Send-outs-omics

- Jane Dickerson, PhD, DABCC
- Jessie Conta, MS, LGC
- Bonnie Cole, MD
- Michael Astion, MD, PhD, HTBE
- Department of Laboratories, Seattle Children's Hospital
- Departments of Laboratory Medicine and Pathology, University of Washington

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Send-outs-omics

- "Omics" = Study of many constituents considered collectively
  - Pre-analytical: Provider orders test, sample collection, sample transport
  - Analytical: Not our lab
  - Post-analytical: Result entry, result acknowledgement

Objectives

- Identify challenges related to interpreting and processing test orders that contribute to diagnostic error
- Evaluate the patient safety risks related to variable processes of entering test results
- Design pre and post-analytical workflows for optimal lab test coordination

Diagnostic error

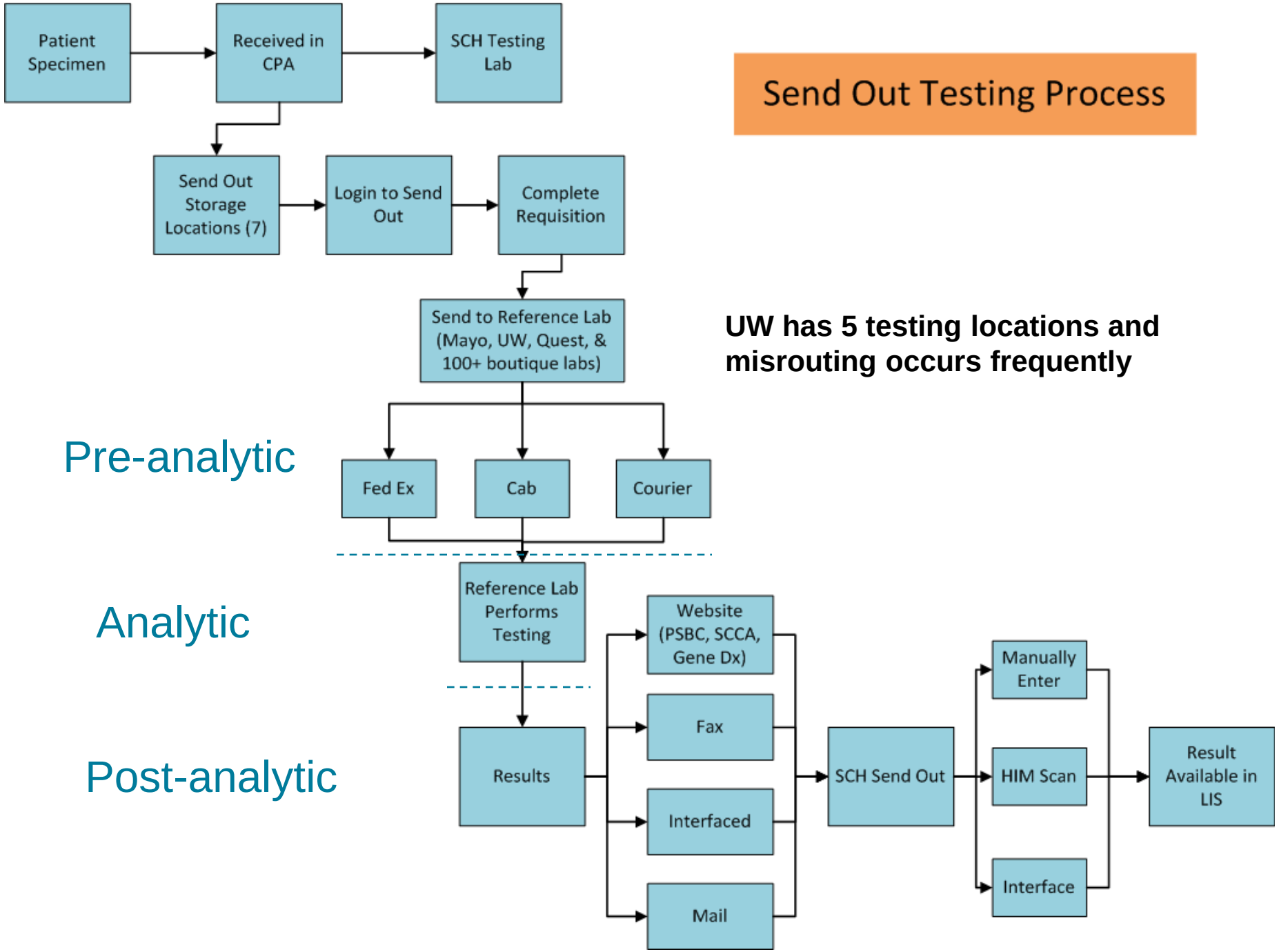
- “an accurate and timely explanation of a patient's health problem”
- Estimated to reach 5% of outpatient visits in the U.S. (12,000,000)
- Significant portion of diagnostic errors are associated with the testing process
  - Test Selection
  - Test Interpretation
  - Test Retrieval

National Academics of Science Engineering, Medicine. *Improving diagnosis in healthcare*. Washington, DC: The National Academies Press; 2015.
Singh H, Meyer AND, Thomas EJ.*BMJ Quality & Safety* 2014.
Singh H, Giardina T, Meyer A, et al. *JAMA Internal Medicine* 2013;173:418-425.

The Send-outs Problem

- Send-out tests include all clinical lab tests which are sent to other clinical labs
- SCH lab sends to >100 labs; 20% of send-outs are genetic tests
- Nationally, testing is increasing at a rate of ~15-20%
- Biggest growth is in proprietary, overbundled tests
- Motivation to improve lab use is to ↑value of lab tests to patient and society

