ITEM #44

(Exhibit 4 – Healthcare Ordinance Report)

ADDITIONAL MATERIAL

REGULAR MEETING

OCTOBER 19, 2021

SUBMITTED AT THE REQUEST OF

OFFICE OF THE COUNTY ATTORNEY

Exhibit 4

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MEMORANDUM

TO: Board of County Commissioners

FROM: René D. Harrod, Chief Deputy County Attorney

DATE: October 14, 2021

RE: **Broward County Preventive Health Care Program Report**

Item 44 on the Board's October 19, 2021, agenda (the proposed Broward County Preventive Health Care Program Ordinance) indicates that Exhibit 4, the report by Dr. Ricardo Cury, would be distributed as Additional Material when final. Attached hereto is that report, which was finalized this morning. In light of the short time period before the Board's consideration of this item, this memorandum provides a very brief summary of Dr. Cury's report and the proposed preventive health care program.

The report provides a detailed assessment of the health of County residents, including the first and second leading causes of death: heart disease and cancer. Approximately half of County residents suffer from heart disease, and 1 in 4 deaths are from heart disease. The plan proposes to utilize a 0.5% sales surtax to provide "Cardiovascular Disease Prevention Clinics" for persons who are poor or medically indigent and to fund innovative technology for heart disease screenings for all County residents. The proposed initial allocation of surtax proceeds is as follows:

- 35% for primary and preventive care through Cardiovascular Disease Prevention Clinics; limited to persons who are indigent or medically poor;
- 40% for imaging facilities and screening services (plus any unused allocation from other categories); this is available for all Broward County residents;
- 20% for cardiac-related hospital services; limited to persons who are indigent or medically poor; and
- 5% for continuity of care and data monitoring and analysis.

However, the plan provides for data collection and analysis and reassessment of local health needs, which would be expected to result in periodic amendments to the plan and adjustments to the allocations.

If you have questions regarding any of the foregoing, please contact the County Attorney or me (x7618).

RDH
Attachment

c: Bertha Henry, County Administrator
Bob Melton, County Auditor
Andrew J. Meyers, County Attorney

Analysis of Broward County Health Care Needs and Available Services and Recommendations for Broward County Preventive Health Care Program

Author:
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Dr. Maros Ferencik, Section Head Cardiovascular Imaging at Oregon Health & Science University
Dr. Thomas Mayrhofer, PhD Lecturer on Radiology, Massachusetts General Hospital, Harvard Medical School, and Stralsund University of Applied Sciences

Summary: This sets forth a brief assessment of the current health care needs of Broward County, focusing materially on the indigent and the medically poor, and recommends a Health Care Services Plan ("Plan") for providing health care services to qualified residents of Broward County, to be funded by a voter-approved .5% surtax pursuant to Section 212.055(4), Florida Statutes. This report contemplates that the Plan would be periodically reviewed and amended based upon operational experience, data collected, feedback from the stakeholders and participants, and the current medical needs of Broward County residents. The initial phase of the Plan focuses on preventive and diagnostic heart disease screening to address the number one leading cause of death for Broward County residents. The second phase of the Plan will focus on the preventive and diagnostic cancer screening to address the number two leading cause of death for Broward County residents.

1. Overview of Health Care Needs of Broward County

a. Indigent and Medically Poor in Primary, Preventive, and Hospital Services

Population Size: Broward County is one of the three counties in South Florida[1] that make up the Miami metropolitan area[2], which was home to an estimated 6,138,333 people in 2020. According to the 2020 Census[3], Broward County had a population of, 1,944,375 making it the second-most populous county in the state of Florida and the 17th-most populous county in the United States. Within Broward County there are about 756,657 households with approximately 2.55 persons per household[3].

Age & Gender: According to 2019 population estimates by the United Stated Census Bureau[3], the age of the population in Broward County was distributed as follows: 12% between the age of 0-9; 12% between the age of 10-19; 13% between the age of 20-29; 13% between the age of 30-39; 14% between the age of 40-49; 14% between the age of 50-59; 11% between the age of 60-69; 7% between the age of 70-79; and 4% age 80 or greater[5]. The median age was 40.4 years, and about 51.3% of the population is female. For every 100 females in the total population of the county, there were 94.9 males. For every 100 females age 18 and over, there were 92.8 males.

Race & Ethnicity: Within Broward County, the largest racial/ethnic groups identified in the 2020 census are White (33.1%), Hispanic (31.3%), and Black (26.6%)[6].

Income/Employment Status: As of the most recent 5-year American Community Survey by the US Census, the median income for a household in the county is $59,547, and the median income for an individual is $32,415. The mean household income in Broward County is higher at $85,851. About 65.8% of individuals

aged 16 years and over in Broward County are employed, with the remaining 34.2% not in the labor force. There are an estimated 534,996 people not in the labor force in Broward County. The unemployment rate in Broward County is about 6.1%. About 9.3% of families and 13.1% of the population are below the poverty line, including 18% of those under the age 18 and 13% of those aged 65 or over. The overall poverty rate in Broward County is currently estimated at 13.1%. In 2019, the Black population in Broward County was found to have a poverty rate over 18.1%, which was nearly twice as high as the White population (9.1%).

Healthcare Insurance Status: As a state, Florida has the third highest rate of uninsured residents under the age of 65 in the United States,[9] with about 2.6 million people uninsured. According to the American Community Survey by the US Census, about 85.8% of the population in Broward County has health insurance coverage, leaving about 14.2% of people in Broward County uninsured. Among individuals with health insurance in Broward County, 62.7% have private health insurance and 30.8% have public coverage.

Disease: A 2019 Broward Community Health Needs Assessment Report demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight, and 85.2% have at least one cardiovascular risk factor[10]. Over 82% of non-Hispanic Black adults in Broward County reported being overweight or obese. In 2014, approximately 190 males per 100,000 and 121 females per 100,000 were found to have ischemic heart disease within Broward County[11]. In 2018 approximately 178 males per 100,000 and 104 females per 100,000 died due to heart disease in Broward County[12]. Heart disease is the leading cause of death in Broward County, responsible for 23.6% of deaths[10].

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Approximately 1 in every 2 people in the United States suffers from some type of cardiovascular disease.[14] As a state, Florida has the 7th highest incidence of heart attacks in the country [15]. About 655,000 Americans die from heart disease each year, which is equivalent to 1 in every 4 deaths[16]. The median cost of hospitalization and care for a heart attack is $53,384, and bypass surgery costs range from $85,891-$177,546 (AHA, 2017)[15]. From 2014 to 2015, heart disease cost the United States about $219 billion[16]. Coronary artery disease is the most common type of heart disease, affecting about 18.2 million adults over the age of 20, and resulting in a death rate of 365,914 people in 2017[16]. Key modifiable risk factors for heart disease include high blood pressure, high cholesterol, smoking, diabetes and obesity.

As a state, Florida has the 7th highest incidence of heart attacks in the country.

b. Gaps Analysis: Existing Gaps in Health Care Primary, Preventive, and Hospital Services to Indigent and Medically Poor

Gaps in Diagnostic Services for Heart Disease

Heart disease is still the number one cause of death globally[17]. Many diagnostic tests currently considered the standard of care for detecting heart disease simply do not provide enough information, are not sensitive enough and lack predictive power. Sadly, this has resulted in ineffective screening strategies in asymptomatic individuals and overutilization of invasive cardiac testing in symptomatic individuals. Moreover, there is a significant minority of individuals presenting to emergency departments with chest pain who are sent home despite undetected imminent cardiac risk.

Among the existing noninvasive tests available for detecting coronary artery disease (CAD) are stress testing – including exercise treadmill tests, SPECT, and stress echo – as well as a coronary computed

tomography (CT). A number of recent studies have shown that a coronary CT-first pathway has benefits over the traditional stress testing approach[18,19].

Looking to the United Kingdom provides an example of how this shift to a CT-first strategy can happen systematically. The UK's National Institute of Health and Care Excellence (NICE) issued a clinical guidance that recommended patients with suspected anginal chest pain get a coronary CT first, rather than stress testing. In this Clinical Guidance, the NICE found that CT is the most cost-effective front-line test for patients with stable chest pain based on careful cost-effectiveness analysis[36].

Healthcare Disparities

In a community health needs assessment conducted by Cleveland Clinic Florida[8], Broward County residents who were Black, Hispanic, or recent immigrants or refugees from the Caribbean or South America were identified as being particularly vulnerable to disparities in healthcare. More recent data from the CDC showed that 57.3% of African Americans and 61.8% of Hispanics in Broward County suffer from heart disease[13]. The prevalence of heart disease is significantly greater among African Americans and Hispanics in Broward County compared to Caucasians in this region. This disparity may be due to a higher poverty rate among African Americans and Hispanics, which amplifies risk factors and negatively impacts patient ability to seek appropriate medical care. Cultural factors are another important consideration, as many Hispanic families consume diets rich in complex carbohydrates which are associated with higher risk of developing diabetes. Some local healthcare practitioners cite a mistrust of physicians among the African American community in Broward County, which results in non-adherence to prescribed medication regimens and ultimately leads to poor outcomes. Healthcare practitioners must be sensitive to these cultural issues and employ patient-centered communication in order to bridge gaps in understanding and promote healthy behaviors.

Health Literacy

The Cleveland Clinic Florida Community Health Needs Assessment of Broward County found that significant contributions to the existing healthcare gaps in the region include lack of resident knowledge and awareness of available services and poor understanding of how to navigate the current healthcare system. Broward County has a robust immigrant population, many of which have limited English proficiency. This language barrier is an important factor contributing to the current healthcare gap, which may be a target for improvement moving forward.

The Plan as implemented must include expansive efforts to promote health literacy, and should provide information in English, Spanish, Haitian Creole, and French to provide the critical information in the first- and second-languages of applicable communities. Implementation should include on the ground door-to-door health coaches that are reaching the community that needs to be reached in a manner that can be heard and one that inspires the confidence of the community. Community awareness and knowledge of available services may be addressed through health fairs and partnership with local medical schools such as Florida International University Herbert Wertheim College of Medicine to educate the community and build trust.

Other Factors

Several other factors are involved regarding existing healthcare gaps in Broward County. These include language barriers, gaps in community awareness and knowledge of available services, and lack of coordination of care among healthcare organizations. It is also worth noting that there is currently a lack in collaboration and coordination of care among healthcare providers in the county, which contributes to patient difficulty in accessing care as well as maintaining continuity of care. Florida recently began

integrating Health Information Exchange (HIE) services, which enable healthcare practitioners to safely access and share patient information electronically across sites. As patients transition from inpatient units in the hospital to outpatient clinics in the community, integration of these services would be helpful to bridge gaps in communication and coordination of care among healthcare providers.

2. Description of Proposed Services to Meet Current Gap(s) in Health Care Services

a. Expand Primary Care Support to Include Prevention for Heart Disease

The following are the Top 10 insights from the 2019 AHA/ACC Guidelines on the Primary Prevention of Cardiovascular Disease[20]:

1. The most important way to prevent atherosclerotic coronary and vascular disease, heart failure, and atrial fibrillation is to promote a **healthy lifestyle throughout life**.

2. A **team-based care approach** is an effective strategy for the prevention of cardiovascular disease. Clinicians should evaluate the social determinants of health that affect individuals to inform treatment decisions.

3. **Adults who are 40 to 75 years of age** and are being evaluated for cardiovascular disease prevention **should undergo 10-year atherosclerotic cardiovascular disease (ASCVD) risk estimation** and have a clinician–patient risk discussion before starting on pharmacological therapy, such as antihypertensive therapy, a statin, or aspirin. In addition, assessing for other risk-enhancing factors can help guide decisions about preventive interventions in select individuals, as can **coronary artery calcium scanning**.

4. All adults should consume **a healthy diet** that emphasizes the intake of vegetables, fruits, nuts, whole grains, lean vegetable or animal protein, and fish and minimizes the intake of *trans* fats, red meat and processed red meats, refined carbohydrates, and sweetened beverages. For adults with overweight and obesity, **counseling and caloric restriction are recommended for achieving and maintaining weight loss**.

5. Adults should engage in at least 150 minutes per week of accumulated **moderate-intensity physical activity** or 75 minutes per week of vigorous-intensity physical activity.

6. For adults with **type 2 diabetes mellitus, lifestyle changes**, such as improving dietary habits and achieving exercise recommendations, are crucial. If medication is indicated, **metformin is first-line therapy**, followed by consideration of a sodium-glucose cotransporter 2 inhibitor or a glucagon-like peptide-1 receptor agonist.

7. All adults should be assessed at every healthcare visit for **tobacco use**, and those who use tobacco should be assisted and strongly advised to quit.

8. **Aspirin should be used infrequently** in the routine primary prevention of ASCVD because of lack of net benefit.

9. **Statin therapy is first-line treatment** for primary prevention of ASCVD in patients with elevated low-density lipoprotein cholesterol levels (≥190 mg/dL), those with diabetes mellitus, who are 40 to 75 years of age, and those determined to be at sufficient ASCVD risk after a clinician–patient risk discussion.

10. **Nonpharmacological interventions are recommended** for all adults with elevated blood pressure or hypertension. For those requiring pharmacological therapy, the target blood pressure should generally be <130/80 mm Hg.

Cardiovascular disease (CVD) remains the leading cause of mortality in the US, and importantly coronary artery disease (CAD) is the most common cause of premature and avoidable death in the US. Despite all preventative efforts sudden cardiac death is the first presentation of heart disease in more than half of patients emphasizing the role of screening and prevention. The burden of its management and treatment requires substantial health-care resources and places a burden on patients, families and the healthcare system. The United Kingdom NHS Long Term Plan, published in 2019, recognized this burden and stated that it was "the single biggest area where the NHS can save lives over the next 10 years". It recognized that the "early detection and treatment of CVD can help patients live longer, healthier lives. Too many people are still living with undetected, high-risk conditions", and within their report they set out a series of goals, including increasing work on the prevention of heart attacks.

The role of screening programs in the prevention and detection of early disease across healthcare settings and specialties continues to expand. Optimizing screening strategies enables potential intervention earlier in disease pathways to improve patient outcomes[21,22].

