Identifying Benefits for Patients, Providers & Payers

7th Annual Research Symposium October 16, 2017 | Dallas, TX







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Note

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Welcome and Introduction

Paula J. Eichenbrenner, CAE

AMCP Foundation Executive Director





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Congratulations, Scholarship Recipients

Lindsay Adair	The Ohio State University, College of Pharmacy
Shana Barkhordari	Western University of Health Sciences
Alex Britcher	University of Maryland School of Pharmacy
Fahim Faruque	University of Maryland School of Pharmacy
Stephen Meninger	University of Maryland School of Pharmacy
Insiya Poonawalla	Humana
Tayla Poretta	Northeastern University
Tyrane Roberts-LaGrone	UNT System College of Pharmacy
Erin Solano	Huron Consulting Group
Chuka Udeze	University of Maryland School of Pharmacy





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Thank You to Our Partners for Generous Support

















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AMCP Foundation Webinar

Research Symposium Highlights and Proceedings
Thursday, November 30

2:00 p.m. - 3:00 p.m. ET

Free registration open at www.amcp.org/2017Fdn_Symp/







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Paying for Value In Health Care

Cliff Goodman, Senior Vice President & Director, Center for Comparative Effectiveness Research, Lewin Group Symposium Moderator



Susan A. Cantrell AMCP CEO and AMCP Foundation Chair



Elizabeth Powers Senior Principal, QuintilesIMS





Considerations About How We Pay for Value in **Health Care**

Clifford Goodman, PhD Senior Vice President The Lewin Group clifford.goodman@lewin.com





Why the Great Interest in Value?

- Payers' push to shift from volume to value
- Great attention to new therapies that improve outcomes but have high costs (high unit price and/or high budget impact)
- Recognition that "value" depends on stakeholder perspective
- Increased interest in patient perspective and patient-centered outcomes
- Increased understanding of patient differences and "heterogeneity of treatment effects" in patient subgroups
- Increased interest in personalized preferences in health care decisions
- Interest in factors beyond cost/QALY for determinants of value
- Growing capacity for generating real-world evidence (RWE) of value
- Alternative value-based payment mechanisms ("value-based contracting," "outcomes-based risk sharing agreements," "indicationbased pricing," etc.)



Value Frameworks: What Are They?

A value framework (or value assessment framework) is a structured approach that identifies, organizes, and analyzes a set of factors (or criteria) that are important to particular stakeholders when making decisions about alternative interventions (e.g., therapies).

Different stakeholders (e.g., patients, providers, payers, government) value different factors/criteria.

Examples of factors or criteria for value:

- Quality (methodological strength) of evidence
- Magnitude of treatment effects (outcomes)
- Probability of adverse events
- Costs, cost-effectiveness, other economic
- Other benefits (e.g., innovation, addresses unmet need)





Value Frameworks: More, Evolving

- American Society of Clinical Oncology (ASCO)
- American College of Cardiology/American Heart Association (ACC/AHA)
- European Society of Medical Oncology (ESMO)
- Evidence and Value Impact on Decision Making (EVIDEM)
- FasterCures (Milken Institute)
- HTA agencies: NICE (UK), PBAC (Australia), etc.
- Innovation and Value Initiative
- Institute for Clinical and Economic Review (ICER)
- Memorial Sloan Kettering Cancer Center DrugAbacus
- National Comprehensive Cancer Network (NCCN)
- Premera BlueCross BlueShield





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Value Frameworks: Diverse

One size will not fit all

- Different stakeholders
- Different purposes
- Different target audiences
- Different domains

For example ...



