



**Seattle Children's<sup>®</sup>**  
HOSPITAL • RESEARCH • FOUNDATION

**PLUGS<sup>®</sup>**

Patient-centered  
Laboratory Utilization  
Guidance Services

**PLUGS<sup>®</sup>**

Patient-centered Laboratory  
Utilization Guidance Services

Est. 2013

# PLUGS History & Evolution

## Challenges

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

**PLUGS** evolved beyond pediatrics & 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 access, ordering, retrieval, interpretation and reimbursement.

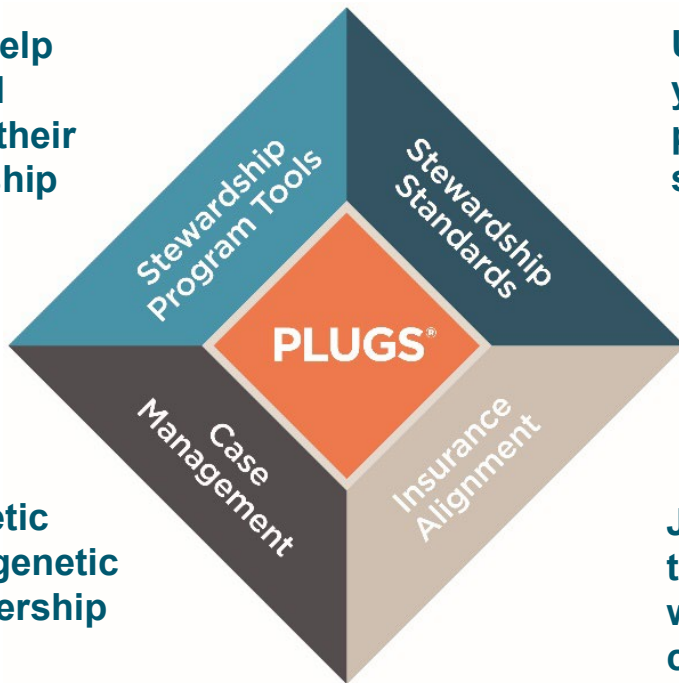
## VISION

Be the #1 advocate for laboratory test stewardship.

A healthcare “ethic that embodies responsible planning and management of resources”

# PLUGS Initiatives

Tools and education to help hospital laboratories and practitioners implement their own laboratory stewardship programs.



Use the checklist to assess your laboratory stewardship program against defined stewardship standards.

Contract laboratory genetic counseling services for genetic test case review in partnership with Metis Genetics.

Join our efforts to increase testing approval for patients who meet medical necessity criteria.

# The Power of the PLUGS® Network

ACL Laboratories  
Adventist Health  
Aetna  
Akron Children's Hospital  
Arkansas Children's Hospital  
Avalon Healthcare Solutions  
Baptist Health  
Baylor Genetics  
Blue Shield of California  
Boston Children's Hospital  
Bronson Methodist Hospital  
CentraCare Health  
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 National Health System  
ChristianaCare  
Cincinnati Children's Hospital Medical Center  
Cleveland Clinic  
CommonSpirit Health  
Concert Genetics  
Cone Health  
Cook Children's Medical Center  
Dayton Children's Hospital  
East Tennessee Children's Hospital  
Fairview Health Services  
Fred Hutchinson Cancer Center  
Froedtert Health

Geisinger  
GeneDx | Sema4  
Genetic Support Foundation  
Global Genes  
Guardant Health  
Gundersen Health System  
HealthPartners (Park Nicollet / Regions and Methodist Hospitals)  
Highmark, Inc.  
Intermountain Healthcare  
Johns Hopkins Hospital  
Kaiser Foundation Health Plan of Washington  
Kaiser Permanente – SCAL Region  
Kaiser Permanente NW Regional Lab  
LAC+USC Medical Center  
Lahey Hospital and Medical Center  
Le Bonheur Children's Hospital  
Legacy Health  
Lifespan Academic Medical Centers  
Lurie Children's Hospital of Chicago  
MaineGeneral Medical Center  
MedStar Health  
Metis Genetics  
MultiCare Tacoma General Hospital  
Nationwide Children's Hospital  
Nemours Children's Health  
New York Presbyterian Hospital  
Nicklaus Children's Hospital  
NW Rare Disease Coalition  
Ochsner Health System  
Oregon Health Sciences University (OHSU)  
OU Health  
Parkview Health  
Phoenix Children's Hospital  
Project Santa Fe Foundation – Lab 2.0  
Providence Health & Services

Providence Sacred Heart Medical Center  
Quest Diagnostics  
Rady Children's Institute for Genomic Medicine  
Saint Francis Health System  
Salem Health  
Sanford Health  
SSM Health Cardinal Glennon Children's Hospital  
SSM Health St. Mary's Hospital - Madison  
St. Jude Children's Research Hospital  
St. Luke's Health System  
St. Luke's University Health Network  
Stanford Health Care  
Sutter Health  
Texas Children's Hospital  
TriCore Reference Laboratories  
UCLA Health  
UCSF Benioff Children's Hospital Oakland  
United HealthCare Services, Inc.  
University of Florida Health  
University of Kentucky Chandler Medical Center  
University of Miami  
University of Michigan Health System  
University of Missouri  
University of North Carolina  
University of Virginia School of Medicine  
UW Health University Hospital  
Valley Children's Hospital  
Vanderbilt University Medical Center – Vanderbilt Medical Laboratories  
Versiti  
Wake Forest Baptist Health  
WellSpan York Hospital  
Yale University – Lab Medicine

