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Systems Engineering for the ED – Systems Engineers Section
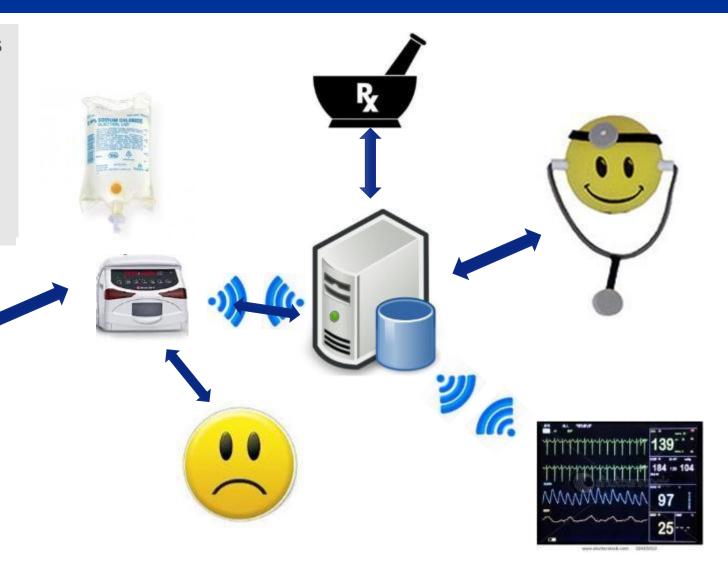## or

Designing Products that Customers Like – Using Observational Studies to Improve Safety and Satisfaction

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January 31, 2016

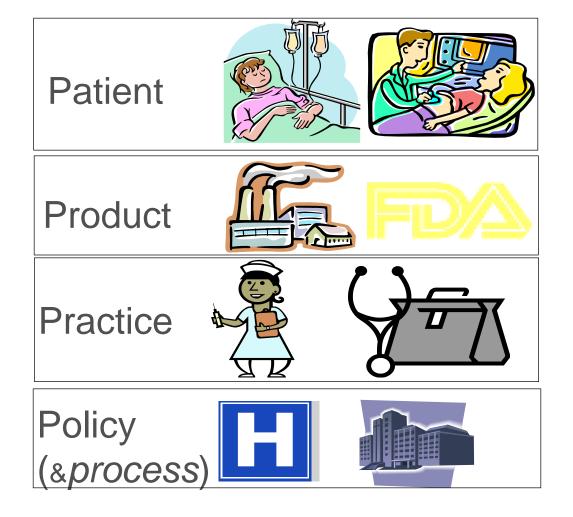In the future, devices will be more context aware, enabling clinicians to make smarter healthcare choices.

All these innovations, yet…

John's Hopkins has an infusion pump safety project [AHRQ grant HS20460], and at a project kickoff meeting, the first thing that their nurses brought up was air-in-line alarm sensitivity. The nurses wanted the manufacturer's to make a less sensitive alarm, and did not know that their hospital policy sets the alarm threshold.

A manufacturer performed an analysis of dose limit usage across 471 hospitals. 51% of hospitals did not have hard upper limits on a critical drug.

Monitors are not being properly set for the patient age / condition, resulting in alarm fatigue. [Alarm Fatigue: MedSun Small Sample Survey Summary, MedSun Newletter #65, October 2011]
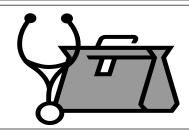
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4P Framework – Ideal State

Patient

Product

Practice

Policy (&*process*)

Misalignment

Patient

Product

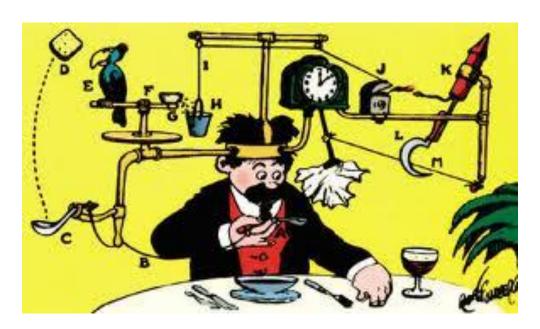Practice

Policy (&*process*)

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Opportunities

Step 1: Traditionally, engineers innovate incrementally within the current definition of "the system"

Step 2: When engineers exhaust the innovation opportunities within a system, we then redefine the system & add more features.

