

# **PREEMPTIVE PHARMACOGENETIC TESTING: EXPLORING THE KNOWLEDGE AND PERSPECTIVES OF UNITED STATES PAYERS**

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# OBJECTIVE

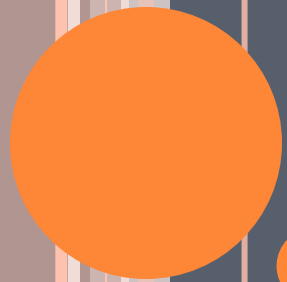
- Coverage policies and reimbursement of pharmacogenetic testing remains a challenge for broader implementation
- The purpose of this study was to investigate payer's knowledge, awareness, and perspectives on preemptive pharmacogenetic testing.
  - Framed around decision making processes for new health technologies

# QUALITATIVE APPROACH

- Payers recruited from an established panel of pharmacy and medical directors who routinely participate in interviews on new coverage policies
- In-depth interviews using a semi-structured guide
  - Conducted via telephone
  - Screener survey to determine eligibility and record demographic data
  - Pre-read document was provided to the payer
  - Face validity assessments conducted with several individuals/groups that led to a condensing of the guide and refining of questions

# DATA ANALYSIS – INTERVIEWS

- Blended inductive and directed content analysis
- Constant comparative methodology
  - Robust iterative reading process
    - Coded and categorized meaning units used develop themes and subthemes
    - Two authors read all transcripts three times and met to discuss inter-reader consensus
    - A third author served to mediate any disputes
- Manual coding rather than qualitative analysis software
  - Avoidance of potentially deterministic and quantity driven analysis
  - Underdeveloped area of knowledge



# RESULTS

# FINAL SAMPLE

- Initial sample included 35 payers
  - Six responses were not eligible for any analysis
  - Final sample size for screener survey – 29
- 14 of these payers agreed to participate in the in-depth interviews
  - Nine pharmacy directors and five medical directors
  - 30 – 45 minute interviews
  - Analysis of the screener survey revealed no noticeable differences between those interviewed and those not interviewed

<b>Demographics of <u>interviewed payers</u> (N=14)</b>	<b>Mean</b>	<b>Minimum</b>	<b>Maximum</b>
<b>Number of lives covered on plan</b>	8,708,898	200,000	50,000,000
<b>Commercial PPO/POS (%)</b>	47.5	0	100
<b>Commercial HMO (%)</b>	24.3	0	75
<b>Medicare (%)</b>	11.4	0	25
<b>Medicaid (any) (%)</b>	16.4	0	85
<b>Other (%)</b>	0.4	0	5
<b>Length of time beneficiary stays with organization (years)</b>	4.9	2	10

**Variety of organization types:**

Large national and regional plans

Pharmacy Benefit Management companies

Integrated health systems

Large individual medical groups

**122 million total lives  
covered by these payers**

## THREE MAJOR THEMES EMERGED

1. **Potential benefits but more evidence**
2. **Measuring downstream economic benefit**
3. **Population health and the role of other stakeholders**

# THE SUB-THEMES

- **Potential value and evidence needs**
  - Potential value of pharmacogenetics
  - Types of clinical/research data needed
  - Testing and treating versus treating and monitoring
  - Metrics – number needed to test (NNT)
  - CPIC and actionability
- **Upfront costs and downstream benefits**
  - Stratifying subsets of beneficiaries for testing
- **Population health and the role of other stakeholders**
  - Positioning as a preventive service
  - The role of the FDA and CMS
  - Implementation projects



# POTENTIAL VALUE AND EVIDENCE NEEDS

# PREEMPTIVE PHARMACOGENETICS DOES NOT ALIGN WITH STANDARD COVERAGE DECISION MAKING PROCESSES

- Payers want a yes/no decision dichotomy from testing
- There seems to be a lack of understanding (or general disinterest) to evaluate the potential benefits of a preemptive test
  - The dilemma for payers is that paying for this upfront does not fit the mental model for many organizations
- "The challenge is if it's A, then can I say, yeah, it should be built in policies; if it's D, then I'm gonna say I'm not gonna cover this. But if it's B or C, I can't make a – I can't enforce a decision or a policy around that. So, no, this is – it might help physicians guide, but, again, it's a guidance and it's not something that a payer can definitively use to make a decision on. That's the challenge." *Pharmacy Director #5 - PBM w/ medical policy*

