BODHIVRUKSHA JOURNAL OF DIVERSE DISCIPLINE
E-ISSN : 3139-1486
An Open Access, Peer-Reviewed, Multidisciplinary Scholarly Journal
Bi-monthly | Multilingual (English, Hindi, Marathi) | Academic Research
@ Volume 2, Issue 5 (September-October 2026) (Special Issue 1) ISSN: 3139-1486 (Online)

Context-Aware Multimodal Generative AI Framework for Insulin Stacking Risk Assessment and Clinical Decision Support

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Abstract

There is an increased risk of hypoglycemia with insulin stacking, which involves taking a new insulin dose while the previous dose is still working. The works reviewed focus on dose titration or automated delivery of medication, or conversational counseling in recent studies on artificial intelligence (AI), but do not discuss stacking directly. This paper summarizes nine papers on insulin stacking, AI enabled insulin dosing and LLM-enabled clinical support, finding that no study, in its available abstract and/or text, integrates the four factors of continuous glucose monitoring (CGM), insulin history, meals, physical activity, and health-record context, into a stacking risk assessment and communication framework with explicit safety constraints for both the clinician and the patient. We suggest a new five-layer framework that builds a separation between a deterministic clinical core (insulin-on-board estimation, projected-glucose risk tiers, hard safety rules) and a retrieval-grounded generative layer which explains, but will not compute, risk. The framework is theoretical (not implemented) and no experimental or clinical results are provided. Future work is suggested in an evaluation protocol.

Keywords : clinical decision support, diabetes management, explainable AI, generative AI, insulin stacking, insulin-on-board, large language models, multimodal learning, retrieval-augmented generation.

I. INTRODUCTION

With insulin therapy, multiple insulin dose calculations are needed based on current glucose, carb, activity and the insulin remaining from previous doses. Insulin stacking can result in insulin effect and hypoglycemia. In a single-center hospital quality-improvement study, 42% of patients received dinner-time correctional and bedtime insulin less than four hours apart before the intervention; moving one scheduled

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order time was followed by a 28% reduction in stacking at one year [1]. Automated insulin delivery (AID) presents another challenge in ambulatory care: automatic correction boluses made up approximately 18.3% of total daily insulin in a retrospective study of 287 patients with type 1 diabetes who used one AID system [2]; and the current display of insulin-on-board (IOB) in AID systems has been argued to be misleading [3].

The use of AI techniques for insulin dosing is becoming a common practice. In a new review, researchers discuss the promise of personalized insulin recommendations and the issues of privacy, transparency, and clinical adoption of AI [4]. A decision support system was found to improve HbA1c outcomes after 12 weeks in a randomized trial without causing severe hypoglycemia [5] and a transformer-based model has been proposed that combines an LLM-based meal estimator with an LLM-based glucose-prediction check and an LLM-based titration model [6]. At the same time, AI diabetes helpers have been tested [7, 8] and the results suggest that there are potential issues with general-purpose models providing inconsistent advice and indicate that they are not suitable for autonomous use.

Even with all this progress, a significant gap in the reviewed literature is what methods are available to evaluate stacking risk at the time of a dosing decision with the full patient context, and how this risk can be communicated safely to a clinician and patient. This paper makes the following contributions:

- an overview of the nine studies on insulin stacking, insulin dosing with the help of AI, and AI support in clinical care (Table I);
- an explicit gap analysis and three research questions grounded in such a synthesis (Section IV);
- the proposed five-layer architecture separating deterministic computation from generative explanation (Section V, Fig. 2);
- A clinician-configurable formal IOB, projected glucose, and tiered stacking-risk classification (Section VI); and
- A validation protocol for future validation (Section VII).

Status of the work : This paper is at the literature-review and conceptual-design stage. There is no implementation of the framework, the analysis of the dataset is not performed and there are no claims on the performance, safety, or clinical benefit. Equations and thresholds are proposed design options and not validated results. Figure 1 is an arithmetic representation and not patient data.

