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Original Article

Many definitions, one measurement problem: developing the Self-Medication in Older Adults-Core framework for self-directed medication use in older adults

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ABSTRACT

Background: Self-directed medication use among older adults may contribute to preventable medication-related harm, but prevalence estimates are difficult to compare because studies apply different definitions, product scopes, authorization rules, recall periods and denominators. We developed the Self-Medication in Older Adults-Core (SMOA-Core) as a testable framework for reconstructing medication-use episodes rather than relying on a single self-medication label. Methods: We conducted a framework-development study informed by a structured, purposive evidence scan last updated on 21 July 2026. We descriptively compared five older-adult prevalence studies from India and Pakistan and four global reviews, then mapped their measurement problems to survey-methods, medication-safety and reporting guidance. We did not pool prevalence or claim systematic-review, consensus or validation methods. Each framework rule was labelled as evidence-informed or an author-proposed convention requiring empirical appraisal. Results: Across the five illustrative studies, reported prevalence ranged from 19.7% to 88.5%, alongside material differences in sampling, product scope, authorization criteria and recall periods. SMOA-Core separates behaviour, authorization, professional involvement, regulatory status, verification and safety into distinct fields. It supplies an episode rule, plain-language behavioural screen, minimum dataset, derivation algorithm and reporting checklist. Safety-priority flags are reported separately; they are not presented as a validated composite risk scale. Conclusion: SMOA-Core is a transparent, testable survey architecture rather than a validated standard. Stakeholder appraisal, cognitive interviews, cross-language work, recall-window calibration, reliability testing and field evaluation remain prespecified future work. Keywords: self-medication; older adults; medication safety; survey methodology; measurement framework; prevalence.

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INTRODUCTION

Population ageing is accelerating, and adults aged 60 years or older account for a growing share of people living with multimorbidity and complex medicine regimens [1-3]. Medication management in community-dwelling older adults, the World Health Organization (WHO) medication-safety challenge and current prescribing criteria underscore the importance of measuring medication decisions accurately while separating common self-care from potentially unsafe use [4-6].

Published estimates of self-medication in older adults vary widely, and part of that variation is methodological rather than epidemiological. Foundational work and reviews identify differences in the meaning of self-medication, included products, respondent populations and measurement procedures [7-10]. Medication-related harm is also defined inconsistently, so prevalence and safety should not be collapsed into one construct [11, 12].

Five relevant older-adult studies from India and Pakistan illustrate the problem: estimates range from 19.7% to 88.5%, but the studies differ in sampling, allopathic versus traditional-product scope,

prescription criteria and recall periods [13-17]. These studies are informative examples, not a representative evidence base for all of South Asia. Systematic evidence on antibiotics and antimicrobials obtained without prescription further shows why country- and date-specific regulatory coding is essential [18, 19].

SUMMARY BOX

What is already known on this topic is that Older-adult self-medication surveys use inconsistent definitions, product categories, recall windows, denominators and authorization rules, limiting direct comparison of their prevalence estimates. What this study adds, SMOA-Core reconstructs product-specific episodes and codes behaviour, authorization, professional involvement, regulatory status, verification and safety on separate axes. A five-study comparison table and an evidence-to-rule matrix distinguish observed evidence from proposed conventions. How this study might affect research, practice or policy, Researchers and reviewers gain an auditable starting architecture and reporting checklist. The framework should be treated as provisional until older adults, caregivers, pharmacists, prescribers and regulatory experts have appraised it and its questions have undergone cognitive and field testing.

Existing resources address parts of the problem but do not provide a complete survey architecture. WHO guidance concerns regulatory assessment of products suitable for self-medication [20], while reviews describe heterogeneous definitions and outcomes without prescribing a common episode-level dataset [8-10, 12]. Survey-methods and medication-safety guidance can inform a solution, but the final boundaries remain design choices that require stakeholder and empirical appraisal.

We therefore aimed to develop the Self-Medication in Older Adults-Core (SMOA-Core), a transparent framework for measuring self-directed medication use in adults aged 60 years or older. The objectives were to compare directly the operational features of illustrative studies; define an episode unit and outcome boundaries; separate observed behaviour from authorization, regulatory and safety judgments; and specify a survey module, minimum dataset, analysis rules and future validation agenda.

METHODS

Study design

This article reports a framework-development study rather than a prevalence study, diagnostic-accuracy study, systematic review or completed consensus exercise. The design combined a structured comparison of published measurements, mapping to methodological guidance, author development of explicit operational rules and an internal consistency audit. Stakeholder appraisal and empirical testing were deliberately retained as future stages.

Evidence sources

SMOA-Core draws on three evidence streams. First, five illustrative prevalence studies from India and Pakistan show the practical consequences of inconsistent definitions and survey choices [13-17]. Second, five reviews describe variation in definitions, prevalence and adverse outcomes [8-10, 12, 21]. Third, content-validity and cognitive-interviewing methods informed item development [22-26], while verification, proxy-response and translation sources informed administration [27-31]. Prevalence appraisal, survey-disposition and reporting sources informed study-design recommendations [32-38]. Regression, complex-survey, standardization, missing-data and causal-structure sources informed analysis recommendations [39-45]. Consensus-method guidance applies only to the future appraisal [46-48]. These sources informed the architecture; they did not confer consensus or validation.

Identification of evidence sources

Evidence identification was structured but purposive. Targeted searches in PubMed, including Medical Literature Analysis and Retrieval System Online (MEDLINE), and citation lists were last updated on 21 July 2026 using combinations of “self-medication”, “self directed medication”, “older adult*”, “elder*”, “geriatric”, “survey”, “prevalence”, “definition”, and the names of South Asian countries. Prevalence studies were eligible when they included adults aged 60 years or older, or reported an extractable ≥60-year subgroup, and described self-medication measurement in India, Pakistan, Bangladesh, Nepal, Sri Lanka, Bhutan, Maldives or Afghanistan. Reviews and methods sources were selected for direct relevance to construct definition or survey implementation. Selection was not exhaustive, no claim of compliance with

the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) is made, and the estimates were not pooled.

