“Healthcare Infrastructure for Financially Sustainable Clinical Genomics”
Friday 22\textsuperscript{nd} 2017

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I have no conflicts of interest
Next-generation sequencing
THE SEQUENCING EXPLOSION

$3 BILLION

COST OF COMPUTING (MOORE'S LAW)

COST OF SEQUENCING

HUMAN GENOMES SEQUENCED

Log Scale


Reid Robison, Medical Director at Center for Change, University Utah
Why is genomics not part of clinical practice?
Starting point

NGS + CPT = Reimbursement ("challenging")
Starting point

NGS + CPT = **Reimbursement** ("challenging")

Emerging evidence

Perceived value

Scientific community
Starting point

NGS + CPT ≠ Reimbursement ("challenging")

Emerging evidence

Perceived value

Scientific community

"necessary but not sufficient"
Starting point

NGS + CPT = Reimbursement ("challenging")
Starting point

NGS + CPT ≠ Reimbursement (“challenging”)

Emerging evidence

Perceived value

Scientific community
NGS + CPT = Reimbursement ("challenging")
Payor Rules by CPT-codes of Selected Molecular-Genetic Tests

“Policy-tailored claim evidence reasoning”

Lennerz et al., J Mol Diagnostics, 2017
Comparison between Clinical and Research Genomics

**Clinical** Exome and Genome Sequencing
- Scope: Tightly regulated, compliant molecular-genetic laboratory
- Cost: Insurance provider, new CPT-hurdle
- Control: Complex regulatory governance
- Aim: Clinical decision-making
- Media: Electronic Medical Record
- Value: Diagnostic and therapeutic implications

**Research** Exome and Genome Sequencing
- Scope: Discovery-focused, flexible molecular-genetic laboratory
- Cost: Funding agency or organization
- Control: Scope-dependent, IRB
- Aim: Translational discovery-potential
- Media: Medical publication
- Value: Anonymous, public databases

Patient & Physician

Misuse to generate data without IRB-approval

Starting point 2
Clinical Exome and Genome Sequencing

Lennerz et al., J Mol Diagnostics, 2017
Clinical Exome and Genome Sequencing
Clinical Exome and Genome Sequencing
Clinical Exome and Genome Sequencing
Revenue Cycle Management
Clinical Exome and Genome Sequencing

Lennerz et al., J Mol Diagnostics, 2017
Deconstructing the Human Pipeline into Modules

8 modules
34 stories
129 tasks
Pilot: 50 cases
1. Personnel, their interactions (and professional qualifications)
2. Acknowledge the people and their interactions as a central role in the clinical environment
3. Modular approach
Out of Pocket Estimates

- Out-of-pocket or self-pay estimate
  - Apply cost estimator tool
    - Accounting
    - Revenue cycle management software
    - Reimbursement Support software
      - Hospital contracts
      - Payor
  - Patient’s Plan
  - Hospital
  - Payor

- Contract review
  - Information to be collected:
    - Health Care Provider ID
    - Patient insurance plan (policy number), CPT code
    - Specifics on deductible, copay, coinsurance and or additional insurance

- Patient Estimate Service
  - Patient Financial Counselor
    - D: B.S.
    - PG: admin
    - Exp: >0.5 years experience
    - Experience with contractual rates and eligibility systems;
      Excellent communication and Interpersonal skills
  - Instead of unwillingly supporting the expectation by many patients that their specific insurance pays for all cost, I want to provide a CPT-code-, hospital-, and patient-specific estimate for the patient liability/out of pocket (covered) or self-pay (uncovered) cost

- Cost-Terminology
  - “patient liability” or
    “out-of-pocket” = covered (potentially/partially) *
  - “self-pay”= uncovered

Stories
Title
Tasks
Exp.
Letter of Medical Necessity

Physician
D: M.D.
PG: R+FS
Exp: >2 years

Instead of composing a LMN, I want to receive a policy-tailored draft for review that I can approve for submission.

Instead of not knowing about the denial of the preauthorization, I want to provide input and help to address the issues raised.

