Unmet Needs Analysis
Innovation in Med-Tech
IDR Medical’s focus is on working with our clients to define and scope next generation products. A key element in this task is to identify unmet need in the current generation of medical devices. This is a challenging task for a number of reasons…

Finding common reference points is challenging

- Perceptions of unmet need are often tied to the products currently available to the clinicians
- Often multiple products, brands and generations of product are present in their place of work, making common reference points difficult

Unmet needs are not typically obvious

- Clinicians and patients using medical devices in their daily work tend not to be able to imaginatively identify unmet needs or areas for improvement, unless these are very obvious, i.e. there is already an identified problem, which is rare

Unmet need is not always defined by incumbent technologies

- Unmet needs are not necessarily defined by perceived limitations of incumbent technologies
- When users of medical technology are questioned on unmet needs they tend to focus on the parameters delivered/not delivered by current devices, i.e. they don’t identify peripheral unmet needs which could be delivered by future products

Clinician mindset

- Even when clinicians are prompted with innovative ideas they don’t find it easy to prioritise these outside of their work environment i.e. they need context

As a result, IDR Medical has developed a comprehensive approach to identifying unmet need, which utilises workflow analysis, human factors research, clinician diaries and qualitative and quantitative research methodologies to uncover unmet need and drive device innovation. This approach addresses a wide range of clinician types in a variety of medical settings and where relevant, can also include patients.
Unmet Needs Analysis (UNA) in Product Development

Summary of approach...

**Set Up**

**Approach**
- Define customer touch points
- Understand potential innovation routes

**Outputs**
- Agree research approach

**Device Use & Workflow Analysis**

**Approach**
- Viewed Assessment & Analysis (VAA)
  - Onsite Audits
  - Clinical Simulation Center
  - Viewing Facility

**Outputs**
- Analysis by Customer Touch-point
- Prioritization
- Innovation Assessment Tool

**Validation**

**Approach**
- Web Surveys
- Max Diff
- Conjoint

**Outputs**
- Validation

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TM = Meeting with Core Project Team
The objective of the project set up is to define the customer touch points of the product category and gather internal perspectives on potential innovation routes

- This is achieved via an initial project workshop, followed by a period of analysis to assimilate data and a follow up meeting to agree the methodology.
Unmet Needs Analysis (UNA) in Product Development

IDR Medical work with the client to define customer touch points and workflows…

Core Users

- IDR Medical work with the client to define the desired outcomes of the device "the jobs it needs to get done"
- These desired outcomes are mapped for the primary users of the device and are typically structured into workflows with supporting tasks

Other Customer Touch-points

- Other customers' touch-points are also considered and the relevant workflows and tasks mapped

<table>
<thead>
<tr>
<th>Core Users</th>
<th>Other Customer Touch-points</th>
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<tbody>
<tr>
<td>Surgeon</td>
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<tr>
<td>Nurse</td>
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<tr>
<td>Biomedical Engineer</td>
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Set Up
A second component of the project set up is to identify and scope potential directional routes for device innovation

- This is done in conjunction with the client team
- Although there are exceptions, the general "innovation categories" are the mostly the same, these categories are not mutually exclusive, but provide a logical framework for idea generation
- For each category, the potential for innovation is discussed and ideas brainstormed, the potential innovation opportunity is assigned to 1 of 3 buckets based on the perceived level of effort & investment required; LOW/ MEDIUM/ HIGH
- During the primary research these innovation ideas are tested to evaluate potential market impact

### Typical “Innovation Categories”

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<tr>
<th>Category</th>
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<tbody>
<tr>
<td>Clinical Efficacy &amp; Patient Outcomes</td>
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<tr>
<td>Use Profile: Indications, Settings</td>
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<tr>
<td>Physical Factors: Size, weight, form factor</td>
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<tr>
<td>Usability/Ease of Use (User interface etc.)</td>
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<tr>
<td>Efficiency &amp; Cost Reduction</td>
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<tr>
<td>Other Performance Factors (Durability/ Maintenance)</td>
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Unmet Needs Analysis (UNA) in Product Development

