ACADEMIC PUBLICATION SET

VIEN GUT MODEL

Integrated Outpatient Care for Complex Chronic Multimorbidity

Part A — Foundations

Academic Publication Set — Vien Gut Model

DOCUMENT A.1

EBM REFERENCE FRAMEWORK: WHAT + HOW + DATA-TO-OPERATE

From Gap to Operable Structure

Vien Gut Model — Academic Publication Set
First Systematic Compilation — March 2026
Ho Chi Minh City, Vietnam

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1. Practice origin

This document originates from a question that Vien Gut had to answer after years of clinical operation: why do well-trained physicians, equipped with comprehensive international guidelines, still encounter difficulty when treating patients with complex chronic multimorbidity? And why do treatment outcomes fail to improve despite the publication of ever more guidelines?

The answer does not lie in the quality of guidelines. The answer lies in the fact that guidelines — however good — constitute only one of three layers necessary to operate integrated care. The remaining two layers — HOW and DATA-to-operate — do not exist within the current EBM chain as systematically designed components.

Document A.1 systematizes this three-layer framework — analyzing why the current EBM chain encounters a structural break point when applied to complex chronic multimorbidity, and how the Vien Gut Model's WHAT–HOW–DATA-to-operate framework fills that gap. Detailed definitions of the three layers WHAT, HOW, and DATA-to-operate are presented in Document A.2 (Foundational Concept Set).

2. The current EBM chain — from basic research to clinical application

Evidence-based medicine (EBM) was built as a rigorous scientific logic chain, from basic research to clinical application [1]. This is the great achievement of 20th- and 21st-century medicine — creating the strongest WHAT foundation medicine has ever had.

STEP IN THE EBM CHAIN	METHODS AND DETAILED CONTENT	OUTPUT PRODUCED	HOW + DATA
1. Basic Research	In vitro/in vivo experiments, animal models, gene expression, proteomics — identifying pathogenesis, molecular targets (e.g., cytokine pathways in autoimmune/chronic inflammatory diseases)	Hypotheses for diagnosis and treatment — foundation for the next step	No clinical HOW/DATA required — this is the basic science tier
2. Diagnostic Development (Translational Research)	Diagnostic criteria (e.g., ACR criteria for arthritis), imaging techniques, biomarkers — evaluation of sensitivity/specificity through diagnostic accuracy studies	Accurate and reproducible disease recognition tools	Diagnostic HOW is standardized — diagnostic DATA is systematic
3. Treatment Goal Definition	Based on disease mechanisms and epidemiological data (burden of disease) — short-term goals (symptom control) and long-term goals (preventing progression, improving QoL); individualization via patient-centered care	Clear WHAT formed: scientifically defined treatment targets	HOW for achieving targets in single diseases begins to emerge — single-axis outcome DATA
4. Drug & Intervention Development	From screening to molecular design (e.g., biologics such as anti-TNF), preclinical studies for safety/efficacy — including gene therapy and non-pharmacological interventions (physical therapy)	Evidence-based treatment tools with preclinical evidence — prepared for human trials	HOW for safe drug use in single diseases — preclinical DATA
5. Clinical Trials	Phase I (safety/dose, n=20–100) → Phase II (preliminary efficacy, n=100–300) → Phase III RCT double-blind (n=300–3000) → Phase IV post-marketing; GCP compliance, ClinicalTrials.gov; includes pragmatic trials	Efficacy and safety evidence in humans — foundation for guidelines. NOTE: RCTs typically exclude patients with severe multimorbidity	HOW within controlled RCTs — homogeneous DATA. But real-world populations are excluded
6. Evidence Pyramid (OCEBM)	From low to high: Expert opinion, case reports → Cross-sectional (OCEBM level 4: good for prevalence, weak for causality) → Case-control, cohort → Single RCTs → Systematic reviews, meta-analyses (Cochrane) — assessed by GRADE	Evidence ranking by OCEBM — foundation for guideline recommendations	Cross-sectional: useful for detecting gaps in fragmented care — population DATA but no individual longitudinal DATA
7. Guideline Development	Synthesized by EULAR, ACR, KDIGO, ESC, EASL, NICE, AHA, etc. via Delphi/consensus — strong/weak	Complete WHAT at the highest tier: internationally standardized guidelines	Single-disease HOW is clear within guidelines — but multi-disease HOW

	recommendations based on GRADE; periodic updates or when new evidence emerges	accepted by the global medical community	and multi-axis DATA-to-operate are NOT described
8. CLINICAL APPLICATION ← STRUCTURAL BREAK POINT	Clinical reality: typically fragmented care model — each specialty applies its own guideline without structural coordination → repeated tests, omissions, high costs, reduced adherence. Particularly severe in multimorbidity	Outcomes worse than expected from guideline evidence — large gap between efficacy (RCT) and effectiveness (real world)	Integrated multi-axis HOW DOES NOT EXIST in the EBM chain. Individual longitudinal DATA-to-operate is NOT structured. This is the gap that the Vien Gut Model fills

2.1. The feedback loop — and why it is insufficient to fill the HOW gap

The EBM chain includes a feedback loop designed for self-improvement: when limitations are identified from clinical practice — for example through cross-sectional studies on the poor effectiveness of fragmented care [5] — that data is fed back to the research tier to initiate new studies, update guidelines, or design better interventions.

