

**Glad you brought it up: A patient-centred programme to reduce proton-pump inhibitor prescribing in general medical practice**

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## Quality improvement in action

# Glad you brought it up: a patient-centred programme to reduce proton-pump inhibitor prescribing in general medical practice

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### ABSTRACT

**Background** Many patients unnecessarily receive proton-pump inhibitor (PPI) drugs long term with significant financial and safety implications. Educating, empowering and supporting patients to self-manage their symptoms can lead to significant and sustained reductions in PPI prescribing. We aimed to implement a programme to reduce inappropriate PPI prescribing.

**Method** Eligible patients in one general medical practice in rural Scotland were invited for participation between November 2008 and February 2010. Patients attended special nurse advisor clinics, completed dyspepsia questionnaires, received information, formulated self-management plans and were offered flexible support.

**Results** Of the study population, 437/2883 (15%) were prescribed PPIs. Of these, 166 (38%) were judged eligible for participation. After 12 months, 138/157 (83%) had reduced or stopped their PPIs, while 19/157 (11%) had reverted. The estimated

annual net saving in the prescribing budget was £3180.67. Self-reported understanding of symptom self-management increased from 6/20 (30%) to 18/20 (90%) patients after participation in the programme.

**Conclusion** A patient-centred programme delivered by a specialist nurse significantly reduced PPI prescribing with financial and potential therapeutic benefits. The vast majority of eligible patients were able to 'step down and off' or 'step off' PPI use after 12 months without any complications or deteriorating symptom control. Further research with larger cohorts of practices and patients is needed to develop a feasible, acceptable and effective programme if similar benefits are to be achieved for primary care in general.

**Keywords:** alginate, gastro-oesophageal reflux, general medical practice, non-ulcer dyspepsia, primary care, proton-pump inhibitor

### How this fits in with quality in primary care

#### What do we know?

Many patients continue proton-pump inhibitor (PPI) drugs long term with no clinical need, significant costs and potential adverse effects. Supporting patients to self-manage their symptoms can lead to significant and sustained reductions in PPI prescribing.

#### What does this paper add?

A patient-centred programme delivered by a specialist nurse, providing information, self-management plans and flexible support significantly reduced PPI prescribing with financial and potential therapeutic benefits.

## Introduction

Proton-pump inhibitors (PPIs) are one of the most commonly prescribed healthcare products internationally and in the UK. The number of dispensed items has increased substantially from 19.9 million (2004) to 39.5 million (2010) in England<sup>1</sup> and from 2.6 million (2004) to 4.4 million (2010) in Scotland.<sup>2</sup> The estimated financial cost to the NHS exceeds £230 million annually and global expenditure has been estimated at £7 billion.<sup>1-3</sup> It has been suggested that as much as 70% of PPI prescriptions and expenditure may be unnecessary.<sup>3,4</sup>

Gastro-oesophageal reflux disease (GORD) and non-ulcerative dyspepsia (NUD) are common in developed countries, with an estimated population incidence of 20–40%.<sup>5</sup> PPIs are commonly prescribed for these conditions, even though they do not prevent reflux and do not reduce bile salts or pepsin implicated in GORD.<sup>6</sup> Up to 61% of patients have refractory symptoms in spite of regular PPI use.<sup>7-9</sup> Long-term acid suppression may also have significant safety implications.<sup>10</sup> PPIs have been associated with increased risk of hip,<sup>11</sup> spine, wrist and forearm fractures<sup>10,12</sup> and increased prevalence of hospital- and community acquired pneumonia,<sup>13,14</sup> *Campylobacter enteritis*- and *Clostridium difficile*-associated disease.<sup>15</sup>

National guidelines have aimed to rationalise prescribing of PPIs in primary care to ensure best practice and cost-effectiveness in the management of GORD and NUD.<sup>16,17</sup> It is recommended that patients with these conditions be reviewed regularly, should receive disease-specific information and lifestyle advice, and that they should be encouraged to self-treat with antacids or alginates. The latest guidelines also recommend a 'step-down', 'on-demand' and 'step-off' approach to PPI therapy, tailored to individual patient needs. Recent studies suggest that implementing this alternative approach to continuous, daily PPI usage may effectively manage up to 70% of patients.<sup>18,19</sup>

Reducing unnecessary PPI prescribing and returning patients to self-care are clearly desirable, given the potential patient harm, financial implications and

clear guidance recommending this as best practice. We aimed to implement and evaluate the effectiveness of a structured educational intervention to reduce PPI prescribing in one general medical practice. The main outcome measure was the number of patients that successfully 'stepped down' or 'stepped off' PPIs. A second outcome measure was the net financial effect on the prescribing budget.

