

Improving the clinical trials system

AFTER the Institute of Medicine (IOM) released a report last month on the weaknesses of Cooperative Group cancer clinical trials, the National Cancer Institute (NCI) discussed four main measures it would take to improve the system in its May 2010 NCI Cancer Bulletin.

The IOM report, A National Cancer Clinical Trials System for the 21st Century, recommends that NCI increase enrollment in clinical trials, expand insurance to cover the cost of the trials, encourage doctors to improve clinical communication, and take action to diversify clinical cancer research.

EXPANDING INSURANCE COVERAGE

Many patients who qualify to participate in clinical trials do not enroll or enroll but then drop out because their insurance companies will cover a standard treatment but not a clinical trial treatment, according to the NCI Cancer Bulletin.

In response, 33 state governments and the District of Columbia have adopted laws that address the coverage of clinical trials or require that insurers cover them. Medicare and the US Department of Defense, through its TRICARE health insurance plan, now also cover such costs.

Despite the progress, the report noted that some issues still need to be clarified, particularly addressing some of the gaps in coverage at the state level and



identifying what the term *routine care* encompasses.

IMPROVING DOCTOR-PATIENT COMMUNICATION ABOUT TRIALS

Only 3% to 5% of adult cancer patients participate in clinical trials, but no one knows how many patients are offered the chance to participate in one, the report found.

In a 2008 study, researchers found that 75% of patients chose to enroll in a trial when they were explicitly offered one, yet only 20% out of 235 patients recorded during the study received explicit offers.

Doctors can increase communication by becoming aware of their own psychosocial barriers, such as doubt about patients' willingness to take a randomly assigned treatment.

According to the report, more patients could participate in trials if doctors had access to a system, such as tablet computers, that would help them quickly identify which patients are eligible

Tablet computers could help doctors to identify patients eligible for trials.

for which trials. Training programs, such as those developed by the Education Network to Advance Cancer Clinical Trials (ENACCT), may also increase enrollment by familiarizing patients with clinical trials.

DIVERSIFYING CLINICAL CANCER RESEARCH

Close to 90% of those who do enroll in NCI clinical trials are white, with Hispanics and Latinos accounting for only 5.6% of that amount, the report found. This means that minority, elderly, and other underserved patient populations receive less cutting-edge care.

According to the report, community-based programs such as NCI's Division of Cancer Prevention's Minority-Based Community Clinical Oncology Program (MB-CCOP) largely help recruit minority populations at cancer centers, university centers, and community programs.

If health care providers target specific sociodemographic factors that prevent underrepresented groups from joining clinical trials, they can improve the situation.

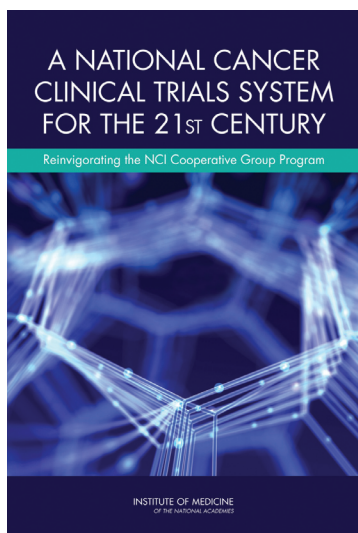
OVERCOMING AGE LIMITS

Enrollment in clinical trials is especially low for adolescents and young adults (AYA) ages 15 to 39 years. Inadequate health insurance, lack of access and referrals to specialized centers, and lack of physician knowledge about trials for this age group all heighten the problem.

To solve the problem, AYA patients should enroll in clinical trials created specifically for their age group that ensure pediatric treatments are not too toxic for them. Physicians can increase AYA participation by referring such patients to comprehensive cancer centers, which are most familiar with age-appropriate trials.

Despite these problems, the report noted that more physicians and researchers have recently begun studying AYA cancers, which translates into more clinical trials and research for this age group.

It found that physicians should also focus on recruiting adults older than 65 years, who may not enroll in trials due to lack of transportation, lack of data showing that such treatments increase survival, or previous health conditions such as diabetes that make them ineligible for trials. To improve, the bulletin noted, trials shouldn't include prior malignancies if there is no reason not to. ■



The Institute of Medicine report on cancer clinical trials

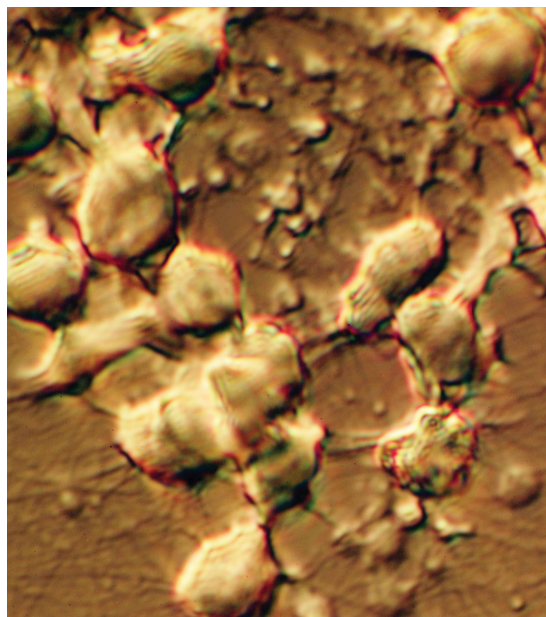
Disparities across gender and race for BM transplantation

AFRICAN-AMERICANS and women are less likely to undergo bone marrow transplantation to treat their cancer, according to a study published in *Cancer* (2010 May 24 [Epub ahead of print]).

