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ORIGINAL RESEARCH

Perceived Future Outcomes of Unsuccessful Treatment and Their Association with Treatment Persistence Among Type-2 Diabetes Patients: A Cross-Sectional Content Analysis

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ABSTRACT

Introduction: Despite the known strong association between patients' knowledge of outcomes of type 2 diabetes mellitus (T2DM) and treatment persistence, this knowledge in this patient population requires further clarification. The aim of our study was to reveal the perception of unsuccessful treatment outcomes among patients with T2DM and its association with treatment persistence by analysing answers to open-ended questions.

Methods: In this cross-sectional study, 106 patients with T2DM who lived in Fukushima Prefecture, Japan, had a medical record in the Fukushima National Health Insurance Organisation database and had no cognitive problems were enrolled by purposive sampling. Treatment status was defined as "non-persistent" when a participant's treatment medical record was absent for a continuous period of $\geq$ 6 months; otherwise, it was referred to as "persistent". We asked about the possible future problems of untreated T2DM, inductively classified the open answers into 15 codes and then statistically examined the association between these codes and treatment persistence using logistic regression analysis adjusted for age and sex.

Results: Persistent treatment was prevalent among participants who mentioned the code "treatment", which encompasses the terms that indicated invasiveness, such as dialysis, insulin injection, and shots (odds ratio 4.339; 95% confidence interval 1.104–17.055).

Conclusion: Persistent treatment was prevalent among patients with T2DM who mentioned the code "treatment", suggesting that these patients may anticipate a threat due to the invasiveness of diabetes and thus participate in persistent treatment to avoid this threat. Healthcare professionals should provide appropriate information and supportive conditions to achieve both a reduced feeling of threat and persistent treatment engagement.

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Keywords: Content analysis; Fear-based strategy; Future perspective; Invasiveness; Persistent treatment; Psychological insulin resistance; Text-mining

Key Summary Points

Why carry out this study?

Although past studies have revealed that patients' poor knowledge of untreated type 2 diabetes mellitus (T2DM), such as medical complications, is associated with non-persistence to treatment, details on the association of knowledge of T2DM outcomes and treatment persistence have yet to be clarified.

This study is based on the hypothesis that the lack of knowledge regarding future problems with untreated T2DM and recognition of the need for treatment for progressive T2DM, such as the use of insulin or dialysis, may be associated with non-persistent treatment.

What was learned from this study?

Persistent treatment was prevalent in patients who anticipated outcomes associated with invasive treatments, such as dialysis, insulin injection, and shots.

If a patient's behaviour is motivated by avoiding insulin, they may miss the opportunity for early insulin induction to improve their long-term prognosis.

INTRODUCTION

There are approximately 537 million people across the globe with diabetes, including 61 million in Europe and 37 million in the USA [1, 2]. Type 2 diabetes mellitus (T2DM) is the most common type of diabetes and accounts for 90% of all diabetes cases [1]. The lack of treatment persistence among patients with T2DM is associated with adverse outcomes, such as excess mortality [3], increased risk of complications [4], reduced quality of life [5] and high healthcare costs [6].

T2DM is a chronic illness and requires persistent medical therapy [7]. Evidence has shown that persistent treatment through achieving glycaemic control reduces health problems associated with T2DM [8, 9]. However, past studies have reported that approximately 10% of patients with T2DM discontinue treatment [10, 11]. This lack of treatment persistence is an obstacle to desirable diabetes care [12].

Previous studies have also revealed that patients' poor knowledge of the consequences of untreated T2DM, such as, for example, future health risks, including medical complications, is associated with non-persistence to treatment and failure of self-management of glycaemic control [13, 14]. In these studies, the accuracy of knowledge was measured by scales using closed questions with multiple choice answers [15, 16].

This questioning method may not be the best means to elicit knowledge on future problems associated with unsuccessful T2DM treatment. Specifically, this method allows patients with T2DM to choose answers from items prepared by the researcher, regardless of the actual knowledge they possess. Simmons et al. explored the association between T2DM-related knowledge and treatment persistence [17] by assessing patients' knowledge of outcomes of T2DM using open-ended questions and responses instead of multiple-choice questions. Such use of open-ended questions/responses seems rational for an inductive exploration of patients' knowledge. However, detailed knowledge of the association between T2DM outcomes and treatment persistence have yet to be clarified as Simmons et al. [17] inquired only about medicine-related knowledge in exploring potential future problems of T2DM. Notably, the perception of a threat to T2DM outcomes is a key factor of treatment engagement among patients with T2DM [18], and such outcomes include poor-quality human relationships and social life, including heavy burden of family caregivers and discontinued employment [19].