For each prevalence study, the comparison recorded setting, age threshold, sample size, sampling approach, operational definition, product scope, recall period, denominator and prevalence. A second source check reconciled the table with the published report. Because the aim was framework construction rather than effect estimation, study limitations are described in Table 1 but no pooled estimate or formal risk-of-bias summary is presented.

Table 1. Direct comparison of five illustrative older-adult prevalence studies from India and Pakistan. Differences in population, sampling, definition, product scope and recall preclude a regional pooled interpretation. Over-the-counter (OTC).

Study and setting	Population and sampling	Definition and product scope	Recall	Prevalence; measurement implication
[13] Mahmood et al, 2014; Karachi, Pakistan	n=124, age >60; descriptive cross-sectional; purposive sampling	Self-medication/inappropriate medicine use; operational wording and product boundary incompletely reported	Not reported	84.7%; limited reproducibility because wording and recall were unclear
[14] Parmar et al, 2015; Ahmedabad, India	n=200, age ≥60; tertiary-care/health-check sample	Medicine without consulting a doctor; allopathic medicines, home remedies and Ayurveda included	6 months	88.5%; broad product scope and clinic sampling affect comparability
[15] Pandey et al, 2023; Ludhiana, India	n=280, age ≥60; urban community; systematic random sampling	Allopathic medicine without a valid prescription, or modification of treatment; non-allopathic products excluded	Not reported	72.9%; combines initiation and regimen change but excludes traditional products
[16] Das et al, 2025; six Indian cities	n=600, age ≥60; community; systematic random sampling	OTC or prescription medicine without a legitimate prescription, or prescribed medicine not used as instructed	3 months	19.7%; explicit recall and urban probability-based design
[17] Kanougiya et al, 2026; rural Tamil Nadu, India	n=520, age ≥55; five purposively selected villages; household recruitment	Self-initiated allopathic, Ayurvedic/home, homeopathic or pharmacist/family-sourced treatment	3 months	41.7% at ≥55; 39.5% in directly calculated ≥60 subgroup (163/413); product classes not collected

Framework development process

Framework construction proceeded in four linked steps (Figure 1). We first compared population, sampling, denominator, definition, product scope, recall window and outcome coding using relevant definition, review and prevalence sources [8, 10, 13-17, 22] and the complementary geriatric review [21]. We then mapped each observed measurement problem to methodological evidence, translated the mapping into explicit episode and classification rules, and audited the rules for internal consistency, especially the separation of behaviour, authorization, professional involvement, regulatory status, verification and safety.

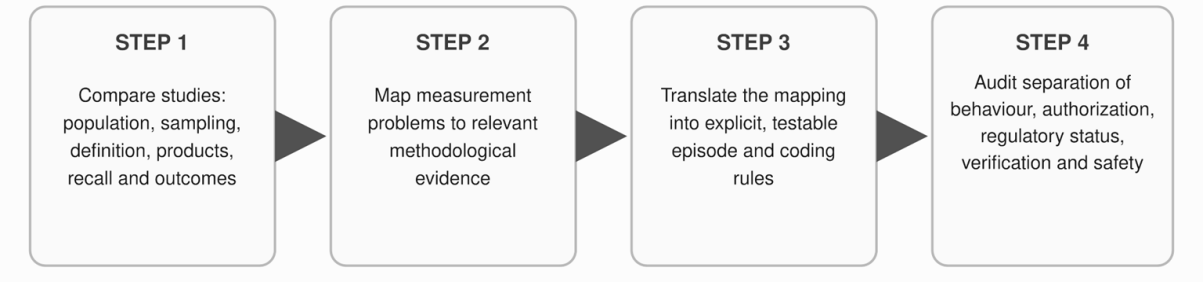

Figure 1. Four-step SMOA-Core development process: comparison of published studies, mapping of methodological guidance, translation into explicit rules and internal consistency audit.

Interpretive rule. Reviews diagnose definition and outcome variation [8-10, 12], while the five illustrative studies show how it appears in practice [13-17]. Content, cognitive and verification sources inform item design [22, 24, 26-28, 30, 31]; survey and analysis sources inform prevalence recommendations [32, 34-36, 39, 41, 42, 44]; and regulatory and safety sources inform independent flags [5, 6, 11, 18, 20, 49]. Table 2 identifies whether each response is evidence-informed or an author-proposed convention. No rule is described as stakeholder-endorsed or empirically validated.

Stakeholder appraisal as a future research agenda

A structured stakeholder appraisal was not conducted as part of this study. It is prespecified as the first future research stage, not represented as completed work. The planned modified Delphi appraisal will include older adults, caregivers, pharmacists, prescribers, survey-methods researchers and regulatory or policy experts, followed by cognitive interviews and field testing.

Future agreement will be reported by stakeholder group so that an overall percentage cannot conceal disagreement among older adults or caregivers. Recruitment, attrition, item-level denominators and

consensus rules will be reported in line with Delphi-method evidence and the ACcurate COnsensus Reporting Document (ACCORD) [46, 48].

Appendix 1 provides the prespecified future appraisal protocol, including panel composition, consensus thresholds and ACCORD-aligned reporting requirements [48].

Table 2. Evidence-to-rule matrix. "Evidence-informed" means that cited sources support the problem or method; it does not mean that stakeholders have endorsed or empirically validated the SMOA-Core rule.

Measurement problem	Direct evidence	SMOA-Core response	Status
Definitions and numerators vary	Reviews and five illustrative studies	Product-course episode; behaviours and secondary events separated	Evidence-informed response; exact boundary is proposed
Recall is inconsistent or unreported	Illustrative studies and reviews	7-day inventory, 3-month primary outcome, 12-month consequences	Author-proposed convention requiring calibration
Product scope differs	Illustrative studies	Record all medicinal products; report product-specific strata	Evidence-informed response; local examples require testing
Respondents may not know legal status	Regulatory and access evidence	Ask observable questions; researchers apply a country-and-date map	Evidence-informed procedure requiring local legal review
Self-report and records may conflict	Brown-bag and verification studies	Retain source, verification and conflict fields	Evidence-informed; adjudication algorithm requires testing
Older adults may need accessible modes or proxies	Cognitive and proxy research	Offer accommodations; record assistance and proxy source	Evidence-informed; wording requires cognitive interviews
Safety is multidimensional	Risk, adverse-event and medication-safety sources	Code authorization, product class, interaction, deviation and consequence separately	Evidence-informed separation; no validated composite claimed
Population estimates require design-based inference	Prevalence, survey and reporting guidance	Probability sampling, denominators, weights, clusters and transparent reporting	Established methodological guidance

Patient and public involvement

Patients and the public were not involved in designing or conducting this literature-based framework-development study. This limitation is reported explicitly. Structured involvement of older adults and caregivers, alongside professional and regulatory stakeholders, is prespecified for the next research stage and will be reported using Guidance for Reporting Involvement of Patients and the Public 2 (GRIPP2) where applicable [50].