**THANK YOU TO OUR SPONSORS  
AND PARTNERS!**

**FOUNDING PARTNER**

**UW Medicine**

**LABORATORY MEDICINE  
& PATHOLOGY**

**GOLD**



**MAYO CLINIC  
LABORATORIES**

**BRONZE**



**CORPORATE**

**illumina®**

**ThermoFisher  
SCIENTIFIC**



**PARTNERS**



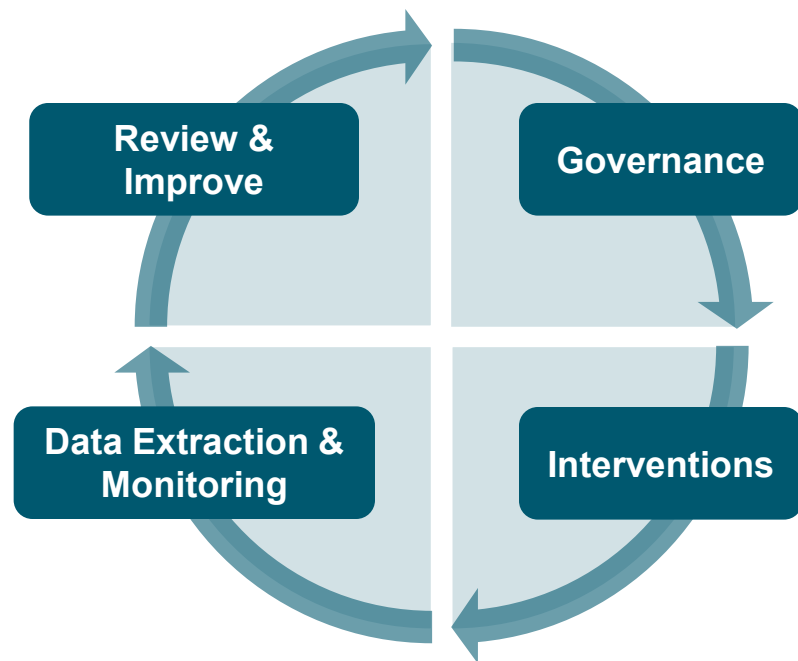
**PLUGS®**

Patient-centered  
Laboratory Utilization  
Guidance Services

# Four Elements of Laboratory Stewardship Programs

To periodically assess and improve the whole program.

To identify problems and assess interventions.



The people who make the program happen, and the way they are organized.

To improve test ordering, result retrieval, accuracy of interpretation, and payment.

# 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...

Seattle Children's  
Administrative Policy-Procedure  
Insurance Pre-Authorization for Genetic Testing

**POLICY:**  
To minimize the risk of excessive financial liability for either the family or the hospital, insurance pre-authorization must be requested and obtained when possible prior to ordering genetic testing. Families should be informed about potential significant financial liability related to genetic testing.  
This policy does not apply to genetic tests that are critical to the emergent medical management of the patient or to genetic tests related to the evaluation of neonatal already present in the patient.

**PURPOSE:**  
To protect patient's financial liability when there is time to assess the value of the genetic test.

**PROCEDURE:**  
The ADDENDUM below describes the current standards and procedures.

Originated by: Jessie Coats, MS, Genetics Counselor, Clinical Laboratory  
Jane Dickerson, PhD, Senior Laboratory Scientist  
Blaine Cole, MD, Pathology  
Mike Austin, MD, PhD, Chief, Laboratory Medical Division  
Eduard Jack, PhD, Senior Laboratory Scientist

Reviewed by: Suzanne Vanderwerff, Senior Director, Revenue Cycle  
Mark Del Baccaro, MD, VP, Medical Affairs  
Eric Merline, Manager, Laboratory

