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Integration of Digital Therapeutics into Community Pharmacy Practice

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ABSTRACT — Digital therapeutics (DTx)—clinically evaluated software that delivers evidence-based interventions—are moving from early pilots to routine care. Community pharmacies, as the most frequently accessed point of care, are uniquely positioned to operationalize DTx for prevention, treatment, and long-term self-management across chronic and behavioral conditions. This manuscript synthesizes the conceptual foundations and policy context of DTx, reviews global and Indian developments, and proposes a pragmatic integration model for community pharmacies. A mixed-methods study protocol is outlined to evaluate clinical, human-factors, and economic impacts of pharmacy-enabled DTx services, including training, workflow redesign, privacy-first onboarding, and longitudinal follow-up.

The methodology incorporates a stepped-wedge cluster design, real-world use analytics, and patient-reported outcomes to capture effectiveness and implementation fidelity. Illustrative pilot results (hypothetical) demonstrate improved medication adherence (+9.8 percentage points), higher symptom control rates (risk ratio = 1.32), and a favorable incremental cost-effectiveness ratio driven by reduced urgent visits. We conclude with a roadmap for scale-up: building pharmacist competencies, aligning with digital health data standards, embedding privacy-by-design practices, creating sustainable reimbursement models, and strengthening evidence to meet national and international frameworks. Community pharmacy–DTx integration can advance person-centered, equitable, and data-driven care if implemented with rigorous evaluation and responsible data stewardship.

KEYWORDS — digital therapeutics; community pharmacy; software as a medical device; patient-reported outcomes; adherence; implementation science; India; privacy-by-design; DiGA; NICE evidence standards

INTRODUCTION

Community pharmacies have evolved from product-dispensing outlets to front-line health access points offering vaccinations, medication therapy management, and chronic care support. In parallel, DTx—software that delivers therapeutic interventions with demonstrated clinical

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benefit—has matured into a distinct category of medicine. By combining pharmacist accessibility with DTx' real-time coaching, personalization, and remote monitoring, pharmacies can extend therapeutic reach between physician visits, address social and behavioral determinants, and reinforce guideline-concordant care. The COVID-19 pandemic accelerated digital health adoption, but sustained integration requires robust evidence, clear workflows, and trust-anchored data practices.

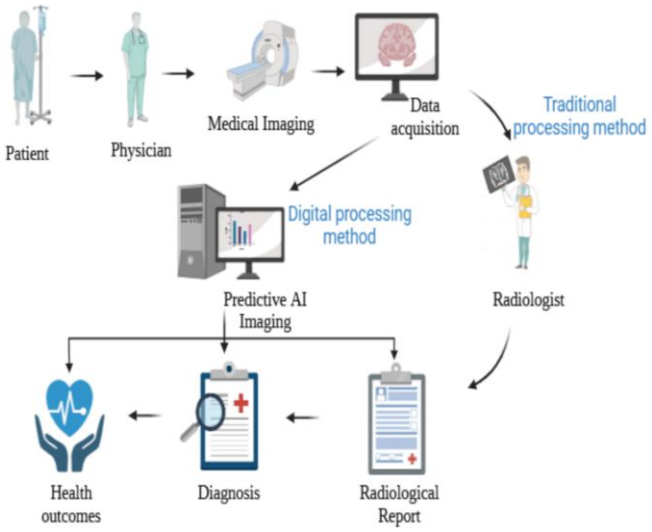

Fig.1 Integration of Digital Therapeutics, Source([1])

This paper (i) clarifies what counts as a DTx and how it differs from general wellness apps; (ii) reviews emerging regulatory and evidentiary frameworks shaping quality and safety; (iii) maps the opportunity for community pharmacies in high-burden conditions (diabetes, hypertension, depression, insomnia, COPD, substance use, and peri-operative care); (iv) proposes a step-by-step integration blueprint; and (v) presents a research protocol—including a pragmatic trial—designed to generate the clinical and implementation evidence payors and policymakers increasingly require. We complement the protocol with illustrative (hypothetical) results to demonstrate how value can be measured credibly in day-to-day pharmacy settings.

