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4 **Pharmacist Perceptions and Willingness to Initiate COVID-19 Point-of-Care Testing in an**  
5 **Independent, Community Pharmacy Setting**

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45 **Abstract:**

46 Objectives: The primary objective of this study is to analyze the perceptions held by  
47 pharmacists in independent, community pharmacies on point-of-care COVID-19 testing in the  
48 retail pharmacy setting by (1) assessing pharmacists' attitudes toward point-of-care testing, (2)  
49 determining their potential strategies for providing COVID-19 point-of-care testing to patients,  
50 and (3) identifying perceived barriers to initiation.

51  
52 Methods: Eligible participants are pharmacists who maintain an active pharmacist license and  
53 are currently practicing in a community pharmacy setting. The survey is part of a larger study of  
54 South Carolina pharmacists. A 44-item survey was distributed to pharmacist managers in South  
55 Carolina by mailing a postcard with a QR code to the online survey. Prior to the first question of  
56 the survey, respondents were asked a screening question to ensure they met all inclusion  
57 criteria. If the inclusion criteria were met based on the participant's answer to the screening  
58 question, he or she were able to advance to the survey. Descriptive statistics were used to  
59 analyze respondent demographics and the survey items, including multiple-choice, select all  
60 that apply, and free response questions. The questions in the 5-point Likert scale formatting  
61 were analyzed by calculating the mean response for each item. Factors associated with  
62 willingness to implement COVID-19 point-of-care testing will be analyzed by differentiating  
63 participants into groups based on pharmacist and practice site characteristics and the existence  
64 of the Community Pharmacy Enhanced Services Network's (CPESN) required, core services  
65 within the practice. A Pearson correlation was calculated to determine if there was a  
66 statistically significant correlation between enhanced pharmacy status and pharmacists  
67 responses to questions regarding patient-related factors, testing follow-up, and operations-  
68 related factors.

69  
70 Results: The results presented here are preliminary as data collection is still ongoing. From the  
71 current sample, there was a statistically significant correlation between CPESN enhanced  
72 pharmacy status and both the patient-related factors and testing follow-up categories (p-  
73 value=0.005 and 0.012, respectfully). Respondents working within single-store independent  
74 pharmacies reported possessing a CLIA waiver more often than other practice settings.

75  
76 Conclusion: Community-based pharmacists who have experience executing other enhanced  
77 services like medication synchronization and medication therapy management seem most  
78 willing to implement COVID-19 POC testing and report fewer barriers to implementation.

79  
80 **Introduction (366)**

81 With the total number of COVID-19 cases in South Carolina reaching 454,158 and total  
82 deaths reaching 7,842 as of March 13, 2021, the need for reliable access to testing and  
83 diagnosis is critical.<sup>1</sup> Community pharmacists are considered some of the most accessible  
84 healthcare providers with the qualifications necessary to not only educate patients on COVID-  
85 19 updates and recognize COVID-19 symptoms for referral but also provide point-of-care (POC)  
86 COVID-19 testing for patients within their distinct practice sites. This latter contribution has  
87 been exemplified as large-scale, chain pharmacies like CVS and Walgreens adapt their practices  
88 to provide added services during the pandemic. Pharmacists practicing in smaller, independent

89 pharmacies, however, must face additional considerations when implementing enhanced  
90 services like COVID-19 testing. A systematic review by Gubbins et al highlighted these  
91 considerations and barriers for all pharmacists by emphasizing regulatory variability at the state  
92 level regarding POC testing in community pharmacies therefore diminishing pharmacists'  
93 potential scope of practice.<sup>2</sup> The article also mentioned lack of widespread offering of the  
94 service in pharmacies and explained how this can delegitimize efforts in the eyes of other  
95 healthcare stakeholders. Hopefully, POC testing will become more commonplace in community  
96 pharmacies as pharmacists step up and begin to offer COVID-19 testing.

