**PhenX Genomic Medicine Implementation Working Group (WG)**

**In-Person All-Day Meeting Minutes**

November 18, 2019

Hyatt Regency Bethesda

**Attendees**

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| **WG Members**  Wendy Chung, Co-chair  Kyle Brothers, Co-chair  Angela Bradbury  Sirisak Chanprasert  Lori Orlando-via phone  Ali Torkamani  Heather Zierhut  Marylyn Ritchie (SC Liaison) | **NHGRI**  Natalie Pino  Erin Ramos | **RTI Staff**  Lynda Grahill  Carol Hamilton  Tabitha Hendershot  Michael Phillips  Jennifer Schoden |
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**Action Items and Decisions**

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| **Action** | **Responsible Person** |
| Identify groups and individuals who would provide valuable input on the proposed measures. | All WG Members |
| Email Julie O’Daniel regarding pharmacogenomics manuscript and see if the survey described int eh paper is available. | Erin Ramos |
| Include Access to Services in the Uptake measure | Angela Bradbury and Heather Zierhut |
| Checklist for Implementation Science—follow-Up protocols, with references | Angela Bradbury |
| Create a checklist for compliance with guidelines for three CDC Tier 1 conditions | Heather Zierhut |
| Review protocols for Decision Satisfaction | Heather Zierhut |
| Volunteered to review the measure for Understanding of Health Implications of Genomics | Ali Torkamani |

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| **Decisions** |
| 18 measures recommended for datasheet creation and outreach; the measures and protocols are listed in the scorecard |

**Welcoming Remarks, Introductions, & Goals of the Meeting**

Dr. Chung and Dr. Brothers, the Co-Chairs, introduced themselves, followed by the rest of the WG, the SC Liaison, NHGRI staff, and RTI staff. Dr. Chung went over Goals for the Meeting and indicated that we will revisit discussions and make decisions at the end of the day.

Goals of the Meeting:

* Listen to and discuss WG member presentations and recommendations
* Select 15-18 measures and associated protocols for community outreach

**PhenX Terminology and Guidance**

Mr. Phillips, the WG Supervisor, presented the PhenX definitions and selection criteria. A WG member asked what was meant by “well-established”. Dr. Carol Hamilton, the Principal Investigator, responded that you should identify protocols that are sufficiently established and the best options available. Dr. Ritchie indicated that some of the protocols may not be as broadly validated as other protocols in the PhenX Toolkit, and that is acceptable. She added that genomic medicine is new territory for PhenX, and we cannot expect comprehensive coverage, but it will be helpful to put a stake in the ground for new investigators.

**Presentations:**

**Return of Results**

Dr. Chung presented her findings for the Return of Results scope element, as some of what she reviewed might be more appropriately discussed under other elements later. Her slide presentation covered the most commonly used protocols for Return of Results to Patients and Return of Results to Providers. Under Return of Results to Patients, she referenced the American College of Medical Genetics and Genomics (ACMG) 59 Patient and Provider Survey (**ACMG59), Information Seeking**, and **Family Communication**. Dr. Chung indicated that the ACMG59 questions were not that useful. For Information Seeking, there was few protocols available, and nothing was validated. For Family Communication, she presented the Feelings about Genomic Testing Results (FACToR) protocol, which seemed most promising. FACToR comes from Electronic Medical Records and Genomics (eMERGE) Network and Clinical Sequencing Evidence-Generating Research (CSER) (and all four of its domains) use this protocol. But she indicated that the FACToR protocol may fit better into Patient Outcomes, which will be discussed later.

For Return of Results to Providers, Dr. Chung suggested the **Healthcare Personnel (HCP) Confidence in Condition** assessment, used in CSER2 and eMERGE. This survey is not as comprehensive as she would like but its questions are not bad. Dr. Carol Hamilton noted that at this point, anything can be included on the possible list. Dr. Ramos suggested the instrument from EMERGE. That is maybe FACToR also includes return of results to providers. Dr. Chung noted that the return of results to providers will not focus on patient-facing information. For providers, “unexpected results” gets at the incidental outcomes information providers might want.

For Information Seeking, Dr. Chung noted some unvalidated measures used for CSER2 and Implementing GeNomics in PracTiCe (IGNITE). The CSER2 Post Return of Results version 2 of Information Seeking looks most promising. Version 2 gets at the question of what sources of information patients or relatives might consult after they have received test results. Dr. Zierhut noted that she had assumed this measure would look at information processing post-test results, e.g. anxiety in cancer patients. The WG discussed this difference a bit and the fact that the protocol chosen cannot be changed, though guidance on use can be provided. Dr. Zierhut noted that many researchers tend to create their own protocols to get at this information. Dr. Brothers mentioned taking a subset of questions from a protocol, as they did in CSER.

