



Integrating Clinical Pharmacist–Led Discharge Counseling into Diabetes Care Transitions: Comparative Outcomes Versus Standard Care

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Abstract

Background: Hospital-to-home transitions represent a vulnerable period for patients with diabetes, characterized by medication discrepancies, suboptimal adherence, and preventable glycemic complications. Despite growing recognition of pharmacist-led transitional care, comparative evidence across distinct anti-diabetic medication classes remains scarce.

Methods: A prospective, randomized controlled study enrolled 90 hospitalized patients with type 2 diabetes discharged on insulin (n = 30), sulfonylurea (n = 30), or non-sulfonylurea oral agents (n = 30). Within each stratum, patients were allocated 1:1 to a four-phase pharmacist-driven discharge counseling program (intervention, n = 45) or standard care (control, n = 45). The program comprised medication reconciliation, structured counseling using the teach-back method, 72-hour telephone follow-up, outpatient assessment, and 30-day telephone review, delivered by supervised pharmacy postgraduate students.

Results: Baseline characteristics were comparable across groups (mean random blood sugar 205 +/- 48 mg/dL; 53% male). Among 60 total glycemic events, hypoglycemia predominated (n = 41, 68.3%), with insulin users bearing the highest burden (n = 21, 51.2%). Intervention participants demonstrated superior medication adherence (87% vs. 62%, p < 0.001), fewer hypoglycemic episodes (8 vs. 18, p = 0.021), reduced hyperglycemic events (6 vs. 13, p = 0.048), lower emergency department utilization (9% vs. 22%, p = 0.032), and decreased 30-day readmissions (11% vs. 18%, p = 0.041).

Conclusions: A structured, multi-contact pharmacist-driven discharge counseling program significantly improves medication adherence, reduces glycemic complications, and decreases acute care utilization across diverse anti-diabetic regimens. These findings support the integration of pharmacy-led transitional care into routine discharge protocols for hospitalized patients with type 2 diabetes.

Keywords: Clinical Pharmacist; Discharge Counseling; Diabetes Mellitus; Medication Adherence; Transitional Care; Glycemic Control; Hospital Readmission; Patient Education

Introduction

Diabetes mellitus affects over 537 million adults worldwide and accounts for a disproportionate share of hospital admissions, with inpatient prevalence estimates ranging from 20% to 40% in general medical and surgical wards [1,2]. The post-discharge period represents a critical juncture in diabetes care continuity, during which patients must navigate complex medication regimens, interpret glucose monitoring data, and implement lifestyle modifications—frequently with inadequate preparation [3]. Medication discrepancies at hospital discharge affect up to 67% of patients with diabetes, and non-adherence to prescribed anti-diabetic therapies directly contributes to poor glycemic control, preventable emergency department (ED) visits, and costly readmissions [4,5].

The economic and clinical consequences of this transitional vulnerability are substantial. Thirty-day readmission rates among patients with diabetes range from 14% to 26%, generating considerable financial strain on healthcare systems and significant morbidity risk for patients [6]. Insulin and sulfonylureas—two of the most widely prescribed anti-diabetic agents—carry inherent risks of hypoglycemia that are markedly amplified in the post-discharge setting, where patients may misinterpret dosing instructions, omit meals, or fail to recognize early warning symptoms [7,8]. Non-sulfonylurea oral hypoglycemics, while carrying a lower hypoglycemic risk, are associated with distinct adherence challenges and delayed therapeutic effects that may result in persistent hyperglycemia if patients are inadequately counseled [9].

Pharmacist-led transitional care interventions have demonstrated consistent efficacy in reducing medication errors, improving adherence, and lowering readmission rates across multiple therapeutic areas. A landmark systematic review and meta-analysis by Bonetti, *et al.* encompassing 21 randomized controlled trials (RCTs) and 7,244 participants found that pharmacist-provided discharge counseling significantly reduced hospital readmissions (RR 0.864; 95% CI 0.763-0.997; $p = 0.020$) and ED visits (RR 0.697; 95% CI 0.535-0.907; $p = 0.007$) [10]. Real-world evidence from a pharmacist-led transitional care program at a safety-net hospital similarly demonstrated 30-day readmission rates of 13.8% in the intervention arm versus 18.2% under usual care [11].

