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LAI, Y.S. and AFSETH, J.D.

2019

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# A review of the impact of utilising electronic medical records for clinical research recruitment

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*Clinical Trials*

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DOI: 10.1177/174077451829709

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## Abstract

**Introduction:** Recruitment is an important aspect of clinical research, as poor recruitment could undermine the scientific value of a trial or delay the development process of new treatments. The development of electronic medical records provides a new way to identify potential participants for trials by matching the eligibility criteria with patients' data within electronic medical records.

**Methods:** A literature search was performed to examine the effectiveness and efficiency of the electronic medical record recruitment method using MEDLINE, PubMed, PubMed Central, CINAHL Plus with Full Text, ScienceDirect and Cochrane Library databases. These searches generated 11 articles that met the eligibility criteria, and handsearching reference lists generated two additional articles bringing the total number of articles to 13. These articles were subjected to critical appraisal utilising the Effective Public Health Practice Project tool.

**Results:** Out of the 13 included articles, 11 provided quantitative data on recruitment effectiveness while 7 articles provided quantitative data on recruitment efficiency. The automation in screening and patient identification by using alerts, a notification system, to notify research staff of a potential participant, was observed to contribute to higher recruitment yield and reduced workload due to its specificity on participant screening. The use of electronic medical record alerts was found to be associated with better recruitment outcomes when they were sent to dedicated research staff rather than physicians. Using electronic medical records for recruitment was found to be effective due to its capability for patient identification outside working hours and fast processing time, which was particularly useful for clinical trials in acute conditions. Several challenges may hinder the impact of the electronic medical record recruitment method, including the lack of conformity of clinical trial eligibility criteria and electronic medical record data structure and missing data. 'Alert fatigue' could also impact on the effectiveness of this method in the long term.

**Conclusion:** The results from this review supports electronic medical record being an effective and efficient method for clinical trial recruitment. Recommendations were made in order to maximise the potential of the electronic medical record recruitment method and also for future research in order to improve the quality of evidence to support this strategy for recruitment.

## Keywords

Electronic medical record, recruitment, clinical research, clinical trial, electronic health record

## Introduction

Clinical research plays an important role in advancing medical knowledge, including the development of new treatments by forming the evidence base for safety and therapeutic efficacy.<sup>1</sup> The success of trials depends on several factors such as trial design, project planning, training of research staff and on having a sufficient sample size, with recruitment of participants in a timely manner<sup>2</sup> and good participant retention.<sup>3</sup>

Recruitment of participants to trials has been reported to be one of the main barriers to their

completion.<sup>4</sup> Only 31.1% of trials funded by the United Kingdom Medical Research Council managed to reach

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their original recruitment targets, and 54% of these requested for an extension of timelines.<sup>5</sup> As recruitment of trial participants could incur large costs,<sup>6</sup> the costs of developing the drug could also be increased due to poor recruitment of participants. This significant economic impact was demonstrated in a phase IIb breast cancer prevention clinical trial at one site in the United States, which reported that the costs of recruiting 150 participants through internal referrals as well as advertisements was US\$164,585.<sup>7</sup> In clinical research recruitment, advertisements have been associated with higher costs than other methods like direct mailing or referrals.<sup>8,9</sup>

There are several barriers or challenges in the recruitment of participants to clinical research. One of the commonly reported barriers is the lack of access to the target group for the clinical trial.<sup>10</sup> Another challenge that is commonly cited is the difficulty in identifying participants who fulfil all the inclusion and exclusion criteria of the trial.<sup>11</sup>

Traditionally, many trials have relied on physicians' referral for recruitment of participants.<sup>12</sup> Approaches to enhance this recruitment method include screening patients' medical records and reminding clinicians about the trial.<sup>13</sup> Advertisements to improve clinical research recruitment can be delivered in a variety of ways (e.g. posters, newspapers, radio), although the effectiveness of this method is debatable.<sup>14–16</sup> A

Cochrane review of interventions to improve trial recruitment revealed that improvements in recruitment rates were seen when the design of the trial was open label as compared with blinded and by making telephone reminders to potential participants if they did not respond to a postal invitation.<sup>17</sup> However, it is not always possible to modify the trial design, as this could impact its scientific integrity, and it is uncertain if the telephone reminders will work in all trials. With advances in technology, there is a need to evaluate new methods of recruitment to determine their effectiveness.

Increasing numbers of healthcare institutions in different countries have started using electronic medical records, also known as electronic health records, to store patients' medical information.<sup>18,19</sup> Electronic medical records, due to their richness and structure, can provide data for the conduct of clinical research.<sup>20,21</sup> In addition, they can also be utilised to match and shortlist patients who might be potentially eligible to join clinical studies.<sup>22</sup>

There are a few reviews published in the literature on electronic medical record-enhanced recruitment. Cuggia et al.<sup>23</sup> concluded that electronic medical record systems are most effective in enhancing recruitment when implemented in the pre-screening phase. Another review by Ko'pcke and Prokosch<sup>24</sup> focused more on the components of the electronic medical records that might be utilised for recruitment purposes and with only limited information on the impact of this method on recruitment. This review aims to provide a more

comprehensive and updated review of the impact of electronic medical records on clinical research recruitment with a focus on its effectiveness and efficiency. The effectiveness of the recruitment method will be considered both in terms of the number of potential patients being identified and the number of patients enrolled in the trial. The efficiency of the recruitment methods will be considered in terms of the time and effort required to perform the recruitment activities.

## Methods

Table 1 details the literature searches conducted using MEDLINE, PubMed, PubMed Central, CINAHL Plus with Full Text, ScienceDirect and Cochrane Library databases. A two-step screening approach was utilised to assess the eligibility of the literature (Figure 1.)

