Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

_____

Dana M. Urban 12/03/2019

Ethically Including Individuals Who Are Incarcerated in Clinical Research: A Cross-Sectional Survey Exploring the Perspectives of Cardiovascular Researchers

By

Dana M. Urban
MPH

Hubert Department of Global Health
Rollins School of Public Health

_____

Dabney P. Evans, PhD, MPH
Committee Chair

_____

Anne Spaulding, MD, MPH
Committee Member

_____

Jodie Guest, PhD, MPH
Committee Member

Ethically Including Individuals Who Are Incarcerated in Clinical Research: A Cross-Sectional Survey Exploring the Perspectives of Cardiovascular Researchers

By

Dana M. Urban
B.A. University of Richmond, 2014

Thesis Committee Chair:
Dabney Evans, PhD, MPH

Thesis Committee Members:
Anne C. Spaulding, MD, MPH
Jodie Guest, PhD, MPH

An abstract of a thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Health
Fall 2019

ABSTRACT

Ethically Including Individuals Who Are Incarcerated in Clinical Research: A Cross-Sectional Survey Exploring the Perspectives of Cardiovascular Researchers

By Dana M. Urban

Background: Cardiovascular disease, the leading cause of morbidity and mortality in the United States, disproportionately affects individuals in jails and prisons. Incarceration and cardiovascular disease share many of the same risk factors, and both affect minority groups at higher rates than the general population. Federal and ethical guidelines designed to protect vulnerable populations often inadvertently exclude individuals who are incarcerated in clinical research. This leads to underrepresentation of key subsets of the population in study results, including individuals who are incarcerated. Clinical research is important to accurately identify and find solutions to reduce health disparities.

Objective: To explore the barriers to including incarcerated individuals in clinical research studies by investigating cardiovascular researchers' attitudes and experiences, and to determine whether additional resources targeting researchers could assist in overcoming these barriers.

Methods: A web-based cross-sectional survey was conducted to look at the current practices and attitudes on this topic among cardiovascular researchers. Cardiovascular researchers from the Heart Failure Clinical Research Network were recruited via email to participate in the study. Data were analyzed using SAS™.

Results: Fifty-six cardiovascular researchers completed the survey, for a response rate of 34.4%. Most researchers (89.3%) were unfamiliar with protocols to retain subjects who become incarcerated while enrolled in their research studies. While 17.9% of respondents were aware of a subject's incarceration during a study, only two (3.6%) had worked on a study that discussed subsequent incarceration in the protocol or consent. The majority (55.4%) felt it would be valuable to be more familiar with this process, and most (71.4%) were willing to use resources to facilitate this in future studies.

Conclusion: There is demonstrated interest and perceived value among cardiovascular researchers in the development of resources to assist in ethically including individuals who are incarcerated in studies. By increasing representation of underserved groups in research, we can gain a greater understanding of health disparities, and ultimately find ways to improve overall health outcomes.

Ethically Including Individuals Who Are Incarcerated in Clinical Research: A Cross-Sectional Survey Exploring the Perspectives of Cardiovascular Researchers

By

Dana M. Urban
B.A. University of Richmond, 2014

Thesis Committee Chair:
Dabney Evans, PhD, MPH

Thesis Committee Members:
Anne C. Spaulding, MD, MPH
Jodie Guest, PhD, MPH

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Health
Fall 2019

TABLE OF CONTENTS

FIGURES AND TABLES

CHAPTER 2 FIGURES

CHAPTER 2 TABLES

CHAPTER 3 TABLES

I. CHAPTER 1: INTRODUCTION

A. CONTEXT, PROBLEM, AND PURPOSE

Clinical research is a vital aspect of the identification and mitigation of health disparities. Individuals who are incarcerated experience higher rates of chronic diseases and worse health outcomes compared to the general population.[2,3]

Ethical guidelines that are intended to protect vulnerable populations often inadvertently serve as barriers to the inclusion of underrepresented groups in clinical research. Federal regulations on the protection of human subjects in research have specific guidelines regarding research with individuals who are incarcerated. The Common Rule, which guides research funded by the U.S. Department of Health and Human Subjects, allow for the enrollment of persons who are incarcerated or become incarcerated.[4] In reality, however, when a study participant is incarcerated after enrollment in a clinical research study, they are typically censored and ultimately excluded from participating in the completion of the study.[5,6]

Omitting subsequently incarcerated subjects in studies poses an issue in clinical research with populations who are at high risk for incarceration, leading to an underrepresentation of vulnerable groups.[5,7-9] Studies suggest that high incarceration rates, especially among minority groups, may be impacting the ability to accurately identify, examine, and ultimately mitigate health disparities across all populations.[5-7] Vulnerable groups are also subsequently excluded from the prospective benefits of participation in clinical studies, limiting the potential for improved health outcomes for their communities that can arise from this research.

Increasing the participation of underserved and minority populations in clinical research is seen as a vital step in finding ways to reduce health disparities.[5,6,10] In order to achieve more accurate representation in study populations, it is important to retain subjects in studies who are part of underserved and minority groups, including those who are incarcerated. This is especially important when studying conditions that disproportionately impact individuals at higher rates of incarceration, such as studies on cardiovascular disease (CVD).[2,11] Incarceration is an independent risk factor for the development of CVD.[7,8] There is a significantly higher prevalence of CVD in incarcerated populations compared to the general population, and individuals who are incarcerated have higher mortality rates due to CVD.[3] [12]

Little is known about the perceptions of clinical researchers regarding their knowledge of the inclusion of incarcerated individuals in clinical research. Understanding the views of researchers can help identify the barriers to the inclusion of incarcerated individuals in research. Providing more information and resources to researchers regarding the issue could ultimately lead to improved representation of underserved groups in clinical research.

The purpose of this study was to explore the barriers to including incarcerated individuals in clinical research studies, and to determine whether additional resources targeting researchers could assist in overcoming some of these barriers. In order to investigate the current attitudes, views, and experiences of cardiovascular researchers regarding the inclusion and retention of incarcerated individuals in clinical studies, this study focused on researchers' familiarity with retaining subsequently incarcerated subjects, perceived value of doing so, and willingness to utilize resources on this topic, as well as the factors influencing these factors.

B. Research Questions

1. **Research Question:** How familiar are cardiovascular researchers with including subsequently incarcerated populations in research?

   Null Hypothesis: Cardiovascular researchers are neither familiar nor unfamiliar with including subsequently incarcerated subjects in studies.

   H_0: $\mu = 3$ (neutral on Likert scale)

   H_a: $\mu \neq 3$

2. **Research Question:** Do cardiovascular researchers perceive including incarcerated individuals in their research as valuable to their field?

   Null Hypothesis: Researchers perceive the inclusion of incarcerated subjects in research as neither valuable nor not valuable to their field of cardiovascular research.

   H_0: $\mu = 3$ (neutral on Likert scale)

   H_a: $\mu \neq 3$

3. **Research Question:** Are cardiovascular researchers willing and interested in using additional resources to help facilitate the inclusion of incarcerated subjects in studies?

   Null Hypothesis: CVD researchers are neither willing nor unwilling to use additional resources to facilitate the inclusion of incarcerated subjects in their future research.

   H_0: $\mu = 2$ (neutral on Likert scale)

   H_a: $\mu \neq 2$

4. **Research Question:** What characteristics, or experiences are associated with the aforementioned self-reported familiarity, perceived value, and interest/willingness?

   Null Hypothesis: There are no associations between familiarity, value, or willingness with job title, years since degree, gender, race, a previously incarcerated friend or family member,

knowledge of a subject being incarcerated, working on a study whose protocol addressed incarceration.

5. **Research Question:** Are there associations between the experiences of researchers (knowledge of subject becoming incarcerated, working on a study where the protocol addressed incarceration, or having a previously incarcerated friend or family member) and researchers' experiences or characteristics (job title, years since degree, gender, race)?

   Null Hypothesis: There are no associations between researchers reporting knowledge of a subject becoming incarcerated, working on a study with a protocol that addressed incarceration, or having a previously incarcerated friend or family member, and these experiences or job title, years since degree, gender, or race.

Variables and Outcomes of Interest

The primary outcomes of interest were 1) familiarity, 2) value, and 3) willingness. The secondary outcomes of interest were 4) protocol addressing incarceration, 5) prior subject incarcerated, and 6) friend or family incarcerated. The seven independent variables were 1) Job title, 2) years since terminal degree, 3) gender, 4) race, 5) protocol addressing incarceration, 5) subject incarcerated, and 6) family or friend incarcerated.

The following are definitions and questions used to obtain data on the variables and outcomes:

Familiarity: Self-reported familiarity with retaining subjects in studies who are subsequently incarcerated; *"How familiar are you with how to incorporate language in an IRB protocol and a study consent form about unexpectedly incarcerated subjects?"*

Value: Self-reported perceived value of including incarcerated subjects in cardiovascular research; *"I can see the potential value to my field of a training on the inclusion of incarcerated subjects in research."*

Willingness: Self-reported willingness to use resources to facilitate inclusion of incarcerated subjects in the future; *"How willing would you be to use a toolkit regarding how to accommodate unexpectedly incarcerated persons in research protocols?"*

Protocol Addressing Incarceration: Prior experience working on a study where the protocol or consent addressed subsequent incarceration; *"Have you ever worked on a study whose IRB protocol and/or study consent form included language about what would happen if the subject experiences incarceration?"*

Subject Incarcerated: Knowledge of prior subject becoming incarcerated while enrolled in a research study; *"Of all the multi-visit studies you have been professionally involved in, are you aware of any instance where a study subject was incarcerated during the course of the study?"*

Friend or Family Incarcerated: Reporting having a close friend or family member who has been incarcerated; *"Do you have any close friends or family members who are or have been incarcerated?"*

C. Definitions of Terms

Acronyms

BMI: Body Mass Index

BJS: Bureau of Justice Statistics

CDC: Centers for Disease Control and Prevention

CV: Cardiovascular

CVD: Cardiovascular disease

HFN: Heart Failure Network or Heart Failure Clinical Research Network

IOM: Institute of Medicine

IP: Internet Protocol (e.g. IP Address)

NCHS: National Center for Health Statistics

NHANES: National Health and Nutrition Examination Survey

NHIS: National Health Interview Survey

NIH: National Institutes of Health

NIH: National Inmate Survey (NIH-3 is the third iteration of the survey)

NoMAD: Normalization MeAsure Development

U.S.: United States

Definition of Terms [2,13,14]

Bureau of Justice Statistics (BJS): A subsidiary of the U.S. Department of Justice, Office of Justice Programs that collects and analyzes data regarding criminal justice in the U.S. and publishes reports.

Cardiovascular disease: Term for various diseases that affect the heart and blood vessels; Comprised of coronary heart disease, heart failure, stroke, and hypertension.

Community supervision: Probation or parole; individuals under community supervision must comply with certain conditions (e.g. regular reporting, payment of fines or court fees, treatment programs, repayment of fines or court fees), and may be incarcerated if they fail to meet these requirements. Also referred to as *community corrections*.

Correctional facility: Secure facilities where individuals are confined following arrest, conviction, and/or sentencing; Includes jails, prisons, and facilities operated by special jurisdictions (e.g. U.S. Immigrations and Customs Enforcement, the U.S. armed forces, U.S. territories).

Correctional population: Includes individuals under all forms of correctional supervision, including incarceration in a correctional facility (e.g. jail or prison) and community supervision (e.g. conditional probation or parole).

Heart Failure Clinical Research Network: An initiative of the National Hearth Lung and Blood Institute, a division of the National Institutes of Health, consisting of 27 academic hospitals across North America who collaborate on clinical trials and research studies pertaining to cardiovascular disease; Also referred to as Heart Failure Network (HFN).

Imprisonment: Individual confined to prison (does not include individuals in jail).

Incarceration: Individual confined to jail or prison, or other secured correctional facility where they are unable to come and go freely.

Inmate: Individual who is incarcerated in a correctional facility, includes individuals confined to jails and prisons.

