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1 Safety Events and Privilege Utilization Rates in Advanced Practice Physical Therapy  
2 compared to Traditional Primary Care: An Observational Study

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4 Short Title: Advanced Practice Physical Therapy Safety & Utilization

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1 INTRODUCTION: The general practitioner shortage in the United States coupled with a  
2 growing number of Americans living with disability has fueled speculation of non-  
3 physician providers assuming a greater role in musculoskeletal healthcare. Previous  
4 physician shortages have been similarly addressed, and expanding physical therapy  
5 (PT) scope of practice may best serve to fill this need. Resistance to expanding PT  
6 practice focuses on patient safety as PTs assume the roles traditionally performed by  
7 primary care providers. While studies have shown advanced practice PT to be safe,  
8 none have compared safety events in advanced practice PT compared to traditional  
9 primary care to determine if there are increased patient risks. Therefore, the purpose of  
10 our study is to examine the rate of safety events and utilization of services in an  
11 advanced practice PT clinic compared to a primary care clinic. A secondary aim of our  
12 study was to report safety events associated with spinal manipulation and dry needling  
13 procedures.

14 MATERIALS & METHODS: Productivity and safety data were retrospectively collected  
15 from Malcolm Grow Medical Center from 2015-2017 for the Family Health Clinic (FHC)  
16 and an advanced practice Physical Therapy Clinic (PTC). Chi square tests for  
17 independence, risk ratios (RR) and 95% confidence intervals (95%) were used to  
18 compare the relationship between the frequency of 1) patient encounters and clinical  
19 procedures and 2) clinical procedures and safety events.

20 RESULTS: 75% (12/16) of safety events reported in the PTC were defined as near  
21 misses compared to 50% (28/56) within the FHC (RR 1.5; 95% CIs: 1.0 to 2.2). Safety  
22 events were more likely to reach patients in the FHC compared to the PTC (RR 1.9;  
23 95% CIs: 0.8 to 4.7). Safety events associated with minor harm to patients was n=4 and

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24 n=3 in the FHC and PTC respectively. No sentinel events, intentional harm events, nor  
25 actual events with more than minor harm were reported in either clinic. Significant  
26 relationships indicated that prescriptions, laboratory studies, imaging studies and  
27 referrals, were all more likely to be ordered in the FHC than the PTC ( $p<0.01$ ). The  
28 PTC ordered one diagnostic imaging study for every 37 encounters compared to one in  
29 every 5 encounters in the FHC. The PTC similarly referred one patient to another  
30 healthcare provider for every 52 encounters, fewer than the one per every 3 encounters  
31 in the FHC. There was a significant relationship between encounters and diagnoses,  
32 indicating a higher number of diagnoses per encounter in the FHC, though the  
33 difference of 0.31 diagnoses per encounter may not be clinically meaningful ( $p<0.01$ ). A  
34 total of 1,818 thrust manipulations and 2,910 dry needling procedures were completed  
35 without any reported safety events.

36 **CONCLUSION:** These results suggest advanced practice PT has a similar safety profile  
37 to traditional primary care. The authority to order musculoskeletal imaging and refer to  
38 other clinicians were among the most commonly utilized privileges and may be of  
39 primary importance when establishing an advanced practice PT clinic. These results  
40 support research showing advanced practice PT may lead to reductions in specialty  
41 referrals, diagnostic imaging, and pharmaceutical interventions.

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## 1 INTRODUCTION

2 The number of Americans living with a disability has increased by 26% in the last 2  
3 decades.<sup>1,2</sup> Musculoskeletal conditions are the second leading cause for disability in  
4 the United States and are the leading reason for primary care visits.<sup>2,3</sup> Despite the rise  
5 in disability, the US has one of the lowest number of physician visits per capita.<sup>4</sup>  
6 Potential reasons that Americans see their physicians so infrequently are limitations of  
7 health care access and increasing costs. Health care costs in the US have grown  
8 exponentially over the previous 2 decades.<sup>5</sup> The Commonwealth Fund reported the  
9 United States had the highest health care expenditure as a percentage of Gross  
10 Domestic Product (GDP) and in health care spending per capita of the 18 industrialized  
11 nations examined.<sup>4</sup> One third of Americans reported cost-related barriers to  
12 healthcare in the US, highest among examined countries.<sup>4</sup> Only citizens of Switzerland  
13 experience higher out of pocket health care costs than the US.<sup>4</sup> In 2016, the  
14 Organisation for Economic Co-Operation and Development (OECD) reported the US  
15 has one of the lowest ratios of general practitioners per capita within reporting nations.<sup>6</sup>  
16  
17 Previous US physician shortages have been addressed, in part, by expanding practice  
18 of non-physician health care professions.<sup>7,8</sup> Expanding the scope of care for US  
19 physical therapists (PTs) may be a solution to help reduce health care costs while  
20 improving access to care. In recent years, health care practices throughout the world  
21 have been shifting away from more physician-centric models and transitioning to more  
22 team-based approaches.<sup>9-11</sup> Further, research has found that team based approaches  
23 benefit both patients as well as medical professionals.<sup>12,13</sup> The shift to team-based care