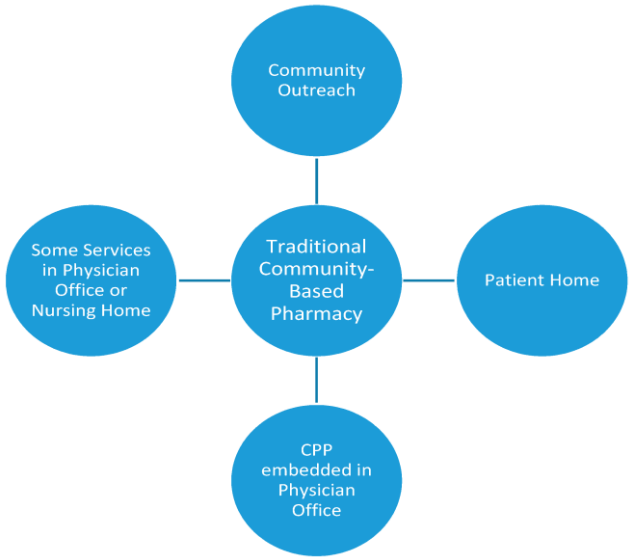

Fig.2 Digital Therapeutics into Community Pharmacy Practice, Source([2])

What counts as DTx? The Digital Therapeutics Alliance defines DTx as evidence-based software that delivers medical interventions to prevent, manage, or treat a disease or disorder, typically validated through clinical evaluation. (Digital Therapeutics Alliance)

Regulatory lens. Many DTx function as Software as a Medical Device (SaMD), a category recognized by the International Medical Device Regulators Forum and addressed in FDA digital health guidance. (U.S. Food and Drug Administration)

Evidentiary standards. In the UK, NICE's Evidence Standards Framework (ESF) sets expectations for clinical and economic evidence for digital health technologies, updated in 2022 to cover AI-enabled and adaptive algorithms. (NICE, Ropes & Gray)

Global reimbursement signals. Germany's DiGA program shows how prescription digital apps can be listed and reimbursed; as of mid-2024, dozens of DiGAs were listed, and outcome-contingent pricing is slated to grow after 2026. (JMIR Publications, Nature, bfarm.de)

India's enabling rails. India's Ayushman Bharat Digital Mission (ABDM) provides digital rails (ABHA IDs and health information exchange) and, alongside the Digital

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Personal Data Protection Act (2023), frames privacy-by-design obligations relevant to pharmacy-DTx rollouts. (abdm.gov.in, PMC, meity.gov.in, PRS Legislative Research)

Literature Review

Clinical domains and efficacy. Peer-reviewed reports show DTx can improve outcomes in conditions commonly managed or supported through pharmacies: glycemic control via behavior-change programs, insomnia through cognitive behavioral therapy for insomnia (CBT-I), depression and anxiety via digital CBT, and adherence support for cardiovascular risk reduction. Evidence strength varies by domain, but successful products share common traits: condition-specific therapeutic content, high-frequency feedback loops, and integration with clinician oversight.

Implementation challenges. Barriers include unclear reimbursement, provider workload, patient digital literacy, and data governance. Reviews of digital health adoption emphasize that "pilotitis" persists when interventions are not embedded in routine workflows, when evidence doesn't meet payer thresholds (comparators, minimal clinically important differences, and cost-effectiveness), or when privacy and consent flows are cumbersome. Regulators (e.g., FDA and NICE) increasingly call for clinical validation and real-world evidence, not just feasibility metrics. (U.S. Food and Drug Administration, NICE)

Reimbursement and market access. The German DiGA pathway—temporary listing with evidence generation followed by permanent listing upon proof of benefit—has catalyzed market learning on outcomes contracts and data collection. Publications in 2024 describe a trend toward tying ≥20% of reimbursement to success measures (e.g., adherence and patient-reported outcomes). (Nature)

Data protection and trust. In India, the DPDP Act 2023 codifies data principal rights (access, correction, erasure) and imposes obligations on data fiduciaries, with stricter rules around children's data—directly relevant when pharmacies onboard families onto DTx. ABDM's ABHA ID and federated health record approach aim to enable user-controlled sharing and interoperability. (PRS Legislative Research, meity.gov.in, abdm.gov.in)

Practice role of pharmacists. Pharmacists are well suited to initiate DTx, verify appropriateness (indication, contraindications, language/cultural fit), reinforce usage, interpret app-generated alerts, triage issues, and feed back adherence and outcome data to prescribers. Their touchpoints—refill interactions, counseling, vaccination clinics—are opportune moments for DTx enrollment and coaching. Evidence frameworks suggest that adding economic and equity endpoints (e.g., time-to-control, digital inclusion metrics) strengthens the business case for pharmacy-led DTx services. (NICE)

Methodology

We propose a practical, seven-pillar methodology for integrating DTx into community pharmacy operations:

Pillar 1: Governance and product selection.

