

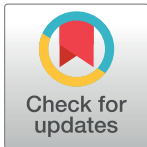
RESEARCH ARTICLE

# Evaluation of a strategy for enrolling the families of critically ill patients in research using limited human resources

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## Abstract

### Rationale

Clinical trials of interventions aimed at the families of intensive care unit (ICU) patients have proliferated but recruitment for these trials can be challenging.

### Objectives

To evaluate a strategy for recruiting families of patients currently being treated in an ICU using limited human resources and time-varying daily screening over 7 consecutive days

### Methods

We screened the Johns Hopkins Hospital medical ICU census 7 days per week to identify eligible family members. We then made daily, in-person attempts to enroll eligible families during a time-varying 2-hour enrollment period until families declined participation, consented, or were no longer eligible.

### Measurements and main results

The primary outcome was the proportion of eligible patients for whom  $\geq 1$  family member was enrolled. Secondary outcomes included enrollment of legal healthcare proxies, the consent rate among families approached for enrollment, and success rates for recruiting at different times during the day and week. Among 284 eligible patients, 108 (38%, 95% CI 32%-44%) had  $\geq 1$  family member enrolled, and 75 (26%, 95% CI 21%-32%) had their legal healthcare proxy enrolled. Among 117 family members asked to participate, 108 (92%, 95% CI 86%-96%) were enrolled. Patients with versus without an enrolled proxy were more likely to be white (44% vs. 30%,  $P = .02$ ), live in a zip code with a median income of  $\geq \$100,000$

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(15% vs. 5%,  $P = .01$ ), be mechanically ventilated (63% vs. 47%,  $P = .01$ ), die in the ICU (19% vs. 9%,  $P = .03$ ), and to have longer ICU stays (median 5.0 vs. 1.8 days,  $P < .001$ ). Day of the week and time of day were not associated with family presence in the ICU or consent rate.

## Conclusions

Family members were recruited for more than one third of eligible patients, and >90% of approached consented to participate. There are important demographic differences between patients with vs without an enrolled family member.

## Introduction

The majority of ICU patients lack decision-making capacity and rely on family members to communicate with clinicians.[1,2] In the past 15 years, the Society of Critical Care Medicine and American Thoracic Society have endorsed clinical practice guidelines and policies on supporting and engaging family members in shared decision making.[3,4] Research on ICU families has also proliferated over the past two decades. Investigators have explored the experiences of ICU families via qualitative interviews,[5–7] quantified conflict between families and clinicians,[8–10] assessed family understanding of prognostic information,[11–13] and trialed interventions to assist families making treatment decisions.[14,15] Recent research has demonstrated that many family members experience long-term mental health issues, including symptoms of depression[16–19] and post-traumatic stress disorder,[20–23] which have been termed post-intensive care syndrome-family or PICS-F.[24,25]

Recruiting families of ICU patients to participate in research can be challenging. Families who are caring for children, continuing employment, or traveling long distances to the hospital may visit infrequently or outside regular business hours. A recent study of bereaved ICU family members was unable to contact 69% of eligible family members because of inaccuracies in the patient record.[26] Families who are emotionally overwhelmed or distrustful may avoid the ICU or family meetings. Importantly, when the association between exposure and outcome differs between families who participate and those who do not, selection bias occurs.[27] These issues apply both to randomized trials and observational studies, and recruitment strategies for studies of ICU families must plan for these challenges.

Hence the objective of our research was to design and evaluate a strategy for recruiting family members of ICU patients exploiting a time-varying approach to daily screening within the common constraint in clinical research of having limited human resources. We evaluate the strategy's ability to recruit a family member within 7 days of patient eligibility, as well as whether participants were the patient's legal healthcare proxy, and the representativeness of recruited families. Moreover, we compare recruitment rates and family characteristics across different times and days of the week.

