

Performance Monitoring, Resources, and Effects on Quality of Care for Tuberculosis Patients: Facility Audit in the Tigray Region, Northern Ethiopia

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ABSTRACT

Background: Tuberculosis (TB) is a disease caused by a single infectious agent and is the ninth leading cause of death worldwide ranking above HIV/AIDS. Though the global efforts improved the supply, material, and human workforce, still the quality of TB care remains poor in sub-Saharan African countries. Ethiopia is among the 30 high TB burden countries with an absolute number of estimated incident cases (10,000 per year). Hence, evidence of health facility audit in assessing the quality of TB care is insufficient.

Objective: This study aimed to assess the quality of TB care in the health facilities in terms of input and processes of TB diagnosis and treatment.

Methods: Facility based cross sectional study was carried out in Tigray region from March to June 2019. A tailored checklist which was adopted from the TB national guideline was applied for data collection. The research team members conducted the audit and collected the data from 36 health facilities. Data were cleaned prior to data analysis. Frequencies, proportions, mean and other relevant descriptive statistics were calculated.

Results: A facility audit was performed in 36 health facilities. Due to the absence of laboratory technologists, three health facilities quit to perform laboratory activities for the period of six months. Only 12 health facilities had electronic medical recording data bases. Less than two third (61%) of the TB focal persons obtained monitoring and supportive supervision. Regular mentoring and case base discussion were conducted in only 4 and 3 of ten facilities, respectively.

Conclusion: Despite the availability of reasonable input at the audited health facilities, quality of TB care in terms of process, diagnosis and outcome remains poor. The practice of performance monitoring and supportive supervision was seen to be highly compromised. Standardized mentoring and integrated supportive supervision tailored to quality of TB care need to be strengthened.

Keywords: Facility audit; Health care delivery; Communicable diseases; Infectious diseases; Low socio-economic status; Vulnerable communities; Instability; Middle income countries

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Abbrevations: AFB: Acid Fast Bacilli; EMR: Electronic Medical Recording; HEWs: Health Extension Workers; HF: Health Facility; HIV/AIDS: Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome; IPC: Infection Prevention and Control; LTFU: Lost To Follow Up; MAF-TB: Multi-sectorial Accountability Framework for Tuberculosis; MDR -TB: Multi Drug Resistant-TB; M and E: Monitoring and Evaluation; NGOs: Non-Governmental Organization; PHCU: Primary Health Care Unit; SOP: Standard Operating Procedure; SSA: Sub-Saharan Africa; TRHB: Tigray Regional Health Bureau; TB: Tuberculosis; WHO: World Health Organization

INTRODUCTION

Tuberculosis (TB) is a disease caused by a single infectious agent, and the ninth leading cause of death worldwide ranking above Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS). An estimated 10.4 million new people fall sick with the disease and 1.7 million died due to TB [1-3]. The global community in collaboration with the World Health Organization (WHO) has been committed in improving quality of TB care through developing global TB strategies, and enhancing Sustainable Development Goal (SDG) frameworks [4,5]. These commitments were carried out to strengthen the means of implementation, to reduce TB deaths and accelerate progress towards ending TB. Despite the persistence endeavor that has been made by UN organizations most of the WHO regions and many high TB burden countries are not on track to reach the 2020 milestones of the End TB Strategy. On top of that the reduction of TB deaths in Sub-Saharan Africa (SSA) countries remains very low. The implementation of National TB Guideline is recommended by WHO for all low-income countries to foster quality of TB care.

LITERATURE REVIEW

The quality of TB care is an approach aimed at identifying gaps in TB services and prioritizing interventions to improve care across countries with high TB burden. Improving quality of TB care is the most fundamental process that facilitates to move towards the end TB strategy [6,7]. It also scrutinizes the gaps between current practices and desired standards. Low income countries should investigate the level of the quality of TB care through conducting a facility audit on inputs, structures, processes, and outcomes of TB care.

