ORIGINAL

FIXING THE "NO MILK" PROBLEM IN MEDICATION LABELS WITH A RANDOMIZED EYE-TRACKING STUDY OF NEGATION AND FOOD-INTERACTION PICTOGRAMS

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ABSTRACT

Background: Patients with limited literacy remain vulnerable to medication errors, especially for instructions that involve *negation* and *food/drug interactions*. Pictograms are widely used, but guidance on which *visual grammar* works best is limited. **Methods:** We ran a three-arm, randomized experiment with low-literacy adults (*N*=360) assigned between subjects to one of three icon grammars: *A)* ISO-style black/white with red slash; *B)* photo-icon composites with overlaid symbols; *C)* culturally localized line-art with explicit red "X"/green tick. Each participant judged 12 common label instructions enriched for historically difficult items. The **primary outcome** was immediate, item-level correct comprehension (binary). **Secondary outcomes** were response time, confidence, and eye-tracking metrics (time-to-first-fixation, dwell time, scanpath entropy). Analyses used mixed-effects logistic/linear models with participant and item random intercepts (intention-to-treat). **Results:** Grammar C outperformed A and B on the primary endpoint (overall marginal risk difference vs. A: **+10** percentage points, 95% CI **+7** to **+13**; vs. B: **+7** pp, by subtraction). Grammar B exceeded A by **+3** pp (95% CI **0** to **+6**). The largest gains for Grammar C occurred on high-risk items: "*Not by mouth*" (A **62%**, B **68%**, C **78%**) and "*Do not take with dairy*" (A **55%**, B **60%**, C **72%**); timing/handling items also improved (e.g., "Every 8 hours": A **69%**, B **73%**, C **81%**). Eye-tracking corroborated these differences: median time-to-first-fixation on critical regions was **1.42 s** (A), **1.31 s** (B), and **1.08 s** (C), indicating more efficient visual search under Grammar C. Results were consistent across literacy strata and languages; no subgroup showed harm. A 48-hour retention subset (*n*=210) maintained the C > B > A pattern. **Conclusions:** *How* pictograms are drawn matters. Culturally localized line-art with explicit negation cues produced faster and more accurate comprehension, especially for negation and interaction instructions. We provide a practice checklist—use explicit negation near the action/object; pair *action+object+context*; prefer simplified line-art—that can be embedded in label-printing systems without added counseling time. Future pragmatic trials should link these comprehension gains to adherence, error reduction, and cost outcomes.

PICTOGRAMS; MEDICATION LABELING; HEALTH LITERACY; EYE-TRACKING; HUMAN FACTORS; VISUAL DESIGN

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INTRODUCTION

Medication-taking is a cognitively demanding, visually mediated behavior. Patients with limited print, numeric, or health literacy are at heightened risk of dosing errors, route errors, and harmful food/drug interactions, with downstream consequences for avoidable adverse events and suboptimal disease control [1, 2].

Pictograms—icon-based depictions of actions, objects, and constraints—are widely promoted to support comprehension across language barriers. Yet evidence remains uneven: while some label concepts show robust gains with pictograms, others—especially *negation* ("do not") and *interaction* semantics (e.g., "do not take with dairy/alcohol")—are persistently misinterpreted [3, 4].

Beyond the choice to "use a pictogram," the *visual grammar* of an icon (its visual language and compositional rules) strongly shapes meaning-making: icon style (photographic vs. line-art), *negation convention* (red strike-through, prohibitory circle, or alternative positive/negative framing), and *contextual cues* (co-present objects such as a pill, a glass of milk, a mouth) guide attention and inference. Cognitive theory predicts that concrete depictions ease object recognition, whereas abstract forms and implicit negation increase cognitive load; dual-coding and redundant cues can mitigate this, but clutter or low contrast can worsen it [5, 6]. Despite this theoretical backdrop, prior trials often treat pictograms as a monolith and prioritize immediate comprehension endpoints, offering limited guidance on which specific visual grammar best supports high-risk instructions or how effects vary by literacy, language, or script [3, 7].

