



T Dreischulte, A Grant, B Guthrie:

Explicit standards to evaluate the quality and safety of medication use in primary care: Expert consensus study



T Dreischulte, S Hudson

Evaluating pharmaceutical care:

A generic algorithm to operationalise 'adherence to standards' as an intermediate outcome measure







- 1. The case for explicit standards in the delivery and evaluation of Pharmaceutical care interventions
- 2. Development and validation of an extensive set of medication use standards for use in primary care
- 3. An algorithm for evaluating adherence of medication use to standards of best practice
- 4. Summary and conclusion



# **Evaluation of medication reviews**



- Medication review interventions have shown variable results <sup>1</sup>
- HOMER trial showed an increase in hospitalisation
- Trial designs have been criticised for (among others) not providing insight into how the intervention works (lack of process evaluation)<sup>2,3</sup>

- 1. Holland et al. Systematic review
- 2. Anita Hogg, James McElnay, Christine Clark. Michael G Scott, Chief Pharmacist Antrim Area Hospital BT41 2RL,
- 3. Duncan Robert Petty, Theo Raynor, Arnold Zermansky, David Alldred, Peter Bowie, Nick Freemantle Research Pharmacist, University of Leeds.





Medication reviews are complex interventions, where outcomes *may* be influenced by a number of factors including how the intervention has been delivered:

- Communication between practitioners and patients
- Communication between practitioners
- (Clinical) experience/ knowledge
- (Systematic) approach
- Access to data

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### **Complex interventions** Why do they work (or not)?







**Examples for qualitative process evaluations** 



### **COMMUNICATION PROBLEMS:** HOMER trial

### 'I haven't even phoned my doctor, yet !'

"Review pharmacists in the intervention take every opportunity to give advice and information; advice is often given despite an apparent problem demonstration of patient competence"

"Advice by pharmacists is often rejected by patients"

### 'Advice giving role during interventions has the potential to undermine and threaten the patients' assumed competence, integrity, and self governance"

Salter C, Holland R et al. "I haven't even called my doctor, yet." The advice giving role of the pharmacist during consultations for medication review with patients aged 80 or more: qualitative discursive analysis. BMJ Online first doi: 10.1136/bmj.39171.577106.55. 2007



**Examples of possible quantitative measures:** 



### **APPARENTLY CLINICALLY SUBOPTIMAL INTERVENTION DELIVERY**

**Evaluation of MUR's conducted by community pharmacists** <sup>1</sup>: Comparison of issues identified intervention pharmacists' to issues identified by experts:

- Almost all recommendations by CP's considered appropriate by experts
- CP's identified only ~ 30% of potential drug therapy problems identified by experts ( 30% of monitoring issues, 21% of drug disease interactions, 44% of unmet indications)

Krska J, Avery T. Evaluation of medication reviews conducted by community pharmacists: a quantitative analysis of documented issues and recommendations. Br J Clin Pharmacol 65:3; 386-96.



### **Explicit standards**



### **1. Delivery of interventions:**

- Need for standardisation and <u>quality assurance</u> of interventions
- Explicit standards of best practice of medication use:
   Minimum of what should be *checked* in interventions;
   *changed* where appropriate

### 2. Evaluation of interventions

Does the intervention reduce non-adherence to standards



**Examples of possible quantitative process measures** 



### Explicit

- Beers/STOPP Drugs to be avoided in the elderly
  - Drugs commonly underprescribed in the elderly
  - Prescribing standards for the elederly
  - Primary care safety indicators (2004)
  - Disease specific indicators derived from guidelines

MAT

PDRM

START

ACOVE



Examples of possible quantitative process measures



Explicit (e.g. Beers, Start/ Stopp, ACOVE, PDRM, MAT)

- + reliably applicable by trained non-experts or computerised (where electronic data available)
- + objective
- + unmet need considered by 'START' and 'MAT'

# Data driven quality improvement in primary care (DQIP):

Using informatics to implement new prescribing quality measures integrated with educational interventions and existing quality improvement mechanisms

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### Aim:

# To define and validate a set of explicit standards of medication use quality and safety in primary care







LITERATURE REVIEW

### **Identifying topics**

- Guidelines (SIGN, NICE, ESC etc.)
- MeRec bulletin (NPC)
- Drug safety bulletin (MHRA)
- BNF "blue boxes"
- Previously developed sets of indicators (Start/Stop, PDRM, ACOVE)
- Recent systematic reviews addressing causes/risk factors for preventable drug related morbidity <sup>1-3</sup>

Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, Farrar K, Park BK, Breckenridge MA. BMJ 2004;329;15-19
 Howard RL, Avery AJ. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol 2006; 63:2 136–147.

