INCREASING PARTICIPATION OF MINORITIES IN CANCER CLINICAL TRIALS: SUMMARY OF THE "MOVING BEYOND THE BARRIERS" CONFERENCE IN NORTH CAROLINA

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A day-long seminar was held at Wake Forest University School of Medicine to address barriers among ethnic minorities in cancer clinical trials and explore ways that individuals who design and conduct clinical trials could increase minority representation. Speakers addressed implications of under-representation of minorities and identified barriers to minority participation. State-wide focus group results were presented and revealed suspicion of medical research among minorities and the need for bridging to minority communities to improve participation in cancer clinical trials. Working groups assembled and identified barriers specific to trial design, providers, and participants. Attendees were encouraged to devise strategies within their institutions to overcome barriers to minority participation. (*J Natl Med Assoc.* 2002;94:31–39.)

Key words: cancer treatment ♦ clinical trials ♦ minorities ♦ recruitment ♦ barriers

Cancer incidence and mortality data indicate that a disproportionate share of the cancer burden in the United States is borne by ethnic minorities. African Americans have the highest overall age-adjusted cancer incidence and mortality rates of any population group in the United States.[1] Native Americans also have an increased mortality rate for certain cancers.[1] These higher mortality and prevalence rates among various minority groups suggest the need for greater involvement of minorities in large-scale clinical trials to ensure access to and benefit from more advanced cancer treatment.[2] Other research has highlighted the difficulty of generalizing research findings to minorities not included in clinical trial research.[3] However, less than 3% of all patients with cancer enroll in clinical trials, and the participation of minorities diagnosed with cancer is even lower.[4]

Critical to the successful recruitment and retention of minorities in clinical trials is the education of researchers, clinical trial staff and physicians about the cultural barriers that may inhibit minority populations from participating.[4–7] Additionally, it is im-

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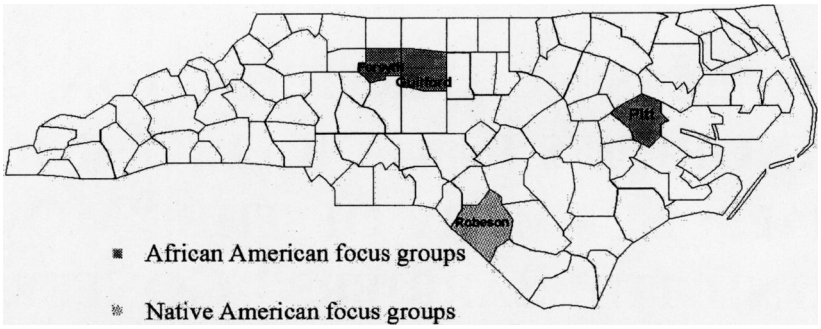

County Sites for African-American and Native-American focus groups.

portant to educate cancer patients and communities about the importance of clinical research for advances in clinical research to be generalized to the entire population. To understand and address that issue, the "Moving Beyond the Barriers: Increasing Minority Involvement in Cancer Clinical Trials" conference, cosponsored by the comprehensive cancer centers of North Carolina and funded by a grant from the National Cancer Institute, was convened. The Conference was held on September 18, 1997 at Wake Forest University School of Medicine in Winston-Salem, North Carolina. The objectives of this paper are to: 1) provide a summary of the state conference, and 2) discuss the implications of conference findings.

SETTING

North Carolina is a state of approximately seven million people with a substantial number of minority and underserved populations, including African Americans, Native Americans and a growing number of Hispanics. The state has three comprehensive cancer centers with a substantial focus on clinical trials. The planning committee for the conference included representatives from these three comprehensive cancer centers, regional cancer centers, two state professional medical societies (NC Oncology Society and Old North State Medical Society), the NC Central Cancer Registry, the NC Advisory Committee on Cancer Coordination and Control, the American Cancer Society, Southeast Cancer Control Consortium, Inc., Department of Health and Human Services (DHHS) Office of Minority Health, and the National Black Leadership Initiative on Cancer. The one-day conference was funded by a grant from the National Cancer Institute (CA-96-015) and financial support from the Comprehensive Cancer Center of Wake Forest University, Duke University Comprehensive Cancer Center, UNC Lineberger Comprehensive Cancer Center, and Leo Jenkins Cancer Center of East Carolina University.

