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ORIGINAL ARTICLE

Community pharmacist-initiated screening program for osteoporosis: randomized controlled trial

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Abstract
Summary This study evaluated the effect of a multifaceted intervention (screening and patient education) by community pharmacists on testing or treatment of osteoporosis. One hundred and twenty-nine patients randomized to receive the intervention were compared to 133 patients who did not receive the intervention. Twice as many patients who got the intervention received further testing or treatment for osteoporosis.
Introduction The objective of this study was to determine the effect of a community pharmacist screening program on testing and treatment of osteoporosis.

Trial Registry: ISRCTN 54746861

Methods In this randomized, controlled trial, 262 patients meeting bone mineral density (BMD) testing guidelines [men or women aged ≥ 65 years or 50–64 years with one major risk factor including previous fracture, family history of osteoporosis, glucocorticoids for > 3 months, or early menopause] were allocated to intervention (129) or control (133). Intervention consisted of printed materials, education, and quantitative ultrasound. Primary outcome was a composite endpoint of BMD or prescription for osteoporosis medication within 4 months.
Results Primary endpoint of BMD or osteoporosis treatment was achieved by 28 intervention patients (22%) compared with 14 controls (11%) (RR 2.1, 95% CI 1.1–3.7). This was driven by BMD testing (28 (22%) vs. 13 (10%) for controls, p=0.011). Calcium intake increased more among intervention patients than controls (30% vs. 19%, RR 1.6, 95% CI 1.0–2.5). There was no effect on knowledge or quality of life.
Conclusion A pharmacist screening program doubled the number of patients tested for osteoporosis. Nevertheless, many patients eligible for BMD did not receive appropriate care suggesting more intensive interventions are needed.

Keywords Osteoporosis · Pharmacists · Quality improvement · Randomized controlled trial · Screening

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Introduction

The most important clinical consequence of osteoporosis is fracture [1]. Fractures cause pain, deformity, disability, reduced mobility, and loss of independence [1–4]. With an aging population it is estimated that the incidence of hip fractures (the most devastating complication of osteoporosis) will quadruple in the next 50 years [2]. Nevertheless,

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rates of osteoporosis screening remain low [5–7]. For example in one study of over 200,000 healthy US women, close to 50% had previously undetected low bone mineral density (BMD) [5]. Other studies in the USA, Canada, and elsewhere have demonstrated substantial underdiagnosis and undertreatment of osteoporosis [5–8]. Better methods of identifying patients at high risk of osteoporosis are needed [5–8].

One of the major barriers to screening is that patients who are relatively "healthy" (asymptomatic) do not present to their family physicians office to seek preventive care [9]. Patients with multiple risk factors for osteoporosis are neither identified nor appropriately screened [5–7, 10]. There have only been a handful of randomized studies evaluating interventions to improve osteoporosis screening [11–15]. These interventions have included electronic reminders to physicians [11], academic detailing [12, 14], physician audit and feedback [13], patient specific education and mailings [15], or combinations of these strategies [11, 12]. Overall, these trials have had mixed results and all but one have been conducted through physicians' offices.

Community pharmacies provide an ideal setting for preventative health programs as they are easily accessed and patients see pharmacists more often than any other health provider [16, 17]. Pharmacists' involvement in health screening and disease management has been described for a variety of areas including cholesterol management [18], hypertension [19], asthma follow-up [20], and others [21]. To our knowledge, there have been no randomized trials of osteoporosis screening conducted in community pharmacies.

Therefore, we undertook a randomized controlled trial to determine the effect of a multifaceted osteoporosis intervention by community-based pharmacists on subsequent testing and treatment of osteoporosis compared with usual care.

Materials and methods

Study participants and setting

This was a randomized controlled trial with blinded ascertainment of outcomes conducted in 15 community pharmacies (Save on Foods Pharmacies) in the province of Alberta, Canada. Patients were recruited by community pharmacists based on national guidelines (Osteoporosis Canada) for bone mineral density testing with central dual energy X-ray absorptiometry (DXA) [1]. We included all patients 65 years or older, or between 50 and 64 years with at least one major risk factor (i.e., previous fracture, family history of osteoporosis, systemic glucocorticoids for >3 months, or early menopause). We excluded patients who had a BMD test in the past 2 years, were on current treatment for osteoporosis, were unwilling to participate, or were non-English speaking. The study was approved by the University of Alberta Health Research Ethics Board.

