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Optimal Care Forum for Evidence-Based Medicine

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Activity description	Practicing evidence-based medicine (EBM) is important in today's health care environment. This model of care offers clinicians a way to enrich quality, provide patient satisfaction, reduce costs and improve outcomes. A common implementation of EBM involves the use of clinical practice algorithms during medical decision-making to encourage optimal care. This widely recognized practice is designed to address the persistent problem of clinical practice variation with the help of actionable information at the point of care. These e-newsletters enable health care professionals to put new EBM into practice.
Learning objectives	• Discuss the national costs of breast cancer screening in the U.S. and examine 3 national screening guidelines and how the different recommendations in these guidelines contribute to the high cost of screening • Determine the therapeutic value of oseltamivir (Tamiflu) in non-severe influenza and Fexolinetant for treatment of post-menopausal hot flushes • Describe the benefits of Mineralocorticoid Receptor Antagonists (MRAs) across different types of heart failure • Analyze the post-op radioiodine treatment for thyroidectomy in low-risk papillary thyroid cancer, the use of pre-biopsy MRI assessment of suspected prostate cancer to decrease unnecessary biopsies, and the impact of bodyweight loss on type 2 diabetes remission rate

Accreditation statement

In support of improving patient care, this activity has been planned and implemented by Optum Health Education and Optum. Optum Health Education is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC) to provide continuing education for the health care team.

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Optum Health Education designates this enduring activity for a maximum of 1.00 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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A certificate of attendance will be provided to learners upon completion of activity requirements, enabling participants to register with licensing boards or associations that have not been pre-approved for credits. To apply for credit types not listed above, participants should use the procedure established by the specific organization with which they wish to obtain credit.

Provided by

This activity is provided by Optum Health Education and Optum.

Commercial support

No commercial support was received for this activity.

National costs of breast cancer screening in the U.S.

Our current national health care spending was $4.5 trillion in 2022 and equates to over $13,000 for each person in the U.S. Breast cancer screening costs in the U.S. are more than threefold higher than other wealthy nations, yet our breast cancer survival rates are similar.[1] In a recent study from the University of California San Francisco (UCSF) and the Optum Translational Research team at the Optum Center for Research and Innovation (OCRI), breast cancer screening costs were estimated using the 3 national screening guidelines.[2]

Ideally, we would have an evidence-driven single national guideline for breast cancer screening, but this is lacking. In its place, we have 3 guidelines that vary considerably. They include the American College of Radiology ACR 2021 guideline, the American Cancer Society 2015 guideline, and the U.S. Preventative Services Task Force (USPSTF) 2024 guideline.[3] The different recommendations in these guidelines contribute to the varying and high cost of screening in the U.S. Another contributing factor is the almost complete transition from digital mammograms to digital breast tomosynthesis (3-D).

Table 1: Breast cancer screening guidelines model

Guideline	Risk	Start age	Stop age	Frequency and modality
2021/2023 American College of Radiology [4,5]	High*	30 or 40†	Per woman's health status‡	Alternating MRI and mammogram every 6 months
	Average	40		Annual mammogram
2024 United States Preventive Services Task Force [3]	High*	40	74	Biennial mammogram
	Average			
2007/2015 American Cancer Society [6,7]	High*	30	Per woman's health status and life expectancy >10 years‡	Alternating MRI and mammogram every 6 months
	Average	45		Annual mammogram: age 45–54 Biennial mammogram: age 55+

* See online supplemental methods and online supplemental table S1 for definitions of high risk.

† Women with a lifetime risk of breast cancer of 20% or greater according to risk assessment tools, with pathogenic mutations or first-degree relatives start screening at 30 years. Women with dense breasts who desire supplemental screening start at 40 years.

‡ Screening simulation stopped at 84 years.