Send Out Testing Process



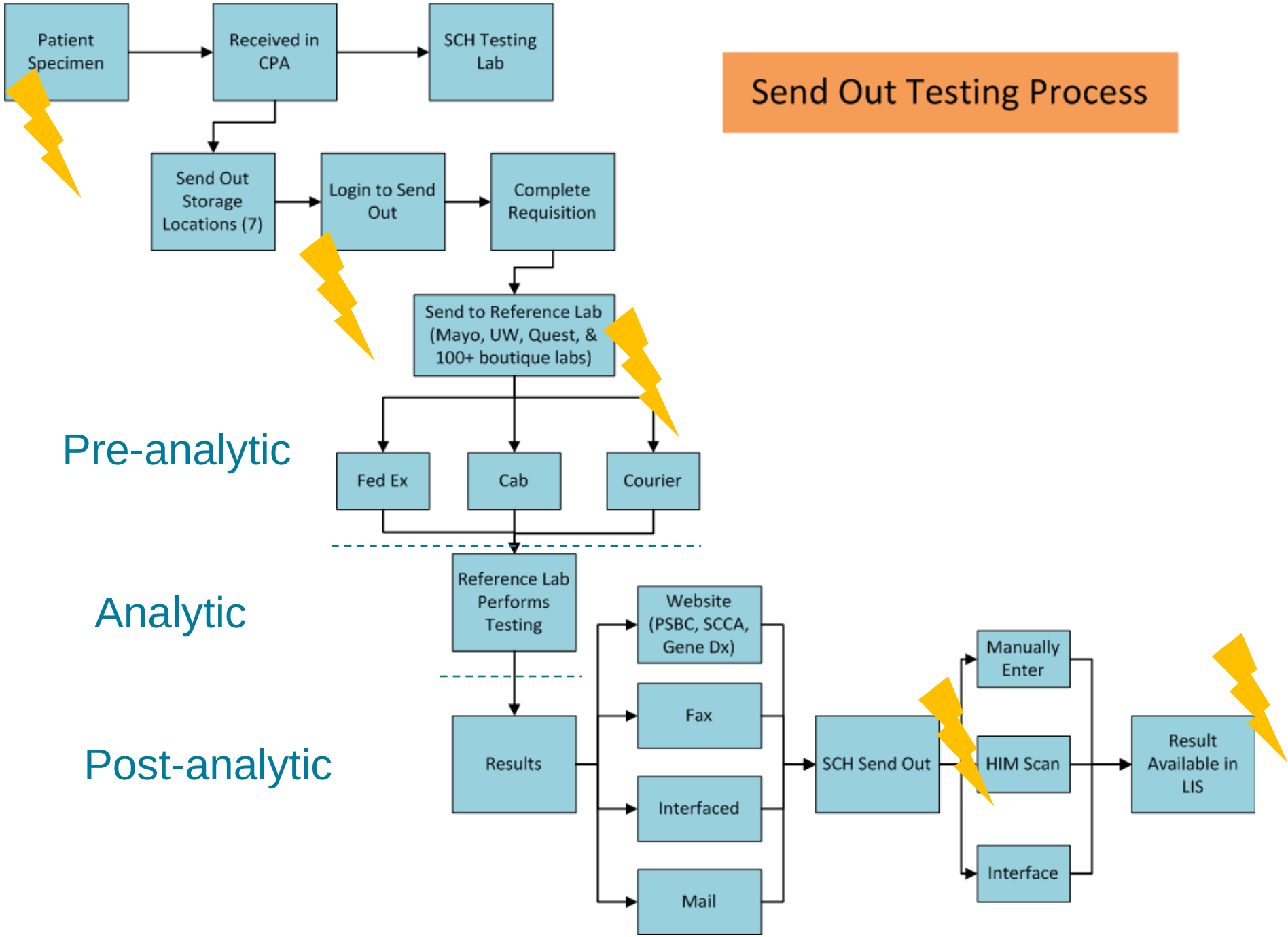
UW has 5 testing locations and misrouting occurs frequently

Pre-analytic

Analytic

Post-analytic

Send Out Testing Process



Test Selection

- Approximately what % of orders are entered electronically by the clinician or designee, e.g. CPOE?
- How is test selection by clinicians facilitated?
  - Customized order templates or order sets
  - Consultative services by lab personnel or reminders or prompts based on patient history
  - Algorithms, guidelines, clinical pathways
  - None of the above

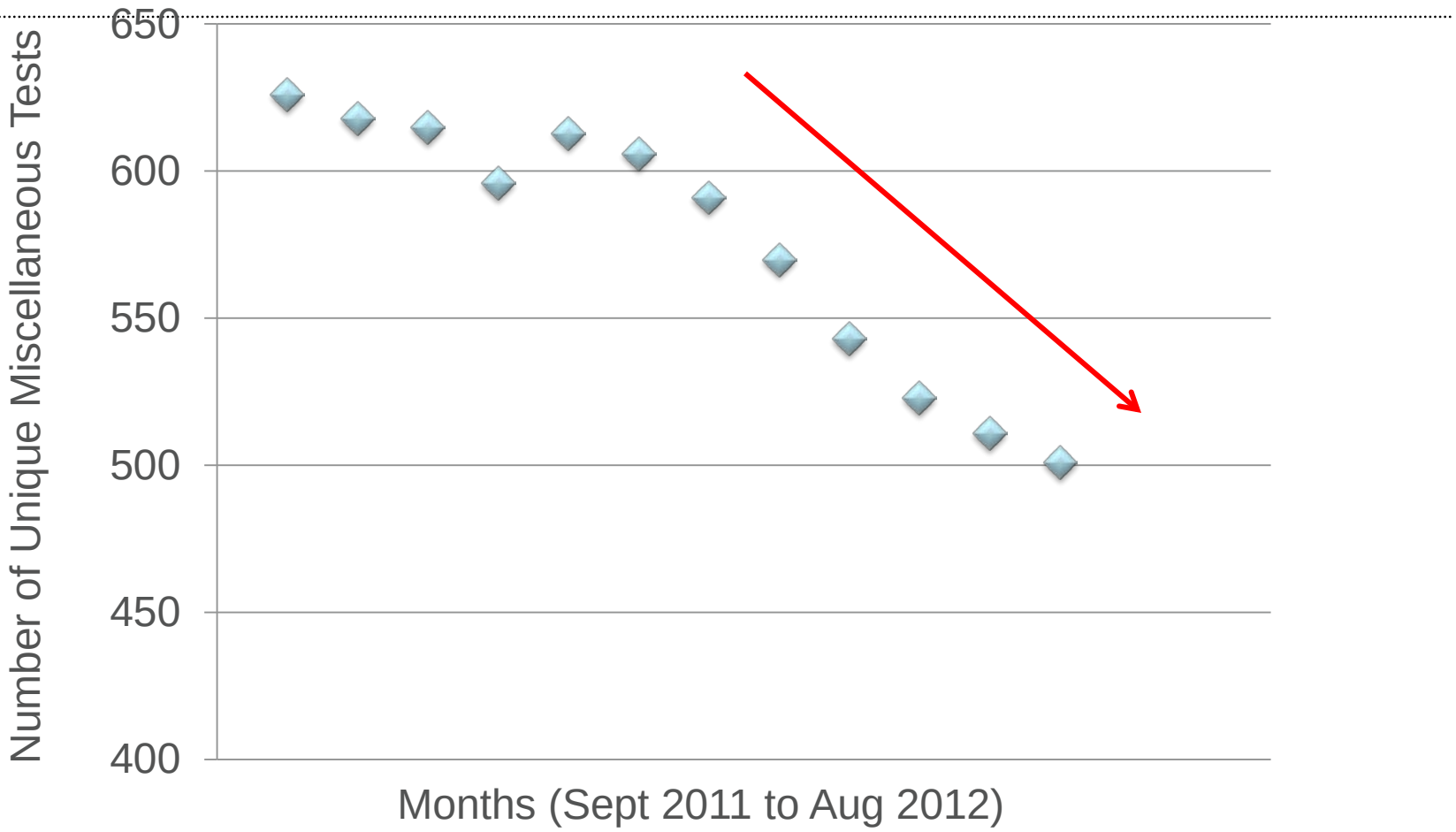
Clin Chim Acta. 2014 Jul 1;434:1-5

Case Example

- 12 y/o boy admitted with hyperparathyroidism, bilateral renal stones and hydronephrosis, chronic constipation, parathyroid adenoma
- Resident on-service is told to order genetic testing for MEN2 syndrome
- Submits a miscellaneous request for:

  “send ret testing”
- Lab staff look up “ret” in test catalog and find Rett Syndrome

Reduction of Miscellaneous Tests



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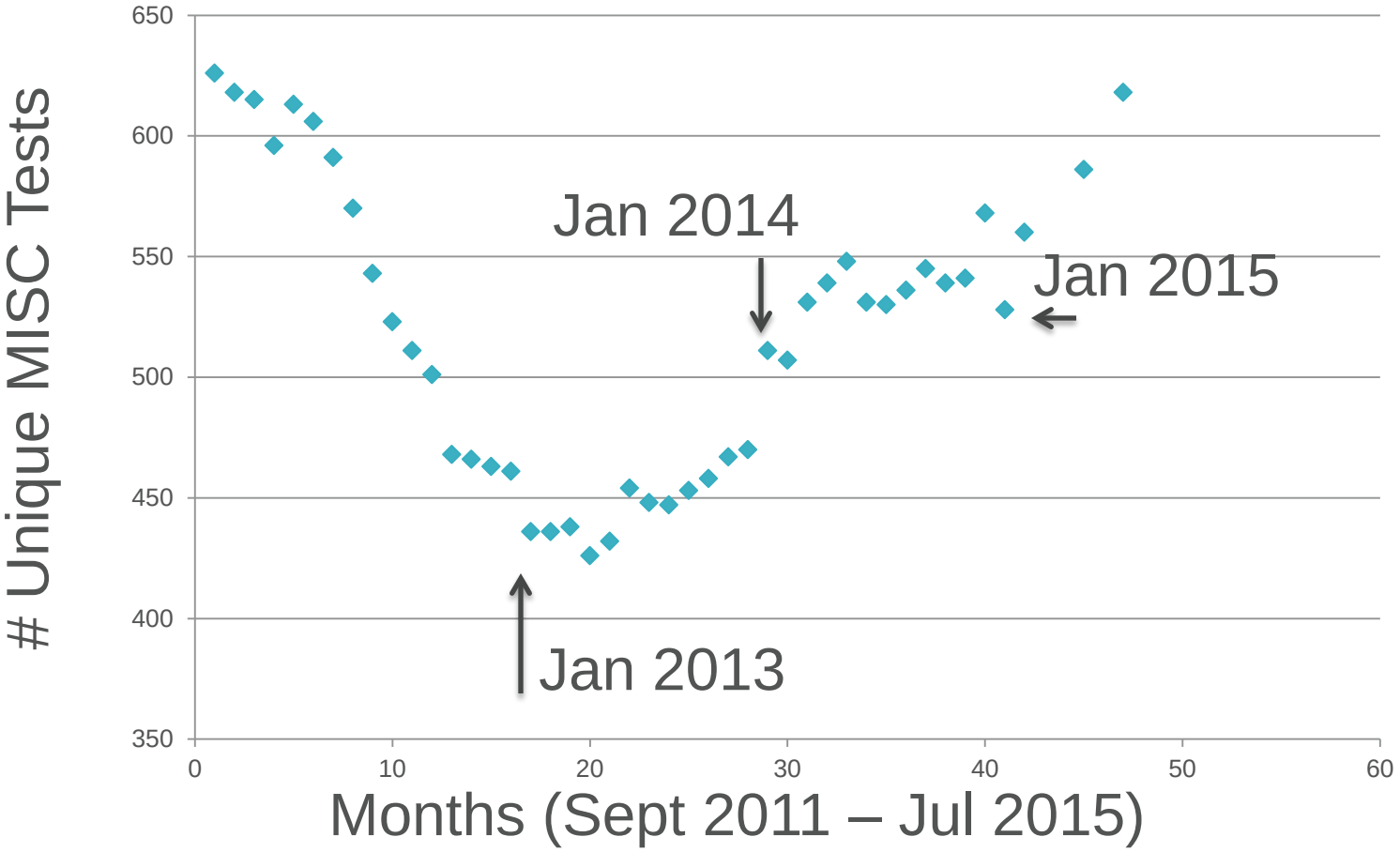
Miscellaneous growth over time



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Sample processing

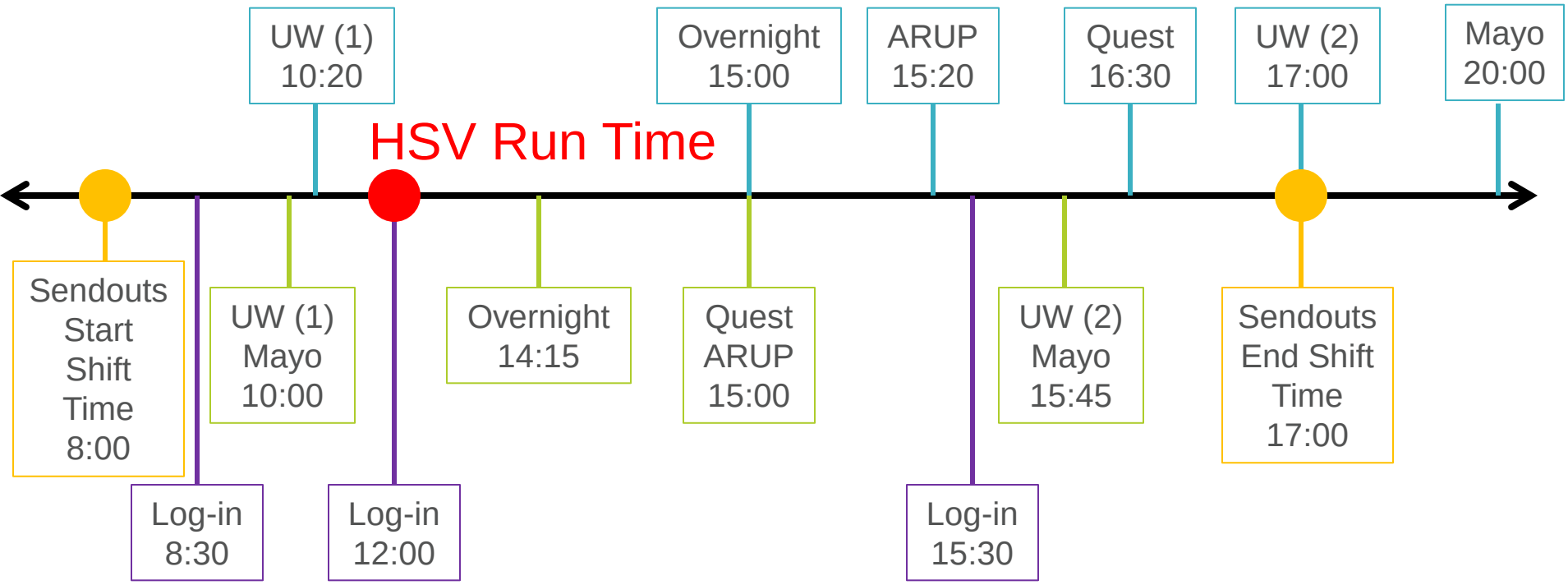
- Do you maintain a dedicated space to process send-out samples?
- What is the least amount of time any employee processing send-out samples will do this activity?
- How often are you notified by a referral lab that a test cannot be performed due to a sample issue?
- How often are you notified that a send-out test cannot be performed because the sample was not received within an allowable time?
- When a send-out specimen is lost, do you have a tracking system that lets you know at which stage it was lost?

