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# Pharmacy Practice Research – A Call to Action

## Introduction to Pharmacy Practice Research

Pharmacists have a societal duty of care. How to best provide that type of care requires a scientific approach. Pharmacy practice research is a type of health services research. Although there is no universally accepted definition for pharmacy practice research, the International Pharmaceutical Federation Pharmacy Practice Special Interest Group (FIP PPR SIG), has defined it as the scientific discipline that studies the different aspects of the practice of pharmacy, and its impact on health care systems, medicine use, and patient care. The scope of pharmacy practice's research has expanded over the past 50 years to encompass clinical, behavioural, economic, and humanistic implications of the practice of pharmacy, as well as practice change and implementation of innovations such as health interventions and patient-care services in routine practice. These are often provided in collaboration with other health care professionals, supporting an interdisciplinary care and integrated healthcare delivery. The drive for the expanded role of pharmacists in most settings has undoubtedly been stimulated by patient demand, a natural professional evolution, but also facilitated by pharmacy practice research. As such, pharmacy practice research will continue to assist in shaping the future of the pharmacy profession.

It has been said that "*professions exist to serve society*"<sup>1</sup>, otherwise, especially with the technological revolution, they will disappear. The mission of the pharmacy profession must address the medicines and health needs of individual patients and the society<sup>1</sup> which have changed over the past decades. The traditional roles of pharmacists have been historically focused on drug compounding and then on drug supply. These were originally challenged by the clinical pharmacy movement and then by the concept of Pharmaceutical Care, defined as "*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*"<sup>2</sup>. These changes have led to emerging roles for the pharmacy profession, mainly through the provision of health interventions and patient-care services, aiming at either optimizing the medication use process or at improving health<sup>3,4</sup>.

Evidence-based practice requires that healthcare decisions are made based on the best available, current, valid, and relevant evidence<sup>5</sup>. Evidence-based practice is essential to deliver high quality patient care. Over the past years, pharmacy has increasingly used research to evaluate a wide range of new pharmacist-led services and interventions and their contribution to existing and new models of healthcare. These interventions have been tested in research environments, many of which have

33 provided supporting evidence for the role of pharmacists in improving clinical, economic and  
34 humanistic outcomes in different conditions and populations <sup>6-15</sup>. Designing feasible patient-care  
35 services and generating robust evidence of their impact (not only for patients but also for the  
36 different stakeholders involved in healthcare) is essential to influence policies that support their  
37 implementation and funding. Based on this evidence, researchers and pharmacy leaders called for  
38 patients, governments, and health insurance companies to remunerate pharmacists for their patient-  
39 care services. As a result, services such as medication reviews, smoking cessation counselling, minor  
40 ailment programs, chronic disease management, or vaccinations have been remunerated in various  
41 countries <sup>16,17</sup>.

42 A large number of these innovations are not yet fully integrated into routine practice of pharmacists  
43 and the healthcare system, mainly due to lack of implementation programs and evidence-based  
44 implementation strategies<sup>18</sup>. These services will only continue to be remunerated if their ongoing  
45 contribution to patient care is proven. The ultimate goal is to achieve their sustainability, crucial to  
46 reaching their long-term integration and continuity into a given setting <sup>19</sup>. Therefore, developing  
47 effective services and achieving their long-term implementation and sustainability in daily practice is  
48 crucial to explore innovative models of care that address population needs, and in turn supporting  
49 the advancement and future existence of the pharmacy profession. Pharmacy Practice Research is a  
50 critical enabler to achieve these goals.

51

## 52 **Pharmacy Practice Key Strategic Areas of Research**

53 The development, evaluation, implementation and sustainability of health interventions and patient-  
54 care services represents a challenging process for pharmacy practice researchers. Traditional  
55 approaches such as the evaluation of health interventions through randomized controlled trials  
56 (RCTs), may not be sufficient to achieve practice and policy changes. A sole emphasis on the  
57 intervention's evaluation phase, in detriment of the development and implementation phases make  
58 these interventions weaker, decreasing the chances of its future implementation<sup>20</sup>. To address this  
59 problem, pharmacy practice researchers can go through a number of stages in the planning and  
60 execution of their research, including design, impact evaluation, implementation, and sustainability.  
61 One of the potential failures in PPR has been trying to aggregate all these steps involved in health  
62 services research, rather than using a multistage approach. The Medical Research Council  
63 Framework, provides an structured approach to develop, evaluate, and implement complex  
64 interventions (like professional pharmacy services) in health using a wide range of qualitative,

