

Potentially Inappropriate Prescribing (PIP): evidence and potential solutions

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Centre Aims and Objectives

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Primary care is facing many challenges in the 21st century. Not least are the complexities of managing multiple conditions in patients who span the primary/secondary care interface, maintaining evidence-based practice in terms of diagnosis and referral; and making sure that patients receive appropriate and safe medicines.

The HRB Centre for Primary Care Research (CPCR) aims to establish standards for the quality of care for vulnerable patient groups, namely older adults, children, drug users and pregnant women, with a particular emphasis on effective medicine monitoring ([work package 1](#)). Evidence-based diagnoses are also a priority for the Centre ([work package 2](#)). A register of clinical prediction rules (CPRs) has been established, in conjunction with systematic reviews of common clinical conditions in relation to the

Overview

- Background & context
 - Medicines utilization
 - Potentially inappropriate prescribing indicators
- Observational epidemiology PIP
 - National & International comparisons
 - Healthcare utilization
 - Adverse drug events & quality of life
 - Medical practice variation
- Quality Improvement RCT of PIP

The medicalisation of old age

BMJ 2002; 324 doi: <http://dx.doi.org/10.1136/bmj.324.7342.861> (Published 13 April 2002)

Cite this as: *BMJ* 2002;324:861

Should be encouraged

Shah Ebrahim, *professor of epidemiology of ageing* (shah.ebrahim@bristol.ac.uk)

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The *Oxford English Dictionary* describes medicalisation as pejorative, initially applied to the over-investigation and treatment of sexually active teenage girls. Since Ivan Illich's popularisation of the term, its use has spread to conditions such as pregnancy and childbirth, sexual orientation, mental illness, and the menopause. There is legitimate concern about the medicalisation of dying,¹ and because old people die, it is tempting to extend such concern to old age.

In the 1930s, Marjory Warren showed that old people in workhouse wards had treatable diseases and could be rehabilitated and discharged. Apparent social problems were in fact a result of patients being poorly served by health services. With the realisation that something could be done for elderly patients and that such

Epidemiology of medicines in the elderly population

- Prescribing for older people is a challenging process
- Multiple drug regimens
- Multi-morbidity
- Age-associated physiological changes
 - Pharmacokinetic*
 - Pharmacodynamic*
 - Cognitive impairment*

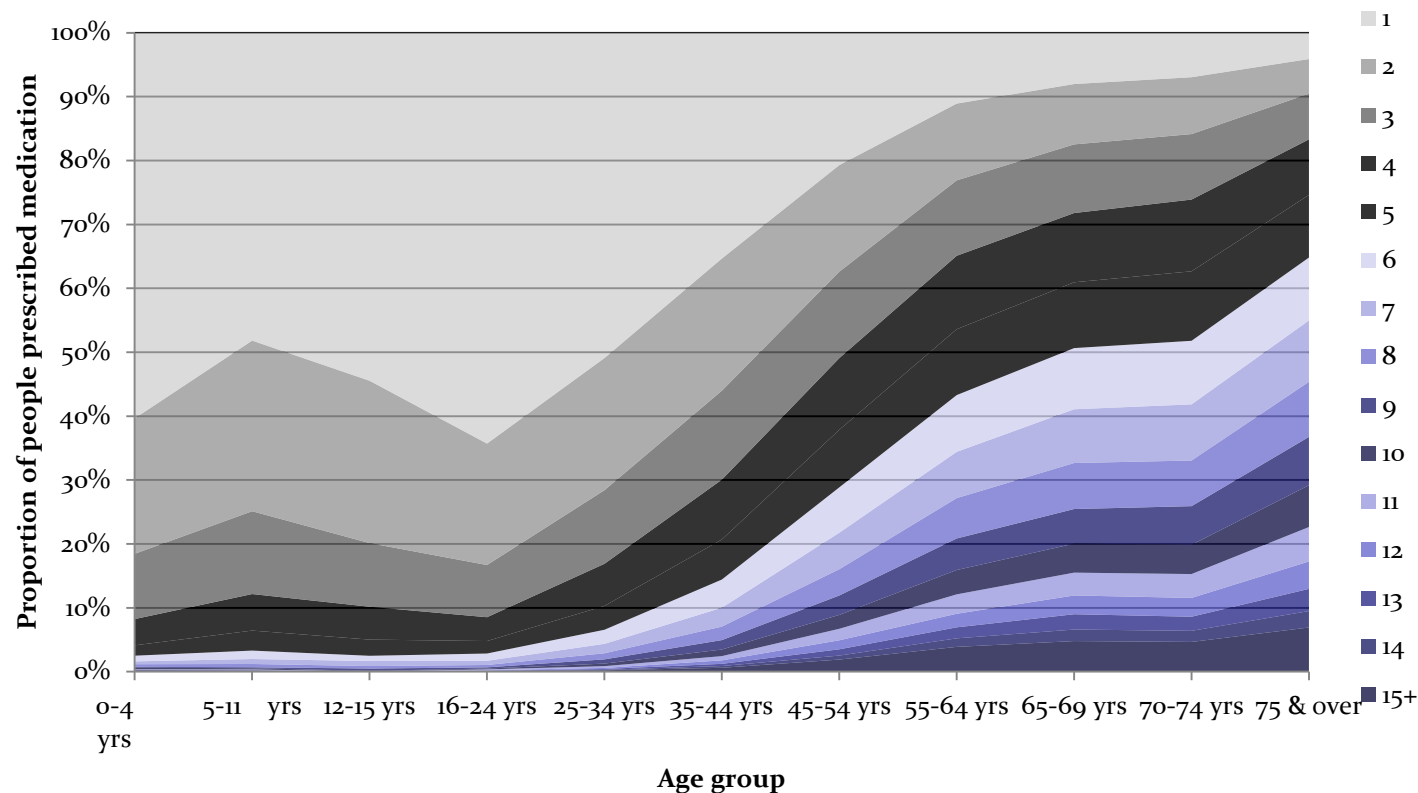
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Primary Care Reimbursement Scheme (PCRS) 2002



