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Research and Applications

Procurement of patient medical records from multiple health care facilities for public health research: feasibility, challenges, and lessons learned

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ABSTRACT

Objectives: Studies that combine medical record and primary data are typically conducted in a small number of health care facilities (HCFs) covering a limited catchment area; however, depending on the study objectives, validity may be improved by recruiting a more expansive sample of patients receiving care across multiple HCFs. We evaluate the feasibility of a novel protocol to obtain patient medical records from multiple HCFs using a broad representative sampling frame.

Materials and Methods: In a prospective cohort study on HIV pre-exposure prophylaxis utilization, primary data were collected from a representative sample of community-dwelling participants; voluntary authorization was obtained to access participants' medical records from the HCF at which they were receiving care. Medical record procurement procedures were documented for later analysis.

Results: The cohort consisted of 460 participants receiving care from 122 HCFs; 81 participants were lost to follow-up resulting in 379 requests for medical records submitted to HCFs, and a total of 343 medical records were obtained (91% response rate). Less than 20% of the medical records received were in electronic form. On average, the cost of medical record acquisition was $120 USD per medical record.

Conclusions: Obtaining medical record data on research participants receiving care across multiple HCFs was feasible, but time-consuming and resulted in appreciable missing data. Researchers combining primary data with medical record data should select a sampling and data collection approach that optimizes study validity while weighing the potential benefits (more representative sample; inclusion of HCF-level predictors) and drawbacks (cost, missing data) of obtaining medical records from multiple HCFs.

LAY SUMMARY

This study evaluated the feasibility of a method for obtaining patient medical records from multiple health care facilities (HCFs). This method is especially beneficial when a single HCF or system does not fully represent the group of people being studied or when the research is designed to include factors related to the HCFs themselves. The research was conducted within the context of a study on HIV prevention among 460 patients receiving care from 122 HCFs. After obtaining voluntary authorization from participants, medical records were obtained and analyzed. The response rate was 89%, with 343 medical records obtained. However, the process was time-consuming, and less than 20% of the received medical records were electronic. Health Information Exchanges (HIEs), which securely share patient electronic health information between hospitals, are not generally accessible for research purposes. Overall, the method was feasible but presented challenges, including some unattained records and relatively high costs. Recommendations for improving the method include creating a centralized database for tracking HCF requirements, implementing a proactive approach to authorization forms, and advocating for increased accessibility of HIE systems for research purposes. Researchers should carefully consider the potential benefits and drawbacks of obtaining medical records from multiple HCFs when designing their studies.

Key words: medical record procurement, health care facilities, medical research

INTRODUCTION

Patient medical records are increasingly utilized as a rich source of data contributing to many types of clinical, epidemiological, public health, and health services research.[1–3] Depending on the research question, it is frequently necessary to supplement medical record data with primary data collected from participants in the form of health surveys or additional biological measures.[4] Studies that combine medical record and primary data often first identify eligible study participants from the electronic health records (EHRs) of a single

health care facility (HCF) or integrated health system, then collect primary data from those patients who voluntarily enroll in the study. [4] Although appropriate in many situations, there may be circumstances in which this recruitment and data collection approach is not appropriate or optimal—for example, when the centralized EHR sampling frame is not representative of the target population resulting in limited generalizability[3,5,6] or when the study objectives include testing HCF-level predictors across multiple HCFs.[7,8] Under such circumstances, other methods are required to acquire a more representative sample of the target population or to obtain data from patients receiving care at multiple HCFs.

In this article, we describe such a method employed in a prospective cohort study examining the use and clinical management of HIV pre-exposure chemoprophylaxis (PrEP) across multiple HCFs in a large metropolitan area (New York City). Rather than first identifying patient medical records from a centralized EHR sampling frame and then collecting primary data from these patients, we recruited a representative sample of community-dwelling patients from which we first collected primary data, then obtained authorization to access participant medical records from the HCFs at which they were receiving care. Study participants' medical records were then obtained across these multiple HCFs and integrated with primary data. The purpose of this article is to describe this method and assess its feasibility and challenges and provide recommendations to enhance its efficiency.