## MANY PAYERS STILL PREFER THE RCT BUT THERE WAS INTEREST IN OTHER STUDY DESIGNS

- Payers have the means to run cohort studies using their own data and patient populations
  - Some showed interest in pilot type programs, but proactively moving into it was another question
- "I quite frankly do think you need the randomized control trials. Those clinical reports may be helpful. If you're going to do this, it really depends on the disease process in terms of that. You have to establish an outcome." *Medical Director #4 - Large National Health Plan.*
- "You almost wonder if the best way to do this is in some kind of real-world type of population based study where you test a large group of people and then look retrospectively to see if you can then document a rationale for maybe a drug problem or a failure to respond they had in the past." *Medical Director #2 - Drug Benefit Collaborative with medical policy management*

# PAYERS ARE WILLING TO ACCEPT TRIAL AND ERROR

- Payers questioned the use of a test on low cost treatments where it might be cheaper to treat and monitor
- "If it's a very low cost drug you know, you try one and then maybe try another. Because one of the concerns was some of the testing is what it's going to lead you to maybe pick first line." *Pharmacy Director #6 - Large National Health Plan*
- Several payers mentioned using the number needed to test metric for evaluation
- "You know, again, like anything else, if five percent of the patients are avoided, I don't know if it's worth it. If 40% have a drug change or are avoided, depending on the cost of the test, it may be worth it. So, it's going to be the number needed to test, sensitivity, specificity..." *Medical Director #4 - Large National Health Plan*



# **UPFRONT COSTS AND DOWNSTREAM BENEFITS**

# LARGE UPFRONT COSTS AND DIFFICULTY DETERMINING DOWNSTREAM BENEFITS

- Many traditional payers work on a 1-year time frame for budgeting purposes
  - The economic value of preemptive pharmacogenetics extends beyond this time frame
  - Those from integrated systems seemed more willing to move towards this
- “I'll spend a few hundred dollars or even a couple thousand dollars on a test if it tells me the best way to handle a \$100,000 a year anti-cancer therapy...let's think about pharmacogenetic testing that you're going to apply to large populations... Let's say it's even a ridiculously low, low price of 100 bucks. If I got a million members that I got to test, I just spent a (hundred) million dollars and I don't know what my return on that investment is going to be.”  
*Medical Director #2 - Drug Benefit Collaborative with medical policy management*

# PAYERS DO SEE THE DOWNSTREAM POSSIBILITIES

- “No, we're obviously very interested in hospitalizations and preventing re-hospitalizations and expense of adverse events. If these tests do show robust predictive value, then we would be interested in using them. Again, this is probably going to be on a case-by-case basis.” *Medical Director #3 – Integrated medical group with insurance*
- “Would we focus it on where we had potential risks either in preventable admissions or hospital readmissions and have offsets? Yes. I think when it trickles down through all that triage, to what’s good for society and good for the patient to get an earlier experience, I’m gonna suggest probably funding and resources run out before we get to that level of compassion and empathy.” *Pharmacy Director #6 - Large National Health Plan*

