Negative: MCED

By “Coach Vance” Trefethen

***Resolved: The United States federal government substantially reform the use of Artificial Intelligence technology***

Case Summary: The AFF plan passes the Medicare Multi-Cancer Early Detection Screening Coverage Act, a bill pending in Congress but not yet enacted. It amends Title XVIII of the Social Security Act to allow Medicare to cover any MCED tests that are approved by the FDA. MCED is an AI-driven revolutionary technique for early detection of cancer. It can detect cells deposited in the blood that are markers for dozens of types of cancer, many of which have zero methods of early screening today. A simple blood test can catch cancer much earlier and allow treatment before it gets too bad to treat.  
 This NEG brief tells us “not so fast” – AFF is getting ahead of the science with all the hype. No MCED has been approved by the FDA yet, so there’s nothing for Medicare to pay for. Let’s do more study and make sure this works before we worry about paying for it. And if it does work, we’d all be better off NOT having Medicare pay for it, since Medicare has a habit of stifling innovation and driving higher prices.

Negative: MCED 3

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Critical gaps in current knowledge about MCEDs means uncertainty about how, and how well, they will work. More study needed to determine costs and benefits 3

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Increased screening = overtreatment due to increased detection of forms of cancer that aren’t dangerous 8

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Negative: MCED

SOLVENCY

1. More study needed

Critical gaps in current knowledge about MCEDs means uncertainty about how, and how well, they will work. More study needed to determine costs and benefits

Dr [Ruth Etzioni,](javascript:;) Roman Gulati, and Dr. Noel S Weiss 2021 (All 3 are with Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle. Etzioni – PhD. Gulati – M.S. Weiss – MD, DrPH) Multicancer Early Detection: Learning From the Past to Meet the Future 27 Aug 2021 <https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djab168/6358734> (accessed 11 Nov 2021)

Multicancer early detection (MCED) tests may soon be available to screen for many cancers using a single blood test, yet little is known about these tests beyond their diagnostic performance. Taking lessons from the history of cancer early detection, we highlight 3 factors that influence how performance of early detection tests translates into benefit and benefit-harm trade-offs: the ability to readily confirm a cancer signal, the population testing strategy, and the natural histories of the targeted cancers. We explain why critical gaps in our current knowledge about each factor prevent reliably projecting the expected clinical impact of MCED testing at this point in time. Our goal is to communicate how much uncertainty there is about the possible effects of MCED tests on population health so that patients, providers, regulatory agencies, and the public are well informed about what is reasonable to expect from this potentially important technological advance. We also urge the community to invest in a coordinated effort to collect data on MCED test dissemination and outcomes so that these can be tracked and studied while the tests are rigorously evaluated for benefit, harm, and cost.

MCED research is still in early stages. We don’t know yet whether it will provide meaningful clinical impact

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These advantages stand to alter the way we diagnose these cancers and, if they can translate into positive clinical impact, would dramatically change the practice of early detection. The investigation of whether diagnostic performance translates to meaningful clinical impact is typically a lengthy endeavor. In 2002, the Early Detection Research Network of the National Cancer Institute codified the typical sequence of studies required to establish benefit into a pipeline, the Phases of Biomarker Development (PBD). This pipeline labels retrospective diagnostic performance studies as early phase (phase 2) and randomized screening trials as the ultimate phase (phase 5) before a test can be judged beneficial. From a PBD perspective, MCED research is indeed still early phase. We do not yet know what the clinical impact of the technology will be, nor are we yet able to assess whether it will produce a sustainable benefit.

More study needed on MCED deployment strategy

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Determining how to deploy MCED tests is more complex because the various target cancers may have different preferred strategies. If an MCED test is offered annually, the harm-benefit trade-off will be very different than if it is offered every few years. Even if we knew for certain that the best way to utilize MCED tests is as a complement to existing screening tests, determining a preferred strategy would require much more information about the natural history of the target cancers than is currently known.