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24 has coincided with the physical therapy (PT) profession seeking and attaining greater  
25 levels of clinical responsibility.<sup>14</sup> Specifically, all 50 states and the District of Columbia  
26 had some form of direct access by 2014.<sup>15</sup> Additionally, Wisconsin became the first  
27 state to authorize radiograph orders by PTs in 2015.<sup>16</sup> Despite this, there are still  
28 significant reimbursement and legislative hurdles to overcome in expanding PT scope of  
29 care. For instance, some state practice acts still restrict PTs from making a clinical  
30 diagnosis or from performing thrust manipulation.<sup>17,18</sup>

31  
32 PTs within the US military have been practicing in advanced roles since the 1970s.<sup>19</sup>  
33 US military PTs operate as advanced practice PTs, and are authorized to see patients  
34 without a referral (direct access), and may order diagnostic imaging, laboratory studies,  
35 refer to other clinicians, and prescribe a limited set of medications. Additionally, all  
36 military PTs are authorized to perform thrust manipulations and may be credentialed to  
37 perform dry needling. This broad scope of practice has been called advanced practice  
38 PT, and is seldom realized in non-military settings within the US. Advanced practice PT  
39 has gained overwhelming support in the literature, both in the US and abroad. An  
40 abundance of research has shown that advanced practice PT has led to a decrease in  
41 health care utilization.<sup>20-31</sup> Patients treated by advanced practice PTs experience  
42 improved outcomes compared to traditional models.<sup>23-26,32,33</sup> Perhaps most impactful is  
43 that advanced practice PT achieved these results while simultaneously reducing health  
44 care costs.<sup>20-22,24,25,27,29,32,34</sup>

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46 Some of the main opponents of liberating restrictions on PT practice have argued such  
47 actions would put patients at increased risk of harm due to lower perceived educational  
48 standards when compared to primary care providers.<sup>35,36</sup> Essentially, it is suggested  
49 PTs taking on responsibilities typically performed or ordered by primary care providers  
50 such as diagnosis, ordering musculoskeletal imaging, or ordering laboratory studies  
51 would receive inferior care compared to traditional primary care leading to a higher rate  
52 of adverse events. Subsequent evidence has shown PTs to have superior or similar  
53 knowledge of managing orthopedic conditions when compared to other medical  
54 professions.<sup>37-40</sup> Further, all US PT programs advanced to an entry-level doctoral  
55 degree by 2017 which required the addition of pharmacologic, medical screening,  
56 nutrition, diagnostic imaging, and other content areas.<sup>41,42</sup>

57  
58 Despite evidence supporting PT knowledge and education, safety of patients being  
59 treated by PTs in advanced roles remain a valid concern. While previous studies have  
60 shown advanced practice PT to be safe,<sup>43-45</sup> it has not been shown how advanced  
61 practice PTs compare to primary care providers in relation to safety events. As  
62 advanced practice PTs take on responsibilities traditionally performed by primary care, it  
63 is unknown if patients are at a higher risk of an adverse event relative to the traditional  
64 primary care pathway. It is also unknown if advanced practice PT would result in lower  
65 utilization rates of ancillary services. Therefore, the purpose of our study is to examine  
66 the rate of safety events and utilization of services in an advanced practice physical  
67 therapy clinic compared to a primary care clinic. We hypothesized that advanced  
68 practice PTs would have similar rates of reported safety events and lower utilization

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4 69 when compared to primary care providers. A secondary aim of our study was to report  
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6 70 safety events associated with treatment techniques which are not universally authorized  
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9 71 within US PT practice acts (specifically: spinal manipulation and dry needling  
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11 72 procedures).  
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## 16 74 METHODS

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19 75 Data was retrospectively collected from Malcolm Grow Medical Clinic and Surgery  
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21 76 Center (MGMC), Joint Base Andrews (JBA), Maryland from calendar years 2015-2017  
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23 77 for the Family Health Clinic (FHC) and Physical Therapy Clinic (PTC). MGMC is a  
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26 78 United States Air Force (USAF) facility and primarily serves active duty military  
27  
28 79 personnel, retired military personnel, and the dependents (including but not limited to  
29  
30 80 spouses and children) of those personnel. At MGMC, patients with primary complaints  
31  
32 81 which may potentially be musculoskeletal in nature (i.e. back pain, knee pain, etc) could  
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34 82 contact the PTC directly to be seen as a direct access patient. Patients were also able  
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36 83 to schedule appointments via centralized booking clerks, who were authorized to  
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38 84 schedule patients either with the FHC or PTC depending on clinical availability.  
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41 85 Patients scheduled with the FHC could be transferred to an on-site PT to be seen as  
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43 86 direct access. Patients could also be referred to the PTC via a primary care provider,  
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45 87 orthopedic surgeon, or other provider.(Figure 1)  
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53 89 The FHC utilizes medical doctors, doctors of osteopathy (DO), physician assistants, and  
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55 90 nurse practitioners. The FHC is the main primary care clinic for patients largely within  
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58 91 the ages of 18-64, as younger patients tend to be seen in Pediatrics and older or more-



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92 sickly patients are typically seen within Internal Medicine. While DOs practiced as  
93 primary care providers in this setting, they could also perform joint manipulations in this  
94 setting.