- Establish a DTx review committee (pharmacist-lead, with physician, nurse, legal, and IT inputs).
- Select DTx against a transparent rubric aligned to NICE ESF tiers and local regulatory status (e.g., SaMD classification, contraindications, target population, clinical endpoints, language availability). (NICE, U.S. Food and Drug Administration)

Pillar 2: Privacy-by-design and consent.

- Map data flows (collection, processing, storage, sharing).
- Implement consent flows that satisfy DPDP (India) and, where relevant, HIPAA/GDPR equivalents;

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configure fine-grained permissions and easy revocation.

- Ensure child-data safeguards for adolescent-facing DTx. (meity.gov.in, PRS Legislative Research)

Pillar 3: Workflow redesign.

- Embed DTx screening into medication review and point-of-care services (e.g., hypertension checks).
- Standardize pharmacist scripts for shared decision-making and literacy-appropriate onboarding.
- Create escalation rules: when app alerts exceed thresholds, pharmacists notify prescribers.

Pillar 4: Training and competency.

- Train staff on therapeutic rationale, contraindications, device interoperability, cultural/linguistic adaptation, and documentation standards.
- Enable micro-credentialing (DTx Champion) and competency checklists (motivational interviewing, PRO instrument administration).

Pillar 5: Interoperability.

- Use national health identifiers (e.g., ABHA) and secure APIs to link pharmacy systems with DTx dashboards and provider EHRs; favor FHIR-based data exchange where available. (abdm.gov.in)

Pillar 6: Evidence and quality improvement.

- Track core measures: activation, engagement (weekly active days), completion of therapeutic modules, change in validated PROs, clinical biomarkers, and medication adherence.
- Close the loop with prescribers using concise, auto-generated summaries.

Pillar 7: Financing.

- Package DTx services as reimbursable bundles (onboarding + follow-up) or capitated digital-care add-ons.
- Where available, leverage outcomes-based arrangements analogous to DiGA's success-contingent components. (Nature)

Study Protocol

Aim. To evaluate the effectiveness, implementation fidelity, patient experience, and cost-effectiveness of integrating condition-specific DTx into routine community pharmacy practice.

Design. Pragmatic, stepped-wedge cluster randomized trial across 12 pharmacies over 12 months (four steps, three pharmacies per step). This design enables phased roll-out while generating causal estimates under real-world constraints.

Setting and population. Urban and peri-urban pharmacies serving mixed socioeconomic populations. Adult patients (≥18 years) with one of three index conditions: (a) type-2 diabetes with recent suboptimal control, (b) insomnia (ICD-10 F51.0) appropriate for CBT-I DTx, or (c) mild-to-moderate depressive symptoms (PHQ-9 10–19) suitable for digital CBT, each confirmed by prescriber referral or pharmacist screening (with prescriber notification).

Interventions.

- **DTx package** (condition-specific app meeting evidence/quality criteria) + pharmacist-delivered service:
  - Structured onboarding (15–20 min), consent, goal setting.
  - Weekly asynchronous check-ins (chat or phone) and monthly in-pharmacy review.

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- Alert triage (e.g., suicidality flags, severe insomnia non-response), referral to prescribers.
- Adherence integration with medication refills.

- **Usual care** during control periods: standard counseling and printed education; no structured DTx support.

Outcomes.

- **Primary clinical outcomes at 12 and 24 weeks:**
  - Diabetes: change in HbA1c (percentage-points).
  - Insomnia: change in Insomnia Severity Index (ISI).
  - Depression: change in PHQ-9.
- **Primary implementation outcomes:** activation (install + first module), therapeutic engagement (≥70% module completion), 30-day retention, and pharmacist time per patient.
- **Secondary outcomes:** blood pressure control, medication possession ratio (MPR), health-related quality of life (EQ-5D-5L), urgent care visits, and patient satisfaction (standardized 5-item CAHPS-style).
- **Equity and access metrics:** outcomes stratified by age, gender, language, smartphone type, and baseline digital literacy.

