

Impact of Order Restrictions on Hemoglobin A1c Requests at Primary Health Care Centers in Riyadh, Saudi Arabia

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Purpose: The aim of the study was to assess the effect of policy intervention on the physician ordering of HbA1c for the patients seen at the primary health care center in Riyadh, Saudi Arabia.

Methods: The study included patients over the age of 18 for whom HbA1c tests were ordered before and after the policy restrictions were implemented at the three main Primary Health Care Centers under the Ministry of National Guard Health Affairs (MNGHA) in Riyadh, between October 2020 and August 2023. Several data management steps and restrictions were carried out to identify the patients seen before and after the intervention and controlled for the confounders. The outcome variable was inappropriate testing, and early testing was defined based on standard cutoffs of HbA1c, diabetic control, and patient history. The logistic regression analysis was used to identify predictors for early testing.

Results: Among 16,290 participants, the mean age was 50 ± 16 years, with a predominance of females (66.5%). Approximately 22.3% of participants were diabetic, and the mean HbA1c level was $6.2 \pm 1.55\%$. About 89.6% of tests were deemed inappropriate based on criteria for glycemic control, diabetic status, and duration of testing. Policy restrictions led to a 70.3% reduction in the odds of early testing (OR = 0.297, 95% CI: 0.246–0.358, $p < 0.001$). Each unit increase in HbA1c decreased the odds of early testing by 1.517 (OR = 0.219, 95% CI: 0.193–0.249, $p < 0.001$). Additionally, younger participants were more likely to undergo early testing, with odds decreasing by 3% for each additional year of age (OR = 0.970, 95% CI: 0.966–0.974, $p < 0.001$).

Conclusion: We conclude that policy restriction alone might not be effective in reducing the burden of early testing. The early testing tendency was less in the post-intervention period. However, early testing was a common practice in both pre- and post-intervention phases. As physicians are the ones ordering the tests, deeper insight is needed from the physician's perspective.

Keywords: HbA1c, policy, Saudi Arabia, laboratory-testing, physicians

Introduction

Diabetes mellitus is a major public health concern with a significant economic burden on countries all over the world.^{1,2} Saudi Arabia is among the top ten countries with the greatest prevalence of type 2 diabetes.³ According to the findings of a recent meta-analysis, the overall prevalence of type 2 diabetes in Saudi Arabia is 16.4%, and the overall prevalence is predicted to rise.^{4,5} In 2014, the Saudi healthcare expenditure was 47.98 billion US dollars, and approximately 6.66 billion US dollars were spent on the diabetic population alone. This indicates that diabetes costs Saudi Arabia approximately 13.9% of its total health expenditures.³ Currently, there is a growing pressure on healthcare budgets globally to cut costs while maintaining the quality of care.^{6,7} Considering that seventy to eighty percent of clinical decisions about diagnosis or therapy involve laboratory tests, appropriate utilization is crucial for ensuring patient care.⁸

Inappropriate laboratory utilization is defined as “any test ordered in violation of a guideline produced by a government or professional society”.⁹ If a test is ordered before the recommended duration, it is considered early testing and vice versa. Overutilization of laboratory tests may result in unneeded blood draws, the possibility of obtaining false-positive results, increased expenses, and worse outcomes due to unnecessary interventions.^{10,11} The “Choosing Wisely” initiative was launched in 2019 by the Saudi Arabian Ministry of Health in an effort to enhance patient care by reducing waste, unnecessary early testing, and procedures.¹² Hemoglobin A1c (HbA1c) is one of the many tests considered when diagnosing diabetes, evaluating the degree of disease control, and signaling medication regimen adjustments.^{1,13} Despite the significant increase in HbA1c testing, few studies have attempted to determine how the test is being utilized. In 2012, a study done in the UK showed that only 49% of requested HbA1c complied with UK NICE guidance documents for type 1 and type 2 DM.¹⁴ Additionally, there is consistent growth in the raw number of HbA1c tests with a noticeable shift in the early ordering pattern with the introduction of rapid repeat testing.¹⁵ In the year 2019, it was found that approximately 11% of the HbA1c tests that were requested were unnecessary. From March 2020 to January 2021, a total of 14,247 tests were conducted at a tertiary care academic hospital in Toronto, Canada, 11% of which were deemed unnecessary.¹⁶ According to the findings of a study that evaluated the appropriate request of six tests, including HbA1c, 16% of these six tests were inappropriately repeated. This represents an annual internal cost of between \$0.6 and \$2.2 million Canadian dollars.¹⁷ To reduce unnecessary ordering of HbA1c, interventions of restriction were applied to all orders of less than 90 days. This resulted in savings of \$145,422 in costs during the first 14 months of the provincial intervention.¹⁶