95  
96 The PTC is an advanced practice outpatient orthopedic clinic typically seeing patients  
97 aged 18-64 years. Within the JBA PTC, PTs may diagnose and treat patients with  
98 unlimited direct access, and may autonomously perform spinal manipulation or dry  
99 needling, order musculoskeletal imaging or laboratory studies, prescribe a limited set of  
100 medications, and refer to other healthcare providers such as orthopedic surgery. The  
101 PTC was staffed by physical therapists and physical therapy technicians. The PTs in  
102 this study included active duty military personnel, reserve military personnel,  
103 government civilians, and contractors.

104  
105 PTs within USAF as a whole are mostly trained in civilian universities, with only 1-2  
106 military trained PTs entering service per year. Similarly, most PTs within the JBA PTC  
107 during this period were trained through civilian PT programs, with only one PT  
108 graduating from U.S. Army-Baylor University. During the hospital credentialing process,  
109 PTs new to the military system are typically granted “supervised” privileges for  
110 advanced PT practice such as ordering diagnostic imaging. While under supervised  
111 privileges, the PT would need permission from a qualified PT to utilize an advanced  
112 practice skill and the supervising PT would subsequently cosign the corresponding  
113 clinical note. After successfully completing the 6 months of supervised privileges, the  
114 PT would typically advance to independent privileges. No additional formalized or

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115 continuing education is mandated to attain advanced practice which speaks to the  
116 educational similarity of USAF PTs compared to a civilian practice.

117  
118 Productivity statistics for all patient encounters and procedures for the FHC and PTC  
119 clinics for calendar years 2015-2017 were accessed via the Military Health System  
120 Management Analysis and Reporting Tool (M2). Procedures of interest included, 1)  
121 pharmaceutical prescriptions, 2) clinical diagnoses, 3) laboratory orders, 4) diagnostic  
122 imaging orders, 5) referrals to other clinics, 6) thrust manipulations, and 7) dry needling.

123 In an effort to minimize risk, no identifiable patient data were accessed nor associated  
124 with the data set. The study was determined to be “non-human research” by the 59th  
125 Medical Wing Institutional Review Board (IRB) which is geographically separated from  
126 the clinics in this study but is nevertheless the governing IRB for said clinics.

127  
128 Safety reports were pulled from the Patient Safety Reporting database (PSR). The PSR  
129 is an internal database which allows for documentation of safety events without fear of  
130 reprisal and not-accessible by legal entities. Reports may be entered by medical  
131 personnel within their clinic, medical personnel reporting a safety concern in another  
132 clinic, via patient complaints to the patient advocate, or via patient complaints to the  
133 safety officer. Patient Safety Reports are categorized into near miss, actual events,  
134 sentinel events, and intentional unsafe acts.<sup>46</sup> Near misses are considered to be  
135 potential unsafe event that never reaches a patient. Actual events are defined as  
136 events that have reached a patient and are subsequently categorized by the level of  
137 harm endured by the patient. Increasing near-miss reporting is thought to reduce actual

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138 events.<sup>47</sup> The target benchmark of near-miss events for MGMC was at least 72% of  
139 overall safety reports. The command atmosphere during the collection period was one  
140 of non-retribution for completing safety reports. During the period of data collection,  
141 MGMC informed the researchers that the facility as a whole consistently surpassed the  
142 72% near-miss metric suggesting safety reports were being documented at reasonable  
143 level. For the purposes of this study, PSR reports were further categorized by 2 blinded  
144 researchers using standard definitions (Table 1) consistent with PT practices that are  
145 not universally allowed within PT practice across the entire US. If there was  
146 disagreement on the categorization of a safety report, a third researcher served to break  
147 the tie.

148  
149 Statistical analyses were performed in SPSS version 24.0 (IBM Corp), with  $\alpha=0.05$  set a  
150 priori for all analyses. Chi square tests for independence, risk ratios (RR) and 95%  
151 confidence intervals (95%) were used to compare the relationship between the  
152 frequency of 1) patient encounters and clinical procedures and 2) clinical procedures  
153 and safety events in each of the previously mentioned categories. The procedure rate  
154 was calculated as the total procedures per 1000 encounters.

## 156 RESULTS

157 The number of providers practicing in the FHC per calendar year ranged from 15-21  
158 physicians and 13-32 level-two providers (i.e. physician assistants or nurse  
159 practitioners. The number of providers practicing in the PTC per calendar year ranged  
160 from 6-11 PTs. Within the 3 years analyzed in this study, the FHC was responsible for

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161 more encounters (207,241 vs. 41,656), prescriptions (208,946 vs. 28), diagnoses  
162 (357,549 vs. 59,234), laboratory studies (71,277 vs. 32), imaging studies (41,548 vs.  
163 1,122), and referrals (67,652 vs 803) when compared to the PTC. There was a  
164 significant relationship between encounters and the following procedures in the FHC  
165 and PTC indicating that prescriptions ( $\chi^2=38389.9$ ,  $p<0.01$ ), laboratory studies  
166 ( $\chi^2=13636.8$ ,  $p<0.01$ ), imaging studies ( $\chi^2=5790.1$ ,  $p<0.01$ ) and referrals ( $\chi^2=11221.0$ ,  
167  $p<0.01$ ), were all more likely to be used in the FHC than PTC. There was a significant  
168 relationship between encounters and diagnoses ( $\chi^2=772.1$ ,  $p<0.01$ ) in the FHC and  
169 PTC, indicating a higher number of diagnoses per encounter in the FHC than PTC,  
170 though a difference of 0.31 diagnoses per encounter may not be clinically  
171 meaningful.(Table 2)

