The National Health Council:

Value Framework Get-Ready Checklist For Patient Organizations

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NATIONAL HEALTH COUNCIL

National Health Council • 1730 M Street NW, Suite 500, Washington, DC 20036-4561 • 202-785-3910

Companion piece to NHC's Patient-Centered Value Model Rubric

Overview: What is Happening in Value and What do Patient Groups Need to Know?

The Issue

The U.S. health care system is undergoing a transformation in how it delivers and pays for care. As traditional fee-for-service payments give way to value-based payment arrangements, understanding the "value" of health care treatments has become a national priority. Value frameworks and various models have emerged as tools to help stakeholders assess new treatments. But, the utility and role of these new tools are being debated.

What are value frameworks?

Value frameworks are tools and approaches that seek to compare and quantify the positives, negatives, and costs for one or more treatments to assess which seems to be the best choice. Framework developers generally try to do this in a data-driven, scientifically credible fashion.

An important component of many value frameworks is often a supporting economic model (e.g., cost-effectiveness or budget impact). These models typically use complex mathematical equations to rate options under specifically outlined circumstances. Economic models like these are usually developed and used by payers and the biopharmaceutical industry. Payers may use models to help them determine which treatments and services should be covered by their plans. An example is the UK government's National Institute for Health and Care Excellence (NICE). Industry may use models to try to demonstrate the value of new products to payers. Some of these models are published in journals or included in information companies provide to health plans (e.g., models are referenced in the Academy of Managed Care Pharmacy (AMCP) format). So, past models have mostly come from the private sector.

What has drawn attention to value frameworks?

Recently, third-party organizations have released value frameworks and supporting models, gaining significant attention. In 2015, four organizations – the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), the National Comprehensive Cancer Network (NCCN), and Memorial Sloan Kettering Cancer Center (MSK) – released value frameworks described as intending to support physicians and/or payers in assessing treatment value. While each addresses different questions using different methods, they are essentially intended to help determine if a treatment is "worth it" to a user. The frameworks have focused on drug treatments but can be used to evaluate other health care interventions given heightened focus on all costs.

What are the controversies regarding frameworks?

Framework developers have been taking different approaches to their assessments. Stakeholders – including the National Health Council – have voiced important concerns with the frameworks released last year. They include but are not limited to: Lack of apparent patient engagement, methods or data issues, how frameworks might be used in decisions, impact on patient access, or insufficient testing with users when intended as patient-doctor shared-decision making tools, sources of data on costs or including only short-terms costs.

Value frameworks can be useful tools, but only with patient involvement!

Value frameworks and supporting models can help advance the national dialogue on value in health care, but only if they incorporate the patient voice throughout. Developers are working to improve how they gather and use patient inputs in their value frameworks.

Why the Get-Ready Checklist?

This Checklist is intended to help patients and patient advocacy groups become more engaged in discussions on value, and with value framework developers regarding the ways in which they can better consider the patient perspective. Not all patient groups will need to activate immediately. But, for those learning that value frameworks are planned for the disease and treatments they care about, the Checklist serves as a guide to begin their education and activation.

The National Health Council
Value Framework Get-Ready Checklist
For Patient Organizations

Value As The Focus

The U.S. health care system is undergoing a transformation in the way it delivers and pays for care. As the traditional fee-for-service payment system gives way to more value-based payment arrangements, understanding and defining the value of health care treatments and interventions has become a national priority.

Value frameworks have emerged as the latest tool to help health care stakeholders assess the value of new treatments. In 2015, four organizations – the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), the National Comprehensive Cancer Network (NCCN), and Memorial Sloan Kettering Cancer Center– released frameworks that developers have described as intended to support physicians and/or payers in evaluating the value of treatments, as defined by their effectiveness and cost.

