

The Project IMPACT Experience to Date: Increasing Minority Participation and Awareness of Clinical Trials

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Objective: This study evaluated activities of Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials), a National Medical Association (NMA) project chartered to identify ways to increase minority physician and patient involvement in clinical trials. Project IMPACT included physician education and training workshops, establishment of a physician-investigator database and other activities to facilitate minority-physician clinical trial participation.

Methods: A descriptive survey was used. The survey was distributed to 542 African-American physicians. Physicians were queried about prior involvement in clinical research, barriers and facilitators to clinical trial participation by patients and physicians, and perceptions regarding Project IMPACT.

Results: Two-hundred physicians responded to the survey. Common practice characteristics were self-employment (51%), solo practice (39%) and office based (58%). Prior involvement in clinical trials was generally low. Barriers to participation included lack of awareness of clinical trial opportunities and lack of resources to conduct clinical trials. However, most respondents had referred patients to clinical trials. Project IMPACT participants who responded were highly satisfied with the project.

Conclusions: Minority physicians are interested in participating in clinical trials. However, multiple barriers, including lack of awareness and lack of access to clinical research coordinators, continue to exist and must be addressed. Clinical trials training programs alone are not enough.

Key words: minority health ■ clinical investigation ■ barriers ■ race/ethnicity ■ National Medical Association

severity of disease than whites for most if not all of the leading causes of morbidity and mortality in the United States. These include heart disease, cancer, stroke, diabetes and unintentional injuries.³ If issues of health disparities are to be addressed appropriately, it is important that observations from clinical trial populations that are sufficiently diverse with respect to the race and ethnicity of the participants and the investigators be incorporated into evidence-based medical practice.^{4,5} Indeed, well-designed, adequately controlled clinical trials are the basis for modern clinical decision-making in the prevention, diagnosis and treatment of disease, and in the development of policies that guide medical interventions.⁶⁻⁸ Therefore, racial and ethnic minority groups must be active in all aspects of biomedical research if disparities in health are to be overcome.⁹

Innovative discovery and development of pharmaceutical and biotechnology products have had a tremendous impact on the quality and quantity of life the American population has come to enjoy over the past century. Diseases such as cancer, diabetes, asthma, depression, cardiovascular disease and HIV/AIDS that disproportionately impact African Americans^{10,11} and other minorities have become imminently treatable as a result of many significant therapeutic advances, yet major disparities in morbidity and mortality persist between African Americans and white Americans for many of these conditions.¹ A factor which has been postulated to contribute to this phenomenon is the paucity of clinical studies of new therapeutics that include adequate representation by African-American patients^{12,13} and investigators sufficient to allow statistically valid inferences regarding the appropriateness of the patient evaluation and treatment regimen. Consequently, a lack of valid scientific findings from clinical trials data relevant to the African-American population may not support adequate guidance to physicians on the best care for these patients.

Major reasons given for underrepresentation of minorities in clinical trials include "mistrust" of researchers,^{5,14-18} lack of awareness of clinical trials by minorities and inadequate involvement of minority investigators.¹⁹⁻²³ However, there are limited data available reporting the actual number of African Americans participating in clinical

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In recent years, the nation has focused attention on disparities in health that exist between white Americans and its racial and ethnic minorities.^{1,2} Racial and ethnic minorities have higher rates and greater

trials of new therapeutics, a major component of modern medical practice. A study by Evelyn and colleagues²⁴ reported a retrospective evaluation of the participation of racial and ethnic groups in clinical trials of new molecular entities included in new drug applications submitted to the Food and Drug Administration's Center for Drug Evaluation and Research from 1995–1999. This report included findings from medical reviewer comments rather than an actual collation of patient data in these applications. Although this evaluation revealed heterogeneity in racial and ethnic group participation in clinical trials, it also revealed that African-American participation in trials had declined steadily over a four-year period, i.e., 12% in 1995 to 6% in 1999. Out of nearly 500,000 patients that were included in these trials, race and ethnicity was determinable in only 53% of cases. Therefore, even with enactment of the National Institutes of Health 1993 Revitalization Act encouraging researchers to include minorities as participants in clinical research,²⁵ the implications of the data for African Americans were unlikely to be identifiable in the majority of the studies.

It has been proposed that greater involvement of African-American physicians as investigators in clinical research may facilitate greater African-American patient participation. Although intuitive given the higher likelihood of these physicians to provide care to patients from the same racial group, the hypothesis has not been subjected to rigorous scientific investigation. However, Mouton and associates²⁶ noted that African-American women indicated they would be more likely to participate in a clinical trial if the researcher was also African American. Furthermore, in a 2001 unpublished study that cross-matched the InRoll® database (a proprietary clinical investigator database derived from a listing of physicians who submitted FDA Form 1572) and the National Medical Association's (NMA) listing of known African-American physicians practicing in the United States, it was estimated that <1% of the physicians listed in the InRoll database were African American.²⁷ Thus, a substantial opportunity exists for improving African-American representation in clinical trials via the education, training and development of African-American physicians as clinical researchers.

Project IMPACT

The NMA created Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials) with the goal of improving the validity of clinical trials data supporting the development and use of therapeutic innovations in the minority community. The objectives of Project IMPACT were to educate minority physicians about clinical research and to encourage them either to assume the role of clinical investigator or, at a minimum, to develop sufficient knowledge of the process to advise their patients appropriately about clinical trial participation. The initial focus of Project IMPACT has been the African-American community with an ultimate objective to collaborate

with other groups to address the needs of other minority communities across the United States. Although not the subject of this survey, additional objectives of Project IMPACT include establishing networks and collaborations to facilitate minority clinical trial inclusion and engaging in activities that elevate the level of knowledge and awareness within the minority community regarding clinical research and its value and protections.