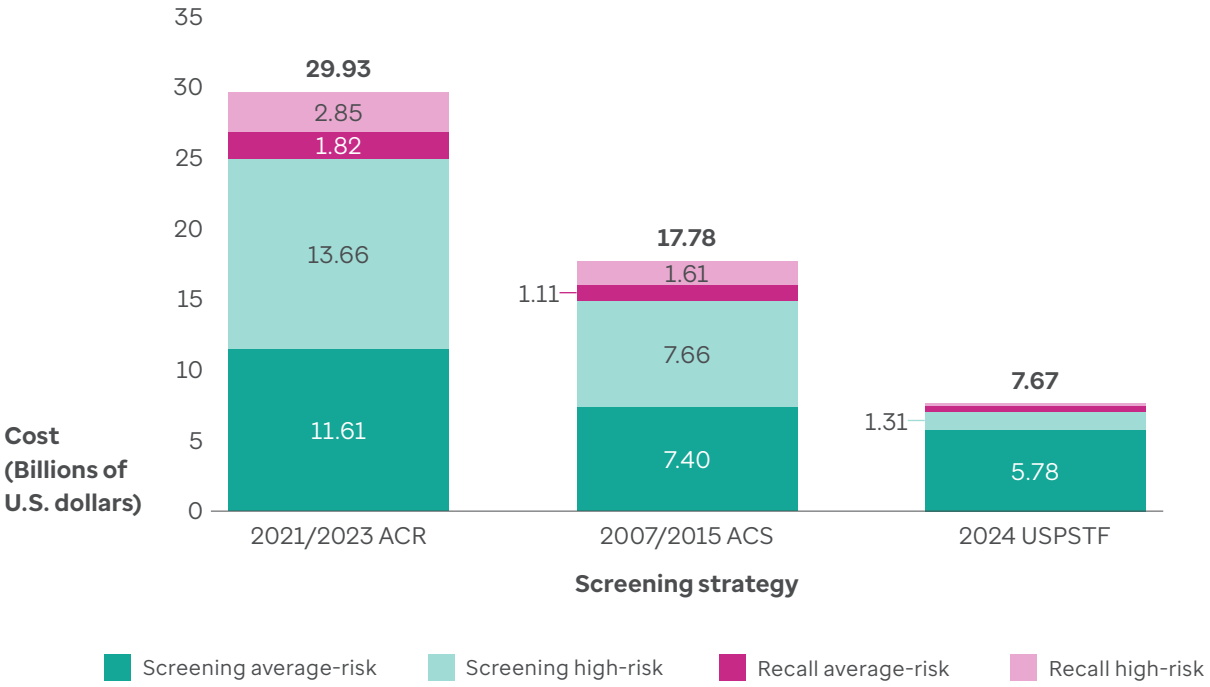
Using real-world data from the Optum Labs Data Warehouse, this study estimated the total national direct expenditure on breast cancer screening in the U.S. from 2019–2022 using a cohort of 940,000 women (70% commercially insured and 30% insured through Medicare Advantage). Additionally, it estimated the average costs associated with each guideline, including the average lifetime cost to screen one woman until age 74.

The aggregate cost of screening and recall per year was approximately $11 billion with a yearly participation rate of 37% of eligible women (recall that the guidelines vary in their recommendations of yearly vs. biennial mammograms). The cost to detect one invasive cancer or ductal carcinoma in situ (DCIS), excluding all treatment costs, was $55,000 for 3D mammography and $44,000 for 2D mammography. If all eligible women in the U.S. were screened, the projected costs to the nation's healthcare system across the 3 guidelines varied widely, recalling that breast cancer survival rates are similar across all 3.

- The cost using the ACR guideline was $30 billion.
- The cost using the ACS guideline was $18 billion.
- The cost using the USPSTF guideline was $7.7 billion.

Screening high-risk women contributed 55% to the cost of ACR, 52% to the cost of ACS and 19% to the cost of USPSTF. The average lifetime cost to screen a woman using each guideline until age 74 was $13,400 for ACR, $7,900 for ACS and $6,900 for USPSTF.

Figure 1



Of U.S. women who get screened, 82.7% screen annually, consistent with the most expensive guideline from the ACR.[4] The ACR and ACS guidelines are the most expensive, partly because a substantial proportion of women (8% to 17%) may meet the criteria for high risk and are recommended supplemental MRI screening. The ACR and ACS guidelines recommend using risk models that consider family history such as BRCAPRO and Tyrer-Cuzick, where the proportion of women determined to have a lifetime risk greater than 20% was shown to range twenty-fold from 0.6% to 12%, respectively.[5] Improved concordance between risk models on who is determined to be high risk is needed, since this is a significant driver of costs. Further, the 2023 ACR guidelines for high-risk women also recommend that women with dense breasts who desire supplemental screening have an MRI beginning at 40 years old. This recommendation was a major driver of costs, based on the estimate that approximately 9% of women would need MRI screening. There are data on improved breast cancer detection rates using MRI screening in women with dense breasts, but survival data from randomized controlled trials (RCTs) is currently lacking.[6]

Although breast cancer mortality has significantly declined over the past 50 years, only approximately 25% of that decline is related to screening, with 75% related to advances in treatment.[7] With all 3 major breast cancer screening guidelines having similar reductions in breast cancer mortality, the USPSTF guideline is the most cost effective for our healthcare system.

