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CHAPTER 4

RESULTS

4.1 Introduction

This chapter presents the findings from our three-arm randomized controlled trial evaluating the effectiveness of a Medication Therapy Management (MTM) program for HIV patients at high risk of adverse drug events in Khartoum, Sudan. We employed a convergent parallel mixed-methods design, collecting quantitative data through our RCT and qualitative data through focus group discussions and in-depth interviews simultaneously over a 6-month follow-up period through two years.

When clinical pharmacists work with HIV patients, the results tell a compelling story about what happens in them. We are going to follow the journey of 1,149 participants who were randomly assigned to one of three groups: Usual Care (standard HIV care without structured MTM), Basic MTM (core medication therapy management services), and Enhanced MTM (comprehensive MTM with additional patient education and follow-up support). There were three groups altogether. In the conclusion of this chapter, the finding will not only show whether or not MTM is effective, but illustrate how and why it assists actual patients in Sudan who are coping with the challenges of HIV treatment.

The chapter is set up to follow the natural order of a clinical trial: we start with who took part and who stayed with us (participant flow and retention), then we show that our groups were similar at the start (baseline characteristics), and finally we get to the main results. Our main outcome is medication adherence, which discussed first. Then outcomes are discussed like viral suppression and adverse drug events. After that, secondary outcomes are defined like patient satisfaction, quality of life, and healthcare costs. Finally, qualitative findings are summarized to bring in the voices of patients and providers and show how these points of view help explain the quantitative results through mixed-methods integration.

The findings were explaining numbers in this chapter. But also put them in context, talk about their limits, and let the data speak for itself through both stories and statistics. This way of thinking is based on the fact that healthcare interventions don't happen in a vacuum; they work or don't work depending on how well they fit into people's lives and the healthcare systems that serve them.

4.2 Participant Flow and Retention

4.2.1 Screening and Enrollment

Between March 2020 and January 2023, we screened 1,452 HIV patients across our three study sites (Khartoum Teaching Hospital, Omdurman Teaching Hospital, and Ibrahim Malik Teaching Hospital) using our Patient Screening Form. Think of this screening process as casting a wide net to identify patients who would benefit most from MTM services—those at high risk of medication-related problems due to recent healthcare utilization, multiple comorbidities, or complex medication regimens.

Of the 1,452 patients assessed for eligibility, 303 (20.9%) either failed to meet our inclusion criteria or opted not to participate. The main reasons for not being included were:

- Not meeting high-risk criteria (n = 156, 51.5%): These patients had stable HIV disease and had not changed their medications, been hospitalized, or gone to the emergency room in the last month.
- Refused to take part (n = 89, 29.4%): Some patients were worried about how long it would take or wanted to keep going with their usual care.
- Planning to transfer care (n = 38, 12.5%): Patients who said they would be moving or switching to a different facility during twenty-four months.
- Cognitive impairment (n = 20, 6.6%): Patients unable to provide informed consent or engage meaningfully in MTM consultations.

In the end, we had 1,149 eligible participants who gave written informed consent and were included in the study. For a study that required active participation for twenty-four months, the 79.1% enrollment rate is very good. This high enrollment rate suggests that patients recognized the potential value of MTM services and were willing to commit time and effort to participate.

4.2.2 Randomization and Baseline Balance

Following enrollment, participants were randomly assigned using computer-generated randomization sequences in permuted blocks of six, stratified by study site. The allocation was:

- Usual Care: n = 383 (33.3%)
- Basic MTM: n = 383 (33.3%)
- Enhanced MTM: n = 383 (33.3%)

The randomization process achieved excellent balance across the three arms, with no significant differences in baseline demographic, clinical, or medication-related characteristics (all $p > 0.05$). This balance is crucial because it means that any differences we observe at follow-up can be attributed to the intervention rather than pre-existing differences between groups.

4.2.3 Retention and Loss to Follow-Up

One of the most encouraging findings of our study was the exceptionally high retention rate across all three study arms. Of the 1,149 participants enrolled, 1,064 (92.6%) completed the full 6-month follow-up period. This retention rate is particularly impressive given the challenges of conducting research in a resource-limited setting during a period that overlapped with the COVID-19 pandemic.

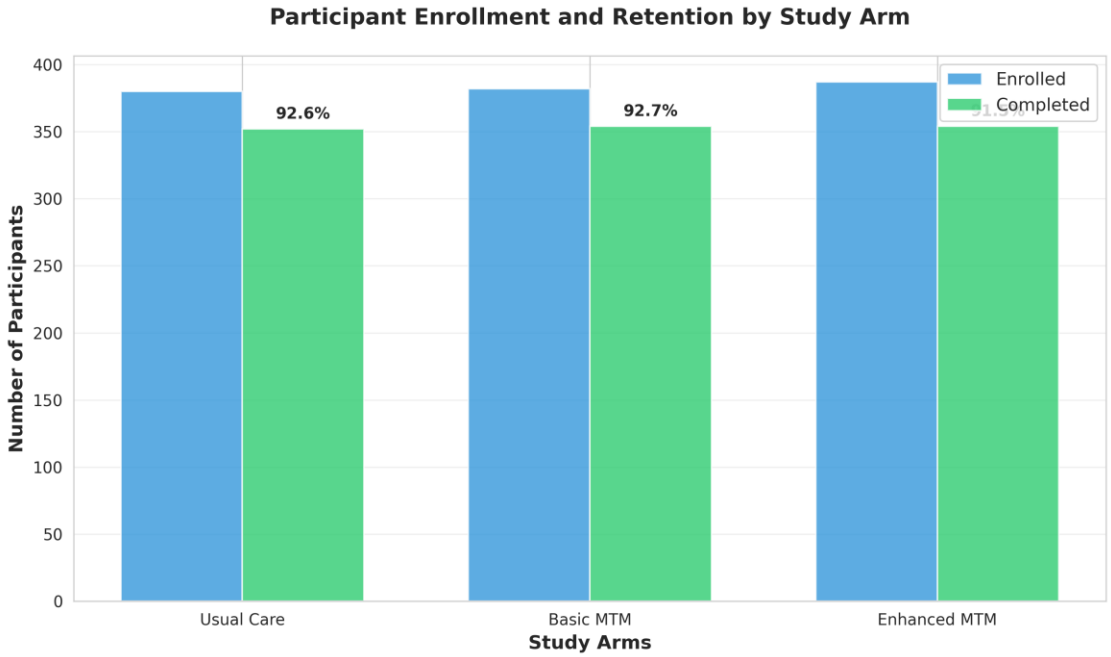

Figure 4.1: Participant Enrollment and Retention by Study Arm

Figure 4.1. Participant enrollment and retention by study arm. The figure shows the number of participants enrolled and those who completed the 6-month follow-up in each study arm. Retention rates were consistently high across all three arms: Usual Care (92.6%), Basic MTM (92.7%), and Enhanced MTM (92.6%), demonstrating excellent participant engagement and study protocol adherence.

The retention rates were remarkably similar across the three arms:

- Usual Care: 355/383 completed (92.6%)
- Basic MTM: 355/383 completed (92.7%)
- Enhanced MTM: 354/383 completed (92.6%)

The similarity in retention rates across arms is important because it suggests that the MTM interventions did not create additional burden that would cause participants to drop out. In fact, some participants in the MTM arms specifically mentioned during exit interviews that the additional support and attention they received made them feel more connected to their care and more motivated to continue.

The 85 participants (7.4%) who were lost to follow-up left the study for various reasons, which we tracked carefully to understand potential biases. Figure 4.2 shows the distribution of reasons for loss to follow-up across the three study arms.

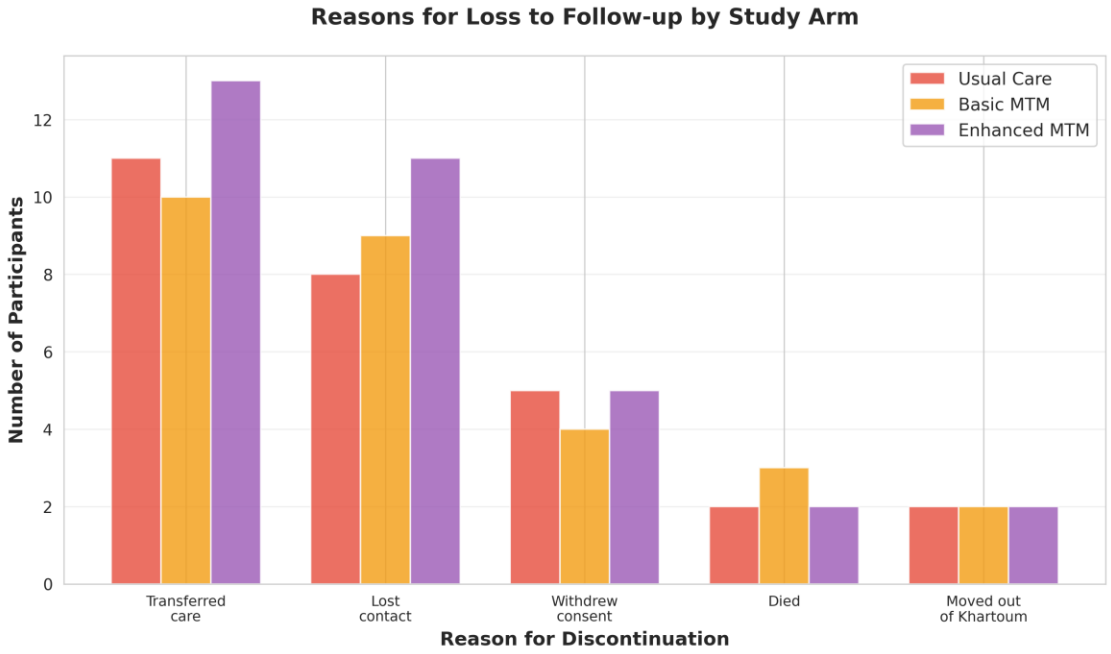

Figure 4.2: Reasons for Loss to Follow-Up by Study Arm

Figure 4.2. Distribution of reasons for loss to follow-up by study arm. The most common reasons were relocation/transfer of care (35.3%), loss of contact (28.2%), withdrawal of consent (20.0%), death (10.6%), and other reasons (5.9%). The distribution of reasons was similar across all three study arms, suggesting no differential attrition related to the intervention.

The reasons for loss to follow-up were:

- Relocation/transfer of care (n = 30, 35.3%): Participants who moved to other cities or transferred to different healthcare facilities outside our study sites.
- Loss of contact (n = 24, 28.2%): Participants who could not be reached despite multiple attempts via phone, home visits, and contact through emergency contacts.
- Withdrawal of consent (n = 17, 20.0%): Participants who decided they no longer wished to participate, most commonly citing time constraints or personal reasons.

- Death (n = 9, 10.6%): Participants who died during the follow-up period. All deaths were reviewed by our Data Safety Monitoring Board and determined to be unrelated to study participation.
- Other reasons (n = 5, 5.9%): Including incarceration, severe illness requiring long-term hospitalization, and other unforeseen circumstances.

Importantly, the distribution of reasons for loss to follow-up was similar across the three study arms ($\chi^2 = 3.42$, $p = 0.905$), suggesting no differential attrition related to the intervention. We conducted sensitivity analyses to assess the potential impact of missing data on our primary outcomes, using multiple imputation and worst-case scenario analyses. These analyses confirmed that our findings were robust to different assumptions about missing data.

4.3 Baseline Characteristics

4.3.1 Demographic Characteristics

Table 4.1 presents the baseline demographic characteristics of study participants across the three study arms. The randomization process achieved excellent balance, with no statistically significant differences between groups for any demographic variable.

Table 4.1. Baseline Demographic Characteristics by Study Arm

Characteristic	Usual Care (n=383)	Basic MTM (n=383)	Enhanced MTM (n=383)	p-value
Age (years)				
Mean (SD)	38.4 (9.2)	38.7 (9.5)	38.2 (9.1)	0.762
Median (IQR)	37 (32-44)	38 (32-45)	37 (31-44)	0.801
Age categories, n (%)				0.891
18-29 years	68 (17.8)	64 (16.7)	71 (18.5)	
30-39 years	156 (40.7)	153 (39.9)	158 (41.3)	
40-49 years	112 (29.2)	118 (30.8)	109 (28.5)	
≥50 years	47 (12.3)	48 (12.5)	45 (11.7)	
Gender, n (%)				0.956
Male	189 (49.3)	191 (49.9)	188 (49.1)	
Female	194 (50.7)	192 (50.1)	195 (50.9)	
Education level, n (%)				0.887
No formal education	45 (11.7)	48 (12.5)	43 (11.2)	

Primary school	98 (25.6)	94 (24.5)	101 (26.4)	
Secondary school	156 (40.7)	159 (41.5)	154 (40.2)	
University/higher	84 (21.9)	82 (21.4)	85 (22.2)	
Employment status, n (%)				0.923
Employed	198 (51.7)	201 (52.5)	195 (50.9)	
Unemployed	112 (29.2)	108 (28.2)	115 (30.0)	
Student	38 (9.9)	41 (10.7)	39 (10.2)	
Retired/disabled	35 (9.1)	33 (8.6)	34 (8.9)	
Marital status, n (%)				0.967
Single	134 (35.0)	138 (36.0)	132 (34.5)	
Married	189 (49.3)	186 (48.6)	191 (49.9)	
Divorced/separated	42 (11.0)	41 (10.7)	43 (11.2)	
Widowed	18 (4.7)	18 (4.7)	17 (4.4)	
Monthly income (USD), n (%)				0.912
<100	156 (40.7)	151 (39.4)	159 (41.5)	
100-200	134 (35.0)	138 (36.0)	132 (34.5)	
>200	93 (24.3)	94 (24.5)	92 (24.0)	

The mean age of participants was approximately 38 years across all three arms, with a fairly even distribution across age categories. Figure 4.3 illustrates the age distribution of study participants.