II. BACKGROUND

A. Insulin on Board and Stacking

IOB is a tool that estimates the insulin that has previously been administered and is still working. Let the dose of insulin be dose Di to be administered at time ti, and let the duration of insulin action be TDIA. The IOB at time t is the sum over all doses with ti ≤ t of the individual doses multiplied by the fraction remaining at time t:

$$IOB(t) = \Sigma i\ Di \cdot f(t - ti) \qquad (1)$$

$$f(\tau) = max(0,\ 1 - \tau/TDIA) \qquad (2)$$

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The action curve in linear decay is a conscious and deliberate simplification for transparency, although other shapes of action curves are possible and IOB presentation in AID systems has been queried [3]. Fig. 1 applies (1) and (2) to three hypothetical boluses (4 U, 3 U, 3 U at 0, 1.5, and 3 h) with an assumed TDIA of 4 h. Even though no single dose is more than 4 U, the cumulative effect of the multiple doses with the third dose makes a total of 5.875 U immediately after the third dose.

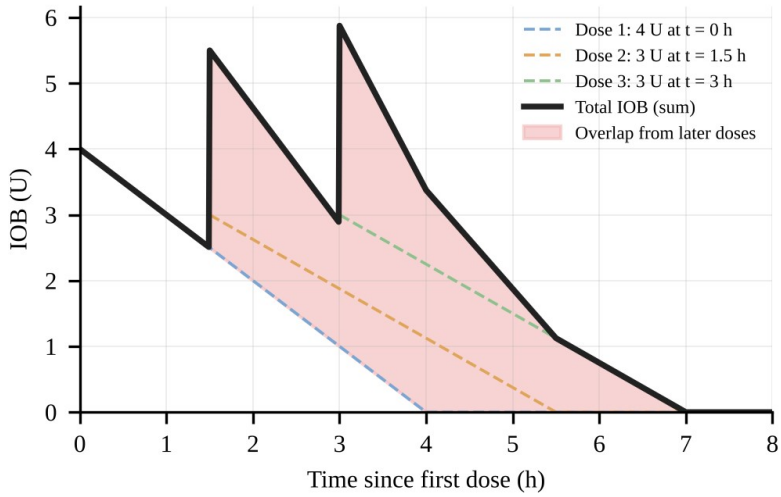


Fig. 1. Illustrative IOB from Eqs. (1)–(2) for three hypothetical boluses with assumed T_{DIA} = 4 h. The shaded area is insulin activity added by later doses. Synthetic arithmetic example; not patient data.

B. Conventional Bolus Calculation

The bolus-calculator formula that is commonly used is a combination of a meal component and a correction component, minus IOB:

Dcalc = max(0, CHO/ICR + (Gt − Gtgt)/ISF − IOB(t))(3)

CHO is the amount of carbohydrates to be consumed (in grams), ICR is the amount of insulin per gram of carbohydrate (in units/gram), ISF is the amount of insulin required to lower glucose by 1 mg/dl per 1 unit (mg/dl/unit), Gt the current glucose level and Gtgt the target glucose level. The inputs themselves are not physical activity or larger context of health record, and that is what motivates the multimodal design proposed here.

III. RELATED WORK

A summary of the nine studies reviewed is shown in Table I. Only the abstracts or text reports accessible are acceptable as entries; if only an abstract is accessible, this is indicated.

A. Stacking, Dose Timing and Automated Delivery

Moolchandani et al. conducted a study at a Veterans Affairs hospital and showed that most of the doses of insulin were scheduled and within four hours of each other, if not at the same time, when they were

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corrected or at the time of sleep. When the bedtime order was changed from 21:00 to 22:00, a reduction in stacking (23% immediately, 28% at 1 year) and a reduction in glucose readings < 70 mg/dL (50% at 1 year) were observed [1]. It was a single site, uncontrolled design with a fixed rule for all patients. In one AID system, Papa et al. has reported that automatic correction bolus was correlated with a decrease in time in range as analyzed in a retrospective study [2]. Riddell et al. cover the boundaries of IOB in the context of AID systems [3]. These works collectively lay the foundations for stacking and IOB as clinically relevant, but without providing individualized, real-time risk assessment.

