

The Role of Clinical Quality Measures to Promote Long-Term Follow-up of Newborn Screening

Presented to the Advisory Committee on Heritable Disorders in Newborns and Children

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What are Quality Measures?

Why are they so important now?

- Quality measures
 - Standardized, quantitative assessment tools (“evidence-based”)
 - Typically ratios e.g. “% of children with sickle cell disease with penicillin”
 - Can track process (e.g. vaccine given), health outcomes (e.g. mortality, function), or attitudes (e.g. provider communicates well)
- Key component of a learning health care system
 - Quality improvement activities
 - Proactive clinical decision support
 - Maintenance of certification
 - Value-based reimbursement (“How do you measure quality?”)
- *The wrong measures can adversely affect health and health care!*

ACHDNC – Genetics in Medicine (2008)

Long-term follow-up after diagnosis resulting from newborn screening: Statement of the US Secretary of Health and Human Services' Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children

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- Central components
 - Care coordination
 - Evidence-based treatment
 - Quality improvement
- Features
 - Quality chronic disease management
 - Condition-specific treatment
 - Care throughout lifespan

ACHDNC – Genetics in Medicine (2011)

What questions should newborn screening long-term follow-up be able to answer? A statement of the US Secretary for Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children

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- Central components
 - Care coordination
 - Evidence-based treatment
 - Quality improvement
- Perspectives
 - State and nation
 - Primary/specialty providers
 - Families

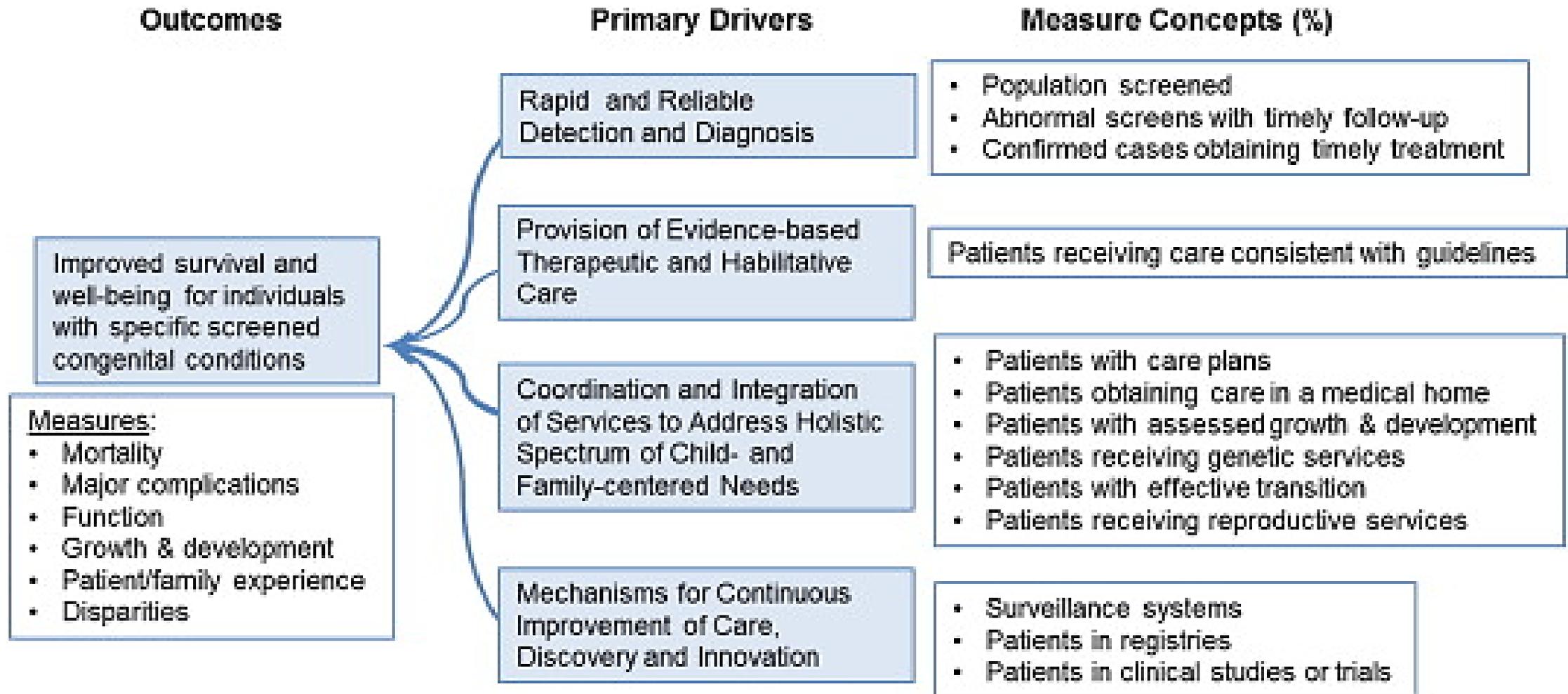
ACHDNC – Molecular Gen & Metab (2016)

Mol Genet Metab. 2016 Aug;118(4):221-9. doi: 10.1016/j.ymgme.2016.05.017. Epub 2016 May 31.