As indicated by WHO, the major factors that facilitate TB quality of care include a) Staff training, b) Standard performance monitoring, c) Availability of guidelines and manuals, and d) Standard health service delivery in the process of TB diagnosis and treatment. As part of improving the process of TB diagnosis and treatment, updated guidelines, roadmaps and tools have been dispatched to all member states by WHO [8,9]. Furthermore, the Multi-sectorial Accountability Framework for TB (MAF-TB) was developed as a strategy of strengthening accountability for the response of TB at all levels [10]. Even with the global and national efforts in improving the supply, material human workforce and other potential inputs such as guidelines and protocols, still the quality of TB care in diagnosis and management remains poor in SSA countries [11].

Ethiopia is among the 30 high TB burden countries with an absolute number of estimated incident cases (10,000 per year) for the period of 2016-2020 [12]. Even though the estimated

number of TB suspected population is very high in the nation; the incidence was reported 379 per 100,000 populations which is much lower than the nationally established target. Inadequate performance monitoring and mentoring, lack of standardized supervision by district experts were among the main reasons for poor quality of TB care [13,14]. Moreover, the shortage and irregular supply of acid-fast bacilli reagents and consumables are deterring quality of care. Inadequate supervision by district health officials and untrained health service providers were also additional reasons for the poor quality of TB care [15-17]. Studies of health facility audit are robust in assessing the quality of TB care.

Health facility audits are mechanisms to assess quality of care by assessing performance monitoring, investigating the availability and functionality of potential inputs and the processes of diagnosis and care provided to TB patients [18]. To the best of our knowledge there is insufficient evidence of health facility audit in assessing the quality of TB care. Therefore, this study aimed to assess the quality of TB care in terms of potential inputs such as supply, (trained human resources, and medical equipment) and the process of its implementation in Tigray state, Northern Ethiopia.

METHODS

Study area: Tigray is one of the nine states located in Northern Ethiopia. The topography of the state is subjugated by a fragmented plateau that forms a rolling upland ranging from about 1000 to more than 3500 meters in altitude [19]. The Tigray state comprises seven administrative zones which are further subdivided to a total of 93 woredas (districts) and 673 Tabias (sub-districts). The total population in FY 2020 was estimated to be about 6.5 million. The current health care tier system is composed of Primary Health Care Units (PHCU), secondary (general hospital) and tertiary (referral hospital) structures. The PHCU contains primary hospitals, health centers and five satellite health posts within the catchment area of the health center. The health posts are the lower structure unit of the health system staffed with two Health Extension Workers (HEWs). HEWs are responsible in mobilizing households to seek health care when TB symptoms and individuals with history of contacts are identified. Besides tracing dropouts, counseling TB patients to adhere to their treatments are among the duties of HEWs [20]. This facility based cross sectional study was carried out from March to June 2019.

Sampling and sampling technique: Four health zones namely, Eastern, South-Eastern, Mekelle and Southern zones all located in the Tigray region, were purposively selected for Health Facility (HF) audit to assess the quality of TB care. The research

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team members consulted a person in charge of disease prevention and control from the Tigray Regional Health Bureau (TRHB). The lead researcher had discussions with HF heads and CEOs to recruit HFs with high load of TB patients. In addition to the discussions, essential documentation and annual reports were retrieved for review. This was preceded by the purposeful selection of a tertiary, five zonal, five primary hospitals and twenty-five health centers. Prior to the visit, all the selected HFs were informed about the audit performance and its purpose. The TB focal persons and laboratory professionals were notified, and data collection was scheduled based on their convenience.

Data collection and procedure: Tools for data collection were adopted from the TB national guideline and updated WHO protocols. Various protocols, guidelines, and essential registration charts and forms were checked and collected from TRHB to familiarize the research team members. A tailored checklist was developed and distributed among the research team members for further comments and amendments. A half-day discussion was made to verify the clarity of the checklist. Pretest was conducted in a hospital which was outside of the selected health facilities. The data was collected by the research team members. Repetitive phrases, statements not easy to understand, and uncommon questions were omitted from the checklist and new inquiry which was reflected from the health workers (such as preparing specimen rejection guideline) were complimented. An adequate number of checklists were printed for data collection. Data was collected by the trained research team members. During the actual data collection, checklists were plaid twice in a day for their completeness and consistency.

