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How Real World data can transform medication use and prevent drug-related harm: A vision for Pharmacoepidemiology in Bavaria

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Disclosure

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- The conclusions drawn in this presentation are based on personal opinions and do not necessarily reflect the funders beliefs.

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Outline

1. **What is Pharmacoepidemiology?**

2. **Polypharmacy - A key challenge for health care**

3. **RWD – A key to adress polypharmacy**

4. **Opportunities for Bavaria**

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1. What is Pharmacoepidemiology ?

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What is Pharmacoepidemiology ?

➢ Utilisation and effects of medicines in large populations

Risk identification/quantification:
- Post-marketing surveillance of drug effects
- Drug effects in vulnerable groups

→ Regulatory decision making (eg BfArM)

Drug utilisation:
- Identifying gaps in quality or safety of medication use
- Evaluation of interventions

→ Clinical decision making
Health policy (eg G-BA)

Prediction:
- Treatment benefits/risks in individuals
- Risk stratification for targeting of services

→ Continuous Quality Improvement (eg KVB)

➢ Utilisation of RWD: Claims data, registries, EHR data

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Key challenge – Polypharmacy !

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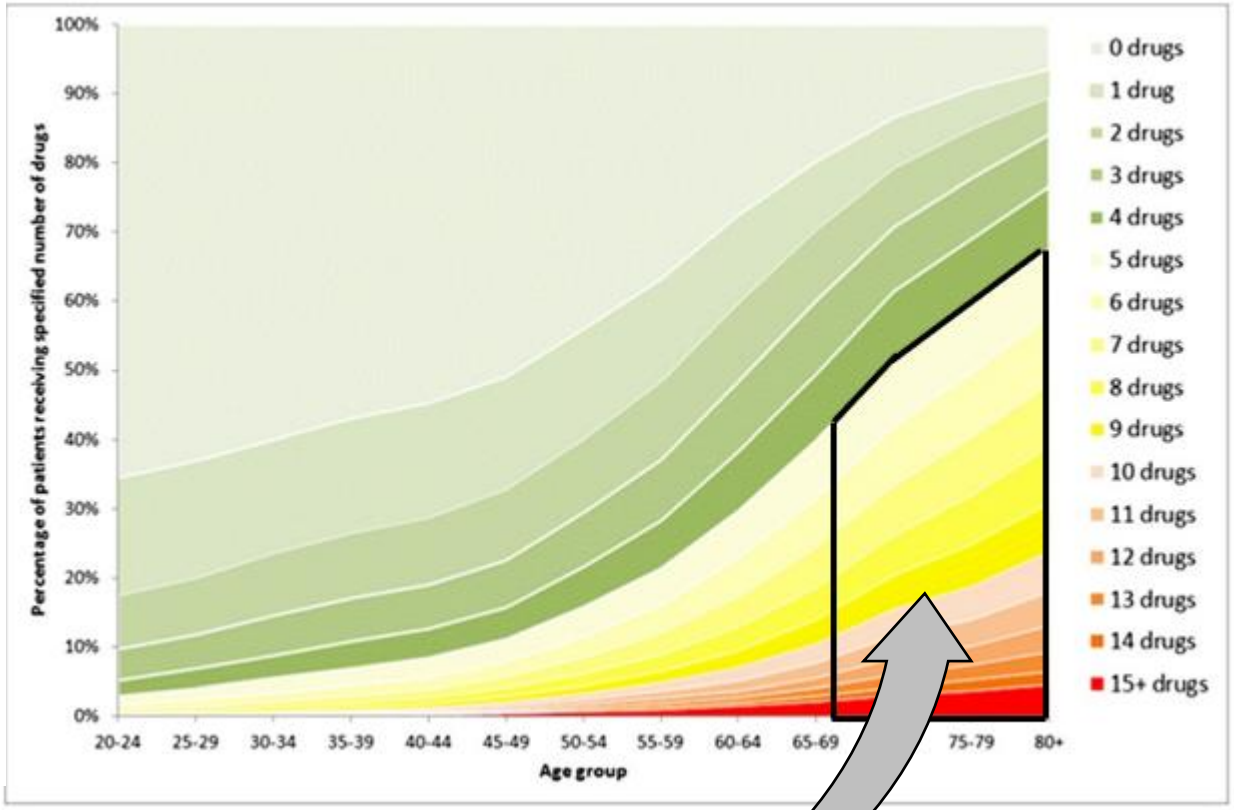
Key challenge – Polypharmacy !

≥1 in 20 emergency admissions drug related

> 1 billion EUR treatment costs in Germany in 2012

≥70% of drug related admissions in patients ≥65 years on ≥5 drugs

~10 million Germans aged 67 years or older with polypharmacy in 2030



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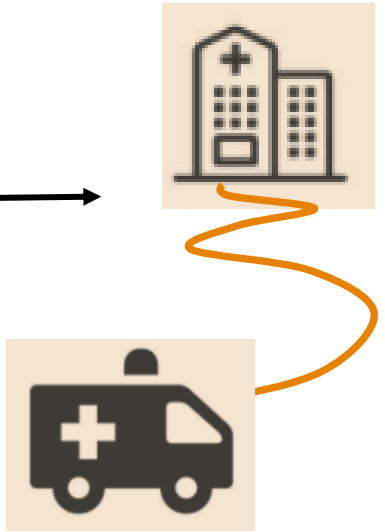
Key challenge – Polypharmacy !

Consultation
Prescribing → Self-
Administration →



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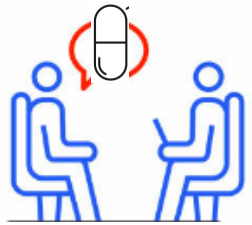

Periodic Medication review

Education
Tools
Incentives

Consultation
Prescribing

Self-
Administration

Acute risk alerts

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Polypharmacy – RWD driven improvement