METHODS

The major objectives of the conference were to: 1) understand the impact of low participation rates of minorities in cancer clinical trials; 2) identify the major issues related to minority participation in cancer clinical trials; 3) describe the process of improving access to cancer clinical trials in the region; and 4) identify the necessary steps to increase and improve minority participation in cancer clinical trials.

The conference format included a report on the results of minority focus groups held across the state, a review of findings and experiences of researchers involved in minority recruitment to clinical trials, and a panel discussion followed by four break-out sessions or workshops. Each of the four workshops addressed one of the major barriers to participation—personal/cultural, economic, physician and trial design. The goal of each workshop was to detail the components that contribute to each barrier and develop strategies to address each barrier. Participants were encouraged to draw upon their experiences as well as the literature for solutions to barriers.

Two mandates of the conference were to: 1) produce a set of recommendations on how to improve minority recruitment; and 2) develop a booklet entitled, *In Their Own Voices: People of Color Talk About Clinical Trials.* The booklet describes the qualitative results of the focus groups held in four areas of North Carolina—Winston-Salem, Greensboro, Greenville, and Pembroke (Fig. 1.). These areas were selected to obtain geographic and cultural diversity within the state. Focus group results were recorded,

transcribed and analyzed by one of the authors (A.W.) for key themes and issues to present during the conference.

RESULTS

The conference attracted 97 participants, the majority of whom were hospital based (51%) or worked in a variety of settings, such as social service, educational institutions, or community organizations (33%). Clinical researchers (16%) or research staff (49%) comprised the majority of occupational designations, while 13% of those attending were nurses, and 7% were physicians. Thirty-four percent of attendees were minorities, either African American (30%), Hispanic (2%), or Asian (2%).

Conference Overview

The focus of this conference was to explore ways that individuals who are involved in the design and conduct of cancer clinical trials could increase their awareness of the issues that directly relate to minority populations in order to increase minority representation in research studies. The program was designed to provide participants with an overview of the problem on both national and regional levels, to present information that identified various barriers to participation, and to structure small group problem-solving sessions. The keynote speaker, Dr. Sarah Moody Thomas of the Stanley Scott Cancer Center at Louisiana State University Medical Center, discussed the national implications of minority under-representation in cancer trials. Other speakers presented data from the NC Central Registry on distribution of cancer morbidity and lessons learned from Minority Community Clinical Oncology Programs (CCOPs)—a program to improve minority participation in clinical trials—to demonstrate the degree to which a lack of minority participation is a problem.

To make the information on low accrual of minorities relevant for the participants, prior to the conference, conference planners conducted focus groups with minority cancer survivors to identify factors that contributed to participation or nonparticipation in research. Groups were held in four different cities: Greensboro, Winston-Salem, Pembroke, and Greenville. The findings were compiled in a booklet, "In Their Own Voices," which was distributed to all participants and are reviewed later in this paper. Marion White, Executive Director of the NC Advisory Committee on Cancer Co-ordination and Control, summarized the focus group results at the conference and instructed conference participants to address barriers within three categories: study design (eligibility, allocation of funds for recruitment, staff time for administration of forms, participant incidental expenses); logistics (language, physician education/recruitment, pre-enrollment tests and paperwork, office record prompts); and patient factors (lack of knowledge of trials, attitudes and beliefs, family support, fears of randomization).

Four panelists provided overviews of how trial design, economics, personal and cultural issues, and physician attitudes could each present barriers to participation. Panel members consisted of a Native-American cancer survivor, the director of the regional CCOP, an epidemiologist who was an experienced Principal Investigator on large research studies, and a health educator specializing in cancer prevention and control.

The panel presentations formed the basis for more in-depth discussions in small group workshops, each of which were tasked with addressing a particular barrier identified by panelists. The workshops were repeated in the afternoon, allowing conference participants to attend two different presentations. Each group workshop was facilitated by experts in the areas addressed and instructed to develop workable strategies for overcoming barriers identified from the ideas and experiences of the participants.

