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New Algorithms for Cancer Screening (CitiScreen project)

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Abstract

There is a huge void in cancer screening and prevention worldwide. Many improvements have been achieved in the five-year survival and cure rate of cancers of the colon, ovary, prostate, childhood leukemias, among others. Most cancer are slow growing, which gives us the opportunity for early detection. In cancer statistics, the earlier the stage the better the outcome. Thus, a five-year survival of stage one ovarian cancer is over 95% while for stage four, it is less than 5%. Unfortunately, the area of cancer screening and early detection is the most deficient in most healthcare systems. Most of the screening and prevention programs are in the hands of general practitioners and family physicians who lack propertraining and are busy treating other conditions (common cold, diarrhea, pregnancy, arthritis cardiovascular diseases, among others). The US and other countries' health systems don't have a screening system for most treatable cancers. CitiScreen is here to fill that void. We developed a screening algorithm for most common treatable cancers using the disease's prevalence, patient's age and family history, geneticrisk factor, among other parameters.

The goal of CitiScreen is to put together the currently fragmented screening system by creating screening algorithms for the following cancers: Lung, ovary, breast, prostate, cervix, thyroid, colorectal, pancreas, and skin, among others. The use of individual screening algorithms, which combine ultrasound, MRI, CT imaging, genetic and tumor markers, as well as other technologies, allows us to detect cancer or its precursor lesions at an early stage at which point treatment is most effective. From the practical point of view, screening starts with obtaining family, personal, and social historyas well as demographics for identification of risk factors for * Trademark Serial Number: 88898021 Various cancers. All of this information is entered into a newly created cancer screening computer program, which produces screening recommendations for each individual.

CitiScreen Steps of Cancer Screening:

- Screening for risk factors (healthy individuals at risk), e.g., BRCA gene for breast cancer.
- Screening for cancer precursors, e.g., cervical dysplasia for cervical cancer, complex endometrial hyperplasia for endometrial cancer.
- Blood screening for early stage cancers, e.g., tumor markers.

Cervical cancer screening is a true success story of preventive medicine for the following reasons:

- HPV virus is a known cause in a majority of cervical cancer cases.
- The natural history of disease progression from precursor lesions to invasive cancer is well understood.
- Screening and detection via cervical smears and colposcopy is available.
- The timely treatment of precursor lesions is shown to prevent invasive disease.
- And finally, the HPV vaccine may "lead to the outright eradication of cervical cancer.

The Center for Disease Control and Prevention recommends the vaccine "for all males and females starting at age 11 and up to the age of 26." Data from the National Cancer Institute indicate more than "100 million doses of the vaccine have been given in the United States and more than 270 million worldwide, and no pattern showing that it caused any dangerous or lethal outcomes has been found." Breast, cervical, colorectal, and prostate cancers accounted for nearly 40% of all new cancers diagnoses and about 20% of cancer deaths. Funded by the US Department of Health and Human Services, Healthy People 2020 Project objectives for use of cancer screening tests include increasing the proportion of women aged 21 to 65 screened for cervical cancer, women aged 50 to 74 screened for breast cancer, and men and women aged 50 to 75 screened for colorectal cancer. We put together a screening program based on updated screening algorithms, which can be used in most medical practices (academic institutions, health care clinics, group practices, etc.).

CitiScreen is designed to utilize the latest achievements in cancer prevention research. CitiScreen provides potential patients with updated information and allows to make choices of screening procedures. In selecting cancers for screening, we used World Health Organization's principles (modified Wilson and Jungner criteria).

• The condition sought should be an important health problem.
• There should be an accepted treatment modality.
• There should be a recognizable latent or early cancer stage.
• There should be a suitable test or examination.
• The natural history of the condition, including development from latent to declared disease, should be adequately understood.

Below, please find an algorithm for ovarian cancer screening.

High grade carcinomas account for 90% of all ovarian cancer deaths. Increasing evidence suggests that most ovarian tumors arise in the fallopian tube and subsequently implant on the ovarian surface. This might explain the low sensitivity of cancer screening for early disease, when no ovarian involvementis yet detectable. Tumor DNA could be detected in the vaginal tract of women with ovarian cancer. A recent study showed that ovarian cancers shed cells, allowing detectable amount of tumor DNA to be found in the fluids obtained during routine Pap tests. Our screening program is based on cancer antigen 125 (Ca-125) as a tumor marker, transvaginal ultrasound (TVU), and potentially multimarker panels. Human Epididymis Proteins4 (HE4), unlike Ca-125, is less frequently elevated than in benign ovarian neoplasms. Equally important, HE4 has been shown to have greater sensitivity in patients with early-stage disease compared with Ca-125.

Risk of malignancy index (RMI): The RMI provides a quantitative risk assessment of malignant disease in patients with pelvic masses. The RMI is intended to provide a quantitative assessment for the risk of malignancy.

Risk of Ovarian Malignancy Algorithm (ROMA): The ROMA score considers patient's menopausal status in combination with serum Ca-125 and HE4 levels and does not incorporate imaging. Based on the pilot and prior validation trials, for premenopausal patients, a ROMA score of ≥ 13.1% is considered high risk for malignancy, and for postmenopausal patients a ROMA score of ≥ 27.7% is considered high risk for malignancy. Similar algorithms are applied to screening for other malignancies. Our metanalysis data and a pilot study demonstrated high demand and acceptance of CitiScreen program by the patients.