PLUGS®
Patient-centered Laboratory Utilization Guidance Services
Est. 2013
PLUGS History and Evolution

Challenges

- High out-of-pocket cost for low-value testing, e.g., Genetics
- Labs bear the cost for the many patients who can’t pay
- Issue exaggerated in pediatrics because of rare diseases

PLUGS evolved beyond pediatrics and genetic tests to broad laboratory stewardship advocacy

Today, we collaborate with:
- Adult and Pediatric Clinical Labs
- Lab IT and Healthcare Companies
- 3rd Party Payers including government
PLUGS Mission & Vision

**MISSION**
Improve test ordering, retrieval, interpretation and reimbursement.

**VISION**
Be #1 advocate for laboratory test stewardship.

Value = \( \frac{\text{Quality}}{\text{Cost}} \)
PLUGS Initiatives

Case Management

Tools for Stewardship Program Development

Laboratory Stewardship Standards

Insurance Alignment
PLUGS Initiatives

- **Laboratory Stewardship Program Guidance, Tools & Education** to help hospital laboratories and practitioners implement their own laboratory stewardship programs. These programs improve patient safety by reducing errors, and significantly reduce laboratory testing expenses.

- **Insurance Alignment** to guide national consensus policies related to laboratory tests and framework and guidance to build partnerships with local payors to improve efficiencies around test review and improve reimbursement outcomes. This will ultimately increase testing approval for patients who meet medical necessity criteria.

- **Case Management** service for genetic tests provided in partnership with Metis Genetics to clients who are interested in contracting additional laboratory genetic counseling services for case review.

- **Laboratory Stewardship Standards** created by the National Committee for Laboratory Stewardship (NCLS) will include checklists for promoting and formalizing laboratory stewardship programs. The core elements will also be helpful for independent commercial clinical laboratories.
The Power of the PLUGS® Network

THANK YOU TO OUR SPONSORS AND PARTNERS:

GOLD

SILVER

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PARTNERS

PLUGS®

Patient-centered Laboratory Utilization Guidance Services

Seattle Children's®
Hosptial • Research • Foundation

Accumen
ACL Laboratories
Akron Children's Hospital
Alverno Laboratories
Ann & Robert H. Lurie Children's Hospital of Chicago
Arkansas Children's Hospital
ARUP Laboratories
BayCare Health System
Baylor Genetics
Baylor Scott & White Health-Scott & White Memorial
Blueprint Genetics
Boston Children's
Bronson Methodist Hospital
Carle Foundation Hospital
CentraCare Health
Centura Health Laboratories
Children's Health
Children's Healthcare of Atlanta
Children's Hospital Colorado
Children's Hospital of Los Angeles
Children's Hospital of Philadelphia
Children's Hospital of Pittsburgh of UPMC
Children's Hospital of Wisconsin
Children's Hospitals and Clinics of Minnesota
Children's Mercy
Children's National Health System
Children's of Alabama
Christus Santa Rosa Health Systems
Cincinnati Children's Hospital Medical Center
Cleveland Clinic
Cook Children's Medical Center
Dayton Children's Hospital
Dell Children's Medical Center of Central Texas - Seton Healthcare
East Tennessee Children's Hospital
Fairview Health Services
Froedtert Health
Geisinger
GeneDx
Genetic Support Foundation
Global Genes
HealthPartners (Park Nicollet / Regions and Methodist Hospitals)
Illumina, Inc.
InformedDNA
Intermountain Primary Children's Hospital
Invitae
Johns Hopkins Hospital
Kaiser Permanente - SCAL Region
Kaiser Permanente NW Regional Lab
LAC+USC Medical Center
Le Bonheur Children's Hospital
Legacy Health
Mayo Clinical Labs
Memorial Regional Hospital
Metis Genetics
MNG Laboratories
MultiCare Tacoma General Hospital
National Decision Support Company (NDSC)
Nationwide Children's Hospital
Nemours/Alfred I. duPont Hospital for Children
Ochsner Health System
Oregon Health Sciences University (OHSU)
Penn State Hershey Medical Center
PerkinElmer Genomics
Phoenix Children's Hospital
PreventionGenetics
Providence Regional Laboratories
Providence Sacred Heart Medical Center
Quest Diagnostics
Rady Children's Institute for Genomic Medicine
Roche Diagnostics
Royal North Shore Hospital
Salem Health
Sanford Health
Southern Illinois Healthcare
SSM Health Cardinal Glennon Children's Hospital
SSM Health St. Mary's Hospital - Madison
St. Jude Children's Research Hospital
St. Louis Children's Hospital
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STANFORD HEALTHCARE
Sutter Health
Swedish Medical Center
Texas Children's Hospital
TriCore Reference Laboratories
UC Davis Health
UCLA Health
UCSF Benioff Children's Hospital
University of Florida Health
University Of Kentucky Chandler Medical Center
University of Michigan Health System
University of North Carolina
University of Virginia School of Medicine
University of Washington
UW Health University Hospital
Valley Children's Hospital
Versiti
Wake Forest Baptist Health
WellSpan York Hospital

