

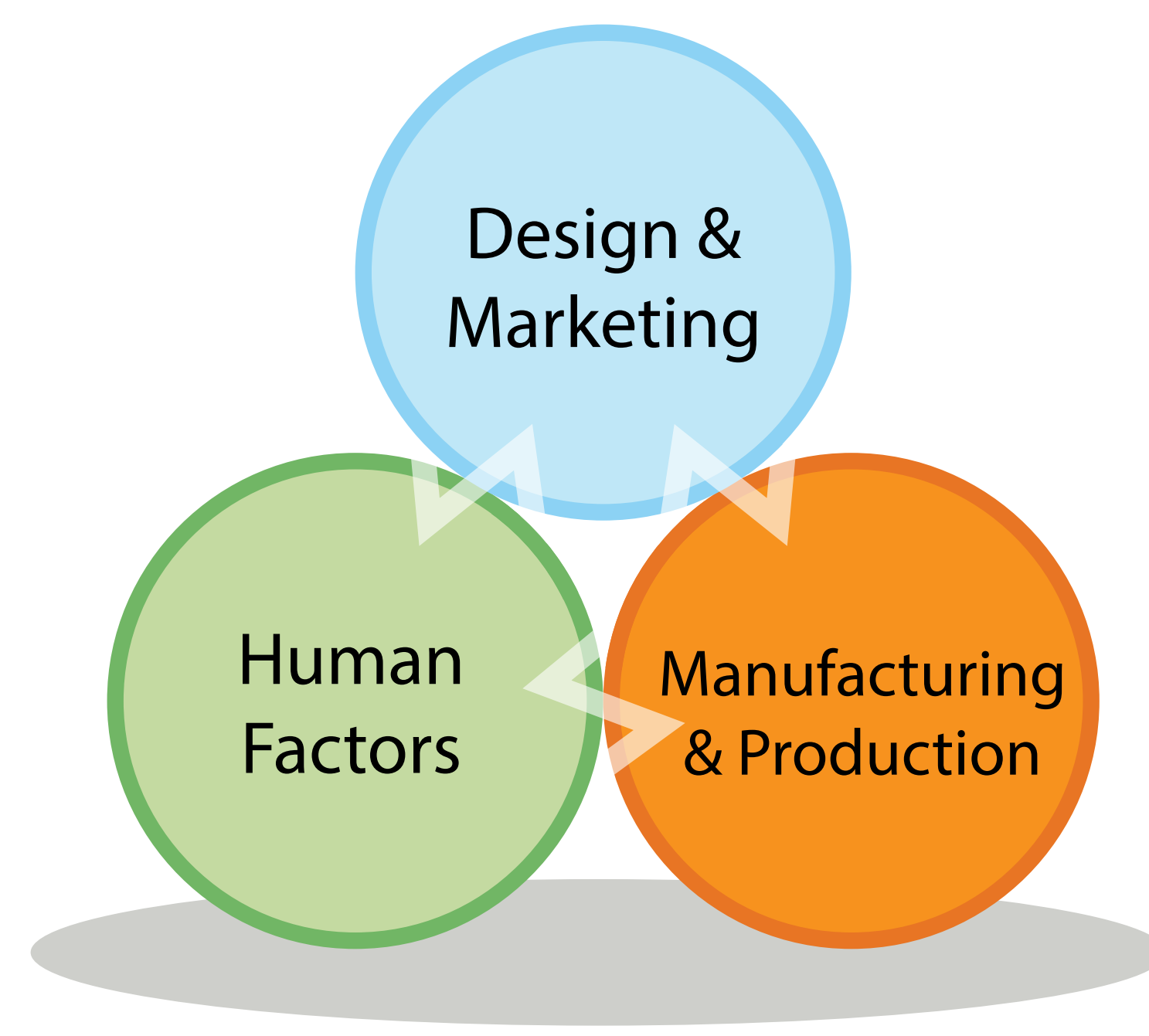
Finding the “Sweet Spot” for IFUs: Balancing Human Centered Design and Manufacturability at Scale