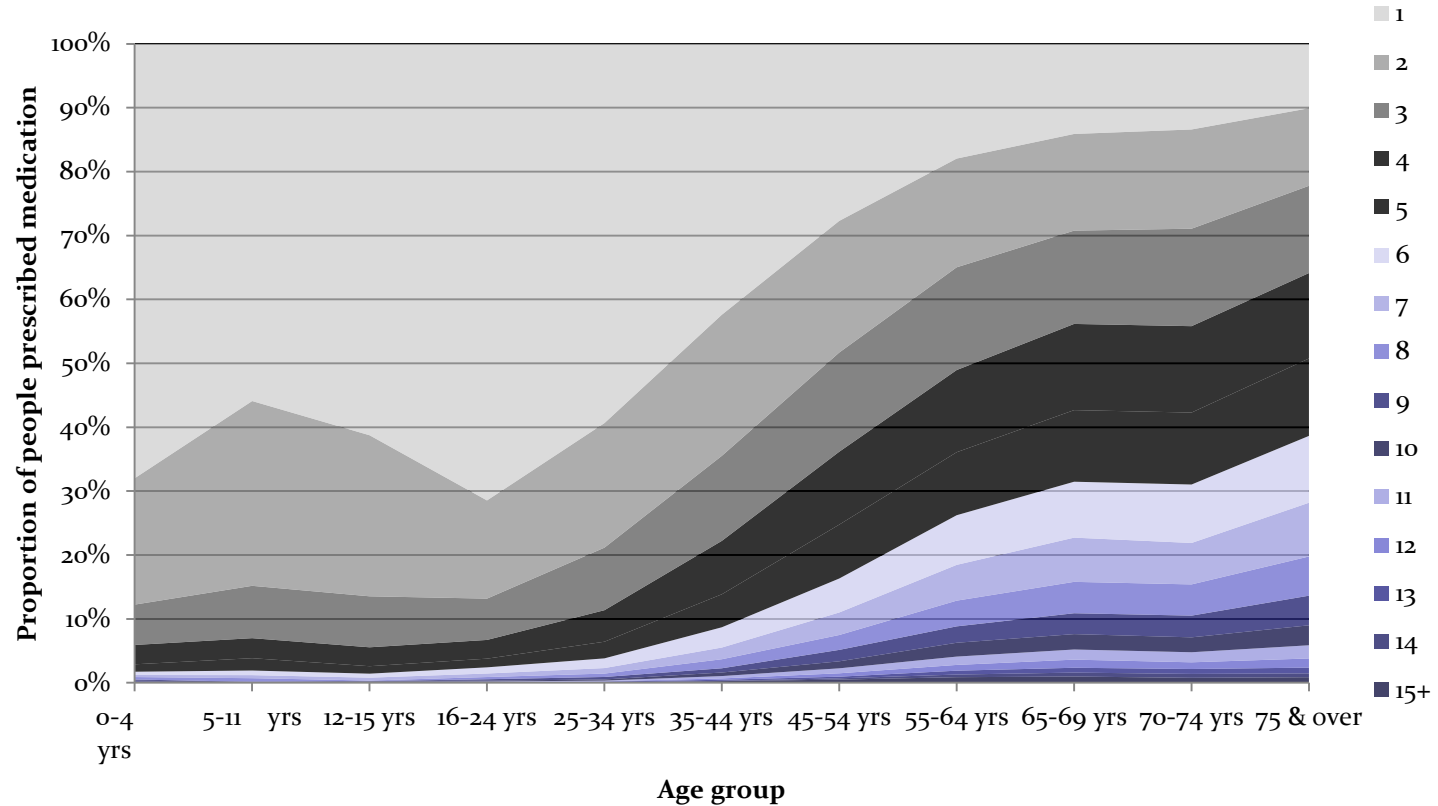
2012



Primary Care Reimbursement Scheme (PCRS) 2012



2002



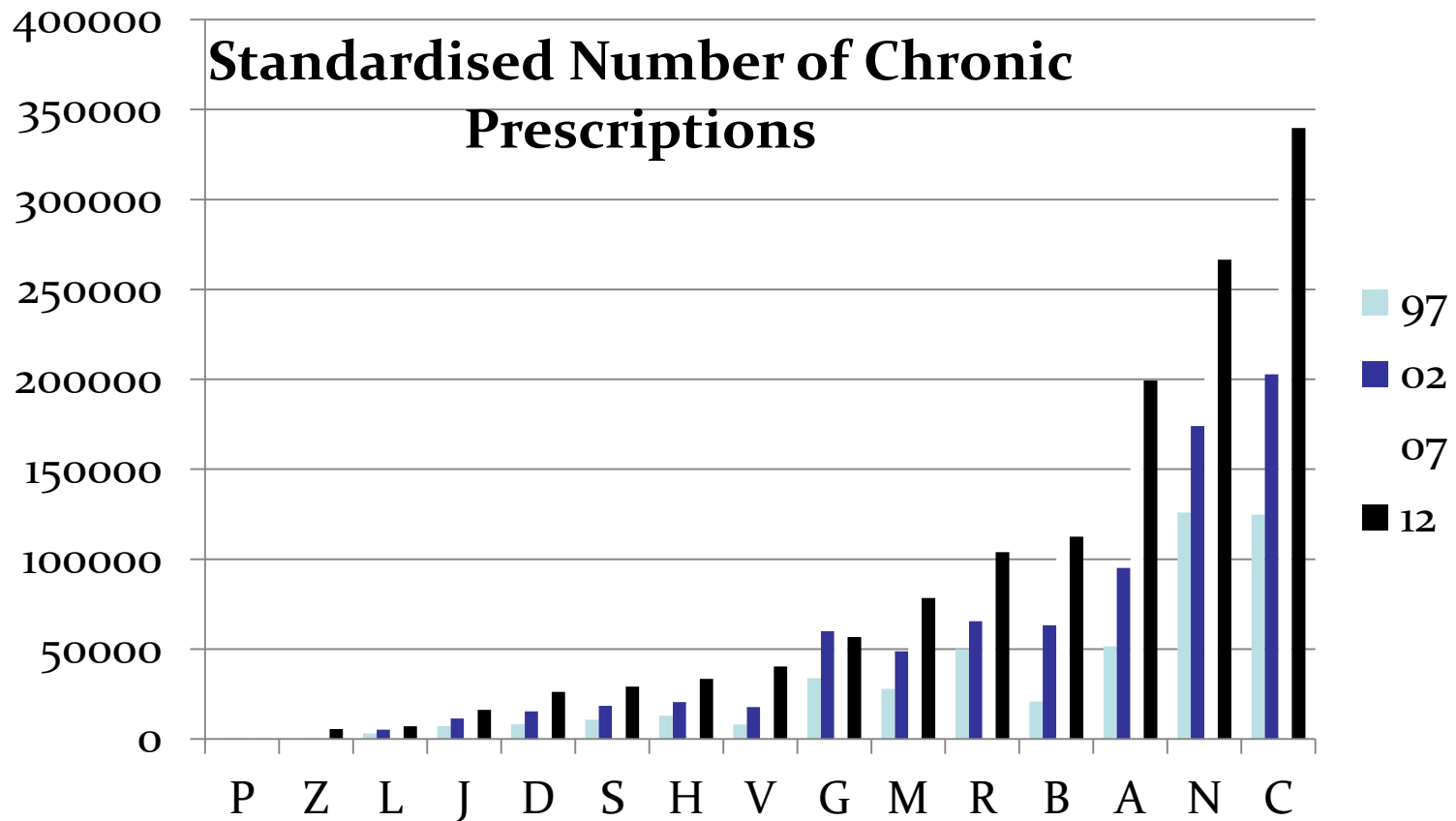
PCRS- Polypharmacy (≥ 5 medicines) across age category

| Age category | Adjusted odds ratio | Lower 95% CI | Upper 95% CI |
|--------------|---------------------|--------------|--------------|
| <5 Years | 0.07 | 0.06 | 0.08 |
| 5-15 Years | 0.09 | 0.08 | 0.10 |
| 16-44 Years | 1 (reference) | – | – |
| 45-64 Years | 7.01 | 6.89 | 7.14 |
| 65+ Years | 16.25 | 15.99 | 16.52 |

PCRS- Polypharmacy (≥ 5 medicines) over time

| Year | Adjusted odds ratio | Lower 95% CI | Upper 95% CI |
|------|---------------------|--------------|--------------|
| 1997 | 1 (reference) | – | – |
| 2002 | 2.02 | 1.98 | 2.05 |
| 2007 | 3.32 | 3.26 | 3.37 |
| 2012 | 3.82 | 3.76 | 3.88 |

Quantity of prescribing over time (PCRS)



Quality of care for elderly residents in nursing homes and elderly people living at home: controlled observational study

Tom Fahey, Alan A Montgomery, James Barnes, Jo Protheroe

Abstract

Objectives To assess the quality of care given to elderly people and compare the care given to residents in nursing homes with those living in their own homes.

Design Controlled observational study.

Setting Primary care, Bristol.

Subjects Elderly individuals (aged ≥ 65 years) registered with three general practices, of whom 172 were residents in nursing homes (cases) and 526 lived at home (matched controls).

Main outcome measures The quality of clinical care given to patients was measured against explicit standards. Quality indicators were derived from national sources and agreed with participating general practitioners.