Approved by Medical Director

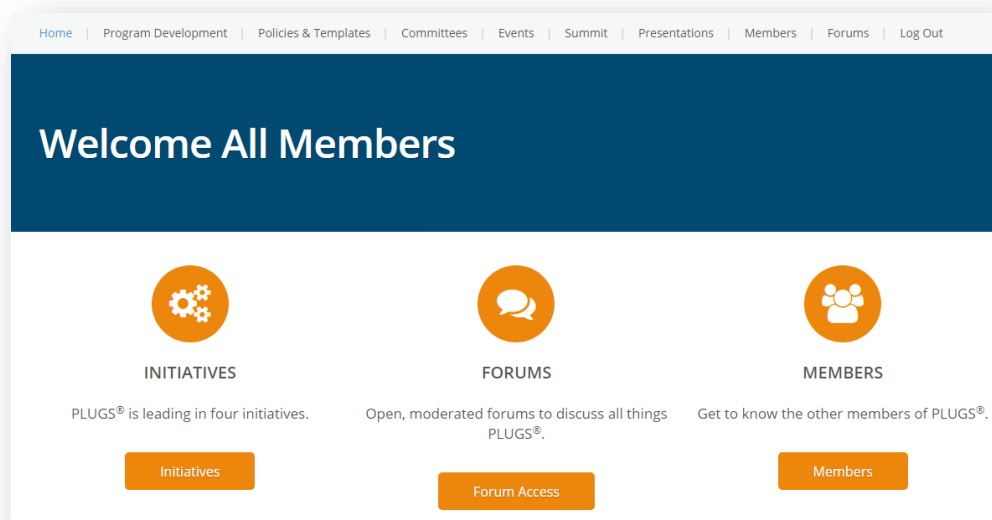
ID: 1438  
Patient Name: Conla, Jessie  
MIDN: 123456  
Accession Number:  
Ordering Provider: Wallace, Stephanie  
Resident: ☒  
Provider Specialty 1: Genetics  
Request Date: 6/1/2013  
Handled by: Jane Dickerson  
Contact Mode: Email  
Test Request: FBN1 sequencing, reflex to del/dup  
Test Request Sent: FBN1 sequencing, reflex to del/dup  
Genetic Test: ☒  
Reference Lab: CTGT  
Reference Lab Sent: CTGT  
Cost: \$2,400.00  
Cost Sent: \$1,200.00  
Specimen Type: DNA Banking  
Resolved: 6/2/2013  
Solution to Problem: Sequential Testing  
MG: Hold: ☒  
Institution: PLUGS

requires follow up: Yes  
Assigned To: Darc Sternes  
Demographics: 10 year old female with mild stable aortic root enlargement, scoliosis, pectus excavatum and a paternal family history concerning for  
Patient Type: Outpatient  
Clinical Necessity: Testing to establish dx & guide appropriate mgmt.  
Impressions: Sequential testing requested, possible cost savings if del/dup not needed.  
Seq - \$1,200  
O/d - \$1,200  
Updates:  
Preauthorization: No  
Cost Savings: \$1,200.00  
Results Expected:  
Result: Pending  
Result Details: FBN1 pnt



# Be Connected

- ✓ PLUGS Committees
  - Informatics Committee
  - Insurance Alignment Committee
  - Ambassadors Committee
- ✓ Weekly Newsletter
- ✓ Quarterly Member Meetings
- ✓ Website: [www.schplugins.org](http://www.schplugins.org)
- ✓ Discussion Forum
- ✓ Office Hours/Call Center



# Education

- ✓ Annual and regional conferences
- ✓ Quarterly member meetings
- ✓ Monthly webinars



**PLUGS<sup>®</sup>**  
SUMMIT

Join us for the annual PLUGS Summit, where stakeholders gather to learn practical tools for laboratory stewardship program development and insurance alignment that will apply to hospitals, health systems, reference labs, insurance payers, and patients.



The savings from eliminating unnecessary esoteric laboratory tests pays for a PLUGS membership **in about 5 days.**

**The other 360 days of savings are for your health system & your patients.**

---

APPENDIX 1:

# Seattle Children's Hospital Laboratory Stewardship Program

# Laboratory Test Stewardship: 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”

$$\text{Value} = \frac{\text{Quality}}{\text{Cost}}$$

Source: National Research Council. *Controlling Costs and Changing Patient Care?: The Role of UM*. Washington, DC: The Natl Academies Press, 1989.