Peer-reviewed quantitative research articles were included if they measured the impact of using electronic medical records for clinical research recruitment. Specifically, only if they measured the number of participants identified or recruited and clearly specified the time or manpower spent on the recruitment process. Another inclusion criteria was that articles had to be written in English and published between 2007 and 2017. Articles were excluded if they involved hypothetical generation of data (e.g. modelling studies), as these do not reflect the actual impact of electronic medical record recruitment methods. In addition, articles were excluded if they did not measure the specific impact of electronic medical record recruitment (e.g. when used in combination with other recruitment methods) or articles that measured the electronic medical record recruitment method without a comparator or control as the actual impact could not be compared with other recruitment methods.

The Effective Public Health Practice Project was used to assess the quality of the articles which provided a standardised and systematic method in evaluating the quality of research studies.<sup>25</sup>

## Results

The literature search was conducted using a variety of search terms in six scientific databases and yielded a total of 1773 results and 11 articles that met the eligibility criteria.

In addition, the reference lists of the 11 included articles, as well as those from the Ko'pcke and Prokosch<sup>24</sup> review were handsearched for articles which also fulfilled the eligibility criteria. Two additional articles were identified from this method, providing a total of 13 articles for this review.<sup>26–38</sup> The overall process of this literature search and article identification is illustrated in Figure 1.

Table 1. Details of literature searches and the number of articles included articles identified.

Search number	Database	Search terms	Number of results	Number of articles after filtering of article titles (Step 1)	Number of included articles after filtering their Full Text from Step 1 (final)
1	MEDLINE	(clinical trial) AND (recruitment) AND (EMR)	5	3	2
2	MEDLINE	(clinical trial) AND (recruitment) AND (electronic health records)	27	7	0
3	MEDLINE	(clinical trial*) AND (recruit*) AND (participant*) AND (system)	302	9	1
4	MEDLINE	(clinical trial*) AND (recruitment) AND (strategies)	251	37	1
5	PubMed	(clinical trial*) AND (selection) AND (electronic health records)	123	16	3
6	PubMed	(clinical trial) AND (recruitment) AND (alert*)	26	11	1
7	PubMed	(clinical trial) AND (recruitment) AND (automat*)	106	19	1
8	CINAHL Plus with Full Text	(clinical trial) AND (patient) AND (recruitment) AND (system)	159	23	0
9	PubMed Central	(clinical trial) AND (recruitment) AND (EMR)	413 <sup>a</sup>	22	2
10	ScienceDirect	(clinical trial*) AND (recruitment) AND (electronic medical record*)	123 <sup>a,b</sup>	5	0
11	ScienceDirect	(clinical trial*) AND (enrol*) AND (electronic health record*)	151 <sup>a,b</sup>	7	0
12	Cochrane Library	(clinical trial) AND (electronic medical records) AND (recruitment)	39 <sup>a,c</sup>	9	0
13	Cochrane Library	(clinical trial*) AND (recruit*) AND (system)	48 <sup>a,c</sup>	1	0

<sup>a</sup>As the option of filtering articles based on language was not available in PubMed Central, ScienceDirect, and Cochrane Library, the English language limit was not applied for searches 9, 10, 11, 12 and 13.

<sup>b</sup>An additional limit of 'clinical trials as topic' was applied due to a large number of search results of 4768 and 9716 in searches 10 and 11, respectively.

<sup>c</sup>The keywords were searched in 'Title, Abstract, Keywords' due to a large number of search results when searching the keywords using 'Search All Text', which yielded 2674 and 3867 results in searches 12 and 13, respectively.

The characteristics of the included articles are presented in Table S1 in the online supplementary materials. All included articles presented data from recruitment in the United States, except Treweek et al.<sup>26</sup> and Dugas et al.,<sup>33</sup> which were conducted in Scotland and Germany, respectively. Among the included articles, there were greater representation of diabetes trials, followed by cardiology and oncology trials. In addition, only Rollman et al.,<sup>27</sup> Dugas et al.<sup>33</sup> and Penberthy et al.<sup>36</sup> featured more than one clinical study in their data collection in the assessment of the impact of the electronic medical record recruitment method.

Only four out of the 13 included articles compared the characteristics of participants between the various recruitment methods. In the study by Rollman et al.,<sup>27</sup> participants that were recruited by the electronic medical record recruitment method were more likely to have higher levels of anxiety and more likely to be non-

White and male. In a study by Johnson et al.,<sup>35</sup> the electronic medical record method were more likely to recruit older participants, with lower body mass index and waist circumference. It was also noted by Johnson et al.<sup>35</sup> that majority of the ethnic minority participants, as well as all of the 3% of female participants were recruited from electronic medical record method. Schroy et al.<sup>29</sup> and Herasevich et al.<sup>32</sup> did not detect any major differences between the characteristics of participants recruited by different methods.

