Bold Insight

Lessons from the Field

ETHNOGRAPHIES IN MEDICAL DEVICE RESEARCH

Bold Insight

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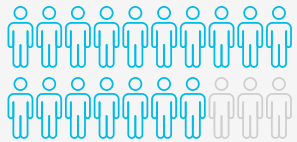
Bold Insight has a highly specialized healthcare practice



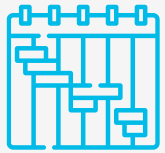
17 of TOP 20

Medical device manufacturers trust us with their research.

60%

Of our work is in medical device, surgical, and digital health UX/HF

100+



Healthcare research and design **engagements** our team members have planned, managed, and executed **over the past year**

200+

Years of combined experience applying HFE to med device development according to industry standards and FDA guidance

Agenda

Lessons from the field

- DEFINITION AND DRIVERS
- GETTING IN THE DOOR
- DISCOVERING HIDDEN HAZARDS
- ETHICAL CONSIDERATIONS
- TECH-ENHANCED OPPORTUNITIES

Definition and drivers of in-home ethnos for med device research

Defining ethnographic research

We use the contextual inquiry definition as a backbone to define ethnographic research

WHAT ARE ETHNOGRAPHIES

"Observing representatives of the intended users interacting with a currently marketed device (similar to the device being developed) as they normally would and in actual use environment)."

– *Applying Human Factors and Usability Engineering to Medical Devices* (February 2016)

OBJECTIVE

"To understand how design of the user interface affects the safety and effectiveness of its use, which aspects of the design are acceptable, and which should be designed differently."

– *Applying Human Factors and Usability Engineering to Medical Devices* (February 2016)

WHEN TO USE

"This process can help with understanding the users' perspectives on difficult or potentially unsafe interactions, effects of the actual use environment, and various issues related to work load and typical work flow."

– *Applying Human Factors and Usability Engineering to Medical Devices* (February 2016)

What does ethnographic research provide?

- Provides deep contextual understanding
- Uncovers early usability risks
- Reveals overlooked workflows
- Highlights gaps
- Reinforces human centered design

Getting in the door: Recruit & consent

Addressing recruitment friction

- SCREENING
- SCHEDULING
- TRUST BUILDING

Addressing recruitment friction: Screening

ISSUES & FRICTION

Time and budget constraints: Limited resources for a hefty overrecruit approach.

Overly narrow criteria: Recruit pools shrink quickly when requiring specific behaviors, demographics, and environments.

Criteria disconnect: Last-minute group switches or criteria misunderstanding cause sunk costs, timing setbacks, and data loss.

Drop-outs: When participants discover the study involves longer or personal observations, or more touchpoints, drop-out rates can increase.

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LESSONS & STRATEGIES

Verify, and then verify again: Have your recruiter ask for photos of devices.

Set clear expectations in the screener: Outline session length, what will happen, who/how many people are coming.

Define space & needs: Clarify where the session takes place, needed space, and special requirements (e.g., strong internet, distraction-free areas).

Widespread recruiting: If budget allows, cast a wider recruit net.

Addressing recruitment friction: Scheduling

ISSUES & FRICTION

Off-hours observation: Treatments and medication management might occur early in the morning or later in the evening.

Logistical limits: Travel time between locations limits the number of ethnographic observations in a single day.

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LESSONS & STRATEGIES

Flexible (but reasonable) scheduling: Adapt to fit participants' schedules and consider multiple modes (in-person, remote follow-ups, asynch video feedback).

Time limits: Try to not exceed 90-minute visits.

Team setup: Enlist multiple teams to cover more ground, and sync after each other's sessions.

Addressing recruitment friction: Trust

ISSUES & FRICTION

Sensitive information: Participants may feel uneasy allowing researchers in private or sensitive contexts.

Burden: Observation can unintentionally disrupt routines; even highly motivated participants may withdraw.

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LESSONS & STRATEGIES

Pre-visit intro calls: Showing up at their door should not be the first touchpoint.

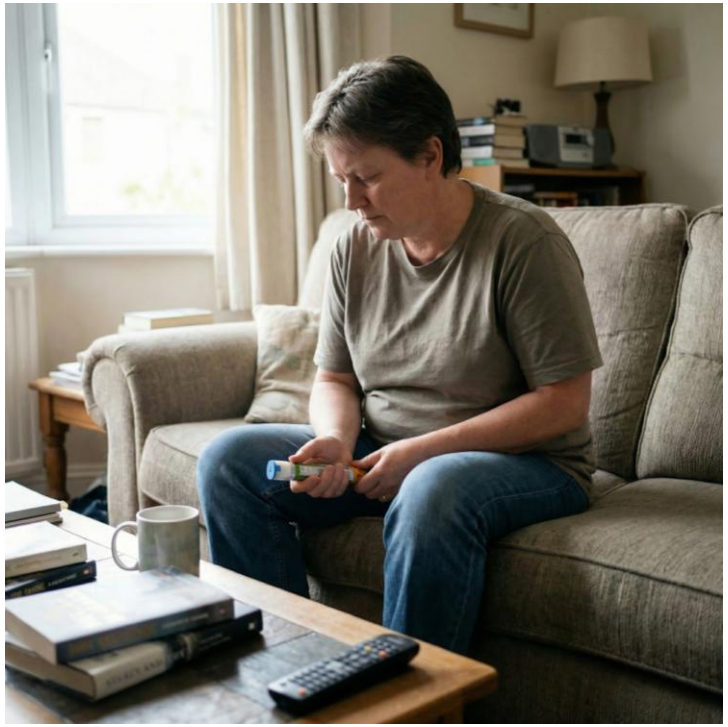
Ensure transparency: Address expectations for time commitment, data methods, and privacy.