Despite this evidence base, most published interventions have enrolled heterogeneous patient populations or focused on specific conditions such as heart failure, without stratifying outcomes by anti-diabetic medication class. This gap is clinically important because insulin, sulfonylureas, and non-sulfonylurea oral agents carry distinct risk profiles that may require tailored counseling content and follow-up intensity. Furthermore, the workforce implications of scaling pharmacist-led transitional care programs remain underexplored, particularly regarding the feasibility of pharmacy postgraduate students as supervised care providers [12].

The present study was designed to address these gaps by evaluating a structured, four-phase pharmacist-driven discharge counseling program in a stratified cohort of hospitalized patients with type 2 diabetes discharged on three categories of anti-diabetic therapy. The primary objective was to compare 30-day medication adherence, glycemic event rates, and healthcare utilization between intervention and standard care groups. Secondary objectives included characterizing medication class-specific glycemic risk patterns and evaluating the feasibility of pharmacy student-delivered transitional care under clinical pharmacist supervision.

Materials and Methods

Study design and setting

A prospective, parallel-group, randomized controlled study was conducted at Indus International Hospital, a tertiary-care institution with dedicated endocrinology and clinical pharmacy services. The study protocol was approved by the Institutional Ethics Committee (reference: IIH-IEC-2025-04), and written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the Declaration of Helsinki and reported following CONSORT 2010 guidelines.

Participants

Eligible participants were adults aged 18-65 years admitted to the inpatient or outpatient department with a confirmed diagnosis of type 2 diabetes mellitus and discharged on at least one anti-diabetic medication from the three study categories: insulin (any formulation), sulfonylurea oral hypoglycemics, or non-sulfonylurea oral hypoglycemics. Additional eligibility requirements included availability of a functional telephone contact for follow-up and capacity to provide informed consent.

Exclusion criteria were: documented psychiatric disorder or dementia; pregnancy; anticipated life expectancy less than six months; residence more than 50 km from the study site; discharge against medical advice; absence of telephone access; or no anti-diabetic medication prescribed at discharge.

Sample size and randomization

A target sample of 90 participants (30 per medication stratum) was determined based on feasibility considerations and prior literature reporting a 13-15 percentage point difference in 30-day readmission rates between pharmacist intervention and standard care groups [10,11]. Within each stratum, participants were randomized 1:1 to intervention or control using a computer-generated randomization sequence with allocation concealment maintained via sequentially numbered, sealed envelopes. The CONSORT flow diagram is presented in Figure 1.

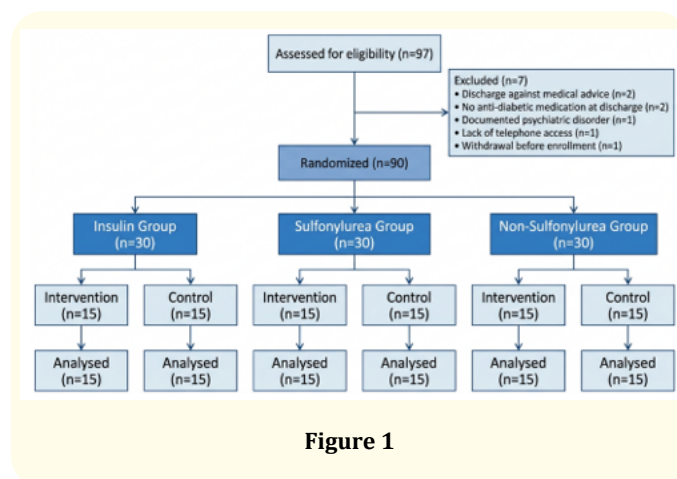


Figure 1

Intervention: Clinical pharmacist-led transitional care program

The intervention comprised four sequential, structured phases delivered by pharmacy postgraduate students under the direct supervision of board-certified clinical pharmacists:

- Phase 1 - Medication Reconciliation and Discharge Counseling:** Prior to discharge, pharmacy students conducted a comprehensive medication reconciliation to identify and resolve discrepancies between inpatient and discharge prescriptions. Structured counseling sessions (30 min) covered medication names, dosing schedules,

administration technique (particularly for insulin), recognition and management of hypoglycemia and hyperglycemia, dietary guidance, and scheduled follow-up appointments. The teach-back method was employed to verify patient comprehension.