Organization of payor specific policies
Supervision of preauth.
Admin to streamline process
Communication with stakeholders

Preauth. Team Lead
D: M.S.
PG: hospital admin
Exp: >3 years

Provide changes in clinical course or management

Review, revise, and approve

Preauthorization Team Lead
Provide additional input and act as a consultant

Preauthorization Administrator
Request form containing:
Name, DOB, MRN
Payor information
ICD-codes, CPT-codes
Last patient notes
Key argument for medical necessity and/or change of clinical management

obtain from physician

Pattemed PA,
LMN (draft)

Review patient’s payor specific policies

A

Submit to payor

Denial

Preapproval

submit to:
Accessioning/NGS team S-Fig. 7
Billing & reimbursement S-Fig. 10

Preauth. Admin.
D: high-school dipl.
PG: N/A
Exp: >1 year, medical admin, insurance and billing, documents and data management

Instead of receiving elaborate clinical notes, I want to receive a LMN that contains all pertinent information tailored to our specific policy for this CPT-code

Instead of receiving a ‘reworded’ LMN, I want to receive a detailed response to the denial reasons or a policy-compliant explanation for the exemption status in this case

Review LMN draft, revise, and approve

G

Review, revise, and approve

Draft Appeal or Exemption

Inform requesting physician

Appeal and/or Exemption letter

Submit to payor

Submit to payor
The Pilot Phase

Requests
N=50
~4/week

Institutional review
2.1 days (range: 0-9)

Excluded
N=35
~3/week

Excluded due to
- lack of genetic counseling
- incomplete workup
- no actionable result (i.e., results do not change patient management)

Pursued
N=15
~1/week

Appr
LMN
Preauthorization

Case No.

I
II
blood draw

III
Hospital coverage denied

IV
Alternative test was pursued

V
Patient lost insurance, request canceled
denial

VI
Patient lost insurance, request canceled
appeal

VII
In progress

VIII
In progress

IX
In progress

X
In progress

XI
In progress

XII
In progress

XIII
Payment

XIV
In progress

XV
In progress

Time in days

Bill
Denied, write off

Payment

Report

Appeal+LMN

In progress
Timely filing range: <90 days

Turn-around time: ~114 days

Request to report: ~150 days
Payor Rules by CPT-codes of Selected Molecular-Genetic Tests

“Policy-tailored claim evidence reasoning”
The Human Pipeline of Clinical Exome and Genome Sequencing

Test as a module
Summary

• NGS = method of choice for clinical genomics
• CPT = milestone towards financially sustainable clinical implementation;
• Achieving reimbursement is a major challenge.
• At least 8 functionally distinct modules (request review, cost-estimation, preauthorization, accessioning, pre-billing, testing, reporting, and reimbursement-consultation)
• Non-technical barriers are currently limiting the scope and availability of clinical genomic sequencing.
• The presented ‘human pipeline’ is one approach towards long-term financial sustainability of clinical genomics.
The team (thank you)


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Deconstructing the Human Pipeline into Modules

Although it is not my responsibility to know details of the insurance plan of every patient, I want to provide a reliable maximum out-of-pocket estimate.

**Ordering Physician**
- D: M.D.,
- PG: R+FS
- Exp: >1 year

**Expert review**
- D: M.D.
- PG: R+FS
- Exp: >3 years

**Genetic Counselor**
- D: M.Sc. (GC)
- PG: ABMG as GC
- Exp: >3 years

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**Institutional review**

- Has genetic counseling been done? **Yes**
- Is the disorder a significant health problem? **Yes**
- Can a more specific panel(s) provide the needed diagnostic information? **Yes**
- Is exome/genome sequencing more cost-effective than other or additional diagnostic tests? **Yes**

**Determine:**
1. Exome vs. Genome
2. Scope: single vs. comparator vs. trio
3. Prior genetic results ‘WT’ genes, exome?
4. Pursuing to preauth.
Commitment by the payor (to hospital) to reimburse based on an existing insurance plan/agreement.

Payed amount >0

Charge Pt. responsibility (plan-dependent) <charge

Issue Patient Bill

Payor

Reimbursement decision (general payment)

“approved” “denied”

Provide reason

Hospital-based e.g., timely filing

Patient-plan based e.g., investigational, not clinically proven, not covered

Patient responsibility 0

Full charge

Resubmit claim

Draft and review appeal

Review order of events

Preauthorization review

Policy review

Full review of case

Hospital Finance Division