RESULTS

The synthesis produced five connected outputs: (1) a conceptual definition and product-course episode unit; (2) orthogonal classification fields; (3) a survey architecture and provisional recall convention; (4) participant-level outcome algorithms; and (5) a future appraisal and validation agenda. Table 1 shows the empirical measurement differences that motivated these outputs, and Table 2 links those differences to proposed rules.

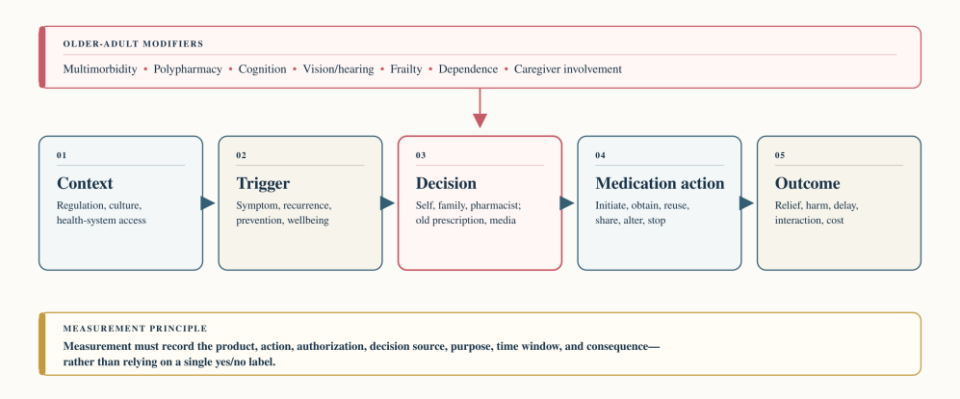

Figure 2. The SMOA-Core conceptual pathway for measurement, informed by self-medication and older-adult medication-safety literature. Older-adult modifiers are specified as influencing the full pathway; later outcomes may influence subsequent episodes.

Conceptual model and operational definition

Figure 2 summarizes the conceptual pathway from contextual triggers and medication decisions to actions and outcomes, while showing that older-adult modifiers may influence every stage [5-9, 11, 12, 20].

Broad conceptual family

SMOA-Core uses self-directed medication behaviour as an umbrella term for actual product use, intentional regimen change, acquisition without use, receipt or donation of shared medicines, and

caregiver-directed decisions. These behaviours are recorded separately; the umbrella term is not itself the primary outcome.

Qualifying use episode

A qualifying self-directed medication-use episode is a bounded, product-specific occurrence or course in which an older adult actually uses a medicinal product or remedy, or intentionally changes an existing regimen, following a decision made by the older adult or caregiver outside the instructions currently recorded for that product and episode. Professional involvement, legal authorization and regulatory status are coded separately rather than inferred from the behaviour question [7, 8, 20].

Acquisition without use and donor sharing are secondary behaviours outside the primary use numerator [7, 8, 11]. Accidental forgetting and unintentional administration errors are also excluded from the self-directed-use numerator and may be captured in a separate medication-error module.

Episode segmentation rules

The framework uses a product-course unit: one product used for one indication under one continuous decision or plan is one episode. A new episode begins when the product, indication or governing decision changes, or when a stopped course is intentionally restarted. Concurrent products are separate episodes linked to the same illness occurrence; repeated doses under one continuous plan remain one episode [7, 8]. Acquisition without subsequent use is recorded as an acquisition event rather than a use episode; donating medicine is recorded as donor sharing; and receiving and using shared medicine is a recipient use episode [7, 8, 20]. Intentional stopping, dose reduction, dose escalation, frequency change, restarting, or extension is classified as regimen deviation and reported separately from self-initiation [7, 8, 11, 20]. Supplementary Figure S1 translates the conceptual family and episode-segmentation rules into an operational hierarchy that separates actual use and intentional regimen change from acquisition-only and donor-sharing behaviours [7, 8, 11].

Mandatory classification fields

Definition, regulatory, medicine-verification and proxy-response evidence informed the episode-classification fields [7, 8, 20, 27-30]. Table 3 lists the fields carried by each reported episode. They are deliberately orthogonal: a legal OTC episode may be self-directed but not unauthorized, while an unauthorized prescription-only episode may or may not have an independently coded safety consequence.

Table 3. SMOA-Core episode-classification fields, informed by definition, regulatory, verification and proxy-response evidence. Regulatory status is assigned by the research team from a country-and-date map, not judged by the respondent.

Field	Minimum categories	Coding rule
Product identity	Ingredient or locally verified product name; strength; formulation; route	Unknown product remains reportable but cannot enter product-specific estimates
Observed behaviour	Self-initiation; reuse; recipient use; intentional dose/frequency/duration change; intentional stop/restart; caregiver-directed use	Multiple behaviours may apply; acquisition-only and donor sharing remain secondary events
Episode authorization	Current advice/instruction for this product and episode; prior only; none; contrary to current instruction; unclear	Ask about observable advice or prescriptions; do not ask the respondent to interpret law
Regulatory status	OTC; prescription-only; controlled; traditional product; supplement; locally unclassified	Research team assigns status from a versioned country-and-date map
Professional involvement	Prescriber; pharmacist; nurse; traditional practitioner; informal dispenser; none	Record role and locally lawful scope separately from behaviour
Decision source	Older person; caregiver; shared; professional; family/friend; media/internet; previous experience	Allow multiple influences and identify the primary decision-maker
Purpose and time	Participant-stated purpose; start/end; frequency; course duration; recall window	Use anchored ranges when exact dates are unavailable
Verification	Container; photograph; prescription; receipt; pharmacy record; self-report only; conflict	Verification informs identification; it does not automatically negate self-report
Safety-priority flags	Unauthorized prescription-only use; antibiotic; sedative; anticoagulant; duplication; interaction; intentional deviation; care delay; suspected harm	Code each flag independently; do not assume a validated composite score
Consequence	Perceived benefit; none; symptom; consultation; urgent care; hospital care; cost; unclear	Report perceived, clinician-communicated and independently adjudicated consequences separately

Outcome boundaries

Supplementary Table S1 applies the orthogonal fields to common boundary scenarios and states the corresponding reporting rule, drawing on definition, risk, regulatory and medication-safety sources [5-8, 11, 18, 20].