# Lab Stewardship Interventions

**Table 1. Stewardship intervention examples by strength.**

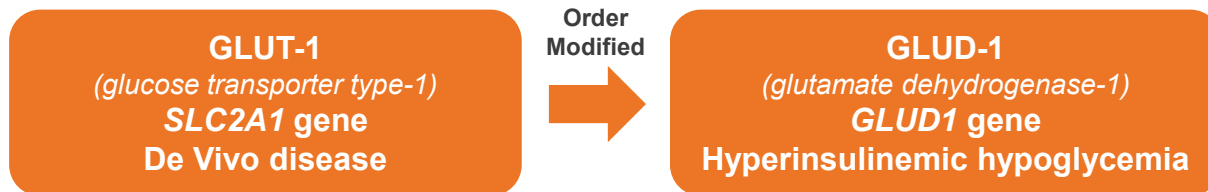
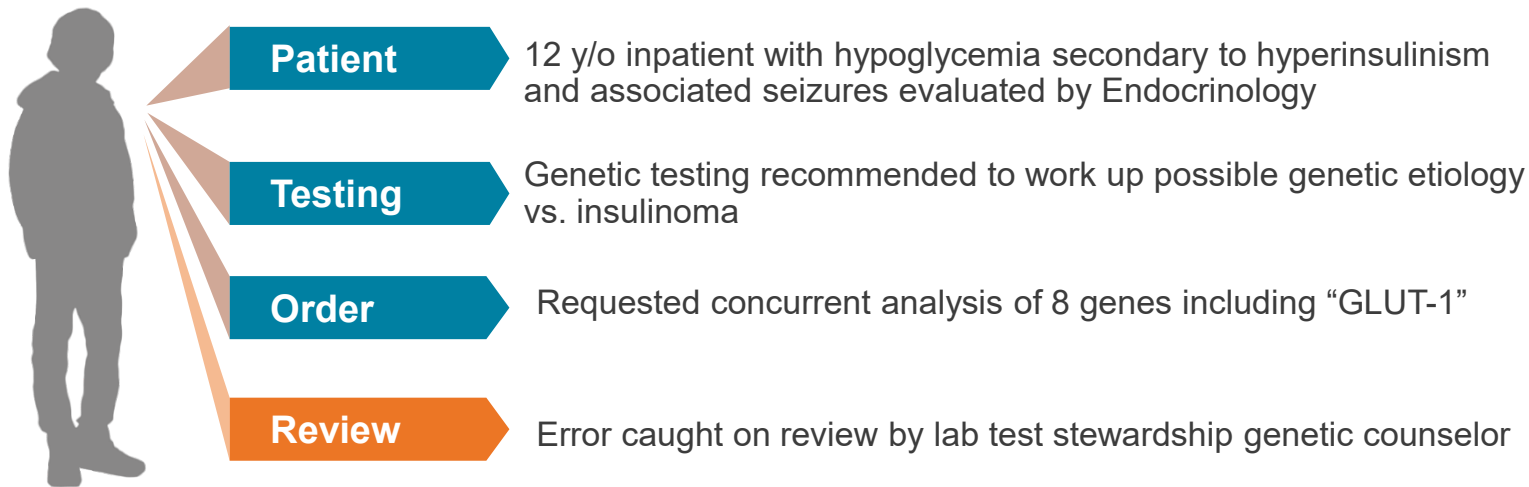
Gentle	Medium	Strong
Posting guidelines on the requisition	Utilization report cards	Utilization report cards with peer or leadership review
Computerized reminders regarding utilization guidelines	Changes to manual requisitions	Privileging specific tests to specialty providers
Educational lectures	Hiding tests in CPOE systems	Laboratory formulary including send-out formulary
Consensus reference laboratory preselection for specialized testing	Periodically reviewing and updating physician preferences	Requirement for high-level approval or consultation
Providing relative cost information in CPOE		Rules requirement CPOE: Hard stops

**Gentle Guidance**



**Strong Guidance**

# Case





# Interventions at SCH

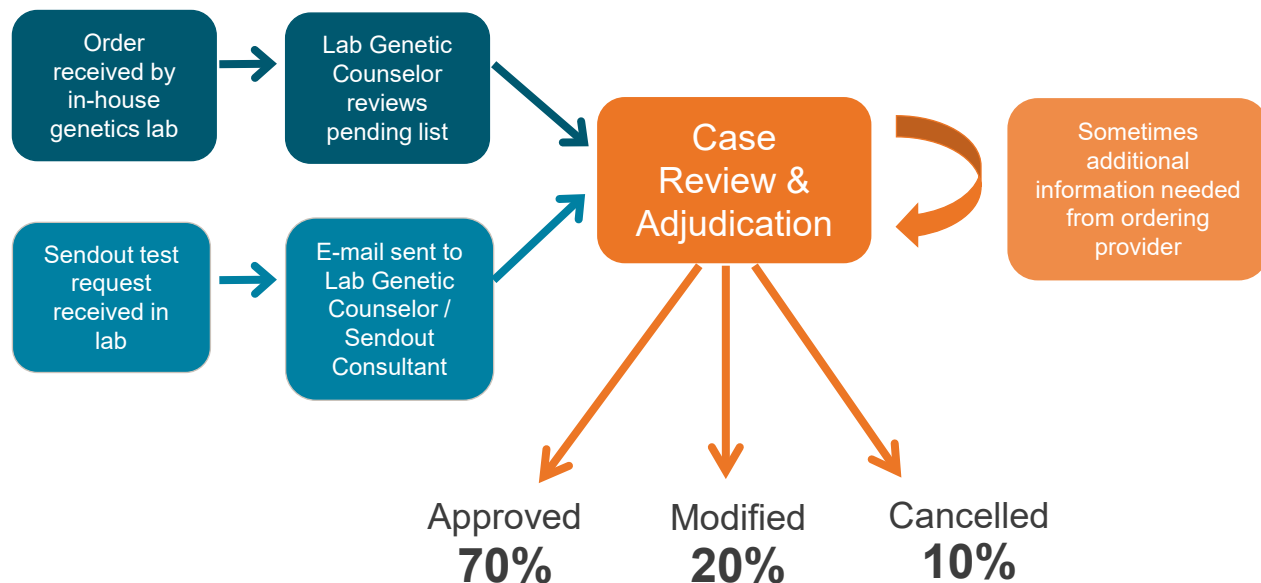
## HYPOTHESIS

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...



\*Based on Seattle Children's Hospital data

# Lab Genetic Counselors Review Genetic Test Orders

## ~30% order modification/cancellation rate

- Cancellations include duplicate testing and tests that are not medically necessary.
- Modifications include correcting erroneous test orders and improving an order.
- >\$3 million in cost avoidance since 2011, with 50% accruing to patients and 50% to organization.