## Methods

### Setting

This evaluation was conducted prospectively as part of an ongoing pilot study to evaluate the acceptability of a brief educational intervention to prepare families to act as surrogate decision-makers in the medical ICU of Johns Hopkins Hospital in Baltimore, Maryland. The pilot

study's total budget of \$5,000 restricted our ability to compensate study personnel. This subsequently limited the time available for recruiting and interviewing participants each week. All participants provided in-person, oral consent. Johns Hopkins Medicine IRB Committee X approved this study number: IRB00080137. The IRB deemed oral consent as appropriate because participating in the study did not involve any procedure for which written consent is normally required outside of the research context. Details of the intent of the proposed study, its design, the type of information collected, and potential risks and benefits of participation were discussed. The time, date, and identify of the participant was recorded in the study record.

## Participants

Study participants were the family members of all eligible patients. Patients became eligible 24 hours after medical ICU admission and remained eligible for 7 consecutive days or until death or ICU discharge. We waited 24 hours before approaching families to ensure they had an opportunity to speak to a clinician before enrollment. Patients who were incarcerated or <18 years old were not eligible. Family members were excluded from participation if they were unable to understand or speak English, <18 years old, or never visited the medical ICU. We defined family using the Society of Critical Care Medicine 2004–2005 task force definition which includes individuals who may be related or unrelated and with whom the patient has a significant relationship.[28]

## Procedure

Enrollment started on January 4<sup>th</sup>, 2016. We screened Johns Hopkins Hospital's medical ICU census 7 days per week to identify eligible patients. Every day, a study team member was physically present in the medical ICU for a 2-hour period termed the "daily enrollment period." The three team members trained to recruit and enroll family members were white females of similar age (25–35 years old). Each week, 2-hour enrollment periods were scheduled between 09:00 and 17:00 on three weekdays, between 17:00 and 21:00 on two weekdays, and between 09:00 and 17:00 on weekends. All communications with study participants were conducted in-person.

A family's "recruitment window" started 24 hours after the patient's admission to the medical ICU and continued for 7 consecutive days or until the patient's death or ICU discharge. [S1 Fig](#) illustrates how recruitment using this strategy could have occurred for a single hypothetical patient. Permission to approach family members for consent was obtained from both the attending physician and bedside nurse. The legal healthcare proxies, defined as the patient's healthcare agent(s), surrogate(s), or guardian under Maryland state law, was preferentially enrolled if more than one family member was present during a specific recruitment window. [29,30] If the family member initially enrolled was not the patient's legal health care proxy using a standardized algorithm provided in [S2 Fig](#), additional attempts were made to also enroll the legal healthcare proxy, so that a maximum of two family members were enrolled for each eligible patient. When a patient's legal healthcare proxy did not wish to participate or was not expected to visit the ICU, another adult family member advocating for the patient was approached for enrollment.

We made daily attempts, 7 days per week, to enroll a family member for each eligible patient during the 7 day recruitment window until all available family members declined participation, a proxy consented, the patient was discharged from the medical ICU or the patient died. Availability of family during the daily recruitment period was recorded each day as one of the following (1) no family present, (2) no permission from attending physician or nurse,

(3) family deferred participation, (4) family declined participation, or (5) family consented. Interviews with enrolled family members were conducted in a private area outside the patient's room. Participants were asked to provide basic demographic information and feedback on the educational materials. Most interviews required between 15 and 30 minutes. Participants received a \$10 gift card upon interview completion.

Data collection for all eligible patients included age, sex, race, zip code, location prior to hospitalization, admission diagnosis, advance directives at ICU admission, code status 24 hours after ICU admission, and presence of a phone number for an emergency contact in the electronic medical record. Length of hospital and ICU stay, disposition at hospital discharge, mechanical ventilation status (ever/never), and withdrawal of life support were collected at hospital discharge. We reviewed nursing records and consulted with the patient's multidisciplinary clinical team to determine whether a patient had ever been visited by a family member during the recruitment window. Data collected about enrolled family members included relation to the patient, age, gender, race, years of formal education, and previous experience supporting a family member while in the ICU were obtained via in-person interview.