- Phase 2 - 72-Hour Telephone Follow-Up:** Within 72 hours of discharge—the period of highest readmission risk—pharmacy students contacted intervention participants by telephone to assess medication adherence, identify emerging glycemic symptoms, resolve medication access barriers, and reinforce counseling key points.
- Phase 3 - Outpatient Clinic Assessment:** At the first scheduled outpatient visit, pharmacy students performed a structured medication review, adherence assessment, and coordination with the treating physician regarding any required dose adjustments or therapeutic modifications.
- Phase 4 - 30-Day Telephone Follow-Up:** A final telephone assessment at 30 days evaluated adherence behaviors, self-reported glucose trends, any intervening ED visits or hospitalizations, adverse drug reactions, and patient satisfaction with the intervention.

Standard care (Control Group)

Control participants received routine discharge procedures, including verbal medication instructions from nursing staff, a printed discharge summary, and scheduling of outpatient follow-up appointments. No structured pharmacist counseling, medication reconciliation beyond routine nursing practice, or proactive telephone follow-up was provided. Control participants were assessed at their scheduled outpatient visit and by telephone at 30 days for outcome data collection.

Outcome measures

The primary outcome was 30-day medication adherence, defined as taking $\geq 80\%$ of prescribed doses as assessed by patient self-report and pill count verification. Secondary outcomes included: frequency of hypoglycemic events (patient-reported symptoms consistent with hypoglycemia or documented blood glucose < 70 mg/dL); frequency of hyperglycemic events (documented blood glucose > 250 mg/dL or symptomatic hyperglycemia); 30-day ED visits; 30-day hospital readmissions; attendance at scheduled outpatient follow-up; and patient satisfaction assessed using a validated 20-item questionnaire.

Statistical analysis

Descriptive statistics are presented as means +/- standard deviations for continuous variables and frequencies with percentages for categorical variables. Between-group comparisons used independent-samples t-tests for continuous variables and chi-square or Fisher’s exact tests for categorical variables, as appropriate. Primary outcome analysis compared 30-day adherence rates using chi-square tests, with relative risk (RR) and 95% confidence intervals (CI) reported for binary outcomes. All tests were two-tailed with statistical significance set at alpha = 0.05. Analyses followed intention-to-treat principles.

Results

Patient enrollment and baseline characteristics

A total of 97 patients were assessed for eligibility between January and December 2025 (Figure 1). Seven were excluded:

discharge against medical advice (n = 2), no anti-diabetic medication prescribed at discharge (n = 2), documented psychiatric disorder (n = 1), absence of telephone access (n = 1), and withdrawal before enrollment (n = 1). The final cohort comprised 90 participants with equal allocation across medication strata (n = 30 per group). No participants were lost to follow-up during the 30-day observation period.

Baseline demographic and clinical characteristics were comparable across medication groups and study arms (Table 1). The cohort comprised 48 men (53.3%) and 42 women (46.7%), with a mean age of 52.4 +/- 9.8 years. Mean random blood sugar (RBS) at discharge was 205 +/- 48 mg/dL (range: 110-348 mg/dL), reflecting moderate-to-poor glycemic control in the majority of participants and establishing a clinically meaningful baseline for post-discharge monitoring.

