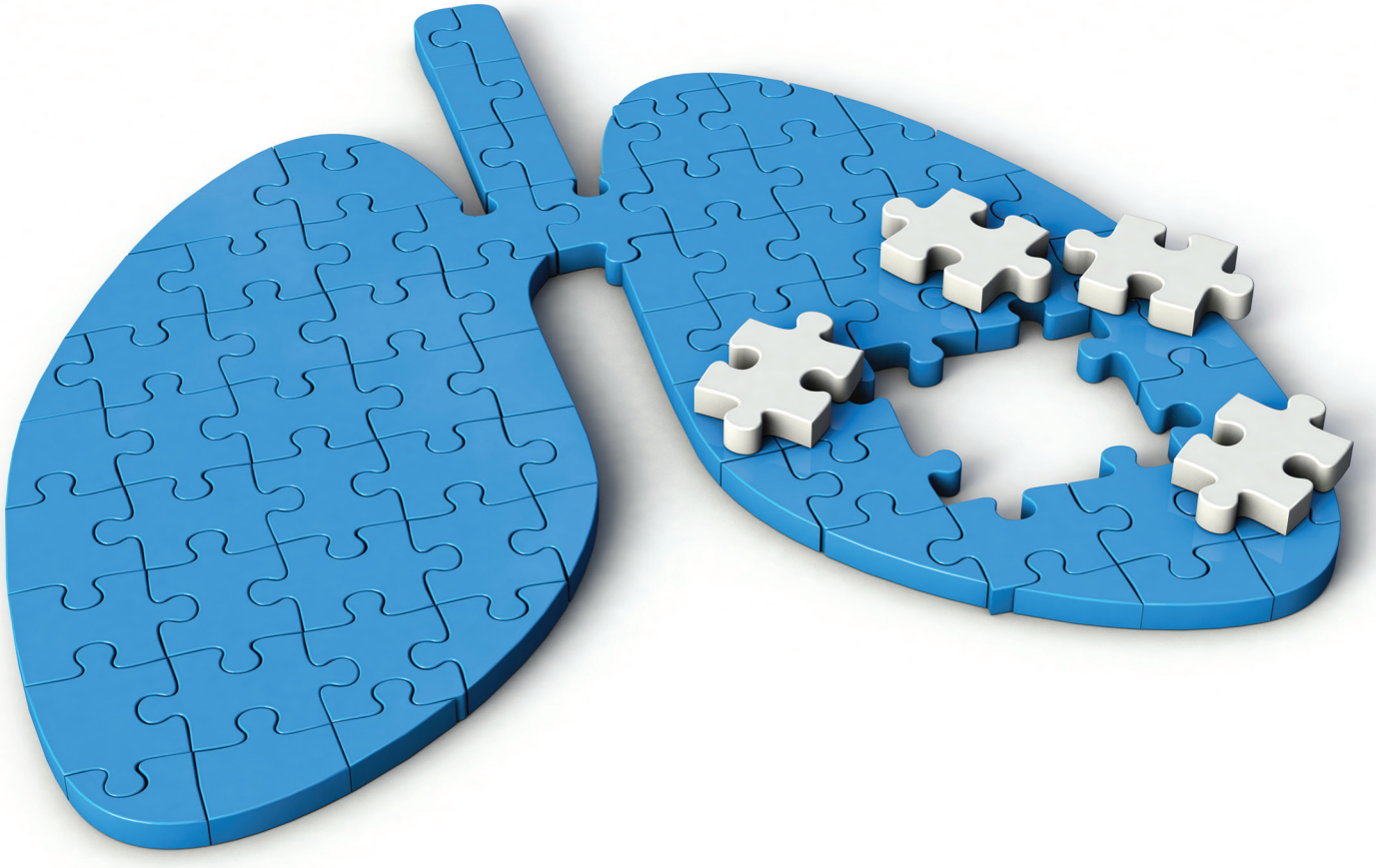
A 3D Lung Nodule Tool Improves Patient Distress Following LDCT