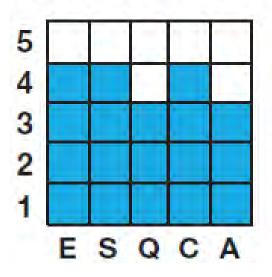


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Example: NCCN

NCCN EVIDENCE BLOCKS CATEGORIES AND DEFINITIONS



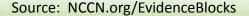
E = Efficacy of Regimen/Agent

S = Safety of Regimen/Agent

Q = Quality of Evidence

C = Consistency of Evidence

A = Affordability of Regimen/Agent





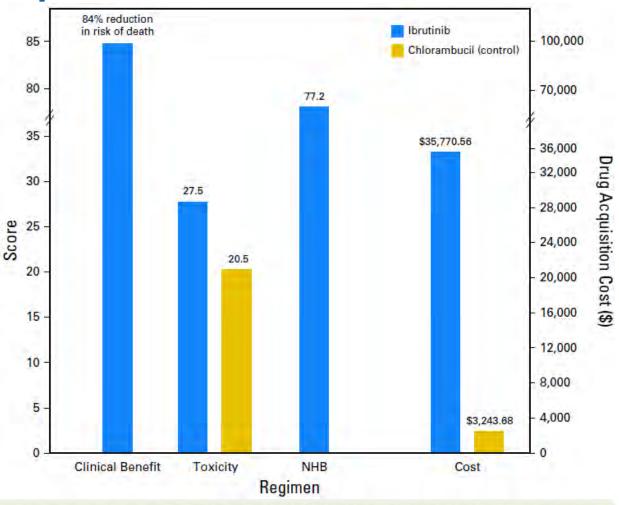


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Example: ASCO

Ibrutinib vs. Chlorambucil for Chronic Lymphocytic Leukemia



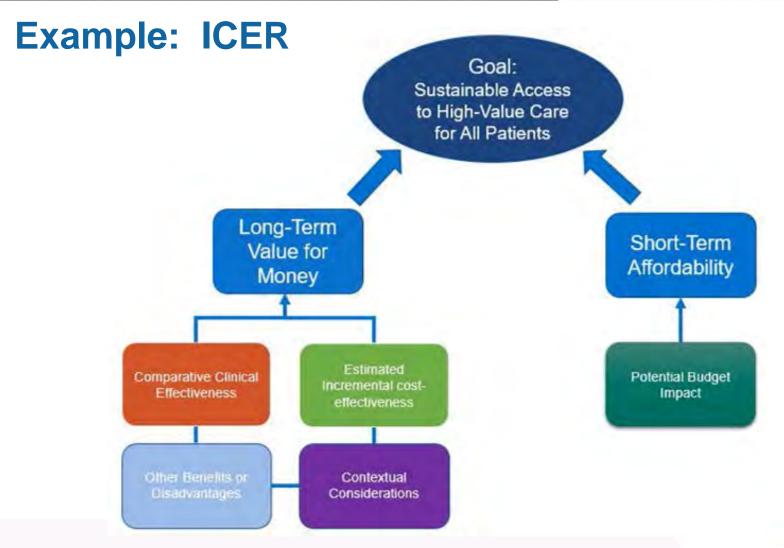
Source: Schnipper LE, et al. American Society of Clinical Oncology Statement: Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received. J Clin Oncol May 31, 2016.





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Source: ICER. Final Value Assessment Framework for 2017-2019.





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FOUNDATION

Example: MSKCC DrugAbacus

\$12,000-\$300,000)
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Dollars per Year: Tell us the price that Abacus should use for a year of life

0%-30%

Toxicity Discount: Tell us the maximum discount Abacus should apply to drugs with severe side effects

1.0-3.0

Novelty Multiplier: Tell us the maximum premium Abacus should apply to drugs with novel mechanisms of action

1.0-3.0

Rarity Multiplier: Tell us the maximum premium Abacus should apply to drugs that treat rare illnesses

1.0-3.0

Population Burden of Disease: Tell us the maximum premium Abacus should apply to drugs that address large population health burdens

1.0-3.0

Cost of Development: Tell us the maximum premium Abacus should apply to drugs tat are expensive to develop

1.0-3.0

Prognosis: Tell us the maximum premium Abacus should apply to drugs that treat aggressive illnesses