65 quantitative, and mixed-method research approaches<sup>20</sup>. This framework has been widely used in  
66 health services research, helping researchers make methodological and practical choices. The  
67 application of these techniques to Pharmacy Practice Research seems relevant, and an adaptation of  
68 the different phases that could be applied to health interventions and services are discussed below.

69

70

71 *Needs assessment - Identifying unmet population needs.*

72 Before the development of any health intervention or patient-care service, Pharmacy Practice  
73 Researchers must identify societal health needs that can benefit from pharmacists' care or from  
74 wider healthcare system changes<sup>21</sup>. Unless a health intervention is able to respond to current or  
75 future societal needs, its future sustainability is likely to be compromised. This is undertaken through  
76 a health needs assessment, which is the systematic method of identifying unmet health and  
77 healthcare needs of a population and making changes to meet these unmet needs<sup>21</sup>. Health needs  
78 assessment can provide clear objectives to design interventions and services which meet patient and  
79 population needs.

80 Societal health needs have been defined as *"the requirements at the individual, family, community  
81 and population levels -across the continuum of care- to achieve physical, cognitive, emotional, social,  
82 and spiritual wellbeing, taking into account the broad determinants of health"*<sup>22</sup>. Based on this  
83 definition, there are four key elements to be considered when undertaking a needs assessment.

84 1) Firstly, local, community and global environments are to be examined, assessing health at  
85 an individual, community and population level. A population centred need perspective  
86 implies that: (a) there is an epidemiological approach to the problem, (b) there is a focus on  
87 the needs of individuals, communities and population (so disparities are reduced and health  
88 equity is maximised) and (c) community orientation and engagement is ensured<sup>22</sup>.

89 2) It is important to recognise that needs, - i.e. gaps between a current and a desired state of  
90 being - can be objective or subjective and physical or psychological, and are likely to change  
91 over time.

92 3) Efforts should be made to ensure a continuum of care, with integrated services ranging  
93 from illness prevention, health promotion, public health and screening, to chronic disease  
94 management, long-term care, and palliative care amongst others. This continuum of care  
95 would include services that are able to respond to current public healthcare crises (e.g.  
96 opioid abuse) or public health emergencies of international concern (e.g. communicable

97 disease outbreaks). Effective needs assessments can potentially lead to integration of the  
98 results into planning and commissioning of local services<sup>21</sup>.

99 4) Lastly, health is a broad concept influenced by multiple determinants which incorporate  
100 wider social and environmental factors. These must be carefully examined to fully  
101 understand the nature of the problem<sup>22</sup>. The analysis is key to determine if the identified  
102 determinants could be targeted with a pharmacy intervention and if this intervention would  
103 be within pharmacists' scope of practice. Social factors influencing patient medicine use  
104 studied in social pharmacy, such as medicine and health-related beliefs, attitudes, rules,  
105 relationships, and processes, are just some of the many aspects to be considered in  
106 pharmacy practice research<sup>23</sup>.

107 Specific attention should be paid to the local context in which this unmet need is identified and the  
108 feasibility of implementing an intervention. It must be noted that in some countries, especially in  
109 those with an ageing population, it is common to find a shortage of primary health care professionals  
110 such as physicians and nurses. This situation creates healthcare gaps that in some cases can be  
111 covered by pharmacists.

112 It has been recommended that societal health needs are identified through a collaborative process  
113 that is patient-focused, culturally sensitive, evidence-based, and outcome-focused<sup>22</sup>. The process  
114 involves a range of research designs which will ultimately help to determine priorities for the most  
115 effective use of resources, balancing clinical, ethical, humanistic and economic factors<sup>21</sup>. Approaches  
116 during this phase include - but are not limited to - qualitative research (when an in-depth  
117 understanding of a particular phenomenon is needed, with a focus on perceptions and experiences  
118 from the perspective of the patient or other stakeholders)<sup>24</sup>, epidemiological approaches such as  
119 observational studies (used to describe the health status of populations and identify possible  
120 determinants of health outcomes) or systematic reviews and meta-analyses (used to synthesize the  
121 results of different studies when conflicting evidence exists in a given area).