Screening Program Criteria:

1. The screening program should respond to a recognized need.

Need: *Cardiovascular disease (CVD) remains the leading cause of mortality in the US, and importantly coronary artery disease (CAD) is the most common cause of premature and avoidable death in the US.*

2. The objectives of screening should be defined at the outset.

Objective: *Early detection and treatment of ASCVD can help patients live longer, healthier lives. Too many people are still living with undetected, high-risk conditions.*

Early detection and treatment of CVD can help patients live longer, healthier lives.

3. There should be a defined target population.

Target Population: *40-75 y/o high risk ASCVD asymptomatic individuals, diabetic patients, patients with familial hypercholesterolemia, or patients with strong premature history of heart disease.*

4. There should be scientific evidence of screening program effectiveness.

Evidence: *AHA/ACC guidelines supporting primary prevention of heart disease. Total coronary plaque burden and non-calcified plaque are associated with increased risk of adverse outcome*

5. The program should integrate education, testing, clinical services, and program management.

Integration: *Primary Care prevention clinics will integrate the information of clinical assessment, labs, and testing, and follow specific guidelines to treat patients.*

6. There should be quality assurance, with mechanisms to minimize potential risks of screening

Quality Assurance: *A quality assurance program will be in place to ensure patient follow-up and compliance, track patient outcomes, downstream cost, and to minimize patient risk.*

7. The program should ensure informed choice, confidentiality, and respect for autonomy.

Shared decision making: *The program will ensure shared decision-making respecting patient autonomy, confidentiality, and informed choice.*

8. The program should promote equity and access to screening for the entire target population.

Equity: *One of the main goals of the program is to ensure that indigent population and the medically poor will have access to this program including the ability to get tested.*

9. Program evaluation should be planned from the outset.

Evaluation: *A Medical Advisory Board should be in place with support from data analysts, statisticians, and health economists. It is planned to build a centralized information repository in order to track patient outcomes, coordination of care, and cost-effective strategies.*

10. The overall benefits of screening should outweigh the harm.

Benefits: *Simple well validated risk stratification tools will be used to triage patients who need the most attention for follow-up care and additional imaging investigation, at the same time reducing any potential harm.*

SUMMARY: *The proposed Plan follows the latest 2019 AHA/ACC guidelines for Primary Prevention of Heart Disease with an emphasis in expanding primary care access for the indigent and medically poor with the goal of proposing a systematic approach for screening for cardiovascular disease using the 10-year atherosclerotic cardiovascular disease (ASCVD) risk estimation, followed in selective individuals (patients with intermediate or high risk) with the use of imaging. Emphasis will be placed in using a team-based approach to evaluate the socials determinants of health with promotion of a healthy diet with counseling and caloric restriction for the overweighed and obese; promoting physical activity; tobacco cessation strategies; improving dietary habits and promoting exercises for diabetic patients; and selecting appropriate pharmacological therapy on a personalized basis with the guide of imaging tools.*

b. Use of Coronary Artery Calcium Score Testing for Early Detection of Coronary Artery Disease and to Guide Prevention Therapy

The 2018 ACC/AHA Cholesterol Guideline suggests that coronary artery calcium (CAC) testing should be used in adults 40-75 years of age without diabetes mellitus and with LDL-C levels ≥70 mg/dl-189 mg/dl at a 10-year atherosclerotic cardiovascular disease (ASCVD) risk of ≥5% to <20% (i.e., intermediate risk group) if a decision about statin therapy is uncertain.[23] In such patients, if CAC is zero, treatment with statin therapy may be withheld or delayed, except in cigarette smokers, those with diabetes mellitus, and those with a strong family history of premature ASCVD. According to the guideline, a CAC score of 1 to 99 favors statin therapy, especially in those ≥55 years of age. For any patient, if the CAC score is ≥100 Agatston units or ≥75th percentile for age and sex, statin therapy is indicated unless otherwise deferred by the outcome of clinician-patient risk discussion.

In explaining the rationale for the inclusion of CAC, the authors of the guideline stated, "Identification of subclinical atherosclerosis rather than use of serum biomarkers is preferred, because of the extensive body of evidence demonstrating the superior utility of atherosclerosis disease assessment, particularly

with CAC measurement, over any serum biomarker for the prediction of future ASCVD events, including both coronary heart disease and stroke."[24]

Top three take home points from the guideline:

1. **When to consider CAC testing?** In intermediate-risk or selected borderline-risk adults (premature family history of heart disease), it is reasonable to use a CAC score in the decision to withhold, postpone, or initiate statin therapy.
2. **Emphasis on "power of zero": use CAC testing to identify low risk patients.** As opposed to risk enhancers and screening tools that may be used to identify higher risk patients, CAC testing is now mostly used for identifying lower risk patients among those who would otherwise be candidates for statin therapy but who have a preference to avoid such therapy. Therefore, a CAC score of zero is helpful in reclassifying risk to a lower risk group[25].
3. **Communication of results.** It is important to appropriately communicate the results of CAC testing with patients. Patients should understand that the presence of CAC implies that they have coronary plaque (evidence of disease), and thus are at higher risk of ASCVD events. There is data that showing patients pictures of their scans may be helpful in promoting better adherence with lifestyle and medical therapies. Thus, clinicians should be encouraged to review test results with patients. This is also important as it has been shown that the identification of CAC leads to a higher rate of initiation or of lipid lowering and blood pressure lowering therapies, as well as favorable changed in diet and exercise.[26]

Despite the significant role of CAC testing in the 2018 cholesterol guideline, this test is still not widely covered by payors. As a result, many patients often pay out-of-pocket for this test (generally costing $100 - $200. Better coverage for this test and greater access to it are needed, and hopefully will occur as a result of the new guideline. While the cost of the test is relatively low, it is disproportionally discouraging the indigent and medically poor to get tested.

SUMMARY: *Therefore, one of the goals of this Plan recommendation is to provide access to CAC scanning to the indigent and medically poor who are at intermediate risk of ASCVD and to patients with strong family history of premature ASCVD. This test will help to guide therapy in patients who most need it, and avoid pharmacological therapy in patients who don't need it.*

> ***Provide access to coronary artery calcium scanning to the indigent and medically poor who are at intermediate risk of atherosclerotic cardiovascular disease, and to patients with strong family history of premature atherosclerotic cardiovascular disease.***

c. Use of Coronary CT Angiography to Assess High-risk Asymptomatic patients

CAD remains a leading cause of morbidity and mortality in the US, suggesting a significant role for improving screening and primary prevention. CVD risk scores have inherent flaws and cardiac imaging may improve risk stratification. Both the development of CCTA technologies and rapidly evolving evidence-base is frequently identifying new prognostic tools provided by CCTA over and above CAC testing in high-risk asymptomatic patients.

ASCVD preventive services are delivered both at the general population level (promoting healthy lifestyle behavior), and at the individual level by tackling unhealthy lifestyles and by targeted pharmacotherapy for causal CV risk factors[27].

High-risk (or above) category includes key co-morbidities, such as type I diabetes mellitus, familial hypercholesterolemia, or chronic kidney disease (CKD). The detection of coronary calcification is significant, and indicates a higher risk of myocardial infarction and stroke. However, calcification is well described to represent a later stage process in the pathogenesis of atherosclerosis. As a result, imaging techniques that detect atherosclerosis at earlier stages of development will be more applicable in a CVD prevention strategy. CCTA confers numerous advantages to CAC[28]. First, consider whether the presence of coronary calcification alone is sufficient, or whether an assessment that includes the anatomical location, plaque composition and degree of stenosis adds important value. The Coronary Artery Disease Reporting and Data System (CADS-RADS) criteria have been established as the gold standard for reporting the anatomical assessment of luminal stenosis on CCTA[29]. This has been proven to effectively stratify patients according to risk for adverse events. In addition to degree of luminal stenosis, CCTA offers the opportunity to assess for multiple other markers of additional prognostic value to the pure assessment of CAD presence, not available with CAC[30]. These include:

- Presence of non-calcified plaque, which is itself associated with a higher risk of future adverse events than calcific disease. In patients presenting with stable chest pain, low attenuation plaque burden was recently proven as the strongest predictor of fatal or nonfatal myocardial infarction. These findings challenge the current perception of the supremacy of current classical risk predictors for myocardial infarction, including stenosis severity[31].
- Overall plaque burden. While a low CAC has an excellent predictive value for excluding obstructive CAD[32], the relevance of this finding, particularly in an asymptomatic population is unclear. Recent evidence demonstrated that overall plaque burden, which CCTA provides, rather than obstructive coronary stenosis is a more important prognostic marker[33].
- Detection of high-risk plaque features, as markers of “vulnerability” based on the plaque composition (e.g. positive remodeling, low attenuation, spotty calcifications), and plaque location, which predict MI risk[34].
- Artificial Intelligence evaluation of CCTA now provides the potential for a full coronary plaque burden quantification and stenosis detection in a single study.

CCTA is already being used in these asymptomatic patients. In a large study, which enrolled >25,000 patients across six countries between 2003 and 2009, at least 28% of patients (>7,500) who underwent CCTA were classified as asymptomatic.[35]

One could argue that the NICE recommendation for CCTA in the assessment of patients with nonanginal chest pain if potential important ECG changes are present[36] is a screening of a borderline asymptomatic population given the lack of convincing symptoms to support assessment for anything other than prognostic (rather than truly symptom driven) benefit. Interestingly, the Scottish Computer Tomography of the Heart (SCOTHEART) investigators reported that in the 5-year outcome follow-up data, the most significant relative reduction in coronary events was observed in those with non-anginal chest pain irrespective of their cardiovascular risk score[37]

The Intervention

In the case of early CAD, relatively cheap, effective, and proven interventions that are simple to institute are well established. This can include behavioral intervention, with advice on lifestyle factors, review and optimization of important co-morbidities (e.g., hypertension and diabetes), or consideration of well-established medications such as statin therapy, or (more contentiously) aspirin. In the presence of CCTA proven CAD, the institution of these interventions would be supported with evidence of underlying pathology that may in itself have added benefit to patient behavior and compliance.

The additional risk of a higher radiation dose associated with CCTA vs CAC has also significantly reduced with modern scanners and acquisition techniques[38], and in many cases they are now on a par. As a result, this is now less of a consideration in a direct comparison between full dose CAC and CCTA, where now the relative merits of the two should be considered. Contrast reaction rates are very low, particularly for severe adverse reactions. Availability of CT scanners (> 64-slice MDCT) and expertise in reporting CCTA is very important to achieve good results and minimize risks to the population.

Diagnostic and Prognostic Value

A recent large published study (SCAPIS – Swedish Cardiopulmonary Bioimage Study)[39] including 25,182 asymptomatic individuals age 50 to 64 that underwent CCTA demonstrated presence of atherosclerosis in 42.1% and any significant coronary stenosis greater than 50% in 5.2% individuals. Significant left main, left anterior descending artery or 3-vessel disease was found in 1.9% individuals and any non-calcified plaques in 8.3% of the population. In participants with Zero CAC and Intermediate risk, 9.2% had CCTA-verified atherosclerosis. In conclusion, using CCTA in a large, random sample of the general population without established disease, this study showed that silent coronary atherosclerosis is common in this population. High CAC scores convey a significant probability of substantial stenosis, and 0 CAC does not exclude atherosclerosis, particularly in those at higher baseline risk. Indeed, the study showed that CCTA-detected atherosclerosis was present in a subset of the population with a CAC score of 0 who were currently smokers (6.8%), had a strong family history of MI (6.0%), or had diabetes (8.1%).

A cohort study of 711 patients concluded that CAD prevalence by CCTA in asymptomatic high-risk patients is high. Calcium Score of zero does not exclude CAD. CCTA is highly accurate to exclude CAD. Total coronary plaque burden and non-calcified plaques, even if only one segment is involved, are associated with an increased risk of adverse outcome[40].

CCTA may be used to screen for clinically significant CAD in asymptomatic male patients, particularly those with positive family history or potentially high-risk patients with >3 risk factors for CAD. A recent metanalysis of studies involving 5012 asymptomatic patients with diabetes mellitus demonstrated the ability of CCTA plaque burden to predict future cardiac events[41]. Thus, it is conceivable that even asymptomatic individuals at high risk for atherosclerotic disease due to diabetes mellitus, FH or family history of premature CAD may benefit from individual risk stratification by CCTA and subsequent tailored pharmacologic therapies.

In the study by Pérez de Isla and colleagues[42], subclinical coronary atherosclerosis visualized by CCTA was highly prevalent in asymptomatic patients with definite FH. Multivariable regression analysis demonstrated that plaque burden was predictive of future outcomes (5 ACS and 10 revascularization procedures), independent of conventional risk factors, coronary artery calcium, laboratory markers and lipid lowering medications. Hence, this is the first study to highlight the role of non-calcified atherosclerotic plaque burden as a predictor of subsequent cardiac events in asymptomatic individuals with FH.

CCTA may help identify asymptomatic individuals at high risk for future events and improve cardiac outcomes in this context, as currently being investigated in the randomized SCOT Heart 2 study (ClinicalTrials.gov Identifier: NCT03920176). The randomized SCOTHEART 1 study already demonstrated that the use of CCTA is associated with significantly lower rates of cardiac death and nonfatal infarctions compared to standard care in symptomatic patients[43]. Modern CT scanners enable CCTA acquisitions with a radiation exposure of <1mSv[44], and the small risk inherent to this low radiation dose should be weighed against the potential benefit of therapeutic interventions that reduce the risk of cardiovascular events.

The study by Pérez de Isla et al.[41] provides evidence that CCTA can improve risk stratification in high-risk asymptomatic individuals with FH. Our health care system will also need to consider adapting reimbursement structures, providing incentives for prevention strategies based on CCTA over more costly and often less effective invasive procedures in this context.

