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#### 1 Pharmacist-led academic detailing intervention in primary care: A mixed methods

#### 2 feasibility study

#### 3 Introduction

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4 The International Continence Society (ICS) has defined urinary incontinence as "the complaint

of any involuntary leakage of urine" [1]. Despite the availability of evidence-based guidelines,

some patients do not receive recommended treatment because of their reluctance to report this

condition. In addition, when patients do seek help, many physicians are not familiar with the

latest information on the appropriate methods of evaluating and treating patients with this

9 condition [2].

Academic detailing is an interactive, convenient, and user-friendly approach that provides noncommercial evidence-based medical information tailored to the needs of an individual. A key tenant of the intervention is eliciting the provider's beliefs and attitudes and addressing those specifically during the encounter [3]. Academic detailers (who are usually pharmacists, nurses, or physicians) are trained to provide accurate, balanced, and up-to-date syntheses of the evidence on a clinical topic in an engaging format with healthcare professionals in their work environment [4]. These educational visits appear to be especially effective in improving prescribing appropriateness in general practice [5]. Other approaches to optimise prescribing behaviour include a healthcare professional such as a pharmacist carrying out medication reviews and providing feedback to GPs [6]. Computerised decision support systems (CDSS) are widely used tools that can support prescribing practice activities. They provide narrative information usually in the form of an alert at the time of prescribing or at the end of the patient consultation [7]. However, these approaches have their limitations, for example, there have been conflicting results reported for medication reviews conducted by pharmacists [8,9]. CDSS alerts can lead to alert fatigue, cognitive overload and desensitisation raising questions about the effectiveness of decision support [10]. This suggests that other interventions such as academic detailing are required to optimise clinical outcomes and patient care.

To date, no studies have evaluated the feasibility and acceptability of an academic detailing intervention with General Practitioners (GPs) in Ireland. Prior to implementing an intensive intervention like academic detailing on a national scale, it is prudent to evaluate the potential effect in a feasibility study. Eldridge *et al.* have defined a feasibility study as a study asking "whether something can be done, should we proceed with it, and if so, how". They are used to estimate important parameters that are needed to design larger studies, for example: feasibility of recruitment, number of eligible participants, and selection of appropriate outcomes [11]. As the burden of urinary incontinence can impact on the lives of people worldwide (especially older adults), this would underline why a feasibility study of an academic detailing intervention is needed.

# Aim of the study

- 39 The aim of this study was to assess the feasibility and acceptability to GPs of a pharmacist-led
- 40 academic detailing intervention in Ireland.

#### **Ethics approval**

- 43 Ethical approval for this study was granted by the clinical research ethics committee of the
- 44 Cork University Teaching Hospitals, Cork (reference ECM 4 (s) 10/05/16 & ECM 3 (ddddd)
- 45 07/03/17) and the Mallow Primary Health Centre (MPHC), Cork Ethics Committee. Informed
- consent was obtained from all individual participants included in the study.

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#### Methods

## Study type

In this study a convergent parallel mixed methods design was used. This involves the separate collection and analysis of quantitative and qualitative data with the intent of merging the results of both analyses. The premise of a mixed methods approach is that the use of quantitative and qualitative methods in combination provides a better understanding of research problems than either approach alone [12]. The aim was to collect, analyse, and interpret integrated quantitative and qualitative data to assess the feasibility to GPs of an academic detailing intervention in primary care. The quantitative prescribing patterns of the GPs and their qualitative responses from the focus groups were integrated and synthesised.

# Setting

This study was carried out in six General Practices in County Cork, Ireland. The primary researcher (D.O.R.) arranged a meeting with the lead GP in each practice, and a brief summary of the study was given. Other potential participants in each practice were contacted by telephone and invited to participate. Twenty-three GPs participated in the intervention. All GPs who participated in the study received a certificate of participation and a certificate for their continuing professional development (CPD).