The appropriate qualitative methodology is selected for the viewed assessment and analysis

Device Use & Workflow Analysis: Qualitative Insights

Viewed Assessment & Analysis (VAA)

- In depth assessment of how the device is used in target environment(s), respondents ‘use’ & physically demonstrate devices. Focus on most up to date, state of the art devices
- IDR Medical utilize the following research environments for the Viewed Assessment & Analysis (VAA)
- The optimal environment(s) selected depends on the type of device, the care setting in which used and the importance of context and the workflows in which it is used
- In addition, the potential areas for device innovation & development (clinical impact, form factor, UI, connectivity etc.) are also a factor

1. Onsite Audit
   - Most realistic, actual setting
   - Spatial & logistical factors
   - Complex usage workflows
   - Constraints on access
   - No/minimal viewing/video capture

2. Clinical Simulation Centre
   - Replicates actual setting (less so than on-site)
   - Replicates high acuity/sensitive areas
   - Simulates complex workflows
   - Potential for viewing & video capture

3. Viewing Facility
   - Non replica setting, no environmental interaction
   - Devices with less complex usage workflows (standalone)
   - Most developed viewing opportunity & video capture
The vast majority of IDR Medical's Unmet Need Analysis projects are focused on clinicians, from a wide range of specialities including physicians, nurses and other health care professionals.

Patient research is also a key area of focus, in particular where patient interaction with the device is critical.

The most common driver of patient research is where compliance/adherence factors are an issue in treatment.

The Viewed Assessment & Analysis (VAA) provides 2 key information sources:

**Observation:**
- Assessing how the respondent uses and interacts with the device (in whichever research setting is utilized)

**Discussion:**
- Identifying challenges, issues and bottlenecks in use of the device and in the context of the clinician’s work and patient care in general
- Investigating opportunities to improve the user experience & enhance workflows

A combination of human factors experts and highly experienced qualitative moderators can be used depending on where focus of development lies.

Skilled interviewers identify opportunities which are not necessarily anchored to the device itself i.e. more general ways to improve efficiencies or patient care, but not so far away from the device that the discussion is irrelevant.

**Clinicians**
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**Patients**
- Patient research is also a key area of focus, in particular where patient interaction with the device is critical.
- The most common driver of patient research is where compliance/adherence factors are an issue in treatment.
Use Diaries

- Use Diaries may be employed after VAA
- Areas of interest (challenges & opportunities) identified in VAA can be further investigated in this phase plus identification of other unmet needs & opportunities
- Diaries enable the assessment of actual experiences with the device in daily use with patients (which is rarely possible, even during On-site Audits)
- A range of techniques and technologies can be used, including video, audio and written diaries supplemented by questionnaire/survey interaction which also utilizes a range of technologies (web/app etc.)
Unmet Needs Analysis (UNA) in Product Development

Project outputs include a map of unmet need by customer touch-point and an innovation assessment tool that can be used to gage the success of potential innovations.

- Unmet needs are defined by user group, and assigned to the relevant innovation category.

Unmet Need Analysis by Customer Touch-point

- Qualitative research can provide a high level prioritization of the unmet needs identified.

Prioritization of Unmet Need

- Additional quantitative research can be undertaken to validate this with a more representative sample demographic (See next slide).

Innovation Assessment Tool

- As part of the deliverable IDR Medical provides a reference tool which can be used to gage the success of potential innovations.

- A simple points system is used to quantify the anticipated value an innovation presents, considering the unmet needs it can fulfill.

- This can make follow up VOC research targeted at a specific concept more efficient.
An additional phase of quantitative research can be undertaken to quantify and prioritize unmet need

Quantitative Research

- This phase of research is typically conducted as a web survey, with a representative sample demographic.
- A variety of quantitative techniques can be used. Max Diff is a common approach undertaken by IDR Medical in UNA and can be used effectively to prioritize a set of actionable need statements.
- Quantitative research tends to be undertaken once the client company has assimilated the information and moved to the next phase of concept development.
- As such, this phase of research is typically incorporates high level concept testing components in addition to unmet needs quantification.