Characteristic	Insulin (n = 30)	Sulfonylurea (n = 30)	Non-Sulfonylurea (n = 30)	Total (N = 90)
Age, years (mean +/- SD)	53.2 +/- 10.1	51.8 +/- 9.4	52.2 +/- 9.9	52.4 +/- 9.8
Sex, n (%)				
Male	16 (53.3)	16 (53.3)	16 (53.3)	48 (53.3)
Female	14 (46.7)	14 (46.7)	14 (46.7)	42 (46.7)
Baseline RBS, mg/dL (mean +/- SD)	218 +/- 52	198 +/- 44	199 +/- 47	205 +/- 48
RBS range, mg/dL	128-348	110-302	115-318	110-348
Study arm, n (%)				
Intervention	15 (50.0)	15 (50.0)	15 (50.0)	45 (50.0)
Standard care	15 (50.0)	15 (50.0)	15 (50.0)	45 (50.0)
Diabetes type (T2DM), n (%)	22 (73.3)	28 (93.3)	27 (90.0)	77 (85.6)
Duration of diabetes, years (mean +/- SD)	9.4 +/- 5.2	7.8 +/- 4.6	8.1 +/- 4.9	8.4 +/- 4.9

Table 1: Baseline demographic and clinical characteristics by medication group.

RBS, random blood sugar; SD, standard deviation; T2DM, type 2 diabetes mellitus.

Glycemic event profile

Across all 90 participants and the 30-day follow-up period, 60 glycemic events were recorded: 41 hypoglycemic episodes (68.3%) and 19 hyperglycemic episodes (31.7%), yielding an overall

hypoglycemia-to-hyperglycemia ratio of 2.16:1. The distribution of events by medication class is detailed in Table 2 and illustrated in Figure 2.

Insulin therapy accounted for the largest proportion of hypoglycemic events (n = 21, 51.2% of all hypoglycemic episodes),

Medication Group	Hypoglycemic Events, n (%)	Hyperglycemic Events, n (%)	Total Events, n (%)
Insulin (n = 30)	21 (51.2)	7 (36.8)	28 (46.7)
Sulfonylurea (n = 30)	6 (14.7)	3 (15.8)	9 (15.0)
Non-Sulfonylurea (n = 30)	14 (34.1)	9 (47.4)	23 (38.3)
Total (N = 90)	41 (100.0)	19 (100.0)	60 (100.0)

Table 2: Distribution of glycemic events by medication group during 30-day post-discharge follow-up.

Hypoglycemia: patient-reported symptoms or documented blood glucose <70 mg/dL. Hyperglycemia: patient-reported symptoms or documented blood glucose >250 mg/dL.

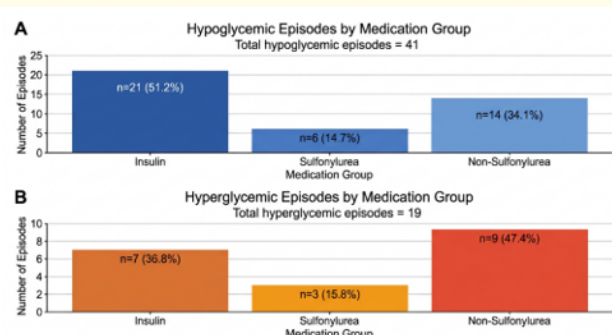


Figure 2. Distribution of glycemic events across medication groups during 30-day post-discharge follow-up.

Figure 2

consistent with its potent glucose-lowering action and narrow therapeutic index. Non-sulfonylurea oral agents were the second most frequent contributor to hypoglycemia (n = 14, 34.1%), while sulfonylurea users experienced the fewest episodes (n = 6, 14.7%). The pattern was reversed for hyperglycemia: non-sulfonylurea users accounted for the highest proportion of hyperglycemic events (n = 9, 47.4%), followed by insulin users (n = 7, 36.8%)

and sulfonylurea users (n = 3, 15.8%). The predominance of hyperglycemia in the non-sulfonylurea group is consistent with the delayed onset of action of agents such as metformin and DPP-4 inhibitors.

Medication adherence and behavioral outcomes

Medication adherence data are summarized in Table 3. Intervention participants demonstrated significantly higher adherence rates than control participants (86.7% vs. 62.2% achieving the $\geq 80\%$ threshold; $p < 0.001$; mean adherence $91.3 \pm 8.7\%$ vs. $73.4 \pm 18.2\%$). Non-adherence patterns identified across the cohort included missed doses (≥ 1 per week) in approximately 15% of participants, inconsistent medication timing in 12%, dietary non-compliance in 20%, and medication access barriers in 10%. Dietary non-compliance and medication access issues did not differ significantly between study arms ($p = 0.598$ and $p = 0.727$, respectively), suggesting that these factors represent structural barriers requiring targeted systemic interventions beyond the scope of individual counseling.