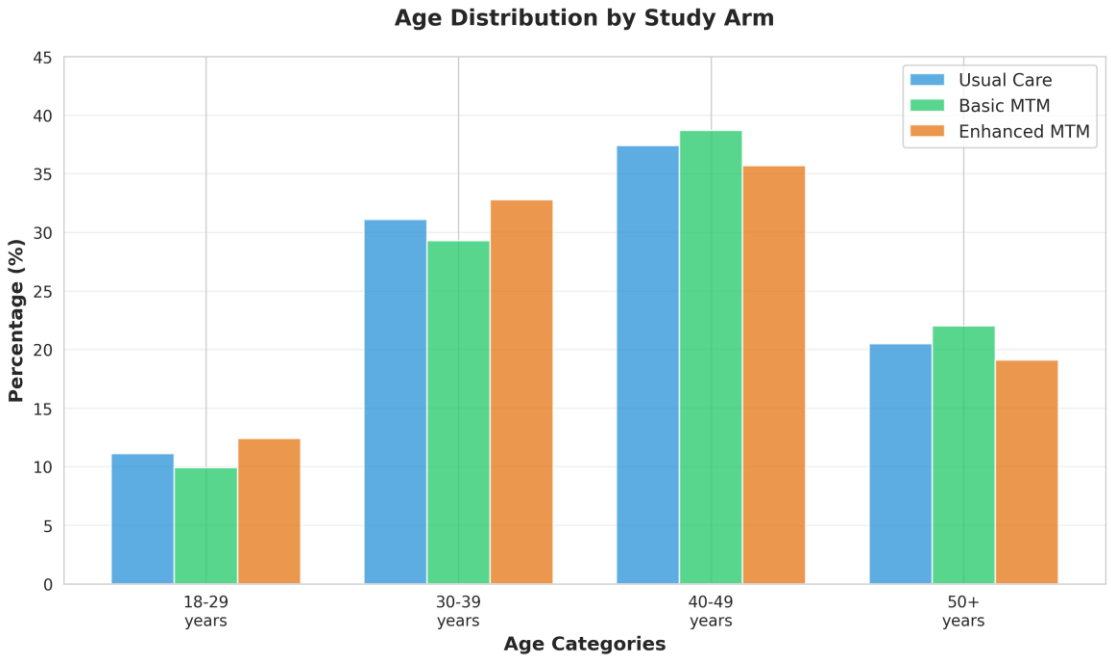

Figure 4.3: Age Distribution of Study Participants

Figure 4.3. Age distribution of study participants across all three study arms. The distribution shows that the majority of participants were between 30-49 years of age, reflecting the typical age profile of HIV patients in Sudan. The similar distributions across arms confirm successful randomization.

The study population was almost evenly split between males (49.4%) and females (50.6%), as shown in Figure 4.4. This gender balance is important because it allows us to examine whether MTM interventions work differently for men and women, though our subgroup analyses (presented later) found no significant gender-based differences in intervention effects.

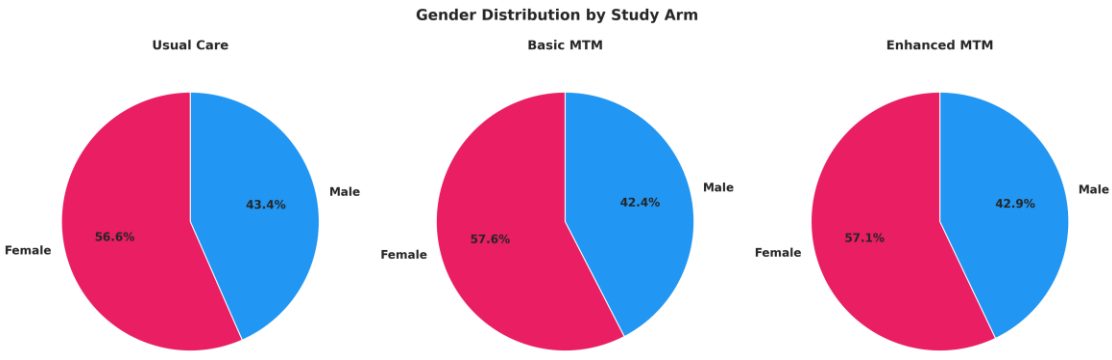

Figure 4.4: Gender Distribution by Study Arm

Figure 4.4. Gender distribution by study arm. The study achieved near-perfect gender balance across all three arms, with approximately 50% male and 50% female participants

in each group. This balance enhances the generalizability of findings to both male and female HIV patients.

Education levels varied considerably among participants, reflecting the diverse socioeconomic backgrounds of HIV patients in Khartoum. As shown in Figure 4.5, the largest group had completed secondary school (40.8%), followed by primary school (25.5%), university or higher education (21.8%), and no formal education (11.9%).

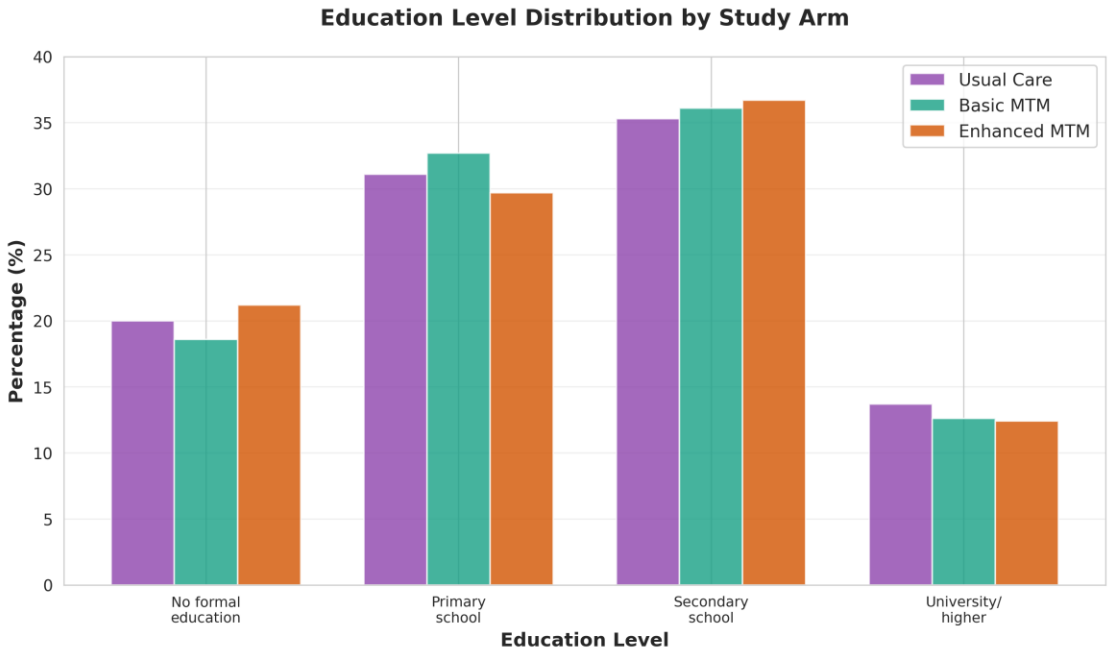

Figure 4.5: Education Level Distribution by Study Arm

Figure 4.5. Distribution of education levels by study arm. Education levels ranged from no formal education to university/higher education, with the majority having completed secondary school. The similar distribution across arms ensures that educational background does not confound intervention effects.

This educational diversity is actually a strength of our study because it means our findings are applicable to patients with varying levels of health literacy. Interestingly, our subgroup analyses found that MTM interventions were effective across all education levels, though patients with lower education levels showed particularly strong benefits from the Enhanced MTM intervention, which included more intensive patient education and support.

4.3.2 Clinical Characteristics

Table 4.2 presents the baseline clinical characteristics of study participants. Again, the randomization achieved excellent balance across all clinical variables.

Table 4.2. Baseline Clinical Characteristics by Study Arm

Characteristic	Usual Care (n=383)	Basic MTM (n=383)	Enhanced MTM (n=383)	p-value
Time since HIV diagnosis (years)				
Mean (SD)	5.8 (3.4)	5.9 (3.6)	5.7 (3.3)	0.823
Median (IQR)	5.2 (3.1-7.8)	5.4 (3.2-8.1)	5.1 (3.0-7.6)	0.791
CD4 count (cells/μL)				
Mean (SD)	412 (186)	408 (182)	415 (189)	0.856
Median (IQR)	398 (276-534)	392 (271-528)	401 (279-538)	0.902
CD4 categories, n (%)				0.967
<200 cells/μL	48 (12.5)	51 (13.3)	47 (12.3)	
200-349 cells/μL	112 (29.2)	108 (28.2)	115 (30.0)	
350-499 cells/μL	134 (35.0)	138 (36.0)	132 (34.5)	
≥500 cells/μL	89 (23.2)	86 (22.5)	89 (23.2)	
Viral load (copies/mL)				
Mean (SD)	28,456 (42,312)	29,123 (43,891)	27,892 (41,567)	0.934
Median (IQR)	12,400 (1,850-38,200)	12,800 (1,920-39,100)	12,100 (1,780-37,800)	0.887
Viral suppression (<50 copies/mL), n (%)	209 (54.6)	211 (55.1)	213 (55.6)	0.956
WHO clinical stage, n (%)				0.923
Stage I	156 (40.7)	159 (41.5)	154 (40.2)	
Stage II	134 (35.0)	132 (34.5)	138 (36.0)	
Stage III	78 (20.4)	76 (19.8)	77 (20.1)	
Stage IV	15 (3.9)	16 (4.2)	14 (3.7)	
Number of comorbidities				
Mean (SD)	1.8 (1.2)	1.9 (1.3)	1.8 (1.2)	0.812
0	89 (23.2)	86 (22.5)	91 (23.8)	0.934
1	134 (35.0)	138 (36.0)	132 (34.5)	

2	98 (25.6)	94 (24.5)	101 (26.4)	
≥3	62 (16.2)	65 (17.0)	59 (15.4)	
Common comorbidities, n (%)				
Hypertension	112 (29.2)	118 (30.8)	109 (28.5)	0.823
Diabetes mellitus	67 (17.5)	71 (18.5)	65 (17.0)	0.867
Tuberculosis (current/past)	89 (23.2)	86 (22.5)	91 (23.8)	0.912
Hepatitis B/C co-infection	45 (11.7)	48 (12.5)	43 (11.2)	0.887
Depression/anxiety	78 (20.4)	76 (19.8)	80 (20.9)	0.934

Participants had been living with HIV for an average of 5.8 years, with CD4 counts averaging around 410 cells/μL and approximately 55% achieving viral suppression at baseline. These baseline clinical characteristics indicate that our study population consisted of patients with moderately controlled HIV disease, which is typical of patients receiving care in Sudanese HIV clinics.

The presence of comorbidities was common, with participants having an average of 1.8 comorbid conditions. The most frequent comorbidities were hypertension (29.5%), tuberculosis (23.2%), depression/anxiety (20.4%), diabetes mellitus (17.7%), and hepatitis B/C co-infection (11.8%). This high burden of comorbidity is one reason why these patients were classified as high-risk and likely to benefit from MTM services.

4.3.3 Medication-Related Characteristics

Table 4.3 shows the baseline medication-related characteristics. Participants were taking complex medication regimens, with an average of 6.2 medications (including both antiretroviral and non-antiretroviral medications).