172  
173 There were 56 documented safety events within the FHC (of which 20 were categorized  
174 into 1 of the 7 procedural definitions and 36 which were categorized as “other”) and 16  
175 within the PTC (all of which were categorized as “other”) (Table 3). The safety events in  
176 the “other” category were consistent with findings in previous studies<sup>47</sup> and included  
177 such items as failure in the electronic health records systems. 75% (12/16) of safety  
178 events reported in the PTC were defined as near misses compared to 50% (28/56)  
179 within the FHC (RR 1.5; 95% CIs: 1.0 to 2.2). Reciprocally, safety events were more  
180 likely to reach patients in the FHC compared to the PTC (RR 1.9; 95% CIs: 0.8 to 4.7).  
181 The number of safety events associated with minor harm to patients was n=4 and n=3  
182 in the FHC and PTC respectively.(Table 4) No sentinel events, intentional harm events,  
183 nor actual events with more than minor harm were reported in either clinic.

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A total of 1,818 thrust manipulations (Figure 2) were performed with 197 and 1,621 occurring in the FHC and PTC respectively. Within the PTC, 2,910 dry needling procedures were performed.(Figure 3) Within the three years of data collection, no safety report was filed in relation to a thrust manipulation nor a dry needling procedure.

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## DISCUSSION

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Results indicate that PT has a similar safety profile to traditional primary care within the specified domains of advanced practice PT. This is consistent with previous studies which found no differences in harm-rates in advanced practice PT when compared to traditional referral-based PT.<sup>34</sup> This additionally supports research that shows PTs make correct triage decisions when presented with cases which may not be musculoskeletal in nature.<sup>48-50</sup>

197

Mintken et al deemed advanced practice PT to be safe in their decade-long retrospective analysis. 12,976 patients were seen in PT at the University of Colorado without a physician referral. No serious medical pathology went unidentified, no adverse events were reported, and no licensure or disciplinary action of any kind was pursued against the PTs. Mintken et al concluded that patients were at “minimal to no risk for negligent care when evaluated and treated by PTs.” Moore et al reported a multicenter retrospective analysis reviewing advanced practice PT within 25 military clinics. During the 40 month analysis, 95 PTs recorded 472,013 encounters with no adverse events recorded, with no disciplinary action pursued, and with no litigation filed

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207 against the US Government.<sup>43</sup> Deyle concluded risks associated with advanced  
208 practice PT are “extraordinarily low.”<sup>44</sup>

209  
210 PTs were also found to utilize significantly fewer additional services such as laboratory  
211 studies and imaging when compared to FHC. These findings, however, are not  
212 intended to suggest superiority of either clinic in this regard as the roles of providers  
213 within the FHC and PTC are not identical. While advanced practice PTs utilize  
214 laboratory studies to screen for pathology, primary care providers must also use them  
215 for other functions such as tracking disease progression or identifying proper dosages  
216 for pharmaceutical interventions. Likewise, the number of images ordered by the PTC  
217 may be deflated if the patient had already received the imaging at the FHC. Rather, the  
218 reader should understand the utilization of services in expanded practice PT and use  
219 the FHC utilization only as a reference point.

220  
221 Notably, this study shows a PT imaging study order rate of 1 imaging study for every  
222 37.13 encounters or 2.69% of encounters. This is substantially lower than previous  
223 reports which have reported PT imaging rates of 10-15%.<sup>49,51</sup> However, those studies  
224 reported imaging studies ordered “per patient” and not “per encounter” as in our study,  
225 which may explain these statistical differences. When looking at the domains of  
226 musculoskeletal imaging, laboratory studies, prescriptions, and referrals to other  
227 practitioners, the most commonly utilized skill of advanced practice PTs was to order  
228 diagnostic imaging studies. To that end, pursuing diagnostic imaging authority may be

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229 of utmost importance if pursuing advanced practice physical therapy within a practice  
230 act or within a healthcare organization.

231  
232 The ability to refer to other clinicians such as orthopedic surgeons was a close second  
233 in order of utilization, occurring 1 in every 51.88 encounters or 1.93%. Similar to  
234 imaging orders, previous studies reported a substantially different rate of referral at  
235 16%, but those studies were also reported “per patient” and not “per encounter” as we  
236 reported in this study.<sup>49</sup> Ordering laboratory studies and prescribing medicine were  
237 utilized markedly less frequently by the advanced practice PTs. Our findings are  
238 consistent with previous research into ancillary services utilization in direct access PT  
239 compared to traditional care.<sup>20,21,52,53</sup> Frogner et al similarly found significant reductions  
240 in healthcare utilization including pharmaceuticals and imaging services when patients  
241 accessed physical therapy first before traditional care.<sup>22</sup>