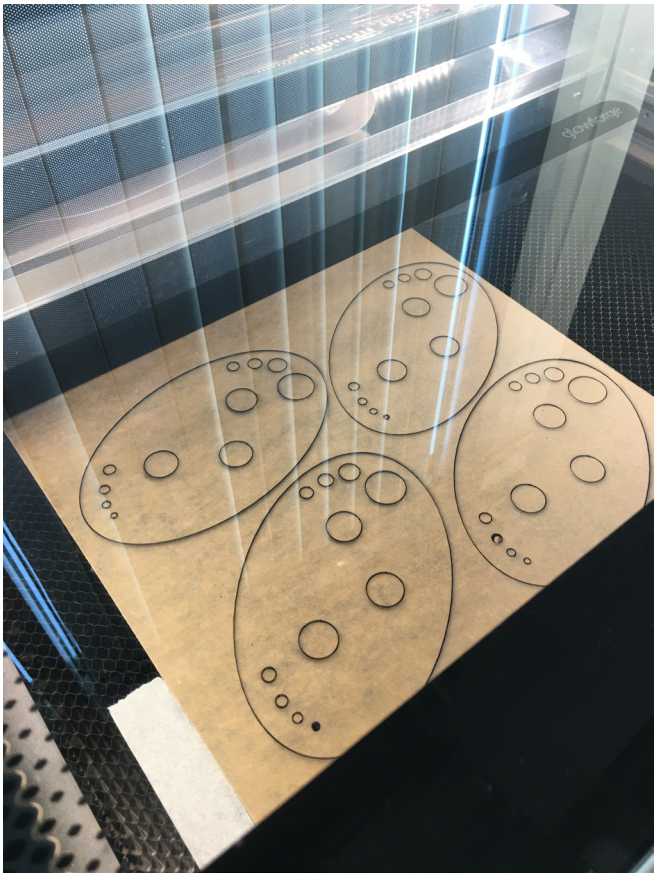
BY THERESA ROELKE, MSN, RN, AGNP-C

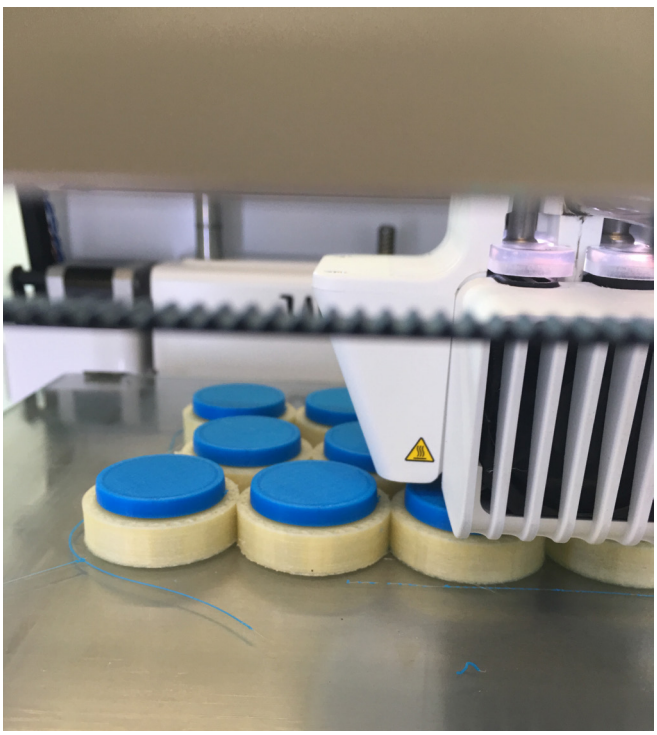
A 2017 study published in the journal *Heart, Lung and Circulation* showed that incidental nodules are seen in 13.9 percent of computed tomography (CT) angiograms performed across the country.[1] Today, thousands of Americans learn they have pulmonary nodules from low-dose computed tomography (LDCT) scans taken during annual lung cancer screenings. These patients experience high levels of distress owing to limited understanding of lung nodules and misconceptions about cancer risks. To improve the care of these patients, MaineHealth, Maine Cancer Care Network designed a study to explore the use of a 3D lung nodule tool to help providers educate patients during shared decision-making consults.