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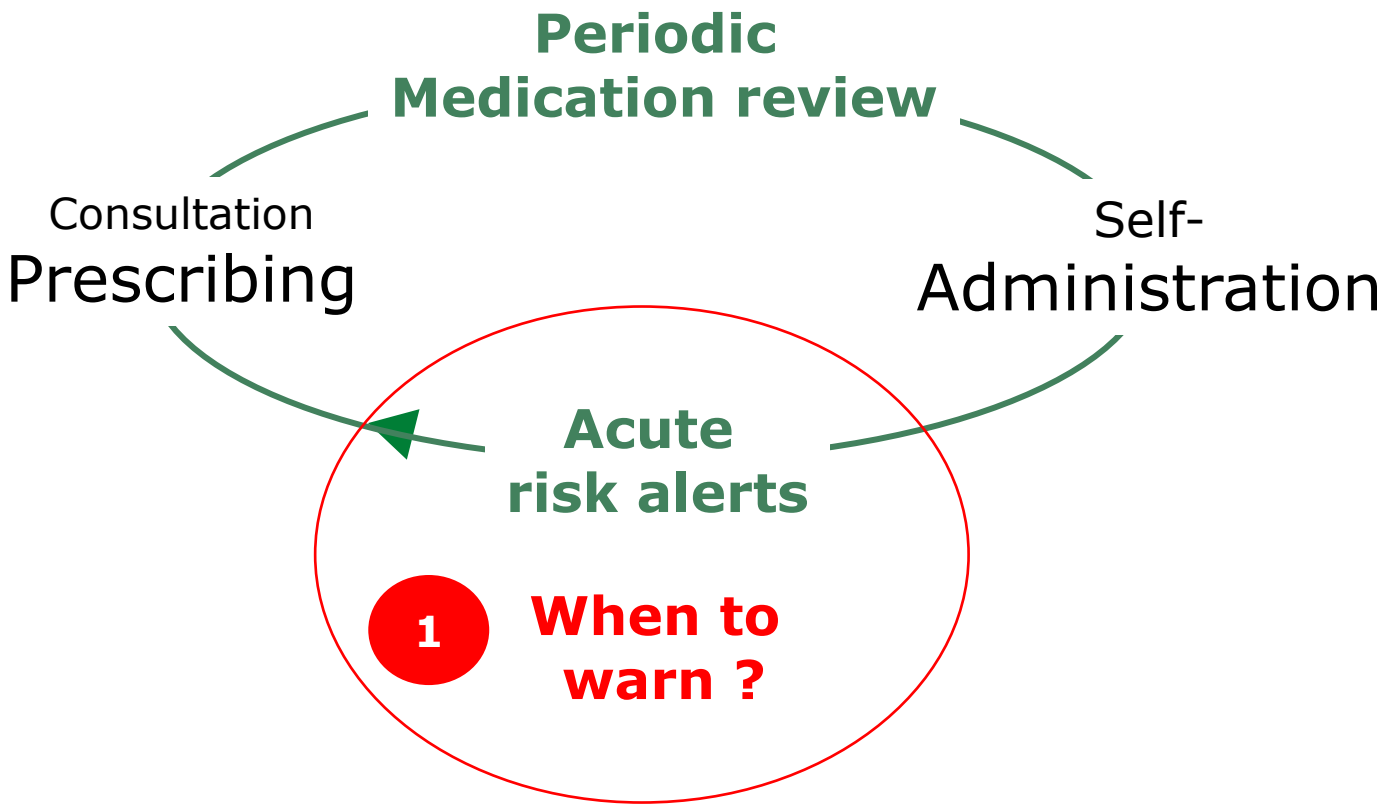
RWD-driven improvement – When to warn?

Education
Tools
Incentives



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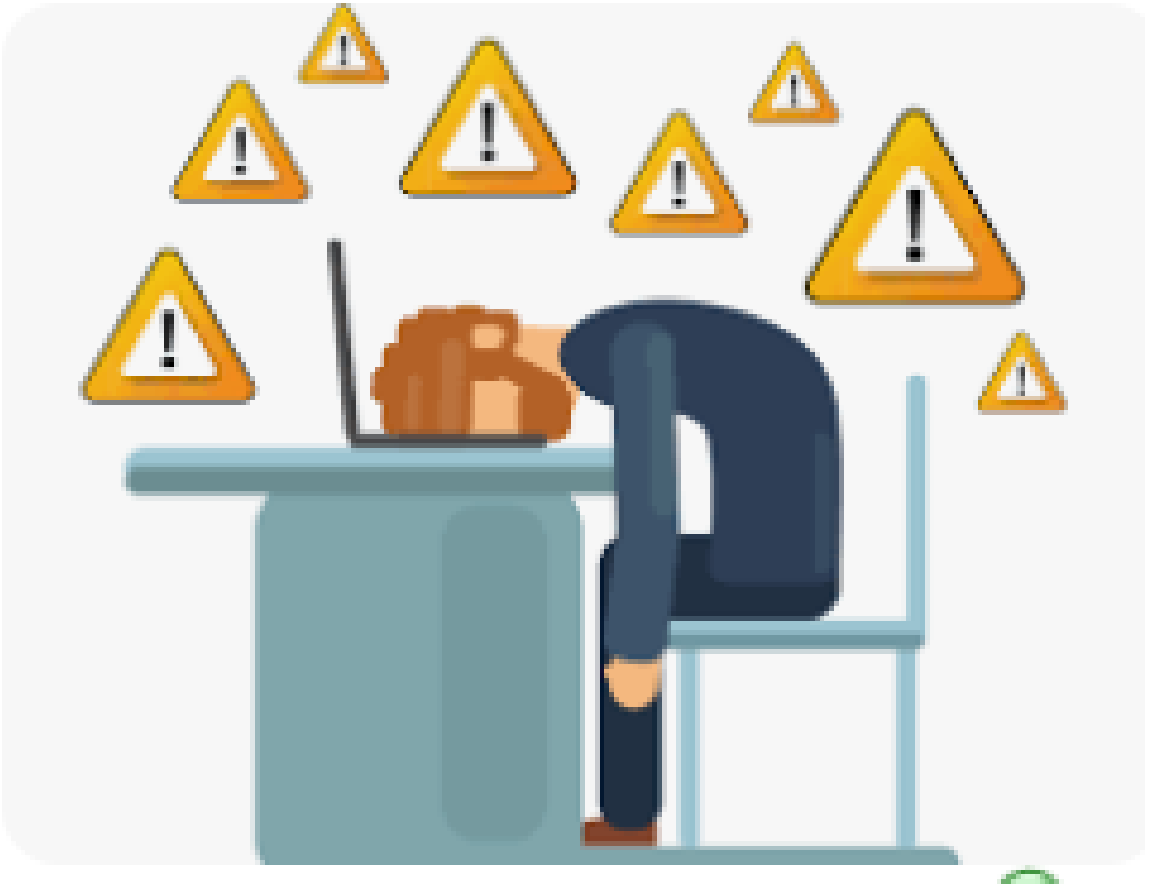
Acute risk alerts - When to warn?

- Current warning systems typically based on theoretical considerations
- Many irrelevant alerts
- **Alert fatigue**



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Acute risk alerts - When to warn?

