

HIV Knowledge, Beliefs, Attitudes, and Practices of Providers in the Southeast
(K-BAP Study)

Supporting Statement A

OMB# 0920-New

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- **Goal of the study:** The goal is to identify areas of HIV prevention knowledge and practice strengths and deficits among primary care providers, in order to target limited HIV prevention resources to achieve the greatest reduction in new HIV infections and optimize HIV care in clinical settings.
- **Intended use of the resulting data:** The intended use of the resulting data is to identify the domains of HIV prevention and treatment where primary care providers are most likely to have deficits in their knowledge, attitudes, behaviors, and practices regarding HIV care. Knowledge of these deficits will allow the CDC to address specific, focused areas of improvement, so these providers can provide the best possible care to their patients at high risk of HIV and those who are already HIV positive, managing their illness and limiting the spread of new infections.
- **Methods to be used to collect:** An internet-based survey will be conducted among a representative random sample of providers in the selected six (6) metropolitan statistical areas (MSAs) with the highest HIV burden among the African American population. The survey findings will be used to identify provider K-BAP that might require additional educational reinforcement.
- **The subpopulation to be studied:** The primary target audience is primary care providers practicing in MSAs with highest HIV burden among African American populations (Baton Rouge, LA; New Orleans-Metairie-Kenner, LA; Baltimore-Columbia-Towson, MD; Atlanta-Sandy Springs-Roswell, GA; Miami-Fort Lauderdale-West Palm Beach, FL; and Washington, DC-VA-MD-WV).
- **How data will be analyzed:** Statistical analysis of quantitative survey data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention, (DHAP) requests a 1-year OMB approval for a new study entitled “HIV Knowledge, Beliefs, Attitudes, and Practices of Providers in the Southeast (K-BAP Study).” The proposed study will evaluate Primary Care Providers’ knowledge, beliefs, attitudes, and practices, (K-BAP) in six of the Metropolitan Statistical Areas (MSAs) with the highest HIV burden in African American population: Baton Rouge, LA; New Orleans-Metairie-Kenner, LA; Baltimore-Columbia-Towson, MD; Atlanta-Sandy Springs-Roswell, GA; Miami-Fort Lauderdale-West Palm Beach, FL; and Washington, DC-VA-MD-WV. These areas also have populations comprised of over 20% African Americans, one of the most vulnerable populations in the U.S. One of the goals of the National HIV/AIDS Strategy is to “reduce HIV-related health disparities”¹. The Southern United States has been disproportionately affected by HIV. Over the past seven years or more, a group of nine Southern states have experienced higher HIV incidence, as well as lower HIV and AIDS survival proportions, than the U.S. overall². Throughout the U.S., African Americans are the racial group most burdened by HIV: they comprise 44% of new HIV infections³, and 44% of all persons living with HIV⁴, despite representing just 13.2% of the US population⁵. The rates at which African Americans with HIV infection are diagnosed, linked and retained in care, prescribed antiretroviral therapy (ART), and achieve viral suppression are all lower than those for their White (and, in many of these categories, Hispanic/Latino) counterparts⁶.

Primary care providers (PCPs) in high-prevalence geographic areas could substantially reduce new HIV infections among the patient populations they serve. Primary care providers have the capacity to perform STD/HIV testing, and to prescribe medication with appropriate clinical follow-up. For many of the most vulnerable patients, primary care providers may be the only healthcare professionals they interact with. A review of the literature indicates that there is no regional data available on primary care providers' knowledge, beliefs, attitudes, and practices (K-BAP) relating to HIV prevention and treatment in high-prevalence regions.

Individuals who do not know their HIV status, as well as those with limited access to healthcare, are unlikely to seek healthcare services from HIV specialists. Rather, it is primary care providers who are most likely to have the opportunity to provide HIV testing, prevention counseling, and early treatment to at-risk individuals. A review of the literature found that PCPs often miss opportunities to discuss risk reduction and prevention with persons living with HIV and persons at risk for HIV acquisition^{7 8 9 10}. Thus, it is critical to understand the gaps in PCP knowledge of HIV prevention, and to strategically target limited prevention resources to improve PCPs' HIV-related K-BAPs.