Across the United States, as well as within Maine, there is limited access to screening. Increased public awareness, patient education about screening, and state facilities that perform LDCT screening can improve patient outcomes and quality of life.[7]

A Brief History of LDCT Lung Cancer Screening

Every two and a half minutes someone in the United States is diagnosed with lung cancer, and an estimated 234,030 new cases in the U.S. were diagnosed in 2018.[2] The national five-year survival rate for lung cancer is 18.1 percent, which means that four out of five people diagnosed with lung cancer will not survive longer than five years.[3] In December 2013, the U.S. Preventative Services Task Force (USPSTF) issued its final recommendation on lung cancer screening. It states that annual lung cancer screening with LDCT is recommended for adults age 55 to 80 years who have a 30-pack a year smoking history and who currently smoke or have quit within the last 15 years.[4] As a result of the USPSTF recommendation, the Centers for Medicare & Medicaid Services agreed to cover LDCT lung cancer screening, with the stipulation that there must be a documented shared decision-making visit between the patient and the referring clinician. A shared decision-making consult educates patients about the risks and benefits of screening, including follow-up diagnostic testing, overdiagnosis, false positive rates, total radiation exposure, and the impact of comorbidities.[5] Currently, only 6 percent of the estimated seven





Top: Face plate laser cut from high gloss acrylic sheets. Bottom: Nodules being 3D printed with dissolvable PVA supports.

million adults who fall under USPSTF recommendations for lung cancer screening undergo LDCT screening.[6] Reasons behind this low patient volume include:

- Patients' lack of trust in the U.S. healthcare system
- Stigma and shame around smoking
- Limited patient education and knowledge
- Screening availability of providers and clinics
- The clinical nature of smoking addiction.

Across the U.S., as well as within Maine, there is limited access to high-quality lung cancer screening. Increased public awareness, patient education about screening, and state facilities that perform LDCT screening can improve patient outcomes and quality of life.[7] As these guidelines are widely implemented across the country and awareness and education on lung cancer screening increase, the number of people who undergo LDCT screening is expected to rise dramatically.

Pulmonary Nodules 101

A pulmonary nodule is defined as a single lesion in the lung that is surrounded by functional lung tissue and has a diameter less than 3 cm without associated pneumonia, atelectasis (complete or partial collapse of the lung), or lymphadenopathy. Pulmonary nodules are mostly benign growths caused by prior infection or areas of scarring on the lungs.[8] The vast majority of positive lung cancer screening results involve the detection of pulmonary nodules.[9] According to the National Cancer Institute's National Lung Screening Trial,[10] the rate of positive screening tests is 24.2 percent, of which 96.4 percent are false positives. To support clinicians who read and interpret LDCT findings, the American College of Radiology developed a standardized process called LungRADS,® which, based on the radiographic appearances of the lung nodules, assigs LDCT scans to one of five categories[11]:

- RADS 0: Insufficient data for interpretation
- RADS 1: A negative scan
- RADS 2: Nodules with benign appearance or behavior
- RADS 3: Nodules that are probably benign
- RADS 4A: Suspicious findings
- RADS 4B: Very suspicious findings.

The recommended follow-up (with CT, positron emission tomography [PET]/CT, or biopsy) depends on the nodule's malignant probability. Statistically, 90 percent of lung nodules are categorized as RADS 1 or RADS 2. These are nonexistent or very small, benign-appearing nodules (usually less than 6 mm) with less than 1 percent risk of becoming malignant. The recommended follow-up for these categories of nodules is to continue annual LDCT screening. Five percent of lung nodules are category RADS 3 and have a 1 to 2 percent risk of becoming malignant. In these cases, the recommended follow-up is LDCT screening in 6 months. Two percent of lung nodules are category RADS 4A and have a 5 percent to 15 percent risk of malignancy. A follow-up LDCT in three months or a PET/CT is recommended. Finally, 2 percent of lung nodules are category RADS 4B, which have more than a 15 percent risk of malignancy. Chest CT, with or without contrast; PET/CT; and/or sample biopsy is recommended for these cases.