Recommended survey design

1. Define the target population and denominators

Definition and classification of the older-adult population. SMOA-Core uses 60 years or older as its primary survey boundary because it is a widely used policy and research convention, not a universal biological threshold [1-3, 51]. Gerontological age-group labels have also varied historically [51, 52]. Studies using another threshold should therefore justify it and record exact age so estimates can be recalculated.

Within the target population, descriptive age bands of 60–74, 75–84 and ≥85 years may be reported when sample sizes permit. These bands should not replace exact age, and sparse categories should be combined according to a prespecified rule rather than after inspecting results.

The five illustrative studies used thresholds of ≥60 years or provided an extractable ≥60-year subgroup [13-17]. SMOA-Core therefore recommends recording exact age and reporting the full eligible denominator, completed interviews, usable outcome records and reasons for exclusion at each stage.

Separate sampling frames and reporting are recommended for community-dwelling and institutional populations because prevalence is defined by the target population, sampling frame, case definition and survey disposition rules [32-38]. Eligibility should not depend on medication use, symptoms, pharmacy attendance, clinic use or caregiver presence, because such restrictions would redefine the target population.

2. Use probability-based sampling for population prevalence

Probability-based population inference requires known or defensible selection probabilities and analysis consistent with the sample design [32, 36, 41]. A multistage design may select areas, households and one eligible participant per household; every selection stage and substitution rule should be documented.

Survey documentation should retain selection probabilities, strata, clusters, nonresponse adjustments, calibration factors, and any finite-population corrections needed for design-based estimation [36, 41]. Sample size should address the most demanding prespecified objective, including subgroup precision and design effects [32, 41]. The design effect (DEFF) and intracluster correlation coefficient (ICC) are related by $DEFF = 1 + (m - 1) \times ICC$, in which m is the average cluster size; this expression applies only to simplified equal-cluster settings; variable cluster sizes and unequal weights require design-specific assessment [41].

Supplementary Table S2 provides worked sample-size examples based on prevalence-survey and complex-survey principles [32, 41]. They are illustrations only; the final calculation must match the primary objective, anticipated prevalence, precision, design effect, subgroup requirements and nonresponse.

3. Use nested recall windows as a provisional convention

Supplementary Table S3 sets out provisional nested recall windows. Recall is vulnerable to memory and inference effects, and the older-adult reviews do not establish an optimal window [9, 10, 12, 53]. The primary 3-month window is therefore a comparison convention that must be calibrated, not a validated optimum.

The older-adult reviews do not identify direct calibration studies comparing recall windows for self-directed medication episodes [9, 10, 12]. The proposed 7-day inventory, 3-month primary outcome and 12-month serious-consequence module must therefore be tested against respondent burden, episode frequency and record-based corroboration [53].

4. Administer behavioural questions before the inventory

Neutral, concrete behaviour questions precede the medicine inventory and avoid asking respondents to interpret legal terms. Cognitive-interviewing evidence supports testing comprehension, retrieval, judgment and response mapping in the target population [24-26]. Because medication use and other potentially sensitive behaviours can be affected by disclosure conditions, privacy, neutral wording and nonjudgmental administration should also be tested [54]. The research team—not the respondent—subsequently applies country-specific authorization and regulatory codes.

5. Verify medicines without treating records as a perfect gold standard

Brown-bag review can identify prescription medicines, OTC products, vitamins, supplements, topicals, inhalers, injections and other products brought by the participant [27]. Because self-report, interviews, pharmacy records and therapeutic-group documentation can disagree, verification source and conflicts are retained as data rather than treating any one source as an unquestioned gold standard [28, 29].

6. Design for sensory, cognitive, literacy, and language needs

Cognitive-survey research with older adults supports interviewer attention to comprehension, retrieval, hearing, vision, literacy and burden [24, 26]. The module therefore requests accommodations, uses one behaviour per question where feasible and permits breaks and show cards.

Direct self-report is preferred when feasible, but assistance and proxy reporting may be necessary. Proxy status, relationship, reason and item source are recorded because proxy and self-reports may differ, especially for subjective consequences [30].

Ethics, capacity, and participant safety

International ethical guidance requires locally approved protections for consent, capacity, privacy, vulnerable participants, and management of research-related risks [55]. The framework therefore recommends a decision-specific capacity process; lawful representative-consent arrangements; continuing assent; separation of proxy consent from proxy response; private interview opportunities; separate permission for container inspection and photography; item-level refusal; secure handling of identifiable labels; and a prespecified clinical-escalation pathway [55]. Urgent thresholds and referral procedures must be approved for each country and site rather than assumed to transfer unchanged [55].

Questionnaire development and validation

SMOA-Core specifies its core as a formative classification of heterogeneous behaviours rather than a reflective symptom scale. Content validity therefore concerns relevance, comprehensiveness and comprehensibility; internal-consistency coefficients are not treated as evidence that the behaviours form one latent trait [22, 23].

The future development programme begins with stakeholder content appraisal and cognitive interviews in each language and literacy group [22-26, 31]. It then evaluates verification and proxy procedures [27-30], consensus-derived boundaries [46-48], field feasibility, classification reliability and cross-cultural calibration. Supplementary Table S4 presents this prespecified future pathway; no stage is claimed as completed.

Minimum core dataset

The proposed minimum dataset covers survey design and participant descriptors; episode behaviour and context; and verification, regulatory and safety fields. Supplementary Table S5 lists the provisional variables, drawing on definition and medication-safety sources [4-8, 11] and survey, verification, proxy and complex-design sources [27-30, 32, 38, 41]. The set should be reduced if future cognitive and feasibility work identifies unacceptable burden.