1.0-3.0

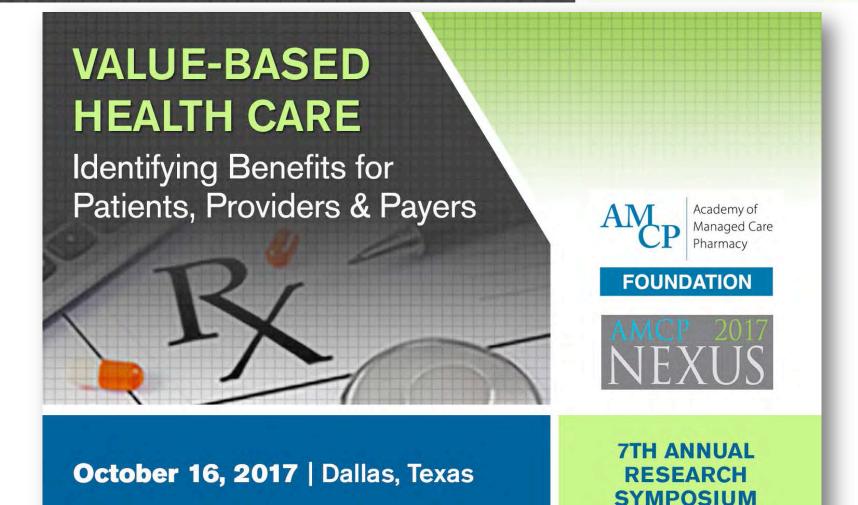
Unmet Need: Tell us the maximum premium Abacus should apply to drugs that treat illnesses for which there are few or no other treatments available

Source: Memorial Sloan Kettering DrugPricing Lab, 2017.



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AMCP Leadership on Value

Susan A. Cantrell, RPh, CAE

AMCP CEO and AMCP Foundation Chair





In our DNA

- Value's always been a major part of what we do
- Central tenet of managed care pharmacy:

"Getting the right medication to the right patient at the right time, while optimizing health care resources."





Leader in product communications

- AMCP forums helped put in motion policy changes expanding:
 - Post-market communications under FDAMA Sec. 114 via FDA draft guidance and Cures Act
 - Pre-approval sharing via FDA Draft guidance
- AMCP now leading effort to pass H.R. 2026
 - Safe harbor for pre-approval pharmaceutical information exchange or PIE





Leader in biosimilars

- Advocates for market entry and acceptance, from Capitol Hill to the States
- Informs via Biosimilars Resource Center policy neutral, nonpromotional
- Monitors for safety and efficacy via Biologics and Biosimilars Collective Intelligence Consortium
 - BBCIC's post-market surveillance intended to reassure prescribers, patients





AMCP Partnership Forum on Value-Based Contracting (VBC)

- Participants >30 leaders from payers, IDNs, PBMs, data, analytics, biopharmaceutical companies
- Goals
 - A definition
 - Strategies for developing and utilizing performance benchmarks
 - Best practices for implementing VBC
 - Action plans to reduce legal/regulatory barriers





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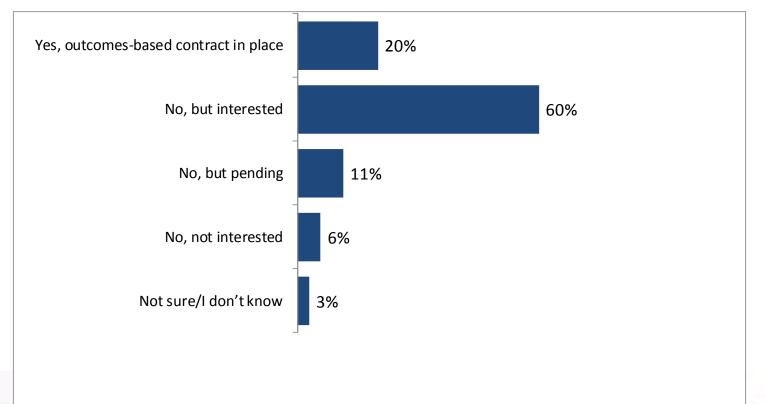
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AMCP/Xcenda Survey





