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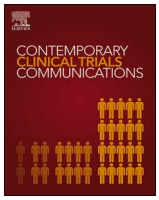

Targeted electronic health record-based recruitment strategy to enhance COVID-19 vaccine response clinical research study enrollment

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ABSTRACT

Efficient recruitment of eligible participants is a significant challenge for clinical research studies. This challenge was exacerbated during the COVID-19 pandemic when in-person recruitment was not an option. In 2020, the University of Minnesota was tasked, as part of the National Cancer Institute's Serological Sciences Network for COVID-19 (SeroNet), to recruit participants for a longitudinal serosurveillance clinical research study with a goal of characterizing the COVID-19 vaccine-elicited immune response among immunocompromised individuals, which necessitated reliance on non-traditional strategies for participant recruitment. To meet our enrollment target of 300 transplant patients, 300 cancer patients, 100 persons living with HIV, and 200 immunocompetent individuals, we utilized targeted electronic health record (EHR)-based recruitment in addition to traditional recruitment tools, which was an effective combination of recruitment strategies. A significant advantage of patient portal messaging or other digital recruitment strategies such as email communication is timing. We reached 85 % (769 out of 900) of our enrollment target within one year with a 14.3 % response rate to invitations to participate in our study. This achievement is perhaps more salient given the COVID-19 pandemic-related constraints within which we were operating. We demonstrated that the EHR can be leveraged to quickly identify potentially eligible study participants either via EHR communication or mail. We also illustrate how the online portal MyChart can be used to efficiently send targeted recruitment messages.

1. Introduction

Effective clinical research studies depend on the ability of researchers to meet established recruitment goals. Recruitment is one of the most challenging aspects of conducting human subjects research due to several factors, including time, cost, and access to eligible and willing participants. Some of the limitations of traditional clinic-based recruitment include the time required by providers to inform their patients about their potential eligibility for various research studies, and the requirement for providers to recall the unique inclusion criteria for several of the studies for which they might be requested to recruit participants [1].

During the COVID-19 pandemic, traditional provider-based recruitment was significantly limited due to considerably restricted in-person clinic visits. These limitations, combined with a shift towards telehealth, created an opportunity to pivot to the use of remotely-conducted research procedures, including an electronic health record (EHR)-based recruitment approach using patient portal recruitment messaging [2]. The EHR contains abundant information that may be used efficiently to screen patients for their eligibility for study participation based on the study's inclusion and exclusion criteria. The medical and demographic information extracted from the EHR, including International Classification of Diseases, 10th revision (ICD-10) diagnosis codes, can greatly facilitate targeted recruitment for clinical research studies [3–7]. Patients identified through the EHR can be contacted using a variety of methods such as telephone, postal mail, email, and direct messaging through EHR patient portals such as MyChart [3,6,8,9]. EHR-based recruitment for clinical research studies has been shown to yield high volumes of participant enrollment and it is more efficient in time and cost compared to traditional recruitment methods [10–12].

Abbreviations: COVID-19, coronavirus disease 2019; EHR, Electronic Health Record; FDA, Food and Drug Administration; PBMC, Peripheral Blood Mononuclear Cells; RBD, Receptor-Binding Domain; SeroNet, Serological Sciences Network for COVID-19; SOT, Solid Organ Transplant.

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Table 1
COVID-19 vaccine response study design.

Cohorts	Cohort Size	Enrolled	Time points	Sample Types	Assays
HIV positive	100	39	Pre-vaccine, 1–3 M, 6 M, 12 M, 18 M, 24 M post vaccine	Serum Plasma PBMCs	Serology (Spike RBD and nucleocapsid) Assays assessing cellular immunity on a subset
Transplant recipients (solid organ & HCT)	300	197			
Cancer survivors	300	257			
Immunocompetent Control Cohort	200	276			

Table 2
Eligibility criteria.