This study aimed at measuring the rate of the appropriateness of HbA1c test orders, pre-, and post-applying a restriction policy to assess the impact of this restriction in Primary Healthcare Centers (PHCs).

Methods

Study Design and Setting

We used a pre-post, open-label interventional study design from October 2020 to August 2023. The study included three primary health care (PHC) centers working under the Ministry of National Guard Health Affairs (MNGHA) in Riyadh, Saudi Arabia. All centers provide comprehensive and contentious outpatient medical care, including health promotion, disease prevention, patient education, diagnosis, and treatment of acute and chronic diseases.¹⁸ Out of the total nine MNGHA PHC centers located in the Riyadh region, three centers were selected using the cluster sampling technique, and all the ordering requests for HbA1c were followed before and after the intervention period for the selected centers. The three PHCs included the King Abdulaziz City Housing (Iskan Yarmouk) facility, the National Guard Comprehensive Specialized Centre (NGCSC), and the Health Care Specialty Centre (HCSC). Iskan Yarmouk clinics and HCSC serve Riyadh's eastern region, while NGCSC serves the city's northern region.

Intervention Details

The order of any laboratory test at the clinic is done via the electronic recording system called BEST Care ([Bundang Hospital Electronic System for Total Care], Seoul National University, South Korea).¹⁸ A policy restriction initiated by the MNGHA imposed restrictions for ordering HbA1c, preventing physicians from ordering it at intervals of less than 3 months. From October 2020 to April 2022 due to some technical issues, the restriction was inactivated, and physicians were able to order the test at any time interval. Since the ordering restrictions were not operational, this period was taken as a reference pre-interventional policy period. The post-restriction policy period was from May 2022 to August 2023.

Outcome Variable and Duration of Testing

The outcome variable was the appropriateness of the duration between the two test durations. The American Diabetes Association guidelines were used to define the appropriateness of requested orders.¹⁹ As per the guidelines in a normal population, screening for diabetes should start at the age of 35 years. The test should be repeated after 3 completed years (1095 days) unless the patient develops new symptoms or acquired risk factors. In pre-diabetic patients (HbA1c 5.7–6.4), the test should be repeated annually (365 days).¹⁹ In diabetic patients, the interval of testing depends on the diabetic control; for patients who are meeting treatment goals, it should be every 6 months (180 days) and at 3 months (90 days)

for patients who are not meeting glycemic goals.¹⁹ The appropriate HbA1c goal for many non-pregnant adult females without significant hypoglycemia is <7%.¹⁹

For defining the outcome variable, several data management steps were taken. There were patients who were tested multiple times during the study period, in order to control the measurement bias and confounding, only those who had been tested twice during the study period were included for final analysis. The duration of days between the two orders was calculated by taking a difference in the number of days between the consecutive visits. This duration was labeled as appropriate or inappropriate based on three variables, ie, patient glycemic control, diabetic status, and duration of days as per guidelines. A total of N = 16290 patient data were finally included for the final analysis (Figure 1).

The outcome variable was initially dichotomized as appropriate vs inappropriate. For measuring those tests that were ordered either too early or too late, the duration of the testing variable, which was continuous (number of days), was categorized into four groups: tested too early, tested appropriately, and tested too late/inappropriately. For creating this variable with three levels of appropriateness, we measure the accuracy of the testing duration between two orders. In order to account for differences that are close to the appropriate duration but do not fully meet the defined cut-off points for testing, we adopted the grey zone approach.²⁰ This approach was selected to better reflect the real-time variability of the outcome variable, rather than relying on strict cut-off thresholds.²¹ This accounts for the reduced misclassification bias resulting from the forced classification of the variable based on the strict cutoffs, especially those missing by a relatively small gap.²² The other independent variables included were gender, age at testing and age at data collection (years), name of the testing facility, and patient diabetic status (diabetic, non-diabetic, and pre-diabetic).