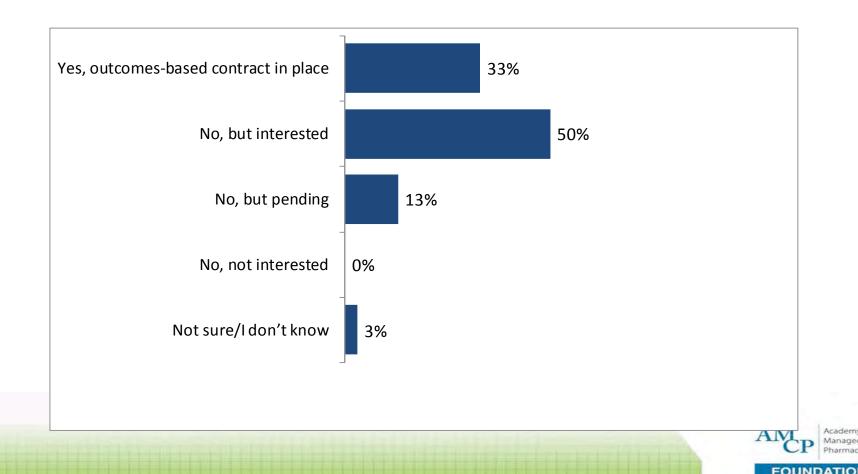
While 20% of payers use outcomes-based contracts, most are interested







One-third of manufacturers use OBCs, but half are interested





Value-based contracting defined

- Lack of accepted definition frustrates advocacy for process improvements, friendlier regulation
- Goal: craft definition broad and flexible enough to
 - Capture array of agreements
 - Allow for innovation in contracting & health care





Value-based contract is....

"A written contractual agreement in which the payment terms for medications or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures."





Factors to consider regarding capacity to collect and analyze data

- What are the sources?
- How will it be collected, validated and analyzed?
- How will the patient populations be defined?
- Is the infrastructure there to perform these data collection and analytical functions?





"Primary barriers" to VBC growth

- Federal anti-kickback statute
 - AMCP should advocate for new safe harbor or clarification of existing rules
 - Long-term, fundamental reforms to fraud, waste, and abuse laws needed
- Medicaid's Best Price rule
 - Possible solution: CMS exception for VBC
 - Further study in AMCP white paper





Forum Proceedings now available

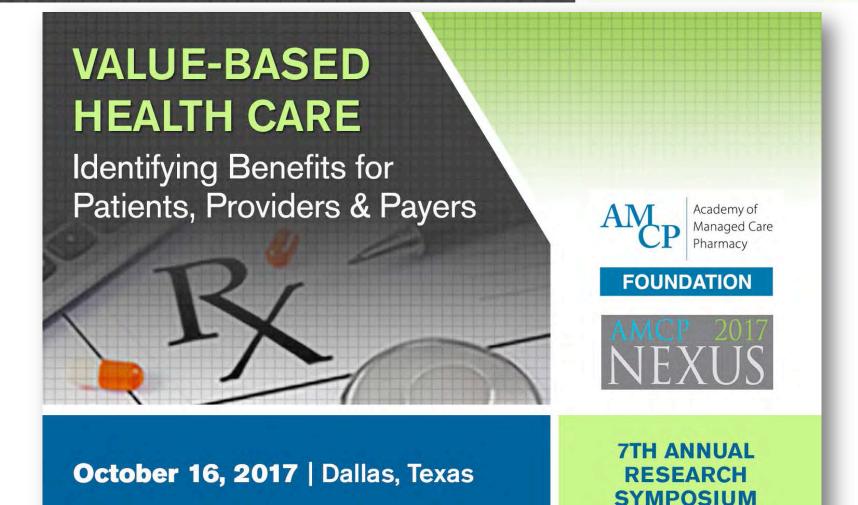
- Now posted online at www.jmcp.org
- Print version delivered with November JMCP
- October JMCP: Value Changing the Way We Pay for Pharmaceuticals
 - Read it online