General criteria
● ≥18 years of age
● With or without prior history of COVID-19 infection
● Planning to receive or have already received a COVID-19 vaccine
Cohort-specific criteria
● *HIV*: People living with HIV (PLWH)
● *Cancer*: Cancer patients who have undergone chemotherapy, immunotherapy, radiation therapy and/or targeted treatment
● *Transplant*: Patients who have received a solid organ or hematopoietic cell/bone marrow transplant and immunosuppressive therapy

Table 3
ICD-10 codes utilized for targeted study participant recruitment.

HIV	Solid organ transplant	Cancer
Human Immunodeficiency Virus (HIV) disease [B20.*]	Heart Transplant [Z94.1]	Hodgkin Lymphoma [C81.*, Z85.71]
Asymptomatic Human Immunodeficiency Virus (HIV) [Z21]	Kidney Transplant [Z94.0]	Leukemia [C92, C93, C90.1, C91, C95.92, C95.91, C91.92, C90.11, C91.02]
	Liver Transplant [Z94.4]	Malignancy Astrocytoma [C71.*]
	Lung Transplant [Z94.2]	Malignancy Breast [C79.81, Z85.3, C50.*]
	Pancreas Transplant [Z94.83]	Malignancy CNS [C72.9]
	Transplanted Organ and Tissue Status [Z94.*]	Malignancy Genitourinary [C68, C57.9]
		Malignancy Hepatoblastoma [C22.2, Z85.05]
		Malignancy Liver [C22.8, Z85.05]
		Malignancy Lung [C7A.090, C34.10, C34.30, C34.92]
		Malignancy Skin Melanoma [C43.*]
		Malignancy Thyroid [C73]
		Malignancy Tongue Throat [Z85.810, C02.*, C02.1, Z85]
		Non-Hodgkin Lymphoma [Z82.72]

We successfully employed EHR-based recruitment combined with traditional recruitment tools for our National Cancer Institute-sponsored Serological Sciences Network for COVID-19 (SeroNet) clinical research study that is designed to longitudinally evaluate COVID-19 vaccine responses in immunocompromised individuals in Minnesota. SeroNet is the nation's largest coordinated effort to study the human immune response to COVID-19 [13]. The effectiveness of EHR-based targeted recruitment was demonstrated in our study by achieving 85 % of our enrollment goal (300 transplant patients, 300 cancer patients, 100 people living with HIV (PLWH), and 200 immunocompetent individuals) within one year.

2. Methods

2.1. Recruitment

To compare the COVID-19 vaccine durability between immunocompetent and immunocompromised individuals, we established four cohorts as shown in Table 1. To measure the vaccine response and durability, participants are scheduled for the following visits: pre-vaccine, 1–3, 6, 12, 18 and 24 months after vaccine administration.

We recruited our study participants from within the M Health Fairview healthcare system. M Health Fairview is a healthcare system representing a collaboration among the University of Minnesota Medical School, University of Minnesota Physicians, and Fairview Health Services, which comprises 60 clinics, 10 hospitals, and over 3,300 providers.

2.2. EHR-based participant eligibility criteria

The eligibility criteria for our clinical research study are shown in Table 2. For cohort specific criteria, we used ICD-10 codes as shown in Table 3.

2.3. Recruitment messaging via patient portal and mailed letters

To recruit our desired target population, we leveraged the research recruitment support services provided by M Health Fairview to the University of Minnesota. From June 6, 2021 to June 6, 2022, 250 letters were sent via direct mail and 500 MyChart messages were sent on a weekly basis. Approximately 70 % of the patients in the M Health Fairview healthcare system use MyChart. The content of the study recruitment letter/message (**Supplementary data**) generically stated that the patient may be eligible for the research study but did not directly refer to the specific medical condition(s) making the patient eligible. This language was deemed critical by our IRB, to avoid confusion or alarm by patients, in the case their chart had been inadvertently mis-coded with the wrong ICD-10 diagnosis code. The M Health Fairview research recruitment support services limited the total number of studies that could use EHR-based messaging to ensure that patients received a limited number of research study enrollment requests.

