



# Differentiating between Emergency Medicine and other Specialties when it Comes to the Factors that Influence Clinical Trial Participation

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## ABSTRACT

**Introduction:** This research evaluated variables that affect emergency medicine (EM) patients' choices to participate in clinical trials and if the effect of these factors varies from those of other medical specialties.

**Methods:** While waiting for an appointment, a survey was handed out to patients in the emergency department (ED), family medicine (FM), infectious disease (ID), and OB/GYN waiting rooms. Survey participants had to be at least 18 years old and able to complete it without any help from their caregivers. Comparing participant replies using Kruskal-Wallis tests and ordinal logistic regression analysis revealed significant differences.

**Results:** We contacted 2,893 people who were qualified, and 1,841 questionnaires were included in the final analysis. Eight of the 10 driving variables between EM and one or more of the other specializations were found to be statistically significant ( $p < 0.001$ ). The connection between the patient and their doctor was more motivating to patients in other specialties than to EM patients (FM [odds ratio OR:1.752, 95 percent confidence interval [CI]:1.285-2.389], ID [OR:3.281, 95 percent CI:2.293-4.695], and OB/GYN [OR:2.408, 95 percent CI:1.741-3.330]). "How effectively the study was communicated," and "whether the information obtained will assist others," were EM's top two motivating criteria, and they were shared by other specialties as well. When comparing EM to the other eight disciplines, there were statistically significant differences ( $p < 0.008$ ) in each one of the nine obstacles. "The potential of unanticipated side effects" was cited as the greatest obstacle by participants of all disciplines. No matter whether patients' race, "time commitment" was a barrier for other specialties (FM [OR:1.613, 95% confidence interval 1.218-2.136]; ID [OR:1.340, 95% confidence interval 1.006-1.784]; or Ob/Gyn [OR:1.901, 95% confidence interval 1.431-2.526].) Patients who are considering taking part in a clinical trial may use just one of the six resources evaluated to assist them make that decision.

**Conclusion:** There are considerable variations between EM patients and those of other disciplines in the variables that determine their involvement in clinical trials. Providing literature in the patient's native language, explaining the study clearly, and demonstrating how their involvement can benefit others in the future may assist to enhance enrolment in EM-based clinical studies. [West J Emerg Med. 2017;18(5)846-855.

## INTRODUCTION

Evidence of an increase in EM clinical research efforts may be seen in the recent formation by the National Institutes of Health of the Office of Emergency Clinical Research. With no prior physician-patient interaction and with acute and sometimes undifferentiated disorders, research in EM presents unique problems. Patients' willingness to participate in clinical trials has been examined in several research across a wide range of medical specialties, including: 1,2, 3-23 Patients' gender, race, ethnicity, language ability, and socioeconomic level have all been cited as factors in their desire to participate in clinical research. The quality of clinical treatment, the clinical staff

with whom they engage, the research team's communication, and other external variables are all thought to have a role in the success of the study. 7-10,13-23 How thoroughly the research was described to them was cited as a motivating factor by those who participated in the study. A good patient-physician relationship, 7,14-16 the understanding that their involvement will assist someone in the future, 7-9,17-18 and pay for participating were all important considerations for the participants in this study. 19 Other identified hurdles to participation include mistrust in doctors, 7,20-23 danger of unknown side effects, 7,20-23 and linguistic differences. 7,20-23. Despite the vast number of research, there is no evidence that these characteristics are affected by the sort of clinical



specialization one works in. For example, we predicted these influences would differ for cancer and obstetric patients because of the different specialties involved. For patients with several physical and psychological stresses, each motivation or barrier could be seen differently while deciding whether or not to participate in a clinical study. We wanted to learn what factors influence EM patients' decision to participate in clinical trials and whether or not their impact differs from other selected medical specialties, because EM researchers would benefit from knowing what matters to their patients and how to use this knowledge to customize and optimize their recruitment approach.