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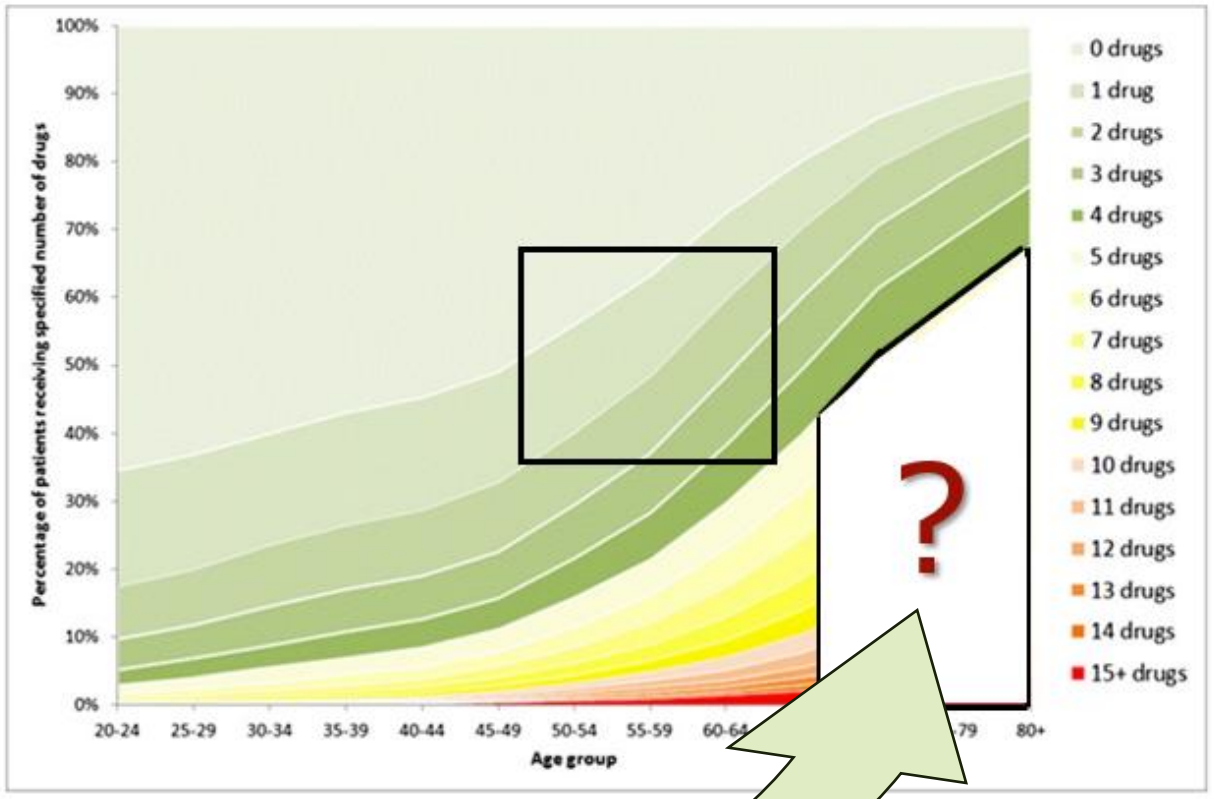

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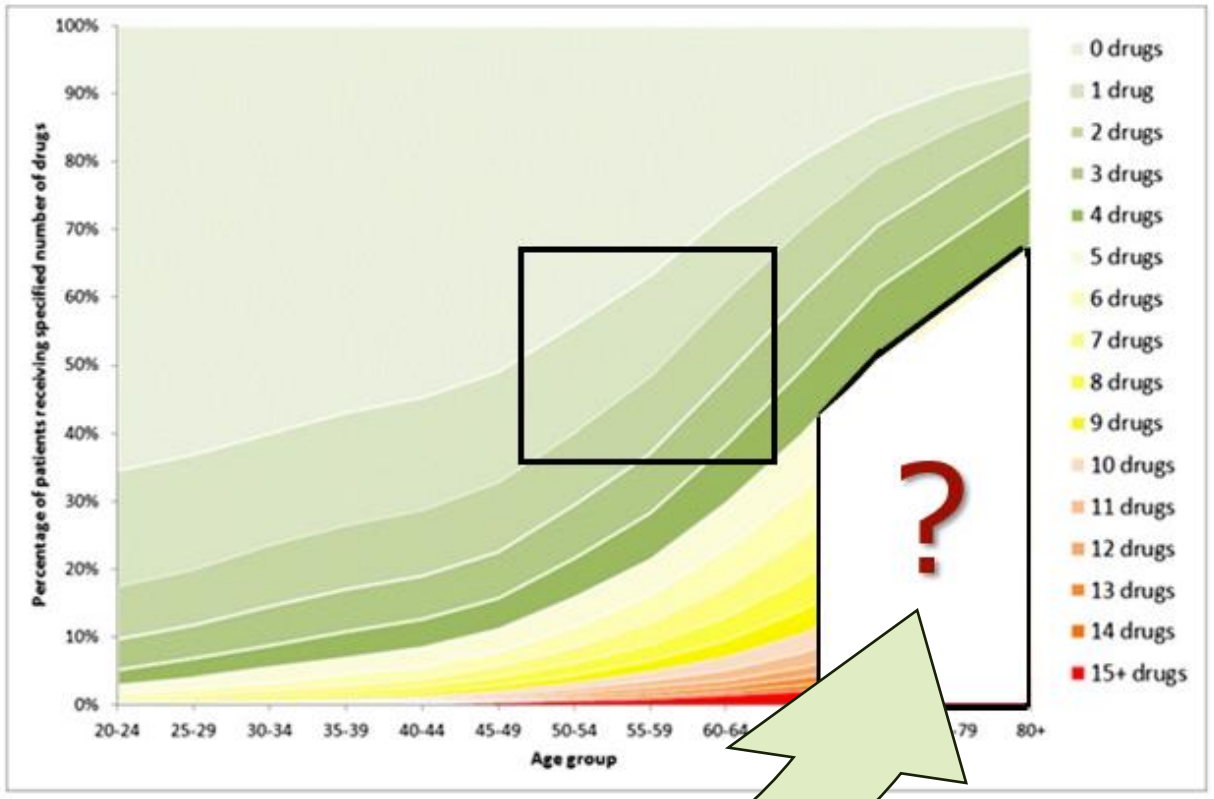
Acute risk alerts - When to warn?

- Current warning systems typically based on theoretical considerations
- Many irrelevant alerts
- Alert fatigue
- Risks not quantified

Observational research based on claims data



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Acute risk alerts - When to warn?

