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MINISTRY OF EDUCATION, YOUTH AND SPORTS

NETPHARM
New Technologies for Translational Research in Pharmaceutical Sciences

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A TRADITION OF INDEPENDENT THINKING

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Polypharmacy, Care of the Older Person, What is the Potential role of a Pharmacist?

Prof. Stephen Byrne
Deputy President and Registrar
Chair in Clinical Pharmacy Practice

20th June 2024

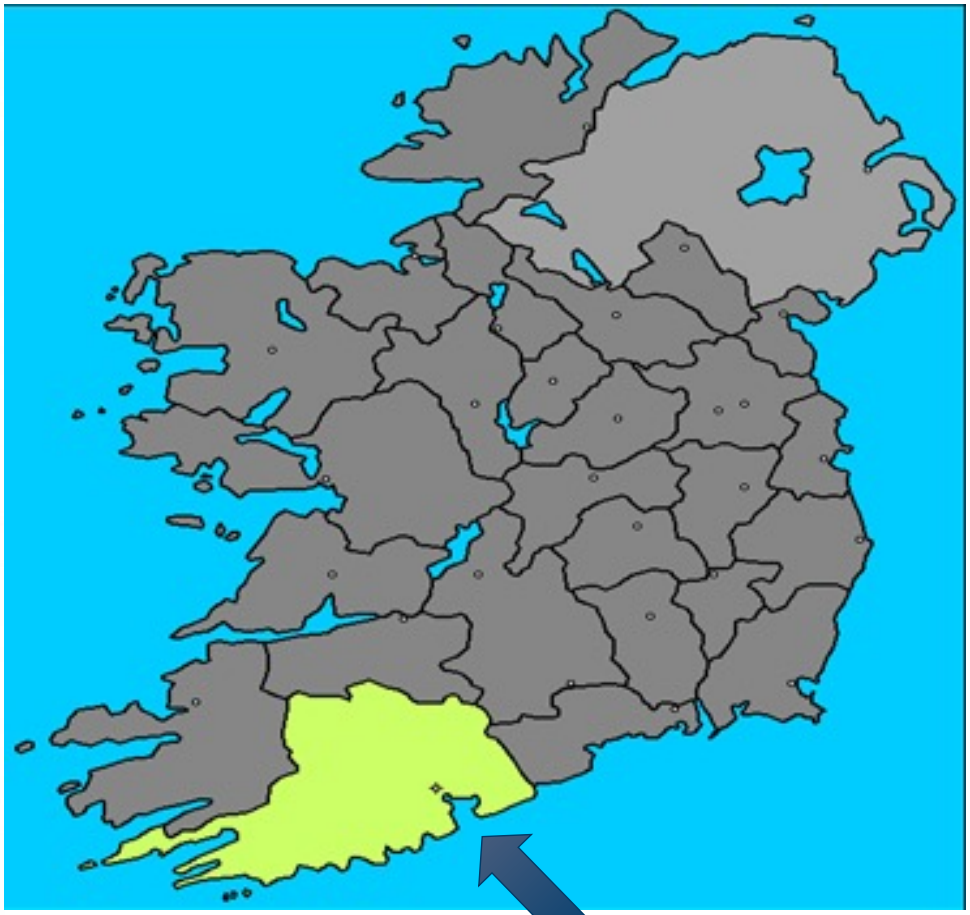
Declaration

Research funding relevant to care of the older person research are shown on this slide.

Co-inventor/author of STOPP/START Criteria.

I've participated in the following EU / H2020 care of the elderly trials:

- TRUST (https://pubmed.ncbi.nlm.nih.gov/28402245/)
- SENATOR (https://pubmed.ncbi.nlm.nih.gov/32484850/)
- OPERAM (https://pubmed.ncbi.nlm.nih.gov/34257088/)



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UCC Quick Facts 2023

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24,300
registered students

16,200
undergraduates

6,400
postgraduates

+ 1,700
adult and continuing education professional students

17% International Students
from 130 countries

3,400
academic, research & professional staff

200,000+
alumni worldwide

€113m
research income

€450m
annual income

8,000
graduates
Per year

€2.4m per day
Contribution to the economy

Ranked 58th in the world for Impact

Global Sustainability University of the year 2023

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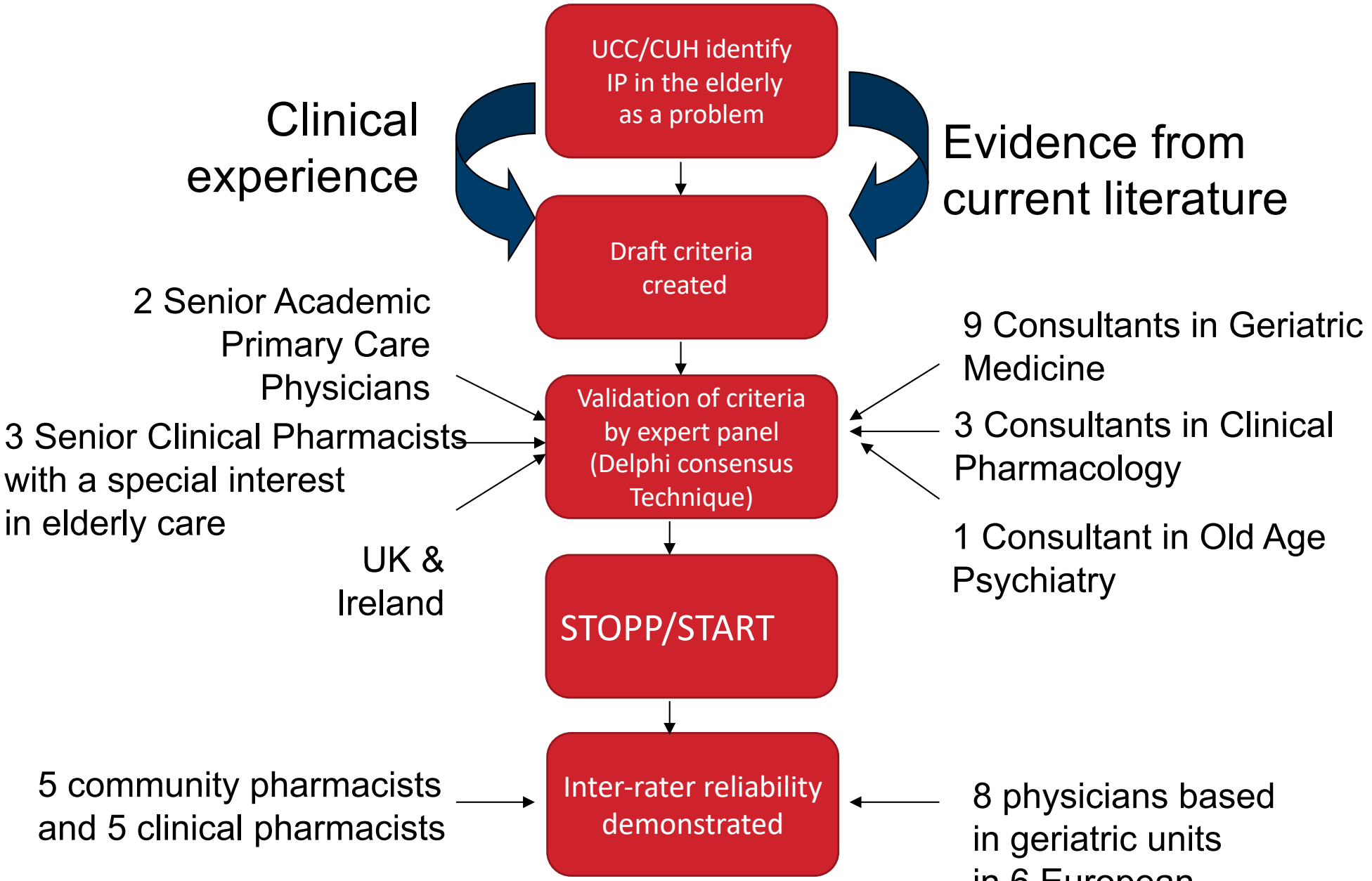
Origins of STOPP/START

