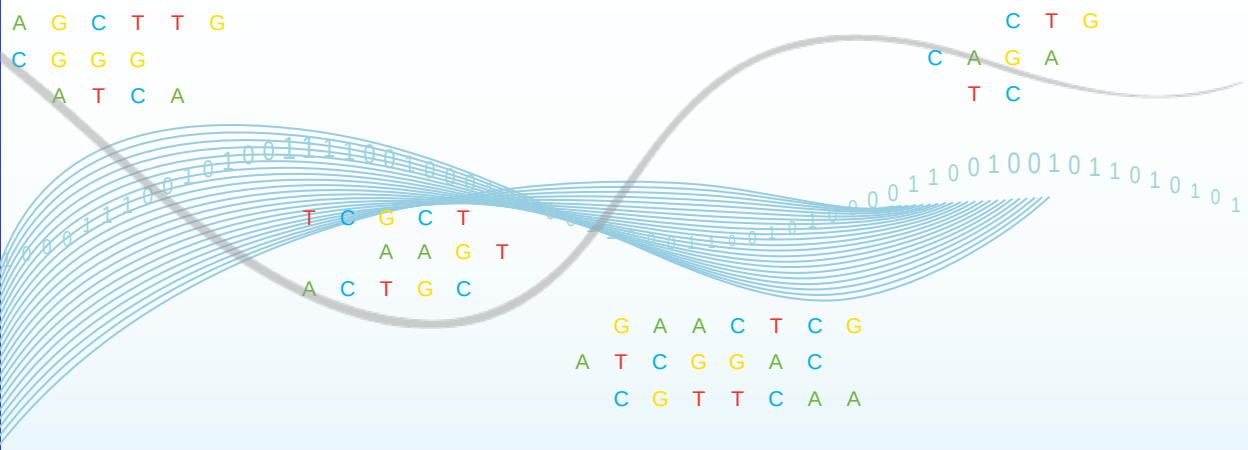
Using ‘Payer’ Data to Analyze Impact of Pharmacogenomic Approaches



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Robert S. Epstein, MD, MS

President, Advanced Clinical Science and Research

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Why are ‘Payer’ Data Useful?

- Data can be useful for confirming hunches (e.g. phenocopying) – or investigating clinical utility

- Data and system itself – can be used to promulgate the use of testing where appropriate

What do we mean by “payer” data?
In U.S. – eligibility, insurance, claims ± genomics

- Linked and longitudinal across large numbers of patients

- Eligibility – 65 million lives (at Medco) – monthly feeds
  - > AGN – artificially generated number for linkage – cross-walks for aliases
  - > Age, gender, household relationships
  - > Comorbidity (if coded on medical claims or by proxy with drug claims)
- Insurance information (e.g. copays, deductibles, P.A.s, etc)
- Claims data
  - > Prescription data – manufacturer, drug, strength, number supplied, duration of therapy, refills (when compliant, persistent or not)
  - > On the Rx data – prescriber information
  - > Medical claims – ICD-9 coded visit data, outpatient hospital, lab and diagnostic test absence/presence, inpatient hospital stays
- Genomic information on subset
  - > Specific test data/information
  - > Biobanked DNA

A Structured Retrospective Database Study Could be something like…….

DRUG	PGx Test	Potential Outcomes
X	Yes	MD behavior (selection, dose, duration)
	No	Patient behavior (compliance, persistence)
		E.R. visits and why
		Hospitalizations and why
		Other tests /change or additions in therapy
		Costs

By definition – non-randomized designs requiring adjustment for confounding

Phenocopying 2c19 Effect on Clopidogrel – 1 year longitudinal study of new starts to therapy

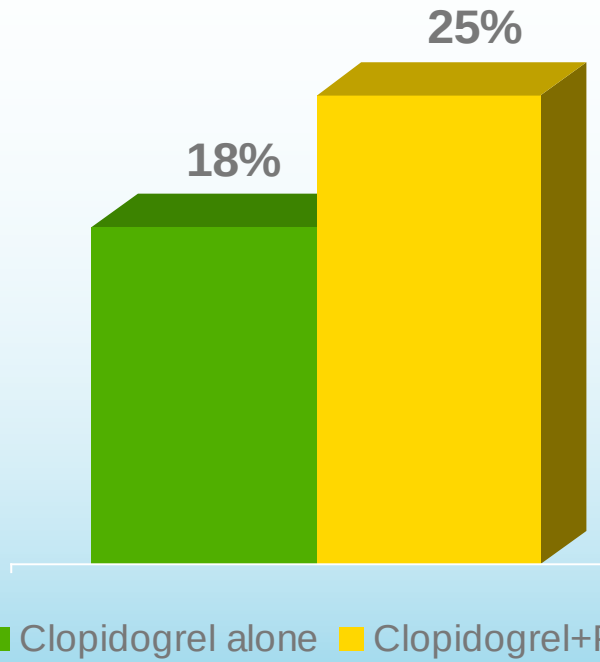
Presented at American Heart Association 11/11/08*

