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University College Cork, Ireland Coláiste na hOllscoile Corcaigh Pharmacist-led academic detailing intervention in primary care: A mixed methods
 feasibility study

3 Introduction

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 condition [2].

Academic detailing is an interactive, convenient, and user-friendly approach that provides non-10 11 commercial 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 12 specifically during the encounter [3]. Academic detailers (who are usually pharmacists, nurses, 13 14 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 15 environment [4]. These educational visits appear to be especially effective in improving 16 prescribing appropriateness in general practice [5]. Other approaches to optimise prescribing 17 behaviour include a healthcare professional such as a pharmacist carrying out medication 18 19 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 20 information usually in the form of an alert at the time of prescribing or at the end of the patient 21 22 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 23 24 alerts can lead to alert fatigue, cognitive overload and desensitisation raising questions about 25 the effectiveness of decision support [10]. This suggests that other interventions such as academic detailing are required to optimise clinical outcomes and patient care. 26

27 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 28 intervention like academic detailing on a national scale, it is prudent to evaluate the potential 29 effect in a feasibility study. Eldridge et al. have defined a feasibility study as a study asking 30 "whether something can be done, should we proceed with it, and if so, how". They are used to 31 estimate important parameters that are needed to design larger studies, for example: feasibility 32 33 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 34 35 older adults), this would underline why a feasibility study of an academic detailing intervention is needed. 36

37

38 Aim of the study

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

41

42 **Ethics approval**

Ethical approval for this study was granted by the clinical research ethics committee of the
Cork University Teaching Hospitals, Cork (reference ECM 4 (s) 10/05/16 & ECM 3 (dddd)
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.

48 Methods

49 Study type

50 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 51 52 of both analyses. The premise of a mixed methods approach is that the use of quantitative and 53 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 54 and qualitative data to assess the feasibility to GPs of an academic detailing intervention in 55 56 primary care. The quantitative prescribing patterns of the GPs and their qualitative responses from the focus groups were integrated and synthesised. 57

58 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).

65 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.

71 Academic detailing materials

For the academic detailing sessions, materials developed by the Alosa Foundation were used. 72 The Alosa Foundation in Boston is a non-profit organization and is independent of the 73 pharmaceutical industry. It produces educational materials and decision making tools for 74 Academic Detailers, and provides training on academic detailing internationally. The Alosa 75 76 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 77 incontinence, an overview of the pharmacological and non-pharmacological interventions, cost 78 of drugs to treat the condition, and key messages. 79

80 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.

86 **Piloting the intervention**

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.

91 **Delivery of the intervention**

92 The intervention was delivered face-to-face with each GP in their practice. D.O.R contacted93 the GP's receptionist in advance to book a 15-minute time slot with each GP for the meeting.

94 One of the tenets of academic detailing is to provide evidence based information over a succinct95 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.

103 The academic detailing intervention was rolled out to participating GPs between June and104 September 2016. Supplementary Figure I shows the timeline of the study.

105 **Quantitative method**

106 A before and after analysis of patient medical records was conducted. All patients aged ≥ 65 years with urinary incontinence treated by participating GPs were included. These patients 107 were identified by searching GP databases and notes. D.O.R. extracted data from medical 108 109 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, 110 if the intervention was delivered to a GP in June 2016, data extraction and audit of their patient 111 medical records was performed retrospectively in December 2016 for the following months: 112 December 2015, March 2016, June 2016, September 2016 and December 2016. Patients were 113 identified as having urinary incontinence based on a diagnosis by the GP or referral letters from 114 consultant urologists. In some cases, prescription drugs (e.g. mirabegron, tolterodine) 115 identified from medical records were used as proxies to indicate a diagnosis of urinary 116

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

119

120 The following criteria were applied to the patient data recorded:

121 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].

128

129 The Drug Burden Index (DBI)

The DBI measures the cumulative exposure to anticholinergic and sedative medicines in older 130 people and its impact on physical and cognitive function [14]. For each drug, the DBI ranges 131 from 0-1, with 0 being no burden, 0.5 being exposure to the minimum daily dose, and upwards 132 to 1 as the dose is increased exponentially [15]. In this study, the list of drugs with clinically 133 significant anticholinergic and sedative effects were defined from a composite list developed 134 from a review by Duran et al. 2013, the Anticholinergic Cognitive Burden (ACB) scale 135 136 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). 137

138

140 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.

149

150 Outcomes

151 The three outcomes of interest were the overall changes in scores of LUTS-FORTA, DBI, and152 ACB in the patients.

153

154 Statistical analysis

155 It is important to note that a feasibility study is not a hypothesis testing study [20]. One of the 156 key aspects of these studies is that they do not evaluate effectiveness as they are not powered 157 to do so [21]. The main focus of this study was to assess feasibility of the intervention, and 158 therefore the data were analysed using descriptive statistics. Continuous variables were 159 presented as mean with standard deviation (SD) and range, or median with interquartile range 160 (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].
173	
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).
177	
178	Results
	ACSUL5
179	
179 180	Quantitative results
180	Quantitative results

186 LUTS-FORTA score

Figure I shows the number of patients prescribed drugs identified by the LUTS-FORTA criteria 187 over time. According to the criteria, no patient was prescribed a drug rated in category A 188 189 (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 190 profiles), over time, while there was no change in the number of patients prescribed drugs in 191 category B (beneficial: drugs with proven efficacy) and D (don't: avoid in older people) over 192 time. Supplementary Table III shows the drugs that were identified by the LUTS-FORTA 193 criteria in this study. 194

195 Drug Burden Index

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

197

198 Anticholinergic cognitive burden (ACB) scale

199 Thirty-four percent of patients at T_{-6} months and 31% of patients at T_6 months had an ACB 200 score of 0.

201

202 **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.