Study design

The design of this trial has been published previously [22]. Participants were recruited through newspaper advertisements and notices posted in the study pharmacies, as well as by pharmacists' identification of potentially eligible patients presenting to the pharmacy (i.e. for a prescription refill). Patients who met the inclusion and exclusion criteria, and provided written informed consent were randomized via a secure internet randomization service (using a sequence stratified by site with a block size of 4) to intervention or control. All participants provided written informed consent and baseline data was collected from each participant, including total calcium and vitamin D intake (diet and supplementation).

Intervention

Patients in the intervention group were asked to return to the pharmacy on a structured clinic day. Patients were scheduled into 30-min appointments on the clinic day, with all interventions completed by a designated community pharmacist. The intervention involved a tailored education program on aspects of osteoporosis; including risk factors, bone mineral density testing, lifestyle measures, calcium and vitamin D intake, and medications. Patients were provided with printed osteoporosis educational materials (brochure from Osteoporosis Canada plus a pamphlet developed by the study investigators [available from http://www.epicore.ualberta.ca]) and a quantitative heel ultrasound (QUS) measurement using McCue C.U.B.A.® Clinical Bone Density Sonometer (McCue, Sarasota, FL, USA). Interpretation of the results was discussed with each patient, as well as reinforcement of the QUS as a tool to help with the osteoporosis risk assessment rather than as a diagnostic test for osteoporosis. Prior to the start of the study, all participating community pharmacists were trained by the investigators.

Patients were encouraged to follow-up with their primary care physician for further management. Additionally, study details were sent to the primary care physician for each patient, including information that their patient was eligible for BMD testing with central DXA based on national guidelines, as well as the QUS results with clinical interpretation. The intervention group received follow-up phone calls at 2 and 8 weeks and were asked to return to the pharmacy at 16 weeks. The follow-up reinforced the previously delivered educational messages and determined if any of the study endpoints had been reached.

Control group: usual care

The control group reflected "usual care" in the community pharmacy with respect to osteoporosis management. In addition, patients assigned to the control group were provided with the same printed materials from Osteoporosis Canada. We acknowledge that even the targeted provision of printed educational materials to patients may be more than what is considered "usual care" in most community pharmacies. Patients were asked to return to the pharmacy at 16 weeks to determine if any of the study endpoints had been reached. After the main study was completed, control patients were offered the same counseling session and QUS measurement as in the intervention.

Outcome measures

The primary outcome was a composite endpoint of a BMD test with central DXA or the initiation of a new prescription medication for osteoporosis (any bisphosphonate, nasal calcitonin, raloxifene, teriparatide, or hormone therapy) within 4 months of study entry. This endpoint is consistent with the currently used HEDIS measures for quality of osteoporosis care adopted by the National Committee on Quality Assurance [23] and previous studies of osteoporosis quality improvement [11, 12, 14]. Endpoints were measured by patient self-report and confirmed by receiving a copy of the BMD measurement from the primary care physician and a copy of the prescription from the dispensing pharmacy. As a composite endpoint, only the first event in the cluster was counted. Secondary outcome measures included each component of the primary outcome; total daily calcium and vitamin D intake; patient's osteoporosis-related knowledge using the previously validated "Facts on Osteoporosis Quiz" (FoOQ) [24]; and changes in generic health status (SF-12) [25] and osteoporosis-specific quality of life (OPTQoL) [26]. All outcomes were ascertained without knowledge of allocation status, but given the nature of the study all patients were aware of taking part in an osteoporosis quality improvement study.

Statistical analyses

The patient was the unit of allocation, analysis, and causal inference. Assuming an event rate of 20% in the usual care group over 4 months and an increase to 40% in the intervention group, a two-sided alpha of 0.05, and 90% power, a total sample size of 218 patients was estimated. This was increased to 262 patients, to allow for dropouts, loss to follow-up, and additional power for secondary analyses. All analyses were according to the intention-to-treat principle. Between-group differences in binary outcomes were assessed with frequencies and Chi-square tests. In the event that randomization was not successful, we prespecified that we would use multivariate logistic regression to adjust for age, sex, and any baseline clinical characteristics that were imbalanced at $P<0.10$ degree of significance. Continuous variables, such as quality of life, were analyzed using means (standard deviations) and *t*-tests. All analyses were conducted with SAS version 9.1 (SAS Institute, Cary, North Carolina).