Dr. Chung reviewed the protocols for Family Communication (derived from CSER2, eMERGE, and IGNITE), noting they are not validated. The CSER2 has 2–15 questions; eMERGE is more burdensome. Dr. Chung suggested combining questions from both to develop a protocol for family communication to relatives. Dr. Hamilton noted the guidance that PhenX warns against creating a “patchwork quilt” protocol from multiple validated or well-established protocols, though the WG could add two protocols together if the protocols are complementary and address the same concept. Dr. Chung introduced the protocol from IGNITE. It contains a single question about sharing results, which is not particularly granular but does get at how families share the information. Dr. Brothers noted that CSER has adult and pediatric versions of the Family Communication protocol. Dr. Zierhut broached the relative merits of quantifying and qualifying measures, noting that sometimes a pedigree is useful (especially in public health research). Dr. Chung noted that pedigrees can be difficult to do and take time so many studies may not collect pedigrees. Dr. Hamilton suggested that the collection of pedigree might go in Supplemental Information. In the discussion regarding inclusion of the pedigree, the WG agreed that some research would be best represented quantitatively and other qualitatively. Dr. Chung noted that the two protocols, CSER2 and eMERGE, and then IGNITE, act as a gateway from one to another, with the CSER2 and eMERGE assessing the ‘who’ and IGNITE getting at the ‘why’. Dr. Hamilton made the point that experts in the field know what they want to measure; those less expert appreciate the guidance that the Toolkit might offer. Dr. Ritchie proposed for it to be noted in the Toolkit, “for qualitative research, use X; for quantitative research, use Y,” if multiple protocols are included in the Toolkit.

**Implementation Science**

Dr. Angela Bradbury and Dr. Lori Orlando presented on Implementation Science (IS) measures. Dr. Bradbury began with the definition of implementation science in this context: the study of methods to promote the adoption and integration of evidence-based practices, interventions, and policies into routine heath care and public health settings. She noted that they elected to select measures based on IS frameworks, like RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) and Consolidated Framework for Implementation Research (CFIR), the most widely used. CFIR is large and overarching, with 26 constructs. The implementation constructs are multi-level and often qualitative. There are some that are validated. Dr. Bradbury and Dr. Orlando selected 5 that are widely used in genomic medicine, noting that future versions of the Toolkit could have more: Relative Advantage, Compatibility, Organizational Readiness for Change, Reach, and Adoption.

Dr. Orlando described the **Relative Advantage** measure. This measure gets at stakeholders’ perceptions of the advantage of switching to a new intervention and was originally developed from Roger’s Diffusion Theory. There are no validated measures available but IGNITE has used two relevant questions in the provider pre-implementation survey. The WG had some reservations about the word “risk” in the protocol question, as assessing risk may not be the goal. Dr. Orlando suggested that the questions might assess readiness to switch interventions, rather than getting at why a provider might switch.

Next, Dr. Orlando reviewed **Compatibility** - the degree of tangible fit between meaning and value attached to the intervention by involved individuals. This measure gets at the idea that if what the provider is being asked to do is not valuable for patients, the provider will not do it. It was ranked highly important to genomic medicine implementation by the IGNITE network and was developed as part of a cross-network pre-implementation provider survey. It is not validated. There are three relevant questions in the survey, and they include a 5-point Likert scale. Next, Dr. Orlando reviewed the **Organizational Readiness for Change** measure, also considered very important to genomic medicine implementation. There are two protocols in use, and they are well validated: Organization Readiness for Implementing Change (ORIC), and Organizational Readiness to Change Assessment (ORCA). ORIC is more recently validated and shorter with 12 items; ORCA, is older and longer, with 77 items. Dr. Orlando recommended ORIC. Dr. Brothers noted that CSER took a 19-item subset from ORCA, and that worked, but that might not change the recommendation of ORIC. Dr. Orlando wondered if there were any psychometric assessments of this subset and Dr. Bradbury wondered if a factor analysis had been done. Possibly, the ORIC is good now and the CSER subset could work in the future. Dr. Brothers noted that Sara Knight at Utah would be the best contact on CSER to determine if CSER validated use of the subset. As of now, moving forward with ORIC would be fine because it is freely available, and it has been used in one published study.