2003: First draft of STOPP criteria

2004: First draft of START criteria

2006: Refinement of STOPP/START criteria

2007: Delphi validation of STOPP/START criteria and preparation of manuscript for publication.



Gallagher P et al., *Int J Clin Pharmacol Ther* 2008; 46: 72-83

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International Journal of Clinical Pharmacology and Therapeutics, Vol. 46 – No. 2/2008 (72-83)

Original
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ISSN 0946-1965

STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation

P. Gallagher[1], C. Ryan[2], S. Byrne[2], J. Kennedy[2] and D. O'Mahony[3]

[1]Department of Geriatric Medicine, Cork University Hospital, Wilton, Cork, [2]School of Pharmacy and [3]Department of Medicine, University College Cork, Cork, Ireland

Gallagher *et al., Intern J Clin Pharm Ther 2008.*

Age and Ageing Advance Access published October 16, 2014

Age and Ageing 2014; **0:** 1–6
doi: 10.1093/ageing/afu145

STOPP/START criteria for potentially inappropriate prescribing in older people: version 2

Denis O'Mahony[1,2], David O'Sullivan[3], Stephen Byrne[3], Marie Noelle O'Connor[2], Cristin Ryan[4], Paul Gallagher[2]

Application of STOPP and START Criteria: Interrater Reliability Among Pharmacists

Cristin Ryan, Denis O'Mahony, and Stephen Byrne

The Annals of Pharmacotherapy ■ *2009 July/August, Volume 43*

METHODS: Ten pharmacists (5 hospital pharmacists, 5 co
were given 20 patient profiles containing details includin
sex, current medications, current diagnoses, releva
biochemical data, and estimated glomerular filtration
applied the STOPP and START criteria to each patient
PEOs identified by each pharmacist were compared wit
pharmacists who were highly familiar with the application
An interrater reliability analysis using the κ statistic (chanc
agreement) was performed to determine consistency betw

RESULTS: The median κ coefficients for hospital pharm
pharmacists compared with the academic pharmacists for
0.88, respectively, while those for START were 0.91 and 0

Table 2. Comparison of PIMs and PEOs by Pharmacists Using STOPP and START

Comparators	ppos	pneg	Median κ (p < 0.01; 95% CI)
STOPP			
SA			
HPs	0.87	0.99	0.89 (0.68 to 1.0)
CPs	0.88	0.99	0.88 (0.67 to 1.0)
Inter HPs	0.80	0.99	0.82 (0.55 to 1.0)
Inter CPs	0.75	0.99	0.78 (0.46 to 0.99)
START			
SA			
HPs	0.83	0.99	0.91 (0.75 to 1.0)
CPs	0.87	0.99	0.90 (0.76 to 1.0)
Inter HPs	0.83	0.99	0.90 (0.70 to 1.0)
Inter CPs	0.79	0.99	0.82 (0.57 to 0.99)

CPs = community pharmacists; HPs = hospital pharmacists; Inter = comparison among pharmacists working in the same setting; PEO = potential errors of omission; PIM = potentially inappropriate medicines; pneg = proportion of negative agreement; ppos = proportion of positive agreement; SA = standard answers; START = Screening Tool to Alert doctors to Right Treatment; STOPP = Screening Tool of Older Peoples' Prescriptions.

ORIGINAL INVESTIGATION

LESS IS MORE

Potentially Inappropriate Medications Defined by STOPP Criteria and the Risk of Adverse Drug Events in Older Hospitalized Patients

Hilary Hamilton, MB, MRCPI; Paul Gallagher, PhD, MRCPI; Cristin Ryan, PhD, MPSI; Stephen Byrne, PhD, MPSI; Denis O'Mahony, MD, FRCPI

Arch Intern Med. 2011;171(11):1013-1019

- "Any noxious, unintended and undesired effect of a drug, excluding therapeutic failures, intentional or accidental poisoning, and drug abuse." WHO 1969

- Severe ADE →
  - Immediate discontinuation of suspect drug
  - Required resuscitative or antidote treatment
  - Caused or contributed to hospitalization
  - Caused or contributed to death