## METHODS

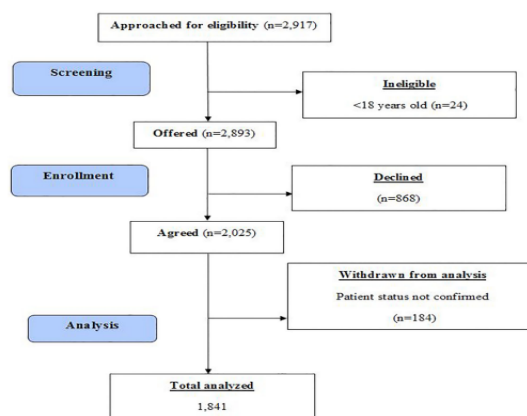
Medical patients visiting outpatient clinics linked with a single health network were surveyed in a prospective, cross-sectional, self-administered research at three separate hospital locations. The primary investigator (PI) reached out to experts in a variety of fields in preparation for the study. An OB/GYN, an FM, and an infectious disease specialist consented to participate (ID). It was then done at two OB/GYN facilities, four FM facilities, two ID facilities and three emergency rooms across the network (EDs). Surveys were only given to people who were waiting for appointments at the time of the survey's distribution. It was not possible to poll patients who arrived at the ED via ambulance or otherwise avoided having to wait in the waiting area. Over a nine-month period, an anonymous, voluntary, and confidential survey was conducted (June, 2014 through March, 2015). In addition to English, members of the study team proficient in either Spanish, simplified Chinese, or traditional Chinese addressed potential respondents. Participants had to be at least 18 years old, active patients on the day of the survey, and able to complete the survey without help to be eligible for participation. As well as being prepared by EM specialists, the survey was also evaluated by colleagues from other departments, a statistician, and an advisory board for EM-related research. The survey was reworked and piloted with 15 non-clinical and non-research hospital staff members based on their input. These pilot participants were given a short questionnaire to get their thoughts on the survey's objective, length, and clarity of the questions, as well as any other issues they encountered. Volume 18, Number 5: August 2017 was correctly identified by the surveyors of the Western Journal of Emergency Medicine 848 Other medical specialties are less likely to participate in clinical trials than those in the EM field. For the objective of the survey, Kurt et al. found the duration of the survey to be adequate. In order to assure a consistency of interpretation of the survey results of these pilot participants of two weeks, we re-distributed the survey and compared their second replies to their first. As necessary, revisions were made. A member of the research team contacted patients in the "check-in" section of each specialized clinic and inquired for their age before offering them the survey if they were 18 or older. Researchers

offered an oral introduction to the survey's objective, which was to get patients' views on clinical research studies in which physicians evaluate novel treatments or equipment, in addition to a cover page explanation. Confirmation was acquired that the patient had not previously done the survey at any of our network's sites. Researchers questioned if patients were able to conduct the survey themselves and, depending on their desire, gave them a copy of the survey in English or one of the three other translations.. Only surveys in which the respondent stated that he or she was an active clinic patient were included in the data analysis. According to possible influences on involvement in research, the individuals were asked to rank each element on the five-point Likert scale as either having no (0), minimal (1), moderate (2), or significant (3) importance. Excel files were created by two qualified research colleagues after the completion of the survey. Every 20th survey was inspected by the PI to guarantee data input correctness, consistency, and the integrity of the database. A chi-square test was used to compare demographic factors among specializations. If there is a strong correlation,

## RESULTS

A total of 24 respondents were judged ineligible because of their age throughout the screening procedure; 2,893 people were contacted and 2,025 (70 percent) took the survey. There was a 73.3 percent response rate for emergency medical services, 67.2 percent for general medicine, 62.8 percent for id, and a 76.4 percent response rate for OB/GYN (Table 1). In addition, 184 respondents were omitted from the study because they were unable to attest that the information they supplied was correct. Another 1,841 questionnaires were analyzed in all. Demographics were substantially associated with a person's specialty.

	EM	FM	ID	OB/GYN
Offered	726	734	693	740
Agreed	532	493	435	565
Response rate %	73.3	67.2	62.8	76.4



**Figure.** CONSORT flow diagram.

In addition to those who stated they knew English but had difficulty speaking it (42.4%), there were also a significant number of respondents (9.1%) who indicated they could not

communicate in the language (7.3 percent ). Only 48.5% of the EM participants were White, whereas 68.1% of the FM participants, 59% of the ID participants, and 55.5 percent of the OB/GYN participants were.

### **Examination of Conceivable Driving Elements**

Motivational variables in the field of Emergency Medicine (EM) were scored lower than those in other specialties. Eight of the eleven driving variables between EM and one or more specializations were statistically significant. According to the study, “my desire to please the physician” and “the physician doing research has the same race/ethnicity as me” were not significantly different between EM and any other discipline. EM patients cited “how effectively the study is described to me” and “the information obtained from my involvement would help someone in the future” as the two most important criteria in their decision to participate in research (Table 3).