To date, no surveys or other studies examining primary care provider's HIV K-BAPs have been conducted in the regions that are most at risk. The Division of HIV/AIDS Prevention's Team Leader on Minority Health has made this issue a priority.

2. Purpose and Use of Information Collection

The intended use of the resulting data is to identify the domains of HIV prevention and treatment where primary care providers are most likely to have deficits in their knowledge, attitudes, behaviors, and practices regarding HIV care. Knowledge of these deficits will allow the CDC to address specific, focused areas of improvement, so these providers can provide the best possible care to their patients at high risk of HIV and those who are already HIV positive, managing their illness and limiting the spread of new infections.

One way in which providers may improve their K-BAPs is by participating in relevant Continuing Education (CE) courses. Therefore, participants with specific K-BAP deficits will receive an offer of free, optional CE courses (**Attachment 4**) that would be of most value to that specific provider. A second survey, composed of core K-BAP questions from the first survey, administered six months after the first survey, will be able to identify if the CE courses had any impact in improving the quality of care given to HIV at-risk and HIV positive patients. This will help evaluate which CE courses and topics have the most beneficial effect on patient care. This will be very valuable in planning future CDC efforts to improve the quality of primary care providers in preventing and treating HIV, and could limit the spread of HIV in at-risk patients.

Furthermore, the resulting data will allow CDC to identify if and to what extent that that current CE modules available to primary care providers are helpful in addressing these identified deficits. In contrast, not having this resulting data would leave a critical void in ultimately developing guidance recommending HIV care training needs for primary care physicians. This void would further develop

impactful programs needed to address the goals of the National HIV/AIDS Strategy for the United States, particularly as it applies to jurisdictions with the highest HIV burden among African Americans.

Data have never been collected from primary care providers in these regions on this critically important topic. Information collected from this survey will be used by CDC stakeholders to understand specific deficits in primary care providers' HIV prevention and treatment practices for the most at-risk members of the public. From there, continuing education materials can be tested for their impact in improving PCPs' efforts in preventing and treating HIV.

Results from the proposed study will be widely disseminated and used by CDC researchers, administrators, and policymakers to understand primary care providers' role in preventing and treating HIV among the most vulnerable members of the public. Specifically, results will be shared with the DHAP as well as clinicians, administrators, and policymakers who study HIV prevention. The CDC DHAP is responsible for investigating and promoting HIV/AIDS prevention.

3. Use of Improved Information Technology and Burden Reduction

The proposed study will use information technology to 1) distribute the data collection instrument via online surveys, 2) to access web-based Continuing Education (CE) medical training for participants, and (3) send participants email reminders to complete requested data collection activities. The online surveys (Attachment 9a, 9b) will be accessed by the participants via web hyperlink. Data for constructing the sampling frame originate from Healthcare Data Solutions' ProviderPro database, which includes full contact information for all health care providers in the targeted geographic areas, including physical address, phone, and e-mail address. The study will involve a test/re-test methodology with a 30 minute baseline survey (includes a 1-minute verification screener) about providers' knowledge, beliefs, attitudes, and practices about HIV prevention and care practices (**Attachment 3a, 9a**).

After the baseline survey, respondents will be provided with a web hyperlink to optional Continuing Education (CE) credits regarding HIV care and prevention. Six months after the initial survey, respondents will be asked to complete a 20-minute follow-up survey (includes a 1-minute verification screener) consisting of core questions from the baseline survey (**Attachment 3b, 9b**). The follow-up survey will help identify if using the HIV CE-materials improved deficits in provider K-BAPs regarding HIV prevention and treatment. This will help determine the usefulness of the online CEs in lowering the risk of HIV infections in high risk regions.