Jail: Short-term correctional facilities for individuals awaiting trial, awaiting sentencing, awaiting transport after conviction, or who have been sentenced to terms of less than one year; Average length of stay is under one month, but may be as short as one day. They are locally operated (e.g. by county, city, or municipality).

Parole: Supervised release from prison, where individuals are conditionally allowed to complete their sentence under community supervision.

Prison: Longer term correctional facilities for individuals serving sentences of more than one year; operated by the state government or federal government (Federal Bureau of Prisons). There are also private prisons contracted by the local, state, and federal government. Six states (RI, VT, DE, AK, HI) have correctional systems that combine jails and prisons.

Prisoner: Inmates confined to a long-term correctional facility, typically a prison.

Probation: Court-ordered conditional community supervision, either as an alternative to incarceration, or as a combined sentence following incarceration.

Subsequently incarcerated subject: A participant of a research study who was enrolled while in the community and was later incarcerated for any length of time during a multi-visit study.

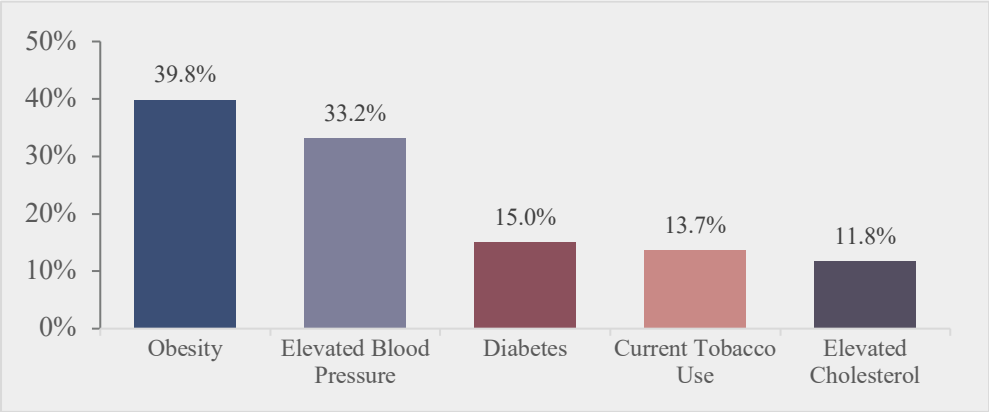
II. Chapter 2: Background and Literature Review

A. Cardiovascular Disease in the United States

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States.[2] Nearly half of adults in the U.S. are affected by some form of CVD, which includes coronary heart disease, heart failure, stroke, and hypertension.[15] CVD accounts for 30.6% of deaths in the U.S., causing more than 800,000 deaths each year.[2]

Along with increasing age, the three main risk factors for the development of CVD are elevated blood pressure, elevated cholesterol, and tobacco smoking.[2] Poor diet, high BMI, low physical activity, and family history are also associated with significantly increased rates of CVD[2,16,17] Additionally, co-morbid conditions including HIV infection and Diabetes are associated with increased rates of CVD.[2] Each of these risk factors are prevalent in the general population (Figure 1). Diet is considered the highest attributable risk factor for CVD.[18] Modifiable risk factors are estimated to account for 80% of the CVD burden in the U.S., and nearly 20% of deaths from CVD could be prevented by addressing risk factors and treating underlying health conditions.[19]

Figure 1. Current Prevalence of Selected Cardiovascular Disease Risk Factors Among the General Population.



Data Sources[15,20,21]
National Health Interview Survey, 2019
Centers for Disease Control, 2019
National Center for Health Statistics, 2017

Racial Disparities in CVD

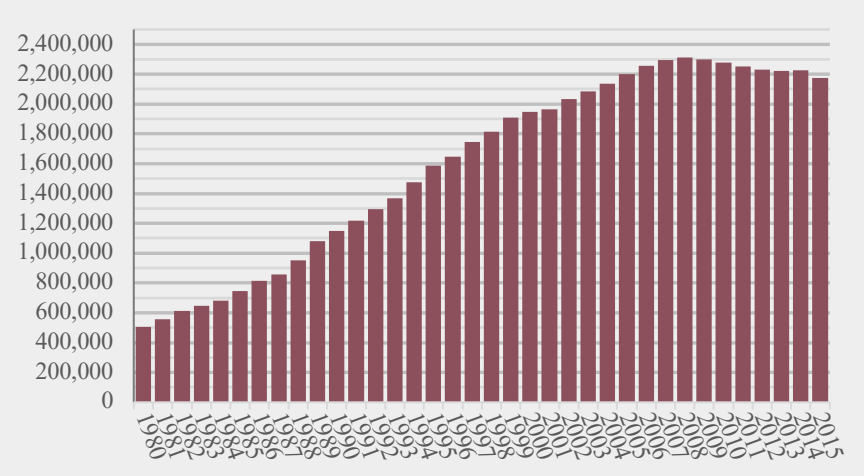
Black Americans are affected by cardiovascular disease at higher rates than White Americans. Black men and women are more likely to develop hypertension and heart failure at younger ages, leading to increased mortality rates from CVD. Risk factors including diabetes, obesity, and elevated blood pressure are also more prevalent in Black Americans.[2] Among adults in the U.S., non-Hispanic Blacks have the highest rates of heart disease, with more than 46% of Black adults currently living with heart disease.[2,22]

An analysis of mortality data from 2001-2010 found that the preventable death rate from cardiovascular diseases was nearly double among Black Americans than White Americans.[19] Underlying risk factors for cardiovascular disease may account for the increase in CVD events in Black Americans compared to their White counterparts; a large analysis found that 90% of these events in Black participants could be attributed to specific CVD risk factors, compared to 65% in White participants.[16] Overall, Black men die from CVD at rates 20% higher than White men.[6]

B. Incarceration in the United States

The United States has 20% of the world's prison population, even though it accounts for less than 5% of the world's overall population.[23] Since 1980, the number of individuals in U.S. jails and prisons has increased four-fold (Figure 2).[24] While incarceration rates have begun to decline in the past decade, more than 2.1 million individuals remain incarcerated, 1 in every 117 adults at any given time (Figure 3).[1,24,25] At the end of 2001, more than 5.6 million adults had served time in prison.[26] It is estimated that at least 1 in every 20 adults will serve time in prison during their lifetime.[1,26-28] More than 95% of individuals who are incarcerated will return to the community after completing their sentence.[28]

Figure 2. U.S. Incarcerated Population, 1980-2015.

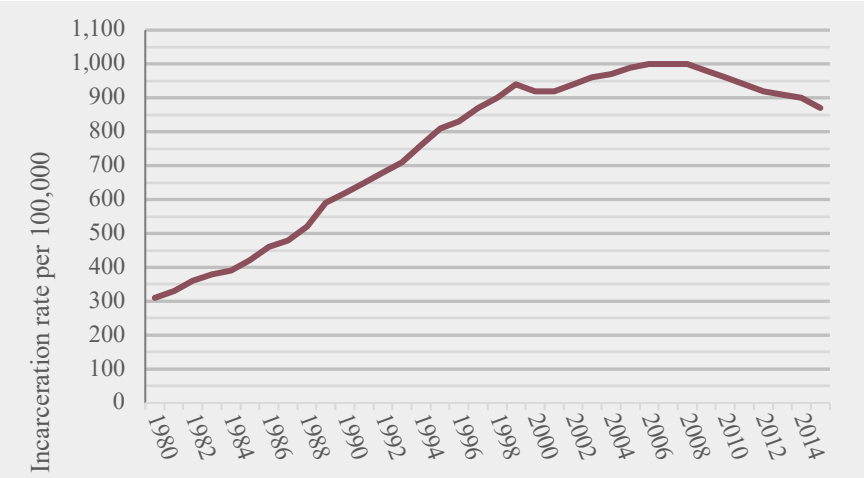


Data Source: Bureau of Justice Statistics, 2016 [24]

U.S. Correctional Population

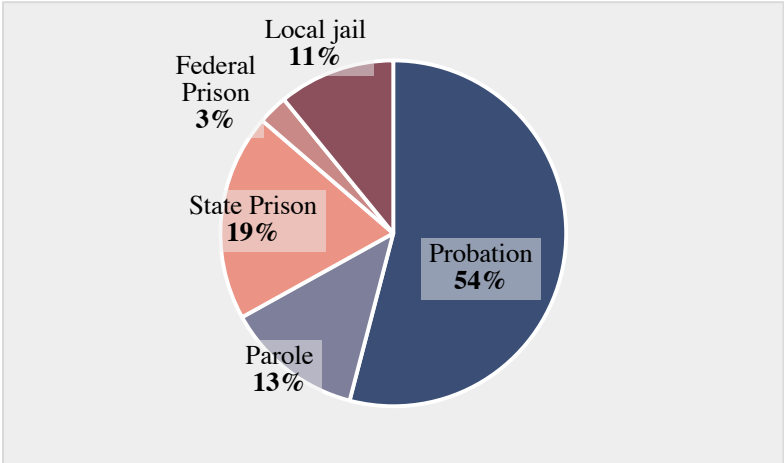
Individuals under correctional supervision may be incarcerated (e.g. in jail or prison) or be under community supervision (e.g. probation or parole). As of 2016, 1 in 38 U.S. adults were under some form of correctional supervision.[24] Of the correctional population, 68% were under community supervision, whereas 32% were incarcerated in either local jails, or state or federal prisons (Figure 4) displays trends in correctional populations by type of supervision.

Figure 3. U.S. Adult Incarceration Rate per 100,000 U.S. Residents, 1980-2015.



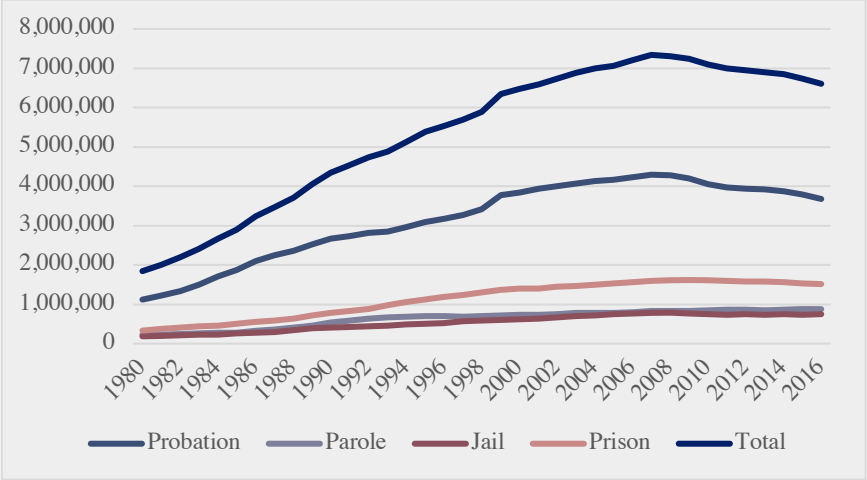
Data Source: Bureau of Justice Statistics, 2016 [24]

Figure 4. U.S. Correctional Population by Type of Supervision 2016.



Data Source: Bureau of Justice Statistics, 2016 [24]

Figure 5. Trends in the Correctional Population by Location, 1980-2016.



Data Source: Bureau of Justice Statistics, 2016 [24]

Incarceration: Jail and Prison

In 2016, 2,162,400 individuals were incarcerated in the United States, with about 1/3 of those in jails and 2/3 in prisons.[24] Jails are short-term correctional facilities that are locally operated. Individuals in jail are either awaiting trial, awaiting sentencing, or serving a sentence of less than one year. Typically, these sentences involve misdemeanors. The average length of stay in jail across the U.S. is less than one month (27 days), and in some states the average stay is less than one week.[25] Jails are operated by local counties and cities. Recidivism is common, and the average jail detainee visits jail 1.4 times per year.[29]

Prisons are longer-term correctional facilities. Individuals in prison have typically been convicted and sentenced, and are serving terms of greater than one year, to up to life in prison. Prisons are typically operated by the state or federal government. There are also some private prisons run by third-party contractors; since data regarding individuals in private prisons are not readily available, private prisons will not be included in this paper.

