# SECTION A

# Invent: Innovation and Creative Thinking

# CHAPTER 1

# CLINICAL NEED FINDING

| HIGHLIGHTS | |
|---|---|
| **Must–Dos** | **Must–Donts** |
| ✔ Go to the point of care across shifts and settings, directly observing workflows, handoffs, delays, and safety risks. | ✘ Don't start with a favorite technology or a single dramatic case unless you are positive of your original take. |
| ✔ Craft solution–agnostic, measurable need statements anchored to a specific context–of–use and named stakeholders. | ✘ Don't ignore constraints or payers; needs failing sterility, interoperability, staffing, or coverage stall. |
| ✔ Quantify and validate early–estimate incidence, delays, complications, and costs–and test generalizability across settings. | ✘ Don't collapse distinct pain points into one omnibus statement; separate safety, efficiency, and experience needs. |
| **Key Tips** | |
| 💡 Triangulate methods–brief interviews, time–motion notes, incident logs–and sample nights, weekends, and peak census to reveal stress–dependent problems. | |
| 💡 Keep a living need log with evidence links, confidence ratings, and explicit disconfirming signals; prune aggressively to maintain credibility and momentum. | |
| 💡 Use a standard template ("a way to [improve outcome] for [population] in [context] without [undesired trade–off]"), then run a pre–mortem with stakeholders. | |

*The real tragedy of the poor is the poverty of their aspirations.*

Adam Smith

Clinical need finding begins before prototypes, with ethnography and shadowing revealing how care is actually delivered, not merely how protocols depict it, illuminating frictions, workarounds, and latent risks that rarely surface in meetings (**Figure 1.1**). Think of this chapter as your field guide to observing work–as–done versus work–as–imagined, with disciplined curiosity yielding insights that later anchor indications, claims, verification metrics, and eventual reimbursement arguments.

When done well, need finding generates thick data that complements quantitative dashboards, capturing context, sequence, and meaning in ways spreadsheets cannot, while preserving traceability from raw notes to synthesized opportunities and ultimately prioritized problem statements. Plan deliberately: define decision questions, success criteria, and constraints; select wards or clinics where the target condition manifests; secure approvals and consent pathways that respect HIPAA or GDPR, and negotiate access

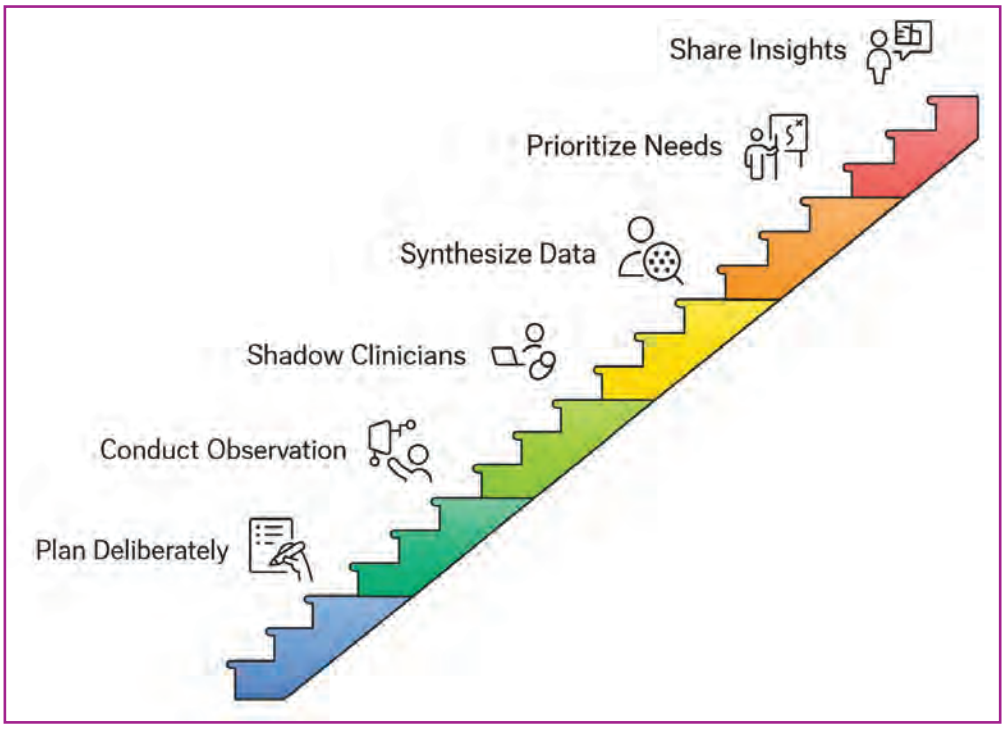



Figure 1.1. Key steps in the ethnographic research progress.

with gatekeepers like nurse managers. Compose a sampling frame balancing extremes and typicals, capturing weekday peaks, night shifts, and low–resource settings, with outliers often exposing system seams and create sharper design requirements than sanitized, idealized daytime observations ever will. Develop briefing materials that clarify your role, what you will record, and what you will not, minimizing observer effects while honoring ethical duties to patients, clinicians, and institutional partners who enable the work.