The comparison methods presented in the included studies mostly consists of manual identification of participants, through a variety of methods including referrals, chart reviews and advertisements. Participant identification via automated electronic medical record screening were utilised in all studies, but their execution varied widely, with the most common one being an alert system, notifying the staff of an appointment or admission or during an encounter of a potential

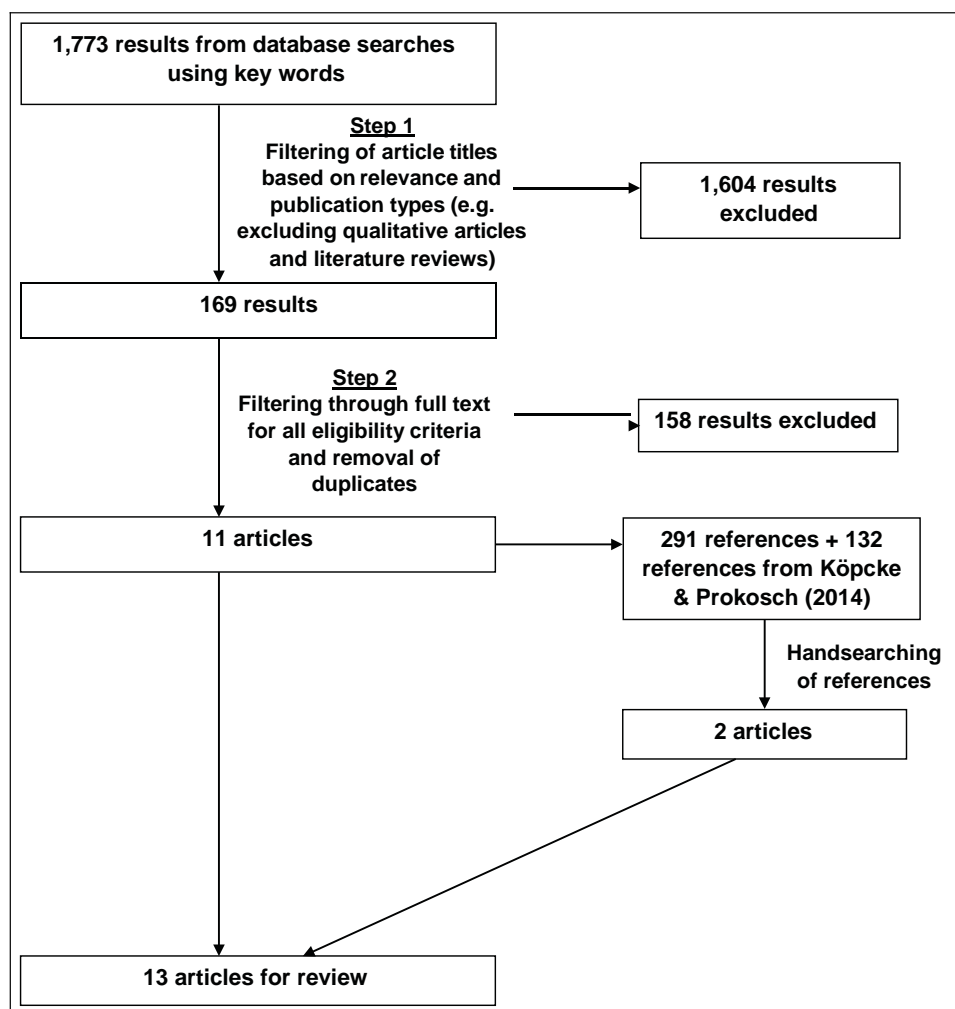


Figure 1. Flow chart of literature search and identification of articles.

participant, while others used mailings or calls to contact potential participants after they were identified from their electronic medical records.

Of the 13 articles included, 7 utilised an alert system. The alerts in studies of Treweek et al.,<sup>26</sup> Rollman et al.<sup>27</sup> and Schroy et al.<sup>29</sup> provided a prompt on the computer screen which allowed the user to respond by clicking buttons or hyperlinks to generate referrals. The alerts in studies of Weng et al.<sup>31</sup> and Dugas et al.<sup>33</sup> were sent via emails, which contained hyperlinks, to the research team to allow them to log in to the system to check the participants' eligibility. Herasevich et al.<sup>32</sup> and Cardozo et al.<sup>38</sup> had the alerts sent via their respective institutional paging system. However, no details were provided on the method or interface which these alerts were sent. In addition, these alerts were sent to different groups of staff. In studies of Treweek et al.,<sup>26</sup> Rollman et al.<sup>27</sup> and Dugas et al.,<sup>33</sup> the alerts were sent to physicians. For Weng et al.<sup>31</sup> and Herasevich et al.,<sup>32</sup> the alerts were sent to research coordinators, and the alerts in studies of Cardozo et al.<sup>38</sup> were sent to

investigators. The Click method by Schroy et al.<sup>29</sup> stated that the alerts were sent to the research team without specifying their roles.

All eligible literature articles from the search were subjected to quality appraisal by two reviewers using the Effective Public Health Practice Project tool (Appendix 1 and Appendix 2 in the online supplementary materials).<sup>25,39</sup> This was done independently and then discrepancies in the ratings between the reviewers were discussed before reaching a final decision. The final scores are attached in Appendix 3 in the supplementary materials.

Due to the nature of implementation of electronic medical record referral, which required major changes to recruitment workflow, most of the studies were unable to blind the research team during their execution, and this had a significant impact on the quality rating. The only article which managed to do so was Cardozo et al.,<sup>38</sup> where the recruitment team were able to remain blinded, as the source of referrals from either physicians or electronic medical records were masked

from them. As a result, other than Cardozo et al.,<sup>38</sup> seven articles were rated as moderate quality, and five articles were rated as weak quality.

All articles presented quantitative data on recruitment effectiveness. However, only seven articles had presented quantitative data on recruitment efficiency. These findings were also summarised in Table 2.

Of the 11 studies which provided data with regards to recruitment outcomes, eight indicated an increase in the number of actual recruited participants or an increase in the number of potential participants identified with the electronic medical record recruitment strategy. Two articles, Treweek et al.<sup>26</sup> and Dugas et al.,<sup>33</sup> reported mixed outcomes with increased recruitment or identification of participants only in some parts of their data. In contrast to the other articles, Rollman et al.<sup>27</sup> reported a lower number of participants enrolled as compared to manual identification via recruiters.