Stanford Healthcare
Sutter Health
Swedish Medical Center
Texas Children's Hospital
TriCore Reference Laboratories
UC Davis Health
UCLA Health
UCSF Benioff Children's Hospital
University of Florida Health
University Of Kentucky Chandler Medical Center
University of Michigan Health System
University of North Carolina
University of Virginia School of Medicine
University of Washington
UW Health University Hospital
Valley Children's Hospital
Versiti
Wake Forest Baptist Health
WellSpan York Hospital
Stewardship Program Development Tools

- Customized strategic assessment from the PLUGS Team
- Policies, procedures & communication templates that help providers reduce unnecessary testing & correct test orders
- Database for collecting, tracking, & analyzing cases
- Tool to assess the risk of errors in send-outs area
- Provider-satisfaction survey to solicit feedback regarding the program
- And much more…
Be Connected

- PLUGS Committees
  - National Committee for Laboratory Stewardship (NCLS)
  - Laboratory Formulary
  - Insurance Advocacy

- Weekly Newsletter

- Bi-monthly Member Meetings

- Website: www.schplugs.org

- Discussion Forum

- Office Hours/Call Center
Education

- Monthly webinars
- Annual and regional conference
- Bi-monthly member meetings

PLUGS® Summit 2020
JUNE 24th-26th
SEATTLE, WA
Clinical Laboratory Stewardship: Tips, tricks, and tools to benefit patients, labs and payers.
The savings from eliminating unnecessary esoteric laboratory tests will pay for a PLUGS membership in about 5 days.

The other 360 days of savings are for your health system and your patients.
APPENDIX 1: Seattle Children’s Hospital Lab Stewardship Program
Test Utilization: Four Big Problem Areas

1. Misordering tests
2. Misinterpreting test results
3. Failure to retrieve and act on test result
4. Unnecessary cost to patients and healthcare system

Laboratory Test Stewardship

Refers to a healthcare “ethic that embodies responsible planning and management of resources”

\[
\text{Value} = \frac{\text{Quality}}{\text{Cost}}
\]

### Lab Stewardship Interventions

#### Levels of Guidance

<table>
<thead>
<tr>
<th>Gentle</th>
<th>Medium</th>
<th>Strong</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Posting of guidelines on the requisition</td>
<td>✓ Utilization report cards</td>
<td>✓ Privileging specific tests to specialty providers</td>
</tr>
<tr>
<td>✓ Computerized reminders regarding utilization guidelines</td>
<td>✓ Changes to manual requisition</td>
<td>✓ Lab test formulary</td>
</tr>
<tr>
<td>✓ Educational lectures</td>
<td>✓ Hiding tests in computerized provider order entry systems</td>
<td>✓ Utilization report card with peer or leadership review</td>
</tr>
<tr>
<td>✓ Consensus reference laboratory pre-selection for specialized testing</td>
<td>✓ Periodically reviewing and updating physician preferences</td>
<td>✓ Requirement for high-level approval (e.g. Pathologist) or consultation (e.g. genetic counselor)</td>
</tr>
<tr>
<td>✓ Providing relative cost information in CPOE</td>
<td></td>
<td>✓ CPOE: Hard stops</td>
</tr>
</tbody>
</table>

Case

12 y/o inpatient with hypoglycemia secondary to hyperinsulinism and associated seizures evaluated by Endocrinology

Genetic testing recommended to work up possible genetic etiology vs. insulinoma

Requested concurrent analysis of 8 genes including “GLUT-1”

Error caught on review by utilization management GC

---

**GLUT-1**
*(glucose transporter type-1)*

**SLC2A1** gene
De Vivo disease

**GLUD-1**
*(glutamate dehydrogenase-1)*

**GLUD1** gene
Hyperinsulinemic hypoglycemia
Interventions at SCH

HYPOTHESIS
By implementing a review process for expensive genetic sendout tests, we will save $ and improve value for patients.

