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## Development and Testing of Circulating-Free Methylation DNA as a Prognostic Biomarker for Recurrent Kidney Cancer

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PUBLIC ABSTRACT

Kidney cancer is among the most common cancers in the United States, where approximately 65,000 individuals will be diagnosed with the disease by the end of the year 2018, and 15,000 individuals will die. Most of the kidney cancer cases are localized, meaning the tumor is less than three inches and has not spread outside the kidney. The preferred treatment for most people with localized renal cell carcinoma (RCC) is surgery to remove part, or all, of the kidney, if necessary. After surgery, up to 4 out of 10 individuals may have their cancer recur after surgery. However, there is currently no way of telling precisely who will experience a recurrence. The measures that doctors currently rely on do not provide an accurate identification of those most likely to recur. This is why most doctors recommend regular follow-up visits, and national guidelines advocate for rigorous check-ups after surgery to monitor for signs that the cancer has returned. While there are many medical treatment options available for patients who have a kidney cancer return after surgery, the current evidence suggests that medical treatment for all individuals after surgery is largely ineffective. In consequence, the medical and research community are working towards developing a tool that can better help clinicians identify those who are more likely to recur, in other words, a tool that can more precisely narrow down those four individuals whose cancer will come back. In the last years, tremendous progress has been made with regard to the treatment of patients diagnosed with kidney cancer. For those where the disease has spread throughout the body, we now have an array of treatment options and strategies. For localized disease, a lot of research has been dedicated to evaluating the best treatment approach, such as whether to operate on a patient or not, as well as how to operate on a patient (i.e., surgical approach). However, not much progress has been made with regard to assessing the risk of a cancer coming back. The models that clinicians currently rely on in determining that risk have not evolved over the last decade. Moreover, these models rely on more or less the same risk factors. Clearly, there is a void that needs to be filled for such patients.

In that regard, the use of a non-invasive biomarker, a measurable indicator of a biological state that causes no harm to the patient has gained a lot of attention in recent years. Our proposed work is to examine one derivation of such biomarkers, namely, circulating-tumor DNA (ctDNA). Essentially, these are fragments of DNA that are released in the blood. Higher levels of ctDNA have been observed for patients with cancer, especially those who have an advanced state of the disease. As this technology is still in the development state, scientists have attempted, through various ways, to improve the approach in using ctDNA so that it can produce more accurate and consistent results. Our novel approach focuses on the methylated form of ctDNA, which may be more accurate and specific than traditional ctDNA assessments. We are hoping to investigate and further develop this technology with experts in this field for the purpose of helping clinicians select patients most likely to recur after surgery. Having a better idea of a patient's risk of recurrence after surgery in RCC is especially important because it is a key factor in deciding whether a patient will require additional treatment. It will also test how this tool can be used to predict how well a patient will respond to medical treatment.

In this context, we can surmise that in 2018, if 65,000 new individuals will be diagnosed with RCC, 45,500 individuals (70%) will have localized disease and be treated with surgery, where up to 18,200 individuals will recur within 3 years thereafter (40%). Currently, using existing tools, there is no way of reliably knowing who these individuals are. Developing a tool that can better help clinicians identify such individuals means that 18,200 patients may be offered further medical treatment options following surgical management and possibly reduce the risk of the cancer coming back. What this also means is that we can spare the remaining 27,300 (60%) patients who will not experience a cancer recurring and, in turn, avoiding exposure to unnecessary additional treatment; avoiding unnecessary exposure to side effects that can occur with such treatments; avoiding unnecessary exposure to further stress and anxiety related to thinking their cancer might come back; and avoiding unnecessary pressure to spend more money on cancer treatment. The development of this tool may also be examined in other management paradigms of kidney cancer. For example, future studies may focus not only on patients with localized RCC, but also on those with more advanced disease, allowing us to see if the tool can help predict whether a patient will benefit from a certain type of medical treatment as opposed to another. This tool can also eventually be evaluated for the purpose of screening for kidney cancer and possibly used as a method for earlier detection.

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