The luncheon speaker, Dr. Lovell Jones, Professor, MD Anderson Cancer Center, discussed perceptions of the medical system held by the minority community. Following the afternoon group workshops, the results of the workshop discussions were summarized and presented in the final plenary session by Dr. Electra Paskett of Wake Forest University School of Medicine. Dr. Paul Godley of UNC School of Medicine presented a final call to action based on the day's experiences, requesting that each participant list two specific changes that they plan to implement as a result of the conference. Actions listed by participants are presented in Table 1.

Focus Groups: "In Their Own Voices"

The booklet, " In their Own Voices," summarized the findings of the focus groups conducted prior to the conference. A total of 26 participants (19 Afri-

Table 1

Physician-Related Barriers
- Reduce time required of physician to recruit patient
- Use nursing and ancillary staff to answer patient questions
- Educate physicians regarding importance of research that includes minorities

Economic Barriers
- Lobby for legislation to mandate medical insurance and managed care coverage for experimental therapies
- Stipends to cover other financial costs such as transportation, care-givers

Personal and Cultural Barriers
- Link with community leaders to build community trust of research
- Maintain ongoing relationships with community and develop community involvement with research
- Establish trust with minority patients: hire minority staff; understand and address cultural beliefs that discourage participation in clinical trial research
- Use easy to understand consent forms
- Develop more patient-friendly clinic models with flexible scheduling
- Use community based services for transportation and child care to improve access to clinic

can American and 7 Native American)—18 women and 8 men—volunteered to participate in focus groups to assess knowledge of, attitudes about and participation in clinical trials. Of the focus group participants, 14 (53.8%) had participated in clinical trials and one had a parent who had participated in a study. Focus groups lasted approximately 2 hours and were divided according to ethnicity (four groups were African American and one was Native American), and gender (two groups were with men and three with women). The groups ranged in size from 2 individuals to 10, and the age of participants ranged from 39 to 76 years, with an average age of 51 years. Focus groups were presented with open-ended questions to elicit information about broad issues of basic health care attitudes and practices, religion/cultural issues, and perceived barriers to participation in clinical trial research. All focus groups, except the Greenville focus group, were facilitated by faculty and staff from the Department of Public Health Sciences at Wake Forest University School of Medicine. The Greenville focus group was facilitated by staff from East Carolina University School of Medicine.

Common Themes

Despite the diversity of the focus group participants, both ethnically and geographically, common themes emerged. These were: 1) characteristics of clinical trial participants who participated in the focus groups, i.e., urban residents near a medical center; 2) a preference for providers of the same ethnicity to recommend the clinical trial; 3) altruistic reasons for participation in clinical research; 4) the perception of the "typical" participant, i.e., white, middle class, well-connected in the community; and 5) a general sense of distrust of government-sponsored research and the medical establishment.

Most participants who had been part of a clinical trial came from areas near larger cities and medical facilities, whereas those who had not participated in studies lived in more rural towns and presumably had less opportunity to learn about clinical trials. The predominate reason offered by focus group participants who had never participated in a clinical trial was that opportunity had never been offered. Participants also reported that they preferred health care providers and researchers who " looked like them." This was a significant factor in the individual's willingness to participate in any clinical trial recommended by a researcher or provider.

The primary reason cited for participating in a clinical trial was for the future benefit of loved ones, i.e., children, grandchildren, or others generally. African-American participants in particular, expressed interest in research addressing diseases that have been a problem in that community for several generations, such as diabetes, heart disease, and prostate and breast cancer. Nevertheless, focus group participants did not view themselves as typical trial participants.

A common belief held among participants in all groups was the perception of the "typical participant" in clinical trials. The average clinical trial participant was thought to be white, middle to upper middle class, with at least a high school diploma, and well connected in the community. While some

groups of women thought women were more likely to enter studies because they were patients, one group believed that only men enter studies because physicians are more comfortable talking with men about clinical trials. Generally, the focus groups felt that physicians did not feel comfortable explaining clinical research in lay language and did not want to try.

All groups expressed distrust of the government/medical research establishment. African-American men voiced the greatest distrust, citing the Tuskegee Syphilis Experiment. The male participants believed that the only reason that researchers involve minority communities is to obtain funding available to study problems among African Americans. All groups expressed the opinion that there was perhaps a known cure for cancer but that the "cure" was being withheld from the public to avoid the loss of jobs and money for research. They suggested that an effective way to deal with this mistrust was to work with prominent community leaders and to maintain consistent links to the minority community. They cited as an example, a noted community leader who had "gone public" with his health problem and participation in a clinical trial, and observed that his actions had created a sense of trust among African Americans for the research study. Similar attitudes of distrust were expressed regarding a cure for cancer. Finally, participants agreed on the importance of the medical researchers "giving back" to the community through health fairs, free screenings, and community meetings to report research findings.

