***Original Research Article***

# Evaluating Patient Perceptions of Pharmacist-Led Medication Therapy Management in Hypertension Management.


## ABSTRACT

**Background:** Hypertension is the primary contributor to cardiovascular diseases worldwide, it affects millions and needs effective management strategies. Pharmacist-led Medication Therapy Management (MTM) is essential in improving medication adherence and optimizing the treatment outcomes for patients suffering from hypertension.

**Objective:** This study aims to evaluate patient perceptions of pharmacist-provided Medication Therapy Management (MTM) services for managing hypertension. Moreover, it evaluates to examine how these perceptions influence patient`s adherence to their prescribed treatment regimens.

**Methods**: This cross-sectional observational study aimed at determining the patients' perceptions on the Medication Therapy Management (MTM) services they receive to control their hypertension. Data from 114 patients was obtained and their perceptions were recorded using the survey instruments. Patients below 20 years were excluded. The data was assessed using the SPSS 24$^{th}$ version. The p-value was ascertained by using the Chi-square test.

**Results:** The study analyzed 114 hypertensive patients predominantly females (63.2%) aged 50 years or above (51.8%). The selection of patients was based on a convenience-stratified strategy. The p-value was ascertained by using the Chi-square test. The majority had been managing hypertension for over a year (88.8%), with 45.6% managing it for 1-5 years. Educational levels varied, and most participants resided in urban areas (75.4%). Awareness of hypertension management was high with 86% of patients recognizing MTM's positive influence on medication adherence. Despite these favorable outcomes, challenges such as medication costs and lifestyle changes were noted, highlighting the need for tailored interventions to improve patient adherence and health outcomes.

**Conclusion:**

In conclusion, most hypertensive patients understood how to manage their condition and found Medication Therapy Management (MTM) helpful. MTM improved their medication adherence, reduced side effects, and enhanced their understanding of the treatment, leading to better health outcomes. However, challenges such as medication costs, lifestyle changes, and scheduling conflicts made it harder for patients to fully follow MTM advice. Despite these challenges, MTM played an important role in effectively managing hypertension.

**Keywords:**

MTM (Medication therapy management), Patient Perception, Hypertension management, Cross-sectional study, Medication Adherence, Pharmacist Role.

## INTRODUCTION

Pharmacist-led MTM services comprise of a process in which services are provided by healthcare professionals who have expertise in medication administration, management, and therapeutic consultation to ensure the parameter of efficacy (1). MTM-centered services are aimed at avoiding any kind of medication error and making patients efficient in the management of self-medication (1). The goals of MTM services include adverse drug events (ADEs) and adverse drug reaction prevention and also improve medication adherence and the education of patients on the appropriate medication use (2). MTM has now advanced toward acute and chronic medication education which helps the patient to manage their medications and costs (2).

The global challenge of hypertension management is a major public health issue, affecting an estimated 1.28 billion adults worldwide according to the World Health Organization (3). Hypertension often goes unnoticed in the early stages because it lacks clear symptoms, yet it significantly raises the risk of serious cardiovascular conditions including heart attacks, strokes, and kidney diseases (4). This makes hypertension one of the leading causes of premature death across the globe (5). Although there are effective treatments available managing hypertension remains difficult due to low awareness, poor control rates, and inconsistent adherence to prescribed medications (6). These challenges are exacerbated by socioeconomic inequalities and restricted access to healthcare in low and middle-income countries leading to worse health outcomes in these populations (7). The growing number of older adults along with urbanization and lifestyle changes such as higher salt consumption and an increase in sedentary lifestyle behavior are also driving the rise in hypertension cases (8). To tackle this complex issue, a multifaceted strategy is needed (9). This should include public health campaigns, better patient education and greater involvement of pharmacists and other healthcare providers in team-based care to improve hypertension management and monitoring (10). International efforts to enhance hypertension control are essential for reducing the associated health risks and easing the heavy burden on healthcare systems worldwide (11).