2. Estimates of success exaggerated

Knowledge gaps mean estimated benefits of MCED are uncertain and unreliable

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In this commentary, we highlight lessons learned from the history of cancer early detection research about 3 factors impacting how diagnostic performance of a screening test translates to benefit and harm: the ability to readily confirm a cancer signal, the population testing strategy, and knowledge of the natural histories of the targeted cancers. We make the case that knowledge gaps surrounding each of these factors imply that any projection of the likely population impact of MCED tests based on information published to date is highly uncertain and not reliable. We argue that greater awareness is needed of the complexities involved in translating from diagnostic performance to population benefit and harm if we want to ensure that patients, providers, and the public are well informed about what they can expect from MCED technology.

Lack of information about latency periods of most cancers means we can’t estimate the effectiveness of MCED, and short early stage durations will reduce MCED effectiveness

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We have estimates of tumor latency for breast, lung, and prostate cancers, but we lack estimates for cancers not currently screened for, such as pancreatic and liver cancers. Further, little is known about the fraction of the latent period representing early stage disease. The window of opportunity for MCED tests to detect these cancers early is therefore also uncertain. Even if an MCED test shows high sensitivity to detect a certain cancer at an early stage in a retrospective study, the opportunity for that test to detect the cancer at an early stage under a prospective screening protocol will be lower when the early stage duration is shorter.

Earlier screening doesn’t necessarily mean better patient outcomes. Example: Breast and prostate cancer went up after screening got better

THE LANCET ONCOLOGY 2014(a medical journal; article was co-authored by: [Prof. Laura J. Esserman](https://www.ncbi.nlm.nih.gov/pubmed/?term=Esserman%20LJ%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Ian M. Thompson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson%20IM%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Brian Reid](https://www.ncbi.nlm.nih.gov/pubmed/?term=Reid%20B%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Peter Nelson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nelson%20P%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. David F. Ransohoff](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ransohoff%20DF%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. H. Gilbert Welch](https://www.ncbi.nlm.nih.gov/pubmed/?term=Welch%20HG%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Shelley Hwang](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hwang%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Donald A. Berry](https://www.ncbi.nlm.nih.gov/pubmed/?term=Berry%20DA%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. Kenneth W. Kinzler](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kinzler%20KW%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. William C. Black](https://www.ncbi.nlm.nih.gov/pubmed/?term=Black%20WC%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Mina Bissell](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bissell%20M%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Howard Parnes](https://www.ncbi.nlm.nih.gov/pubmed/?term=Parnes%20H%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, and [Sudhir Srivastava](https://www.ncbi.nlm.nih.gov/pubmed/?term=Srivastava%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD) May 2014 Addressing overdiagnosis and overtreatment in cancer: a prescription for change https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/

Screening is based on the assumption that cancer has an orderly and gradual progression ([figure 1A](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/figure/F1/)). Good survival outcomes for patients with the earliest stages of disease led to the conclusion that detection of cancer at an early stage would dramatically reduce cancer mortality. For some cancers, incidence of disease dropped after screening was initiated (eg, cervical and colon cancer), but it increased for others (eg, breast and prostate cancer). In breast and prostate cancer, for example, screening has not had as big an effect on mortality, or elimination of regional (stage II or III) disease, as was expected, which begs the question: why not, and what can we do to improve this situation?

No way to accurately predict what percentage of cancers will be caught earlier and at what stage they would be caught

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Given the gaps in our knowledge about natural history for most cancers included in MCED tests, we cannot reliably project how often the tests will successfully shift cases from advanced to early stage at diagnosis. Clarke et al. projected the implied cancer mortality reduction from redistributing all stage IV cases equally across stages I-III for a range of cancers to be 24% assuming that cases shifted to an earlier stage by screening would receive a corresponding shift in disease-specific survival. We believe that this projection is likely to be optimistic.

3. Treatment confusion

If the mult-cancer test doesn’t identify the “Tissue Of Origin” (TOO) it leads to confusion, endless testing, and doubt

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For multicancer tests, the problem of confirming the test result is compounded. If the test does not label the TOO, then whole-body scanning might be done, with its own sensitivity limitations and the risk of identifying incidental benign lesions. If the test labels the TOO but no tumor is visualized, this may be indicative that no cancer is present. However, it could also be a false-positive result. In practice, the patient must contend with a dilemma: whether to reevaluate the same TOO, move down the list of likely sites of the tumor produced by the test, or consider the test to be a false positive (which does not automatically imply that no cancer is present, only that none of the cancers targeted by the test are present). And how to do this optimally—whether to proceed according to the test’s ordering, or disease prevalence, or personal risk (eg, due to family history of a specific cancer)—could substantially impact benefit, harm, and cost. In the absence of any guidance as to the most efficient procedure for confirming a positive MCED test result, we are almost completely in the dark about how often the test might lead to unnecessary confirmation imaging exams and biopsies.