B. AI-Based Insulin Dose Recommendation

Panagiotou et al. summarize a range of papers on insulin recommendation using AI, highlighting the challenge of personalization and the issues of privacy, transparency, and adoption [4]. Kobayati et al. compared 84 adults who used multiple daily injections to a decision support system or a non-adaptive bolus calculator for 12 weeks and found that HbA1c dropped from 8.6% to 8.1% in the former group compared to 8.6% to 8.5% in the latter group, without any severe hypoglycemia or ketoacidosis being reported [5]. Zeng et al. propose DIETS, which is based on a fine-tuned meal nutrient estimation LLM, a titration model, and a glucose-prediction check, and show an improvement over baselines on three public data sets (no figures are provided in the abstract). The most closely reviewed papers to the present proposal are those of DIETS, however its abstract does not mention the aspects of IOB-overlap stacking assessment, activity and health-record context, or role specific explanations, and the full paper was not available for this review.

C. LLMs for Diabetes and Medication Safety

Guo et al. evaluated a retrieval grounded LLM agent against clinicians on 12 CGM cases, using 864 blinded ratings; the LLM agent improved overall (4.37 compared to 3.58), safety concerns occurred in 3 of 432 (7.8%) ratings for the LLM agent and 3 of 432 (7.8%) ratings for clinicians, and the LLM agent did not provide individual therapeutic advice. According to the authors, their results are not conducive to independent therapeutic choice [7]. Hussain and Grundy concluded that ChatGPT-3.5 and GPT-4 provided inconsistent responses, sometimes without explanation of the query, and suggested a layer of commonsense evaluations and external memory stores retrieved by the model [8]. In general, medication safety, Ong et al. developed a retrieval-augmented LLM system to detect prescribing errors, which a pharmacist working with the system found to have the highest accuracy, recall, and F1 for moderate-to-severe problems across 61 errors in 23 vignettes [9] [10]. Oracle-enhanced generation (RAG) [11] ensures that the model generates content that is grounded in retrieved documents, while clinical LLM studies reveal significant capabilities and areas for improvement compared to clinicians [12].

TABLE I. SUMMARY OF REVIEWED STUDIES AND GAPS RELATIVE TO THE PROPOSED WORK

Ref.	Design and data	Reported findings	Gap relative to this work
[1]	Single-center VA hospital quality improvement; bedtime insulin order moved 21:00→22:00; before/after comparison	42% of patients had two doses <4 h apart before change; stacking −23% (immediate), −28% (1 yr); true hypoglycemia (<70 mg/dL) −50% at 1 yr	Fixed population-level timing rule; uncontrolled; no individual context or explanation

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Ref.	Design and data	Reported findings	Gap relative to this work
[2]	Retrospective; 287 people with T1D; one AID system; four centers	Automatic corrections ≈18.3% of total daily insulin, 33.1% of bolus insulin; larger share associated with lower time in range	Single system; association only; no stacking-risk estimate
[3]	Commentary on IOB in AID systems	Argues current IOB presentation can be misleading; traces IOB evolution	Conceptual; no decision-support implementation
[4]	Review of AI-based insulin recommendation (preprint)	Potential for personalization; barriers: privacy, transparency, adoption	Review only; no framework or stacking focus
[5]	12-week open-label RCT; 84 adults, MDI; decision support vs. non-adaptive bolus calculator	HbA1c 8.6→8.1% vs. 8.6→8.5%; effect −0.40 points (95% CI −0.75 to −0.051); no severe hypoglycemia or DKA reported	Weekly titration; abstract describes no real-time stacking alerts or generative explanation
[6]	DIETS: LLM meal estimation + titration + glucose-prediction check; three public datasets (preprint, abstract only)	Reported better than baselines at insulin recommendation; no figures in abstract	Stacking/IOB overlap, activity and EHR context, dual-audience explanation not described in abstract
[7]	Retrieval-grounded LLM vs. clinicians; 12 CGM cases, 6 clinicians, 864 ratings (preprint)	Agent 4.37 vs. 3.58 overall; major safety concerns 3/432 in each group; no individualized therapy advice; not supportive of autonomous use	Counseling only; no dose-safety or stacking assessment
[8]	ChatGPT-3.5/GPT-4 on diabetes self-management questions (preprint)	Uneven accuracy and bias; personalized advice only with sophisticated prompting; often no clarifying questions	General-purpose model; mitigations proposed, not stacking-specific
[9], [10]	RAG-based LLM for prescribing-error detection; preprint: 61 errors in 23 vignettes	Pharmacist + LLM co-pilot best for moderate-to-severe problems; published version spans 16 specialties (not accessed)	General medication safety; vignette-based; not insulin-specific