Recruitment was also observed to be higher in studies which had utilised an alert system, as compared to studies which did not. In a study by Effoe et al.,<sup>28</sup> the electronic medical record method had a lower yield (22.4%) than physician referral (27.5%). Although not explicitly specified, in the study by Johnson et al.,<sup>35</sup> targeted mailing only had a recruitment yield of 2.5% (69 of 2,764) from the electronic medical record screening as compared with a yield of 16.39% (20 of 122) from other recruitment methods. This was in contrast to those studies which had utilised an alert system as seen in previous studies.<sup>27,32,38</sup> In the study by Rollman et al.,<sup>27</sup> the electronic medical record recruitment enrolled 4.86% (176 of 3621) of those screened as compared with 2.38% (193 of 8095) of those screened via manual screening. In the study by Herasevich et al.,<sup>32</sup> the number patients enrolled per month doubled after the implementation of automatic electronic medical records screening with alerts ( $p < 0.05$ ), with similar numbers of patients screened before and after the implementation. In a study by Cardozo et al.,<sup>38</sup> the recruitment yield increased from 6% to 86% ( $p < 0.0001$ ) when alerts were generated from electronic medical records.

All seven studies that provided data related to workload showed that electronic medical record recruitment had generally led to improved efficiency. A reduction in the time required for electronic medical record recruitment was reported by Schmickl et al.,<sup>30</sup> Dugas et al.<sup>33</sup> and Beauharnais et al.<sup>34</sup> with time savings quantified per day or per patient. Efficiency was also quantified by requiring lesser manpower in terms of fewer full-time employment staff, fewer man hours and fewer working days in studies by Rollman et al.,<sup>27</sup> Penberthy et al.<sup>36</sup> and Weng et al.,<sup>37</sup> respectively. A faster processing time to identify a potential patient using electronic medical records was also reported by Weng et al.<sup>31</sup> Dugas et al.<sup>33</sup> and Penberthy et al.<sup>36</sup> both looked at a number of clinical trials and while some did not

demonstrate a saving in time or workload, both authors concluded that electronic medical records did result in time saving overall.

Only Schroy et al.<sup>29</sup> provided data on the actual costs of the electronic medical record recruitment method in comparison with other methods demonstrating its cost-effectiveness. The average cost per patient enrolled for its *Click* method with manual screening from electronic medical records was US\$129, the *Letter* method with manual screening from electronic medical records was US\$1967, the *Call* method with manual screening from electronic medical records was US\$156 and the *IT-Call* method with automated screening was US\$99.

## Discussion

### *Effectiveness of the electronic medical record recruitment method*

This review appears to support that the electronic medical record recruitment is more effective than other traditional methods. In contrast to the review undertaken by Köpcke and Prokosch,<sup>24</sup> which only found favourable data for the effectiveness of electronic medical record recruitment, this review included additional studies which demonstrated some mixed or negative findings. The effectiveness of the electronic medical record method could be attributed to its ability to target specific populations of participants, where it functions similarly to targeted mailing,<sup>40</sup> allowing recruiters to focus on those who have a higher chance of being eligible and thereby improving the trial's accrual rate.

Although electronic medical record screening generally increases the number of participants recruited, an interesting observation from the results was that studies which utilised electronic medical records for merely for filtering of potential participants and did not utilise an alert system had a lower recruitment yield than those which had used an alert system. Therefore, the effectiveness of the electronic medical record recruitment method could be partially attributed to the notification capability of the system<sup>41</sup> that allows it to prompt physicians or other research staff to review the eligibility and invite participants in the same setting or within a short period of time.

The effectiveness of the electronic medical record recruitment method could also be used to increase in capacity and scope of the recruitment. An increase in capacity could be linked to its efficiency where potential participants were available, but manual labour could not keep up with the capacity. In addition, the effectiveness of this recruitment method could be attributed to its ability to be implemented beyond the scope of working hours or for clinical trials that require prompt identification, such as acute situations in emergency departments.<sup>42</sup> This was observed in the study by

Table 2. Summary of findings of included articles.