Case Example

- Newborn baby admitted with fever and rule out sepsis, including HSV
- Testing for HSV PCR in blood and CSF was ordered
- Results expected following day by care team, but were not received until 2 days later
- This delay prolonged patient discharge by > 12 hours. Patient received at least 2 additional doses of Acyclovir, a potentially nephrotoxic drug, while awaiting test results.

Current Schedule

Log-in times | Package times | Pick-up times



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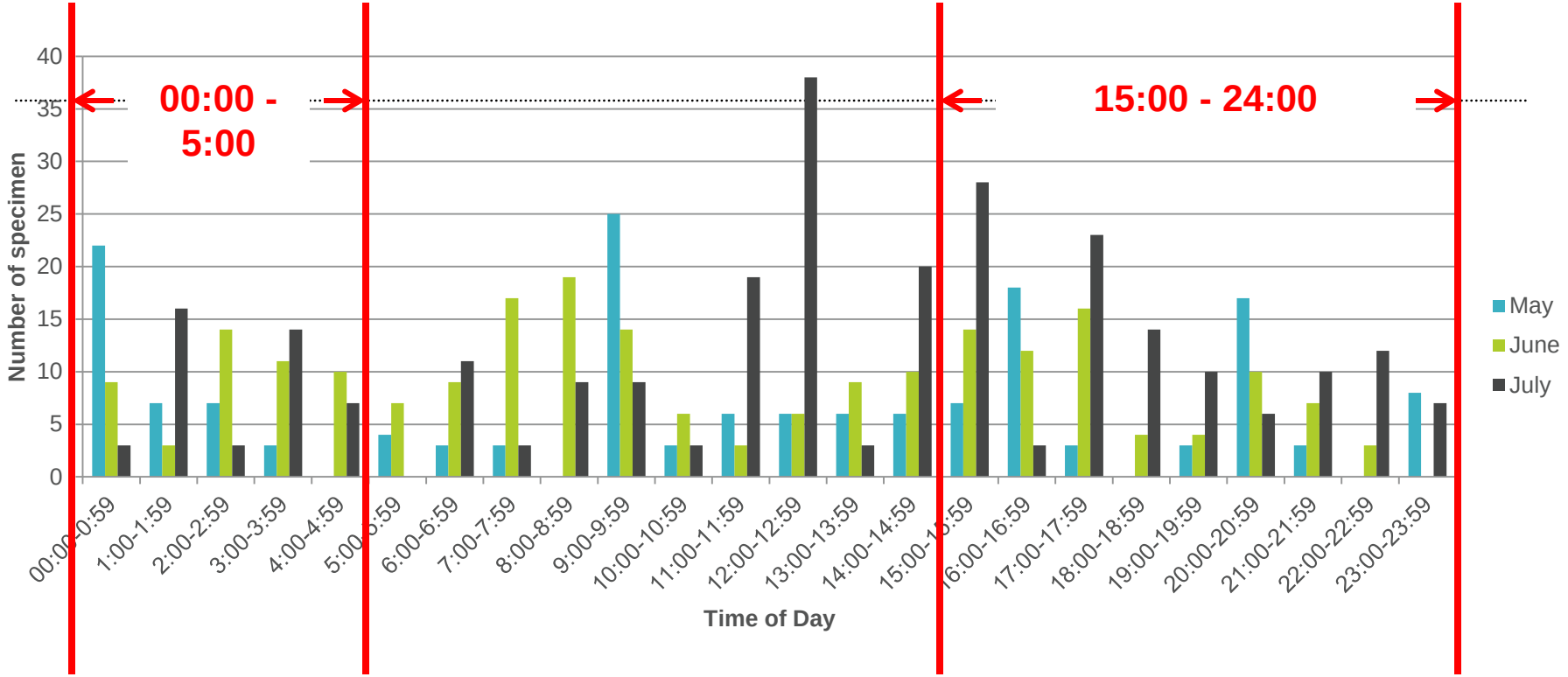
UW HSV Specimen Draw Times: May 2014 - July 2014