In order to meet project objectives, three education and training units were developed to educate African-American physicians about clinical trials and encourage their participation. These included: 1) a one-hour presentation that provided an overview of clinical trials and the clinical trials process; 2) a half-day CME-approved program focused on training African-American physician investigators to participate in clinical research; and, 3) an in-depth 2–3-day CME-approved program emphasizing Good Clinical Practices, cultural competence and skills-building for research participation. Twenty-six educational programs were conducted by the project team throughout the United States; Puerto Rico; and Nassau, Bahamas, between 1999 and 2003. Although the attendees were predominantly African American, >600 physicians and other healthcare professionals of varying ethnicity attended the programs. In an effort to facilitate participation in some level of the research process, a physician investigator database was established. The database contained the names and contact information for 542 minority physicians who participated in Project IMPACT, had research experience or expressed an interest in clinical research.

This article presents the results of a follow-up study to assess the role of Project IMPACT in facilitating minority participation in clinical research. The study was designed to: 1) examine the posttraining experiences of minority physicians who participated in the Project IMPACT clinical trial training program(s); 2) identify barriers to clinical trial participation; and 3) identify factors which could positively influence minority physician participation in clinical trials.

METHODS

Study Design

The study included qualitative and quantitative components. The first phase of the study used a qualitative approach to collect data for use in the design of a survey questionnaire for the second phase of the study. The second quantitative phase employed a descriptive survey design to evaluate the role of the NMA's Project IMPACT in a national population of African-American physicians. The study design was approved by the NMA's Clinical Trials Follow-Up Study Advisory Panel.

Study Population

The study population included Project IMPACT's database of individuals who had participated in ≥ 1 clini-

cal trial physician education programs in 1999, 2000, 2001, 2002 or 2003, and a random sample of physicians

who were included in the project's database of experienced clinical investigators. All of the 542 individu-

Figure 1. NMA Project IMPACT

NMA PROJECT IMPACT FOLLOW-UP SURVEY

The National Medical Association's (NMA) mission is to promote the science and art of medicine and the betterment of public health. To accomplish this mission, the NMA developed Project IMPACT to facilitate greater involvement of African Americans physicians and patients in all levels of clinical research. The importance of this initiative is underscored by scientific evidence suggesting ethnic and racial differences in disease progression and treatment. The NMA is conducting a follow-up study of individuals with experience in clinical trials and/or individuals who attended Project IMPACT training programs. We ask that you take a few minutes to complete this questionnaire. The information you provide is extremely important to us and will be used to understand potential barriers and solutions to increasing minority participation in clinical trials. Your responses will be completely confidential. No information that identifies individual respondents will be released or published.

ABOUT YOUR PRACTICE

1. How many physicians are in your practice?

2. How many years have you been with this practice?

3. What is your specialty? (Check one box only.)
 1. Internal Medicine
 2. Pediatrics
 3. Family Practice
 4. Obstetrics and Gynecology
 5. Psychiatry
 6. Cardiology
 7. Pulmonology
 8. Endocrinology
 9. General surgery
 10. Ophthalmology
 11. Other subspecialty _____

4. Are you board certified or board eligible? (Check one box only.)
 1. Board Certified
 2. Board Eligible
 3. Neither _____

5. What percentage of your practice is... (Check one box in each row.)

	[1] 0-25%	[2] 26-50%	[3] 51-75%	[4] 76-100%
a. Office-based	_____	_____	_____	_____
b. Hospital-based	_____	_____	_____	_____
c. Academic	_____	_____	_____	_____
d. Other	_____	_____	_____	_____

6. Who makes the decisions about clinical trials participation for your practice? (Check one box only.)
 1. You
 2. Practice Partners
 3. Hospital
 4. Managed Care Organization
 5. Other (Specify) _____

7. Which of the following best describes your current position? (Check one box only. If you hold more than one position, answer for the position at which you spend the most time.)
 1. Self-employed
 2. Hospital employee
 3. Private Practice, salaried employee
 4. HMO employee
 5. Federal employee (other than Veterans Administration)
 6. Veterans Administration
 7. Other (Specify) _____

8. How many patients are in your practice? _____

9. How would you describe your patient population? (Check the box for your best estimate of the percentage for each type of patient.)

	[1] 0-25%	[2] 26-50%	[3] 51-75%	[4] 76-100%
a. Female	_____	_____	_____	_____
b. Male	_____	_____	_____	_____
c. < 18 years old	_____	_____	_____	_____
d. > 65 years old	_____	_____	_____	_____
e. Non-Hispanic White	_____	_____	_____	_____
f. African American	_____	_____	_____	_____
g. Asian	_____	_____	_____	_____
h. Native American	_____	_____	_____	_____
i. Hispanic	_____	_____	_____	_____
j. Other	_____	_____	_____	_____
k. Medicare	_____	_____	_____	_____
l. Medicaid	_____	_____	_____	_____
m. Self-pay	_____	_____	_____	_____
n. Charity Care	_____	_____	_____	_____
Managed Care:				
o. Capitated contracts	_____	_____	_____	_____
p. Non-capitated contracts	_____	_____	_____	_____