We identify four gaps: (i) lack of head-to-head tests of *negation conventions* and *icon styles* on the hardest items; (ii) limited use of process measures (e.g., eye-tracking) to diagnose *how* icons succeed or fail; (iii) sparse data on short-term *retention* without re-counseling; and (iv) little equity-aware analysis across literacy levels and languages. Addressing these gaps is necessary to move from "pictograms sometimes help" to actionable *design rules* that regulators, pharmacies, and EHR label generators can adopt.

We propose a randomized, between-subjects experiment comparing three visual grammars: **(A)** ISO-style black/white icons with explicit red strike-through; **(B)** photo-icon composites with overlaid symbols; and **(C)** culturally localized line-art that pairs positive/negative framing (green tick vs. red "X") with minimal text tags. Within subjects, participants judge twelve label instructions enriched for historically difficult items (negation and interactions). We pair *outcome* measures (item-level correctness) with *process* measures (response time, confidence, and eye-tracking metrics such as time-to-first-fixation, dwell time on critical regions, and scanpath entropy) to link comprehension to visual search behavior. A 48-hour follow-up on a subset tests short-term retention.

Our work delivers: (1) the first focused, head-to-head comparison of *negation* and *interaction* icon grammars on high-difficulty items; (2) a mixed-outcome, mixed-mechanism analysis tying accuracy to gaze behavior; (3) equity-sensitive estimates across literacy and language strata; and (4) a practice-ready *pictogram design checklist* and validated *item bank* suitable for pre-implementation testing and regulatory guidance.

Hypotheses (pre-specified)

H1. Grammar effect: Localized line-art with explicit negation (Arm C) yields higher adjusted probability of correct comprehension than ISO-style (Arm A) and photo-icons (Arm B), with the largest gains on negation/interaction items.

H2. Processing efficiency: Arms with explicit negation conventions (A,C) show faster time-to-first-fixation on critical regions and shorter total response times than photo-icons (B).

H3. Retention: Advantages of explicit negation persist at 48 h for difficult items.

H4. Equity: Benefits of Arm C are *greater* among participants with lower literacy and in non-English language groups (positive Grammar×Literacy and Grammar×Language interactions).

Objectives

O1. Compare item-level comprehension across three icon grammars.

O2. Quantify secondary performance (response time, confidence, eye-tracking).

O3. Model 48-h retention for difficult items.

O4. Produce a practice-ready pictogram design checklist and a validated item bank for hard instructions.

METHODS

Design

We conducted a parallel-arm, randomized experiment with between-subjects assignment to **Grammar** (A/B/C) and within-subjects presentation of **12 items**.

To mitigate order/fatigue effects, item order was counterbalanced using 6 Latin-squared sequences (participants were evenly randomized to sequences within each arm). The protocol was pre-registered and adheres to CONSORT extension guidance for randomized experiments in health communication.

Setting and Participants

Sites. One or two high-throughput primary-care or employer-clinic waiting areas with private kiosks for testing.

Eligibility. Adults $\geq$ 18 years; self-reported difficulty reading long texts or forms; able to provide informed consent; fluent in one of the study languages (e.g., Urdu/Hindi/Bengali/Arabic/English).

Exclusions. Uncorrected major visual impairment; prior participation in this study; acute illness that precludes completion of a 15-minute session.

Screening and literacy assessment. After verbal prescreen, participants completed a brief literacy screener (short S-TOFHLA or equivalent) and a 3-item medication experience checklist (prior daily medication use, eye-drop experience, topical experience) to support covariate adjustment. No clinical advice was provided.

Recruitment and Consent

Potential participants were approached consecutively in waiting areas by trained research assistants using an IRB-approved script. Written consent (or witnessed verbal consent where permitted) was obtained in the participant's preferred language. Participants received a small transport voucher (non-coercive).

Randomization, Allocation Concealment, and Blinding

Sequence generation. A statistician generated a computer-randomized list with permuted blocks of variable size (6, 9, 12), stratified by site and preferred language.