A framework for assessing outcomes from newborn screening: on the road to measuring its promise.

Hinton CF¹, Homer CJ², Thompson AA³, Williams A⁴, Hassell KL⁵, Feuchtbaum L⁶, Berry SA⁷, Comeau AM⁸, Therrell BL⁹, Brower A¹⁰, Harris KB¹¹, Brown C¹², Monaco J¹³, Ostrander RJ¹⁴, Zuckerman AE¹⁵, Kaye C¹⁶, Dougherty D¹⁷, Greene C¹⁸, Green NS¹⁹; Follow-up and Treatment Sub-committee of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

Framework for Assessing Outcomes from NBS



Follow Up and Treatment Workgroup: Quality Measures Project

ACHDNC Identified Priority Projects for the Workgroup (Spring 2016):

- Promoting the role of clinical quality measures to promote long-term follow-up
- Examine State Infrastructure for long-term follow-up

The Workgroup Identified Activities to Address Quality Measures:

- Review the state of the art of clinical quality measures
- Assess the use of clinical quality measures for newborn screening
- Assemble case studies on the use of clinical quality measures

Activities to Date Include:

- Regular meetings to discuss this vast and rapidly changing field
- Drafted a background document to focus on areas of need and opportunities for long-term follow-up
- Develop case studies that provide examples of how quality measures are used in NBS
 - describe success or barriers

The CMS/AHRQ Pediatric Quality Measures Project (PQMP)

- This AHRQ/CMS partnership was mandated by the CHIPRA 2009 to address the lack of child health quality measures and the desire to improve quality of care for all children including those in Medicaid and CHIP.
- Phase 1 supported 7 centers of excellence to increase the portfolio of evidence-based child health quality measures.
- Phase 2 supported 6 sites to study the feasibility of implementing measures in the real world.
- Several Sickle Cell Disease measures were developed and are being tested.
- Lessons Learned:
 - Evidence based measures are difficult and expensive to develop, validate, and implement.

Sickle Cell Disease Measures as an Example of Tracking Proven Therapies in Use

- There have been deficiencies in care identified through quality measures – immunizations, prophylactic antibiotics, ultrasonography screening.
- Improved outcomes and decreases in Emergency Room use have been documented.
- It is important to encourage cooperation and engagement of primary care, specialists, and emergency physicians to optimize care.
- Lessons Learned:
 - There are gaps in delivering services to children identified by NBS that can be addressed by using QM for LTFU of NBS.
 - Optimal care makes a difference.

University of Maryland Study of LTFU of Newborn Screening in Primary Care

- Use of quality measures for long term follow-up of newborn screening was evaluated in three primary care practices.
- Sickle cell disease and Hearing loss were the target conditions and the total number of cases was small.
- NCQA tools were used to evaluate medical home capabilities and capacity to care for children with special needs and their families.
- Improving communication is key to address incomplete information that primary care providers have about follow-up of newborn screening.
- Lessons Learned:
 - Primary care can participate, measure medical home status, and sometimes track children not identified by NBS.

Cystic Fibrosis Foundation Comparative Outcomes

- The Cystic Fibrosis Foundation funds a nationwide network of centers of excellence that are required to report and share outcome measures.
- Over the years, this work has led to significant new knowledge discovery about which treatments are most effective leading to important improvements in care and long term outcomes.
- Lessons Learned
 - Quality measures can be an important tool for new knowledge discovery.
 - Privacy protections are an important part of building cooperative data sharing and limit outside access to data, but yield important shareable findings.
 - National networks can be a valuable and productive resource.

Mountain States MCADD Checklist

- An MCADD checklist was integrated into their EPIC EHR to collect data on several quality measures.
- Deficiencies in care and documentation were identified by this process and addressed by improving documentation and communication at each visit.
- The tool was helpful as a reminder to new providers and in the Emergency Department.
- Lessons Learned:
 - Integrating quality measures into routine care is an excellent strategy for continuous quality improvement and eliminates the need to fund data collection.

CDC EHDI Measures Approved by NQF

- The CDC has become the custodian for Early Hearing Detection and Intervention (EHDI) measures that were certified by the National Quality Forum (NQF).
- Having certified electronic measures has helped improve data reporting from the states.
- Large numbers of infants screened before hospital discharge and after discharge were compared for time to audiological testing completion.
- Lessons Learned:
 - The NQF process of developing electronic measure formats and gaining certification is time consuming and difficult but feasible for some conditions.
 - Standardized measures can help improve completeness of data reporting.

California Department of Health Long Term Follow-up

- California has conducted many long term follow-up studies because the CA newborn screening fee includes funding for long term follow-up and data collection.
- Studies of Congenital Hypothyroidism and Cystic Fibrosis are excellent examples of what health departments can do when they have access to data.
- Lessons Learned:
 - Many health departments feel that they do not have the resources or mission to replicate the California methods, but the model has earned considerable respect.
 - Follow-up that ends at age 5 will not be adequate for some of the newer conditions.