Fall-risk-increasing drugs (FRIDs) and fracture risk

STOPPFall (Screening Tool of Older Persons Prescriptions in older adults with high fall risk): a Delphi study by the EuGMS Task and Finish Group on Fall-Risk-Increasing Drugs

Lotta J. Seppala[1], Mirko Petrovic[2], Jesper Ryg[3], Gulistan Bahat[4], Eva Topinkova[5], Katarzyna Szczerbińska[6], Tischa J.M. van der Cammen[7], Sirpa Hartikainen[8], Birkan Ilhan[9], Francesco Landi[10], Yvonne Morrissey[11], Alpana Mair[12], Marta Gutiérrez-Valencia[13], Marielle H. Emmelot-Vonk[14], María Ángeles Caballero Mora[15], Michael Denkinger[16], Peter Crome[17], Stephen H.D. Jackson[18], Andrea Correa-Pérez[19], Wilma Knol[20], George Soulis[21], Adalsteinn Gudmundsson[22], Gijsbertus Ziere[23], Martin Wehling[24], Denis O'Mahony[25], Antonio Cherubini[26], Nathalie van der Velde[1]

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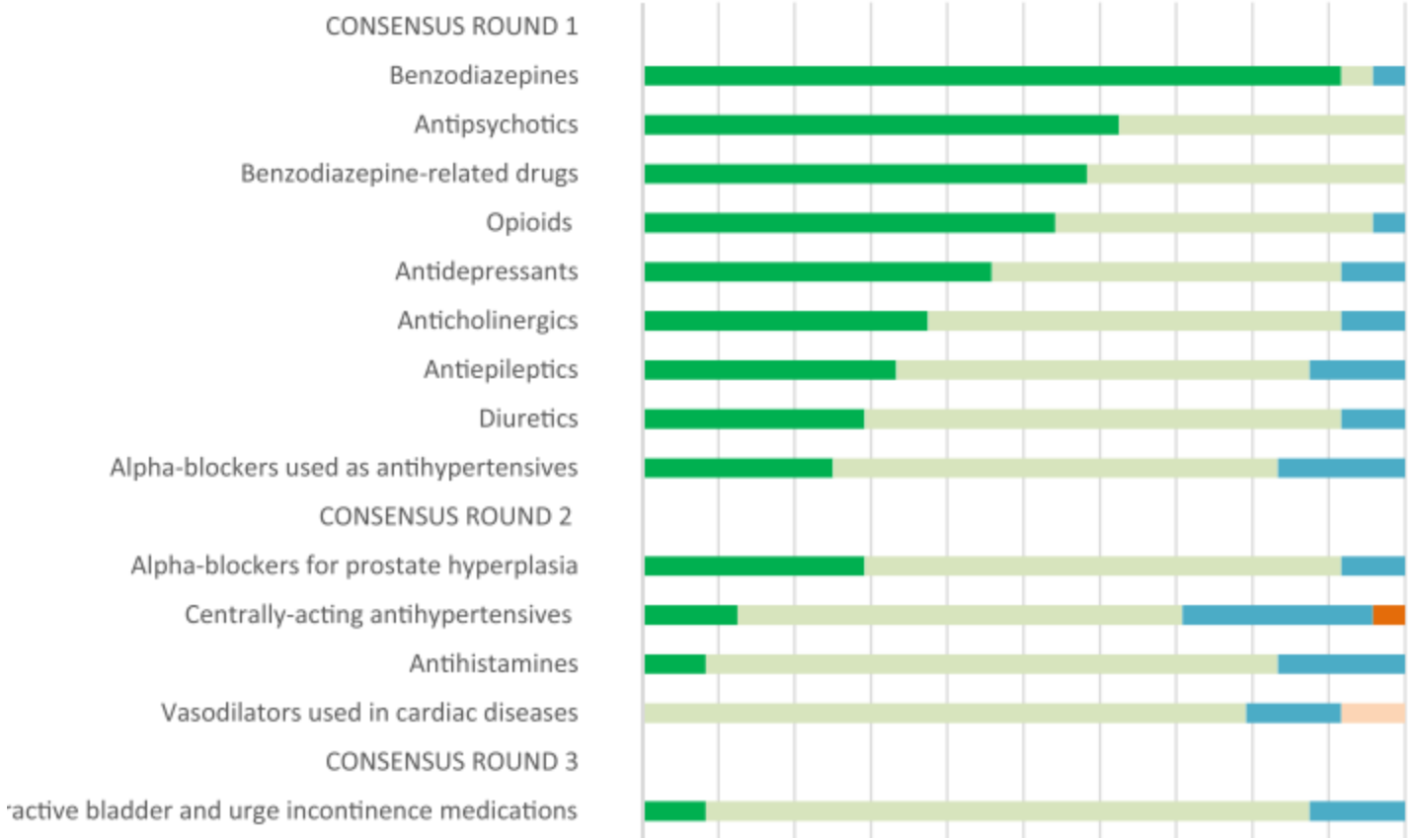

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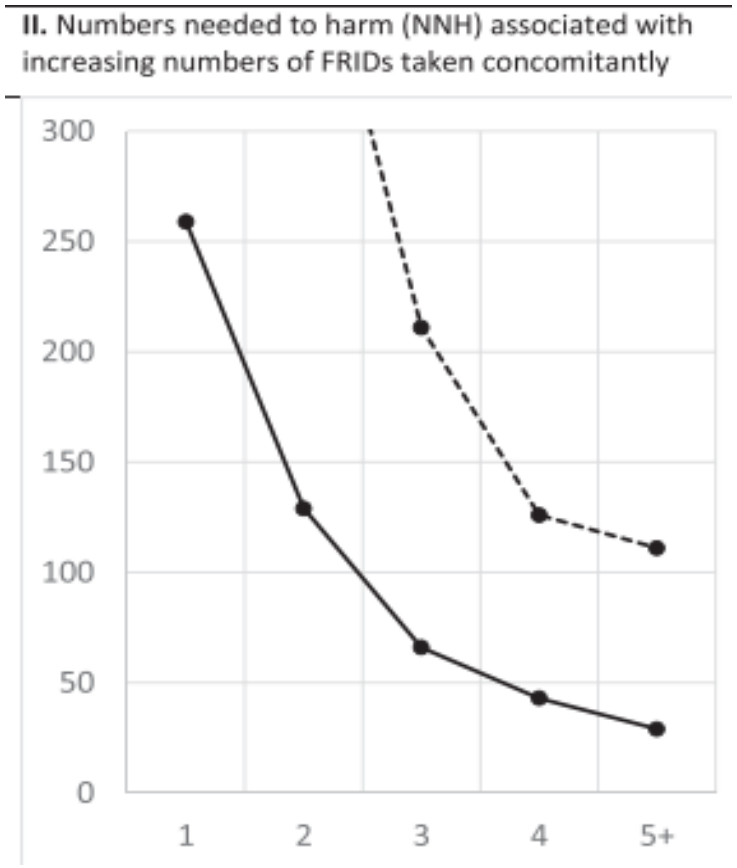
Acute risk alerts - When to warn?