Is oseltamivir (Tamiflu) of any value in non-severe influenza?

The World Health Organization (WHO) guidelines for management of severe illness caused by influenza conditionally recommend the use of oseltamivir. However, most of the evidence supporting this recommendation was of low or very low certainty, leaving optimal management in doubt. Previous network meta-analyses have assessed effects of antiviral drugs for treating influenza but have been limited in failure to provide absolute effects of interventions and overlooked crucial patient-important outcomes including mortality and hospitalization.[8,9,10]

A recent meta-analysis has updated the impact of oseltamivir and antivirals available in other countries by including newer studies looking at the impact of antiviral treatment of influenza.[11] There were 73 RCTs included in this analysis. With respect to oseltamivir, there was little or no reduction in mortality in either low-risk or high-risk patients (estimated benefit approximately 1 per 3,000 treated patients). Hospital admission was not reduced in low-risk patients, and the reduction in high-risk patients was only 4 per 1,000 treated patients. There was also little impact on admission to the ICU at a reduction of 2 per 1,000 treated patients. The mean decrease in symptom duration with treatment was less than one day. There was moderate certainty that oseltamivir increased adverse effects, predominantly nausea and vomiting.

In conclusion, the authors commented that "oseltamivir was found to have little or no effect on mortality and hospital admission, likely has no important effect on time of symptom alleviation, and likely increases risk of adverse events related to treatment." Unless patients present with test-positive severe influenza, the data does not support the use of oseltamivir.

Fexolinetant for treatment of post-menopausal hot flushes

Fexolinetant has emerged as a novel treatment option for managing hot flushes, a common symptom experienced by many individuals after menopause. According to a Phase 3b RCT published in the *British Medical Journal*, this medication may be indicated for those with moderate to severe vasomotor symptoms, and who cannot tolerate or should not take hormone replacement therapy for personal or medical reasons.[12]

The multicenter RCT of 453 adults from the target population measured the primary endpoint of mean change in daily frequency of moderate to severe vasomotor symptoms over a 24-week period. The 2 comparable groups received a daily 45mg dose of fexolinetant or placebo. The study was done with predominantly white subjects (96.7%) from Europe and Canada.

At the end of the study, the mean frequency of daily events in the fexolinetant group went from 10.58 (SD 3.57) to 2.61 (SD 3.14) while for the placebo group, it went from 10.75 (SD 4.08) to 4.67 (SD 4.80). The least squares mean percentage change from baseline of daily moderate to severe vasomotor symptoms was -75.66% (95%CI -80.13% to -71.19%) for fexolinetant and -59.12% (-63.71% to -54.52%) for placebo. Of note, reduction in the primary endpoint was seen as early as week one of treatment. Additionally, no difference in safety events or concerns was reported between groups. The secondary endpoints of change in patient reported outcome measures for vasomotor symptoms and for sleep disturbance both favored the fexolinetant group. In terms of cost effectiveness, the difference between groups suggests a number needed to treat (NNT) of 6. However, the difference in the number of daily events between the treatment and the placebo group was only 2 per day. Fexolinetant is roughly $6,000 for a one-year supply.[13]

Mineralocorticoid receptor antagonists (MRAs) in heart failure meta-analysis

Based upon the available literature, the use of generic MRAs (spironolactone and eplerenone) is an AHA/ACC Class 1a, high-value recommendation to treat patients with HFrEF, provided GFR is >30 ml/min and serum potassium is < 5.0 mEq/L.[14] These recommendations are based on mortality reduction, reduction in hospitalization and cost effectiveness. In patients with HFpEF, the AHA/ACC has given the use of MRAs a Class 2b recommendation (might be reasonable/effectiveness is uncertain).

