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High Incarceration Rates Among Black Men Enrolled In Clinical Studies May Compromise Ability To Identify Disparities

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Abstract

In 1978 the federal government restricted research on prison and jail inmates in medical studies, the result of decades of unethical research in correctional institutions. We evaluated the impact this policy has had on studies of health outcomes in minority populations, particularly studies involving black men, who are disproportionately incarcerated. Specifically, we explored the effect of incarceration on follow-up rates of fourteen prospective clinical studies funded by the National Heart, Lung, and Blood Institute. We estimated that during the past three decades high rates of incarceration of black men may have accounted for up to 65 percent of the loss to follow-up among black men in these studies. The impact of incarceration was far less among white men, black women, and white women. These estimates suggest that the ability of those studies to examine racial disparities in health outcomes, as well as to understand the experience of this group, could be compromised. We believe that community-recruited subjects who are incarcerated should be allowed to continue participating in observational clinical research that poses minimal risk to participants.

More than 2.2 million people served time in US jails (correctional facilities whose inmates serve sentences of less than one year) and prisons (whose inmates have longer stays) in 2008.¹ Since 1978 the federal government has placed significant restrictions on inmates' participation in medical research, as a result of decades of unethical research in correctional facilities.² The regulations bar study participants from participating once they are incarcerated, unless the study investigators apply for special permission through their Institutional Review Board (IRB) to include incarcerated participants in their study. If studies do not specify otherwise, community-recruited participants who enroll in studies

cannot be followed while they are incarcerated. In certain jurisdictions, they cannot be followed after their release.

The disproportionate incarceration of minority populations may have an adverse impact on the generalizability of clinical research. In 2009, 40 percent of the men and women who were incarcerated were black;³ more than one-third of black men are incarcerated at some point in their lives.⁴ Under these circumstances, the results of longitudinal studies may fail to represent accurately the experience of black populations and may bias estimates of racial disparities by either excluding people in jail or prison or discontinuing longitudinal follow-up at the time of incarceration.^{5,6}

To investigate this issue and its potential impact, we studied the association of federal policies and rates of loss to follow-up of study participants in longitudinal cohort studies. We first describe study policies on including incarcerated participants and then estimate the degree to which those policies cause studies to lose participants to follow-up, analyzing this effect by sex and race. We chose to examine cohort studies funded by the National Heart, Lung, and Blood Institute (NHLBI) because that is the only one of the National Institutes of Health that systematically requires researchers to submit for public use all protocols and data.

Study Data And Methods

We reviewed NHLBI cohort study protocols to identify policies on including incarcerated participants or following participants who were initially recruited in communities after they were incarcerated or after their release. We calculated the cumulative risk of participants' being incarcerated at any point during the study period using study data, when available, and the rate of loss to follow-up for each NHLBI study.

If data on participant incarceration were not available, we used life-table methods to estimate the potential cumulative risk of incarceration. Life-table methods are traditionally used to show the cumulative probability of experiencing demographic processes such as death and marriage. Recently, however, they have been used in studying the cumulative risk of imprisonment by accumulating age-specific first-imprisonment rates over the life course.⁷

Study Selection

We used the NHLBI Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) to identify all cohort studies sponsored by the NHLBI.⁸ All NHLBI-funded cooperative agreements, clinical trials, or epidemiological studies that receive \$500,000 or more in direct funding each year or that include five hundred or more participants are required to submit study research protocols and questionnaires, study specimens, and data sets to BioLINCC.

We included in our analysis BioLINCC cohort studies that were based in the United States, had complete study data sets in BioLINCC, recruited black men ages 15–65, and had more than two years of follow-up. We received approval from BioLINCC to download each study's protocol, questionnaires, and data.

Studies' Policies On Incarcerated Participants

For the studies that met our inclusion criteria, we determined how each study treated incarcerated participants, including whether it excluded incarcerated populations from participation, whether IRB approval was obtained to follow participants into correctional facilities, and whether participants were asked about their incarceration history at follow-up. We abstracted information from the study protocol about the exclusion of incarcerated participants as well as requests made by researchers to the IRB to follow community-recruited participants when they were incarcerated or after their release. We abstracted information about participants' histories of incarceration from study questionnaires and data.