Dr. Bradbury introduced the measure of **Reach**, which represents the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative. This is a key construct in RE-AIM and other frameworks, sometimes conceptualized as uptake, though it is more detailed. There is nothing in the Toolkit yet; the RE-AIM Reach measure should be included, though it is guidance and does not have specific questions to ask of a study participant.

Finally, Dr. Bradbury reviewed **Adoption**, another key metric in RE-AIM, also conceptualized as uptake of an intervention. It can be reported by individuals or confirmed through medical records. Adoption is the absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program at the system or provider level. RE-AIM Adoption protocol has five items at each of the setting and staff levels. Dr. Brothers noted that gathering some of the requested information might require hunting down information in clinics and that this would make this a high burden protocol. Dr. Bradbury felt the requested information would be valuable to studies in community settings, particularly in determining who might be excluded from a study. Dr. Hamilton suggested this protocol go in Supplemental Information, with a more specific title to make it more appropriately searchable. The WG settled on “Uptake of Genetic Testing or Services.” Dr. Ritchie brought up the informatics approach to this measure and wondered if the WG should note in some way that there might be some informatic engine involved in data collection - this need not be information gathered by a human. Dr. Hamilton suggested that some guidance could be added to the Toolkit to note this and that PhenX generally is not responsible for how researchers actually get the data. A checklist might be a better fit for the data in this instance; informatics and data mining could become increasingly common.

**Education (Patient and Provider)**

Dr. Ali Torkamani presented his research on the **Education** measure, specifically baseline knowledge of genetics and post-genomic medicine implementation knowledge. The measure would look to get at basic knowledge of genomic science and its role in society, from personal decisions to civic and cultural affairs. Two important concepts to inform the measure are genomic science literacy and genomic health literacy. Robert Green’s 2015 study, the one validated measure of genetic literacy, is verbal and constrained by many condition-specific elements, so not particularly useful. Dr. Torkamani also reviewed the ClinSeq instrument from Kaphingst et al., 2012, but noted that it was found to be less reliable. There is nothing currently in Toolkit to cover this topic; therefore, Dr. Torkamani recommends the Langer et al., 2017, UNC Genomic Knowledge Scale as the protocol for Baseline Knowledge. It is 25 questions covering both genomic science and health. He noted that most studies develop their own protocol for this measure., so there is no measure that is widely used. Dr. Torkamani also recommends the Sanderson et al., 2018, Knowledge of Genome Sequencing (KOGS), protocol for Post-Genomic Medicine Implementation. KOGS is short, 9 questions, focused more on health literacy, and addresses more advanced knowledge of genomics. It was developed in the United Kingdom for the 100,000 Genomes Project in the UK. Dr. Torkamani notes that no study has everything the WG is looking for, but these two are validated. He prefers the UNC measure for pre- to post-test studies, as patients would not know how to answer most of the questions in the KOGS.

The WG discussed the UNC Scale, noting that the questions were focused on sequencing, but might be replaceable. Answers are true/false, and the scale is disease agnostic. Dr. Bradbury noted that while researchers might consider what is in the Toolkit the gold standard, this may not measure up. Dr. Chung noted they survey may have the feel of a quiz to participants, but this scale may be the best protocol available to measure the current knowledge gap. Dr. Hamilton noted that picking and choosing questions would not be the best approach. Dr. Brothers urged considering a demographics approach—this gets at understanding genetics rather than understanding results.

**Change in Management and Treatment**

Dr. Sirisak Chanprasert presented his research into the Change in Management and Treatment measures. He suggested that **Pharmacogenomics (PGx)** is a tool to establish precision medicine - tailoring treatment to a patient’s genetic makeup. Information on PGx can be obtained through patient surveys or interview, in pre-test counseling with post-test follow-up, or extracted from patient charts. Providers should be familiar with genetic testing, and researchers should be wary that patient charts may not be complete. The measure from IGNITE is general and not suitable for this purpose. Dr. Chanprasert found two other potential measures. One from the Netherlands is promising. It measures PGx knowledge covering five areas and is fairly short, though it is for pregnant women. It covers demographic information, chronic diseases, medication side effects, and some common knowledge of PGx, as well as attitude and willingness. The other, Treatment Satisfaction Questionnaire for Medication (TSQM), is good and well validated, very comprehensive, and quantitative, but primarily covers satisfaction with prescriptions and not much PGx. The TSQM is also very long, though there is a shortened version, the TSQM9.