242  
243 In recent years, dry needling has seen large gains in clinical application fueled by  
244 multiple legislative updates or legal decisions regarding its implementation by PTs.  
245 However, medical literature on dry needling is limited, especially as applied by PTs.  
246 This dearth of evidence is compounded when looking for risks associated with dry  
247 needling.<sup>54</sup> Brady et al performed a prospective study evaluating adverse events in  
248 7,629 treatments of dry needling. Zero significant adverse events were reported,  
249 suggesting an upper significant risk rate of  $\leq 0.04\%$ .<sup>55</sup> Gonzalez-Perez et al performed  
250 a randomized controlled trial in which a total of 72 dry needling interventions were  
251 performed.<sup>56</sup> They reported no adverse events occurred within their treatment

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252 population of 24 subjects. Cotchett et al treated 84 patients with weekly dry needling  
253 interventions for a period of six weeks in their randomized controlled trial, and no  
254 adverse events were reported.<sup>57</sup> In this study, 2,910 dry needling treatments were  
255 performed over a three-year period by PTs with zero reported safety events. Our  
256 findings are consistent with multiple literature reviews which have reported no significant  
257 adverse events or a low level of risk from dry needling.<sup>58-60</sup>

258  
259 Reporting of adverse events (or lack thereof) in spinal manipulation trials has  
260 significantly improved since 2010 when the Consolidated Standards of Reporting Trials  
261 statement was published.<sup>61</sup> The subsequent literature has consistently reported  
262 adverse events tied to thrust manipulations to be absent or minor and transient.<sup>62-70</sup>  
263 Studies which have reported adverse events in relation to manipulative therapy have  
264 been determined to be anecdotal without a clear connection between the treatment and  
265 the adverse event.<sup>71,72</sup> Multiple systematic reviews have concluded thrust manipulation  
266 is low-risk<sup>73-76</sup> Despite the reported safety of thrust manipulation as well as physical  
267 therapist application of the techniques, there are still practice acts within the US which  
268 limit PTs from practicing these techniques.

269  
270 One of the criticisms of safety reporting within the contexts of spinal manipulation is  
271 “competing intra- and inter-professional narratives” which can influence reporting and  
272 study results.<sup>77</sup> To that end, Rozmovits et al suggested a collaborative and anonymous  
273 inter-professional reporting system which would liberate reporting from associated  
274 consequences, promoting greater learning opportunities.<sup>77</sup> To some extent, this study



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275 touches on those aims as the PSR is an anonymous inter-professional reporting  
276 system. It is notable that a combined 1,817 thrust manipulations (197 FHC, 1,621 PTC)  
277 were performed with no reported safety events. However, a larger database of  
278 interventions must be assessed given serious events tied to spinal manipulation are  
279 rare and are estimated to occur once in every 20,000 to 250,000,000 manipulations.<sup>78</sup>

280

281 Limitations of this study include being a single-center study in a military beneficiary  
282 population, which limits the generalizability of our results. Additionally, the PSR system  
283 is not inherently sensitive, as more significant safety and/or harm events would likely be  
284 captured within this system while more mild adverse events such as post manipulation  
285 soreness or mild medication side effects would not likely be captured. Mild, transient,  
286 and self-limiting adverse events, however, would similarly not be likely to drive  
287 legislative decisions which we've approached in this paper. While limiting patient data  
288 allowed for a much wider collection of encounter data, it limited our ability to more  
289 closely match or compare patient populations between the FHC and PTC. The  
290 magnitude of the data collection spanning approximately 249,000 encounters also  
291 restricted the ability to collect outcomes, though previous research has consistently  
292 found superior outcomes within advanced practice PT.<sup>23-26,33</sup> While the literature is  
293 supportive of advanced practice PT, research on adverse events within this practice  
294 setting are limited. Further research on safety rates within advanced practice PT  
295 settings will be useful to support PT practice act expansions.

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297 CONCLUSION

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298 Advanced practice PT has a similar safety profile and lower utilization rates of ancillary  
299 services when compared to traditional primary care within their respective patient  
300 populations. This may indicate that advanced practice PT can provide a safe and  
301 efficient first line of treatment for MSK conditions.

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509  
510 **FIGURES**

- 511 Figure 1. Patient flow diagram
- 512 Figure 2. Number of spinal manipulation procedures per month in the Physical Therapy  
513 Clinic (PTC) and the Family Health Clinic (FHC)
- 514 Figure 3. Number of dry needling procedures per month in the Physical Therapy Clinic