Barriers to Participation in Clinical Trials

Each of the focus groups offered their perception of barriers to clinical trial participation. The African-American women cited two key issues—the time required and the unknown effect of taking medication or possibly a placebo. One woman remarked that flexibility of clinic hours, i.e., being offered several options for appointments, was an important factor in her willingness to enter a study. Another woman described a racial incident that resulted from the insensitivity of another study participant. Apart from these issues, however, the women who had participated in clinical trials found the experience to be positive.

The focus groups comprised of Native-American women and African-American men cited no particular barriers to participation when asked directly; however, discussions within the group revealed underlying mistrust of the medical establishment. Another barrier identified in the analysis of focus group discussions was a lack of understanding and knowledge by participants about clinical trial research and why clinical trials are conducted.

Breakout Sessions

Breakout sessions allowed participants to identify barriers to minority participation in clinical trials, based on conference presentations and personal experience. The session also provided the opportunity for the development of strategies to remove barriers. Participants identified barriers within four major classifications: 1) trial design; 2) physician-related; 3) economic; and 4) personal/cultural factors (see Table 1). The results of each breakout session are summarized below.

Trial Design

Participants addressing trial design barriers noted that several facets of a clinical trial—the study design, recruitment plan, operation/implementation, data analysis and reporting results— may present problems to recruitment. First, participants noted that the *study design* may have stringent exclusion criteria that impede the recruitment of minority participants, and should be avoided unless absolutely necessary. Second, studies with exclusion criteria should be modified to improve minority recruitment. Another potential problem of the study design identified in the group workshop was the questionnaire and consent form. Surveys and consent forms are often difficult and/or time consuming to explain or understand, particularly for those patients who have poor language skills. Participants suggested that incorporating appropriate, easy-to-read language or administering the consent form by reading it to the participant could help. Session participants concluded that researchers should shorten questionnaires, eliminate redundancy in consent and survey forms, and test the instruments using advisory boards or focus groups. Finally, the group noted that study designs may fail to draw minority participation because the research may not address health issues of primary concern to the minority community. Rather than imposing research topics on a minority community, participants suggested that researchers provide community edu-

cation, work directly with the community to develop research problems, and be willing to broaden the research focus to improve minority participation.

Similarly, the *recruitment plan* requires building confidence and trust within the community. Workshop participants suggested that researchers invest time in the community, use appropriate communication with minority members, and identify key minority leaders to aid in building trust. Second, the group suggested that minority community members can assist in recruitment, particularly those who may have personal experience with clinical trials. Lastly, session participants identified the need to raise funds, perhaps through lobbying, to support the special efforts needed for minority recruitment.

Four components of *study operation* and *implementation* in the trial design were cited as potential barriers to minority participation: time availability, access to the clinic, communication, and implementation of the questionnaire. Session participants identified several ways to eliminate barriers associated with study operation and implementation. For instance, problems of time availability and clinic access could be reduced with extended clinic hours and child-care and transportation services. Workshop participants noted that transportation services could be available through existing resources, such as churches and schools. When possible, home visits could produce greater participation. Session participants also noted that communication was a key barrier that may require the use of bilingual/minority staff or staff members with an appropriate attitude and level of cultural sensitivity. Similarly, implementation of the questionnaire could require staff training to understand the language patterns.

Finally, workshop reports noted that in the case of *data analysis,* studies must have adequate power to examine the effect on minority populations. Adequate numbers of minorities are needed in the sample to allow for analysis of variations within race and ethnic groups. Participants recommended that once the study results are complete, all participants should be informed of the results either through mailings or community meetings to report the results.