Outcome	Intervention (n = 45)	Standard Care (n = 45)	p-Value
Medication adherence			
Adherent ($\geq 80\%$ doses), n (%)	39 (86.7)	28 (62.2)	<0.001
Mean adherence rate, % (mean $\pm$ SD)	91.3 $\pm$ 8.7	73.4 $\pm$ 18.2	<0.001
Non-adherence patterns, n (%)			
Missed doses (≥ 1 per week)	4 (8.9)	10 (22.2)	0.012
Inconsistent timing	3 (6.7)	8 (17.8)	0.028
Dietary non-compliance	8 (17.8)	10 (22.2)	0.598
Medication access issues	4 (8.9)	5 (11.1)	0.727
Patient satisfaction (intervention only)			

Satisfied/very satisfied with counseling, n (%)	42 (93.3)	-	-
Telephone follow-up helpful/very helpful, n (%)	40 (88.9)	-	-

Table 3: Medication adherence and behavioral outcomes at 30-day post-discharge follow-up. SD, standard deviation.

SD, standard deviation.

Healthcare utilization outcomes

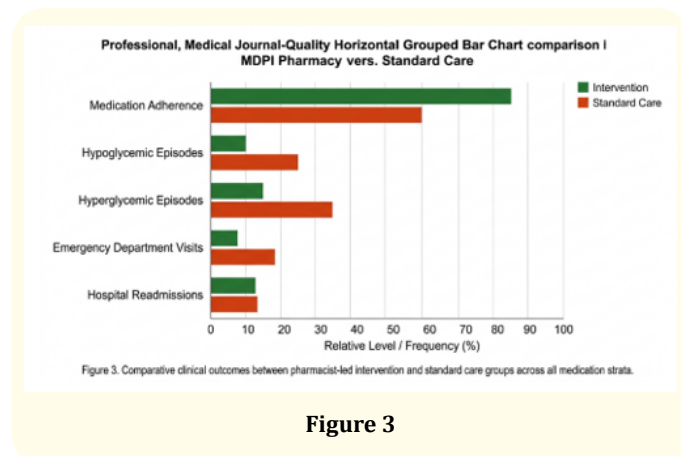
Comparative outcomes between intervention and standard care groups are presented in Table 4 and Figure 3. Intervention participants experienced significantly fewer hypoglycemic episodes (8 vs. 18; RR 0.44, 95% CI 0.21-0.93; $p = 0.021$), hyperglycemic episodes (6 vs. 13; RR 0.46, 95% CI 0.19-1.11; $p = 0.048$), and any glycemic event (26.7% vs. 51.1%; RR 0.52, 95% CI 0.31-0.87; $p =$

0.009). ED visit rates were 8.9% in the intervention group versus 22.2% in the control group (RR 0.40, 95% CI 0.14-1.15; $p = 0.032$). Thirty-day readmission rates were 11.1% and 17.8%, respectively (RR 0.63, 95% CI 0.22-1.77; $p = 0.041$). Attendance at the first scheduled outpatient physician visit was higher in the intervention group (91.1% vs. 75.6%; $p = 0.042$).

Outcome	Intervention (n = 45)	Standard Care (n = 45)	Relative Risk (95% CI)	p-Value
Glycemic events				
Hypoglycemic episodes, n	8	18	0.44 (0.21-0.93)	0.021
Hyperglycemic episodes, n	6	13	0.46 (0.19-1.11)	0.048
Any glycemic event, n (%)	12 (26.7)	23 (51.1)	0.52 (0.31-0.87)	0.009
Healthcare utilization				
ED visits, n (%)	4 (8.9)	10 (22.2)	0.40 (0.14-1.15)	0.032
30-day readmissions, n (%)	5 (11.1)	8 (17.8)	0.63 (0.22-1.77)	0.041
Outpatient follow-up				
Attended scheduled visit, n (%)	41 (91.1)	34 (75.6)	1.21 (1.01-1.44)	0.042

Table 4: Comparative clinical outcomes: intervention versus standard care at 30-day post-discharge follow-up.