Results The overall standard of care was inadequate when judged against the quality indicators, irrespective of where patients lived. The overall prescribing of beneficial drugs for some conditions was deficient—for example, only 38% (11/29) (95% confidence interval 20% to 58%) of patients were prescribed β blockers after myocardial infarction. The proportion of patients with heart disease or diabetes who had had their blood pressure measured in the past two years (heart disease) or past year (diabetes)

Introduction

Concern has been expressed about the quality of medical care that elderly residents receive in residential and nursing homes.¹ General practitioners are responsible for the delivery of such care to residents in these homes. The number of elderly patients living in nursing homes rose substantially in the late 1980s and in the 1990s, resulting in a rise in workload for general practitioners.^{1,2} Concern has been expressed that the reduction in provision of long stay NHS beds for elderly people has increased the demand on general practitioners in this group of patients with high morbidity and disability.^{1,2} In response to these increasing demands, the arrangements made by general practices for delivering care to nursing homes seems to be inconsistent and idiosyncratic.³

More widespread concern has been expressed about drug treatment in elderly people.⁴ Anxiety about the risks of excessive prescribing of, for example, inappropriate neuroleptic drugs,⁵ is matched by concern about the consequences of the underprescribing of potentially beneficial drugs.⁴

Care of elderly people is now a national priority,⁶ and the quality of care delivered to patients is coming under increasing scrutiny through the use of explicit measures—"quality indicators"—which seek to judge the process of care against specific standards.^{7,8} No study has

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Measuring inappropriate prescribing

- Appropriate prescribing- “Maximise efficacy and safety, minimise cost, and respect patient’s preferences”
- Inappropriate medications
 - Unclear indication
 - Increased risk of adverse events
 - Not cost effective
- Measuring inappropriate prescribing
 - Process or outcome measures
 - Implicit (judgment based) / Explicit (criterion based)

Background

- Screening Tool of Older Person's potentially inappropriate Prescriptions (STOPP)
 - 64 clinically significant criteria
 - Drug-drug and drug-disease interactions
 - Doses and duration

STOPP

A. Cardiovascular System

1. Digoxin at a long-term dose $> 125\mu\text{g}/\text{day}$ with impaired renal function* (*increased risk of toxicity*).
2. Loop diuretic for dependent ankle oedema only i.e. no clinical signs of heart failure (*no evidence of efficacy, compression hosiery usually more appropriate*).

Inappropriate prescribing: a systematic overview of published assessment tools

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Kurt E. Hersberger · Markus L. Lampert

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Abstract

Background Criteria to assess the appropriateness of prescriptions might serve as a helpful guideline during professional training and in daily practice, with the aim to improve a patient's pharmacotherapy.

Objective To create a comprehensive and structured overview of existing tools to assess inappropriate prescribing.

Method Systematic literature search in Pubmed (1991–2013). The following properties of the tools were extracted and mapped in a structured way: approach (explicit, implicit), development method (consensus technique, expert panel, literature based), focused patient group, health care setting, and covered aspects of inappropriate prescribing.

Results The literature search resulted in 46 tools to assess inappropriate prescribing. Twenty-eight (61%) of 46 tools were explicit, 8 (17%) were implicit and 10 (22%) used a

in choosing a tool, either for research purposes or for daily practice use.

Keywords Drug-related problems · inappropriate prescribing · assessment tool · drug safety

Introduction

The appropriate prescription of medication should “maximise efficacy and safety, minimise cost, and respect patient's preferences” [1]. Choosing the most appropriate medication for each patient in order to achieve desired therapeutic outcomes is a challenge for healthcare professionals in their daily practice [2]. Criteria to assess the appropriateness of prescriptions and to improve a patient's pharmacotherapy might serve as a

Systematic review PIP indicators

- Following a ‘systematic literature search’, identified 46 different tools
 - English and German publications only
- 36 named older people as target patients
 - 10 did not specify target age group
 - Various settings
- Consensus methods used in development of 19 tools
- Over-, under- and mis-prescribing

No perfect set of indicators

- The **ideal set** of indicators-
 - Cover all aspects of appropriateness
 - Be developed using evidence-based methods
 - Show significant relationship between degree of appropriateness and clinical outcomes
 - Be applicable not only in research context but in health care practice

Table 1

Prevalence of potentially inappropriate prescribing by individual STOPP criteria in 2007

| Criteria description | n | % | Proportionate prescribing per indication (%)* |
|---|---------|-------|---|
| Cardiovascular system | | | |
| Digoxin >125 µg day ⁻¹ (increased risk of toxicity) | 1 211 | 0.36 | 4.97 |
| Thiazide diuretic with gout (exacerbate gout) | 1 216 | 0.36 | 10.34 |
| β-adrenoceptor blocker with COPD† (risk of increased bronchospasm) | 7 924 | 2.34 | 21.20 |
| β-adrenoceptor blocker with verapamil (risk of symptomatic heart block) | 800 | 0.24 | – |
| Aspirin and warfarin without histamine H ₂ -receptor antagonist (except cimetidine) or PPI† (high risk of gastrointestinal bleeding) | 3 693 | 1.09 | 2.69 |
| Dipyridamole as monotherapy for cardiovascular secondary prevention (no evidence of efficacy) | 219 | 0.06 | – |
| Aspirin >150 mg day ⁻¹ (increased bleeding risk) | 5 712 | 1.69 | 3.58 |
| Central nervous system and psychotropic drugs | | | |
| TCA† with dementia (worsening cognitive impairment) | 609 | 0.18 | 4.34 |
| TCA and glaucoma (exacerbate glaucoma) | 465 | 0.14 | 4.44 |
| TCA and opiate or calcium channel blockers (risk of severe constipation) | 6 944 | 2.05 | – |
| Long-term (i.e. >1 month), long-acting benzodiazepines (risk of prolonged sedation, confusion, impaired balance, falls) | 17 676 | 5.22 | 40.37 |
| Long-term (i.e. >1 month) neuroleptics (risk of confusion, hypotension, extrapyramidal side-effects, falls) | 5 688 | 1.67 | 13.96 |
| Long-term (i.e. >1 month) neuroleptics with parkinsonism (worsen extrapyramidal symptoms) | 1 298 | 0.38 | 13.87 |
| Anticholinergics to treat extrapyramidal side effects of neuroleptic medications (risk of anticholinergic toxicity) | 1 527 | 0.45 | 71.43 |
| Phenothiazines with epilepsy (may lower seizure threshold) | 813 | 0.24 | 7.69 |
| Prolonged use (i.e. >1 week) of first-generation antihistamines (risk of sedation and anti-cholinergic side-effects) | 3 248 | 0.96 | 85.71 |
| Gastrointestinal system | | | |
| Prochlorperazine or metoclopramide with parkinsonism (risk of exacerbating parkinsonism) | 726 | 0.21 | 7.66 |
| PPI for peptic ulcer disease at maximum therapeutic dosage for >8 weeks† (dose reduction or earlier discontinuation indicated) | 56 560 | 16.69 | 38.89 |
| Respiratory system | | | |
| Theophylline with COPD (risk of adverse effects due to narrow therapeutic index) | 4 008 | 1.18 | 10.69 |
| Nebulized ipratropium with glaucoma (exacerbate glaucoma) | 50 | 0.01 | 0.32 |
| Musculoskeletal system | | | |
| Long-term use of NSAID† (i.e. >3 months) for pain relief (simple analgesics preferable) | 29 691 | 8.76 | 23.19 |
| Warfarin and NSAID (risk of gastrointestinal bleeding) | 2 535 | 0.75 | – |
| Urogenital system | | | |
| Antimuscarinic drugs with dementia (risk of increased confusion, agitation) | 1 568 | 0.46 | 7.21 |
| Antimuscarinic drugs with chronic glaucoma (>3 months) (risk of acute exacerbation of glaucoma) | 0 | <0.01 | – |
| Endocrine system | | | |
| Glibenclamide or chlorpropamide with type 2 diabetes mellitus (risk of prolonged hypoglycemia) | 976 | 0.29 | 3.27 |
| Duplicate drug class prescription (optimization of monotherapy within a single drug class) | | | |
| Two concurrent opiates | 4 185 | 1.24 | 6.18 |
| Two concurrent NSAIDs | 7 532 | 2.22 | 5.88 |
| Two concurrent SSRIs† | 79 | 0.02 | 0.19 |
| Two concurrent antidepressants | 834 | 0.25 | 4.56 |
| Two concurrent loop diuretics | 332 | 0.10 | 0.58 |
| Two concurrent ACE inhibitors† | 3 643 | 1.08 | 4.10 |
| All duplicates | 16 201§ | 4.78 | – |