Physician-Related Barriers

Session participants identified several physician-related barriers. First, physicians often lack the time necessary to recruit patients to studies, and may experience difficulty establishing patient trust. Second, the doctor may lack the necessary funds for minority recruitment. Furthermore, physicians will be unwilling to accrue patients to a study they believe to be poorly designed, or they may have a bias about recruiting minorities. Workshop participants recommended that more ancillary or nursing staff could be used to provide information or answer patient questions to address the physician's lack of time to spend on recruitment. They suggested that minority staff can aid in establishing trust among minority patients and that National Institutes of Health funding may be necessary to support the staff needed to implement strategies to improve minority participation. The group noted that physicians must be educated about the importance of minority participation in clinical trials and strategies they can use to reduce physician bias. Finally, session participants advised researchers to seek community assistance in recruitment and provide community education in support of minority participation in research studies.

Economic Barriers

A primary barrier identified in the economic barriers group workshop was the problem of managed care and insurance coverage for clinical trials. For instance, difficulties recruiting patients from health maintenance organizations (HMOs), as well as patients covered under medical insurance were cited, since coverage may not extend to experimental therapies. Limitations may exist as to the types of care and treatment covered or provided for certain insurance plans. Other barriers identified in the session included coverage for caregiver costs, if needed, and transportation to treatment/research centers. Within the medical institution, problems such as long waiting times and staff shortages could require supplemental funds to correct. One strategy to address problems of insurance coverage proposed by session participants was the need for legislation mandating coverage of research studies by insurance companies and HMOs. Finally, session members recommended that financial costs to the patient for transportation and time from work be mediated by providing a stipend.

Personal and Cultural Barriers

Fear and mistrust of the medical community was a primary obstacle to minority recruitment cited by

this workshop group. Strategies offered in the session focused on increasing community involvement and linking with community leaders to address fear and distrust. However, all noted that physicians must work to establish trusting relationships with their patients. In addition, physicians could work with their staff to understand and address, in a culturally sensitive way, the beliefs that discourage minority participation in clinical trials. Consent forms were mentioned as a part of this process and should be written in an understandable, appropriate language style. A third approach cited in the session was to develop new clinic models to eliminate inflexible clinic scheduling problems. Fourth, patients with no experience with clinical trials or understanding of trial results should be informed and educated. Participants mentioned that an ongoing relationship with the minority community and links to community leaders could promote a sense of ownership of the clinical trial within the community. The group suggested that access to care could be enhanced by using community-based services, particularly for transportation, an important barrier to access.

DISCUSSION

The one-day conference on improving minority recruitment held at Wake Forest University School of Medicine in September, 1997 was designed for health care researchers and research staff based in hospitals and health care settings. The format of the workshop combined speakers, results of focus groups held in various locations throughout the state, and participant workshop group sessions.

Barriers were classified as: 1) trial design; 2) physician-related; 3) economic; and 4) personal/cultural. Specific barriers within trial design identified during the conference included stringent eligibility criteria, long, difficult to read and understand consent and survey forms, and protocols that physicians and/or patients do not support or that are difficult to explain and understand. Physician-related barriers highlighted were time limitations to discuss and explain a clinical trial to the patient, a bias toward recruiting minority patients to clinical research, and a lack of awareness of the views and needs of the minority community and their priorities. Economic barriers addressed patient and provider issues, including inadequate funding to take the necessary measures to minority communities and nonexistent medical coverage for participation in clinical trials. Personal/cultural barriers related to the general distrust of medical research by minorities, problems with child/elder care, transportation, and fear of the risk associated with unproven treatments.

Strategies to improve minority participation focused on taking the necessary steps to bridge to the minority community through education, including minorities in design and conduct of research, linking with community leaders, reporting results, hiring minority staff, and using appropriate language in explanations and study forms. Additionally, participants suggested that studies be designed so that communities can support the research, as well as their physicians, and have enough power to demonstrate variation within the minority population studied.

The strategies outlined at the conference are supported by other studies addressing minority recruitment. Much of the research in this area examines the issue from the perspective of patient, health care providers, or the study/design.[4,6,8–11] Patient-related barriers to minority recruitment have been classified as sociocultural/demographic, and economic factors. Sociocultural barriers include low levels of education, rural residence that limits access to health care, language barriers, prior negative experience of the patient's family with the health care system and distrust of government and research scientists—specifically the Tuskegee Syphilis Experiment for African Americans.[5,10,12] These factors also emerged from the minority recruitment focus groups. Similarly, religious beliefs have not contributed to low minority recruitment,[5,6] as noted in the focus group findings presented at the conference.