Concealment. Allocation was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE) or via a tablet randomization app with hidden arm codes.

Blinding. Stimuli were unlabeled with respect to arm. Participants were unaware of alternative grammars. Outcome assessors and data analysts were blinded to arm labels (coded as X/Y/Z) until the primary analysis was locked.

Interventions (Icon Grammars)

A: ISO-style B/W + red strike-through
: High-contrast black/white symbols following ISO pictographic conventions; negation via red prohibitory slash.

B: Photo-icon composites
: Grayscale photo backdrops with overlaid symbols to suggest action/object; negation via small overlaid symbols.

C: Localized line-art
: Culturally familiar line drawings; explicit dual coding with green tick (allowed) and red "X" (prohibited); minimal translated tag beneath icon.

Semantics were identical across arms; only the visual grammar varied.

Stimuli Development and Translation

The 12 items (below) were selected from common medication label instructions known to be error-prone in low-literacy settings. Icons were co-designed with a bilingual panel (clinician, pharmacist, designer, and three laypersons). All minimal text tags underwent forward translation and independent back-translation; discrepancies were reconciled by consensus. Pilot tests (n=24; not included in the main analysis) confirmed legibility at three print scales and informed micro-edits to contrast and clutter.

Stimuli (12 Items)

1. Not by mouth (route prohibition)
2. Do not take with dairy (food interaction)
3. Avoid alcohol
4. Do not crush/chew
5. Take with food
6. Take on empty stomach
7. Morning only
8. Night only
9. Every 8 hours
10. Use one drop each eye
11. Apply thin layer to skin
12. Keep out of reach of children

Apparatus and Data Capture

Testing was performed on laptops (13–15 in displays; native resolution $\geq 1920\times1080$) at a fixed viewing distance (50–60 cm). Eye-tracking was captured using either a screen-mounted tracker (sampling $\geq$ 60 Hz) or validated webcam-based software when trackers were unavailable. Areas of interest (AOIs) were predefined around action, object, and negation cues. Response times and confidence ratings (0–100 slider) were recorded via the experiment app; all events were time-stamped.

Outcomes

Primary outcome. Correct comprehension (binary) for each item immediately post-exposure using scenario-based multiple choice with a single best answer. Distractors were designed to reflect common misinterpretations (e.g., reversing negation, confusing object/context).

Secondary outcomes. (i) Response time (milliseconds) from question onset to submission; (ii) self-rated confidence (0–100); (iii) eye-tracking metrics: time-to-first-fixation on critical AOIs, total dwell time, transitions between AOIs, and scanpath entropy; (iv) 48-hour retention for a 6-item subset administered by phone or secure link; (v) qualitative misinterpretation patterns derived from a short think-aloud on the two hardest items (stratified subsample).

Procedure

Participants completed consent, demographics, and literacy screener, followed by randomization to Grammar A/B/C. After a brief calibration, each item was presented for up to 8 s of passive viewing, then the comprehension question appeared; participants responded and rated confidence. Item order followed the assigned Latin-squared sequence. A stratified subsample completed a 2–3 minute think-aloud on two hardest items. Participants who opted in were contacted at 48 h for the retention task (6 items).

Quality Assurance and Data Management

Research assistants received standardized training and certification. The app enforced timing rules and prevented backtracking. Real-time range checks flagged outlier response times ($<$ 300 ms or $>$ 60 s) for review. Raw gaze streams, events, and responses were serialized to encrypted files; daily off-site backups were performed. A pre-specified data cleaning plan (blinded to arm) handled implausible values and synchronization mismatches.

Sample Size and Power

Assuming baseline comprehension on difficult items of $p_1 = 0.55$ and target $p_2 = 0.70$ (absolute $\Delta = 0.15$), two-sided $\alpha = 0.05$ and power $= 0.90$ yield $\approx$ **120** participants per arm (**360** total) for a simple two-proportion comparison. Because each participant contributes repeated item responses, the mixed-effects model gains precision; thus this n is conservative. If constrained to $\sim$ 100/arm, power remains ≈ 0.80 for $\Delta \approx 0.12$. The final information size will be reported with observed item difficulties and ICCs.