SUMMARY: *Therefore, one of the goals of this Plan recommendation is to provide access to CCTA scanning to the indigent and medically poor who are at high risk of ASCVD, patients with diabetes, smokers and/or patients with premature ASCVD or familial hypercholesterolemia. This test will help to guide therapy and detect and quantify the severity of coronary plaque and degree of obstruction/stenosis in patients who most need it, and avoid pharmacological therapy or other testing in patients who don't need it.*

d. Use of Coronary CT Angiography to Assess Low to Intermediate Risk Symptomatic Patients as a First-Line Test in the Outpatient and Hospital Setting

Outpatient Setting – Stable CAD

CCTA is now considered first-line strategy (Class I) for use in acute and chronic coronary syndromes by several Guidelines (Society of Cardiovascular CT Expert Consensus[45], American College of Radiology appropriateness criteria[46,47], European Society of Cardiology consensus[48], NICE guidelines[36]) particularly in symptomatic patients with low to intermediate pre-test probability of suspected obstructive coronary artery disease[49]. Overall, the guidelines recommend performing CCTA as the first line test for evaluating patients with no known CAD who present with stable typical or atypical chest pain, or other symptoms which are thought to represent a possible anginal equivalent (e.g. dyspnea on exertion, jaw pain) [36,47]. It is also recommended to perform CCTA following an inconclusive functional test, in order to obtain more precision regarding diagnosis and prognosis[49]. Importantly, choosing CCTA as the first line test for symptomatic CAD results in a significant reduction in cardiovascular death and myocardial infarct over the course of 5 years, with more appropriate preventive therapy[43, 49]. Moreover, there has been progression in our understanding of detection, quantification, classification, and prognostic value of atherosclerotic plaque burden by CCTA. Several prospective trials have provided evidence of the clinical utility of coronary CTA and the relevance of CT findings in the context of suspected stable coronary artery disease. They include the PROMISE[50] and SCOT-HEART[51] trials, which demonstrated that coronary CTA is clinically useful as an alternative to (PROMISE) or in addition to functional testing (SCOT-HEART). Based on these trials and the CONFIRM registry, the prognostic value of the Coronary Artery Disease Reporting and Data System (CAD-RADS) has been confirmed, demonstrating that higher CAD-RADS scores were associated with increased risks of fatal and non-fatal MI [30,52,53]. The intent of CAD-RADS was to create a standardized reporting system for patients undergoing coronary CT angiography (CCTA) that is aligned with the clinical reasoning which may guide the next steps in patient management. The CAD-RADS classification has been shown to accurately predict major adverse cardiovascular events (MACE), defined as unstable angina, myocardial infarction, or death, in patients with stable chest pain with better performance than traditional risk factors, other risk stratification scores, the coronary artery Calcium Score and the previous SCCT

coronary stenosis scoring system [39,54,55,56,57]. CAD-RADS has also been demonstrated to correlate with the degree of stenosis measured by invasive coronary angiography (ICA) with high diagnostic accuracy [58-59]. Recent publications have highlighted that the adoption of CAD-RADS in clinical practice has resulted in reduced downstream testing and cardiology referral rates in patients with non-obstructive coronary artery disease[60] and have observed an impact on medical therapy and systolic blood pressure control[61].

A recent cost-effectiveness analysis simulating life-time cost and outcomes using individual-level patient data from the PROMISE trial found that over a lifetime, patients undergoing CCTA gained – on average – an additional 6 months in perfect health compared with functional testing. Moreover, the CCTA approach was highly cost-effective with cost below $4,000 per additional year in perfect health (in comparison, established strategies, such as lung cancer screening costs $130,000 per additional year in perfect health). Results were similar when stratifying between women and men as well as in individuals older than and younger than the age of 60 years or when taking reduced adherence to medical therapy into account[62].

Hospital Setting – Acute chest pain

Coronary computed tomography angiography (CTA) improves the quality of care for patients presenting with acute chest pain (ACP) to the emergency department (ED), particularly in patients with low to intermediate likelihood of acute coronary syndrome (ACS). Coronary CTA is a proven strategy to safely expedite diagnosis and limit resource utilization for patients presenting with ACP in the ED. Several large randomized trials (CT-STAT, ACRIN-PA, ROMICAT II and CT-COMPARE) have compared coronary CTA to the current standard of care in patients with acute chest pain[63-66]. Complemented by "real world" implementation data[67-68] they consistently demonstrate the safety of discharging patients from the emergency department based on a negative coronary CTA, resulting in guidelines supporting the use of CCTA in low to intermediate risk patients presenting with acute chest pain to the emergency department[52]. In general, these trials demonstrate that a strategy with CCTA is safe, faster and cheaper when compared to the traditional strategy of observation and stress testing. Coronary CTA offers rapid evaluation of the degree of coronary stenosis and atherosclerosis, allows significant reduction in time-to-discharge, and ensures high risk patients are appropriately triaged to cardiac catheterization.[69-71] Rapid chest pain triage also limits nosocomial infection transmission between patients and medical staff, which is of particular importance during the Covid-era. Coronary CTA is complementary to hs-cTn assays in the ED by improving specificity for ACS and identifying vulnerable anatomy[72]. Coronary CTA can detect high-risk plaque features associated with greater risk of plaque rupture and ACS, independent of stenosis severity.[73-77] This is particularly important in the ED setting, as most precursors of ACS and culprit lesions are non-obstructive.[78-79] High-risk plaque and atherosclerosis burden on coronary CTA provide additional clinical biomarkers that predict ACS above and beyond stenosis severity.

In general, a strategy beginning with CCTA has the advantage of reducing cardiovascular mortality and myocardial infarct. It visualizes the stenosis and the atheromatous plaque as opposed to making an educated guess about its presence, as with physiologic testing. CCTA has excellent sensitivity for identifying flow limiting disease and has very high negative predictive value for the exclusion of significant stenosis, making it the strongest test to rule out flow limiting CAD, especially in symptomatic patients with low to intermediate risk. It has the best evidence to date for decreasing the number of procedures in patients in whom a decision to define coronary anatomy with invasive catheterization has already taken based on other non-invasive criteria. Moreover, deferring ICA has been shown to be safe. Using CCTA as the first test for stable chest pain syndromes also reduces unnecessary invasive cardiac catheterization. This has led to the NICE guidelines from the United Kingdom to recommend CCTA as the first line test for the entire National Health System in patients without known CAD who present with new onset typical or atypical chest pain.

A recent study[80] estimated the cost-effectiveness of CCTA compared to alternative management strategies for ACP patients over a lifetime using a simulation approach based on individual-level patient data from the ROMICAT II trial. Compared to standard of care (i.e. functional testing), CCTA in the ED resulted in a gain of 17 days in perfect health which translates to around $14 000 per additional year in perfect health. To put these results into perspective, the ACC/AHA Guideline statement on cost and value methodology classifies interventions resulting in gains per additional year in perfect health costing < $50K as a high value, $50–100K as an intermediate value, and > $100K as a low value[81].

SUMMARY: *Therefore, one of the goals of this Plan recommendation is to provide access to CCTA scanning to the overall population, but particularly to the indigent and medically poor who are presenting with symptoms of chest pain or chest pain equivalent and are low to intermediate risk of having obstructive coronary artery disease. This test will help to guide management in a more accurate and rapid fashion and detect and quantify the severity of coronary plaque and degree of obstruction/stenosis in patients who most need it, and avoid other testing in patients who don't need it. Moreover, a CCTA first strategy leads to reduction in cardiovascular mortality and myocardial infarction, serving as a gatekeeper to more expensive invasive catheterization. It is cost-effective and better allocates the use of high cost downstream testing as well.*

e. Additional Innovative Health Care Programs

The innovative health care program proposed herein features CAC and advanced CCTA technology in the context of primary and preventive care services. The expansion of this technology into primary and preventive care is innovative and offers tremendous savings in terms of individual health through treatment and prevention of the advancement of serious disease and public health through coordination of care, systemic approaches, and cost-effective strategies.

An additional component of the potential utilization of innovative technology included in this proposal is to use Artificial Intelligence Digital Care Pathway for full coronary tree evaluation to prevent heart attacks. Artificial intelligence (AI) shows promising to use multi-level CCTA data visualization platform aims to improve understanding of heart disease for both basic and advanced users. Using AI-powered imaging technology, providers and suppliers are utilizing a digital-first approach to preventing heart attacks. An AI platform is designed to take in non-invasive CT angiography scans of the heart and determine who may be at the greatest risk, based on an analysis of the plaques built up in their coronary arteries.

An AI system's algorithms—e.g., relying on a database of millions of annotated lab images, plus clinical data from trials of more than 50,000 patients—aim to measure the severity of and provide more detail into any potential blockages that could fatally cut off the supply of oxygen to the heart muscle. The AI tool would be an automated, end-to-end platform that will also package its results with interactive tools for primary care physicians as well as patients to help them better understand the current state of a person's arteries without needing advanced training in reading medical images.

About one million coronary angiograms and ten million functional stress tests are performed annually in the U.S. Traditional stress tests demonstrate low specificity and sensitivity and often both miss significant disease and are prone to frequent false positive results. Coronary angiograms are expensive invasive studies that have been shown to be "normal", i.e., without actionable disease, in a majority of patients who are imaged.

Nuclear stress tests are a current standard used to indicate patients who require coronary angiograms. Nuclear stress testing costs range from approximately $1,400 to over $6,000, 2-3x the cost of a CCTA with AI analysis. If a CCTA with AI coronary plaque analysis is performed instead of stress testing, the number of false positive results is significantly reduced, and this cuts referrals for invasive angiograms by 49%.

Therefore, inclusion of an AI platform to analyze Coronary CTA images would provide additional insights and enable comprehensive quantification and characterization of plaque build up in each of the heart arteries. These findings will support the identification of plaques that may cause heart attacks using FDA cleared technology.

3. Specific Recommended Services to be provided:

A broad range of health care services for both indigent persons and the medically poor, including, but not limited to, primary care and preventive care, imaging services, as well as hospital care, as follows:

a. Primary Care:

This proposal recommends supporting the creation of Primary Care Physician (PCP) and/or Nurse Practitioner (NP) run *Cardiovascular Disease Prevention* clinics to the indigent and medically poor for clinical assessment and risk stratification of atherosclerotic cardiovascular disease (ASCVD). These *Cardiovascular Disease Prevention* clinics would increase access to preventive cardiovascular care, particularly to those with greater social stress. Cardiovascular risk evaluation and treatment will be protocol driven and thus improve quality and consistency of care. The PCP/NP leading these CVD Prevention Clinics would also be charged with community education with regard to cardiovascular risk factors, heart-healthy living, and preventive medications.

The Broward County population is made up as follows:

18-74y/o = 1,377,371 (51.2% female/ 48.8% male)
18-40y/o = 537,013
40-74y/o = 840,358

All adults between the ages of 18 – 75 years old without established cardiovascular disease, should undergo cardiovascular risk assessment at a Cardiovascular Disease Prevention Clinic. These evaluations will include the following:

1. Height, weight (with calculation of body mass index), and blood pressure measurement
2. Physical examination
3. Laboratory testing (including comprehensive metabolic profile, lipid panel, and hemoglobin A1c)
4. Estimate of 10-year ASCVD risk by the Pooled Cohort Equations

Appropriate individuals will be referred for subclinical atherosclerosis imaging with either CAC testing or CCTA, as will be detailed later in this section.

Based on all the collected information, recommendations with regards to heart-healthy living +/- preventive medical therapy will be made, particularly as it relates to statins, aspirin, and antihypertensive therapy. Please see **Appendix 1** for hypertension treatment.

This proposal expands access to PCP/NP Practitioner run *Cardiovascular Disease Prevention* clinics to the indigent and medically poor for clinical assessment and risk stratification ASCVD. In all individuals, irrespective of cardiovascular risk, heart-healthy lifestyle should be emphasized. Beyond lifestyle approaches, there are specific populations that benefit from initiation of statin therapy. As per the 2018 AHA/ACC Cholesterol guideline, there are four statin benefit groups – 1) established ASCVD, 2) Diabetes, 3) Severe hypercholesterolemia (LDL-C ≥190 mg/dL), and 4) adults 40-75 years of age not in categories 1-3 with a 10-year ASCVD risk estimate >7.5%. The 10-year ASCVD risk estimate predicts the composite of fatal and non-fatal myocardial infarction and stroke and is based on the Pooled Cohort Equations, which are age, sex, and race specific.

There are instances when statin initiation is not straightforward, such as:

1. Estimated 10-year risk is between 5 to 7.5%
2. Estimated 10-year risk is between 7.5 to 19.9% but risk estimate is primarily based on age without other uncontrolled risk factors
3. Patient is reluctant to start statin therapy.

In these instances, risk-enhancing factors as introduced in the 2018 AHA/ACC Cholesterol guideline can be used to guide the statin decision. A recent paper by Patel et al found that among participants with CAC scores of 0, the presence of risk-enhancing factors was generally not associated with an overall ASCVD risk that was higher than recommended treatment threshold for the initiation of statin therapy[82]. Rather, the use of CAC scoring was associated with significant improvement in reclassifying risk in these individuals. Thus, CAC scoring can be used as an adjunct to risk-enhancing factor assessment to classify risk more accurately in individuals estimated to be at intermediate risk for ASCVD who otherwise may benefit from statin therapy.

Therefore, this proposal suggests that for individuals aged 40 – 75 years old who fall into the true primary prevention (Statin benefit group #4) whose estimated 10-year ASCVD risk is between 5 to 19.9%, a non-contrast cardiac CT for coronary artery calcium score should be performed. Treatment recommendations can then be tailored according to CAC as detailed in Section 3b.

There are subpopulations where CAC testing is not recommended. Specifically, the 2018 AHA/ACC Cholesterol guideline does not recommend CAC testing in individuals with a family history of premature ASCVD (male first degree relative below the age of 55; female first degree relative below the age of 65), smokers, and those with diabetes. In this proposal, a CCTA can be considered in these instances. Each of these subpopulations can be considered separately (**see Table 1**).

Family history of premature ASCVD. Because many of these individuals need an ASCVD risk evaluation prior to the age of 40, considerations of the diagnostic characteristics with respect to age need to be considered. Given the time (age) dependency of coronary artery calcification, CAC testing is less useful in younger individuals. Therefore, in the patient with a family history of premature ASCVD who presents for evaluation even before the age of 40 (and after), a CCTA is recommended in this proposal.