A recent study looked at a newer brand of nonsteroidal MRA, finerenone (Kerendia), in patients with HFpEF or HFmEF.[15] Although that study showed a positive composite endpoint of mortality or reduction in heart failure admission, the benefit was limited to reduction in admissions with no impact on mortality. Using the trial data, 68 patients would need to be treated for one year to prevent one hospital admission for worsening HF. Using the finerenone wholesale acquisition cost of $8,800 yearly, the cost to prevent one hospital admission would be approximately $600,000, a far cry from cost effectiveness.

Added to this body of literature is a new meta-analysis looking at the 4 large RCTs on MRA use in HF, which included the above noted trial (FINEARTS-HF), along with RALES, EMPHASIS-HF and TOPCAT.[16] The primary outcome of the analysis was again the composite of cardiovascular death or hospitalization for heart failure. Approximately 13,846 patients were included in the 4 trials. MRAs reduced the risk of cardiovascular death or heart failure hospitalization (hazard ratio 0.77 [95% CI 0.72–0.83]). The impact was far greater in HFrEF (0.66 [0.59–0.73]) compared with HFmrEF or HFpEF (0.87 [0.79–0.95]). Cardiovascular death was reduced in the HFrEF trials (0.72 [0.63–0.82]) but not in the HFpEF trials (0.92 [0.80–1.05]). Both HFpEF trials, FINEARTS-HF and TOPCAT, showed a reduction in heart failure admissions with no change in cardiovascular mortality. Additionally, there are 2 ongoing RCTs looking at spironolactone in patients with HFpEF. With an MRA, the risk of hyperkalaemia was doubled compared with placebo (odds ratio 2.27 [95% CI 2.02–2.56]), but the risk of hypokalaemia (potassium <3·5 mmol/L) was halved (0.51 [0.45–0.57]; 7% vs 14%).

Given the lack of cost effectiveness of finerenone and the robust data supporting the use of generic MRAs, spironolactone and eplerenone should be favored for use in patients with HFrEF and possibly in selected patients with HFmEF/HFpEF given the limited benefit and the class 2b ACC/AHA recommendation.

Thyroidectomy without radioactive iodine in low-risk thyroid cancer

An important area of over-treatment and associated harm is the aggressive treatment of low-risk papillary thyroid cancer. When papillary thyroid cancers are small, most of these patients should be managed with active surveillance and not thyroidectomy, with the safety of this approach established now for greater than 10 years of follow-up.[17] This recommendation is based on data showing that these tumors have a favorable prognosis, with a mortality rate of just 0.5 per 100,000 in women and 0.3 per 100,000 in men.

Added to this body of evidence is an important new study showing that in those patients with low-risk thyroid cancers who undergo thyroidectomy, post-operative radioiodine can also be safely omitted.[18] Included patients were aged 18 years or older, had differentiated thyroid cancer (such as papillary, follicular or oncocytic), tumors ≤ 2 cm, and the absence of extra-thyroidal extension. The study looked at 698 patients who were evaluable 5 years after randomization to surgery with or without the addition of radioiodine. An adverse event was described as abnormal uptake on thyroid scanning, abnormal neck ultrasound, elevated thyroglobulin levels, or any combination of these. Approximately 93.2% of patients in the no-radioiodine group and 94.8% of patients in the post-op radioiodine group were adverse event-free at 5 years, the difference not being statistically different. These data suggest that post-op radioiodine treatment can be safely omitted in this patient population.

Pre-biopsy MRI can safely identify who does not need immediate prostate biopsy

A recent study summarized in a previous Forum issue demonstrated strong evidence in support of pre-biopsy MRI assessment of suspected prostate cancer to decrease unnecessary biopsies.[19] In that study, clinically significant disease was detected at the same rates as systematic transrectal ultrasound (TRUS) without MRI, while unnecessary biopsy of clinically insignificant disease was avoided.