207

208

210 Themes

211 Theme 1: The Academic detailing experience

212 **Subtheme:** Convenience of academic detailing

213 Participants highlighted the convenience of the academic detailing session being carried out in

their working environment. They welcomed this educational visit being delivered with little

disturbance to their daily practice. They also reported that they are prepared to block out some

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 available for GPs, for example: attending conferences, continuing medical education meetings, 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.

222

223 Subtheme: The interaction between participant and academic detailer

Participants described the interaction between the GP and the academic detailer as being important to the success of the intervention. They reported that the session worked because it felt relaxed and free of pressure. This was in contrast to their experience with some pharmaceutical drug representatives who they described as having an aggressive approach combined with an overload of information, which seemed to aggravate participants.

229

230

232 **Subtheme:** The educational materials

Participants said they liked the educational materials because they had a clear layout and were
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.

236

237 **Subtheme:** The topic: Urinary incontinence

238 The topic of urinary incontinence was agreed by a number of GPs prior to rolling out the study.

239 Participants reported that this topic was relevant and suitable to general practice. The relevance

240 of this topic facilitated the delivery of the intervention to GPs.

241

242 Theme 2: Behaviour change

Participants described the likelihood of changing their behaviour in treating patients with urinary incontinence following the intervention. However, this change in behaviour could be influenced by environmental resources, such as the availability of primary care physiotherapists.

247

248 **Subtheme:** Knowledge gained

Participants were asked if they had gained any knowledge from the intervention. Some participants of recent medical experience were not aware of the important role that non-pharmacological methods play in treating urinary incontinence.

For some participants, the intervention served to refresh their knowledge with the topic rather than gain new knowledge as some of the treatment options may be more commonly used than others.

256 **Theme 3: Sustainability**

257 Subtheme: Academic detailing ownership

Participants were asked how this type of educational intervention could be rolled out to a wider group of GPs in Ireland. Some suggested that it could be affiliated with the Irish College of 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 detailing among GPs.

263

- 264 **Subtheme:** Alternative formats of educational material
- 265 Participants suggested an online version of the educational material, which would be easier for
- them to manage in a setting where print materials over-accumulate or go missing.

267

268 **Subtheme:** Desire for practice staff involvement

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 roleof nurses in primary care.

272

273

275 **Subtheme**: Future participation

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

278

279 **Discussion**

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

Participants described the possibility of behaviour change following the intervention; however, 282 this was partly dependent on the availability of primary care resources such as physiotherapists. 283 284 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 285 these exercises are often demonstrated by physiotherapists [24]. Therefore, if academic 286 detailing interventions are successful, then the treatment modalities recommended by academic 287 detailers need to be resourced. Participants described the educational materials as being high 288 quality. These materials contain evidence-based information on the prevalence of urinary 289 incontinence, an overview of the interventions and cost of drugs to treat the condition, and key 290 messages which may be very beneficial for GPs. However, if this information is not easily 291 retrievable for GPs then they may not be used as a treatment resource during a patient 292 consultation [25]. This may have limited the change in prescribing outcomes in the study. 293 Participants called for these materials to become available as an online resource as they could 294 295 be of value in optimising the diagnosis and management of urinary incontinence.

296

298 Comparison with existing literature

Allen et al. used a mixed methods study (a questionnaire and semi-structured telephone 299 300 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 301 approach adopted, and the educational material used [26]. These findings are similar to those 302 303 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 304 presented to them in their practice and they also described the educational materials used as 305 being of high quality. Soumerai recommends that educational materials should be brief and 306 clearly presented [27]. For this intervention, all GPs received one visit from the detailer, 307 however research has indicated that frequent reinforcement visits can optimise behaviour 308 change [28]. In this study, GPs indicated a willingness to participate in future academic 309 detailing studies. Hartung et al. and Anthierens et al also reported similar findings [4,25]. 310

311 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 312 conducted with a view to effecting change in prescribing outcomes, rather to see if the 313 314 intervention was feasible and acceptable to GPs and whether this preliminary research was appropriate for successful implementation in subsequent larger studies. Our findings suggest 315 316 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 317 318 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 nonpharmacological. Alternative topics for example, hypertension, atrial fibrillation, opioids in chronic pain may provide more scope to examine subsequent change in prescribing behaviours.

327

328 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 338 study designs as they may enhance their approach or avoid similar pitfalls [29]. In future 339 340 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 341 implementing any suggested changes. It would also give the academic detailer an opportunity 342 343 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 344 colleagues and this would help to build a pool of competent academic detailers. Finally, 345

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

348

349 Conclusion

This mixed methods study explored the feasibility and acceptability to GPs of a pharmacist-350 led academic detailing intervention. Overall, participants reported that this evidence-based 351 approach was beneficial and welcomed further visits. The selection of a relevant topic appeared 352 353 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. 354 Our findings provide a useful platform for the evaluation of academic detailing in primary care 355 on a larger scale. Further research is needed in a larger population to determine the impact on 356 patient outcomes and the cost-effectiveness of academic detailing. 357

358

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370	There are no conflicts of interest to declare.
371	
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