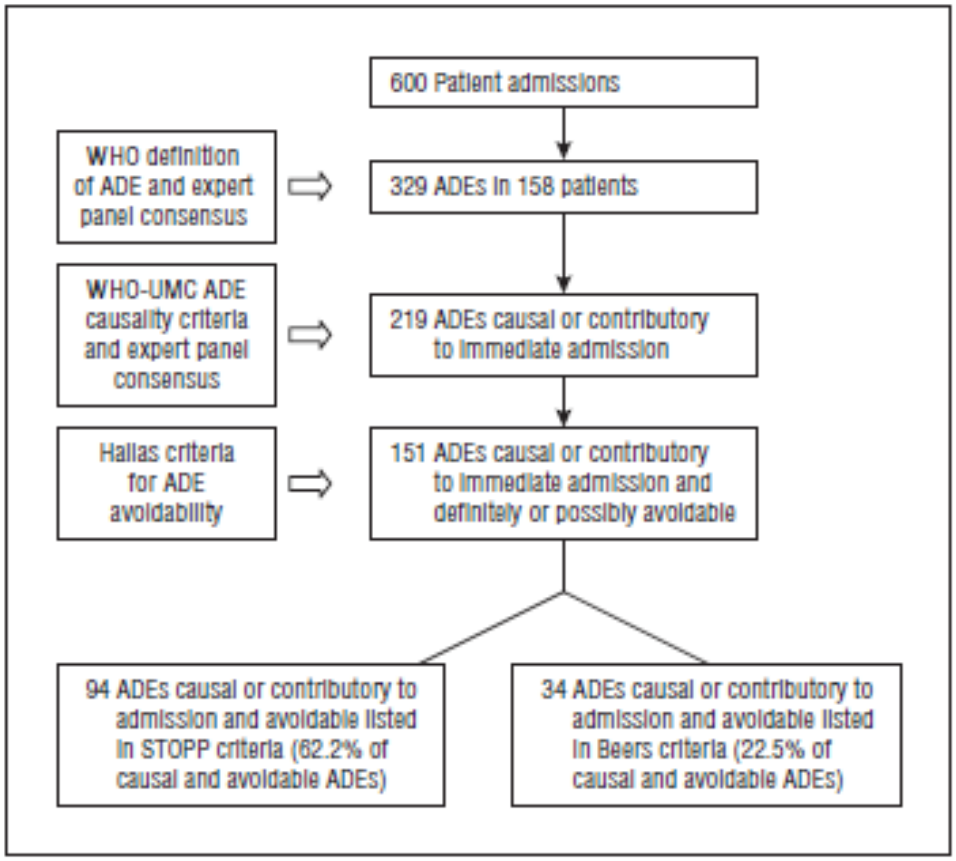

Figure. Flow chart showing how 600 consecutively hospitalized older patients were classified according to the ADEs identified. The chart shows whether ADEs were causal or contributory to admission (WHO-UMC criteria plus expert panel consensus) and whether ADEs were avoidable or possibly avoidable (Hallas criteria). ADEs indicates adverse drug events; STOPP, Screening Tool of Older Persons' potentially inappropriate Prescriptions; WHO, World Health Organization; and WHO-UMC, World Health Organization–Uppsala Monitoring Centre.

- 40% male; median age 77
- 34% taking ≤ 5 meds;
- 46% taking 6-10 meds;
- 20% taking > 10 meds
- 329 ADEs identified in 158 pts (26.3%)

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Drugs Aging
DOI 10.1007/s40266-014-0172-6

ORIGINAL RESEARCH ARTICLE

The Impact of a Structured Pharmacist Intervention on the Appropriateness of Prescribing in Older Hospitalized Patients

David O'Sullivan · Denis O'Mahony · Marie N. O'Connor · Paul Gallagher · Shane Cullinan · Richard O'Sullivan · James Gallagher · Joseph Eustace · Stephen Byrne

Abstract

Background Throughout the literature, drug-related problems (DRPs), such as medication reconciliation issues and potentially inappropriate prescribing, have been reported to be associated with adverse outcomes in older individuals. Both structured pharmacist review of medication (SPRM) interventions and computerized decision support systems (CDSSs) have been shown to reduce DRPs.

Objective The objectives of this study were to (i) evaluate the impact of a specially developed SPRM/CDSS intervention on the appropriateness of prescribing in older Irish hospital inpatients, and (ii) examine the acceptance rates of these recommendations.

Methods We prospectively reviewed 361 patients, aged ≥65 years who were admitted to an Irish university teaching hospital over a 12-month period. At the point of admission, the patients received a SPRM/CDSS intervention, which screened for DRPs. Any DRPs that were identified were then communicated in writing to the attending medical team. The patient's medical records were reviewed again at 7–10 days, or at the point of discharge (whichever came first).

Results Of the 361 patients reviewed, 181 (50.1 %) were female; the median age was 77 years [interquartile range (IQR) 71–83 years). A total of 3,163 (median 9, IQR 6–12) and 4,192 (median 12, IQR 8–15) medications were prescribed at admission and discharge, respectively. The SPRM generated 1,000 recommendations in 296 patients. Of the 1,000 recommendations, 548 (54.8 %) were implemented by the medical teams accordingly. The SPRM/CDSS intervention resulted in an improvement in the appropriateness of prescribing as defined by the medication appropriateness index (MAI), with a statistically significant difference in the median summated MAI at admission (15, IQR: 7–21) and follow-up (12, IQR: 6–18); $p < 0.001$. However, the SPRM did not result in an improvement in appropriateness of underprescribing as defined by a modified set assessment of care of vulnerable elders (ACOVE) criteria.

Conclusion This study indicated that DRPs are prevalent in older Irish hospitalized inpatients and that a specially developed SPRM intervention supported by a CDSS can improve both the appropriateness and accuracy of medication regimens of older hospitalized inpatients.

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Published online: 06 May 2014

1 Introduction

Older individuals aged ≥65 years constitute approximately 12 % of the Irish population, with this figure expected to almost double by 2045 [1]. During the same period the

Drugs Aging
DOI 10.1007/s40266-015-0329-y

ORIGINAL RESEARCH ARTICLE

Prevention of Adverse Drug Reactions in Hospitalised Older Patients Using a Software-Supported Structured Pharmacist Intervention: A Cluster Randomised Controlled Trial

David O'Sullivan[1] · Denis O'Mahony[2,3] · Marie N. O'Connor[2] · Paul Gallagher[2,3] · James Gallagher[1] · Shane Cullinan[1] · Richard O'Sullivan[1] · Joseph Eustace[4] · Stephen Byrne[1,2]

Abstract

Background Proven interventions to reduce adverse drug reactions (ADRs) in older hospitalised patients are lacking. Previous randomised controlled trial (RCT) data indicate that a structured pharmacist review of medication (SPRM) can reduce inappropriate prescribing in older hospitalised patients. However, no RCT data show that an SPRM reduces ADRs in this population.

Methods We performed a cluster RCT comparing a clinical decision support software (CDSS)-supported SPRM intervention with standard pharmaceutical care in older patients hospitalised with an acute unselected illness. Over 13 months, we screened 1833 patients aged ≥65 years admitted to specialist services other than geriatric medicine for study inclusion. We randomised 361 patients to the trial intervention arm and 376 patients to the control arm, applying the intervention at a single timepoint within 48 h of admission. The primary endpoint (ADR incidence) was assessed at 7–10 days post-admission or at discharge (whichever came first). The secondary endpoints were the median hospital length of stay (LOS) and hospital mortality rate.

Results Attending clinicians in the intervention group implemented 54.8 % of SPRM/CDSS prescribing recommendations. Ninety-one ADRs occurred in 78 control patients (20.7 %) compared with 61 ADRs in 50 intervention patients (13.9 %), i.e., an absolute risk reduction of 6.8 %. The number needed to treat (NNT) to prevent one patient having one ADR was 15; the total NNT to prevent one ADR was 14. The median LOS and hospital mortality were not significantly different.

Conclusion An SPRM delivered on a CDSS platform significantly reduces ADR incidence in acutely hospitalised older people.

Key Points

This study demonstrated the ability of a clinical pharmacy medication review supported by computerized clinical decision support software to reduce adverse drug reactions (ADRs) amongst older patients.

An ADR trigger list proved to be very effective in the identification of serious and non-trivial ADRs amongst older patients.

Pharmacists have the potential to reduce the occurrence of in-hospital ADRs and optimise prescribing for older patients.

