An Ultrasound Screening Exam During Medicare Wellness Visits May Be Beneficial

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Objectives—The physical exam component of a periodic health visit in the elderly has not been considered useful. Standard Medicare Wellness visits require no physical exam beyond blood pressure and most physicians perform limited exams during these visits. The objective of this study was to test the feasibility, potential benefit, and costs of performing a screening ultrasound (US) exam during Medicare Wellness visits.

Methods—A physician examiner at an academic internal medicine primary care clinic performed a screening US exam targeting important abnormalities of patients 65–85 years old during a Medicare Wellness visit. The primary care physician (PCP) recorded the follow-up items for each abnormality identified by the US examiner and assessed the benefit of each abnormality for the participant. Abnormality benefit, net exam benefit per participant, follow-up items and costs, participant survey results, and exam duration were assessed.

Results—Participants numbered 108. Total abnormalities numbered 283 and new diagnoses were 172. Positive benefit scores were assigned to 38.8%, neutral (zero) scores to 59.4%, and negative benefit scores to 1.8% of abnormalities. Net benefit scores per participant were positive in 63.9%, 0 in 34.3%, and negative in 1.8%. Follow-up items were infrequent resulting in 76% of participants without follow-up cost. Participant survey showed excellent acceptance of the exam.

Conclusions—The US screening exam identified frequent abnormalities in Medicare Wellness patients. The assessed benefits were rarely negative and often mild to moderately positive, with important new chronic conditions identified. Follow-up costs were low when the PCPs were also US experts.

Key Words—internal medicine; physical exam; primary care; screening ultrasound

Introduction

he value of the periodic health visit has been debated for decades.¹⁻¹¹ Physicians have noted benefits from these visits, but few have defended the value of the traditional physical exam component beyond the "laying on of hands." Standard Medicare Wellness visits require no physical exam beyond blood pressure and most physicians perform limited exams during these visits.

A study published in 2000 reported that an ultrasound (US) screening exam as part of a periodic health visit in 72 elderly

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Abbreviations

PCP, primary care physician; US, ultrasound

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patients identified clinically meaningful findings undetected by a traditional exam.¹² We began a primary care clinic US program in 2013 and decided to further evaluate the feasibility and potential benefit of a screening US exam during Medicare Wellness visits using optimal technology and physician training.¹³

Materials and Methods

The Allina Health Institutional Review Board approved this study (Allina Health IRB; Reference 1380364). Informed consent was obtained for all patients participating in the study.

The US Physician and Clinic

The US examiner, a physician with 43 years of clinical experience, the last 6 years of which were devoted to extensive US training and experience in primary care, performed all US screening exams. The 20-internist clinic was associated with an IM residency, but residents were not involved in Wellness visits in the clinic.

Patient Selection

All patients screened were established with 1 of 6 primary care physicians (PCPs) who had advanced training in US but had not used it for screening during Wellness visits. These PCPs had strong knowledge to integrate US findings into clinical decision-making and could expertly perform indicated follow-up US exams. Potential participants were at least 65 years old, but not over 85 years.

The US examiner screened the medical records of patients scheduled for Wellness visits with the 6 PCPs between July 25, 2019, and March 13, 2020. Patients with body mass indices 35 or greater were excluded because such patients often have suboptimal US exams of the heart and/or abdomen. Patients with a documented CT scan of the abdomen or formal echocardiogram in the previous 2 years were also excluded because these studies would likely have identified the abnormalities that a screening US exam would detect and thus potentially blunt the assessed benefit of the US exam. The US examiner reviewed no other part of the medical record. PCPs then determined whether reduced life expectancy, impaired mobility, or mental status problems should exclude a patient. The PCPs also excluded patients known to have currently complicated medical situations requiring additional time during the visit. If several eligible patients were scheduled for Wellness visits at about the same time, males were preferentially selected because of the known female-predominant Medicare population.

The PCP informed and invited the remaining candidates, obtaining written consent if they accepted. The PCP did not perform a traditional exam of body regions that would be covered by the US exam. The study goal was to enroll 150–200 participants over 12 months but was terminated after 108 participants and 8 months because of the COVID-19 pandemic.

The US Exam

Each participant was examined with a GE Venue US device (version 302.0 GE Healthcare, Chicago, IL), utilizing 3Sc (2.5–4.5 MHz) phased array, C1-5 (3.0– 6.0 MHz) curvilinear, and L12n (7.0–12.0 MHz) linear probes. GE had no role in the study and provided no funding. There was no patient charge for the US exam.