*Proportionate prescribing per indication, e.g. prevalence of STOPP criteria as a proportion of the overall disease or drug prevalence, e.g. digoxin >125 µg as a proportion of overall

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Prevalence of PIP

- PIP is prevalent in the older population (> 70 years)
 - Republic of Ireland 36%
 - Northern Ireland 34%
 - United Kingdom 29%

BJCP British Journal of Clinical Pharmacology

Potentially inappropriate prescribing and cost outcomes for older people: a national population study

Caitriona Cahir,¹ Tom Fahey,¹ Mary Teeling,² Conor Teljeur,³ John Feely² & Kathleen Bennett²

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PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Potentially inappropriate prescribing and cost outcomes for older people: a cross-sectional study using the Northern Ireland Enhanced Prescribing Database

Marie C. Bradley • Tom Fahey • Caitriona Cahir • Kathleen Bennett • Dermot O'Reilly • Carole Parsons • Carmel M. Hughes

Results-PIP prevalence rates RoI (n=338,801)

| STOPP | % | n |
|--------------------|------------|----------------|
| ONE PIP | 25% | 83,959 |
| TWO PIP | 8% | 27,392 |
| > THREE PIP | 3% | 10,103 |
| OVERALL PIP | 36% | 121,454 |

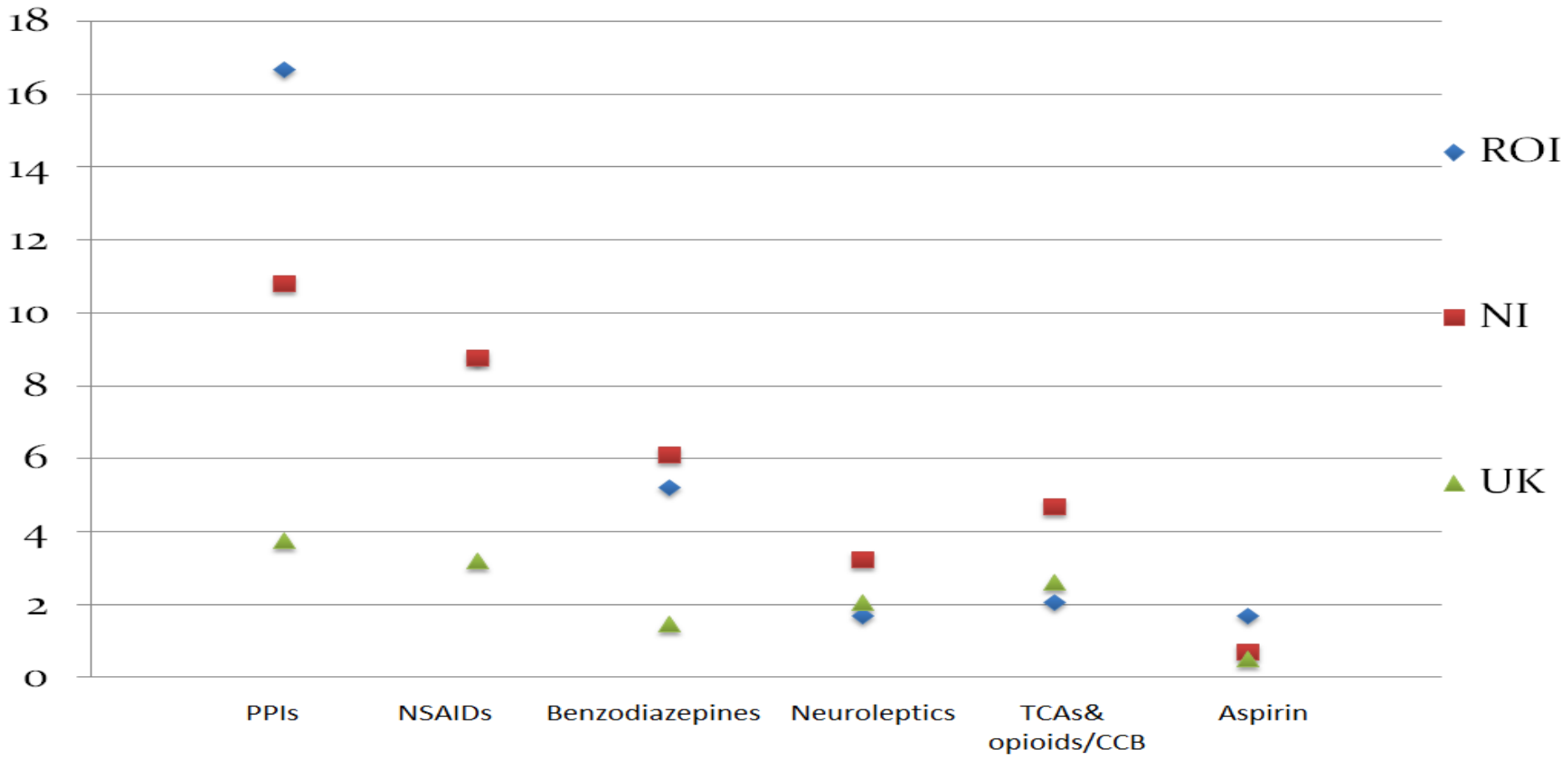
5 highest prevalence rates -RoI(n=338,801)

| | STOPP DESCRIPTION | PREV % | OR GENDER (F vs M) | OR AGE (>75 vs 70-74) |
|------------------|---|--------|-----------------------|--------------------------|
| Gastrointestinal | PPI > 8 weeks full therapeutic dose (dose reduction, discontinuation) | 16.69% | 0.80 (0.78-0.81) | 1.05 (1.02-1.07) |
| Musculoskeletal | NSAID >3M (simple analgesics preferable) | 8.76% | 1.25 (1.22-1.28) | 0.78 (0.76-0.81) |
| CNS | >1M Long-acting benzodiazepines (risk of falls, fractures) | 5.22% | 1.72 (1.65- 1.78) | 0.89 (0.87-0.92) |
| Duplicates | NSAIDs, SSRIs, Antidep, ACE, Loop diuretics, opioids (optimisation of monotherapy) | 4.78% | 1.19 (1.15-1.23) | 0.74 (0.71-0.76) |
| Cardiovascular | Beta-blocker with COPD (risk of increased bronchospasm) | 2.34% | 0.53 (0.51-0.56) | 0.84 (0.80-0.89) |