Dr. Chanprasert recommends the Netherlands questionnaire, which is focused on pregnant women but could be adjusted for the general population. It is a good survey and not high burden. Patients should be interviewed before and after testing, and information may be extracted from charts.

For the **Health Surveillance** measure, Dr. Chanprasert noted that health surveillance is the practice of diagnostic testing to treat early-stage disease. Health surveillance guidelines are generated by population studies, and genetic testing can refine health surveillance. Information can be collected in patient interviews. There are no protocols currently in the Toolkit, and there is nothing in the main Genomic Medicine Implementation studies (CSER, eMERGE, IGNITE). From PubMed, Dr. Chanprasert found a survey study from Poland that covers three areas: attitudes toward testing to prevent disease, personal interest in testing to prevent disease, and attitudes toward assessing family history for risk. This is a short survey, easy for providers, but would need adjustment for the Toolkit. Dr. Chanprasert felt the Netherlands survey would be best, if adjusted for a broader population. Dr. Hamilton noted that it would have to be annotated (as it is clearly for pregnant women) with WG guidance on how to make it apply more broadly. Certain questions could be deleted; 1–7 are basic demographics covered elsewhere and specific to pregnant women. In addition, the Toolkit currently has a protocol to measure medication use. Dr. Ramos referred to a relevant paper about public attitudes towards pharmacogenomics, which included a survey of diverse populations and was published by Julianne O’Daniel from UNC. She will reach out to Dr. O’Daniel and ask about the survey. Dr. Brothers indicated that CSER considered a measure for “Change in Management and Treatment” but he does not recommend that we include it and would like to revisit after Dr. Zierhut’s presentation.

For Health Surveillance, the WG discussed the value of a disease-specific measure versus a generalizable measure. Although something applicable to cancer might be most widely used, something generic would be even more useful. Dr. Bradbury mentioned the CDC Behavioral Risk Factor Surveillance System (BRFSS), which is not perfect but is extensive and may be a good starting point.

**ELSI (Ethical Legal and Social Implications)**

Dr. Brothers presented his research on ELSI protocols. He noted the difference between ethics and morality—ethics is rooted in external, observable, actions, and legal actions are subject to regulation. Social implications relate to society at large. These concepts are not quantitative or measurable, other than in terms of a particular ethical system and compliance. Empirical ELSI study involves data from other domains through opinion polling on ethical appropriateness, voluntariness, outcomes, and decliner surveys. Measures related to voluntariness of research and quality of decision-making are most appropriate for genomic medicine. There are three decision-making type measures in the Toolkit already including “Gambling and Risk Taking”, “Shared Decision Making in Clinical Encounters”, and “Delayed Reward Discounting”. However, the only one that seems to be relevant, “Shared Decision Making in Clinical Encounters”, does not appear to be used for genetic research.

Dr. Brothers suggested that there are shared decision-making (SDM) tools focused on the patient-participants and provider perspective, and the observer perspective. SDMQ-9 is the best known and validated with 9 statements related to the decision-making in a consultation; however, it is redundant with the other SDM protocol in the Toolkit and has not been used for genomics. The Multidimensional Measure of Information Choice (MMIC) is also widely used and validated, but specific to Down Syndrome, and not readily adaptable, so not recommended as an addition to the Toolkit. The **Decision-Regret Scale** is also widely used, has been used in genetics studies, and is easily adaptable to new clinical contexts. Dr. Brothers recommends adding the Decision-Regret Scale to the Toolkit.

Dr. Zierhut noted that there is a four-item scale, SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement), in use at Brigham and Women’s Hospital for women and cancer, similar to SDMQ-9, that might be appropriate but has not been published yet. Dr. Bradbury noted the difficulty of measuring patient knowledge and the value of a measure that could collect this information. Dr. Chung noted a difference between Decision Regret and Decision Satisfaction and that they are both valuable. Dr. Zierhut to review Decision Satisfaction.