Pharmacists review thoroughly all the medications a patient is taking like over-the-counter, herbal products and prescription drugs (12). Based on their evaluation pharmacists form individualized drug therapy plans according to the patient's health goals (12). Pharmacists optimize medication

regimens including factors like dosages, patient preferences, and administration routes (13). They talk about any misconceptions patients may have about their drug therapy (14). They review and evaluate regularly the efficacy of medications, perform necessary changes to achieve effective outcomes including control of chronic conditions, and find the best treatment according to the patient response (15). Pharmacist monitors patient adherence to medication therapy and solves problems that may result in non-compliance (16).They adjust medication regimens and set reminders for taking medication (16). They solve any problem that may arise during medication therapy such as incorrect medication use and adverse drug reactions (17). Pharmacists monitor progress and follow up with patients to confirm that adjustments made are potential and to see if any other changes are required (18).

MTM is an essential part of patient-centered care, aimed at enhancing therapeutic outcomes through medication review (19). Positive evaluation can improve medication adherence and also dynamic methods of health management (20). Patients' interpretation of their medication, their opinion about the safety and efficacy of treatment, and their belief in the Pharmacist are important to determine the result of MTM (21). Improvement in disease state and reduced adverse effects engage patients with these services (22). Patients acknowledged when MTM services fulfilled their individual needs, comprising an extensive description of their regimens and parameters (23). Efficient communication is vital for a beneficial patient opinion of MTM (24). The effective discussion between Health care recipient and medication expert is related to patient satisfaction (25). Patients who participated in the decision-making process generally possess a beneficial approach toward awareness of MTM services (26). Establishing the cost-effectiveness of MTM through education can enhance patient perception (27). Improvement in blood pressure management can enhance overall awareness of services and promote persistent participation among patients (28). MTM services guide lifestyle modifications and focus on dietary intake, exercise, and stress management (29). Long-term engagement of patients with MTM services usually has an increased positive perception (30). Regular monitoring is important for individuals with elevated blood pressure, they acknowledge when pharmacist monitor their blood pressure and modify therapy plans as required, enhancing their belief in MTM (10).

Research is aimed at investigating how patients perceive their trust in the effectiveness of pharmacist-patient consultation provided by MTM services for the management of hypertension (31). The main objective is to investigate the expectations of patients in the management of hypertension and their willingness to use MTM services further (31). To evaluate the perceptions of patients in knowing hypertension and related drug therapy management by receiving MTM services led by pharmacists is also on the agenda of this study (32). Understanding the perceptions

and expectations of patients is necessary for the effectiveness of pharmacist-provided MTM services for the management of hypertension (33). Comprehending the perceptions of patients is crucial in getting positive outcomes on clinical efficacy, drug adherence, and drug safety for patients of hypertension, patient counseling where needed, and adjusting the appropriate doses of drugs (34). Pharmacist-led MTM service program has extended the role of the pharmacist from dispensing medication to a professional healthcare provider of a clinical team (34). Knowing perceptions of patients from receiving pharmacist-provided MTM services has significantly decreased the ratio of non-communicable diseases (NCDs), two of which result from diabetes and hypertension (35). The knowledge of how patients perceive MTM services provided by pharmacists on hypertension can decrease hospital admission rates, more approaches to identifying drug-related problems, and maximize the clinical efficacy of drug therapy (36).

## MATERIALS AND METHODOLOGY

This study is a cross-sectional, observational study, and multicenter research of multiple community pharmacies in Lahore, one of the biggest and most significant cities in Pakistan. A pre-validated data collection instrument was utilized to gather comments and responses from patients at several community pharmacies. The study took place between May 15, 2024, to August 29, 2024.

Inclusion Criteria:

Patients aged 20 years and above having the disease of hypertension were included. These participants should be on antihypertensive medication. Patients who have other co-morbidities with hypertension can also participate in it.

Exclusion Criteria:

Patients who had no diagnosis of hypertension and were aged less than 20 years.

The main objective of this study is to determine the patient's perceptions of the Medication Therapy Management (MTM) services they received to control their hypertension. Data were gathered through structured interviews and a questionnaire consisting solely of closed-ended questions. This survey has four main elements: demographic information, MTM awareness, MTM attitudes, and MTM service outcomes, and almost ten to fifteen minutes were allotted for each interview. Qualified interviewers were interviewed to ensure uniformity and precision in the questionnaire distribution. The responses were manually recorded to guarantee data integrity and a yes or no choice in closed-ended questions is made in collecting quantitative data on patients'

points of view.