Data processing and analysis: Data entry template was created including coding different categorical variables followed by data entry in STATA version 14.2 statistical software. Data were cleaned prior to data analysis. Frequencies, proportions, mean and other relevant descriptive statistics were calculated. Missing values were considered and then excluded from the denominator while computing percentages for each category of a variable. Since the unit of analysis were health facilities (hospitals and health centers), quality of TB care related to input, process and outcome levels were described using number (frequency) and percentage. The laboratory diagnosis outcome for each health facility was reported using Acid Fast Bacilli (AFB) positivity rate as an indicator of TB quality of diagnosis. Likewise, the TB quality of treatment for each health facility was also reported as cure, completion, Lost To Follow Up (LTFU), death, treatment failure and unevaluated rates (i.e., all were expressed in number and percentage) as indicators of TB quality of treatment.

RESULTS

Input

Human resources characteristics of health facilities: A facility audit was performed in 36 health facilities. All the health facilities have TB focal persons and 22 (62.9%) were with less than 5 years' experience. Four of ten (14/36) and one third (12/36) of the TB focal persons were BSc nurses, and health

officers by profession respectively. Nine of ten TB focal persons (91.7%) provided a positive response when they are asked if they are ever trained for TB guideline. While only half of them (52.8%) received on job training on TB diagnosis and treatment. Less than half of the TB focal persons had undergone mentorship. Six of ten focal persons (61%) obtained monitoring and integrated supportive supervision. The facility audit attested failure of three health facilities to perform laboratory investigations for the period of six months due to the lack of laboratory technologists. medical Twenty-three medical laboratory technologists (65.7%) were trained on TB diagnosis and treatment. Only six health facilities were staffed by 5 or more medical laboratory technologists. Refill to turn over of TB staff was not executed among one fourth (25%) of the health facilities.

Material resources (laboratory supply and TB guidelines): Availability of HIV screening service kit, and stock and bin card of TB drugs was 88.9%, and 83.3% respectively. Three fourth (75%) of the TB examination rooms were with ventilated set up. Health facilities with operational plan for TB care and treatment were 29 (81%). Only half (51.4%) of the health facilities had infection prevention guideline. Tuberculosis monitoring and evaluation protocols were not available among (83%) eight of ten TB units. Hence, all health facilities were observed with recent TB registration book. Only nine (25%) of the health facilities were equipped with x-ray and ultrasound examination devices. Almost six of ten (58.8%) laboratory facilities were observed with standard ventilation. Running water was not available in one quarter (23%) of the laboratory units. Illumination was noticed as standard in nine of ten (91%) laboratory units. Nine of ten health facilities ensured the availability of ESR rack (91.6%) and hematocrit centrifuge machines (94.3%). The team witnessed availability of falcon tube in 28 (80%) of the facilities. However, only five (14.3%) reported the utilization of gene expert technology. None of the health facilities reported the functionality of culture and sensitivity testing procedure.

TB diagnosis guidelines: The availability of patient education and specimen rejection guidelines was reported in less than one quarter (22.9%) and 48.6% of laboratory units respectively. Eight of ten health facilities had TB diagnosis protocol, Standard Operating Procedure (SOP) for TB laboratory diagnosis and internal quality control. Almost all health facilities were observed to have AFB registration book and laboratory request forms.

TB diagnosis characteristics of health facilities: Triage service was available in half (51.4%) of the health facilities. More than nine of ten TB focal persons mentioned coughing, fever, sweating and weight loss as common symptoms of TB. Seven of ten facilities attested that priority is given for patients with 'danger' signs. Routine patient education was reported in nine of ten health facilities (91.7%). Health information dissemination coverage related to TB varies from topic to topic. The topics conveyed on coughing or expectoration, sputum collection, and sputum disposal were reported 78.8%, 69.7%, and 75.8% respectively. The availability of defaulter tracing mechanism was reported by 34 health facilities (94%). Only

seven health facilities were observed with separate waiting areas for care takers. Nine of ten facilities noticed that the schedule for sputum collection is spot-spot.

Eleven health facilities (30.6%) use x-ray and gene expert to diagnose cases suspected with extra pulmonary TB. Whereas only six (16.7%) hospitals and two (5.6%) health centers carry out the procedures of histopathology and AFB microscopy to diagnose extra pulmonary TB respectively.