National Survey of Children's Health

- National Survey of Children's Health (NSCH)
 - In 2016 the Survey of Children with Special Health Care Needs was combined with NSCH.
 - Questions cover a range of consumer satisfaction issue and access to services.
 - There is currently no way to identify children identified through newborn screening, but there is a question on whether the condition is heritable.
- Lessons Learned:
 - The survey provides important data on access to medical homes, adequacy of insurance coverage, and availability of services.
 - Some health departments, such as Hawaii, have used some of these questions in their own newborn screening family surveys.

Organic Acidemia Association Collects Data Directly from Families

- The Organic Acidemia Association (OAA) collects data directly from member families that can provide key insights into the natural history of disease and availability of services and support.
- Lessons Learned:
 - It is important and feasible to collect data directly from consumers.
 - The self-selected nature of the sample may not be representative of the entire population living with a condition.

What are the Gaps and Barriers in Applying Quality Measures to Newborn Screening?

- **Are there Gaps in Evidence?**

- Many conditions have sub-types or can present with a range in severity.
 - The best treatment options are not always clear, posing a challenge for developing condition specific clinical measures.
- Cystic Fibrosis has demonstrated that quality measures can be a pathway to evidence.

- **Are there Gaps in Developing Measures?**

- Developing measures is a challenge for rare disorders with late onset.
- The NQF certification process is difficult for NBS and validating measures is costly.
- The lack of pediatric quality measures led to the CMS/AHRQ PQMP.

- **Are there Gaps in Adopting and Using Measures?**

- The cost of data collection, and small numbers of patients in a single practice, are challenges to integrating quality measures into routine care may help
- Measures for Sickle Cell disease are now available and expected to increase in use.
- Some models used by health departments are hard to replicate due to variation in health departments and the communities served.

Moving Beyond Disease Specific Measures

- Traditional approaches to quality measurement may fall short for newborn screening.
- We need to include Public Health or Newborn Screening System measures to track that services are available, that individuals are not lost to follow-up, and transition into adult care.
- We need child-specific measures that focus on access to medical homes, available treatment, child well-being, and family satisfaction with the care process.
- Data sources may need to move beyond healthcare providers.

Including the Consumer Perspective on Quality Measures

- Patients and families have their own definition of quality.
- We need to listen to them and identify needs and gaps that providers and the system may be missing. These include:
 - Patient care
 - Ability to participate in research studies
 - Access to specialists
 - Insurance coverage for their conditions.
- Several disease advocacy organizations have successfully collected important disease specific data directly from patients and families using general surveys and patient natural history registries.

Quality Measures for Newborn Screening: Possible Resources

- Quality measures are hard to do, new tools can make it easier in the future.
- ONC, CMS, and AHRQ have an Electronic Clinical Quality Improvement Resource Center.
 - <http://ECQI.HealthIt.gov>
 - Access to Health IT standards for quality measure definition and reporting
 - Access to available quality measures and incentive programs
- NewSTEPs case definitions and care reporting databases can help define the denominator for NBS quality measures.
- NBSTRN has an LPDR database with definitions of data fields and including core and public health variables.

Summary of Key Findings

- Quality measures are a crucial part of health and health care system
 - Research; improving clinical outcomes; reimbursement
 - Rewarding quality requires measures that reflect patient outcomes or process of care
- Many different types of quality measures
 - Process - did something happen? (e.g. vaccine given)
 - Access to care - are patients able to get the care? (e.g. physician communicates well)
 - Health outcomes - hospitalizations, HGB A1C level, stroke
 - Quality of life - school attendance, perception of well-being
- Collecting/accessing data for these measures can be challenging
 - NBS conditions are rare; difficult to demonstrate QMs = outcomes
 - State NBS programs do long-term follow-up in many ways; no national standard
 - LTFU of NBS unlikely to be included in CMS measure set (except SSD, EHDI)
- Different perspectives are needed to develop quality measures, including the patient/consumer perspective

Status of the Follow Up and Treatment Workgroup's Quality Measures Project

- The QMs Sub-workgroup has (mostly) completed its task assigned in Spring 2016
 - Drafted a Report on *Promoting the Role of Clinical Quality Measures to Promote Long-Term Follow-up in Newborn Screening*
 - Covers areas of need and opportunity
 - Includes cases studies
 - Plan to finalize for Nov 2017 meeting
- SACHDNC input needed to prioritize next steps:
 - Finalize Report in coming months
 - Identify future activities

Quality Measures (QMs)

Possible Next Steps for the Follow-up and Treatment Workgroup

- Develop strategies to encourage development/validation of QMs for LTFU of NBS
- Identify a core set of long-term follow-up QMs for state NBS programs
 - e.g. mortality at age 5 years for all infants identified in a NBS program
- Address gaps identified related to QMs for NBS
 - e.g. Leveraging new HIT standards for implementing QMs
- Develop strategies to educate/engage stakeholders in using QMs for LTFU of NBS
- Determine feasibility of NBS in the National Survey of Children's Health (NSCH) and other consumer surveys