Conference presenters and participants identified economic barriers documented by Swanson and Ward,[6] who note that time lost from work or other responsibilities as a result of participation, costs of participation not covered by insurance or the study reimbursement, a lack of access to health care, or complete lack of health care as a result of being uninsured or low income can act as economic barriers. One result of economic constraints, poor diet, may lead to comorbidities that preclude clinical trial participation. [6] The issue of comorbidities and clinical trial eligibility was addressed during the conference and has been found in other studies as a study design issue. For instance, Gotay[4] and others[11,13] documented numerous research design fea-

tures that contribute to low minority participation. Research designs limiting participation based on stage of cancer or the presence of comorbidities, as a result, often exclude minority populations.

Other studies have examined physician-related factors associated with poor minority participation. Studies that do not meet normal care standards or the care thought to be appropriate to either the physician or patient may be unacceptable to both.[12,14] The physician's role in recruitment is central to the process, and associated barriers have also been identified. For instance, Baines[12] found that recruitment was impeded when physicians knew little about the study, or were critical of the design. Physicians may feel threatened by studies that "steal" their patients [12], alter the relationship with the doctor [15], or involve new treatments not prescribed by the physician.[6] These problems are significant, as Gotay [4] found in her review of eight studies on patient accrual to clinical trials, which revealed physician-related variables to be the greatest factor in the failure of studies to accrue patients.

Focus group results presented at the conference provided insight into why minority patients decide to enter or remain in studies, but were not always consistent with prior studies. Million-Underwood and colleagues[2] found in a survey among African American men and women that perceived efficacy of the clinical trial was the greatest influence on their willingness to enter the study, whereas focus group participants in North Carolina cited altruistic reasons as a prime motivator. Gorelick and colleagues [16] found that African American participants entered a clinical trial primarily to improve their health and to help others who might develop the condition. Those who either left the study or refused to participate cited concerns over being the subject of an experiment and of government research involving African Americans, another concern raised during the focus groups in this conference.

Several studies [9,17–20] offer strategies to improve minority recruitment similar to those provided during the conference. A central component of any minority recruitment strategy is sufficient advance planning,[20] extensive efforts to establish community awareness, and making personal contacts.[19] Transportation to conveniently located research sites is important for many. Lovato and colleagues[9] recommended the minority-based CCOP as a way to improve minority recruitment, the use of registries to inform both physicians and patients about clinical, work-site screening, minority-directed media coverage, and direct mailing and telephone calls.[9,12]

Gorelick and colleagues [21] and others[18] have proposed accessing the community network to improve African-American recruitment. This includes establishing a community advisory panel and community service coordinator[21] to develop the community awareness network by linking with government and community civic and religious organizations. Paskett and colleagues[18] identified eight strategies to increase participation by African Americans in cancer control studies. The first of these is to fully and accurately define the target population for recruitment, using criteria that are representative of the population for a given condition under study. The strategy also involves including members of the target population by: 1) recruiting in the planning stages to assist with the development of successful recruiting strategies and opening networks by establishing community advisory boards, focus groups; 2) using established community organizations and networks; 3) enlisting a community spokesperson; and 4) ensuring that the community receives benefit from the research. Staff sensitivity to the issues and concerns of the target population and public education of the target population about the importance of prevention and early detection are also essential.

Literature addressing Native American participation in clinical trial and other medical research stresses community involvement through participatory research[22–26] extending through the entire research process.[25] The need for extensive outreach and commitment to community involvement is the result of mistrust and concerns about anonymity and government intervention among Native American peoples,[7,27] as well as a lack of understanding and knowledge about clinical trials.[7]

The workshop provided participants with the basic information and tools to begin actively targeting minorities for clinical trial participation. Limited time for the seminar precluded detailed assessments and strategy development for each institution represented; however, the conference results provide a model for education of researchers on a regional level to begin increasing minority participation in medical research.

CONCLUSION

The one-day seminar targeted researchers and providers in an effort to provide background on the problems involved in minority participation in clinical trial research and to address ways to improve minority participation. The conference highlighted the need to involve minorities in clinical trial research through community education and building relationships with patients and communities, particularly community leaders. Finally, the conference underscored the fact that to gain minority participation, providers, health care staff, communities, and state and national governments must commit the necessary resources to those communities (i.e., funding, services).

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