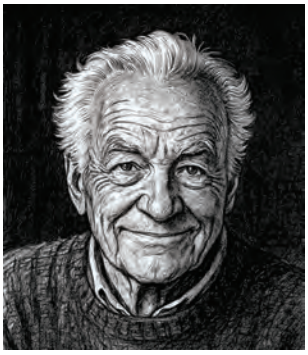
During observation, write in short, time–stamped bursts, noting actors, artifacts, spaces, and interruptions, then sketch simple sequence diagrams that track a patient, specimen, device, or order as it traverses the clinical microsystem. Capture workarounds, copy–and–paste habits, double documentation, and informal communications. These microbehaviors often signal mismatches between information systems and cognitive workflows that generate preventable errors, delayed decisions, or unnecessary clinician burden. Mark critical incidents and near misses with asterisks in your notes, returning later to reconstruct antecedents, guardrails, and consequences, thereby converting anecdotes into analyzable episodes that inform risk controls and usability requirements. Shadowing differs from stationary ethnography by immersing you alongside a clinician through a shift, revealing task switching, temporal pressure, social dynamics, and the choreography of handoffs that shape safety, efficiency, and emotional labor. Use structured prompts during quiet moments–what surprised you, what felt risky, what routinely breaks–while avoiding advice

or disruption, because the objective is understanding, not performance improvement during the observation itself. Collect verbatim quotes, ambient noise cues, and spatial sketches that convey cognitive load and environmental stressors, then translate these signals into candidate needs whose owners, contexts, and triggers are traceable and testable. Synthesis begins as soon as you leave the floor, with quick debriefs, affinity clustering of notes, and journey maps that link actors, touchpoints, delays, and emotions into coherent narratives that expose leverage points. Triangulate qualitative themes against small quantitative probes–cycle times, queue lengths, error tallies–so claims about harms of the status quo rest on evidence, not anecdotes, and can withstand skeptical scrutiny from clinicians, administrators, and regulators. Link patterns to Jobs–to– Be–Done by asking what functional, social, and emotional progress users are trying to make, then convert gaps into outcomes and constraints that guide later ideation without prematurely prescribing solutions.

Write need statements with disciplined structure: a target user, a problem in context, a measurable outcome, and constraints, deliberately excluding mechanisms, products, or technologies that would bias solution generation or foreclose better alternatives. Prioritize needs using criteria such as severity, frequency, payer relevance, and addressability, then socialize them with frontline clinicians to validate salience and to uncover hidden barriers that only insiders notice and name. Document traceability from observation to need to metric in a simple matrix, enabling later claim drafting, verification plans, and financial models to reference the same empirical spine without ambiguity or reinvention.

Guard against bias through reflexive memos, alternating observers, and member checks, while protecting confidentiality with de–identification and secure storage that satisfies institutional policies and the trust your participants extend to you. Close each cycle by returning synthesized insights to the field in brief, respectful share–backs, inviting corrections and clarifications that sharpen your understanding and reinforce collaborative relationships essential for subsequent prototyping and clinical piloting. In this way, ethnography and shadowing become disciplined engines for opportunity discovery, producing credible, actionable needs that respect clinical realities and provide a durable foundation for invention, protection, and responsible commercialization.

## TRAILBLAZING INVENTOR: KURT AMPLATZ



Austrian–born radiologist–inventor Kurt Amplatz (1924–2019) trained in Innsbruck, emigrated to the United States, and performed pioneering percutaneous cardiac catheterization in 1958. He later developed the Amplatzer family of occlusion devices–including Septal, Cribriform, and VSD occluders–that provided a minimally invasive alternative to open surgical repair of congenital heart defects. Amplatz founded AGA Medical, accumulated more than one hundred patents, and ultimately saw his company acquired by St. Jude Medical for over $1 billion in 2010. His career exemplifies clinically anchored problem–solving translated into transformative device innovation.