# A HYPOTHETICAL ON STRATIFYING BENEFICIARIES FOR COVERAGE

- “Maybe if you were 22 to 30, or 22 maybe 40, you wouldn't really have to do that testing for those patients because usually they're relatively healthy. I say usually but you don't know. Then you look at it, maybe you relegate it to 50 and above I guess if you wanted to do that type of testing. You might relegate it to specific disease states too...
- (continued)...if you have a patient that's 60 years old...you may decide that at that age 60, it's time that he has or she has this information in his file so the \$500 gets spent. I think that's going to be really up to the physician on how they view the patient. But I don't think we are going to go out and promote a multi-gene testing for everybody over 65 or everybody over 60 just because the consortium or the guidelines or whatever say that is the right patient for these." *Pharmacy Director #2 - Regional Health Plan*
- “I'd even consider in high-risk populations, the possibility you have here of the preemptive testing. If there's evidence that every childhood asthmatic should get preemptive testing or evidence that every patient post-myocardial infarction should get preemptive testing, I'm willing to consider that also.” *Pharmacy Director #8 – Integrated Health Plan*



# POPULATION HEALTH AND THE ROLE OF OTHER STAKEHOLDERS

# PREEMPTIVE PHARMACOGENETICS AS AN OFFICIAL PREVENTIVE HEALTH SERVICE

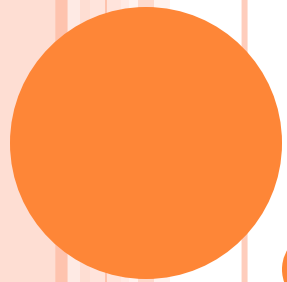
- An interesting and unprompted discussion on pursuing endorsement from the USPSTF
  - Payers indicated they would be bound to a mandated decision but this would likely be a contentious issue, as are many USPSTF recommendations
- "The other way it could be is all plans and payers have annual refreshment and linkage to preventative health guidelines in quality metrics when it's used... If it ever became a part of an annualized preventative health guideline, published and adopted and/or became a quality metric that will help you, then it would become, and we would pay for it." *Pharmacy Director #9 - Large Regional Health Plan*

## SOME PAYERS INDICATED THE NECESSITY OF HAVING A PHARMACOGENETIC TEST INCLUDED ON AN FDA LABEL

- FDA labeling is a key reference point for payers in coverage decisions
- If the label specifically requires testing, coverage is likely
- “The FDA is the biggest standard. The second biggest one is the societal guidelines. Really, behind those two, the secondary level is –again, it’s a subjective opportunity for a plan.” *Pharmacy Director #2 - Regional Health Plan*
- “I think it's still going to have to be approved by the FDA. It has to be part of the product labeling. You don’t see too many other ways around that.” *Pharmacy Director #5 - PBM w/ medical policy*

# THE ROLE OF IMPLEMENTATION PROJECTS

- "I'd also like to see their data and how it's made a difference, and what specific entity, what diseases they treated, and what were the outcomes based on the choices that they've made. If you're going to proactively do this, tell me what your physicians did with that information. Did they actually change the medication, did they alter the dose of the medication, what were the outcomes, and was the patient discharged sooner or having a shorter length of stay?"  
*Medical Director #4 - Large National Health Plan.*
- "I think that when those organizations implement those programs and then they're able to show results, that's likely to eventually start to siphon over into things like treatment pathways and treatment guidelines..." *Chief Pharmacy Officer #1 – Regional PBM*



# THE CPIC ROLE

# OVERVIEW OF CPIC FROM PAYER PERSPECTIVE

- Payers were encouraged by the work of CPIC on making pharmacogenetics more actionable
  - Payers were unfamiliar with the work of CPIC
    - Only one revealed any previous knowledge
  - Several payers compared CPIC to NCCN guidelines
    - A couple speculated whether CPIC should extend the guidance to when and whom should be tested
  - The importance of integration in the EHR was also discussed
  - Payers have high regard for the use of guidelines for decision making
    - Referenced in discussions around CMS, implementation projects, and from previous literature (Leung et al. 2012, *JMCP*)

# PAYERS REALIZE THE VALUE OF CPIC BUT DESIRE MORE

- “Ostensibly, are they saying here that – I can see where this makes sense in terms of the results of the test can potentially change the prescription and change the drug. Quite frankly, what's concerning here is I don't think there's a consensus. I think there's a lack of studies. I think the overall clinical utilization of these tests is unclear.” *Medical Director #4 – Large National Plan*
- "Again, I think any of that type of information (CPIC) would be valuable. I think the biggest issue in thinking about this is that some of the tests that we have may not be definitive for rule-in, rule-out. There's always going to be a gray area.” *Medical Director #2 - Drug Benefit Collaborative with medical policy management*