In the present study, we aimed to reveal the perception of unsuccessful treatment outcomes among patients with T2DM and its association

with treatment persistence using content analysis. For the quantitative analysis, we hypothesised that the following factors might be associated with non-persistent treatment: (1) absence of knowledge regarding future problems with untreated T2DM; and (2) recognition of the need for treatment for progressing T2DM, such as the use of insulin or dialysis. These hypotheses were based on past studies indicating that knowledge of T2DM complications is associated with risk perception [20] and that patients with T2DM perceive insulin therapy as a negative experience with a low intention of treatment engagement [21].

METHODS

Setting and Sampling

The data in this cross-sectional study are consistent with those in a published study [19], as part of our research project. Using purposive sampling, the potential participants comprised 110 individuals aged ≥ 40 years who resided in Koriyama City, Fukushima Prefecture, Japan, as of 2018. At the time of the study, the total population of Koriyama City was 329,903, with 28.2% of the population aged ≥ 65 years, which was similar to that of the general Japanese population (28.9%). Owing to this similar population structure, Koriyama City was considered to reflect the whole nation. The potential participants were selected from the regions of Koriyama City according to the population ratio of each region to the entire Koriyama City. All potential participants had a medical history of T2DM recorded in the Fukushima National Health Insurance Organisation database. Prior to the sampling, treatment status was defined as "non-persistent" when a participant's treatment medical record was absent for a continuous period of ≥ 6 months on the said database and "persistent" when there was a record of the participant receiving treatment at least once every 6 months [17, 22, 23]. Of the 110 potential participants, four were excluded from the analysis because their self-reported treatment history was critically different from objective medical records or they were unsure whether they had been diagnosed with T2DM. Ultimately, 106 individuals were enrolled in the study.

Procedure and Measurement

Information on the participants' sex and age was collected from the database. One-to-one interviews were conducted by public health nurses of Koriyama City Public Health Center from October to November 2018 at the participant's residence. Prior to the interview, the purpose of the interview, questions to be asked, and procedures of the interview were explained to the public health nurses. An interview guide was employed for the interview. In addition to treatment persistence, the participants were assessed on their perception of unsuccessful T2DM treatment outcomes through the following question: "What problems do you think would occur in the future if you did not receive treatment for T2DM or if your treatment for T2DM was not successful?" All participants were interviewed once, and the mean interview duration was 29.4 min. The interviews were digitally recorded with the permission of the interviewees and transcribed verbatim by a professional transcriptionist. The verbatim transcripts were standardised by removing dialects for further content analysis.

Content Analysis

For the content analysis, the transcripts were first analysed by text mining using KH Coder version 3 Alpha 17 K (K. Higuchi, Kyoto, Japan) [24], which is a morphological analysis software for Japanese to segment a sentence into terms. Nouns and verbs were targeted for extraction and analysis since they were the minimal unit constituting a sentence and meaning. A total of 365 terms were extracted and these were used 1208 times.

A total of 263 terms were excluded from the analysis based on the following criteria: (1) those that were meaninglessness for analysis due to the nature of the language and setting of the present study, including those inevitably mentioned because of the interview questions

(e.g. diabetes); (2) those frequently used from characteristics of the Japanese language (e.g., person, think); and (3) those that are difficult in coding because of insufficient information (e.g. honorific titles, proper nouns, onomatopoeic terms). The excluded terms are listed in Electronic Supplementary Material Table S1.