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Outcomes Based Contracting

Elizabeth Powers

Example of Flow of Funds

Oct 3, 2017





RWE is becoming a key input into day to day healthcare decision making

Growing payer/provider demands

 Increasing use of RWE/RWI for day-to-day operations

Evolving regulatory environment

 21st Century Cures Act request for FDA to determine appropriate use of RWE

Patient decision accountability

- Increased financial engagement...
- ...Not yet reflected in behavior engagement



Rapid innovation in tech/data

- Real world data explosion
- Technology for integration/hosting
- Privacy capabilities
- Advanced, agile analytics

Increasing pricing pressures

- Continued rebate growth
- Increasing influence of ICER and pressure to regulate drug prices
- Reality of biosimilars
- Optimizing drug value while minimizing wastage





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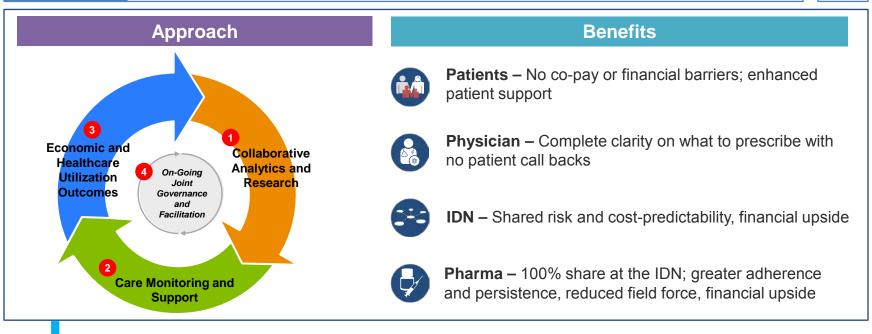
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A direct-to-provider risk based contract allows multiple stakeholders to capture value from RWE

Objective

Maintain coverage for a primary care brand once faced with generic competition





Outcome

Through leveraging outsourced patient generated data to advance its internal RWE generation capabilities, the company managed to extend the contract for another year





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BLINDED EXAMPLE

Example flow of funds for insulin-dependent T2DM population at mid-sized IDN under a traditional contract

Traditional Rebate-Based Contracting

- Pharma discounts (rebates and copay cards) total to 50% off WAC in exchange for preferred status with payer, for a WAC drug price of \$450 per patient per month
- Provider IDN receives quality bonus payment from private payer based on HbA1c control (<7.5%)
- Adherence rate of 40%

Net revenue/year -\$11 m \$1,630/patient Pharma IDN/ACO State WAC Bonus Payment (variable) Payer

Assumptions

- 13,500 total diabetic patients eligible for pharma's class of drug with in the IDN
- 50% share of volume
- 60% overall adherence





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BLINDED EXAMPLE

Example flow of funds for insulin-dependent T2DM population at mid-sized IDN under full risk contract

Outcomes-Based Contracting with IDN

- Pharma takes full risk with target HbA1c <=7.5% in exchange for exclusive access to insulin-dependent patients through IDN/ACO and 50% of the combined value created
- Pharma/IDN collaboratively identify and intervene with patients at risk of non-adherence, increasing adherence to 55%

Flow of Funds



Net revenue/year

~\$12m from outcomes contract + \$4.5m from 2,800 patients under traditional payer contracts

\$1,542/patient

Pharma

50% share of value

Annual value created through improved HbA1c control:

- Reductions in:
 - Hypoglycemic events (\$10m)
 - CV disease (\$10m)
 - Amputations (\$2m)
 - Increased quality bonus (\$2m)

Total \$24 million

IDN/ ACO Diabetes related bonuses \$7m

Payer

Patient baseline

13,500 total patients:

 ~5,600 achieve HbA1c control – traditional contract

In-scope patients

- ~1,900 adherent, not achieving control
- ~6,000 non-adherent patients (33% baseline adherence)





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Best Poster Presentation:

Medication Therapy Management Services and the Impact to Health Care Utilization

Laura Happe

Editor-in-Chief, Journal of Managed Care & Specialty Pharmacy (JMCP)

Erin Ferries

Research Scientist, Humana

Lilian Ndehi

MTM Value and Quality Manager, Humana Pharmacy Solutions





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Medication Therapy Management Services and the Impact to Healthcare Utilization

Erin Ferries, PhD, MPH

Benjamin Hall, PhD, FSA, MAAA

Lilian Ndehi, PharmD, MBA

Andy Papa

Jamieson Vaccaro, MA

Joseph Dye, PhD, RPh

Research Scientist, Humana

Actuarial Director, Humana

MTM Manager, Humana Pharmacy Solutions

MTM Director, Humana Pharmacy Solutions at the time of the Study

Research Scientist, Comprehensive Health Insights

Head of HEOR-Neurology US, UCB Inc. (Research Consultant, Comprehensive Health Insights at time of the study)







- All Part D sponsors must establish MTM programs as a quality improvement requirement¹
- Medication therapy management (MTM) programs must²
 - Ensure optimum therapeutic outcomes through improved medication use
 - Reduce the risk of adverse events, including adverse drug events
- Research indicates positive clinical and economic benefits of MTM, however there is wide variation in study design and reported returnon-investment (ROIs) across the literature^{3,4,5,6}

^{1 -} Drug utilization management, quality assurance, and medication therapy management programs (MTMPs). CFR. Title 42. Chapter IV. Section 423.153.

^{2 -} Centers for Medicare & Medicaid Services. CY 2017 Medication Therapy Management Program Guidance and Submission Instructions. Baltimore, MD; 2016.

^{3 -} Brummel, A.; Carlson, A.M. Comprehensive Medication Management and Medication Adherence for Chronic Conditions. J. Manag. Care Spec. Pharm., v.22, n.1, p.56-62, 2016.

^{4 -} Gazda, N.P., Berenbrok, L.A., Ferreri, S.P. Comparison of two Medication Therapy Management Practice Models on Return on Investment. J Pharm Pract. 2016;30:282–285.

^{5 -} Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc (2003). 2008;48(2):203-11.

^{6 -} Bunting BA, Cranor CW. The Asheville project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. J Am Pharm Assoc (2003). 2006;46(2):133-47.

Comprehensive Medication Review (CMR)^{1*}

- Comprehensive, real-time, interactive medication review and consultation with patient
- Assess medication use for presence of medication-related problems (MRPs)
- Includes individualized written summary

Targeted Medication Review (TMR)¹

- Focused on specific actual or potential MRPs
- Assessments can be person-to-person or system generated
- Follow-up to resolve MRPs or optimize medication use
- Examples include adherence, high risk medications, drug-drug interactions, needs therapy

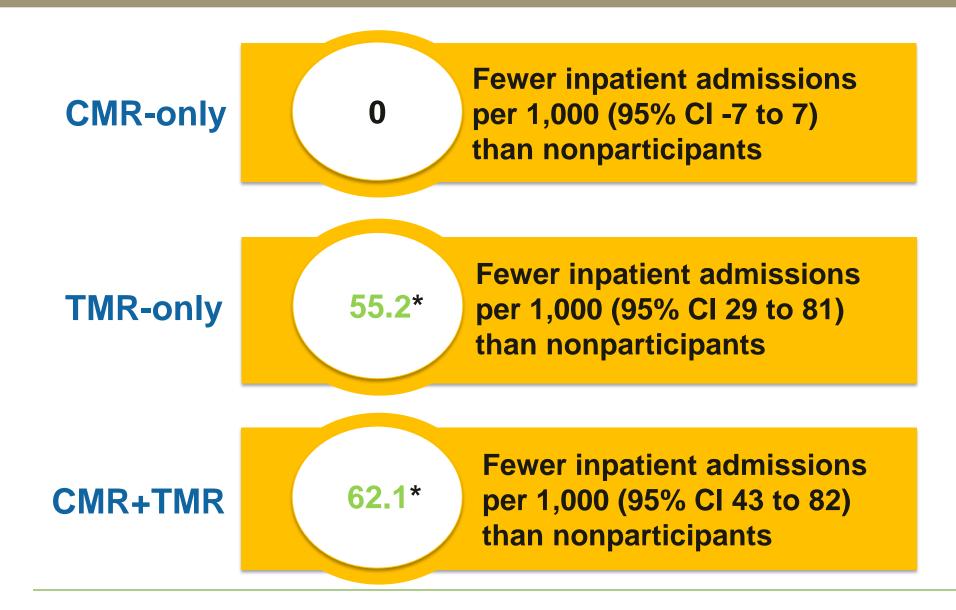
* MTM program **CMR completion rate** is a part D process Star measure²

