ROHINI
COLLEGE OF ENGINEERING & TECHNOLOGY
(AUTONOMOUS)
Approved By AICTE & Affiliated to Anna University
NBA Accredited for All Eligible B.E/B.Tech Programs | NAAC Accredited with A+ Grade
Near Anjugramam - Kanyakumari Main Road, Palkulam, Variyoor P.O.-629401, Kanyakumari Dist, Tamil Nadu.

DEPARTMENT OF BIOMEDICAL ENGINEERING
VI Semester
BIOMEDICAL DEVICE DESIGN
UNIT- I INTRODUCTION TO BIOMEDICAL DEVICE DESIGN AND CLINICAL NEED IDENTIFICATION

1.3 Clinical Need Identification and Problem Definition:

➢ **Why start with a clinical need?**

Most failed medical products fail not because the engineering is poor, but because they solve a problem that clinicians, patients or payers do not actually have, or do not value enough to pay for. Successful device design therefore begins with a **well-characterised clinical need** rather than with a technology.

Table 1.15 Need-pull versus technology-push innovation

Aspect	Need-pull (needs-based)	Technology-push
Starting point	An observed unmet clinical problem	A new technology, material or invention
Question asked	"What problem is worth solving?"	"Where can this technology be used?"
Risk	Lower; user demand is validated early	Higher; solution may not match a real problem
Typical outcome	Clear target users and value proposition	May need years to find an application
Example	Low-cost infant warmer for rural hospitals	Laser technology searching for medical use

> **Key idea**
> Principle of needs-based design: **"A well-characterised need is the DNA of a successful medical technology."** Define the problem first, delay the solution.

➢ **Clinical need identification process**

A widely used framework (Stanford Biodesign "Identify" phase) divides the early stage into need finding, need screening and need statement, followed by need criteria and selection. The sequence is iterative: new observations may force the team to revise the need statement.

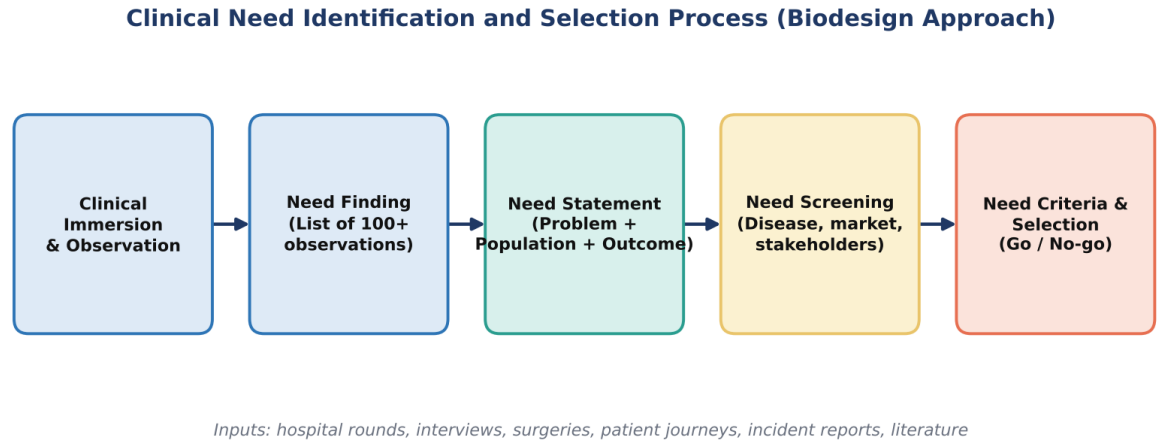


Fig. 1.9 Clinical need identification and selection process

Step 1: Clinical immersion and observation

Engineers observe in the real clinical environment instead of relying on imagination. The aim is to collect many raw observations (typically 100 or more) without jumping to solutions.

Table 1.16 Methods of need finding

Method	What is done	What it reveals
Clinical immersion / shadowing	Spend days in wards, OTs, ICUs, labs and clinics watching procedures and workflows	Workarounds, delays, errors, unmet needs
Stakeholder interviews	Structured and open interviews with doctors, nurses, technicians, patients, caregivers	Pain points, priorities, constraints
Patient journey mapping	Trace the patient from first symptom to follow-up	Gaps in diagnosis, treatment and follow-up
Literature and guideline review	Study journals, clinical guidelines, epidemiological data	Disease burden, standard of care, evidence gaps
Adverse event databases	Review incident reports (for example the US FDA MAUDE database, India Materiovigilance Programme)	Known device failures and use errors
Surveys and questionnaires	Collect quantitative data from many users	Frequency and ranking of problems
Market and patent scan	Study competitor products and patent landscape	Existing solutions and white space

Step 2: Need statement

The observations are converted into a short, solution-independent statement. A good need statement contains three elements: the **problem**, the **population** affected and the desired **outcome**.