Nine of ten health facilities performed screening for people having contact with MDR TB. The contact logbook for Multi Drug Resistant-TB (MDR-TB) patients was available in eight of ten facilities (81.8%). The availability of TB HIV integration service was reported by all health facilities. Thus, all patients diagnosed with either TB or HIV are screened for HIV or TB. Thirty-four health facilities (94%) provide ART service for patients who are found reactive for HIV. Almost ninety two percent of the health facilities provide INH prophylaxis for newly diagnosed HIV patients.

TB treatment characteristics of health facilities in **TB** quality of care: The practice of appropriate TB treatment regimen prescription was reported by all health facilities (100%). All providers reported standard management on side effects of TB treatment except in two health facilities. Health providers in nine of ten facilities consulted to the senior clinician if they are not capable to manage the side effects. Health providers in 7 of 10 (72%) health facilities record and document the adverse reactions related to TB treatment. The performance of prevention counseling, prevention treatment counseling and appropriate counseling are reported by all health facilities.

Only one fourth (25%) of the health facilities provide psychosocial support for TB patients. More than three quarters (77.8%) of the health facilities notified the application of compassionate, respectful, and caring approach by the health professionals. Almost one third (36%) of the HFs had an Electronic Medical Recording (EMR) data base in the TB unit. The execution of timely and complete reporting was testified by 30 health facilities (91%). However, four of the health facilities failed to record the data of transfer in and transfer out of TB patients. Furthermore, five health facilities (13.9%) did not use the data of TB treatment for facility level decision making.

In this facility audit, only six of ten (58.8%) facilities executed the task of identification of high-risk groups among the community. Four of ten (39.4%) health facilities disclosed not performing review meetings. Moreover, regular mentoring and case-based discussions were conducted in less than half (45.5%) and only 12 (36.4%) of the health facilities respectively.

TB diagnosis outcome from AFB investigation in the laboratory: Total of 8343 patients is investigated for AFB during the period of two quarters (six months) in all health facilities. Only 389 patients were positive which accounts for 4.66%. Among the investigations 7213 tests were performed in 4 general and one referral hospitals (secondary and tertiary hospitals) while 752 and 378 tests in 23 health centers and 5 primary hospitals respectively. Based on the aggregate result of the records, the test result showed 4.8% AFB positivity rate, for the secondary and tertiary hospitals, and 4.5%, and 3.1% for

Primary hospitals and HCs respectively. According to the reports of each health facility, seven health facilities reported AFB positivity rate with a range of 10.6% to 28.6%. Health facilities showing higher proportion of AFB test result include: Meswaet health center followed by Chercher health center and Alamata hospital reported AFB positivity rate of 28.6%, 25%, and 20% respectively. Twelve health facilities reported from 0.9% to 10% positivity rate of AFB whereas, of the investigations carried out in 13 health facilities none of the patients were positive for TB.

TB treatment outcome: The treatment outcome status is reported as cured, completed, LTFU, and death. The cure rate of smear positive Pulmonary TB patients at health centers and primary hospitals is 90% and 68.4% respectively. Fourteen TB patients of the total in both health centers and primary hospitals were reported as cases of Lost To Follow Up (LTFU), ten in the former and four in the latter. The total death rate of TB patients in both health facilities was 3.48%. The death rate was further calculated 2.65% and 6.7% in health centers and primary hospitals respectively.

DISCUSSION

The number of health facilities in this audit was almost identical with another study of African countries where 39 health facilities audits were reported [21]. However, these facility audits were higher than the nine facilities audits reported from the Oromia region,but lower than the 44 and 99 facilities audits reported from eight other Ethiopian districts, and South Africa, respectively [22].

Elsewhere, a USAID funded project reported a quality Tuberculosis service assessment at 435 facilities in the Philippines [6] that was much higher than the current study. The availability of TB focal person in each institution was in line with the recommendation of the TB national guideline [23]. It is also consistent with other studies where focal persons exist in all health facilities. The findings of the current study showed better status where the TB care is running by trained TB focal persons in 33 of 36 (92%) health facilities compared to a study that reports only 30 TB focal persons trained in 44 (68%) health facilities. The high impact interventions that have been conducted in the era of Health sector development program and the various initiatives of in-service training provided by various stakeholders might have contributed to the increased proportion of trained TB focal persons in the current study.