- 1 Centers for Medicare & Medicaid Services. *CY 2017 Medication Therapy Management Program Guidance and Submission Instructions*. Baltimore, MD; 2016.
- 2 Centers for Medicare & Medicaid Services. 2017 Medicare Part C & D Star Rating Technical notes.

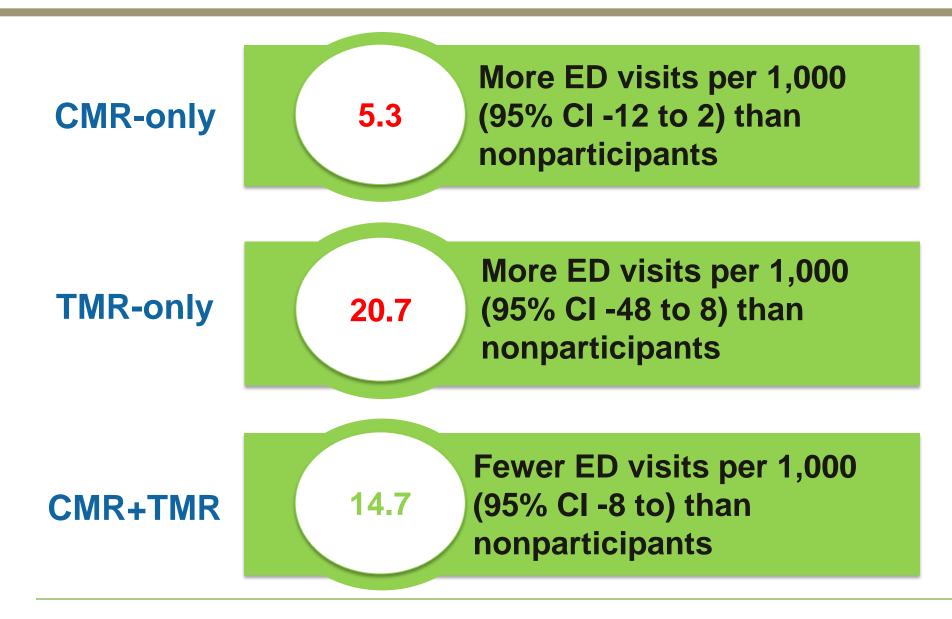
- Objective: Compare patients participating in MTM services (CMR and/or TMR) to eligible, non-participating patients on acute inpatient (IP) admissions and emergency department (ED) visits
- **Design**: Retrospective, cohort analysis comparing patients who received MTM services (participants) to patients eligible for MTM in 2014 (nonparticipants) for the following strata:
 - CMR only
 - TMR only, also matched on TMR problem category
 - CMR+TMR at any time in 2014, also matched on TMR problem category
- 1:1 propensity score matching employed for participants and nonparticipants within each strata
- Outcome: Change in IP admissions per 1,000 and ED visits per 1,000 analyzed from pre to post period for 12 months post MTM service/eligibility
- Data source: Deidentified Humana administrative claims

- Matched pairs (participants and nonparticipants):
 - 64,801 CMR-only
 - 5,692 TMR-only
 - 9,876 CMR+TMR