# Case Review ROI

## Cost-Avoidance Model for Genetic Test Review:\*

- 10 requests/week (\$1330 average charge per test)
- 30 minutes/request
- 30% modification rate
- \$100 saved/request
- **ROI:** \$1000 saved/week with 5 hr consultant time/week=
  - \$52,000 saved/yr - ~\$11,250 consultant salary/yr\*\*)=
  - **\$40,750 annual cost avoidance**

\* Data from Seattle Children's Hospital 2022-2023 genetic test sendout case review, N= 5808.

\*\* Estimates to illustrate example using annual GC salary of \$90K. Specific costs per test, salary details, and cost-avoidance will vary and are unique to each institution.

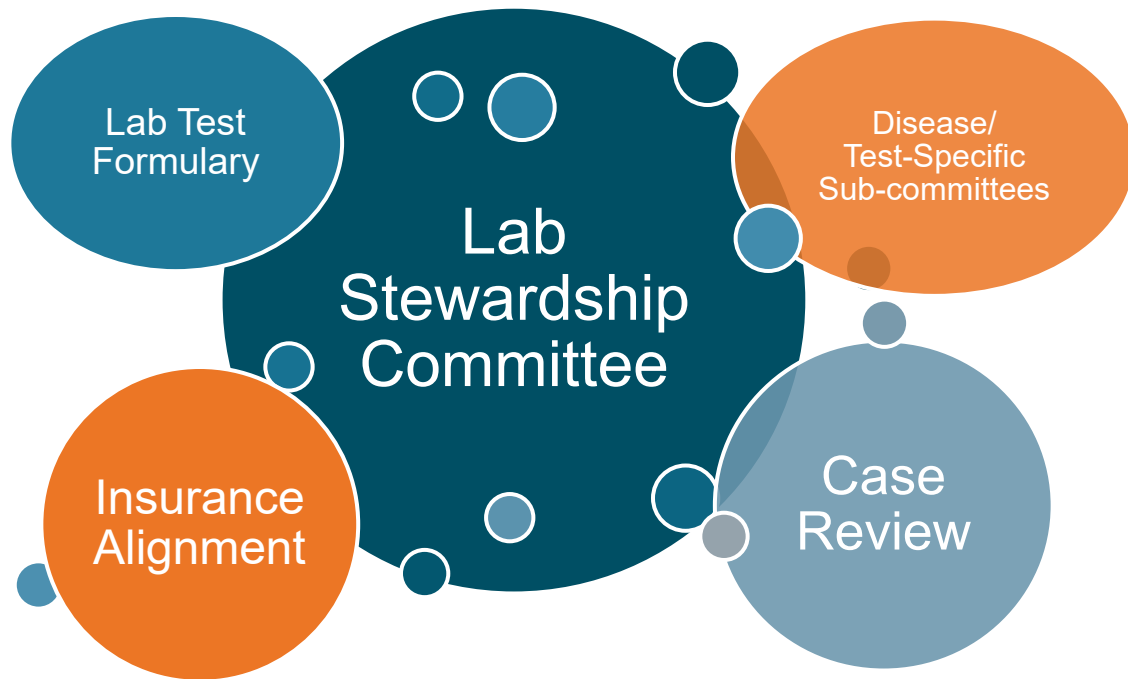
# Surveys Reveal Positive Provider Response

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!

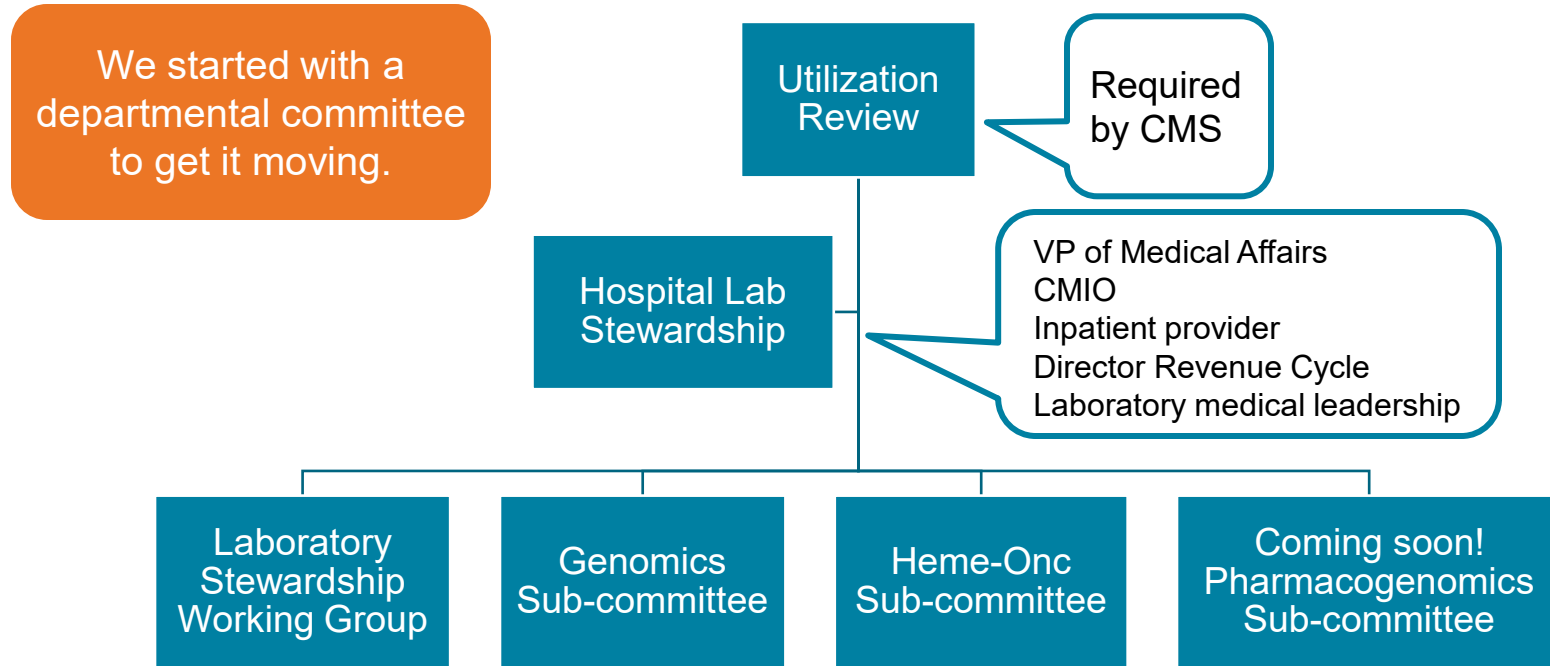
I think the lab UM team overall is doing a phenomenal job. Their **services are definitely helpful**, if not necessary, for genetics and non-genetic providers alike to **appropriately plan and carefully select laboratory tests**.