Nearly half of individuals in federal prisons are serving drug-related offenses. An additional 19% of sentences are related to weapons, explosives, or arson.[1] About one-fourth of federal prison inmates are serving sentences of less than 5 years, one-fourth are serving 5-10 year sentences, the remaining half are serving sentences between 10 years and life.[30] Fewer than 3% of federal prisoners are serving life sentences.

Community Supervision: Probation and Parole

Over 95% of individuals who serve terms in prison will be released to their community.[28] Approximately 25% are released without conditions, while 75% leave with conditional release, either probation or parole. While these individuals are no longer incarcerated, they remain part of the criminal justice system under community supervision. As of 2016, 1 in 55 U.S. adults were under community supervision, either probation or parole.[31] Probation is a court-ordered supervision, either as an alternative to incarceration, or as a combined sentence following incarceration.[28] Parole is a supervised release from prison, where individuals are conditionally allowed to complete their sentence under community supervision. In both cases, individuals under community supervision must comply with certain conditions (e.g. regular reporting, payment of fines or court fees, treatment programs, repayment of fines or court fees), and may be incarcerated if they fail to meet these requirements.

Admissions, Release, and Recidivism

In 2017, 29% of the over 600,000 prison admissions were due to violations of the conditions of probation or parole.[1] Among individuals released from state prisons in 2005, 44% were re-arrested during their first year following release, 68% were arrested within 3 years, and 83% were re-arrested over the nine years following release.[32]

Table 1. Prison Admissions and Releases, 2017.

	Admissions			**Releasees**	
Total	606,571		**Total**	691,072	
New	418,579	69.0%	Unconditional	160,596	25.8%
Violation of conditions	174,210	28.7%	Conditional	466,785	75.0%

Data Source: Bureau of Justice Statistics, 2019 [1]

Racial and Gender Disparities in Incarceration

The demographics of state and federal prisoners are displayed in Table 2. The rates of incarceration differ significantly based on gender and race (Table 3). Men make up 93% of the prison population and are 13 times more likely to be incarcerated than women.[1,30] Non-Hispanic Blacks are incarcerated at more than five times the rate of non-Hispanic Whites and nearly double the rate of Hispanics.

Table 3. Demographics of State and Federal Prisoners, 2017.[1]

	%
Total	
Male	92.7
Female	7.3
Total	
White	34.2
Black	23.4
Hispanic	13.4
Other	12.2
Men	
White	29.0
Black	23.8
Hispanic	13.0
Other	13.0
Women	
White	46.8
Black	18.7
Hispanic	18.5
Other	1.6

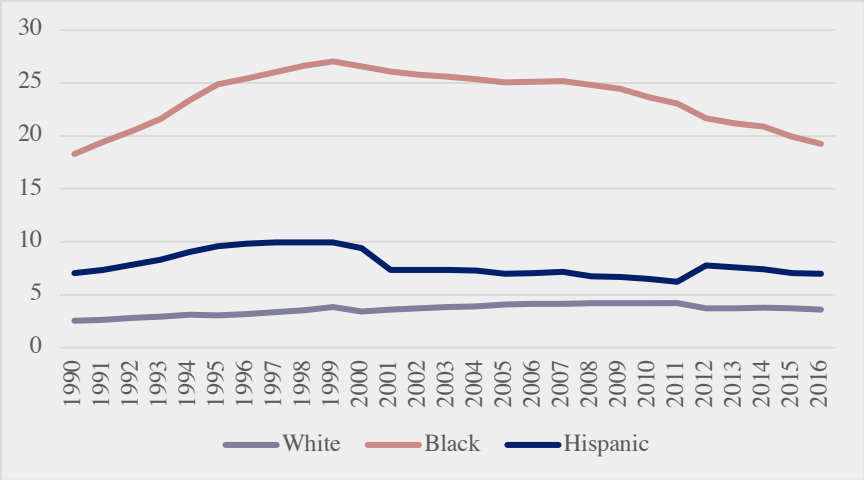
Data Source: Bureau of Justice Statistics, 2019 [1]

Table 2. Rate of Imprisonment by Demographic, 2017.

	Rate per 100,000 residents (all ages)
Total	440
Men	
All Men	829
White	397
Black	2336
Hispanic	1054
Other	1257
Women	
All Women	63
White	49
Black	92
Hispanic	66
Other	114

Data Source: Bureau of Justice Statistics, 2019 [1]

Figure 6. U.S. Imprisonment Rate per 1,000 Adults by Race, 1990-2016.

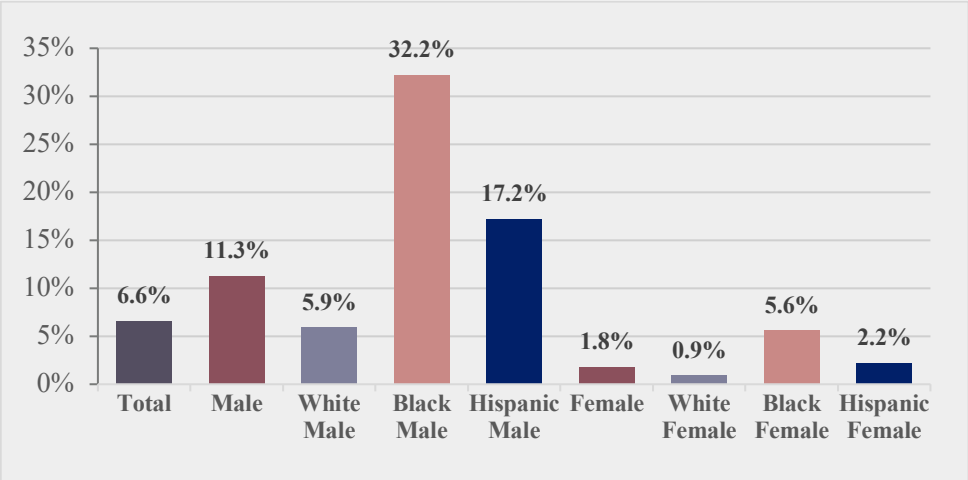


Data Sources[33,34]
Bureau of Justice Statistics, 2017
Centers for Disease Control, 2019

Lifetime Risk of Incarceration

A 2003 analysis of prison incarceration by the Bureau of Justice Statistics (BJS) found that based on the 2001 incarceration rates, one in every 15 individuals born in 2001 (6.6%) would serve a prison sentence during their life.[26] These estimates vary greatly by race and gender (Figure 7). Men are six times more likely to be incarcerated than women, with one in nine men (11.3%) being incarcerated during their life, compared to one in 56 women (1.8%). One in every three Black men born in 2001 is likely to be incarcerated at some point during their life (32.2%), more than five times the risk of White men (5.9%).

Figure 7. Lifetime Likelihood of Prison Incarceration by Gender and Race, Individuals Born in 2001.

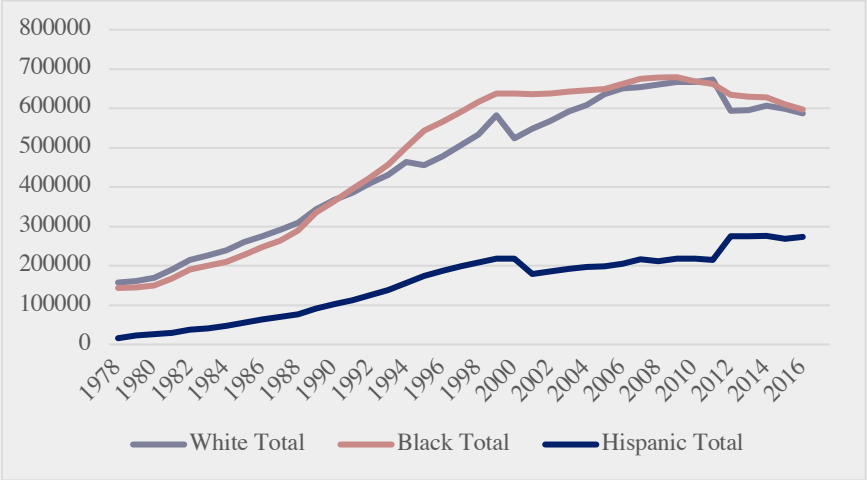


Data Source: Bureau of Justice Statistics, 2003 [26]

It is important to note that these estimates on lifetime risk of imprisonment are based on the incarceration rates in 2001.[26] Since then, the population of individuals in state and federal prisons has increased by more than 100,000 (Figure 2).[35] The number of White and Black Americans incarcerated has decreased, while Hispanic incarceration numbers have increased since 2001 (Figure 8). In 2016, there were 419,028 new court commitments to prison, increased up from 405,422 in 2001 (Figure 9).[35] The overall rate of imprisonment has decreased between 2001 and 2016 (Figure 5). In 2001, the imprisonment rate was 490 per 100,000, and in 2016 it was 464 per 100,000 (Figure 3).

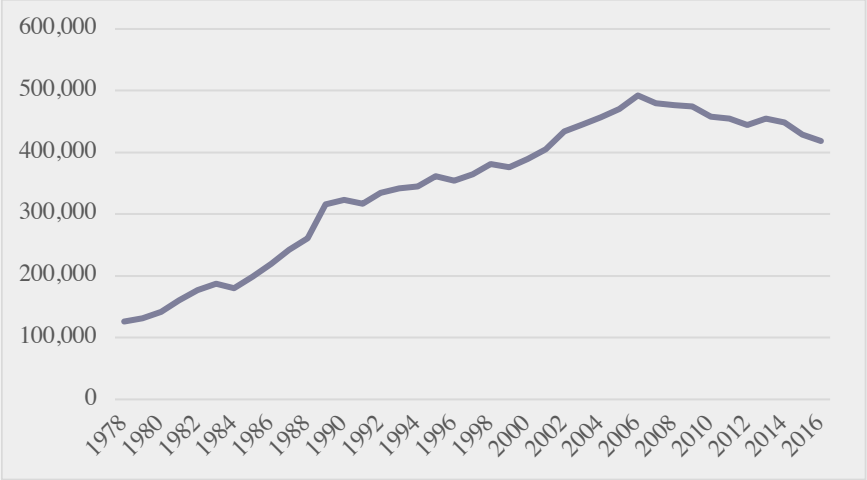
The rate of imprisonment for Blacks and Hispanics has decreased slightly, while there has been a mild increase in the rate for White Americans since 2001 (Figure 6). While the lifetime imprisonment estimates are likely to be somewhat different today than when they were calculated in 2001, the lack of significant change in imprisonment rates indicate that they are likely reflective of the current estimates if the incarceration rates fail to significantly decrease in future decades.

Figure 8. Total Number of U.S. Prison Inmates by Race, 1978-2016.



Data Source: Bureau of Justice Statistics, 2017 [34]

Figure 9. Number of New Court Commitments Admissions to Prison, 1978-2016.



Data Source: Bureau of Justice Statistics, 2018 [35]

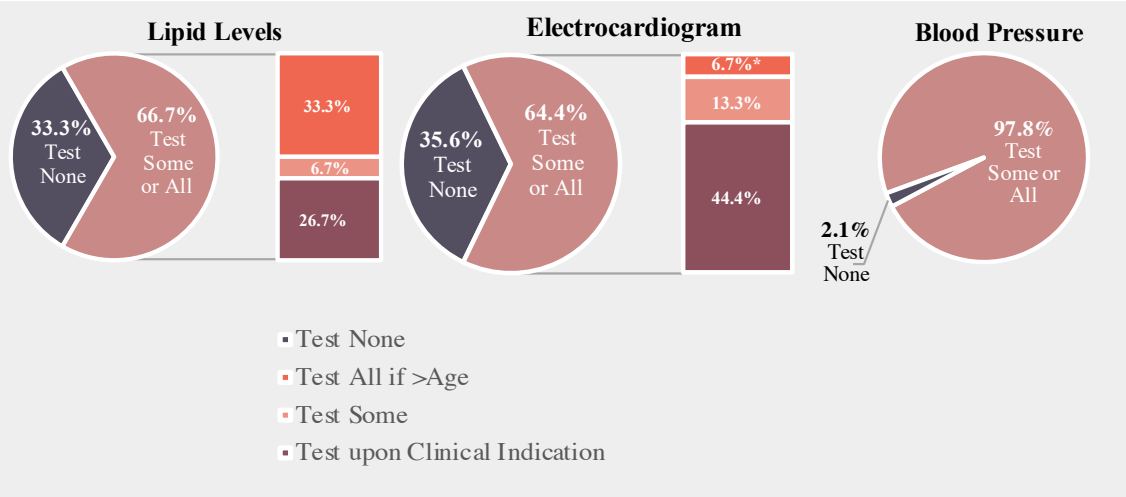
C. Health of Correctional Populations

Medical Care in Correctional Facilities

The 1976 Supreme Court case Estelle v. Gamble determined that correctional facilities cannot show "deliberate indifference" towards the medical needs of a prisoner, as it violates the Eighth Amendment of the Constitution.[36] As a result, jail and prisons are required to provide health care for individuals while they are incarcerated, either at the correctional facility or via access to referral centers outside the facility walls. In practice, the medical care provided varies greatly depending on the facility.