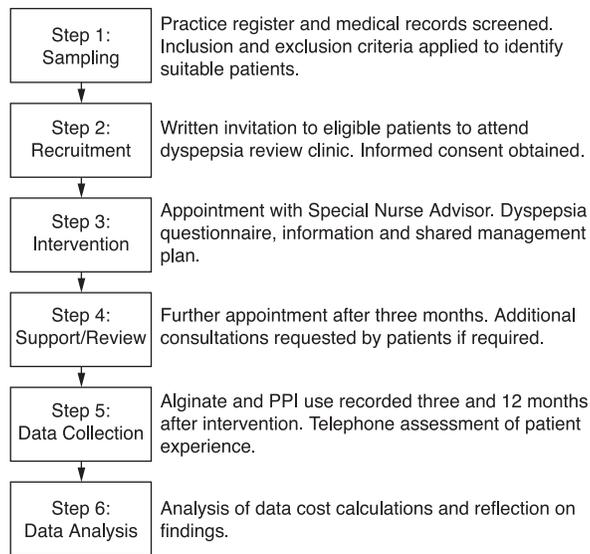
## Method

### Study design

The study was a prospective intervention with formal patient education on their condition, therapeutic management options and potential lifestyle modifications. The methodology was applied in a step-wise manner and is summarised in Figure 1.

### Sample and setting

All patients in one general medical practice in Scotland with long-term PPI usage were considered for participation. Long-term PPI usage was defined as prescriptions for a minimum of two consecutive months that were obtainable by the patient without a consultation, i.e. a 'repeat' item. A PPI unit was defined as a 28-day supply of the drug at whatever dose the general practitioner (GP) had intended. The practice's electronic register was searched to identify all potentially suitable patients. Their medical records were subsequently screened by a specialist nurse advisor (SNA) who applied agreed inclusion and exclusion criteria (Box 1). Patients could also be excluded if their GP advised against involvement. Between November 2008 and February 2010 all eligible patients were sent written invitations to consent to and attend a 20-minute dyspepsia clinic appointment with an SNA.



**Figure 1** Study methodology

### Box 1 Inclusion and exclusion criteria

#### Inclusion criterion

A repeat PPI prescription issued for at least the preceding two months AND  
 Aged > 18 years AND  
 A diagnosis of GORD or NUD

#### Exclusion criteria

Patients on healing doses of PPIs < one month for uninvestigated dyspepsia  
 Patients on maintenance dose PPIs < one month for non-ulcer dyspepsia  
 Patients on healing doses of PPIs < two months for GORD/peptic ulcer disease  
 Patients currently on *Helicobacter pylori* (HP) eradication therapy  
 Patients under review at gastrointestinal clinic or awaiting referral  
 Patients awaiting gastroscopy or review after procedure  
 Zollinger Ellison Syndrome  
 Patients > 90 years old  
 Patients with a terminal illness  
 Patients with grade III or IV oesophagitis  
 Patients on high-dose steroids with life-threatening or chronic diseases, e.g. patients awaiting transplant, post-transplant patients  
 Patients receiving immune-suppression therapy  
 Patients undergoing chemotherapy or radiotherapy  
 Patients with oesophageal strictures or previous oesophageal dilatation  
 Patients with a history of oesophageal varices  
 Patients with 'red flag' symptoms/alarm signs

#### Exceptions

The following patients were considered for step-down to the lowest maintenance dose of PPI but were not considered for 'step off' and self-management only plans:  
 Patients with a history of peptic ulceration but negative *Campylobacter*-like organism (CLO) tests status  
 Patients diagnosed with Barrett's oesophagus (maintenance dose omeprazole)  
 Patients who must unavoidably continue with non-steroidal anti-inflammatory drugs apart from high risk of ulceration, including the elderly  
 Patients on aspirin to prevent cardiovascular disease apart from high risk of ulceration including the elderly

## Nurse-led dyspepsia clinic

During the initial visit, all patients were asked to complete a 'patient counselling questionnaire' to obtain a structured history of previous investigations and to screen for 'alarm' symptoms. Patients with 'alarm' symptoms such as persistent vomiting, bleeding  $\pm$  anaemia, unexplained weight loss or difficulty swallowing were referred to their GP. Patients who had not undergone screening for *Helicobacter pylori* infection were referred to the practice nurse for testing and re-entered into the programme on completion of eradication therapy.