## Analysis

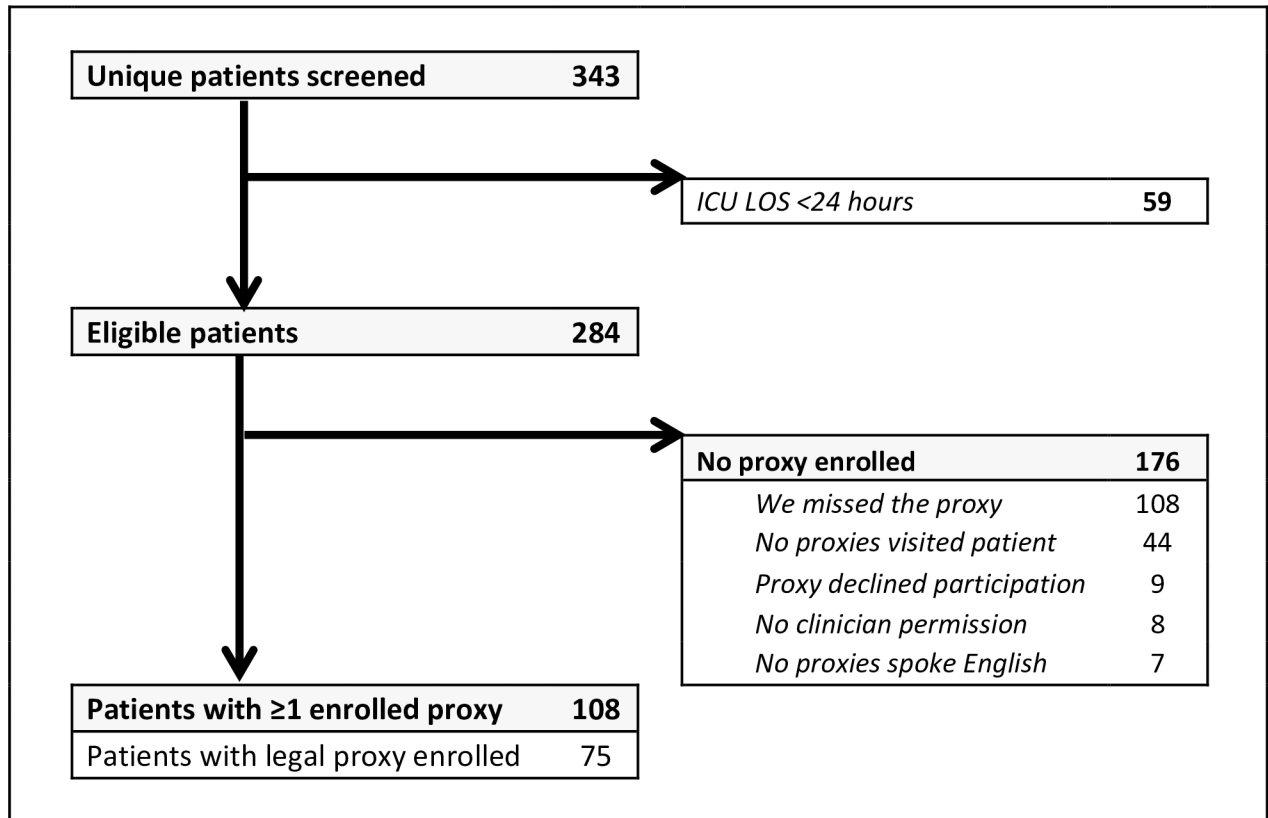
Our primary outcome was the proportion of eligible patients for whom at least 1 family member was enrolled. Family members were considered enrolled if they consented to participate and completed >50% of the survey. Secondary outcomes included the proportion of eligible patients for whom a legal healthcare proxy was enrolled, and the consent rate for families who were asked to participate. To estimate the proportion of eligible patients for whom at least 1 family member can be enrolled with a 5% margin of error and a 95% confidence level ( $\alpha = .05$ ), we planned to screen 369 consecutive ICU patients. For patients who were readmitted to the ICU during the study, only data from their first ICU admission was included in analysis.

To assess whether family members were more likely to be enrolled after 5pm on weekdays or on weekends versus during regular business hours, we conducted a patient-day level analysis. Patients contributed patient-days to this analysis during the recruitment window until death, ICU discharge, or enrollment of a legal proxy. In addition, we compared the characteristics of proxies and patients enrolled between 09:00 and 17:00 on weekdays versus outside of this time frame. Differences in continuous variables were tested using the Wilcoxon-Mann-Whitney two-sample test. All descriptive statistics and plots were generated using the R programming language version 3.3.0 (Vienna, Austria) using two-sided significance tests, with  $P < .05$  indicating statistical significance.