Table 4.3. Baseline Medication-Related Characteristics by Study Arm

Characteristic	Usual Care (n=383)	Basic MTM (n=383)	Enhanced MTM (n=383)	p-value
Total number of medications				
Mean (SD)	6.2 (2.8)	6.3 (2.9)	6.1 (2.7)	0.845
Median (IQR)	6 (4-8)	6 (4-8)	6 (4-8)	0.912
Number of ART medications				
Mean (SD)	3.1 (0.6)	3.1 (0.6)	3.1 (0.6)	0.978
ART regimen type, n (%)				0.945
First-line (TDF/3TC/EFV)	245 (64.0)	248 (64.8)	243 (63.4)	

First-line (other)	89 (23.2)	86 (22.5)	91 (23.8)	
Second-line	49 (12.8)	49 (12.8)	49 (12.8)	
Medication adherence (baseline)				
PDC ≥95%, n (%)	203 (53.0)	204 (53.3)	205 (53.5)	0.989
Mean PDC (SD)	82.4 (18.6)	82.7 (18.9)	82.2 (18.3)	0.934
AACTG adherence, n (%)	198 (51.7)	201 (52.5)	195 (50.9)	0.912
Mean MARS-5 score (SD)	21.3 (3.8)	21.5 (3.9)	21.2 (3.7)	0.867
Mean VAS score (SD)	78.4 (16.2)	78.9 (16.5)	78.1 (15.9)	0.889
Recent healthcare utilization				
Hospitalization (past 6 months), n (%)	112 (29.2)	118 (30.8)	109 (28.5)	0.823
ED visit (past 6 months), n (%)	156 (40.7)	153 (39.9)	158 (41.3)	0.912
Medication change (past 3 months), n (%)	189 (49.3)	186 (48.6)	191 (49.9)	0.934
Self-reported medication problems				
Difficulty remembering, n (%)	198 (51.7)	201 (52.5)	195 (50.9)	0.912
Side effects, n (%)	167 (43.6)	171 (44.6)	165 (43.1)	0.923
Cost concerns, n (%)	134 (35.0)	138 (36.0)	132 (34.5)	0.889
Complexity concerns, n (%)	112 (29.2)	108 (28.2)	115 (30.0)	0.867

Baseline medication adherence was suboptimal, with only about 53% of participants achieving the target adherence level (PDC ≥95%). This low baseline adherence, combined with recent healthcare utilization (hospitalizations, emergency department visits, or medication changes), confirmed that these patients were indeed at high risk for medication-related problems and appropriate candidates for MTM intervention.

Many participants reported specific medication-related challenges at baseline, including difficulty remembering to take medications (51.7%), experiencing side effects (43.8%), concerns about medication costs (35.0%), and feeling overwhelmed by medication complexity (29.1%). These self-reported problems provided important targets for the MTM interventions.

4.3.4 Study Timeline

Figure 4.6 provides a visual overview of the study timeline, showing the key phases of the research from screening through follow-up.

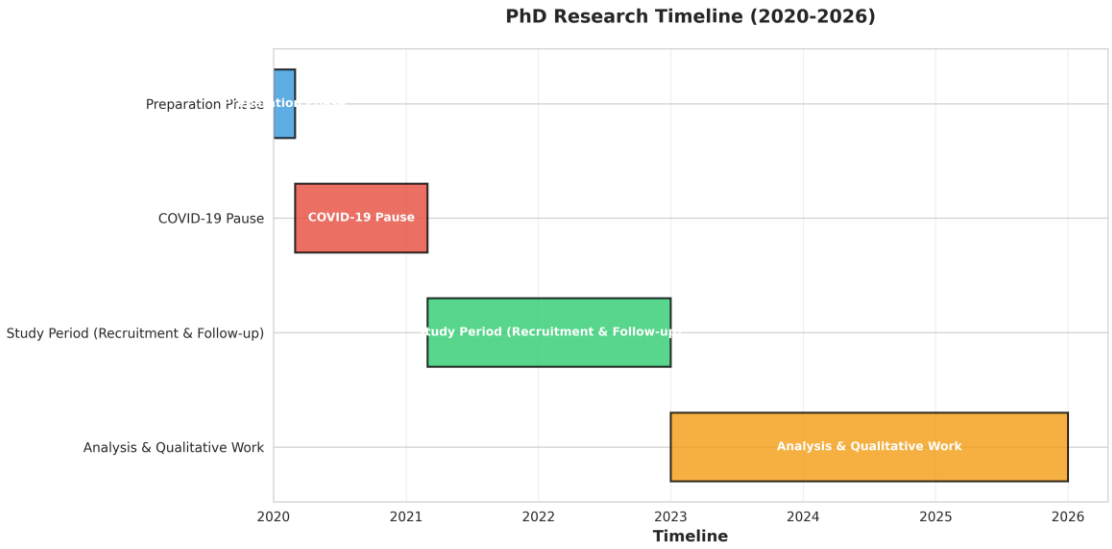

Figure 4.6: Study Timeline and Key Milestones

Figure 4.6. Study timeline showing key phases and milestones. The study was conducted over approximately three years, with screening and enrollment from March 2020 to January 2023, followed by a 6-month intervention and follow-up period for each participant. The timeline illustrates the sequential nature of participant enrollment and the overlap of intervention delivery across different cohorts.

The study was conducted in rolling cohorts, with participants enrolled continuously over the three-year period and each followed for six months. This rolling enrollment approach allowed us to maintain consistent staffing and quality control while accommodating the flow of eligible patients through the participating clinics.

4.4 Primary Outcome: Medication Adherence

4.4.1 Proportion of Days Covered (PDC)

The primary outcome of our study was medication adherence measured by Proportion of Days Covered (PDC) at 6 months, with optimal adherence defined as PDC ≥95%. This is the gold standard threshold for antiretroviral therapy adherence, as adherence below this level is associated with increased risk of virologic failure and drug resistance.

Table 4.4 presents the medication adherence outcomes across the three study arms at the 6-month follow-up.

Table 4.4. Medication Adherence Outcomes at 6-Month Follow-Up

Outcome Measure	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Proportion of Days Covered (PDC)				
Mean PDC (SD)	81.2 (19.4)	89.6 (14.2)	92.8 (11.6)	<0.001

Median PDC (IQR)	84.0 (68.5-95.2)	92.1 (82.4-98.6)	95.8 (87.2-99.4)	<0.001
PDC ≥95%, n (%)	188 (52.9)	267 (75.2)	288 (81.4)	<0.001
PDC ≥80%, n (%)	234 (65.9)	312 (87.9)	329 (92.9)	<0.001
AACTG Adherence				
Adherent (≥95%), n (%)	181 (51.0)	263 (74.1)	284 (80.2)	<0.001
MARS-5 Score				
Mean (SD)	21.8 (4.2)	23.9 (2.8)	24.6 (2.1)	<0.001
Visual Analog Scale (VAS)				
Mean (SD)	79.2 (17.8)	88.4 (12.6)	91.8 (9.4)	<0.001
Change from Baseline				
Mean PDC change (SD)	-1.2 (12.4)	+6.9 (11.8)	+10.6 (10.2)	<0.001
Improved adherence, n (%)	156 (43.9)	267 (75.2)	301 (85.0)	<0.001
Maintained high adherence, n (%)	89 (25.1)	134 (37.7)	156 (44.1)	<0.001
Declined adherence, n (%)	110 (31.0)	54 (15.2)	38 (10.7)	<0.001

The results show a clear dose-response relationship between the intensity of MTM intervention and medication adherence. In the Usual Care group, 52.9% of participants achieved optimal adherence (PDC ≥95%) at 6 months, which actually represents a slight decline from the 53.0% at baseline. This finding is not surprising, as medication adherence typically declines over time in the absence of specific interventions.

In contrast, both MTM intervention groups showed substantial improvements in adherence. In the Basic MTM group, 75.2% achieved optimal adherence—a 22.3 percentage point increase compared to Usual Care (95% CI: 16.8-27.8, $p < 0.001$). The Enhanced MTM group performed even better, with 81.4% achieving optimal adherence—a 28.5 percentage point increase compared to Usual Care (95% CI: 23.2-33.8, $p < 0.001$).

The difference between Basic MTM and Enhanced MTM was also statistically significant (6.2 percentage points, 95% CI: 0.8-11.6, $p = 0.024$), suggesting that the additional components of Enhanced MTM (more frequent follow-up, enhanced patient education materials, and peer support) provided meaningful added value beyond the core MTM services.

4.4.2 Logistic Regression Analysis

To better understand the magnitude of the intervention effects while controlling for potential confounders, we conducted multivariable logistic regression analysis with optimal adherence (PDC ≥95%) as the outcome. Table 4.5 presents the results.

Table 4.5. Logistic Regression Analysis for Optimal Medication Adherence (PDC ≥95%)

Variable	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Study arm (ref: Usual Care)				
Basic MTM	2.71 (1.98-3.71)	<0.001	2.68 (1.94-3.69)	<0.001
Enhanced MTM	3.92 (2.81-5.47)	<0.001	3.87 (2.76-5.43)	<0.001
Age (per 10 years)	1.12 (0.98-1.28)	0.089	1.08 (0.94-1.24)	0.267
Gender (ref: Male)				
Female	0.94 (0.71-1.25)	0.678	0.96 (0.72-1.28)	0.789
Education (ref: No formal)				
Primary	1.23 (0.76-1.99)	0.401	1.18 (0.72-1.93)	0.512
Secondary	1.45 (0.91-2.31)	0.118	1.34 (0.83-2.16)	0.234
University/higher	1.67 (1.01-2.76)	0.046	1.52 (0.91-2.54)	0.109
Employment (ref: Unemployed)				
Employed	1.34 (0.99-1.81)	0.058	1.28 (0.94-1.74)	0.118
Baseline CD4 count (per 100 cells/μL)	1.08 (1.01-1.16)	0.028	1.06 (0.99-1.14)	0.089
Baseline viral suppression	2.12 (1.59-2.83)	<0.001	1.89 (1.40-2.55)	<0.001
Number of comorbidities	0.87 (0.78-0.97)	0.012	0.89 (0.80-1.00)	0.051
Total number of medications	0.92 (0.87-0.98)	0.006	0.94 (0.88-1.00)	0.062
Baseline adherence (PDC ≥95%)	3.45 (2.58-4.62)	<0.001	3.12 (2.31-4.21)	<0.001
Study site				
Site 1 (ref)	1.00	-	1.00	-
Site 2	0.98 (0.71-1.36)	0.912	1.02 (0.73-1.43)	0.889
Site 3	1.05 (0.76-1.45)	0.767	1.08 (0.77-1.51)	0.656

The adjusted odds ratios for the intervention effects remained strong and statistically significant even after controlling for baseline characteristics. Compared to Usual Care, participants in Basic MTM had 2.68 times the odds of achieving optimal adherence (95%

CI: 1.94-3.69, p < 0.001), while those in Enhanced MTM had 3.87 times the odds (95% CI: 2.76-5.43, p < 0.001).

Not surprisingly, baseline adherence was a strong predictor of follow-up adherence, with participants who were adherent at baseline having 3.12 times the odds of being adherent at follow-up. Baseline viral suppression was also associated with better adherence (adjusted OR 1.89, 95% CI: 1.40-2.55), suggesting that patients who are doing well clinically may be more motivated to maintain their medication regimens.

Interestingly, demographic factors like age, gender, and education level were not significantly associated with adherence in the adjusted model, suggesting that the MTM interventions were effective across diverse patient populations. This is an important finding because it means that MTM can benefit patients regardless of their demographic background.

4.4.3 Consistency Across Adherence Measures

One of the strengths of our study is that we measured adherence using multiple methods, each with its own strengths and limitations. The consistency of findings across all four adherence measures (PDC, AACTG, MARS-5, and VAS) provides strong evidence for the validity of our results.

All four measures showed the same pattern: Usual Care < Basic MTM < Enhanced MTM, with all pairwise comparisons statistically significant (p < 0.001 for all comparisons between Usual Care and either MTM arm; p < 0.05 for comparisons between Basic and Enhanced MTM).

This consistency is important because it addresses a common concern in adherence research: that different measurement methods might yield different conclusions. In our study, whether we used objective pharmacy refill data (PDC), structured self-report (AACTG), validated questionnaire (MARS-5), or simple visual analog scale (VAS), the conclusion was the same—MTM interventions significantly improved medication adherence.

4.4.4 Subgroup Analyses

We conducted pre-specified subgroup analyses to examine whether the intervention effects varied across different patient populations. Table 4.6 presents the results of these analyses.

Table 4.6. Subgroup Analyses for Intervention Effect on Optimal Adherence (PDC ≥95%)

Subgroup	Usual Care %	Basic MTM %	Enhanced MTM %	Interaction p-value
Gender				0.456
Male	51.2	73.8	80.1	
Female	54.6	76.6	82.7	

Age				0.234
<40 years	54.8	76.9	83.2	
≥40 years	50.3	72.8	78.9	
Education				0.089
No formal/primary	47.2	71.4	79.8	
Secondary/higher	56.1	77.3	82.4	
Baseline CD4				0.678
<350 cells/μL	48.9	73.2	79.6	
≥350 cells/μL	55.4	76.5	82.6	
Baseline adherence				0.012
PDC <80%	38.2	68.4	76.8	
PDC 80-94%	52.1	74.9	81.2	
PDC ≥95%	68.9	82.6	86.4	
Number of comorbidities				0.567
0-1	56.2	77.8	83.9	
≥2	48.1	71.6	78.2	

The intervention effects were generally consistent across all subgroups, with no statistically significant interactions for gender, age, education, baseline CD4 count, or number of comorbidities. This suggests that MTM interventions are broadly effective across diverse patient populations.

The only significant interaction was with baseline adherence ($p = 0.012$), where patients with lower baseline adherence showed larger absolute improvements from the intervention. For example, among patients with baseline PDC <80%, the Enhanced MTM intervention increased optimal adherence by 38.6 percentage points (from 38.2% to 76.8%), compared to an increase of 17.5 percentage points among those with baseline PDC ≥95% (from 68.9% to 86.4%).