Statistical Analysis

The data was initially collected in Microsoft Excel and later imported to statistical software R version 4.3.2 for data management, and analysis of some figures were generated using SPSS™ version 29.0.2.0.²⁰ The initial extracted data was summarized as a descriptive table, including frequency and percentages out of the total for categorical variables, while the numerical variables were presented as mean, max, min, and standard deviation. The denominator was considered the number of HbA1c tests performed in the specific pre- and post-intervention period. To measure the intervention efficacy, the differences in the pre- and post-intervention periods were tested using logistic regression.²³ The results were reported as odds ratio and 95% confidence intervals for the independent predictors of the appropriate testing. For assessing the predictors of too-early treatment, excluding those who were tested too late, a logistic regression was applied. The probability of too-early testing was computed based on the coefficients from the logistic regression model. All statistical tests were conducted at a significance level of $\alpha = 0.05$.

The current study was approved by the ethical review committee of King Abdullah International Medical Research Center (KAIMRC).

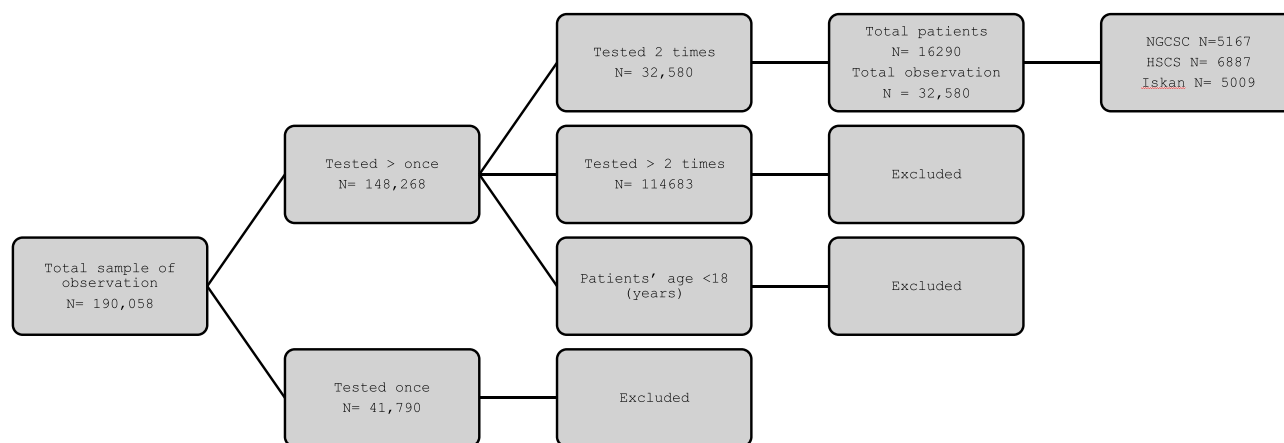


Figure 1 Data Management Steps.

Abbreviations: NGCSC, National Guard Comprehensive Specialized Centre; HCSC, Health Care Specialty Centre.

Results

Table 1 provides a comprehensive summary of the data for 16,290 participants. The distribution by gender showed a predominance of females at 10835(66.5%). The mean age of participants was 49 ± 15 years, while at the time of testing, the mean age at the time of the study was 50 ± 16 years, the minimum age was 18, and the maximum was 110 years. Facility distribution reveals that the majority of tests were conducted at Khashm Alan Clinic 6887 (42.3%). Approximately one-fourth 3635(22.3%) of participants were diabetic, and the majority were nondiabetic 9249(56.8%). The mean HbA1c level was $6.2 \pm 1.55\%$. Most participants 12737(78.2%) were seen in the post-intervention period. The duration of tests varied from 0 to 3 months 467(2.9%) to more than 12 months 7038 (43.2%). Nine out of ten tests, 14598(89.6%), were ordered inappropriately based on the criteria of glycemic control, diabetic status, and duration of testing.