1 Introduction

Adverse drug reactions (ADRs) represent a major public health problem in the globally expanding older population [1–5]. Multi-morbid illness and associated polypharmacy,

✉ Stephen Byrne
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4 Health Research Board of Ireland Clinical Research Facility, University College Cork, Cork, Ireland

Published online: 23 November 2015

Drugs Aging
DOI 10.1007/s40266-016-0348-3

ORIGINAL RESEARCH ARTICLE

Structured Pharmacist Review of Medication in Older Hospitalised Patients: A Cost-Effectiveness Analysis

James Gallagher[1] · David O'Sullivan[1] · Suzanne McCarthy[1] · Paddy Gillespie[2] · Noel Woods[3] · Denis O'Mahony[4,5] · Stephen Byrne[1]

Cost Component	Description	Unit Cost
Pharmacist	Per application of SPRM/CDSS	€40
Non-consultant hospital doctor	Per review of pharmaceutical care plan	€5.06
Inpatient day	Cost of care per hospital in patient day	€850
Software costs	One off installation of software programme	€1000

- Outcome – Incremental cost-effectiveness ratio (ICER)
- Incremental analysis – Multi-level mixed effect regression models
- Uncertainty – Cost-effectiveness acceptability curves

Outcomes

	INTERVENTION (N = 361)	CONTROL (N = 376)
COST ANALYSIS	Mean (SD)	Mean (SD)
Total Cost (€)	13242 (15530)	15465 (19310)
EFFECTIVENESS ANALYSIS	N (%)	N (%)
ADR Event	50 (13.85)	78 (20.74)
No. of ADR Events	N (%)	N (%)
0	311 (86.15)	298 (79.26)
1	40 (11.08)	65 (17.29)
2	9 (2.49)	12 (3.46)
3	1(0.28)	0 (0.00)
	Mean (SD)	Mean (SD)
	0.169 (0.456)	**0.242 (0.503)**

	Incremental Analysis Intervention versus Control
Incremental Cost:	
Mean cost difference	**-815**
(95% CI's) (p-value)	**(-3451, 1820) (0.544)**
Incremental Effect:	
ADR Event Odds Ratio	**0.655**
(95% CI's) (p-value)	**(0.431, 0.994) (0.047)**
Incremental Effect:	
No. of ADR Events	**-0.064**
Difference in Mean	**(-0.135, 0.008) (0.081)**
(95% CI's) (p-value)	

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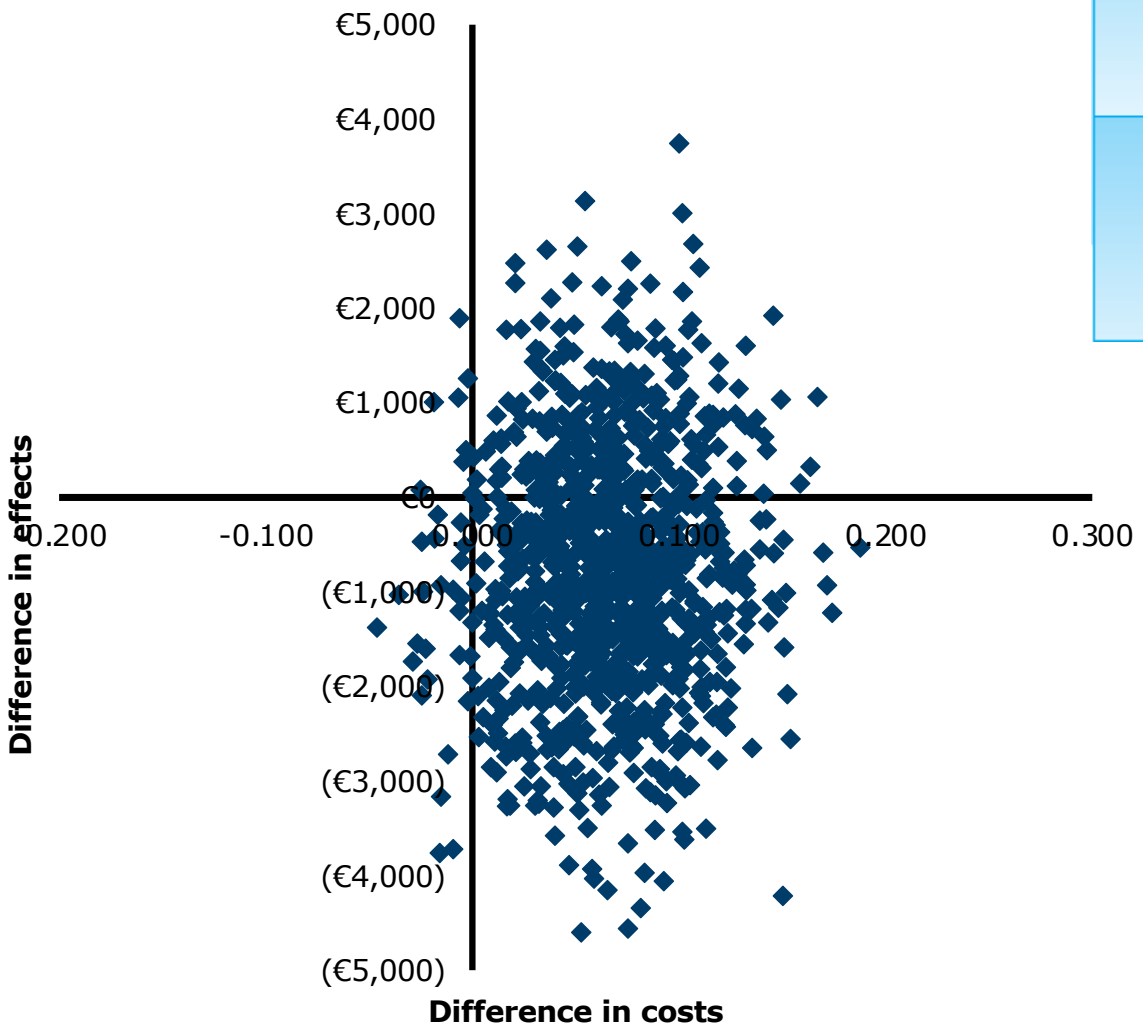
Incremental cost-effectiveness ratio of SPRM/CDSS



★ depending on threshold

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Drugs & Aging
https://doi.org/10.1007/s40266-018-0627-2

ORIGINAL RESEARCH ARTICLE

Prescriber Implementation of STOPP/START Recommendations for Hospitalised Older Adults: A Comparison of a Pharmacist Approach and a Physician Approach

Kieran Dalton[1] · Denis O'Mahony[2,3] · David O'Sullivan[1] · Marie N. O'Connor[3] · Stephen Byrne[1]

	Physician		Pharmacist
STOPP Recommendations Implemented	237/292	p < 0.0001	100/255
% STOPP Recommendations Implemented	81.2		39.2%
START Recommendations Implemented	139/159	p < 0.0001	13/44
% START Recommendations Implemented	87.4%		29.5%
Total STOPP and START Recommendations Implemented	376/451	p < 0.0001	113/299
% STOPP/START Recommendations Implemented	83.4%		37.8%