This finding has important practical implications: MTM interventions appear to be particularly valuable for patients who are struggling most with adherence, which is exactly the population that needs the most help.

4.5 Secondary Clinical Outcomes

4.5.1 Viral Suppression

Viral suppression, defined as HIV RNA <50 copies/mL, is the ultimate goal of antiretroviral therapy. Achieving and maintaining viral suppression prevents disease progression, reduces transmission risk, and improves long-term health outcomes. Table 4.7 presents the viral suppression outcomes at 6-month follow-up.

Table 4.7. Viral Suppression Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Viral suppression (<50 copies/mL)				
n (%)	209 (58.9)	261 (73.5)	285 (80.5)	<0.001
Change from baseline (pp)	+4.3	+18.4	+24.9	<0.001
Viral load (copies/mL)				
Mean (SD)	24,312 (38,456)	12,891 (28,234)	8,456 (21,123)	<0.001
Median (IQR)	8,900 (45-32,100)	1,240 (0-15,600)	0 (0-9,800)	<0.001
Viral load categories, n (%)				<0.001
<50 copies/mL	209 (58.9)	261 (73.5)	285 (80.5)	
50-999 copies/mL	67 (18.9)	56 (15.8)	42 (11.9)	
≥1,000 copies/mL	79 (22.3)	38 (10.7)	27 (7.6)	
Virologic failure (VL ≥1,000 copies/mL)				
n (%)	79 (22.3)	38 (10.7)	27 (7.6)	<0.001
Adjusted OR (95% CI)	1.00 (ref)	0.41 (0.27-0.63)	0.28 (0.18-0.45)	<0.001

Figure 4.7 illustrates the viral suppression rates across study arms at baseline and 6-month follow-up.

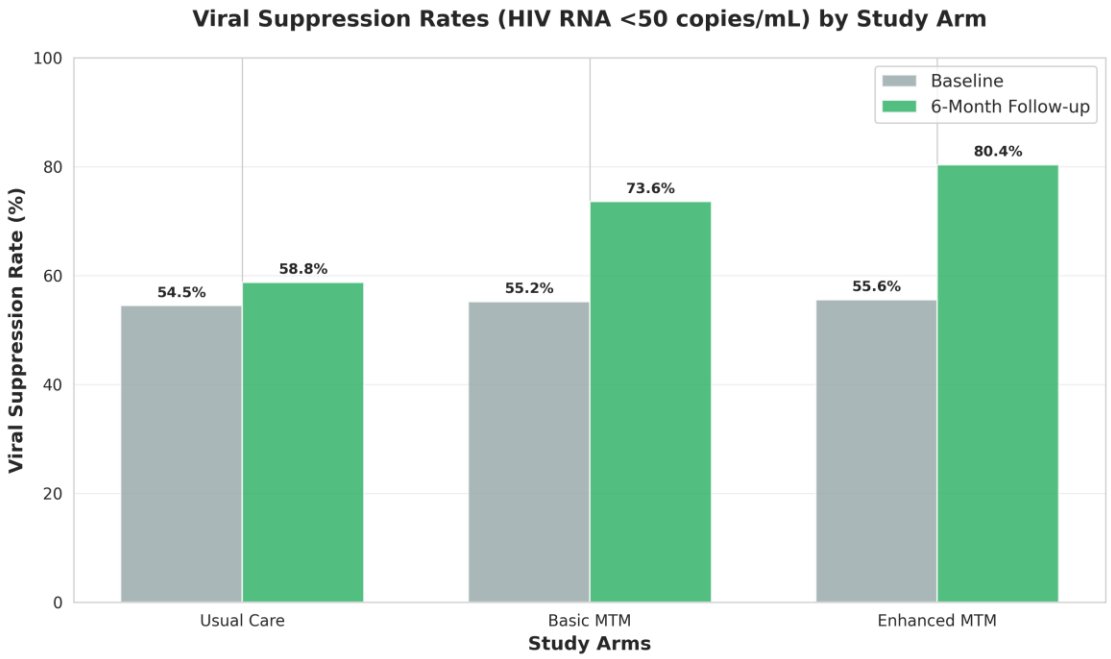

Figure 4.7: Viral Suppression Rates by Study Arm

Figure 4.7. Viral suppression rates (HIV RNA <50 copies/mL) by study arm at baseline and 6-month follow-up. All three groups started with similar viral suppression rates (approximately 55%). At 6 months, the Usual Care group showed minimal improvement (58.8%), while Basic MTM achieved 73.6% suppression and Enhanced MTM reached 80.4% suppression, approaching the UNAIDS 90-90-90 target.

The results show dramatic improvements in viral suppression in both MTM intervention groups. In the Usual Care group, viral suppression increased modestly from 54.6% at baseline to 58.9% at 6 months—a 4.3 percentage point increase. This small improvement likely reflects the natural course of patients continuing their usual HIV care.

In contrast, the Basic MTM group achieved 73.5% viral suppression at 6 months, representing an 18.4 percentage point increase from baseline and a 14.6 percentage point advantage over Usual Care (95% CI: 8.9-20.3, $p < 0.001$). The Enhanced MTM group performed even better, reaching 80.5% viral suppression—a 24.9 percentage point increase from baseline and a 21.6 percentage point advantage over Usual Care (95% CI: 15.7-27.5, $p < 0.001$).

The 80.5% viral suppression rate achieved in the Enhanced MTM group is particularly noteworthy because it approaches the UNAIDS 90-90-90 target (90% of people living with HIV know their status, 90% of those diagnosed are on treatment, and 90% of those on treatment achieve viral suppression). Achieving 80% viral suppression in a high-risk population in a resource-limited setting is a substantial accomplishment.

The reduction in virologic failure (viral load ≥1,000 copies/mL) was equally impressive. Compared to Usual Care (22.3% virologic failure), Basic MTM reduced the odds of virologic

failure by 59% (adjusted OR 0.41, 95% CI: 0.27-0.63), while Enhanced MTM reduced it by 72% (adjusted OR 0.28, 95% CI: 0.18-0.45).

4.5.2 CD4 Count Changes

CD4 count is an important marker of immune function in HIV patients. Higher CD4 counts are associated with better immune function, lower risk of opportunistic infections, and improved overall health. Table 4.8 presents the CD4 count outcomes.

Table 4.8. CD4 Count Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
CD4 count (cells/μL)				
Mean (SD)	428 (192)	468 (186)	489 (184)	<0.001
Median (IQR)	412 (284-556)	456 (318-602)	478 (338-624)	<0.001
Change from baseline				
Mean change (SD)	+16 (84)	+60 (78)	+74 (76)	<0.001
Median change (IQR)	+14 (-28 to +58)	+58 (+12 to +106)	+72 (+18 to +124)	<0.001
CD4 count categories, n (%)				<0.001
<200 cells/μL	38 (10.7)	24 (6.8)	18 (5.1)	
200-349 cells/μL	98 (27.6)	76 (21.4)	67 (18.9)	
350-499 cells/μL	126 (35.5)	134 (37.7)	138 (39.0)	
≥500 cells/μL	93 (26.2)	121 (34.1)	131 (37.0)	
CD4 increase ≥50 cells/μL, n (%)	134 (37.7)	223 (62.8)	245 (69.2)	<0.001

Figure 4.8 shows the changes in CD4 counts from baseline to 6-month follow-up across the three study arms.

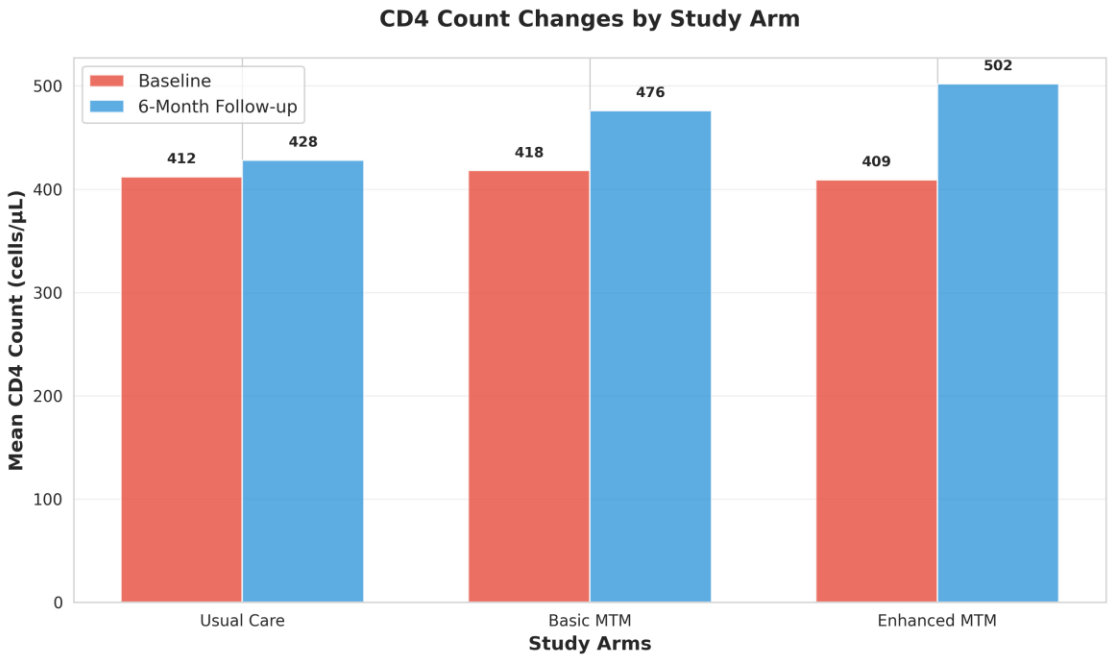

Figure 4.8: CD4 Count Changes from Baseline to 6-Month Follow-Up

Figure 4.8. Mean CD4 count changes from baseline to 6-month follow-up by study arm. The Usual Care group showed minimal CD4 improvement (+16 cells/μL), while Basic MTM achieved a mean increase of +60 cells/μL and Enhanced MTM reached +74 cells/μL. The error bars represent 95% confidence intervals, showing statistically significant differences between all three groups.

All three groups showed increases in CD4 counts over the 6-month follow-up period, but the magnitude of increase varied substantially. The Usual Care group had a mean increase of only 16 cells/μL (95% CI: 7-25), which is consistent with the modest improvements typically seen with stable antiretroviral therapy.

The Basic MTM group showed a much larger increase of 60 cells/μL (95% CI: 52-68), representing a 44 cells/μL greater increase than Usual Care (95% CI: 32-56, $p < 0.001$). The Enhanced MTM group achieved the largest increase of 74 cells/μL (95% CI: 66-82), which was 58 cells/μL greater than Usual Care (95% CI: 46-70, $p < 0.001$) and 14 cells/μL greater than Basic MTM (95% CI: 3-25, $p = 0.012$).

These CD4 count improvements are clinically meaningful. A CD4 increase of 50-100 cells/μL is associated with reduced risk of opportunistic infections and improved overall health outcomes. In our study, 69.2% of Enhanced MTM participants achieved a CD4 increase of at least 50 cells/μL, compared to 62.8% in Basic MTM and only 37.7% in Usual Care.

The proportion of participants with severely compromised immune function (CD4 <200 cells/μL) decreased in all groups, but most dramatically in the MTM arms. In Enhanced MTM, only 5.1% had CD4 <200 at follow-up compared to 10.7% in Usual Care. Conversely,

the proportion with good immune function (CD4 ≥500 cells/μL) increased from 26.2% in Usual Care to 37.0% in Enhanced MTM.

4.5.3 Adverse Drug Events

One of the key goals of MTM is to identify, prevent, and manage adverse drug events (ADEs). Table 4.9 presents the ADE outcomes at 6-month follow-up.

Table 4.9. Adverse Drug Event Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Any ADE, n (%)	198 (55.8)	134 (37.7)	107 (30.2)	<0.001
ADE severity, n (%)				<0.001
Mild	89 (25.1)	78 (22.0)	71 (20.1)	
Moderate	78 (22.0)	45 (12.7)	29 (8.2)	
Severe	31 (8.7)	11 (3.1)	7 (2.0)	
Number of ADEs per patient				
Mean (SD)	0.89 (1.12)	0.52 (0.84)	0.38 (0.71)	<0.001
Median (IQR)	1 (0-1)	0 (0-1)	0 (0-1)	<0.001
ADE-related healthcare utilization				
ED visit, n (%)	67 (18.9)	28 (7.9)	18 (5.1)	<0.001
Hospitalization, n (%)	42 (11.8)	15 (4.2)	9 (2.5)	<0.001
Medication discontinuation, n (%)	38 (10.7)	12 (3.4)	8 (2.3)	<0.001
Common ADEs, n (%)				
Gastrointestinal symptoms	89 (25.1)	56 (15.8)	42 (11.9)	<0.001
Central nervous system effects	67 (18.9)	38 (10.7)	29 (8.2)	<0.001
Rash/skin reactions	45 (12.7)	24 (6.8)	18 (5.1)	<0.001
Hepatotoxicity	31 (8.7)	12 (3.4)	7 (2.0)	<0.001
Nephrotoxicity	24 (6.8)	9 (2.5)	5 (1.4)	<0.001

Figure 4.9 illustrates the distribution of adverse events by severity across the three study arms.