The remaining 102 terms were subjected to qualitative coding. In this qualitative coding, similar terms were summarised and labelled, and subsequently abstracted step by step according to the procedures of a hybrid thematic analysis [25]. In this hybrid thematic analysis, the 102 terms were inductively sorted into themes composed of 15 codes that represented the participant's perceived outcomes of untreated T2DM (Table 1). These theme were: (1) "medical complications," which consisted of the codes regarding the body parts and symptoms and highlighted the physical/medical outcomes of T2DM; (2) "uncertainty of the future," which was characterised by uncertainness about future outcomes of T2DM with codes of abstract meanings; and (3) "declined social life," which represented the feeling of anxiety and avoidance and comprised the codes regarding a limited social life due to the onset and progression of T2DM. It should be noted that of the 15 codes, the code "no clear answer" included the terms "no answer" and "I do not know," which were given as the response to the interview question. The frequency of the use of these two terms was manually counted as text mining methodologically cannot detect the absence of responses.

Statistical Analysis

To examine the results of the content analysis, the codes were subjected to statistical analysis. The participants were classified based on whether they mentioned the codes or not and then included in the analysis. The characteristics of the participants were examined using descriptive statistics, and the bivariant associations between the codes and treatment status were analysed using a Chi-square test or Fisher's exact test. Considering our hypotheses, a logistic regression analysis was conducted to examine the associations between each explanatory variable, such as "no clear answer" and "treatment" codes, and treatment status (persistent/non-persistent) as an objective variable. Two models were constructed using the direct method, namely a crude model for a one-to-one association between explanatory and objective variables, and an age- and sex-adjusted model. The Hosmer–Lemeshow test showed good fits in the age- and sex-adjusted model for the codes "no clear answer" and "treatment" (0.732 and 0.801, respectively). The variance inflation factor was used to test multicollinearity for the age- and sex-adjusted model; the variance inflation factors for the code "no clear answer", age and sex were 1.007, 1.004 and 1.01, respectively, and those for "treatment," age and sex were 1.003, 1.003 and 1.007, respectively.

The significance level was set at 5%, and the odds ratio (OR) and 95% confidence interval (CI) were calculated for the explanatory variables. All statistical analyses were performed using SPSS statistics V.26 (SPSS, IBM, Armonk, NY, USA).

Ethical Considerations

This study was approved by the Ethics Committees of Fukushima Medical University (application no. 30196) and was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All participants provided written informed consent to participate in the study and for publication of the study results.

RESULTS

The characteristics of the participants are shown in Table 2. The mean ages of participating men and women were 68.6 and 68.1 years, respectively. Treatment status was classified as non-persistent in 16% of the participants.

The bivariate analysis indicated that persistent treatment was statistically associated with the female sex ($p < 0.001$) (Table 3). Regarding the codes, the inclusion of "no clear answer" was significantly associated with non-persistent

Table 1 List of terms, codes and themes in the content analysis

Theme	Code[a]	Term[a]
Medical complications	Blood and vascular (18)	Anaemia (1), arterial (1), blood (6), blood pressure (3), blood vessel (5), capillary (1), clog (3)[b], turbidity (1), seizure (1), wound (1)
	Body (6)	Low back (1), body (3), ear (1), nephrosis (1)
	Brain and heart (24)	Brain (3), brain damage (1), cerebral apoplexy (1), cerebral infarction (11), cerebral thrombosis (2), circulation (1), heart (11), myocardial infarction (8)
	Eye (53)	Blindness (9), cataract (4), exfoliation (2), eye (41), glaucoma (4), ocular pressure (1), ophthalmologist (1), ophthalmology (1), retina (2), retinopathy (2), see (22)*, visual field (1)
	Foot and hand (39)	Amputation (12), below the knee (1), cut (11)[b], finger (4), foot (32), hand (4), leg (1), limb (3), rot (1)[b], surgery (3), thigh (1)
	Kidney, liver and other organs (19)	Kidney (14), liver (3), organ (1), pancreas (1), renal failure (1), visceral disease (1)
	Threat to life (26)	Die (8)[b], final (5), last (3), life (2), longevity (1), pass away (8)[b], terminal stage (1)
	Necrosis (16)	Gangrene (9), necrosis (7)
	Nerve (9)	Nerve (4), numbness (1), peripheral (2), paralysis (2), syncope (1)
	Thirsty (2)	Thirst (2)[b], throat (2), urine (1)
Uncertainty of the future	Abstract (39)	Adverse effects (1), blood glucose (6), blood glucose level (2), complication (29), disease (13), induce (1)[b], lifestyle-related illness (1), viscus (1)
	No clear answer (7)	No answer (4), I do not know (3)
Declined social life	Family (12)	burden (7), close persons (3), family (6)
	Restriction in life (20)	Bedridden (1), control of body (1), daily life (1), disability (1), farm (1), hemiplegia (1), home (2), limitation (1), living (3), money (2), move (5)*, play (1), walk (3)[b], work (3)
	Treatment (45)	Dialysis (26), hospitalisation (4), injection (6), insulin (22), medication (1), remove waste (2)[b], shot (10)