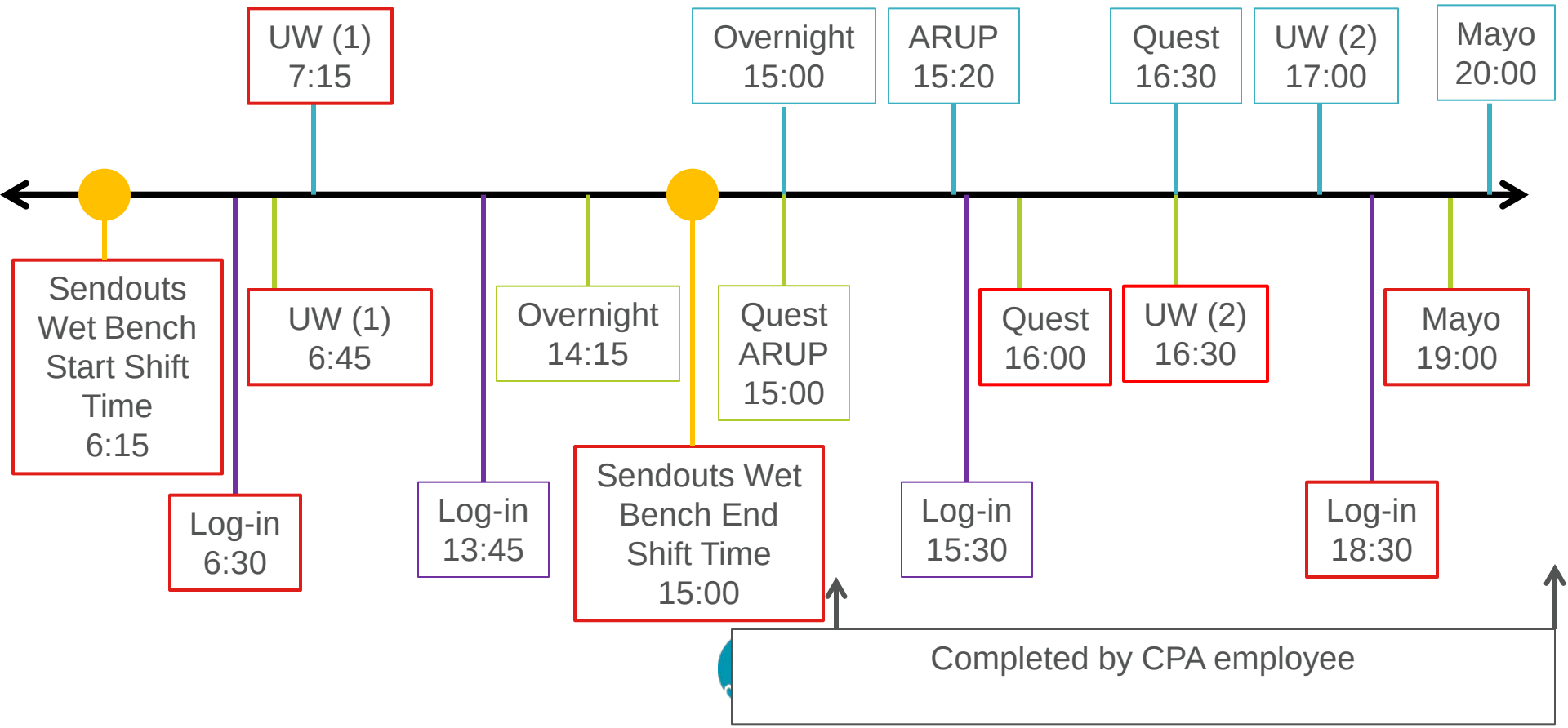


	May	June	July
Number of specimen 1500-500 (per month)	98	117	156
Number of specimen between 1500-500 (per day/per month)	3.16	3.90	5.03
Total UW HSV specimen (per month)	160	217	271
Percent of total specimen drawn between 1500-500 (per month)	61.3%	53.9%	57.6%

Solution:
(1) CPA completes all packaging and log-ins after 15:00
(2) Move morning UW pick-up to 07:15 (change Sendouts wet bench shift start)

Log-in times | Package times | Pick-up times

Changes in wet bench duties



Utilization Management

- How often do you actively manage and intervene in test utilization?
- Who determines the rules for implementing utilization management?
- How are the utilization management rules enforced?
- How often is a test delayed due to the review process?
- How often are orders cancelled or modified as a result of UM review?

Case Example

- 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

Order Modified

GLUD-1 (glutamate dehydrogenase-1)
GLUD1 gene
Hyperinsulinemic hypoglycemia

What harm does poor utilization cause?

INCREASED COST WITHOUT INCREASED VALUE

- Patients receive large (unexpected) bills
- Increased societal cost

INCREASED RISK OF FALSE POSITIVES

- Increased worry and associated harm
- Especially in low prevalence populations

INCREASED RISK OF FALSE NEGATIVES

- Falsely reassuring when the wrong test is ordered

Lewandrowski K. Managing utilization of new diagnostic tests. *Clin Leadersh Manag Rev*. 2003 Nov-Dec;17(6):318-24.

Methods for guiding or restricting lab testing

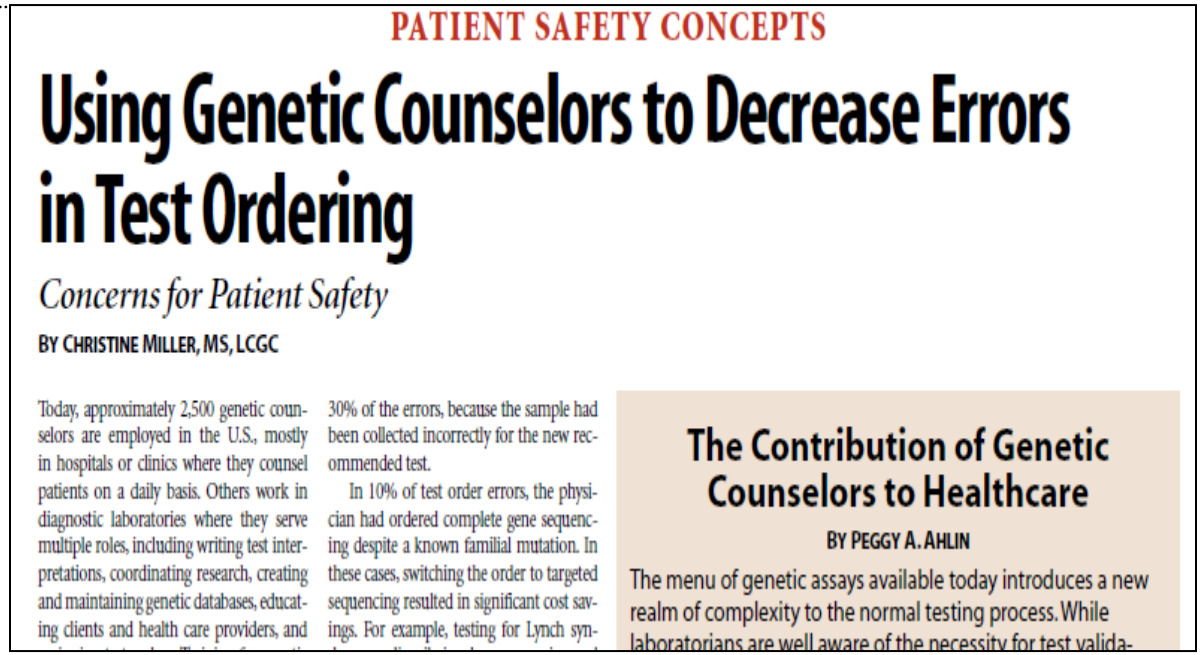
Gentle	Medium	Strong
• Posting of guidelines on the requisition • Computerized reminders regarding utilization guidelines	• Utilization report cards • Changes to manual requisition or CPOE	• Privileging • Send-outs formulary • Utilization report cards with peer or leadership review • Requirement for high level approval (e.g. Pathologist) or consultation (e.g. genetic counselor) • Rules Requirement

Gentle Guidance → → → **Strong Guidance**

Solomon DH et al. Techniques to improve…use of diagnostic tests. *JAMA*. 1998; 280:2020-2027.
Calderon-Margalit et al. An administrative intervention to improve the utilization of laboratory tests within a university hospital *International Journal for Quality in Health Care* 2005; 17(3): 243–248

Genetic Counselors as a form of enhanced supervision

- **In this study: 1 / 3 of genetic test orders were in error and correcting the order improved patient care and saved $ for patients and hospitals.**



PATIENT SAFETY CONCEPTS

Using Genetic Counselors to Decrease Errors in Test Ordering

Concerns for Patient Safety

BY CHRISTINE MILLER, MS, LCGC

Today, approximately 2,500 genetic counselors are employed in the U.S., mostly in hospitals or clinics where they counsel patients on a daily basis. Others work in diagnostic laboratories where they serve multiple roles, including writing test interpretations, coordinating research, creating and maintaining genetic databases, educating clients and health care providers, and

30% of the errors, because the sample had been collected incorrectly for the new recommended test.

