A Voice of the Customer Process for Medical Device Development

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Abstract. Medical device developers are always looking for an optimized method to translate a clinical need or a problem into a device, service, or combination product. Established companies are searching for methods to improve this transition, and newer companies, in general, do not have this capability in any form. Using a Voice of the Customer (VOC) process on a new problem or just to improve on an existing product is a systematic and effective way to listen to the stakeholders and glean information that allows a team to be truly innovative in the solution and ultimately better meet the stakeholders' needs. Battelle's Medical Device Solutions (MDS) team has developed a standardized, scalable approach to performing VOC as part of our medical device design and development process.

Introduction

VOC can be defined as the collective insight into customer needs, wants, perceptions, and preferences gained through direct and indirect questioning. (BusinessDictionay.com 2009) The value of a VOC effort has been shown in many studies to decrease the amount of work on the back end of product development significantly, where changes are more costly. (Mello 2002, 17-8) The Food and Drug Administration (FDA), which regulates medical devices, repeatedly states the importance on the systematic development of a product which meets the needs of the users in its publications and guidance documents. The VOC process is vital in the development of a device or combination product that meets the needs of the users, fits within the environment appropriately, and will be accepted in the market. The VOC process is the beginning phase of the overall product requirements development process, as shown in Figure 1. Note that the use of the term "customer" in this paper refers to the end-user (doctor, nurse, patient, etc.) that will be affected by the product or service eventually developed from this effort.

Nothing Product Specific

- Interview transcripts
- Survey feedback

NEED
Problem Statement

SURVEY
Written
Focus Group
1-on-1 Interview

VOICE OF CUSTOMER
I want…
I need…
You have to have...

Grouped and Ranked
VOICE OF CUSTOMER

Requirements

House of Quality Input

- Review exisitng data
- Create customer profile
- Create interview guide

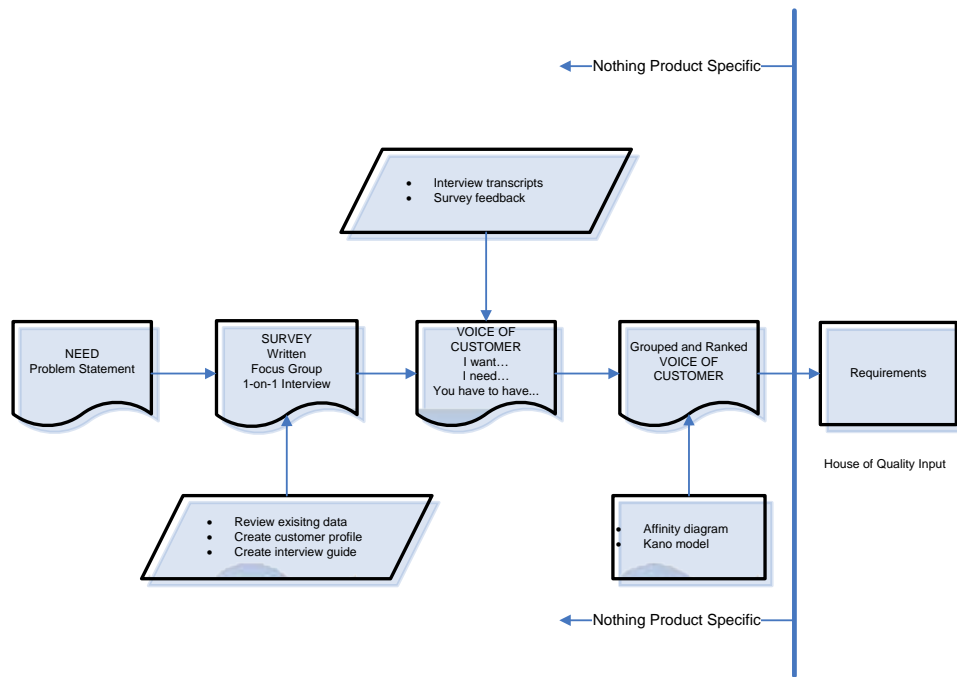- Affinity diagram
- Kano model

Nothing Product Specific

Figure 1. Requirements Development Process

The high-level steps for conducting a VOC study are:
1. Develop the VOC Objective Statement
2. Review the Existing Data to Gain Background Knowledge
3. Develop the Customer Profile Matrix
4. Develop an Interview Logistics Plan
5. Create the Interview Guide
6. Conduct the Interviews
7. Derive the Requirements

