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Brief Communication

Selection biases in technology-based intervention research: patients' technology use relates to both demographic and health-related inequities

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ABSTRACT

Objective: Researchers conduct studies with selection biases, which may limit generalizability and outcomes of intervention research. In this methodological reflection, we examined demographic and health characteristics of implantable cardioverter defibrillator patients who were excluded from an informatics intervention due to lack of access to a computer and/or the internet.

Materials and Methods: Using information gathered from surveys and electronic health records, we compared the intervention group to excluded patients on demographic factors, computer skills, patient activation, and medical history.

Results: Excluded patients were older, less educated, less engaged and activated in their health, and had worse health (ie, more medical comorbidities) than nonexcluded patients.

Discussion: Although excluded from the intervention based solely on lack of access to a computer and/or internet, excluded patients may have needed the intervention more because they were sicker with more comorbidities.

Conclusion: Researchers must be mindful of enrollment biases and demographic *and* health-related inequities that may exist during recruitment for technology-based interventions.

Key words: research inequity, methodology, informatics, technology use, health characteristics

BACKGROUND AND SIGNIFICANCE

The integration of technology into health care, especially in the self-management of health, has had a profound impact on care from medical processes to health outcomes to the lived experiences of those involved—including patients, families, and clinicians.¹ Methodologically sound intervention studies are necessary to determine the extent to which technologies or protocols are cost-effective, useful, and beneficial. Unfortunately, patients from disadvantaged groups (eg, seniors, minorities, and those with lower socioeconomic status [SES]) may not be using the technologies needed to test the

interventions^{2–4} or may be using technology in ways that do not fit traditional models of use,^{5,6} thereby potentially creating a problem of inequitable access to study enrollment.⁴ This enrollment bias is just 1 research inequity that may plague informatics or other technology-related health research,⁷ which could potentially limit the generalizability of findings and even intervention outcomes.

Although technology ownership is increasing across all demographics, those in disadvantaged groups may have limited access to websites or applications because they do not have computers or internet access.² Notably, among those with incomes lower than

\$30 000, 36% do not have a smartphone and 47% do not have broadband internet service as compared to 5% and 6% of top-income earners, respectively.² This criterion alone, that is, a patient's ability to access the internet via a phone or computer, may create an unintended enrollment bias. Presently, it is clear that technology use is associated with demographic inequities²⁻⁴; however, it might also be related to health inequities that may decrease the generalizability of findings from medical research studies.

Objective

In this methodological perspective work, we discuss enrollment disparities that emerged in our informatics intervention study.⁸ The intervention aspect of our study necessitated use of a web-based messaging portal available via the internet; therefore, only those who had access to computers and/or internet were included in the study (and randomly assigned to either the control or intervention group). However, this created an unintended but analyzable group—a group of patients who agreed to participate in the study but did not meet intervention inclusion criteria because they did not have “access to a computer and/or the internet”—which we will refer to as “Group C.” This article focuses on the demographic and health characteristics of Group C, the unintended research inequities that may emerge when conducting technology-focused health interventions, and the benefits and shortcomings of research that employs similar methods.

MATERIALS AND METHODS

Background

The purpose of our original study⁸ was to assess the impact of delivering data from remote monitoring of implantable cardioverter defibrillators (ICDs). The impact was assessed through patient engagement, patient-provider communication, and health care utilization. We anchor our discussion on health care disparity and research methodology within this case study.

Study population, setting, and recruitment

Participants were identified through a cardiology outpatient clinic, part of a large health system in northeast Indiana and northwest Ohio. Specifically, the Arrhythmia Diagnostic Clinic provided a list of 590 patients with a St. Jude Medical ICD to the project research nurse. The research nurse screened the patient records to include those 18 years and older and actively participating in remote monitoring. The research nurse made phone contact with eligible patients to introduce the study and inquire about interest in study enrollment. A total of 191 patients agreed to participate. See [Figure 1](#).

So that participants could be randomly assigned to study groups, only those participants with access to a computer and/or the internet were included in the intervention. A total of 144 patients were randomly assigned to 1 of 2 groups: Group A received electronic summaries of their ICD monitoring data via MyChart (the electronic patient record portal), and Group B received paper ICD summaries via postal mail. Participants who did not have access to a computer and/or the internet received only standard of care (Group C). Randomization into all 3 study groups was not possible due to limited resources; the study budget did not permit providing computers and/or internet access. Study participants received \$30 compensation.