In 10% of test order errors, the physician had ordered complete gene sequencing despite a known familial mutation. In these cases, switching the order to targeted sequencing resulted in significant cost savings. For example, testing for Lynch syn-

The Contribution of Genetic Counselors to Healthcare

BY PEGGY A. AHLIN

The menu of genetic assays available today introduces a new realm of complexity to the normal testing process. While laboratorians are well aware of the necessity for test valida-

Miller *C. Clin Lab News.* 2012: 38(1). www.aacc.org/publications/cln/2012/january

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Intervention UM

Hypothesis:

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

Study Design:

All sendout tests meeting certain criteria require approval. Data from each case is recorded and analyzed.

Test Review Criteria

Tests costing the lab > $700

Multiple genetic tests on same requisition

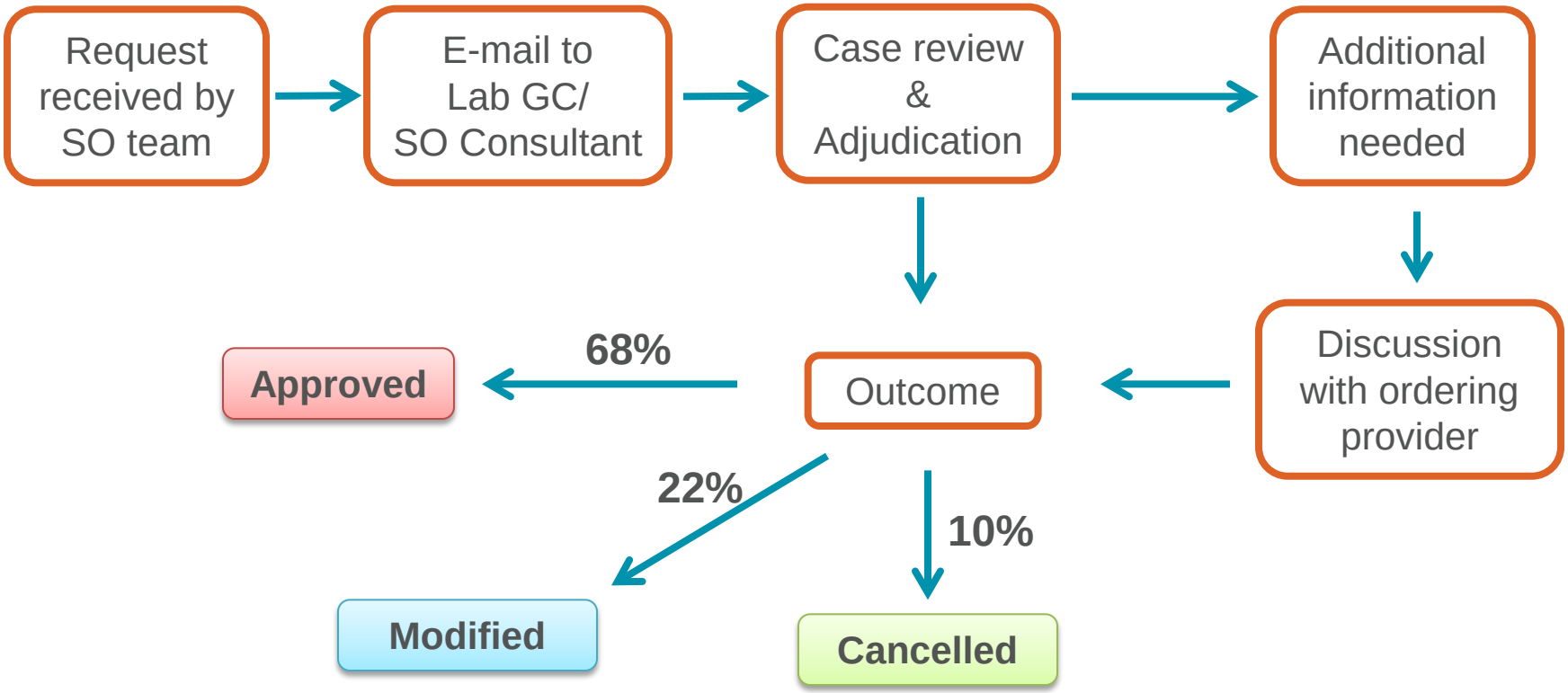
Requests to send to non-preferred laboratory

Requests to send to international laboratories

Requests to send tests which are performed in-house

Tests which are defined under management

A day in the UM life at SCH… 32% of genetic test requests are canceled or decreased



Email template to physicians who are not Medical Geneticists but who are ordering expensive genetic tests

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Dear Dr. (Fill in Name),

The lab received a request on patient (name), MRN (#), for (blank) genetic test for (name of) syndrome. In the past, patients have been billed up to $(X) for this test and may not be reimbursed by insurance (perhaps you know if it has been preauthorized by insurance). In many cases like this, the patient has to bear quite a bit of the cost of the test.

Suzanne Vanderwerff, the head of patient financial services, has suggested that it is a good idea to let providers know this, especially outside of medical genetics. This is because of recent patient complaints about the cost of genetics tests.

There are several options for how you can proceed with this test:

1) We can involve the laboratory genetic counselor to review the order (to assess probability of disease and likelihood of reimbursement) or you can order a genetics consult.

2) We can hold the sample until insurance pre-authorization is obtained* and then…
   a) Proceed with the testing in a step-wise manner, beginning with the most likely gene (we can involve the lab GC to provide guidance on an appropriate testing strategy)
   b) Proceed with the testing as you have ordered it.

3) Proceed with the test as you have ordered it, but if you do this you should let the patient know that these are often not covered by insurance

Please let me know if I can be helpful and how you want to proceed.

*The Division of Genetic Medicine developed a preauthorization protocol in coordination with the Insurance Processing Department (IPD) that can help patients obtain insurance preauthorization prior to testing. I would be glad to share brief instructions to assist you with this process, if you are interested.

ADDITIONAL INFORMATION REGARDING INSURANCE PRE-AUTH:

To request assistance with insurance preauthorization for this genetic test, please send an e-mail to the Insurance Processing Department (IPD) (ipd@seattlechildrens.org), and include the following information:

- Patient name and medical record #
- Test name (*example*, "PTEN gene sequencing")
- CPT codes (usually found at the reference laboratory website)
- ICD9 code (diagnosis code)
- Ordering Provider (for future communication)

An IPD staff member will communicate the request to the insurance plan and will update you by e-mail regarding the status of the request. In some cases, additional information related to the medical necessity of testing is needed and you will be asked to provide details for the IPD staff member to share with the insurance plan. The IPD staff member is also available to communicate directly with the family regarding the details of the authorization and potential out-of-pocket expense.