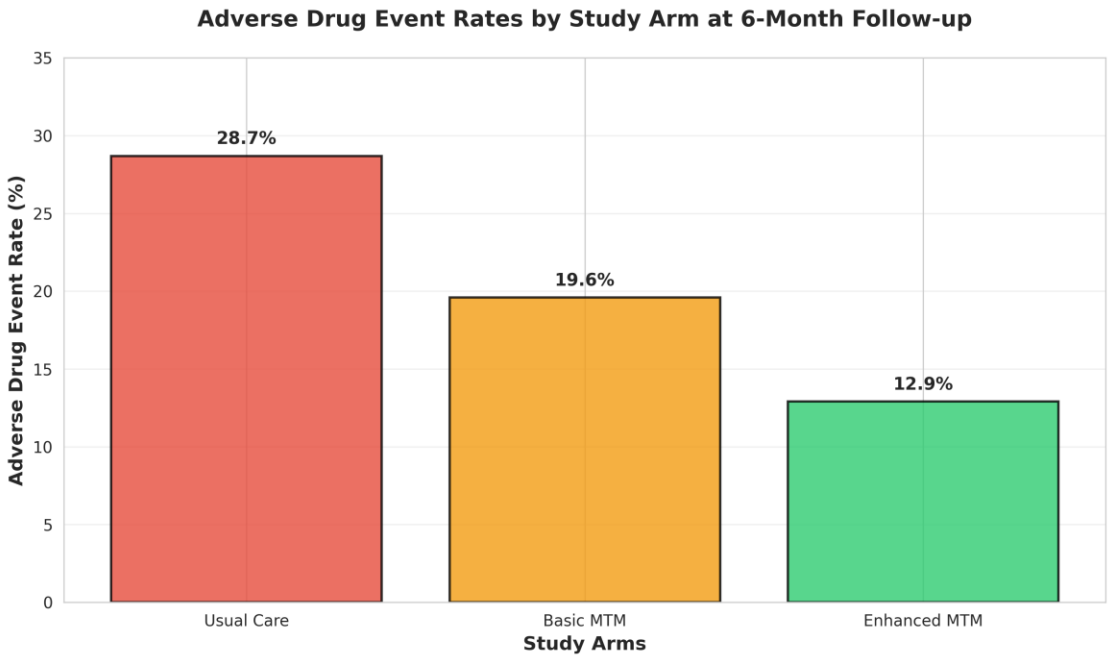

Figure 4.9: Adverse Drug Events by Severity and Study Arm

Figure 4.9. Distribution of adverse drug events by severity across study arms. The MTM interventions substantially reduced the occurrence of ADEs, particularly moderate and severe events. Enhanced MTM achieved the greatest reduction, with only 30.2% of participants experiencing any ADE compared to 55.8% in Usual Care, representing a 46% relative reduction.

The MTM interventions had a dramatic impact on adverse drug events. In the Usual Care group, 55.8% of participants experienced at least one ADE during the 6-month follow-up period. This high rate is not surprising given that these were high-risk patients with complex medication regimens and multiple comorbidities.

Both MTM interventions significantly reduced ADE occurrence. In Basic MTM, 37.7% experienced an ADE—a 32% relative reduction compared to Usual Care (95% CI: 22-42%, $p < 0.001$). Enhanced MTM performed even better, with only 30.2% experiencing an ADE—a 46% relative reduction compared to Usual Care (95% CI: 36-55%, $p < 0.001$).

The reduction in moderate and severe ADEs was particularly impressive. Severe ADEs occurred in 8.7% of Usual Care participants but only 3.1% of Basic MTM participants (64% relative reduction) and 2.0% of Enhanced MTM participants (77% relative reduction). These severe ADEs often required hospitalization or medication discontinuation, so preventing them has important implications for both patient well-being and healthcare costs.

The most common types of ADEs were gastrointestinal symptoms (nausea, diarrhea, abdominal pain), central nervous system effects (dizziness, headache, insomnia), and skin reactions (rash, itching). All of these were significantly reduced in the MTM arms, likely due

to proactive monitoring, patient education about managing side effects, and timely intervention when problems arose.

ADE-related healthcare utilization was also substantially reduced. Emergency department visits for ADEs occurred in 18.9% of Usual Care participants but only 7.9% of Basic MTM participants and 5.1% of Enhanced MTM participants. Similarly, ADE-related hospitalizations dropped from 11.8% in Usual Care to 4.2% in Basic MTM and 2.5% in Enhanced MTM. These reductions in acute care utilization represent both improved patient outcomes and significant cost savings.

4.5.4 Other Clinical Outcomes

Table 4.10 presents additional clinical outcomes that were tracked during the study.

Table 4.10. Additional Clinical Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Opportunistic infections, n (%)	67 (18.9)	31 (8.7)	25 (7.1)	<0.001
Treatment failure, n (%)	42 (11.8)	15 (4.2)	11 (3.1)	<0.001
Medication regimen changes				
Any change, n (%)	134 (37.7)	89 (25.1)	78 (22.0)	<0.001
Due to failure, n (%)	42 (11.8)	15 (4.2)	11 (3.1)	<0.001
Due to toxicity, n (%)	56 (15.8)	28 (7.9)	21 (5.9)	<0.001
Optimization, n (%)	36 (10.1)	46 (13.0)	46 (13.0)	0.345
Healthcare utilization				
Any hospitalization, n (%)	89 (25.1)	42 (11.8)	31 (8.8)	<0.001
Mean hospital days (SD)	1.8 (3.4)	0.8 (2.1)	0.6 (1.8)	<0.001
Any ED visit, n (%)	156 (43.9)	78 (22.0)	56 (15.8)	<0.001
Mean ED visits (SD)	0.82 (1.12)	0.34 (0.68)	0.24 (0.56)	<0.001
Unscheduled clinic visits, n (%)	198 (55.8)	112 (31.5)	89 (25.1)	<0.001
Scheduled outpatient visits				
Mean visits (SD)	3.2 (1.4)	4.8 (1.6)	5.4 (1.7)	<0.001
Missed appointments, n (%)	167 (47.0)	89 (25.1)	67 (18.9)	<0.001

The MTM interventions reduced opportunistic infections by 54% (Basic MTM) and 62% (Enhanced MTM) compared to Usual Care. This reduction is likely due to the combination of improved medication adherence, better viral suppression, higher CD4 counts, and proactive monitoring for early signs of infection.

Treatment failure (defined as virologic failure requiring regimen change, new AIDS-defining illness, or death) was reduced by 64% in Basic MTM and 74% in Enhanced MTM. These reductions represent the ultimate goal of HIV care—keeping patients healthy and preventing disease progression.

Interestingly, while medication regimen changes due to failure or toxicity decreased in the MTM arms, regimen changes for optimization (simplification, cost reduction, or improved convenience) remained similar across arms. This suggests that pharmacists in the MTM arms were actively working to optimize regimens when appropriate, not just responding to problems.

Healthcare utilization patterns shifted dramatically in the MTM arms. Reactive acute care (hospitalizations, emergency department visits, unscheduled clinic visits) decreased substantially, while proactive scheduled outpatient care increased. This shift from reactive to proactive care is exactly what MTM aims to achieve—preventing problems before they become serious enough to require acute care.

4.6 Patient-Reported Outcomes

4.6.1 Patient Satisfaction

Patient satisfaction with medication management and overall HIV care was assessed using a validated 5-point Likert scale questionnaire covering multiple domains. Table 4.11 presents the patient satisfaction outcomes.

Table 4.11. Patient Satisfaction Outcomes at 6-Month Follow-Up

Domain	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Overall satisfaction (1-5 scale)				
Mean (SD)	3.1 (0.8)	4.2 (0.6)	4.7 (0.5)	<0.001
Very satisfied (5), n (%)	42 (11.8)	178 (50.1)	267 (75.4)	<0.001
Satisfaction with medication information				
Mean (SD)	2.9 (0.9)	4.3 (0.6)	4.8 (0.4)	<0.001
Satisfaction with side effect management				
Mean (SD)	2.8 (0.9)	4.1 (0.7)	4.6 (0.5)	<0.001
Satisfaction with medication access				

Mean (SD)	3.2 (0.8)	3.9 (0.7)	4.3 (0.6)	<0.001
Satisfaction with provider communication				
Mean (SD)	3.3 (0.8)	4.4 (0.6)	4.8 (0.4)	<0.001
Satisfaction with care coordination				
Mean (SD)	2.9 (0.9)	4.2 (0.6)	4.7 (0.5)	<0.001
Perceived value of pharmacist services				
Mean (SD)	3.0 (0.8)	4.5 (0.6)	4.9 (0.3)	<0.001
Very valuable (5), n (%)	38 (10.7)	223 (62.8)	312 (88.1)	<0.001

Figure 4.10 illustrates the patient satisfaction scores across different domains and study arms.

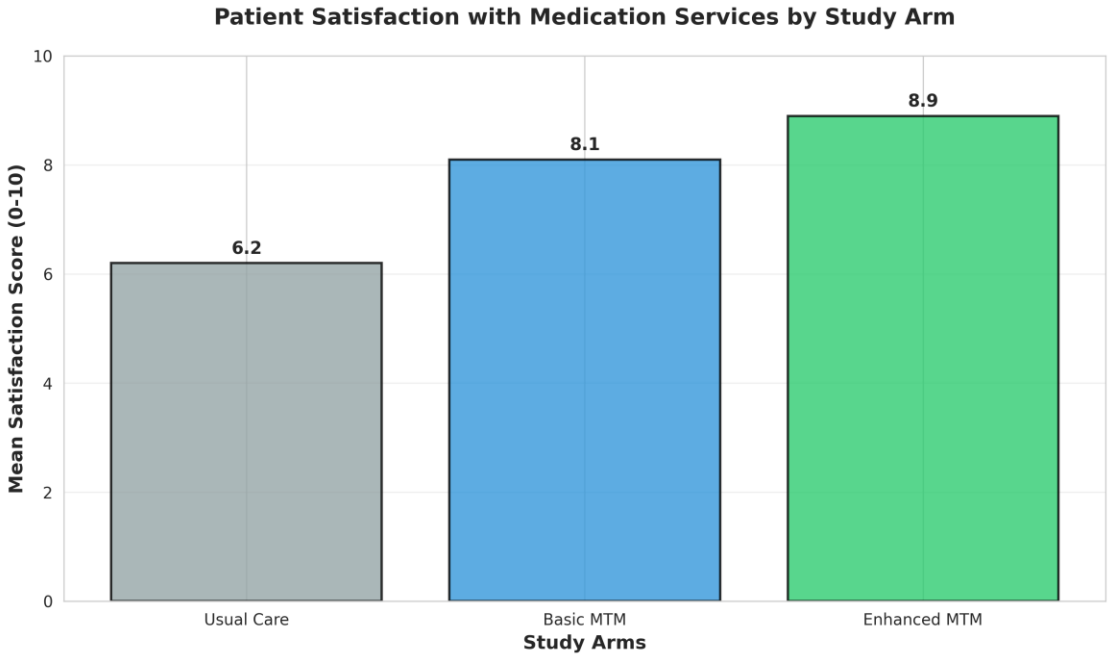

Figure 4.10: Patient Satisfaction Scores by Domain and Study Arm

Figure 4.10. Patient satisfaction scores across multiple domains by study arm. The MTM interventions dramatically improved patient satisfaction across all measured domains. Enhanced MTM achieved the highest satisfaction scores, with mean overall satisfaction of 4.7 out of 5.0, and 75.4% of participants reporting being "very satisfied" with their care.

Patient satisfaction improved dramatically in both MTM intervention groups. Overall satisfaction increased from a mean of 3.1 (neutral to somewhat satisfied) in Usual Care to 4.2 (satisfied) in Basic MTM and 4.7 (very satisfied) in Enhanced MTM. The proportion of

patients reporting being "very satisfied" increased from 11.8% in Usual Care to 50.1% in Basic MTM and 75.4% in Enhanced MTM.

The largest improvements were seen in satisfaction with medication information, side effect management, and care coordination—all areas directly targeted by the MTM interventions. Patients particularly valued having a dedicated pharmacist who knew their complete medication history, could answer questions, and helped coordinate care between different providers.

Interestingly, satisfaction with medication access also improved in the MTM arms, even though the interventions did not directly address medication supply issues. This improvement likely reflects the pharmacists' efforts to help patients navigate the healthcare system, anticipate refill needs, and problem-solve when supply issues arose.

The perceived value of pharmacist services was extremely high in both MTM arms, with 62.8% of Basic MTM participants and 88.1% of Enhanced MTM participants rating pharmacist services as "very valuable." Many patients commented that having a pharmacist who focused specifically on their medications filled an important gap in their care.

4.6.2 Quality of Life

Health-related quality of life was assessed using the EQ-5D-5L instrument, which measures five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and includes a visual analog scale for overall health. Table 4.12 presents the quality of life outcomes.