IV. RESEARCH GAP AND RESEARCH QUESTIONS

From the above, we can conclude that there are four limitations that keep recurring. Stacking is examined in the context of fixed timing rules [1] or through the lens of AID behavior [2] and [3] than as an individual, real-time risk. (ii) AI dosing is centered around titration and glucose forecasting [5, 6]. (iii) Caution for self-use of the studies is found in most LLM studies which are counseling or general medication-safety assessments [7]–[10]. Not a single system was reported that combines CGM, insulin history, meals, activity, and health-record context for stacking-risk assessment for both patients and clinicians as described in the

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abstracts of the reviewed works, or as accessible text. This statement refers to the nine studies reviewed here and does not necessarily extend to literature in general.

The proposed design is guided by the following questions:

- RQ1. What is the best way to integrate multimodal context for timing the dosing decision for stacking risk at the time of the dosing decision?
- RQ2. How to control generated explanations to stay consistent with deterministic risk computation?
- RQ3. What is the difference between a clinician's and a patient's risk communication, and how can the authority of the clinician be maintained?

V. PROPOSED FRAMEWORK

The proposed five layer architecture is presented in Fig. 2. From the evidence reviewed four design principles follow. However, unlike the issues of unqualified advice and missing clarification highlighted in [8], all numerical risk calculations are performed by the deterministic testable code (L3) and the LLM (L4) explains and asks clarifying questions without making the calculations. Grounding: explanations retrieved from passages in guidelines and policies (P2). If input is missing, stale or inconsistent, escalation is initiated – not a best guess. P4, human authority: as in [7] a qualified clinician has final treatment authority, with overrides recorded.

For L1–L2 (data and ingestion), the inputs include CGM glucose readings, insulin or pump logs, health record parameters (such as ICR, ISF, target, TDIA), meal entries, and activity logs. L2 carries out unit harmonization, aligns the timestamps, identifies any missing data, and performs de-identification and consent checks.

For the L3 (deterministic core), IOB and carbs-on-board (COB) are calculated together with the predicted glucose level and the stacking-risk tier (as described in Section VI), and the hard safety rules are applied.

In the case of L4 (the generative layer), guideline passages are provided by a retrieval component; the large language model prepares an explanation and any additional questions that are needed based on the outputs

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from L3; then a verifier ensures that all the numbers and risk statements in the draft correspond to the values from L3 and discards any drafts that are inconsistent.

For L5 (interfaces), the clinician's view displays the contributing factors, the retrieved evidence, and the audit trail, while the patient's view provides alerts in plain language; in both cases the views can be reviewed by the clinician (see Fig. 3).