Lab received expensive, unusual request on your patient:

You have 3 options:

1. Involve genetics or lab GC

2. Hold for pre-authorization

3. Proceed after telling $cost to patient

Info on completing insurance pre-auth

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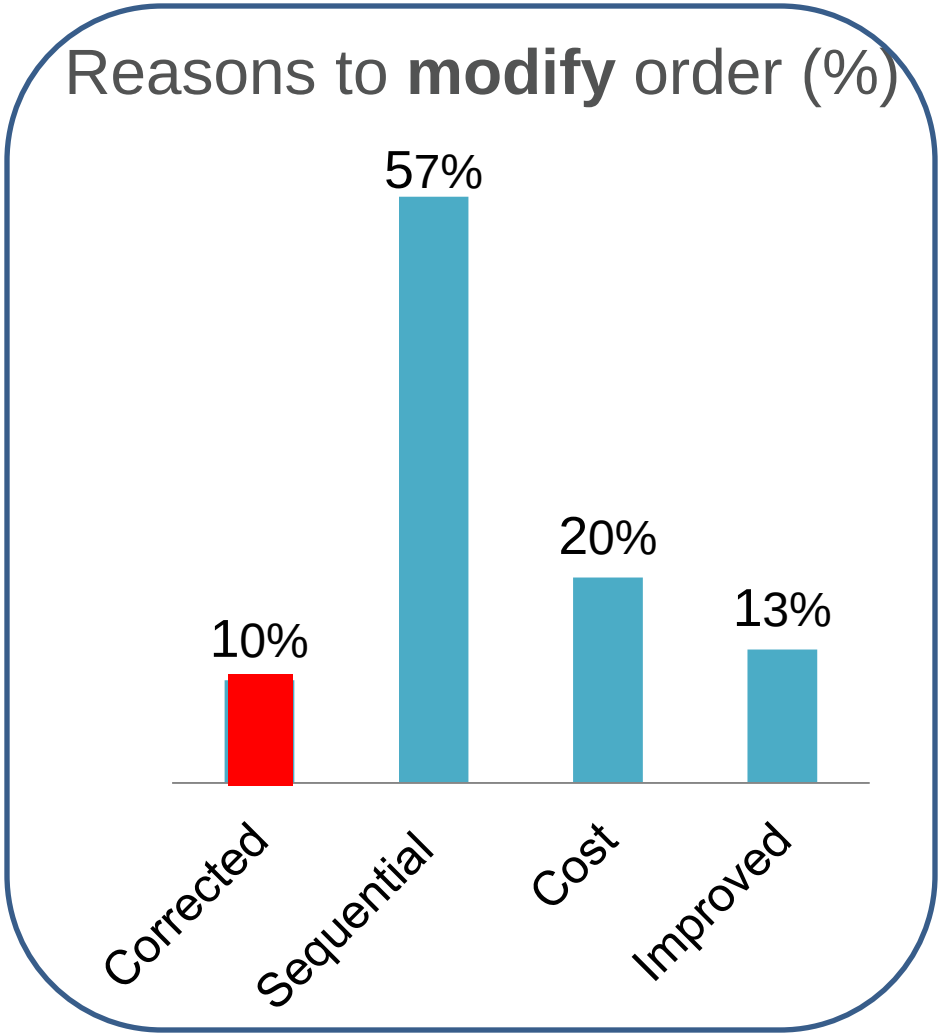
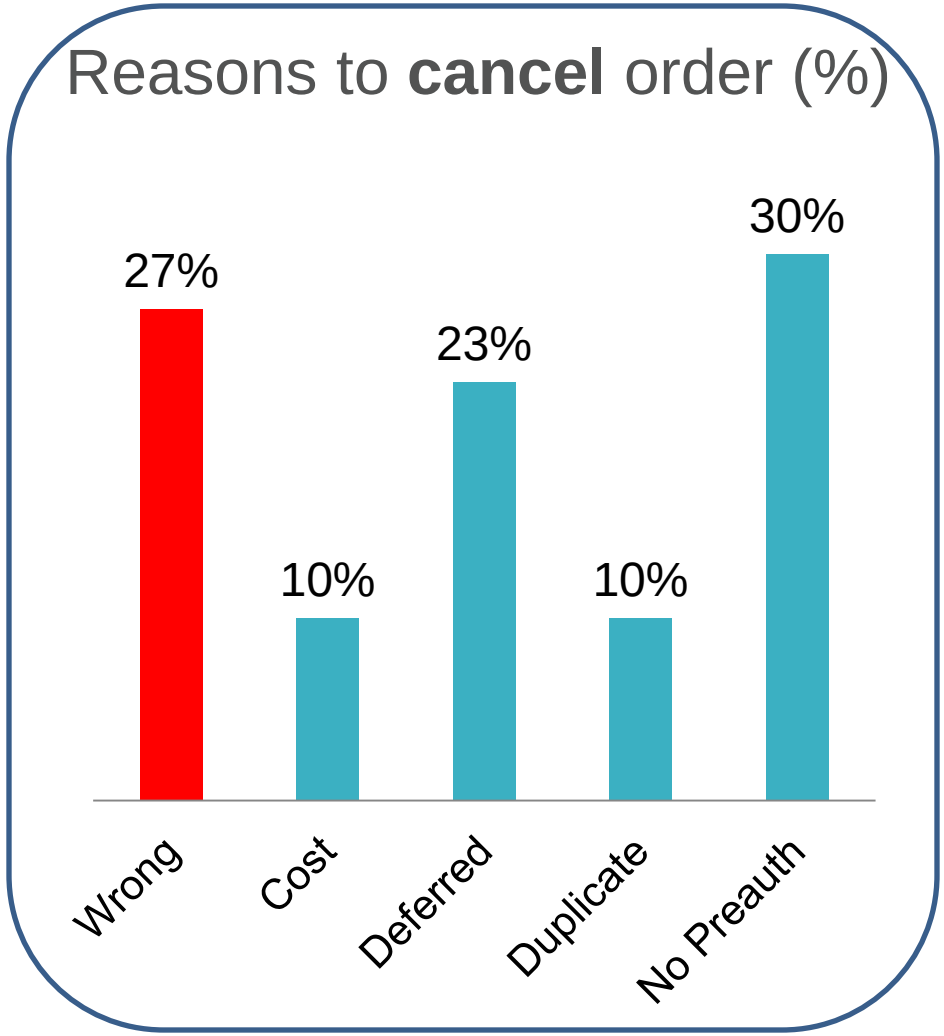
10% of modifications and 27% of cancellations are the result of order entry errors.