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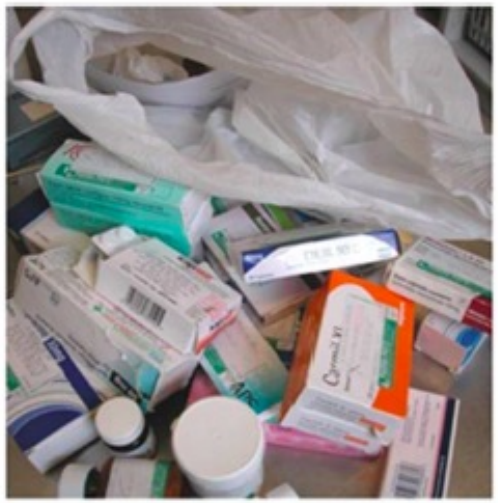
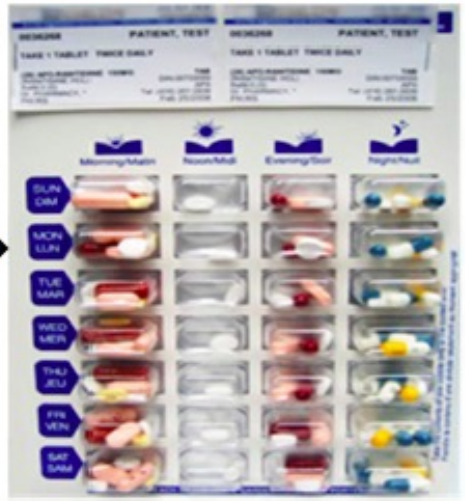
Eye on the patient benefit prize



SENATOR



ADRs, Cost ↓

SENATOR is a Collaborative Project funded by the European Commission under the 7th Framework Programme

SEVENTH FRAMEWORK PROGRAMME

School of Pharmacy
University College Cork

2003 - 2013

Background to the SENATOR study

- Multi-centre randomised controlled trial (RCT).

Intervention:

- computer-generated recommendations targeting PIP to prevent in-hospital ADRs in older adults.

Interim analysis:

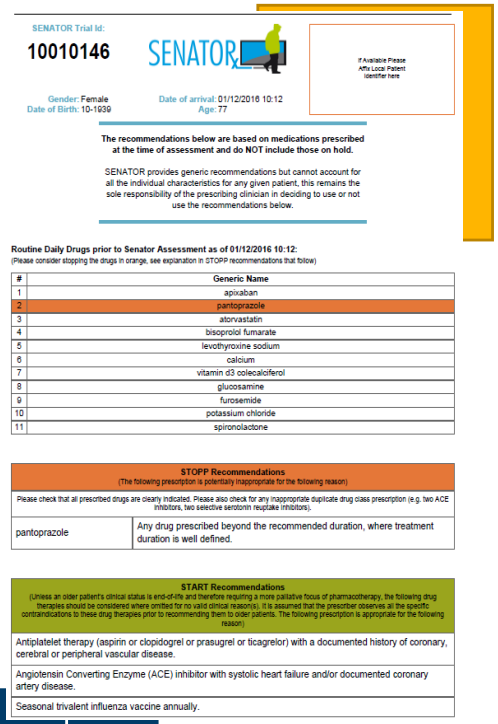
- prescriber implementation rates: ~ 17%

➢Factors affecting implementation must be identified.

Age and Ageing 2020; **49:** 605–614
doi: 10.1093/ageing/afaa072
Published electronically 2 June 2020

RESEARCH PAPER

Prevention of adverse drug reactions in hospitalized older patients with multi-morbidity and polypharmacy: the SENATOR* randomized controlled clinical trial



SENATOR Trial Id: 10010146

SENATOR

If Available Please Affix Local Patient Identifier here

Gender: Female
Date of Birth: 10-1939

Date of arrival: 01/12/2016 10:12
Age: 77

The recommendations below are based on medications prescribed at the time of assessment and do NOT include those on hold.

SENATOR provides generic recommendations but cannot account for all the individual characteristics for any given patient, this remains the sole responsibility of the prescribing clinician in deciding to use or not use the recommendations below.

Routine Daily Drugs prior to Senator Assessment as of 01/12/2016 10:12:
(Please consider stopping the drugs in orange, see explanation in STOPP recommendations that follow)

#	Generic Name
1	apixaban
2	pantoprazole
3	atorvastatin
4	bisoprolol fumarate
5	levothyroxine sodium
6	calcium
7	vitamin d3 colecalciferol
8	glucosamine
9	furosemide
10	potassium chloride
11	spironolactone

STOPP Recommendations
(The following prescription is potentially inappropriate for the following reason)

Please check that all prescribed drugs are clearly indicated. Please also check for any inappropriate duplicate drug class prescription (e.g. two ACE inhibitors, two selective serotonin reuptake inhibitors).	
pantoprazole	Any drug prescribed beyond the recommended duration, where treatment duration is well defined.

START Recommendations
(Unless an older patient's clinical status is end-of-life and therefore requiring a more palliative focus of pharmacotherapy, the following drug therapies should be considered where omitted for no valid clinical reason(s). It is assumed that the prescriber observes all the specific contraindications to these drug therapies prior to recommending them to older patients. The following prescription is appropriate for the following reason)

Antiplatelet therapy (aspirin or clopidogrel or prasugrel or ticagrelor) with a documented history of coronary, cerebral or peripheral vascular disease.
Angiotensin Converting Enzyme (ACE) inhibitor with systolic heart failure and/or documented coronary artery disease.
Seasonal trivalent influenza vaccine annually.

Category of clinical relevance	0 - Adverse significance	1 - No clinical relevance	2 - Possibly low relevance	3 - Possibly important relevance	4 - Possibly very important relevance	Total
STOPP Recommendations (% Total STOPP)	19 (3.4%)	129 (22.9%)	212 (37.7%)	171 (30.4%)	32 (5.7%)	563
START Recommendations (% Total START)	26 (7.2%)	70 (19.3%)	108 (29.8%)	114 (31.5%)	44 (12.2%)	362
Difference between proportion of STOPP and START at different categories of relevance	$p = 0.0086$	$p = 0.1964$	$p = 0.0147$	$p = 0.7191$	$p = 0.0005$	-

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Barriers / Facilitators to implementation

Drugs & Aging
https://doi.org/10.1007/s40266-020-00787-6

ORIGINAL RESEARCH ARTICLE

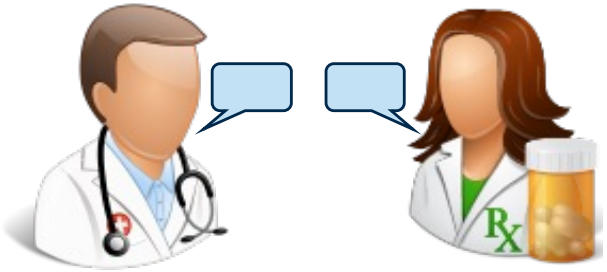
Factors Affecting Prescriber Implementation of Computer-Generated Medication Recommendations in the SENATOR Trial: A Qualitative Study

Kieran Dalton[1] · Denis O'Mahony[2,3] · Shane Cullinan[4] · Stephen Byrne[1]