# SCH Lab Stewardship Program



# Lab Stewardship Committee Hierarchy



# Laboratory Stewardship Committee

- **Meets Bi-Weekly**
- **Committee includes:**
  - Pathologists, clinical chemists, laboratory genetic counselors, specialty labs manager, lab business operations manager, medical geneticists, clinical genetic counselors
- **Weekly working meeting includes:**
  - Case review
  - Test build & reference lab discussions (e.g. lab formulary)
  - Focused intervention project development/management





# Hospital Laboratory Stewardship Committee

- **Meets Quarterly (or as needed)**
- **Established Jan 2017**
  - High-level decision making:
  - Clinician Test Requests (Pleximmune)
  - Peri-mortem genetic testing policy
  - “Free” testing policy
  - Policies/coverage for rapid exomes/genomes and tumor testing

## WHO:

VP of Medical Affairs

CMIO

Inpatient provider

Director Revenue Cycle

Laboratory medical leadership

## Improve lab test formulary:

- ✓ Monitor Miscellaneous 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.

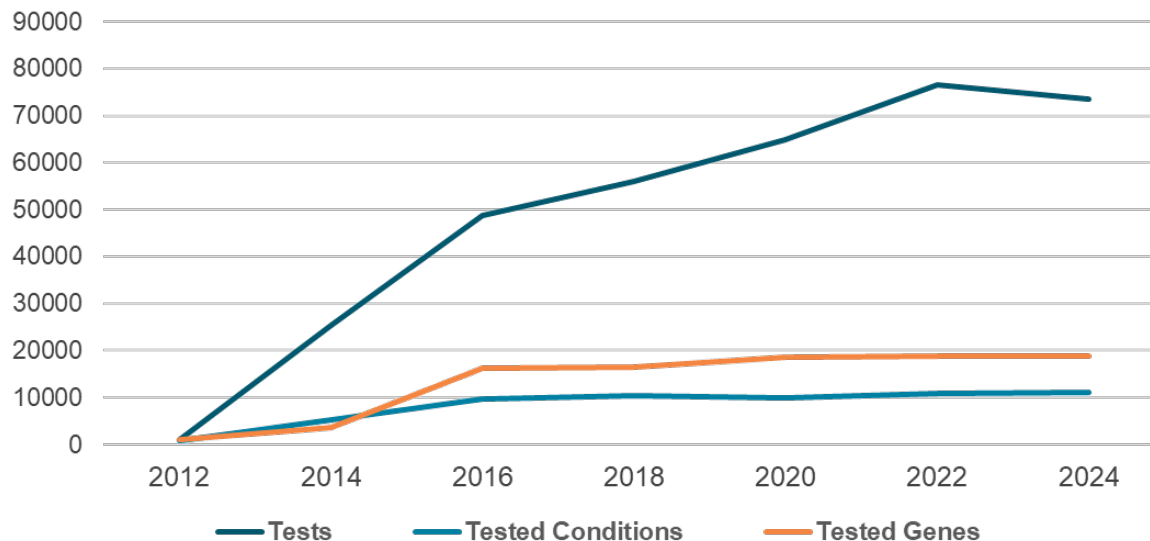
---

APPENDIX 2:

# Case Management

# Making the Case for Case Management

## Genetic Test Registry Trends 2012 - 2024



# Case Management from Reference Labs

RESEARCH ARTICLE

AMERICAN JOURNAL OF  
medical genetics PART A

## Genetic Counselor Review of Genetic Test Orders in a Reference Laboratory Reduces Unnecessary Testing

Christine E. Miller,\* Patti Krautscheid, Erin E. Baldwin, Tatiana Tvrdek, 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

