



University of Dundee

Current perceptions of the term Clinical Pharmacy and its relationship to Pharmaceutical Care

Dreischulte, Tobias; Fernandez-Llimos, Fernando

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1 Introduction

2 The "Clinical Pharmacy" movement is commonly believed to have its origin among a group of
3 students at the University of Michigan in the early 1960s, where Don Francke, the alleged "Father of
4 Clinical Pharmacy", was teaching^{1,2}, although the term "Clinical Pharmacy" appeared in the
5 literature as early as 1952.³ When David Burkholder, one of Don Francke's students, finished his
6 degree and moved to the University of Kentucky, he promoted the involvement of pharmacists in
7 clinical decision-making via drug information.^{1,2} The term Clinical Pharmacy was almost immediately
8 adopted in Europe.⁴

9 Since that time, a series of definitions of Clinical Pharmacy have emerged, and table 1 contains an
10 illustrative collection of definitions originating from the United States and Europe. Although all listed
11 definitions agree that Clinical Pharmacy is concerned with the use of medicines or its effects, there
12 are differences. For example, some authors describe Clinical Pharmacy as a body of knowledge⁵,
13 rather than a professional practice that draws on or applies such knowledge, and some definitions
14 describe the aims of Clinical Pharmacy in terms of improving processes ("rational and appropriate
15 use of medicinal products and devices" ⁶), while others place emphasis on achieving optimal
16 outcomes for individual patients.^{5,7} The term Pharmaceutical Care has been used since 1975⁸, also
17 with different definitions, the most widely cited to date being Hepler and Stand's "responsible
18 provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's
19 quality of life."⁹

20 -----Please, insert table 1 approximately here -----

21 Both terms have been used to help establish a new field of professional activity that focuses on the
22 therapeutic use of medicines and drug therapy outcomes, as opposed to their development or
23 manufacturing, but it is unclear whether and how the terms differ and whether the distinction
24 should be maintained. For example, Barber suggested in 2001 that the term Pharmaceutical Care
25 placed an emphasis on patient's subjective rather than objective (scientifically determined) drug
26 therapy needs, but argued that "the future of pharmacy depends on a philosophy that bring(s)
27 together" both.¹⁰ Other authors suggest that the distinction may be related to the setting, arguing
28 that the term 'clinic' invites associations with the hospital sector.^{11,12} Possibly in response, some
29 countries use the term Pharmaceutical Care primarily or exclusively in the community pharmacy
30 setting. It has been suggested in the early 1990s to abandon the term Clinical Pharmacy, because it is
31 outdated¹¹, while others call for an unambiguous definition and accurate use of the term in
32 practice.¹²

33 Compiling the key components and core aims of Clinical Pharmacy and Pharmaceutical Care could
34 facilitate the creation of a global definition of Clinical Pharmacy and clarify its relationship to

35 Pharmaceutical Care.¹³ However, in order to gain support for a common definition, current
36 differences in the definition and use of the term across different countries and health care settings
37 should be considered.¹⁴

38 **Aims of the study**

39 The primary aim was therefore to identify current disagreements among pharmacists from different
40 countries and professional backgrounds regarding what the term Clinical Pharmacy encompasses
41 and whether and how it differs from Pharmaceutical Care. To further inform discussions around a
42 harmonised definition of Clinical Pharmacy, a secondary aim was to explore the extent to which
43 pharmacists with an interest in Clinical Pharmacy were willing to accept responsibility for drug
44 therapy outcomes.

45 **Methods**

46 **Survey development and validation**

47 We drafted a survey targeting potential areas of disagreement around the term Clinical Pharmacy
48 identified by members of an ESCP steering committee on 'The future of Clinical Pharmacy' based on
49 their experience. These potential disagreements included whether Clinical Pharmacy was solely a
50 term to describe a set of professional activities, what the specific activities were, who could provide
51 them in which setting, and to which end, and whether and how it differed from Pharmaceutical
52 Care.

53 The draft survey was subjected to a 2-round content validation exercise, in which 9 'experts'
54 (selected by virtue of having substantive experience in pharmacy practice and/or academia) from 9
55 countries (pragmatically selected for geographical spread from countries with representation in
56 ESCP: Sweden, the United Kingdom, the Netherlands, Belgium, Germany, Switzerland, France, Italy
57 and Czech republic) rated each item with respect to its clarity of wording and relevance to informing
58 a harmonised definition of Clinical Pharmacy or Pharmaceutical Care on a 4 point scale (1 = Not
59 relevant, 2 = Unable to assess relevance without item revision, 3 = Relevant but needs minor
60 alteration, 4 = Very relevant and succinct) and were invited to suggest additional items. Items
61 included in the draft survey were revised in light of experts' comments and those items that
62 achieved a median rating of 3 or higher in the second round were included in the survey.

63 The final survey comprised 7 questions and is provided in the online appendix. Questions 1 to 5
64 listed a number of (1) professional activities, (2) providers, (3) settings, (4) aims and (5) general

65 descriptors and asked participants to state their personal opinion as to whether each item
66 constituted (a) 'Clinical Pharmacy only', (b) 'Pharmaceutical Care only', (c) both or (d) neither.

67 In order to examine to which extent Hepler and Strand's stipulation that pharmacist's patient
68 oriented services should be provided 'responsibly' resonated with participant's attitudes towards
69 their own practice, questions 6 and 7 asked them to state their willingness as pharmacists to accept
70 (a) ethical responsibility, (b) legal responsibility or (c) neither for services necessary to achieve
71 desired outcomes (drug therapy effectiveness, safety, patient centeredness and cost-effectiveness).
72 We distinguished between (6) 'current' and (7) 'ideal' working conditions, respectively, in order to
73 account for the possibility that pharmacists' willingness to accept responsibility may be limited by
74 currently available resources (e.g. time, access to medical notes) or support from their environment
75 (e.g. employers or other health care professionals). For the purposes of this survey, 'ethical
76 responsibility' was defined as a moral obligation to provide necessary services to achieve these
77 outcomes, whereas 'legal responsibility' was defined as legal accountability for a failure to provide
78 necessary services.