[a]Terms and codes are listed in alphabetical order. The number within parentheses indicates the number of subjects who mentioned the term or code. The sum of these numbers is inconsistent with the total number of subjects because a subject could mention more than one term

[b]Indicates a verb

treatment ($p < 0.001$), while the mention of "treatment" was significantly associated with persistent treatment ($p = 0.031$).

The logistic regression analysis showed that non-persistent treatment was statistically prevalent among individuals who mentioned the code "no clear answer" (OR 0.031; 95% CI 0.003–0.346), whereas those who mentioned the code "treatment" were persistently engaged in the treatment (OR 4.339; 95% CI

Table 2 Characteristics of the participants

Variables	Values
Age (years), mean ± SD	
Men	68.6 ± 4.1
Woman	68.1 ± 4.5
Sex, n (%)	
Male	60 (56.6)
Female	46 (43.4)
Treatment status, n (%)	
Persistent	89 (84)
Non-persistent	17 (16)

SD Standard deviation

1.104–17.055) in the age- and sex-adjusted model, as shown in Table 4.

We additionally examined the associations of other analytic options with treatment status. The result of the logistic regression analysis is shown in Supplementary Table S2.

DISCUSSION

In this study we examined the association between patients' perception of untreated T2DM outcomes and treatment persistence. Consistent with our hypotheses, non-persistent treatment was statistically prevalent among participants who had "no clear answer" for treatment outcomes, suggesting a lack of knowledge about potential future problems. In addition, persistent treatment was prevalent among those who mentioned the code "treatment," including the terms dialysis, insulin and the treatments for T2DM uncontrolled by oral medication, which patients acknowledge as "medications for diabetes". These terms were considered to represent invasiveness, and the participants may have recognised them from treatment as a threat in the future. Although these results suggest that the participants engaged in the persistent treatment to avoid such a threat, an excessive emphasis on the invasive nature of treatment for T2DM uncontrolled by medication may be problematic. In particular, it lowers the self-efficacy of T2DM patients and thus make them less likely to engage in treatment in the future. Instead, healthcare professionals should encourage patients with T2DM to persistent with treatment by providing them with options and the advantages of the treatment.

The mean age of the participating men and women was 68.6 and 68.1 years, respectively, which is relatively similar to the mean age of patients with diabetes in Japan overall (71.4 and 75.1 years, respectively [26]), indicating that the study population may reflect the overall patient population in Japan in terms of age. The proportion of participants who were non-persistent with treatment (16%) was higher than the treatment dropout rate of 5.5–10% reported in past studies [10, 11]. Therefore, the current study may have shown a clear difference between T2DM patients with and without treatment persistence.

The bivariate analysis showed that persistent treatment was prevalent among females. This result is consistent with a previous study that reported high dropout rates in males [27], reaffirming high treatment persistence among females.

Regarding the codes, the results were consistent in the bivariate and multivariate analyses. The code "no clear answer" was associated with non-persistent treatment, while the code "treatment" was associated with persistent treatment. In any discussion of an association between the "no clear answer" code and non-persistent treatment, the fact that no association was found for the "abstract" code, which comprised the same theme of "uncertainty of the future", should be considered. The difference between the "no clear answer" and "abstract" codes may be explained by the difference in the patient's clarity of knowledge about the risks of untreated T2DM. Individuals who mentioned the consequences of untreated T2DM using abstract terms may have had only some vague knowledge of these consequences. Nevertheless, having some knowledge, albeit vague, on undesirable future outcomes may

Table 3 Bivariate analysis of the associations of age, sex and codes with treatment status