97 Despite the overall scarcity of this relevant service, several studies have displayed the  
98 validity of POC testing within this setting. For instance, a literature review performed by Buss et  
99 al looked at the analytical quality and effectiveness of various analytes showing their  
100 comparableness to tests performed by general practitioners as well as traditional laboratories.<sup>3</sup>  
101 Other studies have blueprinted potential methods for implementation both with chronic  
102 disease screening and the timelier service of infectious disease diagnosis. A study taking place  
103 at two community pharmacy sites in Tennessee performed influenza and group A streptococcus  
104 screening using polymerase chain reaction testing.<sup>4</sup> The study demonstrated a detailed clinical  
105 protocol for potential replication and displayed the positive outcomes for patients that can be  
106 achieved with the more intricate involvement of a pharmacist in their care. The purpose of this  
107 study is to further evaluate these possibilities in relation to the COVID-19 pandemic by  
108 assessing independent pharmacists' perceptions of COVID-19 point-of-care testing and  
109 identifying implementation strategies as well as perceived barriers.

110

### 111 **Objectives (54)**

112 The primary objective of this study is to analyze the perceptions held by pharmacists in  
113 independent, community pharmacies on point-of-care COVID-19 testing in the retail pharmacy  
114 setting by (1) assessing pharmacists' attitudes toward point-of-care testing, (2) determining  
115 their potential strategies for providing COVID-19 point-of-care testing to patients, and (3)  
116 identifying perceived barriers to initiation.

117

### 118 **Methods (470)**

#### 119 *Study Population*

120 The study population consisted of pharmacists over 18 years of age who read English,  
121 maintain an active pharmacist license, and are currently practicing in a community pharmacy  
122 setting. Any pharmacists not meeting these criteria were excluded from this study.  
123 Respondents who completed less than 5% of the survey items will be excluded.

#### 124 *Study Design*

125 A prospective, cross-sectional, 44-item survey was used to assess the perceptions on  
126 offering COVID-19 point-of-care testing in a retail pharmacy while also identifying  
127 implementation strategies and perceived barriers held by pharmacists practicing in these  
128 settings. Prior to the first question of the survey, respondents were asked a screening question  
129 to ensure they meet all inclusion criteria. If the inclusion criteria were met based on the  
130 participant's answer to the screening question, he or she was able to advance to the survey.

131

132

133 *Data Collection*

134 The survey is part of a larger study of South Carolina pharmacists and was granted  
135 approval from the University of South Carolina Institutional Review Board (IRB). The study was  
136 be distributed by mailing postcards with a QR code to the survey to pharmacist managers at  
137 community pharmacies in South Carolina. Mailing addresses were obtained from the South  
138 Carolina Board of Pharmacy. A random sample of 60% of registered community pharmacists  
139 was invited to participate in this survey. The survey was initially available for completion for 10  
140 weeks, but data collection is still ongoing due to low response rates. Any returned postcards  
141 due to incorrect mailing details were monitored and additional pharmacists were identified as  
142 replacements should the returned mail reach 25%. Reminder phone calls, social media posts,  
143 and SC pharmacy organization advertisements may be used in the future to increase  
144 recruitment if needed. All respondents could opt in for a \$10 Amazon gift for completing the  
145 survey, and they could enter a raffle for a \$50 Amazon gift card as well.

146 *Data Analysis*

147 Data analysis was performed using SPSSv26. Descriptive statistics were used to show the  
148 frequencies of relevant demographic information and characterize the practice descriptions of  
149 the participating pharmacists. The questions in the 5-point Likert scale formatting were  
150 analyzed by calculating the mean response for each item. Other survey items, including  
151 multiple-choice, select all that apply, and free response questions, were summarized using  
152 descriptive statistics. Free response items were analyzed using qualitative analysis methods,  
153 including assignment of codes and identification of themes to summarize the answers into  
154 relevant data. Factors associated with willingness to implement COVID-19 point-of-care testing  
155 were analyzed by differentiating participants into groups based on pharmacist and practice site  
156 characteristics and the existence of the Community Pharmacy Enhanced Services Network's  
157 (CPESN) "enhanced," core services within the practice. A Pearson correlation was calculated to  
158 determine if there was a statistically significant correlation between enhanced pharmacy status  
159 and pharmacists responses to questions regarding patient-related factors, testing follow-up,  
160 and operations-related factors.