Rachel Poker¹, Krista I. A. Smith², and Joseph Cordova¹

Abstract

Human factors (HF) practitioners have made significant advances in designing clear, user centered Instructions for Use (IFUs) for medical products, guided by robust methodologies and regulatory standards. However, a persistent gap remains between IFU design intent and the realities of commercialization and manufacturing at scale. Design decisions made to accommodate printing, packaging, cost, translation, and local regulatory requirements can unintentionally degrade usability if HF considerations are not incorporated early and maintained through production. However, HF practitioners designing IFUs may lack visibility into manufacturing constraints, while those responsible for production may lack HF expertise, creating downstream challenges. This work highlights common blind spots across human factors, manufacturing, and graphic design, and emphasizes the importance of early collaboration to find the “sweet spot” that balances human centered design with manufacturability—ultimately supporting safe and effective product use with IFUs developed to be manufactured at scale and across global markets.

What you see here is not poor design—it’s a broken handoff.



Each “problematic” example began as a human centered IFU that worked in testing. Usability issues emerged when design intent met real world constraints such as printing limits, folding equipment, packaging space, translation, local regulatory requirements, operational efficiency, and cost. These visuals illustrate why HF expertise must extend beyond content and layout to include manufacturability and commercialization considerations, and apply these throughout development.



Don’t Wait Until the Human Factors Validation Study to Find Out Common Issues Discovered when Manufacturability is not Considered Before Commercialization

a. Plan for Assembly

IFU layout should account for manufacturing considerations, including designated “safe spaces” for automated assembly features (e.g., registration marks, barcodes, and serial information), folding process accommodations such as compression zones, and securing methods such as glue dots, stickers, and/or banding.

b. Did You Buy That Font?