Results – Main Themes

1. Clinical relevance and complexity of the recommendation

2. Interprofessional communication



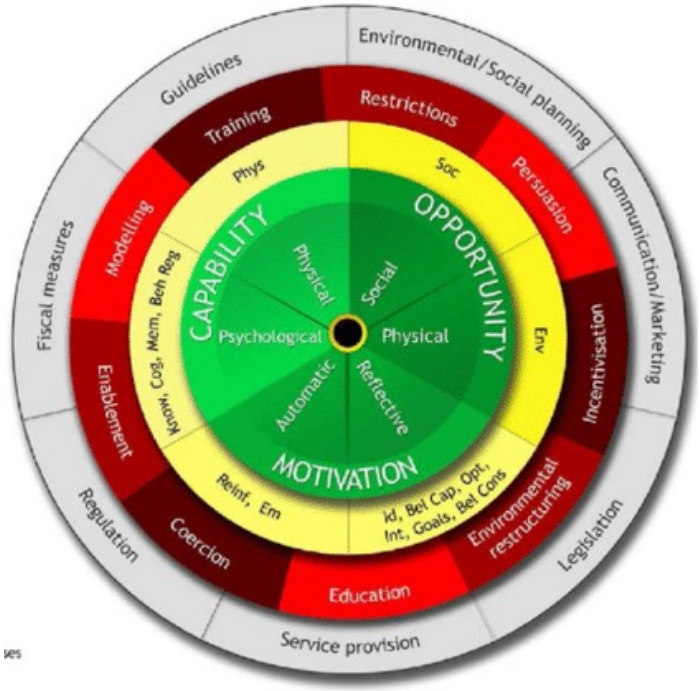
3. Prescriber role and identity

4. Knowing each other and developing trusting relationships

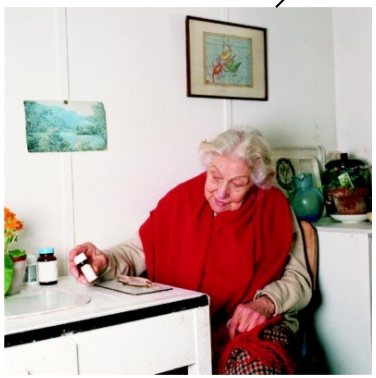
5. The hospital environment

Key factors affecting implementation

1. Clinical relevance of the recommendation.
2. Method of communication and integration into prescriber workflow.
3. The hospital environment.
4. Prescriber identity and Prescriber inertia.
5. Source of the recommendation.



Optimal Pharmacotherapy for older people



Optimisation of pharmacotherapy must be multi-faceted & patient-centred

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Age and Ageing Advance Access published January 10, 2016

Age and Ageing 2016; **0:** 1–9
doi: 10.1093/ageing/afv190

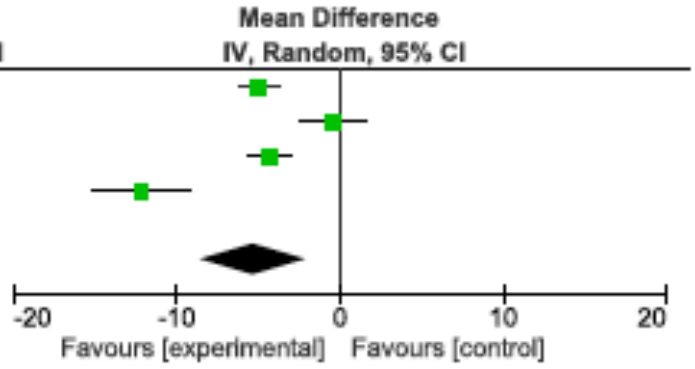
SYSTEMATIC REVIEW

Improving the appropriateness of prescribing in older patients: a systematic review and meta-analysis of pharmacists' interventions in secondary care

KIERAN ANTHONY WALSH[1,2], DAVID O'RIORDAN[1,2], PATRICIA M. KEARNEY[2], SUZANNE TIMMONS[3], STEPHEN BYRNE[1]

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Gillespie 2013	5	4.2	182	10	7.3	186	26.6%	-5.00 [-6.21, -3.79]
Hellstrom 2011	4.5	7.99	109	4.9	7.25	101	24.8%	-0.40 [-2.46, 1.66]
Schmader 2004	5.3	4.9	202	9.6	8.2	198	26.4%	-4.30 [-5.63, -2.97]
Spinewine 2007	7.1	7.5	96	19.3	12.5	90	22.2%	-12.20 [-15.19, -9.21]
Total (95% CI)			**589**			**575**	**100.0%**	**-5.27 [-8.44, -2.11]**

Heterogeneity: Tau² = 9.44; Chi² = 41.43, df = 3 (P < 0.00001); I² = 93%
Test for overall effect: Z = 3.26 (P = 0.001)



Optimizing Therapy to Prevent Avoidable Hospital Admissions in Multimorbid Older Adults (OPERAM): cluster randomised controlled trial

Blum MR; Sallevelt BTGM; Spinewine A; O'Mahony D; Moutzouri E; Feller M; Baumgartner C; Roumet M; Jungo KT; Schwab N; Bretagne L; Beglinger S; Aubert CE; Wilting I; Thevelin S; Murphy K; Huibers CJA; Drenth-van Maanen AC; Boland B; Crowley E; Eichenberger A; Meulendijk M; Jennings E; Adam L; Roos MJ; Gleeson L; Shen Z; Marien S; Meinders AJ; Baretella O; Netzer S; de Montmollin M; Fournier A; Mouzon A; O'Mahony C; Aujesky D; Mavridis D; Byrne S; Jansen PAF; Schwenkglenks M; Spruit M; Knol W; Dalleur O; Trelle S; Rodondi N

OPERAM

thebmj

Blum et al. BMJ. 2022.