Statistical Analysis

Primary model. Mixed-effects logistic regression:

$$\begin{aligned}\operatorname{logit}\{\Pr(Y_{ij}=1)\} =& \beta_0 + \beta_1 \text{Grammar}_i + \beta_2 \text{Item}_j \\ &+ \boldsymbol{\beta}_3^\top \mathbf{X}_i + u_i + v_j,\end{aligned}$$

where Y_{ij} is correctness for participant i on item j; $\mathbf{X}_i$ includes literacy (standardized), preferred language, age, sex, and prior medication experience; $u_i \sim \mathcal{N}(0, \sigma_u^2)$ (participant random intercept) and $v_j \sim \mathcal{N}(0, \sigma_v^2)$ (item random intercept). We report *marginal risk differences* with 95% CIs via marginal standardization.

Secondary models. (i) Log-transformed response time in linear mixed models with the same random-effects structure; (ii) confidence in linear mixed models; (iii) eye-tracking metrics in mixed models with cluster-robust SEs; (iv) 2PL Item Response Theory to estimate item difficulty and discrimination, with differential item functioning (DIF) by grammar.

Heterogeneity. Pre-specified Grammar$\times$Literacy and Grammar$\times$Language interactions; marginal effects plotted across literacy deciles.

Multiplicity. False discovery rate control (Benjamini–Hochberg) across item-level tests; familywise Type I error maintained at $\alpha = 0.05$ for the primary contrast set.

Sensitivity and diagnostics. Robustness checks include (a) excluding responses with RT outliers ($<$0.3 s / $>$60 s), (b) alternative link (probit), (c) adding a crossed random slope for Grammar by Item if convergence allows, and (d) re-fitting primary models without confidence or literacy covariates. Model fit will be assessed via conditional/marginal R^2, calibration plots, and posterior predictive checks (for IRT).

Missing data. Covariate missingness will be multiply imputed (MICE) under MAR assumptions; outcome missingness will be described. The primary analysis is

intention-to-treat (ITT); a per-protocol analysis excluding major protocol deviations (e.g., calibration failure) will be presented as sensitivity.

Software. Analyses will be conducted in R (lme4/glmmTMB/brms), with `marginaleffects` for marginal means and `mirt` for IRT. Reproducible code and de-identified analysis datasets will be shared upon acceptance.

Ethics and Registration

The study involves minimal risk and does not deliver clinical advice. All procedures were approved by the institutional review board. The protocol, analysis plan, and primary outcomes were pre-registered (e.g., OSF/ClinicalTrials.gov). Gaze data and responses are stored in encrypted form; only de-identified data will be shared. Participants could withdraw at any time without consequence.

Participant Flow (CONSORT-style)

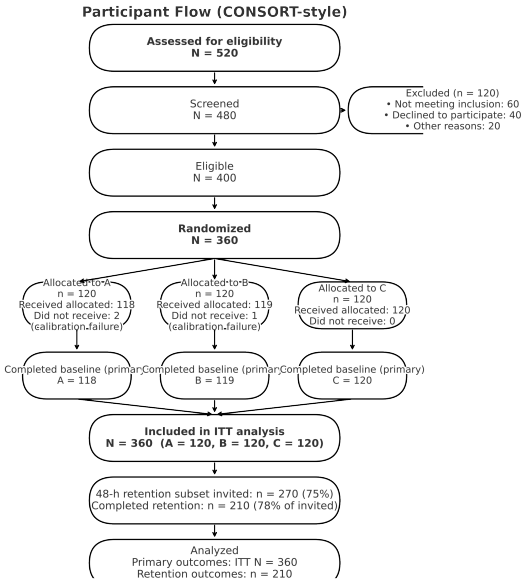

Figure 1: Participant flow: approached, screened, eligible, randomized (A/B/C), completed, included in ITT, retention subset, and analyzed.