Step 3: Repeat

However, engineers need to look back to see if customer's are actually using these innovations, and if not, find out why.

Step 1: Look for workarounds, signs, notes, and unused features.

Step 2: Then find out which 4P elements are not aligned.
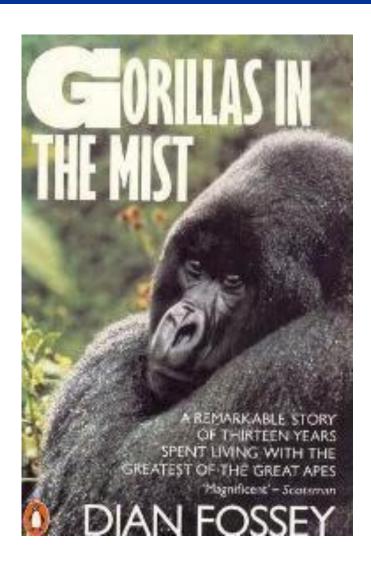
Step 3: Repeat.

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Customer's don't want more medical devices, they want solutions to their problems. People buy to add value to their lives.

As designers, we think of clever ways of meeting <u>perceived</u> user needs.

My management prefers clever ways of meeting <u>actual</u> needs.

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What is an Observational Study?

Diane Fossey was an anthropologist and spent over a decade studying primates in their native environment.

Perhaps a similar field study of Clinicians would find hidden user needs.

Places to Look for Innovation Opportunities

Look in the direction that no one is looking – many times unmet user needs come from unmet users.

Look at the entire use cycle / life cycle of the product – many teams focus on the primary use case, but ignore the secondary and tertiary uses.

Look for post-it notes, signs, workarounds – these compensate for defects.

Look at adjacent equipment – can your product do their work?

Look at what users do immediately before and after using your device – can your product do their work?

Look at how users make decisions – this drives how they use -- or chose not to use -- your product.

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Questions to ask yourself:

What organizational challenges exist at customer sites that prevent or slow the adoption of new innovations.

What existing systems (obvious and non-obvious) does your device need to work within?

Do customers need new features, or do they need to use the existing features? What features do customers use often vs. not even aware they exist vs. misuse? This is a good gage for both your and your competitor's products.

Look for legacy products that are still in use – find out why.
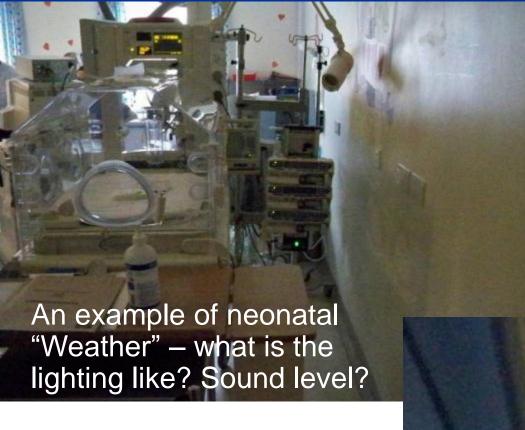
Document and Challenge Your Assumptions

Assumptions need to be perpetually challenged.

You won't know all your assumptions until you find a counter-example. So be vigilant.