#### 122 *Intervention development – Designing and modelling processes and outcomes*

123 During this phase pharmacy practice researchers should aim at designing and modelling the  
124 intervention or patient-care service, in order to address the needs identified during the assessment  
125 phase. Identifying relevant evidence, Appraising other national and international services, and  
126 exploring the practical feasibility of an intervention in a given context are required. It is important to  
127 note that just picking up a service protocol from one country to another without contextual analysis

128 is fraught with problems. Moreover, poor design during the development of a service may result in a  
129 future implementation failure.

130 Exploring existing theories, models, and frameworks from within pharmacy and other disciplines that  
131 are applicable to the service model is required. This is a vital preparatory step in designing a service.  
132 When based on theory, health interventions are more likely to have positive effects on its target  
133 population<sup>25</sup>. Theory can assist researchers to understand the likely outcomes for a complex  
134 intervention and therefore enable the modelling of the process. Process and outcome indicators that  
135 monitor the intervention's performance during the evaluation, implementation and sustainability  
136 phases have to be established. Special attention should be paid to the identification of indicators  
137 that can be used in the future when monitoring the intervention's fidelity (i.e. the degree to which  
138 the intervention is delivered as described)<sup>26</sup>.

139 Many other components can be considered when developing a service that contributes to improved  
140 patient outcomes and adds value to healthcare. Some examples include patient and market demand,  
141 current local and national agreements, potential funders/payers, local policies, interdisciplinary care  
142 and collaborative practice models, pharmacists' scope of practice and stakeholders' views, amongst  
143 many others. Considering the different perspectives from all stakeholders involved is crucial for  
144 success. For example, involving patients in this stage has been associated with more effective  
145 services<sup>27</sup>, better relationship with the healthcare professional, and increased patient satisfaction<sup>28</sup>. A  
146 missed viewpoint or issue not identified early on may cause major difficulties during implementation.  
147 A possible approach during this stage could be the use of co-design (also known as participatory  
148 design, experience-based co-design, co-production, co-creation, or co-operative design). Co-design is  
149 increasingly being used in healthcare settings, including pharmacy<sup>29</sup>, to increase the participation and  
150 engagement of stakeholders in the development of health services. Stakeholders could include  
151 individual patients, other health care professionals, groups, or organisations who may influence or be  
152 affected by decision-making on a particular action, aim, or policy. During a co-design process, future  
153 implementation and dissemination strategies are also covered.

#### 154 *Intervention evaluation – Assessing the intervention's feasibility and impact*

155 Evaluating the impact of a health intervention or patient-care service is a key step in the process of  
156 establishing the added value and contribution of pharmacists. The main objective of this phase is to  
157 assess either the efficacy or effectiveness of the intervention or service on pre-defined study  
158 outcomes. This step is critical to generate evidence on its benefits and convince potential service  
159 payers, policy makers and other stakeholders to support its future implementation. However, it is

160 essential to consider the value from many other stakeholders' perspectives involved in patient care  
161 to achieve a balanced overview of the intervention's impact. This is often achieved using the Kozma's  
162 ECHO (Economic, Clinical, Humanistic Outcomes) model<sup>30</sup>. It implies assessing the clinical impact (eg.  
163 clinical outcomes, important from the perspective of the health care provider), humanistic impact  
164 (e.g health-related quality of life, important from the patient perspective) and economic impact (e.g  
165 cost-effectiveness and cost-utility of the service, important from the policy maker and payer  
166 perspective). Examples of potential outcomes are shown in table 1.