The level of education of TB focal persons (BSc degree) in the current study was not comparable with a study reported from Philippines where their level of schooling was mixed type comprising of post graduates. Ethiopia's National TB Guideline mandates regular on job training. However, half of the TB focal persons in this study reported interruption of on-the-job training; hence they did not meet the recommended standards. The possible reasons for interruptions of on job training included, but were not limited to a) The regular turnover of trained health workers from the health facilities, b) Inappropriate transition of the mentorship program from external stakeholders (mentors) to internal stakeholders (staff), c) The type of on job training

provided may not be inclusive, with t key training elements lacking the quality improvement aspects, and d) Discontinuation of project interventions on health systems coordination.

When exiting plans for projects are not in place from the onset; sudden interruption of on job training risk creating critical challenges for health facilities aiming to improve compliance. Evidence revealed the role of supportive supervision in various health facilities improves quality of care in TB management [24]. Though TB guidelines of monitoring and evaluation recommends undertakings of regular supportive supervision and review meetings [25,26], significant number of health facilities (four of ten) in this study neither conducted review meetings, nor received supportive supervision, from the responsible health care authorities. Despite the bi-annual integrated supportive supervision which is known to be performed at the health facilities, the supervision delivered may not be appreciated as supportive for the TB focal persons. Moreover, the supervision might not specifically be tailored to assess the gaps that hinder quality of TB care. Failure of supervisors in explaining treatments plans and protocols to service providers constructively may have played a role, resulting to poor compliance of quality of care.

The result of this facility audit is comparable with other study in terms of availability of recommended anti TB drugs and treatment guidelines. This facility audit complies with the national guideline fulfilling the minimum stock of TB drugs in all audited facilities during the study period which is consistent with the findings of that reported no interruption of supply of TB drugs and standard patient treatment registers. In this study the availability of supply items such as (registration books, registration formats, stock card, bin card, job aids, TB treatment guidelines, TB manuals and reporting formats) were reported in all health facilities. Hence, still more than half of the health facilities are observed with the critical deficit of essential supply and material resources (such as patient education guideline, infection prevention guideline, and specimen rejection guideline and monitoring and evaluation protocols). In contrast to our study, the deficit of supply and material resources were not of concern. The health facilities in this study were almost always compliant with the standards. For example, 34 of 36 (94%) facilities successfully managed drug side effects which is significantly higher and better than that in a study that reported that 27 of 44 (60%) TB focal persons were not capable to manage adverse effects of TB drugs.

The most critical problem observed in this facility audit was the clear gap on the process of TB detection and diagnosis. Though WHO recommends systematic and active screening of high risk groups among household members for TB detection and diagnosis [27,28], almost two third of the health facilities in this study failed to conduct the recommended practice of active case finding. The poor performance of not conducting active case findings in this facility audit might be due to a)Weakness of the health system, b) Poor supportive supervision, and c) Failure to introduce regular mentoring with monitoring to improve quality of care. Moreover, poor commitment of health system, lack of

performance-based evaluation, might be among the factors that hinder the poor identification of high-risk groups for TB detection at health facilities.

In this study, almost nine of ten health facilities (92%) ensured the timeliness and completeness of data which was consistent with a study conducted in South Africa. However, the health facilities in this study had limitations to apply EMR on TB data which would have been beneficial for earlier decision making. Availability of EMR in health facilities optimizes better information access and data security [29]. WHO recommends using EMR [30] as it offers several prospective benefits over the old-fashioned paper-based systems, such as, improved data quality and completeness, with enhanced data entry and analysis? Hence, our study is in difference with the WHO recommendation where almost 2/3 (64%) of the health facilities didn't use the EMR.

Performance monitoring of health facilities is known to strengthen and improve delivering quality of care and to enhance access to high quality primary health care services [31]. Inconsistent to this evidence, our finding reported monitoring was not conducted in more than four of ten health facilities. Moreover, the situation worsens due to in-availability of TB Monitoring and Evaluation (M and E) protocols in eight of ten facilities. The findings of this study clearly revealed the absence of the M and E protocols in significant number of health facilities which indicates early dispatching of the guidelines. In line with this, the reason for not conducting performance monitoring of health facilities might be low level of understanding among health professionals regarding the benefit of M and E. Low level of consideration to develop M and E plan might also be an additional barrier.