Watch for assumptions in both directions – assuming factor X is very important to the user, and assuming factor Y is unimportant; assuming A is easy to do but B is complicated…Sometimes you have to ask "obvious" questions to validate those assumptions.
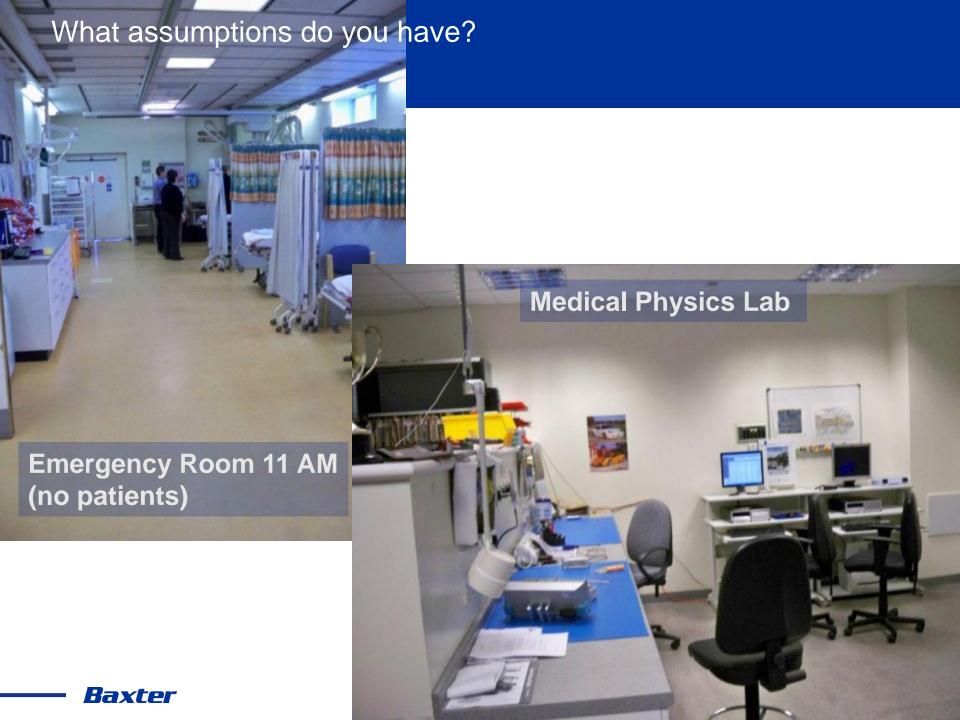
Gaining Customer Intimacy…

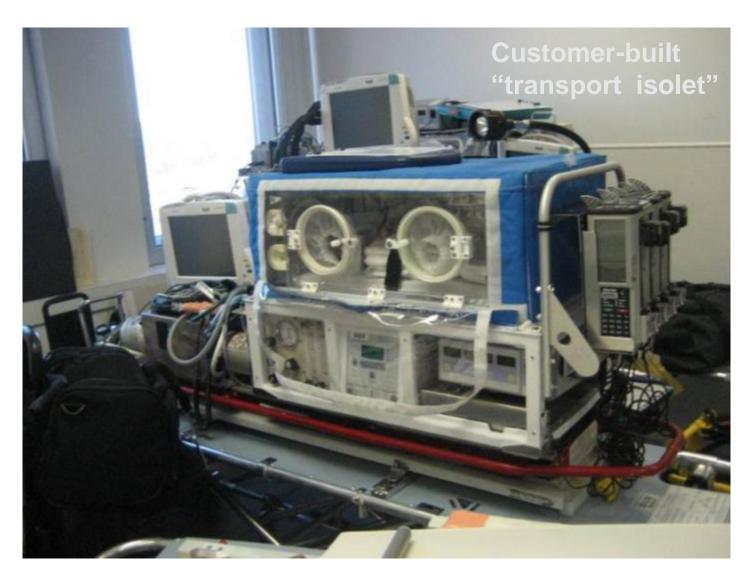An example of neonatal "Weather" – what is the lighting like? Sound level?

Difficult access to equipment.