MATERIALS AND METHODS

The medical record procurement approach described here was employed in a 5-year prospective cohort study, entitled the Magnetic Couples Study, designed to examine patterns and multi-level determinants of HIV oral PrEP utilization and clinical management among HIV-serodifferent heterosexual couples (couples in which one member is HIV-negative and the other is living with HIV). The Magnetic Couples Study protocol has been described in detail elsewhere[9] and was approved by the University of Rochester Institutional Review Board (STUDY00000568). Briefly, the study cohort consisted of 230 HIV-serodifferent couples (460 individuals) recruited through dissemination of study materials (eg, pamphlets and posters), passive referral from HCFs, social media (eg, Facebook and Twitter), advertisements (newspapers, magazines, subway signs, and radio), and peer-referral. Eligible couples were adults age 18 years and older in a primary sexually active HIV-serodifferent relationship (test confirmed), with the HIV-negative partner receiving PrEP care from their HCF at the time of enrollment. Eligible couples were invited to visit a research facility at which they were individually enrolled, screened for HIV, administered a health survey, and for the HIV-negative partner, administered a blood draw for quantification of PrEP blood levels and serum creatinine. Couples were observed for 18 months with research assessments conducted quarterly. In addition, participants were asked to voluntarily authorize access to their medical records from the HCF at which they were receiving care.

Collection of medical record data from both members of each couple was critical to addressing important research questions related to health care utilization and clinical management of HIV-negative partners receiving PrEP care and partners with HIV receiving antiretroviral therapy. For example, PrEP use and adherence by the HIV-negative partner could be affected by whether the HIV-positive partner maintained an undetectable HIV viral load, data that can be obtained from medical records. Thus, each enrolled participant was asked to voluntarily provide Health Insurance Portability and Accountability Act (HIPAA) authorization to release their medical records from their HCF delivering PrEP care (for HIV-negative participants) or antiretroviral therapy (for participants living with HIV). Participants were explicitly told that signing the authorization form was strictly voluntary and that declining to release medical record data would have no impact on their participation in the study or on the compensation they would receive—each participant was paid $75 USD per assessment visit. Authorization forms (DOH-2557; NYS OCS-960) were completed and signed at intake and updated at follow-up assessment visits in case there were any changes. HIPAA forms were held until a participant's terminal follow-up visit; authorization forms along with a written request to release medical records covering the preceding 36 months (18 months prior to enrollment plus 18 months during study enrollment) were then submitted to their HCF.

HIPAA forms were accompanied by a request letter that contained study contact information in case there were issues with the request. Requests were marked "Attention: Health Information Management" or "Attention: Medical Records." All HCFs had a separate department and/or specific person handling medical records. Each HCF required HIPAA forms to be completed in a particular manner. For example, some required a physician's name to be included on the form whereas other HCFs rejected forms with physician names. In addition, each HCF required HIPAA forms to be submitted in a specific way: the majority preferred documents to be faxed, some others required postal mail requests, and a few accepted email requests. HCFs sometimes charged fees for medical record handling and dispatch. Therefore, each HCF was contacted before the request was sent to document fees and ensure that records were requested in the proper manner. Maintaining a separate database of HCF contacts, procedures, and form requirements was essential for efficient medical record attainment. Medical record requests, follow-ups, and receipts were originally tracked using a shared Excel spreadsheet, but this approach was soon found to be inefficient; tracking was therefore transferred to a shared relational database programmed in FileMaker Pro (ver. 19, Claris), which allowed for more customized data queries and report generation. Follow-up phone calls or emails were dispatched if medical records were not received within 4–6 weeks; requests were resent as necessary.

To assess the feasibility of obtaining medical record data across multiple HCFs from a community sample of participants enrolled in a prospective health study, we compiled data on three dimensions of feasibility—participant acceptability, HCF compliance, and practicality.[10] Acceptability was measured as the proportion of participants who willingly volunteered to provide authorization for releasing their medical records; compliance was measured as the proportion of HCFs that provided the requested medical records; practicality was assessed by examining the efficiency of procurement management, resources in staff time, and monetary costs involved in carrying out the procedures. In addition, data were collected on the number and type of HCFs from which medical records were requested and the proportion and types of media used to convey medical records. Descriptive analyses

were performed on these data (eg, mean, range, proportion). Further analyses were conducted to examine differences between participants from whom medical records were obtained versus not obtained by selected demographic variables and HCF type.