The 2012 National Survey of Prison Healthcare found that among the 45 states who responded, the vast majority of states (97.8%, n=44) tested for cardiovascular conditions and risk factors during the prison admissions process (Figure 10).[37] More than one-third of states reported that at admission to the system, they tested no one for abnormal electrocardiograms or high lipid levels – two key risk factors for heart disease.[37] Furthermore, 88% of incarcerated individuals reported receiving better healthcare prior to incarceration than they received at the correctional facility.

Figure 10. Percentage of States Who Test for Selected Risk Factors During Prison Admission Process, 2012.



Data Source: Bureau of Justice Statistics, 2016 [37]

Chronic Disease Prevalence Among Correctional Populations

Correctional populations face a significant burden of chronic diseases. Approximately 44% of incarcerated individuals have at least one chronic health condition, as displayed in Table 4.[3] Due to the nature of incarceration in the United States, individuals with chronic conditions are left with treatment interruptions and inconsistent medical care through cycles of release and re-incarceration. An estimated 3,581,054 persons with chronic diseases are released from jails and prisons in the U.S. each year – a rate of nearly 10,000 every day. Individuals with recent criminal justice involvement are more likely to have higher hospital and emergency room costs post-release.[38]

Table 4. Estimated Disease Prevalence in Jails and Prisons, 2012.

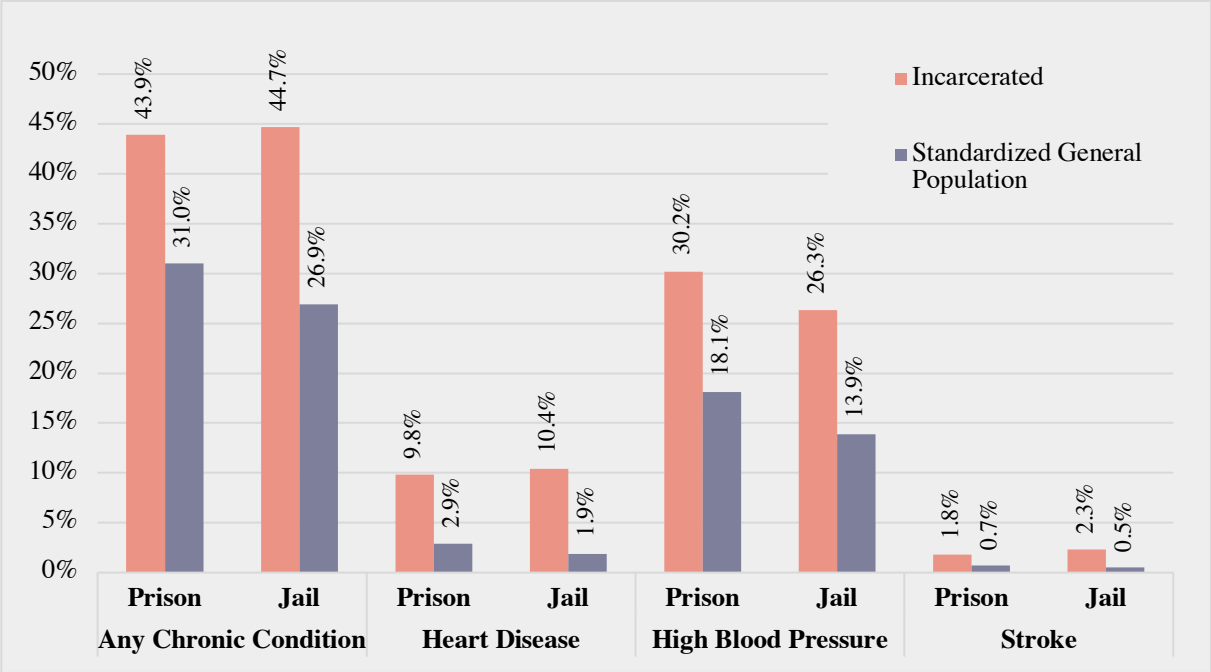
Estimated Prevalence		Estimated Cases
Jail	**Prison**	**Total**
Any Chronic Condition		
44.7%	43.9%	989,508
Heart Problems		
10.4%	9.8%	223,992
High Blood Pressure		
26.3%	30.2%	647,973
Stroke		
2.3%	1.8%	44,009
Diabetes		
7.2%	9.0%	188,413
Asthma		
20.1%	14.9%	372,101
Liver Cirrhosis		
1.7%	1.8%	39,595
Any Chronic Condition^		
44.7%	43.9%	989,508
Tuberculosis		
0.4%	0.5%	10,467
Hepatitis		
0.9%	1.1%	23,175
HIV/AIDS		
0.3%	0.4%	8,227

Data Sources[3,39]
Bureau of Justice Statistics, 2016
Bureau of Justice Statistics, 2013 [39]

D. Cardiovascular Disease Burden in Correctional Populations

As previously discussed, cardiovascular disease is the leading cause of morbidity and mortality in the United States.[2] Individuals who are incarcerated face a disproportionate burden of cardiovascular disease when compared to the general population (Table 4, Figure 11).[2,11] The age distribution of correctional populations is significantly younger than the general population. When adjusted for age, sex, and race, the prevalence of heart disease is three times more common among individuals in prison and five times more common among those in jails compared to the general population (Figure 11).[3,24]

Figure 11. Prevalence of Chronic and Cardiovascular Diseases Among Correctional Populations, 2011-12.



Data Source: Bureau of Justice Statistics, 2016[3]

Incarceration and CVD share many of the same risk factors.[7,8,40,41] Black men experience significantly higher rates of cardiovascular disease and incarceration. Individuals with history of drug or tobacco use and lower socioeconomic status are also at increased risk for both incarceration and CVD.

Compounding these underlying risk factors, incarceration is also an independent risk factor for CVD.[7,8] Young adults with a history of incarceration are more likely to develop hypertension, atherosclerosis, and early signs of heart failure when compared to their peers, even when controlling for smoking, alcohol, drug use, and income.[8] Increased stress, physical inactivity, lack of healthy dietary options, and poor access to preventive care may exacerbate these underlying risk factors among individuals who are incarcerated, leading to higher rates of morbidity and mortality during and after incarceration.

Cardiovascular disease is the leading cause of mortality in incarcerated populations, and leads to a higher proportion of deaths than in the general population.[12] Between 2001 and 2013, heart disease accounted for 45.2% of natural deaths in U.S. jails (e.g. deaths not due to suicide, homicide, or accident), compared to just 28.1% of natural deaths in the general population (Table 5).[12,42,43] Deaths due to heart disease among correctional populations increased more than 10% between 2008 and 2013, while heart disease deaths in the general population decreased by 2.3% during the same period.[2,3,12]

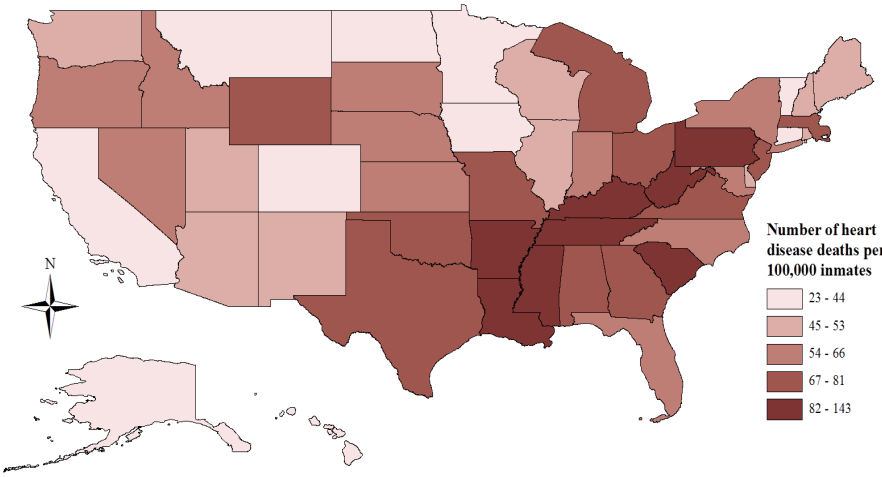
Table 5. Natural Deaths Due to Heart Disease in Local Jails and State Prisons Compared to the General Population, 2001-2013.

	Local Jails		State Prisons		Jails and Prisons		General Population[#]	
	N	%	N	%	N	%	N	%
Natural Deaths[+]	6,595	100	37,374	100	43,969	100	29,334,859	100
Heart Disease Deaths[^]	2,978	45.2	10,795	28.9	13,773	31.3	8,245,090	28.1

[^] Includes ICD codes for 'Diseases of the heart' I00-I09, I11, I13, I20-I151.
[#] Individuals ≥15 years old
[+] Deaths due to illness, e.g. classified as "non-injury, no intent"

Data Sources [12,43]
Bureau of Justice Statistics, 2015
Centers for Disease Control and Prevention, 2019

Figure 12. Rate of Deaths Due to Heart Disease Among U.S. Jail and Prison Inmates, 2001-2013.



Data Source: Bureau of Justice Statistics, 2015 [12]

E. Data on the Health of Incarcerated Persons

The vast majority of information on correctional populations is derived from data collected by the U.S. Department of Justice Bureau of Justice Statistics (BJS).[7] In 1926, the U.S. government began collecting data on correctional populations, following a congressional mandate.[35] The BJS was established in 1970 with the mission "to collect, analyze, publish, and disseminate information on crime, criminal offenders, victims of crime, and the operation of justice systems

at all levels of government. These data are critical to federal, state, and local policymakers in combating crime and ensuring that justice is both efficient and evenhanded."[44]

The most comprehensive data on medical problems among individuals who are incarcerated comes from the National Inmate Survey, conducted by the BJS. In 2011-12, BJS conducted the third National Inmate Survey (NIS-3) as a part of the federal requirements under the Prison Rape Elimination Act.[45] NIS-3 consists of two questionnaires: a survey on sexual victimization and a survey on mental health, physical health, and substance abuse. Inmates surveyed were randomly assigned to one of the surveys. Access to the full dataset is restricted; however, summary data of medical problems released in 2015 by BJS is publicly available.[3] NIS-3 used a sample of 10% of all correctional facilities, including at least one jail and one prison in each state. Participants are asked about their current and past medical history. For example, in order to assess history of heart problems, the survey asked: "Has a doctor, nurse, or other health care provider ever told you that you had a problem with your heart?"