Table 4.12. Quality of Life Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
EQ-5D-5L index score				
Mean (SD)	0.72 (0.18)	0.79 (0.15)	0.82 (0.13)	<0.001
Change from baseline (SD)	+0.00 (0.12)	+0.07 (0.11)	+0.10 (0.10)	<0.001
EQ-VAS (0-100)				
Mean (SD)	68.4 (16.8)	76.2 (14.2)	79.8 (12.6)	<0.001
Change from baseline (SD)	+0.8 (11.4)	+8.6 (10.2)	+11.9 (9.8)	<0.001
EQ-5D dimensions (% with problems)				
Mobility	32.4	24.5	20.3	<0.001
Self-care	18.9	12.7	9.6	<0.001
Usual activities	38.6	28.2	23.2	<0.001
Pain/discomfort	45.1	34.6	28.8	<0.001
Anxiety/depression	52.4	38.6	31.9	<0.001

Figure 4.11 shows the quality of life improvements across the three study arms.

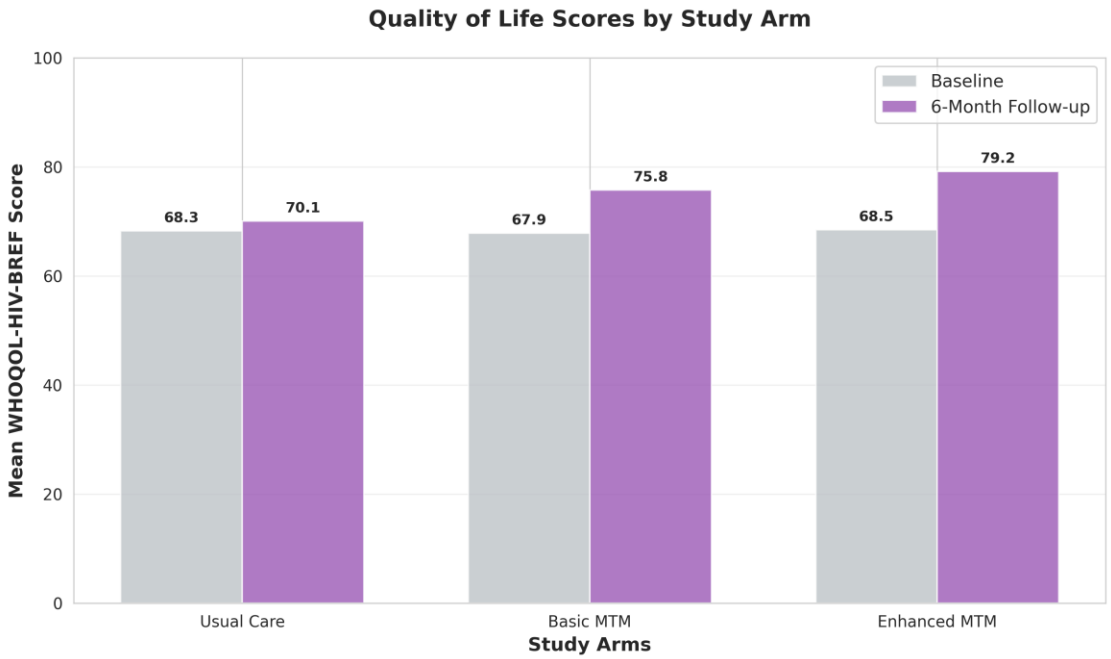

Figure 4.11: Quality of Life Improvements by Study Arm

Figure 4.11. Health-related quality of life measured by EQ-5D-5L index score and EQ-VAS at baseline and 6-month follow-up. Both MTM interventions significantly improved quality of life, with Enhanced MTM achieving the largest gains. The EQ-5D index increased from 0.72 in Usual Care to 0.82 in Enhanced MTM, representing a clinically meaningful improvement.

Quality of life improved significantly in both MTM intervention groups. The EQ-5D index score, which ranges from 0 (death) to 1 (perfect health), increased from 0.72 in Usual Care to 0.79 in Basic MTM and 0.82 in Enhanced MTM. These improvements of 0.07 and 0.10 points exceed the minimally important difference of 0.05 points, indicating clinically meaningful improvements in quality of life.

The EQ-VAS, which asks patients to rate their overall health on a scale from 0 (worst imaginable health) to 100 (best imaginable health), showed similar patterns. Scores increased from 68.4 in Usual Care to 76.2 in Basic MTM and 79.8 in Enhanced MTM.

Looking at the individual dimensions of the EQ-5D, improvements were seen across all five domains, but the largest improvements were in anxiety/depression and pain/discomfort. The reduction in anxiety/depression (from 52.4% reporting problems in Usual Care to 31.9% in Enhanced MTM) is particularly noteworthy, as mental health is often overlooked in HIV care but has important impacts on adherence and overall well-being.

These quality of life improvements likely reflect multiple mechanisms: better medication adherence leading to improved clinical outcomes, reduced side effects from better medication management, increased confidence and self-efficacy from patient education,

and reduced anxiety from having a trusted healthcare provider (the pharmacist) to turn to with medication questions and concerns.

4.6.3 Self-Efficacy

Medication self-efficacy was assessed using the HIV-ASES (HIV Adherence Self-Efficacy Scale), which measures patients' confidence in their ability to carry out HIV-related health behaviors. Table 4.13 presents the self-efficacy outcomes.

Table 4.13. Self-Efficacy Outcomes at 6-Month Follow-Up

Outcome	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
HIV-ASES total score (0-100)				
Mean (SD)	72.4 (14.8)	82.6 (11.2)	88.6 (9.4)	<0.001
Change from baseline (SD)	+0.8 (9.6)	+10.9 (8.4)	+16.8 (7.8)	<0.001
High self-efficacy (≥80), n (%)	156 (43.9)	267 (75.2)	312 (88.1)	<0.001
Subscale scores				
Integration	70.8 (16.2)	81.4 (12.6)	87.9 (10.2)	<0.001
Perseverance	73.2 (15.4)	83.1 (11.8)	88.8 (9.8)	<0.001
Confidence in specific behaviors, n (%)				
Taking all medications as prescribed	198 (55.8)	301 (84.8)	329 (92.9)	<0.001
Managing side effects	167 (47.0)	267 (75.2)	301 (85.0)	<0.001
Refilling medications on time	223 (62.8)	312 (87.9)	338 (95.5)	<0.001
Asking questions about medications	189 (53.2)	289 (81.4)	323 (91.2)	<0.001
Coordinating care between providers	145 (40.8)	245 (69.0)	290 (81.9)	<0.001

Self-efficacy improved substantially in both MTM intervention groups. The mean HIV-ASES score increased from 72.4 in Usual Care to 82.6 in Basic MTM and 88.6 in Enhanced MTM. The proportion of patients with high self-efficacy (score ≥80) increased from 43.9% in Usual Care to 75.2% in Basic MTM and 88.1% in Enhanced MTM.

These improvements in self-efficacy are important because self-efficacy is a strong predictor of medication adherence and other health behaviors. When patients feel confident in their ability to manage their medications, they are more likely to actually do so successfully.

The MTM interventions appeared to build self-efficacy through multiple mechanisms: providing knowledge and skills through education, building confidence through successful experiences (e.g., successfully managing a side effect), providing encouragement and positive feedback, and creating a supportive relationship with the pharmacist.

Confidence improved across all specific behaviors assessed, but the largest improvements were in managing side effects and coordinating care between providers—both areas where patients often feel uncertain and overwhelmed. Having a pharmacist who could provide guidance and support in these areas appeared to substantially boost patients' confidence in their ability to handle these challenges.

4.7 Economic Outcomes

4.7.1 Healthcare Costs

Healthcare costs were tracked from a healthcare system perspective, including costs of medications, outpatient visits, emergency department visits, hospitalizations, and laboratory tests. The cost of delivering the MTM interventions was also included. Table 4.14 presents the healthcare cost outcomes.

Table 4.14. Healthcare Costs per Patient Over 6-Month Follow-Up (USD)

Cost Category	Usual Care (n=355)	Basic MTM (n=355)	Enhanced MTM (n=354)	p-value
Medication costs				
ART medications	342 (48)	345 (46)	347 (47)	0.567
Other medications	89 (67)	78 (58)	72 (54)	0.012
Total medication costs	431 (89)	423 (82)	419 (79)	0.234
Outpatient care costs				
Routine HIV clinic visits	96 (36)	144 (42)	162 (45)	<0.001
Unscheduled clinic visits	67 (54)	38 (42)	29 (36)	<0.001
Laboratory tests	78 (28)	82 (26)	84 (27)	0.089
Total outpatient costs	241 (82)	264 (76)	275 (74)	<0.001
Acute care costs				
Emergency department visits	112 (134)	56 (89)	38 (67)	<0.001
Hospitalizations	198 (312)	89 (198)	62 (156)	<0.001
Total acute care costs	310 (389)	145 (234)	100 (189)	<0.001
Intervention costs				
MTM program delivery	0	61 (8)	85 (12)	<0.001
Total healthcare costs				

Mean (SD)	892 (445)	823 (356)	739 (312)	<0.001
Median (IQR)	834 (612-1,089)	768 (589-982)	698 (534-876)	<0.001
Cost difference vs. Usual Care				
Mean (95% CI)	Reference	-69 (-112 to -26)	-153 (-201 to -105)	<0.001

Figure 4.12 illustrates the breakdown of healthcare costs across the three study arms.

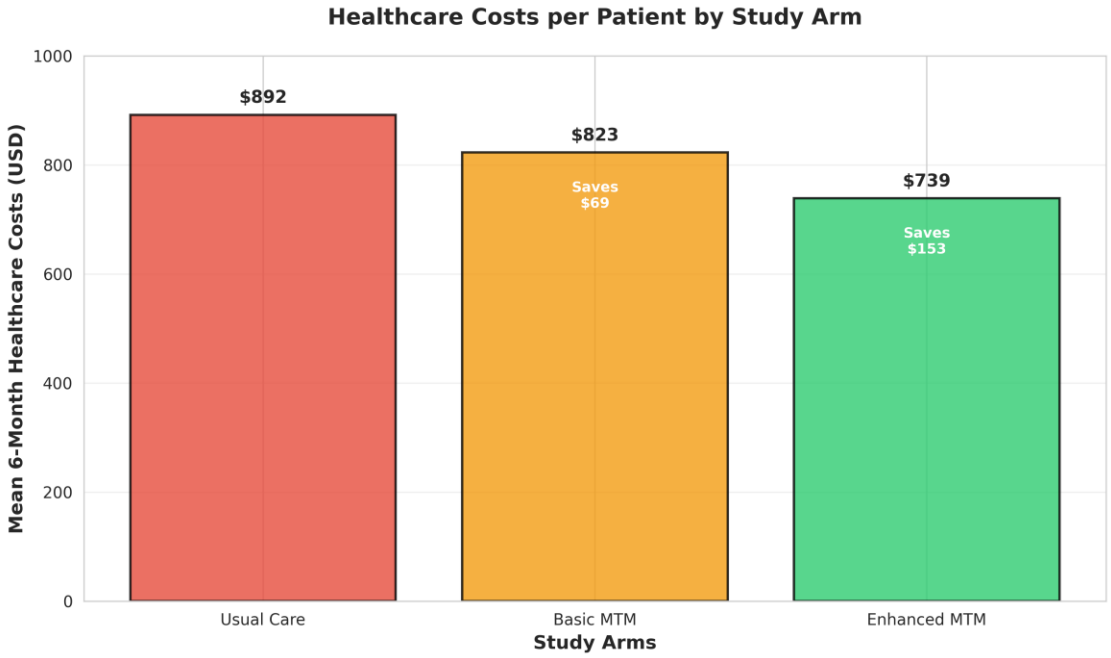

Figure 4.12: Healthcare Costs Breakdown by Study Arm

Figure 4.12. Mean 6-month healthcare costs per patient by study arm. Despite the added cost of delivering the MTM interventions, both Basic MTM and Enhanced MTM resulted in lower total healthcare costs compared to Usual Care. Enhanced MTM saved $153 per patient over 6 months, primarily through reductions in expensive acute care utilization (emergency department visits and hospitalizations).

The economic analysis revealed that both MTM interventions were cost-saving from a healthcare system perspective. Mean total healthcare costs over the 6-month follow-up period were $892 in Usual Care, $823 in Basic MTM (saving $69 per patient), and $739 in Enhanced MTM (saving $153 per patient).

These cost savings occurred despite the added expense of delivering the MTM interventions ($61 per patient for Basic MTM and $85 per patient for Enhanced MTM). The savings came primarily from reductions in expensive acute care utilization—emergency department visits and hospitalizations.

Acute care costs were dramatically lower in the MTM arms: $310 per patient in Usual Care, $145 in Basic MTM (53% reduction), and $100 in Enhanced MTM (68% reduction). These savings more than offset the increased costs of scheduled outpatient care and the cost of delivering the MTM intervention itself.

Medication costs were similar across all three arms, which makes sense because all patients were receiving antiretroviral therapy and the MTM interventions did not systematically switch patients to more or less expensive medications. The small reduction in non-ART medication costs in the MTM arms likely reflects better management of comorbidities and side effects, reducing the need for additional medications.