RESULTS

A flow chart summarizing medical record procurement results for the Magnetic Couples Study is presented in Figure 1. All 460 participants enrolled in the study voluntarily agreed to sign the authorization forms at intake. Despite all study participants initially volunteering to sign medical record release forms, two primary obstacles resulted in 117 (25%) unattained medical records: loss to follow-up prior to updating the release forms, which accounted for 81 of 117 (69%) unattained records, and denials or nonresponse from HCFs, which accounted for the other 36 of 117 (31%) absent records. Table 1 provides data on selected demographic variables describing the study sample, overall and by medical record procurement status. No statistically significant differences (at $\alpha = .05$) were found on these variables comparing participants
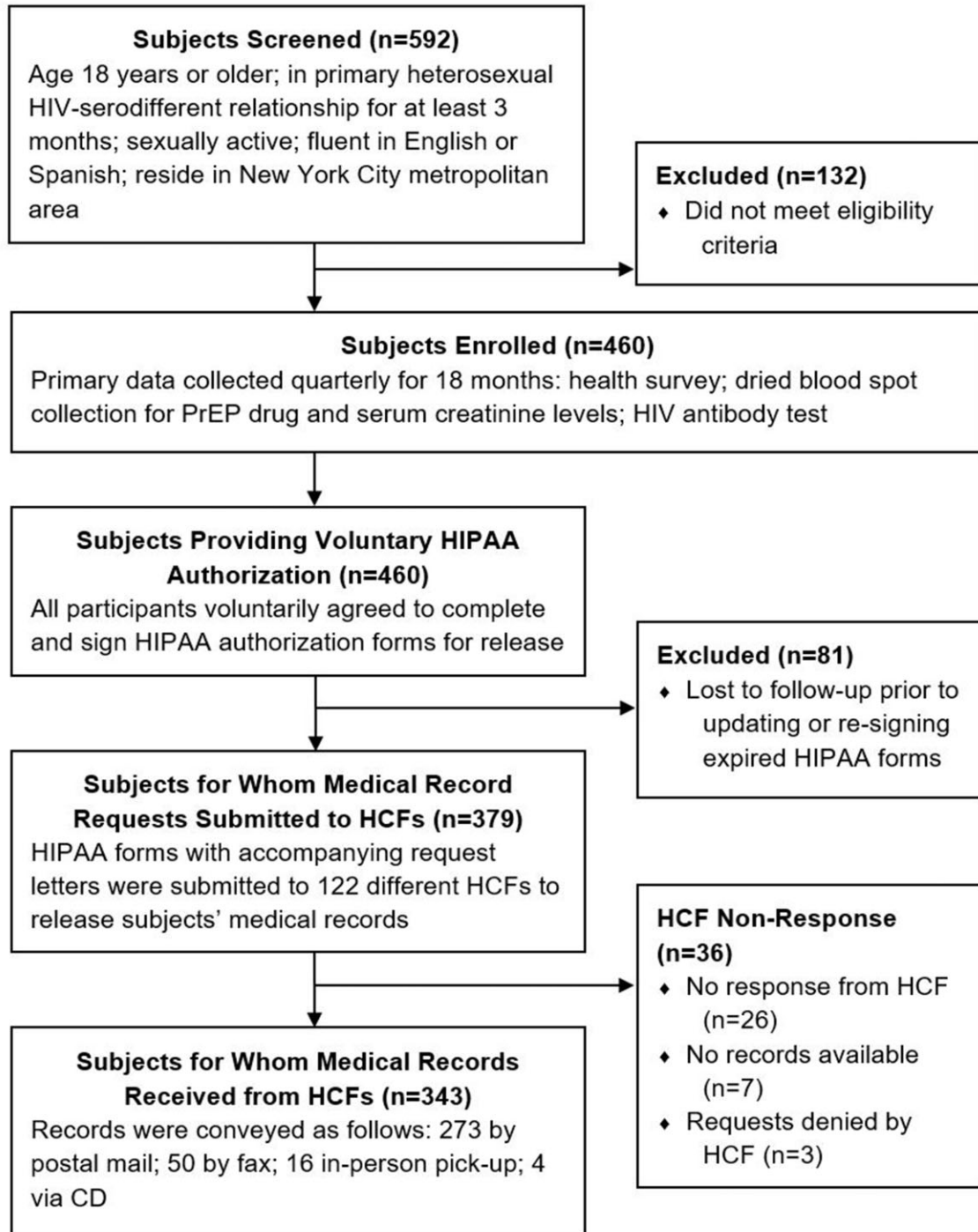

Figure 1. Magnetic Couples Study flow chart for procurement of subject medical records from multiple health care facilities.