79 Recruitment of survey participants

80 An invitation to participate (with 2 reminders) in the online version of the survey was sent out by
81 email in September 2014 to 1,285 individuals from 57 countries, who were either current ESCP
82 members or had registered for one or more ESCP symposia since 2012.

83 Outcome measures and data analysis

84 In order to identify key areas of disagreement around the term Clinical Pharmacy (objective 1), we
85 examined agreement between participants for each item listed in questions 1 to 5 regarding
86 whether it applied to Clinical Pharmacy or not. To this end, participants' scores were dichotomised
87 into (a) 'Clinical Pharmacy only' or 'both' vs (b) 'Pharmaceutical Care only' or 'Neither'. In order to
88 identify key areas of disagreement around the *relationship* between Clinical Pharmacy and
89 Pharmaceutical Care (objective 2), we examined to which extent participants who linked each item
90 to Clinical Pharmacy distinguished between the two terms, i.e. rated that the item applied to Clinical
91 Pharmacy only but not Pharmaceutical Care. For both objectives (1) and (2), 'strong agreement'
92 was defined as 90% or more of respondents opting for either option, 'agreement' as more than 80%
93 but less than 90% opting for either option, and 'disagreement' otherwise.

94 For items with disagreement regarding whether they applied to Clinical Pharmacy (objective 1), we
95 used logistic regression to investigate whether the following participant characteristics were
96 independently associated with linking the item to Clinical Pharmacy (i.e. responded "Clinical
97 Pharmacy only" or "both" vs "Pharmaceutical Care only" or "Neither"): geographical origin (classified
98 as Europe North, Europe West, Europe East, Europe South, non-European), year of qualification as a

99 pharmacist (classified as before versus after the year 2000), academic activity (classified as either
100 teaching or conducting research versus no such activity), working in a hospital. We examined
101 univariate associations first. Variables that were significant at the $p=0.05$ level in univariate analysis
102 were included in a multivariate model. Other variables that did not achieve this level of significance
103 in univariate analysis were retained if their addition to the model altered the point estimates of
104 other variables by 10% or more. In the multivariate model, associations were defined as significant
105 at the $p=0.05$ level.”

106

107 In order to examine participants’ perception of the relationship between Clinical Pharmacy and
108 Pharmaceutical Care further, we pooled ‘CP only’, ‘PC only’ and ‘both’ ratings across questions at
109 participant level and examined the proportion of participants who fell into each of five groups
110 representing potential relationships between CP and PC (see figure 1). For questions 6 and 7, we
111 considered the proportions of participants willing to accept any form of responsibility, i.e. ‘ethical’ or
112 ‘legal’, and of those willing to accept ‘any’ and ‘legal’ responsibility under ‘ideal’ but not ‘current’
113 working conditions, respectively.

114 -----Please, insert figure 1 approximately here -----

115 Ethical issues

116 All procedures performed were in accordance with the ethical standards of National Health Service
117 research ethics committees and with the 1964 Helsinki declaration and its later amendments. The
118 study did not include patients or other vulnerable groups. Ethical approval was not required.

119 .

120 Results

121 Survey participants

122 Table 2 shows that a total of 263 participants from 54 different countries completed the
123 questionnaire (response rate 20.5%). The majority of participants (90.1%) were from Europe and the
124 vast majority of respondents were qualified pharmacists (97.3%). Just over half of respondents
125 (57.4%) had completed their pharmacy training before the year 2000. Just under half of respondents
126 primarily worked in hospital settings (48.7%) and 11.4% primarily worked in community pharmacy
127 settings (11.4%). The majority of respondents had been members of ESCP for one year or longer
128 (60.1%), with 15.2% serving or having previously served on an ESCP committee.

129

130 -----Please, insert table 2 approximately here -----

131

132 Opinions regarding the term Clinical Pharmacy

133 Figure 2 shows the proportions of participants who linked each item to 'Clinical Pharmacy only',
134 'Pharmaceutical Care only' or 'both', with the remainder linking the item to 'neither'.

135 *General understanding of the terms* - There was strong agreement among participants that Clinical
136 Pharmacy referred to a 'scientific discipline' (94.2%) and 'set of professional activities' (93.9%), and
137 agreement for 'professional behaviour' (89.7%), and 'set of professional values or principles'
138 (89.4%).

139 *Outcomes targeted* - There was strong agreement among participants that Clinical Pharmacy
140 targeted medication safety (95.4%) and effectiveness (95.1%) and agreement that Clinical Pharmacy
141 targeted patient-centeredness (86.0%) and cost-effectiveness (83.5%).

142
143 -----Please, insert figure 2 approximately here -----

144
145 *Professional activities* - There was strong agreement that the term Clinical Pharmacy accommodated
146 'drug therapy optimisation at patient level (93.2%)', 'laboratory monitoring of drug therapy (93.5%)'
147 and 'treatment individualisation (93.9%)', and there was agreement that it encompassed 'managing
148 an individual's drug therapy(86.7%)', 'drug therapy optimisation at provider level (87.5%)', 'ensuring
149 accurate drug history and transfer of information(88.2%)', 'informative counselling (87.1%)' and
150 'compassionate counselling (81.0%)'. However, participants disagreed regarding the remaining
151 activities, with the following proportions of participants *not* linking the following activities to Clinical
152 Pharmacy: 'compounding (71.1%)', 'drug logistics (60.5%)', 'filling a prescription/ dispensing
153 (54.8%)', 'drug administration (42.6%)' and 'public health promotion (43.5%)'.

154 Table 3 shows that compared to participants from Western European countries, those from
155 Southern European countries were significantly more likely to link 'compounding' (adjusted OR 2.93
156 [95% CI 1.37, 6.29], p=0.008) to Clinical Pharmacy and those from Southern (adjusted OR 3.21 [95%
157 CI 1.53, 6.74], p=0.001) and Eastern (adjusted OR 2.36 [95% CI 1.08, 5.13], p=0.022) European
158 countries were significantly more likely to link 'drug logistics' to Clinical Pharmacy. Having an
159 academic background was significantly associated with *not* linking 'dispensing' (adjusted OR 0.43
160 [95% CI 0.24, 0.76], p=0.004), 'compounding' (adjusted OR 0.33 [95% CI 0.20, 0.69], p=0.002), and
161 'drug logistics' (adjusted OR 0.40 [95% CI 0.22, 0.75], p=0.004) to Clinical Pharmacy, as was working
162 in a hospital with respect to 'drug logistics' (adjusted OR 0.33 [95% CI 0.18, 0.59], p<0.001).