# COMMUNIQUE

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

AJMG AMERICAN JOURNAL OF  
medical genetics PART A

[Explore this journal >](#)

RESEARCH LETTER

## 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

## Preventing Genetic Testing Order Errors With a Laboratory Utilization Management Program

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

The Journal of Molecular Diagnostics, Vol. 17, No. 3, May 2015



ELSEVIER

the Journal of  
Molecular  
Diagnostics

jmd.amjpathol.org

### SPECIAL ARTICLE

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

Jacquelyn D. Riley,\* Gary W. Procop,\* Kandice Kottke-Marchant,\* Robert Wyllie,<sup>1</sup> and Felicitas L. Lacbawan\*<sup>†</sup>



© American College of Medical Genetics and Genomics

ORIGINAL RESEARCH ARTICLE

Genetics  
in Medicine

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

Carlos J. Suarez, MD<sup>1</sup>, Linbo Yu, MS<sup>2</sup>, Natalie Downs, MS<sup>2</sup>, Helio A. Costa, PhD<sup>3</sup> and David A. Stevenson, MD<sup>4</sup>

# Optimize Your Lab Test Stewardship Program

**Do you want to perform  
genetic test stewardship  
but lack the  
Genetic Counselor resources ?**

# GeneTestAdvisor can help



## GeneTestAdvisor (GTA)

Genetic counselors helping optimize genetic test selection

Created in collaboration between Metis Genetics® and PLUGS®,  
**GTA is a genetic test stewardship service providing:**



**Medical necessity**



**Optimal test selection**

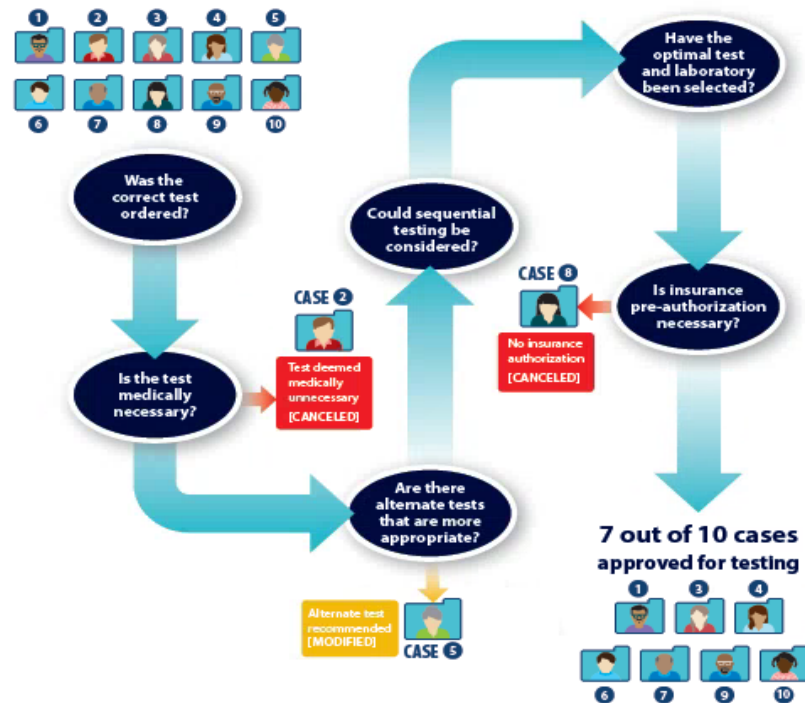


**Cost efficiency**



# GeneTestAdvisor: Our Process

Cases submitted for review (10)






**30%** of genetic tests ordered are inappropriate and should be modified or canceled<sup>3,4</sup>



- Customizable yet systematic approach
- Follow existing processes
- Interaction with ordering provider to define optimal test selection
- Prioritize medical necessity and professional guidelines
- Request appropriate clinical documentation

# Case Study: Texas Children's Hospital

Case example: GTA potential cost savings on WES orders <sup>2</sup>		
WES Order Review Guidance	Number of Cases	Estimated Cost Savings
 <b>CANCELED</b>	<b>30</b>	<b>\$122,000</b>
 <b>MODIFIED</b>	<b>6</b>	<b>\$ 17,000</b>
 <b>APPROVED</b>	<b>8</b>	<b>\$ 0</b>
<b>Net cost savings*</b>		<b>\$130,000</b>

The above example is based on simulated prospective case review of Whole Exome Sequencing (WES) orders. Estimated test charges were \$3000–\$4500 for WES, based on the average charge at three major reference laboratories; and \$890–\$2500 for panel tests.

\*Net cost savings was calculated after case review fee applied.

## GeneTestAdvisor pays for itself.

30%

Average modification rate

Includes:

- Recommendation of different test or less expensive test
- Cancelling order

\$  
Review

Cost savings per review

Dependent upon:

- Average test cost
- Ordering department
- Insurance contracts

---

APPENDIX 3:

# Insurance Alignment

# PLUGS Beliefs

- Understanding the insurance industry enables collaboration for fair payment for patients, labs, and insurers.
- The average lab or hospital executive is not more (or less) intelligent or ethical than the average insurance executive.