Smokers. Smokers have a higher prevalence of non-calcified plaque, rendering CAC testing less useful. CCTA can therefore be considered for ASCVD risk evaluation in smokers.

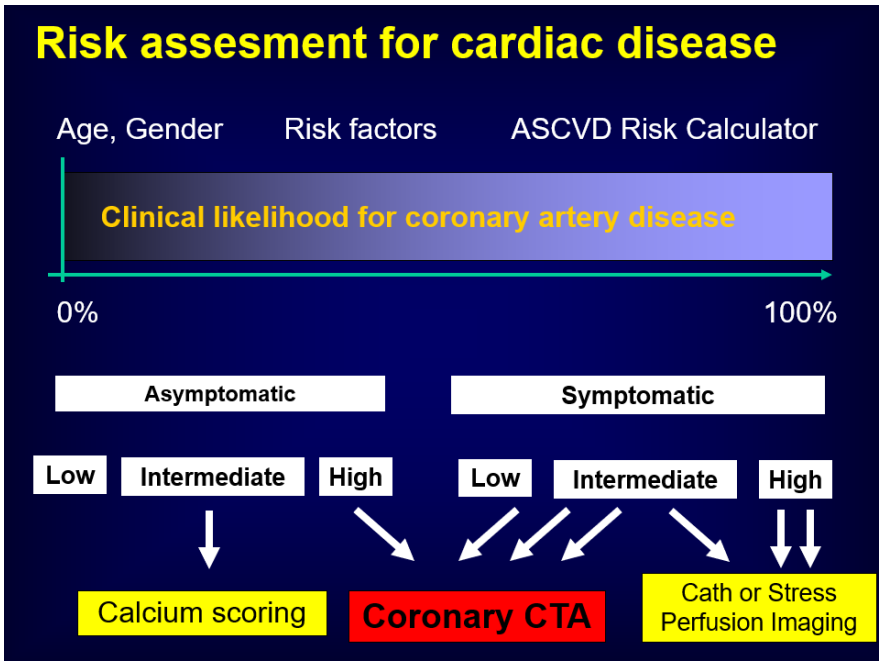
Diabetes. According to the 2018 AHA/ACC Cholesterol guideline, in patients 40 to 75 years of age with diabetes and LDL-C ≥70 mg/dL, the recommendation is to start moderate-intensity statin therapy without calculating 10-year ASCVD risk. In patients with diabetes at higher risk, especially those with multiple risk

factors or those 50 to 75 years of age, it is reasonable to use a high-intensity statin therapy. However, in those with long standing diabetes below the age of 40, or for those diabetics with estimated ASCVD risk <7.5%, it may still be reasonable to pursue a strategy of non-invasive subclinical atherosclerosis imaging. In this situation, a CCTA will provide a more reliable assessment of risk than CAC testing.

Table 1. Special populations in whom Coronary CTA should be considered

Family history of premature ASCVD	These individuals should be evaluated even before the age of 40. CAC testing is less sensitive in younger individuals. A CCTA should be used to refine risk assessment.
Smokers	These individuals have a higher prevalence of non-calcified plaque. Thus, CCTA is the preferred test.
Diabetes	In individuals with long standing diabetes below the age of 40, or for those diabetics with estimated ASCVD risk <7.5%, it may be reasonable to pursue a strategy of CCTA, as it will provide a more reliable assessment of risk than CAC testing.

Therefore, a CCTA is recommended in patients presenting with diabetes or long-standing diabetes, family history of premature ASCVD (even before 40y/o) and smokers (40-75 y/o).



b. Preventive Care Treatment Recommendations

The Cardiovascular Disease Prevention Clinic treatment recommendations as outlined in this proposal are consonant with national guidelines. This proposal takes the liberty of simplifying certain primary prevention algorithms and further, integrating the results of subclinical atherosclerosis imaging when obtained.

1. In all individuals, emphasize a heart-healthy lifestyle across the life course. A healthy lifestyle reduces ASCVD risk at all ages. In younger individuals, healthy lifestyle can reduce

development of risk factors and is the foundation of ASCVD risk reduction. In all age groups, lifestyle therapy is the primary intervention for metabolic syndrome.

2. In patients with severe primary hypercholesterolemia (LDL-C level ≥190 mg/dL), begin high-intensity statin therapy without calculating 10- year ASCVD risk.
3. In patients 40 to 75 years of age with diabetes and LDL-C ≥70 mg/dL, start moderate-intensity statin therapy without calculating 10-year ASCVD risk.
4. In adults 40 to 75 years of age without diabetes mellitus and with LDL-C levels ≥70 mg/dL, at a 10-year ASCVD risk of ≥7.5%, start a moderate-intensity statin if a discussion of treatment options favors statin therapy.
5. In section **3a**., recommendations for subclinical atherosclerosis imaging were proposed. However, unless treatment recommendations are specifically tied to imaging results, outcomes will not improve. What follows are treatment recommendations according to CAC and CCTA findings:

CAC score	**Treatment Recommendation**
0	Therapeutic lifestyle changes (TLC) only (see Table)
1-100	TLC + moderate-intensity statin therapy
>100	TLC + high-intensity statin therapy + initiation of aspirin 81 mg daily

CCTA findings	**Treatment Recommendation**
No plaque (CAD-RADS 0)	Therapeutic lifestyle changes (TLC) only
Mild non-obstructive CAD (CAD-RADS 1)	TLC + moderate-intensity statin therapy
Moderate non-obstructive CAD (CAD-RADS 2)	TLC + high-intensity statin therapy + initiation of aspirin 81 mg daily
Obstructive CAD (CAD-RADS 3 or greater)	TLC + high-intensity statin therapy + initiation of aspirin 81 mg daily; **Referral to Cardiology**

Table. Therapeutic Lifestyle Recommendations (from 2019 AHA/ACC Prevention Guideline)

Diet

- A diet emphasizing intake of vegetables, fruits, legumes, nuts, whole grains, and fish is recommended to decrease ASCVD risk factors
- Replacement of saturated fat with dietary monounsaturated and polyunsaturated fats can be beneficial to reduce ASCVD risk
- A diet containing reduced amounts of cholesterol and sodium can be beneficial to decrease ASCVD risk
- As a part of a healthy diet, it is reasonable to minimize the intake of processed meats, refined carbohydrates, and sweetened beverages to reduce ASCVD risk
- As a part of a healthy diet, the intake of trans fats should be avoided to reduce ASCVD risk

Physical Activity

- Adults should be routinely counseled in healthcare visits to optimize a physically active lifestyle

- Adults should engage in at least 150 minutes per week of accumulated moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity (or an equivalent combination of moderate and vigorous activity) to reduce ASCVD risk
- For adults unable to meet the minimum physical activity recommendations (at least 150 minutes per week of accumulated moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity), engaging in some moderate- or vigorous-intensity physical activity, even if less than this recommended amount, can be beneficial to reduce ASCVD risk
- Decreasing sedentary behavior in adults may be reasonable to reduce ASCVD risk

Tobacco Use

- In adults who use tobacco, a combination of behavioral interventions plus pharmacotherapy is recommended to maximize quit rate
- In adults who use tobacco, tobacco abstinence is recommended to reduce ASCVD risk
- All adults and adolescents should avoid secondhand smoke exposure to reduce ASCVD risk

c. Hospital Care and Outpatient Care of Patients with Symptoms Suggestive of CAD:

Chest pain and other symptoms suggestive of obstructive CAD (e.g., shortness of breath) are among most common presentations in both hospital setting/emergency department and outpatient clinics (internal medicine, primary care, family medicine and cardiology). In the following section, we will provide recommendations to address the Top Priorities of the Broward Health Community Health Needs Assessment Advisory Council Prioritization in both inpatient/emergency department and outpatient setting. This proposal will recommend algorithms of care including CCTA, which promise to be safe, lead to improved health outcomes and health care cost savings.

Hospital Care

Patients presenting with chest pain or angina to the Emergency Department or to the Hospital setting, a CCTA first line strategy should be prioritized for low to intermediate risk patients.

Numerous professional societies have embraced coronary CTA as a first-line triage strategy for ACP in select patients. In the 2015 Multi-Society Appropriate Utilization of Cardiovascular Imaging in Emergency Department Patients with Chest Pain document[83], coronary CTA was designated “appropriate” in ACP patients with low or intermediate pretest likelihood of ACS, and for patients with equivocal initial diagnosis of NSTEMI where initial troponin is equivocal or elevated without additional evidence of ACS. In 2016, the National Institute for Health and Clinical Excellence within the United Kingdom updated their chest pain guidelines,[84] recommending that all patients with typical or atypical angina without STEMI be referred directly for coronary CTA as a first-line test, reserving functional testing as a second-order test for patients with non-diagnostic or inconclusive CT exams. In the 2020 European Society of Cardiology guidelines for the management of ACS in patients without persistent ST-segment elevation,[85] coronary CTA received a Class I recommendation (level of evidence A) for early triage of patients with low-to-intermediate risk chest pain with normal ECG and negative troponins, and in patients with inconclusive or equivocal troponins. The evidence also prompted inclusion of coronary CTA as a usually appropriate initial imaging strategy in the American College of Radiology Appropriateness Criteria on acute nonspecific chest pain with low probability of coronary artery disease.[86]

Evaluating Pre-Test Likelihood of ACS

Patients presenting with suspected acute coronary syndrome (ACS, myocardial infarction or unstable angina) are initially evaluated by taking medical history and physical exam. Clinically appropriate patients should have reasonable clinical suspicion of ACS. A careful history and physical examination should precede any cardiac testing, to exclude alternative non-coronary diagnoses and to help define the pre-test likelihood of ACS. ECG should be acquired and reviewed for STEMI within 10 minutes of arrival to the ED. The initial evaluation is followed by the performance of 12-lead electrocardiogram and cardiac troponin in accordance with ACC/AHA guidelines. High sensitivity troponin assays are preferred for establishing a diagnosis of acute myocardial infarction due to their improved performance over contemporary cTn.[87, 88] Clinicians should be familiar with 99th percentile upper reference limit for the hs-cTn or conventional cTn assay used at their local institution. High-risk patients (e.g patients with acute ST segment elevation myocardial infarction, patients with persistent chest pain and dynamic ECG changes and/or abnormal cardiac troponin consistent with diagnosis of type 1 non-ST segment elevation myocardial infarction, patients in shock) are managed with interventional strategy and undergo urgent catheterization. However, the majority of patients are qualified as intermediate risk for ACS and undergo further observation and testing. Multiple studies demonstrated superior performance of CCTA for the evaluation of this patient population. CCTA can decrease time to diagnosis, time to discharge, while being cost-neutral during initial evaluation and cost-saving in long term.

Risk stratification tools for ACS can help categorize patients into low-, intermediate- and high-risk. Commonly used tools in Emergency Medicine include the HEART pathway[89], EDACS[90], and ADAPT[91] (based on the TIMI risk score), which incorporate the results of troponin testing and have established value in clinical practice (**Table 1**). Risk stratification should be performed in parallel with serial troponin measurements to exclude myocardial injury. For hs-cTn assays, baseline sample collection should be obtained followed by a repeat measurement in 1-3 hours, depending upon the baseline measurement. For conventional troponin assays, repeat sample collections are generally advised between 3 and 6 hours.

Clinical decision making after Chest Pain Evaluation:

1. Very Low risk – discharge, referral to primary prevention. The patients will be discharged home without further testing. Extensive research has shown that very low risk patients have a very low risk of major adverse cardiovascular events and can be discharged without further testing. However, the encounter with the health care system provides an opportunity for introduction of preventative measures. The framework described in the section 3A of this proposal can lead to improved outcomes.
2. Low to Intermediate risk – further diagnostic testing, recommend CCTA based on available evidence. As described in previous sections, CCTA is an ideal test for rapid triage of patients in the low to intermediate risk category. Below, we described the specific recommendations after the results of CCTA are obtained.
3. High risk – cardiology consultation and consideration of invasive coronary angiography

The management of patients in high-risk group, which basically represents patients with ACS is further guided by appropriate ACC/AHA guidelines.

STEMI should be managed according to recent guidelines[92], with prompt ICA as the only appropriate imaging study. Patients with documented NSTEMI should also follow guidelines-directed management,[93,94] with consideration of early coronary CTA in limited scenarios.

Low-to-Intermediate Risk for ACS: Coronary CTA is most effective in patients with a low-to-intermediate pretest likelihood of ACS. This includes patients with normal or nonischemic ECG changes, and normal or equivocal baseline cTn, or baseline hs-cTn below the 99th percentile. Using risk stratification tools, low-

to-intermediate pretest risk is defined by HEART scores 1-6, and TIMI risk scores 1-4. This category also includes patients with inadequate or mildly abnormal functional testing during the index ED visit or within the previous 1 year.

d. Coordination of Care

In patients who undergo CCTA, the scan will be performed and interpreted in accordance with appropriate societal guidelines. The results will be reported in accordance with standard institutional practice and using CAD-RADS system[95]. CAD-RADS system provides recommendations for further clinical management and coordination of care summarized on the following Table:

Table 3
CAD-RADS Reporting and Data System for patients presenting with acute chest pain, negative first troponin, negative or non-diagnostic electrocardiogram and low to intermediate risk (TIMI risk score <4) (emergency department or hospital setting).