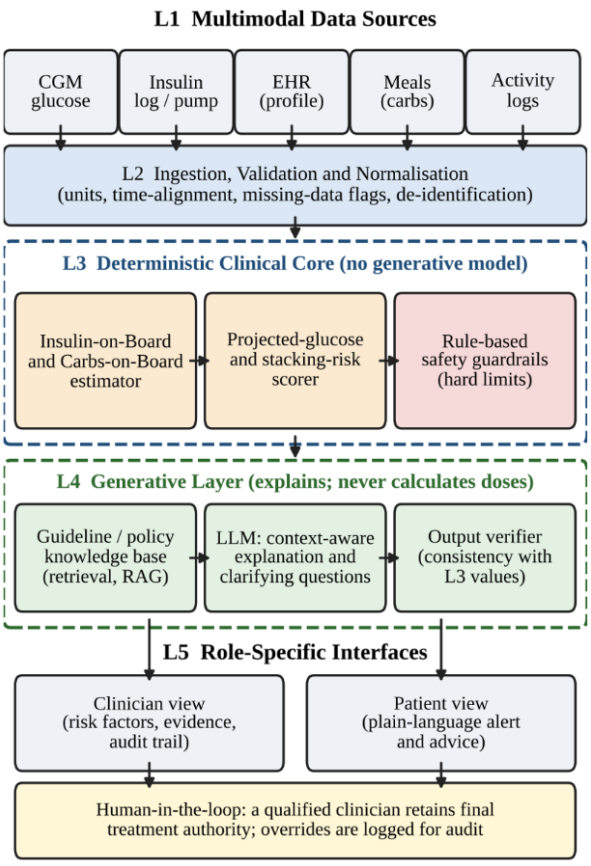


Fig. 2. Proposed five-layer framework (conceptual; not implemented). Dashed boxes separate the deterministic clinical core (L3) from the generative layer (L4).

VI. METHODOLOGY

A.Projected Glucose

For a candidate or requested dose D, a first order projection of eventual glucose is

$$\hat{G}(D) = Gt - ISFeff \cdot (IOB(t) + D) + (ISF/ICR) \cdot COB(t) \quad (4)$$

$$ISFeff = (1 + \delta ctx) \cdot ISF \quad (5)$$

where COB(t) is the grams of carbohydrate not yet absorbed and $\delta ctx \geq 0$ is a clinician-set margin that increases assumed insulin sensitivity when recent or planned activity is recorded. Eq. (4) ignores

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absorption dynamics and basal insulin, and δctx is a placeholder to be calibrated; it is not a validated quantity.

B. Risk Tiers

Table II lists the proposed tiers, which use glucose thresholds from the international consensus on CGM metrics, which define level 1 hypoglycemia as <70 mg/dL and level 2 as <54 mg/dL [13]. A watch margin m is clinician-configurable. A stacking flag is raised when IOB(t) > 0 and a new dose is requested before TDIA has elapsed since the last bolus.

TABLE II. PROPOSED STACKING-RISK TIERS (DESIGN CHOICE; NOT VALIDATED)

Tier	**Condition on $\hat{G}(D)$**	**Proposed system response**
High	$\hat{G} < 54$ mg/dL	Withhold dose suggestion; escalate to clinician; show fail-safe message
Moderate	$54 \leq \hat{G} < 70$	Show warning with computed values; require clinician-defined confirmation
Watch	$70 \leq \hat{G} < 70 + m$	Inform user; display stacking flag and IOB breakdown
Low	$\hat{G} \geq 70 + m$	Standard display

C. Retrieval, Generation, and Verification

Fig. 3 shows the runtime workflow. After L3 and the guardrail check, the retrieval step finds guideline passages relevant to the calculated risk and context. The LLM gets only the outputs from L3 and the retrieved text and is instructed to cite the retrieved passage for each recommendation and to ask clarifying questions in case of ambiguous inputs. The verifier rejects drafts whose numbers or tier differ from the

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outputs of L3; a rejected draft is replaced by a templated message. The explanation content lists the factors that drove the tier.