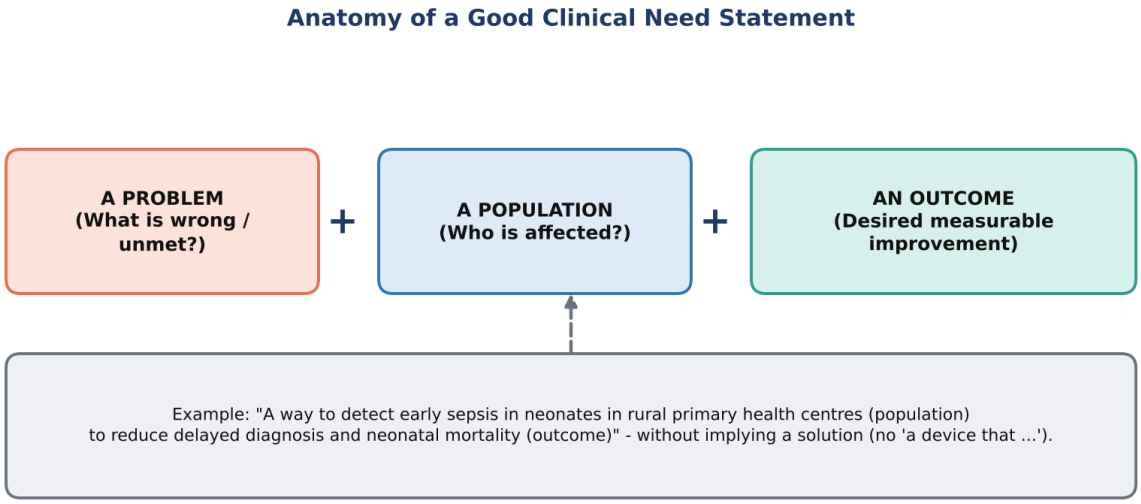


Fig. 1.10 Anatomy of a good clinical need statement

Table 1.17 Good versus poor need statements

Poor (embeds a solution)	Better (solution-independent)	Why better
"A new glucometer with Bluetooth"	"A way for elderly diabetics to track blood glucose without finger pricks, to improve adherence and glycaemic control"	Defines user and outcome; many solutions possible
"A smart bed with sensors"	"A way to prevent pressure ulcers in bed-ridden patients to reduce hospital-acquired infections"	Focuses on the clinical problem
"An AI app for X-ray"	"A way to detect pulmonary tuberculosis early in remote areas lacking radiologists to reduce diagnostic delay"	Highlights context and benefit

Step 3: Need screening

Each need statement is tested against four broad criteria so that effort is directed towards needs with real potential.

- **Disease state fundamentals:** incidence, prevalence, mortality, morbidity, risk factors, current standard of care and its limitations.
- **Existing solutions:** products, procedures, drugs and workarounds already available and their shortcomings.
- **Stakeholder analysis:** patients, physicians, hospitals, payers, regulators and suppliers; who benefits, who decides and who pays.
- **Market analysis:** total addressable market (TAM), serviceable market (SAM), obtainable share (SOM), pricing, reimbursement and competition.

Step 4: Need criteria and selection

The surviving needs are scored using weighted criteria. Teams commonly use a **needs filter** (decision matrix) to rank them objectively.

Table 1.18 Example weighted needs filter (score 1-5)

Criterion	Weight	Need A: neonatal jaundice screening	Need B: wound monitoring	Need C: sleep tracking	Notes
Clinical impact (severity, patients affected)	30%	5	3	2	High neonatal burden
Market size and reimbursement	20%	3	4	4	Public health programmes
Feasibility (technology, regulatory)	20%	4	3	5	Optical sensing known
Competition and IP freedom	15%	3	3	2	Few low-cost options
Team fit and resources	15%	4	3	3	Optics expertise
Weighted total	100%	3.95	3.20	3.15	Need A selected

(Calculation for Need A: 0.30 x 5 + 0.20 x 3 + 0.20 x 4 + 0.15 x 3 + 0.15 x 4 = 1.50 + 0.60 + 0.80 + 0.45 + 0.60 = 3.95. Need A scores highest and is selected.)

➢ Problem definition

After a need is chosen, the team must define the problem precisely enough to guide design. **Problem definition** states what must be achieved, for whom, under what conditions and within what limits, without prescribing the solution.