Analysis recommendations

The primary broad numerator comprises participants with at least one qualifying actual-use or intentional regimen-change episode during the provisional past-3-month window; acquisition-only and donor-sharing events are excluded. Report separately: (1) unassisted self-directed use, with no current clinician or lawfully acting pharmacist input; (2) use of a prescription-only product without current lawful authorization; (3) caregiver-directed use; and (4) each prespecified safety-priority flag. A composite “high-risk” prevalence should not be reported unless its exact algorithm and measurement properties have been established.

For common outcomes, survey-weighted Poisson regression with robust variance or marginal standardization can estimate prevalence ratios; direct prevalence-ratio methods are preferable to uncritical odds-ratio interpretation when outcomes are common [39, 40, 43]. Report absolute prevalence

with confidence intervals first, account for weights, strata and clusters, and age-standardize only when the target standard and rationale are prespecified [41, 42]. Causal adjustment sets should be prespecified from substantive knowledge, with directed acyclic graphs used where appropriate rather than relying only on statistical significance [45].

Prespecified missing-outcome rules and an indeterminate category are required when product, action or authorization information is insufficient [34-36]. If multiple imputation is used, the imputation model should reflect the survey design, predictors of missingness and analysis model, with complete-case and alternative-classification sensitivity analyses [44].

Outcome derivation algorithm

Participant-level outcomes are derived from Appendix 2 using a fixed algorithm. A broad-use case requires at least one positive behavioural screen confirmed in Module C as actual product use or intentional regimen change within 3 months. Module C then assigns behaviour, authorization, professional involvement, decision source and verification. The research team derives regulatory status from the prespecified country-and-date map and applies each safety-priority flag independently.

Pharmacist-assisted self-care is reported separately because pharmacist authority varies by jurisdiction [18, 20]. Caregiver-directed use is also reported separately, with the respondent and decision-maker identified. Episodes with unresolved product or authorization status remain in the broad behavioural outcome but are excluded from the affected authorization-specific estimate and counted as indeterminate.

Perceived and verified harm

Adverse-drug-reaction assessment requires attention to alternative explanations, timing, dose, dechallenge, rechallenge, and other clinical evidence; a respondent's attribution alone does not establish causality [49]. This limitation is especially relevant when several medicines and comorbidities are present [5, 6, 9, 12]. The 12-month consequence module is therefore limited to signal generation and linkage, distinguishing perceived consequences, clinician-communicated problems, record-confirmed events, and formally adjudicated harm [5, 49]. Verification of service use confirms the event, not its causal attribution [49].

Reporting and open science

Use the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) for survey reporting and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational-design reporting. Apply the Preferred Reporting Items for Complex Sample Survey Analysis (PRICSSA) when complex-sample analysis applies and the Checklist for Reporting a Knowledge, Attitude and Practice Study (ChecKAP) when a knowledge-attitude-practice component is included [34-37]. Report sex- and gender-related variables in line with the Sex and Gender Equity in Research (SAGER) guidelines where relevant [56]. Each output should state the framework and questionnaire version, country/date regulatory map and any departures from the core algorithm.

Open-science standards support access to questionnaires, codebooks, derivation code, regulatory maps and prespecified analysis plans where ethical and legal constraints allow [57]. Every language version and cognitive-interview change log should carry a version identifier.

Ten provisional core recommendations

The framework condenses into ten provisional recommendations. First, ask about concrete behaviours and reconstruct outcomes rather than relying on a self-applied label. Second, record exact age, target population and denominators. Third, use a product-course episode rule. Fourth, separate actual use, intentional regimen change, acquisition-only, recipient sharing, donor sharing and caregiver-directed use. Fifth, code behaviour, authorization, professional involvement, regulatory status, verification and safety on separate axes. Sixth, use probability-based sampling for population prevalence and retain design variables [32, 36, 41]. Seventh, verify products where feasible without treating records as a perfect gold standard [27, 28]. Eighth, document accessibility, assistance and proxy response [24, 26, 30]. Ninth, apply prespecified

outcome, missingness and survey-analysis rules [34-36, 39, 44]. Tenth, publish versioned instruments, maps and code [57].

DISCUSSION

Principal findings and interpretation

SMOA-Core's principal contribution is to shift measurement from self-identification toward reconstruction of a product, action, decision source, authorization context and time. This makes the numerator auditable and allows investigators to reproduce a published definition or apply an alternative one without re-asking the survey.

Separating acquisition without use, actual use, intentional regimen change, caregiver-directed use, recipient sharing and donor sharing protects the meaning of each numerator. Orthogonal coding also avoids labelling every self-directed OTC episode as unauthorized or clinically unsafe.

The framework also separates construct measurement from prevalence estimation. Behavioural questions, episode reconstruction, verification, and proxy flags address what is being measured, whereas probability-based sampling, documented selection probabilities, survey weights, and design-based analysis determine which population the estimate represents [27, 28, 30, 32, 34-36, 41]. Neither component can compensate for major weaknesses in the other [32, 34-36, 41].

Comparison with existing approaches

SMOA-Core differs from existing resources in scope. WHO guidance addresses products suitable for self-medication [20]; reviews document heterogeneous definitions, prevalence and adverse outcomes [8-10, 12]; and medication-safety criteria address potentially inappropriate prescribing rather than survey reconstruction [5, 6]. SMOA-Core connects these concerns through a proposed episode-level dataset, but it does not supersede any of those resources.

Against this background, SMOA-Core contributes a proposed episode unit, explicit segmentation rules, country-and-date regulatory mapping, separate behavioural and authorization outcomes, verification fields and accessible administration procedures. These are testable design propositions, not settled standards.

Implications for research, peer review, and policy

Researchers can use SMOA-Core to prespecify the target population, denominator, episode boundaries, product scope, recall window, verification sources, proxy rules, regulatory map and analysis algorithm [32, 34-36, 41]. Reporting broad, unassisted, authorization-specific, caregiver-directed and independent safety outcomes may improve interpretability, but it does not establish cross-language or cross-country equivalence. Equivalence requires cognitive testing, classification studies, reliability assessment, recall calibration, jurisdictional review and multicountry field evaluation [24, 26, 28, 30, 31].

