

1 How prepared are pharmacists to support atrial fibrillation patients in adhering to newly
2 prescribed oral anticoagulants?

3
4 **Introduction**

5 Atrial fibrillation (AF) is the most common cardiac arrhythmia in clinical practice with an
6 estimate of 1.36 million people in England living with the condition.¹ It is a major predisposing
7 factor for stroke, increasing the risk of individuals by fivefold and contributing to
8 approximately 20% of all ischaemic strokes.²⁻⁴ Oral anticoagulants (OACs) have been shown
9 to be the most effective agents for the prevention of AF-related strokes and there is extensive
10 evidence demonstrating their underuse in practice.⁵⁻⁷ Vitamin K antagonists (VKAs),
11 predominantly warfarin, have been the main OAC used in England for prevention of AF-related
12 strokes.⁷ The availability of Non-vitamin K antagonist Oral Anticoagulants (NOACs) have
13 shown to be non-inferior to warfarin and the latest National Institute of Health and Care
14 Excellence (NICE) guidelines for AF recommend the choice of using a VKA or a NOAC based
15 on patients' clinical features and preferences with a personalised package of care.⁸ This
16 intention is to encourage patients' involvement in shared decision making as well as
17 recognising the opportunity to minimise the reported wastage of medicines due to non-
18 adherence.⁹

19 Patients starting on VKA in England traditionally attend a dedicated anticoagulation
20 management service for monitoring their treatment and are more closely supported by a
21 healthcare professional upon initiation.^{8,10} Option of VKA patient self-monitoring is also
22 available and taken up by a small number of patients.^{11,12} Those that are started on a NOAC
23 do not require regular blood monitoring and guidelines recommend a first follow up
24 appointment four weeks following treatment initiation.¹³ Although these features can raise a
25 potential concern on adherence, it is unclear whether VKAs or NOACs are a better option for

26 improved adherence, since most recent studies focus on comparison of adherence patterns
27 within NOACs.^{14,15}

28

29 Challenges of patient adherence in the context of oral anticoagulants used for stroke prevention
30 in AF are similar to those that arise from other **long term conditions** (LTC), with evidence
31 illustrating a third to half of patients are likely to stop taking their medication, resulting in a
32 negative impact on their quality of life, mortality and the NHS economy¹⁶⁻¹⁸. Studies have also
33 demonstrated patients are more likely to become non-adherent in the first month of being
34 initiated a new medicine for LTCs¹⁹. Patients newly initiated on medicines frequently
35 encountered unmet needs for information and required additional support. Hence, an
36 intervention, based on a perceptions and practicalities approach^{20,21}, recognising adherence is
37 influenced by beliefs and/ or symptoms that are unique to each patient was proposed, where
38 pharmacists adopt a patient centred approach by listening to the patient, providing information
39 and reassurance in response to expressed needs during telephone consultations.²² This
40 intervention was shown to improve adherence and led to the development of a nationally
41 commissioned service called New Medicine Service (NMS). This service was implemented
42 into practice in 2011 as part of the Advanced Services under the National Health Service (NHS)
43 community pharmacy contractual framework, whereby community pharmacist can opt to
44 provide the service from their pharmacy.²³

45 In 2014 an evaluation of the NMS was undertaken and showed to improve adherence by 10%
46 to people who were started on new medication for asthma/COPD, type 2 diabetes, and
47 hypertension or antiplatelet/anticoagulant treatment. The NMS comprises three consultations
48 arranged between the pharmacist and patient over a month following initiation of any new
49 medicine in the above mentioned indications. Each visit allows the pharmacist to determine
50 and address patients' lack of understanding or knowledge needs, assess any health system or

51 personal barriers that may contribute to non-adherence and most importantly, facilitate
52 appropriate interventions with individual patients' that are tailored to support their needs²⁴. To
53 undertake this role, community pharmacists acquire a number of skills and knowledge that can
54 address the clinical and behavioural components required for supporting adherence. At present
55 pharmacists have access to a range of learning materials developed to support the introduction
56 of the NMS and are required to sign a declaration of competency. However, an assessment of
57 pharmacists' needs in providing a NMS consultation on oral anticoagulants has not been
58 formally undertaken.

59

60 **Aim of the study**

61 To assess community pharmacists' current practice, perceived skills and knowledge in
62 supporting patients' medication adherence as part of NMS on OAC for stroke prevention in
63 patients with AF. Also, we intended to evaluate pharmacists' perceived needs for additional
64 support or education to increase the implementation of the service.

65

66 **Ethical approval**

67 Ethical approval was not sought because this survey was an assessment involving no changes
68 to the current services being delivered. The questionnaire was anonymous and pharmacists
69 were free to decline participation. As such, the principles of ethical research, such as
70 confidentiality and anonymity, were followed.