Article	Summary of findings on recruitment outcomes or participant identification outcomes	Summary of findings on recruitment time or workload
Treweek et al. <sup>26</sup>	Number of participants recruited in cohort 1: EMR (2), letter (3), clinic (2), practice nurse (5). Number of participants recruited in cohort 2: EMR (9), letter (7), clinic (2), practice nurse (0)	No data
Rollman et al. <sup>27</sup>	Number of participants screened: EMR (3,621), waitroom recruiters (8095). Number of participants enrolled: EMR (176), waitroom recruiters (193)	Number of full-time staff utilised for each recruitment method: EMR (1.75), waitroom recruitment (3.5)
Effee et al. <sup>28</sup>	Number of enrolled patients for each method: EMR (160), physician referral (66), media (15), community screening (3), unknown sources (16). Recruitment yield for each method: physician referral (27.5%) followed by EMR (22.4%), advertisements (20.5%), community screening (13.6%)	No data
Schroy et al. <sup>29</sup>	Number of patients identified in 6 months: <i>Click</i> (100), <i>Letter</i> (1551), <i>Call</i> (758), <i>IT-Call</i> (10,260). Number of patients enrolled in 6 months: <i>Click</i> (12), <i>Letter</i> (17), <i>Call</i> (188), <i>IT-Call</i> (98). After excluding ineligible patients, the enrolment rates were: <i>Call</i> method (35.4%), <i>Click</i> method (16.7%; $p = 0.002$ ), <i>Letter</i> method (2.1%; $p \ll 0.001$ )	No data
Schmickl et al. <sup>30</sup>	No data	Time savings of 40 min/day (76% of pre-screening workload) for automated electronic screening
Weng et al. <sup>31</sup>	Number of enrolments: EMR alerts (176) in 12 months, manual identification through admission lists (7) in 3 months, manual identification through catheterization procedure lists (99) in 10 months	Estimated processing time for each identification: EMR (2 min), admission list (15 min), catheterization list (15 min)
Herasevich et al. <sup>32</sup>	Chart review screened 4149 patients in 8 months and 17 days and enrolled 37 patients. EMR alerts in addition to chart review screened 4460 patients in 9 months and 4 days and enrolled 68 patients. The number of enrolled patients per month doubled after EMR alerts implementation ( $p \ll 0.05$ )	No data
Dugas et al. <sup>33</sup>	Physicians survey for six studies after EMR alerts implementation: three studies reported 40% increase in recruitment, three studies reported no change in recruitment	Physicians survey for six studies after EMR alerts implementation: three studies reported an estimated 10 min time savings per recruited patient, one study reported an estimated 5 min time savings per recruited patient, two studies reported no change in time
Beauharnais et al. <sup>34</sup>	Number of patients enrolled: EMR (20), chart review (11). Enrolment rate increased from 0.17 to 0.32 participants per pre-screening day ( $p = 0.0001$ )	Total hours spent pre-screening per day decreased from 4 h to 2 h after EMR recruitment implementation
Johnson et al. <sup>35</sup>	Number of potential participants identified: traditional recruitment strategies (122), EMR (2,764). A total of 69 of the 89 enrolled patients (77%) were identified via the EMR targeted mailing approach	No data
Penberthy et al. <sup>36</sup>	No data	Four of five studies reported man hours savings ranging from 1.5 times to 19.4 times when using the automated EMR screening as compared to the manual chart review. Only one study reported 1.25 times more man hours used for automatic screening as compared to the manual process
Weng et al. <sup>37</sup>	Number of participants enrolled: registry screening (14), EMR screening (30)	Number of working days required for screening: registry screening (14), EMR screening (59)
Cardozo et al. <sup>38</sup>	A significant increment from 16% to 56% of potentially eligible participants was identified after the implementation of the EMR screening and alerts ( $p = 0.0012$ ) with the proportion of eligible patients enrolled also increased from 6% to 86% ( $p \ll 0.0001$ )	No data



Herasevich et al.,<sup>32</sup> where recruitment alerts were generated outside office hours to improve the identification of potential participants and their eligibility could be reviewed earlier, allowing them to be approached before interventions were commenced which would make them ineligible.

Interestingly, the articles which sent the alerts to physicians had reported mixed or reduced effectiveness of the electronic medical record methods as compared to the articles which had sent the alerts to research coordinators, where all three articles reported an improvement in recruitment outcomes. Moreover, there was stronger evidence presented in the study by Herasevich et al.<sup>32</sup> which had utilised inferential statistics in its analysis, where the number of patients enrolled per month doubled ( $p \leq 0.05$ ) after the electronic medical record method was being rolled out, further supporting the effectiveness of sending alerts to dedicated research staff. This suggests that physicians' clinical workload might have contributed to less favourable recruitment outcomes as compared to dedicated research staff. However, there were no trends observed between the methods of executing the alerts via a prompt with click interface and those which sent periodic emails to recruiters. This could suggest that the implementation method did not matter as long as the recruiter can receive the notification in time for recruitment purposes.

### *Efficiency of the electronic medical record recruitment method*

The efficiency of the electronic medical record recruitment method can be attributed to the reduction in the amount of time and workload of the research teams during the identification of a potential participant, with a higher chance of fulfilling eligibility criteria by the elimination of those that were clearly ineligible.<sup>43</sup> Consistent with the literature,<sup>44</sup> Schmickl et al.<sup>30</sup> was able to accurately identify potential participants with satisfactory levels of sensitivity and specificity due to the level of precision which electronic medical records data correlate with the eligibility criteria, resulting in low levels of false positives and false negatives. The presence of structured elements in the electronic medical record allows the data to be matched with similar elements in the eligibility criteria for trials.<sup>45</sup> These structured elements confers an advantage over a registry search, as seen in the study by Weng et al.,<sup>37</sup> where although a more sophisticated query system was needed for electronic medical record searches, the number of working days required for electronic medical record recruitment was lower than the registry method. However, the aim for electronic medical record pre-screening in terms of sensitivity and specificity can be argued to be study specific, for example, if there is a

very small group of potential participants, it should be to minimise false negatives,<sup>37,46</sup> which may differ from another trial with a large number of potential participants. Therefore, in each clinical trial, the main objective of implementing the electronic medical record recruitment method should be clear, whether it is to increase the number of potential participants, or to specifically filter out ineligible participants as much as possible.

### *Cost-effectiveness of the electronic medical record recruitment method*

The cost analysis of the various methods of recruitment by Schroy et al.<sup>29</sup> showed that automation in the screening process over a 6-month period greatly reduced the cost per enrolled patient. This was attributed to fixed one-time costs for setting up the system for automatic screening. However, there was a reduction in variable costs subsequently to contact potential participants. Similar to what was discussed previously regarding the efficiency of the recruitment system, the number of potential participants required to be approached or contacted after the automatic screening process was smaller than those from manual identification which required lesser manpower and, therefore, lower manpower costs for this method. Hypothetical costs generated by Beauharnais et al.<sup>34</sup> also supported this argument where the projected costs for the electronic medical record recruitment were much lower than the costs for manual chart reviews when the sample size was projected at 100. This was due to the widening difference in cost between the two groups as the sample size increases from 10 to 100. This suggests that the automated screening of the electronic medical record data would prove to be a cost-effective option for larger clinical trials.