10. What are the three diseases that you most commonly treat?
 a. _____
 b. _____
 c. _____

11. From the following list of factors, please select the two that you believe are the most important determinants of patient response to therapy. (Check two boxes only.)
 a. Genetic factors
 b. Cultural practices
 c. Socioeconomic factors
 d. Environmental factors
 e. Other factors (Specify): _____

12. Do you believe there is racial and/or ethnic variability in response to medications? (Check one box only.)
 1. Racial variation only
 2. Ethnic variation only
 3. Both racial and ethnic variation
 4. Neither racial nor ethnic variation

13. Do you feel that adequate information on racially and ethnically diverse patient populations is available to you when prescribing drugs? (Check one box only.)
 1. Yes (Skip to question 15.)
 2. No (Answer question 14.)

14. If "no" to question 13, how does the absence of information impact your ability to prescribe medications effectively? (Check all that apply.)
 1. No effect (Continue with question 15.)
 2. Delays my use of medications until more information is available
 3. Other effect (Specify) _____

15. Please rate the importance of each of the following factors using a rating of 1 = "very important," 2 = "important," and 3 = "not important."

Rating
 a. Drug efficacy in targeted patient populations
 b. Drug safety in targeted patient populations
 c. Drug interactions in targeted patient populations
 d. Identifying optimal drug dosage and regimen
 e. Other factor (Specify) _____

PARTICIPATION IN CLINICAL TRIALS

16. Have you participated in a clinical research study or clinical trial? (Check one box only.)
 1. Yes (Answer question 17.)
 2. No (Skip to question 22.)

ABOUT PROJECT IMPACT

17. If "yes" to question 16, please indicate your role(s) in the clinical research study or clinical trials. (Check all that apply.)
 a. Principal Investigator
 b. Co-investigator or investigator
 c. Coordinator
 d. Patient
 e. Other (Specify) _____

18. Did you participate in clinical trials during medical and/or postgraduate training? (Check all that apply.)
 a. Yes, during medical school
 b. Yes, during residency
 c. Yes, during fellowship
 d. Yes, other time (Specify) _____
 e. No

19. Are you currently an investigator in an ongoing clinical trial? (Check one box only.)
 1. Yes, for how many years? _____
 2. No

20. As an investigator, have you ever withdrawn from a clinical trial? (Check one box only.)
 1. Yes (Answer question 21.)
 2. No (Skip to question 22.)

21. If "yes" to question 20, which of the following factors contributed to the situation? (Check all that apply.)
 a. Lack of access to a clinical research coordinator
 b. Lack of adequate personnel time
 c. Lack of physician time
 d. Lack of patient interest in participation
 e. Too much paper work
 f. Lack of adequate information systems, such as computers and high speed Internet access
 g. Difficulty with protocol and/or case report forms
 h. Limited patient population due to protocol inclusion/exclusion criteria
 i. Other (specify) _____

22. Have you ever attempted to participate in clinical trials as an investigator but were denied participation? (Check one box only.)
 1. Yes (Skip to question 23.)
 2. No (Answer question 24.)

23. If "yes" to question 19, indicate reasons you believe contributed to your not being selected. (Check all that apply.)
 a. Failed site visit
 b. Lack of access to clinical research coordinator
 c. Unable to enroll sufficient number of patients
 d. Lack of adequate information systems, such as computers and high speed Internet access
 e. Other reason (Specify) _____

24. Have you ever been invited to participate in clinical trials? (Check one box only.)
 1. Yes (Skip to question 26.)
 2. No (Answer question 25.)

25. If "no" to question 24, please indicate reasons why you think you were not invited. (Check all that apply.)
 a. Lack of access to a clinical research coordinator
 b. Not approached by pharmaceutical company
 c. Not affiliated with major academic center
 d. No interest in participating
 e. Lack of experience
 f. Other (Specify) _____

26. Do you have an interest in conducting clinical trials? (Check one box only.)
 1. Yes
 2. No
 3. Not sure

27. Do you have access to a clinical research coordinator in your practice? (Check one box only.)
 1. Yes (Skip to question 29.)
 2. No (Answer question 28.)
 3. Not sure (Answer question 28.)

28. If "no" or "not sure" to question 27, if you could share a clinical research coordinator with other practices, would you be interested in participating in clinical trials? (Check one box only.)
 1. Yes
 2. No
 3. Not sure

29. What barriers have you faced when attempting to participate in clinical trials as an investigator? (Check all that apply.)
 a. Lack of access to a clinical research coordinator
 b. Lack of awareness of clinical trials opportunities
 c. Lack of time
 d. Concerns about patient safety
 e. Inadequate reimbursement
 f. Not affiliated with major academic center
 g. Lack of access to an Institutional Review Board
 h. None
 i. Other (Specify) _____

30. Have you ever been audited by the FDA? (Check one box only.)
 1. Yes (passed the audit)
 2. Yes (provisionally failed the audit)
 3. Yes (failed the audit)
 4. No, never audited by FDA

31. Have you ever worked with an Institutional Review Board? (Check one box only.)
 1. Yes (Answer question 32.)
 2. No (Skip to question 33.)

32. Have you ever had a proposal denied by an Institutional Review Board? (Check one box only.)
 1. Yes
 2. No

33. Have you referred any of your patients to a clinical trial? (Check one box only.)
 1. Yes (Skip to question 35.)
 2. No (Answer question 34.)
 3. Not sure (Skip to question 35.)