## Results

Over 96 days, there were 369 admissions to the medical ICU for 343 unique patients (Fig 1). There were 59 (17%) patients discharged within 24 hours of ICU admission, leaving the families of 284 patients eligible for enrollment. A total of 108 (38%, 95% CI 32% – 44%) eligible patients had at least one family member enrolled. We enrolled a legal healthcare proxy for 75 (26%, 95% CI 21% – 32%) eligible patients. Family members of 30 patients (28%, 95% CI 20% – 37%) reported that the patient had a document naming a legal healthcare agent, but only 5 (17%) of these patients had a copy of the document in their medical chart (S3 Fig).

Among 117 family members who were asked to participate, 108 (92%, 95% CI 86% – 96%) enrolled in the study. Eligible patients with versus without an enrolled proxy were more likely to be white (44% vs. 30%,  $P = .02$ ), to live in a zip code with a median income of  $\geq \$100,000$  (15% vs. 5%,  $P = .01$ ), to be mechanically ventilated (63% vs. 47%,  $P = .01$ ), to die in the ICU (19% vs. 9%,  $P = .03$ ) (Table 1) and to have longer ICU stays (median 5.0 vs. 2.5 days,  $P < .001$ ).



**Fig 1. Patient screening, study eligibility and enrollment.** 369 ICU admissions for 343 unique patients were screened. Only a patient's 1st ICU admission during the study period was analyzed. Eight patients had two proxies enrolled.

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Family members were equally likely to be present in the medical ICU on weekday evenings (30%), weekends (31%), and during daytime (09:00–17:00) on weekdays (29%) (Table 2). Similarly, there was little difference in agreement to participate by eligible family members approached during these 3 time frames (76%, 73% and 69%, respectively). Family members approached on Day 2 versus Day 1 were less likely to participate (80% vs 58%,  $P = .03$ ); however, the consent rate rose on Days 3 and 4 (78% and 63%, respectively, Table 2).

During the 7-day recruitment window, a family member was most likely to be enrolled on Day 1, with families less likely to be available in the ICU with each subsequent day of eligibility (Fig 2).

Among enrolled proxies, the median age was 51 years old, 74 (69%) were female, 61 (56%) were non-white, and 70 (65%) had prior experience supporting a loved one in an ICU (Table 3). There were no significant differences in the characteristics of proxies enrolled during weekdays versus evenings or weekends.

## Discussion

In this pilot study of a brief educational intervention for adult family members of patients in a racially and socio-economically diverse medical ICU, 92% of families approached in the ICU and asked to participate provided consent. By screening the MICU for 2 hours per day, 7 days per week, for up to 7 consecutive days, we were able to enroll a proxy for 38% of eligible patients. Patients with an enrolled proxy were more likely to be white, live in a zip code with a