### *Challenges and limitations of electronic medical record recruitment method*

As electronic medical records were primarily used in the collection of data for healthcare and clinical needs, the structure of the data present in these systems might not always be compatible with the trials' eligibility criteria.<sup>45,47</sup> Other than modifying or transforming the way in which the eligibility criteria were phrased,<sup>48,49</sup> the compatibility of the electronic medical record data structure might have an impact on its usability and recruitment effectiveness. Moreover, the completeness of data within the electronic medical records might not be suitable for recruitment purposes. This was shown in a study where a mere 35% of the data in electronic medical records were found to be suitable for clinical research recruitment.<sup>50</sup> This lack of conformity between the clinical and research data may also contribute to



false positives and negatives, which was reported in the study by Schmickl et al.,<sup>30</sup> where the discrepancies between the structured and unstructured data in the electronic medical records led to false positives during participant identification.

Another challenge of the electronic medical record recruitment method is the possibility of ‘alert fatigue’, where too many alerts may lead to the desensitisation of clinicians and eventually results in the alerts being ignored.<sup>51</sup> This challenge could also be possibly overcome by providing the alerts to dedicated research staff (e.g. research coordinators) instead of physicians, which was also reported to be more effective in achieving recruitment targets.<sup>52</sup>

### Limitations of this review

There were methodological limitations of the included studies as seen in their quality appraisal, as no studies were randomised controlled trials. In addition, blinding was difficult due to the nature of electronic medical record recruitment implementation, which could potentially introduce bias in the results. This, however, was similar to the studies included in other reviews of clinical research recruitment, thereby giving rise to weaker evidence.<sup>53</sup> In addition, the methods and comparison groups as well as the endpoints in each of the included articles varied widely which made comparisons across various studies difficult for analysis. The lack of inferential statistics in the results of many of the included articles also limits the quality of the evidence, as the probability of these results being due to chance could not be determined. The representativeness of the population recruited using the electronic medical record method also could not be determined, as only 4 of 13 included studies had reported the demographics of the recruited population.

### Conclusion and recommendations

The results collected in this review for recruitment efficiency generally support electronic medical records being an effective recruitment method against other traditional recruitment methods, including chart reviews and physician referrals, especially when the scope of recruitment requires expansion. Recruitment was observed to be higher in studies which involves higher automation of electronic medical record recruitment by using alerts. Better recruitment outcomes were also observed when these alerts were sent to dedicated research staff rather than physicians, whom might have to fulfil both clinical and research roles within the same setting.

In healthcare institutions with established electronic medical record systems, the use of these systems could potentially be used to support clinical research recruitment. It should especially be considered in the

recruitment of patients requiring real-time identification, such as the recruitment of acute cases or those in the emergency departments to boost trial enrolment.

As the electronic medical record systems for clinical research recruitment requires higher costs, time in its initial set up and little variable costs in its subsequent execution, it is recommended that institutions conducting multiple trials or those with large participant volumes implement this method at their sites. The one-time initial start-up costs is cost-efficient by benefitting current and future clinical trial recruitment.

Larger studies, in more geographical locations (particularly outwith US region) which include robust statistical analysis are needed to help establish the effectiveness of electronic medical record recruitment method. Although blinding of research staff might be challenging to execute, randomisation of the type of recruitment being conducted over the pre-determined periods of time could possibly improve the methodological rigour.

Finally, it is to be remembered that clinical research recruitment is complex and many interacting factors contribute to its success, and the variability of its outcome is dependent on the tailoring of these factors. The electronic medical record recruitment method is no different, with varying degrees of automation and different groups of staff being involved various stages of its execution. Therefore, it must be fine tuned in order to maximise its potential depending on the institution workflow and requirements of each trial.

### Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.


### Funding

The author(s) received no financial support for the research, authorship and/or publication of this article.

### Supplemental material

Supplemental material for this article is available online.

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### References

1. Turner JR and Hoofwijk TJ. Clinical trials in new drug development. *J Clin Hypertens (Greenwich)* 2013; 15(5): 306–309. DOI: 10.1111/jch.12085.
2. Farrell B, Kenyon S and Shakur H. Managing clinical trials. *Trials* 2010; 11: 78. DOI: 10.1186/1745-6215-11-78.