~17,000 Patient Study

- All underwent coronary procedure
- 1-year follow-up for cardiovascular outcomes
- Clopidogrel alone: n= 9862
- Clopidogrel + Potent 2c19 Proton Pump Inhibitor (PPI): n = 6828

Hospitalization*

Relative Risk 1.50 (1.39-1.62)



* For MI, Stroke, Angina, or CABG

*Source: Kreutz RP et al: Impact of PPIs on the effectiveness of clopidogrel after Coronary stent placement: the CMOS. Pharmacotherapy 2010:30(8):787-796.

Example of VA data on same topic

Table 2. Adverse Outcomes Following Hospital Discharge for Acute Coronary Syndrome (ACS)

Outcome	No. (%) of Events: Clopidogrel Without PPI (n = 2961)	No. (%) of Events: Clopidogrel With PPI (n = 5244)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)[a]
Primary outcome				
Death or rehospitalization for ACS	615 (20.8)	1561 (29.8)	1.62 (1.45-1.80)	1.25 (1.11-1.41)
Secondary outcome				
Rehospitalization for ACS	205 (6.9)	764 (14.6)	2.29 (1.95-2.69)	1.86 (1.57-2.20)
Revascularization procedures	353 (11.9)	815 (15.5)	1.36 (1.19-1.55)	1.49 (1.30-1.71)
Death (all-cause)	493 (16.6)	1042 (19.9)	1.24 (1.10-1.40)	0.91 (0.80-1.05)

Abbreviations: CI, confidence interval; OR, odds ratio; PPI, proton pump inhibitors.
[a] Adjusted for all variables in Table 1 except male sex.

Ho, P. M. et al. JAMA 2009;301:937-944

JAMA

Could also study: do physicians 'act' on a PGx study result?

Patients who had pgx tests for warfarin whose MD changed tx within 21 days of test

Warfarin sensitivity	% patients	Mean weekly dose change (SE)	P-value
< Normal	29.0%	+6.65 mg (1.98)	<0.01
Normal	28.1%	+1.10 mg (1.40)	0.50
Mild	11.6%	+3.21 mg (3.41)	0.21
Moderate	25.0%	-3.65 mg (1.56)	<0.01
High	4.0%	-10.14 mg (3.18)	0.04
Very high	2.4%	-17.33 mg (4.54)	<0.01

Source: Epstein RS et al: Warfarin genotyping reduces hospitalization rates: results of from the MM-WES. JACC 2010:55.