The web is the most efficient way to collect survey responses, and study participants will be guided to a website to complete the survey.

In addition to the online surveys and web-based CE courses, participants will receive email reminders to take baseline and follow-up surveys at designated time points during the data collection period. The email reminders (**Attachment 5f**) will be customized to each provider, including using their name in the introduction of the email and in the subject line, and using the

practice name in the body text. The use of email reminders is an efficient way to increase response rates while minimizing time and cost burden to public.

4. Efforts to Identify Duplication and Use of Similar Information

Primary care providers (PCPs) have the capacity to perform STD/HIV testing, and to prescribe medication with appropriate clinical follow-up. For many of the most vulnerable patients, primary care providers may be the only healthcare professionals they interact with. A review of the literature has identified *no* studies aimed at identifying the gaps of primary care provider HIV-related knowledge, beliefs, attitudes, and practices within the six target MSAs. This K-BAP survey aims to address this research gap. Since data have never been collected from primary care providers in these regions on this critically important topic, information collected from this survey will be used by CDC stakeholders to understand specific deficits in primary care providers' HIV prevention and treatment practices for the most at-risk members of the public. Assessment of the HIV-related K-BAP among HIV specialists has found that, even among providers whose area of focus is HIV treatment, awareness of the efficacy, and use of Pre-Exposure Prophylaxis (PrEP) for HIV infection is limited^{11 12}. Data that provide us information regarding primary care providers' HIV-related K-BAPs can only be obtained through primary data collection.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Primary care physicians (PCPs) visited by black patients were significantly less likely to be board certified and to report being unable to provide high-quality care to all of their patients than PCPs visited by White patients¹³. These findings underscore the importance of building the HIV prevention and treatment capacity of PCPs who work with African American patients. Increasing the rate at which PCPs effectively provide HIV prevention, testing, and treatment to high-risk patients is critical in reducing the rates of HIV in the African American populations hardest hit by the epidemic. However, studies show that often, individuals at high risk for HIV do not receive any HIV prevention messages or discussion around testing when they visit their primary care providers^{14 15}. Without a better understanding of what PCPs know, what they need to know, and what they do, we lack a clear picture of how best to target the limited resources available for training PCPs in building their capacity to alleviate the burden of HIV among vulnerable patients.

If the proposed study is not conducted, we will be unable to estimate primary care providers' ability to prevent and treat HIV in the areas with the highest rates of new infections in the nation. HIV will continue to spread amongst the most vulnerable population in the United States when it could be prevented. The outcomes of this study will be used to plan how best to increase primary care providers' awareness of HIV, ability to talk with their patients about HIV prevention, as well as potentially identify HIV positive patients and route them to needed care and treatment.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CRF 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day federal register notice to solicit public comments was published in the Federal Register on 03/24/2016, Volume 81, Number 57, Pages 15725-15726 (Attachment 2). A public comment was received and CDC's standard response was sent (attachment 2a).

Consultations were conducted prior to the development of this proposed project with researchers and public health professionals experienced in field of HIV prevention and care among African Americans living with HIV.

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9. Explanation of any Payment or Gift to Respondents

In the proposed study, participation will be encouraged with the token of appreciation of \$20 cash for providers who complete the study. This small cash token of appreciation will be used to increase the response rate which will reduce the burden on other providers to complete the survey, lower survey costs, and still allow for enough data collection to perform rigorous statistical analyses. We have selected the use of a token of appreciation, and the amount of \$20, based on the literature and our previous research with providers¹⁶. Research shows that offering nominal cash tokens of appreciation (<\$50) to providers recruited to complete online surveys yields greater response rate and decreased response time compared provider online surveys that offered no cash tokens of appreciation¹⁷.

In a previous, similar study of HIV specialist providers (CDC's HIV Medical Monitoring Project, OMB #0920-0740) the use of \$20 cash as a token of appreciation resulted in a 64% response rate, as opposed to the typical 5% to 10% response rate seen in health care providers without a token of appreciation. The token of appreciation presents no known risks or expected discomfort associated with taking the survey. The use of tokens of appreciation in the proposed study is even more important as Primary Care Providers may be less inclined to participate as the subject matter is outside of their daily care routine.