4. All current “success” studies are flawed or inconclusive

Studies showing benefit of MCED don’t prove much because 1) no proof of benefit/harm tradeoff; 2) don’t know when cancer would have been found without MCED; 3) don’t know what patient outcome would have been without MCED

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Ongoing prospective studies, which are using these tests to screen large numbers of individuals in the target population, will provide important data regarding the ability of MCED tests to detect latent disease, the diagnostic testing pathways following a positive test, and the frequency of unnecessary confirmation tests. But even if these studies show that the tests can detect some targeted cancers before they would have been diagnosed clinically, this alone will not be a guarantee of adequate population benefit or sustainable benefit-harm trade-offs. With these single-arm prospective studies, we can know how many cancers are found by the test, what type, and what stage, but we do not know if or when those cancers would have been found without the test. Most importantly, we cannot know whether the fate of persons with these cancers would have been different in the absence of the test.

Current studies are insufficient: Much bigger and longer-term randomized screening trials of MCED are needed to prove its effectiveness

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There is a reason why randomized screening trials are considered to be the gold standard for evaluating cancer screening tests. In principle, these trials provide empirical validation that the screening test and disease natural history are likely to come together in a way that translates favorable diagnostic performance into clinically significant benefit, as well as permitting assessment of the harms of the test. Randomized screening trials are the ultimate phase of the Early Detection Research Network’s PBD, and they are an evidence gold standard used by national policy panels such as the US Preventive Services Task Force. Yet, randomized screening trials require vast sample sizes and (for many forms of malignancy) long follow-up. Further, they can only examine a small number of possible screening strategies. And, despite being simple in concept, they tend to be complex to implement, analyze, and interpret. The promise of MCED testing and the uncertainty about its population impact have created a need for randomized trials. It is hoped that such trials can be conducted expeditiously and designed to terminate early in case of a strong early signal of benefit or lack thereof. Shortening the typically long timeline for screening trials would clearly be welcomed by the public, but this is challenging because benefit accrues over time, so short-duration trials may not show a large clinical benefit.

5. Not approved yet

Link: Plan pays for MCED after they’re approved by FDA

Failure: No MCED test has been approved

**[Note: In context this article is talking about approval in both the U.S. and the United Kingdom]**

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” <https://www.nature.com/articles/s41416-021-01498-4>

No MCED test is licensed for use so none have a price yet (and as

with many therapeutic drugs would be determined after deﬁnitive

RCTs have completed and negotiation with payers). The cost of an

MCED test will depend on where blood samples are taken. Current

cancer screening (except for bowel using FIT) is undertaken at

specialist screening units. However, screening for cardiovascular

disease involving a blood draw for lipid levels is already performed

in primary care.

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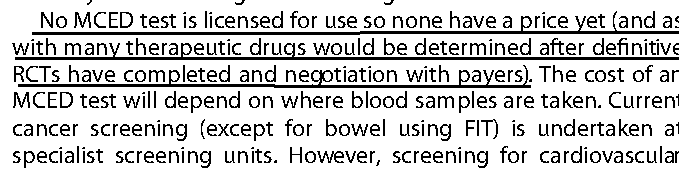
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DISADVANTAGES

1. Harmful Overdiagnosis & Overtreatment

Why rushing ahead without more study is bad: Early cancer detection can create negative net benefits - Risk of overdiagnosis and overtreatment

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Furthermore, even if benefit can be established, a central lesson of single-cancer screening is that the value of early detection can be a double-edged sword. For many cancers, earlier detection and treatment is more likely to result in cure, yet for some cancers, it can also lead to overdiagnosis and overtreatment. As a consequence, evaluation of both benefit and harm of a novel early detection technology is required before it can be recommended for general use in the population.