Within the first year of the study, a total of 11,250 mailed letters and 22,500 MyChart messages were sent to potentially eligible participants. Most of the individuals who received a MyChart message also received a letter (Transplant cohort: 1,369 MyChart messages, 1,512 letters; HIV cohort: 898 MyChart messages, 1,719 letters; Cancer cohort: 4,366 MyChart messages, 5,928 letters; Immunocompetent cohort: 15,867 MyChart messages, 2,091 letters). Responses were not tracked based on the method of contact. Initially, M Health Fairview patients with specialty diagnoses (SOT, Cancer, HIV) were contacted and then immunocompetent individuals were contacted. The geographic region from where the immunocompetent individuals were selected was initially defined by the region's proximity to the Twin Cities of Minneapolis and St. Paul. The catchment area was then expanded to include additional regions to identify individuals who would be the most willing to come for an in-person visit at the University of Minnesota Twin Cities. The final catchment area included a total of 44 zip codes covering 2,977 mi^2.

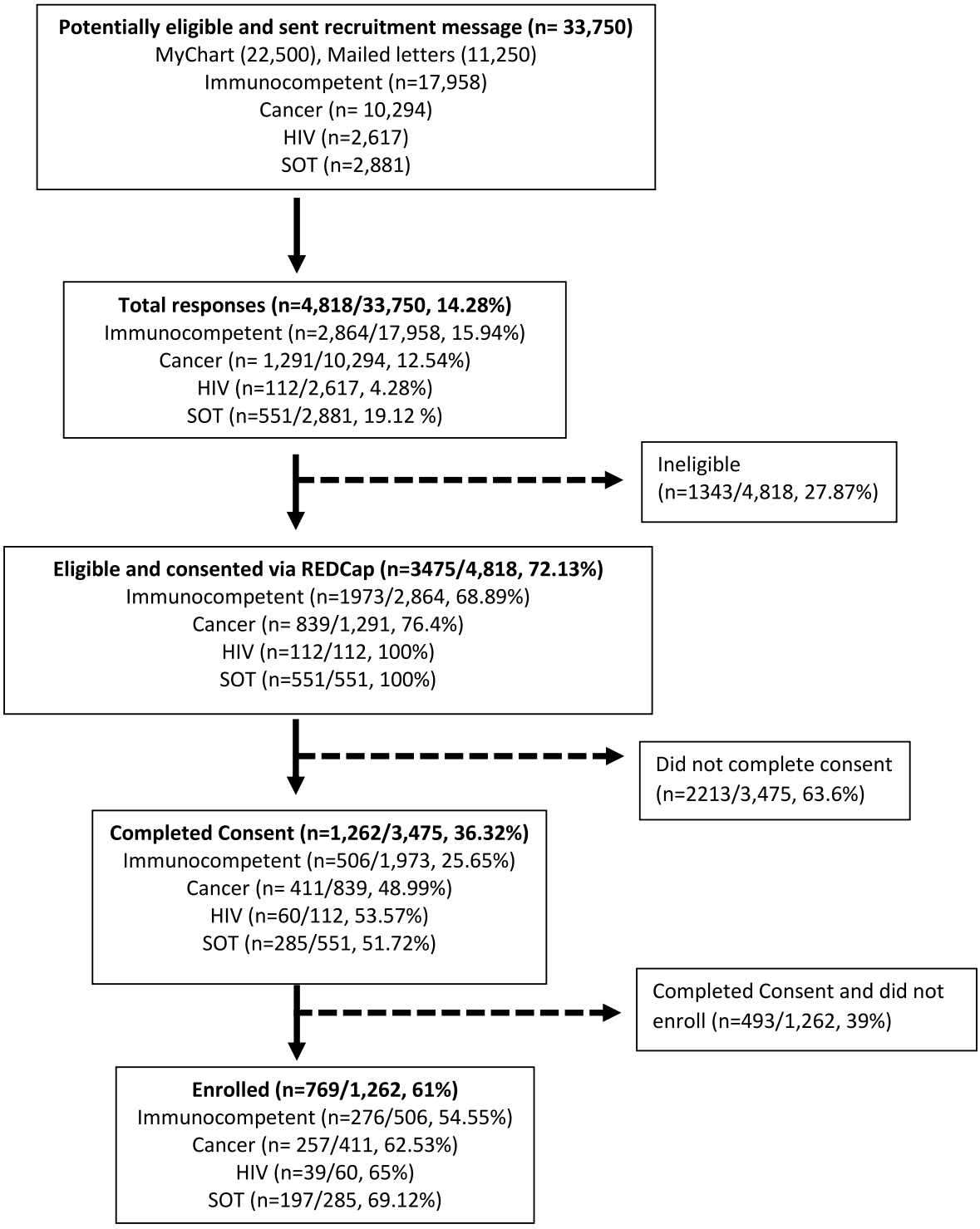

Fig. 1. Study recruitment workflow. A total of 4,818 individuals responded to the targeted messages. Among them, 28 % were ineligible and 72 % were eligible. Consent forms were sent to all eligible participants; 36 % completed the consent form. Among those who consented, 61 % enrolled in our study.

2.4. Statistical analysis