Patients were given verbal and written educational information about their condition, its causes, risk factors, alternative treatment options to PPIs and lifestyle advice. Risk factor management included a brief alcohol intervention and smoking cessation advice if relevant. The SNA also assisted patients to formulate and agree specific action plans to reduce and/or stop their PPI usage. As part of this plan participants were offered a prescription for Gaviscon Advance Aniseed Suspension® (active substances sodium alginate and potassium bicarbonate), an alginate licensed for rebound dyspepsia and breakthrough symptoms.<sup>20</sup> Further appointments were offered to all patients according to their individual needs and schedules. Patients who had consented to participate but did not attend the clinic were sent two further invitation letters offering flexible appointment times.

## Data collection

All patients were encouraged to attend the clinic at least once more for review 12 weeks after the initial meeting. During this consultation, the SNA recorded the patient's progress, alginate and PPI use and provided more information and support if required. After six months, the SNA randomly selected a convenience sample of 20 patients and administered a structured interview template with five questions telephonically to assess their experience of the intervention. Finally, during July and August 2011 patients' records were reviewed by the SNA to retrospectively record patient's PPI and alginate use for the 12-month period following the intervention.

## Data analysis

The data were coded in a Microsoft Office Excel 2003 spreadsheet. Simple descriptive statistics were used to calculate the number and percentages of patients who had reduced or stopped their PPIs after 3 and 12 months. Pearson's correlation coefficients were calculated in PASW Statistics version 17.0 to test for associations between subgroups (patients who successfully stepped down or off and those that reverted) and variables

(age, gender, smoking status, weight and alcohol use). The net financial costs of PPI and alginate use were calculated for the 12-month period. All annualised cost estimates were derived from *Drug Tariff* and *British National Formulary* prices at the end of the study. Annual savings were calculated by comparing monthly PPI costs at baseline with PPI costs and additional 'Gaviscon Advance' at the conclusion of the programme. The results were verified by an NHS Lanarkshire pharmacist.

## Results

### Patient and practice demographics

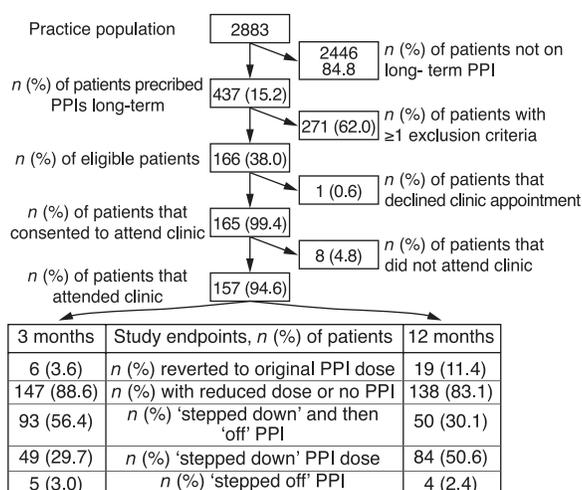
The practice is situated in Lanarkshire and serves a rural, former mining community. The incidence of chronic disease and obesity, levels of deprivation and percentage of elderly patients are all higher than the local or national averages. Of the study population of 2883 patients, 437 (15%) were prescribed PPIs as repeat items (Figure 2).

Applying the inclusion and exclusion criteria 166/437 (38%) of potentially eligible patients were identified. Of these, 92 (55.4%) were female and 72 (43.4%) male. Their ages ranged from 32 to 89 years with a median age of 63.3 years (SD = 14.1). Table 1 summarises patients' recorded body mass index (BMI), smoking status and alcohol consumption.

### Prescribing outcomes

One hundred and forty-seven patients (147/157; 88.6%) had successfully 'stepped off' their PPI or reduced the dose three months after the intervention, while 6/157 (3.6%) had reverted to their original usage. After 12 months, 138/157 (83.1%) had reduced or stopped PPI use, with 19/157 (11.4%) reverting back to their original use. The numbers that 'stepped down', 'stepped off' or 'stepped down then off' are shown in Figure 2. There were no statistical significant differences detected between patients who successfully stepped down or off and those that reverted for the following variables: gender ( $P = 0.107$ ), age ( $P = 0.210$ ), smoking status ( $P = 0.267$ ), alcohol use ( $P = 0.996$ ) or BMI ( $P = 0.413$ ).