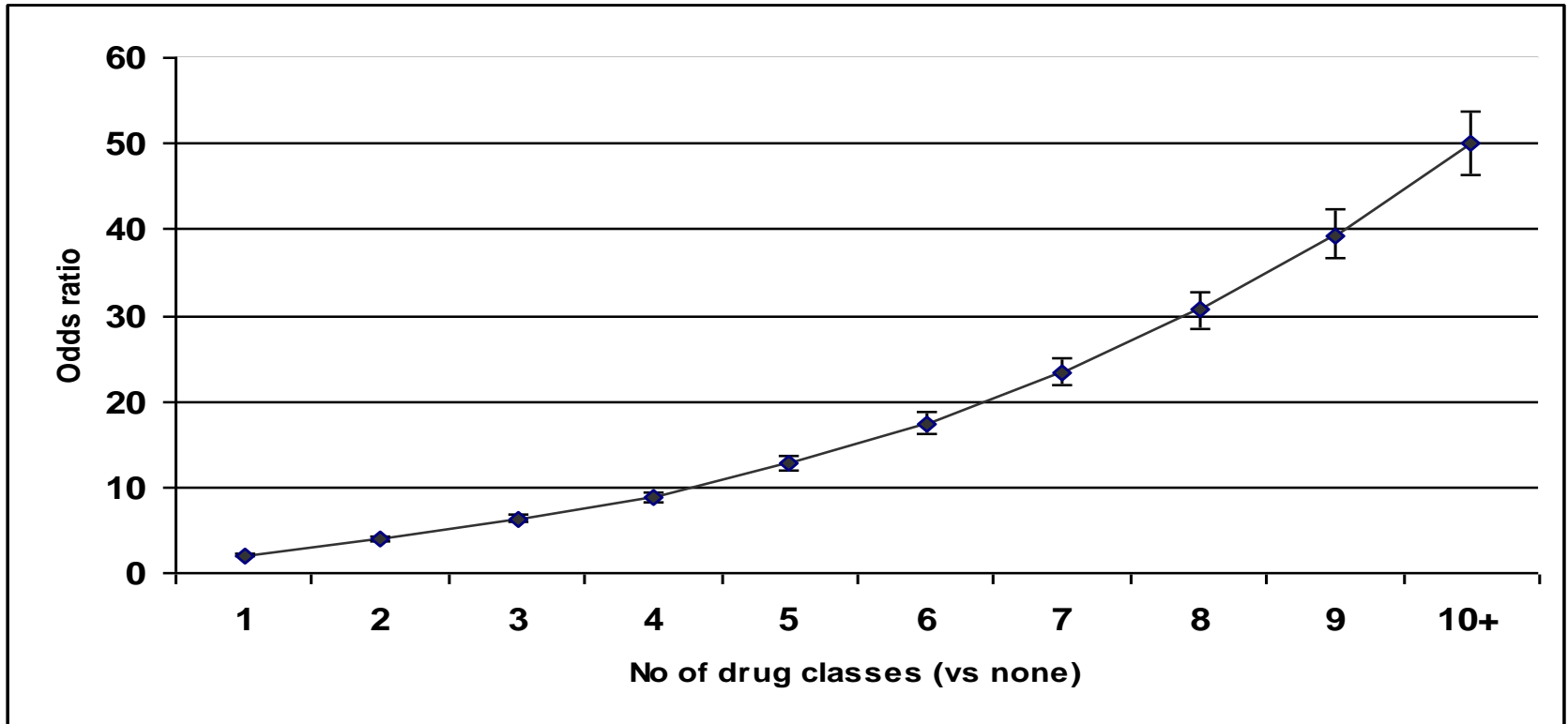
Cost of PIP-RoI

- Gross cost of PIP for one year (2007) €38,664,640
- Total expenditure (gross cost, VAT,+pharmacist dispensing fee) €45,631,319
- Total expenditure accounted for 9% of overall expenditure on pharmaceuticals in those aged ≥ 70 years in 2007

The prevalence of the most common STOPP/START PIP indicators across three regions



Association between the number of different drug classes (polypharmacy) and PIP (STOPP) in 2007 (95% CI)-RoI



* Linear and quadratic trend $p < 0.0001$



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TILDA is a nationally representative survey of the Irish population aged 50 and over and their spouses or partners.

Welcome to The Irish Longitudinal Study on Ageing (TILDA)

The Irish Longitudinal Study on Ageing (TILDA) is a large-scale, nationally representative, longitudinal study on ageing in Ireland, the overarching aim of which is to make Ireland the best place in the world to grow old.

TILDA collects information on all aspects of health, economic and social circumstances from people aged 50 and over in a series of data collection waves once every two years. TILDA is unique amongst longitudinal studies in the breadth of physical, mental health and cognitive measures collected. This data, together with the extensive social and economic data, makes TILDA one of the most comprehensive research studies of its kind both in Europe and internationally.

NEWS & EVENTS

RESEARCH THEMES

TILDA PARTICIPANTS



APRIL 2014

Table 3 START (Screening Tool to Alert doctors to Right Treatment) criteria applied to TILDA data for all those aged ≥ 65 years in Ireland in 2010

| START criteria description | Potential prescribing omissions (n) | Potential prescribing omissions (%) | Proportionate prescribing omission per indication (%)* |
|--|-------------------------------------|-------------------------------------|--|
| Cardiovascular system | | | |
| Warfarin in the presence of chronic atrial fibrillation | 270 | 7.82 | 75.00 |
| Antihypertensive therapy where systolic blood pressure consistently >160 mmHg \dagger | 341 | 9.87 | 18.62 |
| Angiotensin Converting Enzyme (ACE) inhibitor with chronic heart failure | 23 | 0.67 | 42.59 |
| ACE inhibitor following acute myocardial infarction | 126 | 3.65 | 47.19 |
| Beta-blocker with chronic stable angina | 151 | 4.37 | 45.21 |
| Central nervous system | | | |
| L-DOPA in idiopathic Parkinson's disease with definite functional impairment and resultant disability | 3 | 0.09 | 17.65 |
| Antidepressant drug in the presence of moderate-severe depressive symptoms lasting at least 3 months \S | 44 | 1.30 | 70.97 |
| Endocrine system | | | |
| ACE inhibitor or Angiotensin Receptor Blocker in diabetes with nephropathy, i.e., overt urinalysis proteinuria | 13 | 0.38 | 44.83 |
| Antiplatelet therapy in diabetes mellitus if one or more co-existing major cardiovascular risk factor present (hypertension, hypercholesterolaemia, smoking history) | 110 | 3.18 | 35.48 |
| Statin therapy in diabetes mellitus if one or more co-existing major cardiovascular risk factor present | 235 | 6.80 | 75.81 |

*Proportionate prescribing omission per indication, e.g. prevalence of PPO as a proportion of the overall disease, e.g. no warfarin with chronic atrial fibrillation as a proportion of chronic atrial fibrillation prevalence

\S 70 (2.03 %) missing data for depressive symptoms variable

\dagger 1,119 (32.40 %) missing data for blood pressure variable

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NEWS & EVENTS

RESEARCH THEMES

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Healthcare utilisation- hospital visits

- TILDA participants- 26% reported a hospital visit in previous 12 months at baseline interview
- 1 visit: 12.5%, 2 visits: 7.4%, 3 visits: 2.3%, ≥ 4 visits: 3.8%
- Separate multivariate poisson regression models for each screening tool adjusting for:
 - Sex (54% female)
 - Age (mean [SD] = 74.8 [6.2] years)
 - SES/education (31% secondary, 17% tertiary)
 - No. of chronic conditions (mean [SD] = 2.4 [1.6])
 - No. of medicines (mean [SD] = 4.1 [2.9])
 - Private health insurance status (43%)

Results – hospital visits

| | Hospital visits | |
|--------------------------------------|-------------------------|-----------------------|
| | Unadjusted IRR (95% CI) | Adjusted IRR (95% CI) |
| Number of STOPP PIPs | 1.35 (1.27-1.44)** | 1.24 (1.15-1.35)** |
| Sex (female) | 0.92 (0.71-1.18) | 0.78 (0.61-0.99)* |
| Age (in years) | 0.99 (0.97-1.02) | 0.99 (0.96-1.01) |
| Level of education | 1.03 (0.88-1.21) | 1.08 (0.91-1.28) |
| Number of repeat drug classes | 1.14 (1.10-1.18)** | 1.05 (0.99-1.13) |
| Number of chronic conditions | 1.25 (1.16-1.36)** | 1.12 (0.99-1.27) |
| Private health insurance | 0.87 (0.68-1.10) | 0.89 (0.68-1.16) |