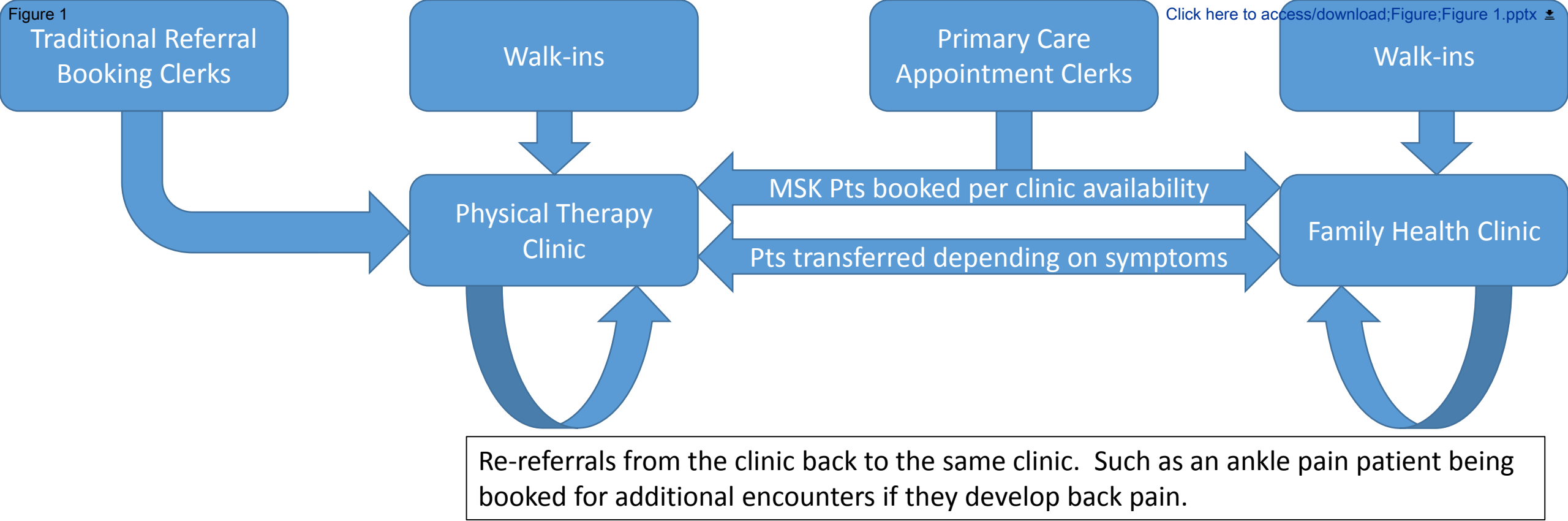




Figure 2