The estimated annual cost of alginate rescue prescribing increased by £513.02, while PPI prescribing costs were reduced by between £3693.69 and £4521.40. The estimated annual *net* savings for the practice were £4008.38 based on PPI costs at the start of the intervention and £3180.67 when based on PPI costs at the end.



**Figure 2** Summary of the study process and main outcomes, i.e. discontinuation of PPI or reduction in PPI dose at three and 12 months

**Table 1** Demographic data and potential risk factors of eligible patients.

	Male <i>n</i> = 72	Female <i>n</i> = 92	Total <sup>a</sup> <i>n</i> = 166
<b>Smoking status</b>			
Non-smoker	30 (43.5)	52 (57.1)	82 (51.3)
Ex-smoker	22 (31.9)	16 (17.6)	38 (23.8)
Smoker	17 (24.6)	23 (25.3)	40 (25.0)
<b>Body mass index (BMI)</b>			
Underweight (< 18.5)	0 (0.0)	0 (0.0)	0 (0.0)
Normal weight (18.5–24.9)	13 (19.4)	10 (11.4)	23 (14.8)
Overweight (25.0–29.9)	22 (32.8)	37 (42.0)	59 (38.1)
Obese (30.0–34.9)	23 (34.3)	20 (22.7)	43 (27.8)
Very obese (≥ 35)	9 (13.4)	21 (23.9)	30 (19.4)
<b>Alcohol consumption</b>			
Tee total	13 (19.4)	29 (32.2)	42 (26.8)
Within recommended limit	50 (74.6)	60 (66.7)	110 (70.1)
More than recommended limit	4 (6.0)	1 (1.1)	5 (3.2)

<sup>a</sup> Missing data are included in the total where applicable.

## Patient perceptions

All 20 patients reported that the intervention had been helpful and 18/20 (90%) were happy with their symptom relief (Table 2). Reported understanding of symptom self-management increased from 6/20 (30%) to 18/20 (90%) patients after participation in the programme.

## Discussion

The vast majority of eligible patients had successfully stopped their PPI or 'stepped down' the dose 12 months after participating in an educational specialist nurse-led programme. The estimated financial impact on the practice prescribing budget was a net saving of several thousand pounds annually, even though alginate use increased. Additional benefits of the intervention may include a reduction in future adverse incidents resulting from inappropriate PPI use and participating

**Table 2** Patients' (*n* = 20) understanding of symptom self-management and perceived usefulness of intervention

Question	Yes <i>n</i> (%)
Did you understand how to manage your symptoms before the clinic?	6 (30)
Did you find the clinic helpful?	20 (100)
Do you now have a clearer understanding how your medication works?	20 (100)
Do you feel you can now manage your symptoms effectively?	18 (90)
Are you happy with your symptom relief?	18 (90)

patients' reported increased confidence and ability to self-manage their symptoms and condition.

## Comparison with literature

The vast majority of patients successfully 'stepped down' or 'stepped off' PPIs after participating in this programme. This is an achievable aim for patients with GORD or NUD in other primary care settings. For example, Cawston and Evans implemented a comparable specialist nurse-led programme in England. They reported that the vast majority (1106/1331; 83.1%) of eligible patients had successfully 'stepped down' or 'stepped off' PPIs after three months.<sup>21</sup> In North America, Inadomi *et al* found their PPI 'step-down' programme to be feasible, with 41/71 (58%) of patients with GORD asymptomatic after 12 months.<sup>22</sup> Cote *et al* reported that 111/223 (50%) of patients could be successfully maintained on once rather than twice daily PPI dosing, whereas 23/223 (10%) had discontinued treatment after 12 months.<sup>23</sup>

Prescribing reductions can still be achieved with less resource-intensive interventions. In the Netherlands, 14/59 (24%) of patients had stopped or reduced their PPI use 20 weeks after being sent an information leaflet, with no reported deterioration in their symptom severity or perceived quality of life.<sup>24</sup> One reason for the potentially large reductions in prescribing may be that a significant proportion of patients would never have tried stopping PPIs, often despite several years of regular use without a verified indication.<sup>9</sup> Educational leaflets or invitations to participate in a programme may supply the necessary trigger to contemplate change.

Discontinuation of acid-suppressive therapy can induce significant rebound acid hypersecretion for up to 11 months, which may, in turn, cause an exacerbation of GORD and NUD symptoms.<sup>25,26</sup> This rebound phenomenon is a potentially important barrier to reducing and withdrawing PPI therapy.<sup>9</sup> Alginates do not change the pH of gastric content and may be useful to control symptoms during this period. Suc-

cessful self-treatment of symptoms with a variety of non-PPI antacids have previously been reported in other settings.<sup>23,27</sup> A key part of our intervention was to explain this concept to patients and to offer 'as required' alginates to self-manage expected symptoms.