	Degree of maximal coronary stenosis	Interpretation	Management
CAD-RADS 0	0%	ACS[a] highly unlikely	- No further evaluation of ACS is required. - Consider other etiologies.
CAD-RADS 1	1–24%[b]	ACS highly unlikely	- Consider evaluation of non-ACS etiology, if normal troponin and no ECG changes. - Consider referral for outpatient follow-up for preventive therapy and risk factor modification.
CAD-RADS 2	25–49%[c]	ACS unlikely	- Consider evaluation of non-ACS etiology, if normal troponin and no ECG changes. - Consider referral for outpatient follow-up for preventive therapy and risk factor modification. - If clinical suspicion of ACS is high or if high-risk plaque features are noted, consider hospital admission with cardiology consultation.
CAD-RADS 3	50–69%	ACS possible	- Consider hospital admission with cardiology consultation, functional testing and/or ICA[d] for evaluation and management. - Recommendation for anti-ischemic and preventive management should be considered as well as risk factor modification. Other treatments should be considered if presence of hemodynamically significant lesion.
CAD-RADS 4	**A** – 70–99% or **B** – Left main >50% or 3-vessel obstructive disease	ACS likely	- Consider hospital admission with cardiology consultation. Further evaluation with ICA and revascularization as appropriate. - Recommendation for anti-ischemic and preventive management should be considered as well as risk factor modification.
CAD-RADS 5	100% (Total occlusion)	ACS very likely	- Consider expedited ICA on a timely basis and revascularization if appropriate if acute occlusion[e] - Recommendation for anti-ischemic and preventive management should be considered as well as risk factor modifications.
CAD-RADS N	Non-diagnostic study	ACS cannot be excluded	Additional or alternative evaluation for ACS is needed

The CAD-RADS classification should be applied on a per-patient basis for the clinically most relevant (usually highest-grade) stenosis.
All vessels greater than 1.5 mm in diameter should be graded for stenosis severity. CAD-RADS will not apply for smaller vessels (<1.5 mm in diameter).
MODIFIERS: If more than one modifier is present, the symbol "/" (slash) should follow each modifier in the following order:
First: modifier N (non-diagnostic)
Second: modifier **S (stent)**
Third: modifier **G (graft)**
Fourth: modifier **V (vulnerability)**
[a] ACS – acute coronary syndrome
[b] CAD-RADS 1 – This category should also include the presence of plaque with positive remodeling and no evidence of stenosis
[c] CAD-RADS 2 **- Modifier 2/V** can be used to indicate vulnerable/high-risk plaque
[d] ICA – invasive coronary angiography.
[e] Unless the total coronary occlusion can be identified as chronic (through CT and clinical characteristics or patient history)

We also propose to harness more detailed information that CCTA provides on detection and quantification of coronary atherosclerosis. We recommend that patients will have CAC score scan prior to CCTA. This will permit quantification of CAC score. We also recommend quantitative assessment of coronary plaque burden using AI software. Prognostic value of the extent of coronary plaque (both calcified and non-calcified) has been extensively studied and therefore possibly benefiting from preventive therapies irrespective of their coronary artery calcium score. Data from the SCOT-HEART trial suggest that non-calcified low CT attenuation plaque burden of >4% is the best predictor of increased risk of future major cardiovascular events.

Patients will be referred to appropriate outpatient clinic based on the results of CCTA. The guidelines for this process are as summarized below:

No coronary atherosclerosis

- No coronary artery calcium (coronary artery calcium score = 0)
- No non-calcified plaque on coronary CTA portion of the test (SIS=0)
- No stenosis:

Management recommendations:

- No evidence of subclinical atherosclerosis
- Low risk of cardiovascular events in the next 10-15 years
- No need for preventive treatments (no need for statin or aspirin)
- Patient will be referred to PCP/NP visit with the results of the test
- Recommend heart healthy diet and exercise
- Weight loss if elevated body mass index
- Materials to provide written recommendations will be provided to participating centers

Mild coronary atherosclerosis

- Mild coronary artery calcium (coronary artery calcium score = 1-100 and below 75th percentile for age, gender and race/ethnicity)
- Segment involvement score below 75th percentile for age and gender on coronary CTA
- No stenosis of 50% or higher on coronary CTA:

Management recommendations:

- Mild coronary atherosclerosis
- Mildly elevated risk of cardiovascular events in the next 10-15 years
- As compared to somebody with CAC score 0 and no non-calcified coronary plaque, the risk is approximately 2-4 times higher
- The patient will be referred to the clinic, which is proposed in the section 3A
- Discuss preventive treatment with moderate dose of statin, the benefit of statin in this group is borderline and mostly accrued after 5-10 years[96]
- Statin treatment lead to ~20% relative reduction of the risk of cardiovascular events
- Aspirin is not recommended as the risk of adverse events (mostly bleeding, number needed to harm vs. number needed to treat) exceeds the benefit
- Recommend heart healthy diet and exercise
- Weight loss if elevated body mass index
- Materials to provide written recommendations will be provided to participating centers

Moderate to severe coronary atherosclerosis

- Moderate to severe coronary artery calcium (coronary artery calcium score >100 and above 75th percentile for age, gender and race/ethnicity)
- Segment involvement score above 75th percentile for age and gender on coronary CTA
- Low CT attenuation plaque burden >4%
- No stenosis of 50% or higher:

Management recommendations:

- Moderate to severe coronary atherosclerosis
- Elevated risk of cardiovascular events in the next 10-15 years
- As compared to somebody with CAC score 0 and no non-calcified coronary plaque, the risk is approximately 4-10 times higher
- Recommend moderate dose statin

- Statin treatment may lead to ~40-60% relative reduction of the risk of cardiovascular events
- Recommend aspirin 81 mg once daily [97]
- Aspirin treatment may lead to ~12-18% relative reduction of the risk of cardiovascular events
- Aspirin can lead to ~36% reduction of the risk of death in patients with non-obstructive CAD
- Recommend heart healthy diet and exercise
- Weight loss if elevated body mass index
- Materials to provide written recommendations will be provided to participating centers

Obstructive coronary artery disease

- Presence of at least one stenosis of 50% or higher:

Management recommendations:

- Management of patients with obstructive CAD as recommend by AHA/ACC guidelines, typically including cardiology consultation and admission, early invasive coronary angiography based on the guidelines
- Consider assessment of hemodynamic significance of stenosis
- As compared to somebody with CAC score 0 and no non-calcified coronary plaque, the risk is approximately 5-15 times higher
- The risk is higher in those with high-risk coronary anatomy (left main coronary disease with stenosis >50%, three vessel CAD with stenosis >70%, two vessel disease with >70% stenosis and involvement of the proximal LAD)
- Recommend preventive therapies (as described in section on moderate to severe coronary atherosclerosis) for all patients with obstructive CAD, irrespective of the extent of coronary atherosclerosis (coronary artery calcium score and SIS)
- Recommend moderate to high dose statin
- Statin treatment may lead to ~40-60% relative reduction of the risk of cardiovascular events
- Recommend aspirin 81 mg once daily
- Aspirin treatment may lead to ~12-18% relative reduction of the risk of cardiovascular events
- Recommend heart healthy diet and exercise
- Weight loss if elevated body mass index
- Materials to provide written recommendations will be provided to participating centers

Summary of recommendations in Table

Extent of coronary atherosclerosis	CAC score 0 and no coronary plaque	CAC score 1-100 and SIS <75th percentile	CAC score 101-300 or >75th percentile or SIS >75th percentile	CAC score >300 or SIS >8	Obstructive CAD (stenosis of 50% or more)
Amount of coronary atherosclerosis	No	Mild	Moderate	Severe	-
Relative increase of cardiovascular risk	-	2-4x	4-8x	8-12x	10-15x
Benefit of statin treatment	No	Borderline	Significant	Significant	Significant

Relative risk reduction with statin treatment	No	~20%	~60%	~40%	~60%
Benefit of aspirin treatment is higher than the risk	No	No	Yes	Yes	Yes

Appropriate referral from the ED/Hospital to Preventive clinics
ED or hospital visit provides a unique opportunity to engage with medical care. This is particularly important for the population with limited medical literacy and indigent care. This proposal will include referral of patients evaluated in the ED/hospital setting. The implementation of preventative treatments based on the evaluation of coronary atherosclerosis has a potential to lead to improved long-term cardiovascular outcomes. We propose to create referral system and coverage of outpatient preventative care. This approach will emphasize continuity of care in the most cost-effective setting, taking into consideration both a high quality of care and geographic access.

Monitoring and Analysis of the Data: We propose the creation of a database of members benefiting from this program. This database will include the monitoring on long-term health care outcomes and resource utilization.

Summary: Coronary CTA is endorsed by multiple professional societies as a first-line triage strategy for low to intermediate risk patients presenting with chest pain to the ED/ Hospital setting, including the American College of Cardiology and the European Society of Cardiology.

4. Providing Facilities

The foregoing services shall be rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital where appropriate. The Cardiovascular Disease Prevention clinics and the imaging facilities must be sited in a manner to ensure accessibility for the persons utilizing the services, with special emphasis on accessibility for persons who are indigent or medically poor. The location of Cardiovascular Disease Prevention clinics and the imaging facilities must be based on consideration of at least the following factors: accessibility for users (including consideration of issues such as public transportation, childcare, and hours of operation); current location of primary care clinics (included publicly-funded primary care provided by local hospitals and federally qualified health centers); location of and proximity to high-risk populations; current utilization rates of existing clinics; current screen capabilities of existing clinics; ability to expand current clinics to include screening technologies (including physical footprint, financial abilities, current patient utilization numbers, etc.).

a. Primary Care Clinics/Cardiology Prevention Clinics

Preventive clinical services will be provided at established primary care clinics, federally qualified health centers, cardiology offices, or other identified locations including the possibility of newly established heart disease prevention clinics, with focus in heart disease prevention supporting a multidisciplinary team of primary care physicians, nurse practitioners, social workers, preventive cardiologists and administrative personal. Services will be contracted through existing networks (or, potentially, new or expanded networks) in the Broward County healthcare community. Additionally, integrated referral systems should be created for primary care physicians who have existing relationships with patients so they have access to the technology and related services proposed.

The initial assessment can be performed by a registered nurse (RN) or nurse practitioner (NP) with standardized protocols collecting the following data: 1- Height, weight (with calculation of body mass index), and blood pressure measurement; 2- Physical examination; 3- Laboratory testing (including comprehensive metabolic profile, lipid panel, and hemoglobin A1c; 4- Estimate of 10-year ASCVD risk by the Pooled Cohort Equations and 5- Appropriate individuals will be referred for subclinical atherosclerosis imaging with either CAC testing (Intermediate risk 5-19.9% of ASCVD) or CCTA (smokers, diabetics or patients with premature family history of heart disease, as detailed above). The follow-up visit should be performed by a primary care physician or preventive cardiologist following standardized protocols with all the information collected, as described above in Section 3. In order to enhance outreach, Health Kiosks in underserved areas should be considered for the initial assessment and follow-up care can be enhanced with Telehealth visits to ensure continuity of care and higher retention rates.

Broward County has established contracts to provide primary care services through the North Broward Hospital District (d/b/a Broward Health) and the South Broward Hospital District (d/b/a Memorial Healthcare System). These contracts can be augmented with the focus in prevention for heart disease and following the criteria and clinical pathways established above. New clinics, Health Kiosks and contracts could be established to expand access to care and to add additional sites in neighborhoods with a higher proportion of indigent and medically poor population.

A significant emphasis should be placed on healthcare literacy and facilitating community understanding and appreciation for the value of cardiology prevention care at these clinics. This emphasis should include:

- Navigators or the equivalent to present the health risks and available primary and prevention care in a culturally-sensitive and community-relevant way;
- Staffing centers with qualified personnel from the local community;
- Available interpretations services, printed materials in other languages (e.g. Spanish, Haitian Creole, and French)
- Early inclusion of community leaders (both formal and informal) from the target communities in the development of the outreach plan and clinic operational plans; and
- Planned outreach to patient with high risk/high CAC scores to pursue follow-up care.
- Digital Telehealth should also be used to facilitate outreach for the initial visit or follow-up of patients.

b. Imaging Facilities:

Imaging services with Calcium Score testing (CAC) and Coronary CT Angiography (CCTA) should be provided that meet or exceed the following criteria:

- For calcium score testing, a minimum of 16-slice Multi-detector CT scanner (MDCT) should be used with cardiac gating capabilities and calcium score software. Ideally, a 64-slice CT scanner or above is preferred in order to improve image quality and minimize radiation dose.

- For Coronary CT Angiography (CCTA) testing, CT scanner equipment should include multi-detector scanners with a minimum of 64 detector-rows and appropriate cardiac software. A 256-slice MDCT scanner is recommended to achieve superior image quality, better diagnostic accuracy and to minimize exposure to radiation dose. Modern CT scanners provide higher temporal resolution (ranging from 66-150 msec), allowing for coronary CTA imaging with less

contrast, lower radiation, and fewer artifacts. Patient-specific tube potential and current adjustment should be available. Patient safety equipment including advanced cardiovascular life support (ACLS) equipment should be present in the patient preparation and scanner areas. Scanners should be equipped to perform prospectively-triggered axial scanning with ECG-gated tube current modulation. Low dose acquisition modes such as volumetric acquisition or high-pitch scan mode are advantageous and should be utilized if available and appropriate. The use of iterative or model-based reconstruction for dose reduction is also strongly recommended. Periodic review of the site's radiation levels and comparison with published references should be performed at least once a year. Image interpretation should be performed with 3D post-processing software capable of displaying reconstructed axial data, multi-planar reconstructions (MPRs) including curved MPRs and maximum intensity projections.

These technologies can be sited at the primary care/prevention clinics, as standalone facilities, or both, depending on a number of factors, including existing clinic capabilities, expansion opportunities, target locations and populations, and how the program is administered. A detailed review should be undertaken of the current location, capabilities, and utilization of existing scanning equipment at availability facilities. Special care should be taken to tailor the quantity and capabilities of the scanning equipment to the expected needs of and projected utilization by the local community, so as to avoid financial exposure in the acquisition of underutilized equipment (e.g., overburdening health care facilities with additional costs not offset by appropriate utilization) and appropriate allocation of technology and funding to permit the intended medical benefits to reach all areas of the population, with special emphasis on the indigent and medically poor communities.

Financial considerations include whether to utilize existing imaging equipment (depending upon availability and capability at existing locations), provide new imaging equipment, or provide funding toward to acquisition of new imaging equipment. A market and economic analysis should be done to determine the appropriate method of ensuring the necessary imaging equipment is available and appropriately utilized. One method would be to allow market forces to provide for the acquisition of the necessary equipment based upon public funding of the services to be provided utilizing that equipment (e.g., reimbursement for services based upon a percentage of the Medicare fee schedule); under this approach, the medical market would adjust to the implementation of this Plan and the associated funding for primary and preventive cardiac health services, and the medical community would provide the equipment and services, assume the associated capital obligation, and reap the associated tax benefits. Another method would be for the County to fund the needed technology, whether through direct acquisition and distribution or through the provision of funding to the medical facilities to acquire the equipment. Under this method, the County could incentive the placement of the imaging equipment in appropriate locations by enhanced funding to medical facilities in the desired locations.