167 Once the study outcomes have been identified and defined, an appropriate study design should be  
168 selected to evaluate the intervention's impact. The study design and length might be dependent on  
169 the study outcomes to be tested. RCTs are the gold standard to evaluate innovations in health and  
170 should always be considered as the most robust option. However, in some circumstances it is  
171 preferable to randomly assign groups or clusters of people instead of individuals. Cluster RCTs  
172 (cRCTs), widely used in health services research, have become essential to evaluate some types of  
173 interventions when contamination between study groups is to be avoided<sup>31</sup> When a RCT or cRCT is  
174 not feasible, alternative experimental approaches can be considered. Pragmatic designs such as  
175 stepped-wedge cluster randomised trials, or sequential multiple assignment randomised trials  
176 (SMART) are expected to increase in the future<sup>32</sup>.

177 Some complex interventions and services may incur in an expensive and long evaluation process.  
178 Therefore, where there is uncertainty about the practicability of a RCT or an alternative design, a  
179 feasibility study would be appropriate<sup>31</sup>. Different types of feasibility studies have been defined,  
180 according to their ultimate objective<sup>31</sup>. Feasibility studies are not designed to address the  
181 effectiveness of an intervention. Rather, they are used to determine whether an intervention is  
182 appropriate for further evaluation<sup>33</sup>. They also allow weaknesses to be identified, methods and  
183 procedures to be tested and refined, and they can offer significant information regarding the design  
184 so potential problems do not arise in the evaluation and implementation phases<sup>20</sup>. Feasibility studies  
185 can address the stakeholders' intervention acceptability (e.g. patients, providers, other health care  
186 professionals, policy makers), intervention demand, participant recruitment, retention rates,  
187 intervention's implementability in a given setting or its practicality. They can also provide valuable  
188 information to estimate potential effect sizes and sample sizes for the main trial. Potential research  
189 approaches and methods vary depending on the study focus, and these often include a mix of  
190 qualitative and quantitative approaches through structured or semi structured interviews, nominal or  
191 focus groups, direct or participant observation and surveys. It must be noted that in some cases,

192 more than one feasibility study might be needed. Once the appropriate feasibility testing has been  
193 finalised, one should be confident the intervention's effectiveness can be evaluated in a larger trial.

#### 194 *Intervention implementation– incorporating innovations into practice*

195 There is extensive evidence supporting the role of pharmacists in a range of disease states. However  
196 these benefits cannot accrue unless there is effective implementation<sup>34</sup>. Implementation science  
197 emerged to address the challenges associated with the incorporation of evidence-based innovations  
198 into practice<sup>35</sup>, seeking to understand and work within real world conditions<sup>36</sup>. Like in other  
199 disciplines, implementation research has become a rapidly progressing interest for pharmacy  
200 practice researchers. Numerous frameworks, theories and models have been developed to address  
201 the science to practice gap, which have predominantly been targeted to specific disciplines, including  
202 pharmacy<sup>37</sup>. These conceptual approaches, which vary depending on their ultimate objective, have  
203 been acknowledged as a key element to facilitate the implementation of health innovations into  
204 practice <sup>34,38</sup>. For example, process models describe a number of implementation stages (e.g.  
205 exploration, adoption, installation/preparation, initial implementation, full operation) that guide the  
206 implementation process. Determinant frameworks, classic theories and implementation theories  
207 usually aim to understand and explain what factors influence implementation outcomes. Finally,  
208 evaluation frameworks provide a range of outcome indicators (e.g. acceptability, adoption,  
209 appropriateness, costs, feasibility<sup>26</sup>) that can be used to determine implementation success<sup>26</sup>. The  
210 application of these approaches vary depending on the implementation research question.  
211 Nevertheless, some criteria exist to help researchers identify an appropriate approach, instead of  
212 using theories that are convenient but not appropriate to meet the research objectives<sup>39</sup>.

213 Different implementation research designs have been suggested, some of which have been  
214 successfully applied in pharmacy<sup>18,40–42</sup>. Hybrid designs, in which design components of clinical  
215 effectiveness and implementation research are blended according to the study's main objective, are  
216 widely used and reported in the implementation science literature<sup>43</sup>. Experimental epidemiological  
217 designs already described, qualitative and mixed method approaches such as quality improvement  
218 studies and participatory action research are common<sup>36</sup>. Extensive research has been undertaken to  
219 explore barriers and facilitators for services implementation. However, there has been a call for more  
220 rigorous implementation studies in pharmacy, which should consider using implementation theories,  
221 frameworks or models and report on appropriate implementation outcomes<sup>44</sup>. Therefore,  
222 researchers may want to question themselves: Has an implementation theory, model or framework  
223 been selected? Is it the most appropriate? Is the research design appropriate to meet the study



224 objectives? Have implementation process and outcome indicators being defined? How are they going  
225 to be assessed?