Dibley *et al* recently implemented a nurse-led non-pharmacological GORD education programme in UK primary care. While patients reported enhanced self-management and symptom improvement after three months, their overall PPI use had remained unchanged.<sup>28</sup> Our experience may support their proposal that an educational intervention should be combined with medical management to achieve reduced PPI prescribing for selected patients.

No statistically significant difference has previously been found between PPI tapering or discontinuing strategies.<sup>27</sup> In our experience, the majority of patients were able to 'step down' their PPI use after 12 months, a minority could be 'stepped down then off' over the same period, but only a very small minority could be 'stepped off' PPIs directly and permanently. The number of patients who successfully 'stepped down only' increased substantially between 3 and 12 months, whereas the number who 'stepped down then off' decreased. This may indicate that tapering may ultimately be a more realistic goal than discontinuation for the majority of patients.

The majority of patients who are unable to 'step-down' or 'step off' their PPI will revert within the first month.<sup>23</sup> This can be observed in the small reduction in number of patients who had reverted and who successfully stepped down or off PPIs at 3 and 12 months. The availability of flexible support offered by our programme to patients during the initial vulnerable period may have helped to prevent more patients reverting. This was also the rationale to recommend a minimum of at least one further face-to-face follow-up appointment within 3 months to all patients during their initial attendance.

Self-management has been promoted as an effective approach to various chronic medical conditions.<sup>29</sup>

Our study suggests that empowering patients to self-manage their symptoms with alginates and targeted education and support can lead to significant and sustained change.<sup>28</sup> Our experience, and experience from comparable programmes, may help to inform effective future programmes to address inappropriate repeat prescribing for other chronic or recurrent symptoms and conditions.

## Strengths and limitations

The programme was patient-centred. Patients were actively involved, offered support tailored to their specific needs and empowered to self-manage their symptoms. Although the programme content was structured, delivery was flexible to accommodate patients' individual requirements and time schedules. The observed reduction in PPI prescribing is comparable with or exceeds previously reported outcomes. The follow-up periods of 3 and 12 months provided a measure of the sustainability of prescribing changes. Patients reported high levels of satisfaction with the programme and reported increased understanding and ability to self-manage their symptoms. A range of educational tools was developed during the course of the programme to facilitate implementation of a similar intervention in other general practices, including: a patient consent form, counselling questionnaire, practice and patient information leaflets, a video consultation and patient feedback questionnaire.

The study has a number of limitations. It was conducted in a single general medical practice which may not be representative of local or national demographics and patient motivation. There was no control group, so improvements may be a result of intervening, rather than attributable to the intervention. It is also impossible to know the relative contribution prescribing an alginate made to the overall intervention or whether an alternative antacid may have been equivalent or even superior. The financial assessment of the intervention did not consider the cost and time of the SNA. The same person conducted all clinics, which ensured parity of experience for patients. However, her unique characteristics may have introduced some bias to the observed outcome effect. Finally, reducing PPI prescribing may be associated with increased diagnoses such as erosive oesophagitis or peptic ulcer disease.<sup>23</sup> We did not find evidence of any adverse effects within the study period, but this issue may have patient safety and resource implications.

## Conclusion

A patient-centred programme delivered by a specialist nurse significantly reduced PPI prescribing with financial and potential therapeutic benefits. The vast majority of eligible patients were able to 'step down and off' or 'step off' PPI use after 12 months without any complications or deteriorating symptom control. Further research with larger cohorts of practices and patients is needed to develop a feasible, acceptable and effective programme if similar benefits are to be achieved for primary care in general.

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#### ETHICAL APPROVAL

The study was judged to be service evaluation and therefore no ethical review was sought. Informed consent was secured from patients in writing before the first consultation. Data were stored and handled in accordance with the Data Protection Act (2003). Patient confidentiality has been maintained in all representations of the data.

#### PEER REVIEW

Not commissioned; externally peer reviewed.

#### CONFLICTS OF INTEREST

Jane Allen is an independent special nurse adviser and Ray Simmonds is a Consultant Pharmacist employed by Pharmexx UK Ltd who was sponsored by Reckitt Benckiser manufacturers of Gaviscon Advance® to provide services to the practice, commissioned by NHS Lanarkshire.

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