Descriptive statistics for total participants and those enrolled in the study were calculated. All analyses were conducted using SAS, version 9.4 (SAS Institute Inc). Univariate contingency tables and Chi-square tests were calculated among variables. We used Fisher exact test to evaluate differences between categories when there were <5 counts in individual categories.

3. Results

The recruitment flow of eligible participants for our study is shown in Fig. 1. Among the 33,750 messages sent, we received 4,818 (14.3 %) responses. Among the responders, 3,475 (72.1 %) were deemed eligible after review of responses. Online consent forms were sent to all eligible participants via Research Electronic Data Capture (REDCap) [14,15], which is a secure web application for building and managing online surveys and databases. Among the eligible participants, 1,262 (36.3 %)

Table 4
Eligibility rate, response rate and enrollment rate.

		Recruitment Efficacy				
	Total messages	Response rate	Eligibility rate (% based on response rate)	Enrollment rate (% based on response rate)	Enrollment goal	Total number of participants after 1 year
Total	33,750	4,818 (14.28 %)	3475 (72.13 %)	769 (15.96 %)	900	769 (85 %)
Immunocompetent	17,958	2,864 (15.94 %)	1973 (68.89 %)	276 (9.64 %)	200	276 (100 %)
SOT	2,881	551 (19.12 %)	551 (100 %)	197 (35.75 %)	300	196 (65 %)
HIV	2,617	112 (4.28 %)	112 (100 %)	39 (34.8 %)	100	39 (39 %)
Cancer	10,294	1,291 (12.54 %)	839 (76.4 %)	257 (19.9 %)	300	258 (86 %)

Table 5
Demographics of study participants.