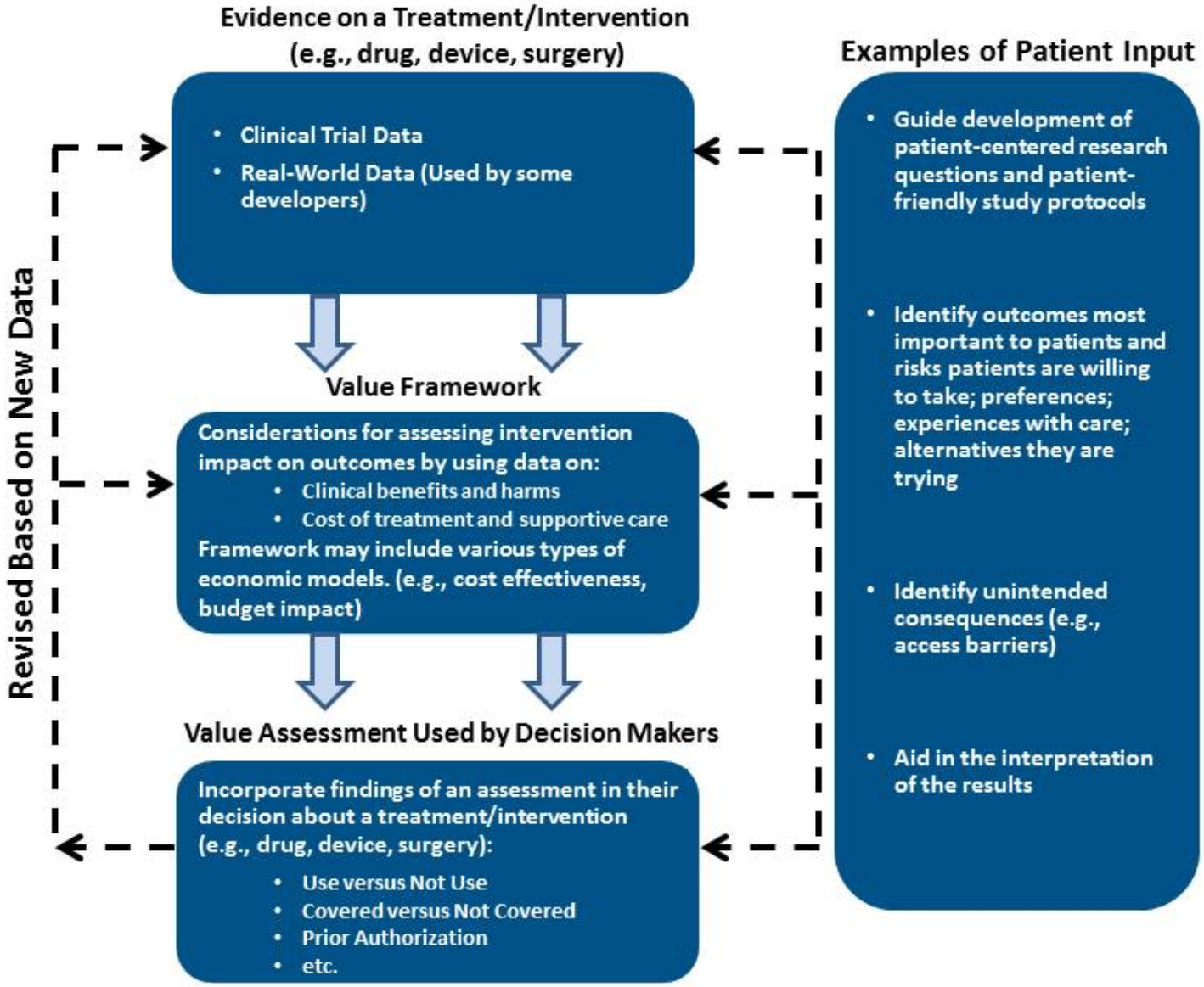
Patient perspectives on value can differ significantly from that of physicians and payers, often integrating considerations beyond clinical outcomes and cost, such as a treatment's ability to help patients achieve personal goals.[1] To have true utility, value frameworks must incorporate these other value-influencing factors. The only way to achieve this is by having robust processes in place to incorporate the patient voice. Such action is particularly important if physicians and payers look to these tools to inform shared decision making and decisions that can affect the treatment options available to a patient.