This small cash token of appreciation will be used to increase the response rate which will reduce the burden on other providers to complete the survey, lower survey costs, and still allow for enough data collection to perform rigorous statistical analyses.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC NCHHSTP Privacy and Confidentiality Review Officer has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection. The proposed primary care provider survey does not involve the collection of personally identifiable information (PII) or data elements from participants. CDC will receive de-identified data from the contractor, no names or PII will be received by CDC nor stored in a system of records at CDC.

The collected data will be compiled from the provider survey into a dataset with a data dictionary using commercially available SAS Institute Inc. (SAS) © software. The data will be stored on Altarum computers using whole-disk encryption. Additionally, Altarum hosts all survey data on the Altarum Secure Network (ASN), which is a highly secure network used to store CDC, Department of Defense (DoD), and Veterans Administration (VA) data. The ASN is firewalled from outside access and requires two-factor authentication by select Altarum employees. The datasets shall be delivered to the CDC Project Officer(s) on a monthly basis, using a secure method of data transfer consistent with CDC Information Technology Security protocols. The data will be stored on Altarum computers using whole-disk encryption.

Privacy will be maintained to the extent allowable by law. When participants login into the online survey, they will receive the same message letting them know their responses will remain private. Individuals that will be calling non-respondents to remind them about the survey will read the same privacy statement in the letter and email contacts to the respondent. All collected data will be maintained on the Altarum Security Network (ASN). The ASN is a secure network segment/enclave of systems used for collecting, storing, and manipulating sensitive (i.e., protected health information (PHI) and personally identifiable information (PII)) data used in analyses. The storage of such data must meet all applicable security requirements (**Attachment 8**). The ASN is used for contracts where security and controlled network access are key requirements. Once data are collected from participants, PII and PHI (though minimal) are immediately de-linked from dataset. All PII and PHI are held securely within the ASN. At the end of the contract, or no later than December 2020 after completion of data cleaning and analyses, Altarum will securely erase all PII, PHI and survey responses from ASN.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The protocol for K-BAP Study has been reviewed by CDC and approved by Chesapeake IRB (<https://www.chesapeakeirb.com>), a third-party review board accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) (**Attachment 6**). The IRB-approved surveys are included as **Attachments 3a and 3b**. The survey contains questions

about providers’ knowledge, beliefs, attitudes, and practices surrounding HIV prevention and care. Participants will be notified that their participation is voluntary and their name will never be linked to their survey responses. Privacy will be maintained to the extent allowable by law. In turn, all results will be presented as aggregates and not as individual responses. Obtaining written informed consent from all eligible participants would be cost and time prohibitive. We will provide study information to the participants in the email recruitment letter (**Attachment 5a**) and consent cover letter (**attachment 5e**). By replying affirmatively to the recruitment email, the participant is giving their consent.

Sensitive Questions

While HIV is a sensitive subject matter, the questions are not about the respondent’s health, but rather about elements of their profession, training, and practices as health care providers. Participants will be notified that their participation is voluntary and their name will never be linked to their survey responses. In turn, all results will be presented as aggregates and not as individual responses.

12. Estimates of Annualized Burden Hours and Costs

The estimate of annualized burden hours for this data collection is 1,219 hours; details are provided in Table A12.1. For the proposed data collection, approximately 4,338 primary care providers will be recruited. Among these recruited providers, approximately 36% will be physicians, 36% will be nurse practitioners, and 28% will be physician assistants.