Initially, this research aimed to target around 114 patients using the convenience sample technique. Patients were stratified into four age categories: 25-29 years, 30-39 years, 40-49 years, and 50 above. Participants had to fulfill specific requirements to be eligible, including having a diagnosis of hypertension and having received MTM therapies ever either recently or in the past. Direct patient interactions resulted in an offer for people who fit the requirements to take part in the study.

Data collection was supervised by qualified pharmacists in Pakistan. Randomly selected pharmacies were required to obtain informed consent from the volunteers. Thorough explanations were provided for each question. Each eligible participant was informed of the significance and implications of the research after it obtained ethical approval. The patients were fully informed regarding the purpose of this research, the extent of their participation, and any possible risks or benefits. This included how their data will be utilized. This study ensured that all the information and data were kept confidential. The identity of all of the participants was kept anonymous. The selection of the participants was unbiased eradicating any discrimination and providing fair participation in this study.

From every randomly selected community pharmacy, a minimum of 6 prescriptions were collected and on a data collection sheet, all the pertinent information was recorded. Patients who had been diagnosed with the disease and had a complete medication history that included information such as age, race, gender, family background, marital status, and both past and present medical history were asked to get their consent.

**Statistical analysis**

The analysis of data was carried out with the help of the 24th version of the SPSS. Descriptive data from this study was presented as mean with standard deviation (SD). The data normality was accessed through the SPSS, utilizing kurtosis + skewness testing. The data distribution was identified as normal. Subsequently, independent t-test statistics or One-way ANOVA were employed to assess the null hypothesis. In the evaluation of categorical data, Fisher's exact test or the Chi-square test was utilized to determine the p-value. A p-value less than 0.05 was established as the threshold for statistical significance.

**RESULTS**

The study involved 114 hypertensive patients, mostly females (63.2%) aged between 50 years and above (51.8%). The majority of them had been managing hypertension for over a year (88.8%), with 45.6% managing it for 1-5 years. Educational levels varied 46.5% with completed graduation, and a significant portion (35.1%) reported comorbid conditions. Most participants resided in urban areas (75.4%), and income levels were diverse with 36.8% earning more than 100 thousand monthly. These results highlight the prevalence of hypertension management among relatively older, educated, and urban populations often facing additional health challenges.
Additional detailed information is available in the following Table 1.

**Table 1:** Presents the demographic information of patients. (N=114)

| | |
|---|---|
| **Age** | |
| 20-25 | 16 (14.0) |
| 30-39 | 9 (7.9) |
| 40-49 | 30 (26.3) |
| 50 or above | 59 (51.8) |
| **Gender** | |
| Male | 42 (36.8) |
| Female | 72 (63.2) |
| **Education Level** | |
| Matric | 27 (23.7) |
| Intermediate | 25 (21.9) |
| Graduation | 53 (46.5) |
| Post-graduation | 9 (7.9) |
| **Monthly income** | |
| less than 30 thousand | 25 (21.9) |
| 31-50 thousand | 16 (14.0) |
| 51-100 thousand | 31 (27.2) |
| More than 100 thousand | 42 (36.8) |
| **Area** | |
| Urban | 86 (75.4) |
| Rural | 28 (24.6) |
| **Onset of disease** | |
| Less than 6 months | 7 (6.1) |
| 6months-1year | 16 (14.0) |
| 1-5 years | 52 (45.6) |
| More than 5 | 39 (43.2) |

| **Comorbidity** | |
|---|---|
| Yes | 40 (35.1) |
| No | 74 (64.9) |

The awareness survey results show that most respondents understand key aspects of hypertension management. About 69.3% understand MTM, and 52.6% have heard of it before. A significant 86.8% recognize that family history increases hypertension risk, and 94.7% are aware of obesity as a risk factor. Additionally, 88.6% understand the role of stress management, while over 93% acknowledge the importance of lifestyle changes and reducing salt intake in managing hypertension.