The patient community must be involved in defining value as the end recipient of care. Patients, like other stakeholders, are eager to take part in the value discussion because the cost of and access to drugs have direct impact on their health and well being. Yet, it is not apparent that individual patients or patient organizations have been engaged throughout the creation of these frameworks or contributed to their development from conception.

The National Health Council (NHC) has developed the *Value Framework Get-Ready Checklist* to help guide patient organizations as they prepare to engage with other stakeholders in the development, implementation, and assessment of value frameworks and supporting models. This Get-Ready Checklist has been created as a step-by-step guide for your organization on how to prepare to engage in this important process.

[1] Fowler FJ Jr, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. *Health Affairs (Millwood)*, 2011; 30: 699–706.

Value Frameworks and Assessments: Incorporating The Patient Voice



The figure above depicts the process of incorporating data into a value framework and using that framework to produce recommendations that potentially feed into decision-making, and how patient-provided information can contribute. Evidence is gathered and incorporated into the framework, which tries to capture what is known about the benefits, risks, and costs related to the treatment and care. The framework is used to produce an assessment. The findings of that assessment can be incorporated by decision makers such as payers, providers, and patients. The assessment does not drive the decision but is incorporated into the decision making process. Patients should have a role in contributing input throughout.

Instructions for Using This Checklist

The Get-Ready Checklist is intended to be used as a tool by patient groups. It can assist an organization in actively planning, preparing for engagement, and collaborating in the value debate. With this tool, patient groups will be better able to prepare to help developers incorporate the patient perspective in a meaningful way in the development, dissemination, and use of value frameworks and assessments.

This tool can be used by your staff, or an organization's committee responsible for monitoring and engaging with framework developers. To get the most from this Checklist, we recommend that you review the entire document and each section and questions in the checklist before beginning the specific tasks.

Understanding what needs to be done from the start will make your collaborations with all applicable members, partners, developers, stakeholders, and experts easier throughout the Checklist process.

Suggestions Before You Begin

For each activity:

- Take notes in a separate document.
- Plan for the time you will need to dedicate for each task.
- When you have completed the task, check the corresponding box.

NHC Value Framework Get-Ready Checklist

Get-Ready Activity	✔
Step 1. Advance Preparation – As Early as Possible Know which organizations are developing a framework for your disease of interest (or similar diseases); it will help you to be better prepared. These organizations should come to regard you as a partner in this process, but some may still need to be convinced of the value of your input. Being prepared in advance will help you demonstrate that value. The steps below help you to begin to prepare.	
A. Search: Who are the framework developers working in your area of interest?	
○ Find the organizations known for developing frameworks. Right now, those organizations include ICER, ASCO, NCCN, and MSK. They are the most well known and talked about.	
○ Network with other patient organizations and relevant health professional associations to learn from their past experiences with developers and to find out if new framework-development organizations are appearing on the scene.	
○ Some health insurance plans and pharmaceutical companies also develop economic models. Find out about them in the published literature, in the press, or through conversations with other patient organizations or organizations representing providers who treat your condition of interest.	
○ Do your homework to identify and learn about these organizations; gather and share information among patient groups as you learn more.	
○ Look at developers' websites. Is your disease or a relevant treatment listed? Has the organization developed a framework or model in the past that is relevant to your area of interest? Is it going to update that work? Is it planning to develop a new framework or model?	
○ Sign up to receive alerts and newsletters so you know what work is planned for the future. Some organizations put out lists of projected topics for the coming year.	
B. Assess: Understand the processes of each framework-development organization working in your area of interest.	
○ Does this organization's existing process already seek patient input? Are there clear opportunities for engagement? Look for policies, calls for comment, and calls for nominations. You don't have to be limited to just those opportunities, but you should be aware of what they are.	
○ What does their announced or typical timeline look like? Are your opportunities to engage clearly outlined? Track those dates and prepare for them. If no dates are published, use the schedule of released frameworks to help you develop a work plan for meeting deadlines.	
○ Who is the target audience for their frameworks? Payers? Physicians? This is often stated outright. Knowing this can help you to understand and, if necessary, refute approaches used or assumptions made.	