Participant Incarceration

In studies that included participant-reported rates of incarceration, we used study data to calculate the rate of incarceration by sex and race. In studies without reported rates of incarceration, we used life-table methods to estimate each participant's cumulative risk of being incarcerated at some point between the start of the study and each follow-up year. To do this, we first estimated the age-specific risks that participants would be incarcerated after the beginning of the study. The probability of a participant's first incarceration at any given age is the number of first-time prison admissions among the study cohort since the onset of the study divided by the number of participants of the same age, race, and sex.

To calculate the probability of a first admission to prison at any given age, we combined data from the Surveys of Inmates in State and Federal Correctional Facilities⁹ with data from the National Corrections Reporting Program.¹⁰ There are insufficient data to estimate admission to jail, so the estimate of incarceration is an underestimate. The second set of data correct for the fact that the Surveys of Inmates in State and Federal Correctional Facilities undercount short prison stays. Specifically, we also included yearend estimates of prisoners from the Bureau of Justice Statistics, because the surveys of inmates tend to happen early in the year.

The Surveys of Inmates in State and Federal Correctional Facilities were conducted approximately every five years between 1974 and 2004. We interpolated data for intersurvey years to provide annual estimates of first-time rates of incarceration by age, race, and sex. Because estimates of the proportion of first admissions were based on survey data recorded at a single time point, we may have missed people who were incarcerated for less than a year. Information about brief stays in prison was incorporated into data from the National Corrections Reporting Program, which has collected individual-level administrative data on prison admissions and releases annually since 1983.

These methods are consistent with those used in previous estimates of the lifetime risk of imprisonment.^{11,12} To use the Coronary Artery Risk Development in Young Adults (CARDIA) study¹³ as an example, the methods described here estimate what proportion of the sample we would expect to be incarcerated at any point between the beginning of the study (in the mid-1980s) and the last follow-up (in the mid-2000s).

We used correctional data to calculate the number of first admissions to prison. In addition, we estimated the risk of future imprisonment among study participants who had not been

imprisoned since the beginning of the study period, including those who had been imprisoned before enrolling in the study. To estimate the population at risk, we adjusted Census Bureau data to take into account all previous first incarcerations among the study sample as well as the population mortality rates. Population counts and mortality rates were taken from the Centers for Disease Control and Prevention's Wide-Ranging Online Data for Epidemiologic Research.¹⁴

The analysis thus allowed us to assess two competing risks: the risk of going to prison and the risk of death (which was considered only in the population that was at risk of experiencing imprisonment). In addition to producing estimates for each entire study sample by age, we also estimated the risks of imprisonment for four demographic groups: black men, black women, white men, and white women.

Rates Of Participant Loss To Follow-Up

We calculated the rates at which participants in the data set were lost to follow-up, using the actual data from each study obtained from BioLINCC. We calculated rates of loss to follow-up for the overall sample as well as for the four demographic groups listed above. We calculated the proportion of the loss to follow-up that might be attributed to incarceration by dividing the percentage of participants estimated to be incarcerated during the course of the study by the percentage of total participants lost to follow-up.

Statistical Analysis

We used a test of proportions to measure the statistical differences among the four demographic groups in terms of percentage of loss to follow-up. We also used a test of proportions to measure the statistical differences among the groups in terms of percentage of loss to follow-up that might be attributed to incarceration. We considered p values of less than 0.05 statistically significant. We obtained approval for this study from the IRB of the Yale University School of Medicine.

Limitations

A number of limitations of this study should be noted. We used data that were available from BioLINCC to determine how studies handled incarceration and incarcerated participants. It is plausible that studies continued to follow participants after their release from correctional facilities but did not mention doing so in the study protocol or document IRB approval for doing so.