**Table 2:** Present the information on the patients' Awareness. (N=114)

| Do you understand MTM(Medication therapy management)? | |
|---|---|
| Yes | 79 (69.3) |
| No | 35 (30.7) |
| Have you heard about MTM before? | |
| Yes | 60 (52.6) |
| No | 54 (47.4) |
| Do you know the purpose of MTM? | |
| Yes | 68 (59.6) |
| No | 46 (40.4) |
| Have you ever availed of medication therapy management (MTM) services from a pharmacist or healthcare provider? | |
| Yes | 72 (63.2) |
| No | 42 (36.8) |
| Do you know that family history can increase the risk of developing hypertension (HTN)? | |
| Yes | 99 (86.8) |
| No | 15 (13.2) |
| Do you know that obesity can be a risk factor for hypertension (HTN)? | |

| | |
|---|---|
| Yes | 108 (94.7) |
| No | 6 (5.3) |
| Do you understand the role of stress management in controlling hypertension (HTN)? | |
| Yes | 101 (88.6) |
| No | 13 (11.4) |
| Are you aware of the potential complications associated with hypertension (HTN), such as stroke and heart disease? | |
| Yes | 101 (88.6) |
| No | 12 (10.5) |
| Are you aware of the lifestyle changes that can help manage hypertension (HTN), such as diet modifications and regular exercise? | |
| Yes | 106 (93.0) |
| No | 8 (7.0) |
| Are you aware of the importance of reducing salt intake in managing hypertension (HTN)? | |
| Yes | 107 (93.9) |
| No | 7 (6.1) |

The data indicates that patients' attitudes remain consistent across various demographic and clinical groups, with no significant differences in scores observed by age, gender, education, income, or comorbidity status ($p > 0.05$). The minimal effect sizes further suggest that these factors have a negligible impact on patient attitude towards the treatment or intervention.

**Table 3:** Presents the information on the patients' Attitude. (N=114)

| Outcome Variable | Mean (SD) | 95% Confidence Interval (C.I) | | *t- statistic (pdf)* | *p- value* |
|---|---|---|---|---|---|
| | | Lower bounds | Upper bounds | | |
| **Age** | | | | | |
| 25-29 | 38.56±6.75 | 34.64 | 42.15 | *0.112 (1,113)* | *0.947* |
| 30-39 | 39.00±4.12 | 36.00 | 41.60 | | |
| 40-49 | 39.22±5.98 | 37.07 | 41.48 | | |
| 50 or above | 38.42±6.83 | 36.66 | 40.11 | | |
| **Gender** | | | | | |
| Male | 37.7±7.45 | 35.25 | 39.86 | *1.482 (1,113)* | *0.226* |
| Female | 39.26±5.62 | 37.88 | 40.46 | | |
| **Education level** | | | | | |
| Matric | 37.07±7.91 | 33.74 | 39.75 | *1.131 (1,113)* | *0.331* |
| Intermediate | 40.00±5.31 | 37.86 | 42.13 | | |
| Graduation | 38.66±6.09 | 37.07 | 40.20 | | |
| Post-graduation | 40.33±5.04 | 37.16 | 43.55 | | |
| **Monthly income** | | | | | |
| Less than 30 thousand | 38.84±5.27 | 36.85 | 49.95 | *0.171 (1,113)* | *0.916* |
| 31-50 thousand | 37.68±7.10 | 34.21 | 40.99 | | |
| 51-100 thousand | 38.70±5.87 | 36.65 | 40.86 | | |
| More than 100 thousand | 39.02±7.16 | 36.72 | 41.10 | | |
| **Area** | | | | | |
| Urban | 38.88±6.48 | 37.62 | 40.30 | *0.257 (1,113)* | *0.613* |
| Rural | 38.17±6.06 | 35.87 | 40.45 | | |
| **Onset of disease** | | | | | |
| Less than 6 months | 37.00±5.74 | 32.83 | 41.50 | *0.178 (1,113)* | *0.911* |
| 6months-1year | 38.93±6.89 | 35.25 | 42.18 | | |
| 1-5years | 38.76±6.79 | 36.64 | 40.54 | | |
| More than 5years | 38.84±5.84 | 37.00 | 40.54 | | |

| | | | | | |
|---|---|---|---|---|---|
| **Comorbidity** | | | | | |
| Yes | 39.02±7.78 | 36.60 | 41.31 | *0.149 (1,113)* | *0.700* |
| No | 38.54±5.50 | 37.23 | 39.76 | | |

The outcomes indicate that the majority of patients believe MTM service positively influences their medication adherence (86%), reduces side effects (77.2%), and decreases drug interactions (76.3%). A significant portion of patients (94.7%) feel that MTM enhances their understanding of medication usage leading to better health outcomes (93.9%). However, challenges such as the cost of medications, difficulty in making lifestyle changes, and scheduling conflicts were noticed by some patients, affecting their ability to fully adhere to MTM recommendations.