Mobile CT imaging for the performance of Coronary Artery Calcium (CAC) scanning should be considered in order to reach out to more underserved communities. CAC scanning is simple and does not need administration of IV contrast. The entire imaging procedure takes approximately 15 minutes and the actual CAC scanning is completed with a breath hold (10 – 15 seconds). As a matter of fact, the combination of Health Kiosks and Mobile CT Imaging may increase the outreach of this program in underserved areas. It is a challenge to perform CCTA in a Mobile CT environment as you need state-of-the-art equipment, nurse supervision for administration of medications (metoprolol to reduce the heart rate and nitroglycerin to achieve coronary vasodilation) and physician supervision during the

administration of IV contrast. Therefore, at the present state only CAC scanning is recommended to be performed in a Mobile setting.

Staffing requirements
CCTA programs should only be initiated only at sites with sufficient capabilities to provide the needed services. This can be determined in various methods, such as experience and case volume (e.g., a minimum of 200 CCTA cases within the previous year, as determined by the American College of Cardiology), and must have sufficient and appropriately trained staff to implement the program. Each location should have at least one technologist with prior experience of at least 100 CCTA scans is recommended to initiate the program. Properly trained ACLS certified nursing or similar qualified staff should supervise premedication of patients, consistent with institutional policy. A rapid response team and/or an ACLS certified physician should be readily available for prompt response to urgent or emergent complications.

Training & Interpreting Physician Requirements
All coronary CTA exams should be performed and interpreted by physicians adequately trained in cardiac CT, who have achieved at least Level II requirements, Fellowship training and Independent Practitioner status as defined in recent training guidelines issued by SCCT.[94] This includes at least 250 mentored CCTA exams, among other criteria. Due to the severe consequences of missed ACS, additional physician experience is recommended for physicians reading ED CCTA scans. Interpreting physicians should be promptly available in person or by phone for consultation about patient preparation and scan protocoling. A qualified physician should also interpret the non-cardiac anatomy on all scans either as the primary reader or as a collaborating physician. The interpretation and reporting of coronary CTA should make use of the Coronary Artery Disease Data and Reporting System (CAD-RADS)[95] and conform to SCCT Guidelines for Interpretation and Reporting of Coronary CTA.[99]

Quality Assurance
A quality assurance program is recommended with quality targets, including: a diagnostic-quality scan rate of ≥95%, a quarterly median radiation dose rate within the reference level and a quarterly comparative review of cases with both coronary CTA and invasive angiography that demonstrates a median accuracy of at least 75% per-patient.

c. Hospital services

One of the goals of this Plan is to ensure that local hospitals treating patients presenting with acute chest pain have adequate imaging technologies, including a cardiac capable MDCT scanner (minimum of 64-slice MDCT scanner and preferable a 256-slice MDCT scanner), as well as adequate and trained staff for CCTA interpretation as delineated above for proper triage and a cardiac catheterization lab in case the need of percutaneous coronary intervention is required. The local assessment of the location of existing imaging equipment should include confirmation that the local hospitals have a sufficient number and sophistication of cardiac capable MDCT scanners.

5. Level I Trauma Center:

Patients presenting with chest pain and suspected myocardial infarction should be directed to hospitals equipped with a cardiac capable MDCT scanner (minimum of 64-slice MDCT scanner and preferable a 256-slice MDCT scanner) with adequate and trained staff for CCTA interpretation as delineated above for

proper triage and a cardiac catheterization lab in case the need of percutaneous coronary intervention is required.

The Plan includes the statutorily-required funding requirement of $6.5 million annually to a Level I Trauma Center in Broward County. There are two Level I Trauma Center in Broward County: Broward Health Medical Center (affiliated with North Broward Hospital District), and Memorial Regional (affiliated with South Broward Hospital District).

6. Funding Methodologies, Reimbursement Agreements, and Economic Analysis

a. Methods of Funding and Reimbursement

The Plan is intended to provide primary and preventive care services for cardiac health for indigent and medically poor populations of Broward County residents, and innovative cardiac screening technology for all Broward County residents, and to then include a second phase to include preventive and diagnostic services for cancer. The funding methodologies and reimbursement strategies contemplated would utilize existing healthcare plans, both private and public, and existing primary care public funding. Typically, public and private health insurance does not cover all of the CAC and CCTA screening for the populations called for in this Plan; therefore, the implementation of this Plan would expand reimbursement for these services for the indigent and medically poor to include the recommended cardiac primary and prevention services and screening detailed herein, but only to the extent such services are not covered by existing public or private insurance or other funding. The patient's existing coverage (if any), whether public or private, would be the initial payor, to the extent such services are covered; the Plan funding would be utilized only if the patient's existing coverage is insufficient. Special attention should be directed during Plan implementation to ensure healthcare plans are not negatively incentivized to exclude coverage from private healthcare plans.

In addition, for all Broward residents, this Plan would provide for the availability of screening equipment at convenient locations throughout the County and qualified professionals to assess the scores and risk profiles of the target population. To provide for the availability of the screening equipment, possible options include incentivizing procurement of the equipment by locations (e.g., through reimbursement for screening services), funding some or all of the cost of the acquisition by the locations, or County procurement of the necessary equipment; the administrators of the Plan would determine the appropriate method for ensuring the availability of the equipment, which may vary based upon the location at issue.

This analysis assumes there would not be direct services agreements with individual facilities, but rather the Plan would utilize existing healthcare networks or negotiate the addition or expansion of healthcare networks to facilitate the provision of these services. The Plan also does not contemplate reimbursement for prescription medicine for treatment of cardiac risk or conditions, except for the indigent or medically poor. Existing public and private healthcare and public funding would be the primary funding mechanism for long-term treatment, following the screening, diagnosis, and initial follow-up addressed in this Plan.

To effectuate the foregoing, the County could negotiate an agreement with a single healthcare plan administrator or negotiate agreements with the applicable healthcare plans. Such agreements will include reimbursement methodologies that take into account the cost of services rendered to eligible patients, recognize hospitals and facilities that render a disproportionate share of indigent care, and provide other incentives to promote the delivery of charity care. These agreements should also promote

the use of these advancement technologies for cardiac health care in medical services and include appropriate mechanisms for cost containment.

One proposed methodology is to follow the Medicare Fee schedule to pay for Part A and Part B services. At least 150% of the corresponding Medicare Fee Schedule would be paid to facilities (prevention heart clinics/ primary care clinics, imaging facilities, and Hospital services) that render a disproportionate share of indigent care and promote the delivery of charity care. In addition, at least 150% of the corresponding Medicare Fee schedule would be provided to imaging facilities that promote the advancement of technology with the use of 256-slice MDCT scanner for CCTA imaging services. Facilities that provide superior services with better quality care and superior outcomes through prevention and early intervention (thus providing cost containment by avoiding subsequent emergency/surgical intervention) and promoting care coordination; the timing for funding based on superior case management could include a 10% bonus payment annually if certain predefined metrics are met.

b. Health-Economic Analysis

Outpatient Setting – Stable CAD

A recent cost-effectiveness analysis[62] simulating life-time cost and outcomes using individual-level patient data from the PROMISE trial found that over a lifetime, patients undergoing CCTA gained – on average - an additional 6 months in perfect health compared with functional testing. Assuming that 25% of the people 40-75 years of age in Broward County will qualify for a CCTA in a 5-year period, this results in 42k individuals per year and therefore 21k additional life years in perfect health.

Hospital Setting – Acute Chest Pain

Goehler et al.[80] estimated the cost-effectiveness of CCTA compared to alternative management strategies for ACP patients over a lifetime using a simulation approach based on individual-level patient data from the ROMICAT II trial. They found that compared to an expedited ED strategy, CCTA in the ED resulted in a gain of 25 days in perfect health. Assuming that 6% of the uninsured population will have at least one chest pain hospital admission, CCTA in the ED will result in around 500 additional life years in perfect health.

Health Economic Evaluation of Proposed Plan

Cost-effectiveness Analysis

From a societal perspective, the use of CCTA may lead to >21.5k additional life years in perfect health per year while the cost for imaging facilities (including CAC testing and CCTA AI Services) and hospital service (including re-admissions) amount to $88M per year. Considering all costs, including primary care clinics and continuity of care, the cost amount to $147M per year. Therefore, the cost per additional life year in perfect health is $4K when considering imaging and hospital service only and $7K when considering all costs. Note that these estimates are very conservative since they are based on the comparison between CCTA and functional testing (whereas the target population currently does not have access to any testing) and because any health gains from primary prevention, CAC testing, or CCTA AI Services are unaccounted for while costs for these are included. To put these results into perspective, the ACC/AHA Guideline statement on cost and value methodology classifies interventions resulting in gains per additional year in perfect health costing < $50K as a high value, $50–100K as an intermediate value, and > $100K as a low value.[100] Therefore, this program is considered as high value from a health-economic standpoint.

Cost-benefit Analysis

The U.S. Department of Transportation (DOT) uses a willingness-to-pay approach when valuing the reduction of fatalities and injuries by regulations or investments. The benefit of preventing a fatality is measured by the Value of a Statistical Life (VSL), defined as the additional cost that individuals would be willing to bear for improvements in safety (that is, reductions in risks) that, in the aggregate, reduce the expected number of fatalities by one. According to the DOT, the current VSL estimate is $11.6 million for analyses using a base year of 2020.[101] The average life expectancy in Broward County is 81.2 years. Assuming – in a very conservative manner – that these would be lived in perfect health, 21.5k additional life years in perfect health would correspond to 265 statistical life's. Taking the VSL into account results in a willingness-to-pay of $3.1 Billion per year for the proposed health care service plan. Compared to the estimated cost of $147 Million per year, the willingness-to-pay outweighs the estimated cost by a factor of 20.

7. Preventive and Early Diagnosis of Cancer

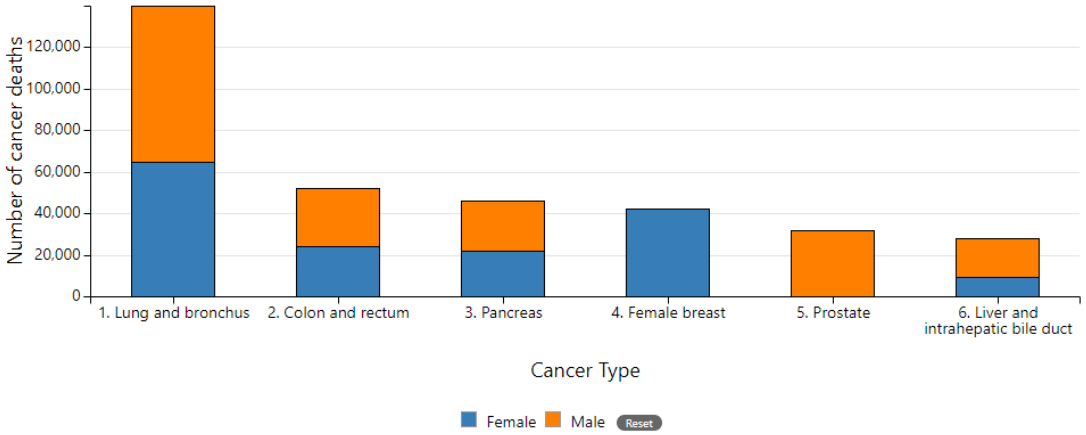
a. Cancer Deaths and Trends in the United States

Cancer was the second leading cause of death, after heart disease, in the United States in 2019. In 2019, there were **599,601 cancer deaths**; 283,725 were among females and 315,876 among males. From 1999 to 2019, cancer death rates went down 27%, from 200.8 to 146.2 deaths per 100,000 population.[101]

Lung cancer was the leading cause of cancer death, accounting for 23% of all cancer deaths. Other common causes of cancer death were cancers of the colon and rectum (9%), pancreas (8%), female breast (7%), prostate (5%), and liver and intrahepatic bile duct (5%). Other cancers individually accounted for less than 5% of cancer deaths. In 2019:

- 139,603 people died of lung cancer (64,743 females and 74,860 males).
- 51,896 people died of colorectal cancer (24,222 females and 27,674 males).
- 45,886 people died of pancreatic cancer (22,154 females and 23,732 males).
- 42,281 females died of breast cancer.
- 31,638 males died of prostate cancer.
- 27,959 people died of liver and intrahepatic bile duct cancer (9,267 females and 18,692 males).

Figure 2. Number of deaths by leading cancer types and sex, United States, 2019

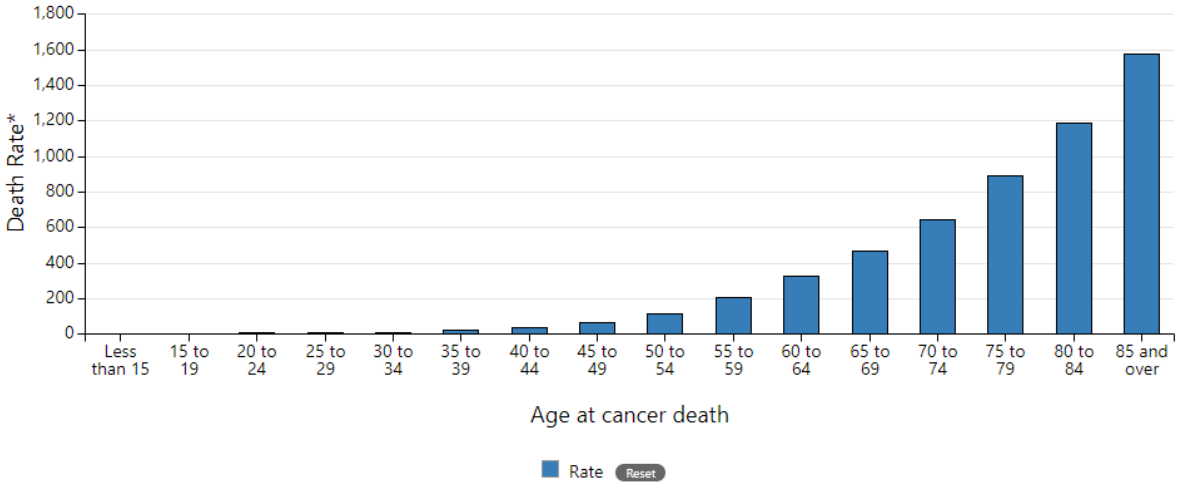


NOTES: Deaths were classified using the International Classification of Diseases, 10th Revision. Cancer deaths were identified using underlying cause-of-death codes C00-C97 (malignant neoplasms).

SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality Data.

Cancer deaths increase with age. In 2019:

- 1,115 children younger than 15 years old died of cancer.
- 9,084 adolescents and young adults between 15 to 39 years old died of cancer.
- 153,928 adults between 40 to 64 years old died of cancer
- 435,462 adults who were 65 years old or older died of cancer.



Previous research suggests that trends in cancer death rates reflect population changes in cancer risk factors, screening test use, diagnostic practices, and treatment advances. Some examples are highlighted below.

- **Cigarette smoking** contributes to the development of cancers throughout the body. Fewer people are smoking cigarettes: in 1965, 42% of U.S. adults smoked cigarettes compared to 14% in 2019. About two-thirds of people who smoke want to quit.
- **Overweight and obesity** also contribute to the development of cancers throughout the body, including cancers of the liver, pancreas, and uterus. Some states and communities are providing support that can help people get to and keep a healthy weight.
- **Cancer screening tests** can find cancer early, when treatment works best. Screening tests for lung cancer such as CT Lung screening can reduce mortality; colorectal cancer can find polyps with CT Colonography or Colonoscopy; 2D and 3D mammography can find early Breast cancer in women; which can be removed before they become cancerous or more invasive.

CDC's framework to reduce cancer deaths includes eliminating preventable cancers, ensuring that all people get the right screening at the right time, and helping cancer survivors live longer, healthier lives. CDC supports foundational programs that aim to reduce the cancer burden through multi-disciplinary collaboration and coordination. These programs include the National Breast and Cervical Cancer early Detection, Colorectal Cancer Control Program and the National Comprehensive Cancer control Program.

b. Gap Analysis in Broward County

A total of 12.6% of surveyed Broward County adults report having been diagnosed with cancer. Among those with past cancer diagnosed 22.2% were diagnosed with melanoma/skin cancer, 13.3% breast cancer and 12.1% prostate cancer. Just as many factors can contribute to cancer risk, disparities in cancer mortality arise from a complex set of factors as well. For example, members of minority groups are more likely to be poor. According to the National Cancer Institute, people in poverty, in turn, often lack adequate medical care and are more likely to be exposed to environmental risk factors, such as air pollution. These disparities do not manifest the same way across the United States, however. Risk factors unique to Broward County may play a vital role in both explaining local disparities in cancer deaths and in preventing those deaths.

One of the most effective ways to reduce cancer morbidity and mortality is through early detection and treatment. Increasing awareness and use of the available screening technologies for breast, cervical, colorectal and lung cancer can contribute to increased survival and fewer deaths. In some communities, people get regular screening, and if cancer is suspected, receive timely and appropriate treatment. However, in other communities, people are diagnosed with breast, cervical, colorectal or lung cancer when it is advanced (late stage) and when the likelihood of successful treatment is lower.

An important report of cancer data in South Florida[102] demonstrated disparity in care and identified areas in South Florida where the percentage of people diagnosed with breast, cervical or colorectal cancer at an advanced stage is higher than other areas of the county, the state or for the US. For example, the percentage of women with breast cancer diagnosed at late stage is significantly higher in eight ZIP Codes in both Broward and Monroe Counties. For colorectal cancer, there are seven ZIP Codes in Broward County and three in Miami-Dade with significantly higher percentages of late stage diagnoses. There is an overlap in only one ZIP Code in Miami Dade and three in Broward. Fewer ZIP Codes have significantly high percentage of late stage cervical cancer (three in Miami-Dade), however, because of the nature of cervical cancer and the high prevalence of precancerous conditions which are not included in the data, the screening may be important throughout the region. With routine screening, all late stage cervical cancers could be eliminated.

ZIP Codes with significantly high percentage of late stage breast cancer cases In Broward County, these ZIP Codes are scattered throughout the central and southern parts of the county – some on the eastern side and some to the west. In Miami-Dade County, there are clusters in the northern part of the county, near the Broward County line, as well as in the central part of the county, west of downtown. Part of the northern cluster is continuous with the areas of Broward County with high percentages.

Broward County: 33004 (Dania) 33023 (Hollywood) 33028 (Hollywood) 33068 (Pompano Beach) 33309 (Fort Lauderdale) 33011 (Fort Lauderdale) 33317 (Fort Lauderdale) 33332 (Fort Lauderdale)

Miami-Dade County: 33016 (Hialeah) 33055 (Opa Locka) 33056 (Opa Locka) 33125 (Miami) 33136 (Miami) 33150 (Miami) 33169 (Miami) 33181 (Miami)

c. Description of Proposed Services

Screening Tests: means checking your body for cancer before you have symptoms. Getting screening tests regularly may find breast, cervical, and colorectal (colon) cancers early, when treatment is likely to work best. Lung cancer screening is recommended for people who are at high risk. CDC supports screening for breast, cervical, colorectal (colon), and lung cancers as recommended by the U.S. Preventive Services task Force.[103]

Breast Cancer: Mammograms are the best way to find breast cancer early, when it is easier to treat.

Cervical Cancer: The Pap test can find abnormal cells in the cervix which may turn into cancer. The HPV test looks for the virus (human papillomavirus) that can cause these cell changes. Pap tests also can find cervical cancer early, when the chance of being cured is very high.

Colorectal Cancer: Colorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests with CT Colonoscopy or regular colonoscopy can find precancerous polyps, so they can be removed before they turn into cancer. Screening tests also can find colorectal cancer early, when treatment works best.

Lung Cancer: The USPSTF recommends yearly lung cancer screening with low-dose computed tomography (LDCT) for people who have a history of heavy smoking, and smoke now or have quit within the past 15 years, and are between 50 and 80 years old.

Screening for ovarian, pancreatic, testicular and thyroid cancers has not been shown to reduce deaths from those cancers. The USPSTF found insufficient evidence to assess the balance of benefits and harms of screening for bladder cancer and oral cancer in adults without symptoms, and of visual skin examination by a doctor to screen for skin cancer in adults.

Therefore, the second phase of the Plan will focus on the preventive and diagnostic cancer screening to address the number two leading cause of death for Broward County residents. First, there are overlapping risk factors, such as cigarette smoking and overweight/obesity, for heart disease and cancer and preventive and treatment strategies will be beneficial for both. Secondly, the infrastructure will be in place to reach out to underserved communities with medical personnel, imaging equipment and screening program. Finally, after the Covid-19 pandemic we have a real opportunity to impact the two leading causes of the death in our County to ensure longevity with quality of life for the population we serve.

8. Proposed Healthcare Plan and Recommended Funding Allocations

All utilization of the surtax-generated funding must be consistent with the requirements of Section 212.055(4), Florida Statutes, and all other applicable law. The proposed funding allocations set forth herein are recommendations for the initial allocations of the funds. The actual implementation of the Plan is likely to vary from these recommendations based upon a number of factors, including the actual proceeds generated and the timing of the funding availability, the current resources and needs of the locations selected for the prevention clinics and the screening services, staffing availability, utilization of the program by the public, etc. Designated staff and medical personnel should periodically evaluate the allocation and recommend appropriate adjustments and amendments.

a. General Overview of Primary, Preventive, and Hospital Services to be Provided by Cardiovascular Disease Prevention Clinics

This Plan recommends supporting the creation of Primary Care Physician (PCP) and/or Registered Nurse (RN) or Nurse Practitioner (NP) run *Cardiovascular Disease Prevention* clinics to the indigent and medically poor for clinical assessment and risk stratification of atherosclerotic cardiovascular disease (ASCVD). These *Cardiovascular Disease Prevention* clinics would increase access to preventive cardiovascular care, particularly to those with greater social stress. Cardiovascular risk evaluation and treatment will be protocol driven and thus improve quality and consistency of care. The PCP/NP leading these CVD Prevention Clinics would also be charged with community education with regard to cardiovascular risk factors, heart-healthy living, and preventive medications.

This proposal expands access to PCP/RN/NP run *Cardiovascular Disease Prevention* clinics to the indigent and medically poor for clinical assessment and risk stratification of atherosclerotic cardiovascular disease (ASCVD). In all individuals, irrespective of cardiovascular risk, heart-healthy lifestyle should be emphasized.

As detailed herein, this proposal suggests that for individuals aged 40 – 75 years old who fall into the true primary prevention (Statin benefit group #4) whose estimated 10-year ASCVD risk is between 5 to 19.9%, a non-contrast cardiac CT for coronary artery calcium (CAC) score should be performed. Coronary CT Angiography (CCTA) is recommended in patients with diabetes, with family history of premature ASCVD and smokers (40-75 y/o). Patients presenting with chest pain or angina to the Emergency Department or to the Hospital setting a CCTA first line strategy should be prioritized for low to intermediate risk patients.

The foregoing services shall be rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital where appropriate. The location of *Cardiovascular Disease Prevention* clinics should be based consideration of at least the following factors: current location of primary care clinics (included publicly-funded primary care provided by local hospitals and federally qualified health centers); location of and proximity to high-risk populations, including geographic communities, public transportation, and impediments to access to care; current utilization rates of existing clinics; current screening capabilities of existing clinics and/or the ability of current clinics to expand to include innovative screening technologies (including physical footprint, financial abilities, current patient utilization numbers, etc.).

Reimbursement methodologies will be structured to allocate higher reimbursement rates to facilities that will provide a higher proportion of care to indigent or medically poor patients, facilities that invest in the

technology needed to achieve better imaging services, and facilities that will provide superior services with better quality care and superior outcomes including through promoting care coordination and appropriate case management.

b. Eligible Populations

The Primary, Preventive, and Hospital Services provided under this Plan will be available to Broward County residents who are indigent or medically poor. The innovative health care programs that provide access to the imaging facilities and their services will be available to all Broward County residents.

As used herein, these terms have the following meanings:

"Indigent" means persons who are qualified by Broward County as meeting all of the following criteria: (i) gross family unit income is below the poverty level for a household of that size; (ii) not eligible to participate in any other state or federal program which provides hospital care (i.e., Medicaid or Medicare); (iii) family unit's assets do not exceed the established limits; (iv) has either no or inadequate private insurance; and (v) does not reside in a public institution as defined under the medical assistance program under Title XIX of the Social Security Act.

"Medically poor" means persons who are qualified by Broward County as having insufficient income, resources, and assets to provide the needed medical care without using resources required to meet basic needs for shelter, food, clothing, and personal expenses; or not being eligible for any other state or federal program, or having medical needs that are not covered by any such program; or having insufficient third-party insurance coverage. In all such cases, this Plan and Broward County are intended to serve as the payor of last resort.

"Broward County resident" means persons who are indigent, medically poor, or to the extent otherwise approved by Broward County for participation in the innovative health care programs set forth herein, provided such persons have established, and currently maintain, Broward County as their domicile (i.e., primary residence) as demonstrated by homestead status, election registration, or other documentation as determined appropriate by the Plan administrators. An applicant that demonstrates uninterrupted residency in Broward County for the twelve (12) months immediately preceding the date of the application for qualification shall be presumed to be a Broward County resident, absent clear evidence to the contrary.

c. Funding Allocations

Based upon the health care needs of Broward County, with special emphasis on the needs of the indigent and medically poor, the recommended allocation of surtax funding to the above-referenced services and program is as set forth below. In accordance with state law, the total funds (100%) allocated under this proposal shall be equal to 95% of the projected proceeds of the .5% healthcare surtax, as required by Section 129.01, Florida Statutes.

The following services will be eligible for funding under this Plan (see additional details in the budget):

1. Primary Care Clinics/ Cardiology Prevention Clinics
   Allocation: 35%
   Multidisciplinary Team: PCPs, family doctors, registered nurse/nurse practitioner, social workers, cardiologist, care coordinators, and administrative support

Capital funding will be used to provide primary care services and prevention services in established or new primary care/ cardiology clinics. The services with be focused on evaluation and screening for heart disease and general clinical evaluation supporting a multidisciplinary team of primary care physicians, nurse practitioners, social workers, preventive cardiologists and administrative personnel. Taking into account the 2019 Broward Community Health Needs Assessment Report that demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight and 85.2% have at least one cardiovascular risk factor, we estimate that 65% of the medically poor and indigent care population (which consists of 14.2% group without insurance between 40 and 75 y/o = 119,331) will need one preventive office visit, one care management services, and one follow-up visit, and one laboratory testing per year and that 30% of the indigent and medically poor will qualify for statin treatment and 10% for aspirin treatment. The remaining 35% of the medically poor and indigent care population will need only one preventive office visit and one laboratory testing per year. We estimate that 5% of patients will not return for a follow-up visit. We also estimate that our target outreach for this program will be 70% of the indigent and medically poor population. Assuming thorough adoption of this Plan by the target audiences, the budget estimated to provide preventive and primary care services per year for this population is approximately $52.8 million per year.