We were unable to calculate the exact number of participants who were incarcerated in each prospective study, and thus we reported estimated cumulative risk of incarceration using life-table methods. Also, in these cases, we estimated the cumulative risk of going to prison for the first time since the beginning of the study and used national statistics on imprisonment. By doing so, we created a conservative estimate of the cumulative risk of imprisonment, especially for studies taking place in cities and in states with high incarceration rates. This is especially relevant since some of the studies included were either exclusively in urban areas (for example, the Coronary Artery Risk Development in Young

Adults, or CARDIA, study) or in states with very high rates of incarceration (such as Mississippi, the site of the Jackson Heart Study).¹⁵

We were also unable to estimate the cumulative risk of incarceration in jail as opposed to the risk of incarceration in prison. This omission likely had a minimal impact on participant follow-up, since the follow-up intervals were all greater than one year. Moreover, we were unable to measure the impact of incarceration on ethnic minorities other than blacks because of the limitations in corrections data.

We report estimated cumulative risk of incarceration from NHLBI cohort studies only. Additionally, we were unable to generalize our conclusions to other cohort studies—including those focusing on HIV and hepatitis C, which disproportionately affect minority populations—because data from these studies are neither systematically shared nor publicly available. Finally, community-recruited study participants are a self-selected group and are not necessarily representative of the overall population.

Study Results

Descriptions Of Studies

Fourteen of the 110 NHLBI-funded studies that sent study protocols and data to BioLINCC met our inclusion criteria (for details about why studies were excluded, see online Appendix Exhibit 1).¹⁶ We excluded 29 of the 110 studies because they had only biospecimens (for example, the Alpha1-Antitrypsin Deficiency Registry)—no data for us to use in estimating incarceration rates.

We excluded another forty-three studies because they followed their participants for less than two years. Many of these were studies based in hospitals or intensive care units, such as the Acute Respiratory Distress Network's Late Steroid Rescue Study. We did not include them because loss to follow-up was expected to be low for these shorter-duration studies, making the issue of loss to follow-up because of incarceration less relevant.

Finally, we excluded twenty-four other studies because the maximum age for participants was less than fifteen, the minimum age was at least sixty-five, or they lacked male or black participants. We did not include these studies because the rates of incarceration for black men are highest for those ages 15–65.

Ten of the fourteen studies we included focused on coronary heart disease; one each focused on hypertension, arrhythmia, sickle cell disease, and sarcoidosis (Exhibit 1). Collectively, these studies recruited 72,261 participants, 37 percent of whom were black. The first began enrolling participants in 1972, and the last began in 2000. The average length of follow-up was five years, with a range of two to twenty years.

Estimated Cumulative Risk Of Incarceration

The estimated cumulative risk of incarceration of participants in the fourteen studies ranged from 1 percent to 27 percent. The estimated cumulative risk of incarceration was highest for

black male participants in CARDIA¹³, the Jackson Heart Study,¹⁵ and the Multicenter Study of Hydroxyurea.¹⁷

In CARDIA, 29 percent of black men, 3 percent of black women, 3 percent of white men, and 0.4 percent of white women could have been expected to be imprisoned between 1985 and 2005. For the Multicenter Study of Hydroxyurea, 10 percent of black men, 1.2 percent of black women, and 2 percent of white men could have been expected to be imprisoned at some point between the beginning of the study in 1992 and its end in 1999. In the Jackson Heart Study, all of whose participants were black, 5 percent of black men and 0.4 percent of black women could have been expected to be imprisoned at some point between the beginning of the study, in 2000, and 2004.

For all fourteen of the studies, the estimated cumulative risk of incarceration was higher among black men than among black women, white men, or white women.