Fall-risk-increasing drugs (FRIDs) and fracture risk: A population-based case–control study (Age & Ageing 2021)

Exposure	Number needed to harm	
	Aged 65 to 74	Aged ≥75
Tricyclic antidepressants	308	**81**
SSRI antidepressants	247	**53**
Antipsychotics	NS	**75**
1 FRID	769	259
2 FRIDs	417	**129**
3 FRIDs	211	**66**
4 FRIDs	126	**43**
5+ FRIDs	111	**29**



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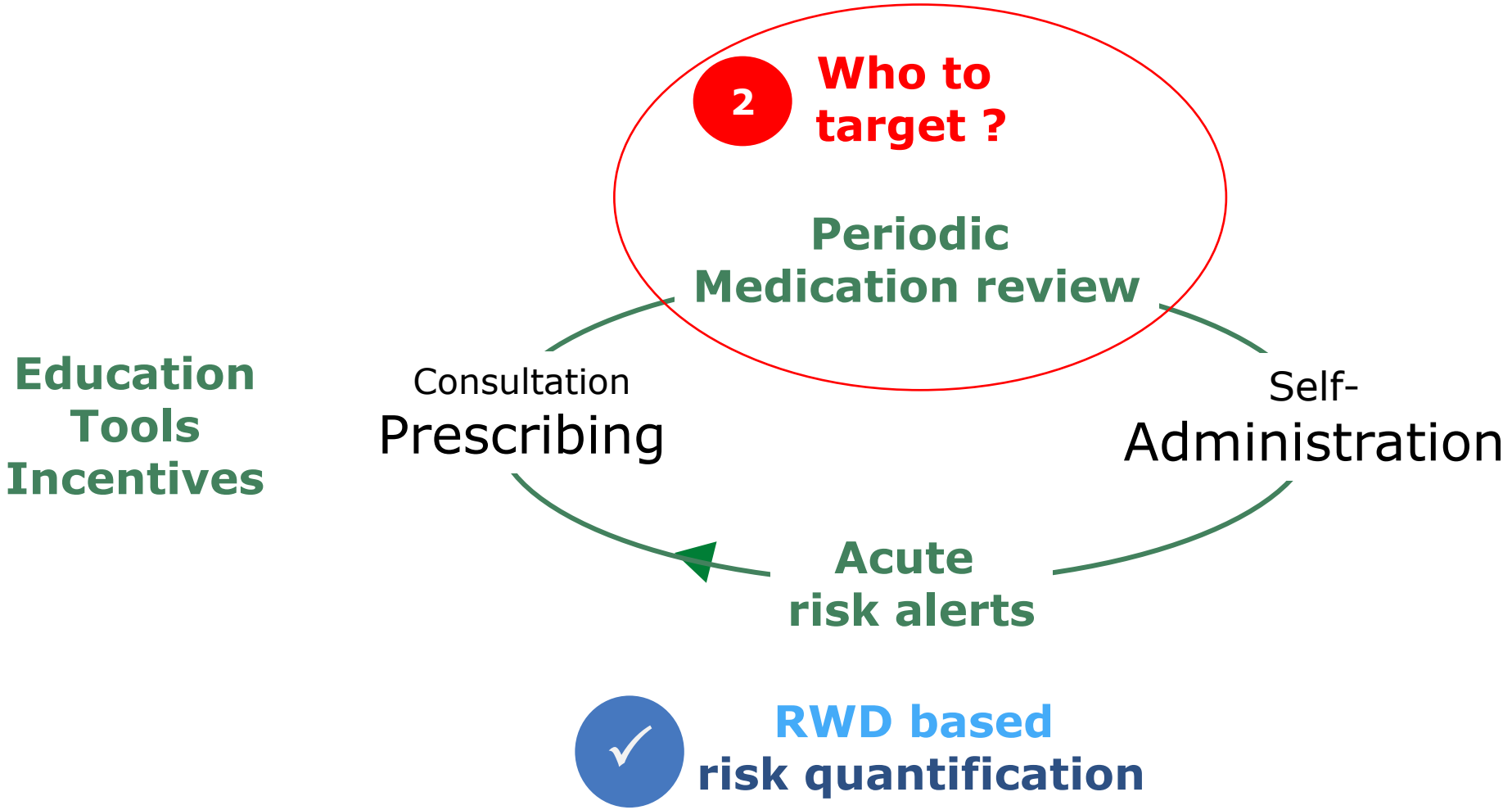
Medication reviews - Who to target?



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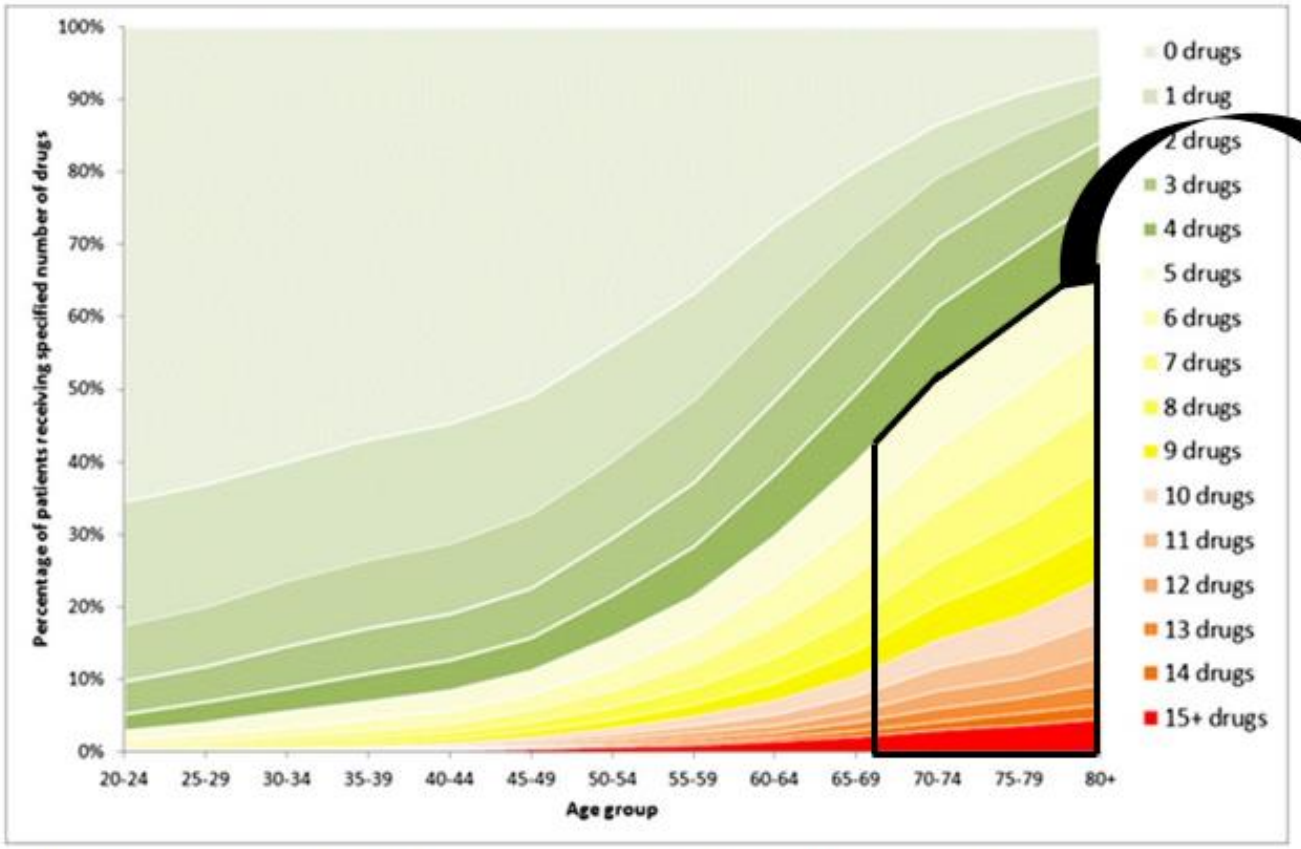
Medication reviews - Who to target?