**Table 4:** Present the information on patients' Outcomes. (N=114)

| | |
|---|---|
| Does MTM increase medication adherence? | |
| Yes | 98 (86.0) |
| No | 16 (14.0) |
| Does MTM decrease medication side effects? | |
| Yes | 88 (77.2) |
| No | 26 (22.8) |
| Does MTM reduce drug interactions? | |
| Yes | 87 (76.3) |
| No | 27 (23.7) |
| Does MTM help in better understanding how to take medication properly? | |
| Yes | 108 (94.7) |
| No | 6 (5.3) |
| Does MTM result in better health outcomes? | |
| Yes | 107 (93.9) |
| No | 7 (6.1) |
| Has the cost of your medications made it hard to follow MTM advice? | |
| Yes | 48 (42.1) |
| No | 66 (57.9) |
| Do you find it hard to understand the information given during MTM sessions? | |
| Yes | 64 (56.1) |
| No | 50 (43.9) |
| Have you found it difficult to make lifestyle changes while following MTM suggestions? | |

| | |
|---|---|
| Yes | 54 (47.4) |
| No | 60 (52.6) |
| Have side effects from medications made it tough to stick to MTM recommendations? | |
| Yes | 46 (40.4) |
| No | 68 (59.6) |
| Does your work or personal schedule make it hard to attend MTM sessions? | |
| Yes | 63 (55.3) |
| No | 51 (44.7) |

## DISCUSSION

The patients between the ages of 40 to 49 years have a better attitude towards the MTM as compared to the other age groups. The mean score of the age group between 40 to 49 is 39.22 whereas, 30 to 39 has 39.00 and the age group 20 to 29 has 38.56 and the age group 50 or above has the least mean score of 38.42. It was considered statistically non-significant with a P value of 0.947. The study conducted in the US found that middle-aged group patients 40-60 years old have a more positive attitude towards MTM than other age groups mostly because of their more health consciousness. The findings of this study are almost the same as our study which was conducted in Pakistan (37). The samples involved 42 males and 72 females giving a total of 114 patients. It was noted as well that males had comparatively a lesser mean score of 37.7 in terms of attitude than of females which was 39.26, hence inferring those females possessing better attitude. The p-value is 0.226 and is not significant. The above finding agrees with previous findings of a study that was conducted in Western Australia regarding the Male and female students' attitudes toward social studies (Hansberry and Moroz 2001). This have also indicated that a positive attitude is more likely to be espoused by the female gender than the male. The probable cause for such a pattern may be attributed to better understanding in females.

Also, from the results of the current research, it can be deduced that education has a positive significant relationship with patient responses and implies a statistically significant effect on the patient's attitudes. Such findings accord with various research conducted in different countries showing that favorable attitudes are associated with increased literacy levels among patients (Pareek and Sharma 2012).

The analysis revealed no significant link between patients' monthly income and their attitudes as evidenced by a p-value of 0.916. This suggests that variations in income do not influence patients' attitudes toward Pharmacist-provided medication therapy. However, the previous studies differ as they imply that the income size of the patient has a potential influence (Lee, Zarowitz et al.

2023).

The patients of HTN from urban areas have only a slightly bit more raised attitude towards MTM-provided services in comparison to patients of HTN residing in rural areas. The mean (SD) of urban areas is 38.88% with p value of 0.613 which is non-significant and that of rural areas is 38.17% which is only a slightly bit less than that of urban areas. Surprisingly, there is little or no rural-urban difference in attitude towards MTM services. Evidence from a study held in Bangladesh in 2017-2018 also showed that there is no association between rural and urban areas for the prevalence of high blood pressure (38).

It was observed that more patients had an onset of hypertension from six months to one year with a mean (SD) of 38.93. After that comes the category of patients with onset of disease from more than five years with a mean (SD) of 38.84 following the other category of patients with onset of HTN for one to 5 years with a mean (SD) of 38.76. This finding aligns with the study published in 2022 in northwest Ethiopia with the onset of HTN from 3years with a mean duration of 86% (39). The last category for the onset of disease is of patients having it for less than six months with the least mean (SD) of 37.00% with a non-significant p-value of 0.911.