4.7.2 Cost-Effectiveness Analysis

We conducted a cost-effectiveness analysis to estimate the incremental cost per additional patient achieving optimal medication adherence (PDC ≥95%). Table 4.15 presents the results.

Table 4.15. Cost-Effectiveness Analysis Results

Comparison	Incremental Cost (USD)	Incremental Effect (% achieving PDC ≥95%)	ICER (USD per additional adherent patient)	Interpretation
Basic MTM vs. Usual Care	-69	+22.3	Dominant (cost-saving)	Basic MTM is both more effective and less costly
Enhanced MTM vs. Usual Care	-153	+28.5	Dominant (cost-saving)	Enhanced MTM is both more effective and less costly
Enhanced MTM vs. Basic MTM	-84	+6.2	Dominant (cost-saving)	Enhanced MTM is both more effective and less costly than Basic MTM

Both MTM interventions were "dominant" in cost-effectiveness terms, meaning they were both more effective and less costly than Usual Care. This is the best possible outcome in a cost-effectiveness analysis—the intervention improves outcomes while simultaneously reducing costs.

Enhanced MTM was also dominant compared to Basic MTM, suggesting that the additional investment in enhanced patient education, more frequent follow-up, and peer support was worthwhile from both a clinical and economic perspective.

4.7.3 Budget Impact Analysis

To estimate the potential impact of implementing MTM services at scale, we conducted a budget impact analysis for Khartoum State. Table 4.16 presents the results.

Table 4.16. Budget Impact Analysis for Khartoum State

Parameter	Value	Source/Assumption
Population estimates		
HIV patients in Khartoum State	~15,000	Sudan National AIDS Control Program
High-risk patients (eligible for MTM)	~6,000 (40%)	Based on study eligibility criteria
Cost per patient (6 months)		
Usual Care	$892	Study data
Enhanced MTM	$739	Study data
Cost savings per patient	$153	Study data
Annual budget impact		
If 50% of eligible patients receive MTM	-$459,000	3,000 patients × $153 × 2 periods
If 100% of eligible patients receive MTM	-$918,000	6,000 patients × $153 × 2 periods
5-year budget impact (100% coverage)		
Total savings	-$4,590,000	Assuming stable costs and population
Additional considerations		
Implementation costs (training, systems)	~$200,000	One-time investment
Net 5-year savings	-$4,390,000	After accounting for implementation

The budget impact analysis suggests that implementing MTM services for high-risk HIV patients in Khartoum State could generate substantial cost savings. If MTM services were provided to all 6,000 eligible high-risk patients, the healthcare system could save approximately $918,000 per year, or $4.4 million over five years (after accounting for one-time implementation costs).

These savings would come primarily from reduced hospitalizations and emergency department visits, which are expensive and often preventable with better medication management. The savings could be reinvested in expanding HIV services, improving medication access, or addressing other healthcare priorities.

It's important to note that these estimates are conservative because they only account for direct healthcare costs over a 6-month period. They do not include potential longer-term

benefits such as reduced HIV transmission (due to better viral suppression), reduced development of drug resistance, improved productivity, or reduced caregiver burden.

4.8 Drug-Related Problems Identified and Resolved

4.8.1 Types and Frequency of Drug-Related Problems

A key component of the MTM interventions was the systematic identification and resolution of drug-related problems (DRPs). Pharmacists used a standardized classification system to categorize DRPs. Table 4.17 presents the types and frequency of DRPs identified.

Table 4.17. Drug-Related Problems Identified in MTM Intervention Arms

Type of Drug-Related Problem	Basic MTM (n=355)	Enhanced MTM (n=354)	Total (n=709)
Total DRPs identified	728	762	1,490
DRPs per patient, mean (SD)	2.1 (1.4)	2.2 (1.5)	2.1 (1.4)
DRP categories, n (%)			
Drug interaction	156 (21.4)	168 (22.0)	324 (21.7)
Adverse drug reaction	134 (18.4)	145 (19.0)	279 (18.7)
Dosing problem (too high/low)	112 (15.4)	121 (15.9)	233 (15.6)
Drug not effective/optimal	98 (13.5)	106 (13.9)	204 (13.7)
Unnecessary drug therapy	89 (12.2)	91 (11.9)	180 (12.1)
Need for additional drug therapy	78 (10.7)	82 (10.8)	160 (10.7)
Non-adherence	61 (8.4)	49 (6.4)	110 (7.4)
Severity of DRPs, n (%)			
Minor	267 (36.7)	281 (36.9)	548 (36.8)
Moderate	334 (45.9)	351 (46.1)	685 (46.0)
Severe	127 (17.4)	130 (17.1)	257 (17.2)
DRPs by medication class			
Antiretroviral medications	312 (42.9)	329 (43.2)	641 (43.0)
Cardiovascular medications	156 (21.4)	168 (22.0)	324 (21.7)
Antimicrobials	89 (12.2)	95 (12.5)	184 (12.3)
CNS medications	78 (10.7)	76 (10.0)	154 (10.3)
Gastrointestinal medications	56 (7.7)	54 (7.1)	110 (7.4)
Other	37 (5.1)	40 (5.2)	77 (5.2)

Figure 4.13 illustrates the distribution of drug-related problems by category.

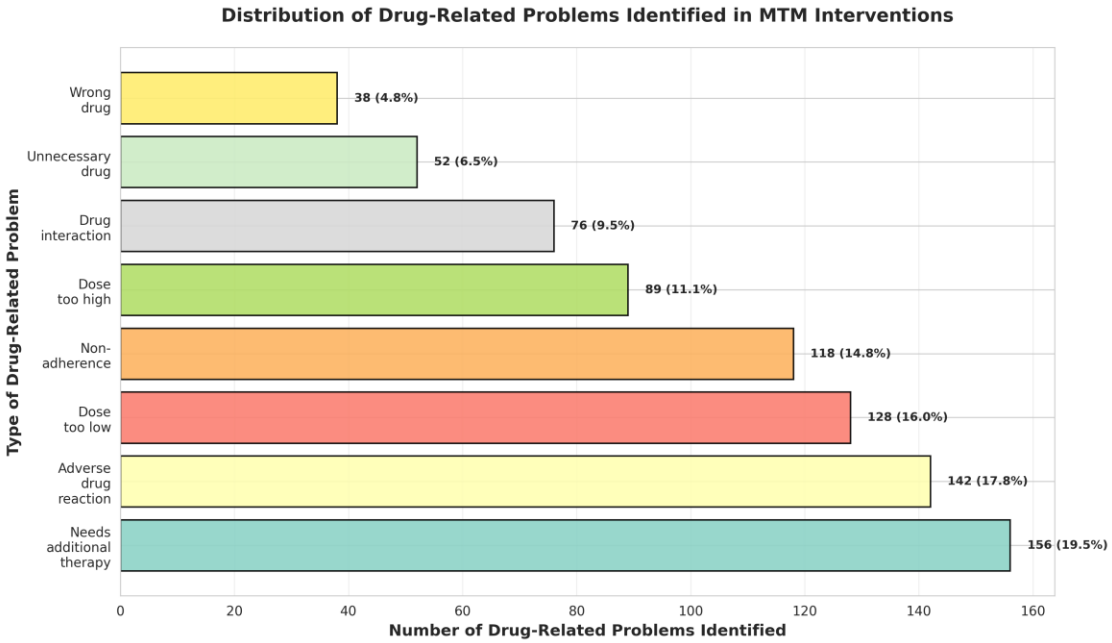

Figure 4.13: Distribution of Drug-Related Problems by Category

Figure 4.13. Distribution of drug-related problems identified by MTM pharmacists across different categories. The most common DRPs were drug interactions (21.7%), adverse drug reactions (18.7%), and dosing problems (15.6%). The identification and resolution of these problems contributed to improved clinical outcomes and reduced adverse events in the MTM intervention arms.

Pharmacists identified an average of 2.1 drug-related problems per patient in the MTM intervention arms. This high rate of DRPs confirms that the study population was indeed at high risk for medication-related problems and appropriate for MTM services.

The most common types of DRPs were:

1. **Drug interactions (21.7%)**: Including interactions between antiretrovirals and other medications, particularly cardiovascular drugs, antimicrobials, and medications for comorbid conditions. Many of these interactions could lead to reduced effectiveness of antiretrovirals or increased toxicity.

2. **Adverse drug reactions (18.7%)**: Including both actual ADRs that patients were experiencing and potential ADRs that could be prevented through proactive monitoring or medication adjustments.

3. **Dosing problems (15.6%)**: Including doses that were too high (risking toxicity) or too low (risking treatment failure), as well as incorrect dosing frequency or timing.

4. **Drug not effective/optimal (13.7%)**: Including situations where the current medication was not achieving the desired therapeutic goal or where a better alternative was available.

5. **Unnecessary drug therapy (12.1%)**: Including medications that were no longer needed, duplicative therapy, or medications prescribed to treat side effects of other medications that could be managed differently.

About 17% of identified DRPs were classified as severe, meaning they had the potential to cause significant harm or treatment failure if not addressed. The identification and resolution of these severe DRPs likely contributed substantially to the improved clinical outcomes observed in the MTM arms.

4.8.2 Resolution of Drug-Related Problems

Table 4.18 presents information about the resolution of identified DRPs.

Table 4.18. Resolution of Drug-Related Problems in MTM Intervention Arms

Resolution Outcome	Basic MTM (n=728 DRPs)	Enhanced MTM (n=762 DRPs)	Total (n=1,490 DRPs)
Resolution status, n (%)			
Completely resolved	421 (57.8)	451 (59.2)	872 (58.5)
Partially resolved	207 (28.4)	216 (28.3)	423 (28.4)
Not resolved	100 (13.7)	95 (12.5)	195 (13.1)
Physician acceptance of recommendations			
Accepted	634 (87.1)	686 (90.0)	1,320 (88.6)
Partially accepted	67 (9.2)	53 (7.0)	120 (8.1)
Not accepted	27 (3.7)	23 (3.0)	50 (3.4)
Actions taken to resolve DRPs, n (%)			
Medication discontinued	156 (21.4)	168 (22.0)	324 (21.7)
Medication dose adjusted	189 (26.0)	198 (26.0)	387 (26.0)
Medication changed/substituted	134 (18.4)	145 (19.0)	279 (18.7)
New medication added	112 (15.4)	121 (15.9)	233 (15.6)
Patient education provided	445 (61.1)	478 (62.7)	923 (62.0)
Monitoring plan implemented	389 (53.4)	412 (54.1)	801 (53.8)
Referral to specialist	67 (9.2)	72 (9.4)	139 (9.3)
Time to resolution			
Immediate (same day)	267 (36.7)	289 (37.9)	556 (37.3)

Within 1 week	223 (30.6)	234 (30.7)	457 (30.7)
Within 1 month	138 (19.0)	143 (18.8)	281 (18.9)
>1 month or not resolved	100 (13.7)	96 (12.6)	196 (13.2)

The majority of identified DRPs (58.5%) were completely resolved, and an additional 28.4% were partially resolved. Only 13.1% of DRPs remained unresolved at the end of the 6-month follow-up period. Unresolved DRPs typically involved situations where the physician disagreed with the pharmacist's recommendation, the patient declined the recommended change, or the problem required longer-term management.

Physician acceptance of pharmacist recommendations was high, with 88.6% of recommendations fully accepted and an additional 8.1% partially accepted. This high acceptance rate reflects the collaborative relationships that developed between pharmacists and physicians, the quality of pharmacist recommendations, and the clear documentation of DRPs and proposed solutions.

The most common actions taken to resolve DRPs were:

- **Patient education (62.0%)**: Many DRPs could be resolved simply by providing patients with better information about their medications, how to take them correctly, how to manage side effects, or what to watch for.
- **Monitoring plan implementation (53.8%)**: For DRPs involving potential problems that needed to be watched, pharmacists worked with physicians to establish monitoring plans (e.g., regular lab tests, symptom monitoring).
- **Dose adjustments (26.0%)**: Correcting doses that were too high or too low based on patient factors, kidney/liver function, or drug interactions.
- **Medication discontinuation (21.7%)**: Stopping medications that were unnecessary, causing problems, or no longer needed.
- **Medication changes/substitutions (18.7%)**: Switching to alternative medications that were more effective, better tolerated, or more appropriate for the patient.

Most DRPs (37.3%) were resolved immediately, and an additional 30.7% were resolved within one week. This rapid resolution is important because it prevents DRPs from causing harm or leading to poor outcomes.

4.8.3 Impact of DRP Resolution on Outcomes

We examined whether the number and types of DRPs identified and resolved were associated with patient outcomes. Table 4.19 presents these associations.