A transparently reported stakeholder-appraisal process, conducted according to Appendix 1, is the first future research priority. Initial cognitive interviews with diverse older adults should follow appraisal and precede claims that the behavioural questions are comprehensible or culturally transferable.

Beyond primary researchers, the framework offers tools for two further audiences. For editors and peer reviewers, the adoption checklist (Supplementary Table S6) provides ten compliance questions that complement CROSS, STROBE, PRICSSA and ChecKAP [34-37]. For regulators and programme planners, country-and-date regulatory mapping separates observed behaviour from legal status, allowing lawful OTC self-care and unauthorized prescription-only use to be reported distinctly [18-20].

Research agenda

The research agenda prioritizes: (1) modified Delphi appraisal with older adults, caregivers, pharmacists, prescribers, survey methodologists and regulatory experts; (2) qualitative elicitation and cognitive interviews across languages, literacy levels and settings; (3) recall-window calibration; (4) field feasibility

and episode-segmentation reliability; (5) verification studies; and (6) cross-country regulatory and classification calibration. These activities are planned, not completed.

Strengths and limitations

Strengths include an explicit episode unit, reproducible classification axes, direct comparison of motivating studies, separation of evidence-informed guidance from proposed conventions, and a complete starting survey module and code structure. The framework also separates construct measurement from prevalence estimation and avoids treating a single high-risk composite as self-evident.

Several limitations are important. SMOA-Core is conceptual and has not undergone stakeholder appraisal, cognitive interviewing or empirical validation. The motivating evidence scan was purposive rather than systematic, and the five illustrative studies come only from India and Pakistan, so they cannot represent South Asia [13-17]. Some source methods and recall windows were incompletely reported. The 3-month window, episode boundaries, minimum dataset and safety-priority flags are author proposals. Regulatory maps must be built locally and updated by date. Feasibility, reliability, validity, burden and cross-language equivalence remain unknown.

CONCLUSION

Available studies and reviews support moving beyond a single self-medication label toward explicit documentation of products, actions, decision sources, authorization, timing and verification. SMOA-Core organizes those elements into a transparent provisional architecture. It should be used as a versioned research template and subjected to stakeholder appraisal, cognitive interviewing and field validation before being promoted as a measurement standard.

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ONLINE SUPPLEMENTARY MATERIAL

The following operational displays support implementation but are not counted as main-text tables or figures. They remain provisional pending stakeholder appraisal and empirical testing.

Supplementary Table S1. SMOA-Core outcome boundaries and reporting rules.

Scenario	Behavioural classification	Authorization/regulatory/safety reporting
OTC product selected and used by the participant	Broad self-directed-use episode	Code pharmacist input; do not label unauthorized or unsafe without separate evidence
Prescription-only product used without current lawful authorization	Broad self-directed-use episode	Prescription-only-without-authorization flag; add safety flags only when criteria are met
Product obtained but never used	Acquisition-only event	Exclude from primary use prevalence
Old prescription reused for a recurrent symptom	Reuse episode	Record time since prescription and whether a current standing plan existed
Intentional dose, frequency, duration, stop or restart decision	Regimen-change episode	Separate from self-initiation and from accidental nonadherence
Forgotten dose or accidental error	Not self-directed use	Optional medication-error outcome
Pharmacist recommends an OTC product within lawful scope	Pharmacist-assisted self-care	Include in broad estimate; report separately from unassisted use
Traditional/herbal product or supplement actually used	Broad self-directed-use episode when self/caregiver selected	Report product category and authorization separately
Caregiver selects and gives medicine	Caregiver-directed use episode	Record respondent, decision-maker, authorization and product status
Older person gives medicine to someone else	Donor-sharing event	Never count as the donor's own use

Supplementary Table S2. Worked sample-size examples derived from prevalence-survey and complex-survey principles.

Objective	Assumptions	Requirement
Overall prevalence	p=50%; ±5%; 95% confidence interval (CI); design effect (DEFF) 1.5; 15% nonresponse	Approximately 680 recruited
Each of 4 reporting strata	p=50%; ±7%; 95% CI; DEFF 1.5; 15% nonresponse	Approximately 350 per stratum; 1400 total
Design-effect caveat	Simple DEFF formula is a simplification; unequal clusters and weights may increase variance	Use design-specific assumptions and report observed design effects
Comparative objectives	If country or subgroup contrasts are primary, power the contrast rather than only each prevalence	Use the most demanding prespecified objective

Supplementary Table S3. Provisional nested recall windows. Recall is vulnerable to memory and inference effects.

Window	Purpose	Recommended content
Current or past 7 days	Medication reconciliation	All products, actual dose/frequency, current authorization, and verification
Past 3 months	Primary participant-level prevalence	Every qualifying use or regimen-deviation episode; provisional until calibrated
Past 12 months	Perceived serious consequences and service use	Attributed symptoms, urgent care, hospitalization, bleeding, falls, kidney problems, delay, and expenditure

Supplementary Table S4. Prespecified future development and validation pathway.

Stage	Required action	Minimum output
Construct definition	Specify actual use, regimen deviation, acquisition, donor sharing, and caregiver-directed use before drafting questions.	Version-locked construct map
Qualitative elicitation	Interview diverse older adults, caregivers, pharmacists, prescribers, and informal dispensers.	Saturation and missing-behaviour report
Content appraisal	Judge relevance, comprehensiveness, comprehensibility, feasibility, and boundary cases.	Stakeholder-specific results
Cognitive interviews	Test comprehension, retrieval, judgment, response mapping, recall anchoring, and classification in each language/literacy group.	Iterative change log
Field pilot	Test sequence, duration, skip logic, privacy, verification, nonresponse, and data synchronization.	Feasibility metrics
Reliability	Repeat stable classifications after 7–14 days; test interrater consistency and episode segmentation.	Agreement and kappa with confidence intervals
Criterion comparison	Compare with containers, prescriptions, receipts, and pharmacy records without assuming a perfect gold standard.	Agreement and conflict analysis

