Measuring the Cost Effectiveness of Pharmacogenomic Testing

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Disclosures:

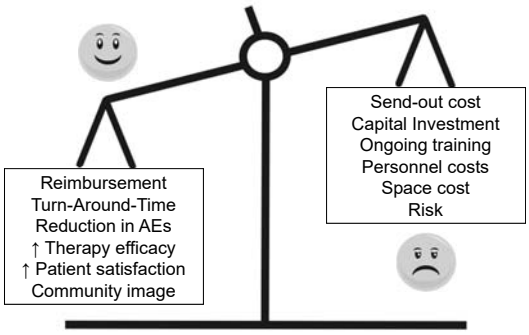
- The author has no disclosures related to the content of this presentation.
- The INGENIOUS trial (NCT02297126) is sponsored by an NIH/NHGRI U01-grant (HG007762)

Learning Objectives

1. Identify expense, revenue and cost saving parameters prior to implementing an in-house pharmacogenomic testing program
2. Selection of key stake-holders, decision makers and implementation team members
3. Formulate and develop critical Electronic Medical Record system requirements to support clinical and cost monitoring

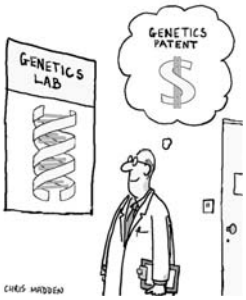
The "Buy or Rent" Decision

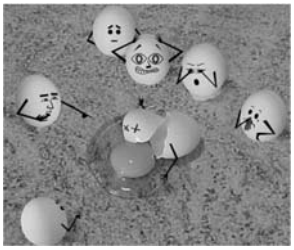
Bringing new diagnostic testing in-house is a strategic decision that must be weighed carefully



Pharmacogenomics Cost Justification

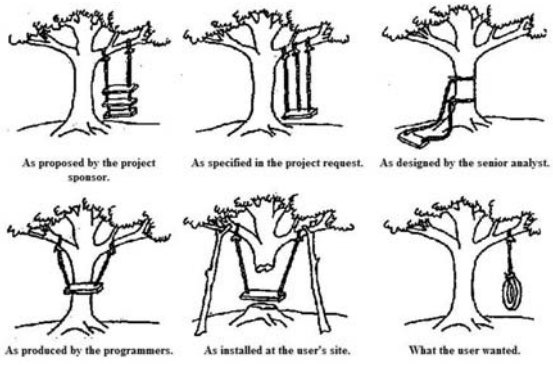
Upfront analysis can help mitigate the risk





Planning and implementation is Critical

Include the right people at the right time



Cost Effectiveness and Sustainability

Keys to a successful program

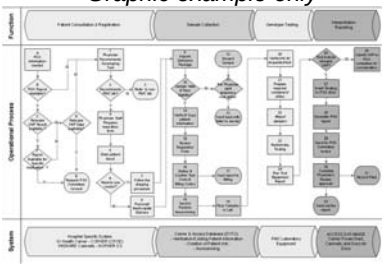
- Detailed pre-planning (with timelines and management tools)
- Experienced project manager
- Alignment with key stakeholder's needs
- Staff training and clinical education
- Full integration (input and output) with the Electronic Medical Records system
- Patient and community education

Project Planning

Understanding current and future processes

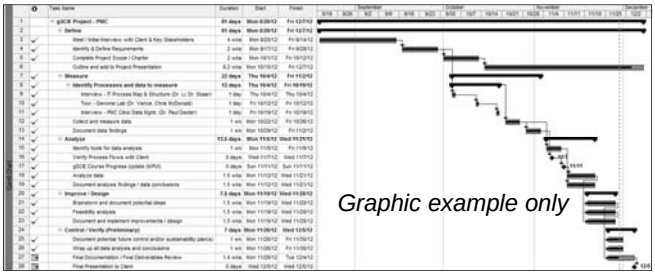
- Identifies gaps and risks
- Confirms sources of costs
- Validates workflow
- Builds cross-functional alignment

Graphic example only



Project Planning and Workflow

- Transitions workflow into tasks
- Creates dependency relationships between tasks
- Helps to prevent surprises and keep project on-schedule and on-budget



Graphic example only

Stakeholder Alignment

- Senior Executive leadership (CEO/President, CMO, CFO, Chief Legal Officer and CIO)
- Senior Clinical leadership (clinical divisions, nursing and pharmacy)
- Pathology services
- Clinical staff
- P&T committee[1]
- Third party payers
- Patient advocates (community awareness)

[1]*ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System*

Key Drivers by Stakeholder

Senior Executive leadership (CEO/President, CMO, CFO, Chief Legal Officer and CIO)

- Impact on clinical outcomes
- Capital budget
- Headcount requirements
- Standards of Care and legal liability
- Impact on community relations/Patient advocacy groups
- Added time and work burden for clinical staff
- Health Economics, return on overall investment (reimbursement vs cost)
- Integration into LIS/HIS (time and cost)

Key Drivers by Stakeholder

Senior Clinical leadership (clinical divisions, nursing and pharmacy)

- Technology adoption (National standards of care)
- Impact on malpractice liability
- Education and training (staff turnover)
- Impact on department headcount
- Clinical relevance for each clinical specialty
- Added time and work burden for clinical staff
- Alignment with current workflow

Key Drivers by Stakeholder

Clinical Staff (physicians, nurses and clinical pharmacists)

- Clinical validation (Peer-reviewed articles, National Standards)
- Clinical Pharmacy consultation availability
- Liability (to act or not act)
- Education (impact on current clinical decision making)
- Alignment with current workflow
- Test turn-around time
- Test reporting format
- Patient education support

