Implementing computed tomography-based lung cancer screening in the community

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CT-based lung cancer screening was recommended as a proven cancer early lung cancer detection test after extensive evaluation and the finding of a 20% mortality reduction in the National Cancer Institute sponsored, National Lung Screening Trial (NLST). That study took just under ten years and a quarter of a billion dollars to complete but it conclusively addressed the critical question of whether CT screening could really save lives. Now under provisions of the Affordable Care Act, private insurance companies and federal insurance programs [Center for Medicare and Medicaid Services (CMS)] are reimbursing for CT-based lung cancer screening without deductibles, co-sharing or co-payments to ensure broad access to this new service. This cancer screening service is now being rolled out responsibly in community settings across the country. In the dialogue about providing this service there was considerable discussion about potential harms that could occur with providing this service. For this reason, the recent article from Miller et al. is important new information that outlines a robustly positive preliminary lung cancer screening experience at one community hospital system (1). Given the extent of interest in this new service; it is worth taking a closer look at their experience.

Moving from trial to practice: what went right

This report arise from outcomes of screening performed in a community hospital setting (WellStar Health System) as this is where most people obtain their care as the authors note. In this setting, twelve hundred people over 5 years were screened (1). Only 2.8% of screening subjects underwent invasive work-up and 83% (30 of 36 procedures) were found to have cancer. Of the diagnosed lung cancers, 64% (18/28) were found to be pathologic stage I. Compliance was excellent at 95%. There was no operative mortality and the five year survival rate was 71%.

These are outstanding results especially in light of dire predictions of untoward outcomes that community centers could not achieve the excellent outcomes reported with the NLST (2). While this issue is a red herring as the NLST protocol entailed screening subject receiving their screening management as defined by their providers as the NLST did not mandate a specific diagnostic approach (3). Nevertheless, the rate of nonproductive invasive diagnostic work-up rate in the Miller report is remarkably lower than the numbers cited in highly quoted articles on lung cancer screening. Previous authors had previously conflated the frequent presence of pulmonary nodules with a false positive lung cancer diagnosis (4). Fortunately this misconception is now recognize as such and groups such as the American College of Radiology as well as I-ELCAP have reported efficient approaches for the evaluation of suspicious nodules in the lung cancer screening setting (5,6). However, the Miller results are still impressive (1).

This favorable experience at WellStar comes at the same time as a recent report was a study based on assessing the psychosocial impact of screening on 4,037 high risk individuals who participated in a randomized, pilot CT screening trial being conducted in the United Kingdom (7). In that careful analysis of psychosocial consequences of screening, the authors confirmed that there was no evidence of long term psychosocial distress for participants of the screening process confirming the previous Dutch report on this issue (8). So a number of lines of evidence support the

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emerging finding that lung cancer screening is being well tolerated and this emerging information should be a core aspect of the information that is shared in the process of shared decision making (9).

A framework for progress

The results obtained by Miller and co-workers were achieved by adhering to a range of "best practices" in managing the screening process. These published outcomes therefore represent a de facto national pilot for community-based lung cancer screening implementation. The architects of this effort are one of the nation's leading lung cancer patient advocacy organization, Lung Cancer Alliance (LCA) and its Board members, working in collaboration with WellStar's multi-disciplinary team of doctors and nurses. From this pilot emerged the vehicle for high quality national lung cancer screening implementation called the National Framework for Lung Cancer Screening Excellence and Continuum of Care. This National Framework is the blueprint developed in 2012 to guide the responsible implementation of screening specifically in community settings. An overarching goal embedded in this discussion was to ensure the public understood that they had a right to know they could be at risk for lung cancer; that they had a right to high quality care that followed best practices to ensure safe and equitable access to high quality care.

The National Framework as a public health blueprint for the scale up of a new preventive service and by also routinely included referral for smoking cessation advice integrated this effort with other best practice preventive approaches. In addition, the Framework also encourages collaborative research for improving early detection in lung cancer such as be identify other appropriate high risk populations. It has helped to increase the public's awareness about risk and their rights to responsible care, including educational resources and campaigns to spread this message; created a framework of agreed upon best practices to guide the safe and responsible development of a screening excellence medical center network that leverages member resources to support each other; and has helped create collaborations and relationships with other professional and advocacy societies and outreach to public and private payers to effect change at the policy level. Over 450 hospital centers have received LCA's screening center of excellence designation to date, with WellStar being the first. The majority are in community settings to address lung cancer screening detractor's concern that good care was not available in such

centers.

Encouraging screening subjects' participation to participate in screening is a profoundly important component of the Framework. A core expectation of Framework sites is that they will provide a frank and truthful discussion of risks and harms related to screening participation as part of a dynamic dialogue that continues as long as a person is in the screening framework. There is a vibrant research process around all the elements of the screening process and the pace of progress with this continuous process improvement approach is moving quickly. However, many questions and opportunities for progress remain and so screening subjects can make a great contribution to this effort by participating in research so a better, more economical and safer process continues to evolve. The WellStar approach to screening work-up benefited from a broad international research effort and as a result, the false positivity rate was 2.8%. Using newly developed minimally invasive surgical techniques, there was no operative mortality. The harms and benefits of screening depend on the process and the process can be continuously improved.

In the follow-up discussion of the paper, Dr Mayfield a co-author on the WellStar manuscript discussed several determinants of process success such as highlighting of working with the institutional administration on coordination of all of the many involved disciplines required for the screening encounter (1). This also allowed efficiencies in linking the relevant services so the wait times for the individuals participating in screening was minimal. A fundamental aspect of sustaining this integration was the critical role of the Nurse Navigator in coordinating the patient and administrative components so that comprehensive screening care was continuously provided. In sharp contrast to the predictions of some, the WellStar experience was associated with 95% compliance with the screening management which is much higher than expected (10).

Another critical aspect of success which was already discussed was the reported favorable surgical outcomes as no surgical mortality was reported. In part the surgical management largely evolved from precedents established by the International-Early Lung Cancer Action Project (11). I-ELCAP evolved their surgical management approach over more than twenty five Screening Workshops over the last 14 years in which best practices in screening management were actively developed under the leadership of thought leaders such as Robert J. Ginsburg, Nasser Altorki and Raji Flores. The WellStar group has also used a collaborative approach including the use of NCCN recommendations

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as again these are dynamic best practice recommendation that arise from a formal evidence evaluation process (12). In a complex field such as screening, networks where process improvement can emerge by the cooperative interaction of stakeholders can drive remarkable progress. Drs. Miller and Mayfield along with their team of committed colleagues provide elegant proof of this approach.

Acknowledgement

The organizations mentioned in the piece conducting continuous process improvement to refine the process of CT-based screening including the International-Early Lung Cancer Action Project and the Lung Cancer Alliance's National Framework for Lung Cancer Screening Excellence and Continuum of Care National Framework for Lung Cancer Screening Excellence and Continuum of Care are volunteer organizations and we acknowledge the contribution of all the subject and health care professionals who are participating in these crucial efforts.

Footnote

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Comment on: Miller DL, Mayfield WR, Luu TD, *et al.* Community-Based Multidisciplinary Computed Tomography Screening Program Improves Lung Cancer Survival. Ann Thorac Surg 2016;101:1864-9.

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