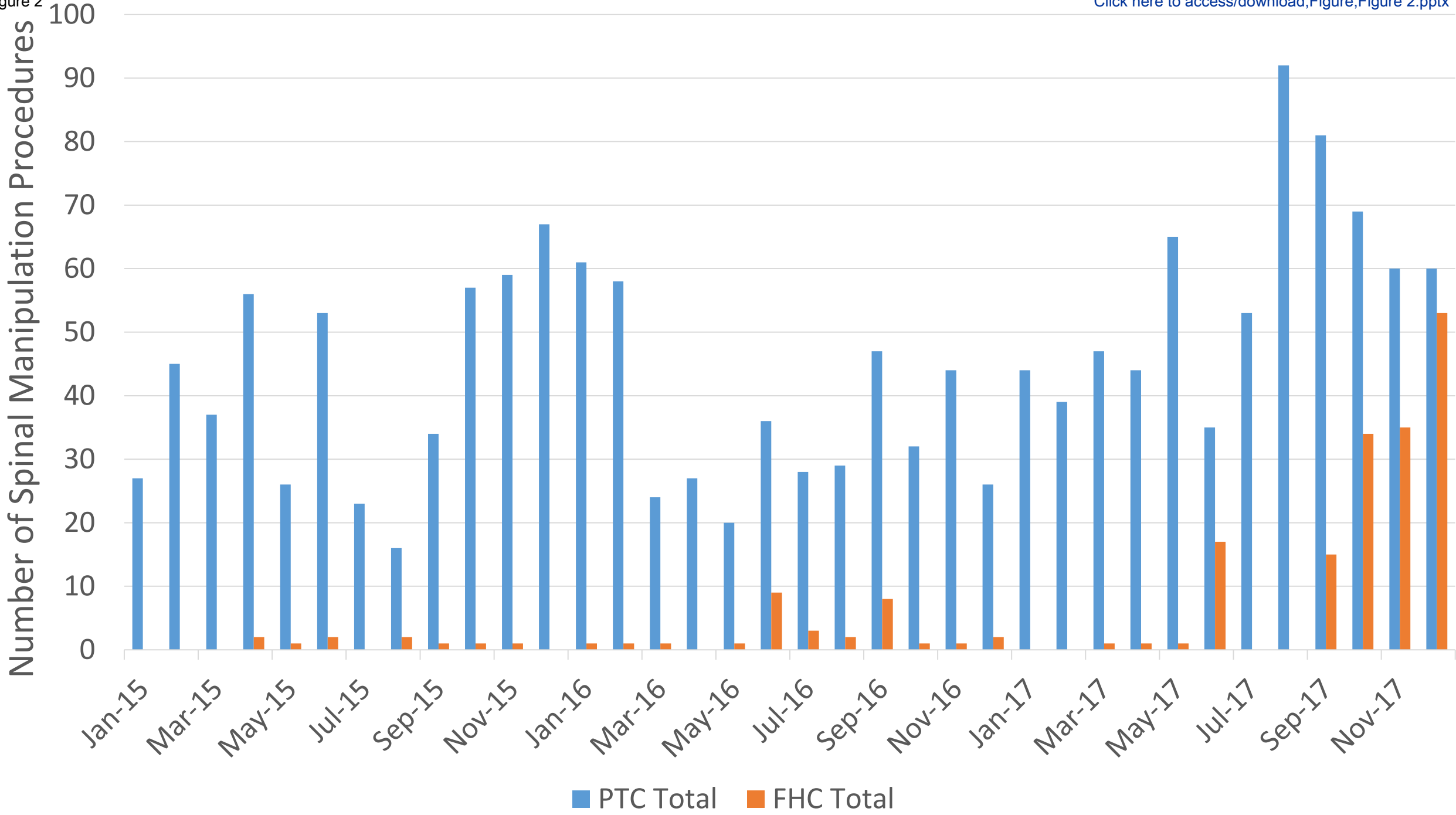
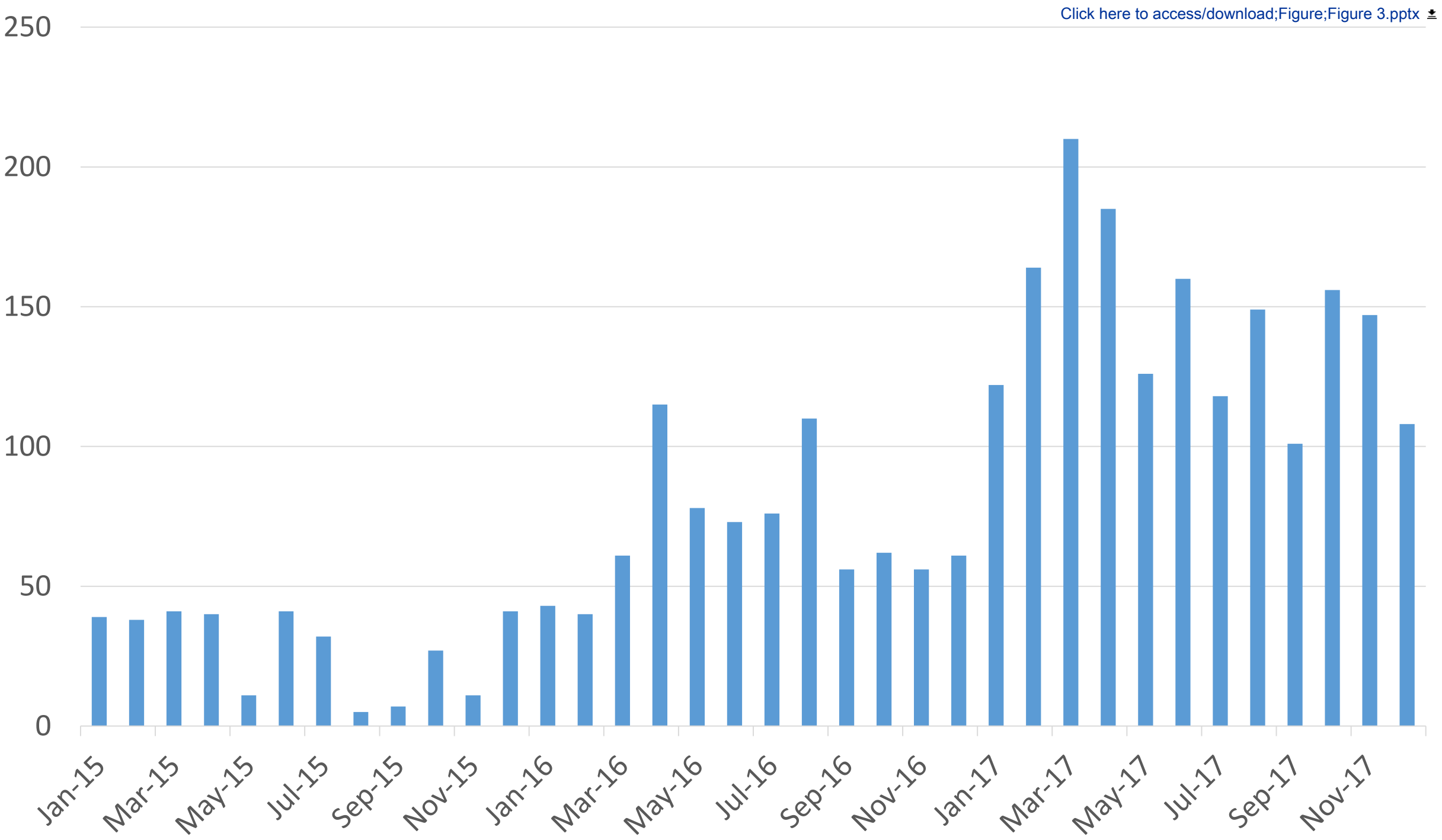