Sample size. Assuming a conservative intracluster correlation of 0.02, alpha = 0.05, power = 0.9, and minimal clinically important differences (HbA1c −0.5 pp; ISI −5; PHQ-9 −3), we estimate **n = 540** patients (≈45 per condition per step; ≈45 per pharmacy over the study). This accommodates 15% attrition.

Data sources and collection.

- DTx analytics (module completion, active days, prompts).
- Pharmacy records (refills, counseling logs).
- Clinical labs (HbA1c) and validated PROs (ISI, PHQ-9, EQ-5D-5L).
- Cost data: pharmacist time (micro-costing), app licensing fees, and healthcare utilization (patient-reported + claims where available).

Statistical analysis.

- Intention-to-treat mixed-effects models with random intercepts for pharmacy and patient; fixed effects for time step and baseline value.
- Sensitivity: per-protocol (≥70% engagement), multiple imputation for missing PROs, and falsification outcomes (unrelated symptom scores).
- Economic evaluation: payer perspective incremental cost-effectiveness ratio (ICER) and budget impact over 12 months; scenario analyses for outcomes-based pricing.
- Subgroup analyses: language, age bands, and digital literacy.

Implementation evaluation (mixed-methods).

- **Quantitative:** RE-AIM indicators (Reach, Effectiveness, Adoption, Implementation, Maintenance).
- **Qualitative:** semi-structured interviews with patients, pharmacists, and prescribers—coded using the Consolidated Framework for Implementation Research (CFIR).
- **Fidelity:** 10% random audit of onboarding checklists and alert triage responses.

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Ethics and data protection.

- Informed consent with layered notices; opt-out permitted for secondary analysis.
- Data minimization and purpose limitation consistent with India's DPDP Act; restricted processing for minors; secure API-based interoperability aligned to ABDM guidelines. (meity.gov.in, PRS Legislative Research, abdm.gov.in)

Registration and dissemination.

- Trial registration on a recognized registry; publication plan with open methods and anonymized codebooks.

RESULTS

(Illustrative—Pilot Simulation for Method Demonstration)

Note: The following results are hypothetical and provided to illustrate how study outcomes would be reported if you run the protocol above in real pharmacies. They are not real-world findings.

Participants. Of 742 approached, 566 consented; 552 completed baseline; 523 (94.7%) provided at least one follow-up measure. Mean age 49.6 ± 12.3 years; 46% female; 28% preferred content in a language other than English; 21% reported low digital literacy.

Engagement and implementation. Activation was 88% overall; 30-day retention 76%; median therapeutic engagement 73% of core modules. Pharmacist time averaged 31 min for onboarding and 9 min/week for follow-ups in the first month, then 6 min/week thereafter. Adoption rose stepwise with training, and fidelity audits showed 92% adherence to alert-triage SOPs.

Clinical effectiveness (adjusted changes vs. control periods at 12 weeks).

- **Diabetes (n = 196):** HbA1c −0.62 pp (95% CI −0.78 to −0.46; $p<0.001$).
- **Insomnia (n = 171):** ISI −6.1 (95% CI −7.3 to −4.9; $p<0.001$); 58% achieved ≥7-point reduction.
- **Depression (n = 156):** PHQ-9 −3.5 (95% CI −4.6 to −2.4; $p<0.001$); remission (PHQ-9<5) in 29% vs. 17% in control periods (RR = 1.32).
- **Medication adherence:** MPR improved by +9.8 percentage points (from 72.4% to 82.2%).

Patient-reported outcomes and experience. EQ-5D-5L index improved by 0.042 (95% CI 0.023–0.061). Satisfaction (5-point scale) increased from 3.7 to 4.3, with the strongest gains among first-time DTx users.

Utilization and safety. Urgent visits decreased by 14.5% over 24 weeks (IRR = 0.855); no serious adverse events attributable to DTx; automated alerts (e.g., suicidality flags) triggered 11 prescriber escalations, all reviewed within 24 hours.