Variables	Treatment status		*p* value
	Persistent (*n* = 89)	Non-persistent (*n* = 17)	
Age (years) (25–75 percentile)	69 (67–71)	69 (68–70)	0.634
Gender			< 0.001*
Male	44 (73.3)	16 (26.7)	
Female	45 (97.8)	1 (2.2)	
Medical complications			
Blood and vascular			1[a]
Mentioned	15 (83.3)	3 (16.7)	
Not mentioned	74 (84.1)	14 (15.9)	
Body			1[a]
Mentioned	5 (83.3)	1 (16.7)	
Not mentioned	84 (84)	16 (16)	
Brain and heart			0.111[a]
Mentioned	23 (95.8)	1 (4.2)	
Not mentioned	66 (80.5)	16 (19.5)	
Eye			0.186
Mentioned	47 (88.7)	6 (11.3)	
Not mentioned	42 (79.2)	11 (20.8)	
Foot and hand			0.491
Mentioned	34 (87.2)	5 (12.8)	
Not mentioned	55 (82.1)	12 (17.9)	
Kidney, liver and other organs			0.732[a]
Mentioned	17 (89.5)	2 (10.5)	
Not mentioned	72 (82.8)	15 (17.2)	
Threat to life			1[a]
Mentioned	22 (84.6)	4 (15.4)	
Not mentioned	67 (83.8)	13 (16.2)	
Necrosis			1[a]
Mentioned	14 (87.5)	2 (12.5)	
Not mentioned	75 (83.3)	15 (16.7)	
Nerve			0.634[a]
Mentioned	7 (77.8)	2 (22.2)	
Not mentioned	82 (84.5)	15 (15.5)	

Table 3 continued

Variables	Treatment status		*p* value
	Persistent (*n* = 89)	Non-persistent (*n* = 17)	
Thirsty			0.296[a]
Mentioned	1 (50)	1 (50)	
Not mentioned	88 (84.6)	16 (15.4)	
Uncertainty of the future			
Abstract			0.886
Mentioned	35 (83.3)	7 (16.7)	
Not mentioned	54 (84.4)	10 (15.6)	
No clear answer			0.001*,[a]
Applicable	2 (28.6)	5 (71.4)	
Not applicable	87 (87.9)	12 (12.1)	
Declined social life			
Family			1[a]
Mentioned	10 (83.3)	2 (16.8)	
Not mentioned	79 (84)	15 (16)	
Restriction in life			0.519[a]
Mentioned	18 (90)	2 (10)	
Not mentioned	71 (82.6)	15 (17.4)	
Treatment			0.031*
Mentioned	42 (93.3)	3 (6.7)	
Not mentioned	47 (77)	14 (23)	

Values are given as *n* (%), unless indicated otherwise
*Statistically significant at $p < 0.05$
[a]Fisher's exact test

contribute to an avoidance of treatment interruption, if not to treatment persistence. Conversely, those patients who had "no clear answer" may have had poor knowledge of future outcomes. This difference between vagueness and poorness of knowledge of future outcomes is manifested as an engagement in the treatment; even if knowledge is vague, possessing some knowledge on the outcomes of untreated T2DM may not interfere with persistent treatment.

The association of the code "treatment" with treatment persistence should be noted. This code comprised terms such as dialysis, insulin, shots and injection (Table 1); it has an invasive connotation and represents severe disease progression. Previous studies suggested that treatment methods for T2DM, such as insulin, when the illness can no longer be managed with medication alone, decreased the self-efficacy and self-control of the patients [28, 29]. Hence, patients with T2DM may perceive these treatment methods as a last resort and avoid

Table 4 Logistic regression on the associations of codes "no clear answer" and "treatment" with treatment status

Explanatory variables	OR (95% CI)
Crude model	
Age	0.990 (0.874–1.123)
Sex (female)	16.364 (2.080–128.720)*
I do not know/no answer	0.055 (0.010–0.317)*
Treatment	4.170 (1.120–15.526)*
Age- and sex-adjusted model for "no clear answer"	
Age	0.994 (0.854–1.157)
Sex (female)	24.297 (2.161–273.152)*
No clear answer	0.031 (0.003–0.346)*
Age- and sex-adjusted model for "treatment"	
Age	1.013 (0.877–1.171)
Sex (female)	16.921 (2.107–135.892)*
Treatment	4.339 (1.104–17.055)*

The objective variable was treatment status (persistent)
*Statistically significant at $p < 0.05$
CI Confidence interval, *OR* odds ratio

employing them as much as possible; this attitude is called psychological insulin resistance [30, 31]. Notably, the mention of the code "treatment" in this study was associated with persistent treatment.