Leverage intermediaries: Build relationships with trusted healthcare sources (e.g., advocacy groups, clinics).

Consenting and reporting

- WHO TO CONSENT
- SUGGESTED FORMS
- ADVERSE EVENTS / PRODUCT COMPLAINTS

Considerations for household consenting



Consent checklist examples

CONSENT

- IRB approval required
- Required for all enrolled and compensated participants
- Adapted existing consent forms to include other types of individuals who may be present in the household:
  - Patient & caregiver
  - Care receiver
  - Friend / family support
  - Adolescents
  - Proxy consent (LAR, non-consenting adult)
- Send digital consent forms to participants to review ahead of their session to save time during the visit
- Have participants sign consent once on-site

VISIT PERMISSION

- Does not need IRB approval
- One form per household – states that they allow the study team to enter their household
- Request participants to review and sign before visit occurs or incorporate into primary consent

MEDIA RELEASE

- Does not need IRB approval
- Commonly included in the main consent

NDAs

- Does not need IRB approval
- Recommend to create an NDA for those in the household who are present but did not actively participate
- Signed during in-home session
- Can be at the research team's discretion when/if NDA should be used

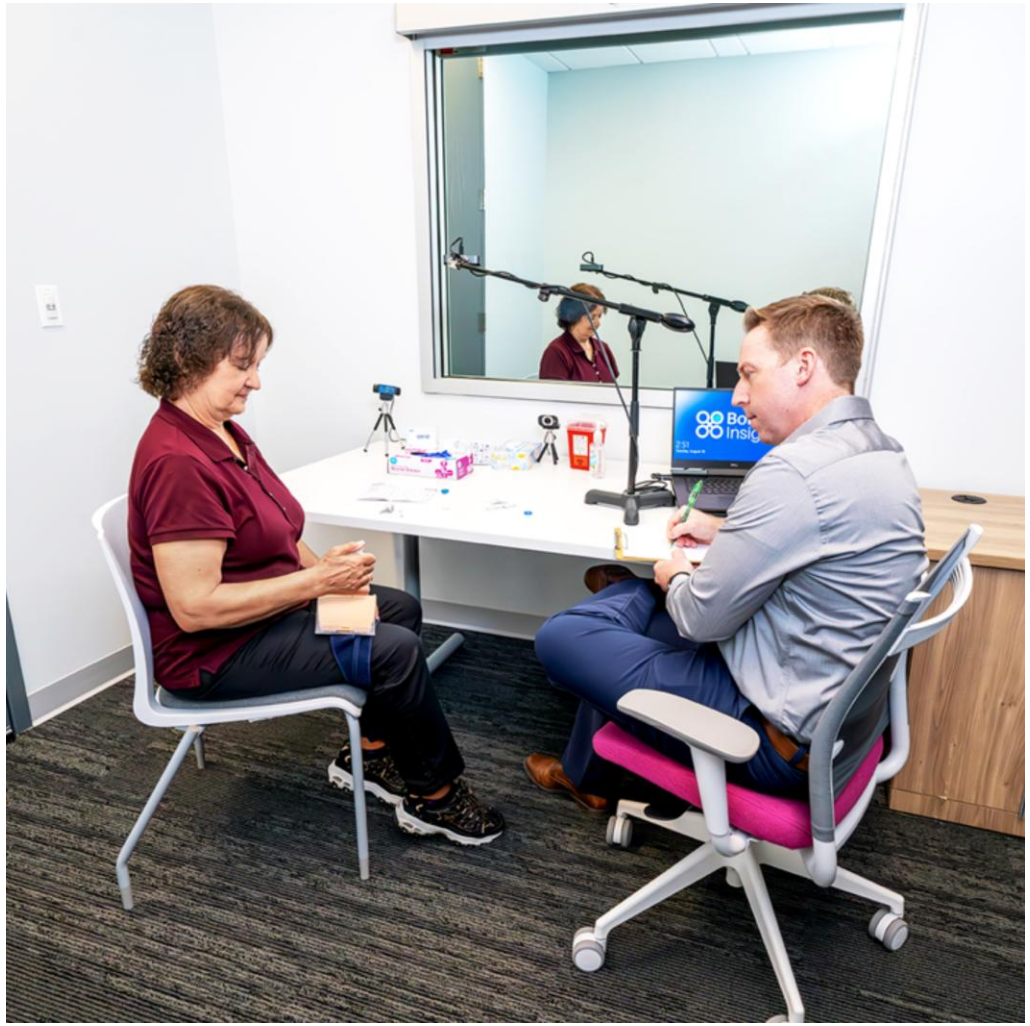
AE / PC

- Digital form / Word Doc
- Anticipated higher than average AE/PC reports during fieldwork
- Have upfront conversations to align on what an AE / PC entailed for this study