Results

From November 2005 to September 2007, 561 patients were screened and 299 patients were excluded. The most common reasons for exclusion were BMD within the past 2 years (118 patients), osteoporosis treatment (56 patients), and refusal (30 patients). Overall, 262 patients were randomized; with 129 allocated to intervention and 133 to control. After allocation, 26 (20%) patients in the intervention group and 23 (17%) controls either withdrew or were lost to follow-up. All 262 patients were included in the analyses (Fig. 1).

Patient characteristics

The median age of the patients was 62 years (interquartile range 56–71), two-thirds were women, and 40% were non-white. Osteoporosis risk factors included 17% with previous fracture and 38% with early menopause. The patients in both groups were comparable, although intervention patients were more likely to have had a family history of osteoporosis (47% vs. 34%, $p=0.03$). Other characteristics stratified according to allocation status are presented in Table 1.

Primary outcome

The endpoint of BMD testing with central DXA or new osteoporosis treatment was achieved by 28 patients (22%) in the intervention group compared with 14 patients (11%) in the control group (relative risk 2.1, 95% CI 1.1–3.7; $p=0.017$). This result was driven by BMD testing (Fig. 2). Specifically, BMD testing was performed in 28 patients (22%) in the intervention group vs. 13 (10%) in the control group (relative risk 2.2, 95% CI 1.2–4.1; $p=0.011$) while a new prescription for osteoporosis medication was attained in six patients (5%) in the intervention group vs. three (2%) in the control group (relative risk 2.1, 95% CI 0.5–8.1; $p=0.30$; Table 2). Adjustment for age, sex, and family history of osteoporosis led to no change in estimate of effect or statistical significance from the unadjusted findings for the primary endpoint (adjusted RR 2.14, 95% CI 1.2–3.8, $p=0.011$).