Figure 3

Number of Dry Needling Procedures



**Table 1.** Safety Event Category Definitions

Category	Definition
Prescription	Safety event stemming from an improperly ordered prescription, a contraindicated prescription, or other harm caused by a prescription which was faulted to the provider/clinic
Diagnosis	Safety event stemming from a missed diagnosis, a failure to report diagnosis to patient, or any other diagnosis related event which was faulted to the provider/clinic
Laboratory Study	Safety event stemming from an improperly ordered laboratory study, a failure to order a laboratory study, or a failure to report to patient the outcome. In an effort to homogenize data, safety events occurring during the collection or handling of laboratory studies were not included as the Physical Therapy Clinic does not perform laboratory collection.
Diagnostic Imaging	Safety event stemming from an improper order for a diagnostic image, a failure to order an appropriate diagnostic image, or other diagnostic imaging events which was faulted to the provider/clinic.
Referral (Out)	Safety event stemming from an improper referral, referral to the wrong clinic, failure to inform patient of a referral, or any other referral related event which was faulted to the provider/clinic
Thrust Manipulation	Safety event stemming a thrust manipulation potentially from improper application, contraindication, or other thrust manipulation event which was faulted to the provider/clinic
Dry Needling	Safety event stemming from dry needling potentially from improper application, contraindication, or other dry needling event which was faulted to the provider/clinic
Other	Any safety event not otherwise captured by any other category

Table 2. Advanced Practice Utilization

	<b>FHC</b>	<b>PTC</b>	<b>p-value</b>
Encounters (Enc)	207,241	41,656	
Prescriptions (Rx)	208,946	28	<b>**&lt;0.01</b>
Enc/Rx	0.99	1,487.71	
Diagnoses (Dx)	357,549	59,234	<b>**&lt;0.01</b>
Dx/Enc	1.73	1.42	
Laboratory Studies (Lab)	71,277	32	<b>**&lt;0.01</b>
Enc/Lab	2.91	1,301.75	
Imaging Studies (IS)	41,548	1,122	<b>**&lt;0.01</b>
Enc/IS	4.99	37.13	
Referrals (Ref)	67,652	803	<b>**&lt;0.01</b>
Enc/Ref	3.06	51.88	

FHC - Family Health Clinic; PTC - Physical Therapy Clinic

\*\* Indicates a statistically significant finding

Table 3. Safety Event Analysis

	<b>FHC</b>	<b>PTC</b>	<b>p-value</b>
Encounters (Enc)	207,241	41,656	
Total Safety Reports	56	16	0.21
Total Safety Reports/100,000 Encs	27.02	38.41	
Prescriptions (Rx)	208,946	28	
Rx Safety Reports	11	0	0.97
Rx Safety Reports/100,000 Rxs	5.26	0.00	
Diagnoses (Dx)	357,549	59,234	
Dx Safety Reports	4	0	0.42
Dx Safety Reports/100,000 Dxs	1.12	0.00	
Laboratory Studies (Lab)	71,277	32	
Lab Safety Reports	3	0	0.97
Lab Safety Reports/100,000 Labs	4.21	0.00	
Imaging Studies (IS)	41,548	1,122	
IS Safety Reports	1	0	0.87
IS Safety Reports/100,000 IS	2.41	0.00	
Referrals (Ref)	67,652	803	
Ref Safety Reports	1	0	0.91
Ref Safety Reports/100,000 Ref	1.48	0.00	

FHC - Family Health Clinic; PTC - Physical Therapy Clinic

Table 4. Safety Event Harm Level

	<b>Family Health</b>					
<b>Category</b>	<b>Safety Reports</b>	<b>Near Miss</b>	<b>Near Miss %</b>	<b>Actual Event</b>	<b>No Harm</b>	<b>Mild Harm</b>
Other	36	23	64%	13	12	1
Medication	11	1	9%	10	8	2
Diagnosis	4	0	0%	4	3	1
Laboratory	3	3	100%	0	0	0
Imaging	1	1	100%	0	0	0
Referral	1	0	0%	1	1	0
Thrust Manipulation	0	0	N/A	0	0	0
Dry Needling	N/A	N/A	N/A	N/A	N/A	N/A
Total	56	28	50%	28	24	4

	<b>Physical Therapy</b>					
<b>Category</b>	<b>Safety Reports</b>	<b>Near Miss</b>	<b>Near Miss %</b>	<b>Actual Event</b>	<b>No Harm</b>	<b>Mild Harm</b>
Other	16	12	75%	4	1	3
Medication	0	0	N/A	0	0	0
Diagnosis	0	0	N/A	0	0	0
Laboratory	0	0	N/A	0	0	0
Imaging	0	0	N/A	0	0	0
Referral	0	0	N/A	0	0	0
Thrust Manipulation	0	0	N/A	0	0	0
Dry Needling	0	0	N/A	0	0	0
Total	16	12	75%	4	1	3

**59th Medical Wing (59th MDW)  
Institutional Review Board (IRB)**  
59th Clinical Research Division/SGVUS/(210) 292-7143  
1100 Wilford Hall Loop, Bldg 4430, Lackland AFB, TX 78236-5300

**10 Jan 18**

**FINAL DETERMINATION –NON-HUMAN RESEARCH**

**Determination Date:** 10 Jan 2018

**Project Lead:** Maj Lance Mabry/11SGC

**Reference Number:** FWH20180057N

**Project Title:** Reported Harm in Military Physical Therapists Practicing in Expanded Roles: A Single Center Study

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your project was determined on 10 Jan 2018 to be considered **not human research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.

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Earl Grant, Jr., PhD  
Designated Exempt Reviewer