Sample Test Review Criteria

- All Miscellaneous requests
  - Requests to send to non-preferred laboratory
  - Requests to send to international laboratories
  - Requests to send tests performed in-house
- All genetic send out tests
- Tests defined as under management
Case Review Process at Seattle Children’s…

Order received by in-house genetics lab
Sendout test request received in lab

Lab GC reviews pending list
E-mail sent to Lab GC / SO consultant

Case Review & Adjudication

45%

45%

Additional information needed from ordering provider

80%

12%

8%

Approved
Modified
Cancelled
Case Review Reduces Errors

Reasons to MODIFY order

- Corrected: 9%
- Sequential: 40%
- Cost: 19%
- Improved: 44%

17%  
n=1711

Reasons to CANCEL order

- Wrong: 9%
- Cost: 1%
- Deferred: 26%
- Duplicate: 11%
- New Info: 11%
- No Preauth: 42%

10%  
n=993

*Data collected  
Sept 2011 – Feb 2019  
N=10,133 genetic cases  
Seattle Children’s Hospital
### Case Review ROI

<table>
<thead>
<tr>
<th>PRICE THRESHOLD &gt; $2500</th>
<th>PRICE THRESHOLD &gt; $1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 requests/week</td>
<td>10 requests/week</td>
</tr>
<tr>
<td>30 min./request</td>
<td>30 min./request</td>
</tr>
<tr>
<td>30% modification rate</td>
<td>30% modification rate</td>
</tr>
<tr>
<td>$740 saved/request</td>
<td>$470 saved/request</td>
</tr>
<tr>
<td><strong>ROI</strong>: $2220/week with 1.5 hr. consultant time</td>
<td><strong>ROI</strong>: $4700/week with 5 hr. consultant time</td>
</tr>
</tbody>
</table>

**$106,560 annual savings**  
**$225,600 annual savings**
Surveys Reveal Positive Provider Response

I really appreciate the efforts of the UM team. **Given the state of our health care system** we definitely need a **team of experts** to navigate these challenging waters!

I think the lab UM team overall is doing a phenomenal job. Their **services are definitely helpful**, if not necessary, for genetics and non-genetic providers alike to **appropriately plan and carefully select laboratory tests**.
SCH Lab Stewardship Program

Lab Stewardship Committee

- Lab Test Formulary
- Disease-specific Subcommittees
- Case Review
- Insurance Advocacy
Committee Hierarchy

Utilization Review

Required by CMS

Hospital Lab Stewardship

VP of Medical Affairs
CMIO
Inpatient provider
Director Revenue Cycle
Laboratory medical leadership

Laboratory Stewardship Working Group

Exome Sub-committee

Heme-Onc Sub-committee
Hospital Laboratory Stewardship at SCH

• Established Jan 2017
• Meets quarterly
• High-level decision making:
  ✓ Clinician Test Requests (Pleximmune)
  ✓ Peri-mortem genetic testing policy
  ✓ “Free” testing policy
  ✓ Policies/coverage for rapid exomes and tumor testing
  ✓ Best-practice guideline for autoimmune encephalopathy

WHO:
  VP of Medical Affairs
  CMIO
  Inpatient provider
  Director Revenue Cycle
  Laboratory medical leadership
Laboratory Stewardship Working Group

Working group includes:

2 clinical chemists, 4 laboratory genetic counselors, 3 pathologists, 2 medical geneticists, specialty labs manager, lab business operations manager, clinical genetic counselors

Weekly working meeting includes:

• Case review
• Test build & reference lab discussions (e.g. lab formulary)
• Focused intervention project development/management
Initiatives

Improve lab test formulary:

- Monitor MISC tests & determine when to build
- Guide systematic process for removing tests from the menu

Example: MTHFR

- Notification process for providers, families & lab staff
- Improved patient care, reduced provider frustration, & reduced cost

Methylene Tetrahydrofolate Reductase, thermolabile

⚠️ Important Note

Analysis of the MTHFR gene for variants c.677C>T & c.1298A>C is no longer offered at Seattle Children's.