Develop the VOC Objective Statement

The objective statement should identify a problem or question, but not a solution. Burchill and Brodie (2005) recommend the use of language such as "to learn," "to discover," and "to explore" to convey the exploratory and investigational nature of the VOC process.

For the purpose of illustration, a fictional consumer/medical products company has created a VOC team. This team is tasked with investigating the healthcare environment as it relates to the H1N1 flu virus. They may create the following objective statement:

- "To learn what materials and equipment are needed in order to improve patient outcomes and reduce professional exposure to the H1N1 virus."

Team members representing different design and development disciplines will have different views on the objective of the VOC study. However, the goal is a single, reasonably simple and concise objective statement. An effective method for this exercise is the affinity diagram (Brassard and Ritter 1994), where each team member submits an objective statement on a

self-stick note, then assembles them into logical groups. The team then decides which group best represents the study objective, and consolidates the ideas within the group into a single statement.

Once the team has settled on the objective statement, it should be refined to the appropriate level of abstraction: (Burchill and Brodie 2005)

- If the objective is too broad or general, the team risks getting too off-topic during the interviews and having too much data to process.
- If the objective is too narrow or specific, the team risks missing out on "outside the box" thinking or key areas of innovation.

With the above guidelines in mind, the team writes the objective statement more broadly. If the new statement sounds acceptable, it is adopted and the broadening process is repeated. If the new statement is not acceptable (i.e., the original objective statement is sufficiently broad), the team tries writing the original statement more narrowly. If this new statement is acceptable, it is adopted and the narrowing process is repeated. Otherwise, the existing statement may be accepted as the objective. This process ensures that the objective statement is at the proper level of abstraction, given the scope of the VOC effort.

Review the Existing Data to Gain Background Knowledge

Before getting too far into the VOC process, VOC teams should ask themselves a critical question: "Should the VOC effort be undertaken at all?" If the market segment they are attempting to enter is already crowded, or there are products/processes in existence that accomplish the outcome of the team's stated objective, it may be wise to use or build upon the already available products or processes. If that is the case, the objective of the VOC will need to be changed in order to 1) find a segment of the existing market that is not currently being tapped and "drill down" to uncover unmet needs to capitalize upon, or 2) to look at the existing problem with a fresh perspective, highlighting areas of opportunity.

The point of the data review exercise is to obtain background and a general knowledge base so the team is not completely new to the area of focus, and understands the state-of-the-market in the area of focus. Aspects that can be explored include:

- Who or what is considered best-in-class in the areas you are focused on?
- Where is the product/process concept on the diffusion of innovation curve? (see Figure 2)

Depending on whether the product/process requires invention, innovation, or refinement will dictate the position on the curve. A product/process positioned farther to the right may not be a viable source of future revenue necessary to offset development costs.
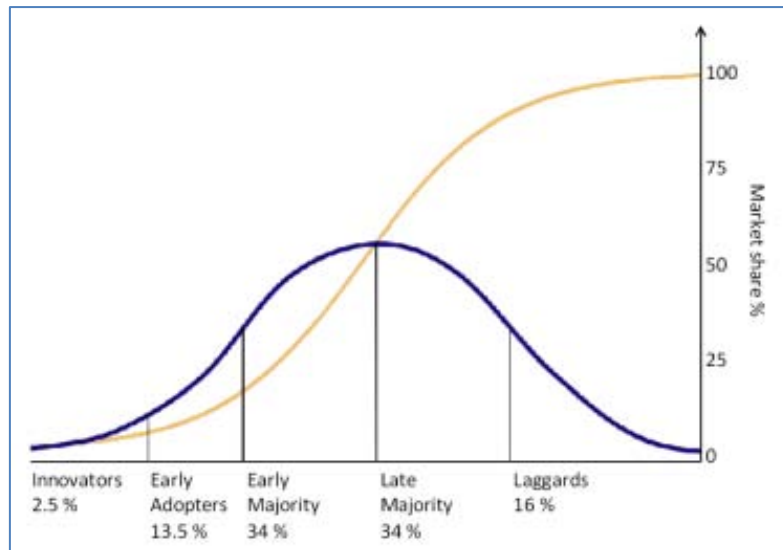
Figure 2. Innovation Adoption Curve (Rogers 1962)