Another study was recently published that further supports the use of MRI in prostate cancer diagnosis and provides additional insights into how to identify appropriate candidates with elevated prostate-specific antigen (PSA) who can safely avoid prostate biopsy.[20] Approximately 593 men from 54 urology practices in Germany underwent multiparametric MRI for elevated PSA, abnormal digital rectal exam (DRE) or both, and were enrolled in the prospective longitudinal cohort study where they were followed for 3 years with clinical assessment recommended every 6 months. Results showed that 286 (48%) of them had a negative MRI, and 242 (41% of the total, 85% of those with negative initial MRI) safely avoided prostate biopsy over 3 years. A Prostate Imaging Reporting and Data System (PI-RADS) scoring of 1 to 2 out of 5 was considered as a negative MRI. Clinically significant prostate cancer was defined as Gleason Group (GG) >1. The negative predictive value of a negative MRI for prostate cancer at 3 years for clinically significant prostate cancer was 96% (95% CI, 94%-98% [275 of 286 patients]). It is important to note that regular follow-up with repeat PSA and DRE identified those few patients who needed a follow-up MRI, prostate biopsy or both, and who developed clinically significant prostate cancer during the 3-year follow-up period. This “oncological safety net” is important (and effective) when following MRI pre-biopsy guidelines.

Impact of bodyweight loss on type 2 diabetes remission rate

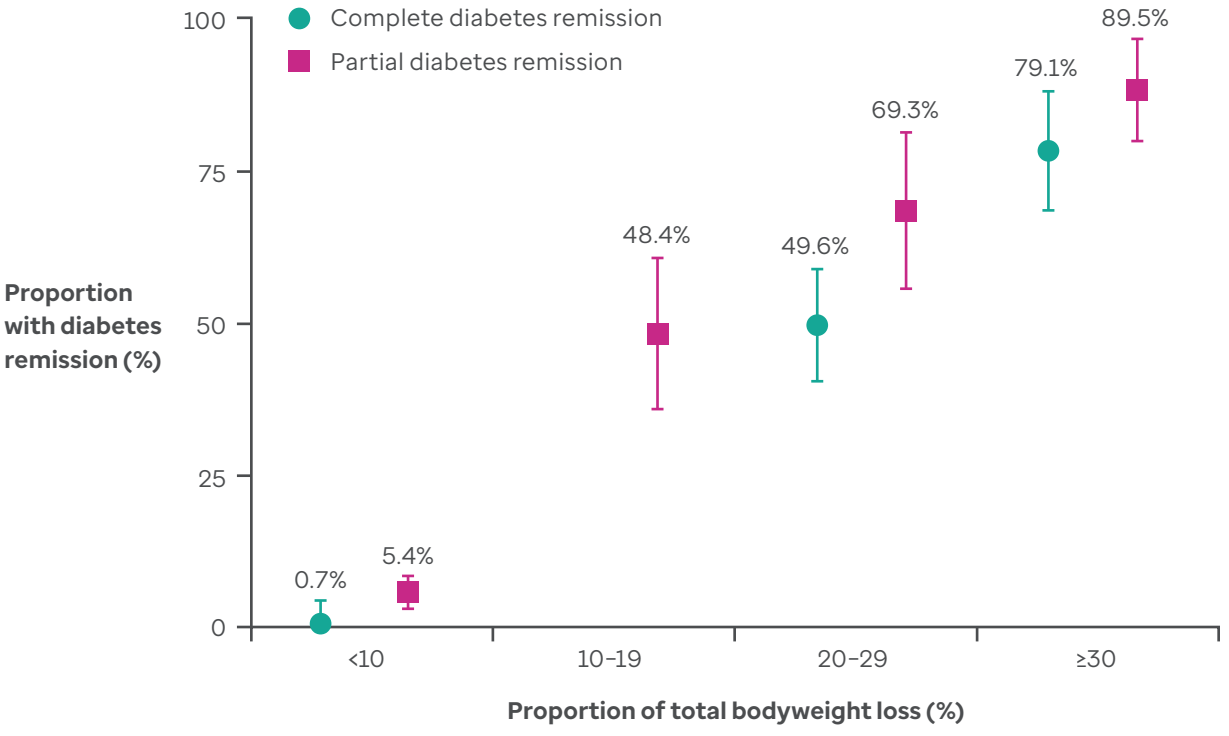
Studies have shown that bodyweight loss is associated with remission of type 2 diabetes and have suggested that younger age, shorter disease duration, better glycemic control and absence of insulin use might improve remission rates. However, the quantitative relationship between the degree of bodyweight loss and probability of remission remains unknown. A recent meta-analysis in *The Lancet Diabetes and Endocrinology* looked at 22 publications that measured remission of type 2 diabetes (DM2) as a function of percent of total body weight loss.[21] Remission was defined as an HbA1c < 6.0% or a fasting plasma glucose (FPG) < 100 mg/dl while off all diabetes medications. Interestingly, the authors defined partial diabetes remission as an HbA1c concentration less than 6.5% or FPG concentration less than 126 mg/dL or both, with no use of glucose-lowering drugs. In the U.S., this definition would meet criteria for complete remission.