Rates Of Loss To Follow-Up

The rates of actual loss to follow-up of all enrolled participants in the fourteen studies ranged from 9 percent to 60 percent (Exhibit 2). The rates of overall loss to follow-up for black men were 8–57 percent; for black women, 16–60 percent; for white men, 5–58 percent; and for white women, 10–63 percent (Appendix Exhibit 2).¹⁶

In seven of the studies, black men had a higher rate of loss to follow-up than any of the other three groups. However, the differences between black men and all other groups were statistically significant in only three studies: CARDIA,¹³ the Atherosclerosis Risk in Communities Study (ARIC),¹⁸ and the Jackson Heart Study.¹⁵ The differences between black men and white participants of both sexes were significant in the Multi-Ethnic Study of Atherosclerosis (MESA).¹⁹

In the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT),²⁰ black men were significantly less likely to be lost to follow-up when compared with black women, white men, and white women. However, loss to follow-up was high among all four groups.

Loss To Follow-Up Attributable To Incarceration

The estimated percentage of loss to follow-up because of incarceration was higher among black men than it was among black women, white men, or white women in five of the studies: ALLHAT, ARIC, CARDIA, the Digitalis Investigation Group,²¹ and MESA (Exhibits 2–5; Appendix Exhibit 3).¹⁶ In CARDIA, for example, 65 percent of black men, 9.5 percent of black women, 13.1 percent of white men, and 1.9 percent of white women lost to follow-up might have been imprisoned during the study.

In seven other studies, there were statistically significant differences between loss to follow-up that could have been because of incarceration between black and white male participants, but not between black and white female participants. Those studies were the Activity Counseling Trial,²² Aspirin-Myocardial Infarction Study,²³ Beta-Blocker Heart Attack Trial,²⁴ A Case Controlled Etiologic Study of Sarcoidosis,²⁵ Enhancing Recovery in

Coronary Heart Disease Patients,²⁶ Multiple Risk Factor Intervention Trial,²⁷ and the Prevention and Treatment of Hypertension Study.²⁸

In the Jackson Heart Study, there was a statistically significant difference between black men and black women in the loss to follow-up that could have been because of incarceration (19 percent and 2 percent, respectively). We were not able to perform a test of proportions in the Multicenter Study of Hydroxyurea because of limitations of the sample size.

Discussion

None of the studies that we analyzed reported obtaining IRB approval to enroll incarcerated people or to follow community-recruited participants into correctional facilities. The high rates of incarceration of black men during the past three decades may have accounted for up to 65 percent of the loss to follow-up among black men in these studies.

Not surprisingly, the estimated impact of incarceration was far less among white men, black women, and white women, who would not be expected to experience as high cumulative risk of incarceration as black men. Moreover, studies such as CARDIA and ACCESS that recruited young black men between 1980 and 2000, at the peak of the incarceration boom, were most likely to be affected.

The implications of having a disproportionate number of black men drop out of prospective cohort studies because of incarceration are significant, even though the differences between loss to follow-up are not always large or significantly different between black men, white men, black women, and white women. Conditions such as cardiovascular disease and sickle cell disease are more common in black men than in white men and have complex factors that influence morbidity and mortality. This makes it important for analysts to have access to a large number of cases so that they can adjust for possible confounders.

If a significant proportion of black male participants are lost to follow-up, much of the necessary statistical power is lost for that group. For instance, in a CARDIA study exploring the association between hostility and coronary artery calcification at year fifteen, researchers were unable to explore race-specific analyses because of statistical power issues.²⁹ In addition, the disproportionate loss to follow-up of black male participants raises concerns about the precision of researchers' estimates. If data are not missing completely at random, results may be biased.

The likely high association between imprisonment and being lost to follow-up in these studies may yield underpowered and biased estimates for black men. Furthermore, participants who are incarcerated are more likely to be sick than are participants who have never been incarcerated.^{30,31} This difference increases the likelihood that disease rates and progression of disease in blacks and black-white disparities will be underestimated.