34. If "no" to question 33, why not? (Check all that apply.)
 a. Patient will be lost to other physicians
 b. Poor communication with people conducting trials
 c. Patient fear of participating in trials
 d. Concern about being removed from the decision-making processes
 e. Concern about potential adverse effects
 f. Patient lack of time
 g. Patient does not understand the need for their participation in the study
 h. Other (Specify) _____

35. Would you be willing to refer your patients to a clinical trial in the future? (Check one box only.)
 1. Yes
 2. No
 3. Not sure

36. Do you feel there are barriers to minority patient participation in clinical trials? (Check all that apply.)
 1. Yes (Answer question 37.)
 2. No (Skip to question 38.)
 3. Not sure (Skip to question 38.)

37. If "yes" or "not sure" to question 36, what barriers do you believe exist? (Check all that apply.)
 a. Lack of patient time
 b. Lack of patient awareness
 c. Patient fear of experimentation
 d. Lack of minority physician participation in clinical trials
 e. Other (Please describe.) _____

38. Have you ever participated in a Project IMPACT training program? (Check one box only.)
 1. Yes (Answer question 39.)
 2. No (Skip to question 46.)

39. If "yes" to question 37, which session(s) did you attend? (Check the box for each year you attended the type of session listed in each row.)

	[1] 1999	[2] 2000	[3] 2001	[4] 2002	[5] 2003
a. 45-minute presentation	_____	_____	_____	_____	_____
b. 4-hour CME program	_____	_____	_____	_____	_____
c. 2-3 day Good Clinical Practices and Skills Building course	_____	_____	_____	_____	_____

40. How important were the following issues in your decision to participate in the clinical trials workshops? (Please rate the importance of the factors listed below using 1 = "very important," 2 = "important," and 3 = "not important.")

Rating
 a. Obtaining background information on clinical trials
 b. Finding opportunities to participate in clinical trials
 c. Obtaining CME credits
 d. Financial considerations
 e. Other factor (Specify) _____

41. Did the clinical trials seminar/workshop/course meet your expectations? (Check one box only.)
 1. Exceeded my expectations
 2. Met my expectations
 3. Did not meet expectations (Please explain.) _____

42. Did the workbook/manual meet your expectations? (Check one box only.)
 1. Yes
 2. No (Please explain.) _____

43. Did you participate in clinical trials prior to attending NMA's clinical trials program? (Check one box only.)
 1. Yes
 2. No

44. Did you participate in clinical trials after attending the seminar/workshop/course? (Check one box only.)
 1. Yes
 2. No

45. Did your overall attitude regarding minority participation in clinical trials change after attending an NMA sponsored clinical trial program? (Check one box only.)
 1. Yes, I was more positive about participation
 2. Yes, I was more negative about participation
 3. There was no change in my attitude
 4. Other change (Please describe.) _____

46. What more can the National Medical Association do to increase your knowledge of and reduce barriers to your participation in clinical trials? (Check all that apply.)
 a. Increase visibility of available programs
 b. Expand types and/or numbers of programs
 c. Serve as clearinghouse
 d. Serve as a liaison to pharmaceutical companies
 e. Establish a mentoring program
 f. Establish an Institutional Review Board
 g. Offer a grant-writing program
 h. Other activity or service (Please describe.) _____

Please return your completed Project IMPACT survey in the enclosed stamped envelope to:

Project IMPACT
 National Medical Association
 1012 10th Street, NW
 Washington, DC 20001

Thank you for your participation.

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als in the database had expressed an interest in clinical research. Completion of the study survey questionnaire was considered tacit consent to participate.

Study Protocol

During the first phase of the project, qualitative interviews were conducted with 10 physicians who were identified as experienced clinical trials physicians by the NMA advisory board. The interviews were conducted by telephone to identify issues of importance to African-American physicians involved in the conduct of clinical trials. Special attention was given to inquiries addressing facilitators and barriers to participation in clinical trials, and the role of the NMA and Project IMPACT on physicians' decisions to be involved in clinical trials.

A draft questionnaire was developed based on initial responses during the qualitative interviews. The draft questionnaire was subsequently reviewed by the project team prior to testing with 50 NMA physicians. This sample represented approximately 10% of the antici-

pated population for the main study. The purpose of the qualitative cognitive interviews was to validate that the respondents viewed the questions on the draft questionnaire in a manner consistent with its intended use. The readability, flow and ease of response to the questionnaire both on paper and over the telephone were assessed. The respondents' ability to recall information over time and to provide detailed empirical information relevant to the main study was also tested. The interview took 20–30 minutes. This process supported the a priori and posteriori content validity of the questionnaire.^{28,29}

The quantitative portion of the study consisted of a mail survey. Prior to the actual survey distribution, a notification about the study was distributed as a postcard seven days in advance. The survey questionnaire was distributed along with a postage-paid reply envelope and a brief cover letter, which explained the purpose of the survey. The questionnaire was labeled with a participant number rather than a name to ensure confidentiality. Two personalized letters from NMA were

Table 1. Practice characteristics of study participants (n=200)