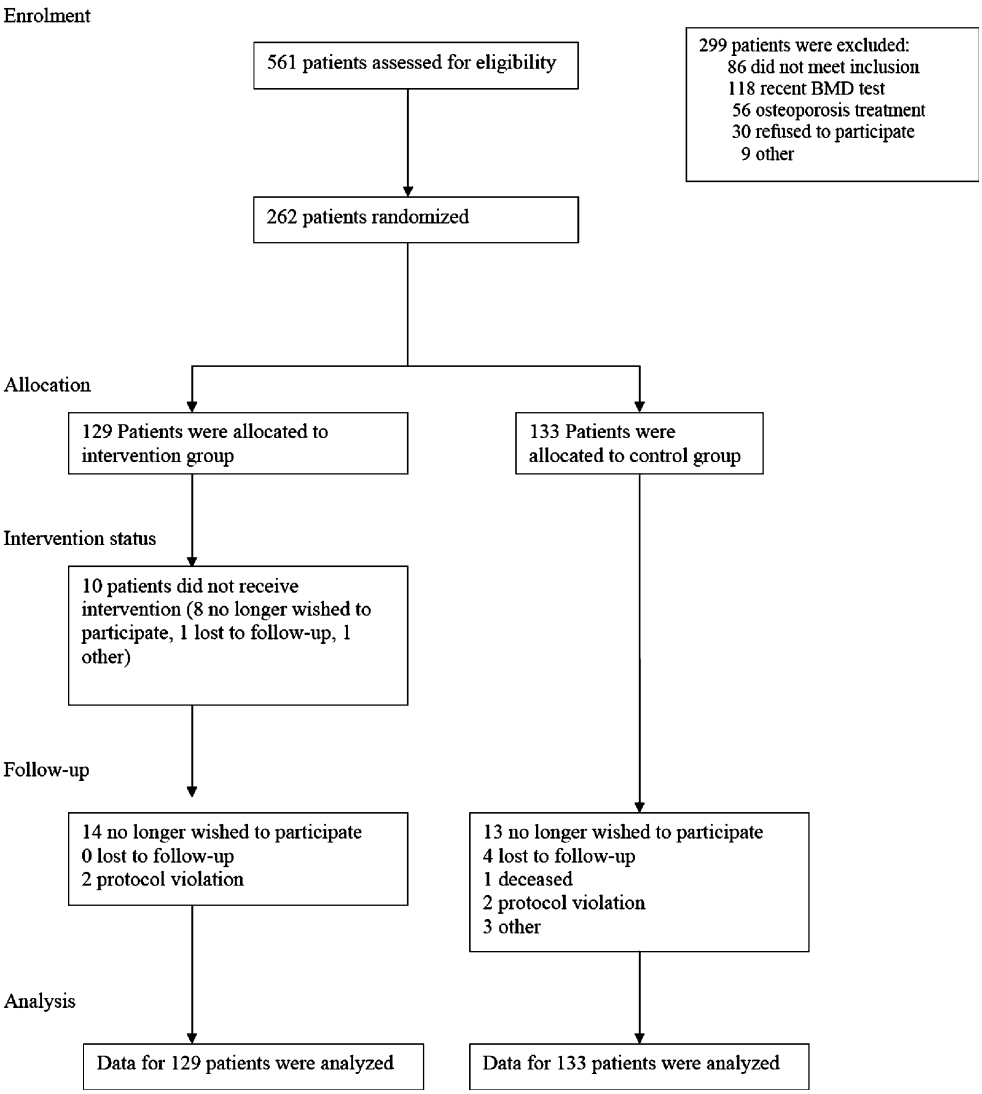

Fig. 1 Study participation and patient flow

Quantitative ultrasound measurements

Sixty-one patients (47%) had QUS results indicating low bone mass at the heel with estimated QUS T-scores of −1 or lower. Interestingly, 71% of patients receiving a BMD test and all of the patients who received an osteoporosis medication had QUS T-scores less than −1.

Calcium and Vitamin D intake

Table 2 includes summary of calcium and Vitamin D outcomes at the end of 16 weeks. Calcium intake increased significantly more among intervention patients than controls (30% vs. 19%, relative risk 1.6, 95% CI 1.0–2.5, $p=0.011$). Vitamin D intake also increased with the intervention, although this was not statistically significant ($p=0.66$).

Patient reported outcomes

Intervention patients did not score higher in the knowledge test than the controls at the end of the 16 weeks (they scored 57% correct in the knowledge survey compared with 54% correct with controls). Health-related quality of life or osteoporosis-specific quality of life did not differ significantly between the intervention and control patients (Table 3). A significantly greater number of patients in the intervention group reported an osteoporosis-specific appointment with their primary care physician as compared to controls (35% vs. 17%, $p<0.001$).

Discussion

Evidence-based practice guidelines advocate early identification of patients at high risk of fracture, but translation of

Table 1 Baseline characteristics in 262 patients by randomized group

Characteristics	Intervention group $n=129$	Control group $n=133$
Age, median (range), year	61 (56–70)	63 (57–71)
Females, *n* (%)	80 (62)	89 (67)
White *n* (%)	85 (66)	75 (56)
Less than high school *n* (%)	19 (15)	19 (14)
Household income less than $30,000 *n* (%)	28 (22)	28 (21)
Health status (SF-12)[a]		
Mean mental component score (SD)	51.9±9.6	48.9±11.0
Mean physical component score (SD)	41.8±11.0	44.2±10.7
Excellent or very good health condition, *n* (%)[b]	21 (16)	27 (20)
Osteoporosis risk factors *n* (%)		
Previous fracture as an adult	18 (14)	27 (20)
Family history of osteoporosis	61 (47)	45 (34)*
Current smoker	22 (17)	12 (9)
Celiac disease	2 (2)	0
Hyperparathyroidism	1 (1)	1 (1)
Rheumatoid arthritis	12 (9)	14 (11)
Hyperthyroidism	3 (2)	0
Menopause before the age of 45	28 (35)	37 (42)
Males: low testosterone	2 (5)	2 (6)
Oral corticosteroids for >3 months	6 (5)	3 (2)
Heparin	11 (9)	8 (6)
Seizure medication	8 (6)	5 (4)
Chemotherapy in past 2 years	3 (2)	0
Males: antiandrogen therapy	1 (3)	0
>4 cups coffee per day	24 (19)	22 (17)
Osteopenia on X-ray or BMD	7 (5)	6 (5)
Alcohol history (>2 drinks per day)	5 (4)	6 (5)
Calcium		
Number of patients reaching total daily calcium of 1,500 mg *n* (%)	35 (27)	26 (20)
Calcium supplements *n* (%)	58 (45)	59 (44)
Vitamin D		
Number of patients reaching total daily vitamin D of 800 IU *n* (%)	23 (18)	16 (12)
Vitamin D supplements *n* (%)	65 (50)	56 (42)