226 *Sustainability - achieving the intervention's sustainment*

227 Sustainability is the last phase in the creation of health interventions and patient-care services, which  
228 is becoming increasingly important for health services researchers and policy-makers. Once an  
229 evidence-based intervention has been implemented in practice, the ultimate objective is to achieve  
230 its long-term sustainability. Despite its importance, there is scarce evidence on how to achieve long-  
231 term sustainability of health interventions and services once the implementation phase is over. In  
232 fact, this step is not considered in the MRC framework.

233 Advancements in this area have resulted in the development of conceptual approaches to guide,  
234 identify determinants and even evaluate the sustainability of innovations in health care settings.  
235 However, there is some debate on how this important stage should be conceptualised<sup>45</sup>.  
236 Nevertheless, a definition for pharmacy practice research has been suggested "*Sustainability is a*  
237 *phase in the process of a professional pharmacy service, in which the service previously integrated*  
238 *into practice during the implementation phase is routinized and institutionalized over time to achieve*  
239 *and sustain the expected service outcomes*"<sup>19</sup>. According to this definition, sustainability seems to be  
240 conceptualised by two dimensions: routinisation and institutionalisation. These elements have also  
241 been identified as essential to achieve sustainable interventions and services in pharmacy<sup>46</sup>. In  
242 sustainability, routinisation refers to the maintenance of the pharmacy's routine for the service  
243 provision, through continuous improvement of the service's protocol and components. According to  
244 this element, sustainability is a dynamic process, with evaluation and continuous monitoring of the  
245 service's performance being critical to ensure the service is working effectively and producing its  
246 expected outcomes (as per the evaluation and implementation phase). This continuous monitoring  
247 can lead to a service adaptation if needed. Service adaptation is given high relevance in the literature  
248 and has been described as essential to ensure the long-term sustainability of evidence-base  
249 interventions<sup>46,47</sup> However, there is uncertainty on how adaptation and fidelity (i.e. the degree to  
250 which an intervention or program is delivered as intended) should be balanced.

251 Institutionalisation refers to the gradual adaptation of the pharmacy's context, structures, and  
252 processes, to the provision of the service. Within the concept of institutionalisation, three  
253 interrelated performance domains (environment, social and economic) with core factors across each  
254 domain, are hypothesised to moderate the service's sustainability. Some of these factors include but  
255 are not limited to leadership, goal setting, funding, staff training, or political support<sup>46</sup>.

256 Pharmacy practice research key priorities during the sustainability phase should aim to validate and  
257 empirically test an evaluation framework in pharmacy. Other areas of interest could include  
258 developing monitoring systems for the intervention's performance through digital platforms, as well  
259 as adaptation and optimisation mechanisms, using innovative approaches such as machine learning.  
260 The development and evaluation of tailored sustainability strategies, targeted at the different  
261 sustainability factors, are to be studied. Research approaches imported from other disciplines such as  
262 change management, service value networks or service operations management seem to be  
263 potentially useful in advancing in this area.

#### 264 **The role of pharmacy practice research in universities**

265 As dynamic institutions, universities have to evolve to identify and meet the demands of the society,  
266 by producing graduates that are able to address those current and future demands. Over the past  
267 years, pharmacy has increasingly been using research in practice. One of the main objectives has  
268 been to evaluate pharmacists' contribution to new models of care through some of the approaches  
269 previously described. Schools of Pharmacy in some countries have significantly contributed to the  
270 advancement of the pharmacy profession either by university institutions or associated pharmacy  
271 practice research centres<sup>48</sup>. Most of their research is guided and driven by national local needs, such  
272 as chronic disease management in developed countries<sup>48</sup> or disease prevention in developing  
273 countries. Their findings have contributed to expand the role of pharmacists in local and global  
274 environments. Despite this and possibly due to its social component, pharmacy practice research has  
275 often been considered as a "soft" science in many pharmacy schools, leading into an erroneous  
276 perception of being a less valid scientific field.