Characteristic	Frequency	%
Years in Practice		
1–5 years	38	19.0
6–10 years	32	16.0
11–15 years	29	14.5
16–20 years	29	14.5
≥25 years	21	10.5
Not provided	51	25.5
Number of Physicians in Practice		
Solo practitioner	78	39.0
2	22	11.0
3	16	8.0
4	10	5.0
≥5	46	23.0
Not provided	28	14.5
Employer		
Self-employed	102	51.0
Hospital	18	9.0
Private practice or salaried employee	21	10.5
HMO	2	1.0
Non-VA federal government	8	4.0
VA federal government	2	1.0
Other	36	18.0
Not provided	11	5.5
Specialty*		
Internal medicine	41	20.5
Pediatrics	16	8
Family practice	29	14.5
Ob/gyn	26	13.0
Other	91	45.5
Primary Practice Type (51–100% of Practice)		
Academic	20	10.0
Hospital	22	11.0
Office based	116	58.0
Other	11	5.5

* Some respondents gave ≥1 response.

sent after the survey was mailed, and telephone follow-up was conducted to encourage participation and return of the questionnaire. During follow-up telephone calls, individuals were offered the option of completing the surveys on the telephone or having another copy of the questionnaire faxed, e-mailed or mailed to them.

The Survey Questionnaire

The survey (Figure 1) consisted of 46 items and was divided into four sections, to obtain information about: 1) the respondent's demographics and practice characteristics, 2) participation in and satisfaction with Project IMPACT, 3) clinical trial experience and opinions about patient and physician barriers to clinical trial participation, and 4) perceptions regarding the NMA's role in enhancing participation by minorities in clinical trials.

The pilot test of the draft questionnaire supported ease of use and sufficient clarity to address the aims of the study. The survey appearance was professionally designed and printed with questions appearing on the front and back-side of a folded 11x17 sheet of paper (Figure 1).

Analysis of Data

Descriptive analysis of the data included the computation of frequencies and percentages.

RESULTS

Study Population

The survey was mailed to a total of 542 individuals and was completed and returned by 203 individuals. Two-hundred questionnaires were used in the data analysis because three surveys were received two months after the study closed. The overall response rate was 37.5%. This rate of response is much higher than the 12% return rate obtained on a previous NMA study³⁰ and the 20% return rate that is typically obtained during mail surveys to clinicians.³¹

The number of years in practice, practice setting and number of physicians in practice mirrored the demographics of the membership of the NMA. Physician respondents were likely to be board certified (75%) and employed in small private practices. The number of physicians in a single practice ranged from 1–>200; however, solo practice was most common. The mean number of years in practice was 7, with 55.5% reporting >5 years of experience. Most respondents were self-employed, and the majority indicated that >50% of their practice was primarily office based and served patients from a variety of ethnic and racial backgrounds. The most frequently cited specialties were internal medicine, family practice, obstetrics/gynecology and pediatrics. These results are consistent with national physician workforce surveillance data.³⁰ Table 1 shows the practice demographics of the study population.

Clinical Research Experiences

For the purposes of this study, clinical research refers to

any systematic evaluation that addresses a patient-related health concern which also included patients in the sample. Therefore, clinical research encompassed studies that describe patient phenomena as well as those that employed an experimental design to test a therapeutic intervention. Clinical trials were defined as studies that included testing of a treatment or other intervention in patients.

Most respondents had prior experience with participation in some type of clinical research. However, when clinical trial participation was considered specifically, <25% indicated prior involvement. More than a third of the sample had prior experience as a principal investigator, and 39.5% had been an investigator on a clinical research study. Twenty-three percent of respondents were investigators in ongoing clinical research. The degree of participation by respondents in clinical research during medical school, residency and fellowships was low.

Barriers and Facilitators to Clinical Trial Participation

Both the physicians' and physician perception of patients' barriers and facilitators to clinical trial participation were considered. Table 3 displays the physician barriers and facilitators to clinical trials participation. A large majority of respondents was interested in participating in clinical trials. However, several barriers interfered with participation. Lack of awareness of clinical trial opportunities was the most commonly reported barrier to participation followed by lack of physician time and lack of access to a clinical research coordinator to facilitate the research. This finding is consistent with prior observations that indicated lack of awareness as the most commonly reported barrier to participation in clinical trials.^{13,22,32,33} Some respondents indicated that they had attempted to participate in clinical trials but had been denied. Reasons for denial or withdrawal from participation included apparent lack of physician and personnel time, lack of a patient population that fit the protocol criteria, and lack of availability of a research coordinator or required information management systems. To facilitate minority physician participation in clinical trials, respondents indicated that the NMA should increase physician awareness of available clinical trials, serve as a "clearinghouse" for information on clinical trials, expand physician training programs and serve as a liaison to pharmaceutical companies who support and/or sponsor clinical trials.

Table 4 shows physician perceptions regarding facilitators and barriers to patient participation in clinical trials. The majority of responding physicians had referred patients to a clinical trial. A large percentage of the respondents (80.5%) also indicated a willingness to refer patients in the future. Some reasons physicians did not refer patients for participation included patient fear, poor communication with those conducting the clinical trial, lack of patient understanding of the need to participate and concern by the physician of being removed from

decision-making in the patient's care. A large majority of these minority physicians (79%) felt that minority patients in particular face barriers to clinical trial involvement. Major reasons cited were patient fear of experimentation, lack of minority physician participation on the research team, lack of patient awareness and lack of patient time.

The survey included a clinical investigator interest form. By returning the completed form, the respondent expressed interest in becoming listed in the Project IMPACT database of clinical investigators or interest in being given consideration as a clinical trial investigator. One-hundred-thirty-six of the respondents (68%) indicated a desire to be included in the Project's database.