Other sources of national health data rarely include correctional populations or the role of past incarceration. The National Health Interview Survey (NHIS) and National Health and Nutrition Examination Survey (NHANES), exclude individuals who are incarcerated.[7] These studies also typically do not address prior incarceration, and when they do, they fail to collect data regarding pertinent factors including length of incarceration or age of incarceration – leading to a paucity of data on the impact of incarceration on health outcomes.[46]

F. Federal and Ethical Guidelines

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in the mid-1970s following gross abuses and exploitation of vulnerable populations by medical researchers.[47] This organization established the foundation for today's ethical guidelines in research, including institutional review boards (IRBs), guidelines on vulnerable populations, disclosure of information, and The Belmont Report. The Belmont Report established the guiding ethical principles of beneficence, justice, and respect for persons, including the need for informed consent and risk-benefit analysis.[48]

In 1991, Federal Regulation Title 45, Part 46, also known was 'The Common Rule,' was established, formalizing ethical guidelines to protect general human subjects in research, adding additional protections for vulnerable groups, including prisoners (Subpart C).[4] Under §46.306, research involving prisoners must meet one of the following categories of permitted research: "(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior…, (ii) Study of prisons as institutional structures or of prisoners as incarcerated persons…, (iii) Research on conditions particularly affecting prisoners as a class…, or (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject."[4]

In 2007, the Institute of Medicine released a report titled "Ethical Considerations for Research Involving Prisoners."[49] The committee met with key stakeholders from a variety of disciplines and compiled recommendations to improve the access to research involving prisoners. The recommendations include substantive proposals that access to participation in research studies is

important to find ways to improve the health of prisoners, a common theme the committee heard in their discussions with incarcerated individuals. The report promotes a risk-benefit approach to approval, versus the current categorical approach. Ultimately, the report advocates a balance between protecting individual rights and maintaining the highest ethical standards, while enabling individuals to benefit from medical research, with the goal of improving the healthcare in correctional facilities and the health of individuals who are incarcerated. As described in the National Institute of Health's Ethical Guidelines for patient recruitment in clinical studies: "The primary basis for recruiting and enrolling groups and individuals should be the scientific goals of the study – not vulnerability, privilege, or other factors unrelated to the purposes of the study…individuals who accept the risks and burdens of research should be in a position to enjoy its benefits, and those who may benefit should share some of the risks and burdens…"[4]

G. Identifying Health Disparities

More than five percent of Black men between the ages of 30-39 years are incarcerated in state or federal prison on any given day, with additional Black men in jail.[50] As many as one-third of Black men are expected to be incarcerated during their lifetime.[1,25-27] In the U.S., Black men experience the highest rates of health conditions including heart disease and CVD mortality.[2,6] Prior studies suggest that the high incarceration rates and exclusion from studies may be impacting the ability to accurately identify, examine, and address health disparities.[5-7]

A secondary analysis of fourteen large national cohort studies through the National Heart, Lung, and Blood Institute estimated that 65% of the Black men who were lost to follow-up were incarcerated, compared to just 13% of the White men in the study.[5] Individuals who are lost to

follow-up do not complete the study, and are often censored from data analysis. These individuals who were subsequently incarcerated are more likely to have chronic health conditions and may have different risk factors.[8,41] This can lead to imprecise and biased results when examining cohort-level health outcomes and health disparities in clinical studies, especially regarding Black men.

Ethical guidelines and regulations were established to protect vulnerable populations so as to not repeat past abuses. In reality, prisoners are largely excluded from participation in clinical research, and individuals who become incarcerated typically are not allowed to continue in studies.[6] Inadvertently, these guidelines serve as a barrier to inclusion, leading to the exclusion of vulnerable groups including subsequently incarcerated individuals from clinical research. This can lead to underrepresentation of underserved groups, ultimately impacting research findings.[5,7-9] Increasing the participation of underserved and minority populations in clinical research is seen as an important step in finding ways to reduce health disparities.[5,6,10]

III. CHAPTER 3: MANUSCRIPT

Intended Journal for First Submission: Journal of Correctional Health Care (JCHC)

Statement of Contribution
My contribution to this project involved preparing the study protocol, submitting for IRB approval/exception, creating the survey instrument, participant recruitment, data collection, analyzing the data, creating the figures and tables, and writing the manuscript.

Dr. Anne Spaulding, MD, MPH served as the primary investigator for this study, and advised and supervised me on many of these steps.

Ethically Including Individuals Who Are Incarcerated in Clinical Research: A Cross-Sectional Survey Exploring the Perspectives of Cardiovascular Researchers

Dana M. Urban[1] and Anne C. Spaulding, MD, MPH[1]

Author Information:
[1] Rollins School of Public Health, Emory University, Atlanta, GA, USA

A. ABSTRACT

Cardiovascular disease disproportionately affects individuals who are incarcerated. Correctional populations are often excluded from general cardiovascular research, and subjects who are subsequently incarcerated are generally censored from longitudinal and multi-visit studies, leading to imprecise health statistics. Few prior studies have explored the perspectives of clinical researchers on this topic. This study consisted of an online survey of cardiovascular researchers assessing their experiences and views regarding the retention of incarcerated subjects in clinical research. We found that most researchers were unfamiliar with retaining subsequently incarcerated subjects in studies. While 96% had never worked on a study that discussed subsequent incarceration in the protocol or consent, nearly one in five were aware of a subject's incarceration during a study. The majority felt it would be valuable to their research to include these groups and were willing to utilize resources to facilitate the inclusion of correctional populations in their studies in the future. Ethically including subsequently incarcerated subjects in studies could help us accurately identify and address health disparities in future studies.

Keywords: correctional health, cardiovascular disease, clinical research, incarceration

B. INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States.[2] Cardiovascular disease, which includes coronary heart disease, heart failure, stroke, and hypertension, causes nearly one in every three deaths and affects 48% of the U.S. adult population. Modifiable risk factors, such as diet, tobacco use, and physical inactivity, are estimated to account for 80% of the CVD burden in the U.S..[2,16,17]

Cardiovascular disease is prevalent in the general population, and individuals who are incarcerated in jails (short-term correctional facilities) and prisons (facilities for individuals serving sentences longer than one year) are impacted at even higher rates.[3] The Bureau of Justice Statistics reports that the prevalence of chronic health conditions in federal jails and prisons is significantly higher than the general population adjusted for age, sex, and race. This is especially true in CVD, where heart disease is three times more common among individuals in prison and five times more common among those in jails compared to the general population.[3,24]

Since 1980, the number of individuals in U.S. jails and prisons has increased four-fold.[24] While incarceration rates have begun to decline in the past decade, more than 2.1 million individuals remain incarcerated, 1 in every 117 adults at any given time.[1,24,25] It is estimated that 1 in every 20 adults will serve time in prison during their lifetime, and more than 95% of individuals who are incarcerated will return to the community after completing their sentence.[1,26-28]

Incarceration and CVD share many of the same risk factors, including Black race, male gender, and lower socioeconomic status.[7,8,40,41] Incarceration itself is an independent risk factor

facilitating the development and progression of CVD.[7,8] Young adults with a history of incarceration are more likely to develop hypertension, atherosclerosis, and early signs of heart failure when compared to their peers.[8] Increased stress, physical inactivity, and lack of healthy dietary options can exacerbate these underlying risk factors among individuals who are incarcerated, leading to higher rates of morbidity and mortality during and after incarceration. Deaths due to heart disease among correctional populations increased more than 10% between 2008 and 2013, while heart disease deaths in the general population decreased by 2.3% during the same period.[2,3,12] Between 2001 and 2013, heart disease accounted for 45.2% of natural deaths in U.S. jails (e.g. deaths not due to suicide, homicide, or accident), compared to just 28.1% of natural deaths in the general population.[12,42,43]

Despite the increased burden of heart disease among correctional populations, cardiovascular research rarely includes these populations in their studies. Ethical guidelines like 'The Common Rule' are intended to protect vulnerable populations including prisoners, while enabling all individuals to participate in research opportunities as long as the ethical principles of beneficence, justice, and respect for persons are preserved.[4] As described in the National Institute of Health's Guiding Principles for Ethical Research: "The primary basis for recruiting participants should be the scientific goals of the study – not vulnerability, privilege, or other unrelated factors.... Specific groups…should not be excluded from the research opportunities without a good scientific reason or a particular susceptibility to risk."[51]

Inadvertently, ethical guidelines and regulations can serve as a barrier to inclusion, leading to the exclusion of vulnerable groups including subsequently incarcerated individuals from clinical

research. This can lead to significant underrepresentation of underserved groups, ultimately impacting research findings.[5,7-9] A secondary analysis of fourteen large national cohort studies through the National Heart, Lung, and Blood Institute estimated that incarceration may account for up to 65% of 'lost to follow-up' among Black men, compared to 13% among White men.[5] Individuals who are lost to follow-up do not complete the study, and are often censored from data analysis. Individuals who started the study and were subsequently incarcerated are more likely to have chronic health conditions and may have different risk factors than the general population.[8,41] This can lead to imprecise and biased results when examining cohort-level health outcomes and health disparities in clinical studies.

Few studies have looked at the perspectives of clinical researchers towards including incarcerated subjects in their research. In order to understand the barriers to including and retaining incarcerated individuals in clinical research, a national survey was conducted to explore current attitudes and experiences of CVD researchers. This study focused on researchers' familiarity with retaining incarcerated subjects, perceived value of doing so, and willingness to utilize resources on this topic, as well as the factors influencing their views.

C. Methods

Study Design

This study was a cross-sectional web-based survey of cardiovascular researchers. This study design allowed us to conduct an exploratory study, efficiently evaluate multiple variables, and reach a wide range of CVD researchers.

A ten-question survey instrument was developed. The survey questions focused on subsequently incarcerated subjects, defined as a study participant who was enrolled while in the community and was later incarcerated for any length of time during a multi-visit study. A review of the literature suggests that subsequent incarceration can impact the accuracy of health statistics.[5,6] Each survey question was chosen to explore a specific variable or perspective. Likert-type scale questions regarding the perspectives of CVD researchers were based off of The Normalization MeAsure Development (NoMAD) Instrument designed to evaluate perspectives of implementing new or complex interventions in healthcare.[52] Questions regarding indirect experience with incarceration and demographics were included to identify whether any of these variables impact researchers' perspectives.

The survey instrument was beta tested by several general researchers at Emory University, then by Emory University cardiovascular researchers who are part of the Heart Failure Clinical Research Network, and subsequently refined prior to participant recruitment. The final survey instrument was comprised of four multiple choice characteristic questions, three yes/no questions, and three Likert-type scale questions.

Participants

The study population consisted of researchers in the Heart Failure Clinical Research Network (HFN). HFN is an initiative of the National Heart, Lung, and Blood Institute, consisting of 27 academic hospitals across North America who collaborate on clinical trials and research studies pertaining to cardiovascular disease.[14] HFN studies were identified through the network's website (www.HFNetwork.org). The names of researchers involved were identified through the

HFN website, ClinicalTrials.gov, and recent publications of HFN study results. Corresponding email addresses were collected through publicly accessible sources, including the HFN website, NIH RePORTer database (www.projectreporter.nih.gov/reporter.cfm), ClinicalTrials.gov, manuscripts on PubMed (www.ncbi.nlm.nih.gov/pubmed/), and websites of academic institutions.

Inclusion criteria included researchers who had served as an investigator, research coordinator, or other key supportive role in at least one HFN study in the previous five years. Individuals who were under the age of 18 years, were not listed as study staff, investigator, or as manuscript co-author, or did not have an identifiable or working email address were excluded from the study. A total of 163 working email addresses were collected for study recruitment.

Data Collection

The survey was conducted in English through the online survey platform SurveyMonkey (www.surveymonkey.com). The 163 HFN researchers identified per the above protocol were sent an email with a description of the study, link to the informed consent statement, and link to the web-based survey. Responses were collected between April 10, 2017 and May 8, 2017. The identified researchers were sent up to three reminder emails throughout the collection period.

Compensation

Participants were given three options for compensation; 1) entry into a drawing to win one of four coffee shop gift cards; 2) allowing the study to donate a bus token for an individual being released from a correctional facility; or 3) to decline compensation. Participants who wished to

enter the drawing submitted their email address via a separate email so their contact information was not associated with their survey response. The compensation was funded by the investigator's faculty discretionary fund.

Ethical Considerations

The study protocol was submitted to the Emory University Institutional Review Board and they determined this study met the criteria for exemption under 45 CFR 46.101(b)(2) (research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior).[4] Prior to beginning the survey questions, participants were asked to read a statement of consent, which specified that participation was voluntary. Individuals who chose to continue selected "accept" and were directed to the survey questions. Respondents were able to withdrawal from the study at any time and could skip any questions. No identifying information (including names, location, place of employment, or IP address) were collected through the survey platform. Participants who chose to submit their name for compensation purposes did so via a separate email and their information remained confidential and was not associated with survey responses.