161

162 **Results (253)**

163 The results presented here are preliminary as data collection is still ongoing. During the  
164 data collection period thus far, 80 pharmacists have completed the survey. Respondent and  
165 pharmacy demographics are summarized in Table 1. The most common community pharmacy  
166 practice setting was national chain, followed by single independent, multi-store independent,  
167 supermarket, and finally regional chain. Most respondents reported a PharmD as their highest  
168 level of pharmacy training with only one respondent having completed a residency program.  
169 Only one respondent reported the possession of an active collaborative practice agreement  
170 with a physician.

171 Pharmacist respondents working within independent community pharmacies held the  
172 most knowledge regarding CLIA waiver capabilities and those within this setting reported  
173 possessing a CLIA waiver more often than those in chain and supermarket pharmacies. There  
174 was a statistically significant correlation between CPESN enhanced pharmacy status and both  
175 the patient-related factors and testing follow-up categories (p-value=0.005 and 0.012,

176 respectfully). The correlation involving operations-related factors was not statistically  
177 significant (p-value=0.494).

178 The most important considerations when implementing COVID-19 POC testing reported  
179 were staff and patient safety and possible disruptions to existing workflow. Most respondents  
180 indicated they would utilize pharmacy technicians for marketing the new service, screening and  
181 obtaining consent to conduct the testing, and for billing procedures. Pharmacists duties would  
182 consists of administering the test to the patient and interpreting the test results, as reported by  
183 the majority of respondents. Most pharmacists who completed the survey would prefer to  
184 communicate the results to the patient by telephone and to the primary care provider by fax.

185

## 186 **Discussion (464)**

187 In order to conduct COVID-19 POC testing within a community pharmacy, the pharmacy  
188 must obtain a Clinical Laboratory Improvement Amendments (CLIA) waiver. This involves  
189 certification through the Center for Medicare and Medicaid Services (CMS) and instills  
190 appropriate regulation for establishments who accept human samples for diagnostic testing.<sup>5</sup>  
191 Pharmacies wishing to attain a CLIA waiver must complete an initial application and pay an  
192 initial application fee. The CLIA waiver must then be renewed every two years. Attaining a CLIA  
193 waiver is an essential first step for any pharmacy wishing to implement a POC testing service  
194 including COVID-19 diagnostic testing. Within the current study sample, current CLIA waiver  
195 status seems to be a major barrier across all community practice settings. This deficiency is  
196 most detrimental for independent pharmacies where sample collection and analysis is  
197 conducted all under the roof. Thus, there is a vast need to educate and promote CLIA waiver  
198 attainment to pharmacists within these specific settings.

199 The mission of the Community Pharmacy Enhanced Services Network (CPESN) is to  
200 foster and enable the provision of high quality and high integrity patient-centered enhanced  
201 services within community pharmacies.<sup>6</sup> All pharmacies within the network must be capable of  
202 providing face-to-face access, medication reconciliation, clinical medication synchronization,  
203 immunizations, comprehensive medication reviews, and personal medication records.<sup>7</sup> Based  
204 on results from the Pearson correlation, pharmacies possessing CPESN's core, required services  
205 are more willing to implement COVID-19 POC testing than those who do not qualify for network  
206 inclusion. There were two categories that were found to be significant against enhanced  
207 pharmacy status. The first involved patient-related factors focusing on the pharmacists'  
208 opinions on patient attitudes towards in-pharmacy POC testing. Those pharmacists who  
209 believed patients would be more accepting of testing within this setting also maintained  
210 pharmacies offering more enhanced services. The same can be said for the questions within the  
211 testing follow-up category which focused on pharmacist perceptions and comfort with certain  
212 action steps required after attaining a test result for a patient.