Participants' Characteristics by Intervention Status

There were significant differences by gender in both the pre- and post-intervention durations, with females slightly higher compared to males (Pre: 67.2% vs 32.8%, Post: 63.9% vs 36.1%, $p < 0.001$). Additionally, the median age of patients at the time of the test in the post-intervention group was younger compared to pre-intervention (Pre: 51 vs Post: 47 years, $p < 0.001$), which is younger than the pre-intervention group, with a mean age of 52.5 years. The duration between the

Table 1 Summary of the Data N = 16290

	Overall (N= 16290)
Gender	
Female	10835 (66.5%)
Male	5455 (33.5%)
Age now (years)	
Mean (SD)	49 (15)
Median [min, max]	48.0 [18, 110]
Age at test (years)	
Mean (SD)	50 (16)
Median [min, max]	50.0 [18, 111]
Facility name	
Iskan yarmouk	4394 (27%)
Khashm alan clinic	6887 (42.3%)
Umalhamam Clinic	5009 (30.7%)
Diabetic status	
Diabetic	3635 (22.3%)
Non-diabetic	9249 (56.8%)
Prediabetic	3400 (20.9%)
HbA1c Result	
Mean (SD)	6.2 (1.55)
Median [min, max]	5.6 [3.6, 19.1]

(Continued)

Table 1 (Continued).

	Overall (N= 16290)
Intervention status	
Postintervention	12737 (78.2%)
Preintervention	3553 (21.8%)
Duration of test	
0–3 months	467(2.9%)
3–6 months	3019 (18.5%)
6–12 months	5766 (35.4%)
More than 12 months	7038 (43.2%)
Appropriateness of testing duration	
Appropriate	1692 (10.4%)
Inappropriate	14598 (89.6%)

two tests significantly differed in the two intervention periods; in a post-intervention 6488 (50.9%) vs pre-intervention 550 (15.5%), $p < 0.001$ were tested after ≥ 12 months. While most of the participants in the pre-intervention group were tested within 6–12 months 1698 (47.8%). The rate of inappropriate testing remained high in both periods (Pre: 89% vs Post: 91.9%, $p < 0.001$). The appropriate testing improved by 3% from 8.1% in pre-intervention to 11% in the post-intervention period (Table 2).

Table 2 Summary Statistics by Intervention Status

Variable	Post-Intervention (N=12737)	Pre- Intervention (N=3553)	P-value
Gender			
Female	8565 (67.2%)	2270 (63.9%)	<0.001*
Male	4172 (32.8%)	1283 (36.1%)	
Age now (years)			
Median [Q1-Q3]	48.0 [38–60]	53.0 [42–65]	<0.001*
Age at test (years)			
Median [Q1-Q3]	47.0 [37–58]	53.0 [42–65]	<0.001*
Facility name			
Iskan yarmouk	3316 (26.0%)	1078 (30.30%)	<0.001*
Khashm alan clinic	5476 (43.0%)	1411 (39.70%)	
Umalhamam Clinic	3945 (31.0%)	1064 (29.9%)	
Diabetic status			
Diabetic	2501 (19.6%)	1134 (31.90%)	<0.001*
Non-diabetic	7625 (59.9%)	1624 (45.7%)	
Prediabetic	795 (22.40%)	806 (22.2%)	
HbA1c result			
Median [Q1-Q3]	5.6 [5.3–6.2]	5.8 [5.3–6.2]	<0.001*
Duration of test			
0–3 months	235 (1.80%)	232 (6.50%)	<0.001*
3–6 months	1946 (15.30%)	1073 (30.20%)	

(Continued)

Table 2 (Continued).

Variable	Post-Intervention (N=12737)	Pre- Intervention (N=3553)	P-value
6–12 months	4068 (31.90%)	1698 (47.80%)	<0.001*
More than 12 months	6488 (50.90%)	550 (15.50%)	
Appropriateness of testing duration			
Appropriate	1404 (11.0%)	288 (8.10%)	
Inappropriate**	11,333 (89%)	3265 (91.9%)	

Notes: * The χ^2 /Mann Whitney-U test is significant at 0.05. **Those tested early or late than recommended duration of testing based on diabetic control.