163 -----Please, insert table 3 approximately here -----

164 *Providers* - There was strong agreement that pharmacists could provide Clinical Pharmacy services
165 (97%), and that informal carers (e.g. relatives) could *not* provide such services (93.1%), but

166 disagreement whether 'other health care professionals' could (74.8% of participants disagreed with
167 this). Compared to participants from Western European countries, those from Southern European
168 countries (adjusted OR 0.36 [95% CI 0.13, 0.98], $p=0.045$) were significantly less likely to state that
169 non-pharmacist health care professionals could provide Clinical Pharmacy services.

170 *Setting* - There was strong agreement among participants that Clinical Pharmacy services could be
171 provided in a 'Hospital Ward or outpatient clinic (96.5%)' and in a 'Hospital pharmacy (92.7%)', but
172 disagreement regarding non-hospital settings (a 'physician's practice' was not considered a site for
173 provision of clinical pharmacy services by 24.1%, 'community pharmacy' by 29.3%, a 'patient's
174 home' by 31.7%, and 'any other private or public space' by 45.6% of participants, respectively).
175 Compared to participants from Western European countries, those from Northern European
176 countries (adjusted OR 0.36 [95% CI 0.13, 0.98], $p=0.045$) were significantly more likely to state that
177 Clinical Pharmacy services could be provided in a physician's practice (adjusted OR 0.36 [95% CI 0.13,
178 0.98], $p=0.045$) while participants from Southern European countries were less likely to state that
179 Clinical pharmacy services could be provided in community pharmacies. None of the participant
180 characteristics tested was significantly associated with excluding non-hospital settings as sites for
181 the provision of Clinical Pharmacy services.

182

183 Relationship between Clinical Pharmacy and Pharmaceutical Care

184 There was disagreement regarding the relationship between the two terms, with less than 80% of
185 participants providing ratings consistent with either of the options A to E illustrated in figure 1.
186 Nevertheless, a majority of participants (76.0%) held that Clinical Pharmacy and Pharmaceutical Care
187 partially overlapped with both also having distinct elements (figure 1, option B). Fewer participants
188 believed that Pharmaceutical Care was part of Clinical Pharmacy (Option E: 11.0%), that Clinical
189 Pharmacy was part of Pharmaceutical Care (Option D: 6.8%), that Clinical Pharmacy and
190 Pharmaceutical Care were synonymous (Option C: 5.7%), and that Clinical Pharmacy and
191 Pharmaceutical Care were completely distinct (Option A: 0.3%) with respect to items included in this
192 survey.

193

194 *General understanding of the terms* - Among participants linking each descriptor to Clinical
195 Pharmacy, there was strong agreement that both Clinical Pharmacy and Pharmaceutical Care could
196 be generally described as sets of 'professional activities' (94.9%), 'behaviours' (97.0%), and
197 'professional values or principles' (95.9%), but there was disagreement as to whether
198 Pharmaceutical Care also constituted a 'scientific discipline (31.7% disagreed with this). Having
199 qualified as a pharmacist in 2000 or later was significantly associated with stating that 'Clinical
200 Pharmacy' but not 'Pharmaceutical Care' constituted a 'scientific discipline'.

201

202 *Outcomes targeted* – There was agreement that both Clinical Pharmacy and Pharmaceutical Care
203 targeted medication safety, effectiveness and patient centeredness but disagreement whether
204 Pharmaceutical Care also targeted cost-effectiveness (23.4% disagreed with this). None of the
205 participant characteristics tested was significantly associated with linking cost-effectiveness to
206 ‘Clinical Pharmacy’ but not ‘Pharmaceutical Care’.

207

208 *Professional activities* - There was disagreement as to whether ‘Pharmaceutical Care’ also
209 comprised the following specific activities (% negating this): ‘managing an individual’s drug therapy ,
210 e.g. supporting the patient to take his/her medicines as agreed’ (20.2%), ‘drug therapy optimisation
211 at patient level, e.g. recommending a certain antibiotic for an individual patient’ (33.1%), ensuring
212 accurate drug history and transfer of information (33.6%), ‘drug therapy optimisation at provider
213 level, e.g. developing and disseminating a new guideline on antibiotic prescribing’ (50.0%),
214 ‘treatment individualisation, e.g. via therapeutic drug monitoring and pharmacogenetic testing
215 (50.6%)’, and ‘laboratory monitoring of drug therapy, e.g. renal function’(56.1%). None of the
216 participant characteristics tested was significantly associated with linking respective activities to
217 ‘Clinical Pharmacy’ but not ‘Pharmaceutical Care’.

218

219 *Providers and settings* - There was agreement or strong agreement that Clinical Pharmacy and
220 Pharmaceutical Care did not differ with respect to providers or settings

221

222 Pharmacists’ willingness to accept responsibility

223 Figure 3 shows that under the conditions of their *current* working practice, over 80% of respondents
224 were willing to accept some form of responsibility, with little difference between the four different
225 domains (94.3% safety, 89.7% effectiveness, 87.1% patient-centeredness, 85.1% cost-effectiveness).
226 However, the proportions of participants who were willing to assume *legal* responsibility were much
227 lower: safety (32.7%), effectiveness (17.9%), patient-centeredness (17.1%) and cost-effectiveness
228 (20.3%).

229 Under *ideal* working conditions, the proportions of participants being willing to assume some form
230 of responsibility increased slightly, but the proportions willing to assume legal responsibility at least
231 doubled (safety: 64.3% , effectiveness: 49.2% , patient-centeredness: 46.2%, cost-effectiveness:
232 44.0%).