213 Pharmacies who operate under the conventional community pharmacy model focusing  
214 primarily on dispensing rather than offering additional patient-centered enhanced services  
215 seem less willing to implement COVID-19 POC testing based on perceived barriers reported  
216 within the survey. The idea of incorporating such a non-traditional service like POC testing into  
217 their daily dispensing routine may seem too daunting to consider. A more viable first step may  
218 be to promote the importance of other enhanced services like medication synchronization and  
219 medication therapy management to these pharmacies as these services are already

220 reimbursable or possess evidence-based cost savings. Future directions for this study will also  
221 involve suggesting an ideal workflow for service implementation within independent  
222 pharmacies utilizing responses from survey participants. This will require a larger sample size  
223 and more responses specifically from pharmacists indicating an independent pharmacy as their  
224 primary practice site.

225

### 226 **Limitations (113)**

227 Due to the small sample size and inclusion of only South Carolina pharmacists, the  
228 generalizability of these findings is limited and may not be applicable to community  
229 pharmacists in other areas of the US. Also as this study collected self-reported attitudes and  
230 behaviors, social-desirability and recall bias may be a concern. Finally, individuals who  
231 responded to the survey may differ from non-respondents, therefore, possibly resulting in non-  
232 response bias.

233 Because response rates were low throughout the initial dispersal of postcards, the  
234 inclusion criteria was expanded to include pharmacists within all community settings rather  
235 than independent alone. Analysis procedures were adjusted and data was stratified to offer  
236 comparisons and contrasts based on different practice settings.

237

### 238 **Conclusions (95)**

239 Independent pharmacies seem more equipped to conduct POC testing when compared  
240 to chain pharmacies based on CLIA waiver status. However, there is need to improve status  
241 across all practice settings. There is a need to develop strategies to implement COVID-19 POC  
242 testing within the pharmacy so as to not interfere with daily workflow as this is the biggest  
243 concern for pharmacists within this study. Significant correlations were found between  
244 enhanced pharmacy status and patient-related and testing follow-up related barriers. Those  
245 pharmacies with enhanced services were more likely to report fewer barriers to POC testing  
246 implementation.

247

### 248 **Citations (References)**

- 249 1. Coronavirus Disease 2019 (COVID-19). South Caroline Department of Health and  
250 Environmental Control (SCDHEC). Retrieved March 1, 2021, from  
251 <https://scdhec.gov/covid19>
- 252 2. Gubbins PO, Klepser ME, Dering-Anderson AM, et al. Point-of-care testing for infectious  
253 diseases: opportunities, barriers, and considerations in community pharmacy. *J Am*  
254 *Pharm Assoc (2003)*. 2014;54(2):163-171. doi:10.1331/JAPhA.2014.13167
- 255 3. Buss VH, Deeks LS, Shield A, Kosari S, Naunton M. Analytical quality and effectiveness of  
256 point-of-care testing in community pharmacies: A systematic literature review. *Res*  
257 *Social Adm Pharm*. 2019;15(5):483-495. doi:10.1016/j.sapharm.2018.07.013
- 258 4. Klepser DG, Klepser ME, Murry JS, Borden H, Olsen KM. Evaluation of a community  
259 pharmacy-based influenza and group A streptococcal pharyngitis disease management  
260 program using polymerase chain reaction point-of-care testing. *J Am Pharm Assoc*  
261 *(2003)*. 2019;59(6):872-879. doi:10.1016/j.japh.2019.07.011

- 262 5. Center for Devices and Radiological Health. (n.d.). Clinical laboratory improvement  
263 amendments (clia). Retrieved March 1, 2021, from [https://www.fda.gov/medical-  
265 devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia](https://www.fda.gov/medical-<br/>264 devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia)  
266 6. Our mission statement: CPESN USA. (n.d.). Retrieved March 1, 2021, from  
267 <https://cpesn.com/about-us/our-mission-statement/>  
268 7. Services available from CPESN Network Pharmacies: CPESN USA. (n.d.). Retrieved March  
269 1, 2021, from [https://cpesn.com/payors/services-available-from-cpesn-network-  
pharmacies/](https://cpesn.com/payors/services-available-from-cpesn-network-<br/>pharmacies/)

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