This is EBM's powerful self-improvement mechanism — and it has worked excellently at the WHAT tier: guidelines are progressively better, evidence is progressively stronger. However, this feedback loop has an important structural limitation:

WHAT improvement loop	Limitation identified → new research → updated guideline. Works well: gout guidelines updated from EULAR 2006 to ACR 2020, KDIGO from 2012 to 2024, ESC heart failure updated 2021.
Loop does not generate HOW	Fragmented care identified as harmful → gap acknowledged → but no integrated operational procedure produced. NICE NG56 (2016) acknowledged the problem, JA-CHRODIS (2016) proposed a framework, but no guideline provides specific HOW for clinicians.
Structural reason	HOW is not a product of basic research or RCTs — HOW is a product of structured integrated clinical practice over an extended period. The EBM chain was not designed to produce this layer.

The Vien Gut Model is practical proof: after 18 years of operation, HOW has been built into a structured architecture — from the first clinical encounter activating the operational system (B.1), to the 4-phase treatment plan (B.2), to the mechanism for identifying and maintaining the opportunity window (B.3). None of these layers were produced by the EBM feedback loop — they were produced by the practice–observation–systematization loop at Vien Gut.

3. The structural break point — why the EBM chain encounters a structural limit at the application step

The fragmented care model — in which each specialty applies its own guideline without structural coordination — is the inevitable consequence of the single-disease EBM chain when confronted with multimorbid patients [2]. In this model, a patient with severe complicated gout accompanied by CKD G4, heart failure, and cirrhosis encounters three separate specialties — and three separate guideline sets — with no one coordinating the whole.

Why the break point appears — structural analysis:

Single-disease guidelines	Each guideline is built from RCTs that exclude patients with severe multimorbidity [6]. Evidence is generated on "clean" populations — and is the only evidence available to clinicians when they encounter complex patients.
No integration mechanism	No guideline describes how to coordinate when a drug beneficial for one axis causes harm on another. No prioritization rules exist between conflicting guidelines [6].

No coordinator	The EBM chain ends at the step “clinician applies guideline” — but does not define who bears overall responsibility when multiple guidelines are simultaneously applied to a single patient.
No longitudinal data	Single-disease guidelines rely on cross-sectional snapshots. But complex chronic multimorbidity requires time-series data to identify trends, pathological spirals, and opportunity windows.

International evidence confirming this break point is presented in detail in Document A.3 (The Global HOW Gap) and Document B.5 (Enabling Conditions), including: Barnett et al. (Lancet 2012) on the scale of multimorbidity, NICE NG56 on single-disease guideline limitations, Hughes et al. (2013) on cumulative treatment burden, Muth et al. (2019) on the lack of clinical decision support, and the guideline paradox when four to seven severe diseases simultaneously conflict on a single patient.

4. The three-layer framework: WHAT – HOW – DATA-to-operate

The Vien Gut Model does not replace EBM — it completes EBM by adding the two missing layers. These three layers are inseparable — they form a single integrated framework enabling structured, traceable, and verifiable care in complex chronic multimorbidity. Detailed definitions of each layer: see Document A.2.

4.1. The WHAT layer — Guidelines and evidence (existing, requiring reorganization)

WHAT encompasses all medical knowledge built through the EBM chain: treatment targets, drugs of choice, intervention thresholds, and evaluation criteria [1]. This is the layer in which modern medicine has invested the most and built the best.

The challenge of WHAT in multimorbidity is not a lack of guidelines — it is reorganizing WHAT from multiple single-disease guidelines into a structured clinical priority map for each individual patient. This is the work of HOW.

4.2. The HOW layer — Structured clinical operations (the missing layer in EBM)

HOW is the layer that describes specifically how WHAT is executed in clinical practice: who does what, when, based on which thresholds, with what response SLA, and when to activate the safety valve. This is the layer that current EBM does not have — and the layer that the Vien Gut Model has built over 18 years of practice.