### **Examining Possible Stumbling Blocks**

There were statistically significant disparities between EM and the other disciplines at all nine of the obstacles. In spite of the fact that “risk of unknown side effects” was the most significant deterrent for all of the patients surveyed, one worry expressed by EM patients was somewhat greater than that of other disciplines. Table 3 shows (as an example)

Examination of conceivable driving elements Motivational variables in the field of Emergency Medicine (EM) were scored lower than those in other specialties. Eight of the eleven driving variables between EM and one or more specializations were statistically significant. According to the study, “my desire to please the physician” and “the physician doing research has the same race/ethnicity as me” were not significantly different between EM and any other discipline. EM patients cited “how effectively the study is described to me” and “the information obtained from my involvement would help someone in the future” as the two most important criteria in their decision to participate in research (Table 3). Examining possible stumbling blocks There were statistically significant disparities between EM and one or more other disciplines in all nine barriers. “My family’s worry” rated somewhat higher for EM patients than other disciplines, despite the fact that all patients placed “risk of unknown side effects” as the highest barrier (Table 3).

### **Analysis of Potential Helpful Resources**

It was shown that among six tools that assist patients decide whether to join in a clinical trial, having all information in my own language was the most useful. With the exception of whether or not they would be able to talk to a patient who had previously participated in a clinical research trial, there was no statistically significant difference in the ranks of these criteria between EM and any other specialty.

### **Ordinal Logistic Regression Analyses for Selected Factors**

Patients in other specialties, including as FM (OR:1.752, 95 percent CI[1.285-2.389]), ID (OR:3.281, 95 percent CI[2.293-4.695]), and OB/GYN (OR:3.281, 95 percent CI[2.293-4.695]), were more likely than EM patients to be motivated by their doctor-patient interaction (OR:2.408, 95 percent CI[1.741-3.330]). It did not matter if the patient was white or black; patients in FM (OR:1.613, 95 percent CI[1.218-2.136]), ID (OR:1.340, 95 percent CI[1.006-1.784]), or OB/GYN (OR:1.901, 95 percent CI[1.431-2.526]), females (OR:1.322, 95 percent CI[1.043-1.676]), and those who graduated college or had higher degrees (OR:1.573, Females (OR:1.505, 95 percent CI[1.163-1.947]), African Americans (OR:1.903, 95 percent CI[1.400-2.587]), Hispanics (OR:1.724, 95 percent CI[1.306-2.276]), multiracial patients (OR:1.761, 95 percent CI[1.060-2.926]), and patients of other races (OR:2.362, 95 percent CI[1.547-3.607]) all had higher odds of stating that their religious beliefs were more of a barrier than male Whites. More educated patients (OR:0.569, 95 percent CI[0.393-0.823]) and those with a two-year degree or less (OR:0.644, 95 percent CI[0.463-0.897]) were less likely than those without a high school education to find their religious views a barrier to treatment.

### **DISCUSSION**

Despite the fact that EM handles a wide and varied patient group, including women, children, the elderly, and people of color, recruiting participants for EM clinical trials seems to be very difficult. 1,2 In order to determine what variables affect EM patients’ desire to participate in clinical trials, we performed this research among ED patients and compared their replies with those of patients from several other medical specialties to see whether these factors differed. When compared to EM, patients in the FM group were more likely to be in need of primary care and already had established ties with their doctors. Adding AIDS Activity Office/Hepatitis Care Center and Travel ID Clinic patients (as well as OB/GYN patients) broadened our sample to include people with infectious diseases. There were good acceptance rates for the four specialties save ID, even though their demographics were diverse. It was not feasible to conduct a non-response bias analysis since the reasons for non-participation were not elicited, and because IRB regulations prohibit the collection of demographic data on non-participants. For the reasons indicated in our survey, the majority of EM and FM patients were less inclined to enroll in clinical trials than OB/GYN and ID patients. There was a notable omission: EM patients who came by ambulance were not issued a survey since all patients in the waiting rooms of each specialty were given one. It is possible that some individuals, such as those who had to be rushed to the hospital because of their serious condition, were not included in the study’s sample. It is probable that EM’s motivational component ratings would have been



