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Molecular-guided therapeutic trials in pediatric cancer

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A fundamental challenge in the area of targeted cancer treatment is how to identify optimal therapeutic combinations that can treat heterogeneous tumors that are both highly adaptive and that exhibit significant inter- and intra-patient variation. Our research program outlines an approach by which we can utilize our expanding knowledge of molecular networks and the mechanisms of action of a growing pharmacopeia to deliver targeted combinations of effective therapies to pediatric cancer patients. The primary objective of our studies have been to evaluate the feasibility and safety of using predictive modeling based on genome-wide mRNA expression profiles and DNA mutations of tumor biopsies to make real-time treatment decisions. Our initial study has shown that the total time from date of biopsy to tumor board was 6-11 days (95% CI: 7.5-10.2) and 7-20 days to treatment (95% CI: 8.9-16.1). The tumor board, which consisted of pediatric oncologists from 15 sites across the US, pharmacists, bioinformatians, pathologists, created individualized therapy regimens for all subjects. Tumors were grown in culture and in mice xenograftsfor validation studies of predicted drug sensitivity. This study has shown that it is feasible to obtain real-time genomic profiling for molecularly guided therapy for use in treatment decision making. All regimens were safe without any unexpected serious adverse events proving that the molecular tumor board is able to make safe decisions similar to hospital tumor boards making treatment decisions without molecular information on the patients. The program is expanding to include DNA exome and RNA sequencing analysis.

Biography

Giselle Sholler, MD, MSc is currently the Chair of the Neuroblasotma and Medulloblastoma Translational Research Consortium. She is the Haworth Family Endowed Director of Innovative Therapeutics Clinic and Head of the Pediatric Oncology Translational Research Programin Pediatric Oncology at Helen DeVos Children's Hospital, Grand Rapids, MI as well as Associate Professor in the College of Human Medicine at Michigan State University, Grand Rapids, MI. She received her MD from New York Medical College, in Valhalla, NY. She was a resident in pediatrics and, subsequently, a fellow in pediatric hematology/oncology at Brown University, before coming to international prominence for her work with relapsed neuroblastoma at the University of Vermont. She then transferred her program to Helen DeVos Children's Hospital, Grand Rapids, MI. As Haworth Endowed Director of the Innovative Therapeutics Clinic, she focuses on early phase clinical trials for pediatric cancers. Her lab research at HDVCH is focused on neuroblastoma and identifying new therapies through preclinical development leading to Phase I clinical trials as well as genomic analysis of tumors for children. With the NMTRC, she opened the first FDA-approved personalized medicine clinical trial in pediatric oncology and has expanded this across 15 centers across the US.

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