Managing Care in The Wave of Precision Medicine

Welcome

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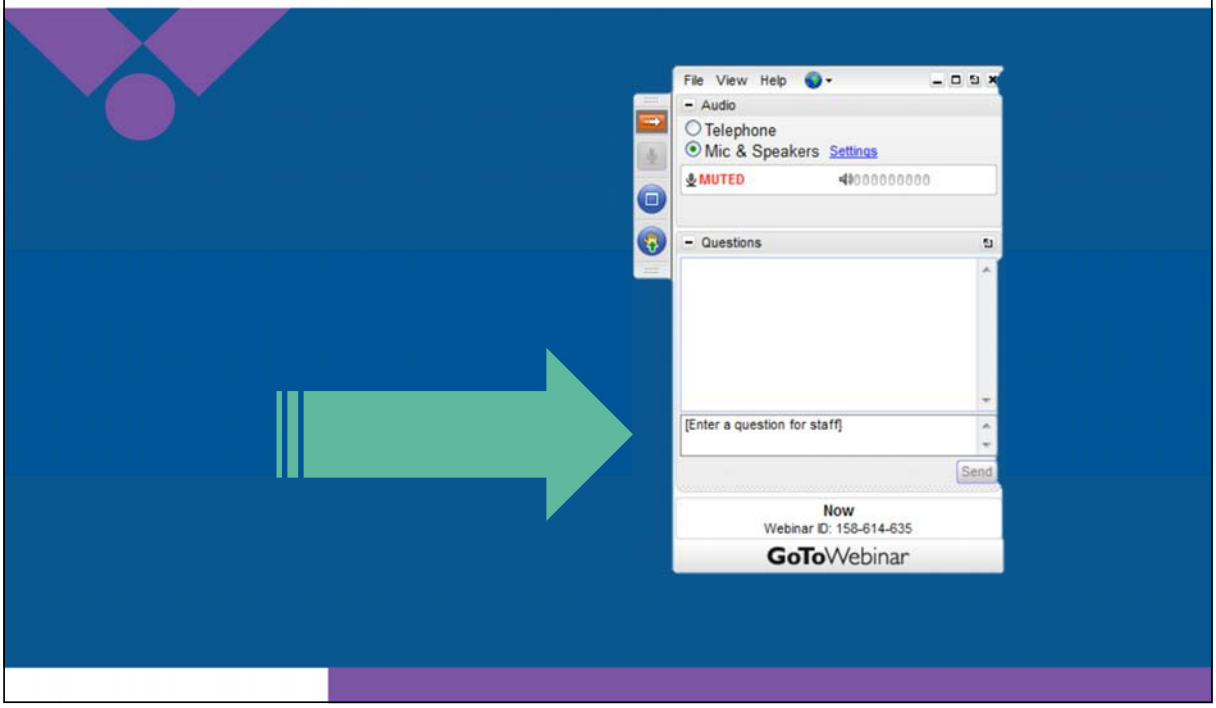
How to Ask Questions



Agenda

1. AMCP Partnership Forums
2. Managing Care in the Wave of Precision Medicine
3. Forum Findings and Recommendations
4. Q&A
5. Next Steps and Action Items

LEADING CHANGE

On health care issues that are important to you

Live and hands-on, AMCP Partnership Forums, bring together key decision-makers in managed care, integrated care, the pharmaceutical industry, and others to drive efficiencies and outcomes in managed care.

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2017 Partnership Forums

- Advancing Value-Based Contracting
- Patient Reported Outcomes – The Missing Link in Defining Value
- Driving Value and Outcomes in Oncology
- Managing Care in the Wave of Precision Medicine

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Why a Partnership Forum on Managing Care in the Wave of Precision Medicine?

1. Precision medicine tailors healthcare to an individual's genetic profile while accounting for biomarkers, preferences, lifestyle, and the environment.
2. Advances in research and data infrastructure have facilitated greater adoption of precision medicine.
3. Precision medicine can promote better access to healthcare, and improve the utility of data sources to inform patient-centered care as well as appropriate drug coverage and reimbursement.
4. There is need for greater stakeholder collaboration and engagement to overcome key barriers.

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Precision Medicine Forum Goals

1. Identify evidence needs for precision medicine
2. Define solutions for challenges with data collection and interoperability
3. Identify innovative benefit design and reimbursement strategies for precision medicine
4. Address approaches to overcome current legal and regulatory barriers to precision medicine adoption

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Forum Participants

30+ participants from health plans, integrated delivery systems, pharmacy benefit managers, employers, data and analytics experts, biopharmaceutical companies and government agencies, including:

AHRQ	Kroger Prescription Plans
Alva10	MedImpact Healthcare Systems Inc.
Amgen	Myriad
Blue Cross Blue Shield Association	National Pharmaceutical Council
Board of Pharmacy Specialties	Oracle
COTA Inc.	Personalized Medicine Coalition
Evidera	PM Connective
Food and Drug Administration	Precision for Medicine
Foundation Medicine	Sanofi
Genentech	Takeda
Gilead Sciences, Inc	University of Florida, College of Pharmacy
Henry Ford Health System	University of Kentucky
Humana Inc.	University of Mississippi School of Pharmacy/St. Jude Children's Research Hospital
Humana Pharmacy Solutions	Walgreens
Inova	Xcenda
InterSystems Corporation	YouScript, Inc.