71

72 **Method**

73 A cross-sectional survey was developed a) to benchmark community pharmacists' existing
74 practice and experience of providing a NMS on OAC for stroke prevention in patients with
75 AF; b) to determine their knowledge and confidence in discussing OAC management with

76 emphasis on supporting adherence and c) to identify training needs and pharmacists' preference
77 of resources for a NMS consultation. Data were collected using an anonymous online survey
78 that was distributed to pharmacists working within community pharmacies in London by e-
79 mail with a link through their Local Pharmaceutical Committees (LPCs). The survey was also
80 advertised by the Royal Pharmaceutical Society (RPS) through their local practice forum to
81 encourage participation.

82

83 A literature search identified a lack in published surveys assessing community pharmacist
84 knowledge, skills and NMS provision on OAC for stroke prevention. Hence, questions were
85 developed internally by author consensus and pre-testing to a sample of twenty community
86 pharmacists and five hospital pharmacists. Feedback was used to ensure the questions were
87 meaningful and to examine their clarity and acceptability. Pilot results were not included in
88 the final analysis, but used to modify and adapt the questions and format (Appendix A). Data
89 obtained from the application of the final version was used to validate the survey (as detailed
90 in statistical analysis), ensuring credible results.

91

92 Survey

93 The survey was designed using Survey Monkey and comprised a summary description of the
94 study and questions designed to collate demographics and professional characteristics of
95 pharmacists, including gender, years of experience and educational background. The current
96 practice of community pharmacist was determined by quantifying the NMS consultation(s)
97 undertaken by respondents in a three month period for all commissioned LTC and more
98 specifically oral anticoagulants. The survey was then organised in several sections, where
99 statements were provided for participants to rate:

- 100 a) Pharmacists' knowledge and confidence based on their perception, subdivided into
101 when advising patients on NOACs and on VKA(5-point Likert scale ranging from
102 strongly agree to strongly disagree).
- 103 b) Perceived helpfulness of information sources available (4-point Likert scale ranging
104 from not helpful to very helpful)
- 105 c) Attributed importance to a list of counselling information to be discussed with patients
106 newly prescribed an OAC (4-point Likert scale ranging from critical to not important).
- 107 d) Resources used during a NMS consultation for oral anticoagulants (list provided and
108 answered as yes/no), followed by an open-ended question for those with a 'yes'
109 response to enter the resource description.
- 110 e) Pharmacists' preference of support material required when discussing oral
111 anticoagulant with patients (4-point Likert scale ranging from critical to not important),
112 with an option of documenting additional resources and/ or tools that were not
113 highlighted.
- 114 f) Pharmacists' views on the importance of soft skills for improving their NMS service
115 provision for OAC (4-point Likert, ranging from very helpful to not helpful).

116 All questions were designed with a skip pattern and respondents had the opportunity to free
117 type additional information for each question.

118

119 The first e-mail invitation was sent on the 4th December 2014 and the survey remained open
120 until 31st January 2015. Reminder e-mails were sent on three different occasions to community
121 pharmacists through LPCs and large multiple community pharmacies' regional managers were
122 also contacted directly to confirm receipt of online survey and encourage its dissemination to
123 their London pharmacy stores.

124

125 Sample size estimation

126 The number of pharmacists working in community pharmacies within London was 3807,
127 representing 28% of the workforce in community pharmacy²². Assuming that 10% of these
128 could be delivering the NMS for OAC²⁵, using a confidence interval of 95% and accepting a
129 3.5% error we expected to receive 277 answers.

130

131 Data analysis

132 The data were analysed in SPSS version 23. Validation of the survey comprised confirmatory
133 factor analysis and reliability analysis (Cronbach's alpha). Data analysis comprised descriptive
134 univariate statistics and bivariate analysis (Wilcoxon test). A confidence level of 95% was
135 considered.

136

137 **Results**

138 A total of 269 responses were received over a two month period, of which 12 were excluded
139 as they only contained demographic data. The majority were male (62%; n=159), with a wide
140 range of experience in practice. Most responders were permanent members of staff.
141 Approximately a third had undertaken further academic qualifications following their
142 registration (table 1).

143 *Please insert table 1 here*

144

145 The survey's validation indicated it comprised 5 domains, all of them with high validity,
146 ranging from 0.676 to 0.892. Detailed information of the survey's validity is presented in table
147 2.