The US screening exam targeted important abnormalities of elderly patients (see Appendix S1 for details of US exam protocol and Appendix S2 for abnormality descriptions). Each participant had a thorough heart exam (without simultaneous electrocardiogram recording) that used M-mode, color flow Doppler, pulse wave Doppler (including tissue Doppler), and continuous wave Doppler to evaluate chambers and valves. Trace severity valve regurgitation was not considered an abnormality. Carotid arteries, hepatobiliary region, kidneys, spleen, and abdominal aorta were also examined. No other asymptomatic structures or regions were examined because of lack of evidence of benefit from US screening. The elapsed time of the exam was recorded, key images were remotely archived, and the exam was documented in the electronic health record.

The US examiner reviewed the findings on the US device with the PCP, who then discussed the exam with the participant and coordinated all subsequent care. The PCPs followed guidelines published by the American College of Radiology for care of new nodules and cysts in the abdomen.¹⁴⁻¹⁶ At the end of the visit, each participant completed an anonymous five-question survey about the US exam. These were not tabulated until the conclusion of study enrollment.

Data Collected

The following data were recorded on the day of the exam: age, sex, zip code, smoking status, weight, height, body mass index (BMI), months since last PCP visit, number of PCP visits in the past 2 years, last abdominal CT date (if any), last formal echocardiogram date (if any), number of chronic prescription medications, and each abnormality noted during the US exam.

Six months after the Wellness visit, the PCP reviewed the medical record and recorded subsequent studies and visits ordered because of the US findings. The follow-up cost of each item was the Medicare reimbursement value. A planned US exam at the next year's Wellness visit was not considered a follow-up item. The records of participants without US abnormalities were also reviewed to identify clinical events that might indicate US false negatives. The intermediate- and long-term interventions and costs of appropriately caring for participants with correct US-initiated new diagnoses were not considered follow-up items in this analysis.

After the 6-month reviews were completed for all participants, the PCPs reviewed their participants again and assigned each abnormality a "benefit score"

Box 1 Abnormality benefit scoring rubric

- (-4) No short-term or potential long-term benefit but serious negative impact occurred because of subsequent care.
- (-3) No short-term or potential long-term benefit but moderate negative impact occurred because of subsequent care.
- (−2) No short-term or potential long-term benefit with minimal negative impact from subsequent care, but major resources were consumed.
- (-1) No short-term or potential long-term benefit with minimal negative impact from subsequent care, but modest resources were consumed.
- (0) Finding(s) already known, no subsequent care needed, OR a new finding with no short-term or potential long-term benefit and no subsequent care needed.
- (+1) Modest short-term or potential long-term benefit with appropriate subsequent care.
- (+2) Moderate short-term or potential long-term benefit with appropriate subsequent care.
- (+3) Major short-term or long-term clinical benefit, worth the subsequent care.
- (+4) Critical clinical benefit, worth all subsequent care.

(Box 1), which considered the participant's age, other medical conditions, and psychosocial situation. This scoring rubric was developed by the authors for the study and had no external validation.

A patient net benefit score was then calculated as the sum of the individual abnormality scores. However, if multiple abnormalities suggested the same condition, only one abnormality score was used in the sum.

New diagnoses resulting from the US exam were recorded when they were entered as new or as modifications of existing problems on the patient problem list.

Data Analysis

The hospital foundation provided support for some aspects of study design and data storage. Study data were collected and managed using REDCap electronic data capture tools hosted at Allina Health.¹⁷⁻¹⁸

Numerical data are described by median, average, and range. Categorical and ordinal data are described by frequency counts and percentages.

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Results

The US examiner reviewed medical records of 256 patients. Females comprised 61% of this group, compared with 54% for our state's Medicare population. Exclusion criteria were met by 112 patients (25 for a BMI 35 or greater, 26 for an abdominal CT less than 2 years ago, 32 for an echocardiogram less than 2 years ago, 21 for mental status compromise, and 8 for a currently complicated medical condition). Only the first exclusion met in this sequence was tabulated.

Of the 144 patients eligible for the study, 28 were not invited because they were scheduled at approximately the same time as another invited patient; males were invited over females when possible. Of the 116 patients invited to join the study, 8 declined. The final enrolled group of 108 participants was 57% female.

Table 1 shows participant characteristics. Males were expectedly taller and heavier than females but had similar body mass indices. The percentage of current smokers (1%) was lower than the recent national rate of 8.4% for people 65 and older.¹⁹ Almost all participants

had been seen at least yearly in clinic and the frequency of abdominal CT scans or echocardiography more than 2 years ago suggested long-term good access to care in the group. The number of prescription medications (median 3.0, average 3.5) for the study group was slightly lower than reported for noninstitutionalized Medicare patients.²⁰

The participants lived independently and resided in 53 different zip codes, concentrated in the southwest Minneapolis metropolitan area. Using available 2017 data for median household income by zip code, the frequency-weighted median income for the zip code distribution of the study group was \$87,256, compared with a statewide median of \$65,699 and a United States median of \$60,336.