2. Imaging Facilities
   Allocation: 40% plus any unused allocation from the other categories
   Innovative technology/equipment and related services, including 64-slice CT scanners for Calcium Score and 256-slice CT scanners or equivalent for CCTA/Technologists/Nurses/Radiology interpretations/AI Digital care pathway services

The capital will be used to fund or acquire screening equipment and to provide Imaging and AI services in established or new imaging facilities. Depending upon the method of funding and acquisition, the screening equipment could be made available through clinics or at designated locations directly by the County to Broward County qualified residents, and the funding and reimbursement mechanisms could include reimbursement methodologies that provide cost-effective alternatives to traditional methods of service delivery and funding such as capitation agreements. The Imaging services will provide Calcium Score testing for asymptomatic patients with intermediate risk (5-19.9%) as per the ACC/AHA ASCVD cardiovascular risk estimator. Patients who will qualify for CCTA services with AI evaluation are diabetics, smokers and patients with premature family history of ASCVD. We plan to expand coverage for imaging services to the medically poor, indigent care, and other Broward residents, including the underinsured population and those with public health insurance, as these services are not covered and is an existing gap in care. Taking into account the 2019 Broward Community Health Needs Assessment Report that demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight and 85.2% have at least one cardiovascular risk factor, we estimate that 40% of Broward County population between 40 and 75 will qualify for a Calcium Score test in 5 years. We also estimate that 25% of the Broward County population between 40 and 75 will qualify for a CCTA testing and of those patients undergoing a CCTA, 80% will qualify for AI full coronary tree evaluation. The

remaining 35% will not need any imaging testing and the recommendation is lifestyle changes. The budget estimated to provide Imaging services per year for this population is approximately $58.4 million per year.

3. Hospital Services
   Allocation: 20%
   Statutory funding for Level I Trauma Center; hospital services "charity care" for the indigent and medically poor who present with chest pain directly to the hospital or patients who are referred to the Hospital by the primary care or prevention clinics; coordinated primary care/preventive services through hospital primary care clinics

Part of the capital will be allocated to hospital "charity care" for the indigent and medically poor who may present with chest pain directly to the hospital or who are referred by the primary care clinics/cardiology prevention clinics. The services will be contracted with hospitals in the Broward County community. We estimate that 6% of the medically poor and indigent care population (which consists of 14.2% group without insurance between 40 and 75 y/o) will need chest pain assessment in the hospital. We also estimate that 0.5% of these population will need a diagnostic cardiac catheterization during admission, another 0.5% will need a diagnostic cardiac catheterization with percutaneous coronary intervention. The budget estimated to provide Hospital services per year for this population is approximately $29.8 million per year.

In addition, the Plan contemplates and annual funding of $6.5 million total to support one or more local Level I trauma center.

4. Continuity and Coordination of Care/Monitoring and Analysis of the Data
   Allocation: 5%
   Medical advisory board oversight, social workers, data analysts, quality analysts, health economic experts and cloud-based IT infrastructure including data storage, data-lake, software, and IT personnel.

In order to ensure continuity and coordination of care, as well as regular monitoring and analysis of the data, the Plan contemplates a material component for medical advisory board oversight, social workers, data analysts, quality analysts, health economic experts/IT infrastructure including data storage, data-lake and IT personnel.

This part of the capital will be allocated to support ongoing monitoring and analysis of the program and the data to ensure patient safety, access to care, coordination of care, continuity of care and cost-effectiveness of the program. A team of professionals will provide guidance, monitoring and oversight including a medical advisory board, social workers, data analysts, quality analysts and health economic experts. A technology infrastructure including the set-up of cloud-base technology infrastructure and storage, cloud-base data-lake, software licenses and IT personnel will need to be assembled in order to collect, store and analyze the data to generate important insights, quality assurance, care coordination, continuity of care and process improvement. Detailed modeling and cost-effectiveness analysis will be performed. The budget estimated to provide this service per year for this project is approximately $6.2 million per year.

Appendix 1. Summary Recommendations of the 2017 ACC/AHA Blood Pressure/Hypertension Treatment Guidelines

Recommendations for Hypertension Management

Chlorthalidone (12.5-25 mg) is the preferred diuretic because of long half-life and proven reduction of CVD risk.

Angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs), and direct renin inhibitors should not be used in combination.

ACE inhibitors and ARBs increase the risk of hyperkalemia in CKD and with supplemental K+ or K+-sparing drugs. ACE inhibitors and ARBs should be discontinued during pregnancy. Calcium channel blocker (CCB) dihydropyridines cause edema.

Non-dihydropyridine CCBs are associated with bradycardia and heart block and should be avoided in heart failure with reduced ejection fraction (HFrEF).

Loop diuretics are preferred in HF and when glomerular filtration rate (GFR) is <30 ml/min. Amiloride and triamterene can be used with thiazides in adults with low serum K+, but should be avoided with GFR <45 ml/min.

Spironolactone or eplerenone is preferred for the treatment of primary aldosteronism and in resistant hypertension.

Beta-blockers are not first-line therapy except in CAD and HFrEF. Abrupt cessation of beta-blockers should be avoided.

Bisoprolol and metoprolol succinate are preferred in hypertension with HFrEF and bisoprolol when needed for hypertension in the setting of bronchospastic airway disease.

Beta-blockers with both alpha- and beta-receptor activity such as carvedilol are preferred in HFrEF.

Alpha-1 blockers are associated with orthostatic hypotension; this drug class may be considered in men with symptoms of benign prostatic hyperplasia.

Initial first-line therapy for stage 1 hypertension includes thiazide diuretics, CCBs, and ACE inhibitors or ARBs. Two first-line drugs of different classes are recommended with stage 2 hypertension and average BP of 20/10 mm Hg above the BP target. Improved adherence can be achieved with once-daily drug dosing, rather than multiple dosing, and with combination therapy rather than administration of the free individual components.

For adults with confirmed hypertension and known stable CVD or ≥10% 10-year ASCVD risk, a BP target of <130/80 mm Hg is recommended. The strategy is to first follow standard treatment guidelines for CAD, HFrEF, previous MI, and stable angina, with the addition of other drugs as needed to further control BP. In HFpEF with symptoms of volume overload, diuretics should be used to control hypertension, following which ACE inhibitors or ARBs and beta-blockers should be titrated to SBP <130

mm Hg. Treatment of hypertension with an ARB can be useful for prevention of recurrence of atrial fibrillation.

CKD: BP goal should be <130/80 mm Hg. In those with stage 3 or higher CKD or stage 1 or 2 CKD with albuminuria (>300 mg/day), treatment with an ACE inhibitor is reasonable to slow progression of kidney disease. An ARB is reasonable if an ACE inhibitor is not tolerated.

Diabetes mellitus (DM) and hypertension: Antihypertensive drug treatment should be initiated at a BP ≥130/80 mm Hg with a treatment goal of <130/80 mm Hg. In adults with DM and hypertension, all first-line classes of antihypertensive agents (i.e., diuretics, ACE inhibitors, ARBs, and CCBs) are useful and effective. ACE inhibitors or ARBs may be considered in the presence of albuminuria.

Metabolic syndrome: Lifestyle modification with an emphasis on improving insulin sensitivity by means of dietary modification, weight reduction, and exercise is the foundation of treatment of the metabolic syndrome. The optimal antihypertensive drug therapy for patients with hypertension in the setting of the metabolic syndrome has not been clearly defined. Chlorthalidone was at least as effective for reducing CV events as the other antihypertensive agents in the ALLHAT study. Traditional beta-blockers should be avoided unless used for ischemic heart disease.

Race/ethnicity: In African American adults with hypertension but without HF or CKD, including those with DM, initial antihypertensive treatment should include a thiazide-type diuretic or CCB. Two or more antihypertensive medications are recommended to achieve a BP target of <130/80 mm Hg in most adults, especially in African American adults, with hypertension.

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Phase Two: Preventive and Diagnostic Cancer

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Primary Care Clinics		Office	Facility	Total
Primary Care Clinics/ Preventive Heart Clinics		Office	Facility	Total
Preventive visit - Initial visit	Low level of medical decision making or 20-29 minutes	$122.69	$84.44	$207
Care Management Services	Care coach/ navigator	$81.30	$81.30	$162.60
Comprehensive follow-up visit	Comprehensive Follo-up visit 45-59 min	$ 150.00	$ 100.00	$ 250.00
Lab testing				$ 140.00
Total without Meds		$354	$266	**$760**
Medication	Statin treatment for 1 year			$ 300.00
Medication	Aspirin treatment for 1 year			$ 30.00
Total with Meds				**$1,090**

40-74y/o = 840,358	840,358		
Uninsured Population	119,331		
Primary/ Preventive Care Costs per year	$52,766,067.05	**Budget**	35.2%

Assumptions:

35% of the uninsured population will have 1 office visit per year + Labs
60% of the uninsured population will have Office visit + Care Management Services + Follow-up visit per year
5% will not return to follow-up/second visit
Program will reach 70% of the unisured population
30% of uninsured patients will qualify for statin
10% of uninsured patients will qualify for aspirin

A 2019 Broward Community Health Needs Assessment Report demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight and 85.2% have at least one cardiovascular risk factor[10]

Cost of statin per year vary $200-400 depending on the medication

The cost for Aspirin Low Strength oral delayed release tablet **81 mg is around $10 for a supply of 120 tablets**

Lab Testing	
Comprehensive Metabolic Profile	$55
Lipid Panel	$50
Hemoglobin A1C	$35
Total Lab Testing cost	$140

Imaging Facilities	Professional Fee	Technical Fee	Total	Medicare 150%	Medicare 200%
Calcium Score	$37	$62	$99	**$148.50**	$222.75
Coronary CTA CPT Code 75574	$116.89	$289.26	$406.15	**$609.23**	$812.30
Coronary CTA of the coronary arteries and bypass grafts with contrast, including 3D image postprocessing					
CCTA AI services Digital Care pathway	$ 50.00	$ 450.00	**$ 500.00**		

40-74y/o = 840,358	840,358
Uninsured Population	119,331
Public Health Insurance	221,855
Funding for Equipment	$ 6,000,000.00
Imaging Costs per year	$58,388,968.17
Budget	38.9%

Assumptions:
40% of the Broward County population will qualify for one Calcium Score Test in a course of 5 years
25% of the Broward County population will qualify for a CCTA in a course of 5 years
20% of the uninsured population + public health insurance will qualify for CCTA AI services in a course of 5 years

A 2019 Broward Community Health Needs Assessment Report demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight and 85.2% have at least one cardiovascular risk factor[10]

Calcium Score: Intermediate risk (5-20% of AHA-ACC ASCVD risk calculator) ~ 40% of the population will qualify
CCTA: Diabetics + Smokers + Premature ASCVD - ~25% of the population will qualify
CCTA AI Services: 80% of patients undergoing CCTA will qualify for Artificial Intelligence Digital Care Pathway for full coronary tree evaluation

Imaging services will be offered to the entire population as CAC and CCTA are not covered by Insurance for primary prevention

256-slice MDCT scanner	Cost of approximately $1.5 Million
64-slice MDCT scanner	Cost of approximately $1 Million

Equipment can be financed or leased

Hospital Admissions	**Cost**			
Chest Pain evaluation	$	2,500.00	14,916,354.50	5966.5418
DRG with cardiac cath only	$	10,000.00	5,966,541.80	
DRG with cardiac cath + stent	$	20,000.00	11,933,083.60	

40-74y/o = 840,358		840,358		
Uninsured Population		119,331		
Hospital Service Costs per year	$	29,832,709.00	**Budget**	19.9%

Assumptions:

5% of the uninsured population will have one Chest Pain Hospital admission

0.5% of the uninsured population will have a cardiac catheterization during the Hospitalization

0.5% of the uninsured population will have cardiac cath + Stent placement during Hospitalization

Common MS-DRGs for Coronary Procedures	Medicare Rate	MS DRG
Percutaneous cardiovascular procedure with drug-eluting stent with MCC or 4+ vessels/stents	$ 19,352.00	246
Percutaneous cardiovascular procedure without coronary artery stent without MCC	$10,244	251

	Budget	
Medical Oversight and Advisory Board	$	1,200,000.00
Social workers	$	400,000.00
Data analysts	$	500,000.00
Quality analysts	$	400,000.00
Health economic experts	$	450,000.00
Clinical/Admin costs	$	2,950,000.00
Overhead 25%	$	737,500.00
Total	$	3,687,500.00
Cloud Technology infrastructure/ Data Storage	$	1,000,000.00
Cloud-base data lake	$	500,000.00
Software licenses	$	400,000.00
IT personnel	$	500,000.00
Overhead IT personnel	$	100,000.00
Total IT costs	$	2,500,000.00
Grand Total	$	6,187,500.00
Budget		4.1%

Hospital Service	
40-74y/o = 840,358	840,358
Uninsured Population	119,331
5% admitted to Hospital per year	7160
QALD gained by CCTA vs Discharge (RII CEA)	25
Sum	178996.254
QALYs	**490**
Cost	$ 29,832,709.00
Incremental Cost-Effectiveness Ratio	**$60,833.33**

Assumptions:
5% of the uninsured population will have one Chest Pain Hospital admission
0.5% of the uninsured population will have a cardiac catheterization
0.5% of the uninsured population will have cardiac cath + Stent placement

Imaging	
40-74y/o = 840,358	840,358
Uninsured Population	119,331
Public Health Insurance	221,855
25% of the population between 40-74y/o will qualify for a CCTA in 5 years	42,018
QALYs gained by CCTA compared to FT (PROMISE CEA)	0.5
QALYs	**21009**
Cost	$58,388,968.17
Incremental Cost-Effectiveness Ratio	**$2,779.24**

Assumptions:
40% of the Broward population will qualify for one Calcium Score Test in a course of 5 years
25% of the Broward population will qualify for a CCTA in a course of 5 years
20% of the uninsured population + public health insurance will qualify for CCTA AI services in a course of 5 years

A 2019 Broward Community Health Needs Assessment Report demonstrated that 35.8% of the population have Hypertension, 36.3% have high cholesterol, 14.7% have diabetes, 61.7% are overweight and 85.2% have at least one cardiovascular risk factor[10]

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CCTA AI Services: 80% of patients undergoing CCTA will qualify for Artificial Intelligence Digital Care Pathway for full coronary tree evaluation

Cost-effectiveness Analysis	
Hospital + Imaging Costs	
QALYs	21499
Cost	$88,221,677
Incremental Cost-Effectiveness Ratio	**$4,103.46**

All Costs	
QALYs	21499
Cost	$147,175,244
Incremental Cost-Effectiveness Ratio	**$6,845.57**

Cost-Benefit Analysis	
Life Expectancy Broward County	81.2
Statistical Lifes (QALYs/LE)	264.7703288
Value of a Statistical Life (Department of Transportation)	$11,600,000
Willingness-to-pay	**$3,071,335,814**

WTP vs Actual Cost per year differ by a factor of 20