## LANDMARK PATENT: AMPLATZER SEPTAL OCCLUDER

The Amplatzer Septal Occluder addressed the need for a percutaneously delivered, fully retrievable, and repositionable device capable of closing atrial septal defects without open surgery. Its foundational U.S. Patent No. 5,725,552 (1998) describes a self–expanding nitinol mesh device with dual discs linked by a central waist, delivered through a catheter and deployed across the septal defect. The claims specify the braided–wire architecture, elastic memory behavior, and controlled deployment mechanism that allow secure defect closure while maintaining conformity with cardiac anatomy. This patent established the structural blueprint for modern transcatheter occlusion systems and permanently reshaped congenital heart disease treatment.

## MULTIPLE CHOICE QUESTION

❓ A clinical fellow observes repeated documentation delays during ward rounds and immediately proposes a voice–to–text tool to speed note entry. The team has not yet mapped workflows across shifts or quantified downstream effects. What is the most appropriate corrective action at this stage?

👉 A) Pilot the voice–to–text tool during daytime rounds to gather preliminary usability data.
B) Rewrite the observation as a solution–agnostic clinical need, specifying users, context, measurable outcomes, and constraints.
C) Benchmark competing speech–recognition vendors to assess technical feasibility.
D) Define success as a 30% reduction in documentation time per patient.
E) Escalate the proposal to hospital leadership to secure early buy–in.

💡 Premature solution selection obscures the real problem and biases evidence collection. Recasting the insight as a structured, solution–agnostic need preserves optionality, enables triangulation across contexts, and anchors later metrics and claims (B).

🎯 B.

# CHAPTER 2

# PROBLEM STATEMENTS AND HYPOTHESIS FRAMING

| HIGHLIGHTS | |
|---|---|
| **Must–Dos** | **Must–Donts** |
| ✔ Write solution–agnostic problem statements with population, setting, workflow step, and measurable outcome. | ✘ Don't bury the problem inside a pitch; avoid solutioneering and buzzwords that mask uncertainty or collapse distinct issues into one omnibus claim. |
| ✔ Frame testable hypotheses as if–then–because statements with a predefined decision threshold, making clear what result will trigger go/redo/stop. | ✘ Don't use vague or vanity outcomes; tie statements to observable metrics with units, time windows, and acceptance criteria. |
| ✔ Define the estimand up front–population, endpoint, treatment condition, intercurrent events, and summary measures. | ✘ Don't rewrite hypotheses post hoc or widen success criteria after interim looks; protect credibility by separating exploratory signals from confirmatory tests. |
| **Key Tips** | |
| 💡 Use a crisp template: "In [population] at [setting/step], the problem is [mechanism of harm], leading to [baseline metric]; we hypothesize [intervention] will change [endpoint] by [effect size] within [timeframe]." | |
| 💡 Pair every primary hypothesis with a null, stopping rule, and sensitivity check (learning curve, site effects, missingness), keeping decisions robust to common real–world violations. | |
| 💡 Align problem and hypothesis with regulatory and reimbursement endpoints early, ensuring what you plan to measure is what clinicians, payers, and regulators will actually care about. | |

*A problem well stated is a problem half solved.*
Charles F. Kettering

Problem statements are the spine of medical innovation, transforming diffuse frustrations into testable claims that can guide design decisions, evidence collection, and ultimately, patentable embodiments without collapsing into premature solutions (**Figure 2.1**).

When teams skip this articulation, prototypes chase symptoms rather than causes, producing elegant devices that underperform clinically, confuse users operationally, or disappoint payers economically despite sounding persuasive in pitch decks. A good problem statement circumscribes scope, names stakeholders, and specifies outcomes, so that hypotheses can be framed as decisions under uncertainty rather than intuition masquerading as strategy. Clarity here reduces rework, aligns incentives, and anchors later claim language, because what is not defined at the beginning becomes expensive to justify when regulators and investors interrogate the value proposition.