Data collection

At enrollment, all participants (including Group C patients) met the research nurse to complete consent forms and baseline measures.

Data collection occurred from October 2014 to August 2015. All study activities for each patient took place over 6 months; however, all measures reported here were collected via surveys or data extracted from patients' electronic health records at baseline.

Relevant measures

Patient characteristics

Participants completed a survey containing demographic questions including age, gender, education background, race/ethnicity, income, and residential area. Additionally, participants were asked “How would you rate your ability to use a computer?” and “How would you rate your ability to use the internet?” responding on a 5-point scale (1 = very poor, 5 = very good). Finally, patients reported date of device implantation.

Patient activation and engagement

The validated and licensed Patient Activation Measure (PAM-13)⁹ was used to evaluate patient activation and engagement. Respondents indicated their agreement with 13 statements (eg, “I understand my health problems and what causes them.”) on a 4-point Likert scale (1 = Disagree Strongly, 4 = Agree Strongly), and their raw scores were transformed into a scaled score of 0–100. PAM scores were then categorized into 4 stages of activation: 1) individual deems patient role as important, 2) individual possesses confidence and health-related knowledge required to act, 3) individual takes health-related actions, and 4) individual continues actions despite stress.

Medical history

Patients' histories of major medical issues (eg, diabetes, chronic lung disease, congestive heart failure, heart attack, bypass surgery, heart failure, sleep apnea, etc.) and their New York Heart Association functional class³ (Class I: No limitations for physical activity, Class II: Slight limitations on physical activity, Class III: Marked limitations for physical activity, Class IV: Physical activity causes discomfort, patient experiences heart failure symptoms at rest) were included in the ICD registry and supplemented by manual health record extractions.

Analysis plan

To measure the extent to which Group C patients differed from those included in the intervention, Groups A and B were combined into 1 intervention group and compared to Group C on patient characteristics, activation and engagement, and medical history. Tests for independence between the intervention group and Group C for categorical variables were conducted using chi-square tests when cell sizes were large and Fisher's exact tests when cell sizes were small (5 or fewer). For continuous variables, independent *t* tests were used to test for group differences. All analyses were conducted using SAS 9.4 software.

RESULTS

Participants were mostly male (67.1%), white (93%), age 66 or older (58%), with a high school diploma or some college (84%), and an annual income between \$20 000 and \$80 000 (73%). However, compared to the intervention group, Group C patients were likely to be older, less educated, and from a lower SES (see [Table 1](#)). Additionally, Group C participants reported lesser abilities in using computers and the internet than the intervention group participants. (See [Figure 2](#) and [Supplemental Table 1](#)). To evaluate possible confounds between computing and internet skills and income, age,

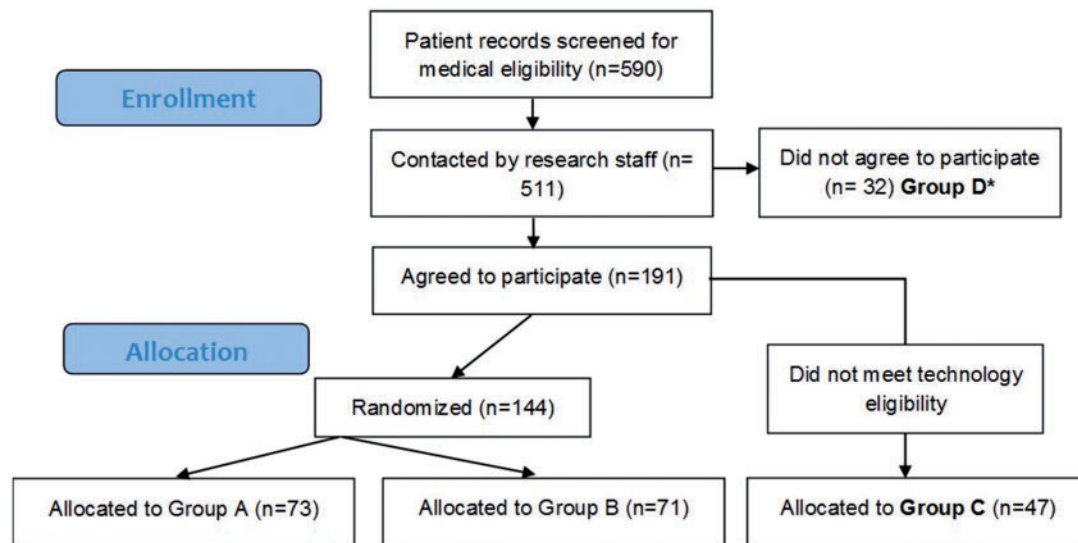


Figure 1. Enrollment and allocation diagram for original study. *Not contacted n includes those who were deceased, had moved, did not have a voicemail to leave a message, or who were otherwise ineligible. **Group D n includes those for whom “decline” was noted in records, but due to a methodological oversight, declines were not always noted.