○ How can you help the developers make their work more patient centered? What can you provide? Make a clear list of what you have to offer. See Appendix II for suggestions.	
○ Find a point of contact at the organization for future communications. Reach out as soon as you can to voice your eagerness for involvement. But, don't reach out to that person until you are adequately prepared for the conversation and know what the objective is for your outreach.	
C. Learn: Familiarize yourself with the developer's website, materials, and past value-related work.	
○ Look for recent publications, press releases, and commentary.	
○ Review other organizations' publicly available comments submitted to the developer. You can learn from the organization's perspectives and may find them a good resource for information and partners.	
○ Make preparation calls to development organizations to inquire about their processes, opportunities to engage, and to gain other pertinent information.	
○ Research external perceptions of the developer through various publicly available resources (e.g. news publications, Facebook, Twitter, etc.)	
D. Investigate: What is the FDA review timeline for products in your disease area, and how will it impact the timeline for value framework development?	
○ Is a new treatment for your disease of interest under FDA review? Some model developers focus on new products and anticipate economic model inputs based on FDA approval.	
○ When is the new treatment(s) expected to be approved? These dates can be critical to economic model release as the price of the product, which will be incorporated, may not be available until the product is launched. The product launch will be predicated on the FDA review timeline. Some economic models are developed prior to approval, but many will rely on product pricing at launch.	
E. Align: Does the developer's work align with the National Health Council Value Model Rubric?	
○ Familiarize yourself with the NHC Value Model Rubric.	
○ Ensure that the developer's processes are patient centered. The NHC defines patient centered as broadly meaning any process, program, or decision that is focused on patients, in which patients play an active role as participants, and with a central focus on optimizing the use of patient-provided information. Where does their work align or differ with the Value Model Rubric? Developers may state they are taking a patient-centered approach, but that does not necessarily mean they are. You need to make your own assessment.	
○ How can you help the developer improve on patient centeredness?	

Get-Ready Activity	✔
Step 2. Decide Whether to Engage Engaging in value framework and economic model development, and value assessment processes can be resource intensive and time consuming. Your organization should carefully make a decision about whether to engage and to what extent, guided by need, urgency, resources, and capacity. If you choose not to engage, the consequences should be carefully considered.	
A. Articulate: Everyone involved should understand the issues.	
○ Create a short paragraph on why this value work is important to your organization. Why should you engage?	
○ Vet this paragraph with colleagues, your organization's Board of Directors, medical board, external research and clinical experts, and others who have relevant experience. As applicable, gain their feedback.	
○ Define the resources your organization will commit to this activity and how frequently you will revisit this commitment.	
○ Communicate to your whole organization – staff, leadership and constituents – that you are taking this process seriously and want patients to be involved. Use various communications channels to state this such as your website, blog, e-news, print publication and social media. These channels can announce specific ways patients can participate.	
B. Evaluate: Internally evaluate your organization's appetite for engagement.	
○ What are the overall goals of your organization? How do your organization's goals align with this issue? Would you consider engaging on value frameworks your role?	
○ What resources do you need to engage? What resources do you have?	
○ Do you have the capacity to take this on? Do you need outside help? Outside help may include external research and clinical experts. Who else will be on the team? What does it take to get them up to speed?	
○ Do you want to engage with this developer at this time, on this topic?	

Get-Ready Activity	✔
Step 3. Consider Coalitions and Partnerships When possible, engaging with key organizations and stakeholders can make this process easier and more impactful.	
A. Mobilize: Bring together relevant organizations and stakeholders	
○ Reach out to provider groups, other patient groups, and other stakeholders in your field as well as other groups in similar disease areas for their input.	
○ Look for their comment letters, press releases, media quotes, and any articles.	
○ A united voice of like-minded individuals and groups is more powerful than a lone voice. You can also work in a collaborative fashion to stress different things in a complementary approach.	
○ Develop strategies for how you might work together.	

