Issues in the Capture of Patient Reported Outcomes in a Heterogeneous Research Network

- GPC agreed to 3 demonstration projects which include surveys of patients
  - Rare disease - ALS
  - Common disease – Breast Cancer
    - Linked tumor registry
    - In the process of writing papers
  - Obesity (Now called height/weight and all networks participated)
- These were all pragmatic studies
  - Pragmatic – not asking patient or physician to do anything they would not normally do
  - Patients filled out paperwork at home
- Asked, what tools do we have in our tool chest to achieve our goals?
  - Academic health centers have hospitals as well as medical centers which are connected to the University instead which will participate in much more research – not like community hospitals
  - Academic health centers make it easier to collect patients reported outcomes
- We sent out surveys asking for Patient Reported Outcomes (PRO) for comparative effectiveness research
  - Typically surveys developed had general questions and also very specific questions with specific answers
  - Surveys had branching logic (if you answer a question a certain way, there would be additional questions asked from the questions presented for other responses)
  - We determined the tools all sites had available for capturing Patient Recorded Outcomes and all sites had some tools for PRO capture, but none of the tools were available at all sites. All tools are:
    - Patient Portal
      - This method was spotty. Most sites use Cerner or Epic
      - All sites are required to have this capability for federal funding but it may not be built into the system
    - REDCap
    - Paper Forms
    - Mark Sensing
    - Patient Journal
    - Custom Web Based Tools
    - PRO instrument selection is driven by researchers, and engagement with healthy system IT governance varies
- When collecting PRO, the most cost effective and unanimous way to collect this information is electronically
  - This is often not a great method for many patients may not be comfortable with a computer or trust the security of the online methods
o Consideration of trust and bias is very important, even monumental
  o Surveys are also very slow and repetitive and do not allow you to go back – this is very frustrating and makes it difficult for patients to complete, so their usability is not very good as this will turn away many patients who may have filled the survey out otherwise
  o Location is also a factor for patients – if they are able to fill them out together in a meeting it makes it much easier
  o Patients may feel like their responses about how they feel with their care and outcomes will not be considered or make any difference or be relevant for them, so this could discourage many from participating in the surveys
  o Patients are also uncomfortable filling out their information online because of data breaches and not being able to trust the security of the system
  o Too many surveys go out to patients for various things which leads to overload, and questioning whether all of them are necessary as there are many similarities – clinical care surveys are the biggest offender which are often sent out by medical students
  o The volume of surveys in today’s society (even for fast food, tire changes, etc.) can cause patients to not feel like filling any of them out because of the great inundation of requests for information
  o Some types of information are easy to obtain at the point of care, such as how did your appointment go? Responses on specific visits etc. are good candidates for this
  o Electronic surveys can require a lot of effort for patients which can be very discouraging
  o Patients do not appreciate being asked to speak with researchers at their appointments because it can be a very time consuming process, and if the patient does not choose to participate they have to wait a very long time for the doctor to come in for their appointment as they have budgeted in time for the research discussion. This is very inconvenient for patients and feels like an ambush as they have not budgeted this time into their schedule. Having the researchers ask for participation after the appointment may be a better option, as patients feel when they ask at the beginning and have to wait in this way the patients feel as though their needs are already not being considered.
  • Many of these surveys are all exactly the same but coming from different doctors at the same address so it is redundant and confusing
  • There should also be options to give different responses for different care-takers, because there could be drastic differences in patients experiences with different people

• Experience at UNMC – Study in the ALS clinic
  o Survey was generally done that was developed a while ago to track patient results
  o This was discussed that the last LEC and a neurologist worked with patients to gather their impressions of the survey
  • Based on this, language was cleaned up and questions important to patients were added
  • A new rating scale was also implemented and patient daily living questions were also added
  o Overall response rate for surveys was 44.44%
  • From a methodology point of view, this is not a good response rate
  • Understanding this particular survey, this is actually a pretty good response rate
- For representative samples this would be fine, but it would be a problem if the responding patients were not a representative sample
- The response rate for the height/weight survey was a much lower rate, and this was expected as ALS patients are much more invested in their disease and contributing to research
  - Many patients are not comfortable discussing their height/weight (this is also common with several other conditions) as they do not appreciate hearing that their BMI is higher than it should be, even though the survey writers were very careful with their language to try to avoid them feeling targeted for being overweight
- Typical response rates for all surveys are not great for conducting research as it does not make it possible to collect enough information for the most accurate results – these outcomes are critical to how we move forward care for patients, and this information cannot be obtained unless the patients provide their experiences and outcomes
  - We need to find out a way to get better response rates that patients will respond to in higher numbers
- Is the consent process sometimes a barrier for patients to fill out these surveys?
  - If patient outcomes were part of the EMR, and patients would agree to share their de-identified data, it would make it much easier to collect the needed information for research
  - Sometimes patients do not give information for their EMR accurate if clinicians are not paying attention to what patients are telling them, so they do not believe their responses to the surveys will be considered
  - Are we sometimes overreaching in our attempt to collect PROs?
    - Many screenings already conducted in clinical care visits could be used to add outcomes information to the EMR without needing to survey patients for these responses
- Patients need to understand how their completion of the surveys will benefit them personally, because they can often affect after-care and patients with certain conditions can be very self-focused rather than others-focused
  - Clinical care surveys and research surveys can look very similar, so patients may be less likely to fill out surveys if they misinterpret the purpose and do not think it is important to respond
  - Patients don’t know if they should expect anything back or not, which is critically important when it comes to research surveys
  - Many results are published and used by other experts in the field – however, patients are often not interested in receiving these publications
  - They would often like to know what the results of the trial were, but the publication would be a bit much. They need information in terms they can understand.
  - Many medical trials do not even end up being published at all, but patients would still expect to receive the results, and when they are published the patients often do not know this has been done
- All researchers fail to make informed consent an ongoing process, and this is very important to patients
  - Part of being successful in this is providing periodic snapshots of findings
- ADAPTABLE trial
  - Many of these lessons we are learning have been put to work in the ADAPTABLE trial
    - Updates are provided
    - There is a patient-centric website
  - The ask for ADAPTABLE is much bigger than the ask to just fill out a survey, although there is still not much interaction involved, so it is not surprising that the response rate was very low
  - We need to focus on things that do make a difference, rather than the ones that have always been used
  - Patients do not want to read updates every day because negative results could cause them to want to drop out of the study even though the final results are not in, so it is unclear how these responses should be interpreted