Genomic test outcomes that can be easily tracked with payer data

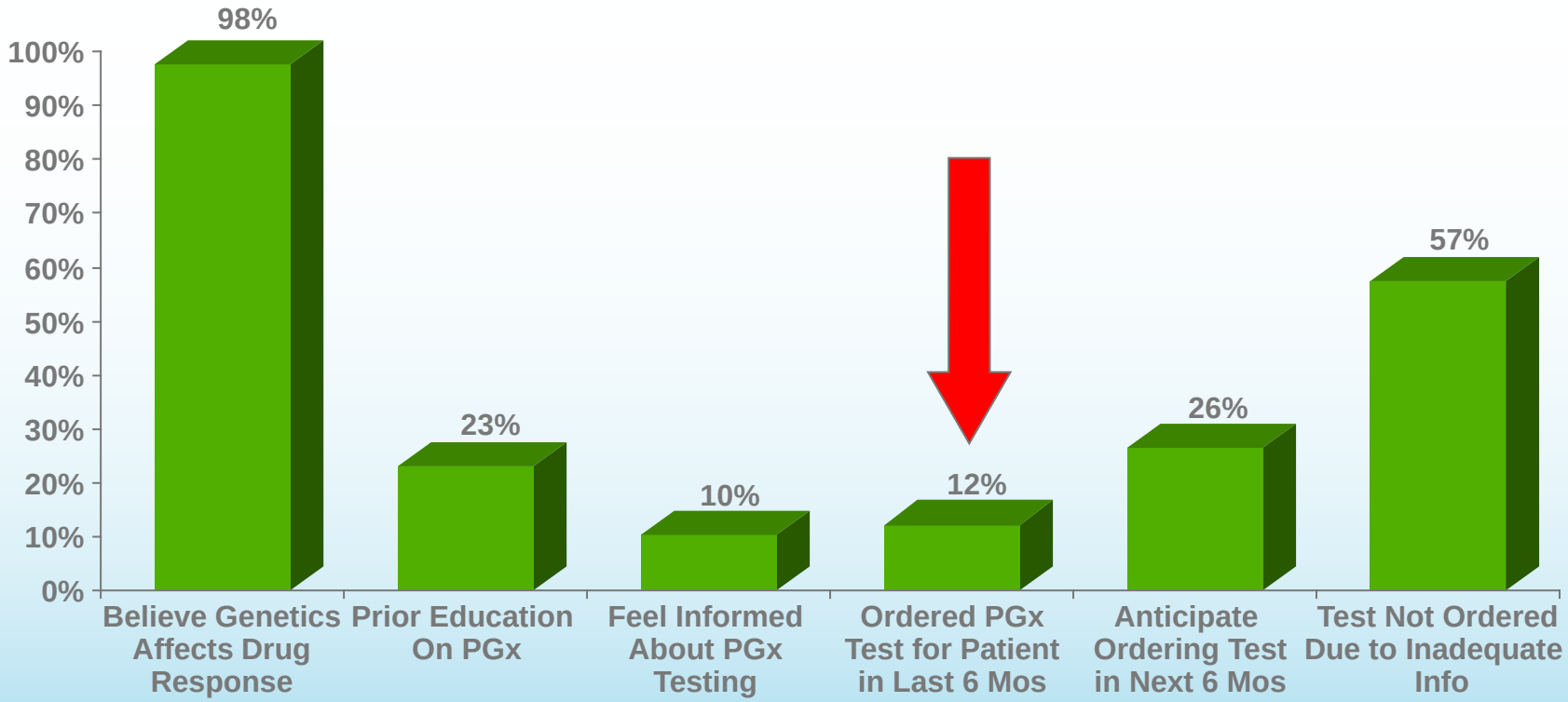
- Compliance – persistence of filling prescriptions (does genomic testing help?)
- Physician behavior change – as a result of genomic testing
- Major clinical events that result in outpatient or inpatient stays that are coded (e.g. myocardial infarctions)
- Total direct medical resource utilization and costs (whether genomic testing changes this or no)

Selected Limitations of Payer Data

- If only medical claims – no laboratory values, coding idiosyncrasies, no PRO data, biometrics
- If not a randomized study – all the usual caveats and adjustments to avoid confounding
- Claims lag on the medical side (up to 5 months) – instantaneous on the drug side

Key Aspect of Promulgating Testing (beyond evidence itself) is: *Physician Awareness of the Field*

Medco/AMA Partnership: Nationwide Survey of >10,000 Physicians (2008)



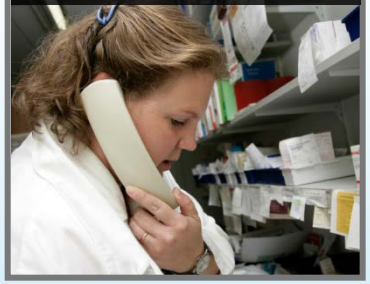
Stanek EJ, Sanders CL, Johansen-Taber KA, et al. Adoption of pharmacogenomic testing by U.S. physicians: Results of a nationwide survey. 2011:;. *Clin Pharmacol Ther* (accepted, in press)

Payer Data/System Can Educate and Foster Adoption of Drug-Specific Tests Where Appropriate

How the US Wired Pharmacy System and Payer Approved Reimbursement Can Promulgate Testing

Automated Identification

Contact MD



Contact Patient

Send Test Kit

Facilitate Lab Test & Interpretation

All about partnerships and collaborations

Acknowledge Partners and Collaborators

The >150 Payers in the Medco Research Consortium and the >50, 000 Patients

Conclusions

- Payer data are useful to frame
  - > Prevalence of use of genomic testing
  - > Among users, who are they?
  - > Comparisons between those who are and are not tested
    - – Compliance
    - – Behavior change
    - – Major clinical events avoided or incurred
    - – Total resource utilization and costs
- Ideal source to promulgate use of testing
  - > When evidence is there…..