**Table 1. Characteristics of eligible patients by enrollment status.**

	Enrolled <sup>a</sup> (N = 108)	Missed family (N = 108)	Proxies ineligible <sup>b</sup> (N = 51)	MD or RN Refused (N = 8)	Family Declined (N = 9)	Total (N = 284)
<b>Age, Median (IQR)</b>	58 (48,69)	56 (45,68)	52 (44,62)	62 (23,66)	55 (51,69)	56 (45,67)
<b>Sex N (%)</b>						
Male	53 (49%)	54 (50%)	26 (51%)	1 (12%)	5 (56%)	139 (49%)
<b>Race N (%)</b>						
Black or African American	47 (44%)	59 (55%)	26 (51%)	5 (62%)	4 (44%)	141 (50%)
White	47 (44%)	35 (32%)	12 (24%)	1 (12%)	4 (44%)	99 (35%)
Other	14 (13%)	14 (13%)	13 (25%)	2 (25%)	1 (11%)	44 (15%)
<b>Location prior to hospitalization N (%)</b>						
House/Apt (independent)	71 (66%)	78 (72%)	36 (71%)	4 (50%)	8 (89%)	197 (69%)
House/Apt (with assistance)	28 (26%)	14 (13%)	8 (16%)	3 (38%)	1 (11%)	54 (19%)
Other	8 (7%)	13 (12%)	6 (12%)	1 (12%)	0 (0%)	28 (10%)
Unknown or missing	1 (1%)	3 (3%)	1 (2%)	0 (0%)	0 (0%)	5 (2%)
<b>Median income of zip code N (%)<sup>c</sup></b>						
<\$40K	31 (29%)	42 (39%)	16 (31%)	1 (12%)	3 (33%)	93 (33%)
\$40K-\$69K	40 (37%)	42 (39%)	25 (49%)	3 (38%)	1 (11%)	111 (39%)
\$70K-\$99K	20 (19%)	18 (17%)	7 (14%)	4 (50%)	4 (44%)	53 (19%)
≥\$100K	16 (15%)	6 (6%)	2 (4%)	0 (0%)	1 (11%)	25 (9%)
<b>In chart at admission screening N (%)</b>						
Advance directive or POA listed in EMR	6 (6%)	5 (5%)	3 (6%)	1 (12%)	0 (0%)	15 (5%)
MOLST Form	5 (5%)	7 (6%)	2 (4%)	0 (0%)	0 (0%)	14 (5%)
<b>Code Status after 24 hours in ICU N (%)</b>						
Full code	94 (87%)	92 (85%)	47 (92%)	5 (62%)	9 (100%)	247 (87%)
Full code with treatment limitations	6 (6%)	8 (7%)	2 (4%)	2 (25%)	0 (0%)	18 (6%)
DNR and DNI	8 (7%)	8 (7%)	2 (4%)	1 (12%)	0 (0%)	19 (7%)
<b>Phone numbers for patient contacts recorded in EMR N (%) *****</b>						
Spouse / Girlfriend / Boyfriend	51 (47%)	26 (24%)	9 (18%)	0 (0%)	5 (56%)	91 (32%)
Adult child	36 (33%)	44 (41%)	13 (25%)	2 (25%)	2 (22%)	97 (34%)
Parent	19 (18%)	24 (22%)	7 (14%)	3 (38%)	1 (11%)	54 (19%)
Sibling	16 (15%)	14 (13%)	8 (16%)	0 (0%)	1 (11%)	39 (14%)
Other	10 (9%)	15 (14%)	8 (16%)	0 (0%)	0 (0%)	33 (12%)
Unknown or not reported	16 (15%)	22 (20%)	16 (31%)	4 (50%)	0 (0%)	58 (20%)
<b>Admission diagnosis, N (%)</b>						
Respiratory failure	47 (44%)	49 (45%)	16 (31%)	4 (50%)	2 (22%)	118 (42%)
Sepsis	23 (21%)	16 (15%)	3 (6%)	2 (25%)	0 (0%)	44 (15%)
Gastrointestinal	10 (9%)	13 (12%)	12 (24%)	0 (0%)	1 (11%)	36 (13%)
Cardiovascular	6 (6%)	11 (10%)	5 (10%)	0 (0%)	2 (22%)	24 (8%)
Other	22 (20%)	19 (18%)	15 (29%)	2 (25%)	4 (44%)	62 (22%)
<b>Mechanical ventilation, N (%)</b>						
Ever mechanically ventilated	68 (63%)	55 (51%)	17 (33%)	4 (50%)	7 (78%)	150 (53%)
<b>ICU Length of stay and disposition</b>						
ICU length of stay, median (IQR)	5 (3,9)	2 (2,4)	3 (2,4)	3 (2,3)	6 (4,7)	3 (1, 5)
Died in ICU, N (%)	20 (19%)	12 (11%)	0 (0%)	4 (50%)	0 (0%)	36 (13%)
Withdrawal of life-support, N (%)	21 (19%)	12 (11%)	0 (0%)	4 (50%)	0 (0%)	37 (13%)
<b>Hospital Length of stay and disposition,</b>						
Hospital length of stay, median (IQR)	11 (7,24)	10 (5,17)	6 (4,14)	6 (2,8)	15 (10,54)	9 (5, 18)
House/Apt (independent)	33 (31%)	52 (48%)	32 (63%)	0 (0%)	4 (44%)	121 (43%)