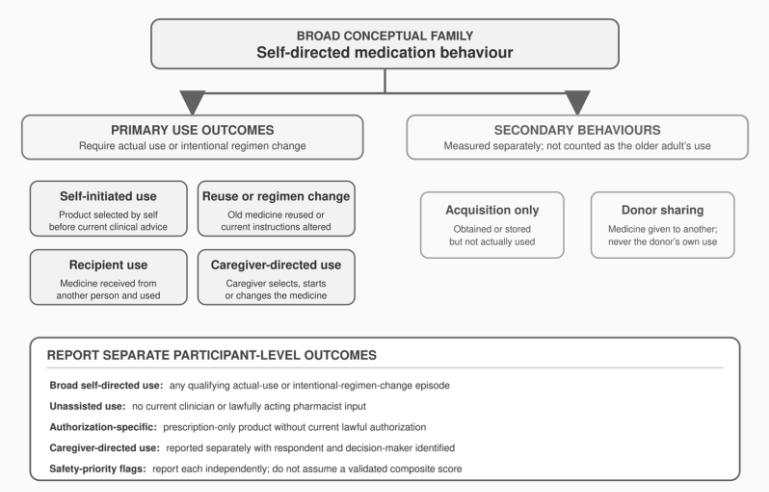
Stage	Required action	Minimum output
Cross-cultural calibration	Use common vignettes and regulatory maps; evaluate classification equivalence and item interpretation.	Country/language calibration report

Supplementary Table S5. Provisional SMOA-Core minimum dataset, derived from the framework fields and survey-methods requirements.

Domain	Minimum variables
Survey design	Country, region, setting, dates, mode, sampling stage, weights, strata, clusters, interviewer identifier, response disposition
Participant	Exact age, sex-related and gender-related variables, education/literacy, living arrangement, dependence, insurance, care access
Clinical vulnerability	Comorbidities, medicine count, polypharmacy, hospitalization, frailty/function, cognition status, caregiver involvement
Episode	Product, regulatory status, action, authorization, professional involvement, decision source, purpose, dates, frequency
Verification	Container, photo, prescription, receipt, record, self-report only, conflict status, reason unverified
Safety	Antibiotic, sedative, non-steroidal anti-inflammatory drug (NSAID), anticoagulant, duplication, interaction, deviation, delay, perceived adverse symptom
Context	Cost, time, distance, service availability, previous experience, trust, media, social influence
Outcome	Perceived benefit, none, symptom, consultation, urgent care, hospitalization, expenditure, adjudication status

Supplementary Table S6. SMOA-Core adoption checklist, synthesized from the framework's cited measurement, survey and reporting sources.

Core recommendation	Compliance question
Behavioural reconstruction	Is the outcome constructed from medication behaviours rather than a yes/no self-label?
Exact age and target population	Are exact age, eligibility threshold, setting, and denominators reported?
Episode rule	Are product-course segmentation, start/end, recurrence, and multiple-product rules specified?
Outcome hierarchy	Are actual use, regimen deviation, acquisition, recipient sharing, donor sharing, and caregiver use separated?
Product and authorization	Are regulatory status, authorization, professional involvement, and country/date mapping distinct?
Recall and sequence	Is the behavioural screen given before inventory, with the recall window named and justified?
Verification	Are verification source, conflict, and unverified-episode rules prespecified?
Accessibility and proxies	Are accommodations, capacity, assistance, proxy source, and subjective-item restrictions reported?
Design-based analysis	Are weights, strata, clusters, standardization, missingness, and nested episodes handled?
Open materials	Are questionnaires, regulatory maps, codebook, algorithm, statistical code, and version history public?



Supplementary Figure S1. SMOA-Core operational hierarchy. Primary outcomes require actual use or intentional regimen change; acquisition-only and donor-sharing events are reported separately. Supplementary note. For Kanougiya et al, the ≥60-year estimate was calculated directly from the published age table: ages 60–74, 131/334 (39.2%); ages ≥75, 32/79 (40.5%); combined ≥60, 163/413 (39.5%). The source study's full ≥55 sample was 217/520 (41.7%).

APPENDICES

Appendix 1. Prespecified stakeholder-appraisal protocol (future research agenda)

The planned two-round modified Delphi appraisal will begin from a version-locked statement bank mapped to evidence and framework elements [46-48]. Purposive recruitment will include older adults, caregivers, pharmacists, prescribers, survey-methods researchers and regulatory or policy experts from varied settings. Older adults and caregivers will form distinct, adequately represented groups rather than a single token category.
A prespecified 9-point appropriateness scale will be used, with a provisional consensus rule of at least 75% rating 7–9 and no more than 15% rating 1–3. The threshold is an author choice informed by Delphi-method evidence and will be reported with item-level denominators and stakeholder-group distributions [46].
In line with Guidance on Conducting and REporting DElphi Studies (CREDES) and the ACcurate COnsensus Reporting Document (ACCORD), the completed future appraisal will report invited and participating denominators, item-specific response, retention, panel composition, feedback, rule changes and unresolved disagreement [47, 48]. No consensus result is claimed in the present manuscript.

Appendix 2. SMOA-Core survey module

Development status. This module is a cognitively untested starting template. Local wording, examples, translations, regulatory maps, interview duration and decision rules require stakeholder appraisal, cognitive interviewing and field evaluation before use as a validated instrument.
The module operationalizes the framework. Definition and question-design sources informed the structure [7, 8, 22, 24, 26, 31]; verification, proxy-response and ethics sources informed administration and coding [27, 28, 30, 55]. These sources support the development process; they do not validate the present wording.
Administration sequence

- Module A: eligibility, consent, capacity, assistance, and privacy.
- Module B: nine neutral 3-month behavioural questions—before announcing medicine inspection.
- Module C: product-specific episode details for every positive behaviour.
- Module D: current/past-7-day medication inventory and verification.
- Module E: 12-month perceived and clinician-communicated consequences.
- Module F: acquisition without use and donor-sharing behaviours.

Interviewer introduction

“People use medicines and remedies in many ways. Some are prescribed, some are bought directly, some are kept from an earlier illness, and some are suggested by family members or pharmacists. There are no right or wrong answers. We want to understand what you actually used. Your answers will not affect your care. Later, with your separate permission, we may ask to see medicine containers or records.”