Only 6 participants (5.6%) had no US exam abnormality. A total of 283 abnormalities was found and Table 2 shows the percentage of participants with each abnormality. The most frequent abdominal abnormalities were liver steatosis and simple kidney cysts while the most common cardiovascular abnormalities were carotid plaque, tricuspid valve regurgitation, and left ventricular diastolic dysfunction. Valve abnormalities greater than trace were found in 48% of all patients, but no abnormality was severe; moderate severity lesions were seen in 15% of all patients and 33% had mild severity lesions.

Table 2 also shows the median, minimum, and maximum of the benefit scores for each abnormality. The lowest score for any abnormality was -2 and the highest was +2. Figure 1 shows the distribution of

Table 1.	Characteristics	of participants
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Characteristic	Median (range)
Age (y)	72 (65–85)
Weight (kg)	74 (46–112)
Height (m)	1.68 (1.47–1.91)
Body mass index (kg/m ²)	27 (18–34)
Never smoker (%)	54
Former smoker (%)	45
Current smoker (%)	1
Months since last PCP visit	7 (0–29)
PCP visits past 2 y	3 (0–16)
Any previous abdominal CT (%)	35
Months since previous abdominal CT	81 (26–187)
Any previous echocardiogram (%)	44
Months since previous echocardiogram	56 (25–167)
Prescription medications	3 (0–10)

CT indicates computed tomography scan; PCP, primary care physician.

Abnormality	Participants $n = 108$ (%)	Benefit Score median (min, max)
Abdomen		
Liver steatosis	25 (23.1)	0 (0, 1)
Kidney cyst, simple	16 (14.8)	0 (0, 0)
Gallbladder stones	9 (8.3)	1(0,2)
Liver cyst	4 (3.7)	0 (0, 0)
Kidney cyst,	3 (2.8)	-2 (-2, 1)
complex	2 (1 0)	
Kidney, small Splenic	2 (1.9) 2 (1.9)	0 (0, 0) 0 (0, 0)
calcification	2(1.9)	0(0,0)
Kidney mass	1(0.9)	0 (0, 0)
Gallbladder wall	1 (0.9)	2 (2, 2)
abnormal	1(0.5)	2(2,2)
Liver enlarged	1(0.9)	0 (0, 0)
Spleen mass	1 (0.9)	-1 (-1, -1)
Cardiovascular	2 (010)	- (-, -)
Carotid plaque	60 (55.6)	0 (0, 2)
TV regurgitation	30 (27.8)	0 (0, 1)
LV diastolic dysfunction	29 (26.9)	1 (0, 2)
MV regurgitation	19 (17.6)	0(0,1)
AV regurgitation	13 (12.0)	1 (0, 2)
TV gradient increase	10 (9.3)	1 (0, 1)
Interventricular	7 (6.5)	0 (-1, 2)
septum	7 (0.5)	0 (-1, 2)
enlarged		
AV stenosis	7 (6.5)	0 (0, 2)
Aorta ascending	7 (6.5)	1 (0, 2)
enlarged	, (0.0)	1 (0, 2)
AV sclerosis	7 (6.5)	0 (0, 2)
Non-sinus rhythm	5 (4.6)	0 (-1, 0)
Interventricular	5 (4.6)	0 (0, 0)
septum DUST		
LV systolic	4 (3.7)	1(0,2)
dysfunction		
Eustachian valve	3 (2.8)	0(0,1)
LV chamber enlarged	2 (1.9)	0 (0, 0)
RA enlarged	2 (1.9)	0 (0, 0)
LA enlarged	2 (1.9)	0 (0, 0)
Carotid stenosis	2 (1.9)	0 (0, 1)
RV chamber	1 (0.9)	0 (0, 0)
enlarged	()	- (-) -)
Patent foramen ovale	1 (0.9)	0 (0, 0)
LV wall motion	1 (0.9)	0 (0, 0)
abnormality	1(0.5)	0(0,0)
LA dysfunction	1 (0.9)	0 (0, 0)

See Appendix S2 for abnormality descriptions.

AV indicates aortic valve; DUST, discrete upper septal thickening; LA, left atrium; LV, left ventricle; MV, mitral valve; RA, right atrium; TV, tricuspid valve.