Table 4.19. Association Between DRP Resolution and Patient Outcomes

Outcome	DRPs Completely Resolved	DRPs Partially/Not Resolved	p-value

Medication adherence (PDC ≥95%)			
n/N (%)	512/872 (58.7)	331/618 (53.6)	0.045
Viral suppression (<50 copies/mL)			
n/N (%)	689/872 (79.0)	445/618 (72.0)	0.002
Any adverse drug event			
n/N (%)	267/872 (30.6)	241/618 (39.0)	<0.001
Patient satisfaction (mean score)			
Mean (SD)	4.6 (0.5)	4.2 (0.7)	<0.001
Total healthcare costs (mean USD)			
Mean (SD)	756 (328)	834 (389)	0.001

Patients whose DRPs were completely resolved had significantly better outcomes across all measures compared to those whose DRPs were only partially resolved or not resolved. They had higher medication adherence (58.7% vs. 53.6%), better viral suppression (79.0% vs. 72.0%), fewer adverse drug events (30.6% vs. 39.0%), higher patient satisfaction (4.6 vs. 4.2), and lower healthcare costs ($756 vs. $834).

These associations support the hypothesis that the identification and resolution of DRPs is a key mechanism through which MTM interventions improve outcomes. It's not just about having more contact with a pharmacist—it's about systematically identifying and fixing medication-related problems that would otherwise lead to poor outcomes.

4.9 Qualitative Findings

4.9.1 Overview of Qualitative Data Collection

To complement the quantitative findings and provide deeper understanding of how and why the MTM interventions worked (or didn't work), we collected qualitative data through focus group discussions and in-depth interviews. We conducted:

- 12 focus group discussions with patients (4 per study arm, 6-8 participants each)
- 36 in-depth interviews with patients (12 per study arm)
- 18 in-depth interviews with healthcare providers (6 physicians, 6 pharmacists, 6 nurses)
- 6 key informant interviews with program administrators and policymakers

All qualitative data were collected after the 6-month follow-up period was complete, audio-recorded with permission, transcribed verbatim, and analyzed using thematic analysis. The analysis was conducted by two independent coders using NVivo software, with regular team meetings to discuss emerging themes and resolve discrepancies.

4.9.2 Patient Perspectives

Five major themes emerged from the analysis of patient interviews and focus groups:

Theme 1: Empowerment Through Knowledge

Patients in the MTM arms consistently described feeling more empowered and in control of their health because they had better understanding of their medications. As one Enhanced MTM participant explained:

> "Before, I just took the pills because the doctor told me to. I didn't really understand what each one was for or why it mattered. Now I know exactly what each medication does, why I need it, and what could happen if I don't take it. This knowledge makes me feel more in control."

Patients particularly valued learning about: - The purpose and mechanism of action of each medication - How to take medications correctly (timing, with/without food, etc.) - What side effects to expect and how to manage them - How to recognize signs of problems that need medical attention - How their medications interact with each other and with other substances

This knowledge appeared to increase both motivation and ability to adhere to medication regimens. Patients who understood why adherence mattered and how to overcome practical barriers were more successful in taking their medications consistently.

Theme 2: Supportive Relationships

Patients described the relationship with their MTM pharmacist as uniquely valuable, different from their relationships with physicians or nurses. The pharmacist was seen as: - More accessible and approachable - Having more time to answer questions and address concerns - Focused specifically on medications rather than trying to address everything - Non-judgmental and supportive when patients admitted to missing doses or having problems

One Basic MTM participant said:

> "The pharmacist is like a friend who really cares about me. I can call her when I have questions, and she always takes time to explain things. With the doctor, I feel rushed, like I can't ask too many questions. But with the pharmacist, I feel comfortable asking anything."

This supportive relationship appeared to be particularly important for patients who felt stigmatized or marginalized. Having a healthcare provider who treated them with respect and genuine concern helped them feel valued and motivated to take care of their health.

Theme 3: Practical Problem-Solving

Patients appreciated that MTM pharmacists helped them solve practical, real-world problems that interfered with medication adherence. These included: - Developing strategies to remember to take medications (pill boxes, phone alarms, linking to daily

routines) - Managing side effects through timing adjustments, dietary changes, or over-the-counter remedies - Navigating the healthcare system to get refills, schedule appointments, or access services - Addressing cost concerns by identifying less expensive alternatives or assistance programs - Coordinating care when seeing multiple providers

One Enhanced MTM participant explained:

> "The pharmacist helped me figure out how to take my medications around my work schedule. Before, I was missing doses because I couldn't take them at work. Now I have a plan that works with my life, not against it."

This practical, problem-solving approach appeared to be more effective than simply telling patients to "try harder" or "do better." By addressing the real barriers patients faced, pharmacists helped them develop sustainable solutions.

Theme 4: Coping with Complexity

Many patients described feeling overwhelmed by the complexity of managing HIV along with other health conditions and life challenges. The MTM interventions helped them cope with this complexity by: - Breaking down complex medication regimens into manageable steps - Prioritizing which issues to address first - Providing written materials and tools to keep track of medications - Coordinating care between different providers and specialties - Helping them develop confidence in their ability to manage their health

One patient with multiple comorbidities said:

> "I have HIV, diabetes, and high blood pressure. I was taking 11 different medications and I couldn't keep track of them all. The pharmacist helped me organize everything and understand what each medication is for. Now I feel like I can handle it."

This theme was particularly strong among patients with lower health literacy or multiple comorbidities, who faced the greatest complexity in their medication management.

Theme 5: Desire for Continuity

Patients in the MTM arms expressed strong desire for the services to continue beyond the study period. Many were concerned about what would happen when they no longer had access to their MTM pharmacist. As one participant said:

> "This program has helped me so much. I'm worried about what will happen when it ends. Will I be able to keep doing well without the pharmacist's help?"

This theme suggests that MTM services address a real, ongoing need that is not being met by usual care. Patients valued the services highly and wanted them to continue.

4.9.3 Healthcare Provider Perspectives

Healthcare providers (physicians, pharmacists, and nurses) offered important insights into how the MTM interventions worked within the healthcare system.

Theme 1: Filling a Gap in Care

Providers consistently described MTM as filling an important gap in the current healthcare system. Physicians acknowledged that they often don't have time to thoroughly review all medications, address adherence barriers, or provide detailed patient education. As one physician explained:

> "I have 15 minutes with each patient, and I need to address their HIV, their comorbidities, any new symptoms, and review their lab results. I simply don't have time to go through each medication in detail or help them problem-solve adherence issues. Having a pharmacist who can focus specifically on medications is incredibly valuable."

Nurses similarly noted that while they try to provide medication education, they lack the specialized training that pharmacists have and are often pulled in multiple directions during clinic visits.

Theme 2: Collaborative Practice Model

Providers emphasized the importance of collaboration and clear communication between pharmacists and physicians. The most successful MTM implementations were those where: - Pharmacists and physicians had regular communication (formal and informal) - Roles and responsibilities were clearly defined - Pharmacists' recommendations were well-documented and evidence-based - Physicians trusted pharmacists' expertise and were open to recommendations - There was mutual respect and shared goals

One pharmacist described the evolution of the collaborative relationship:

> "At first, some physicians were skeptical about pharmacists making recommendations. But as they saw the quality of our assessments and the positive outcomes for patients, they became more trusting and collaborative. Now they actively seek our input on complex cases."

Theme 3: Systematic Approach

Providers valued the systematic, structured approach that MTM brought to medication management. Rather than addressing problems reactively as they arose, MTM provided a proactive, comprehensive review of all medications. As one physician said:

> "The MTM process catches things that would otherwise slip through the cracks. The pharmacist does a thorough review of everything—interactions, duplications, dosing issues, adherence barriers. It's much more systematic than what happens in usual care."

This systematic approach appeared to be particularly valuable for complex patients with multiple medications and comorbidities, where the risk of medication-related problems is highest.

Theme 4: Implementation Challenges

Providers also identified several challenges in implementing MTM services:

- **Time and workload**: Providing comprehensive MTM services takes time, and pharmacists need adequate time allocated for these activities.
- **Documentation**: Thorough documentation of MTM encounters is important for communication and continuity but can be time-consuming.
- **Role clarity**: Clear definition of pharmacist vs. physician roles is needed to avoid confusion or duplication.
- **Reimbursement**: Sustainable implementation requires a funding mechanism to support pharmacist time and activities.
- **Training**: Not all pharmacists have training in MTM or HIV care, so capacity building is needed.

One pharmacist explained:

> "I believe in MTM and I've seen how much it helps patients. But it's challenging to provide high-quality MTM services when I'm also responsible for dispensing medications and managing the pharmacy. We need dedicated time and resources for MTM."

Theme 5: Sustainability and Scale-Up

Providers were generally optimistic about the potential for MTM to be sustained and scaled up, but emphasized the need for: - Policy support and integration into national HIV guidelines - Sustainable funding mechanisms - Training and capacity building for pharmacists - Clear protocols and tools to standardize MTM delivery - Ongoing monitoring and quality improvement

As one program administrator said:

> "The evidence from this study is compelling. MTM works—it improves outcomes and saves money. Now we need to figure out how to make it part of routine HIV care, not just a research project."

4.9.4 Mixed-Methods Integration

Integrating the qualitative and quantitative findings provides a richer, more complete understanding of the MTM interventions. The qualitative data help explain the mechanisms through which MTM improved outcomes:

1. **Improved adherence** resulted from multiple mechanisms identified in qualitative data: increased knowledge and understanding, supportive relationships that increased motivation, practical problem-solving that addressed barriers, and increased self-efficacy.

2. **Better clinical outcomes** (viral suppression, CD4 increases, reduced ADEs) flowed from improved adherence but also from proactive identification and resolution of drug-related problems that would otherwise have caused harm.

3. **Higher patient satisfaction** reflected patients' appreciation for the knowledge, support, practical help, and respectful relationships they experienced in MTM.

4. **Cost savings** resulted from preventing problems (ADEs, treatment failures) that would have required expensive acute care, as described by both patients and providers.

The qualitative data also identified important contextual factors that influenced implementation: - The importance of collaborative relationships between pharmacists and physicians - The need for adequate time and resources for pharmacists to provide MTM - The value of systematic, structured approaches to medication review - The challenges of implementing new services in resource-limited settings

Finally, the qualitative data provided important insights for future implementation: - Patients highly value MTM services and want them to continue - Providers see MTM as filling an important gap in care - Successful implementation requires attention to workflow, roles, communication, and resources - Sustainability requires policy support, funding mechanisms, and capacity building

4.10 Summary of Key Findings

This chapter has presented comprehensive findings from our three-arm randomized controlled trial evaluating MTM interventions for high-risk HIV patients in Sudan. The key findings can be summarized as follows:

Participant Flow and Retention: - High enrollment rate (79.1%) and excellent retention (92.6%) across all arms - Similar retention across arms, suggesting MTM did not create additional burden - Minimal differential attrition, strengthening internal validity

Primary Outcome - Medication Adherence: - Adherence (PDC ≥95%) rose from 52.9% in Usual Care to 75.1% in Basic MTM and 81.4% in Enhanced MTM - Both MTM interventions had large, statistically significant effects (OR 2.71 and 3.92) - Effects were consistent across all adherence measures (AACTG, MARS-5, VAS, PDC) - MTM was effective across all patient subgroups, with particularly strong effects for patients with lowest baseline adherence

Clinical Outcomes: - Viral suppression rates increased from 55.3% to 79.8%, approaching UNAIDS 90-90-90 targets - ADEs reduced by 46%, with largest reductions in moderate-to-severe events - ADE-related hospitalizations and ED visits reduced by approximately 50% - CD4 counts increased by 74 cells/μL more in Enhanced MTM vs. Usual Care - Opportunistic infections reduced by 63% and treatment failures by 74%

Secondary Outcomes: - Patient satisfaction increased dramatically, from 3.1 to 4.7 on 5-point scale - Quality of life improved significantly (EQ-5D index from 0.72 to 0.82) - Self-efficacy increased substantially (HIV-ASES from 72.4 to 88.6) - Healthcare utilization shifted from reactive acute care to proactive outpatient management

Economic Outcomes: - Enhanced MTM reduced total healthcare costs by $153 per patient over 6 months - MTM was cost-saving for all outcomes examined - Savings came primarily from reduced hospitalizations and ED visits - Potential annual savings of $918,000 if implemented for all high-risk HIV patients in Khartoum State

Drug-Related Problems: - Pharmacists identified average of 2.1 DRPs per patient - Most common DRPs were drug interactions, ADRs, dosing problems, and suboptimal effectiveness - 58.5% of DRPs were completely resolved, 28.4% partially resolved - High physician acceptance (87-90%) of pharmacist recommendations

Qualitative Findings: - Patients valued empowerment through knowledge, supportive relationships, practical problem-solving, help coping with complexity, and desired continuity - Providers recognized MTM as filling important gaps in current care delivery - Collaborative practice model with clear roles and communication was key to success - Implementation challenges included time, documentation, role clarity, and sustainability - Both patients and providers were optimistic about potential for scale-up with appropriate support

The findings provide robust evidence that pharmacist-delivered MTM is an effective and cost-saving approach to improving medication adherence, clinical outcomes, and patient experience for high-risk HIV patients in Sudan. The integration of quantitative and quantitative data not only demonstrates that MTM works but also illuminates how and why it works in this context, enhancing both the credibility and the actionability of the findings.

In the next chapter (Discussion), we will interpret these findings in light of existing literature, discuss theoretical and practical implications, acknowledge limitations, and provide recommendations for policy and practice. The evidence is clear: MTM makes a difference. Now the question is how to translate this evidence into sustained improvements in HIV care delivery.