233 -----Please, insert figure 3 approximately here -----

234

236 **Discussion**

237 **Key findings**

238 We found that a panel of 263 pharmacists who had previously attended European Society of Clinical
239 Pharmacy symposia, agreed that the term Clinical Pharmacy encompassed a scientific discipline as
240 well as a set of professional activities, behaviours and values or principles and that the aims of
241 Clinical Pharmacy were to improve medication safety, effectiveness, cost-effectiveness as well as
242 patient-centeredness. Survey participants also agreed that Clinical Pharmacy practice comprised a
243 range of activities at both population and individual patient levels and that Clinical Pharmacy
244 services could be provided by pharmacists but not by informal carers in hospital settings. In contrast,
245 there was disagreement as to whether traditional pharmacy activities (compounding, drug logistics,
246 dispensing), drug administration or public health promotion constituted Clinical Pharmacy activities,
247 where differences in opinion regarding one or more of these items were associated with the
248 presence or absence of an academic background, working in a hospital and geographical residence.
249 There was also disagreement whether non-pharmacist health care professionals could provide
250 Clinical Pharmacy services and whether such services could be provided in non-hospital settings.
251 Approximately three quarters of participants provided ratings that were consistent with Clinical
252 Pharmacy and Pharmaceutical Care partially overlapping, but there was disagreement as to what the
253 distinct elements of Clinical Pharmacy were. Over 80% of survey participants were willing to accept
254 ethical responsibility for processes necessary to achieve desired outcomes. Although less than a
255 third of participants were willing to accept legal responsibility under their current working
256 conditions, under ideal working conditions almost two thirds of participants were willing to accept
257 legal responsibility for medication safety and almost half for effectiveness, patient-centeredness and
258 cost-effectiveness.

259 **Strengths & Limitations**

260 To our knowledge this is the first survey to identify disagreements regarding the term Clinical
261 Pharmacy and its relationship to Pharmaceutical Care. The face and content validity of the survey
262 was established by an expert panel of experienced ESCP members, who were also invited to suggest
263 additional items, and we therefore believe that the main uncertainties around what constitutes
264 Clinical Pharmacy were covered. Data was collected from pharmacists from a wide range of
265 countries and with diverse professional backgrounds and experience, but a limitation to
266 generalisability is that hospital pharmacists and countries with relatively large numbers of ESCP
267 members were overrepresented. A further limitation is a relatively low response rate of 20%,
268 although we do not think that this substantially compromised the identification of key

269 disagreements around the term Clinical Pharmacy and its relationship to Pharmaceutical Care, the
270 primary aim of this survey. When asking about pharmacists' willingness to accept ethical or legal
271 responsibility, a limitation is that we did not explicitly distinguish between sole vs co-responsibility,
272 and it is therefore possible that the proportion of pharmacists who were willing to accept some form
273 of ethical or legal responsibility was underestimated. Similarly, the apparent disagreement regarding
274 whether Pharmaceutical Care constitutes a "scientific discipline (e.g. a branch of pharmacy)" might
275 benefit from further exploration as to what constitutes a scientific discipline in the opinion of
276 stakeholders. We have made no attempt to conduct a conceptual analysis to derive the "true"
277 meaning of the term Clinical Pharmacy, because the interpretation of the term "clinical" will be
278 significantly driven by the cultural and political context it is used in. Finally, although defining
279 disagreement using a cut-off of 80% agreement is arbitrary, we hold that it is a meaningful threshold
280 to identify priorities for further discussions around a harmonised understanding of the term Clinical
281 Pharmacy.

282 Implications

283 Our survey has established that there is general agreement among participants that Clinical
284 Pharmacy is a scientific discipline within pharmacy and one area of pharmacy practice that
285 encompasses a range of professional activities to optimise medicines use, and that the aim is to
286 improve clinical as well as humanistic and economic outcomes of drug therapy. These findings are
287 generally consistent with the ESCP describing Clinical Pharmacy as a 'health specialty, which
288 describes [...] activities and services [...] to [...] promote the rational and appropriate use of
289 medicinal products and devices' to achieve 'better health outcomes and a better use of health care
290 resources'.¹⁵ Although ESCP also specifies that Clinical Pharmacy describes activities of 'pharmacists'
291 and clarifies that the word 'clinical' should not be taken to restrict such services to hospitals, there
292 were disagreements among survey participants regarding who could be providers and in which
293 settings.

294

295 Additionally, and perhaps most importantly, there was disagreement around whether Clinical
296 Pharmacy also encompassed the more traditional pharmaceutical activities of compounding,
297 dispensing and drug logistics. Given that the term Clinical Pharmacy has originally been coined to
298 support a paradigm shift in the pharmacy profession from manufacturing and distributing drug
299 products to a focus on the therapeutic use of medicines, greater clarity by organisations such as
300 ESCP about how Clinical Pharmacy differs from traditional pharmacy practice, may support the
301 intended function of the term. In addition, our finding that participants' opinions regarding the
302 specific activities captured by Clinical Pharmacy differed by professional background and
303 geographical residence highlights that support for a harmonised definition of Clinical Pharmacy

304 should be sought from both academics and non-academics, and from both those working in hospital
305 and community settings in all parts of Europe (and beyond).

306

307 The term Pharmaceutical Care has been coined to support the same development within the
308 pharmacy profession, but the majority of participants distinguished between the terms with distinct
309 elements for both. However, there was no agreement regarding what the distinct elements were.
310 One commonly mentioned difference relates to the setting of practice, consistent with our finding
311 that almost 20% of respondents considered Clinical Pharmacy an exclusively hospital-based activity
312 while almost 30% held that Pharmaceutical Care was exclusively practiced in community pharmacy.
313 Future definitions should make it explicit, whether or not the practice of Clinical Pharmacy is setting
314 specific. A further potential difference relates to the focus of practice. It could be argued that
315 initially, the focus of Clinical Pharmacy was on process rather than outcome¹⁶, and that a key
316 function of the Pharmaceutical Care concept was to shift the focus from process to patient
317 outcomes.¹⁷ The fact that in their latest definition of Clinical Pharmacy, the American College of
318 Clinical Pharmacy states that “The practice of Clinical Pharmacy embraces the philosophy of
319 Pharmaceutical Care [...] for the purpose of ensuring optimal patient outcomes”⁷ can be taken as an
320 indication that the term Pharmaceutical Care has succeeded in this respect. Nevertheless, even with
321 this definition, the word “embrace” leaves room for interpretation where (if any) the boundaries
322 between the two terms lie. In response to ongoing debates around the Pharmaceutical Care concept
323 ¹⁸, the Pharmaceutical Care Network Europe has recently defined it as ‘the pharmacist’s
324 contribution to the care of individuals in order to optimise medicines use and improve health
325 outcomes’.¹⁹ Clarifying the relationship between Clinical Pharmacy and Pharmaceutical Care as well
326 as their functions is likely to be mutually beneficial in order to accomplish the paradigm shift within
327 the pharmacy profession that both terms set out to achieve.

