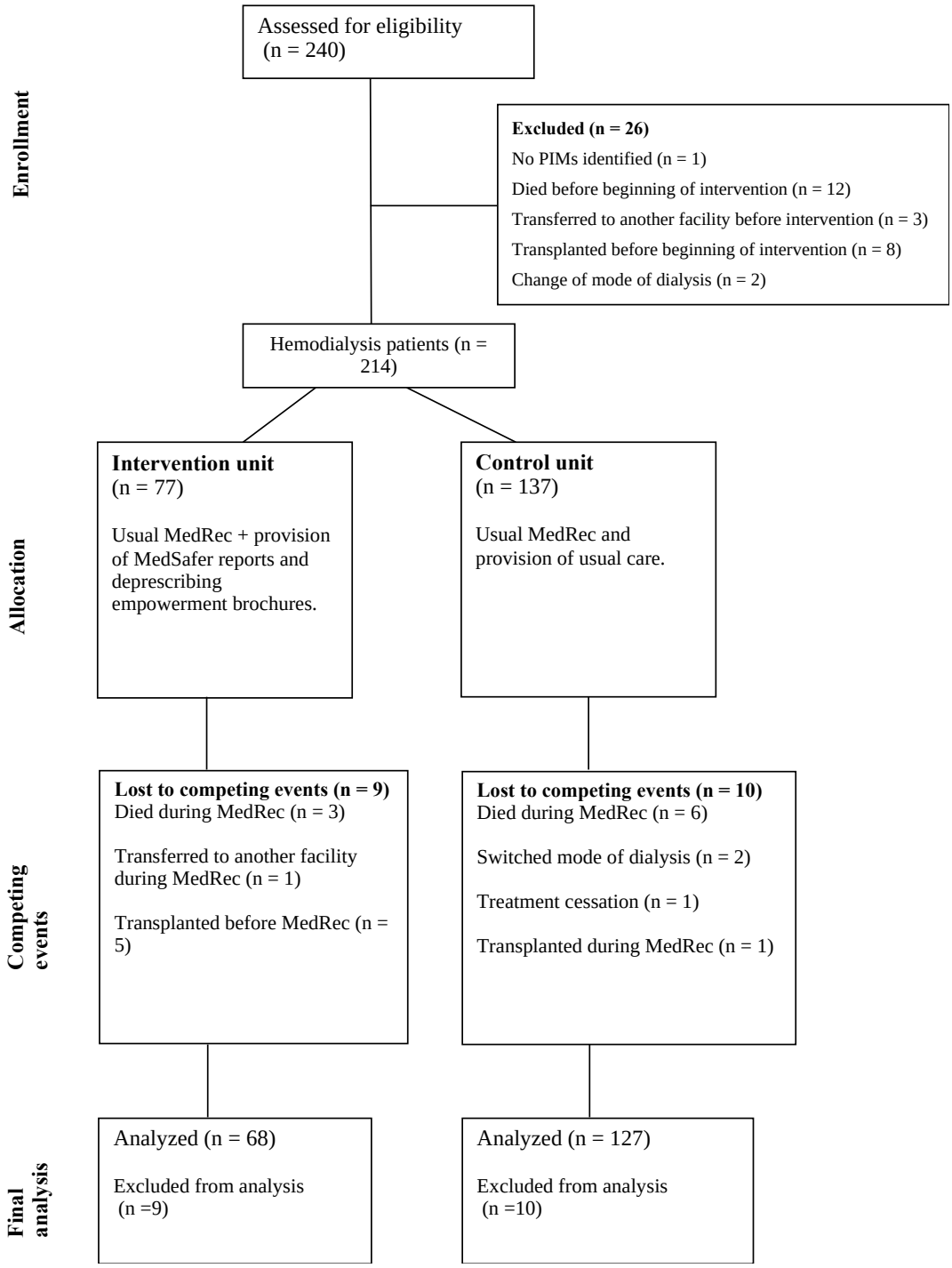
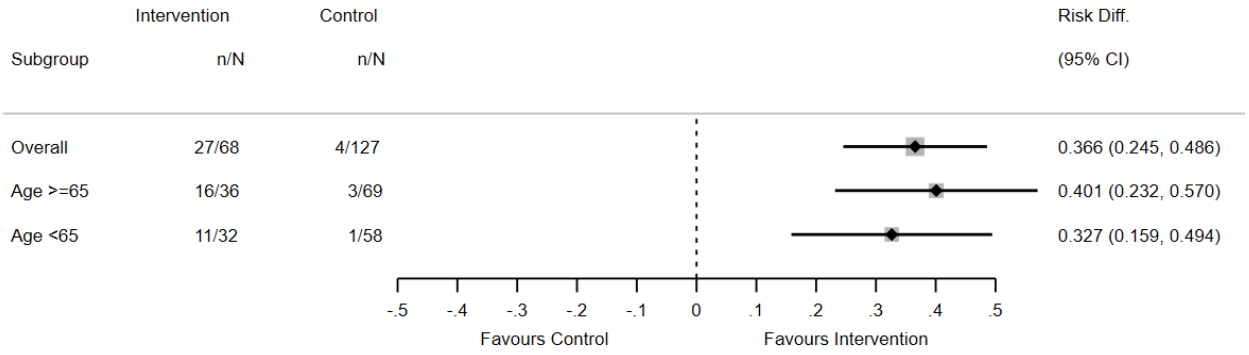


**Figure 3: Subgroup Analysis by Age Group**



Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)

| Text section and item name | Section or item description |
|---|---|
| 1. Title and abstract | Title |
| 2. Abstract | Abstract |
| Introduction | Why did you start? |
| 3. Problem description | Introduction |
| 4. Available knowledge | Introduction |
| 5. Rationale | Introduction |
| 6. Specific aims | Introduction |
| Methods | What did you do? |
| 7. Context | Design and Setting |
| 8. Interventions | The intervention, Planning the Intervention |
| 9. Study of the interventions | Outcomes |
| 10. Measures | Data Collection |
| 11. Analysis | Data Analysis |
| 12. Ethical considerations | Ethics |
| Results | What did you find? |
| 13. Results | Results: PDSA Iterations, Population, Primary Outcome, Secondary Outcomes, Counterbalancing outcomes |
| Discussion | Discussion |
| 14. Summary | Discussion |
| 15. Interpretation | Discussion |
| 16. Limitations | Discussion |
| 17. Conclusions | Conclusion |
| Other information | |
| 18. Funding | Funding |