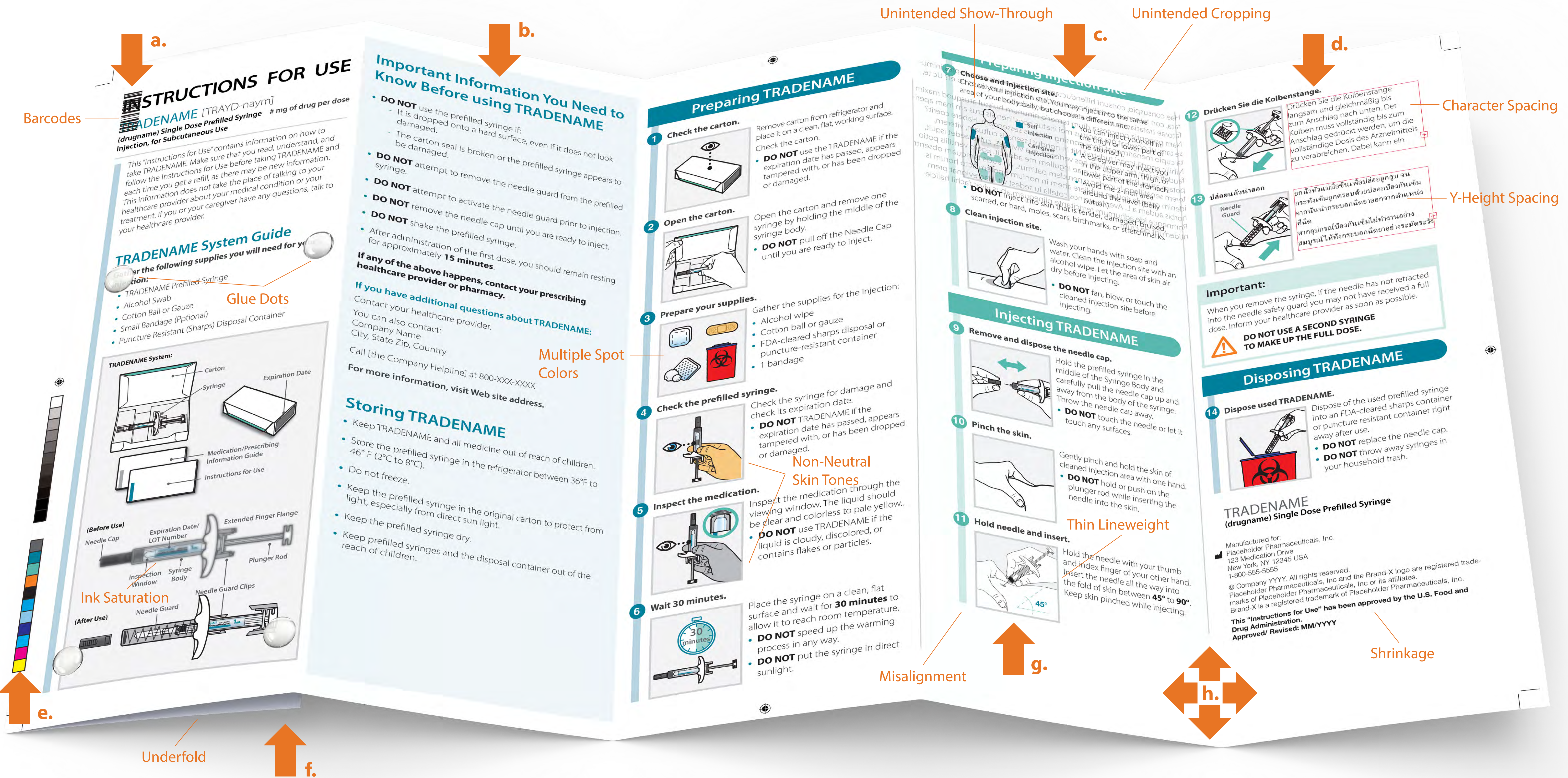
Font selection can influence IFU commercialization, as proprietary or non-standard fonts may introduce licensing, distribution, and implementation costs when scaling to large-volume production. Preserve live text (not outlined), even in images, to support translations, digital IFUs and accessibility tools.

c. The Weight of the Matter

Paper weight can affect IFU manufacturability by limiting folding options, increasing thickness after folding which may differ depending on folding process used (e.g., water-scoring vs. hand-folding) within packaging, and introducing unintended show-through that can interfere with visual communication across page sides.

d. Fit Lost in Translation

IFU layouts should be designed to tolerate translation-related text expansion and adapt to regional manufacturing and regulatory requirements, as differences in language length, packaging formats, printing equipment, and permitted IFU formats can affect information presentation across markets.



Want to learn more? Let us know.

e. Spot or CMY-OK?

Choosing spot (Pantone) versus process (CMYK) colors, and coated versus uncoated paper, affects how IFUs are manufactured, including ink absorption, bleed, color consistency, and printing cost. Spot colors can improve color consistency but typically increase setup complexity and cost.

f. Unintended Origami

Limited folding patterns available during automation and opening sequence can unintentionally alter IFU layout and reading order, increasing the likelihood that safety-critical information is missed when IFUs are not fully opened or are read in partially unfolded sections.

g. Is This an IFU for Ants?

Avoid fine gradients, light tints, thin line weight, and extraneous detail including font selection (e.g., serifs) that may degrade or drop out at production scale. Be sure to check color contrast and visual detail on printed samples, to ensure accessibility and distinguishability across manufacturing lines.

h. One Size Doesn’t Fit All

Standard cut paper sizes are often not suitable for large-scale printing. Offset printing uses sheet-fed or web-fed presses that run oversized (ISO raw format) sheets, which are then cut, folded, and trimmed to their final size after printing. Consider the impact of different layouts and paper sizes based on local regulatory labeling requirements and packaging form factors.

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