The purpose of reviewing existing data is to give the team a strong background in the environment they are exploring. Areas for research may include:

- Client background presentations
- Internet searches
- Existing products and services
- The FDA's Manufacturer and User Facility Device Experience (MAUDE) complaint database and histories
- Journals and trade magazine articles

Thorough review of existing data helps the team avoid duplicating the efforts of others in the research area, and provides context for determining who and what to ask to obtain the VOC.

Develop the Customer Profile Matrix

Obtaining representative and diverse perspectives is critical – what is referred to as the "360° Perspective." (Burchill and Brodie 2005) The key is to use both traditional and non-traditional customer segments, as shown in Table 1.

Table 1: Traditional and Non-traditional Customers

External Projects		Internal Projects	
Traditional	**Non-traditional**	**Traditional**	**Non-traditional**
Industry or sector	Lead users/thinkers	Functions, departments, divisions	People who have worked to solve the issue
Large , med., low volume users or purchasers	Happy customers	Positions in chain of command	People who have resisted solving the issue
Product application (lab, institution, home)	Demanding customers	Position in internal process	Outspoken or demanding employees
Position in supply chain	Dissatisfied customers	Facility (plant, regional center, corp. office)	Conformers
Geographic location	Former customers		Opinion leaders
Economic group	Customers you'd like to have		Influencers
Gender	Leading researchers (academic and corp.)		
Educational level			

The team starts building a customer profile matrix (Burchill and Brodie 2005) by brainstorming populations, classes, and/or organizations that fit the profiles for the traditional customer segment for the product or process the team is researching. Once the customer segments are identified, the customer profile matrix is created by placing the traditional customer segments down the left side and the non-traditional customer segments across the top (see Table 2). Finally, the team chooses which segment combinations to interview (e.g., leading laboratory users) based on the objective of the study (15-20 types of customers are usually sufficient). Table 2 shows what a completed customer profile matrix could look like for a VOC effort exploring H1N1 outcomes, as described earlier. The numbers in selected boxes represent the target number of interviewees for each customer segment combination.

Table 2: Customer Profile matrix

		Leading	Happy	Demanding	Dissatisfied	Former
Home Users	Users	1		2	1	
	Buyers		1		1	2
Healthcare Professionals	Users	1		2	1	
	Buyers		1		1	2

Develop an Interview Logistics Plan

Based on the customer profile matrix, the team should develop a logistics plan that takes into account scheduling interviews and travel, obtaining required management or customer approvals, compensating interview participants, etc. The following is a partial list of typical logistical tasks for medical product VOC interviews conducted by Battelle's MDS team.

- Make a list of contacts that fulfill the roles identified in the customer profile matrix.
- Decide on interview type and location.
  - Hospital visits sometimes require paperwork, vaccinations, or training.
    - HIPAA and infection control training.
    - Immunization/tests for rubella, rubeloa, hepatitis B, chicken pox, TB, tetanus/diphtheria, mumps.
    - Lab tests and immunizations can cost from $25-$250 each.
      - Full course of tests and shots can be up to $700 per person.
  - Local, dedicated market research / focus group firms and internal contacts can be used to find a pool of interviewees and observation sites.
- Prepare Internal Review Board (IRB) and/or other management review packages as required.
- Prepare an estimate of costs to perform the needed interviews.
  - Staff time
  - Interviewee compensation.
    - Doctors, Dept. Heads, Directors: $150-$500/hour.
    - Nurses: $100-$200/hour.
    - Purchasing, Administration: $75-$125/hour.
    - Technicians: $50-$100/hour.
  - Gifts/Lunches: $10-$20/person.
  - Travel.
    - Domestic (US)/Canada: $500-$1000/person/trip.
    - International: $2000-$10,000/person/trip.
      - Visas, immunizations, etc.
- Assign interview teams.