Get-Ready Activity	✔
Step 4. Refine Your Strategy Your organization's strategy(s), objective(s), and rationale should be established before you reach out to developers. They should be clear to all involved.	
A. Assemble: Your strategy is best substantiated with data and facts.	
○ What do you have in-house that can inform a framework, model or assessment? Gather and organize the facts and figures you already have at your organization; keep them up-to-date and accessible. Data may not always be scientifically rigorous and results should not be misrepresented or exaggerated, simply factual.	
○ Sources of data should be inclusive of patient experiences and narratives. This may include patient stories and experiences as well as survey or registry data, both published and unpublished.	
B. Gather: Information from your community is a key asset.	
○ For data you do not yet have on hand, gather insights and information from your patient community.	
○ Do you know your community's opinions, preferences, experiences, and views?	
○ Conduct interviews, focus groups, and surveys to gather the data that can inform the framework.	
C. Search: Fill gaps in data where you are able.	
○ Your patient registry may have valuable data that can inform a framework or model. Tap that resource.	
○ Use external sources such as literature and web searches for other useful data.	
○ An FDA patient-focused drug development meeting and "Voice of the Patient" report may provide valuable data. Check the FDA website for those resources.	
D. Consult: Experts can help you organize and understand the data.	
○ Tap your organization's scientific committee early so they are alerted and ready when you need them.	
○ Consult with outside economic experts who may be familiar with your disease of interest.	
○ If you do not fully understand something, ask for help or obtain training.	
E. Articulate: State your intentions clearly.	
○ Document your strategy(s), objective(s), and rationale with any data you can cite.	
○ Be concise and clear.	
○ Vet with appropriate parties (e.g., members, Board of Directors, partners, etc.).	
○ Be prepared to update your strategy as you gather new information. This will be an iterative process.	

F. Re-evaluate	
○ Assess your strategy(s) and objective(s) as more information is gathered	
G. Message: Have your message ready to deliver.	
○ Prepare consistent messaging. Tailor messages appropriately for various audiences such as your scientific committee, patient and families and developers.	
○ Decide whether or not you want to engage with the media/press; what role you want the press to play; and what you will put on your website about the topic.	
H. Prepare: Be prepared for some negativity toward patient groups.	
○ Some framework developers are concerned about patient group bias. They may claim that patient groups are: ▪ Too vested in finding treatments and vulnerable to accepting treatments that don't work; ▪ Too emotional and can't see/accept the facts; or ▪ Being used or influenced by industry to serve as their advocate.	
○ Be prepared for these views. Be able to clearly explain your organization's funding model and the policies you have in place to avoid conflict of interest, including certification through the NHC Standards of Excellence Program®.	
○ There is no need to defend being pro-patient and pro-treatments for your constituency. However, be armed with data and present your expertise. Rely on more than your passion.	

Get-Ready Activity	✔
Step 5: Engage with Developers Strive for partnership. Expect to be treated like a partner and behave like a partner. This can take time.	
A. Approaching a developer: Have a game plan mapped out.	
○ Reach out to the contact you have identified at the developer organization(s) with a letter of introduction describing your organization and its mission. Send the letter by email and mail. Or, reach out to a contact person you may have met or have already contacted for information.	
○ Explain that you would like to introduce yourself and state your objective(s) (e.g., you want to become more engaged in their framework development activities).	
○ Outline briefly your expertise and what you have to offer (e.g., knowledgeable individuals in your membership about the disease of interest, a list of the leading clinicians in the country with expertise about the disease, or a disease registry of patient-reported outcome data).	
○ Stress the uniqueness of the disease or issues the developer might not be familiar with that you want them to know about as they begin their review. Emphasize things like heterogeneity of the disease, that all patients don't experience the disease the same way, don't respond the same way to treatments, etc. Stress that medical literature can't tell them everything they need to know about your community, its needs, and treatment hopes.	
○ Follow up to arrange an appointment to speak. Request a one-hour call or meeting, but settle for a shorter time if one hour is not available in the reasonable future. You may need to call several times to make the appointment. Don't be discouraged.	
○ Take every opportunity possible to introduce yourself and your organization to the staff at the development organization. Introduce yourself at public meetings and express your desire to partner.	
B. Objective(s): Define your objectives for the conversation.	
○ What are your objectives for the conversation? What do you want to achieve? These should be written down to help you maintain focus. Over time, you will have different objectives for different conversations. For example, on telephone call #1: Introduction, establish your organization's credibility, share your expertise, encourage interaction with your medical experts, or offer to arrange discussions with patients. Get them to understand why they need to engage with you. On telephone call #2: Discuss scientific challenges with the review they plan to do; get them to understand the value in talking with patients directly; share data and scientific information about your community that they might not have access to.	