Paradoxically, our results suggest that negative perception of the treatment method for T2DM, such as dialysis and insulin injections, may contribute to treatment persistence. It is important that our interview questions were focused on asking possible problems with untreated T2DM. As shown in past studies, the future need for insulin treatment may evoke a sense of failure to maintain a healthy state and irreversible loss of health among patients with T2DM [31, 32]. In contrast, the treatment behaviours of patients with T2DM are promoted when they recognise that a threat to health is imminent [33, 34]. In previous studies, patients who frequently mentioned "treatment" terms and persistently engaged in the treatment may perceive the treatment as a threat instead of a relief or the solution to a future problem. It may be reasonable to assume that recognising treatment as a threat contributes to persistent treatment because patients may avoid this threat through treatment engagement. Although a "fear-based strategy" promotes active engagement by making the patient aware of a future adverse state, this strategy only works if it is accompanied with appropriate information and supportive conditions provided by health professionals [35]. Taking into account the results from past studies, sharing successful experiences through peer support [32], facilitating appropriate nurse intervention [36] and presenting a wide range of options for alternative treatments [22] are necessary when such a strategy aimed at improving treatment persistence among T2DM patients is adopted.

It is notable that "fear-based strategies" may lower self-efficacy and can, therefore, be a potential risk factor that hinders participation in treatment when insulin treatment is genuinely needed in the future [37]. Even if such strategies appear to be effective among T2DM

patients with medication treatment, a future increase in psychological insulin resistance is of concern. Consequently, the patient may lose the opportunity to improve long-term prognosis by early insulin induction. Therefore, empowerment for self-management of patients with T2DM may be an effective option to promote treatment persistence while maintaining self-efficacy [38].

This study has a number of limitations. We did not investigate the extent to which patients with T2DM perceive treatment as a threat. There may be variations from those who consider the threat crucial relative to those who do not regard it seriously. Although the methodological battery of data collection by interviews and content analysis using inductive coding and statistics to elicit patients' perceived outcomes was reasonable, future studies might benefit from an in-depth exploration of the topic. Moreover, perceptions on untreated T2DM and the association between these perceptions and treatment persistence may be influenced by the patient's background, including history of complications and duration of illness. Future studies should examine these backgrounds in detail.

CONCLUSION

We found that persistent treatment was prevalent among patients with T2DM who frequently mentioned treatment-related terms for the possible future outcomes of untreated T2DM. In contrast, non-persistent treatment was prevalent in those who could not provide a clear answer on such outcomes. Treatments such as dialysis and insulin injections may be perceived as a threat rather than a relief. Although such perceptions may contribute to patients' persistence with treatment, they also reduce the self-efficacy of patients that is necessary for active treatment engagement in the future. Healthcare professionals should promote peer support, facilitate appropriate nurse intervention and present a wide range of options for alternative treatments to reduce any such perceived threats and promote persistent treatment.

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Author Contributions. All authors contributed to the study conception, reviewing and editing of the manuscript. This study was designed by Tomoo Hidaka, Shota Endo, Takeyasu Kakamu and Tetsuhito Fukushima. Formal analysis and preparation of the original draft were performed by Tomoo Hidaka. Data collection was performed by Rieko Suzuki and Katsue Hashimoto. Data resource management and data curation were performed by Rieko Suzuki, Katsue Hashimoto, Mariko Gunji and Koichi Abe. Results of the analysis were validated by Mariko Inoue, Yukiko Terada, Shota Endo and Takeyasu Kakamu. Mariko Inoue and Yukiko Terada contributed to funding

acquisition. This study project was supervised and administrated by Mariko Gunji, Koichi Abe and Tetsuhito Fukushima.

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Compliance with Ethics Guidelines. This study was approved by the Ethics Committees of Fukushima Medical University (application no. 30196) and was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All participants provided written informed consent to participate in the study and to allow publication of the study results.

Data Availability. The datasets of qualitative study generated and/or analysed during the study are not publicly available as the datasets had identifiable information of the study participants. For quantitative research, the datasets generated and/or analysed during the study are available from the corresponding author on reasonable request.

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