Results – GP visits

| | GP visits | |
|--------------------------------------|-------------------------|-----------------------|
| | Unadjusted IRR (95% CI) | Adjusted IRR (95% CI) |
| Number of STOPP PIPs | 1.16 (1.13-1.20)** | 1.08 (1.04-1.12)** |
| Sex (female) | 0.97 (0.87-1.08) | 0.90 (0.82-0.99)* |
| Age (in years) | 1.01 (0.99-1.02) | 1.0 (0.99-1.01) |
| Level of education | 0.91 (0.85-0.98)* | 0.96 (0.90-1.03) |
| Number of repeat drug classes | 1.09 (1.07-1.11)** | 1.05 (1.02-1.08)* |
| Number of chronic conditions | 1.15 (1.10-1.21)** | 1.07 (1.0-1.15)* |
| Private health insurance | 0.82 (0.74-0.90)** | 0.87 (0.79-0.95)* |

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Potentially inappropriate prescribing and adverse health outcomes in community dwelling older patients

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Previous studies have evaluated the prevalence and patterns of potentially inappropriate prescribing (PIP) in older populations but its effect on health outcomes (adverse drug events (ADEs), health related quality of life (HRQOL) and hospital visits) is still largely unknown.
- Information on ADEs in older populations in hospitals and nursing home settings has grown substantially but there is limited information on ADEs in community dwelling patients.
- Patient reported outcomes and adherence play an important role in assessing the efficacy of drug treatment in community dwelling older populations and few studies have considered such patient centred outcomes.

WHAT THIS STUDY ADDS

- Almost 80% of the cohort of community dwelling older patients experienced at least one ADE in

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Contributors CC, TF, KB and CT planned and designed the study. TF and CC interpreted the STOPP criteria and their application to the prescribing database. CC, KB and CT analysed the study data. CC drafted the manuscript. KB, CT and TF critically reviewed and approved the final manuscript. TF is guarantor.

Keywords

adverse drug events, health care use, HRQOL, older populations, potentially inappropriate prescribing, STOPP

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AIMS

This study aimed to determine the association between potentially inappropriate prescribing (PIP) and health related outcomes [adverse drug events (ADEs), health related quality of life (HRQOL) and hospital accident and emergency (A&E) visits] in older community dwelling patients.

METHODS

A retrospective cohort study of 931 community dwelling patients aged ≥ 70 years in 15 general practices in Ireland in 2010. PIP was defined by the Screening Tool of Older Person's Prescriptions (STOPP). ADEs were measured by patient self-report and medical record for the previous 6 months and reviewed by two independent clinicians. HRQOL was measured by the EQ-5D. A&E visits were measured by patients' medical records and self-report. Multilevel logistic, linear and Poisson regression examined how ADEs, HRQOL and A&E visits varied by PIP after adjusting for patient and practice level covariates: socioeconomic status, co-morbidity, number of drug classes and adherence.

RESULTS

Impact PIP drugs

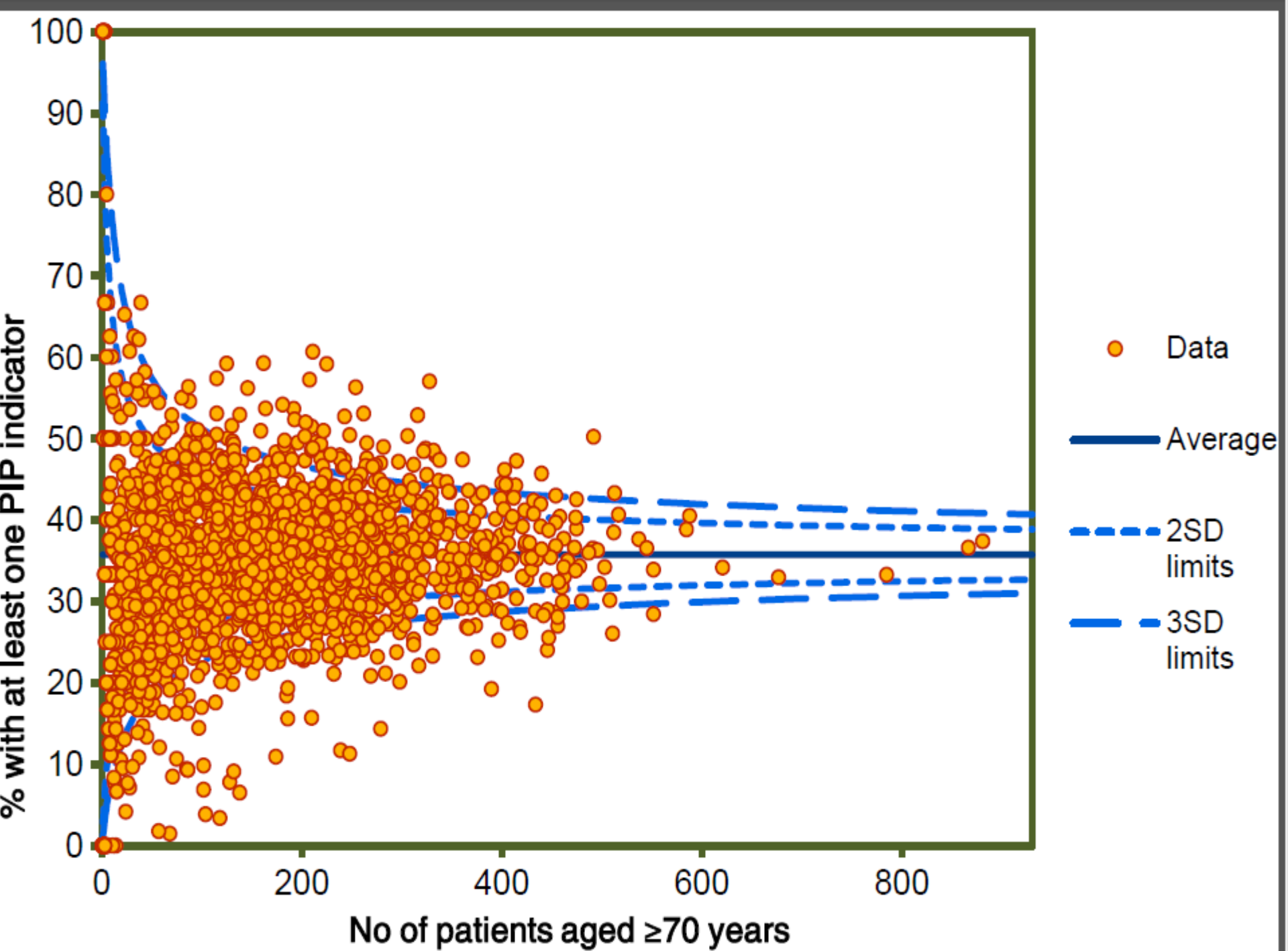
- Overall PIP 42%
- ≥ 2 PIP drugs
 - Increase risk of ADE adjusted OR 2.21, (95% CI 1.02, 4.83)
 - Reduced QOL, adjusted co-efficient -0.09, (SE 0.02)
 - Increased A&E visits, adjusted IRR1.85 (95% CI 1.32, 2.58)

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Practice level variation in PIP

- Is the prevalence of PIP consistent or different across practices in RoI?
- Informs design and conduct of an intervention as part of an RCT



PIP practice level variation

- Unadjusted variation in PIP considerable
 - Median 35% (IQR 30-40%)
- Adjustment for patient-level factors
 - Proportion PIP varied fourfold (0.5 to 2) at practice level
 - Majority of variation not significant
- Multi-level regression
 - Number of repeat drugs (>2 v none)
 - Adjusted odds ratio 4.0 (95% CI 3.7, 43)