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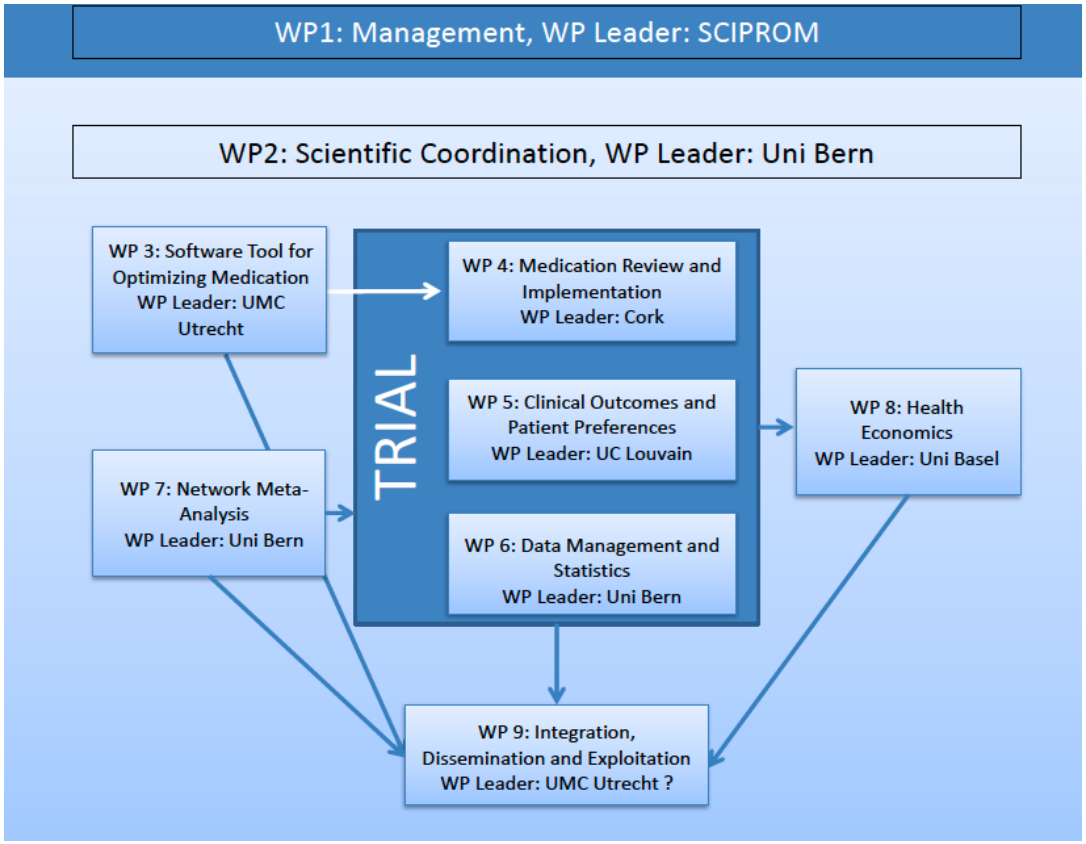
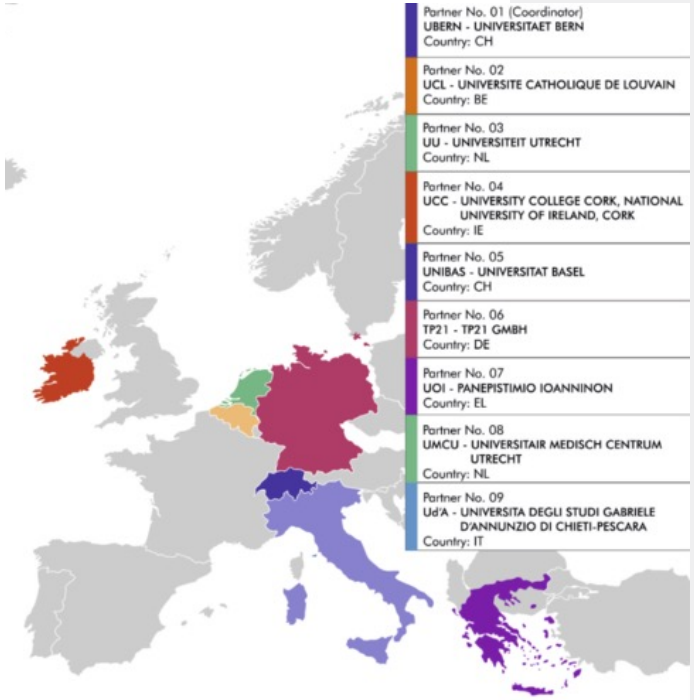
OPERAM – Across 4 Clinical Sites





Countries participating in the OPERAM trial

Source: https://www.operam-2020.eu/index.php?id=1502, accessed 26.08.2022

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OPERAM study participants

Participants

- Adults aged **≥ 70 years**
- Admitted to a participating hospital ward
- **Multimorbidity** (≥ 3 chronic conditions)
- **Polypharmacy** (≥ 5 daily drugs)
- Few exclusion criteria to maximize generalizability

Intervention

- Cluster-randomisation at the level of attending hospital physicians
- 1:1 randomisation to the intervention or control arm
- Intervention performed by team of a doctor and a pharmacist
- Structured assessment of preadmission medication list

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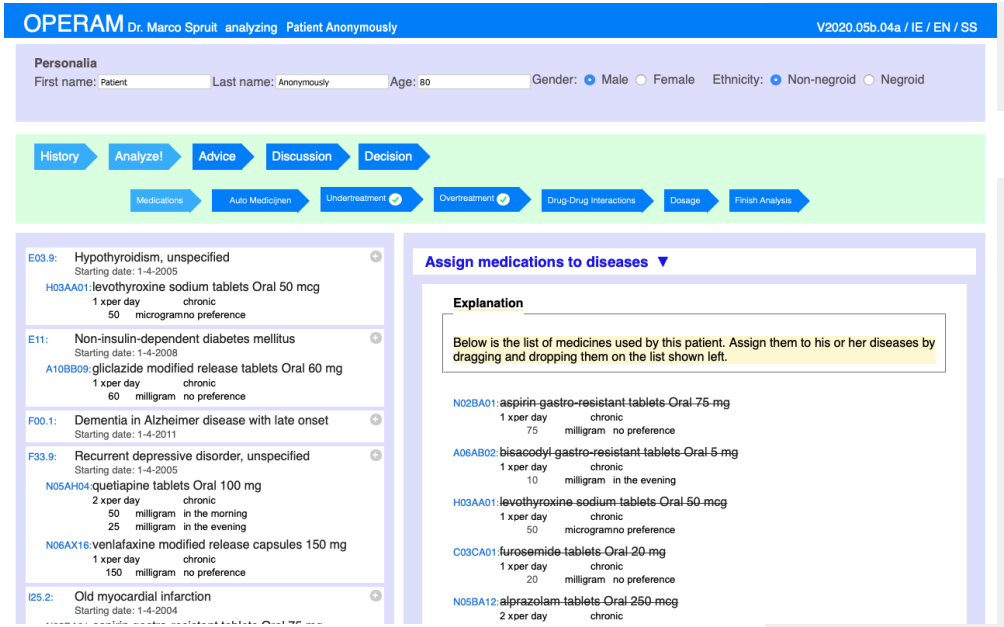
OPERAM Intervention *(contd')*

- Web-based evidence-based structured medication review using STRIP assistant
  - Based on the STOPP/START criteria
- Generation of patient specific prescribing recommendations
- Final report sent to general practitioners with all prescribing recommendations



Excerpt from the 'Systematic Tool to Reduce Inappropriate Prescribing' (STRIP) assistant

Sources: (1) O'Mahony et al. Age Ageing. 2015. | Drenth-van Maanen et al. J Eval Clin Pract. 2018. | Crowley et al. BMC Health Serv Res. 2020. | Adam et al. BMJ Open. 2019