Predictors of Early Testing

Table 3 presents the predictors of early testing, highlighting significant factors associated with the likelihood of early testing. After adjusting for all other variables in the model the policy restrictions significantly reduced the odds of early testing by 70.3% with OR = 0.297, 95% CI: 0.246–0.358, $p < 0.001$. The HbA1c was negatively associated with the early testing; for each unit increase in HbA1c, the odds of early testing decreased by 1.517, OR = 0.219, 95% CI: 0.193–0.249, $p < 0.001$ after holding all the other variables constant. Gender was not a significant predictor for early testing. The early testing was significantly noted among the younger participants with increasing age the odds of early testing reduced OR = 0.970, 95% CI: 0.966–0.974, $p < 0.001$ (Table 3).

Discussion

The study's findings offer critical insights into the patterns of HbA1c test ordering within the Ministry of National Guard Health Affairs (MNGHA) in Riyadh, highlighting both the successes and potential pitfalls of implementing restrictions on test intervals. This discussion explores the legitimacy of these restrictions, possible factors threatening their success and broader implications for the Saudi health system, particularly in the context of free healthcare for all.

The Saudi health system, which offers free healthcare services, including laboratory tests like HbA1c, presents a unique context for this study.²⁴ In systems where patients are responsible for out-of-pocket costs, there is a natural deterrent against over-utilization of healthcare services, including unnecessary testing.²⁵ Research has shown that out-of-pocket costs are

Table 3 Predictors of Early Testing N=13456

Variables	Estimate	Odds Ratio (95% CI)	P-value
Intervention period			
Pre-intervention	Ref		
Post-intervention	−1.214	0.297 (0.246–0.358)	<0.001
HbA1c (%)	−1.517	0.219 (0.193–0.249)	<0.001
Gender			
Male	Ref		
Female	−0.048	0.953 (0.842–1.079)	0.451
Age at test (years)	−0.03	0.97 (0.966–0.974)	<0.001
Facility name			
Khashm Alan Clinic	Ref		
Iskan	−0.183	0.833 (0.717–0.966)	0.016
UmAlhamam Clinic	−0.093	0.911 (0.793–1.047)	0.189

Notes: Chi square = 356.26, $p \leq 0.001$, $R^2 = 0.211$. The sample was restricted to those who were tested early vs appropriately.

associated with reduced utilization of healthcare services, leading to more prudent use of tests and treatments.²⁶ However, in a system like Saudi Arabia's, where patients do not bear the financial burden, the tendency to over-order tests may be higher.²⁷ As noted in our study, the tendency of the early testing was higher in the pre-intervention period when compared to post-intervention. Thereby implying that the policy restriction was successful to some extent in reducing this tendency towards early testing. Although the odds of early testing decreased in the post-intervention period, the tendency of doctors to order tests prematurely remained high. Several previous studies support this finding by showing high rates of unnecessary HbA1C testing and lack of compliance with guidelines recommendations.^{14–17}

Throughout the study period, about 89.6% of the physician's orders were inappropriate. This highlights the lack of compliance at the end of the ordering physician with standard guidelines and based on the duration of testing. The testing guidelines were designed to optimize patient outcomes and resource utilization, aligning with global standards, such as those recommended by the American Diabetes Association.^{13,28} These results indicate that doctors frequently order the HbA1c test without considering the patient's diabetic status or previous HbA1c results (See [supplementary Figure 1](#)). This may raise several exploration aspects of the physician's ordering behavior. Possible justifications include when physicians feel the need to rule out the diagnosis since diabetes is a common disease in Saudi Arabia to avoid potentially missed or delayed diagnosis, especially with increased rates of risk factors including family history.¹

When exploring the sample demographics, older patients were significantly less likely to undergo early testing. This could happen for a number of reasons, one of which is that older patients tend to take a passive approach, trusting physicians to decide, while younger patients actively seek information and participate in decision-making since many of them have access to internet and online resources.^{29,30} The sociocultural aspect should also be considered, as many elderly parents rely on their children for transportation to and from the hospital. This could lead to lower frequency of visits to the hospital, which was noted in our study where the mean age was between 47 and 51 years in both phases. The other reason could be the rising risk of diabetes at an early age compared to before when it was the disease of the elderly. All these could probably lead to increased pressure on physicians to order early tests to satisfy young patients' expectations. In our sample, we observed repeated testing patterns, with some patients tested over 10 times during the study period.

