

New precision medicine guidelines aimed at improving personalized cancer treatment plans

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Tuesday, Jan 19th, 2016, Cleveland: A committee of national experts, led by a Cleveland Clinic researcher, has established first-of-its-kind guidelines to promote more accurate and individualized cancer predictions, guiding more precise treatment and leading to improved patient survival rates and outcomes.

These new guidelines are changing the traditional approach of <u>cancer</u> staging methods for cancer treatment. The new risk calculators - which will complement the existing staging system - will enable physicians to more accurately and precisely determine the best treatment for individual patients.

The American Joint Committee on Cancer (AJCC), which is responsible for periodically evaluating and updating the cancer stages, has acknowledged that cancer stages are imperfect, and it is committed to enhancing the system with more prognostic, statistically based risk calculators in 2016.

In preparation for these changes, the AJCC invited a group of top healthcare statistical experts from across the country to form the Precision Medicine Core (PMC). Led by Michael Kattan, Ph.D., MBA, chair of Cleveland Clinic's Department of Quantitative Health Sciences at Cleveland Clinic's Lerner Research Institute, the group discussed characteristics necessary for developing a quality risk model in cancer



patients. The emphasis centered on performance metrics, implementation clarity, and clinical relevance.

"This represents a new paradigm shift for the future of cancer treatments," Kattan said.

The new guidelines will be published in the highly esteemed journal *CA*: A Cancer Journal for Clinicians on Tuesday, January 19th, 2016.

The Precision Medicine Core (PMC) was tasked with developing a criteria checklist to evaluate possible cancer risk calculators and determine which calculators will be endorsed by AJCC. The group identified 13 inclusion and 3 exclusion criteria for AJCC risk model endorsement in cancer. The following cancers will be the first to be evaluated for existing prediction models: breast, colon, prostate, lung, melanoma, and head and neck cancer, with the goal being to comprehensively include all cancers in the future. The PMC consists of researchers from Cleveland Clinic, The University of Texas MD Anderson Cancer Center, Cedars-Sinai Medical Center, Stanford University, UMC Utrecht, The Netherlands, University of Pennsylvania, Duke University, Sage Bionetworks, Queen's University, University of Illinois Hospital & Health Sciences System, Mayo Clinic, Memorial Sloan Kettering Cancer Center and Arizona State University.

The formulas must predict overall survival or death from a particular type of cancer and have to pass all 16 criteria. "Our checklist should open the door to a wave of statistical prediction models that get used clinically across many different cancers," said Kattan, a pioneer in the development of cancer risk calculators called nomograms. "It could potentially be applied outside cancer as well - anywhere statistical prediction models are being considered for widespread usage."

The current cancer staging system (stages I-IV), otherwise known as



TNM, has been used for decades and is a simple way to universally assess cancer progression in patients around the world. However, many believe that the system is outdated, lumping all cancer patients into 4 stages, which do not account for individual differences in risk factors—such as genetics, age, gender, and lifestyle. As a result, a patient who is, for example, a "bad" stage 3, might be undertreated for a cancer that is likely to metastasize. On the other hand, a "good" stage 3 patient might receive more aggressive treatment than is necessary, which can lead to toxic side effects on the heart, kidneys or other organs.

Now that the guidelines have been established, researchers across the world will be invited to submit their cancer risk formulas for review by AJCC, with the potential of changing the face of cancer treatment for millions of people worldwide.

"When the models get into physicians' hands, the way patients are treated and managed and counseled will be forever changed for the better," Kattan said. "This is truly a great example of how precision medicine will help cancer patients in the not so distant future."

The next step will be distribution of this checklist, as well as the process, to authors of <u>prediction models</u>. They will then be invited to submit their models for consideration.

According to the American Cancer Society, in 2016 there will be an estimated 1,685,210 new cancer cases diagnosed and 595,690 cancer deaths in the U.S. Cancer is the second most common cause of death in the U.S., exceeded only by heart disease, and accounts for nearly 1 out of every 4 deaths.

Provided by Cleveland Clinic



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