328

329 A further function of the term Pharmaceutical Care (as defined in 1990⁹) was to promote providers
330 accepting responsibility for drug therapy outcomes. Hepler stated that responsibilities, and not
331 technical functions, should drive the definition of Clinical Pharmacy²⁰, and theoretical models have
332 been used to fundament the perception of responsibility acquisition by pharmacists providing
333 clinical services.²¹ It is therefore noteworthy that common definitions of Clinical Pharmacy and the
334 PCNE definition do not include this notion. However, the progression from providing advice on
335 medicines use to accepting responsibility for patient outcomes may be the next shift in paradigm
336 that the pharmacy profession has yet to accomplish. Our finding that pharmacists’ willingness to
337 accept legal responsibility at least doubled under ‘ideal’ compared to ‘current’ working conditions,
338 suggests that current working environments are perceived as limiting factors. Further research is

339 required to better understand barriers and facilitators to pharmacists accepting the optimisation of
340 drug therapy outcomes as their core responsibility as health care professionals.

341

342 **Conclusions**

343 The survey demonstrates discrepancies between pharmacists across Europe in their understanding
344 of the term Clinical Pharmacy and its relationship to Pharmaceutical Care. Based on the survey's
345 findings, the main barriers towards a harmonised understanding of the term Clinical Pharmacy relate
346 to who can provide Clinical Pharmacy services in which settings as well as what the specific activities
347 are that differentiate Clinical Pharmacy from traditional pharmacy practice and Pharmaceutical Care.
348 Although ensuring optimal patient outcomes is and continues to be a multidisciplinary task, the
349 responsibilities of pharmacists within clinical teams should become an area of future debate.

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355 **Conflicts of interest**

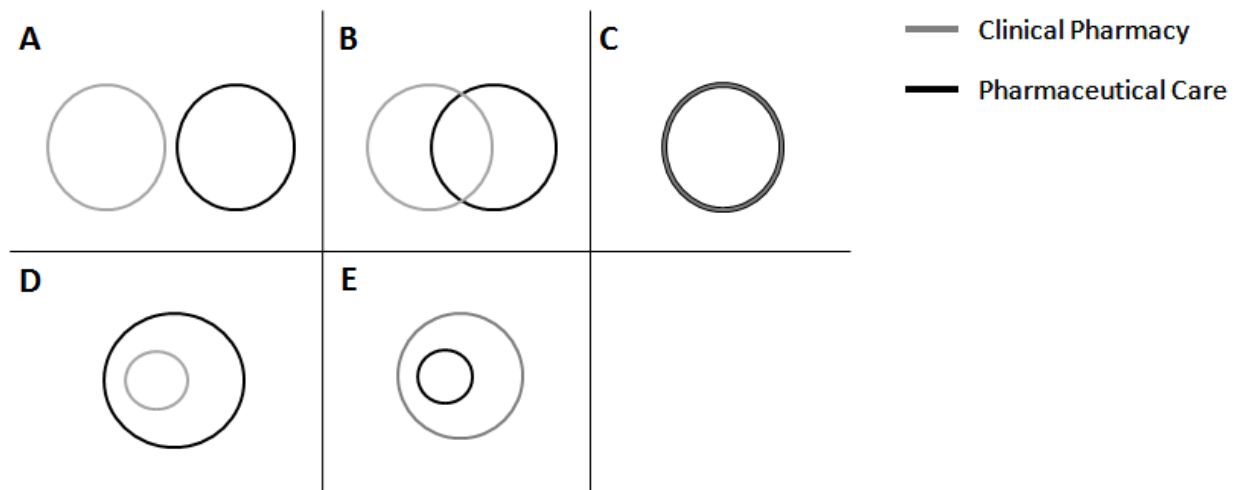
356 The authors declare they have no conflicts of interest.

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Figure 1: Illustration of possible relationships between Clinical Pharmacy and Pharmaceutical Care



A='Clinical Pharmacy (CP)' and 'Pharmaceutical Care (PC)' are completely distinct (reflected by participants rating 'CP only' or 'PC only' for all items); B=CP and PC partially overlap (reflected by participants rating each of 'CP only', 'PC only' and 'both' for one or more items); C=CP and PC completely overlap (reflected by participants who stated 'both' for all items); D=CP is part of PC (reflected by participants who stated each of 'PC only' and 'both' for one or more items); E=PC is part of CP (reflected by participants who stated each of 'CP only' and 'both' for one or more items)

Figure 2: Findings of survey questions targeting participants' understanding of the term Clinical Pharmacy and its relationship to Pharmaceutical Care. For each question, the items are ranked in descending order of the overall proportions of survey participants linking each item to Clinical Pharmacy.