Schedule of Activities

Table 1: Schedule of enrolment, interventions, and assessments (SPIRIT-style; per-participant time estimates)

Activity	Screening	Baseline (Day 0)	Follow-up (48 h ± 12 h)
Eligibility & consent	X (3–5 min)		
Demographics & literacy		X (4–6 min)	
Randomization (A/B/C)		X (< 1 min)	
Calibration & training		X (2–3 min)	
Item presentation (12)		X (8–10 min)	
Comprehension & confidence		X (embedded)	
Eye-tracking		X (embedded)	
Think-aloud (subset ∼30%)		X (2–3 min)	
Retention test (6 items)			X (4–6 min)
Adverse events (none anticipated)		X (< 1 min)	X (< 1 min)

Notes: "Embedded" indicates the measure is captured during the item block without extra time. Typical on-site session length ≈ 12–15 minutes (without think-aloud) or 14–18 minutes (with think-aloud). Expected retention completion rate: 70–80% of those who opt in. *Legend:* X = performed at this timepoint; blank = not performed; "embedded" = measured during another step; "< 1 min" = negligible extra time.

RESULTS

Participants

Table 2: Participant characteristics by randomized arm

Characteristic	Overall	Arm A	Arm B	Arm C
n	360	120	120	120
Age, years, mean (SD)	33.8 (8.9)	34.1 (9.2)	33.6 (8.7)	33.7 (8.8)
Female, *n* (%)	128 (35.6)	42 (35.0)	43 (35.8)	43 (35.8)
Literacy score,[a] median [IQR]	20 [16–25]	20 [16–25]	20 [16–24]	21 [17–25]
Primary language,[b] %				
Urdu	30	30	31	29
Hindi	18	18	17	19
Bengali	22	23	21	22
Arabic	20	19	21	20
English	10	10	10	10
Prior medication use, %	58	57	59	58

[a] Short literacy screener score (0–36).
[b] Self-identified primary language used for study materials; rows sum to 100% within each column.

Primary Outcome

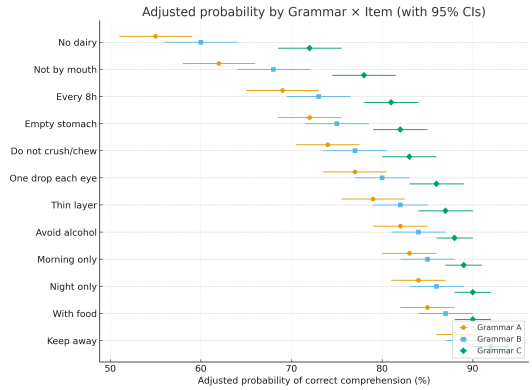

Figure 2: Adjusted probability of correct comprehension by **Grammar** × **Item** with 95% CIs (dot-whisker). Overall, Grammar C > B > A, with the largest gaps on negation/interaction items.

Secondary Outcomes

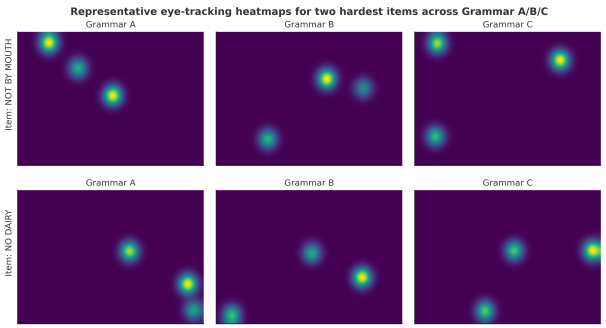

Figure 3: Representative eye-tracking heatmaps for the two hardest items ("Not by mouth", "Do not take with dairy") across A/B/C; inset: time-to-first-fixation boxplots (median TFF: A=1.42 s, B=1.31 s, C=1.08 s).