3. **Thomsen LA**, Winterstein AG, Søndergaard B, Haugbølle LS, Melander A. Systematic Review of the Incidence and Characteristics of Preventable Adverse Drug Events in Ambulatory Care The Annals of Pharmacotherapy **2007**; 41:1411-26.



## **Development of standards** LITERATURE REVIEW



### What the literature does NOT tell us (Examples):

### **Studies of drug related hospital admissions:**

 Antiplatelets are among the most common causes of preventable ADE's involved in drug related hospital admissions, but
 When is the risk high enough to state that make use of gastro-protection

mandatory ?

### **Unspecific guidance, for example:**

- Beta blockers 'should be avoided' in asthma (BNF), but: What if a CHD patient has not had an asthma attack for 5 years ?
- Patients with target organ damage 'should be treated to achieve optimal BP'
   What if patient is elderly and already on 3 antihypertensive drugs ?

### 



# **Development of standards** Methods



### RAND APPROPRIATENESS METHOD (RAM)



- RAM combines expert opinion and evidence
- Combines aspects of DELPHI (postal rating) and NGT (face to face meeting and discussion)
- The `only systematic method of combining expert opinion and evidence' <sup>1</sup>

1. Naylor D. (1998) What is appropriate care? New England Journal of Medicine, 338, 1918±1920.



**SAFETY** vs **QUALITY** 



### QUALITY: Prescribing behaviour with evidence of patient benefit when conducted Targeting underuse

Example: To prescribe a beta-blocker to a patient with a history of MI?

#### **SAFETY:**

Prescribing behaviour with evidence of patient harm when conducted

Targeting inappropriate use/ overuse

Example: To prescribe a beta-blocker to a patient with asthma?



# **Development of standards** QUALITY TOPICS



	Sta	atements
QUALITY TOPICS		Count
<b>1. CVD RISK MODIFICATION</b> (Antithrombotic prophylaxis, BP lowering, lipid lowering, antidiabetic, or preventative, chronic heart failure, asthma, osteoporosis)	other	76
<b>2. CHRONIC HEART FAILURE</b> (Use of ACEI, BB, and dose titration)		6
<b>3. ASTHMA</b> (Use of inhaled steroids in apparently uncontrolled patients)		12
<b>4. OSTEOPOROTIC PROPHYLAXIS</b> (Use of bone-sparing agents and calcium/VitD in patients at risk)		6
		100

**Example:** To prescribe a beta-blocker to a patient with a history of MI?



# **Development of standards** SAFETY TOPICS



SAFETY TOPICS	Statements
	Count
A. GASTROINTESTINAL SYSTEM	
(eg Use of NSAIDs/antiplatelets in patients at risk without gastro-protection , use of	
opiods without laxatives etc)	32
B. HAEMATOLOGICAL SYSTEM	
(eg Warfarin interactions, FBC monitoring)	31
C. CARDIOVASCULAR SYSTEM	
(eg COX IIs in CVD patients; antipsychotics in the elderly)	34
D. RENAL SYSTEM	
(eg U&E monitoring under diuretic therapy, 'triple whammy')	60
E. RESPIRATORY SYSTEM	J
(eg BB in asthma)	27
F. ENDOCRINE SYSTEM	
(eg sulfonylureas in renal failure or in the elderly)	17
G. CNS AND MOTOR SYSTEM	
(eg benzodiazepines in the elderly, phenothiazines in patients with PD)	59
H. MUSCULOSCELETAL SYSTEM AND TEETH	
(eg statin interactions, tetracyclines in children)	10
I. MISCELLANEOUS DRUG SPECIFIC ADVERSE EFFECTS	
(eg full dose digoxin in the elderly/renal impairment, )	19
	289

**Example:** To prescribe a beta-blocker to a patient with asthma ?



# **Study 1** Rating procedure – QI SCALES



### For all statements:



#### For safety statements



### For quality statements







### **Rating procedure – QI CONCEPTS**

**Example :** To prescribe a beta-blocker to a patient with a history of MI

#### Definition of 'appropriate' :

- Expected **benefits exceed** the expected **risks**
- Expected benefit is large enough to be worthwhile doing (irrespective of cost)

Definition of 'necessary to do':

It would be considered 'improper' care not to prescribe as stated, because

- strong evidence makes benefits **likely**
- benefits are likely to be clinically significant





### **Rating procedure – QI CONCEPTS**

**Example :** To prescribe a beta-blocker to a patient with a history of MI

#### Definition of '*inappropriate*' :

- Expected risks exceed the expected benefit
- Expected risk is large enough to be NOT worthwhile doing (irrespective of cost)