Recently, the Institute of Medicine (IOM) released a special report on the ethics of conducting research on prisoners and proposed changes to the current federal regulations.³² The current regulations permit four types of biomedical or behavioral research to use prisoners as subjects: studies of the possible causes, effects, and conditions of incarceration

and of criminal behavior that present minimal risk to the subject; studies of prisons as institutional structures or of prisoners as incarcerated people that present minimal risk; studies of conditions that disproportionately affect prisoners as a class (for instance, hepatitis C), provided that the appropriate experts in penology, medicine, and ethics are consulted; and research on practices that have the intent and reasonable probability of improving the health or well-being of the subject. In all of these cases, researchers need to certify to the health and human services secretary that the relevant IRB approved the study.³³

The current regulations were developed in the 1970s after decades of unethical treatment of prisoners in research, almost all of which was Phase I clinical drug testing.² For community-based, prospective clinical research studies, researchers who anticipate that a portion of participants may be imprisoned must now request IRB approval to continue studying them during their incarceration. Researchers must use Prisoner Subpart C of the regulations, and if the IRB approves the study, it requests certifications of the protocol through the federal Office of Human Research Protections.³³ If that office certifies the protocol, subjects can continue to participate in the study even if they are incarcerated.

However, the IOM has recommended that clinical studies that present minimal risk and recruit participants in the community no longer be required to obtain certification by the Office of Human Research Protections. The loosening of this regulation would permit studies, including those in our analyses, to follow participants into correctional facilities without first obtaining approval from the Office of Human Research Protections.

Our data suggest that restrictions on research that presents minimal risk—in particular, studies that do not test the safety or efficacy of medical products—should be minimized to mitigate the loss to follow-up of black male participants. But the easing of regulations should be considered in the context of the historically unethical treatment of prisoners in research. To minimize any coercion of incarcerated people, regulations should be relaxed only for people who consented to participate in the research while in the community. Also, if subjects who are not incarcerated are remunerated for their participation, subjects who are incarcerated should be also—if not while in prison, at least after release.

Finally, former prisoners should be included in future panels that are convened to discuss the easing of these regulations and the specifics of how epidemiological studies might continue in prisons and jails. We believe that these suggestions would minimize coercion, present minimal risk to incarcerated participants, and preserve the validity of epidemiological research while protecting against the ethical violations that have occurred in the past.

Conclusion

The federal government has invested millions of dollars in studies to quantify and eliminate racial disparities. However, the validity of the studies' conclusions may be jeopardized by barriers to following community-recruited participants into jails and prisons. Our data suggest that prohibitions on research that present minimal risk—specifically, studies that do not involve tests of the safety or efficacy of therapeutic products—should be minimized and that incarcerated people should be allowed to continue their participation in a study.

The bureaucratic barriers that these measures would overcome are not the only ones that can prevent researchers from following community-recruited participants into prisons. Incarcerated participants can end up in any of a number of different correctional facilities throughout a state and sometimes are moved to a different state. Additionally, prisons and jails can pose their own bureaucratic barriers to research. Finally, not all IRBs have a prisoner review committee, and the ones that do exist may meet less frequently than regular IRB committees.

By enabling the participation of incarcerated individuals in epidemiological research of minimal risk, we could increase minority participation in epidemiological research and improve the understanding and elimination of racial disparities in health.

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Exhibit 2. Actual Loss To Follow-Up And Estimated Loss To Follow-Up Because Of Incarceration Among Black Men In Selected National Heart, Lung, And Blood Institute Cohort Studies

SOURCE Authors' analysis of data on selected cohorts from BioLINCC (see Note 8 in text). **NOTES** MRFIT is Multiple Risk Factor Intervention Trial. AMIS is Aspirin-Myocardial Infarction Study. BHAT is Beta-Blocker Heart Attack Trial. CARDIA is Coronary Artery Risk Development in Young Adults study. ARIC is Atherosclerosis Risk in Communities Study. PATHS is Prevention and Treatment of Hypertension Study. DIG is Digitalis Investigation Group. MSH is Multicenter Study of Hydroxyurea. ACT is Activity Counseling Trial. ALLHAT is Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial. ACCESS is A Case Controlled Etiologic Study of Sarcoidosis. ENRICH is Enhancing Recovery in Coronary Heart Disease study. MESA is Multi-Ethnic Study of Atherosclerosis. JHS is Jackson Heart Study.