Table 1. Selected sample characteristics: total and by medical record procurement

Variable[a]	Total (N = 460[b])	Medical records obtained (n = 343[b])	Medical records not obtained (n = 117[b])	Test statistic (P value)[c]
Sex				
Male	230 (50.0)	174 (50.7)	56 (47.9)	
Female	230 (50.0)	169 (49.3)	61 (52.1)	0.29 (.591)
Age	48.14 (11.5)	48.71 (10.8)	46.47 (13.3)	3.32 (.069)
Race				
Black/African American	332 (72.6)	252 (74.1)	80 (68.4)	
White	59 (12.9)	45 (13.2)	14 (12.0)	
Other	66 (14.4)	43 (12.6)	23 (19.7)	3.14 (.208)
Latinx/Hispanic				
Yes	135 (29.5)	94 (27.6)	41 (35.0)	
No	322 (70.5)	246 (72.4)	76 (65.0)	2.29 (.130)
Education				
Did not complete high school	161 (35.2)	121 (35.6)	40 (34.2)	
Completed high school (or GED)	253 (55.4)	188 (55.3)	65 (55.6)	
Completed college or higher	43 (9.4)	31 (9.1)	12 (10.3)	.190 (.909)
Income (USD, monthly)	1068 (785)	1040 (677)	1148 (1039)	1.63 (.202)
HIV status				
Negative	230 (50.0)	175 (51.0)	54 (46.6)	
Positive	230 (50.0)	168 (49.0)	62 (53.4)	.573 (.449)

[a] All variables report number (percentage), except age and income which report mean (SD).
[b] Sample size, unless otherwise indicated.
[c] Test of difference between obtained versus not obtained medical records. *T* test for age and income; Chi-square test for all others.

whose medical records were obtain (n = 343) with participants whose medical records were not obtained (n = 117).

Our intent was to submit each authorization form to the appropriate HCF after a participant completed their terminal 18-month follow-up assessment. However, in New York State, HIPAA authorization forms are only valid for 12 months from the date of signing. We thus implemented a procedure in which participants were asked to report any changes to their HIPAA forms at each assessment, and reapprove and resign HIPAA forms that had been updated or were older than 12 months. Nonetheless, 81 participants were lost to follow-up before their HIPAA forms could be updated and re-signed, resulting in a total of 379 medical record requests sent to HCFs. Several unforeseen events contributed to unattained medical records due to loss to follow-up. COVID-19 lockdown policies toward the end of the study and delays in sending medical record requests due to a severe winter storm on the East Coast during the December 2020 holiday season resulted in several additional expired release forms. Repeated attempts were made to contact participants with outdated or expired forms and many did not respond, or their contact information had changed, while others were deceased; other participants who were lost to follow-up declined to update their HIPAA forms because they were no longer participating in the study.

Of the 379 requests sent to HCFs, 343 medical records were received (90.5% response rate). Three requests were denied, 7 had no records available, and 26 requests met with no response. Medical records were received from 122 HCFs within the New York City metro area, including 28 hospitals, 63 community-based clinics, 18 specialty clinics (eg, HIV/AIDS, addiction treatment, etc.), 12 private clinics, and 1 community-based organization (CBO). Of the 122 HCFs, 16 were umbrella organizations and networks with hospital and/or community-based extension clinics within local neighborhoods throughout the five NYC boroughs. Table 2 presents the number (and percentage) of medical records received versus not received out of the 379 requests sent to HCFs,

Table 2. Health care facility type by medical records received versus not received

HCF type	Medical records received (n = 343)[a]	Medical records denied or nonresponse (n = 36)[a]	Chi-square (P value)
Hospital or Medical Center	70 (20.4)	10 (27.8)	1.83 (.412)[b]
Community Health Facility	185 (53.9)	17 (47.2)	
Specialty Clinic	71 (20.7)	5 (13.9)	
Private Clinic	16 (4.7)	2 (5.6)	
CBO	1 (0.3)	2 (5.6)	

[a] Number (percentage).
[b] Due to small cell sizes, private clinics and CBOs were excluded from the Chi-square test.

categorized by HCF type. No statistically significant differences were found in procurement success across HCF types.