Summary PIP indicators

- High prevalence
 - Between country differences in PIP drug categories
- Impact of PIP
 - Healthcare utilisation, ADEs, HRQOL
- Practice level variation
- Polypharmacy
 - Consistent association with PIP

Overview

- Background & context
 - Medicines utilization
 - Potentially inappropriate prescribing indicators
- Observational epidemiology PIP
 - National & International comparisons
 - Healthcare utilization
 - Medical practice variation
- Quality Improvement RCT of PIP

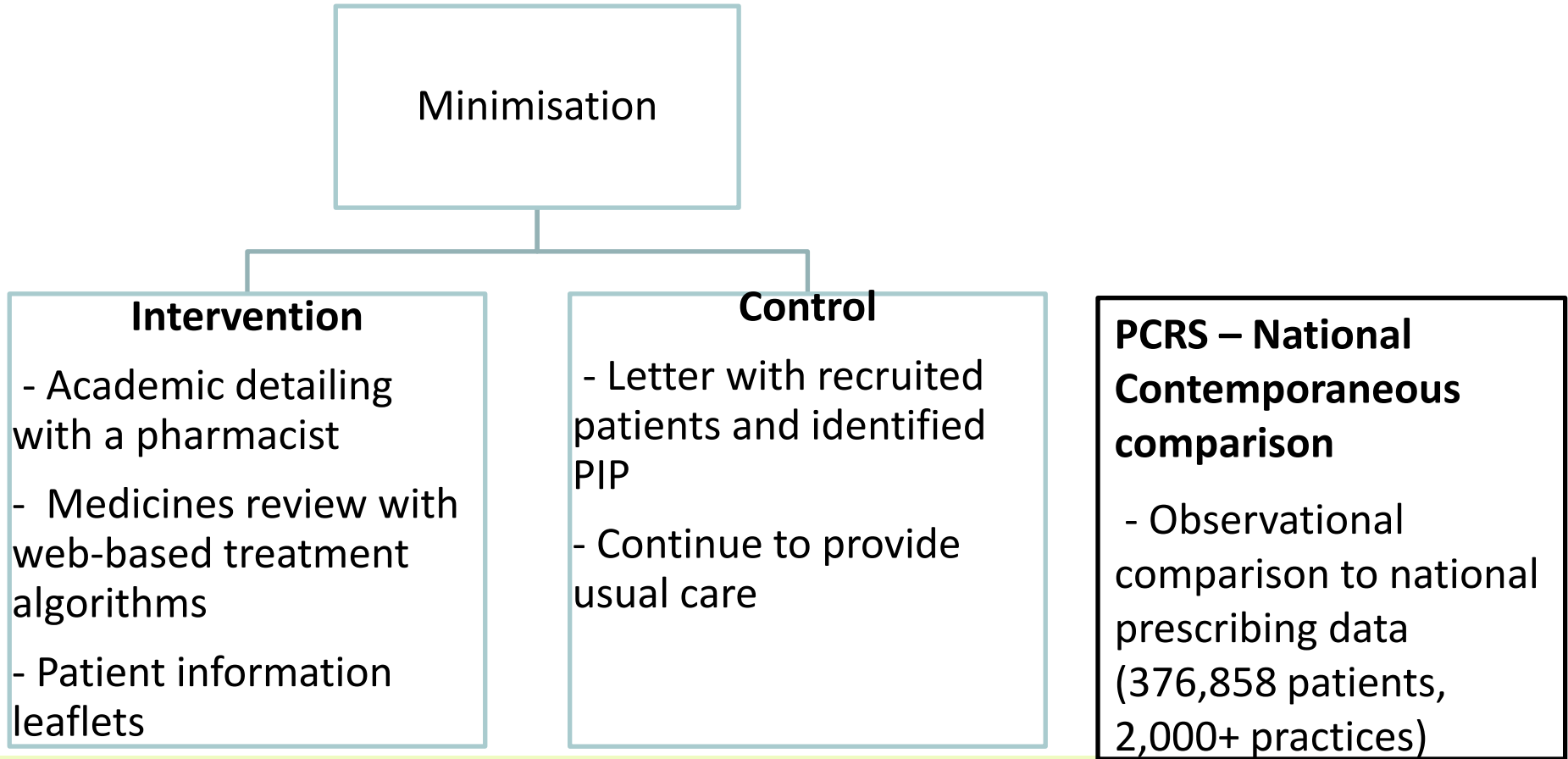
OPTI-SCRIPT study development

- Guided by UK MRC Framework for design of interventions
- Development stage:
 - Literature review to identify criteria (e.g. STOPP, Beers, IPET) and prevalence studies in Ireland and intervention literature
 - Consensus based methodology and patient case studies with panel of experts to determine clinical significance of indicators
 - 34 indicators selected for clinical significant and/or prevalence in Irish primary care
 - Intervention components identified
- Pilot stage:
 - 5 GPs tested the proposed intervention

Study design & methodology – cluster RCT

- GPs inclusion criteria:
 - Based in greater Dublin area
 - 80+ patients aged over 70
- Patients inclusion criteria:
 - Aged 70+
 - Had PIP as per study list
- Recruited and baseline data collection prior to minimisation

Study overview



STUDY PROTOCOL

Open Access

Effectiveness of medicines review with web-based pharmaceutical treatment algorithms in reducing potentially inappropriate prescribing in older people in primary care: a cluster randomized trial (OPTI-SCRIPT study protocol)

Barbara Clyne^{1*}, Marie C Bradley², Susan M Smith¹, Carmel M Hughes², Nicola Motterlini^{1^}, Daniel Clear¹, Ronan McDonnell¹, David Williams³, Tom Fahey¹ and on behalf of the OPTI-SCRIPT study team

Abstract

Background: Potentially inappropriate prescribing in older people is common in primary care and can result in increased morbidity, adverse drug events, hospitalizations and mortality. In Ireland, 36% of those aged 70 years or over received at least one potentially inappropriate medication, with an associated expenditure of over €45 million. The main objective of this study is to determine the effectiveness and acceptability of a complex, multifaceted intervention in reducing the level of potentially inappropriate prescribing in primary care.

Methods/design: This study is a pragmatic cluster randomized controlled trial, conducted in primary care (OPTI-SCRIPT trial), involving 22 practices (clusters) and 220 patients. Practices will be allocated to intervention or control arms using minimization, with intervention participants receiving a complex multifaceted intervention incorporating academic detailing, medicines review with web-based pharmaceutical treatment algorithms that provide

OPTI-SCRIPT website

OPTISCRIP

Online Resource



| | | |
|---|---|---|
| Patient ID: 15 Proton Pump Inhibitors (PPIs) To Do Full Therapeutic Dose > 8 weeks | Patient ID: 18 Long Acting Benzodiazepines Done long acting, long term (>1 month) | Patient ID: 23 Long Acting Benzodiazepines Done long acting, long term (>1 month) |
| PIP Outcome Form To Do Please fill this in for each PIP! | PIP Outcome Form Done Please fill this in for each PIP! | PIP Outcome Form Done Please fill this in for each PIP! |
| Non-steroidal anti-inflammatory drugs (NSAIDs) To Do Warfarin, SSRI, ACE inhibitor, Diuretic, Congestive Heart Failure, Peptic Ulcer Disease, Long-term use for mild osteoarthritis | | Non-steroidal anti-inflammatory drugs (NSAIDs) To Do Warfarin, SSRI, ACE inhibitor, Diuretic, Congestive Heart Failure, Peptic Ulcer Disease, Long-term use for mild osteoarthritis |
| PIP Outcome Form To Do Please fill this in for each PIP! | | PIP Outcome Form To Do Please fill this in for each PIP! |
| | | |