Table 1. Summary of patient characteristics by group and tests for independence

Patient characteristic		Group C(n=47) % or M(SD)	Intervention(n=144) % or M(SD)	χ^2 , t, or P value
Gender	Male	59.6	69.4	$\chi^2(1) = 1.6, P = .21$
Age	18–25	0	2.1	
	26–35	0	0.7	.049
	36–45	0	8.3	
	46–55	12.8	11.8	
	56–65	14.9	22.2	
	66–75	31.9	35.4	
	76–85	36.2	17.4	
	86–90	4.3	1.4	
Race	White	95.7	93.1	1.00
	Other	4.3	6.3	
Residential area	Urban	40.4	38.2	.07
	Suburban	10.6	25.7	
	Rural	48.9	36.1	
Education	Did not graduate high school	23.4	5.6	.002
	High school diploma/GED	42.6	33.3	
	Trade/some college	21.3	35.4	
	College graduate	10.6	15.3	
	Post-graduate degree	2.1	10.4	
Family income	\$0–19 999	40.4	9.0	.0002
	\$20 000–39, 999	25.5	27.1	
	\$40 000–59 999	19.2	24.3	
	\$60 000–79 999	6.4	16.7	
	\$80 000–99 999	2.1	8.3	
	over \$100 000	2.1	7.6	
PAM level	1	10.6	10.5	.002
	2	29.8	10.5	
	3	36.2	30.1	
	4	23.4	49.0	
Computing ability		1.8 (0.8)	3.3 (1.1)	t(99) = 10.3, P = .0001
Internet ability		1.7 (0.8)	3.4 (1.1)	t(187) = 9.7 P = .0001
Implant duration		2.9 (1.6)	3.2 (2.0)	t(184) = 0.89

Abbreviations: GED, general education diploma; SD, standard deviation; M, Mean; PAM, Patient Activation Measure

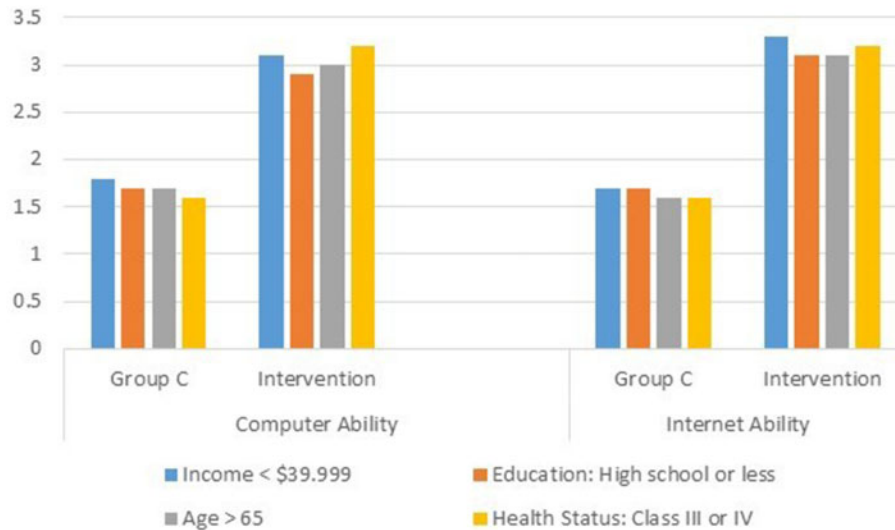


Figure 2. Subsample comparisons of computer and Internet abilities for Group C and Intervention group participants who had incomes < \$39,999, education levels or high school or less, ages > 65, and NYHA health status classifications of Class III or IV.