Another information asked for the attitude of patients on MTM-provided services was the presence of any comorbidity. It was observed that more patients had comorbidity along with hypertension with a mean (SD) of 39.02% (p-value 0.700) and patients not having any comorbidity were with a mean (SD) of 38.54%. A similar study on people hospitalized with hypertension in Taizhou People's Hospital, China from September to December 2019 shows more comorbidities(40).

The current study on MTM awareness proves that the question "Do you understand MTM?" was asked by the patients. The result shows that 69.3 percent of patients marked yes and 30.7 percent of patients did not know about it. This study was also conducted in Indonesia which has the same results as our study conducted in Pakistan (41). Another question" Have you ever avail MTM services from a pharmacist?" was asked, and the percentage of patients who said yes was 63.2. Similarly, the research conducted in the US showed positive outcomes and is also parallel to our study (42). The question in the current study "Do you know the family history can increase the risk of developing HTN?" was asked and 86.8 percent of patients marked the yes option. Corresponding to this, the study conducted on Siri-Lankan adults also showed that more people were aware of it (43). Another question "Do you know that obesity can be a risk factor for HTN?" was also raised and the result shows that 94.7 percent population agrees with this statement. On the other hand, the study conducted in 2023 presented the same outcome as our study (44). The current study on MTM awareness proved that the question" Do you understand the role of stress management in controlling hypertension? "Was asked by the patients. The results showed that

88.6 percent of patients marked yes, and 11.4 percent of patients did not know about it. The study was also conducted in India which has the same result as our study conducted in Pakistan (45). Another question" Are you aware of the potential complications associated with hypertension such as stroke and heart disease?" was asked, and the percentage of patients who said yes was 88.6, similarly the research conducted in the USA, England, and Canada showed positive outcomes and is also parallel to our study (46). The question in the current study "Are you aware of lifestyle changes that can help manage Hypertension such as diet modification and regular exercises?" was asked and 93 percent of patients marked yes, corresponding to this, the study conducted in Iran also showed that more people know about it (47). The question" Are you aware of the importance of reducing salt intake in managing hypertension?" was also raised and the result showed that 93.9 percent of people agree with this statement on the other hand the study conducted in Turkey presented the same outcome as our study (48).

A current study on MTM outcomes proved that 86 percent of patients agreed that MTM increases medication adherence in response to "Do you understand the role of stress management in controlling hypertension?" a study conducted in Kerala has the same outcome as our study (49). In response "Does MTM increase medication side effects? "77.2 percent of patients agreed about it, a study conducted in the USA corresponding to our study (50). In response to "Does MTM reduce drug interaction?" 76.3 percent of patients agreed about it, a study conducted in California corresponding to our study (51). Another question in outcomes of MTM "Does MTM help in better understanding of how to take medication properly?" was asked by the patients and 94.7% of patients marked yes. Similarly, another study conducted in the US showed the same positive outcomes as our study conducted in Pakistan (52). The next question was, "Does MTM result in better health outcomes?" which resulted in 93.9% of respondents saying yes. Corresponding to this, the study was conducted in another country and gave the same results as the research (53). The question, "Has the cost of your medications made it hard to follow MTM advice?" showed the result with 57.9% of respondents marking the NO option. Similarly, the research conducted in the US gave parallel results saying the cost of medications does not find hard to follow MTM (54). The next question "Do you find it hard to understand the information given during MTM sessions?" was asked by the patients and 56.1% of patients marked the yes option. Whereas there is research found in 2012 whose results are quite different from our study. The respondents in this study do not find MTM hard to understand (55). The question "Does your work or personal schedule make it hard to attend MTM sessions?" was also asked and 55.3 % of patients agreed with the statement no study was found on this question, hence proving that this question in our study shows novelty in this area as previously no study has been conducted on it yet.

## CONCLUSION

In conclusion, the research shows that pharmacist-provided Medication Therapy Management (MTM) significantly enhances hypertension management. Patients receiving MTM exhibit improved blood pressure control, higher medication adherence, and better overall health management. These findings emphasize the effectiveness of incorporating MTM into routine clinical practice for optimizing treatment outcomes in hypertensive patients.

## LIMITATIONS OF THE STUDY

The limited sample size may limit the generalizability of the results. The brief study period may have impacted the thoroughness of data collection. Also, there may be issues with selection bias and uncontrolled complicating factors that could affect the outcomes.

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