3. Brueton VC, Tierney J, Stenning S, et al. Strategies to improve retention in randomised trials. *Cochrane Database Syst Rev* 2013; 12: MR000032. DOI: 10.1002/14651858.MR000032.pub2.
4. Kadam RA, Borde SU, Madas SA, et al. Challenges in recruitment and retention of clinical trial subjects. *Perspect Clin Res* 2016; 7(3): 137–143. DOI: 10.4103/2229-3485.184820.
5. Campbell MK, Snowdon C, Francis D, et al. Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study. *Health Technol Assess* 2007; 11: iii, ix–105.
6. Kitterman DR, Cheng SK, Dilts DM, et al. The prevalence and economic impact of low-enrolling clinical studies at an academic medical center. *Acad Med* 2011; 86(11): 1360–1366. DOI: 10.1097/ACM.0b013e3182306440.
7. Dew A, Khan S, Babinski C, et al. Recruitment strategy cost and impact on minority accrual to a breast cancer prevention trial. *Clin Trials* 2013; 10(2): 292–299. DOI: 10.1177/1740774512471452.
8. Kye SH, Tashkin DP, Roth MD, et al. Recruitment strategies for a lung cancer chemoprevention trial involving ex-smokers. *Contemp Clin Trials* 2009; 30(5): 464–472. DOI: 10.1016/j.cct.2009.05.004.
9. Robinson JL, Fuerch JH, Winiewicz DD, et al. Cost effectiveness of recruitment methods in an obesity prevention trial for young children. *Prev Med* 2007; 44(6): 499–503. DOI: 10.1016/j.ypmed.2007.03.004.
10. Foster JM, Sawyer SM, Smith L, et al. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol* 2015; 15: 18. DOI: 10.1186/s12874-015-0012-3.
11. Hanson LC, Bull J, Wessell K, et al. Strategies to support recruitment of patients with life-limiting illness for research: the Palliative Care Research Cooperative Group. *J Pain Symptom Manage* 2014; 48(6): 1021–1030. DOI: 10.1016/j.jpainsymman.2014.04.008.
12. Fletcher B, Gheorghe A, Moore D, et al. Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. *BMJ Open* 2012; 2(1): e000496. DOI: 10.1136/bmjopen-2011-000496.
13. Vickers AJ. How to improve accrual to clinical trials of symptom control 1: recruitment strategies. *J Soc Integr Oncol* 2007; 5(1): 38–42.
14. ChinFeman SP, Nguyen LT, Quilty MT, et al. Effectiveness of recruitment in clinical trials: an analysis of methods used in a trial for irritable bowel syndrome patients. *Contemp Clin Trials* 2008; 29(2): 241–251. DOI: 10.1016/j.cct.2007.08.004.
15. Maghera A, Kahlke P, Lau A, et al. You are how you recruit: a cohort and randomized controlled trial of recruitment strategies. *BMC Med Res Methodol* 2014; 14: 111. DOI: 10.1186/1471-2288-14-111.
16. Hapca A, Jennings CG, Wei L, et al. Effectiveness of newspaper advertising for patient recruitment into a clinical trial. *Br J Clin Pharmacol* 2014; 77(6): 1064–1072. DOI: 10.1111/bcp.12262.
17. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. *Cochrane Database Syst Rev* 2018; 2: MR000013. DOI: 10.1002/14651858.MR000013.pub6.
18. Kokkonen EW, Davis SA, Lin HC, et al. Use of electronic medical records differs by specialty and office settings. *J Am Med Inform Assoc* 2013; 20(e1): e33–e38. DOI: 10.1136/amiainl-2012-001609.
19. Chang F and Gupta N. Progress in electronic medical record adoption in Canada. *Can Fam Physician* 2015; 61: 1076–1084.
20. vanVelthoven MH, Mastellos N, Majeed A, et al. Feasibility of extracting data from electronic medical records for research: an international comparative study. *BMC Med Inform Decis Mak* 2016; 16: 90. DOI: 10.1186/s12911-016-0332-1.
21. Kho AN, Pacheco JA, Peissig PL, et al. Electronic medical records for genetic research: results of the eMERGE consortium. *Sci Transl Med* 2011; 3(79): 79re1. DOI: 10.1126/scitranslmed.3001807.
22. Cowie MR, Blomster JJ, Curtis LH, et al. Electronic health records to facilitate clinical research. *Clin Res Cardiol* 2017; 106(1): 1–9. DOI: 10.1007/s00392-016-1025-6.
23. Cuggia M, Besana P and Glasspool D. Comparing semi-automatic systems for recruitment of patients to clinical trials. *Int J Med Inform* 2011; 80(6): 371–388. DOI: 10.1016/j.ijmedinf.2011.02.003.
24. Koppcke F and Prokosch HU. Employing computers for the recruitment into clinical trials: a comprehensive systematic review. *J Med Internet Res* 2014; 16(7): e161. DOI: 10.2196/jmir.3446.
25. Effective Public Health Practice Project. Quality assessment tool for quantitative studies, 1998, [https://merst.ca/wp-content/uploads/2018/02/quality-assessment-tool\\_2010.pdf](https://merst.ca/wp-content/uploads/2018/02/quality-assessment-tool_2010.pdf) (accessed 3 April 2018).
26. Treweek S, Pearson E, Smith N, et al. Desktop software to identify patients eligible for recruitment into a clinical trial: using SARMA to recruit to the ROAD feasibility trial. *Inform Prim Care* 2010; 18(1): 51–58.
27. Rollman BL, Fischer GS, Zhu F, et al. Comparison of electronic physician prompts versus waitroom case-finding on clinical trial enrollment. *J Gen Intern Med* 2008; 23(4): 447–450. DOI: 10.1007/s11606-007-0449-0.
28. Effoe VS, Katula JA, Kirk JK, et al. The use of electronic medical records for recruitment in clinical trials: findings from the lifestyle intervention for treatment of diabetes trial. *Trials* 2016; 17(1): 496. DOI: 10.1186/s13063-016-1631-7.
29. Schroy PC III, Glick JT, Robinson P, et al. A cost-effectiveness analysis of subject recruitment strategies in the HIPAA era: results from a colorectal cancer screening adherence trial. *Clin Trials* 2009; 6(6): 597–609. DOI: 10.1177/1740774509346703.
30. Schmickl CN, Li M, Li G, et al. The accuracy and efficiency of electronic screening for recruitment into a clinical trial on COPD. *Respir Med* 2011; 105(10): 1501–1506. DOI: 10.1016/j.rmed.2011.04.012.
31. Weng C, Batres C, Borda T, et al. A real-time screening alert improves patient recruitment efficiency. *AMIA Annu Symp Proc* 2011; 2011: 1489–1498.
32. Herasevich V, Pieper MS, Pulido J, et al. Enrollment into a time sensitive clinical study in the critical care setting: results from computerized septic shock sniffer