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Our Faculty

Stuart Goldberg, MD
Chief Scientific Officer
COTA Inc

Kristen Migliaccio-Walle
Director, GHEOR
AmerisourceBergen
Xcenda®, LLC

Evidence Needs

Evidence Needs for Precision Medicine

Evidence requirements for evaluating benefits and risks:	Implementing and analyzing these metrics in a consistent way can be challenging:
Analytic validity and clinical validity – Ensures tests detect what is intended. Clinical utility – Useful for the actual delivery of care i.e. diagnosis, treatment or management.	Clinical trials and registries often measure outcomes differently, making it challenging to assess validity and utility uniformly. Challenging for payers to determine whether to provide access to a new test or diagnostic.

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Evidence Needs for Precision Medicine (cont.)

Traditional clinical trial designs may be inadequate for some precision medicine tests or therapies

1. Traditional clinical trials require large sample sizes and long time periods
2. Many precision medicine therapies target small patient populations
3. Benefits of precision medicine may require a time period to observe vs. traditional clinical trial periods
4. Several new and adaptive trial designs may be more appropriate options in precision medicine

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Best Practice Recommendations to Overcome Evidence Needs Challenges

Short-Term → Long-Term

Standardization & Reliability of Evidence	Novel Trial Designs	Value Assessment Frameworks	Collection & Dissemination of Evidence

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Overcoming Data Collection Challenges

Data and Evidence Sources Used for Decision-Making in Precision Medicine

1. Databases (e.g. PharmGKB)
2. Consortiums (e.g. Clinical Pharmacogenetics Implementation Consortium (CPIC®))
3. Electronic Health Record (EHR) systems
4. Insurance claims
5. Operations data (e.g., employee and supply chain data)

Challenges in Data Generation and Analysis for Precision Medicine

1. Disparate data systems
2. Data systems still have interoperability challenges
3. Businesses may not have correct incentivizes to openly share data

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Challenges in Capturing Heterogeneity of Populations

1. Current medical coding systems do not adequately capture the heterogeneity of patient populations and diseases.
2. Involving patients in data collection is crucial, but there is a lack of information and education around how individual genetic data can be shared and used.
3. Patient-reported outcomes (PROs) are important to care, but many widely-used PROs are too generic to capture patient heterogeneity.

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Best Practice Recommendations
Novel Trial Designs

Short-Term → Long-Term

Short-Term	Long-Term	Long-Term
Novel forms of primary data collection and validated tools and methodologies, coupled with natural language processing	Data analytics and machine learning can reduce workflow, improve data availability and utilization, and help identify patients for novel trials	Greater integration of biometrics (e.g., wearables and smart watches) to better link trial data with real world evidence

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Best Practice Recommendations
Patients and PROs

Short-Term → Long-Term

Short-Term	Long-Term	Long-Term
Multi-stakeholder cross-sector campaign to educate and inform patients about the value of genomic information	Initiatives to support actionable dissemination of genomic testing results to help patients make more informed decisions about their healthcare and treatment	Continued multi-stakeholder efforts are needed to develop and disseminate PRO standards

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Best Practice Recommendations
Safety and Pharmacovigilance

Short-Term → Long-Term

	Need to develop minimum standards to facilitate EHR interoperability and integration	Coordinated voluntary platforms and initiatives that continuously collect patient data to prospectively identify patients at risk	Pharmacists need access to patients' genomic data to support drug utilization reviews and therapy management

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Best Practice Recommendations
Clinical Decision Making

Short-Term → Long-Term

	Communicate the benefits of precision medicine to improve data collection, support therapy decisions and improve patient engagement	Current coding systems should be more detailed and widely implemented	A neutral third party is needed to establish guidelines for data sharing

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Benefit Design and Reimbursement Strategies

Challenges for Payers

Decisions to cover precision medicine therapies, tests or diagnostics can be challenging for payers for a number of reasons:

1. There often is limited or missing evidence
2. Patients change payers frequently
3. Payers may face an information overload and have uncertainties around how to use this data for coverage and reimbursement decisions

Best Practice Recommendations: Benefit Design and Reimbursement

Short-Term → Long-Term

Flexible condition-specific bundles could reduce some risk to payers	Provider & patient incentives to promote portability of patient records could reduce need for expensive & unnecessary retesting	Shorter window from prescribing to dispensing could come through automated prior authorization & smart exception processes	Better distinctions between germline & somatic testing

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Best Practice Recommendations: Value-Based and Outcomes-Based Contracting

Short-Term →

Value based contracting (VBC) requires consideration of risk allocation across stakeholders	Focus on long-term outcomes and benefits, which is where many benefits of precision medicine may accrue	Incentivized payers to cover precision medicine tests and therapies even when benefits of these interventions accrue years later

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Best Practice Recommendations: Value-Based and Outcomes-Based Contracting

Long-term

VBC should be extended to diagnostic technologies that guide therapy

VBC should incorporate validated surrogate endpoints

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Overcoming Operational, Legal and Regulatory Barriers

Operational Barrier

Disconnect between medical and pharmaceutical sides of health plans and care delivery settings

Possible Solution:

- Expand current scope of pharmacists' practice to include ordering and interpretation of clinically necessary genetic tests.
- This could support collaborative care and better inform appropriate selection and management of indicated drug therapies.