Our Laboratory Test Utilization Management Team has determined that there is no proven, evidence-based clinical utility for this test for thrombophilia evaluation or other clinical indications.
APPENDIX 2: Case Management
Making the Case for Case Management

8-10 new testing products per day

Net New Genetic Testing Products
March 1st, 2015 – March 1st, 2017
Genetic Counselor Review of Genetic Test Orders in a Reference Laboratory Reduces Unnecessary Testing

Christine E. Miller,® Patti Krautschefid, Erin E. Baldwin, Tatiana Tyrdik, Amanda S. Openshaw, Kim Hart and Danielle LaGrave
Genetics Division, ARUP Laboratories, Salt Lake City, Utah

Manuscript Received: 1 May 2013; Manuscript Accepted: 3 January 2014

Test Utilization and Appropriate Test Orders:
The Role of the Genetic Counselor

Adding value to genetic testing through utilization management: Commercial laboratory’s experience

Gina K. Londre MS, Christina A. Zaleski MS, Jessie H. Conta MS
Case Management in the Hospital Setting

Improving the Value of Costly Genetic Reference Laboratory Testing With Active Utilization Management

Jane A. Dickerson, PhD; Bonnie Cole, MD; Jessie H. Conta, MS; Monica Wellner, BS; Stephanie E. Wallace, MD; Rhona M. Jack, PhD; Joe Rutledge, MD; Michael L. Astion, MD, PhD

SPECIAL ARTICLE

Improving Molecular Genetic Test Utilization through Order Restriction, Test Review, and Guidance

Jacquelyn D. Riley,* Gary W. Procop,* Kandice Kottke-Marchant,* Robert Wylie,1 and Felicitas L. Lcmbawan*1

Preventing Genetic Testing Order Errors With a Laboratory Utilization Management Program

Patrick C. Mathias, MD, PhD,1 Jessie H. Conta, MS,2 Eric Q. Konnick, MD,1 Darci L. Steren, MS,2 Shannon M. Stasi, MS,2 Bonnie L. Cole, MD,2 Michael L. Astion, MD, PhD,1,2 and Jane A. Dickerson, PhD1,2

Promoting appropriate genetic testing: the impact of a combined test review and consultative service

Carlos J. Suarez, MD,1 Linbo Yu, MS,2 Natalie Downs, MS,2 Helio A. Costa, PhD3 and David A. Stevenson, MD4
GeneTestAdvisor pays for itself.

- Average modification rate: 30%
- Average cost savings per review: $350
Return on Investment
Examples based on test cost and volume

~$92,000
Annual Savings

Test threshold ≥$2500
~3 cases per week

~$166,000
Annual Savings

Test threshold ≥$1000
~10 cases per week

Seattle Children’s Hospital data collected September 2011-September 2013
PLUGS GeneTest Advisor Can Help!
GeneTest Advisor Workflow

Client Lab Submits Genetic Test Request

GC Case Review

If needed, GC requests more information

GC provides recommendation

Client Lab communicates with provider

Test Approved

Test Modified

Test Cancelled

- Was the correct test ordered?
- Is the test medically necessary
- Can sequential testing be considered?

- Are there alternate tests that are more appropriate?
- Has the optimal test & reference lab been selected?
- Is insurance preauthorization required?
APPENDIX 3: Insurance Alignment
Insurance Alignment

Systematic Solutions to improve preauth processes / workflow

- Standardize workflow within institution
- Right person doing right work
- Align approach with payer systems
- Focus on stewardship at all steps

Policy Creation & Improvement

- Develop rational policies using experts
- Distribute policies
- Create infrastructure to ensure policies are kept up-to-date
Insurance Alignment: Systematic Solutions

Le Bonheur Children’s Hospital

Standard SOP for genetic testing preauthorization

Children’s Hospital of Pittsburgh of UPMC

Strong partnership with local payer resulted in significant improvement in authorization & reimbursement for exome sequencing

Seattle Children’s

Robust case review process supports efforts to obtain exemption from payer preauthorization process

Streamlined process that is integrated in Cerner and improves insurance reimbursement rates, reduces time required to obtain authorization and significantly improves efficiency
Help Us, Help You…

Resources created for PLUGS members

- Policies
- Workflow
- Inspiring & educational talks
- Sample presentations to payers

Quick Guides

The following UM Quick Guides provide topic-specific resources to enhance videos, relevant articles, policies, templates and other tools.

- Getting Started
- Managing Reference Labs

Insurance Preauthorization 101

Learn More
A Collaboration
to Develop Policies for Mitochondrial Conditions..