HCFs sent medical records in both paper and electronic form, with 80% received by postal mail and 15% received by fax through a dedicated online fax portal (eFax Corporate, Los Angeles, CA, USA). Approximately 5% of medical records had to be picked up directly from the HCF due to the length of the record. Several electronic records were also received on password protected CDs and secure email, with the passwords sent separately.

The costs incurred in implementing multi-HCF medical record data collection are summarized in Table 3 and include three main categories: (1) HCF fees, (2) postage and eFax services, and (3) research staff effort. Some HCFs charged fees for handling and sending medical records, mostly through third-party vendors. These fees ranged from $26 USD to $200 USD per medical record. Although postage costs were minimal, the cost of maintaining a HIPAA-compliant electronic fax transfer account that could handle large data transfers was $143 USD per month. Staff time involved obtaining and updating HIPAA authorizations from participants,

Table 3. Cost expenditure for medical record procurement (excluding data abstraction)

Expense type	Rate	Cost
HCF fees[a]	$95.55 ($26, $200) × 20 fees	$1911
Postage and FAX transfer costs	$143 per month × 48 months	$6864
Research staff time[‡]	860 h × $37.65 per h	$32 379
Total cost		$41 154
Cost per medical record procured	$41 160/343	$120

Note: [‡] includes benefits.
   [a] Mean (minimum, maximum).

contacting and documenting HCF procedures, sending and following-up on requests to HCFs, and receiving and managing medical records. On average, staff collectively spent about 2.5 h on each medical record obtained. In total, the average estimated overall cost to obtain each medical record was about $120 USD, with staff time accounting for the highest preponderance of this cost. These costs reflect medical record procurement only and do not include costs associated with data abstraction.

DISCUSSION

The selection of an appropriate sampling frame and recruitment and data collection approach involving integrated medical record and primary data should be informed by the study aims and target population. Given this directive, we did not quantitatively compare the multi-HCF method described here with EHR-based sampling methods. In our case, we designed our study to assess the effects of HCF-level predictors on study outcomes and, therefore, using an EHR sampling frame from a single HCF or system was not an option. An alternative approach would have been to select a random sample of HCFs from which to enroll eligible participants; but this approach could have introduced HCF self-selection bias, increased HCF administrative burden and cost, and posed challenges identifying members of our study population (HIV-serodifferent couples) within clinical settings. Even without the imperative of sampling from multiple HCFs, employing a sampling frame limited to patients receiving care at one or a few large health centers could potentially yield a nonrepresentative sample,[6] thus requiring an alternative approach, such as the one described here. A further benefit of this procurement method is the ability to continue to obtain medical record data longitudinally on participants who change HCFs during the study period.

In our study, it is notable that only a small proportion of medical records received from HCFs were in electronic form. This highlights the limited integration of research into the growing EHR interoperability landscape. Although 96% of acute care hospitals nationally have certified EHR technology and over 80% have adopted comprehensive EHR functionalities,[11] the benefits of these advancements have not yet translated effectively into research efforts. For example, the Statewide Health Information Network for New York (SHIN-NY) is a secure health information exchange (HIE) system, enabling nearly all hospitals statewide to share patient health information securely, but its access control and interoperability features restrict the availability of this data for research purposes.[12] Moreover, only about one in eight small

and independent HCFs participate fully in interoperability initiatives, limiting their representation in most HIE systems.[13]

Our findings indicate that obtaining medical record data from participants in our study receiving care across multiple HCFs was acceptable to participants and had relatively high compliance among HCFs. However, the multi-HCF procurement method was time-consuming for staff and relatively costly at $120 USD on average per medical record. Several inefficiencies or challenges in implementing the method were also documented, including heterogeneity of required formats of authorization forms and request policies across HCFs, participant loss to follow-up prior to updating HIPAA forms, and inaccessibility of medical records in electronic format.