Exhibit 3. Actual Loss To Follow-Up And Estimated Loss To Follow-Up Because Of Incarceration Among White Men In Selected National Heart, Lung, And Blood Institute Cohort Studies

SOURCE Authors' analysis of data on selected cohorts from BioLINCC (see Note 8 in text). **NOTES** For full names of studies, see notes to Exhibit 2. Because all participants in the Jackson Heart Study were black, it is not included here.

Exhibit 4. Actual Loss To Follow-Up And Estimated Loss To Follow-Up Because Of Incarceration Among Black Women In Selected National Heart, Lung, And Blood Institute Cohort Studies

SOURCE Authors' analysis of data on selected cohorts from BioLINCC (see Note 8 in text). **NOTES** For full names of studies, see notes to Exhibit 2. Because all participants in the Multiple Risk Factor Intervention Trial were men, it is not included here.

Exhibit 5. Actual Loss To Follow-Up And Estimated Loss To Follow-Up Because Of Incarceration Among White Women In Selected National Heart, Lung, And Blood Institute Cohort Studies

SOURCE Authors' analysis of data on selected cohorts from BioLINCC (see Note 8 in text). **NOTES** For full names of studies, see notes to Exhibit 2. Because all participants in the Jackson Heart Study were black, and all participants in the Multiple Risk Factor Intervention Trial were men, those studies are not included here.

Exhibit 1

Characteristics Of Selected National Heart, Lung, And Blood Institute Cohort Studies

Study	Disease studied	Participants			Study start date	Average follow-up (years)
		Number	Mean age (years)	Percent black		
Activity Counseling Trial (ACT)	CHD	873	51.3	24.7	1994	2
Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)	CHD	10,355	66.9	37.8	1993	5
Aspirin-Myocardial Infarction Study (AMIS)	CHD	4,524	54.8	6.1	1974	3
Atherosclerosis Risk in Communities Study (ARCS)	CHD	15,732	54.0	27.1	1987	9
Beta-Blocker Heart Attack Trial (BHAT)	CHD	3,837	54.8	8.7	1977	2
Coronary Artery Risk Development in Young Adults (CARDIA)	CHD	5,112	24.8	51.6	1985	20
A Case Controlled Etiologic Study of Sarcoidosis (ACCESS)	Sarcoidosis	241	40–49 ^a	46.1	1995	2
Digitalis Investigation Group (DIG)	Arrhythmia	7,788	63.9	14.5 ^b	1990	3
Enhancing Recovery in Coronary Heart Disease (ENRICHD)	CHD	2,481	60.8	18.8	1995	2
Jackson Heart Study	CHD	5,301 ^c	54.9	100.0	2000	4 ^d
Multicenter Study of Hydroxyurea (MSH)	Sickle cell disease	238	30.0	97.1	1992	7
Multi-Ethnic Study of Atherosclerosis (MESA)	CHD	6,814	62.2	27.8	2000	6
Multiple Risk Factor Intervention Trial (MRFIT)	CHD	12,866	46.2	45.6	1972	6–8
Prevention and Treatment of Hypertension Study (PATHS)	Hypertension	1,400	55–64 ^a	25.5	1989	2

SOURCE Authors' analysis of data on selected cohorts from BioLINCC (see Note 8 in text).

NOTES None of the studies reported enrolling incarcerated participants or following participants after incarceration. Only the Coronary Artery Risk Development in Young Adults study (see Note 13 in text) included questions about participants' history of incarceration, which were asked at baseline and at year 2 of the study. We estimated the cumulative risk of incarceration for all studies using life-table methods (explained in the text). CHD is coronary heart disease.

^aMedian age group; average age not available.

^bMinority population.

^cFrom the study website (<https://www.jacksonheartstudy.org/jhsinfo/>).

^dFollow-up period to second exam.