## COMPARISONS TO OTHER GUIDELINES

- "They (NCCN) started creating interest as far as should you cover this, should you not cover that, we rate this one a 2A, we rate this one a B. They have different ratings for the drugs. That really hadn't happened in a long period of time at all. I think that, that model could be used in something like this." *Medical Director #3 – Integrated medical group with insurance*
- "This would almost be like an FCC compendium (USP) type of thing where we may base some of our coverage decisions based on the data that comes about from this type of consortium." *Pharmacy Director #2 - Regional Health Plan*

# THE IMPORTANCE OF CPIC INFORMATION IN THE EHR WAS NOTED

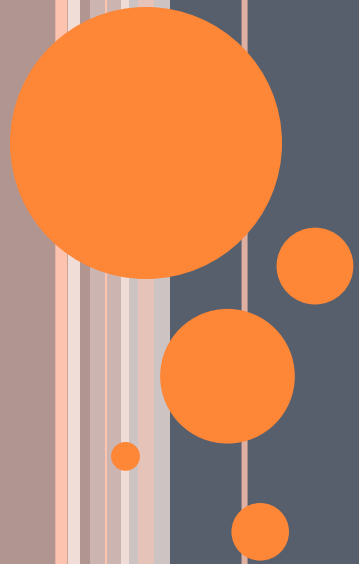
- “If you have a particular drug where a test said this needs to be reduced, this is not just based on – I would speculate to say that this is compelling data. Those things can be built in as alerts. The electronic record, dysfunctional as it is, can be useful for that.”  
*Medical Director #3 – Integrated medical group with insurance*
- “It has to go straight into their ePrescribing tools, it has to be – you cannot pass "go" until the results of this test have been provided, and you'll get electric shock because this is inappropriate. This is wrong. I think it's still going to have to be approved by the FDA. It has to be part of the product labeling. You don't see too many other ways around that.”  
*Pharmacy Director #5 - PBM w/ medical policy*

## CONCLUSION

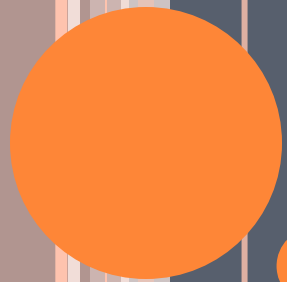
- Payers have had limited exposure to preemptive pharmacogenetics which gave pause to any rapid adoption
- The one year budget evaluation cycle may limit the ability of the payer to judge potential value from a preemptive test
- CPIC guidelines were viewed as a positive step in the implementation of pharmacogenetics
- Further evidence is needed in the form of data from implementation projects, prospective outcome studies, population health metrics, and budget impact models demonstrating downstream benefits

# AUTHORS AND ACKNOWLEDGEMENTS

- Nicholas J. Keeling, MS (**nick.keeling@stjude.org**)
  - Doctoral student - University of Mississippi
  - Graduate Research Assistant – St. Jude Children’s Research Hospital
- Donna West-Strum, RPh, PhD
  - Chair and Professor of Pharmacy Administration and Research Professor in the Research Institute of Pharmaceutical Sciences – University of Mississippi
- Meagen Rosenthal, PhD
  - Assistant Professor of Pharmacy Administration – University of Mississippi
- Amit Patel, PhD
  - Director at Medical Marketing Economics (MME)
  - Adjunct Professor of Pharmacy Administration – University of Mississippi
  - Made available the payer panel
- James M. Hoffman, PharmD, M.S.
  - Chief Patient Safety Officer – St. Jude Children’s Research Hospital
- Cyrine E. Haidar, PharmD
  - Clinical Pharmacogenetics Coordinator - St. Jude Children’s Research Hospital



# Q & A



**THANK YOU!**