considerably lower had we included these patients because of the physical and psychological pressures associated with their severe health problems. On average, ID and OB/GYN patients found four of the ten motivational aspects to be very inspiring, whereas FM patients found three and EM patients found two. Compared to other disciplines, EM patients had lower ratings for motivating factors and higher levels for most impediments. Findings from this study shed light on the difficulties EM investigators and researchers have when seeking to recruit participants for EM-based clinical trials. That different professions have varying views on what drives or discourages patients from participating in research trials is likely unsurprising. In fact, patients in emergency medicine are less likely to be swayed by their doctor's reputation or personal connection. Study participants who already have an established contact with the doctor doing the study are less likely to participate in clinical trials than those who do not. When it comes to emergency medicine patients, it's possible the lack of familiarity with their doctor and lack of time to read online evaluations are preventing them from being as impacted by these two elements. The patient, or if they are present, may be under as much stress and worry as the patients themselves. The supply of written or electronic information, which may be quickly modified by researchers, was assessed as somewhat useful in recruiting for clinical research studies. A patient's own language was also a consideration in this regard. EM had a higher percentage of Latino or Hispanic responses, a lower percentage of college-educated participants, and a lower percentage of competent English speakers than other specializations. It was shown in an earlier study that a significant number of eligible Latinos who did not speak English could not participate in EM research because of language difficulties. 1 Translated content has been shown to be a useful tool in breaking down language barriers for many people. 8-10 Since translated surveys were readily available, the present research was able to include a significant proportion of EM respondents (20.1%). In addition, the number of translated surveys employed in each specialty was directly proportional to the number of respondents who were unable to communicate well in English. As patients in the ED often have a shorter period of time to consent,<sup>27</sup> and the time it takes to explain research might delay rapid therapeutic intervention,<sup>28</sup> the availability of translated information could aid to enhance EM study recruitment. Conducting less complicated, shorter intervention studies<sup>2</sup> and waiving or permitting delayed consent in EM clinical trials are two more possible answers to the enrollment problem for EM patients. a number between 29 and 30 The heterogeneity of the research sample should not be underestimated since demographic characteristics, such as the patient's gender,<sup>3-5</sup> race,<sup>5-8</sup> language capabilities,<sup>8-10</sup> and socioeconomic status<sup>11,12</sup>, are known to impact their participation choices. For example, EM was found to have six out of 10 motivating factors and six out of nine obstacles that differed from OB/GYN, despite the fact that EM had a

substantial female population. Obstetric and gynecological patients scored higher on motivating factors, but they also scored higher on hurdles than patients from other specialties. This helps to explain some of the differences in outcomes between men and women in clinical studies. After OB/GYN patients, ID patients proved to be the second most enthusiastic participants in research, but were less likely to be discouraged by hurdles than patients in other specialties. As a result, people with severe infections may have a greater opportunity of participating in research studies because of their value. Analysis of a few of the most important characteristics that differed substantially between EM and the other disciplines in our sample verified our prediction that factors affecting a patient's choice to participate in clinical trials may vary across various specialties. The "connection with their doctor" was less motivating for EM patients than FM, ID, or OB/GYN patients, regardless of their gender, race, or educational background. This conclusion, as previously explained, follows logically. Patients and emergency doctors often only interact with one another once, and the chances of it happening again are very remote. EM patients, on the other hand, do not have the option of choosing their own doctor for follow-up treatment, but patients in other specialties commonly schedule visits with their chosen doctor. Similar findings were seen when it came to the "time commitment" barrier. "Time commitment" was less of a hurdle for EM patients, men, and those with just a high school graduation regardless of race. Time commitment is less of a concern for emergency room patients since they are more likely to appear with acute and frequently unexplained ailments. Another obstacle, "my religious convictions," was shown to be impacted by variables other than the speciality in regression analysis, which was assessed considerably differently by EM patients than two other specialties (FM and ID). Regardless of demographic features, certain relevant variables have a greater influence on one speciality than another, according to our findings. Because of this, we propose that researchers tailor their recruiting strategy to their specific field of work.

### **The Advantages and Disadvantages**

First large-scale prospective investigation of variables influencing EM patients' participation in clinical trials, to our knowledge. This is the first study to show that the effect of a single component varies depending on the speciality. Many patients participated in this trial, which resulted in a high response rate. Multilingual research personnel and questionnaires in Spanish, simplified Chinese, and traditional Chinese were all readily available, further increasing the study's cultural variety.

Human research participant protection and confidentiality-related rules prevented us from identifying and surveying former clinical trial participants and those who had previously rejected to participate in previous clinical trials. Convenience sampling was adopted in this study instead

of a random-selection strategy, since the research staff was accessible and patients who happened to be in the clinic that day. The waiting rooms of these specializations were also visited by all participants. Because ambulance patients were not included in our study, our results may not apply to the whole population of patients that visit the emergency department. The overall response rate was good, but the findings may have been skewed by a non-response bias. IRB constraints prevented the collection of demographic information on non-participants, hence the reasons for their non-participation could not be determined. Because of this, a non-response bias analysis could not be performed. Additional variables may influence whether or not an individual chooses to participate in a clinical trial, and it is probable that these additional motivators and obstacles were not examined in this research. In light of this, we realize that our survey results may not accurately reflect the actual replies of prospective study participants to an actual invitation.