(Continued)



Table 1. (Continued)

	Enrolled <sup>a</sup> (N = 108)	Missed family (N = 108)	Proxies ineligible <sup>b</sup> (N = 51)	MD or RN Refused (N = 8)	Family Declined (N = 9)	Total (N = 284)
House/Apt (with home care)	14 (13%)	7 (6%)	5 (10%)	2 (25%)	1 (11%)	29 (10%)
Died	29 (27%)	17 (16%)	1 (2%)	4 (50%)	0 (0%)	51 (18%)
Hospice	8 (7%)	6 (6%)	0 (0%)	0 (0%)	0 (0%)	14 (5%)
Other including residential care	24 (22%)	26 (24%)	13 (25%)	2 (25%)	4 (44%)	69 (24%)

**Abbreviation:** DNI, Do not intubate; DNR, Do not resuscitate; EMR, Electronic medical record; ICU, Intensive care unit; IQR, Interquartile Range; MOLST, Maryland Medical Orders for Life Sustaining Treatment; POA, Power of Attorney.

<sup>a</sup> Patients for whom any proxy was enrolled although 31% were not the patient’s legal healthcare proxy.

<sup>b</sup> Patients with ineligible proxies included 44 patients for whom no proxy visited the ICU, and 7 patients for whom no proxy spoke English.

<sup>c</sup> US Census Bureau 2010–2014; \$41,819 median household income for Baltimore City; \$74,194 median household income for MD state. No zip code was provided for 1 patient from Saudi Arabia with an enrolled proxy and 1 homeless patient with ineligible proxies.

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high median income, and had longer ICU stays and higher ICU mortality. Among eligible patients 15% had no visitors at any time during their ICU stay. Family availability and recruitment rates were similar on weekdays, evenings, and weekends, and family members enrolled after normal business hours had similar characteristics to those enrolled on weekdays.

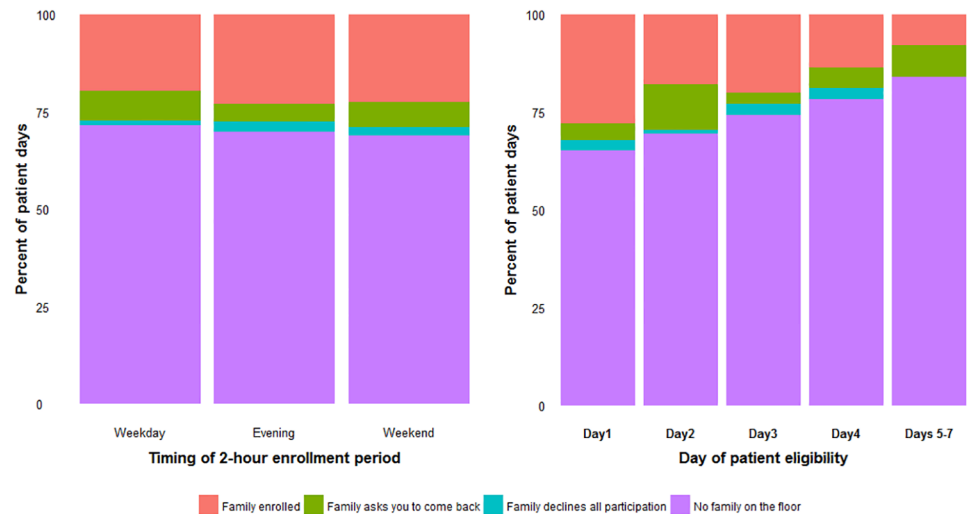
As the effects of critical illness on ICU families[24,25,31] have been recognized, research aimed at understanding family-member needs[32–34], and improving their mental health outcomes[35,36] has expanded. Both eligibility criteria and consent rate for existing studies vary substantially. For example, some studies seek to enroll legal surrogate decision-makers[33], others try to identify the person who spends the most time caregiving for the patient[37], and many qualitative studies of ICU families use a convenience sample.[38] A recent review identified 14 randomized controlled trials of interventions designed to better meet the needs of ICU families, including face-to-face meetings, changes in visitation policies, and educational brochures.[39] To interpret the results of these trials it is important to understand how many ICU

Table 2. Proxy availability and enrollment.