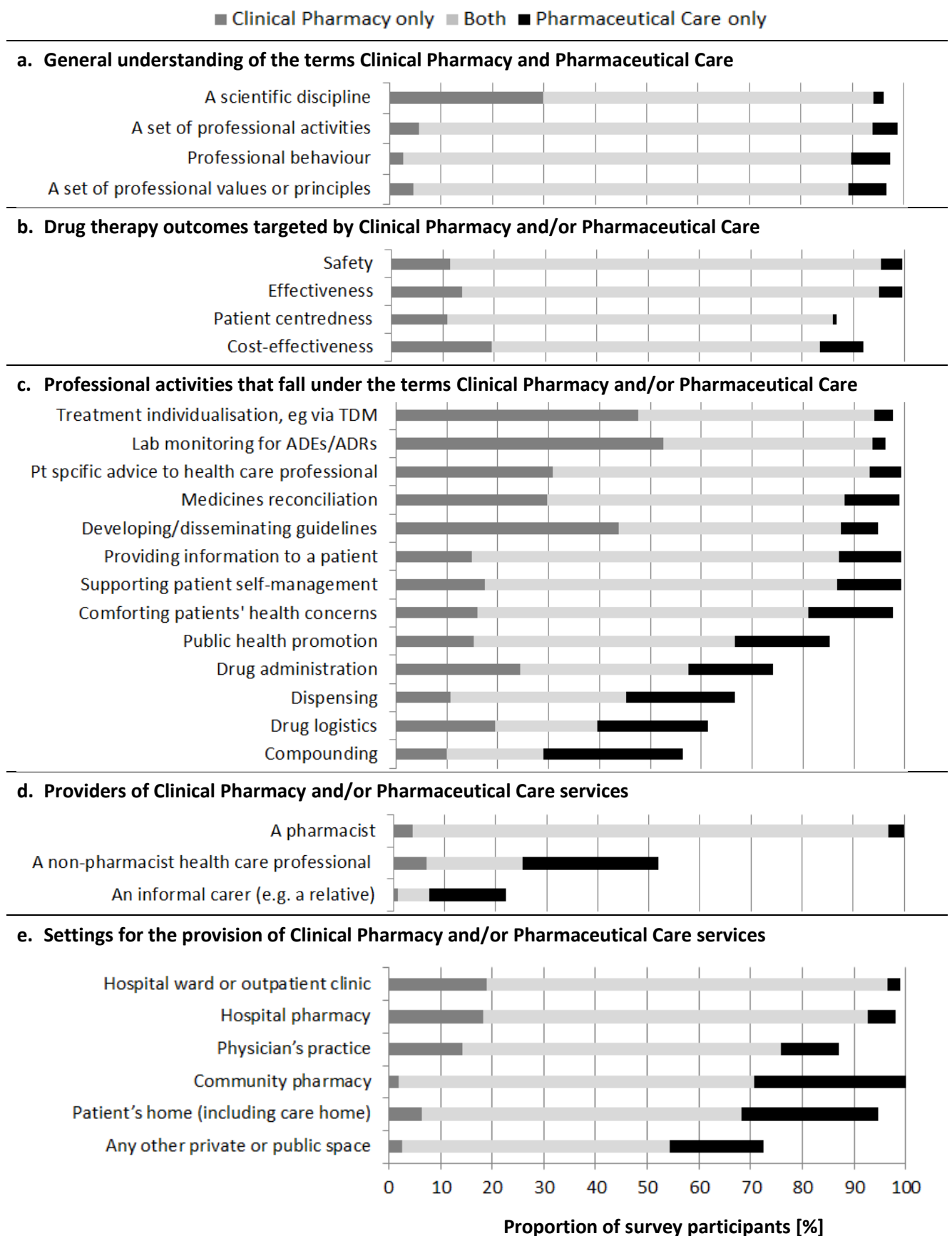


Figure 3: Findings of survey questions targeting participants' willingness to accept ethical or legal responsibility for providing the services necessary to achieve different drug therapy outcomes, distinguishing between a) participants' most current and b) ideal working conditions, respectively.

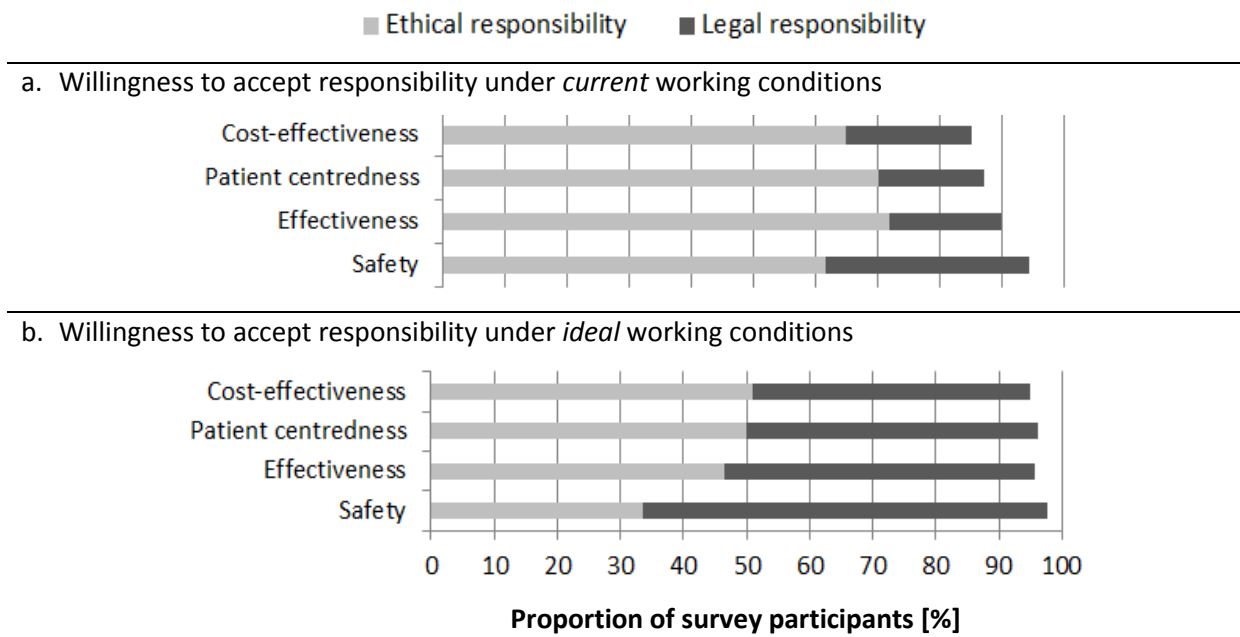


Table 1. Illustrative collection of definitions (original or in their English translation) of the term Clinical Pharmacy highlighting apparent commonalities and differences between them