148 *Please insert table 2 here*

149

150 In a three month period, 87% of pharmacists completed one or more NMS consultations, 68%
151 completed one or more NMS for OAC, and 35% completed one or more NMS for NOACs.
152 Data indicates that 25% of pharmacists had completed six or more NMS consultations for all
153 OAC, of which 11% were for NOACs (figure 1). Those with extra academic qualifications
154 undertook more NMS for OAC ($p=0.012$), whilst proprietor pharmacists undertook less
155 ($p=0.035$).

156 *Please insert figure 1 here*

157

158 Pharmacists were more confident in their knowledge, skills and access to resources for VKA
159 than for NOAC ($p<0.005$). Pharmacists with extra qualifications expressed higher confidence
160 on all the dimensions illustrated in figure 2, except for using a counselling check list, which
161 they use as little as all pharmacists ($p<0.05$). The results also highlight pharmacists'
162 unfamiliarity with NOAC alert cards, as a significantly lower proportion checked for them in
163 comparison with VKA alert cards ($p<0.001$), albeit there is also room for improvement in the
164 latter. Approximately 40% of the pharmacists felt uncertain or lacked the confidence in their
165 knowledge on NOAC, comparable to 23% for VKA (figure 2).

166

167 *Please insert figure 2 here*

168

169 All counselling items were deemed important, although with varying importance (figure 3).
170 The key priorities for pharmacist during their consultation with patient newly initiated on oral
171 anticoagulant was firstly to discuss what actions to take when bleeding occurs, followed by
172 supporting adherence. In this order, the basic mode of action was perceived as the least
173 important dimension when discussing newly initiated OAC with AF patients for stroke
174 prevention.

175 The importance of a patient's alert card was perceived as critical to very important by 78% of
176 pharmacists, more often by those that stated to routinely check for an alert card. Both the
177 correlation coefficients for VKA and NOACs were statistically significant, although weak
178 ($r=0.304$; $p<0.001$ for VKA and $r=0.187$; $p=0.005$).

179

180 *Please insert figure 3 here*

181

182 Around half the pharmacists confirmed they utilised one source of information during a NMS
183 consultation on OAC (51%). The most frequently mentioned was the British National
184 Formulary (BNF), the sole source utilised by a quarter of pharmacists. Online resources were
185 accessed by 34%, of which a third did not specify the websites used. The most popular medical
186 online websites named included patient websites, NHS choice, NICE clinical knowledge
187 summaries and electronic medicine compendium to reach Patient Information Leaflets and/or
188 Summaries of Product Characteristics.

189

190 The most valued resources to have available during a NMS consultation on OAC in AF patients
191 for stroke prevention were check-lists, followed by patient information leaflets, with
192 insignificant differences (figure 4).

193

194 *Please insert figure 4 here*

195

196 Soft skills were acknowledged as important to attain to address the behavioural dilemmas of
197 adherence by over 80% of pharmacists. We have considered these as less tangible constructs,
198 not clinical and often related to social and administrative sciences, such as communication

199 skills²⁵. Within the latter, counselling skills were deemed the most necessary for an effective
200 NMS consultation, albeit all skills were considered important (figure 5).

201

202 *Please insert figure 5 here*

203

204 The preferred training delivery methods for additional education were online educational
205 modules (49.1% considered as very helpful), followed by clinical case studies (43.3%) and
206 practical workshops (43.2%). The least favoured delivery methods within the list were
207 independent study and clinical supervision, with only 24.1% and 16.7% respectively of
208 pharmacist viewing these as very helpful. Seminars or lectures and facilitated group
209 discussions were seen as very helpful by 30.5% and 30.0%, respectively.

210

211 **Discussion**

212 Over eighty five percent of community pharmacists in London are undertaking NMS
213 consultations, of which OAC make up a small proportion. The DoH commissioned report for
214 evaluating the NMS has shown antiplatelet and anticoagulants contributed to 8.5% of all NMS
215 consultations, in line with our findings²⁶. NHS England latest national pharmaceutical list
216 2013-2014 reported a quarter of community pharmacies in London do not provide NMS²⁷.
217 This value is above our results, finding only 13% of pharmacists did not provide this nationally
218 commissioned service. This suggests inconsistencies in access to the NMS services by patients
219 in London and potentially inequalities in the care and support of adherence for their LTC
220 medication, undermining the core principles of NHS. All AF patients initiated on oral
221 anticoagulant for stroke prevention within London should be provided with an equal
222 opportunity to access the NMS support systems rather than occur by chance²⁸.

223

224 Proprietor pharmacists were undertaking fewer NMS consultations, as indicated by the DoH
225 report²⁷. This finding requires further exploration to determine if independent pharmacies
226 require support in adopting the NMS as part of routine practice, especially as the number of
227 independent contractors in London was estimated to be 61% of total community pharmacies in
228 2013-14²⁷.