- Start contacting and scheduling interviewees.
  - *Note: Any discussions that might be product or project specific need a Confidentiality Disclosure Agreement (CDA) in place.*
- Line up a transcription service to transcribe interview recordings.
- Buy/gather equipment.
  - Voice recorder, camera, and other note taking equipment as appropriate.
  - Extra batteries, tapes, note taking supplies.
  - Thank-you tokens.

Create the Interview Guide

Decide on the Interview Approach

VOC is best gathered through personal interaction, usually through one-on-one interviews, focus groups, or lead user analysis. One-on-one interviews can be conducted at either a central facility, or in a contextual environment. Each method has its pros and cons. Table 3 is arranged starting with the lowest cost/difficulty per interview and proceeding to the highest expensive/difficulty per interview (Katz 2009).

Table 3. Interview Method Advantages and Disadvantages

Method	Advantages	Disadvantages
One-on-one, central location	- Less expensive - Easier to schedule	- Analysis intensive - No environmental context
Lead user analysis	- New insights	- Difficult to identify lead users - May not reflect large market segment
One-on-one, contextual	- See product/process at point of use - Can reveal hidden needs - Generates goodwill, trust	- Difficult to schedule/arrange - Expensive (travel) - Time intensive
Focus group	- High volume of users - Can generate consensus - Good opportunity for development team to hear first hand feedback on product offering	- Expensive - Difficult to schedule/arrange on own - Group dynamics can be difficult – need an experienced facilitator - May be impractical
Co-Creation with users	- Real time feedback - User driven product concepts - Real time concept validation	- Ambiguous at start – Where will we end up? - Time intensive - Need experienced facilitator

When deciding on which approach to take, Griffen and Hauser (1993) indicates that:

- 1 hour of work in either a focus group or one-on-one setting yields similar results.
- Focus groups are no more creative than one-on-one interviews.
- It takes about two one-on-one interviews to gather the same percentage of needs as one focus group.

Katz (2009) also points out that:

- Focus group recruitment can be difficult.
- One-on-one interviews are generally more cost effective.
- One-on-one interviews are generally more practical in terms of open-endedness.

One-on-one, contextual interviews should be performed at a minimum if at all possible. Conducting in-person, face-to-face interviews provide invaluable information, and contextual interviews provide the opportunity to experience the customers' environments.

Surveys represent another means of gathering VOC data, but have limited effectiveness since the questions cannot be open-ended. Thus, the opportunity to capture the free flow of the user's thoughts and to prompt for additional clarification and detail is lost. Surveys are more appropriate after the VOC is mapped to product/process features and specific questions can be formulated to gather user opinion and preference.

Create the Questions

The VOC team now designs questions and topics for discussion to reveal the customers' experience—centered on the objective of the study-- and what visions the customers have for improving that experience. Four basic dimensions of exploratory questioning are: (Burchill and Brodie 2005)

- Images: Watching customers in action or having them describe using products, performing actions or executing procedures.
- Past breakdowns & weaknesses: Having customers describe or demonstrate problems have they encountered around the issue being investigated, as these responses may reflect frustrations or unmet needs.
- Current considerations: Having them describe or demonstrate how they currently choose or use a product or service, particularly in light of how the developer or manufacturer envisioned how the product or service is chosen or used.
- Future enhancements: Having them describe where they see things going, what would they like to see in the future, what their "ideal world" would be like.