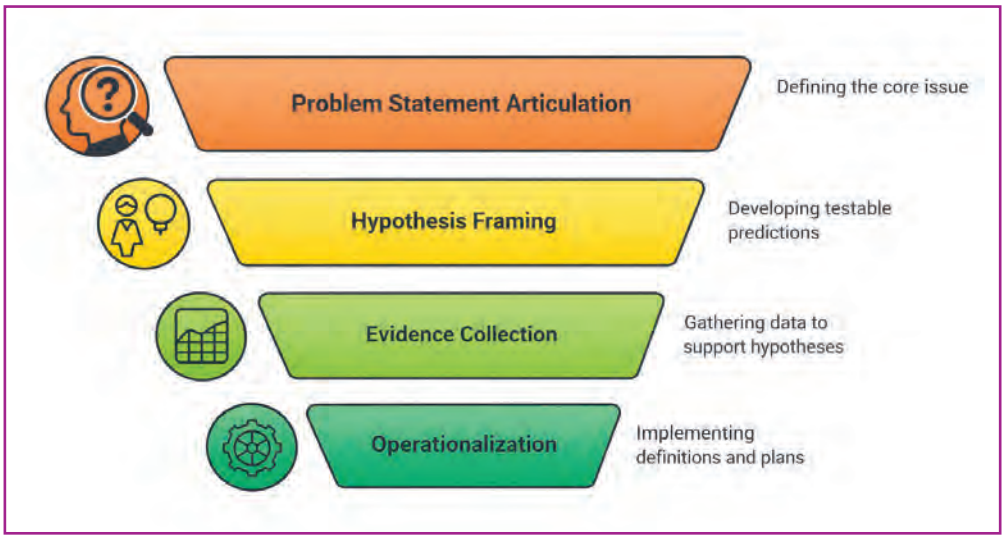



Figure 2.1. Highlights of the medical innovation process.

Anatomy matters: articulate the population, setting, workflow step, and pain mechanism, then enumerate constraints such as training time, sterilization pathways, cybersecurity posture, accessory availability, and reimbursement context influencing adoption likelihood. Couple this with a precise description of the status quo, including competing interventions and their failure modes, so the delta you seek becomes observable rather than aspirational rhetoric. Express the job–to–be–done as a short sentence describing progress desired by a named actor in a specific moment, avoiding buzzwords that mask uncertainty and hide tradeoffs within sparkling generalities. Finally, sketch outcome hierarchies, distinguishing surrogate measurements from patient–centered endpoints, because misaligned metrics can seduce teams into optimizing what is easy to capture rather than what changes lives.

Hypothesis framing translates the problem into falsifiable bets, articulated as if–then–because statements that expose mechanism, boundary conditions, and measurable consequences that can be interrogated with appropriate study designs and early prototypes. Define the estimand by specifying population, endpoint, treatment condition, intercurrent events, and summary measure, because nothing derails teams faster than arguing analysis choices after glimpsing noisy, partial data. State a primary hypothesis aligned to a decision threshold, for example, whether a device reduces fluoroscopy time by five minutes per case without compromising procedural success beyond a prespecified noninferiority margin. Pair this with a concise null hypothesis and predefine what evidence would reverse your belief, making it emotionally safer for teams to pivot rather than rationalize sunk costs.

Choose hypothesis families deliberately: superiority when replacing current practice, noninferiority when reducing burden or cost, and equivalence when interoperability or safety parity enables platform adoption without incremental clinical effect. Directionality matters, as does time horizon; articulate whether benefits are immediate procedural effi-

ciencies, short–term adverse event reductions, or long–term survival gains that demand different study windows and follow–up burdens. Anchor effect sizes in clinical decision thresholds rather than arbitrary round numbers, using prior literature, expert elicitation, and pilot observations to avoid underpowered wishfulness or overpowered trivialities that waste resources. Declare key assumptions about mechanisms, adherence, learning curves, and context, because hidden dependencies masquerade as surprises later, eroding credibility when results diverge from intuitive product narratives and partner expectations.

Collect early evidence with methodological pluralism, triangulating ethnographic notes, usability observations, retrospective data pulls, and micro–experiments that stress the mechanism you believe drives benefit rather than merely demonstrating mechanical function under ideal conditions. Use negative controls and falsification tests deliberately, because hypotheses that survive hostile conditions accumulate credibility faster than those pampered by confirmatory setups and fragile endpoints vulnerable to operational noise. Document sampling frames, missingness patterns, and measurement error explicitly, so the downstream statistical analysis mirrors reality rather than a sanitized story wrapped in attractive graphics and confident voiceover. Where possible, pre–register critical hypotheses or at least time–stamp internal protocols, creating accountability that tempers post hoc rationalization and clarifies which decisions were exploratory rather than inferentially confirmatory.

Operationalize constructs with clear definitions, measurement plans, and acceptance criteria, because words like efficiency, usability, and safety camouflage multiple interpretations unless pinned to instruments, scales, thresholds, and adjudication procedures understandable by clinicians and regulators. Specify data provenance and governance, decide how protocol deviations will be handled, and describe interim looks, stopping rules, and multiplicity adjustments, since analytic discipline is part of ethical responsibility when patients and resources are at stake. Build sensitivity analyses into the plan, exploring robustness to plausible violations of assumptions about missing data, learning curves, or site effects that frequently complicate early adoption of novel procedural tools. Above all, link each hypothesis to a practical decision, such as escalate development, redesign, pause, or sunset, because hypotheses without decision hooks encourage endless analysis detached from responsible portfolio management.