New Strategies to Get Minorities to Participate in Clinical Trials

Developing strategies to increase minority involvement in clinical trials

SUMMARY

The Endocrine Society developed recommendations designed to increase minority participation in clinical research undertaken to discover new biomarkers of disease and to develop medications and technologies to treat illnesses.

Key Recommendations

- All stakeholders—including the Food and Drug Administration (FDA), the National Institutes of Health (NIH), Congress and researchers from both pharmaceutical companies and academia—should:

  - Hold a summit to reach consensus on definitions of ethnicity and race as well as guidelines on the appropriate participation rates in clinical trials of various racial and ethnic groups. Participation rates may vary, depending on the specifics of a given study, because some diseases are more prevalent in certain population subgroups than others.

- The FDA should:

  - Adopt, and then require clinical researchers to adhere to, guidelines on minority participation rates in clinical trials.

- The NIH should:

  - Provide grants to entrepreneurs who want to set up companies dedicated to recruiting diverse populations to participate in clinical studies. These companies could be modeled after contract research organizations, which recruit physician's practices—and their patients—for clinical trials run by pharmaceutical companies.

Funding

The Robert Wood Johnson Foundation (RWJF) supported this project with a $50,000 grant from June 2006 until March 2008.
THE PROBLEM

Increasing the number of minority participants in clinical research studies is an important way to address disparities in health care, according to NIH guidelines on the inclusion of women and minorities in clinical research. This is because a given medical treatment may not work exactly the same way in all population subgroups. Therefore, the best way to ensure the efficacy and safety of a new treatment for all is to study its impact on a diverse group of patients.

The FDA, which approves new therapeutic medications for commercial sale, has not issued specific regulations on participation rates of minorities in clinical trials, but has suggested that pharmaceutical companies follow the definitions of race and ethnicity used by the U.S. Office of Management and Budget, according to a 2005 FDA report.

Some researchers have suggested that minority distrust of clinical trials—perhaps fueled by ethical abuses in the Tuskegee Syphilis Study and other studies—makes it difficult to recruit minority members to participate in clinical trials. Others believe that may not be the case. A research team led by David Wendler, PhD, of the department of clinical bioethics at the National Institutes of Health Clinical Center analyzed the participation decisions of 70,000 individuals from 20 medical studies. They found no statistically significant difference between minorities and non-minorities in their willingness to participate in the studies when asked to do so by their physician. The problem is simply that minorities are less likely than non-minorities to be made aware of opportunities to participate in clinical trials, the researchers concluded in their report, published in *PLoS Medicine* (Available online).

THE PROJECT

In 2006, the Endocrine Society launched a program to create and then publicize recommendations on how to increase the participation of minorities in clinical research projects undertaken to discover new biomarkers of disease as well as to develop new medications and technologies to treat illnesses.

The society kicked off the project at a dinner during its annual convention, ENDO 2006, in June 2006 in Boston. About 50 people attended.

Over the next year, a 21-member task force worked via teleconferences and e-mails to reach consensus on a set of recommendations, which were released to the public at the ENDO 2007 meeting in Toronto. The society staged an informal dinner roundtable, composed of task force members, which 50 people attended. The society also hosted a formal symposium on the recommendations during ENDO 2007, which 75 people attended.
The task force members were academic researchers, pharmaceutical company researchers, Endocrine Society staff and current and former scientists and administrators from the National Institutes of Health and the Food and Drug Administration.

**Communications**

To publicize the recommendations, the Endocrine Society provided a variety of resources. (See the Bibliography.) These included:

- A website, which served as a central repository for a white paper, commentary and other materials.
- A white paper, "Increasing Minority Participation in Clinical Research," which was published in December 2007. (Available online.)
- A commentary on the white paper, which was published in the December 2007 issue of The Journal of Clinical Endocrinology & Metabolism.
- A summary of the white paper.
- A patient fact sheet, which was published by a sister organization, the Hormone Foundation. (Available online.)

**Other Funders**

Novo Nordisk, a pharmaceutical company based in Copenhagen, contributed $5,000 to pay for the project's kickoff dinner in 2006.

**RECOMMENDATIONS**

The white paper, "Increasing Minority Participation in Clinical Research," (available online), included the following recommendations:

- **All stakeholders—including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), Congress and researchers from both pharmaceutical companies and academia—should:**
  
  — Hold a summit to reach consensus on definitions of ethnicity as well as guidelines on the appropriate participation rates in clinical trials of various racial and ethnic groups. Participation rates may vary, depending on the specifics of a given study, because some diseases are more prevalent in certain population subgroups than others.

  — Build a network of community-based physicians who care for patients from diverse racial and ethnic backgrounds. Educate this network of physicians on how to recruit patients to clinical trials as well as the role community physicians play in the clinical trial process.
• **Congress should:**
  - Enact legislation to require the inclusion of minorities in clinical trials as part of the approval process for new medications and technologies.
  - Provide tax incentives or patent extensions to companies that comply with requirements for inclusion of minorities in clinical trials.

• **The FDA should:**
  - Adopt and then require clinical researchers to adhere to guidelines on minority participation rates in clinical trials.

• **The NIH should:**
  - Provide grants to entrepreneurs who want to set up companies dedicated to recruiting diverse populations to participate in clinical studies. These companies could be modeled after contract research organizations, which recruit practicing physicians—and their patients—for clinical trials run by pharmaceutical companies.
  - Maintain a registry of community physicians with patient populations from minority groups.

**LESSONS LEARNED**

1. **When launching a task force of volunteers, it is important to host an initial face-to-face meeting to build personal relationships and commitment to the project.**
   In an effort to save money, the Endocrine Society's task force conducted all business via teleconferences and e-mails. But some task force members dropped out after a couple of conference calls and had to be replaced. To solve the problem, the project team kept recruiting new volunteers until they had a core group of task force members in place. The project director said all concerned agreed it would have been much more efficient to have an initial face-to-face meeting of task force members to achieve commitment to an action plan. (Project Director/Alexander-Bridges)

**AFTERWARD**

The research team gave a poster presentation at the "NIH Summit: The Science of Eliminating Health Disparities," held December 16–18, 2008, in National Harbor, Md.

In February 2009, the Endocrine Society submitted comments to the FDA in response to the agency's January 2009 notice, "Participation of Certain Population Subsets in Clinical Drug Trials; Request for Comment."
BIBLIOGRAPHY

(Current as of date of the report; as provided by the grantee organization; not verified by RWJF; items not available from RWJF.)

Articles


Reports


Grantee Websites

www.endo-society.org/advocacy/health_disparities (no longer available). The Endocrine Society created this website to house products from the grant, including white paper, commentary, news release and patient's guide to participating in clinical trials.