The team must keep in mind that the object of the VOC interviews is exploration, not guidance (that comes later). Therefore, the questions need to be open-ended; nothing product or solution specific. The questions should have unlimited potential answers and use keywords like: "what", "how", "could", and "describe". Questions that limit responses to "yes/no" or "A, B, or C" type answers, or that use limiting keywords such as "are," "do," or "can" should be considered. Allow plenty of room for general discussion, so that the customer can talk, muse,

and ruminate. The team needs to also make sure that they develop questions for all of the groups in the customer profile matrix.

As was the case in developing the objective statement, team members representing different job functions will have different views on what questions should be asked during the VOC study. However, the goal is a small set of general, open-ended questions that serve to explore the customer's experiences. Once again, the affinity diagram is an effective tool for accomplishing this goal. Each team member submits several questions on yellow self-stick notes, and then assembles them into logical groups. The team then writes a single summary question to represent each group, making sure to follow the guidelines above. The team should develop 5 or 6 key questions to form the basis for the interview guide. The questions should be reviewed to ensure the objectives for learning are covered and that they provide the 360° perspective of the issues and questions being addressed by the study.

Enhancing the Interview Guide

Interviewees in a professional or business environment may be skeptical of the interviewer's motives, so the team needs to ensure that the interview introduction includes a full disclosure of why the questions are being asked, what will be done with the data, and how security and confidentiality will be preserved. At the beginning of the interview guide, the following key points are listed to serve as reminders for the team members performing the interviews: (Burchill and Brodie 2005)

- Opportunity for introductions of all participants.
- Brief overview of the purpose of the interview.
- Explanation of the interview process (notes, length, format).
- Explain what will be done with the data.
- Discuss confidentiality (no names will be used).
- Confirm permission to use audio and/or video recording.

Burchill and Brodie (2005) also recommend making other observations during the interview such as characteristics of the physical environment (light, temperature, cleanliness, clutter, noise, etc.) and the emotional environment (friendly, curious, nervous, stressed, rushed, etc.).

Conduct the Interviews

Select the Interviewer/Facilitator

The interviewer or facilitator is an integral part of the VOC gathering process, and the skills required to conduct the interviews differ depending on whether it is one-on-one or with a group. For one-on-one interviews, project team members may be appropriate, but for focus groups, the services of a professional facilitator may be required.

Note that not everyone on a VOC project team is going to be suited as an interviewer (as opposed to an observer or note taker), much in the same way that every journalist cannot be a Barbara Walters or Larry King. It is important that, as much as possible, core team members

are the interviewers so they can take that experience forward with them in the design process. Certain characteristics are required of the interviewer in order for the interviews to reach their maximum potential:

- Balance between passive and active listening.
- Ability to suspend all judgment, both personal and technical.
- Ability to read verbal and non verbal actions.
- Ability to guide conversations and control the situation without "overpowering" the situation (critical to focus group activities).
- Ability to be "kind but firm" in steering conversations.
- Ability to probe from the abstract (judgments, inference, solutions, general information, hearsay) to the concrete (evidence, needs, specific information, personal experience).

Select a Transcriber

If audio or video recording cannot be used, someone must be present besides the interviewer to transcribe the interview. This can be a difficult task depending on the speed of the interview and the speaking speed of the participants. For the VOC interview results to be effective, transcriptions must be word-for-word in the interviewee's voice: no interpretation is allowed. If the transcriber falls behind, they should leave blanks but try to capture key words and phrases that can be filled in during the post-interview debrief.

If audio recording is used, the interviewer should ensure that the recording device is well placed and background noise is minimal. If the interview will take place in a noisy environment, it may be useful to have a transcriber present in case the audio recording is unintelligible.