Mitochondrial Proposal & Funding to…

✔ Develop rational genetic testing coverage policies for mitochondrial conditions
✔ Implement them in a major insurance product
✔ Promote the spread of these policies at healthcare institutions and insurance companies

Funded by Seattle Children’s Mitochondrial Research Guild
http://www.nwmito-research.org/
# Estimated Timeline of Project

<table>
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<tr>
<th>ITEM</th>
<th>TIMEFRAME</th>
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<tr>
<td>Form project committee with an expert national committee of medical providers, genetic counselors, and laboratory directors.</td>
<td>2 mos</td>
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<td>Mito test/condition policies: First 2 complete.</td>
<td>4 mos</td>
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<tr>
<td>Review and update of proposed testing algorithms for mitochondrial conditions.</td>
<td>6 mos</td>
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<tr>
<td>Form strategy for complex mito testing policies.</td>
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<tr>
<td>Develop proposed policies for coverage of additional mito tests, including mitochondrial genome and nuclear mitome.</td>
<td>8 mos – 24 mos</td>
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<tr>
<td>Annual Committee meeting</td>
<td>12 mos</td>
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<tr>
<td>Advocate for adoption of these proposed policies by healthcare systems, insurance companies and other 3rd party payors such as employers and the government.</td>
<td>14 mos - 24 mos</td>
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*Seattle Children's®*

Patient Centered Laboratory Utilization Guidance Services
Mitochondrial Committee Members

Baylor Genetics
Eric S. Schmitt, MS, PhD

Blue Shield of California
Stephanie Gandomi, MS, LCGC

Children’s Hospital of Philadelphia
Kierstin Keller, MsGC

Children’s Hospital of Pittsburgh of UPMC
Jodie M. Vento, MGC, LCGC
Roxanne Acquaro, MS, LCGC
Andrew McCarty, MGC

Kaiser Permanente
Ashley Brazil, MS, LGC

eviCore Innovative Solutions
Lindsey Steckling, MS, CGC

University of Utah and Genome Medical
Steven Bleyl, MD, PhD

Invitae
Tom Winder, PhD, FACMG
Britt Johnson, PhD, FACMG

Mayo Clinic College of Medicine
Amy White, MS, CGC

Concert Genetics
Gillian Hooker, PhD, ScM, CGC

Seattle Children’s Hospital and University of Washington
Russell Saneto, DO

Seattle Children’s Hospital
Rhona Jack, PhD
Darci Sternen, MS, LGC
Networking Strategies

- United Mitochondrial Disease Foundation (UMDF) National Education Conference
- Submit for publication in peer-reviewed journal
- PLUGS network
- Laboratories to incorporate knowledge into test coding
- Network with existing online resources to cross-reference

Payors

- eviCore
- Blue Shield
- Medicaid
- Committee and PLUGS members’ institutions’ insurance payor relations liaisons

Medical / Laboratory Community

Families / Consumers

- UMDF
- Global Genes
- Condition-specific groups
Through PLUGS, leaders from multiple labs partnered with eviCore Healthcare* and other payers to create an exome sequencing policy.

Currently, the exome sequencing policy is associated with >19 MILLION covered lives through multiple payers.

THANK YOU to the collaborators!

PreventionGenetics
Christina Zaleski

Seattle Children’s Hospital
Jimmy Bennett
LabGC Team

St Jude Children’s Research Hospital
Roya Mostafavi

eviCore
Melissa Bennett

Johns Hopkins
Carolyn Applegate

Children’s Hospital of Pittsburgh of UMPC
Jodie Vento

* A third party benefits manager servicing the insurance industry
Insurance Alignment Goals

- Share stories (both successes & opportunities)
- Advocate for single process that is closest to the patient
- Spread the message of stewardship

Systematic Solutions to improve preauth processes / workflow

PLUGS Committee: Insurance Alignment
Co-Chairs: Lindsay Zetzsche and Jodie Vento
Insurance Alignment Goals

Policy Creation & Improvement

- Disseminate policies
- Create new policies

PLUGS Committee:
Insurance Alignment

Co-Chairs:
Lindsay Zetzsche and Jodie Vento
National Committee for Laboratory Stewardship

**MISSION**

Improve the quality and value of clinical care through establishing national standards for laboratory test utilization

**VISION**

To promote and enable the highest standards of effective test utilization in every clinical setting

Committee members:

- Mike Astion
- Rob Carpenter
- Jane Dickerson
- Andrew Fletcher
- Joaquin Garcia
- Brian Jackson
- Gary Procop
- Lee Schroeder
- Ila Singh
Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship

Four basic elements of lab stewardship programs:

1. Governance
2. Interventions
3. Data extraction and monitoring
4. Review and improve
NCLS Progress and Goals

- Gather feedback from published guidelines
- Create detailed checklists

- Formed Committee
- Finalized mission/vision
- Convened at the Summit
- Outlined position statement
- Completed guidelines
- Submitted to JALM
- Disseminate checklist to 10 pilot sites