*$P=0.03$ for between-group difference

[a] SF-12 - Medical Outcome Study 12-item Short Form

[b] Missing 41 (31%) in intervention and 45 (34%) in usual care

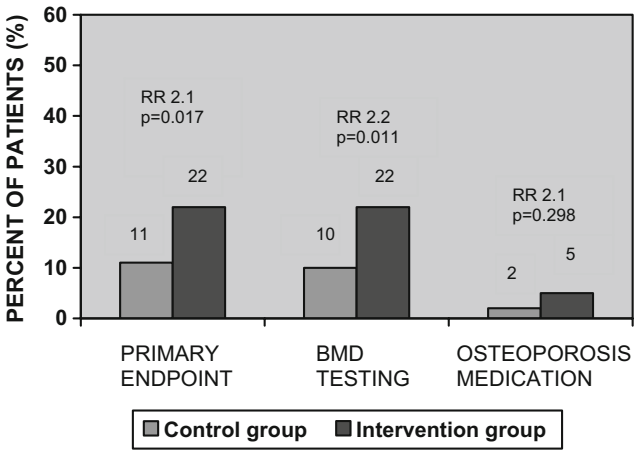

Fig. 2 Patients in each group reaching endpoints by the end of 16 weeks

these recommendations into practice has been poor [6–8]. In our community-based randomized trial, we found that a pharmacist-initiated osteoporosis screening program doubled the number of patients tested or treated for osteoporosis within 4 months when compared to usual care. This was mostly a result of an increase in guideline-concordant BMD testing in this population. The intervention led to an 11% absolute increase in the number of patients tested or treated, which translates to a number needed to treat of 9.

Few randomized controlled trials have looked at improving screening of patients at risk for osteoporosis; the results of these few studies have been mixed, and most have been conducted in physicians' offices [11–15]. Previous non-randomized and uncontrolled studies of osteoporosis screening programs in community pharmacies have suggested a potential impact in identifying patients with low bone mass [27–30]. For example, Elliott et al. reported a case series using peripheral dual energy X-ray absorptiometry in five community pharmacies in rural Wisconsin [27]. Of 133 post-menopausal women assessed, 20% had calcaneal osteoporosis; however, as a result of their intervention, only nine women (7%) eventually received a BMD test with central DXA or started osteoporosis treatment. Naunton et al. screened 345 women through a quantitative heel ultrasound screening program in six community pharmacies in Australia and 38 (11%) underwent a BMD test [28]. In another uncontrolled study of 305 patients screened by pharmacists, about 16% had a BMD test completed [29]. It is noteworthy that in two of these case series, the rates of downstream BMD testing were similar to our usual care rates of 10%.

A novel aspect of our study was the use of QUS. In the last few years, QUS has gained interest as a potential screening tool as it is portable, inexpensive, and easy to use with minimal training. Furthermore, QUS can predict hip fractures almost as well as BMD measurements with central DXA [5, 30–32]. However, we did not use QUS for screening; rather we used the QUS results as a method of engaging patients and as part of an overall osteoporosis risk assessment. Our findings showed that the majority of

Table 2 Rates of testing and treatment for osteoporosis after 16 week intervention

Variable	Intervention group (n=129), n (%)	Control group (n=133), n (%)	Unadjusted relative risk (95% CI)
Primary endpoint[a]	28 (22)	14 (11)	2.1 (1.1–3.7)
Secondary endpoints			
BMD test performed	28 (22)	13 (10)	2.2 (1.2–4.1)
Osteoporosis treatment prescribed	6 (5)	3 (2)	2.1 (0.5–8.1)
Additional patients reaching total daily calcium of 1,500 mg (diet + supplement)[b]	39 (30)	25 (19)	1.6 (1.0–2.5)
Additional patients reaching total daily Vitamin D of 800 IU (diet + supplement)[c]	24 (19)	22 (17)	1.1 (0.7–1.9)