The interventional nature of this study is a key factor that enhances the robustness and validity of the study results and reduces the risk of bias. Also, the application of the grey zone approach contributed to the reduction of misclassification bias. This study was conducted across multiple centers, which enhances its generalizability and applicability in a diverse environment. Another key strength of this study was the restriction of our data to those patients who were seen only twice. This effectively minimized the potential confounding and overestimation as a result of those patients who were able to get repeatedly tested during the study duration. This approach enhances the validity of our findings by focusing on a patient population where testing decisions are less likely to be swayed by repeated requests. One limitation of this study is the uncertainty surrounding the exact year of implementation of the HbA1c test ordering restriction policy. While the policy was in place prior to May 2022, the precise year of its initial implementation was not available. As a result, we defined the post-restriction period starting from May 2022, following the resolution of technical issues that temporarily deactivated the restriction from October 2020 to April 2022. This decision was made to provide a clear reference point for comparing the data before and after the policy's reactivation. However, this limitation should be considered when interpreting the findings, as the lack of an exact implementation date may affect the generalizability of the results. Another limitation of the study is the lack of access to full patient profiles and other demographic variables. Consequently, pregnant women could not be identified and removed from the analysis, even though it was part of the initial research plan. The testing criteria for pregnant women differs from the general population, which could have introduced reporting bias in our results.¹⁹ This study was conducted only at the primary healthcare level, limiting the generalizability. The applied restriction is not as comprehensive as the guideline's recommendations, where some recommendations involve longer intervals between tests, with suggested periods extending to 6 months, 1 year, or even 3 years in some cases, depending on the diagnosis and the control status of the disease. We recognize the concern about the potential disadvantages of restricting the interval for HbA1c measurements, such as the possibility of worsening blood glucose management. However, this study showed an overutilization of HbA1c testing, which

contradicts current guidelines. The policy restricting HbA1c measurement intervals was implemented to align with these guidelines, with the goal of ensuring that testing is performed at appropriate intervals for better management of diabetes. The intent of this policy is not to harm patients but to prevent unnecessary testing and to encourage follow-up based on clinical needs. Although the restriction limits the frequency of testing, it aims to optimize patient care by reducing overutilization and encouraging adherence to recommended testing intervals. This clarification is important when interpreting the study's results, as the policy's aim is to follow guidelines and improve overall diabetes management.

Conclusions and Recommendations

In conclusion, this study's findings highlight that applying restrictions can lead to lower inappropriate unnecessary HbA1C test orders, potentially leading to cost savings and lowering patients' burden. However, there is a tendency for early testing irrespective of the patient's diabetic status or diabetic control. Multiple factors may be at play, emphasizing the need for further research. Although the early testing tendency was less in the post-intervention period, it was still noted as a common phenomenon in both pre- and post-intervention phases. This highlights the fact that the physicians are the ones ordering the tests and deeper insight into this phenomenon must be looked at from the physician's perspective. We emphasize the in-depth understanding of the physician's tendency for early testing should be explored. Implementing ordering restrictions in hospitals alone may not be entirely effective.

Abbreviation

HbA1c, Hemoglobin A1c; OR, Odds Ratio; CI, Confidence Interval; PHC, Primary Health Care; MNGHA, Ministry of National Guard Health Affairs; US, United States; DM, Diabetes Mellitus; ADA, American Diabetes Association; NICE, National Institute for Health and Care Excellence; KAIMRC, King Abdullah International Medical Research Center; NGCSC, National Guard Comprehensive Specialized Centre; HCSC, Health Care Specialty Centre.

Data Sharing Statement

The data for the research are backed by an institutional policy that does not allow the public availability of the data.

Acknowledgments

We want to extend our thanks to Dr Faisal Farhat, Director of Community and Public Health, Infection Prevention and Control Program, MNGHA, for helping with the proposal review.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Disclosure

Ethical approval was granted by the Ethical Review Board of King Abdullah International Medical Research Center, Riyadh, Saudi Arabia (IRB/3055/23, approved on 7 December 2023). This study did not involve any direct or indirect contact with patients at any point during the research. In accordance with the institutional policy of KAIMRC and based on the mode of data collection, the study was exempt from obtaining informed patient consent. This study complies with the principles of the Declaration of Helsinki.

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