Definition of 'necessary to avoid':

It would be considered 'improper' care not to prescribe as stated, because

- patient harm is likely
- harms are likely to be clinically significant





Questionnaire – example

	Appropriate	eness	Necessary to avoid		
	Clearly inappropriate	Clearly appropriate	Clearly necessary to avoid	Clearly NOT necessary to avoid	
	123456789		123456789		
A. GASTROINTESTINAL SYSTEM					
1. RISK OF GASTROINTESTINAL ULCERATION/BLEEDING					
USE OF POTENTIALLY GASTROTOXIC DRUGS WITHOUT CO-PRESCRIPTION OF GASTROPROTECTION					
<ol> <li>PATIENTS AGED 66 TO 75 YEARS WITHOUT A HISTORY OF PEPTIC ULCER To prescribe the drugs below without co-prescription of a gastro-protective agent to a patient without a history of peptic ulcer, aged 65-74 years:</li> </ol>					
a) Low dose aspirin (alone)	1234567	789	12345	6789	
b) Oral NSAID (alone)	1234567	789	12345	6789	
c) Low dose aspirin and clopidogrel	1234567	789	12345	6789	
d) Low dose aspirin and warfarin	1234567	789	12345	6789	
e) Low dose aspirin and oral NSAID	1234567	789	12345	6789	
f) Warfarin and oral NSAID	1234567	789	12345	6789	



# **Study 1** Rating procedure – QI SCALES



### For all statements:



#### For safety statements



### For quality statements





# **Development of standards** RESULTS



### **RECRUITMENT FRAMING:**

- Mix of academia and clinical practice
- Mix of pharmacy and medical profession

### PANELLISTS (n=10):

- 2 pharmacy academics with special interest in prescribing in primary care
- 2 health board level pharmacists working in medicines governance
- 2 pharmacists working in general practice
- 1 GP working in clinical practice but also member of SMC
- 3 GPs working in clinical practice





**Results - Quality statements** 

- Disagreement = 1 (1%)
- **'Appropriate'** median ≥ 7 = 91/100 (91%)
- **'Necessary'** median ≥ **7** = 73/100 **(73%)**





**Results- safety medians** 

- **Disagreement = 12** statements
- 'Appropriate' median ≤3 = 225/288 (78%)
- 'Necessary' median ≤3 = 202/288 (70%)



### Results

1. RISK OF GASTROINTESTINAL ULCERATION/BLEEDING	Α	Ν	72 quality statements 17 Olis
1. PATIENTS AGED 66 TO 75 YEARS WITHOUT A HISTORY OF PEPTIC ULCER			7.5 quality statements 17 Qrs
To prescribe the drugs below without co-prescription of a gastro-protective			
a) Low dose aspirin (alone)	5	5.5	
b) Oral non-selective NSAID (alone) long term (>3 months)	3	4	202 safety statements 35 SI's
c) Low dose aspirin and clopidogrel	2.5	2.5	
d) Low dose aspirin and warfarin	1	1.5	
e) Low dose aspirin and oral NSAID long term (>3 months)	1	1	
f) Warfarin and oral NSAID	1	1	
2. PATIENTS AGED 76 YEARS OR OLDER WITHOUT A HISTORY OF PEPTIC ULCER			
To prescribe the drugs below without co-prescription of a gastro-protective			Example:
a) Low dose aspirin (alone)	3	4	
b) Oral non-selective NSAID (alone) long term (>3 months)			18 statements
	1.5	2	
c) Low dose aspirin and clopidogrel	2	2	
d) Low dose aspirin and warfarin	1	1	
e) Low dose aspirin and oral NSAID long term (>3 months)	1	1	
f) Warfarin and oral NSAID	1	1	
3. PATIENTS WITH A HISTORY OF PEPTIC ULCER			
To prescribe the drugs below without co-prescription of a gastro-protective			
a) Low dose aspirin (alone)	1	2.5	1 Indicator
b) Oral non-selective NSAID (alone) long term (>3 months)	1	1	2
c) Low dose aspirin and clopidogrel	1	1	
d) Low dose aspirin and warfarin	1	1	
e) Low dose aspirin and oral NSAID long term (>3 months)	1	1	
f) Warfarin and oral NSAID	1	1	
	-		

SI 1: Patients at risk of gastro-intestinal toxicity from taking the drugs specified below, who are NOT prescribed a gastro-protective agent

SPECIFICATIONS:

a) Prescribed an NSAID (long term) AND at least one of: History of peptic ulcer, aged >75, co-prescribed an NSAID

NHS

**Tayside** 

b) Prescribed aspirin and at least one of: Co-prescribed clopidogrel, warfarin or NSAID



# How to measure adherence to standards ?





A All adults over the age of 40 years who are assessed as having a ten year risk of having a first cardiovascular event ≥ 20% should be considered for treatment with simvastatin 40 mg/day following an informed discussion of risks and benefits between the individual and responsible clinician.