229

230 Only for NOACs there was no positive relationship between higher education levels and the
231 number of NMS consultations undertaken, which may largely be explained by the minimal
232 exposure community pharmacists have to the patients initially prescribed a NOAC in London.
233 Most current local arrangements across London for initiation of NOAC are largely dependent
234 on shared care guidelines that require secondary care to continue supplying the first two to
235 three months of NOAC and for most patients the NMS is not embedded as part of their care
236 pathway. Furthermore the uptake of NOAC prescribing in London during our survey data
237 collection period was averaged at 6% of the total number of OAC prescriptions, resulting in
238 less opportunity for community pharmacist to undertake a NMS consultation. Further work is
239 required to embed the NMS on oral anticoagulant for stroke prevention in the care pathway of
240 patients with AF as routine practice.

241

242 The level of knowledge and confidence of the pharmacist responding to this survey
243 demonstrates a wide variation, with approximately twice as many feeling uncertain or lack the
244 confidence in their knowledge on NOAC, in comparison with VKA. The unfamiliarity and
245 minimal exposure to NOAC is reflected in their knowledge and confidence. Conversely, VKA
246 have been available for many years with national standardised recommendations and resources
247 for patients and healthcare professionals including community pharmacists¹⁵. These include
248 emphasis on pharmacists' role with the importance of ensuring patients on an OAC receive

249 appropriate verbal and written information at the start and throughout their treatment including
250 a patient safety alert card. The availability of NOAC alert cards is currently dependent on the
251 individual manufacturers, possibly contributing to the low proportion reporting to check for a
252 NOAC alert card and highlights the need to make pharmacists aware and adopt a single oral
253 anticoagulant alert card.

254

255 Responding pharmacists' primary focus during a consultation with a patient was safety
256 followed by adherence to OAC. This reflects the responding pharmacists' own perceptions of
257 their responsibilities that lay in the traditional risk averse roles and is leading to the importance
258 of patients being able to recognise and manage bleeding as a priority to supporting adherence
259 during their consultation. Awareness of our findings is pivotal and should be incorporated into
260 training programmes for NMS on oral anticoagulant for prevention of AF-related strokes.

261 Facilitating a NMS consultation requires skills beyond clinical knowledge that create the
262 correct conditions and behaviours to support patient adherence and lead to safe and effective
263 compassionate care. Almost all pharmacist acknowledged the importance of utilising the
264 appropriate soft skills to build trust and a professional relationship from the start of the
265 consultation. Counselling and coaching skills were also deemed important by the majority for
266 creating the correct conditions and behaviours to support patients' adherence.

267 There was an expressed need for a concise resource to use in practice as a reference guide or
268 access to relevant information when undertaking a NMS consultation. The predominant
269 resource used was BNF, containing legal and professional guidelines, focusing on the clinical
270 effectiveness and safety of medicines but lacking information related to the process or factors
271 impacting on adherence. The diversity of online and other resources accessed may potentially
272 lead to variation in the quality of information used during the consultation. The majority of
273 pharmacist felt the availability of a check-list and patient information leaflets (PIL) during their

274 NMS consultation would be of great benefit. At present there is no single online platform that
275 is available for pharmacist to access information and resources to support their consultation on
276 OAC in England. The American Anticoagulation forum is an example of such a platform that
277 could be adapted to the UK pharmacists' needs by incorporating relevant validated tools,
278 videos, PIL and alert cards²⁹.

279 Online modules were rated as the most helpful education method. The remaining methods
280 highly rated correspond to the existing options used to deliver continuous professional
281 development to pharmacist. Clinical supervision was one of the least favoured, probably
282 because it is not part of routine community practice.

283

284 *Strengths and Limitations*

285 Although the response rate (6.8%) was low, the sample reached was in line with the estimate.
286 Responses originated from all geographical areas of London with a variety in their
287 demographic characterisation, making the results here presented valuable information.
288 Nonetheless, it should be acknowledged that the sample largely represents experienced
289 pharmacists, limiting extrapolations.

290

291 **Conclusion**

292 This survey suggests that community pharmacists' current practice in London is limited in
293 undertaking NMS consultations for OAC, particularly for NOACs for the prevention of AF-
294 related strokes. Pharmacists perceive their knowledge and skills as having some gaps, implying
295 there is an urgent need to revisit the currently implemented training programme for community
296 pharmacists and to develop the most appropriate resources to support consultations, leading to
297 wider dissemination of the service.

298

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304

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308 relate to the work being presented here. The remaining authors declare that they have no
309 financial relationships that might lead to a conflict of interest.

310

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