Use Good Interviewing Techniques

The interview needs to be a combination of passive listening, active listening and probing questions. Burchill and Brodie (2005) present the following suggestions for conducting an effective interview:

- Passive listening
  - Sit at 90° (around the corner of the table) to the interviewee.
    - Can relieve interviewee anxiety.
    - Allows for better view of non-verbal communication (body language).
  - Don't try to fill every silence.
    - Allows interviewee to compose thoughts.
  - User verbal and non-verbal encouragement.
    - Lean forward, nod.
    - Use "uh-huh", "I see" and "go on".
- Active listening.
  - Parrot back what's been communicated, including any inferences you pick up.
    - Example: "You sound frustrated by the speed of service."

- ▪ Pros.
  - Makes speakers feel heard and engaged.
  - Clarifies a speakers meaning.
  - Creates transitions to new topics.
- ▪ Cons (what to watch out for).
  - Can interject interviewer's own interpretation.
  - Can interrupt interviewee's train of thought.
  - Can mislead interviewee into believing some topics are more important than others.
- Probing (digging down).
  - o Move the speaker abstract, broad and general statements to specific concrete examples and personal experiences.
    - ▪ Proposed solutions.
      - When you hear "What we should do…", probe for "What would that do for you?".
    - ▪ Loaded or emotionally charged words.
      - When you hear "This so-called solution…", probe for "Can you give me an example of how it affected your job?".
    - ▪ Speaking in third person.
      - When you hear "They think that…", probe for "Could you describe an instance when this happened to you?".
    - ▪ Inference or judgment.
      - When you hear "This gadget is great!", probe for "What does it do for you that you couldn't do before?".

Derive the Customer Requirements

Once the interviews are complete, the VOC team needs to translate the Voice of the Customer interview transcripts and observations into a set of customer requirements ranked by customer importance. The team will use the customer interview transcripts (often in electronic format), the core team member observations, notes, and experiences, and the purpose statement and objectives for learning to produce affinity diagram(s), Kano (or other) surveys, and a set of ranked customer requirements.

Selecting the Method of Analysis

Prior to analyzing the data, the team should regroup and review the purpose statement and objectives for learning that were developed at the start of the VOC process. The VOC team may have found information that could change these items. A couple of key questions to ask are:

- Are these items still appropriate, given the knowledge we gained in the interviews?
- Is the purpose statement too narrow or too broad?

There are a few different methods of analyzing the "voice" data that has been gathered. The method selected primarily depends on the outputs desired.

Targeted Path Method. If the VOC team is trying to gain insight into a single question, exploring a known problem or weakness, or gathering information for an overview of high-level themes, the *Targeted Path* method (Burchill and Brodie 2005) may be appropriate. Examples of projects that may be appropriate for the *Targeted Path* include:

- Finding an innovative way to mitigate MedicalCo's model J-5000's "on" button failures.
- Understanding how nurses throw away dirty surgical sponges in the ER.
- Gain insight into the use of electronic medical records in hospitals.

Systems Path Method. A second method, the *Systems Path*, (Burchill and Brodie 2005) is intended to analyze multi-dimensional problems. For example, a task to "increase profit margin" may be multi-faceted and include production line changes, realignment of staff, sales strategies, and product cost-cutting measures.

Requirements Path Method. While these first two methods are beneficial in certain instances, most of our device and *in vitro* diagnostic (IVD) related projects fall into the *Requirements Path* (Burchill and Brodie 2005) method. This method is used to define performance requirements for a product or service and generate customer/marketing requirements. Since most of our clients want to develop a medical, IVD or combination product or service, this path is usually appropriate for MDS projects. The H1N1 example project would likely fit into this path. Other examples may include:

- Acme Tongue Depressor Company wants to develop a new product that meets needs not served by current tongue depressors.
- A surgical instrument company wants to understand inefficiencies in OR preparation, and develop a product or service to meet these needs.
- An IVD company wants to expand their technology into the home-use environment.

It is important to note that even though developers and manufacturers often specify that the project output will be a product, this phase of the VOC effort must continue to be solution independent to most effectively facilitate creative solutions and maximize the value of the customers' input.

The following sections detail the *Requirements Path* method to generate customer requirements.