Number of drug classes dispensed in the 84-day period in 1995 and 2010 by age of patient.

~10 million Germans aged 67 years or older with polypharmacy in 2030

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Medication reviews - Who to target?

Assumptions

- ~ 10 million Germans aged 67 years or older with polypharmacy in 2030
- **1 medication review per year**
- Medication review lasting 60 minutes each (including follow up)
- **Cost: EUR 150 per review**
- 44,000 GPs in 2030

Implications

- 216 medication reviews per GP per year
- **5.0 additional working hours per GP/week**
- **Cost: EUR 1.5 billion per year**
- **Need for prediction models to identify patients who are most likely to benefit**

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Medication reviews - Who to target?

RESEARCH ARTICLE

Prediction of Hospitalization due to Adverse Drug Reactions in Elderly Community-Dwelling Patients (The PADR-EC Score)

Nibu Parameswaran Nair[1]*, Leanne Chalmers[1], Michael Connolly[1,2], Bonnie J. Bereznicki[1], Gregory M. Peterson[1], Colin Curtain[1], Ronald L. Castelino[1], Luke R. Bereznicki[1]

1 Unit for Medication Outcomes Research and Education, Division of Pharmacy, School of Medicine, Faculty of Health, University of Tasmania, Hobart, Tasmania, Australia, **2** Royal Hobart Hospital, Hobart, Tasmania, Australia

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Abstract

Background

Adverse drug reactions (ADRs) are the major cause of medication-related hospital admissions in older patients living in the community. This study aimed to develop and validate a score to predict ADR-related hospitalization in people aged ≥65 years.

Methods

ADR-related hospitalization and its risk factors were determined using a prospective, cross-sectional study in patients aged ≥65 years admitted to two hospitals. A predictive model was developed in the derivation cohort (n = 768) and the model was applied in the validation cohort (n = 240). ADR-related hospital admission was determined through expert consensus from comprehensive reviews of medical records and patient interviews. The causality and preventability of the ADR were assessed based on the Naranjo algorithm and modified Schumock and Thornton criteria, respectively.

Results

In the derivation sample (mean [±SD] age, 80.1±7.7 years), 115 (15%) patients were admitted due to a definite or probable ADR; 92.2% of these admissions were deemed preventable. The number of antihypertensives was the strongest predictor of an ADR followed by presence of dementia, renal failure, drug changes in the preceding 3 months and use of anticholinergic medications; these variables were used to derive the ADR prediction score. The predictive ability of the score, assessed from calculation of the area under the receiver operator characteristic (ROC) curve, was 0.70 (95% confidence interval (CI) 0.65–0.75). In the validation sample (mean [±SD] age, 79.6±7.6 years), 30 (12.5%) patients' admissions were related to definite or probable ADRs; 80% of these admissions were deemed preventable. The area under the ROC curve in this sample was 0.67 (95% CI 0.56–0.78).

- Very limited research on predicting drug-related hospitalisations
- One paper had very limited success in predicting drug-related admissions of all causes (AUC 0.67)
- Better models may be possible by predicting specific admissions using claims data

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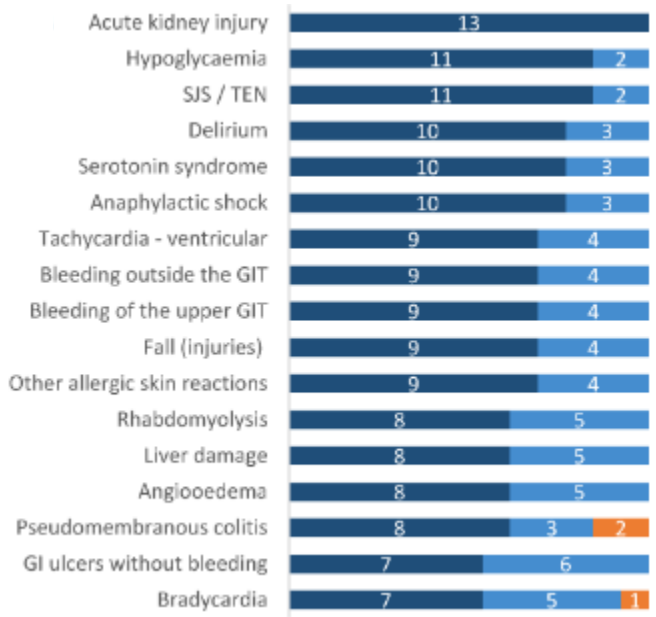
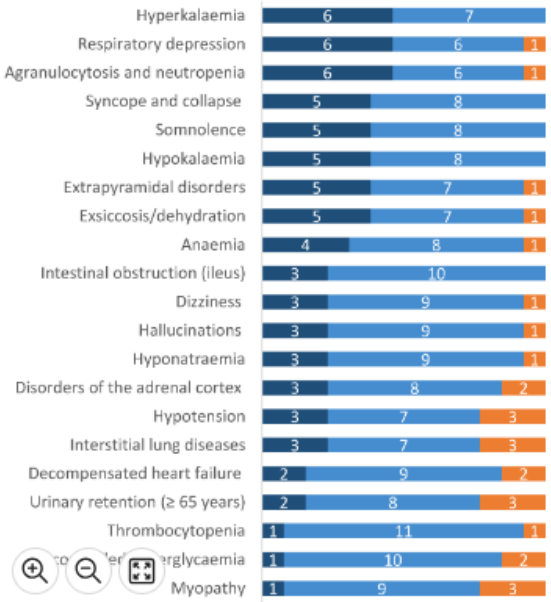
Medication reviews - Who to target?