- See if your IRB will accept one primary consent form that includes different cohorts/users with varying addendums.
- LAR signature lines can be added to the consent document.
- Bring multiple copies of each form – you can't anticipate 100% who will be present during an in-home session

Discovering hidden hazards

Ideal lab conditions



Ideal lab conditions

Real-world environment

Ideal lab conditions

Real-world environment

Ideal lab conditions

Real-world environment

The home as an unregulated care unit

Homes don’t have standard operating procedures – people do.

ACTUAL USE ENVIRONMENTS

Home environments are growing for device usage.

Introduce factors simulated use environments lack, such as lighting, storage, noise, clutter, multitasking, shared spaces, financial constraints.

ANTICIPATED VS. UNEXPECTED USE

Simulated environments are designed by researchers and therefore tend to reveal anticipated use errors rather than unexpected ones.

ENVIRONMENTAL HAZARDS

Observing environmental hazards in context provides early warning signs of potential safety and regulatory concerns.

Insights inform safer design earlier in development and strengthen key HF deliverables, including use specification documentation, task analyses, and use-related risk analysis.

As seen on Chicago's CTA

There are things we can see, there are things we can't see.

Ethnographic metrics reveal reality and hidden hazards

Behavioral deviations

Observe workarounds, skipped steps, and repeated errors to identify potential safety or usability risks early.

Micro-decisions

Track small, inconsistent choices that reveal confusion or points where failures may occur.

Context mapping

Assess environmental factors that could lead to real-world errors.

Frustration markers

Look for verbal cues, signs, or repeated attempts that signal hidden usability risks.

Cognitive load assessment

Evaluate multitasking and planning demands to detect tasks likely to generate mistakes.

Gap analysis

Compare intended workflows with actual practices to uncover mismatches that may compromise safety.

Journey maps

Visualize step-by-step user experiences to highlight friction points and risky process steps.

Storyboards

Create visual narratives of real-world scenarios to make subtle risks tangible to stakeholders.

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The ethical lines of in-home ethnos

Observing the delta

Real-world vs. intended use

THE FDA PERSPECTIVE

Observe the device in the "intended use environment" by the "intended user" without turning it into a supervised training session.

THE REALITY

Regardless of the home’s condition, participants have a system in place. Workarounds are their best attempt at managing care.

THE RULE

Do not teach or train. We uncover the “why” behind behavioral deviations and decisions.

THE EXCEPTION

Only intervene if a behavior presents an immediate safety risk (injury or death).

Unbiased observation vs. clinical safety

RISK CATEGORY	THE "CORRECTION" CONSEQUENCE
CLINICAL	You may override a deliberate, patient-specific medical adjustment.
LEGAL	You are performing an unlicensed clinical intervention in a domestic space.
PSYCHOLOGICAL	You undermine the patient’s confidence in their primary healthcare provider.
METHODOLOGICAL	You mask a "systemic workaround" that the manufacturer needs to see.

The “ethnographer effect”

What changes when researchers walk through the door?

Navigating vulnerability

Micro-ethics & emotion

THE REALITY OF EMOTION

Fear, shame, judgment, and fatigue are central to device safety, altering risk tolerance and disclosure

MICRO-ETHICS ON THE FLY

Managing unexpected revelations like risky behavior, family conflict, or clinician nonadherence

BE PREPARED TO PIVOT

Recording vulnerable moments can be unethical; option to pivot to participant-led narration or sketch mapping

THE GOAL

Translate emotional realities into product/policy implications (messaging, onboarding tone, error recovery language)

Tech enhanced opportunities

Ethno tech basics

- Arrive with charged equipment
- Bring backups (batteries, memory cards, power cables...)
- Plan time for tech setup
- Mobile Wi-Fi hotspot if needed
- Capture only what is allowed
- Backup audio and/or video recording
- Wear a watch; keep track of time
- Keep tech lean to reduce feelings of intrusiveness

Tech opportunities

Goodbye, clipboards

WEARABLE RECORDING DEVICES

- Recording glasses allow picture and video recordings from the moderator's POV.
- Eliminates session disruption and the need to reposition recording equipment.

SENSOR INTEGRATION

- Using small devices or environmental sensors to passively record data on patient activity, interactions, or surroundings.
- Data can include movement, location, device use, or environmental conditions.

METHODOLOGICAL INNOVATIONS

- Asynchronous ethnography as a new genre to compare "in the moment" vs retrospective interviews.
- Ability to analyze voice notes, photos, and text-based responses before or after interviews.

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Thank you!

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