Overtreatment of cancer not only doesn’t help, it can be harmful

THE LANCET ONCOLOGY 2014(a medical journal; article was co-authored by: [Prof. Laura J. Esserman](https://www.ncbi.nlm.nih.gov/pubmed/?term=Esserman%20LJ%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Ian M. Thompson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson%20IM%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Brian Reid](https://www.ncbi.nlm.nih.gov/pubmed/?term=Reid%20B%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Peter Nelson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nelson%20P%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. David F. Ransohoff](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ransohoff%20DF%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. H. Gilbert Welch](https://www.ncbi.nlm.nih.gov/pubmed/?term=Welch%20HG%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Shelley Hwang](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hwang%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Donald A. Berry](https://www.ncbi.nlm.nih.gov/pubmed/?term=Berry%20DA%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. Kenneth W. Kinzler](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kinzler%20KW%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. William C. Black](https://www.ncbi.nlm.nih.gov/pubmed/?term=Black%20WC%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Mina Bissell](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bissell%20M%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Howard Parnes](https://www.ncbi.nlm.nih.gov/pubmed/?term=Parnes%20H%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, and [Sudhir Srivastava](https://www.ncbi.nlm.nih.gov/pubmed/?term=Srivastava%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD) May 2014 Addressing overdiagnosis and overtreatment in cancer: a prescription for change https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/

Historically, screening for neuroblastoma was initiated because this childhood cancer could be detected by urine catecholamines, and seemed to have a better prognosis if diagnosed before the age of 1 year. However, results of a large screening programme (476 694 children) in Quebec, Canada, showed that screening was not effective—in fact it was harmful. The proportion of lethal cases did not decrease, nor did mortality, but many more cases of what is now called neuroblastoma S (the spontaneously regressing type) were detected and treated with surgery and chemotherapy. This spontaneously regressing form had not previously been recognised because, until screening, these tumours rarely came to clinical attention. This example draws attention to two important principles: tumours can regress, and treatment of indolent tumours can often cause harm.

2. Added costs from unnecessary testing and treatment

MCED will have false positives and require a lot of confirmation testing, which will add additional costs

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Societal values about how much confirmation testing is tolerable—and how to follow patients with positive results but no confirmed cancer—are likely to evolve in tandem with protocols for MCED test workup. We also do not know the extent to which the advanced imaging prompted by the test might reveal incidental lesions that are not cancer with their own demands for evaluation and further care. In the National Lung Screening Trial, the percentage of all screening tests that identified abnormalities not suspicious for lung cancer was more than 3 times as high in the group that received low-dose computed tomography screening as in the comparison group that received chest radiography. Beyond the test itself, the burden of confirming MCED test results could turn out to be the costliest aspect of population MCED screening.

Increased screening = overtreatment due to increased detection of forms of cancer that aren’t dangerous

THE LANCET ONCOLOGY 2014(a medical journal; article was co-authored by: [Prof. Laura J. Esserman](https://www.ncbi.nlm.nih.gov/pubmed/?term=Esserman%20LJ%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Ian M. Thompson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson%20IM%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Brian Reid](https://www.ncbi.nlm.nih.gov/pubmed/?term=Reid%20B%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Peter Nelson](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nelson%20P%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. David F. Ransohoff](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ransohoff%20DF%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. H. Gilbert Welch](https://www.ncbi.nlm.nih.gov/pubmed/?term=Welch%20HG%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Shelley Hwang](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hwang%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Donald A. Berry](https://www.ncbi.nlm.nih.gov/pubmed/?term=Berry%20DA%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. Kenneth W. Kinzler](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kinzler%20KW%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Prof. William C. Black](https://www.ncbi.nlm.nih.gov/pubmed/?term=Black%20WC%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), MD, [Prof. Mina Bissell](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bissell%20M%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, [Howard Parnes](https://www.ncbi.nlm.nih.gov/pubmed/?term=Parnes%20H%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD, and [Sudhir Srivastava](https://www.ncbi.nlm.nih.gov/pubmed/?term=Srivastava%20S%5BAuthor%5D&cauthor=true&cauthor_uid=24807866), PhD) May 2014 Addressing overdiagnosis and overtreatment in cancer: a prescription for change https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/

Screening undoubtedly detects indolent disease, best exemplified in prostate cancer, breast cancer, and even lung cancer. This detection of indolent disease is mainly due to the inherent tendency of all screening tests to preferentially detect slower growing cancers because more rapidly growing cancers are more likely to present between screens. Indolent disease might account for 15–75% of all cancers, depending on organ type. Disease-based screening and diagnostic scans for various purposes have contributed to cancer overdiagnosis, which leads to overtreatment when not recognised, thus reducing the overall effectiveness of screening.