For studies with < 10% bodyweight loss (5.2% mean bodyweight loss), the remission rate was less than 1%. The rate increased to 50% for studies with 20%–29% bodyweight loss and further rose to 79% for studies with at least 30% bodyweight loss (figure 2). In terms of partial remission, the rate was 5.4% for those with < 10% body weight loss, increasing to 48% for studies with 10%–19% bodyweight loss, 69% for studies with 20%–29% bodyweight loss, and 90% (80.0–96.6) for studies with at least 30% bodyweight loss.

These results are striking and should serve to further focus our efforts on the use of GLP1-RAs or bariatric/metabolic surgery for patients with DM2 and obesity. We still lack long-term cost effectiveness analyses for the GLP1-RAs associated with DM2 remission that would encompass the quality and cost outcomes related to the reductions in rates of retinopathy, neuropathy, CVD, CKD, joint arthroplasty and spine surgery, obstructive sleep apnea, and metabolic related cirrhosis, among others. Despite the lack of these models, they are likely to prove cost effective over a 5- to 10-year time horizon.

Figure 2: Pooled mean proportion of participants with diabetes remission, categorized by the proportion of total body weight loss.

Error bars represent 95% CIs of the pooled estimates. No studies were identified that reported complete diabetes remission in the 10%–19% bodyweight loss category, preventing data pooling for this group.



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Kenneth Roy Cohen, MD, FACP

Dr. Kenneth Cohen is an experienced physician leader, practicing internist and researcher who has attained national recognition for health care quality improvement. He was one of the founding physicians of New West Physicians, which is the largest primary care group practice in Colorado and now part of Optum Care. He served as chief medical officer from 1995–2020. He now serves as the executive director of Translational Research for Optum Care and co-leads the Optum Center for Research and Innovation. Dr. Cohen has received awards of recognition and distinction for teaching, including the Lutheran Medical Center Physician of the Year award in 2011. Under his stewardship, New West Physicians was awarded the AMGA Acclaim award in 2015 and the CDC Million Hearts Hypertension Champion Award in 2017. He is a Clinical Associate Professor of Medicine and Pharmacy at the University of Colorado School of Medicine and School of Pharmacy. He is a Fellow of the American College of Physicians and a member of the Phi Beta Kappa and Alpha Omega Alpha honor societies.

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With over 20 years of clinical, academic and leadership experience regionally, nationally and internationally, Dr. Jacobs currently serves as primary care engagement lead national medical director for Optimal Care within Clinical Performance at Optum Care. He is a clinical professor of Family Medicine at the Washington State University College of Medicine. He graduated from Pomona College with honors and from the John A. Burns School of Medicine as a member of the Alpha Omega Alpha honor society.

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Dr. Prakash Jayakumar is a surgeon leader dedicated to the value-based transformation of health care at the individual, organizational, and systems level. He serves as Senior Medical Director in Specialist Engagement and Precision Health at Optum, and Assistant Professor of Surgery at Dell Medical School, The University of Texas at Austin. Dr Jayakumar has worked extensively in developing integrated team-based models of specialty care that leverage digital health solutions at the point of care including those that leverage patient generated health data, wearable sensors, real time activity tracking, decision aids, and clinical decision support tools. He holds multiple visiting professorships at institutions in the US and the UK where he completed his medical degree with distinction (Kings College London), Scales Medal in orthopaedic sciences (University College London), orthopedic residency (London Deanery), PhD in Musculoskeletal Sciences (Balliol College, Oxford University), and Masters in Healthcare Design (Royal College of Art). He holds executive certifications in A.I in Health (M.I.T), Value-based Care (Harvard Business School), Health Care Innovation (INSEAD Business School), and a Harkness Fellowship in Health Care Policy and Practice Innovation (Commonwealth Fund).

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