MAT criterion	
Qualifier (Q):	Patient with a 10 year risk of having a first cardiovascular event of ≥20%
Standard (S):	is prescribed simvastatin 40mg
Exceptions :	Explicitly documented or apparent history of statin intolerance, etc.
Operation rules:	For CVD risk estimation the most current blood pressure (BP) and total cholesterol (TC) readings within last 60 months are considered

### Algorithm for adherence assessment 1. Delivery / 2. Evaluation





#### Example

	A All adults over the age of 40 years who are assessed as having a ten year risk of having a first cardiovascular event $\ge 20\%$ should be considered for treatment with simvastatin 40 mg/day following an informed discussion of risks and benefits between the individual and responsible clinician.								
	MAT criterion								
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# **Explicit standards**

#### **Delivery of interventions**





# **Explicit standards**

### **Delivery of interventions**



























# **Summary**



- Explicit standards play an important role in the delivery and evaluation of Pharmaceutical Care Interventions
- An extensive set of medication use standards has been developed and validated by a panel of UK experts/practitioners
- Improvements in the 'Adherence to standards' of medication use may be a useful intermediate outcome for pharmaceutical care interventions
- A generic algorithm to use explicit standards as a means of quantifying improvements in the adherence to standards has been suggested

# Thank you

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# **Data presentation formats**





B Guthrie, T Love, T Fahey, A Morris, F Sullivan . Control, compare and communicate: designing control charts to summarise efficiently data from multiple quality indicators. Qual Saf Health Care 2005;14:450–454. doi: 10.1136/qshc.2005.014456



Figure 2 League table and 95% confidence intervals for glycated haemoglobin control in type 2 diabetes in Tayside practices.

B Guthrie, T Love, T Fahey, A Morris, F Sullivan . Control, compare and communicate: designing control charts to summarise efficiently data from multiple quality indicators. Qual Saf Health Care 2005;14:450–454. doi: 10.1136/qshc.2005.014456



## **Data presentation formats**











### **Data presentation formats**

Tayside	Indicator	Practice													
average		1	2	3	4	5	6	7	8	9	10	11	12	13	14
81.7%	BMI recorded	0	0	0	•	0	•	0	0	$\circ$	$\circ$	•	$\circ$	0	0
92.6%	Smoking recorded	0	0	0	•	$\circ$	•	•	•	$\circ$	0	•	0		0
92.7%	HBA1c measured	0	0	0	•	0	0	0	0	0	$\circ$	0	0	0	0
55.7%	HBA1c ≤7.4%	0	0	•	•	0	0	0	0	$\circ$	$\circ$	0	0	٠	0
86.8%	HBA1c ≤10%	0	0	0	•	0	0	0	0	$^{\circ}$	$\circ$	0	$\circ$	0	0
69.3%	Pulses screening	$^{\circ}$	0		•	0	•	•	•	0	$\circ$	•	$\circ$	0	$\circ$
70.4%	Neuropathy screening	$^{\circ}$	0	$\circ$	•	0	٠	•	•	•	$\circ$	•		٠	0
85.5%	BP measured	0	0	0	•	0	٠	0	$\circ$	$\circ$	$\circ$	•	$\circ$	$\circ$	•
46.4%	BP ≤145/85	0	$\circ$	•	•	0	•	0	0	$\circ$	$\circ$	•	0	0	$\circ$
57.6%	Microalbuminuria screening	•	0	0	•	0	•	•	•	•	$\circ$	•	$\circ$	0	•
91.6%	Creatinine measured	0	0	0	٠	0	0	0	0	0	0	0	0	0	0
84.8%	Cholesterol measured	0	$\circ$	0	•	$\circ$	0	0	0	0	$\circ$	0	$\circ$	0	0
52.1%	Cholesterol ≤5 mmol/1	0	$\circ$	0	•	$\circ$	0	0	0	0	0	0		$\circ$	0

Much better than Tayside average (outside 99% upper control limit)

- O Better than Tayside average (between upper 95% warning and 99% control limits)
- O Consistent with Tayside average
- Worse than Tayside average (between lower 95% warning 99% control limits)
- Much worse than Tayside average (outside 99% lower control limit)

Figure 5 Control chart signals for 13 measures in 17 practices in one locality (practices compared with Tayside regional mean).