Module A. Eligibility, respondent, and privacy

Item	Question	Response/coding
A1	What is your age in completed years?	Exact age; confirm target eligibility
A2	Who is answering the questions?	Direct / assisted / proxy
A3	If assisted or proxy: why, and what is the relationship?	Reason; relationship; who consented
A4	Who usually decides which medicines you take?	Self / shared / caregiver / clinician / other
A5	Would you like any support for hearing, seeing, reading, language, or taking a break?	Accommodation provided / declined
A6	Would you prefer to answer some questions privately?	Private / caregiver present / declined

Module B. Core 3-month behavioural screen

The screen uses concrete actions and does not ask respondents to decide whether a product was legally authorized. During the past 3 months, ask each item separately, record Yes/No/Don’t know/Refused, and complete Module C for every positive response. Accidental forgetting is recorded separately from an intentional change [7, 8, 24, 26].

Item	During the past 3 months, did you…	Response/coding
B1	take a medicine or remedy that you selected yourself, without first asking a doctor or another clinician who can prescribe?	Yes / No / Don’t know / Refused; complete Module C if Yes
B2	reuse a medicine left from an earlier illness or an old prescription, without new advice for this illness?	Yes / No / Don’t know / Refused
B3	take a medicine that came from a relative, friend, neighbour or another patient?	Yes / No / Don’t know / Refused
B4	buy or obtain a medicine from a pharmacy, shop or website without showing a prescription for this illness?	Yes / No / Don’t know / Refused; legal status derived later
B5	deliberately take more, or take it more often, than the current instructions said?	Yes / No / Don’t know / Refused; exclude accidents
B6	deliberately take less, take it less often, or stop it earlier than the current instructions said?	Yes / No / Don’t know / Refused; exclude forgetting
B7	deliberately restart a medicine or continue it longer than the current instructions said?	Yes / No / Don’t know / Refused
B8	take a traditional, herbal, homeopathic, vitamin, supplement or household medicinal remedy that you or your family selected?	Yes / No / Don’t know / Refused; record product category
B9	have a family member or caregiver choose, start or change a medicine for you without first asking the clinician responsible for it?	Yes / No / Don’t know / Refused; caregiver-directed

Module C. Episode details

Record every episode carrying an authorization-specific or safety-priority flag. If numerous other episodes make complete reconstruction infeasible, enumerate all eligible episodes, retain the participant-level broad outcome and select episodes by a prespecified transparent rule. Do not let interviewer judgment determine which episodes appear “important”.

Item	Episode question	Coding
C1	What product was actually used?	Ingredient/brand/class; strength; formulation; route
C2	What problem or purpose was it used for?	Participant wording; coded indication/purpose
C3	When did this course or occurrence begin and end?	Exact dates or anchored ranges
C4	How much was used, how often and for how long?	Dose; frequency; duration; number of courses

Item	Episode question	Coding
C5	Who made the decision, and who else influenced it?	Primary decision-maker plus multiple influences
C6	For this product and illness, had a doctor or prescribing clinician given current advice or a prescription?	Current / previous only / none / participant unsure; record evidence source
C7	Was a pharmacist or another professional involved? What did that person advise?	Role; advice; locally lawful scope derived from regulatory map
C8	How was the product obtained?	Prescribed pharmacy / direct pharmacy / stored / shared / online / informal / other
C9	What happened after it was used?	Better / same / worse / symptom / stopped / care sought / unsure
C10	Did using it delay consultation or another treatment?	No / <24 h / 1–7 d / >7 d / unsure
C11	Can the product or the advice/prescription be checked?	Container / photo / prescription / receipt / record / self-report only / conflict
C12	Researcher-derived classifications	Regulatory status; authorization-specific outcome; independent safety-priority flags; map version/date

Module D. Current/past-7-day medication inventory

After Modules B and C, the proposed inventory asks about prescription and nonprescription medicines, vitamins, supplements, traditional products, topicals, inhalers, injections, loose tablets, organizers, and remedies used now or during the past 7 days, consistent with comprehensive brown-bag review principles [27]. Because records and self-report may disagree, the source is retained rather than treated as a perfect criterion [28]. Separate consent is required before photography [55].

Item	Inventory question	Response/coding
D1	Product name/ingredient, strength, route	Transcribe; photograph only with separate consent
D2	What is it used for?	Indication in participant's words
D3	What current advice or prescription applies to this product?	Current / previous only / none / participant unsure; evidence source
D4	What current instructions apply?	Current / old / none / unknown
D5	How was it obtained most recently?	Prescription / direct / stored / shared / online / informal / other
D6	How was it actually taken during the past 7 days?	Dose; frequency; duration; compare with instructions
D7	Does this reveal an episode not reported in Module B?	No / possible / confirmed; return to Module C

Module E. Perceived and clinician-communicated consequences—past 12 months

SMOA-Core links each reported consequence to a specified episode where possible, but these questions do not establish adverse-drug-reaction causality [49].

Item	Question	Coding
E1	Do you believe a qualifying episode caused a new or worsening symptom?	Yes / No / Unknown; describe; episode ID
E2	Did you seek urgent care, visit an emergency department, or stay in hospital because of that episode?	Yes / No / Unknown; verify service use where feasible
E3a	Did a clinician tell you there was a medicine interaction?	Yes / No / Unknown; source
E3b	Did a clinician identify duplicate medicines?	Yes / No / Unknown; source
E3c	Did a clinician identify overdose or excessive dosing?	Yes / No / Unknown; source
E3d	Did a clinician identify bleeding, a fall, kidney problem, allergy, or antibiotic-related problem?	Separate yes/no response for each; source
E4	How much did you spend because of the episode during the past 12 months?	Local currency; medicine, travel, consultation; zero/unknown

Module F. Secondary acquisition and donor-sharing behaviours

Item	Question	Coding
F1	During the past 3 months, did you obtain or store a medicine that you did not actually use?	Yes / No / Unknown; product and source; acquisition-only event
F2	During the past 3 months, did you give one of your medicines to someone else?	Yes / No / Unknown; donor-sharing event
F3	If yes, what medicine and to whom?	Product class; recipient relationship; reason

Outcome algorithm

The outcome derivation algorithm applied to Modules A–F is presented in the main text (Results, "Outcome derivation algorithm").