Data Analysis

Data were analyzed using SAS™ version 9.4. Descriptive statistics were primarily used to analyze the data. Analytical statistics were used to evaluate associations between characteristics and ordinal values for familiarity, value, and willingness. Characteristic data with multiple options were collapsed into dichotomous variables for analysis. Non-parametric tests were used and the significance level was set at $P<.050$. One-sample Wilcoxon Signed Rank Test was used

to evaluate if the average Likert-type response was significantly different from the neutral value. Associations between characteristics and Likert-type scale data were analyzed using the Mann-Whitney U Test, and associations between dichotomous variables (characteristics and experiences) were analyzed using Fishers Exact Test.

D. RESULTS

The survey was completed by 56 respondents, for a response rate of 34.4%. Characteristics of the respondent are summarized in Table 1. The majority of the respondents identified as male (n=29, 51.8%), White (n=44, 78.6%), worked in investigator roles (n=36, 64.3%), and earned their terminal degree more than a decade prior to completing the survey (n=43, 76.8%).

Of the respondents, 12.5% (n=7) reported having a close friend or family member who has been incarcerated (Table 2). Eighteen percent (n=10) were aware of a subject becoming incarcerated during their enrollment in a previous study. Only two respondents (3.6%) had been involved in a study that included mention of incarceration in the protocol or consent.

Responses to subjective questions on a five-point Likert-type scale are summarized in Table 3 and Table 4. The majority of respondents (n=50, 89.3%) reported being somewhat or very unfamiliar with retaining incarcerated subjects in studies. Only four participants (7.1%) felt somewhat familiar with the process, and no respondents reported being very familiar. The average respondent was very unfamiliar (median=1) which was significantly different from the neutral value of 3 ($P<.001$). More than half of respondents (55.4%, n=31) agreed or strongly agreed that additional training on the inclusion of subsequently incarcerated subjects would be

valuable to the field of cardiovascular research; Thirty-two percent (n=18) were neutral, and 12.5% (n=7) either disagreed or strongly disagreed. The average respondent agreed with the potential value (median=4), which is significantly different from the neutral value of 3 (P<.001). Most respondents (n=40, 71.4%) were willing to use resources to assist them in including subsequently incarcerated subjects in their research in the future; 23.2% were neutral and only 5.4% (n=3) were unwilling. The average respondent was somewhat willing (median=3), which was significantly different from the neutral value of 2 (P<.001).

Associations between characteristics and responses to Likert-type questions of familiarity, value, and willingness are presented in Table 5. Having a close friend or family member who has been incarcerated was associated with greater familiarity, perceived value, and willingness to engage in further trainings pertaining to the inclusion of incarcerated subjects in research (P=.049, P=.041, P=.012, respectively). Male gender was positively associated with subjective value of the inclusion of incarcerated subjects (P=.034). There was also a positive association between being in a non-investigator role and familiarity with retaining incarcerated individuals in studies (P=.013).

There were few significant associations between characteristics and prior experience with incarcerated individuals (Table 6). Individuals who had earned their degree within the past ten years were significantly more likely to have a close friend or family member who has been incarcerated compared to those who earned their degree more than ten years ago (P=.046).

E. Discussion

Cardiovascular disease accounts for a significant amount of morbidity and mortality in currently and formerly incarcerated populations.[3] The results of this study suggest that while the majority of clinical researcher respondents are unfamiliar with retaining subsequently incarcerated subjects in their studies, most appreciate its value to their field of cardiovascular health research. It is important for the research community to consider these populations in the design of their studies, and to develop best practices for understanding the health of incarcerated populations and the impact of incarceration on health outcomes.

Nearly 20% of researchers had been involved in a study where a subject was subsequently incarcerated, supporting the notion that this situation frequently occurs in clinical studies.[7] Of the researchers who were aware of a subject's subsequent incarceration, 90% had never been involved in a study where the protocol or consent discussed what would happen if a subject was subsequently incarcerated – likely leading to the exclusion of these subjects from the study.

Participants in non-investigator roles were more familiar than investigators with including subsequently incarcerated individuals in studies. This is logical as non-investigator researchers are more likely to be involved in the daily operations of studies. These results suggest that investigators may have a larger knowledge gap than their support staff, and therefore may be less likely to include these provisions in study protocols without additional training or resources.

Men reported higher levels of perceived value in retaining incarcerated subjects compared to their female counterparts. Additionally, individuals with a close friend or family member who

has been incarcerated also perceived this as more valuable than those without a personal connection to incarceration. These findings suggest that identifying with a vulnerable group (whether through demographic similarities or indirect personal experience) may increase researchers' perceptions of the value in including these individuals in research.

Individuals who had earned their degree more recently were more likely to have a close friend or family member who has been incarcerated. Assuming that those who earned their terminal degree within the past ten years are overall part of a younger birth cohort than individuals who earned their degree more than ten years ago, younger respondents were more likely to know someone who has been incarcerated. This finding correlates with the increased likelihood of incarceration by birth cohort between 1974 and 2001 within the general population.[26] As younger cohorts are entering the field of scientific research, they may be more likely to have personal connections to incarceration and be more interested in ensuring the representation of underserved groups in research.

Study Strengths and Limitations

This study was designed to be an exploratory study to assess the current attitudes and to identify potential areas for future work regarding the inclusion of incarcerated subjects in clinical research studies. The survey was brief, meaning we only were able to explore a few specific topics. The brevity also served as a strength, as it took most researchers less than four minutes to complete the survey which may have increased participation.

Our study only included CVD researchers who are part of the Heart Failure Clinical Research Network and whose names and email addresses were publicly accessible, which may introduce bias into our sample. The methods of participant recruitment were targeted towards investigators (names identified through publications) and research coordinators (names identified through ClinicalTrials.gov). As expected, nearly 90% of respondents were in these roles, but with this recruitment process, we may be missing the perspectives of additional key support staff. Researchers who are not involved with the HFN were not recruited for the study, meaning that our findings may not be generalizable to clinical researchers outside this group or outside the field of cardiovascular disease.

The response rate was 34%, which is in accordance with the expected response rate of 30-40% for internal surveys (compared to 10-15% for external surveys).[53] While the survey was not sent by a member of the HFN, it was sent by a fellow academic researcher and was clearly directed to members of the group. The relatively small sample size and response rate could introduce selection and self-selection bias. The survey was beta tested by several local HFN researchers and subsequently refined based on their feedback, which we believe helped to strengthen the survey for its intended audience.

Recommendations

Including underrepresented groups in clinical research can lead to improved accuracy of health statistics, especially regarding cardiovascular health.[5,7,8] Retaining incarcerated subjects in studies requires adherence to the highest ethical standards, as to not repeat past abuses of vulnerable populations. Currently, there is a gap between researchers' interest in including

subsequently incarcerated subjects in studies and their knowledge of the steps to incorporate this into practice. The development of training materials focused on retaining these subjects could facilitate more inclusive study populations. Additional research would be beneficial to explore the practical implications of including subsequently incarcerated individuals in clinical research and to quantify the impact that this has on study results. By increasing researchers' knowledge of this process, we can increase the inclusion of incarcerated subjects in research. This will enable study populations to be more representative of the overall population.

F. Conclusion

In this survey of cardiovascular researchers, most were unfamiliar with including subsequently incarcerated subjects in research studies, perceive the retention of incarcerated individuals as valuable to their field of clinical research, and are interested in resources to facilitate this inclusion in future studies.

The results of this study provide a starting point for discussions about the inclusion of vulnerable individuals in clinical research. While protocols rarely anticipate it, subjects do become incarcerated while enrolled in cardiovascular research studies. Allowing subsequently incarcerated individuals to continue in low-risk clinical research studies can improve our understanding of community health and social determinants of health across a more representative population. By increasing representation of underserved groups in research, we can gain a greater understanding of health disparities, and ultimately find ways to improve health outcomes.

G. TABLES

Table 1. Characteristics of Respondents, N = 56.

	n (%)
Gender Identity	
Male	29 (51.8)
Female	27 (48.2)
Other Response	0 (0)
Race/Ethnicity	
White	44 (78.6)
Black or African American	2 (3.6)
Asian	6 (10.7)
Hispanic or Latino	1 (1.8)
Native American	1 (1.8)
Not specified	2 (3.6)
Job Title	
Investigator	36 (64.3)
Research Coordinator	16 (28.6)
Project Manager	2 (3.6)
Research Nurse	1 (1.8)
Not specified	1 (1.8)
Years Since Terminal Degree	
Fewer than 5 years	9 (16.1)
5-10 years	4 (7.1)
More than 10 years	43 (76.8)

Table 2. Researchers' Experience with Incarceration.

	n (%)
Protocol Addressing Incarceration: *"Have you ever worked on a study whose IRB protocol and/or study consent form included language about what would happen if the subject experiences unexpected incarceration?"*	
Yes	2 (3.6)
No	54 (96.4)
Subject Incarcerated: *"Of all the multi-visit studies you have been professionally involved in, are you aware of any instance where a study subject was unexpectedly incarcerated during the course of a study?"*	
Yes	10 (17.9)
No	46 (82.1)
Friend or Family Incarcerated: *"Do you have any close friends or family members who are or have been incarcerated?"*	
Yes	7 (12.5)
No	48 (85.7)
No response	1 (1.8))

Table 3. Frequency of Responses to Subjective Questions – Familiarity, Value, and Willingness.

		n (%)
Familiarity: *"How familiar are you with how to incorporate language in an IRB protocol and study consent form about unexpectedly incarcerated subjects?"*		
	Very Unfamiliar (1)	32 (58.2)
	Somewhat unfamiliar (2)	18 (32.7)
	Neutral (3)	1 (1.8)
	Somewhat familiar (4)	4 (7.3)
	Very familiar (5)	0 (0.0)
Value: *"I can see the potential value to my field of a training on the inclusion of unexpectedly incarcerated subjects in research (e.g., retaining persons already enrolled in the study who were incarcerated after enrollment)."*		
	Strongly Disagree (1)	2 (3.6)
	Disagree (2)	5 (8.9)
	Neutral (3)	18 (32.1)
	Agree (4)	28 (50.0)
	Strongly Agree (5)	3 (5.4)
Willingness: "*How willing would you be to use a toolkit regarding how to accommodate unexpectedly incarcerated persons in research protocols if you or your collaborators were planning a study whose subjects are at high risk for incarceration?"*		
	Unwilling (1)	3 (5.4)
	Neutral (2)	13 (23.2)
	Somewhat willing (3)	16 (28.6)
	Very willing (4)	21 (37.5)
	Eager (5)	3 (5.4)

Table 4. Average Response Compared to Neutral Response – Familiarity, Value, and Willingness.

	Neutral	*Median*	*S*	*P*
Familiarity	3	1	-696	***<.001*
Value	3	4	214	***<.001*
Willingness	2	3	442	***<.001*

Neutral = Neutral value from Likert-type scale
S = One-Sample Wilcoxon Signed-Rank Test Statistic
*** Statistically significant at P<.001*

Table 5. Associations Between Characteristics and Familiarity, Value, and Willingness.

	Familiarity			**Value**			**Willingness**		
	Median	*U*	*P*	*Median*	*U*	*P*	*Median*	*U*	*P*
Job Title		717	*.013		573	.639		653	.339
Investigator	1.0			4.0			3.0		
Non-Investigator	2.0			4.0			4.0		
Years Since Degree		438	.117		418	.326		406	.487
>10 years	1.0			3.0			3.0		
<10 years	2.0			4.0			4.0		
Gender		853	.074		650	*.034		694	.626
Female	2.0			3.0			3.0		
Male	1.0			4.0			3.0		
Race		188	.168		312	.395		297	.626
Non-Caucasian	1.0			4.0			3.0		
Caucasian	1.0			4.0			3.0		
Friend or Family Incarcerated		262	*.049		270	*.041		284	*.020
Yes	2.0			4.0			4.0		
No	1.0			3.5			3.0		
Subject Incarcerated		286	.873		296	.819		369	.063
Yes	1.0			4.0			4.0		
No	1.0			4.0			3.0		
Protocol Addressing Incarceration		83	.170		33	.251		54	.994
Yes	2.0			3.0			3.0		
No	1.0			4.0			3.0		

** = Statistically significant at P<.050*
U = Mann-Whitney U Test Statistic

Table 6. Associations Between Characteristics and Prior Experience with Incarcerated Individuals.