○ **Be conservative and reasonable in your expectations. Possible objectives could be:** ▪ Introductions ▪ Express interest in engagement ▪ Gather information on how to engage ▪ Offer data you have ▪ Establish points of contact ▪ Set up future calls and interactions ▪ Nominate yourself or a member to be on an advisory committee ▪ Suggest changes to the research question ▪ Suggest changes to the data or assumptions ▪ Point out areas of controversy for the project ▪ Describe challenges they may encounter ▪ Propose solutions to those challenges ▪ Suggest patient-centered approaches	
○ Don't expect to get everything you ask for right away. Let the developer know you are committed to a true partnership and are in it for the long haul.	
C. Communication with Developers:	
○ Establish clear avenues of communication and a good working relationship with the contact person you identify to help you gain entry. They need to know who your lead is and who you have access to; you should request the same on their end.	
○ Avoid negativity. Don't be on the attack. Be a good partner and approach the discussions as such.	
○ Stress your mission and willingness to engage.	
○ Rehearse what you will say to keep yourself on track and raise your comfort level. Be concise and direct. Lack of preparation might convey lack of expertise or commitment, and could undermine trust.	
○ Document conversations to ensure transparency.	

Get-Ready Activity	✔
Step 6: Follow Through Build on your initial outreach. Keep the line of communications open.	
A. Follow-up: Demonstrate your continued commitment.	
○ Send a note of thanks that includes important points from the conversation and the next steps committed to by both parties.	
○ Continue to send letters or emails to the organization with information, encouragement when appropriate, and to repeat your asks as needed.	
○ Prepare well-thought-out comments when there are public comment periods.	
B. Visibility: Use every opportunity to be viewed as an important stakeholder.	
○ Make note of every publicly available comment period and opportunities for engagement with value framework developers.	
○ Plan your schedule accordingly and plan to attend all meetings in person to strengthen your presence.	
○ Speak to the media to convey your message. But do this as planned and on your terms.	
○ Advocate when and where needed.	
C. Communication: Keep your constituents informed.	
○ Keep your members, stakeholders, and other constituents informed along the way.	
○ Inform and active your patient community as needed, especially when you need volunteers.	
D. Reliability: Commit for the long haul.	
○ Dedicate the time and resources to fulfilling any commitments you have made to the developer (e.g., serving on a committee, writing a review, providing data, etc.)	

Should you have any questions about using this guide, please do not hesitate to contact the National Health Council at 202-785-3910, info@nhcouncil.org**.**

Appendix I: Acronyms

- ASCO – American Society of Clinical Oncology - www.asco.org/
- FDA – Food and Drug Administration- www.fda.gov/
- ICER – Institute for Clinical and Economic Review - http://icer-review.org/
- MSK – Memorial Sloan Kettering - www.mskcc.org/
- NCCN – National Comprehensive Cancer Network - www.nccn.org/
- NHC – National Health Council - www.nationalhealthcouncil.org/

Appendix II: Information to Share with Framework Developers

- Your mission statement and biographies of leadership team
- Any relevant policy letters that your organization has submitted in the past
- Descriptions of patient-centered programs and research your organization has developed
- Progress and financial reports highlighting trends in the past several years
- Facts regarding treatments of the specific disease relevant to your organization
- Patient data (surveys and registries)
- How you are able to introduce them to patients directly
- Contact information and recommendations of national experts on the disease and their key publications
- Upcoming events and fundraisers, and why these are important to you community
- Partners your organization works with
- Public education and awareness outreach (including social media and publications)

Appendix III: Helpful Resources

- NHC's Stratification Tool – http://www.nationalhealthcouncil.org/sites/default/files/NHCPatientInformationToolandinstructions.pdf
- NHC Value Model Rubric – www.nationalhealthcouncil.org/sites/default/files/Value-Rubric.pdf