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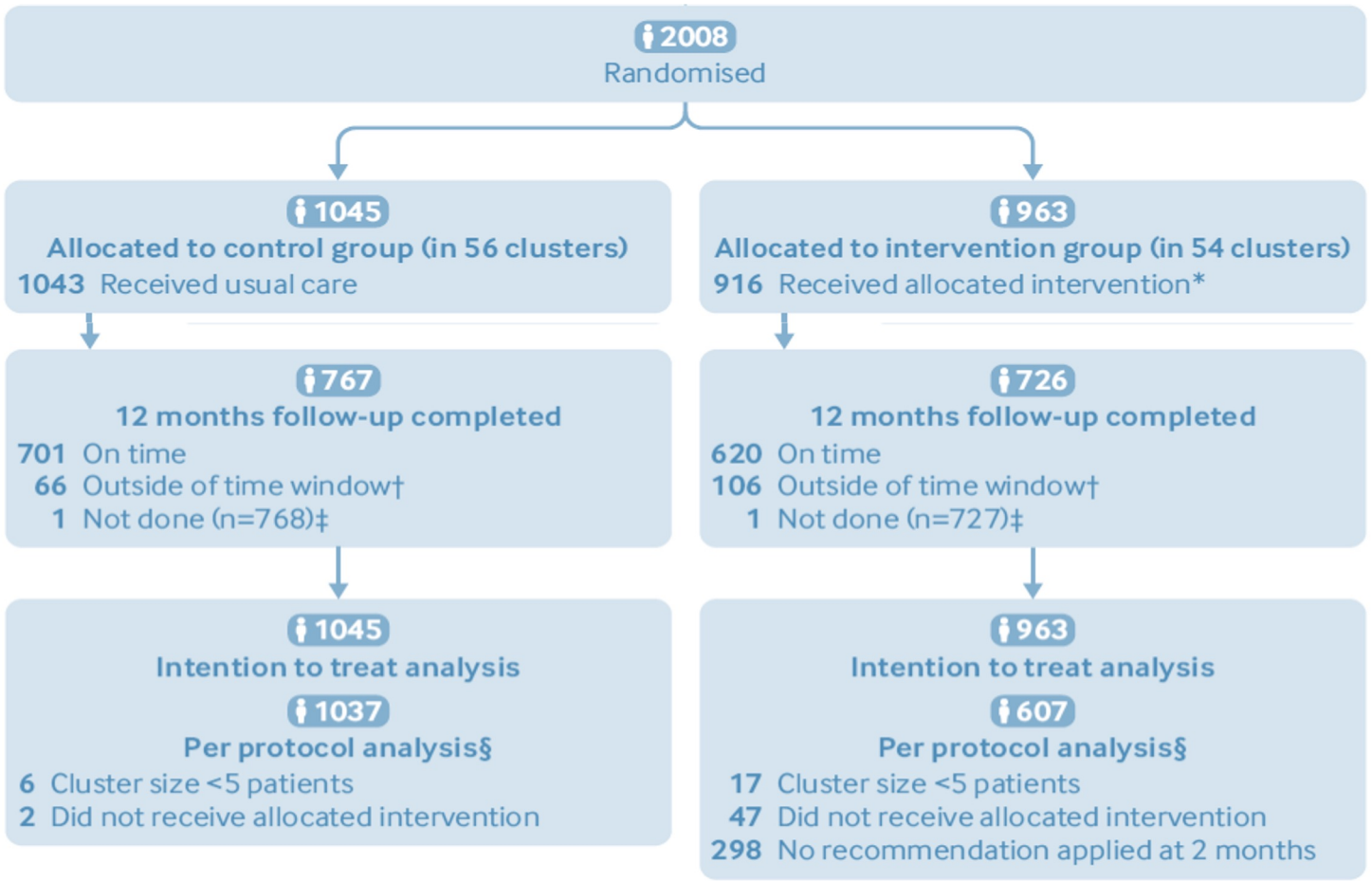
OPERAM - Study Flow Chart



Source: Blum et al. BMJ. 2021.

- Total recruitment:
  - **54 clusters**
  - **2,008 patients**

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OPERAM - Clinical Outcome

	Events (%)		Hazard ratio (95% confidence interval)
	Control	Intervention	
First drug related hospital admission	**234 (22.4)**	**211 (21.9)**	**0.95 (0.77 to 1.17)**
Death	203 (19.4)	172 (17.9)	0.90 (0.71 to 1.13)
First fall	263 (25.2)	237 (24.6)	0.96 (0.79 to 1.15)
First preventable DRA	100 (9.6)	84 (8.7)	0.89 (0.63 to 1.25)
First DRA in patients with ≥1 STOPP recommendation implemented at 2-month follow-up	156/875 (17.8)	64/398 (16.1)	0.88 (0.65 to 1.19)

DRA = drug-related hospital admission

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Lessons learnt from OPERAM

Strengths:

- Enrolment of >2000 patients with multimorbidity with minimal exclusion criteria
- Few patients lost to follow-up
- Addressing limitations of previous trials through
  - Cluster randomisation
  - Maximized blinding
  - Adjudication of hospital readmissions

Limitations

- Perhaps some medication changes in the control arm were similar to the intervention, potential bias
- Single timepoint intervention
- Cluster randomisation at the level of the doctor (not hospital), ? potential for contamination in control clusters

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Frequency and acceptance of CDSS-generated STOPP/START signals

An expert team's involvement in translating population-based CDSS signals to individual patients is essential, **as more than half of the signals for potential overuse, underuse and misuse were not deemed clinically appropriate in a hospital setting**.

Drugs & Aging (2022) 39:59–73
https://doi.org/10.1007/s40266-021-00904-z

ORIGINAL RESEARCH ARTICLE

Frequency and Acceptance of Clinical Decision Support System-Generated STOPP/START Signals for Hospitalised Older Patients with Polypharmacy and Multimorbidity

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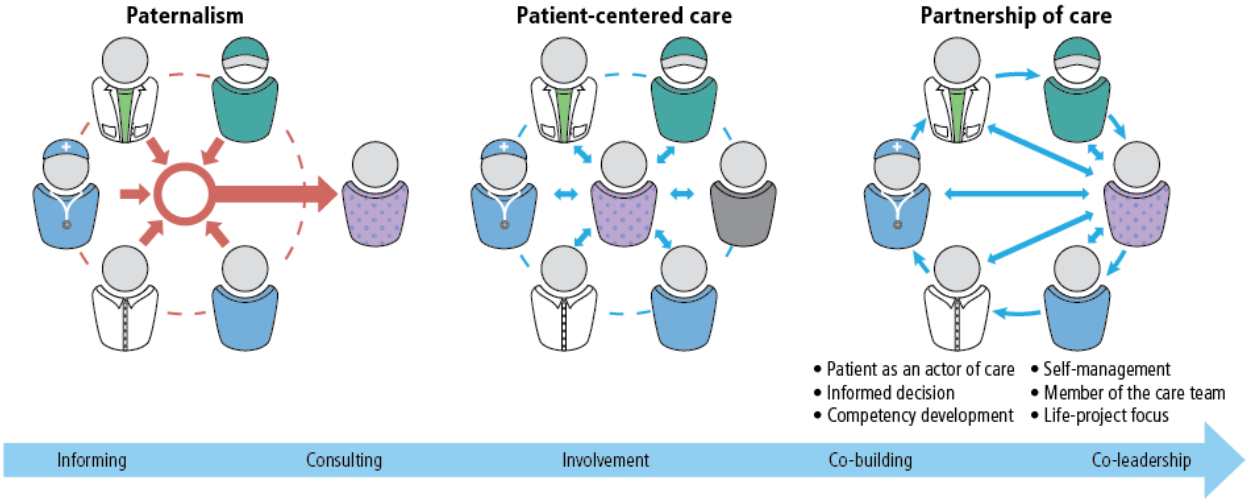

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Questions

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Thank you for your attention

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