Author [Year]	Country	Definition	General description	Focus on process vs outcomes	Provider	Setting
Hutchinson, Burkholder [1971] ²	US	The utilization of a pharmacist's drug knowledge as applied to the specific drug problems of an individual patient	Health care practice	Process	Pharmacist	Not specified
Traub et al [1979] ²²	US	The practice of ensuring that the correct patient received the most appropriate medication and dose for a specific condition, via a rational dosage form and regime, over an appropriate time period; and assisting in the prevention, identification and resolution of untoward effects from these drugs and their interactions; and educating patients with regards to drugs with the intention of limiting these untoward effects and improving compliance.	Health care practice	Process and outcomes	Not specified	Not specified
Franklin BD, van Mil JW [2005] ⁶	US/NL	Clinical Pharmacy is that part of the practice of pharmacy that contributes directly to patient care and develops and promotes the rational and appropriate use of medicinal products and devices.	Health care practice	Process	Pharmacist	Not specified
American College of Clinical Pharmacy [2008] ⁷	US	Clinical Pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of Clinical Pharmacy embraces the philosophy of Pharmaceutical Care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes.	'Discipline'; Health care practice	Outcomes	Pharmacist	Not specified
European Society of Clinical Pharmacy ¹⁵	Europe	A health specialty, which describes the activities and services of the clinical pharmacist to develop and promote the rational and appropriate use of medicinal products and devices.	Health care practice	Process	Clinical pharmacist	Not specified
ABDA/Deutsche Pharmazeutische Gesellschaft [1998] ²³	Germany	Clinical Pharmacy is that discipline of Pharmacy, which encompasses the optimisation of medication use for and by patients based on pharmaceutical natural science	'Discipline'	Process	Not specified	Not specified

United Kingdom Clinical Pharmacy Association (UKCPA) ⁵	UK	The term Clinical Pharmacy [...] (is) used generally to describe the knowledge, skills and attitudes required by a pharmacist to contribute to patient care. As the delivery of healthcare becomes more dependent upon successful multidisciplinary co-operation, increasingly pharmacists see their contributions in terms of overall patient outcomes.	Body of 'knowledge, skills, attitudes'	Outcomes	Pharmacist	Not specified
Belgian Federal Government Working Group on Clinical Pharmacy	Belgium	Clinical pharmacy envisions responsible patient-centered pharmaceutical care and the provision of efficient, effective and safe pharmacotherapy seamlessly assured by a multidisciplinary care team within a global health policy.	Health care practice	Process	Not specified	Not specified
Swiss association of Public Health Administration and Hospital Pharmacists (GASA) [2011] ²⁴	Switzerland	Clinical pharmacy is that part of pharmacy that aims to develop and advance the appropriate and efficient use of medicines. In hospitals, the term Clinical Pharmacy is used to describe the patient centred pharmaceutical activities performed in collaboration with other health care professionals. The Clinical Pharmacist has completed specific training and is responsible for his actions.	'Part of pharmacy'; health care practice	Process	Pharmacist	Not specified
Italian society of Clinical Pharmacy ²⁵	Italy	The scope of Clinical Pharmacy comprises guaranteeing the safe and effective use of medicines by employing clinical pharmacology, counselling, pharmacovigilance, and pharmaceutical technology	Health care practice	Process	Not specified	Not specified
French society of Clinical Pharmacy ²⁶	France	Clinical Pharmacy is the optimal use of pharmacist's pharmaceutical and biomedical judgement and knowledge in order to improve the effectiveness, safety, efficiency and accuracy in the use of medicines and medical devices when treating patients; and this will be achieved using all educational and informative resources, particularly by the use of national and international scientific publications and events.	Health care practice	Process and outcomes	Pharmacist	Not specified
Norwegian society of clinical pharmacy [2007] ²⁷	Norway	Clinical pharmacy is the use of pharmaceutical expertise, clinical data and other relevant information to support correct use of drugs in the individual patient. The work is performed by a Master in pharmacy in cooperation with physicians, and possibly other health professionals and patients themselves.	Health care practice	Process	Master in pharmacy (as part of a team)	Not specified
Danish society of clinical pharmacy ²⁸	Denmark	Clinical pharmacy is a profession, which ensures optimal and rational use of medication for the benefit of the patient and society in collaboration	Health care practice	Process and	Pharmacist (as part of	Not specified

between pharmacists, pharmaconomists, other medication professionals
and the patient

outcomes a team)

Table 2: Participant characteristics (n=263)

Characteristics	n	%
Country of origin		
Europe West ^A	116	44.1
Europe North ^B	43	16.3
Europe South ^C	42	16.0
Europe East ^D	36	13.7
Other ^E	26	9.9
Professional background		
Pharmacy student	7	2.7
Pharmacist	256	97.3
Completed PhD (or equivalent doctorate obtained by research)	101	38.4
Completed Diploma or Master's degree in Clinical Pharmacy awarded by a University	59	22.4
Completed post-graduate specialist training in Clinical pharmacy*	52	19.8
Doctoral student	36	13.7
Other ^F	24	9.1
Year of pharmacy degree (where applicable)		
1960 to 1969	5	1.9
1970 to 1979	35	13.3
1980 to 1989	48	18.3
1990 to 1999	63	24.0
2000 to 2005	41	15.6
2006 to 2010	44	16.7
After 2010	20	7.6
Places of work		
Hospital pharmacy	128	48.7
University	73	27.8
Community pharmacy	30	11.4
Governmental organisation	16	6.1
Professional organisation	16	6.1
Two or more	42	16.0
Professional activities		
Providing Pharmaceutical Care/Clinical Pharmacy services	149	56.7
Conducting research into Pharmaceutical Care/Clinical Pharmacy	134	51.0
Teaching Pharmaceutical Care/Clinical Pharmacy	135	51.3
Managing Pharmaceutical Care/Clinical Pharmacy services	81	30.8
Other	22	8.4
Membership in professional organisations		
European Society of Clinical Pharmacy for 1 year or longer	158	60.1
European Society of Clinical Pharmacy for less than 1 year	75	28.5
Pharmaceutical Care Network Europe (working for an organisation that is a member)	25	9.5
Pharmaceutical Care Network Europe (as an individual member)	23	8.7
Euro Pharm Forum	17	6.5
Other ^G	66	25.1