Enrollment Day Characteristics	Patient-days	Eligible proxy <sup>a</sup> present N (%)	P-value	Eligible proxies enrolled N (%)	P-value
<b>Timing of 2-hour daily enrollment period</b>					
Monday-Friday 09:00–17:00	224	64 (29%)	Ref	44 (69%)	Ref
Monday-Friday 17:00–21:00	152	46 (30%)	.81	35 (76%)	.53
Weekends 09:00–17:00	128	40 (31%)	.68	29 (73%)	.85
<b>Day of patient eligibility</b>					
1	229	80 (35%)	Ref	64 (80%)	Ref
2	118	36 (31%)	.48	21 (58%)	.03
3	70	18 (26%)	.20	14 (78%)	.76
4	37	8 (22%)	.16	5 (63%)	.36
5–7	50	8 (16%)	.01	4 (50%)	.07

<sup>a</sup>The following patients were excluded from day-level analysis: Patients without English-speaking family members, patients with ICU length of stay >24 hours who were discharged before the first 2-hour enrollment period, patients for whom clinician permission to approach family members was not obtained, and two potentially eligible patients who were mistakenly not added to the daily enrollment list on their 1<sup>st</sup> day of eligibility. If the first proxy enrolled for a patient was not the legal healthcare proxy, subsequent days spent attempting to locate the legal proxy were excluded from day-level analysis.

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**Fig 2. Patient-day level analysis of family presence and enrollment in the medical intensive care unit.** The following patients were excluded from day-level analysis: Patients without English-speaking family members, patients with ICU length of stay >24 hours who were discharged before the first 2-hour enrollment period, patients for whom clinician permission to approach family members was not obtained, and two potentially eligible patients who were mistakenly not added to the daily enrollment list on their 1<sup>st</sup> day of eligibility. If the first proxy enrolled for a patient was not the legal healthcare proxy, subsequent days spent attempting to locate the legal proxy were excluded from day-level analysis.

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patients have family members who could potentially benefit from the intervention, and the representativeness of family members enrolled in the trials.

Requiring in-person recruitment and consent during a 2-hour daily enrollment period greatly limited our ability to enroll proxies for patients with short ICU stays as well as those families who visited infrequently or briefly. As a result, about half of eligible patients were not enrolled because a proxy was not available. This is comparable to previous evaluations of recruitment methods for ICU patients in which 40% – 80% of eligible patients who lacked decision-making capacity were not enrolled because no family member was available to provide surrogate consent.[40,41]

While the issue of critically ill, unbefriended patients (those without any family member or friend who can act as a surrogate decisions-maker) is well described in the medicolegal and bioethics literature,[42–44] the disadvantages of lacking someone who is regularly present at the patient’s bedside are less well documented. In addition to these patients and families being less likely to participate in research requiring in-person consent, these families may be less likely to benefit from multidisciplinary family meetings, participating in bedside rounds, communication facilitators[15], decision-aids requiring clinician supervision[14,45,46], and palliative care consultation [47]. Our data also suggest that the association between the absence of family members at the bedside and patient outcomes is likely confounded by socio-economic status and race.

Our high consent rate for approached families may be attributable, in part, to families being asked to complete a single low-burden interview generally requiring <30 minutes.[48] Although none of the study team members recruiting family members were physicians, all were trained to approach family members professionally and to allow families sufficient information, time, and space to make an informed decision about participation.[49] Recent qualitative research on the experiences of ICU families asked to participate in critical care research suggests that family members ultimately weigh the risk of participation against the potential