- Better models may be possible by predicting **specific admissions** using claims data

Prioritisation of Adverse Drug Events Leading to Hospital Admission and Occurring during Hospitalisation: A RAND Survey

by Annette Haerdtlein [1,2,†], Anna Maria Boehmer [3,†], Katharina Karsten Dafonte [4], Marietta Rottenkolber [1], Ulrich Jaehde [3,‡] and Tobias Dreischulte [1,*,‡]





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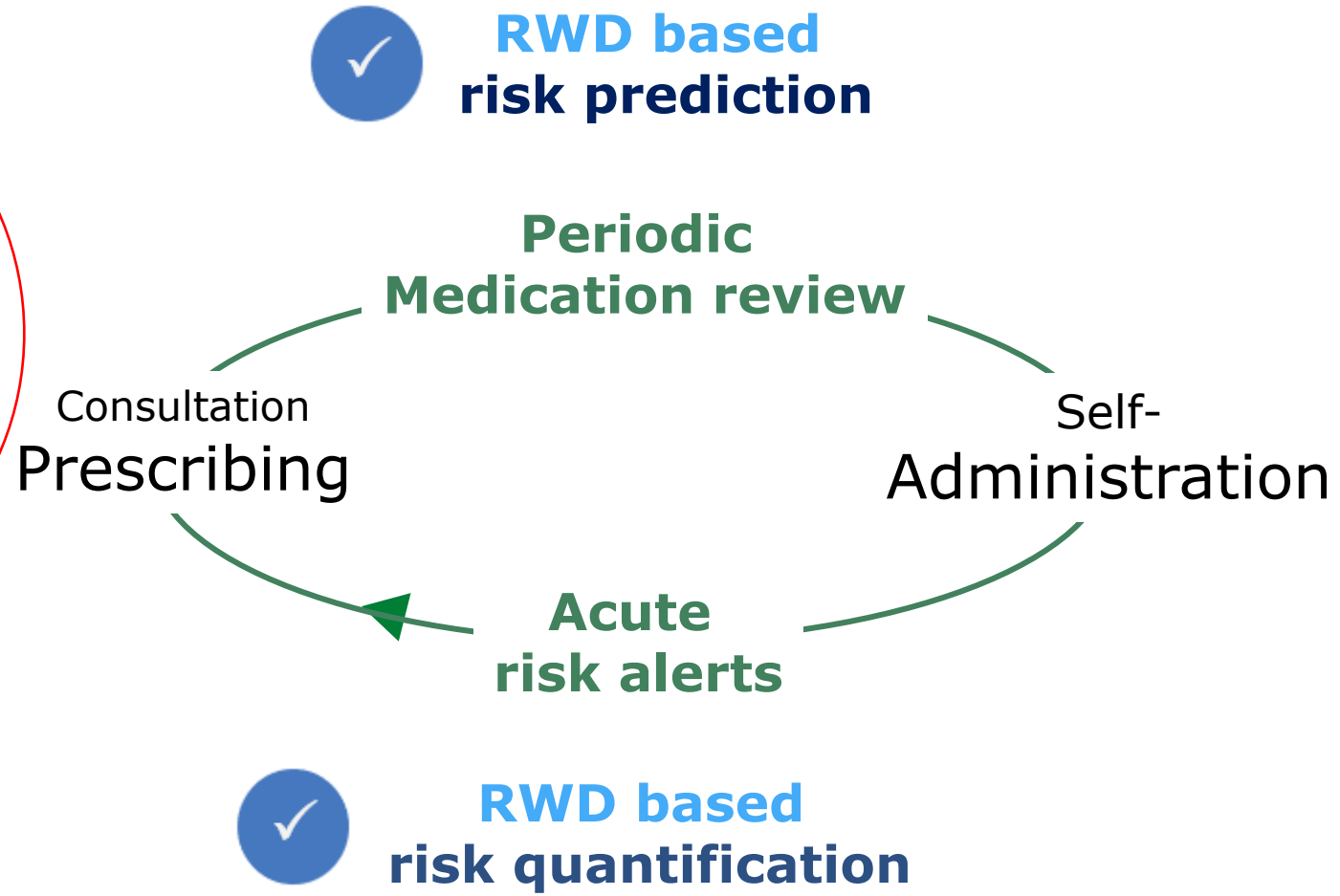
How to ensure implementation?

3

How to ensure implementation?

Education
Tools
Incentives



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How to ensure implementation?

~ 40 GP practices in NHS Scotland

- Data-driven intervention:
  - IT tool based on EHR data:
    → Feedback of prescribing data
    → Identification of **individual** patients at risk of GI bleeds, AKI or heart failure from NSAIDs/antiplatelets
  - Education (~ 1 hour)
  - Incentives: 15 GBP/review

DQIP
Making prescribing safer

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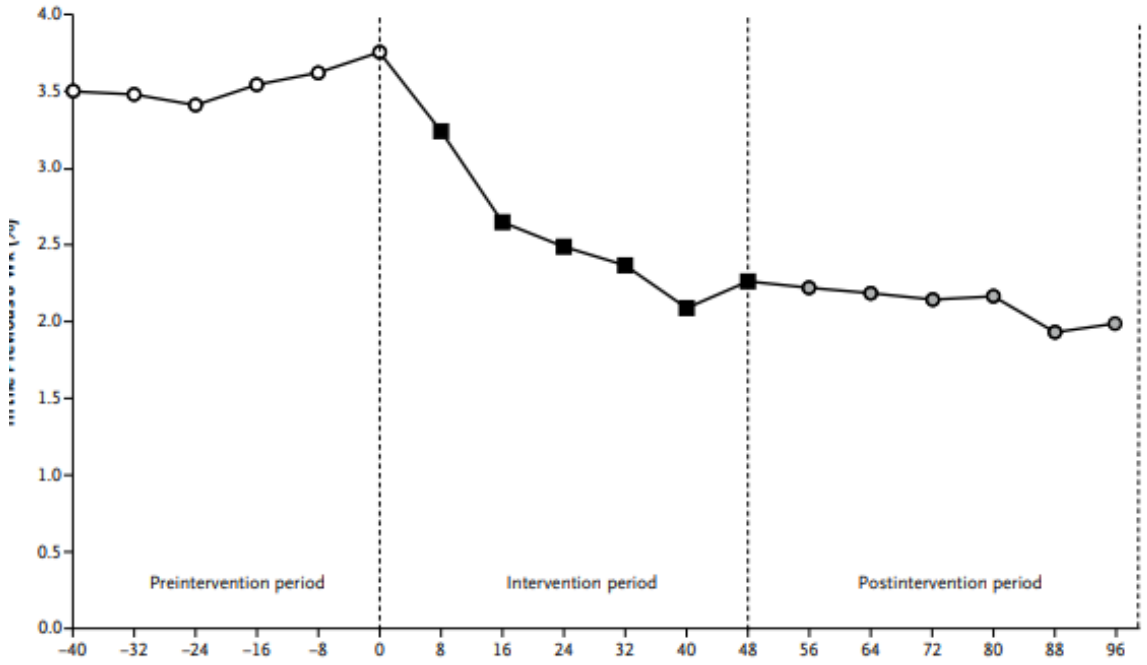
How to ensure implementation?