A = Austria: 7, Belgium: 14, France: 20, Germany: 13, Ireland: 3, Luxembourg: 1, Netherlands: 19, Northern Ireland: 1, Switzerland: 24, United Kingdom: 14; **B** = Denmark: 18, Finland: 5, Iceland: 2, Norway: 10, Sweden: 8; **C** = (Greece: 4, Italy: 5, Malta: 2, Portugal: 11, Spain: 14, Turkey: 6); **D** = Croatia: 3, Czech Republic: 6, Estonia: 2, Hungary: 1, Letvia: 1, Macedonia: 1, Moldova: 1, Montenegro: 3, Romania: 4, Serbia: 1, Slovakia: 4, Slovenia: 4, Ukraine: 5); **E** = Asia Middle East [Iraq: 2, Israel: 1, Jordan: 1, Palestine: 1, Qatar: 1, Saudi Arabia: 3, UAE: 1]; Asia Far East [China: 1, Indonesia: 2, Japan: 2, Phillipines: 1]; Africa [Algeria: 1, Libya: 1, Morocco: 1, Nigeria: 1, Tunisia: 1]; North America [Canada: 1, USA: 2]; South America [Costa Rica: 1, Sint Maarten: 1]; **F** = Clinical pharmacy resident: 2, Independent Prescriber: 1, MPH or MSc in related discipline (MPH, pharmacology): 4, Pharm.D. (US): 3, Specialisation in hospital pharmacy: 6, Specialisation in pharmaco-economics: 1, University lecturer or professor: 7); **G**=National society for clinical pharmacy: 22, other academic organisation: 8, other professional organisation: 36

Table 3: Questionnaire items with <80% agreement on whether they applied to Clinical Pharmacy and participant characteristics associated with stating the item applied to Clinical Pharmacy. Where two sets of odds ratios are provided for the same item, the upper row includes the univariate and the second row the adjusted odds ratios, respectively.

Questionnaire item (number, proportion of participants stating the item applied to Clinical Pharmacy)	Participant characteristics						
	OR and adjusted OR (95% confidence interval) of linking each item to Clinical Pharmacy						
	Geographical origin (Europe West is reference)				Pharmacy degree after 2000 vs 2000 or earlier	Active in teaching or research vs no such activity	Work in hospital vs other
	Europe North	Europe East	Europe South	None- European			
Professional activities							
Public health promotion (n=175; 66.5%)	0.85 (0.42, 1.73)	1.39 (0.62, 3.10)	1.53 (0.71, 3.29)	4.69 (1.33, 16.5)	0.96 (0.58, 1.62)	1.08 (0.62, 1.87)	1.13 (0.68, 1.89)
Drug administration (n=112; 42.6%)	1.07 (0.53, 2.16)	1.17 (0.55, 2.47)	1.87 (0.89, 3.90)	3.11 (1.16, 8.31)	1.19 (0.72, 1.95)	0.83 (0.49, 1.42)	0.86 (0.53, 1.40)
Dispensing (n=119; 45.2%)	0.78 (0.38, 1.61)	0.94 (0.44, 2.01)	1.76 (0.86, 3.59)	1.54 (0.86, 3.62)	0.90 (0.55, 1.47)	0.47** (0.28, 0.81)	0.95 (0.58, 1.54)
	Not included	Not included	Not included	Not included	Not included	0.43** (0.24, 0.76)	0.75 (0.44, 1.26)
Drug logistics (n=104; 39.5%)	1.72 (0.82, 3.58)	2.93** (1.36, 6.34)	4.27** (2.03, 8.98)	1.64 (0.67, 3.99)	0.81 (0.49, 1.33)	0.56** (0.33, 0.95)	0.41** (0.25, 0.69)
	1.40 (0.69, 2.92)	2.36** (1.08, 5.13)	3.21** (1.53, 6.74)	1.47 (0.58, 3.73)	Not included	0.40** (0.22, 0.75)	0.33** (0.18, 0.59)
Compounding (n=76; 28.9%)	0.92 (0.39, 2.15)	1.73 (0.76, 3.93)	3.15** (1.49, 6.64)	1.83 (0.73, 4.59)	1.05 (0.61, 1.80)	0.38** (0.22, 0.67)	1.00 (0.59, 1.71)
	0.90 (0.38, 2.13)	1.47 (0.64, 3.42)	2.93** (1.37, 6.29)	1.86 (0.73, 4.74)	Not included	0.33** (0.20, 0.69)	Not included
Providers of Clinical Pharmacy and/or Pharmaceutical Care services							
Non-pharmacist HCP (n=66; 25.2%)	1.56 (0.74, 3.26)	0.75 (0.31, 1.82)	0.36* (0.13, 0.98)	0.63 (0.22, 1.80)	0.77 (0.44, 1.37)	1.54 (0.81, 2.91)	0.78 (0.44, 1.36)
	1.56 (0.74, 3.26)	0.75 (0.31, 1.82)	0.36* (0.13, 0.98)	0.63 (0.22, 1.80)	Not included	Not included	Not included
Settings for the provision of Clinical Pharmacy and/or Pharmaceutical Care services							
Physician's practice (n=200; 75.9%)	3.40 * (1.12, 10.3)	0.79 (0.35, 1.80)	1.70 (0.33, 1.50)	1.16 (0.43, 3.17)	0.83 (0.47, 1.45)	1.21 (0.66, 2.19)	0.76 (0.43, 1.33)

	3.40 *	0.79	1.70	1.16	Not included	Not included	Not included
	(1.12, 10.3)	(0.35, 1.80)	(0.33, 1.50)	(0.43, 3.17)			
Community pharmacy (n=186; 70.7%)	0.63	0.54	0.45*	1.01	0.85	1.03	0.96
	(0.29, 1.36)	(0.24, 1.20)	(0.21, 0.95)	(0.37, 2.77)	(0.49, 1.45)	(0.58, 1.82)	(0.57, 1.64)
	0.63	0.54	0.45*	1.01	Not included	Not included	Not included
	(0.29, 1.36)	(0.24, 1.20)	(0.21, 0.95)	(0.37, 2.77)			
Patient's home (n=180; 68.3%)	1.77	0.74	0.76	1.05	0.74	1.51	0.65
	(0.77, 4.07)	(0.34, 1.60)	(0.37, 1.59)	(0.42, 2.64)	(0.44, 1.25)	(0.87, 2.62)	(0.39, 1.10)
Other private/public space (n=143; 54.4%)	0.53	1.72	1.64	0.90	0.86	1.13	1.06
	(0.25, 1.13)	(0.81, 3.67)	(0.81, 3.35)	(0.38, 2.13)	(0.53, 1.40)	(0.67, 1.91)	(0.65, 1.72)

Key: *p<0.05; ** p<0.01