*Data collected Sept 2011 – Dec 2014
N=1486 genetic cases

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Financial Implications (n=1486 genetic cases)

*Data collected September 2011 – Dec 2014

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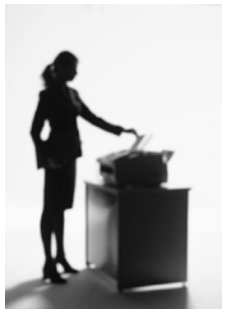
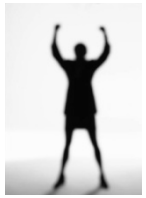
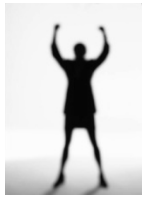
Results Reporting

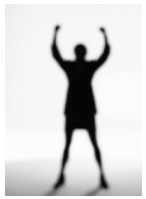
- What methods are used to receive send-out results from the referral lab?
- How often are you aware that an interface to any of your referral labs go down?
- What % of send-out results are provided to providers by electronic access (e.g. EMR)?
- For interfaced results, how frequently have you had reports by providers of result misinterpretations due to result formatting issues in EMR or scanned documents?
- How

Results are Back









Check for duplicate entries

Scan to PDF

Use OCR to transfer to EMR

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Test was ordered, now where are the results?

Problem: You've ordered an expensive genetic test, you're patient has footed the large bill, it's been over 4 weeks and you finally get the result…but you can't (find it, read it, understand it) because it has been *hand-entered* in the patient record.

Error Example

Before

Fanconi Anemia result incorrectly transcribed as abnormal instead of normal.

*** Final Report ***
Document Contains Addenda

BREAKAGE STUDY, NON-NEOPLASTIC

Sample #

IMPRESSIONS AND RECOMMENDATIONS:
The mitomycin C (MMC) treated cultures showed no increase in breaks or radial forms compared to controls. The diepoxybutane (DEB) treated culture produced an insufficient number of cells for analysis. There is no evidence for the diagnosis of Fanconi anemia (FA). If FA is of strong clinical suspicion, a fibroblast breakage study may be useful in addressing potential somatic mosaicism.

Breakage Analysis Summary:

# of Cells With	MMC	Normal Controls MMC	Fanconi Controls MMC
0 break	44	33	2
1 break	3	11	2
2 breaks	0	1	1
3 breaks	1	4	1
4 breaks	0	0	1
5 breaks	0	0	1
6 breaks	0	0	0
7 breaks	0	0	0
>8 breaks	0	0	0
1 Radial	2		

Intervention 4: Resolution

After

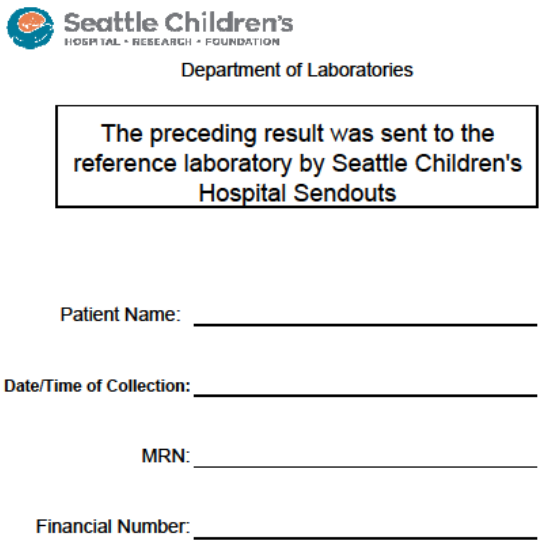
New PROCESS:

Check for duplicate records

Complete an official result form

Take results and forms to Hospital Information Management (2 floors down)

- 3x day
- Scanned within 4 hours



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Department of Laboratories

The preceding result was sent to the reference laboratory by Seattle Children's Hospital Sendouts

Patient Name: _____

Date/Time of Collection: _____

MRN: _____

Financial Number: _____

Differentiates results from outside labs which were not ordered by children's hospital

Additional Intervention Tool: Dashboard

Month	Corrected Report Goal=<0.20%	# Of Manual Reports Left Overnight Goal = <5%
May '11	0.14% (3/2202)	7.80%
June '11	0.13% (3/2251)	3.41% (23/674)
July '11	0.20% (3/2025)	1.47% (6/613)
★ Aug '11	0.01% (2/2428)	4.03% (33/818)
Sept '11	0.14% (3/2178)	4.02% (28/696)
Oct '11	0.13% (3/2303)	1.86% (13/698)
Nov '11	0.05% (1/2133)	2.20% (14/635)
Dec '11	0.04% (1/2328)	0% (0/681)
Jan '12	0.14% (3/2193)	0.46% (3/646)
Feb '12	0.04% (1/2504)	3.91% (29/741)
March '12	0.11% (3/2576)	0% (0/756)
April '12	0.04% (1/2300)	2.46% (18/733)

1 Month Internal Study with Send-Outs

Summary	Number
Total Results	1254
Abnormal	281 (22%)
Unacknowledged	**127 (45%)**
Avg TAT to complete	6.9 days
Median TAT to complete	2.8 days

45% of ABNORMAL results *not documented* in medical record after 90 days

Potential Harm Cases

Mutation in connexin 26 gene result: delayed diagnosis 84 days, which explained cause of deafness in child.

Positive anti-phospholipids (Lupus): failure to treat due to delayed diagnosis 30 days

Thyroglobulin being monitored for thyroid cancer recurrence: potential failure to treat if it had been high (in this case, it was appropriately low.)

How do we monitor the interventions? Quality measures.

- Volume of miscellaneous entered test orders
- Volume of results/orders left unentered after 8 hrs
- # or % of samples that miss pick-up (or run) time
- % results not retrieved or acted on by care team
- Laboratory test volume by analyte
- Utilization management impact (e.g. % orders modified)
- Measures of sample quality (e.g. mislabels, QNS, etc)
- Corrected result rate

Checklist to Improve Send-outs

Preanalytic
1. Establish computer interfaces to major reference labs.
2. Consolidate to as few reference labs as possible.
3. Establish a call center to answer provider questions.
4. Get the specimens out the door as quickly as possible.
5. Implement active test utilization management.
6. Define as many tests as possible in the LIS.
7. Adjust in-house test menu as needed.

Dickerson, *et al.* Clinical Laboratory News 2012: 38(4).
http://www.aacc.org/publications/cln/2012/april/pages/default.aspx#

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Checklist to Improve Send-outs

Postanalytic
8. Establish computer interfaces as much as possible.
9. Have a system to ensure physician acknowledgement of results.
10. Develop quality metrics to ensure the other nine areas are in control.

Dickerson, *et al.* Clinical Laboratory News 2012: 38(4).
http://www.aacc.org/publications/cln/2012/april/pages/default.aspx#

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In Conclusion: Create Standard Practice

- **Dedicated staff**
- **Reduce Manual Processes**
  - **Consolidate reference labs**
  - **Interface**
  - **Build/define tests in LIS**
- **Measure!**
  - **Visual tracking board**