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Challenges for Conducting Clinical Trials for AIDS Malignancies in Resource-Limited Settings

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In this issue of *Current Opinions in Oncology*, Dr. Susan Krown, the Vice-chair for International Programs of the AIDS Malignancy Consortium, discusses some of difficulties in conducting clinical trials for AIDS-associated Kaposi's sarcoma in Sub-Saharan Africa (SSA). Similarly, barriers and difficulties in the treatment of cervical cancer in resource-limited settings are discussed in the paper by Dr. Lynette Denny. Given the broad extent and severe impact of these tumors on individuals with HIV infection in Africa, more information on optimal and pragmatic treatments of these tumor in SSA is critically needed.

Recently, the AIDS Malignancy Consortium (AMC) has undertaken the task of establishing a network of clinical trials sites in four countries in SSA to begin conducting multinational clinical trials specifically to treat and prevent cancers in individuals with HIV infection in this part of the world. This effort was initiated because of the growing incidence of cancer in AIDS and as a cause of morbidity and mortality. Using the initial infrastructure created by the National Institutes of Allergy and Infectious Diseases (NIAID) and the AIDS Clinical Trials Group (ACTG) to support trials for HIV in resource-limited countries, the AMC helped develop two trials to treat AIDS-related Kaposi's sarcoma (AMC066-ACTG 5283 and AMC067-ACTG 5264) which has begun enrolling subjects. At the same time, we undertook a process to select a few sites to serve as initial cores sites of the AMC to undertake additional studies in other areas of AIDS malignancies and cancer preventions. These sites have now been selected, and the sites are being integrated within the framework of the AMC.

Much has been written about the great disparity in treatment outcomes and survival of patients with cancers in high-income vs low- or medium-income countries which have highlighted the need for improvements in treatments, supportive care, earlier diagnostic capabilities and treatment follow-up of patients with cancers. Additionally, conducting clinical trials and interpreting the results of these trials in the context of different social, financial and public health constraints in these resource low-income countries have made it difficult to determine the best strategies of dealing with cancers in this setting. Nevertheless the needs are great and the opportunity to contribute to substantial

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improvements in health outcomes is large. In addition to having a clear and major impact on the standard-of-care for many of the AIDS-defining cancers, the AMC hopes to help improve the research infrastructure (clinic facilities, laboratories, data and specimen acquisition and storage capabilities, QA/QC procedures, etc) at these sites for future cancer clinical trials and to help facilitate training and retention of cancer-trained investigators, pathologists, research pharmacists and study staff at these sites and within these countries. Differences in clinical presentations of cancers, on the pathogenic pathways of malignancies and Information on possible genetic or environmental factors that may impact response to therapies and clinical outcomes will provide much needed clues about differences in cancer development and treatment that may only be possible in places with higher incidences of some of these tumors.

At the same time, we recognize the challenges to setting up and conducting these trials in some parts of SSA where trained and qualified investigators and research staff may be lacking, where data management systems may be primitive or non-existing and where even reliable internet connections and backup power sources may be difficult to acquire or in short supply. Add to this the multiple layers of local and national regulatory review/approvals that are required, difficulties in acquiring and distributing drug supplies, the ability to standardize and assure proper and uniform specimen collection/storage/transfer and pathology review (both local and central review), the challenges of monitoring and conducting QA/QC at the various sites and the difficulties in communicating between US and African investigators due to time and language differences, and we clearly have many obstacles to overcome. Also, unlike the early effort to improve HIV care and to make widely available antiretroviral therapies in many resource-limited countries, efforts to disseminate treatments for malignancies in HIV has been hindered by the widespread perception by patients, family members and even government officials, that cancer is incurable and that treatment provides little benefit to individuals given the late stage of presentation of many cancers and the relatively high cost of treating patients with these diseases.

Yet we must persevere in our efforts to improve cancer clinical care and cancer clinical trials capacity in this setting, not only because it is the right thing to do, but also because only with a healthy and vibrant population and a contributing scientific community can we better improve the standard of living in all parts of the world and expand our understand and ultimately the control of this growing cause of worldwide mortality.