Medical Xpress

Penn docs find successful strategy to expand patient participation in hard-to-enroll clinical trials

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Clinical trials are key to finding new cancer treatments, but with patient participation hovering around 5 percent, new strategies are needed to boost enrollment, particularly to study the rare cancers that have so few cases. One such strategy comes from a new abstract being presented October 28 at the 15th World Conference on Lung Cancer from researchers at Perelman School of Medicine at the University of Pennsylvania studying mesothelioma.

Results from a willingness to participate study, led by Charles B. Simone, MD, chief of Thoracic Oncology and assistant professor of Radiation Oncology at Penn's Abramson Cancer Center, found that focusing on particular factors—including hope for positive outcomes, randomization and altruism— and increasing the time spent with patients increased their likelihood of participating in a clinical trial for malignant pleural mesothelioma (MPM), a rare cancer often diagnosed in people who have been exposed to high levels of asbestos.

"Spending time with patients to thoroughly discuss the details, logistics, risks and benefits of enrollment can allow patients to have a better understanding of the proposed study, empower patients, and make them more likely to consider enrollment," said Dr. Simone. "Furthermore, identifying factors that may serve as obstacles to enrollment of a proposed study is critical and can help to tailor the discussion that researchers have with patients to address, substantiate, or alleviate their

potential concerns."

The team, including Joseph S. Friedberg, MD, chief of the division of Thoracic Surgery and co-director of the Penn Mesothelioma and Pleural Disease Program, demonstrated unusually good results treating MPM with radical pleurectomy (RP), intraoperative photodynamic therapy (PDT), and chemotherapy. To establish if PDT is contributing to the results, a randomized trial of RP with and without PDT is needed. However, finding patients to enroll in such a trial is difficult.

To see if they could conduct the trial, the researchers conducted the willingness to participate study.

Patients with MPM who were candidates for RP plus PDT were enrolled. A total of 25 patients participated in structured interviews, reviewed a written description of a hypothetical randomized controlled trial comparing RP to RP plus PDT, answered open-ended and focused questions regarding their motivations for and concerns about enrollment, and completed a written questionnaire. Willingness to participate was assessed using a 6-point scale: 1=definitely not, 6=definitely.

Once factors were identified in eight patients, researchers trained physicians to spend more time talking about these factors with subsequent patients, and the length of time physician spent discussing the trial increased from 3 minutes to 9 minutes. Such factors included hope for positive outcomes, explaining the randomization process, physician's opinion, and altruism towards other patients. Focusing on such factors in the latter group resulted in a more willingness to participate: 71 percent of subsequent patients stated they would "definitely" or "probably" participate, as opposed to only 25 percent in the first group.

"Performing a willingness to participate study should be considered

before a planned prospective clinical trial, especially for orphan diseases and rare conditions that are typically associated with poor clinical trial accrual," said Dr. Simone.

More information: This study is one of 13 Penn Medicine studies and talks being presented at the International Association for the Study of Lung Cancer's 15th World Conference on Lung Cancer: www.2013worldlungcancer.org/

Provided by University of Pennsylvania School of Medicine

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