	Protocol Addressing Incarceration		**Subject Incarcerated**		**Friend or Family Incarcerated**	
	F	*P*	*F*	*P*	*F*	*P*
Job Title	34	>.999	30	.476	33	.086
Years Since Degree	41	>.999	35	>.999	39	*.046
Gender	25	>.999	21	.497	21	.236
Race	10	>.999	10	.178	9	>.999
Protocol Addressing Incarceration	--		45	.328	46	>.999
Subject Incarcerated	--		--		39	>.999

** = Statistically significant at P<.050*
F = Fisher's Exact Test Statistic

Survey Instrument.

1. Which option best describes your main role in the Heart Failure Clinical Research Network?
Investigator Research Coordinator Other (please specify)
2. How many years has it been since you earned your terminal degree?
Less than 5 years 5-10 years More than 10 years
3. How would you describe your gender?
Female Male Other (please specify)
4. Which of the following best describe(s) your race/ethnicity? (select all that apply)
White Black or African American Hispanic/Latino(a) Asian Other (please specify)
5. Do you have any close friends or family members who are or have been incarcerated?
Yes No
6. Of all the multi-visit studies you have been professionally involved with, are you aware of any instance where a study subject was unexpectedly incarcerated during the course of the study?
Yes No I don't know
7. Have you ever worked on a study whose IRB protocol and/or study consent form included language about what would happen if the subject experiences unexpected incarceration?
Yes No I don't know
8. How familiar are you with how to incorporate language in an IRB protocol and study consent form about unexpectedly incarcerated subjects?
Very Unfamiliar (1) Somewhat Unfamiliar (2) Neutral (3) Somewhat Familiar (4) Very Familiar (5)
9. I can see the potential value to my field of a training on the inclusion of unexpectedly incarcerated subjects in research (e.g., retaining persons already enrolled in the study who were incarcerated after enrollment).
Strongly Disagree (1) Disagree (2) Neutral (3) Agree (4) Strongly Agree (5)
10. How willing would you be to use a toolkit regarding how to accommodate unexpectedly incarcerated persons in research protocols if you or your collaborators were planning a study whose subjects are at high risk for incarceration?
Unwilling (1) Neutral (2) Somewhat Willing (3) Very Willing (4) Eager (5)

IV. CHAPTER 4: CONCLUSION

A. RECOMMENDATIONS AND NEXT STEPS

There is a disconnect between cardiovascular researchers' interest in including subsequently incarcerated subjects in studies and their familiarity with the practical steps to ethically retain these individuals. The development of training materials to facilitate this process could lead to more inclusive study populations and a more accurate understanding of health disparities. The design of these resources should involve key stakeholders, which may include individuals who were previously incarcerated, researchers, bioethicists, correctional staff, and clinicians.

Longitudinal or cohort studies looking at the impact of incarceration on health may help to understand the implications of incarceration and to develop interventions to improve the health of these individuals, as the vast majority of incarcerated individuals return to the community. In order to track the long-term health outcomes of formerly incarcerated persons, it would also be beneficial to introduce questions about incarceration history into surveys like the NHANES, NHIS, and other national health assessments.

Additional research regarding the inclusion of incarcerated subjects in clinical studies would be beneficial to add to the paucity of available literature on the topic. Future research could focus on exploring the practical implications of including subsequently incarcerated individuals in clinical research. This may include studies to quantify the frequency with which research participants are subsequently incarcerated, the cost and feasibility of including these individuals in studies, and the impact of excluding these individuals on study results.

B. Conclusion

In this survey of cardiovascular researchers, most were unfamiliar with including subsequently incarcerated subjects in research studies. Past protocols rarely anticipated subsequent incarceration, yet it was not uncommon for a subject to be subsequently incarcerated while enrolled in a study. The majority of respondents perceived the retention of incarcerated individuals as valuable to their field of clinical research, and are willing to utilize resources to facilitate their inclusion in future studies. Future efforts may focus on developing the resources to provide training to researchers on this process.

The results of this study provide a starting point for improving the inclusion of incarcerated individuals in clinical research. It is important for the research community to consider incarcerated populations in the design of their studies, and to develop best practices for treating the health of the entire populations, including vulnerable groups. Ethically including underrepresented groups in clinical research can lead to improved accuracy of our health statistics, especially regarding cardiovascular health. Allowing subsequently incarcerated individuals to continue in clinical research studies can improve our understanding of overall community health and social determinants of health. We can better identify, understand, and find solutions to reduce health disparities by increasing the representation of underserved groups in clinical research.

V. APPENDICES

A. CONSENT FORM

Information About the Study

Below are the details of this survey. Please read them carefully. If you agree to take this short survey, please click "Agree/Next" at the bottom of the page to continue to the survey.

INTRODUCTION: As a member of the Heart Clinical Research Failure Network (HFN), you are being asked to participate in a survey conducted by the Center for the Health of Incarcerated Persons at Emory University. This form is designed to tell you everything you need to consider before you consent to participate in this survey. It is entirely your choice to complete the survey.

OVERVIEW: This survey is designed to help us get a better understanding of how familiar HFN cardiovascular (CV) researchers are with including and retaining subjects in studies who are incarcerated or at risk for incarceration.

The survey will specifically focus on the unexpected incarceration of a research subject who has previously been enrolled in the community.

RATIONALE: As the HIV epidemic becomes an increasingly important target of CV research, the overlap of incarceration and CV research may become more of an issue, as one in six persons in the U.S. with HIV spends at least part of the year in a correctional facility. There are specific ways to handle enrollment of prisoners permitted under the Common Rule, which guides research funded by the U.S. DHHS.

PRINCIPAL INVESTIGATOR: Anne Spaulding MD MPH, Associate Professor of Epidemiology, Rollins School of Public Health, Emory University, Atlanta GA 30322
Contact: 404-727-3369 or aspauld@emory.edu

FUNDING: Faculty Discretionary Funds (Spaulding)

PROCEDURES: This national survey is being sent to investigators and research coordinators in the HFN. You will be asked 10 questions (multiple choice and Likert-type scale). This survey should take approximately 2-5 minutes to complete.

RISKS: We do not anticipate any risks for participation outside those encountered in daily life.

BENEFITS: The results of this survey will be used to inform future research and training programs concerning the inclusion of underrepresented populations in research. We intend to disseminate the results of this survey in peer-reviewed literature.

COMPENSATION: Individuals may choose to either have the study donate transportation tokens to citizens leaving jail to reintegrate into society, to enter a drawing for a Starbucks gift card, or to decline compensation. To enter the drawing, send your name and email address to the PI, Anne Spaulding (aspauld@emory.edu) You do no* need to participate in or complete the

survey to be eligible for the drawing.

CONFIDENTIALITY: This survey can be completed anonymously. If you choose to include your contact information, such as for compensation, your contact information will not be shared in any publication.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY: Your participation is completely voluntary and you have the right to leave the survey at any time. You may decline to answer any question.

IRB CONTACT: Emory Institutional Review Board, 404-712-0720 or irb@emory.edu

CONSENT AND ENTITLEMENT OF CONSENT FORM: You may print this page for your records. By clicking "Agree" and continuing to the survey, you are agreeing to participate and are giving us consent to use the information you provide. By giving your consent, you will not give up any legal rights.

Do you agree to participate in this survey? *If you do not agree, please exit the survey.*

AGREE

B. Survey Instrument

Exit Survey

Cardiovascular Research for Criminal Justice Involved Persons (CVR4CJ) Survey

EMORY
ROLLINS SCHOOL OF PUBLIC HEALTH

Survey Questions: Please read each question to decide which answer is best and click the appropriate response. Please press "Submit" when finished.

1 **Which option best describes your main role in the Heart Failure Clinical Research Network?** (please choose one)

- ◯ Investigator (PI or Co-I)
- ◯ Research coordinator
- ◯ I prefer not to answer.
- ◯ Other (please specify)

2 **How many years has it been since you earned your terminal degree (e.g., PhD, MD, if applicable, or Master's/Bachelor's degree for non-doctoral level staff)?**

- ◯ Less than 5 years
- ◯ 5-10 years
- ◯ More than 10 years
- ◯ I prefer not to answer.

3 **How would you describe your gender?**

- ◯ Female
- ◯ Male
- ◯ Other
- ◯ I prefer not to answer.

4 **Which of the following best describe(s) your race/ethnicity?** (select all that apply)

- ☐ White
- ☐ Black or African American
- ☐ Hispanic/Latino(a)
- ☐ Asian
- ☐ I prefer not to answer.
- ☐ Other (please specify)

5 **Do you have any close friends or family members who are or have been incarcerated?**

- ◯ Yes
- ◯ No
- ◯ I prefer not to answer.

6 **Of all multi-visit studies you have been professionally involved in, are you aware of any instance where a study subject was unexpectedly incarcerated during the course of the study?**

- ◯ Yes
- ◯ No
- ◯ I don't know.
- ◯ I prefer not to answer.

7 **Have you ever worked on a study whose IRB protocol and/or study consent form included language about what would happen if the subject experiences unexpected incarceration?**

- ◯ Yes
- ◯ No
- ◯ I don't know.
- ◯ I prefer not to answer.

8 **How familiar are you with how to incorporate language in an IRB protocol and a study consent form about unexpectedly incarcerated subjects?**

Very Unfamiliar	Somewhat Unfamiliar	Neutral	Somewhat Familiar	Very Familiar
◯	◯	◯	◯	◯

9 **I can see the potential value to my field of a training on the inclusion of unexpectedly incarcerated subjects in research (e.g., retaining persons already enrolled in the study who were incarcerated after enrollment).**

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
◯	◯	◯	◯	◯

10 **How willing would you be to use a toolkit regarding how to accommodate unexpectedly incarcerated persons in research protocols if you or your collaborators were planning a study whose subjects are at high risk for incarceration?**

Unwilling	Neutral	Somewhat Willing	Very Willing	Eager
◯	◯	◯	◯	◯

C. Recruitment Email

Subject line: Heart Failure Network Researchers

As a member of the Heart Failure Clinical Research Network (HFN), you are being asked to participate in a very brief **survey** from the Center for the Health of Incarcerated Persons (CHIP) at Emory University's Rollins School of Public Health.

We at CHIP are a group of researchers interested in CV research among HIV infected persons, many of whom may periodically face incarceration. We are contacting members of the HFN, since the network recently began a study of cardiomyopathy in HIV infected persons.
The survey consists of 10 questions to help us understand how familiar CV researchers are with working with subjects who are at risk for incarceration. More information can be found on the first page of the survey: https://www.surveymonkey.com/r/8DQCCQF

Thank you so much for your assistance.
Anne Spaulding, MD MPH
Department of Epidemiology
Rollins School of Public Health, Emory University

PS You may be compensated for being approached for this study. Compensation does not depend on completion of the study. See details on the first page of the study (link above). While we have discussed this email with the NHLBI project officer and the Emory site investigators, this voluntary survey is being conducted by us, independent of the NIH and any HFN investigators. This study was reviewed by the Emory University IRB.