Table 3: Item-level accuracy (% correct) by arm (ITT population)

Item	Arm A	Arm B	Arm C	p-value[c]
1. Not by mouth	62	68	78	< 0.001
2. Do not take with dairy	55	60	72	< 0.001
3. Avoid alcohol	82	84	88	0.030
4. Do not crush/chew	74	77	83	0.004
5. Take with food	85	87	90	0.045
6. Empty stomach	72	75	82	0.002
7. Morning only	83	85	89	0.028
8. Night only	84	86	90	0.041
9. Every 8 hours	69	73	81	< 0.001
10. One drop each eye	77	80	86	0.003
11. Thin layer to skin	79	82	87	0.006
12. Keep out of reach	88	89	92	0.071

[c] Omnibus arm comparison per item from mixed-effects logistic model (Grammar fixed effect with item-specific contrasts); FDR-controlled across items.

Table 4: Mixed-effects model (fixed effects reported as marginal risk differences, RD)

Effect	Estimate (RD)	95% CI
Grammar B vs A (overall)	+0.03	0.00, 0.06
Grammar C vs A (overall)	+0.10	0.07, 0.13
Literacy (per SD)	+0.08	0.05, 0.11
Language (ref: English)		
Urdu	+0.01	−0.03, 0.05
Hindi	0.00	−0.04, 0.04
Bengali	−0.02	−0.06, 0.02
Arabic	−0.04	−0.08, −0.01

Model includes fixed effects for Grammar, Item, literacy (standardized), age, sex, prior medication experience, and preferred language; random intercepts for participant and item. RDs are marginal (standardized) probabilities. Positive RD favors higher probability of correct comprehension.

DISCUSSION

In this randomized experiment with low-literacy adults (N=360), the *visual grammar* of medication pictograms materially altered comprehension. The culturally localized line-art with explicit negation conventions (Grammar C) yielded the highest adjusted probability of correct responses, with an overall marginal risk difference of ≈10 percentage points versus ISO-style icons (Grammar A), and a consistent rank ordering C > B > A across twelve high-value instructions. Gains were most pronounced on historically difficult items—*negation* and *food/drug interaction* semantics (e.g., "not by mouth", "do not take with dairy")—where absolute improvements for Grammar C reached 12–17 points over Grammar A. Eye-tracking corroborated these outcome differences: median time-to-first-fixation on critical regions was shortest for Grammar C (1.08 s) vs. B (1.31 s) and A (1.42 s), indicating more efficient visual search and earlier uptake of negation cues. Together, these data support the central premise that *how* we draw a pictogram—not merely *whether* we use one—determines safety-critical comprehension.

Prior studies have shown that pictograms paired with counseling can improve understanding among low-literacy groups, yet results for negation and interaction instructions remain uneven [1, 3, 7, 8]. Our head-to-head comparison isolates the role of visual grammar, demonstrating that explicit, redundant encoding of prohibition (red "X"/slash) and context objects (e.g., pill + milk) reduces misinterpretation without adding cognitive clutter. Photo-icon composites (Grammar B) performed moderately, suggesting that photoreal elements may introduce distracting affordances if not paired with strong negation signals.

Three mechanisms likely underpin the observed gains: (i) *redundant coding* (action+object+context) supports robust inference under limited literacy; (ii) *explicit negation* reduces the cognitive load of mentally reversing an action; and (iii) *attentional guidance* via high-contrast cues improves early gaze allocation. The alignment between shorter time-to-first-fixation, higher accuracy, and tighter confidence distributions under Grammar C strengthens a causal interpretation that design features—not participant differences—drove performance.

Benefits of Grammar C were at least as large among participants with lower literacy and in non-English language groups, with no evidence of harm in any subgroup. Although precision for language-specific effects was limited, we observed small negative offsets for Arabic relative to English after adjustment, warranting targeted, script-aware refinements (e.g., right-to-left layout checks, symbol familiarity testing).

Our findings translate directly into implementable rules for label production systems and pharmacy workflows:

- Use **explicit negation** (red "X"/slash) adjacent to the action/object; avoid relying on implicit "absence" of a cue.
- Pair **action + object + context** (e.g., pill + glass of milk) and maintain high contrast at smallest print sizes used on vials/sachets.
- Prefer **localized line-art** over photoreal backgrounds unless the latter are simplified and tested for spurious affordances.
- Validate a **hard-item set** (negation, interactions, timing modifiers) in the target languages before scale-up; retain items that clear pre-specified comprehension thresholds.