Table 2. Ultrasound abnormalities

individual abnormality benefit scores with negative scores assigned to 1.8%, zero scores to 59.4%, and positive scores to 38.8%.

Figure 2 shows the distribution of net benefit scores per participant. Negative scores occurred in 1.8% of participants, zero scores in 34.3%, and positive scores in 63.9%.

There were 30 total follow-up diagnostic items ordered by the PCPs after the US exams: 8 ambulatory blood pressure monitor studies, 6 single laboratory tests, 5 follow-up appointments with the PCP, 4 limited abdominal US exams, 6 laboratory panels, 2 echocardiograms, 1 electrocardiogram, and 1 CT of the abdomen. Because follow-up items were infrequent, 76% of

Figure 1. Distribution of individual abnormality benefit scores. See Box 1 for benefit score rubric.

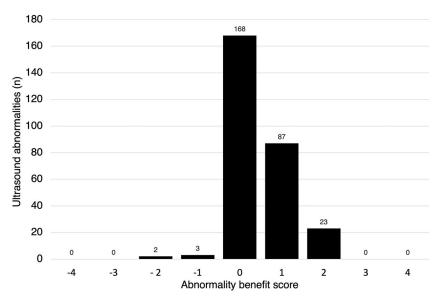
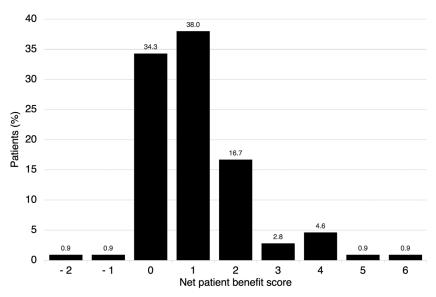


Figure 2. Distribution of patient net benefit scores. Net benefit score was calculated as the sum of the participant's individual abnormality scores.



participants had no follow-up costs after the US exam. Costs between \$5 and 50 accrued for 15% of patients, 6.5% had cost between \$51 and 125, 4.6% had cost between \$126 and 260, and 1 participant had a cost of \$602. This participant had a net benefit score of 0 because a -2 score for a complex renal cyst, requiring 2 imaging studies to decide it was benign, was counterbalanced by a score of +2 for newly identified moderate aortic stenosis. The only 2 participants with net negative benefit scores had costs of \$229 and 75.

Table 3 shows the frequency of the 172 total new diagnoses directly related to the US exam. Some participants had more than one new diagnosis. Medication changes and/or aggressive dietary interventions occurred as the result of new diagnoses, but these were not considered follow-up items for the study.

The participant survey (full survey questions and results available in Appendix S3) showed that about 90% did not think the exam was too long or uncomfortable. About 80% were not worried by the exam and felt better about their health. Two-thirds of participants said they would want a periodic US screening exam while one-third said they might want one. The relationship of the survey responses to the participant US findings could not be assessed because of the anonymity of the survey.

Table	e 3.	New	diagnoses
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Diagnosis	Participants $n = 108$ (%)
Abdomen	
Liver steatosis	20 (18.5)
Kidney cyst, simple	11 (10.2)
Gallbladder stones	9 (8.3)
Kidney cyst, complex	3 (2.8)
Liver cyst	2 (1.9)
Kidney angioma	1 (0.9)
Cardiovascular	
Carotid plaque	47 (43.5)
LV diastolic dysfunction	24 (22.2)
TV regurgitation	15 (13.9)
MV regurgitation	13 (12.0)
AV regurgitation	8 (7.4)
AV stenosis	5 (4.6)
Aorta, ascending enlarged	4 (3.7)
Interventricular septum DUST	4 (3.7)
Pulmonary hypertension	4 (3.7)
Eustachian valve	3 (2.8)
LV wall enlargement	2 (1.9)
Carotid stenosis	1 (0.9)

AV indicates aortic valve; DUST, discrete upper septal thickening; LV, left ventricle; MV, mitral valve; TV, tricuspid valve.

The median US exam time was 28 minutes with a range of 18–32 minutes. The exam time did not vary significantly over the course of the study, but the US examiner's impression was that obesity and multiple abnormalities requiring additional views and measurements lengthened exam times.

Discussion

One or more abnormalities were found in 94% of our participants, the great majority of which would have been undetected by a traditional physical exam. Many participants benefitted from the information and harm was rare and only economic. However, several of the most common abnormalities need discussion.

Carotid US is generally not recommended to screen for asymptomatic carotid stenosis, but the object of this study was only the identification of carotid plaque, which is a marker of increased atherosclerotic vascular risk.²¹ Some study participants received new medication as a result of the carotid study.