Total Participant Response N = 4818						
	Total Participants	Immunocompetent (N = 2864)	Cancer (N = 1291)	SOT (N = 551)	HIV (N = 112)	p value
Gender n (%)						**<.0001***
Prefer not to answer	4 (0.08)	4 (0.14)	0	0	0	
Unspecified	11 (0.23)	5 (0.17)	2 (0.15)	3 (0.54)	1 (0.89)	
None of these describe me	4 (0.08)	3 (0.1)	1 (0.08)	0	0	
Male	1412 (29.31)	672 (23.46)	342 (26.49)	303 (54.99)	95 (84.82)	
Female	3386 (70.28)	2180 (76.12)	946 (73.28)	244 (44.28)	16 (14.29)	
Intersex	1 (0.02)	0	0	1 (0.18)	0	
Race n (%)						**<.0001**$^{+}$
American Indian or Alaskan Native	50 (1.04)	27 (0.94)	9 (0.70)	11 (2.0)	3 (2.68)	
Unspecified	12 (0.25)	5 (0.17)	2 (0.15)	4 (0.73)	1 (0.88)	
Black or African American	105 (2.18)	17 (3.09)	15 (1.16)	17 (3.09)	11 (9.82)	
White	4516 (93.73)	2671 (93.26)	1247 (96.59)	503 (91.29)	95 (84.82)	
Native Hawaiian or Other Pacific Islander	1 (0.02)	0	0	1 (0.18)	0	
Multi-race	3 (0.06)	1 (0.03)	1 (0.08)	1 (0.18)	0	
Asian	131 (2.72)	98 (3.42)	17 (1.32)	14 (2.54)	2 (1.79)	
Ethnicity n (%)						**0.0002**
Not Hispanic or Latino	4713 (97.82)	2796 (97.63)	1276 (98.84)	537 (97.46)	104 (92.86)	
Hispanic or Latino	105 (2.16)	68 (2.37)	15 (1.16)	14 (2.54)	8 (7.14)	
Age Mean (stdev)						**<.0001**
	52.85 (14.65)	47.97 (14.25)	61.92 (11.27)	57.25 (12.59)	51.38 (12.16)	
Enrolled Participants N = 769						
	Total Enrolled	**Immunocompetent (N=276)**	**Cancer (N=257)**	**SOT (N=197)**	**HIV (N=39)**	**p value**
Gender n (%)						**<.0001***
Male	282 (36.67)	71 (25.72)	67 (25.07)	111 (56.35)	33 (84.62)	
Female	486 (63.20)	205 (74.28(	190 (73.83)	85 (43.14)	6 (15.38)	
Intersex	0	0	0	1 (0.54)	0	
Race n (%)						**0.002**$^{+}$
American Indian or Alaskan Native	10 (1.30)	2 (0.72)	3 (1.17)	4 (2.03)	1 (2.56)	
Unspecified	1 (0.13)	0	0	1 (0.51)	0	
Black or African American	11 (1.43)	2 (0.72)	2 (0.78)	3 (1.52)	4 (10.26)	
White	731 (95.06)	261 (94.57)	250 (97.28)	187 (94.92)	33 (84.62)	
Asian	16(2.08)	11(3.99)	2(0.78)	2(1.02)	12.56)	
Ethnicity n(%)						**0.006**$^{\hat{}}$
Not Hispanic or Latino	754 (98.0)	268 (97.1)	257 (100)	192 (97.46)	37 (94.87)	
Hispanic or Latino	15 (2.0)	8 (2.9)	0	5 (2.54)	2 (5.13)	
Age Mean (stdev)						**<.0001**
	56 (12.76)	51.26 (13.77)	61.46 (10.69)	58.63 (11.01)	52.41 (11.09)	

* **(a) Total Participant Response:** p-value was estimated using a Chi square test after excluding 20 participants in "Prefer not to answer", "Unspecified", "None of these describe me" or "Intersex" categories.
* **(b) Enrolled Participants:** p-value was estimated using a Chi square test after excluding 1 participant in the "Intersex" category.
$^{+}$ **(a) Total Participant Response:** p-value was estimated using a Fisher exact test after excluding 4 participants in "Native Hawaiian and Pacific Islanders" and "Multirace" categories.
$^{+}$ **(b) Enrolled Participants:** p-value was estimated using a Fisher exact test after excluding 1 participant in the "Unspecified" category for the "Enrolled Participants" category.
$^{\hat{}}$**Enrolled Participants:** p-value was estimated using a Fisher exact test.

participants completed the consent form. Of the consented participants, 769 (61 %) enrolled in the study.

We reached 85 % of our targeted recruitment within one year. The cohort-based recruitment rates were 100 % for the immunocompetent group, 86 % for the cancer group, 65 % for the SOT group and 39 % for the HIV group (Table 4). A significant majority of all enrolled participants were women (63.2 %; $p < 0.05$). However, men comprised the majority of the HIV (84.6 %) and SOT (56.3 %) cohorts. The number of individuals identifying as white and non-Hispanic or Latino were significantly higher than the number of participants from other races and ethnicities; $p = 0.0038$ and $p = 0.0312$, respectively (Table 5).