CI, confidence interval; ED, emergency department.

**Figure 3**

Patient satisfaction

Among intervention participants, 93.3% rated the pharmacist counseling session as satisfactory or very satisfactory, and 88.9% reported the 72-hour telephone follow-up as helpful or very helpful. Qualitative feedback highlighted the value of individualized counseling, the opportunity to ask questions in a non-clinical setting, and the reassurance provided by proactive follow-up contact.

Discussion

Principal findings

This study demonstrates that a structured, four-phase pharmacist-driven discharge counseling program, delivered

by supervised pharmacy postgraduate students, significantly improves medication adherence, reduces glycemic complications, and decreases acute healthcare utilization in patients with diabetes across three anti-diabetic medication classes. The magnitude of benefit—a 24.5 percentage-point improvement in adherence, a 55% reduction in hypoglycemic episodes, and a 59% reduction in ED visits—is clinically meaningful and consistent with the broader pharmacist transitional care literature.

Comparison with existing literature

The readmission and ED utilization reductions observed in this study align closely with pooled estimates from Bonetti, *et al.* meta-analysis of 21 RCTs ($n = 7,244$), which reported a 13.6% relative reduction in readmissions (RR 0.864) and a 30.3% reduction in ED visits (RR 0.697) attributable to pharmacist discharge counseling [10]. Murray, *et al.* similarly reported 30-day readmission rates of 13.8% versus 18.2% in a pharmacist transitional care program at a safety-net hospital serving predominantly low-income patients with diabetes [11], suggesting that the benefits of structured pharmacist intervention generalize across healthcare settings and socioeconomic contexts.

The adherence improvements observed here are supported by multiple RCTs. Korcegez, *et al.* demonstrated that a pharmacist-led program in patients with type 2 diabetes produced significantly greater HbA1c reductions (-0.74% vs. -0.04% ; $p < 0.001$) and improved medication adherence ($p = 0.013$) compared to usual care [13]. Ting, *et al.* RCT of a structured pharmacist-led group intervention similarly found superior glycemic control and adherence in the intervention arm [14]. Gao, *et al.* 2024 evaluation of continuous pharmaceutical care during care transitions specifically reported improved adherence and clinical outcomes in patients with diabetes, corroborating our findings in a contemporaneous cohort [15].

The medication class-specific glycemic risk patterns identified in this study have not been systematically characterized in prior transitional care research. The predominance of hypoglycemia in insulin users (51.2% of all hypoglycemic events) is consistent with insulin's mechanism of action and the well-documented challenges of insulin self-management in the post-discharge setting [7]. Presley, *et al.* systematic review noted that insulin therapy poses particular challenges due to administration complexity and fear of

hypoglycemia, supporting the need for targeted, insulin-specific counseling content [16].

Mechanisms of intervention effectiveness

The multi-component architecture of the intervention likely contributed to its efficacy through several complementary mechanisms. Medication reconciliation at discharge identifies and resolves prescribing discrepancies that, if uncorrected, can precipitate both hypoglycemic and hyperglycemic crises in the early post-discharge period [17]. Patient-centered counseling using the teach-back method ensures not only information transfer but verified comprehension—a distinction that is critical for complex regimens such as basal-bolus insulin therapy [18]. The 72-hour telephone follow-up targets the highest-risk window for glycemic decompensation, enabling early detection and management of adherence lapses before they necessitate acute care [19]. Coordination with outpatient providers at the clinic visit supports appropriate medication adjustments and reinforces continuity of the therapeutic relationship [20].

Role of pharmacy postgraduate students in transitional care

A distinctive feature of this intervention is its delivery by pharmacy postgraduate students under clinical pharmacist supervision. This model addresses a critical implementation barrier in most healthcare settings: the limited availability of dedicated clinical pharmacy staff for transitional care activities. Existing literature suggests that well-trained pharmacy students can deliver medication counseling at a quality level comparable to pharmacists, particularly for structured, protocol-driven interventions [21]. Our results support the feasibility and effectiveness of this workforce model and suggest that pharmacy schools could serve as a scalable resource for expanding transitional care capacity without proportional increases in staffing costs [22].