- implementation. *J Am Med Inform Assoc* 2011; 18(5): 639–644. DOI: 10.1136/amiajnl-2011-000228.
33. Dugas M, Lange M, Muller-Tidow C, et al. Routine data from hospital information systems can support patient recruitment for clinical studies. *Clin Trials* 2010; 7(2): 183–189. DOI: 10.1177/1740774510363013.
  34. Beauharnais CC, Larkin ME, Zai AH, et al. Efficacy and cost-effectiveness of an automated screening algorithm in an inpatient clinical trial. *Clin Trials* 2012; 9(2): 198–203. DOI: 10.1177/1740774511434844.
  35. Johnson EJ, Niles BL and Mori DL. Targeted recruitment of adults with type 2 diabetes for a physical activity intervention. *Diabetes Spectr* 2015; 28(2): 99–105. DOI: 10.2337/diaspect.28.2.99.
  36. Penberthy L, Brown R, Puma F, et al. Automated matching software for clinical trials eligibility: measuring efficiency and flexibility. *Contemp Clin Trials* 2010; 31(3): 207–217. DOI: 10.1016/j.cct.2010.03.005.
  37. Weng C, Bigger JT, Busacca L, et al. Comparing the effectiveness of a clinical registry and a clinical data warehouse for supporting clinical trial recruitment: a case study. *AMIA Annu Symp Proc* 2010; 2010: 867–871.
  38. Cardozo E, Meurer WJ, Smith BL, et al. Utility of an automated notification system for recruitment of research subjects. *Emerg Med J* 2010; 27(10): 786–787. DOI: 10.1136/emj.2009.081299.
  39. Effective Public Health Practice Project. Quality assessment tool for quantitative studies dictionary, 1998, [https://merst.ca/wp-content/uploads/2018/02/quality-assessment-dictionary\\_2017.pdf](https://merst.ca/wp-content/uploads/2018/02/quality-assessment-dictionary_2017.pdf) (accessed 3 April 2018).
  40. Sanders KM, Stuart AL, Merriman EN, et al. Trials and tribulations of recruiting 2,000 older women onto a clinical trial investigating falls and fractures: vital D study. *BMC Med Res Methodol* 2009; 9: 78. DOI: 10.1186/1471-2288-9-78.
  41. Schreiweis B, Trinczek B, Kopcke F, et al. Comparison of electronic health record system functionalities to support the patient recruitment process in clinical trials. *Int J Med Inform* 2014; 83(11): 860–868. DOI: 10.1016/j.ijmedinf.2014.08.005.
  42. Peters-Lawrence MH, Bell MC, Hsu LL, et al. Clinical trial implementation and recruitment: lessons learned from the early closure of a randomized clinical trial. *Contemp Clin Trials* 2012; 33(2): 291–297. DOI: 10.1016/j.cct.2011.11.018.
  43. Hawkins MS, Hough LJ, Berger MA, et al. Recruitment of veterans from primary care into a physical activity randomized controlled trial: the experience of the VA-STRIDE study. *Trials* 2014; 15: 11. DOI: 10.1186/1745-6215-15-11.
  44. McGregor J, Brooks C, Chalasani P, et al. The Health Informatics Trial Enhancement Project (HITE): using routinely collected primary care data to identify potential participants for a depression trial. *Trials* 2010; 11: 39. DOI: 10.1186/1745-6215-11-39.
  45. Ateya MB, Delaney BC and Speedie SM. The value of structured data elements from electronic health records for identifying subjects for primary care clinical trials. *BMC Med Inform Decis Mak* 2016; 16: 1. DOI: 10.1186/s12911-016-0239-x.
  46. Thadani SR, Weng C, Bigger JT, et al. Electronic screening improves efficiency in clinical trial recruitment. *J Am Med Inform Assoc* 2009; 16(6): 869–873. DOI: 10.1197/jamia.M3119.
  47. Kamau A, Agbor S and Kamau A. Conformity between protocol eligibility criteria for electronic patient identification: a comparison of clinical trials. *Stud Health Technol Inform* 2013; 192: 1167.
  48. Ross J, Tu S, Carini S, et al. Analysis of eligibility criteria complexity in clinical trials. *AMIA Jt Summits Transl Sci Proc* 2010; 2010: 46–50.
  49. Tu SW, Peleg M, Carini S, et al. A practical method for transforming free-text eligibility criteria into computable criteria. *J Biomed Inform* 2011; 44(2): 239–250. DOI: 10.1016/j.jbi.2010.09.007.
  50. Kopcke F, Trinczek B, Majeed RW, et al. Evaluation of data completeness in the electronic health record for the purpose of patient recruitment into clinical trials: a retrospective analysis of element presence. *BMC Med Inform Decis Mak* 2013; 13: 37. DOI: 10.1186/1472-6947-13-37.
  51. Ancker JS, Edwards A, Nosal S, et al. Effects of workload, work complexity, and repeated alerts on alert fatigue in a clinical decision support system. *BMC Med Inform Decis Mak* 2017; 17(1): 36. DOI: 10.1186/s12911-017-0430-8.
  52. Grundmeier RW, Swietlik M and Bell LM. Research subject enrollment by primary care pediatricians using an electronic health record. *AMIA Annu Symp Proc* 2007; 2007: 289–293.
  53. Preston NJ, Farquhar MC, Walshe CE, et al. Strategies designed to help healthcare professionals to recruit participants to research studies. *Cochrane Database Syst Rev* 2016; MR000036.