The participants with reduced left ventricular diastolic function (as measured with tissue Doppler velocities) were all asymptomatic with no evidence of left atrial pressure elevation. This finding is inconclusive and does not create a diagnosis of heart failure with preserved ejection fraction. However, the finding leads to a consideration of undiagnosed or undertreated hypertension, inadequately treated components of the metabolic syndrome, and even infiltrative disease such as amyloid.²²⁻²⁴ We obtain ambulatory blood pressure monitoring (done in our clinic) and carefully consider the common risk factors for diastolic dysfunction before looking for infiltrative disease. Masked hypertension and undertreated hypertension were identified in some study participants and aggressive weight loss was pursued in others.

There were important limitations of this study, including selection bias from the Medicare Wellness visit itself, which only a minority of national Medicare patients complete.²⁵ The study participants were also under the age of 86, did not have greater than stage 1 obesity, and lived independently. Their places of residence by zip code suggested a higher-than-average income for our state and country. Their medical histories suggested a relatively healthy lifestyle and good access to health care. A less healthy population of

Medicare patients with less regular care could have a different spectrum of disease and impact from the same US screening exam.

Another bias was that the US examiner had training and experience greater than available in most primary care clinics and the US device had high resolution and penetration with full Doppler capabilities. Clinics with lower levels of US skill and less advanced equipment could obtain different results. The 6 PCPs in this study were also US experts and could do follow-up exams on their patients, reducing the need for formal imaging tests. This would be unusual in most current primary care clinics but might represent a future in which expert-level US was widespread in primary care IM.

Potential bias was also inherent in the benefit scoring system used for the US abnormalities. The scoring system was based on the authors' opinions and had no external validation. Although the PCPs followed the scoring guidelines, they may have been biased in favor of an US benefit. However, we thought that only the PCP could appropriately assess the impact of an US abnormality on an individual participant's health.

There were no identified false-negative US exams during the 6 months of participant follow-up. However, we continue to be concerned that some participants could be overly reassured by a normal US exam and inappropriately change behavior or fail to respond to some new future symptom.

The great majority of our US abnormalities did not have formal imaging confirmation, so there is no estimate of our false-positive rate. However, the US examiner reviewed (on the US device) all abnormalities with the PCP who was also an US expert, which added a second confirmation of all positive findings, and resulted in no changes in abnormality classification. The 6 participants with imaging confirmation had confirmed abnormalities and studies indicate that well-trained physicians and high-quality US devices should have strong specificity for most of the abnormalities identified in this study.²⁶ We did categorize 2 abnormalities as false positive. The heart US in 1 patient was interpreted as a non-atrial rhythm but was a mistake in a patient with sinus bradycardia. Another patient had a vague lesion of the spleen but detailed US by the PCP a month later failed to find a lesion.

Immediately lifesaving true-positive findings with an US screening exam would be rare, and none were found during the study. Rather, the new abnormalities were markers of chronic disease and we assessed the benefit of identifying most of these as mild to moderately positive. The 15% of our patients with moderate valvular abnormalities is similar to an observational echocardiographic study in elderly patients.²⁷

Our major concern with true-positive US findings was the generation of additional testing, morbidity, and cost without a net health benefit. This concern was lessened when only 2 participants had negative net benefit scores, and both were from the cost of follow-up tests, not from an adverse clinical outcome. A benefit score of 0 was given to 34% of participants and 64% had positive scores.

A relatively small number of follow-up items were ordered in the study participants, so follow-up costs were low. Without the US expertise of our PCPs, an increased number of formal imaging studies and consultations would probably have been ordered, increasing cost.

Although we think screening US during Medicare Wellness visits is probably at least mildly beneficial with low follow-up costs, implementation has current challenges. The equipment used in this study costs roughly \$50,000 in 2021. Physician training costs are difficult to estimate. Only about half of our Wellness patients met the criteria for an US screening exam, so it would not make sense to lengthen every Wellness visit to accommodate US. A separately scheduled 30-minute US exam would be needed, but this can be financially challenging for some clinics.

In summary, the US exam used in this study identified frequent abnormalities in Medicare Wellness patients. The assessed benefit of these abnormalities was rarely negative and often mild to moderately positive, with important new chronic conditions identified. The follow-up costs for these abnormalities were low when the PCPs were US experts. A larger study with multiple US-enabled physicians would be required to assess the generalizability and cost-effectiveness of an US screening exam as part of a Wellness visit. We continue to investigate how to implement an US screening exam for select patients having periodic health visits.

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