277 Pharmacy practice research often integrates concepts and methods from disciplines outside  
278 pharmacy such as psychology, pharmacoeconomics, public health or implementation science, which  
279 stimulates interdisciplinary collaborations. There is evidence collaborative national and international  
280 research in this area is growing, showing an increased contribution to global health research<sup>50</sup>. To  
281 continue with its innovative contribution to the profession and the society, Universities need to  
282 invest in pharmacy practice research, creating departments, research centres, and allowing access to  
283 research funding that allow advances in the discipline. Professional organisations should  
284 continuously inform Universities on the graduate attributes that are needed in the current and  
285 future pharmacy workforce<sup>49</sup>. Universities, health professional organisations, governments, and  
286 consumer groups should work collaboratively to continuously shape the future of the pharmacy  
287 profession, lead innovation, and expand Pharmacy Practice opportunities. This could be done at  
288 national or international level. For example, the International Pharmaceutical Federation (FIP)

289 provides leadership for national pharmacy professional organisations, which in turn provide the  
290 impetus for setting national standards.

291  
292 **International Pharmaceutical Federation and Pharmacy Practice Research**

293 The International Pharmaceutical Federation (FIP) is an international organization representing  
294 pharmacists and pharmaceutical scientists. Since its foundation in 1912, FIP's priorities have evolved  
295 in order to meet the needs and expectations of the profession, manifested through an increase of  
296 healthcare services and integration of emerging scientific innovations in the practice of the  
297 pharmacy. As stated in FIP's 2020 vision and strategic plan, its ultimate vision is to "*improve global  
298 health by advancing Pharmacy Practice and science to enable better discovery, development, access  
299 to and safe use of appropriate, cost-effective, quality medicines worldwide*".

300  
301 The Board of Pharmaceutical Sciences (BPS) deals with FIP's scientific activities, with the ultimate  
302 objective of contributing to the improvement of world health, mainly through disease prevention  
303 and treatment strategies. Within the BPS, there are six Special Interest Groups (SIG's), which are in  
304 charge of continuously developing initiatives to assist FIP and its member organisations achieve this  
305 objective. In 2016, the BPS provided the opportunity to establish the Pharmacy Practice Research  
306 SIG (PPR SIG) as one of its pharmaceutical sciences areas of research. It was created with the main  
307 scope of increasing Pharmacy Practice contributions to global health through the provision of  
308 greater access to the latest high-quality international pharmacy practice research. Based on this  
309 objective, the PPR SIG also aims to cultivate an international forum for the dissemination of quality,  
310 international pharmacy practice research for all stakeholders and stimulate communication,  
311 discussion, networking and collaboration between international Pharmacy Practice stakeholders,  
312 including pharmacists and pharmaceutical scientists for the advancement of best practice. Research  
313 areas and efforts will be targeted at local and global priorities, with the ultimate objective of  
314 improving pharmacists' contribution to global health.

315

316 **Call to action for Pharmacy Practice Research, Pharmacy Practice Education and Practice  
317 of Pharmacy**

318 Based on the elements discussed in this paper, the following actions are proposed:

- 319
- Adopting the Pharmacy Practice definition suggested in this paper.
  - Undertaking a societal health needs assessment before the development of  
320 patient-care services.
- 321

- 322 • Using robust epidemiological research designs when evaluating health  
323 interventions. When sufficient evidence is available, this should be synthesised  
324 using robust meta-analyses.
- 325 • Applying innovative research methods to address challenges that cannot be solved  
326 with current research approaches. This is especially relevant for addressing the  
327 current science-to-service gap, during implementation and sustainability phases.
- 328 • Implementing Pharmacy Practice teaching and research in all pharmacy  
329 curriculums.
- 330 • Stimulating global collaboration across pharmacy practice researchers and  
331 educators in order to support teaching and research.
- 332 • Consolidating a distinctive body of knowledge by creating consistent terminology  
333 and thesaurus and publishing in pharmacy journals when disseminating pharmacy  
334 practice research outputs.
- 335 • Reinforcing local and global pharmacy organisations' role, support and contribution  
336 to Pharmacy Practice Research for the advancement of best practice.

337

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