**Patient Outcomes**

The last scope element for the WG to consider, Patient Outcomes, was reviewed by Dr. Zierhut. Outcomes reflect the impact of the health service on the patient’s health status over time. This could be the ‘gold standard’ in measuring quality, but also could be the result of numerous factors, including some beyond a provider’s control. The Institute of Medicine (IOM) Framework for Healthcare Quality included the concepts of safety, effectiveness, patient-centered care, timeliness, efficiency, and equitability. Concepts of genetics service delivery outcomes that are covered by other protocols include access to services, and the proportion of individuals properly screened for HBOC/LS/FH (hereditary breast and ovarian cancer syndrome/Lynch Syndrome/familial hypercholesterolemia) or proportion of individuals with a family history of X who receive services; the genetic testing process, and FACToR; service delivery provision, and Genetic Counseling Outcomes Scale (GCOS); satisfaction, and GCOS; decisional conflict, and SURE, CollaboRATE, and SDM; and use of genomic services, and the proportion of patients with diagnoses who follow recommended management guidelines. Measures already in the Toolkit include Shared Decision-Making in Clinical Encounters, CollaboRATE; Family history of psychosis or mental health; and Quality of Life (QOL), both adulty and pediatric. To determine what elements might be missing from the Toolkit, Dr. Zierhut considered several factors. (1) There are many ways to categorize genetics service delivery and implementation outcomes; (2) Outcomes should address healthcare quality (IOM) and diverse implementation outcomes (CFIR); and (3) Patient outcomes are not yet covered in sufficient detail. To fill in these gaps, Dr. Zierhut proposes 5 areas for measures: Access to Services; Genetic Testing Process; Service Delivery Provision; Satisfaction; and Use of Genomic Services.

For **Access to Services**, the proportion of individuals who have access to screening, data would easily be collected through retrospective analysis. Dr. Zierhut suggested a checklist, and Dr. Hamilton mentioned the Social Determinants of Health measures under consideration for the Toolkit, which include population diversity information. For **Genetic Testing Process**, Dr. Zierhut suggested FACToR, an adaptation of MICRA (Multidimensional Impact of Cancer Risk Assessment), which is easy and quick to use and offers adult and parent versions and is being used widely. Dr. Chung noted seems like the direction research is headed. Dr. Hamilton suggested the MICRA for Supplemental Information, with FACToR in the Toolkit. For **Service Delivery Provision**, Dr. Zierhut suggested the 6-item version of the GCOS 24-item measure. It is new, but low burden. The 6 items are not a subset of the 24, but are changed, but there is good correlation with previous studies. However, these 6 items are the most applicable and useful, and the consensus seems to be forming around this shortened version of GCOS. For **Satisfaction**, Dr. Zierhut recommended the 6-item Genetic Counseling Satisfaction Scale (GCSS), which is widely used and freely available. Changing “genetic counselor” to provider might be advisable, with a note the scale can be adapted and a caveat to think about how “counseling” is defined. Dr. Zierhut defined **Use of Genomics Services and Adherence to Guidelines** as a measure of the proportion of patients with diagnoses who adhere to recommended management guidelines. There may not be one protocol to gather this information, as guidelines will be disease-. specific. The WG agreed that this, thinking about patient outcomes, is important—better for a protocol, not a checklist. Dr. Chung noted that studies have asked, “What did you change?”, but this question is not scalable. Dr. Bradbury noted that in panel testing, they have used options, but it is a long list and burdensome. Dr. Zierhut noted the question of whether the doctors were following the guidelines, so patients would have the best information to follow. Dr. Ramos noted that ClinGen was working on Act Sheets that might be useful. Dr. Bradbury noted that going to medical records might be the best way to get this information. Dr. Chung broached the question of whether a medication or surgery choice was changed through the use of services. Dr. Brothers noted that CSER tried using SURE but found it burdensome, and the WG agreed that this particular measure (**Understanding Health Implications of Genomics**) was a gap to note in the Toolkit. The WG discussed the KnowGene Scale that gets at cancer genetics knowledge, which could be useful. Dr. Zierhut noted that all five constructs are useful for patient outcomes; however, determining what of all the information available should go in the Toolkit is difficult.

**Finalize Measures/Protocols—Consensus Decisions**

The WG began the discussion of measures and protocols for each scope to send for outreach. These decisions are captured in the scorecard.

For Return of Results to Providers, the WG agreed on the measure Healthcare Personnel (HCP) Confidence in Condition, with eMERGE and CSER2 protocols, low burden, not validated, and not proprietary.

For Return of Results to Patients—Information Seeking, the WG agreed on the measure Information Sources for Patients after Return of Results, with the Post Return of Results (5–7 months) CSER protocol, low burden, not validated, and not proprietary. The WG noted that this subset from the CSER gets at where the patient searched for information.

For Return of Results to Patients—Family Communication, the WG settled on a hybrid measure: Sharing Genomic Information with Relatives, with the CSER protocol to determine with whom, and the eMERGE protocol to determine why—neither of which is high burden, validated, or proprietary; and then Sharing Genomic Information with Relatives—Pedigree Analysis, which is high burden and validated, and not proprietary. The WG discussed the value of including these two protocols in Supplemental Information, the IGNITE protocol and the EMERGE protocol with a pedigree. The WG also discussed PhenX’s recent addition of the My Family Health Portrait in the Toolkit.