Persistent adherence challenges and structural barriers

Despite the overall success of the intervention, non-adherence persisted in a meaningful proportion of participants: 15% reported missed doses, 12% had inconsistent medication timing, and 20% demonstrated dietary non-compliance. Notably, dietary non-adherence and medication access barriers did not differ significantly between study arms, implying that these challenges are not amenable to counseling alone and require structural solutions. Medication synchronization programs, automated refill

reminders, pill organizer provision, and linkage to pharmaceutical assistance programs represent evidence-based adjuncts that could be incorporated into future iterations of this intervention [23,24]. Simplification of anti-diabetic regimens—where clinically appropriate—may also reduce the cognitive burden associated with complex multi-drug schedules [25].

Implications for clinical practice and health policy

These findings provide a strong evidence base for integrating clinical pharmacists and supervised pharmacy students into discharge planning teams for hospitalized patients with diabetes, particularly those prescribed high-risk agents such as insulin and sulfonylureas. Risk stratification by medication class could inform the development of tailored counseling modules and differential follow-up intensity—for example, prioritizing 72-hour telephone contact for insulin users given their higher hypoglycemic burden. From a health policy perspective, the demonstrated reductions in ED visits and readmissions support the cost-effectiveness of pharmacist-led transitional care, reinforcing calls for dedicated reimbursement mechanisms for these services [26,27].

Strengths and limitations

Strengths of this study include its prospective randomized design, medication-stratified allocation enabling class-specific risk characterization, multi-component intervention reflecting real-world clinical complexity, and comprehensive outcome assessment across adherence, glycemic, and utilization domains. Limitations include a modest sample size that may limit statistical power for rare outcomes; single-center design that may constrain generalizability; a 30-day follow-up horizon that precludes assessment of sustained benefits; reliance on patient-reported adherence and glycemic symptoms, which may be subject to recall bias; and absence of HbA1c measurement at 30 days. Future studies should incorporate 90-day follow-up with HbA1c assessment, health economic analyses, and multi-center designs to strengthen the evidence base for this intervention model.

Conclusions

The hospital-to-home transition represents a disproportionately high-risk period for patients with diabetes prescribed insulin, sulfonylureas, or non-sulfonylurea oral hypoglycemics. This prospective, three-arm randomized study demonstrates that a

structured, four-phase pharmacist-driven discharge counseling program—delivered by supervised pharmacy postgraduate students—significantly improves medication adherence, reduces hypoglycemic and hyperglycemic events, and decreases acute healthcare utilization during the 30-day post-discharge period.

Medication class-specific analysis revealed distinct glycemic risk profiles: insulin therapy was associated with the highest hypoglycemic burden (51.2% of all hypoglycemic events), while non-sulfonylurea oral agents were disproportionately represented among hyperglycemic events (47.4%). These differential patterns underscore the importance of tailored counseling content and follow-up strategies calibrated to the specific risks of each drug class.

The successful implementation of this intervention through pharmacy postgraduate students under clinical pharmacist supervision demonstrates a scalable and cost-effective workforce model for expanding transitional care capacity. Persistent non-adherence related to dietary practices and medication access highlights the need for complementary structural interventions beyond individual counseling. Future research should prioritize longer follow-up periods with objective glycemic endpoints, economic evaluations, and multi-center replication to consolidate the evidence base for routine integration of pharmacist-led discharge counseling in diabetes care pathways.

Author Contributions

A.C.: Conceptualization, study design, data interpretation, manuscript writing, and final approval. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of Indus International Hospital (reference: IIH-IEC-2025-04; approval date: January 2025).

Informed Consent Statement

Written informed consent was obtained from all participants prior to enrollment. Participants were informed of the right to

withdraw from the study at any time without consequence to their clinical care.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

The author declares no conflicts of interest.

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