Several recommendations can be made based on lessons learned implementing this multi-HCF medical record data collection approach. To manage the complexity of different authorization requirements across HCFs, we recommend creating a centralized database that tracks each HCF's specific requirements, contact information, and preferred submission methods. This database will streamline the medical record procurement process, improve efficiency, and ensure that requests comply with each HCF's unique protocols. Although HIPAA policies do not impose any specific time limit on signed authorizations, some states have imposed such expiration requirements. For example, in accordance with New York State policy, signatures on medical record release forms are valid for no longer than a period of 12 months. To address the issue of unattained medical records due to outdated HIPAA forms and participant dropouts, we recommend implementing a proactive approach to form management. This approach could involve (1) asking participants to update and resign their HIPAA forms at each follow-up visit, (2) establishing remote signing capabilities for those who miss in-person visits, and (3) submitting forms to HCFs prior to expiration for participants lost to follow-up, allowing for the collection of partial medical record data. While these measures may increase staff effort and participant burden, they could help to minimize the number of unattained medical records. However, researchers should carefully consider the ethical implications of requesting medical record data for participants who have dropped out of the study and develop strategies to address these concerns. The implementation of EHR portals, enabling patients to access their own medical records, is becoming increasingly widespread.[14] These portals present a potential alternative method for obtaining medical records directly from research participants. However, studies have shown that the adoption rates of EHR portals among patients are low to moderate,[15] particularly among older individuals, those with low income or education levels, those living in rural areas, or individuals of Black or Hispanic race/ethnicity.[16–19] A more effective approach would be to increase the accessibility of HIE systems for research purposes, which will require researchers to advocate for such access with stakeholders and policymakers.

Caution must be taken in regard to generalizing our findings to other populations and settings. Our study sample consisted primarily of low-income non-Hispanic Black (64%) and Latinx (29%) participants in heterosexual HIV-serodifferent relationships, and our high rate of voluntary agreement to sign HIPAA forms might not apply to other populations. Moreover, differences in state, local, and HCF policies regarding authorization to release medical records for

research purposes might vary resulting in additional implementation challenges.

This article focused on methods for procuring medical records from community-dwelling research participants receiving care across multiple HCFs. We did not describe methods employed for data abstraction because standard methods are already well-described in the literature.[20,21] However, it is noteworthy that 80% of medical records obtained were in paper form, perhaps not surprising given that most of the HCFs providing care to our participants were community-based clinics or private or specialty practices. Nonetheless, this situation necessitated substantial resources devoted to data extraction and entry. Obviously, working with all or mostly electronic medical records, while it has its own challenges,[2] would be more efficient.

CONCLUSION

Our findings demonstrate the feasibility and challenges of obtaining medical record data from multiple health care facilities providing care to a community-based research sample. In our prospective cohort study, we successfully attained medical records for 75% of the sample. The primary reasons for unattained records were participant loss to follow-up and HCF denials or nonresponse. The medical record procurement rate using this approach will vary depending on the proportion of participants who provide HIPAA authorization, state and local policies regarding expiration of HIPAA forms, study attrition rate, and HCF denial or nonresponse rate. Researchers should carefully consider these factors when integrating primary data with medical record data collected from multiple HCFs. It is essential to weigh the benefits, such as a representative sample of the target population and inclusion of HCF-level predictors, and drawbacks, which include extensive staff effort, cost, and potential for missing data, when adopting this sampling, primary data collection, and medical record procurement approach.

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AUTHOR CONTRIBUTIONS

JMM conceived of the study, with assistance from JEH, and led the development of the manuscript. JMM, JEH, LT, and JB designed the data procurement approach. LT and RQ implemented the procurement protocol and collated aggregate data. JB designed and created the procurement data capture program. JB, EP, and ER managed medical record acquisition and abstraction and collated aggregate data. HFC performed data analysis and data reporting. All authors developed and revised the manuscript.

CONFLICT OF INTEREST

None declared.

DATA AVAILABILITY

The data underlying this article will be shared on reasonable request to the corresponding author.

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