Lab and insurance executives in friendly debate over medical necessity

# Patient Financial Bill of Rights

- ... an itemized bill
- ... protection from surprise out-of-network bills
- ... understand the provider network in the health plan
- ... a stable network
- ... know conflicts of interest
- ... know facility fees
- ... see the price list!
- ... be offered cheaper options
- ... avoid a collection agency

# Challenges Faced by Insurers

- Coding: don't know what they are buying
- High cost/unit for genetic tests, PLAs
- Should they pay for DTC testing?
- Test ordering errors
- Lack lab experts to write policies
- Tests without proven clinical utility
- Billing abuses by labs
  - “free” testing
  - tendency to bill largest panel (respiratory, GI, tox)
  - billing below costs...
- Need for innovative partnerships regarding evidence accumulation

# Three Strategies to Improve Insurance Coverage

1. Collaborate with insurers to...
  - ↓ ↓ fraud, waste, and abuse
  - update medical policies
2. Share best practices to reduce administrative burden and align insurance work with stewardship practices
3. Help patients win ethical insurance grievances



# PLUGS Medical Policy Work: Philosophy

- ✓ Don't be afraid to **land a narrow policy where no policy exists**
- ✓ **Partner with everybody:** IVD (e.g., Illumina), labs, insurers
- ✓ Make as many **policies freely available** as possible
- ✓ **Praise insurers** who keep up to date with evidence



<http://6sme.com/blog/2017/08/01/the-secrets-to-success/>

# PLUGS Medical Policy Work

These PLUGS® policies were developed by experts within the PLUGS network and are intended for use by insurance payers, laboratories, providers, families, and consumer groups to guide coverage and reimbursement for medically appropriate genetic tests.

- ✓ Genomic Sequencing in Rare Disease Policy
- ✓ Rapid Genome Sequencing Policy
- ✓ Epilepsy Genetic Testing Policy
- ✓ Inherited Bone Marrow Failure Syndromes Policy
- ✓ MELAS Genetic Testing Policy
- ✓ MERFF Genetic Testing Policy
- ✓ Mitochondrial Genetic Testing Policy
- ✓ Mitochondrial DNA Deletion Syndromes Genetic Testing Policy
- ✓ LHON Genetic Testing Policy
- ✓ MNGIE Genetic Testing Policy
- ✓ NARP Genetic Testing Policy

# Coding Conundrums

- Lack of specificity of codes in many domains of lab testing
- # of panel **codes** (~40 GSP codes)  $\neq$  # of panel **tests** (WAY more)
- Evolving complexities, including Proprietary Laboratory Analyses (PLA) Codes



Annual increase in PLA codes

# Code Submission for Epilepsy Gene Panel

- Working group from PLUGS Insurance Alignment Committee
- Experts represented a variety of perspectives
- Application for GSP (genomic sequencing procedure) code submitted with support from the American Academy of Neurology
- Code approved! Included in the 2021 CPT code set



**GSP-Epilepsy 81419**

## **CPT® Smart App**

Submit an online application with the CPT® Smart App.

**Start Your Application**

<https://www.ama-assn.org/practice-management/cpt/cpt-code-change-applications>

# PLUGS Preauthorization Toolkit

- Working group from PLUGS Insurance Alignment Committee
- Experts represented a variety of perspectives
- Tool includes practical guidance for insurance preauthorization coordination & workflows

## TABLE OF CONTENTS

### **I. Laboratory Stewardship**

Laboratory Stewardship for Genetic Tests  
Current Procedural Terminology (CPT) Codes  
Coding Genetic Tests: Multi-Gene Panels, Exome Sequencing, & PLA Codes

### **II. Preauthorization**

The Basics  
The Appeals Process  
External Review

### **III. Implementing a Preauthorization Process**

Introductory Assessment Questionnaire  
Workflow Considerations  
External Resources for Preauthorizations

### **IV. Payer Policies, Medical Necessity, & Documentation**

Navigating Payer-Specific Policies  
Medical Necessity Documentation and Required Test Rationale

### **V. Partnering with Payers to Reduce Administrative Burdens**

# Support for a Successful Grievance



**Complex Lab Tests:  
How to Get Them Covered**



**PLUGS<sup>®</sup>**  
Patient-centered Laboratory  
Utilization Guidance Services

**Patient & family tool that provides information about payment systems for complex lab tests & guidance/checklists on navigating an appeal.**



Feedback from patients & families:

*"I wish I would have had access to this guide during my years of struggle to get a diagnosis, it would have made my life a lot easier."*

*"The checklists are extremely helpful and synthesize large amounts of complex information."*

# Insurance Alignment Committee



## Systematic Solutions to improve preauthorization processes/workflow

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



## Coding Transparency

- ✓ Obtain new CPT codes to improve coding transparency
- ✓ Provide evidence reviews for PLA codes



## Policy Creation & Improvement

- ✓ Develop rational policies using experts
- ✓ Distribute policies
- ✓ Create infrastructure to ensure policies are kept up-to-date

# Insurance Alignment: Systematic Solutions



Standard SOP for genetic testing preauthorization



Robust case review process during preauthorization and order triage.



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



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