For Implementation Science—Baseline, the WG agreed on three measures: Relative Advantage, which the WG may rename in the future, with IGNITE protocol of 2 questions; Perceived Compatibility with Current Clinical Practice, with the IGNITE protocol of 3 questions; and the Organizational Readiness for Changes, with the ORIC protocol—the only protocol validated for Implementation Science—Baseline. None of the protocols for Implementation Science—Baseline are high burden or proprietary.

For Implementation Science—Follow-Up, the WG chose two measures, both of which would use protocols that are high burden, but neither validated nor proprietary. The Patient Uptake of Genetic Services measure would be measured by the RE-AIM Reach protocol, and the Provider Adoption of Genetic Serviceswould be measured by the RE-AIM Adoption protocol. The WG agreed that these protocols would be put in a checklist, with references added. Dr. Bradbury was tasked with developing the checklist.

For Education—Patient and Provider, the WG agreed on the Baseline Knowledge of Genomics measure, with the UNC Genomic Knowledge Scale protocol, which is validated, non-proprietary, and low burden. The WG agreed to drop the Post-Genomic Medicine Implementation measure, and that in doing pre- and post-implementation, the UNC survey questions should be used. The WG also agreed on the Understanding of Health Implications of Genomics, with the KnowGene protocol, which is validated, non-proprietary, and low burden.

For Change in Management and Treatment—Pharmacogenomics-Based Drug Selection/Dosing, the WG will await further word on the PGx paper that Dr. Ramos emailed a colleague to secure. The measure Awareness of Pharmacogenomics would be measured by the Netherlands group survey, used with pregnant women, focusing on the questions starting at 8. This protocol is validated, non-proprietary, and low burden. The WG agreed to drop the Health Surveillance measure.

For Ethical, Legal, and Social Implications (ELSI), the WG decided on the Decision-Regret Scale protocol to measure Decision-Regret. The protocol is validated, low burden, and non-proprietary. The WG might consider calling it decision satisfaction and will make a determination after outreach.

For Patient Outcomes, the WG noted first that Access to Services is covered under Uptake, previously settled, with the RE-AIM protocols. The measure Patient Response to Genetic Testing would be measured by the FACToR protocol, validated, low burden, and non-proprietary. The cancer protocol can be added to Supplemental Information. Patient Empowerment after Genetic Services will be measured with the GCOS-6 protocol, validated, low burden, and non-proprietary. Patient Satisfaction with Genetic Services will be measured with the GCSS protocol, also validated, low burden, and non-proprietary.

To measure Adherence to Clinical Practice Guidelines for Genomic Medicine, the WG discussed sharing guidelines and creating a checklist. Dr. Hamilton noted this would be like creating a data collection worksheet, which is a common practice in PhenX. One checklist per guideline might become too numerous; Dr. Ramos suggested creating a checklist for each of the three Tier 1 conditions. Researchers might be able to use these for their own guidelines.

Wrapping up these decisions, Dr. Hamilton congratulated the WG on great progress, noting that none of the protocols are proprietary.

**Community Outreach**

Next Steps

Dr. Hamilton noted that Ms. Schoden and Mr. Phillips will draft the datasheets, and WG members then review them. Generally, the WG member who presented the measure acts as the primary reviewer. The WG can sign up as secondary reviewers, or, as frequently happens, the co-chairs can do final reviews. The WG decided this would be its course, as well. Dr. Torkamani will review the KnowGene datasheet for Dr. Zierhut. The reviews are quality control before vetting the preliminary outreach. After RTI does the first pass at the data sheets, they will reach out to the WG for any missing information or protocols. The data sheets are time consuming, so the WG should be a little patient through this step. Examples of data sheets are on the flash drive distributed to the WG for this meeting.

Timeline

The WG discussed upcoming conferences and other events at which to get some outreach connections, like the ACMG in March. The WG may be able to get some social media outreach through the conference. The American Society of Human Genetics (ASHG) deadline for session proposals is December 12, 2019, and the conference is in October of 2020. PhenX may be able to do a hands-on workshop to show off the new tools and features. The Society of Genetic Counselors is also a worthwhile event at which to target outreach.

The WG plans for community outreach in January to February 2020, with data sheet finalization in early 2020 and a public release of the measures in the spring of 2020.

**Adjourn**

The meeting was adjourned at 2:57 p.m.