Table 2. Summary of medical history (percentage) by group ($n = 191$) and P value for test of independence

Medical history		Group C ($n = 47$) %	Intervention ($n = 144$) %	Test of independence χ^2 or P value
NYHA functional class	Class I	7.0	26.4	.03
	Class II	46.5	40.3	
	Class III	44.2	31.8	
	Class IV	2.3	1.6	
Congestive heart failure		93.0	74.5	.009
Coronary heart disease		88.0	65.3	.04
Prior heart attack		51.1	33.6	$\chi^2(1) = 4.4, P = .04$
Prior bypass surgery		43.2	19.7	$\chi^2(1) = 9.7, P = .002$
Chronic lung disease		27.3	9.5	$\chi^2(1) = 8.8, P = .003$
Diabetes		44.4	21.2	$\chi^2(1) = 9.3, P = .002$

Abbreviation: NYHA, New York Heart Association.

health status, and education, further comparisons were conducted using independent t tests. Using these comparisons, we tested, for example, whether low-income Group C participants reported lower computing skills than their low-income intervention group counterparts. For all subsample comparisons, Group C participants had significantly lower computing and internet abilities (all P s < .0001). See Figure 2.

With regard to patient activation, 49% of the intervention group met the score criterion for Level 4, whereas only 23.4% of Group C met the Level 4 criterion. In a test for independence, patient activation level and membership in Group C were not independent.

Finally, in terms of medical history (Table 2), Group C patients were more likely to be in a higher functional class in terms of physical activity limitations (indicating greater limitations), and were more likely to have histories of congestive heart failure, coronary heart disease, heart attacks, bypass surgery, chronic lung disease, and diabetes. In terms of other medical history items we analyzed (eg, sleep apnea), there were no significant differences between groups.

DISCUSSION

Recently, researchers have suggested that mHealth interventions can widen inequity gaps because underprivileged populations may not

have access to technologies or uptake or adhere to technological interventions.⁴ However, a related problem is that this lack of access can lead to enrollment inequities⁷ that might limit the generalizability of research findings.

Previous research has shown that demographic factors (eg, older age and lower SES) are associated with a lack of access to or familiarity with technology.²⁻⁴ Our study provided additional support for those findings. However, we also found that patients with limited technology access also had a host of medical comorbidities, including a history of diabetes and chronic lung disease, among others, and were less engaged in their health care than those with access. Although computer and internet access is associated with SES, as we showed, these variables are not entirely overlapping, and even older, sicker, and lower SES patients may still report having computer and internet access and abilities.

The findings from this research illustrate a need to re-examine methodological approaches, and associated tensions, within technology studies. Those who did not have access to computers and/or the internet were not only older, less educated, and from a lower SES, but they were also in poorer health than those who did have access. This caused a research inequity at enrollment such that those who were most disadvantaged in several key ways were not enrolled in either intervention group. Clearly, this limits the generalizability of

our main study findings,⁸ as we are uncertain about whether our findings might generalize to these disadvantaged populations. However, we also note that our intervention contrasted the effectiveness of a computer-based versus a paper-based remote monitoring report for providing patients feedback about their implanted device, and we found that the paper-based intervention was just as effective.⁸ Thus, although we did not include patients who did not use computers in our intervention group (to satisfy random assignment), the results of the study may improve care for these very patients.

CONCLUSION

Informatics, clinical, and health science researchers should make efforts to include patients with limited technology access who might be most in need of health-related interventions. As technology offers opportunities for wide-based disbursement of health information and care, it remains a promising mechanism for reaching underserved populations. However, intervention efforts to include disadvantaged patients should also include provision of and training in relevant technological tools; and uptake, utilization, and challenges associated with these tools should continue to be studied.¹⁰ Future research might also examine the characteristics of “Group D” patients (ie, patients who declined participation), as we suspect that these patients might be even more disadvantaged in terms of demographic and health characteristics. As these patients are hard to reach, commercial recruitment services might be necessary for enrollment. However, even without Group C and Group D patients, it is still possible for interventions to benefit these populations (eg, through testing technology methods against nontechnology methods) as long as sample limitations are acknowledged.

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CONTRIBUTORS

TT and MM helped to conceptualize, design, and conduct this study. MD, JP, MF, and RP analyzed and/or interpreted the data and wrote the manuscript with input from all authors. TT was in charge of overall direction and planning of the project. Additionally, all authors drafted or revised this manuscript critically for important intellectual content, approved the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST STATEMENT

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