Key Drivers by Stakeholder

Third party payers

- Clinical validation (National Standards)
- CMS/other third-party adoption (CPT MoPath code/tier assignment and reimbursement direction)
- Demonstrated/documented clinical and economic data addressing investment versus cost prevention (short and long-term plus hard and soft costs)

Key Drivers by Stakeholder

Patient advocates

- Alignment community needs
- Impact on patient care
- Cost (out of pocket) to patients
- Patient/community education programs

Implementation Team Structure

Test Selection – Where to Start

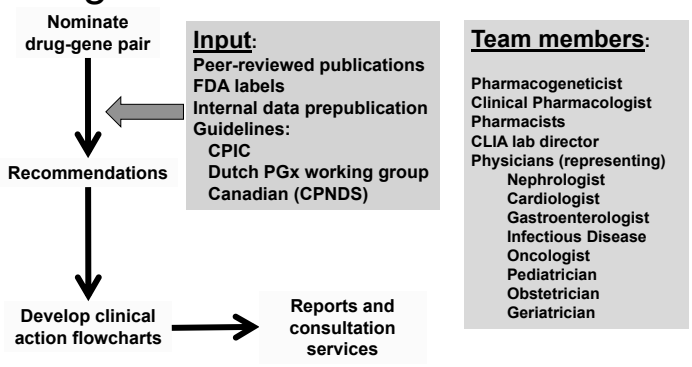
- Identify institution's most common adverse events associated with gene mediated drug metabolism (informatics committee)
- Quantify frequency (12 to 24 months) of selected adverse events within your patient population (informatics committee)
- Obtain institutions drug volume (in and out-patient) for selected medications (informatics committee and pharmacy benefit manager)
- Quantify internal costs (at the patient level) associated with each adverse event identified

Testing Choices

Key Questions/Decisions:

- Will third party payers reimburse for PGx tests not directly linked to an ICD-9 code (i.e panel testing)?
- Prospective (prevention) vs. reactive (at-risk) testing (short vs. long-term impact)
- Individual tests versus disease or medication oriented PGx panels
- Turnaround time (TAT). What is needed vs required? Cost impact linked to changes in TAT

Drug Gene Selection Process



Pharmacogenomics Laboratory

Technology my be the least challenging aspect

- Driven by laboratory services committee
- Space and staff requirements
- Test selection and volume may direct choices (automated vs. manual)
- Equipment acquisition (buy versus lease)
- Plan for future expansion
- Plan for obsolescence

Electronic Medical Records

EMR is the key to a successful program

- Driven by Informatics Committee
- Functional specifications require input from stakeholders
- Lead time – planning, coding, implementing and testing
- Prioritization (internal and vendor)
- Data input and data mining critical
- User defined flexibility (change friendly)

Staff Education

It takes time to change clinical practice

Clinical Training:

- Critical for short and long-term sustainability
- Physician, Nursing and Pharmacy teams
- Pre and post-implementation survey (what went well and what can be improved)
- Training and re-training (consider turnover)
- CME/CE

Patient Education

Demystify genetics

Supporting Patient Ownership:

- Alignment of patient education tools and how to deliver (clinical teams)
- Patient education tools must simplify the concept of pharmacogenomics
- Educated patients are associated with better outcomes[1]

[1] Risk Manag Healthc Policy. 2010;3:61-72. doi: 10.2147/RMHP.S7500. Epub 2010 Oct 14

Measuring Cost Effectiveness

A challenging task

Hard versus Soft Costs:

- Out of pocket costs (capital and variable costs are straight forward measures
- Compare your adverse event rates to national averages
- Benchmark costs per adverse event
- Analyze accuracy of adverse event recording
- Quantifying soft costs takes time (plan for it)

And Finally the Money
Profit and Loss Analysis

- Justification for Laboratory
- Driven by finance committee
- Establish metrics to achieve and measure periodically
- Cash flow, break-even analysis and Net present Value (NPV)
- Operating Profit (OP) before tax and depreciation
- Cumulative Income minimum of 5 years

Graphic example only

Sample P&L

		Year 1	Year 2	Year 3	Year 4	Year 5
Tests per year			3,000	4,500	6,000	7,000
Reimbursement per test			$200	$200	$200	$200
Test total revenue			$600,000	$900,000	$1,200,000	$1,400,000
Expenses						
Test cost (variable)			$ 150,000	$ 225,000	$ 300,000	$ 350,000
Headcount (fixed)			$ 250,000	$ 250,000	$ 250,000	$ 250,000
Lab misc. (variable)			$ 23,400	$ 25,740	$ 28,314	$ 31,145
Tech Support (fixed)			$ 50,000	$ 50,000	$ 50,000	$ 50,000
Total Cost			$ 473,400	$ 550,740	$ 628,314	$ 681,145
Gross Profit			$ 126,600	$ 349,260	$ 571,686	$ 718,855
OP %			52.3%	57.8%	63.8%	73.4%
		capital				
M & D		$ 500,000	$ 60,000	$ 90,000	$ 120,000	$ 140,000
G & A (2%)			$ 60,000	$ 90,000	$ 120,000	$ 140,000
Total Expense		$ (500,000)	$ 593,400	$ 730,740	$ 868,314	$ 961,145
Operating Profit		$ (500,000)	$ 6,600	$ 169,260	$ 331,686	$ 438,855
Cum OP		$ (500,000)	$ (493,400)	$ (324,140)	$ 7,546	$ 446,401
OP %			-14.9%	25.3%	31.8%	39.8%	50.4%
NPV	$105,039.74					
IRR	22%					

Summary

- Adopting in-house pharmacogenomic testing requires clinical and financial strategic commitments
- Project teams require engagement from cross-functional areas within the institution
- EMR integration is critical for reporting and data mining
- Education of clinical staff and patients is required for sustainability