Project IMPACT Workshops

A total of 84 respondents (42%) participated in Project IMPACT (Figure 2A). The most common reason given for participation was to gather background information on clinical trials. This was followed by the belief that participation would increase opportunities

to become involved in clinical trials. Of those respondents who attended Project IMPACT training programs, 89% indicated that the workshops met or exceeded their expectations. Therefore, the large majority of participants were highly satisfied with the Project IMPACT training programs. More than 90% of the physicians who participated in Project IMPACT also reported that they were satisfied with the course materials.

After attending the Project IMPACT training program, 39 respondents (19.5%) reported that they had become involved with a clinical trial (Figure 2B). Participation in Project IMPACT's clinical trials training programs did not result in a sizeable increase in participation in clinical trials. However, the attitudes of the majority of the respondents (68%) about clinical trials did become more positive after participating (Figure 2C).

COMMENTS

One of the main objectives of Project IMPACT was to encourage minority physicians to assume the role of

Table 2. Physician experience with participation in clinical research and clinical trials (n=200)

Nature of Experience	Frequency	%
Clinical Trial Experience during Medical Training		
Medical school	20	10.0
Residency	38	19.0
Fellowship	35	17.5
Other	16	8.0
No response	91	45.5
Prior Participation in a Clinical Research Study or Clinical Trial	121	60.5
Prior Participation in a Clinical Trial	47	23.5
Currently an Investigator in an Ongoing Study	46	23.0
Previous Role in a Clinical Research Study or Clinical Trial*		
Principal investigator	71	35.5
Investigator or coinvestigator	79	39.5
Coordinator	10	5.0
Patient	9	4.5
Other	5	2.5
Has Current Access to a Clinical Research Coordinator	73	35.5

* Some respondents provided multiple responses

Table 3. Barriers and facilitators to physician participation in a clinical trial (n=200)

Barrier or Facilitator	Frequency	%
Interested in Participating in a Clinical Trial	141	70.5
Invited to Participate in a Clinical Trial	136	68.0
Attempted Participation but Denied	23	11.5
Barriers Faced When Attempting to Participate*		
Lack of access to a clinical research coordinator	57	28.5
Lack of awareness of clinical trials opportunities	86	43.0
Lack of time	75	37.5
Concerns about patient safety	21	10.5
Inadequate reimbursement	37	18.5
Not affiliated with a major academic center	36	18.0
Lack of access to an institutional review board	18	9.0
None	29	14.5

* Some respondents provided multiple responses

investigator in clinical trials. The survey data indicate that most of the respondents worked in predominantly office-based solo practices with limited opportunities to develop research capabilities. Such office-based and solo practices are less likely to have the physician time, resources and infrastructure for effective conduct of clinical research. To develop clinical trials capability in this setting would require the commitment of the physician to set aside adequate time for training and attention to the research, identification and training of a research coordinator, and would require the availability of a well-developed patient information system. This represents a substantial investment of time and financial resources often without a clear indication of the value or return on the investment for physicians and their patients.

Most minority physicians serve communities that are often economically underdeveloped with large patient populations, making the challenges of clinical research appear to be an intrinsic barrier. Ten of the survey respondents practiced primarily in academic settings where adequate clinical trial resources are likely to be available. However, it should be noted that the overwhelming majority of respondents had >6 years of practice experience. This represents a high likelihood of medical/clinical experience and patient availability with the potential to add significant value to the clinical research process. Therefore, a solution which successfully integrates this population of patients and physicians into the clinical research process would represent a substantial contribution to furthering medical knowledge and reducing health disparities. Additionally, effective integration of these populations suggests the potential to speed the clinical research process via accessibility to a new and expanding patient resource that heretofore has been difficult to access.

Although respondents in this study were drawn from a

database comprised of those with a known interest in conducting clinical trials, few had prior experience as clinical trial investigators. Some level of experience is often considered important in the preparation of individuals to serve effectively as principal investigators. Therefore, most were not ready to serve in such roles without further training. The low rates of participation in clinical trials during formal medical education suggests that more attention should be given to enhancing research experiences of medical students, residents and fellows if minority physician involvement in clinical trials is to be increased.

The results indicated that most of the minority physicians in this study desired involvement in clinical trials as investigators and would encourage their patients to participate in appropriate trials. However, given the nature of the database from which these respondents originated, it is likely that they have a greater commitment to participation in clinical trials and thus may not be representative of other African-American physicians who were not part of the database. Although there was a great deal of interest, they still perceived major barriers to their participation as investigators. As noted by other authors,^{13,22,32,33} lack of awareness of clinical trial opportunities remain among the most frequently cited barrier. This finding supports the need for an easily accessible mechanism for learning about the available clinical trial opportunities early during the process of clinical site selection.