Table 1.19 Elements of a good problem definition

Element	Description	Example
Background	Disease or clinical context and current practice	Neonatal jaundice detected by visual inspection
Stakeholders	Primary users, secondary users, decision makers	Nurses, mothers, paediatricians
Gap	What current methods fail to do	Subjective, inaccurate in dark skin tones
Objective	Measurable target outcome	Detect bilirubin > 12 mg/dL with +/-1.5 mg/dL accuracy
Scope	Boundaries: what is in and out of the project	Screening tool; confirmatory test excluded
Constraints	Cost, environment, regulation, skills	< Rs. 5,000; no electricity for 4 hours/day

Element	Description	Example
Success criteria	How success will be judged	Sensitivity > 95%, nurse can use after 10 min training

Tools for analysing the problem

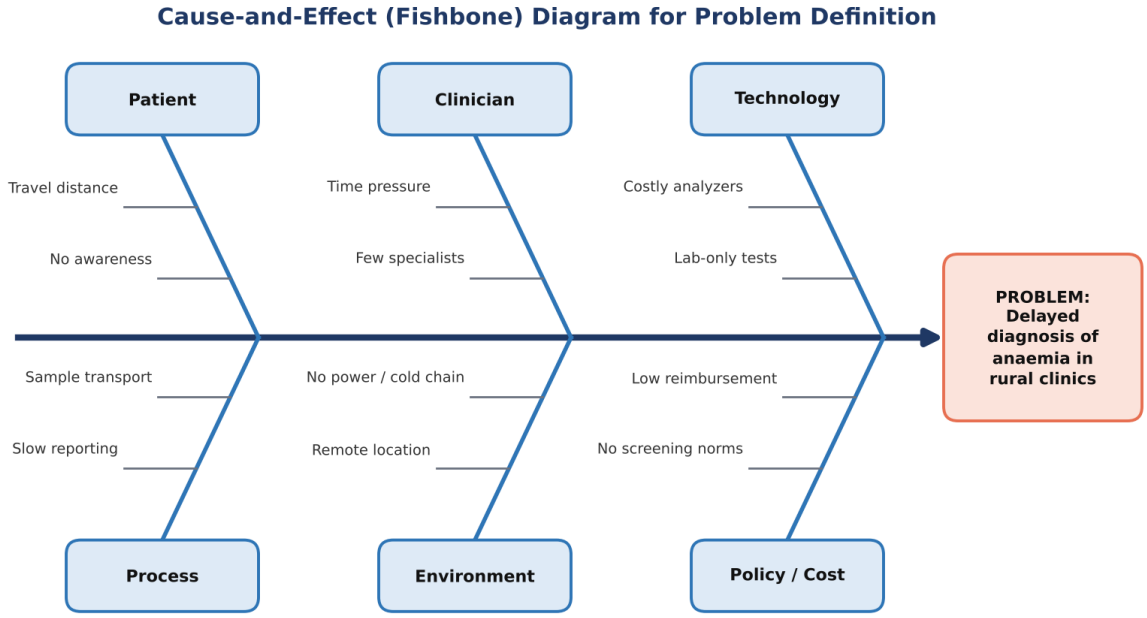


Fig. 1.11 Cause-and-effect (fishbone) diagram for problem definition

Table 1.20 Problem analysis tools

Tool	How it works	Best used for
5 Whys	Ask "why?" repeatedly (usually five times) until the root cause is reached	Finding a single root cause
Fishbone (Ishikawa)	Group causes under Patient, Clinician, Technology, Process, Environment, Policy	Brainstorming multiple causes
Problem tree	Show causes as roots and effects as branches of the core problem	Linking causes to consequences
Pareto analysis	Rank causes by frequency; the vital few cause most problems (80/20 rule)	Prioritising effort
Stakeholder map	Plot stakeholders by power and interest	Engaging the right people
Task and workflow analysis	Break the clinical procedure into steps and find friction	Usability-driven problems

Problem statement versus need statement

- The **need statement** is a short, solution-free description of the unmet clinical requirement (what is wrong, who is affected, what outcome is desired).

- The **problem statement / design brief** expands it with background, goals, scope, constraints and success criteria, and guides the engineering team.

➢ **Worked example: neonatal jaundice screening**

- **Observation:** In primary health centres, nurses judge jaundice by looking at the baby's skin. Results vary with lighting and skin tone, and lab bilirubin tests are far away.
- **Need statement:** "A way to screen newborns for clinically significant jaundice at the primary health centre, without blood sampling, to enable early referral and prevent kernicterus."
- **Disease facts:** Severe hyperbilirubinaemia can cause brain damage; early detection by screening is cost-effective.
- **Existing solutions:** Visual assessment (inaccurate), transcutaneous bilirubinometers (expensive), serum bilirubin (invasive, lab-based).
- **Stakeholders:** Newborn, mother, ANM/nurse, paediatrician, PHC administrators, government health scheme.
- **Design brief:** Low-cost, battery-operated, non-invasive optical screening device with a simple traffic-light output usable by minimally trained staff.

Remember

Exam tip: Sketch the need identification flow, define a need statement with problem + population + outcome, and illustrate with one real example (such as jaundice, sepsis, or anaemia screening).