## CONCLUSION

A patient's choice to enroll in clinical trials is affected by several variables, but we have concluded that the influence of a single component may differ from one speciality to the next. For clinical trials to attract more participants, researchers should tailor their study designs to take advantage of aspects that are more important to their specialized populations than other variables. In terms of clinical research involvement, patients in EM considered their connection with their doctor and the value of their doctor's reputation much less important than patients in other disciplines. Patients of all specializations were most concerned about potential adverse effects. Clinical trials conducted in the field of Emergency Medicine (EM) appear to have a lower rate of patient participation compared to those conducted in other medical specialties, but providing material in a patient's native language; explaining the study thoroughly; and elucidating how their participation might benefit others in future clinical trials may improve patient participation.

## REFERENCES

1. Glickman SW, Anstrom KJ, Lin L, et al. Challenges in enrollment of minority, pediatric, and geriatric patients in emergency and acute care clinical research. *Ann Emerg Med.* 2008;51(6):775-80.
2. Cofield SS, Conwit R, Barsan W, et al. Recruitment and retention of patients into emergency medicine clinical trials. *Acad Emerg Med.* 2010;17(10):1104-12.
3. Jagsi R, Motomura AR, Amarnath S, et al. Underrepresentation of women in high-impact published clinical cancer research. *Cancer.* 2009;115(14):3293-301.
4. Kim ES and Menon V. Status of women in cardiovascular clinical trials. *ArteriosclerThrombVasc Biol.* 2009;29(3):279-83.
5. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: Race-, sex-, and age-based disparities. *JAMA.* 2004;291(22):2720-6.
6. Ford JG, Howerton MW, Lai GY, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer.* 2008;112(2):228-42.
7. Kurt A, Semler L, Jacoby JL, et al. Racial differences among factors associated with participation in clinical research trials. *J Racial Ethn Health Disparties.* 2016;1-10.
8. Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: The influence of structural, cultural, and linguistic factors. *Ann Epidemiol.* 2000;10(8):S22-34.
9. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African American, Latinos, Asian Americans and Pacific Islanders. *Am J Public Health.* 2014;104(2):e16-31.
10. Huang HY, Ezenwa MO, Wilkie DJ, et al. ResearchTracking: Monitoring gender and ethnic minority recruitment and retention in cancer symptom studies. *Cancer Nurs.* 2013(3);36:E1-6.
11. Farmer DF, Jackson SA, Camacho F, et al. Attitudes of African American and low socioeconomic status white women toward medical research. *J Health Care Poor Underserved.* 2007;18(1):85-99. Volume 18, no. 5: August 2017 855 *Western Journal of Emergency Medicine* Kurt et al. Factors Influencing Participation in Clinical Trials: EM vs. Other Specialties
12. Langford A, Resnicow K, An L. Clinical trial awareness among racial/ ethnic minorities in HINTS 2007: Sociodemographic, attitudinal, and knowledge correlates. *J Health Commun.* 2010;15:92-101.
13. Albrecht TL, Eggly SS, Gleason ME, et al. Influence of clinical communication on patients' decision making on participation in clinical trials. *J Clin Oncol.* 2008;26(16):2666-73.
14. Sood A, Prasad K, Chhatwani L, et al. Patients' attitudes and preferences about participation and recruitment strategies in clinical trials. *Mayo Clin Proc.* 2009;84(3):243-7.
15. Bland P. Consent guidance will strengthen doctor-patient relationship. *Practitioner.* 2008;252(1707):4.
16. White J. Discussion of patient recruitment and the informed consent process in clinical drug trials. *NephrolNurs J.* 2005;32(3):354.

17. Schmotzer GL. Barriers and facilitators to participation of minorities in clinical trials. *Ethn Dis.* 2012;22(2):226-30.
18. Limkakeng AT, De Oliveira LL, Moreira T, et al. Systematic review and metasummary of attitudes toward research in emergency medical conditions. *J Med Ethics.* 2014;40(6):401-8.
19. Bernstein SL and Feldman J. Incentives to participate in clinical trials: Practical and ethical considerations. *Am J Emerg Med.* 2015;33(9):1197-200.
20. Rivers D, August EM, Sehovic I, et al. A systematic review of the factors influencing African Americans' participation in cancer clinical trials. *Contemp Clin Trials.* 2013;35:13-32.
21. Fisher JA and Kalbaugh CA. Challenging assumptions about minority participation in US clinical research. *Am J Public Health.* 2011;101:2217-2222.

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