Example: Better screening led to more thyroid cancer treatment, but all the extra cases were non-harmful (“indolent”) tumors, so no actual decline in death rates

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Thyroid carcinoma is an excellent example of how technological advances in diagnostic imaging have led to the detection of a reservoir of indolent disease. Between 1975 and 2009, the incidence of thyroid cancer nearly tripled in the USA (from 4.9 per 100 000 to 14.3 per 100 000), whereas the death rate remained constant (from 0.56 per 100 000 to 0.52 per 100 000). The increase in incidence has been almost entirely due to small (<2 cm) papillary cancers, the most indolent histological type. Results of a study of Finnish adults showed that 36% of participants without any previous history of thyroid disease had at least one papillary carcinoma at autopsy. The rapid growth of ultrasound and fine-needle aspiration in the mid-1980s probably increased detection. Although only 4–7% of the adult US population has a palpable thyroid nodule, about 50% have a thyroid nodule detectable by ultrasound. One thoughtful radiologist has questioned whether it is “time to turn off the ultrasound machines” because the impalpable cancers detected by ultrasound are almost uniformly indolent.

Example: Screening for prostate cancer led to overdiagnosis and overtreatment, leading to harmful side-effects and higher costs from unnecessary surgeries

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Adenocarcinoma of the prostate is probably the tumour with the greatest risk for overdiagnosis and overtreatment. During autopsy, tumours are often detected in the prostate, with older men more likely to have an indolent tumour (ie, a man aged 60 years might have a 50–60% risk of occult cancer).[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/#R12) With repeated prostate-specific antigen (PSA) testing and 10–12-core biopsy of the prostate, often done repeatedly, small, low-grade tumours are frequently detected. Attesting to the relatively low biological potential of these lesions are the 99% and 97% disease-specific survivals at 5 years and 10 years of follow-up, respectively, for men who are simply monitored and only given treatment if they have evidence of a grade or volume increase.[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/#R11) Despite this indolent behaviour, greater than 90% of these tumours are treated with radiation or surgery,[27](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/#R27) generating morbidities of treatment (eg, sexual, urinary, and gastrointestinal side-effects, in about 15–20% of patients), increased risk of secondary malignancies (with radiation), and increased cost.[28](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322920/#R28) Even active surveillance is hampered by the growing risk of sepsis in men undergoing repeated biopsies accompanied by increased cost and anxiety.

False alarms cost billions of dollars in followup tests

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Fuelled by fear of missing the chance for early detection, an aggressive strategy of undertaking biopsies has evolved. When radiologists recommend a biopsy, primary care physicians and oncologists feel compelled to follow the recommendations, unaware that many of these target lesions are benign or indolent, and behave as if the philosophy to leave no stone unturned causes no harm. However, the result is that biopsy samples are taken from hundreds of thousands of benign lesions, and treatment is given for tens of thousands of precancerous lesions that, if left alone, would never be lethal. In addition to needless morbidity, these interventions cost billions of dollars.

Link & Brink: Medicare is on the brink of insolvency, and medical services will be cut when the money runs out

Patricia A. Davis 2021 (Specialist in Health Care Financing with Congressional Research Service) 25 Oct 2021 Medicare: Insolvency Projections <https://sgp.fas.org/crs/misc/RS20946.pdf> (accessed 11 Nov 2021)

In their 2021 report, the Medicare trustees project the HI trust fund will be exhausted in 2026. At that time, there will no longer be sufficient funds to fully cover Part A expenditures; although the trust fund would continue to receive tax and other income, those funds would cover only 91% of Part A expenses. The Medicare trustees have suggested that in the event of HI trust fund insolvency, there could initially be delays in payments to plans and providers and, following soon after, beneficiary access to Part A services could “rapidly be curtailed.”