The perspective of most of the respondents is that minority patients also face barriers to participation in clinical trials. Most respondents identified patient mistrust and fears, lack of minority physician participation in clinical trials and lack of patient awareness of clinical trials as barriers. These barriers are not new.^{4-5,23} However, they do imply that access to clinical trials information that allows patients to make informed choices about partici-

Table 4. Physician perception of barriers to patient participation in clinical trials (n=200)

Barrier or Facilitator	Frequency	%
Physicians Who Have Referred Patients to Clinical Trials	131	65.5
Reasons for Nonreferral of Patients to Clinical Trials*		
Patient will be lost to other physicians	5	2.5
Poor communication with people conducting trials	9	4.5
Patient fear of participating	10	5.0
Concern about being removed from decision-making	7	3.5
Concern about potential adverse effects	1	0.5
Patient lacks time	6	3.0
Patient does not understand the need to participate	9	4.5
Physicians Willing to Refer Patients in the Future	161	80.5
Number of Physicians Who Believe Minority Patients Face Barriers to Participation in Clinical Trials	158	79.0
Physician Perceptions of Barriers Faced by Minority Patients to Participation*		
Lack of patient time	33	16.5
Lack of patient awareness	116	58.0
Patient fear of experimentation	143	71.5
Lack of minority physician participation	142	71.0

* Some respondents provided multiple responses

pation may offer value. Although most respondents have referred patients to clinical trials in the past and expect to do so in the future, several barriers to physician referrals were identified that could reduce patient involvement. Most of these barriers could also be addressed by making appropriate and understandable information about clinical trials available to both physicians and patients.

Those respondents who participated in Project IMPACT generally had positive perceptions of their project workshop sessions and project educational materials. They were highly satisfied with their Project IMPACT experiences and derived from it improved attitudes about

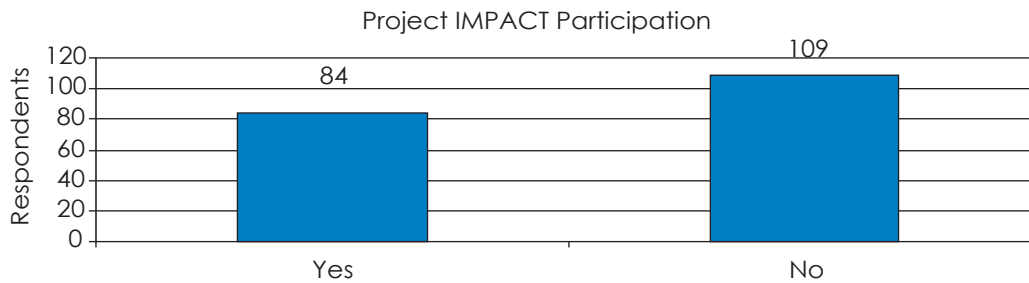
participation in clinical trials. However, it is unclear whether Project participation has improved physician and patient participation in clinical trials. It may be too soon to make a final assessment in this regard. A database of African-American physicians who are interested and willing to become clinical trial investigators has been developed and enhanced by Project IMPACT. The availability of this database to sponsors should contribute to increased minority clinical research participation.

As with all survey research projects, this study had limitations. In some cases, respondents failed to answer all of the questions, which creates the possibility of item

Figure 2. Survey responses regarding Project IMPACT

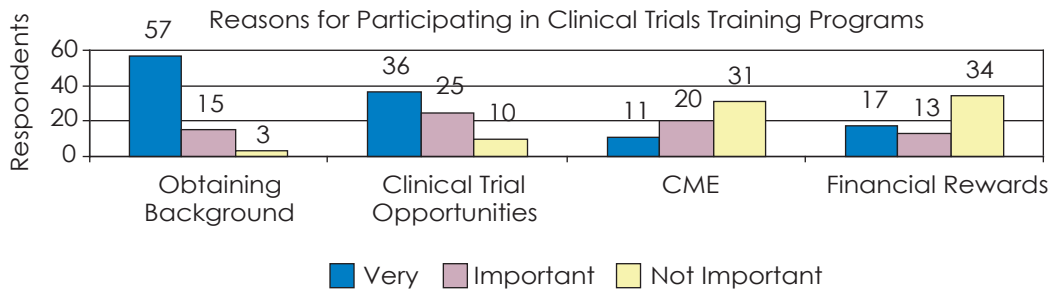
A.

Question 38. Have you ever participated in a Project IMPACT training program? Eighty-four of the respondents (44%) participated in Project IMPACT (n=193).

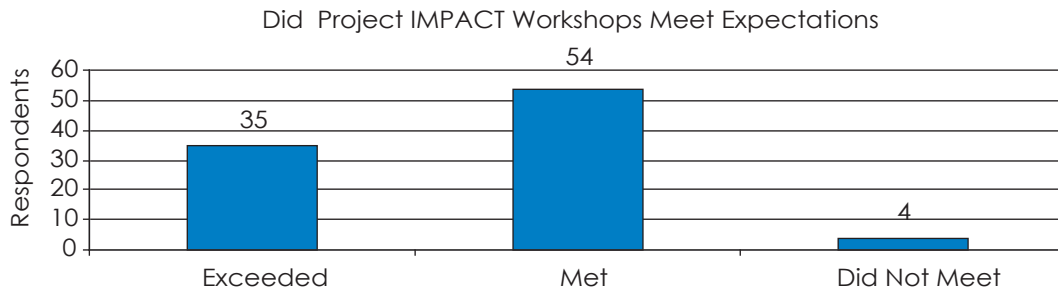


Question 39. Which programs did you attend? The answers varied from the 45-minute to the 2-3 day Good Clinical Practice programs. No significant association was observed between participation in specific programs and responses.

Question 40. How important were the following issues in your decision to participate in clinical trials?



Question 41. Did the clinical trials workshops meet your expectations? (n=93) Some of the respondents who answered no to question 38 answered this question. Variation in definition of a Project IMPACT program may explain the variation in responses. The number of responses for this question is consistent with the number of responses for question 43 and 44.