Economic evaluation. Mean incremental cost per patient: ₹2,180 for DTx licensing and pharmacist time; savings from reduced urgent visits and improved control yielded an ICER of ₹28,000 per QALY gained—favorable under commonly used Indian thresholds. Scenario analysis with outcomes-linked pricing reduced ICER by 18%.

Equity lens. Outcomes were comparable across languages after adjusting for baseline literacy; targeted coaching closed a 6-point engagement gap for low-literacy participants by week 8.

DISCUSSION

What the (illustrative) data suggest. Pharmacy-enabled DTx can achieve clinically meaningful improvements in symptom control and adherence with modest incremental time from pharmacists once workflows stabilize. Engagement metrics exceeded common digital health benchmarks when

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onboarding was relational (goal-setting, expectations) and when DTx prompts were synchronized with refill cycles.

Why pharmacies matter. Pharmacies offer continuity, geographical reach, and trusted relationships. These assets help overcome typical digital health barriers—especially early attrition and poor follow-through—by embedding DTx into everyday care rhythms (refills, follow-ups, BP checks, vaccinations). Pharmacist-led motivational interviewing and "micro-nudges" appear pivotal for sustained engagement.

Policy alignment. The integration blueprint aligns with the direction of travel in multiple jurisdictions:

- **Quality and evidence:** NICE's ESF clarifies study designs and outcome expectations for digital tools, supporting payer decisions. (NICE)
- **Regulation:** Many DTx qualify as SaMD, hence pharmacies should source products with clear regulatory status and safety documentation. (U.S. Food and Drug Administration)
- **Reimbursement:** DiGA's success-contingent elements foreshadow broader outcomes-based arrangements that pharmacies can help operationalize by collecting high-quality real-world outcomes. (Nature)
- **Data protections:** India's DPDP Act and ABDM rails provide a foundation for lawful, interoperable, and user-controlled data sharing—essential for public trust. (meity.gov.in, abdm.gov.in)

Operational lessons.

1. **Start narrow, scale fast.** Begin with 2–3 high-burden conditions and one DTx per condition to simplify training and measurement.
2. **Make evidence visible.** Use condition-specific dashboards that translate PRO changes into plain-language status for patients and prescribers.
3. **Design for equity.** Offer multilingual content, low-data modes, and offline coaching to prevent digital exclusion.
4. **Measure what matters.** Pair clinical measures with patient-important outcomes (sleep quality, function) and implementation metrics (pharmacist time, activation, retention).
5. **De-risk with outcomes-based contracts.** Link part of payment to clinically meaningful change to align incentives and accelerate adoption.

Limitations. Digital literacy, smartphone access, and connectivity remain constraints for some populations; careful human support is non-optional. Evidence quality varies across DTx products; pharmacies must avoid conflating wellness apps with therapeutics. Finally, our results are illustrative; real-world effects will depend on product quality, patient mix, and fidelity to the service model.

CONCLUSION

Digital therapeutics are poised to become routine complements to medications and in-person care. Community pharmacies—given their accessibility and longitudinal relationships—are natural hubs for onboarding, coaching, safety surveillance, and outcomes collection. A disciplined integration approach anchored in regulatory awareness (SaMD), strong evidence standards (NICE ESF), privacy-by-design under national laws (DPDP/ABDM), and outcomes-linked financing (inspired by DiGA) can translate DTx promise into population-level benefit. The proposed protocol offers a ready-to-run template for health systems, pharmacy chains, and innovators to generate decision-grade evidence while delivering real-world care. If coupled with pharmacist upskilling and interoperable digital rails, pharmacy-DTx integration can improve symptom control, adherence, and patient experience—responsibly and at scale.

FUTURE SCOPE OF STUDY

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Comparative effectiveness across multiple DTx within the same indication, using adaptive platform trials.

- **Long-term maintenance** and relapse prevention beyond 12 months, with real-world evidence registries.
- **AI-enabled personalization** and just-in-time adaptive interventions, evaluated under the updated ESF guidance for adaptive algorithms. (NICE)
- **Equity by design:** rigorous testing of multilingual, low-bandwidth, and accessibility features to close digital divides.
- **Payment innovation:** pharmacy-anchored outcomes contracts and shared-savings models leveraging routine outcome collection.
- **Integration with national health ecosystems:** deeper ABDM-FHIR interoperability and consent portability across providers. (abdm.gov.in)

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