To investigate why disparities exist in access to bone marrow transplantation, a team of researchers estimated the annual incidence of leukemia, lymphoma, and multiple myeloma in the United States in people aged 70 years or older. In addition, information on hematopoietic stem cell transplantation (HCT) use was obtained from 1997-2002 data from the Center for International Blood and Marrow Transplant Research.

According to background information provided in the study, HCT is a relatively new treatment that is costly and generally requires lengthy, intensive hospitalization and prolonged follow-up care.

The results of the analysis revealed that whites are 40% more likely to use HCT to treat leukemia, lymphoma, and multiple myeloma compared to African-Americans. Additionally, African-Americans were found to have lower rates of HCT using either their own bone marrow cells or the cells from a donor, which the authors suggest indicates that donor availability cannot fully explain the racial differences seen in the treatment with HCT. "There is a shortage of bone marrow donors who are



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These freshly harvested cells will be used to repopulate the bone marrow of a cancer patient after therapy.

of African-American race. This study may raise the awareness of becoming a bone marrow donor in the minority community," said Thomas Joshua of the Medical College of Georgia and one of the study's researchers.

The researchers also found that men are 10% more likely than women to receive HCT using their own bone marrow cells for reasons that cannot be explained by age or cancer severity.

"Although the reason for this gap cannot be explained by this study, it suggests that the health care system in the United States should endeavor to improve access for all patients while waiting for further studies to better explain the differences and suggest better strategies to reduce the disparities," the authors noted. ■

Melanoma associated with indoor tanning

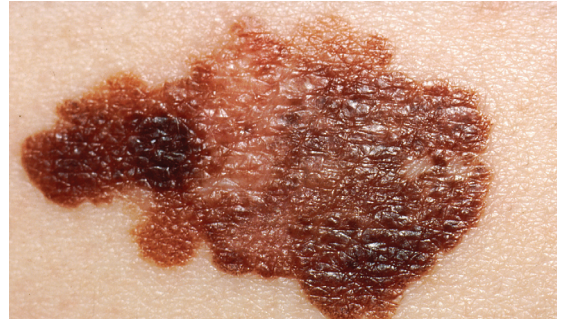
INDOOR TANNING may increase the risk of melanoma, according to researchers from the University of Minnesota's School of Public Health and Masonic Cancer Center.

The study, led by DeAnn Lazovich, PhD, an associate professor of epidemiology at the School of Public Health and coauthor of the Masonic Cancer Center's Prevention and Etiology Research Program, involved 1,167 people with diagnosed melanoma and 1,101 people without melanoma (*Cancer Epidemiol Biomarkers Prev.* 2010;May 26[epub ahead of print]). Among the participants, 62.9% of those with melanoma and 51.1% of those in the control group had tanned indoors. Participants completed a self-administered questionnaire,

followed by a detailed one-hour telephone interview. Frequent use of tanning devices was defined as use of indoor tanning for 50 or more hours, more than 100 sessions, or for 10 or more years.

Researchers found that no tanning is safe, regardless of age, gender, or device. Specifically, people who used any type of tanning bed for any amount of time were 74% more likely to develop melanoma, and frequent users of indoor tanning beds were 2.5 to 3 times more likely to develop melanoma than those who never used tanning devices.

"We found that it didn't matter the type of tanning device used; there was no safe tanning device," said Dr. Lazovich in a press release. "We also found—and this is new data—that the risk of getting



A typical melanoma lesion

melanoma is associated more with how much a person tans and not the age at which a person starts using tanning devices. Risk rises with frequency of use, regardless of age, gender, or device."

According to background information provided by the study authors, melanoma accounts for only about 4% of all skin cancers but causes about 79% of all deaths from skin cancer. ■

New database ranks sunscreen products for safety

THE ENVIRONMENTAL Working Group (EWG) has released an analysis of the safety and effectiveness of more than 700 sunscreen products and developed a database based on these findings to help rate the best products.

According to background information provided in a press release, the FDA has not finalized comprehensive sunscreen standards that have been in development for 29 years. When complete, these rules will standardize a rating system for UVA protection and will prohibit use of misleading and inaccurate claims such as "waterproof" and "lasts all day,"



Some sunscreens may be safer and more effective than others.

which are commonly found on sunscreen products.

The EWG's analysis was based on nearly 400 peer-reviewed studies of the 17 sunscreen chemicals approved for use in the United States, an analysis of sunscreen ingredient toxicity linked to 60 industry and government databases on chemical hazards, and product-by-product assessments of protection from both UVA and UVB radiation.

Researchers found that 84% of 785 sunscreen products with an SPF rating of 15 or higher fail to offer adequate sun protection or contain hazardous ingredients. "Ironically, some popular

sunscreen chemicals break down when exposed to sunlight and must be formulated with stabilizing chemicals," the authors revealed.

"Our research shows that some products are far more effective than others, while presenting fewer safety concerns," said Jane Houlihan, vice president for research at EWG. "Before we launched this Web site, the consumer had no way to identify the safest and most effective sunscreens."

For the complete list of sunscreen products rated by the EWG, visit the database Web site at www.ewg.org/sunscreen. ■