[a] Composite endpoint of obtaining BMD testing or new prescription for osteoporosis medication

[b] Number of additional patients after 16-week intervention with baseline calcium <1,500 mg

[c] Number of additional patients after 16-week intervention with baseline Vitamin D <800 IU

patients receiving a BMD test (71%) or starting on a medication (100%) had QUS results indicating moderate or high fracture risk (T-scores less than −1). Even though all patients would have been candidates for BMD testing and were encouraged to see their primary care physician regardless of the QUS measurement, patients with low QUS T-scores (less than −1) were more likely to get BMD testing. Further study is required to see if and how QUS measurements motivate patient's or physician's actions.

When assessing each component of the primary endpoint it is evident that most of these events were from BMD testing. This is not a surprising finding as this is the initial step in diagnosing osteoporosis. Even though all patients in this study would have had a major risk factor for osteoporosis, not all of these patients would have had low bone density to warrant starting on an osteoporosis medication. One could also argue that the 4-month follow-up may not have been long enough to capture patients starting on medications. However, in our health region, the waiting times for publicly funded BMD tests are less than 1 week and previous osteoporosis studies we have conducted have demonstrated that more than 90% of all BMD testing and treatment initiation that will eventually take place occurs within 3 months of intervention [33, 34].

Our study had several limitations. First, we measured outcomes which reflected processes of care rather than clinical endpoints reductions in fracture or even improvement in bone mineral density. Evidence already exists for fracture reduction with many of the current osteoporosis medications in patients at high risk for fractures [1] and it is well-recognized that in quality improvement trials, process measures are better indicators of quality than clinical outcomes [35]. In fact several published studies have used similar process endpoints [18, 33, 34]. Second, we had a withdrawal and loss to follow-up rate of almost 19%. This did not differ markedly between intervention (20%) and control groups (17%) and most of the withdrawals occurred after randomization with nearly half of the withdrawals occurring before the intervention was actually delivered. Nevertheless, all of our analyses were intention-to-treat. Third, the generalizability of our findings to other community pharmacy settings may be questioned, as we used one chain of pharmacies, with the staff pharmacists undergoing a training session before the start of the study. However,

Table 3 Patient reported outcomes after 16-week intervention

Variable	Intervention group n=129	Control group n=133	Unadjusted p value
Generic health status (SF-12), n (%)	81 (63)	92 (69)	
Mean mental component score	51.6	51.7	0.97
Mean physical component score	43.6	43.5	0.98
Osteoporosis-related quality of life, n (%)[a]	81 (63)	92 (69)	
Physical function score	72.0	72.1	0.99
Adaptation score	67.4	70.1	0.36
Fears score	80.2	78.7	0.69
Osteoporosis-related knowledge, n (%)[b]	81 (63)	92 (69)	
Answered correctly (%)	57.1	54.0	0.31

[a] As measured by the Osteoporosis-Targeted Quality of Life (OPTQoL) instrument (26)

[b] As measured by the Facts on Osteoporosis Quiz (24)

other than additional training for the pharmacists, we believe our intervention would be easily replicable. Indeed, we (and others) have conducted similar screening programs in community pharmacies for conditions as disparate as dyslipidemia, hypertension, and asthma [18–20].

Our intervention was successful in achieving higher rates of BMD testing as compared to the control. Concerningly, even 78% of intervention patients did not receive what would be considered appropriate care within 4 months of the intervention, and even in those with low bone mass on QUS (T-score <−1) only a third of these patients received further testing. One has to wonder why screening rates remained below optimal in both groups, even though all patients would have been candidates for BMD testing. Many barriers to receiving adequate osteoporosis-related care have been reported [36, 37]; however, further study is needed to identify interventions (and more importantly the best mix of targeted interventions) that will break down barriers and further narrow this care gap.

In conclusion, a community pharmacist-initiated screening program directed at high-risk patients doubled the number of patients tested or treated for osteoporosis. Nevertheless, the majority of patients did not appear to receive appropriate care suggesting more intensive interventions delivered by pharmacists or other health professionals are needed.

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