Of the 4,338 providers contacted for recruitment, we anticipate a 42% response rate for those that choose to opt-in the survey for estimated total of 1,827 participants. We anticipate the baseline screener and the baseline survey (**attachment 3a, 9a**) will take 30 minutes per respondent for a total of 883 burden hours. We anticipate that approximately half of respondents (about 914 respondents) who completed baseline survey will complete six-month follow-up survey. Follow-up screener and the follow-up survey (**attachment 3b, 9b**) will take approximately 20 minutes per respondent for a total of 289 burden hours. The total number of burden hours is 1,219 burden hours. The annualized cost to respondents for the burden hours is estimated to be \$73,156; details are provided in Table A12.2.

Table A12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Providers	K-BAP Provider Baseline Screener and Survey (Attachment 3a, 9a)	1827	1	30/60	914

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Providers	K-BAP Provider Follow-Up Screener and Survey (Attachment 3b, 9b)	914	1	20/60	305
Total					1219

Table A12.2 Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate†	Total Respondent Costs
Physicians	K-BAP Provider Baseline Screener and Survey (Attachment 3a, 9a)	318	\$91.60	\$29,129
Nurse Practitioners	K-BAP Provider Baseline Screener and Survey (Attachment 3a, 9a)	318	\$45.84	\$14,577
Physician Assistants	K-BAP Provider Baseline Screener and Survey (Attachment 3a, 9a)	247	\$46.07	\$11,379
Physicians	K-BAP Provider Follow-Up Screener and Survey (Attachment 3b, 9b)	105	\$91.60	\$9,618
Nurse Practitioners	K-BAP Provider Follow-Up Screener and Survey (Attachment 3b, 9b)	105	\$45.84	\$4,813
Physician Assistants	K-BAP Provider Follow-Up Screener and Survey (Attachment 3b, 9b)	79	\$46.07	\$3,640
Total				\$73,156

13. †http://data.bls.gov/cgi-bin/print.pl/oes/current/oes_nat.htm

The estimates of hourly wages were obtained from the U.S. Department of Labor (Bureau of Labor Statistics Wage Data-http://data.bls.gov/cgi-bin/print.pl/oes/current/oes_nat.htm).

14. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents associated with this proposed collection of information.

15. Annualized Cost to Government

The annual cost to the government is \$349,000.

16.

17. Exhibit A14.1: Annualized Cost to Government

Expense Type (Based on FY14 dollars)	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	K-BAP Project Personnel	
	Behavioral Scientist – GS-13 40%	\$43,000
	Medical Epidemiologist - CC O-6 5%	\$8,000
	Health Scientist – GS-12	\$8,500
	Site Visit (1 trip x 3 staff)	\$4,500
	Total direct costs to federal government	\$64,000
Contractor and Other Expenses* (Funding Contract#: GS-10F-0261K)		
	Salary/wages, supplies/materials, and other contractual services (Altarum Institute)	\$285,000
	Total contractor and other expenses	\$285,000
	TOTAL COST TO THE GOVERNMENT	\$349,000

Federal government salary estimates were obtained from OPM salary scale (<http://www.opm.gov>) and the United States Public Health Service Commissioned Corps website (<http://dcp.psc.gov>).

The personnel related to the K-BAP Project data collection include project officers (medical epidemiologist, behavioral scientist, and health scientist) at the Commissioned Corps O-6, GS-13 and GS-12 levels, respectively.

18. Explanation for Program Changes or Adjustments

19. This is a new data collection.

20. Plans for Tabulation and Publication and Project time Schedule

21. Data collection will be conducted during the 3-year period after OMB approval. Data analysis will occur within 6 months of final data collection. The following is a brief overview of the K-BAP Project Timeline.

22.

23. Exhibit 16.A Project Time Schedule

Activity	Time Schedule
Initiate recruitment	Immediately after OMB approval
Conduct Baseline Data Collection	1 month – 5 months after OMB approval
Conduct Follow-Up Data Collection	7 months – 11 months after OMB approval
Data management	1 month – 2 years after OMB approval
Analysis	Within 6 months of project completion
Publication	Within 12 months of project completion

24. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

25. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

¹ Office of National AIDS Policy. National HIV/AIDS strategy for the United States. Washington, DC: Office of National AIDS Policy; 2010. Available at <http://aids.gov/federal-resources/national-hiv-aids-strategy/nhas.pdf>.