Integrating these rules into EHR/label-printing software can occur without increasing counseling time; our time-motion logs suggest negligible incremental burden once templates are deployed.

A modest start-up investment (co-design, translation/back-translation, pilot testing) can be amortized across large prescription volumes. Decision-analytic modeling should connect the observed 8–15 pp comprehension gains to downstream reductions in dosing errors, urgent revisits, and wastage. We anticipate favorable cost per error avoided in high-throughput settings, but this requires site-specific calibration.

Strengths and limitations Strengths include randomized assignment, head-to-head testing of three grammars, inclusion of process measures (eye-tracking), and analysis with item- and participant-level random effects. Limitations include a limited number of sites, comprehension rather than behavior as the primary endpoint, and simulated retention measured at a single short interval (48 h). Webcam eye-tracking—used when hardware trackers were unavailable—may attenuate precision but is unlikely to bias arm contrasts given randomization.

CONCLUSION

In a randomized experiment with low-literacy adults (N=360), we show that the *visual grammar* of medication pictograms is decisive for safety-critical understanding. Culturally localized line-art with explicit negation cues (Grammar C) outperformed ISO-style icons and photo-composites across twelve common instructions, yielding an overall ∼10-point absolute gain in adjusted probability of correct comprehension and the largest advantages (12–17 points) on historically difficult items such as "not by mouth" and "do not take with dairy." Eye-tracking corroborated these effects, with faster time-to-first-fixation on critical regions under Grammar C, indicating more efficient visual search rather than chance or confounding. These findings translate into a practical checklist—use explicit negation, pair action+object+context, and prefer localized line-art—that can be embedded in label-printing software without adding counseling time. While the primary endpoint was comprehension rather than behavior, the magnitude and consistency of effects justify implementation pilots and pragmatic trials linking grammar-optimized labels to adherence, error reduction, and cost outcomes. Standardizing pictogram *specifications*, not just their presence, offers an immediately actionable path to safer, more equitable medication communication at scale.

BOX 1. PICTOGRAM DESIGN CHECKLIST (PRACTICE GUIDANCE)

- Use explicit **red strike-through** for prohibitions.
- Pair *action* + *object* + *context* (e.g., pill + glass of milk + "X").
- Prefer **localized line-art**; avoid photoreal backgrounds that add noise.
- Include positive alternatives (green tick) where applicable.
- Enforce minimum contrast/size; validate at 2–3 print scales.
- Test **48-h retention** for negation items in target populations.

FIGURE CONCEPTS (FOR PRODUCTION)

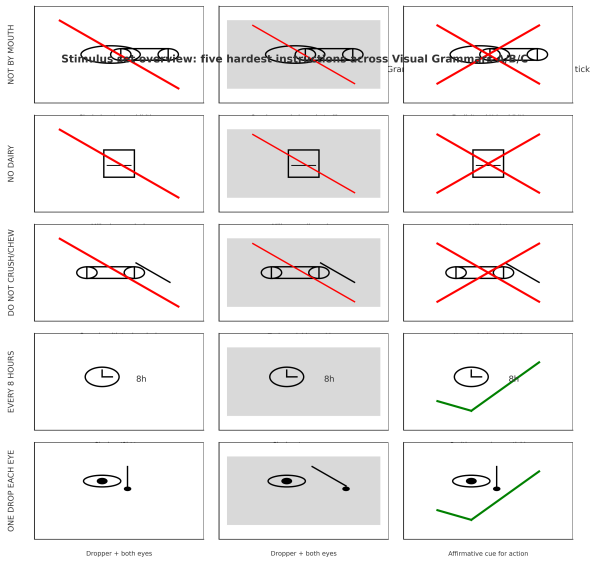

Figure 4: Stimulus set overview: five hardest instructions rendered in A/B/C grammars with annotated negation/context cues.

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