4. Discussion

We demonstrate the feasibility of implementing an EHR-based participant identification strategy for rapid recruitment into an observational study during an extended period of restricted in-person clinic visits due to the COVID-19 pandemic. The main advantages of EHR-based recruitment strategy are efficiency and lower cost compared to traditional clinic-based recruitment methods [6,16–20]. Identifying eligible participants is the most significant barrier to recruitment. Our study proved the efficiency of targeted EHR-based recruitment by rapidly achieving 85 % of our recruitment goal within one year. The EHR query process was used for both screening eligibility based on ICD-10 codes and directly contacting participants. Direct messaging via MyChart was our primary contact method and mailed letters were used for those who opted out of MyChart.

EHR-based MyChart messages were essential to our ability to achieve a high percentage of our recruitment goal in a relatively short period of time. The efficacy of MyChart messaging is largely associated with patients being prompted by email or text message to login to their MyChart account to view a personalized message. One study found that patients place a high degree of trust in EHR-based communication because the messages are presumed to be sent by a credible source, consequently mitigating any privacy concerns [21].

In addition, sending MyChart messages is more cost effective than mailing letters. At our institution, the cost to send 250 MyChart messages was $87.50 compared to $350 for the same number of mailed letters. A study comparing the average cost and time associated with various recruitment methods, including MyChart messages, mailed letters and phone calls demonstrated that the MyChart recruitment method yielded the largest number of enrolled participants in the shortest period of time with the lowest cost [22]. Another study demonstrated that enrollment rates were higher using MyChart compared to mailed letters [3]. In the absence of tracking responses based on the contact methods, we were unable to determine whether the enrolled participants were recruited through MyChart messages or mailed letters. Implementing a system to track recruitment efficiency and engaging a multi-stakeholder group are essential components of using EHR-based recruitment [11].

We acknowledge that a drawback of MyChart-based recruitment methods is the inability to reach potential participants who have limited accessibility to technology and who do not use email on a regular basis. Consequently, this segment of potentially eligible participants would not receive electronic notifications regarding MyChart messages.

Among 33,750 MyChart messages and mailed letters that were sent, 14.3 % participants responded; 72 % of those who responded were eligible and 36 % of eligible participants completed the consent form. A total of 769 participants (85 % of our recruitment goal) were enrolled in our study within one year. This achievement is perhaps more salient given the COVID-19 pandemic-related constraints within which we were operating that prohibited in-person recruitment. Notably, our study's enrollment rate could likely have been enhanced even further were it not for the requirement of multiple visits across 24 months and no compensation at the time of consenting.

Identifying best practices for EHR patient portal recruitment messaging across demographic groups is essential [23]. A limitation of our study is the lack of diversity: 93 % of our enrolled participants are white and non-Hispanic or Latino, 1.6 % are Asian, 1.43 % are Black or African American, and 0.65 % are American Indian or Alaska Native. According to July 2021 U.S. Census population estimates for Minnesota, 78.1 % of the population was categorized as white and not Hispanic or Latino, 5.4 % were Asian, 7.4 % were Black or African American, and 1.4 % were American Indian or Alaska Native [24]. Additional targeted recruitment strategies are needed to increase the diversity of our cohort based on race or ethnicity. Previous studies have shown that community-based recruitment and recruitment by patients' direct healthcare providers are effective for minority groups [25].

The high response rate in our study (14.3 %: 4,818 responses received from 33,750 eligible individuals) was likely influenced by a generally high level of interest among the general public in participating in COVID-related research. Future studies need to evaluate strategies to enhance the diversity of research participants who are recruited using EHR-based strategies and improve workflows to enhance consent completion among the pool of eligible participants who respond to the initial invitation for study participation.

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CRediT authorship contribution statement

Hninn Khine: Writing – original draft. **Alex Mathson:** Data curation, Formal analysis. **Puleng R. Moshele:** Formal analysis. **Bharat Thyagarajan:** Conceptualization, Formal analysis, Funding acquisition, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. **Amy B. Karger:** Conceptualization, Funding acquisition, Project administration, Writing – original draft, Writing – review & editing. **Stefani N. Thomas:** Funding acquisition, Project administration, Supervision, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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