In Part B, HOW is operationalized as: the Clinical Conductor coordinating the whole (B.1, B.2); T1–T4 risk stratification (B.1); the 4-phase treatment plan (B.2); necessary and sufficient conditions for maintaining the opportunity window (B.3); the patient participation competency framework (B.4); and disease–disease / drug–disease conflict resolution (B.5).

4.3. The DATA-to-operate layer — Longitudinal data activating decisions

DATA-to-operate is not research data — it is longitudinal clinical data collected in a structured manner and used to activate HOW decisions in real time. This is the layer connecting WHAT (knowing what to achieve) with HOW (knowing what to do right now) [3].

In Parts B and C, DATA-to-operate is present through: the minimum paraclinical core generating baseline data (B.1); phase-specific data triggering phase transitions (B.2); time series determining whether the window is open or closed (B.3); adherence and patient competency data (B.4); safety valve activation thresholds (B.5); caliper mm^2 ultrasound data verifying crystal-free status (C.1); eGFR time-series data verifying renal

preservation (C.2); BNP/EF data verifying cardiac decompensation reduction (C.3); and Child–Pugh/Fibroscan data verifying hepatic recompensation (C.4).

5. Why the three layers must be integrated — they cannot operate independently

The three layers WHAT–HOW–DATA-to-operate are not three independent tools. They are three layers of a single system — and the absence of any layer renders the entire system inoperable in complex chronic multimorbidity.

Missing layer	Consequence	Clinical illustration
Missing HOW	WHAT remains on paper, not converted into integrated action	Patient with gout + CKD G4 + heart failure: three guidelines in conflict, no one coordinating, opportunity window lost
Missing DATA-to-operate	HOW operates blind, decisions based on isolated snapshots	Clinical Conductor cannot see eGFR sliding downward, activates safety valve too late, patient decompensates
Missing WHAT	HOW + DATA operate without standards, decisions based on intuition	Does not occur in the VG Model — WHAT is always preserved intact from international guidelines

6. Link to the four verification targets

The WHAT–HOW–DATA-to-operate framework is the operational foundation for all four verification targets — none of which can be achieved with WHAT alone:

C.1 Crystal-free	WHAT: T2T urate lowering per ACR/EULAR. HOW: Clinical Conductor phases treatment, manages polypharmacy safely for kidney–liver. DATA: caliper mm² ultrasound for longitudinal urate crystal monitoring.
C.2 Renal preservation	WHAT: KDIGO 2024 CKD management. HOW: resolving conflict between urate-lowering drugs and renal function, dose adjustment by eGFR. DATA: eGFR, creatinine, urine albumin time series.
C.3 Cardiac decompensation reduction	WHAT: ESC 2021 heart failure. HOW: balancing diuretics–urate lowering–renal protection, increased monitoring frequency when BNP rises. DATA: BNP/NT-proBNP, EF, emergency hospitalization frequency.
C.4 Hepatic recompensation	WHAT: EASL 2018 decompensated cirrhosis. HOW: polypharmacy management to avoid hepatotoxicity, albumin adjustment, coagulation monitoring. DATA: Child–Pugh, MELD, Fibroscan, albumin time series.

7. Scope limitations of this document

This document includes: analysis of the current EBM chain and its structural break point; presentation of the three-layer WHAT–HOW–DATA-to-operate framework as an architectural solution; and linking the three-layer framework to the four verification targets.

This document does not include: detailed definitions of the three layers (see A.2); international evidence on the HOW gap (see A.3); detailed operational terminology (see A.4, A.5); specific operational procedures (see B.1–B.5); or clinical evidence on target organs (see Part C).

8. Position within the Vien Gut documentation system

Document A.1 is the central theoretical framework of Part A. It lays the foundation for the entire publication set by identifying the structural break point in the EBM chain and presenting the three-layer framework as the solution. Position: A.0 (architectural declaration) → A.1 (EBM framework — this document) → A.2 (three-layer definitions) → A.3 (gap evidence) → A.4–A.5 (terminology). Part B deploys HOW + DATA-to-operate into operational procedures. Part C verifies outcomes on target organs.

9. Conclusion

The EBM chain is the great achievement of modern medicine — but this chain was designed along single-disease logic. When the subject is a patient with complex chronic multimorbidity — four to seven severe diseases simultaneously, multiple pathological spirals, multiple guideline conflicts — the EBM chain encounters a structural break point at the application step: the WHAT is known but there is no HOW to organize it, and no DATA-to-operate to guide it.

The WHAT–HOW–DATA-to-operate framework of the Vien Gut Model is not a theoretical product. It is the result of systematization from 18 years of integrated clinical practice — where the three layers have been built, operated, and verified on thousands of patients with complex chronic multimorbidity. Part B of the publication set describes in detail how HOW and DATA-to-operate are operationalized into procedures. Part C verifies outcomes on the four target organs.

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