Due to the crucial concern of the global community regarding health care associated infections, WHO had committed to develop and distribute recent Infection Prevention and Control (IPC) guidelines to the member states by 2016, however, half of the facilities in our study lacked IPC guidelines, hence did not meet the national standards/guidelines. Three fourth and more than half health of the facilities in this study were deprived of the process of regular mentoring and case base discussion respectively. In contrast to our study, continuous clinical and administrative mentorship that had been conducted in Ethiopia for 1165 facilities [32] showed greater achievements in progressing quality of care for Tuberculosis. This difference can be explained with some justifications; the mentorship program of the later study was a project-based intervention funded by a Non-Governmental Organization (NGOs). Usually, projectbased interventions which are implemented by NGOs follow the vertical approach of health service delivery where resources are fully allocated for an independent project. Such approach varies from the service provision which is provided by the government where it undertakes the horizontal approach of health service delivery that integrates various programs together.

In this study, the TB diagnosis outcome based on AFB investigation of laboratories of the health facilities was very poor. The finding of sputum for AFB investigation was 4.64% which is very low compared to another study from Ethiopia that reported 48.8% (41/84) [33]. Another hospital based study in

Abuja, Nigeria reported higher AFB positivity rate which contrasts to our study. The reasons for low AFB positivity rate in this study might be explained by various possible justifications. In this study, the record of positivity rate was extracted retrospectively from a registration book, whereas the result of sputum investigations of other studies might be directly documented from the medical records. Besides, the current study included urban and rural health facilities, while the study with high AFB positivity rate included hospitals and health centers from the capital cities, Addis Ababa (Ethiopia) and Abuja (Nigeria). In addition to that the interruption of essential laboratory reagents and critical shortage of skilled medical laboratory technologists on the study area might affect the outcome. Besides, lack of continuous facility assessments and failure to conduct appropriate supportive supervision in a way to improve the quality of care with the existing resources might have affected to the low TB detection rate.

CONCLUSION

This study has highlighted the importance of monitoring of trained personnel, availability, and functionality of medical equipment) and the processes in meeting standards and guidelines in the Tigray Region of Ethiopia. Our findings highlighted the gaps in staff monitoring, mentoring and quality assessment, were almost always linked to funding.

Education attainment of staff, their understanding of the need for monitoring is important factors for consideration when implementing quality assurance and monitoring protocols within health facilities. The gaps identified in diagnosis, may be due to lack of continuous professional education on the part of health personnel and specifically, the TB focal persons.

The role of qualified mentors and supportive supervisors could not be overemphasized. Supervisor knowledge and willingness to educate and support their staff improved compliance by staff in terms of M and E.

There remains a gap in M and E, for TB management in the Tigray Region of Ethiopia. The findings from our study are consistent with findings elsewhere with differences noted and highlighted.

Recommendations for policy makers and for health professionals

- More funding be directed to health facilities to ensure adequate resources (human and physical) are acquired to ensure compliance by facilities for effective TB treatment and management
- Continuous professional development is an important tool for knowledge acquisition to equip providers with new and emerging evidence regarding compliance and TB treatment protocols
- Professionally mentoring staff will enhance compliance, with external and independent mentors preferred
- Necessary equipment is required for proper and timely TB diagnosis

- The use of electronic records as mandated by the WHO will be an asset for health facilities. Resources should be directed at this
- Loss of patients to follow up, remains a concern and an issue. Protocols and guidelines should be directed at this to minimize TB drug resistance and further spread of infection
- TB remains an important communicable disease in Northern Ethiopia and a public health concern. Efforts to reduce its occurrence and subsequent eradication should remain at the fore of policy for the regional and national government in Tigray and Ethiopia, respectively

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study received ethical approval from the ethics review committee of College of Health Sciences Mekelle University, Ethiopia. Permission was obtained from the district health authorities, and informed consent was obtained from each health facility. Confidentiality and privacy were guaranteed, and names and other identifying information were removed. Participants were also informed that they could cease participating at any time, for any reason, without negative consequences.

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