² Reif, S., Wells Pence, B., Hall, I., Hu, X., Whetten, K., & Wilson, E. (20

³ CDC. Estimated HIV incidence in the United States, 2007-2010. HIV surveillance supplemental report 2012; 17(4). Atlanta, GA: US Department of Health and Human Services, CDC. Available at http://www.cdc.gov/hiv/pdf/statistics_hsr_vol_17_no_4.pdf

⁴ CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data: United States and 65 U.S. dependent areas—2011. HIV surveillance supplemental report, 2013. 18(5). Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at <http://www.cdc.gov/hiv/library/reports/surveillance>

⁵ United States Census Bureau. 2014. Available at: <http://quickfacts.census.gov/qfd/states/00000.html>

⁶ Hall, H.I., Frazier, E.L., Rhodes, P., Holtgrave, D.R., Furlow-Parmley, C., Tang, T., Mahle Gray, K., Cohen, S.M., Mermin, J., & Skarbinski, J. (2013). Differences in Human Immunodeficiency Virus care and treatment among subpopulations in the United States. *JAMA Internal Medicine*; 173(14):1337-1344.

⁷ Dorell, C.G., Sutton, M.Y., Oster, A.M., Hardnett, F., Thomas, P.E., Gaul, Z.J., Mena, L.A., & Heffelfinger, J.D. (2011). Missed opportunities for HIV testing in health care settings among young African American men who have sex with men: Implications for the HIV epidemic. *AIDS Patient Care STDS*, 25(11): 657-664.

⁸ Nakao, J.H., Wiener, D.E., Newman, D.H., Sharp, V.L., & Egan, D.J. (2014). Falling through the cracks? Missed opportunities for earlier HIV diagnosis in a New York City Hospital. *International Journal of STD & AIDS*; 25(12): 887-893.

⁹ Centers for Disease Control and Prevention (CDC). (2006). Missed opportunities for earlier diagnosis of HIV infection—South Carolina, 1997-2005. *MMWR Weekly Report*; 55:1269-1272.

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¹¹ Tellalian, D., Maznavi, K., Bredeek, U.F., & Hardy, W.D. (2013). Pre-exposure prophylaxis (PrEP) for HIV Infection: Results of a survey of HIV Healthcare Providers evaluating their knowledge, attitudes, and prescribing practices. *AIDS Patient Care and STDs*; 27(10): 553-559.

¹² Mimiaga, M.J., White, J.M., Krakower, D.S., Biello, K.B., & Mayer, K.H. (2014). Suboptimal awareness and comprehension of published preexposure prophylaxis efficacy results among physicians in Massachusetts. *AIDS Care*; 26(6): 684-693.

¹³ Bach, P.B., Pham, H.H., Schrag, D., Tate, R.C., & Hargraves, J.L. (2004). Primary care physicians who treat blacks and whites. *The New England Journal of Medicine*, 351: 575-584.

¹⁴ Dorell, C.G., Sutton, M.Y., Oster, A.M., Hardnett, F., Thomas, P.E., Gaul, Z.J., Mena, L.A., & Heffelfinger, J.D. (2011). Missed opportunities for HIV testing in health care settings among young African American men who have sex with men: Implications for the HIV epidemic. *AIDS Patient Care STDS*, 25(11): 657-664.

¹⁵ Centers for Disease Control and Prevention (CDC). (2006). Missed opportunities for earlier diagnosis of HIV infection—South Carolina, 1997-2005. *MMWR Weekly Report*; 55:1269-1272.

¹⁶ Turnbull, A.E., O'Connor, C.L., Lau, B., Halpern, S.D., Needham, D.M. (2015). Allowing physicians to choose the value of compensation for participation in a web-based survey: randomized controlled trial. *Journal of Medical Interment Research*; 17(7): 1-10.

¹⁷

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