DQIP
Making prescribing safer

Evaluation using claims/EHR data



Outcome (High-risk prescribing)	Prevalence at baseline	Multi-level adjusted OR	P-value
Primary outcome			
Overall	1102/29537	0.63 (0.57, 0.68)	<0.001
Secondary outcome: Ongoing vs New			
'Ongoing'	766/29537	0.60 (0.53, 0.67)	<0.001
'New'	336/29537	0.77 (0.68, 0.87)	<0.001

Outcome (High-risk prescribing)	Incidence/10,000 (95%CI) pyr's in baseline period	RR (95%CI)	P-value
Irrespective of high-risk prescribing			
GI ulcer or bleeding	55.7 (48.2 to 64.4)	0.66 (0.51 to 0.86)	0.002
Acute kidney injury	102 (87.0 to 119)	0.84 (0.68 to 1.09)	0.19
Heart failure	708 (608 to 823)	0.73 (0.56 to 0.95)	0.02

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PE/RWD based prevention of drug related harm

RWD based
risk prediction

RWD based
intervention/
evaluation

RWD based
risk quantification

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PE in Bavaria? A strategic Case for Investment

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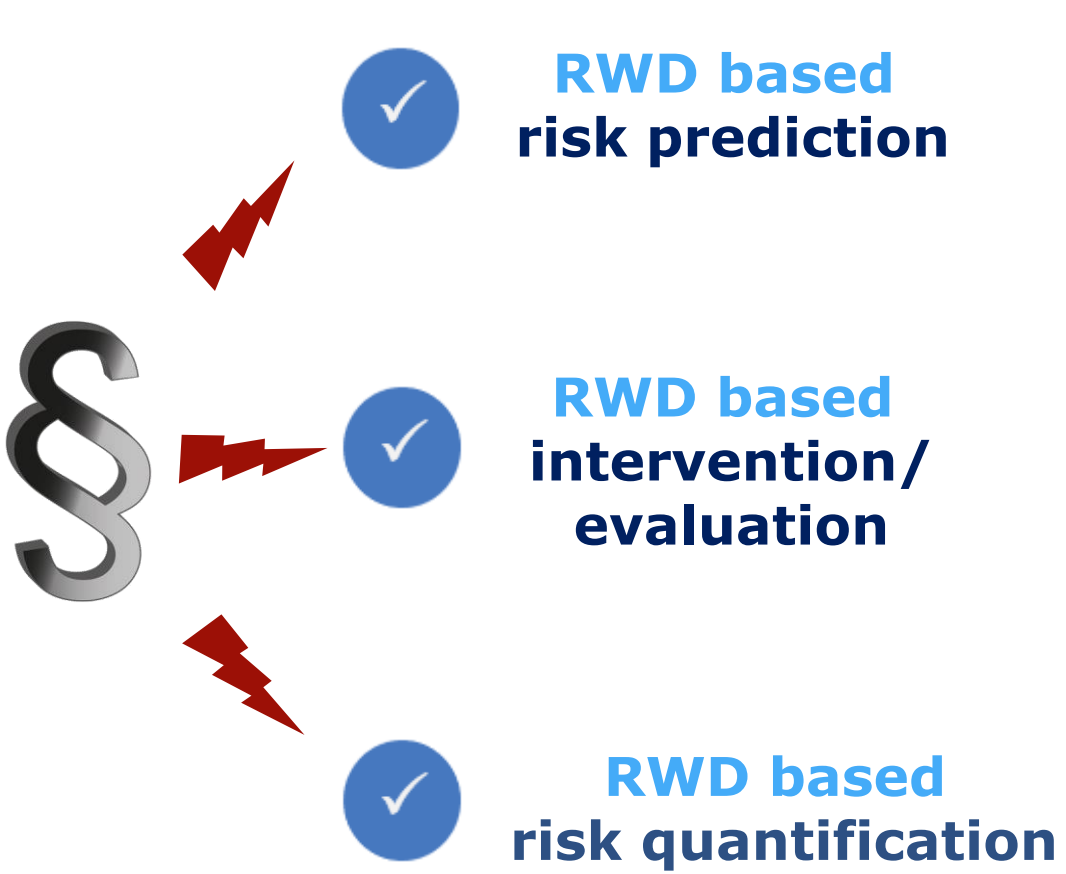
PE in Bavaria? A strategic Case for Investment



RWD based
risk prediction

RWD based
intervention/
evaluation

RWD based
risk quantification

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PE in Bavaria? A strategic Case for Investment

- Federal law supports use of RWD for health research (→ GDNG):
  - Establishment of FDZ Gesundheit at BfArM
  - Data linkage of claims data and other registries

but ….

- Progress in establishing FDZ slow
- Data access likely to remain limited/bureaucratic
- Data linkage initially restricted to cancer registries

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PE in Bavaria? A strategic Case for Investment

Potential for National and International Leadership

- **Strong Research Infrastructure: LMU, TUM, Helmholtz …**
- **Infrastructure for Data Science/ Health Research: BCHR**
- **Access to High-Quality RWD: AOK (40%), data integration centres …**
- **Proximity to the Pharmaceutical Industry**

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PE in Bavaria? A strategic Case for Investment

Potential for National and International Leadership

Infrastructure for Data Science/ Health Research:
Claims data are essential !

Build Research capacity in PE:
Combine expertise in
- Clinical medicine
- Data management
- PE methods

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3rd Intensive Course in Effectiveness & Safety Research with Healthcare Databases

May 12-16, 2025

Prof. Sebastian Schneeweiss (Course director)
Prof. Tobias Dreischulte (Course co-director)

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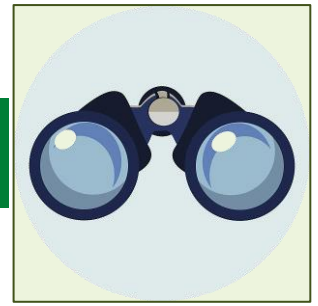
Outlook



- RWD hold enormous potential to improve health research and care
- Polypharmacy is a key challenge for health care in the 21st century
- Pharmacoepidemiology using RWD is key to addressing this challenge
- Bavaria can play a leading role in realizing this potential
- Concerted action by academia, policy and data holders is essential