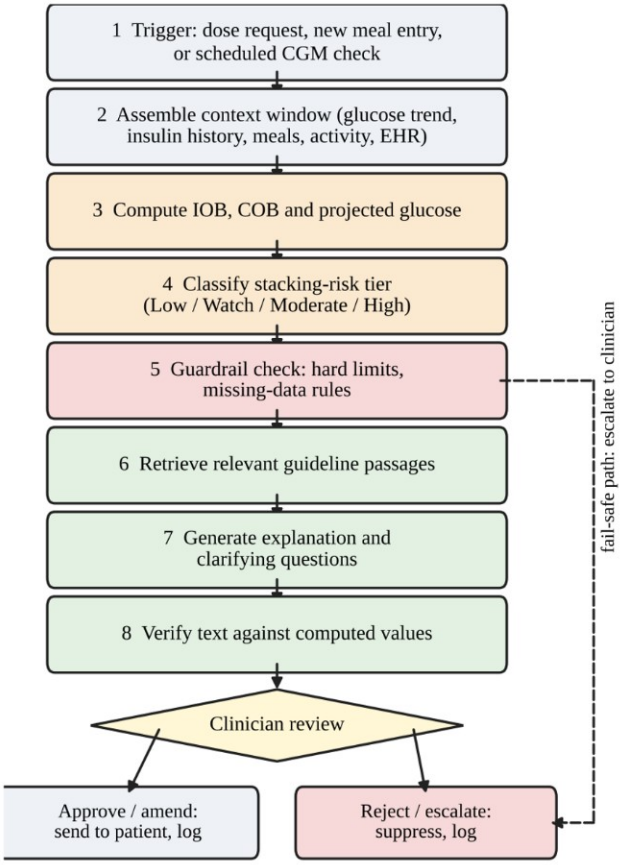


Fig. 3. Proposed runtime workflow with deterministic computation (orange), guardrail (red), generative steps (green), and clinician review. Conceptual; not implemented.

D. Role-Specific Output

The same validated L3 values are used to generate two renderings of the information: a clinician rendering, which incorporates parameters, retrieved evidence and audit trail; and a patient rendering in lay language,

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with a prompt to follow the clinician-agreed plan. Neither rendering can contain content that was not included in the validated draft.

VII. PROPOSED EVALUATION PROTOCOL

- None of the following has been carried out yet. The protocol is presented as it would be to test claims before any deployment.
- Core verification. Testing IOB, COB, and Eqs. (1)–(5) individually against hand-computed cases and reference calculators using unit tests.
- Retrospective replay. On de-identified CGM and insulin-log data, to which one has been granted licensing or ethics approval, compare glucose outcomes after flagged and unflagged dosing
- events: sensitivity, specificity, positive predictive value, calibration, and the amount of alerts
- Generative layer: factual-consistency and hallucination audit, testing with adversarial prompts, evaluation of the behaviour when clarifying questions are asked, blinded clinician ratings of the explanations in the way described in [7], and checks of readability for patient text.
- Simulation and prospective study. This involves carrying out in-silico testing using accepted simulators, followed by prospective evaluation only after the relevant ethics and regulatory approvals have been obtained and with the supervision of a clinician.

VIII. DISCUSSION AND LIMITATIONS

The main assumption is that it is more effective to restrict the generative model to the task of providing explanations than to allow it to consider doses. This hypothesis is based on [7] and [8] and has not been tested in this study. The limitations are as follows. The first is that the framework has not been implemented or verified. The second point is that the linear IOB model and first-order projection are simplifications; actual insulin action and absorption differ from person to person and within individuals, and the AID interactions [3] are not included in the model. Third, the thresholds and margins are configurable defaults and have not been established on a clinical basis. Fourth, several of the sources are preprints or could be accessed only through abstracts (as shown in Table I), so the details might change or be incomplete. Fifth, alert fatigue and automation bias could diminish the benefits; both of these issues need to be investigated. Lastly, putting the framework into practice would require compliance with data protection regulations, clinical governance, and assessment by regulatory authorities for medical software, all of which are beyond the scope of this paper. It should be clearly understood that the framework is intended as a decision-support tool and does not take the place of healthcare professionals.

IX. CONCLUSION

The paper refered at nine studies concerning insulin stacking, AI-based dosing, and LLM clinical support, noticed a gap in the area of context-aware stacking-risk assessment with regard to grounded, role-specific explanations, and suggested a five-layer framework which ensures that the risk calculation remains deterministic and limits the generative model to providing verified explanations. The contribution consists of a conceptual design and an evaluation plan, not of a validated system. In future work the deterministic

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component will be implemented, it will then be tested using retrospective data, and finally the generative layer will be evaluated with clinicians.

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