Transcribe Interviews

The next step in the process is to have the interviews transcribed and delivered in electronic, editable format. The VOC process is greatly facilitated by the use of electronic data. If the interviews are recorded, the files can be saved electronically and stored in the project files for everyone to listen to. In addition, the electronic interview recordings can be sent to transcription agencies to be transcribed. This cost is often significantly lower than internal rates, and the turnaround time and quality are generally good.

Each interview (and associated transcript) must have a unique identifier. This identifier can be used later in the process to look up contextual information, or request it from the interview participants. Below are some example identifier formats that may be used. It is best to keep the identifier short, but provide some context as well:

- Hospital name and customer profile; e.g. RVR-D1 for the first doctor interview at Riverside.
- Country and customer type; e.g. SKdoc01

Identify Customer Concerns from Transcripts

The goal in choosing the key customer concerns is to find statements that answer the question:

- What voices identify key issues, needs, problems, concerns, images, or solutions that will help us understand customer requirements?

The identification of key customer concerns in the transcripts can be done individually or as a group. One efficient way of accomplishing this task is to have the team members that interviewed a particular person identify the associated key statements. The use of the original interviewers is beneficial because they will often remember key "emotional" concerns that may not be reflected well in the transcription. Examples of this may include statements with a sarcastic tone, or associated body language that stresses the emotional nature of the statement.

At this point in the process, the goal is to not look for customer requirements, but clues to generating customer requirements. It is best to be liberal with selection at this point in time, as the statements will be grouped and reduced in the next step.

Using the electronic documents mentioned above as templates, key customer concerns are selected and transferred to yellow self-stick notes. This can be done as the transcripts are completed; the process does not have to be done as a batch. The team should be sure to denote on each note which transcript the note came from, so that the context can be elaborated if necessary. This step in the process should result in 50-500 self-stick note statements.

Select the Strongest Statements

Once all interviews have had key customer concerns selected and placed on self-stick notes, the core team selects and groups the strongest statements. This process is done as a group activity, and takes about a half day to complete.

The team looks for statements with a strong voice, which is clear, concise, specific, and reflective of personal experience. The team then uses the affinity diagram method to group similar statements from all transcripts and picks the strongest, most visual statement from each group. This process continues until 24 or fewer statements exist.

Construct Requirements Statements

The team now translates each customer voice into language that describes specific, unambiguous performance requirements for the product or service to be designed or re-designed.

The process focuses on the translation of the customers' voices into requirements. This may be accomplished by a "translation worksheet" consisting of three sections:

- Verbatim voice and contextual information.
- Key items.
- Customer needs and requirements.

The team records each of the approximately 24 customer voices on to a separate worksheet, adding any contextual information to each voice. For example, if a customer voice in our H1N1 example was "the vaccine shipments are so hard to understand; it's like reading a foreign language," additional supporting photographs or descriptions of observations made may be attached to the worksheet to help support this voice.

The next step is to identify key items related to the customer voice. These statements are used to facilitate the translation process. These key items can be practically anything—any issue or consideration that comes to mind when the voice in context is considered. Key items for the previous example voice may be:

- Simple language
- Clear indication of type, year, and quantity
- Non-medical staff

The next step is to generate one or more customer requirements. This is an iterative process, so there is no need for it to be perfect the first time. The requirements statement(s) should be in the simple sentence structure (Burchill and Brodie 2005) of subject-verb-modifier. Other key points include the use of action verbs and avoiding the use of "is" and "are". The team makes an effort to use of multi-valued language—key terms such as *more*, *improved*, *better*, *quicker*, *more reliable*, etc. Multi-valued language implies "the better it is, the happier I am", as opposed to customer requirements which are pass/fail or "all or nothing" (although in some cases this may be appropriate). Additionally, the use of "and" in a requirements statement usually implies that more than one requirement is embedded in the statement, and should be separated out if possible.