LDCT Screening and Patient Distress

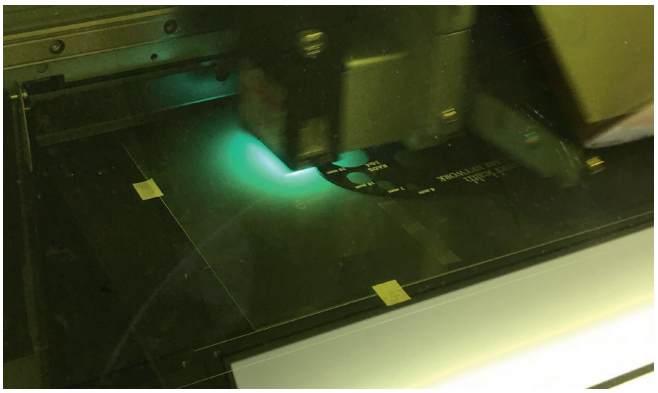
During the shared decision-making consult that accompanies LDCT lung cancer screening, clinicians educate patients about the low risk of malignancy stemming from a lung nodule finding. However, despite the overall low incidence of malignancy, several qualitative and survey studies indicate that lung nodule findings lead to clinically significant distress in as many as 25 percent of patients.[12,13] These patients tend to overestimate their risk of lung cancer. The distress from a lung nodule finding is unique in that patients' distress may persist for months to a year after their initial screening—the length of time before recommended follow-up with radiography. This finding contrasts sharply to patients who experience false-positive mammograms, where the uncertainty is addressed in a shorter window of time via a biopsy.[1,12] These data reveal a clinical unmet need for improved patient understanding of lung nodules, the risk they pose, and their short- and long-term management. Currently, visual lung nodule models are not used during the shared decision-making consult to support patient education. Incorporating a 3D educational tool as part of the shared decision-making process can enhance patient and provider communication, improve patient knowledge about malignancy risk, and reduce emotional distress, thereby improving patient quality of life.

The MaineHealth, Maine Cancer Care Network Experience

In 2018, MaineHealth, Maine Cancer Care Network developed and piloted the first such tool—a brainchild of experienced nurse navigator, Theresa Roelke, MSN, RN, AGNP-C.

After numerous LDCT shared decision-making consults with anxious and distressed patients, Roelke conceptualized the idea of a 3D tool that that could be used to better educate patients about their lung nodules and cancer risks. After developing the design on paper, Roelke reached out to the Maine College of Art in Portland to discuss partnership opportunities. The college connected Roelke to a student, William Kittredge, with expertise in 3D modeling and printing. Working together, Roelke and Kittredge created a nylon and resin prototype with lung nodules of different features and sizes. As a starting point, they used an existing tool of unknown origin and began a process of diagramming and prototyping iterations. The final prototype 3D lung nodule tool represented lung nodules of increasing diameter and with varying physical features.

In May 2018, Roelke piloted the 3D lung nodule tool during shared decision-making consults with patients to address the significance of nodule size, appearance, and malignancy risk. The tool's effectiveness was assessed using a five-question patient survey (four quantitative questions and one qualitative question). Thirty-one surveys were completed during the pilot. Preliminary data indicated that patients found the 3D lung nodule tool helpful, improving their understanding of lung nodules and the significance of nodule size and appearance. The average score for helpfulness (1 being *not helpful* and 10 being *extremely helpful*) was 9.4 out of 10 (see Figure 1, page 18). Preliminary data also showed that use of the 3D lung nodule tool decreased patient distress



Top: UV Printing text and graphics to the face plate. Bottom: 3D printing allows quick variance in color and materials.

Figure 1. Data from Patient Survey of Piloted 3D Lung Nodule Tool

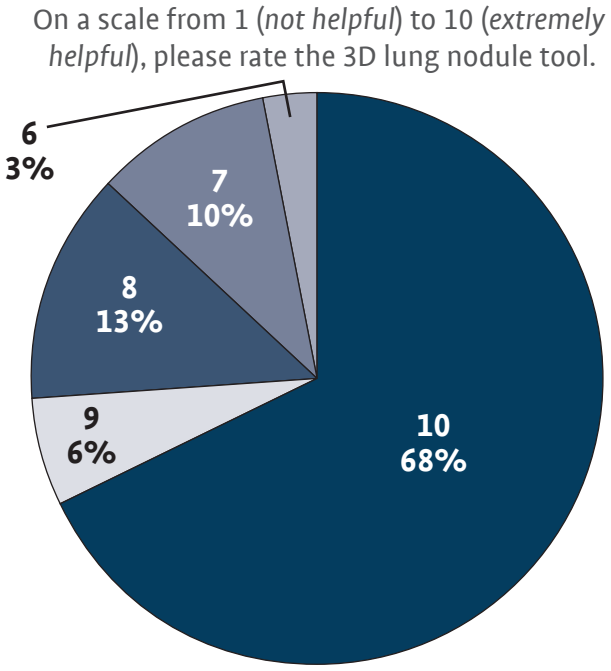


Table 1. Benefits of a 3D Lung Nodule Tool

This tool can be used in any setting where conversations with patients about lung cancer screening findings occur, including primary care practices, pulmonology clinics, emergency departments, hospital inpatient units, and cancer programs or practices to help:

- Create a paradigm shift in LDCT shared decision-making consults by engaging patients and providing them with greater meaning and context.
- Establish a personal connection with patients whether education is offered in person or virtually.
- Engage patients in an experiential learning experience.
- Provide a multi-sensory experience that can help improve patient recall of information and education.
- Improve patient understanding of lung nodules.
- Help patients better understand their imaging report.
- Reduce patient distress.
- Offer patients the opportunity to share education on nodules with family and friends.
- Improve understanding of metric measurements in patients unfamiliar with the measurement system.

LDCT = low-dose computed tomography.

during the shared decision-making consult. Other benefits to this patient education tool are listed in Table 1, below left.

Future Direction

At the height of the pandemic in 2020, collaboration began with the University of Southern Maine Maker Innovation Studio (MIST Lab) to refine the 3D lung nodule tool and print additional units for distribution across MaineHealth. MIST Lab's vision is to partner with healthcare, business, industry, and education to bring experiential learning to providers and patients. Figure 2, page 19, is the 3D lung nodule tool that has undergone refinement in preparation for large volume production. The tool includes nodule characteristics: lobulated shown in yellow, smooth in blue, and spiculated in red, as well as the LungRADS categories. LungRADS 1 and 2 nodule findings are positioned to the right with corresponding nodule sizing and LungRADS 3 and 4 nodule findings are positioned on the left.

In 2021 the team hopes to begin implementing use of the 3D lung nodule tool in lung screening sites across MaineHealth and the Northern New England Clinical and Translational Research Network. The MaineHealth Innovation Center is currently in conversations with a local manufacturer to mass produce the 3D lung nodule tool. The plan is to offer an option to custom print an organization's name on the tool itself. The team is looking to introduce the 3D lung nodule within the primary care setting where lung nodules are commonly discussed with patients.

The end goal is to disseminate the tool to lung screening programs and pulmonology clinics throughout New England and then across the country to improve patient education and shared decision-making around LDCT screening in both the inpatient and outpatient setting.

Another future goal is to develop additional tools to support patient education on nodules found within the context of lung screening and on diagnostic CT chest imaging, including thyroid and vocal cord nodules.

Additionally, there may be future opportunity to collaborate with the Research Bases of the National Cancer Institute Community Oncology Network, of which Maine Cancer Care Network is a member. This may provide a venue for a much larger confirmatory and national Cancer Care Delivery Research study.

Finally, Roelke and her colleagues plan to continue to introduce the 3D lung nodule tool and present future research findings at national and international lung cancer conferences to encourage further discussion around the use of 3D modeling to improve patient health literacy. By initiating these discussions, Roelke's team seeks to challenge lung screening programs across the country to consider more broadly the use of technology and innovation to support patient understanding of commonly found lung nodules, lung cancer, and preservation of lung health as it relates to quality of life. The goal is to collaborate with patients to educate them on a given diagnosis and to establish a plan of care, while also creating meaningful health goals that are uniquely appropriate to individual patients. In doing so, individual patients are empowered to assume health autonomy and health stewardship.

Figure 2. 3D Lung Nodule Tool for Large Volume Production

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Maine Medical Center Cancer Institute won a 2020 Association of Community Cancer Centers (ACCC) Innovator Award for its 3D lung nodule tool. Roelke and colleagues presented this innovation at the ACCC 37th [Virtual] National Oncology Conference. Listen to their on-demand session at courses.accc-cancer.org/p/ACCCNOC. OI

Theresa Roelke, MSN, RN, AGNP-C, is a geriatric nurse practitioner at Maine Medical Center Cancer Institute in Scarborough, Maine.

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