Impact: Losing Medicare means losing health care for older Americans

Bob Rosenblatt 2017 (Senior Fellow with the National Academy of Social Insurance) Why Medicare Matters to All Americans 7 Feb 2017 <https://www.aarp.org/politics-society/advocacy/info-2017/why-medicare-matters-to-all-americans.html> (accessed 11 Nov 2021)

Before Medicare, almost 1 in 2 older Americans had no health insurance and faced a bleak future if they got seriously ill. Their choices often included wiping out their savings, taking money from their children, seeking welfare or doing without care. Medicare delivers a guaranteed level of coverage to people who might not otherwise be able to afford it. And it helps insulate beneficiaries from rising health care costs. People enrolled in the program may still pay thousands of dollars a year for health care, but their access to health care is vastly better than before the program existed.

3. Medicare stifles innovation

**If MCED really does work at some point in the future, the best way to roll it out would be to NOT have it be covered by Medicare.**

New procedures NOT covered by Medicare get better and cheaper over time. Example: Eye surgeries

Dr. Neil Minkoff 2012 (M.D.) 22 May 2012 FORBES “Medicare's Payment System Harms Medical Innovation” <https://www.forbes.com/sites/aroy/2012/05/22/medicares-payment-system-harms-medical-innovation/?sh=1c0878d771c8> (accessed 11 Nov 2021) (**“a 20% increase” is how the original article has it, but it’s supposed to read “a 20% DECREASE” – from $2100 to $1700**)

Here is an example: over the past five years, Medicare reimbursement for cataract surgery rose from around $900 to about $1,050, a 17% increase, despite a growing volume of procedures as the population ages and what would otherwise be an incentive to lower prices to attract this new volume. Conversely, elective visual corrective surgery dropped over a similar time span from $2,100 per eye to $1,700, a 20% increase. The pressure of the market forced providers to innovate better, more cost-effective ways to do the procedure while maintaining a positive, safe patient experience. These providers have tremendous incentive to measure, report and improve quality-of-care, patient experience and cost.

Example: New treatments for kidney failure are more advanced in GUATEMALA than the US because of Medicare

Dr. Brian Blase 2019 (PhD; *served as a special assistant to President Trump at the National Economic Council; president of Blase Policy Strategies LLC; senior fellow with the Texas Public Policy Foundation* ) Why Warren's Plan Will Lead to Worse Health Care <https://www.realclearpolitics.com/articles/2019/11/07/why_warrens_plan_will_lead_to_worse_health_care_141676.html>

For evidence of the devastating impact of Medicare’s control of payments, look no further than the sorry state of American kidney care, with high death rates and outdated, inefficient treatments. Only 12% of American patients undergo dialysis at home, where they could receive treatment while they sleep, compared to 80% in Hong Kong and 56% in Guatemala. One kidney care administrator has remarked: “The last 30 years as a country, all we’ve done is wait for kidneys to fail and we put people on dialysis.”  The reason for this devastating outcome? Medicare has covered all end-stage kidney disease treatment since 1973. Dialysis providers can send large bills to Washington to cover inefficient care. They stand in the way of reform while patients, particularly the most vulnerable, suffer. And Medicare — as the single payer for end-stage kidney disease — is the primary culprit for lack of market innovation and the resulting death and destruction.

Medicare’s payment system blocks health care innovation

Dr. Neil Minkoff 2012 (M.D.) 22 May 2012 FORBES “Medicare's Payment System Harms Medical Innovation” <https://www.forbes.com/sites/aroy/2012/05/22/medicares-payment-system-harms-medical-innovation/?sh=1c0878d771c8> (accessed 11 Nov 2021)

Medicare’s payment system hinders innovation in health care. How? Government is harmful to medical innovation by setting so much of the reimbursement process. By being, by far, the largest payer of healthcare claims in America, the Medicare fee schedule drives the market for all other private payers. In essence, this sets a floor for clinical reimbursement. Hospitals then set budgets based on expected revenue, not based on the cost of providing specific services. Patient experience, convenience and quality of care do not effect, or at least significantly effect, clinical reimbursement in the standard, traditional fee-for-service Medicare program. There is therefore no incentive to find ways to create new value in the system.

Impact: Turn the AFF advantages – NEG gets them better

If you want high tech medical innovation, keep Medicare out of it and let it be done by the free market. You’ll see faster innovation and lower prices and get the advantages, if there are any, of MCED better that way.