Here are a few examples using the guidelines and example above:

- *The receiving worker understands the vaccine receiving instructions more quickly.*
- *The nurse finds the vaccine expiration date faster.*
- *The nurse injects the correct vaccine more often.*

It is important to note that solutions are still being avoided at this phase to keep the solution space as open as possible. This is often difficult to do, especially when product developers are

part of the team. Solutions generated at this point can be placed in a "parking lot"—a whiteboard or easel—for further discussion in later phases. Requirements statements should be monitored for solutions-oriented language. For example, an initial requirements statement may be:

The healthcare provider pierces the septum of the H1N1 vaccine vial more reliably.

If the scope of the project included the H1N1 vaccine packaging, the above statement limits the solution to a vaccine vial with a septum. There may be other methods or technologies that may increase the reliability of successful injection preparation. If the team is not constrained to using a vial, perhaps a better statement may be:

The healthcare provider prepares an H1N1 unit dose more reliably.

The team iterates each worksheet as necessary until the requirements are settled on by consensus. With 24 voices, the team usually ends up with 35-40 requirements (Burchill and Brodie 2005). Each requirement is placed on a yellow self-stick note for the next step in the process.

Assess Requirement Priorities

Now that the customer requirements have been generated, the next step is to prioritize the requirements to find those that will have the greatest potential for delighting the customers.

First, the requirements will be reduced to no more than 24 of the most important requirements. This is accomplished by using a team ranking system (Burchill and Brodie 2005). An affinity diagram is generated, showing groupings of requirements as well as their interrelation.

The customers are solicited for feedback on these final 24 requirements by the use of a Kano Survey or other importance questionnaire. Depending on the customer base, an email or popular web-based survey tools such as SurveyMonkey.com can be used. Typically, 100 to150 customers per market segment are surveyed.

The output is a ranked list of the 24 most important customer requirements. These requirements are now used to generate ideas, concepts, and eventually products with the customers' priorities in focus. Established methods such as the House of Quality and Quality Function Deployment are used to continue the customer focus throughout the product development process.

Conclusion

Battelle's Medical Device Solutions (MDS) team has developed a standardized approach to performing Voice of the Customer (VOC), by tailoring existing VOC best practices specifically for medical device development. Battelle has used the VOC process for a variety of medical and *in vitro* diagnostic device development efforts. These efforts have led into innovative solutions in diverse areas, including products, services, and internal business solutions. In all cases, the VOC effort provides a validated, traceable history of the customer voices that led to product or service solutions.

The VOC process outlined above can be used on a new problem or just to improve upon an existing product. The VOC process is an excellent systematic and effective method for design and development teams to listen to the stakeholders and glean information. It allows a team to be truly innovative in the development of a solution. Most importantly, using the process should better meet the stakeholders' needs and create a superior product or service in the end.

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Biography

Fritz Eubanks is a Systems Engineer with Battelle's Health and Life Science's Medical Device Solutions group, where he is involved in system-level design and analysis of both medical and commercial products, and serves as Safety Risk Management lead engineer. His 18 years of experience includes 8 years civil service in quality engineering with the Air Force Logistics Command, and 10 years in medical and commercial product development at Battelle. He received a B.S. in Mechanical Engineering from Kansas State University in 1982, and M.S. and Ph.D. from Ohio State University in 1992 and 1996, respectively. He is a member of INCOSE and is an ASQ Certified Reliability Engineer.

Chad Gibson is a Systems Engineer with Battelle's Health and Life Science's Medical Device Solutions group. His experience includes systems engineering, product development, Design for Six Sigma (DFSS), and hardware design for diverse *in-vitro* diagnostic and medical device programs. He graduated with a B.S. in Electrical Engineering from The University of Cincinnati in 2002. He is a member of INCOSE.

Melissa T. Masters is a Systems Engineer with Battelle's Health and Life Science's Medical Device Solutions group. Her experience spans systems engineering, product development,

project management, and software and hardware development. She graduated with a B.S. in Electrical Engineering from The Ohio State University in 2001. She is a member of INCOSE, the Association for the Advancement of Medical Instrumentation and the Regulatory Affairs Professional Society.