VI. REFERENCES

1. Bronson J, Carson EA. Prisoners In 2017. *NCJ 252156.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/p17.pdf Published April 2019. Accessed November 2019.
2. Benjamin E, Muntner P, et al. Heart Disease and Stroke Statistics - 2019 Update: A Report From the American Heart Association. *Circulation.* 2019;139:e56-e528. https://ahajournals.org/doi/full/10.1161/CIR.0000000000000659 Published January 31, 2019. Accessed October 2019.
3. Maruschak L, Berzofsky, M., Unangst, J. Medical Problems of State and Federal Prisoners and Jail Inmates, 2011-12. *NCJ 248491.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics https://www.bjs.gov/content/pub/pdf/mpsfpji1112.pdf Published February 2015. Revised October 4, 2016. Accessed April 2017.
4. U.S. Department of Health and Human Services. Protection of Human Subjects 45 CFR §46. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML Published 2019. Effective July 19, 2018. Accessed October 2019.
5. Wang E, Aminawung J, Wildeman C, Ross J, Krumholz H. High incarceration rates among black men enrolled in clinical studies may compromise ability to identify disparities. *Health Aff (Millwood).* 2014;33(5). https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.1325 Published May 2014. Accessed October 2019.
6. Wang EA, Wildeman C. Studying Health Disparities by Including Incarcerated and Formerly Incarcerated Individuals. *J Am Med Assoc.* 2011;305(16):1708-1709. https://europepmc.org/articles/pmc5476220 Published March 31, 2011. Accessed November 2019.
7. Wang EA, Macmadu A, Rich J. Examining the impact of criminal justice involvement on health through federally funded, national population-based surveys in the United States. *Public Health Rep.* 2019;134:225-335. https://journals.sagepub.com/doi/10.1177/0033354918824324 Published May 6, 2019. Accessed October 2019.
8. Wang EA, Pletcher M, Lin F, et al. Incarceration, Incident Hypertension, and Access to Health Care: Findings from the Coronary Artery Risk Development in Young Adults (CARDIA) Study. *Arch Intern Med.* 2009;169(7):687-693. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1108425 Published April 13, 2009. Accessed May 2019.
9. Wildeman C, Wang E. Mass incarceration, public health, and widening inequality in the USA. *Lancet.*389(10077):1464-1474.

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30259-3/fulltext Published April 8, 2017. Accessed November 2019.

10. Erves JC, Mayo-Gamble TL, Malin-Fair A, et al. Needs, Priorities, and Recommendations for Engaging Underrepresented Populations in Clinical Research: A Community Perspective. *J Community Health.* 2017;42(3):472-480. https://www.ncbi.nlm.nih.gov/pubmed/27812847 Published June 2017. Accessed November 2019.

11. Binswanger I, Krueger P, Steiner J. Prevalence of chronic medical conditions among jail and prison inmates in the United States compared with the general population. *J Epidemiol Community Health.* 2009;63:912-919. https://www.ncbi.nlm.nih.gov/pubmed/19648129 Published November 2009. Accessed April 2017.

12. Noonan M, Rohloff H, Ginder S. Mortality in Local Jails and State Prisons, 2000-2013 - Statistical Tables. *NCJ 248756.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics https://www.bjs.gov/content/pub/pdf/mljsp0013st.pdf Published August 2015. Accessed April 2017.

13. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. All Terms and Definitions. https://www.bjs.gov/index.cfm?ty=tda Accessed November 2019.

14. Heart Failure Network. https://hfnetwork.org/ Published 2016. Accessed November 2019.

15. Villarroel MA, Blackwell DL, Jen A. Summary Health Statistics: National Health Interview Survey. Centers for Disease Control and Prevention, National Center for Health Statistics. https://www.cdc.gov/nchs/nhis/SHS/tables.htm Published 2018. Accessed November 2019.

16. Hozawa A, Folsom A, Sharrett A, Chambless L. Absolute and attributable risks of cardiovascular disease incidence in relation to optimal and borderline risk factors: comparison of African American with white subjects--Atherosclerosis Risk in Communities Study. *Arch Intern Med.* 2007;167(6):573-579. https://jamanetwork-com.proxy.library.emory.edu/journals/jamainternalmedicine/fullarticle/412002 Published March 26, 2007. Accessed October 2019.

17. Yang Q, Cogswell M, Flanders W, et al. Trends in Cardiovascular Health Metrics and Associations With All-Cause and CVD Mortality Among US Adults. *JAMA.* 2012;307(12):1273-1283. https://www.ncbi.nlm.nih.gov/pubmed/22427615 Published March 28, 2012. Accessed October 2019.

18. Roth G, Johnson C, et al. The Burden of Cardiovascular Diseases Among US States, 1990-2016. *JAMA Cardiology.* 2018;3(5):375-389. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145754/ Published May 2018. Accessed October 2019.

19. Schieb L, Greer S, Ritchey M, George M, Casper M. Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease — United States, 2001–2010. *Morbidity and Mortality Weekly Report (MMWR).* 2013;62(35):721-727.

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm Published September 6, 2013. Accessed November 2019.

20. Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018. *Morbidity and Mortality Weekly Report (MMWR).* 2019;68(45):1013-1019. https://www.cdc.gov/mmwr/volumes/68/wr/mm6845a2.htm Published November 15, 2019. Accessed November 2019.

21. Hales C, Carroll M, Frayar C, Ogden C. Prevelence of Obesity Among Adults and Youth: United States, 2015-2016. *288.* Centers for Disease Control and Prevention, National Center for Health Statistics. https://www.cdc.gov/nchs/data/databriefs/db288.pdf Published October 2017. Accessed November 2019.

22. Pettit B, Western B. Mass imprisonment and the life course: Race and class inequality in US incarceration. *Am Sociol Rev.* 2004;69(2):151-169. http://www.jstor.org/stable/3593082 Published April 2004. Accessed April 2017.

23. Walmsley R. World Prison Population List. *11th ed.* Institute for Criminal Policy Research. http://prisonstudies.org/sites/default/files/resources/downloads/world_prison_population_list_11th_edition_0.pdf Published 2015. Accessed April 2017.

24. Kaeble D, Cowhig M. Correctional Populations In The United States, 2016. *NCJ 251211.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics https://www.bjs.gov/content/pub/pdf/cpus16.pdf Published April 2018. Accessed November 2019.

25. Zeng Z. Jail Inmates in 2017. *NCJ 251774* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/ji17.pdf Published April 2019. Accessed November 2019.

26. Bonczar TP. Prevalence of Imprisonment in the U.S. Population, 1974-2001. *NCJ 197976.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/piusp01.pdf Published August 2003. Accessed October 2019.

27. Bonczar TP, Beck AJ. Lifetime Likelihood of Going to State or Federal Prison. *NCJ 160092.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://bjs.gov/content/pub/pdf/Llgsfp.pdf Published March 1997. Accessed November 2019.

28. Hughes T, Wilson DJ. Reentry Trends in the United States. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics https://www.bjs.gov/content/reentry/reentry.cfm Published April 2004. Accessed November 2019.

29. Spaulding AC, Seals RM, Page MJ, Brzozowski AK, Rhodes W, Hammett TM. HIV/AIDS among inmates of and releasees from US correctional facilities, 2006: declining share of epidemic but persistent public health opportunity. *PLoS One.* 2009;4(11):e7558. https://www.ncbi.nlm.nih.gov/pubmed/19907649 Published November 11, 2009. Accessed April 2017.

30. U.S. Department of Justice, Federal Bureau of Prisons. Inmate Statistics. https://www.bop.gov/about/statistics/ Published 2019. Accessed November 2019.

31. Kaeble D. Probation And Parole. *NCJ 251148.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/ppus16.pdf Published April 2018. Accessed November 2019.

32. Alper M, Durose M. 2018 Update on Prisoner Recidivism: A 9-Year Follow-up Period (2005-2014). *NCJ 250975.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/18upr9yfup0514.pdf Published May 2018. Accessed November 2019.

33. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. Bridged-Race Population Estimates, United States July 1st resident population by state, county, age, sex, bridged-race, and Hispanic origin. CDC WONDER Online Database. 2019. https://www.cdc.gov/nchs/nvss/bridged_race.htm Accessed November 2019.

34. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. National Prisoner Statistics, 1978-2016. Inter-university Consortium for Political and Social Research; 2017. https://www.icpsr.umich.edu/icpsrweb/NACJD/studies/37003 Accessed May 2019.

35. Carson EA, Mulako-Wangota J. Corrections Statistical Analysis Tool (CSAT),. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics; 2018. https://www.bjs.gov/index.cfm?ty=nps Accessed November 2019.

36. *Estelle v. Gamble*, No. 75-929, 429 U.S. 97 (November 30, 1976). https://www.law.cornell.edu/supremecourt/text/429/97 Accessed November 2019.

37. Maruschak L, Chari K, Simon A, DeFrances C. National Survey of Prison Health Care: Selected Findings. *96.* Centers for Disease Control and Prevention, National Center for Health Statistics and U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.cdc.gov/nchs/data/nhsr/nhsr096.pdf Published July 28, 2016. Accessed April 2017.

38. Frank JW, Linder JA, Becker WC, Fiellin DA, Wang EA. Increased hospital and emergency department utilization by individuals with recent criminal justice involvement: results of a national survey. *J Gen Intern Med.* 2014;29(9):1226-1233. https://www.ncbi.nlm.nih.gov/pubmed/24817280 Published September 2014. Accessed November 2019.

39. Glaze LE, Herberman EJ. Correctional populations in the United States, 2012. *NCJ 243936.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/cpus12.pdf Published December 2013. Accessed April 2017.

40. Yan L, Liu K, Matthews K, Daviglus M, Ferguson T, Kiefe C. Psychosocial factors and risk of hypertension: the Coronary Artery Risk Development in Young Adults (CARDIA) study. *JAMA.* 2003;290(16):2138-2148.

https://jamanetwork.com/journals/jama/fullarticle/197528 Published October 2003. Accessed November 2019.

41. McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ. Differences in control of cardiovascular disease and diabetes by race, ethnicity, and education: US trends from 1999 to 2006 and effects of Medicare coverage. *Ann Intern Med.* 2009;150(8):505-515. https://www.ncbi.nlm.nih.gov/pubmed/19380852 Published April 21, 2009. Accessed April 2017.

42. Heron M, Anderson RN. Changes in the Leading Cause of Death: Recent Patterns in Heart Disease and Cancer Mortality. *254.* Centers for Disease Control and Prevention, National Centers for Health Statistics. https://www.cdc.gov/nchs/products/databriefs/db254.htm Published August 2016. Accessed November 2019.

43. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. Compressed Mortality File years 1999-2016. CDC WONDER Online Database. 2017. https://wonder.cdc.gov/cmf-icd10.html Accessed November 2019.

44. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. About the Bureau of Justice Statistics. https://www.bjs.gov/index.cfm?ty=abu Published 2019. Accessed November 2019.

45. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Data Collection: National Inmate Survey (NIS). https://www.bjs.gov/index.cfm?ty=dcdetail&iid=278 Published 2017. Accessed April 2017.

46. Ahalt C, Binswanger IA, Steinman M, Tulsky J, Williams BA. Confined to ignorance: the absence of prisoner information from nationally representative health data sets. *J Gen Intern Med.* 2012;27(2):160-166. https://www.ncbi.nlm.nih.gov/pubmed/21922160 Published February 27, 2012. Accessed November 2019.

47. U.S. Department of Health and Human Services, Office for Human Research Protections. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html Published April 18, 1979. Accessed April 2017.

48. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Department of Health, Education, and Welfare. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html Published 1979. Accessed November 2019.

49. Institute of Medicine. Ethical Considerations for Research Involving Prisoners. National Academies Press. https://www.nap.edu/read/11692/ Published 2007. Accessed October 2019.

50. Carson EA. Prisoners in 2014. *NCJ 248955.* U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. https://www.bjs.gov/content/pub/pdf/p14.pdf Published September 2015. Accessed December 2019.

51. National Institutes of Health. Patient Recruitment, Ethics in Clinical Research, Ethical Guidelines. https://www.cc.nih.gov/recruit/ethics.htmlAccessed May 2019.

52. Finch TL, Girling M, May CR, et al. NoMad: Implementation Measure Based on Normalization Process Theory. [Measurement Instrument]. 2015. http://www.normalizationprocess.org/media/1017/website-formatted-nomad-instrument-final.pdf Published 2015. Accessed April 2017.

53. Fryrear A. What's a Good Survey Response Rate. 2015. https://www.surveygizmo.com/resources/blog/survey-response-rates/ Published July 27, 2015.Accessed December 2019.