**Table 3. Characteristics of enrolled proxies and their loved ones by enrollment time.**

	Weekdays 9am– 5pm (N = 47)	Evenings & weekends (N = 69)	P-value
<b>Characteristics of Enrolled Proxies (N = 116)</b>			
<b>Age<sup>a</sup></b> , Median (range)	50 (25, 70)	51 (18, 77)	.77
<b>Sex<sup>a</sup></b> , N (%)			
Male	13 (28%)	21 (30%)	1.0
<b>Relationship to patient</b> , N (%) <sup>d</sup>			
Daughter	13 (28%)	16 (23%)	.43
Wife/Girlfriend	10 (21%)	19 (28%)	
Husband/Boyfriend	3 (6%)	11 (16%)	
Son	5 (11%)	3 (4%)	
Other	15 (32%)	19 (28%)	
<b>Race<sup>a</sup></b> , N (%)			
Black or African American	21 (45%)	32 (46%)	.76
White	20 (43%)	29 (42%)	
Other	2 (4%)	6 (9%)	
<b>Years of Education</b> , Median (range)	14 (10, 21)	14 (10, 24)	.17
<b>Have you ever supported a loved one in ICU before?</b> N (%) <sup>b</sup>			
Yes	27 (57%)	43 (62%)	.64
No	17 (36%)	24 (35%)	
Unsure	3 (6%)	2 (3%)	
<b>Is the enrolled subject the patient’s legal proxy?</b> N (%)			
Yes	29 (62%)	46 (67%)	.65
<b>Characteristics of Patients (N = 108)</b>	<b>(N = 44)</b>	<b>(N = 64)</b>	
<b>Median income of zip code</b> , N (%) <sup>c</sup>			
<\$40K	11 (25%)	20 (31%)	.29
\$40K-\$69K	20 (45%)	20 (31%)	
\$70K-\$99K	8 (18%)	12 (19%)	
≥\$100K	4 (9%)	12 (19%)	
<b>Length of stay</b>			
ICU length of stay, median (range)	5 (1, 26)	5 (2, 49)	.44
Hospital length of stay, median (range)	9 (2, 54)	12 (3, 218)	.05

**Abbreviations:** DNI, Do Not Intubate; DNR, Do Not Resuscitate; ICU, Intensive Care Unit; IQR, Interquartile Range

<sup>a</sup> Proxies declined to report information on their age (n = 4), sex (n = 2), and race (n = 6).

<sup>b</sup> Percentages do not sum to 100% due to rounding.

<sup>c</sup> No zip code was provided for 1 patient from Saudi Arabia with a proxy enrolled on a weekday. US Census Bureau 2010–2014; \$41,819 median household income for Baltimore City; \$74,194 median household income for MD state.

<sup>d</sup> We need to figure out how the 2 missing people were related

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benefit to the patient.[50,51] One of the “risks” associated with participation in our study was leaving the patient’s room and missing an update from a physician. We sought to mitigate this risk by explaining that interviews were conducted in a nearby room within the ICU and asking bedside nurses to interrupt the interview if a physician arrived. If families remained concerned, we offered to come back later in the 2-hour daily enrollment period or the next day.

Strengths of our study include its rigorous evaluation of a systematic and well-defined recruitment strategy to identify family members of ICU patients acting as patient proxies. However, the study also has potential limitations. For instance, the results of our study cannot be extrapolated to other more intensive recruitment strategies, or to other ICU populations

such as pediatric or surgical ICUs. Moreover, our results may have also been substantially different if the study intervention required longitudinal follow-up, was interventional or invasive, or was directed at ICU patients without decision-making capacity. We recognize these limitations and encourage other investigators to conduct similar studies in their own institutions in preparation for performing larger scale trials.

In conclusion, a recruitment strategy involving limited human resources and time-varying, daily in-person screening over 7 days enrolled a family member for more than one third of eligible patients with 92% of approached family members agreeing to participate. However, patients with enrolled family members were disproportionately white, wealthy, mechanically ventilated, and had higher ICU mortality. Day of the week, and time of day were not associated with family presence in the ICU or consent rate. Investigators planning trials of interventions for ICU families should test recruitment plans to ensure their studies achieve appropriate power and generalizability.

## Supporting information

**S1 Fig. Schematic of ICU proxy recruitment strategy—Example using a hypothetical patient.**

(TIF)

**S2 Fig. Algorithm used to identify legal healthcare proxies.**

(PDF)

**S3 Fig. Availability of advance directives in patient charts and noted in electronic medical record.** Abbreviations: AD, Advance directive. 1 Percentages do not sum to 100% due to rounding. Quoted language was asked of enrolled proxies by research assistants. Information within tables was obtained from the patient's admission screening note in the electronic medical record.

(PNG)

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