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Potential Ethical Issues

1. Detection of elevated risk levels through genetic testing that are unrelated to primary test indication; patients and clinicians must decide when secondary findings should be communicated.
2. Precision medicine is increasingly marketed directly to consumers, and information conveyed may not be evidence-based.

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Best Practice Recommendations: Legal and Regulatory

Short-Term

	Genetic Information Nondiscrimination Act (GINA) should be expanded to include protections for life and disability insurance coverage, coverage decisions, long-term care and the military	Scope of practice, and subsequent compensation, for pharmacists should be expanded to include ordering and interpretation of genetic tests	Need for regulations to ensure that precision medicine genetic data and information is interpretable and meaningful to patients

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Best Practice Recommendations: Legal and Regulatory (cont.)

Long-term

	Real world evidence should be collected beyond the label in the context of Phase IV trials and post-market trials	Best practices on patient consent should be established so patients can understand how and when genetic information may be shared

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Conclusions

Key Takeaways

1 Precision medicine diagnostics and therapies:	• Enable more individualized and targeted care • Allow for better allocation of resources
2 Recommendations to overcome key operational and scientific barriers that are preventing more widespread use included:	• Promote stronger evidence generation, data collection, benefit and reimbursement design, and updated laws and regulations • Need for multi-stakeholder collaboration to better define endpoints, outcomes, trial designs, and data collection methods • Interoperability and usability of data sets, EHRs, and test results

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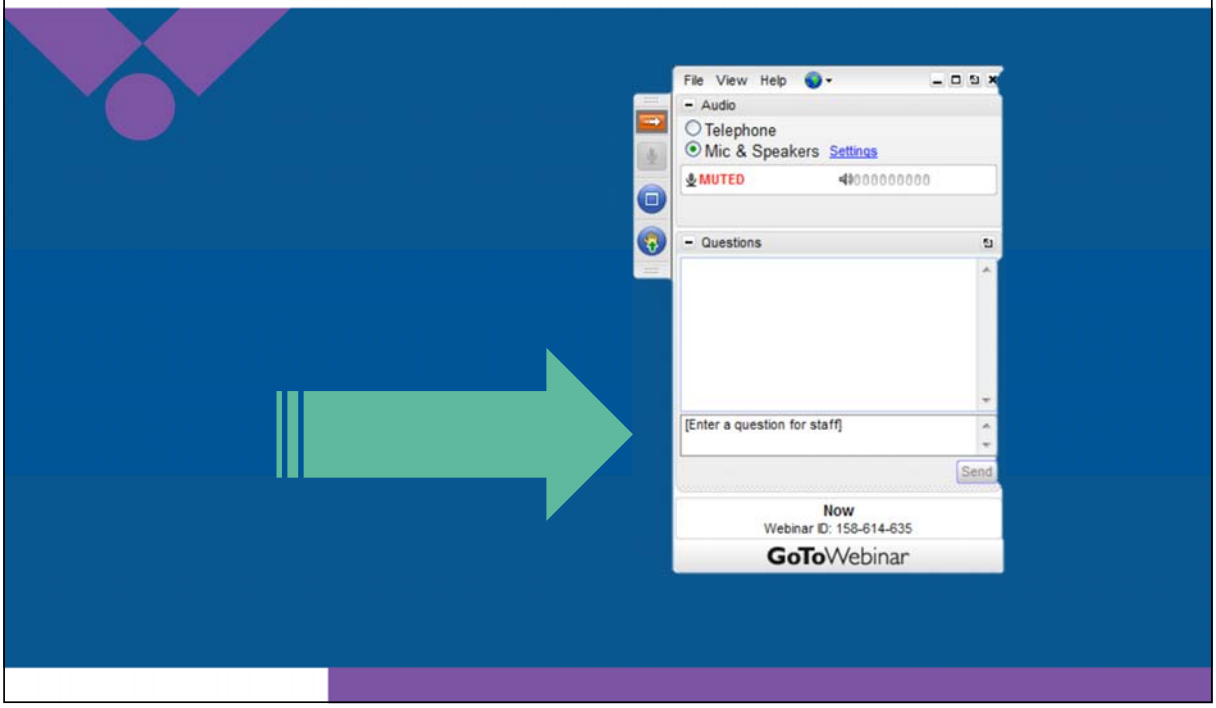
Reminder: How to Ask Questions



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