Long Acting Benzodiazepines

Back to
Patients

Complete
Outcome
Form

Long-acting Benzodiazepines

Section A Potentially Inappropriate Prescription:

Any long-term (>1 month), long-acting benzodiazepine, i.e. chlordiazepoxide, flurazepam, nitrazepam or chlorazepate

OR

Any benzodiazepine with long-acting metabolites, i.e. Diazepam (except for use in benzodiazepine detoxification)

Due to an increased Risk of prolonged sedation, confusion, impaired balance and falls

Section B Alternatives:

Consider the following condition specific alternatives for:

1. [Insomnia](#)
2. [Generalised Anxiety Disorder \(GAD\)](#)
3. [Panic Disorder](#)

Study design & methodology – cluster RCT

- Primary outcome measures:
 - Proportion of patients with no PIP
 - Mean PIP per group
- Data collection baseline & immediate post intervention
- Between group differences:
 - Random effects logistic regression
 - Cluster mean
 - Random effects poisson regression

OPTI-SCRIPT RCT results

- Participants
 - 21 GP practices (32% cluster response rate)
 - 196 patients (37% response rate)
- Minimisation

Intervention

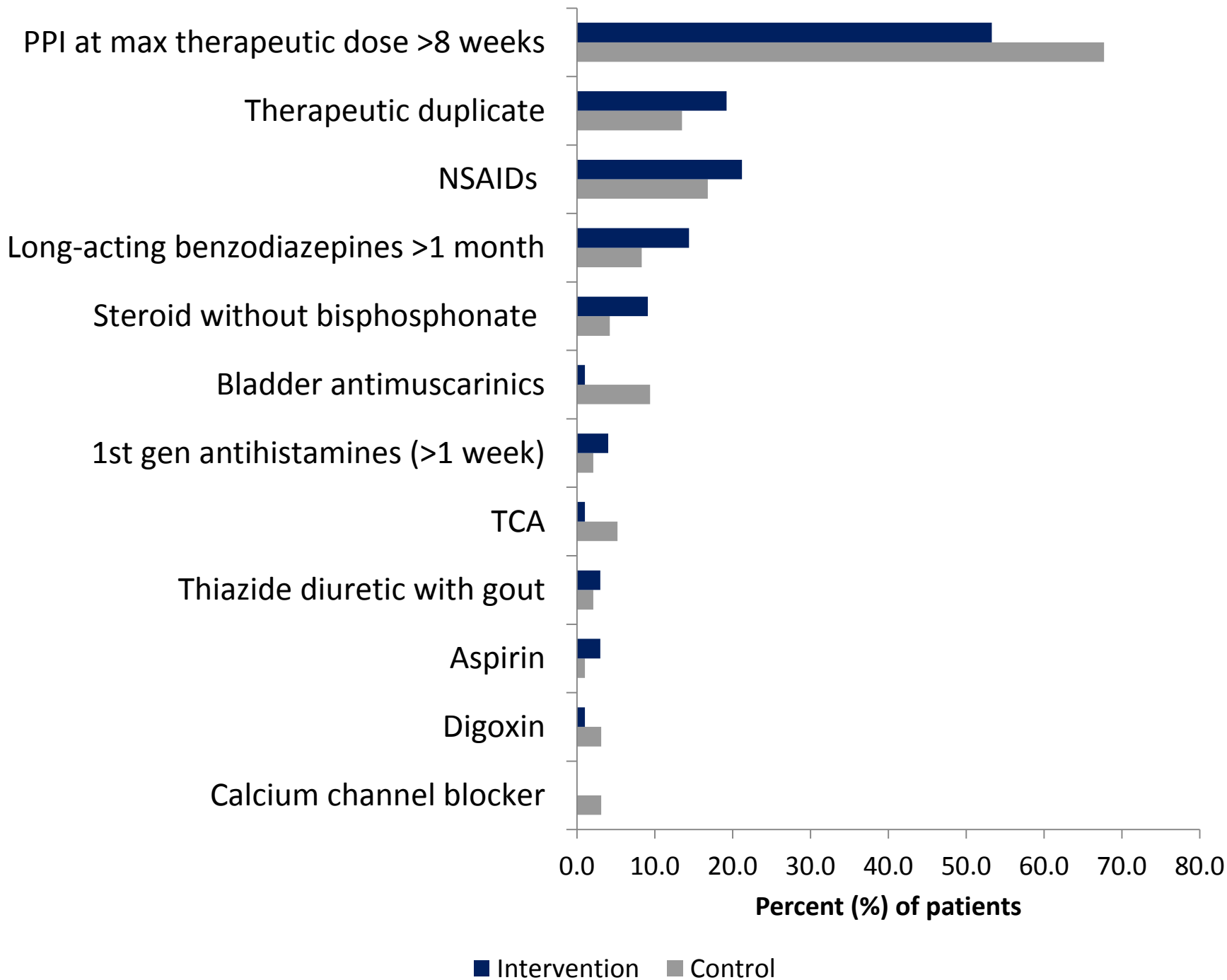
11 practices
99 patients

Control

10 practices
97 patients

Baseline characteristics

| Characteristic | Intervention | | Control | |
|--|---------------|------|---------------|------|
| | N | % | N | % |
| Male | 55 | 55.6 | 50 | 51.5 |
| Mean age | 77.1 (SD 4.9) | | 76.4 (SD 4.8) | |
| Marital status | | | | |
| Married | 56 | 56.6 | 51 | 53.1 |
| Widowed | 26 | 26.3 | 32 | 33.3 |
| Single | 14 | 14.1 | 10 | 10.4 |
| GMS card holder | 88 | 88.9 | 95 | 97.9 |
| Mean number of repeat medications | 10.2 (SD 4.5) | | 9.5 (SD 4.1) | |



Outcome – Proportion with PIP

| Group | N | Number of patients with no PIP | % of patients with no PIP |
|--------------|----|--------------------------------|---------------------------|
| Intervention | 99 | 47 | 47.5 |
| Control | 97 | 22 | 22.7 |

Adjusted odds ratio = 0.32 (95% CI 0.15, 0.70; P<0.01)*

*adjusted for gender, age, baseline PIP, number repeat medications, GP practice size

National contemporaneous control – PCRS

- Cahir (2010) prevalence of 36% for 2007
- Update for intervention period, Sep 2012 – August 2013 prevalence of 38%

Crude odds of having no PIP in OPTI-SCRIPT intervention compared to odds of having no PIP in the national comparison (PCRS)

0.4
(95% CI 0.3, 0.6)

Results PIP drug classes

| | Adjusted odds ratio | Lower 95% CI | Upper 95% CI |
|--------------------------|---------------------|--------------|--------------|
| Maximal dose PPI | 0.30 ** | 0.14 | 0.68 |
| Duplicate drugs | 0.83 | 0.32 | 2.13 |
| Long-term benzodiazepine | 1.31 | 0.47 | 3.68 |

Process evaluation – main findings

- Participants positive about study
 - Barriers identified: GP time, communication, reimbursement
- Revealed intervention not delivered as expected:
 - Patient information leaflets not used at all
 - 1 intervention practice did not complete reviews
 - 2 control practices did alter patient medication
 - 2 intervention practices conducted reviews without patients

OPTI-SCRIPT- summary

- Developed web-based intervention to target PIP in primary care
- Effective in reducing PIP
- Effect confined to maximum dose PPIs; no effect duplicates or long term benzodiazepines
- Effect consistent in relation to national comparison group
- Process evaluation gave insight into intervention delivery and barriers

Conclusions

- Background & context
 - Medicines utilization is international challenge
- Observational epidemiology PIP
 - High prevalence
 - Increased healthcare utilization, adverse drug events, diminished QOL
 - Driven by polypharmacy
- OPTI-SCRIPT
 - Reduce long acting PPIs
 - Other PIP drugs more challenging

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Participating GP clinics