Note: Patient weighs 960gm

What assumptions do you have?

Emergency Room 11 AM (no patients)

Medical Physics Lab

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Customers create their own Systems…

Customer-built
"transport isolet"

Are your products used in isolation?

Biomed Areas…

This is the device inspection area.

Photo shows the entire repair shop for a 220 bed hospital.
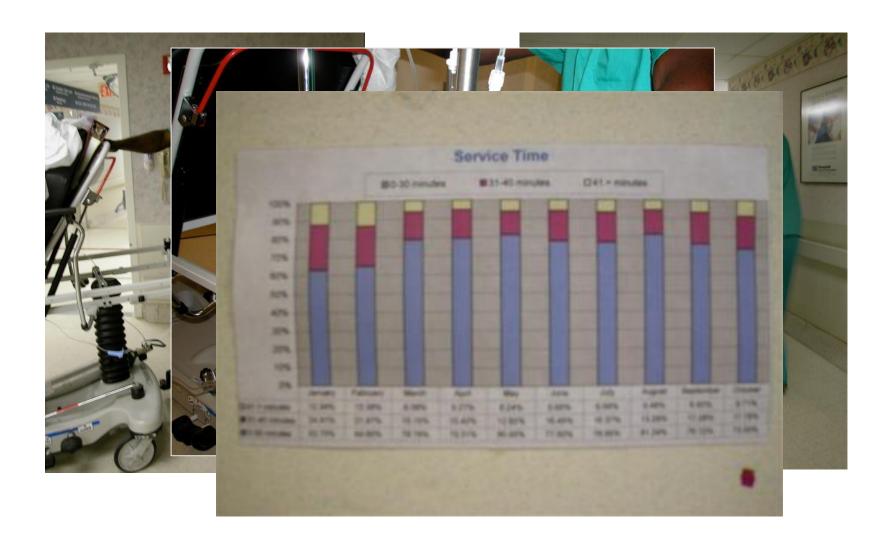
What do cleaning and storage areas look like?
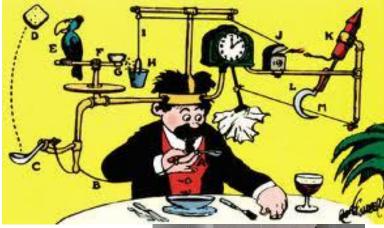
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How are patients (& devices) transported?

To Recap…

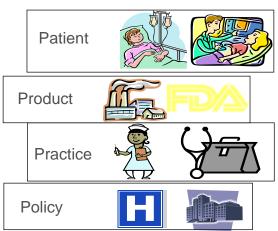Innovation comes by solving your customer's problems.