#### **Academic detailing training**

D.O.R. received formal training in academic detailing by attending a two-day workshop at the National Resource Center for Academic Detailing (NaRCAD) in Boston, USA in May 2016. The workshop provided a critical foundation for the role as an academic detailer. It included sessions on the case for academic detailing and evidence-based medicine, planning a visit, use of educational materials and role plays.

#### Academic detailing materials

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72 For the academic detailing sessions, materials developed by the Alosa Foundation were used.

The Alosa Foundation in Boston is a non-profit organization and is independent of the

pharmaceutical industry. It produces educational materials and decision making tools for

Academic Detailers, and provides training on academic detailing internationally. The Alosa

Foundation granted the authors permission to use their educational materials for this study. The

printed materials consist of evidence-based information on the prevalence of urinary

incontinence, an overview of the pharmacological and non-pharmacological interventions, cost

of drugs to treat the condition, and key messages.

# **Choice of topic**

Prior to commencing GP recruitment, D.O.R. met with three GPs to discuss an intervention

topic. The topic of urinary incontinence was chosen for the academic detailing intervention by

GPs because they highlighted that it was a topic not discussed regularly among themselves,

and currently their only source of information is provided by pharmaceutical drug

representatives.

# **Piloting the intervention**

87 The academic detailing intervention was piloted with three academic GPs in May 2016 before

the study was commenced. The GPs reported that they were very satisfied with this overall

educational approach. The topic delivered and the educational materials used during the visit

were also described as being very beneficial and relevant.

# **Delivery of the intervention**

The intervention was delivered face-to-face with each GP in their practice. D.O.R contacted

the GP's receptionist in advance to book a 15-minute time slot with each GP for the meeting.

One of the tenets of academic detailing is to provide evidence based information over a succinct time period.

During the meeting, D.O.R provided the following key messages to GPs: (i) increase detection of and distinguish incontinence type to guide treatment, (ii) identify and rule out reversible causes of incontinence, (iii) encourage caffeine reduction, pelvic floor muscle training, and weight loss as first-line treatments, and (iv) judiciously prescribe medications for urgency symptoms (but not stress incontinence). GPs were encouraged to discuss these key messages with their patients when they presented for their next GP appointment. After the meeting, GPs were given a copy of the printed materials to use as a reference.

The academic detailing intervention was rolled out to participating GPs between June and September 2016. Supplementary Figure I shows the timeline of the study.

# **Quantitative method**

A before and after analysis of patient medical records was conducted. All patients aged  $\geq$ 65 years with urinary incontinence treated by participating GPs were included. These patients were identified by searching GP databases and notes. D.O.R. extracted data from medical records at five time points: six and three months before the intervention ( $T_{-6}$ ), ( $T_{-3}$ ), at the time of the intervention ( $T_{0}$ ), and three and six months after the intervention ( $T_{3}$ ), ( $T_{6}$ ). For example, if the intervention was delivered to a GP in June 2016, data extraction and audit of their patient medical records was performed retrospectively in December 2016 for the following months: December 2015, March 2016, June 2016, September 2016 and December 2016. Patients were identified as having urinary incontinence based on a diagnosis by the GP or referral letters from consultant urologists. In some cases, prescription drugs (e.g. mirabegron, tolterodine) identified from medical records were used as proxies to indicate a diagnosis of urinary

incontinence. An assessment of patient medical records was carried out at five time points in the study to identify if pelvic floor muscle training was documented.

The following criteria were applied to the patient data recorded:

#### **LUTS-FORTA** criteria

Drugs to treat lower urinary tract symptoms (LUTS) in older people aged ≥65 years are classified on their appropriateness based on efficacy, safety, and tolerability using the Fit fOR The Aged (FORTA) criteria. These criteria classify drugs for the treatment of LUTS into four ordinal categories, A (absolutely: indispensable drug), B (beneficial: drugs with proven efficacy), C (careful: drugs with questionable efficacy/safety profiles), and D (don't: avoid in older people) [13].

