

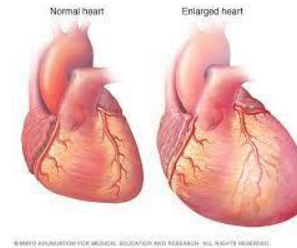
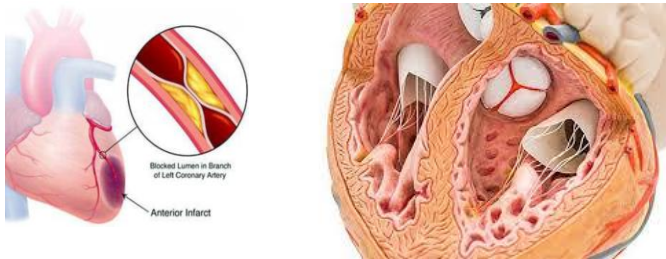
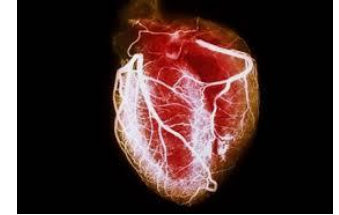
Engaging Patient Advocacy Groups

ERC – Stakeholder Engagement

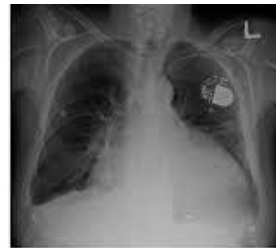


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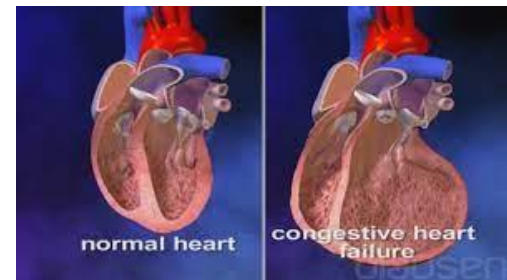
- Heart disease is the leading cause of death in the US ~600k/year and 17M worldwide
- Americans suffer **one million** heart attacks every year
- CMS spends approximately \$6.5 billion per year on heart failure -- ~5% of the total DRG budget (Medicare national reimbursement budget) with annual estimated total costs of \$40B



Normal Size Heart on Chest X-ray

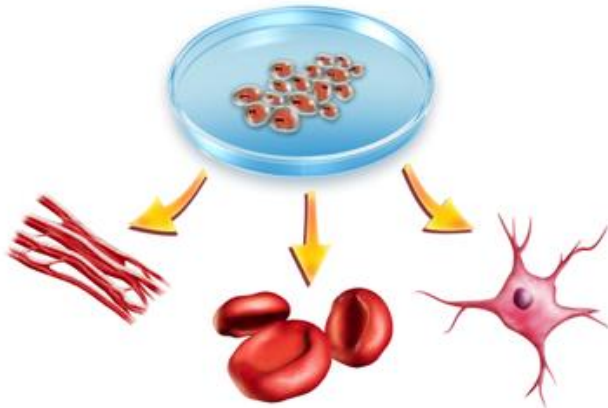


Cardiomegaly on Chest x-ray





- Until recently, tissue damage from a heart attack was considered irreversible.¹
- Induced pluripotent stem cells (iPSC) provide the first viable source of cardiac cells to repair or replace damaged tissue²
- But scalable differentiation (cell engineering) and assembly (tissue engineering) are challenges^{2,3}
- Controlled nanoscale cell adhesion, appropriate microscale scaffold stiffness, adequate vascularization, and multiscale integration are needed to generate functional, engineered tissues.⁴



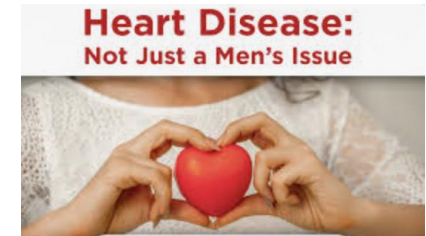
<http://www.lumacyte.com>

We aim to solve this engineering problem

- [1] Jennings RB, *Circulation Research*, [113], 428-438, (2013)
- [2] Laflamme MA, et al, *Nat Biotech*, [25], 1015-1024, (2007).
- [3] Stevens KR, et al, *Tissue Eng Part A*, [15], 1211-1222, (2009).
- [4] Eschenhagen T, et.al *American Journal of Physiology – Heart and Circulatory Physiology*, [303], H133-H143, (2012).

Lack of Diversity in Teams

Women comprise <15% of practicing cardiologists and <5% of interventional cardiologists. This has changed nominally over the last two decades and is unlikely to rise significantly. While there is a greater focus on women's cardiovascular health, the underwhelming rate of change is connected to the underrepresentation of female doctors in the field of cardiology.



Women have been understudied in clinical trials and studies. Policies that exclude women in health and science date back to the women's health movement in the 1970s when few women worked in science and medicine. In 1977, the FDA prohibited women of childbearing age from Phase I and II drug trials (this is linked to drug incidents like the tragedy of the drug thalidomide.) Protests erupted and eventually led to policy changes, but it wasn't lawful to include women in trials until 1993, when Congress wrote the NIH inclusion policy into federal law. A year later, in 1994, the FDA opened the Office of Women's Health to improve the health of women and girls through policy, education, and innovative programs.



"Many Black adults in the U.S. are already at higher risk of developing heart disease due to high blood pressure or type 2 diabetes," **Shanshan Sheehy, ScD**, assistant professor of medicine at Boston University Chobanian & Avedisian School of Medicine, said in a press release. "Current evidence shows that racism may act as a chronic stressor in the human body and chronic stress may lead to high blood pressure, which increases the risk of heart attack and stroke."

Sheehy and colleagues analyzed data from 48,297 participants in the Black Women's Health Study, initiated in 1997, with follow-up through 2019. Participants were free of cardiovascular disease (CVD) and cancer at baseline.





CELL-Met Industry Days

Coronary Heart Disease in Black Women: The Role of Adverse Pregnancy Outcomes

Project Number
5K01HL133600-05

Contact PI/Project
Leader
KELLEHER, SAMANTHA PARKER

Awardee
Organization
BOSTON UNIVERSITY MEDICAL CAMPUS



“The findings of our study have implications for postpartum care, particularly among women without a history of high blood pressure. We were surprised at the number of cases captured more than six weeks after delivery, a period that falls well outside of routine postpartum follow-up. Monitoring during this period could mitigate severe postpartum and long-term cardiovascular complications.”

Samantha Parker, Ph.D., lead study author, assistant professor of epidemiology, Boston University School of Public Health



Black Women's Health Study -Cardiovascular Disease



NSF Engineering Research Center in Cellular Metamaterials Meeting
10.22.2023

Shanshan Sheehy Sc.D.
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- A long-term study of more than 48,000 Black women assessed two measures of perceived interpersonal racism with risk of coronary heart disease.
- Experiencing self-reported interpersonal racism in employment, housing and interactions with the police was associated with a 26% higher risk of coronary heart disease, relative to not experiencing interpersonal racism in those areas.
- Self-reported experiences of racism in everyday life were not associated with an increased risk of coronary heart disease.



K&L GATES

2022 CELL-MET Industry Days

FDA and Drug/Biologic Approvals

K&L GATES

CELL-MET Meeting October 25, 2023

Determining the FDA Regulatory Status of a Proposed Product: The Basics

•Michael H. Hinckle
•K&L Gates LLP



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Thank You