Observe
Observe
Observe
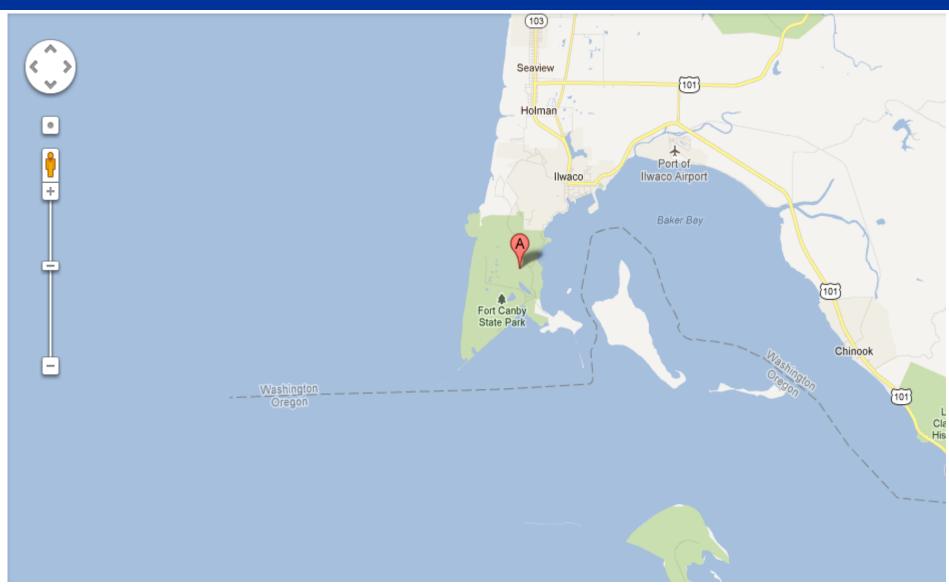

To understand the customer, develop a level of intimacy with them.

Find the alignment gaps and come up with solutions

Patient	
Product	
Practice	
Policy	

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What can we learn from fur traders in the 1800s?

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Questions?

Annex – Lessons Learned from Planning

Defining Boundaries

It's important to realize what this research is NOT:

Does not take the place of focus groups, key opinion leaders, surveys, etc.

While anthropological research often overlaps with Human Factors, that's not its only use.

It is not a way to make design decisions; it is however a feeder into the decision process

Not everyone has the skills and temperament for anthropological research.

Who & What to Observe?

What regions?

What care sites?

What care areas within a site?

What areas are you NOT going to look at and why?

What user tasks do you want to see?

What "corner cases" or "extreme uses" exist?

What tasks are you NOT looking for?

Observational Studies – Planning Example

Local / Regional / Teaching Hospitals

< 100 / 100 – 249 / 250 – 500 / 500 + beds

5 US regions + Canada

General Floor / L&D / Oncology / (N)ICU / Recovery

5 – 8 sites
3 teams of 2 Observers
Shadow for 2 hour shifts / 3 shifts.
Cover 3 – 9 Care Areas per site

Seek out dynamic & corner cases..

Shadow a transport

MRI / hyperbaric / burn center / isolation room

Observe night shift / weekend shift

Collect environmental data..

Temp / humidity / light / noise

devices / # lines / # blinking lights

Before you travel anywhere…

What kinds of formal training does the team need?

- Complaint handling
- Patient privacy
- Environmental Health (e.g. prevent team members from getting sick)

What kinds of informal training does the team need?

What are the different roles of the different team members?

What are the strengths of different team members?

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Logistics

We tapped our sales force to provide access to most of the accounts. They have the best relationships with the customer.

We tapped social networks – a friend of a friend was a nursing supervisor.

Some facilities have a shadowing program – follow a clinician for a few hours.

Split into sub-teams of 1-2 people each. Did not want to overwhelm a customer with a 6-person entourage. A buddy system allows one person to ask questions while the other takes notes.

Allow flexibility in the schedule to chase opportunities as they present themselves.

Take exterior photo of facility at start of day. Take photo for each ward as you enter – makes it much easier to sort out which photos are from which unit later.

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For Every Site Visited…

Pre-Travel – Contact local sales support – they have access and local knowledge. Suggest they follow a team, if they'd like.

Travel !

Pre-visit (day of visit)– Met local sales support face to face; last-minute briefings; determine assignments for the day.

On-Site: Introduction – Meet on-site liaison(s). Describe the goals and plan for the day

On-Site: Observe – Shadow, interview, observe

On-Site: Wrap up – End-of-day summary with liaison & sales support

Lessons Learned – End-of-day summary with team, major learnings, adjustments to process & forms.

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Unexpected Benefit - Leveraging Observational Opportunities

What we found in the planning stage is that Observational Studies can gather valuable ancillary information that affects device design:

"The Weather" – temperature, humidity, lighting, noise

Room layouts & flow – patient rooms, nurses station, repair bench, pharmacy

Count ceiling tiles and pace-off distances to get reasonable measurements

Cognitive environment for users

Competitive Intelligence gathering

Task frequencies for reliability assessments

Takeaway: With a little planning, you can use Observational Studies in new ways

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