#### The Drug Burden Index (DBI)

The DBI measures the cumulative exposure to anticholinergic and sedative medicines in older people and its impact on physical and cognitive function [14]. For each drug, the DBI ranges from 0-1, with 0 being no burden, 0.5 being exposure to the minimum daily dose, and upwards to 1 as the dose is increased exponentially [15]. In this study, the list of drugs with clinically significant anticholinergic and sedative effects were defined from a composite list developed from a review by Duran *et al.* 2013, the Anticholinergic Cognitive Burden (ACB) scale developed by Boustani *et al.* 2008, and from a study published by Ailabouni *et al.* 2017 [16-18]. This composite list consisted of 133 drugs (See Supplementary Table I).

# Anticholinergic Cognitive Burden (ACB) scale

The cumulative effect of taking multiple medicines with anticholinergic properties is defined as the anticholinergic burden [19]. The ACB scale is based on a systematic literature review of medicines with known anticholinergic activity. The scale consists of 88 drugs with known anticholinergic activity and assesses individual drugs that have none, possible, or definite anticholinergic properties with a score ranging from 0 to 3 [17].

D.O.R. applied the LUTS-FORTA, DBI, and ACB to patient-related data retrieved from the electronic medical records. For validation purposes, the three types of criteria were applied independently by a second member of the research team to a random 10% sample of the data.

#### **Outcomes**

The three outcomes of interest were the overall changes in scores of LUTS-FORTA, DBI, and ACB in the patients.

## Statistical analysis

It is important to note that a feasibility study is not a hypothesis testing study [20]. One of the key aspects of these studies is that they do not evaluate effectiveness as they are not powered to do so [21]. The main focus of this study was to assess feasibility of the intervention, and therefore the data were analysed using descriptive statistics. Continuous variables were presented as mean with standard deviation (SD) and range, or median with interquartile range (IQR), as appropriate, and categorical variables as frequency (percentage).

162	Qualitative method
163	After the intervention was delivered to participating GPs by D.O.R., focus groups were
164	conducted with GPs to explore its feasibility and acceptability.
165	The focus groups were carried out by three researchers (E.H., C.S., and S.B.) between July and
166	November 2016. A topic guide was developed based on discussion and consensus among all
167	authors. The topic guide was iteratively refined after each focus group, was transcribed, and
168	analysed to pursue emerging themes.
169	All focus groups were anonymised and fully transcribed and saved in QSR International NVivo
170	Qualitative Data Analysis Software (V.10.22) to facilitate analysis. Data were analysed using
171	thematic analysis. This flexible and useful research approach can potentially provide a rich and
172	detailed account of the data [22].
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174	Standardised reporting guidelines
175	The Good Reporting of a Mixed Methods Study (GRAMMS) framework was used to inform
176	reporting of the findings [23]. (See Supplementary Table II).
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178	Results
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180	Quantitative results
181	The characteristics of 154 patients diagnosed with urinary incontinence included in the study
182	are detailed in Table I. The documentation of pelvic floor muscle training was reported in 15%
183	of patient medical records at only one-time point in the study (T-6).

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#### **LUTS-FORTA score**

Figure I shows the number of patients prescribed drugs identified by the LUTS-FORTA criteria over time. According to the criteria, no patient was prescribed a drug rated in category A (absolutely: indispensable drug) at any time point. There was an increase in the number of patients prescribed drugs in category C (careful: drugs with questionable efficacy/safety profiles), over time, while there was no change in the number of patients prescribed drugs in category B (beneficial: drugs with proven efficacy) and D (don't: avoid in older people) over time. Supplementary Table III shows the drugs that were identified by the LUTS-FORTA criteria in this study.

# **Drug Burden Index**

Almost 65% (100/154) of patients did not show any change in drug burden over time.

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#### Anticholinergic cognitive burden (ACB) scale

Thirty-four percent of patients at T<sub>-6</sub> months and 31% of patients at T<sub>6</sub> months had an ACB score of 0.

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# **Qualitative results**

Five focus groups were conducted in total (n=14 GPs). The mean number of participants per focus group was 3 (range 2 to 4). The focus groups ranged from 19 minutes to 48 minutes. The number of GPs working in a practice ranged from 1 to 7. The characteristics of GPs interviewed are detailed in Table II. Quotes supporting each theme/sub-theme are presented in Table III.