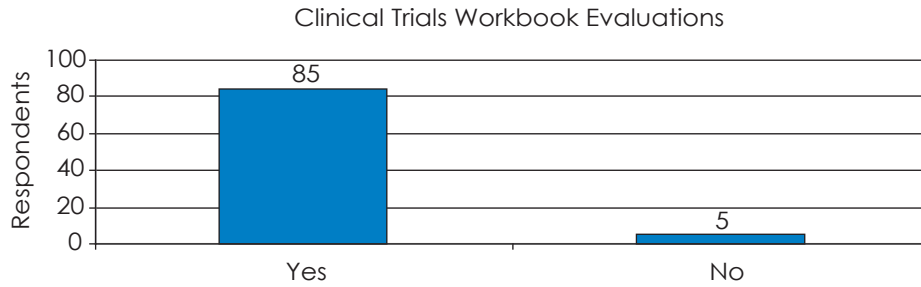
nonresponse bias. Although the overall response rate of 37.5% is good, nonresponse bias may exist if there are differences between the responding and nonresponding phy-

sicians. As with all sample-based research, this study has restrictions on applicability since only physicians who were NMA members were targeted, and physicians who

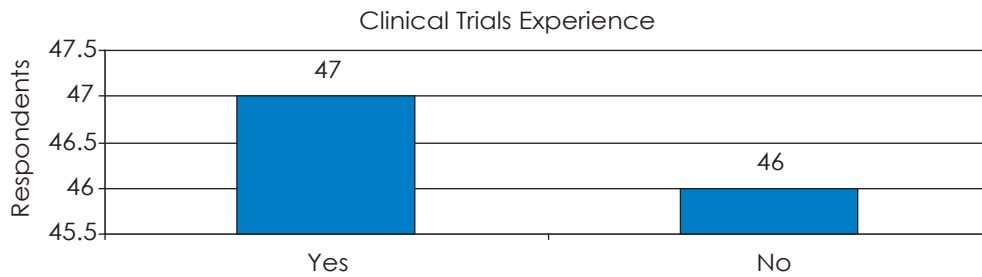
Figure 2. Survey responses regarding Project IMPACT

B.

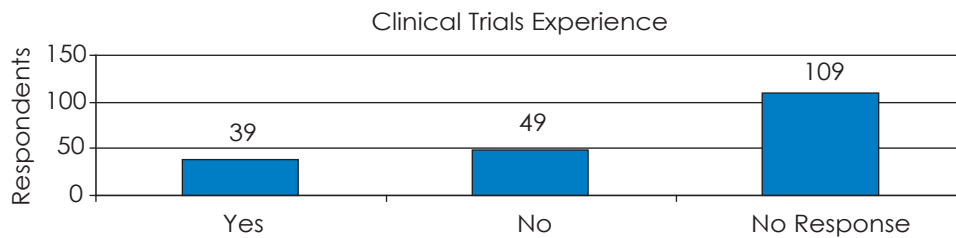
Question 42. Did the workbook meet your expectations? The number of respondents exceeds the number who reported participating in the programs. Some of the respondents to the qualitative interviews reported that they had received course materials but not actually attended a program.



Question 43. Did you participate in clinical trials prior to attending the program? Some of the respondents who answered no to question 38 answered this question. Variation in definition of a PROJECT IMPACT program may explain the variation in responses. The number of responses for this question is consistent with the number of responses for question 41 and 44.

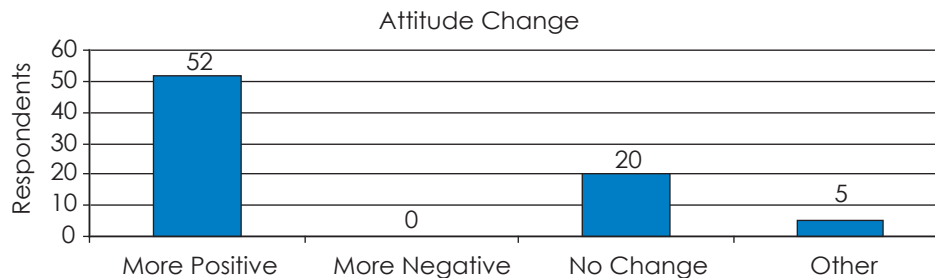


Question 44. Did you participate in clinical trials after attending the program? Some of the respondents who answered no to question 38 answered this question. Variation in definition of a Project IMPACT program may explain the variation in responses. The number of responses for this question is consistent with the number of responses for question 43 and 44.



C.

Question 45. Did your overall attitude change? Fifty-two of the respondents (68%) reported more positive attitude about clinical trials after participating in Project IMPACT (n=77).



had expressed an interest in clinical trials were included. Finally, the authors are aware of the potential for important sample-to-sample variability that influences the applicability of results. While the data may be similar across some samples, other samples may reveal marked differences.

CONCLUSIONS

This study has identified some and confirmed other observations regarding the issues and barriers to minority physician and patient participation in clinical trials. Many of the barriers identified are not new and indicate the need for a new paradigm of support for small medical practice sites to encourage their involvement. The future should also include more attention to the inclusion of clinical trial experiences in formal medical education of physicians and greater access to clinical trials information for both physicians and patients. Although it is unclear to what extent Project IMPACT has increased minority participation in clinical trials, the project participants were highly satisfied with their project-related experiences and training.

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