Theme 1: The Academic detailing experience 211 **Subtheme:** Convenience of academic detailing 212 Participants highlighted the convenience of the academic detailing session being carried out in 213 their working environment. They welcomed this educational visit being delivered with little 214 disturbance to their daily practice. They also reported that they are prepared to block out some 215 216 of their working time to accommodate this source of evidence-based information. 217 This was in contrast to the alternative sources of evidence-based information that are currently 218 219 available for GPs, for example: attending conferences, continuing medical education meetings, 220 or educational events on topics. Participants reported the frustration at not being able to attend courses of interest due to the demands of their work schedule. 221 222 **Subtheme:** The interaction between participant and academic detailer 223 Participants described the interaction between the GP and the academic detailer as being 224 important to the success of the intervention. They reported that the session worked because it 225 felt relaxed and free of pressure. This was in contrast to their experience with some 226 pharmaceutical drug representatives who they described as having an aggressive approach 227 combined with an overload of information, which seemed to aggravate participants. 228 229 230

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**Themes** 

**Subtheme:** The educational materials 232 233 Participants said they liked the educational materials because they had a clear layout and were 234 easy to follow. They reported that they valued the succinct nature of the key messages, while the tables and figures were presented in a straightforward way. 235 236 **Subtheme:** The topic: Urinary incontinence 237 The topic of urinary incontinence was agreed by a number of GPs prior to rolling out the study. 238 Participants reported that this topic was relevant and suitable to general practice. The relevance 239 of this topic facilitated the delivery of the intervention to GPs. 240 241 Theme 2: Behaviour change 242 243 Participants described the likelihood of changing their behaviour in treating patients with urinary incontinence following the intervention. However, this change in behaviour could be 244 influenced by environmental resources, such as the availability of primary care 245 physiotherapists. 246 247 **Subtheme:** Knowledge gained 248 Participants were asked if they had gained any knowledge from the intervention. Some 249 participants of recent medical experience were not aware of the important role that non-250 pharmacological methods play in treating urinary incontinence. 251

For some participants, the intervention served to refresh their knowledge with the topic rather 253 than gain new knowledge as some of the treatment options may be more commonly used than 254 255 others. Theme 3: Sustainability 256 257 **Subtheme:** Academic detailing ownership Participants were asked how this type of educational intervention could be rolled out to a wider 258 group of GPs in Ireland. Some suggested that it could be affiliated with the Irish College of 259 260 General Practitioners (ICGP), the professional and educational body for general practice in Ireland. The association with this recognised body could enhance the credibility of academic 261 detailing among GPs. 262 263 **Subtheme:** Alternative formats of educational material 264 Participants suggested an online version of the educational material, which would be easier for 265 them to manage in a setting where print materials over-accumulate or go missing. 266 267 **Subtheme:** Desire for practice staff involvement 268 269 Participants highlighted the importance of incorporating the wider members of the practice team in the academic detailing sessions. This is especially significant given the expanded role 270 271 of nurses in primary care. 272 273

# **Subtheme**: Future participation

Participants were asked if they would be interested in participating in future academic detailing studies. All indicated a willingness to do so.

#### **Discussion**

This study used a mixed methods approach to explore the feasibility and acceptability to GPs of a pharmacist-led academic detailing intervention.

Participants described the possibility of behaviour change following the intervention; however, this was partly dependent on the availability of primary care resources such as physiotherapists. In Ireland, public patients are often on a waiting list to attend primary care physiotherapists. Pelvic floor muscle training is an effective treatment for women with urinary incontinence and these exercises are often demonstrated by physiotherapists [24]. Therefore, if academic detailing interventions are successful, then the treatment modalities recommended by academic detailers need to be resourced. Participants described the educational materials as being high quality. These materials contain evidence-based information on the prevalence of urinary incontinence, an overview of the interventions and cost of drugs to treat the condition, and key messages which may be very beneficial for GPs. However, if this information is not easily retrievable for GPs then they may not be used as a treatment resource during a patient consultation [25]. This may have limited the change in prescribing outcomes in the study. Participants called for these materials to become available as an online resource as they could be of value in optimising the diagnosis and management of urinary incontinence.

#### **Comparison with existing literature**

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Allen et al. used a mixed methods study (a questionnaire and semi-structured telephone interviews) to explore family physician perceptions of academic detailing and identified several factors that encourage its use. They were: the relevance of the topic, the evidence-based approach adopted, and the educational material used [26]. These findings are similar to those in our study. The GPs selected the topic of urinary incontinence for the intervention and described it as relevant. They welcomed the idea of evidence-based information being presented to them in their practice and they also described the educational materials used as being of high quality. Soumerai recommends that educational materials should be brief and clearly presented [27]. For this intervention, all GPs received one visit from the detailer, however research has indicated that frequent reinforcement visits can optimise behaviour change [28]. In this study, GPs indicated a willingness to participate in future academic detailing studies. Hartung et al. and Anthierens et al also reported similar findings [4,25]. The measures of prescribing assessed: the LUTS-FORTA, DBI, and ACB showed minimal or no change in their scores following the intervention. As a feasibility study, this study was not conducted with a view to effecting change in prescribing outcomes, rather to see if the intervention was feasible and acceptable to GPs and whether this preliminary research was appropriate for successful implementation in subsequent larger studies. Our findings suggest GPs are open to this type of intervention, and recruitment and follow-up are possible. A larger study is required to more accurately examine the potential for meaningful change in clinical care. The choice of topic for the academic detailing intervention was an important influence on GPs' readiness to participate in the study. It was possible that GPs chose urinary incontinence because of the difficulty in minimising the side-effects with associated treatments e.g.

anticholinergic effects and the limited availability of pharmacological options. The choice of urinary incontinence thus addressed GPs' learning needs but made evaluation of changes in prescribing difficult as many of the treatment options highlighted to GPs were non-pharmacological. Alternative topics for example, hypertension, atrial fibrillation, opioids in chronic pain may provide more scope to examine subsequent change in prescribing behaviours.

# **Strengths and limitations**

To enhance the validity of the quantitative results, a sample of the data were independently reviewed by two healthcare professionals. The focus groups were arranged with GPs over a five-month period and this facilitated prolonged engagement with the data.

Although 23 GPs participated in the intervention, only 14 were available to attend the focus groups. All participating GPs were contacted in advance about the focus groups; however, some were away on the scheduled date while others who agreed to participate had to cancel at the last minute due to clinical emergencies or late clinics. One solution to this issue would be to organise them outside of practice hours e.g. at continuing professional development meetings.

The findings from this study may be beneficial to other researchers when developing their own study designs as they may enhance their approach or avoid similar pitfalls [29]. In future studies, a follow-up visit could be arranged with the GPs after four to six weeks to reinforce the key messages from the first visit and to identify if they have been successfully implementing any suggested changes. It would also give the academic detailer an opportunity to answer any additional questions that the GPs may have. Implementing academic detailing on a broader scale may benefit from, a "train the trainer" approach. Instructors could train their colleagues and this would help to build a pool of competent academic detailers. Finally,

randomized controlled trials that are methodologically robust and have large sample sizes should be considered [30].

#### **Conclusion**

This mixed methods study explored the feasibility and acceptability to GPs of a pharmacist-led academic detailing intervention. Overall, participants reported that this evidence-based approach was beneficial and welcomed further visits. The selection of a relevant topic appeared to be an important aspect of their positive response. The printed educational materials were reported as being well-presented and easy to follow, however an online version was preferred. Our findings provide a useful platform for the evaluation of academic detailing in primary care on a larger scale. Further research is needed in a larger population to determine the impact on patient outcomes and the cost-effectiveness of academic detailing.

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# **Conflicts of interest** There are no conflicts of interest to declare. Funding This research was funded by the Health Research Board SPHeRE/2013/1.

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