TMR Problem Category	TMR-Only	CMR+TMR
Adherence	3,474 (61%)	4,984 (50%)
Cost	707 (12%)	1,425 (14%)
Needs Therapy	804 (14%)	1,834 (19%)
High Risk Medications	707 (12%)	1,465 (15%)
Drug-Drug Interaction	0 (0%)	168 (2%)



^{*}Indicates statistical significance



^{*}Indicates statistical significance

- TMR and CMR+TMR MTM services were associated with reductions in inpatient admissions
- CMR services alone did not provide benefit to participants, in terms of IP admissions and ER visits
- Understanding which MTM services will produce positive clinical outcomes among eligible patients is essential to advancing pharmacy provided clinical services

- Refreshed analysis of 2015 MTM data indicates:
 - Consistent reductions in acute admissions and ED visits for TMR-only and CMR+TMR participants
 - No statistically significant reductions in acute admissions or ED visits for CMR-only participants
 - Successful resolution of TMR problems
 - Statistically significant increases in medication adherence rates (PDC) for TMR-only and CMR+TMR participants with a TMR 'adherence problem type'
 - Higher rates of participants discontinuing high risk medications (HRMs), compared to nonparticipants

- Increase prescriber, patient, and caregiver engagement in both CMR and TMR participation
- Optimize medication-related problem (MRP) identification and resolution
 - Determine MRP categories whose resolution have the greatest impact on clinical and economic outcomes
 - Identify at-risk patients
 - Collaborate and follow-up to optimize medication use
- Educate MTM providers, prescribers, patients, caregivers, and payers on the improved clinical benefits as a result of both CMR and TMR MTM services
- Invest resources to drive program optimization

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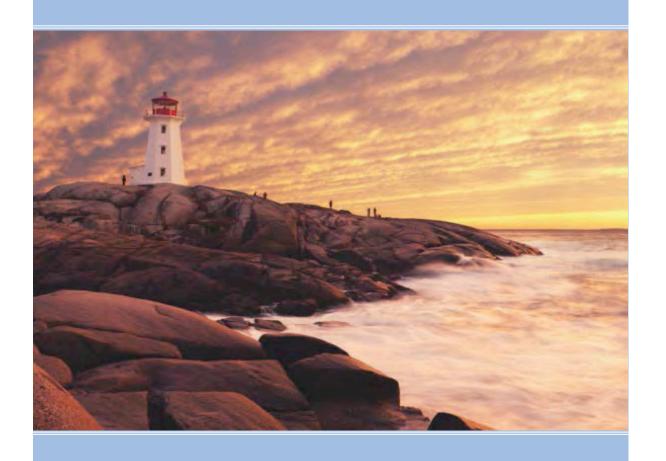
KEYNOTE:

Delivering Value that Matters to Patients

Alan Balch CEO, Patient Advocate Foundation









OUR MISSION

Patient Advocate Foundation is a national 501(c)(3)organization that seeks to safeguard patients ability to access care, maintain employment and preserve their financial stability relative to their diagnosis of chronic, life threatening or debilitating diseases.

Financial Challenges

Self-reported frequency of financial hardship

 Roughly 75 to 90% of PAF patients report experiencing a financial hardship

Impact on medical care?

 For about 25 to 30% of patients, they stop or postpone medical are or do not adhere to prescribed treatment regimens as a result of financial hardship

Impact on Financial Situation

What impact did the financial hardship have on your financial situation?

7 Tode of Tedaded Other Holl Children Household expenses 02/0		I cut or reduced	other non-	-critical house	hold exp	penses 62%
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My utility bills were paid late	40%
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I was unable to afford	groceries	37%
. Was allable to allola	D. 0001100	3. /

I missed rent or mortgage payments 2	25%
--------------------------------------	-----

I missed car payment(s)	13%
-------------------------	-----

▶ I filed or am in the process of filing for bankruptcy 8%

Externalities?

- Need to think about the patient journey and experience outside the four walls of the clinic that is directly impacted by treatment.
- Internalize key variables that impact patient's lives in meaningful ways that are generally considered "indirect" or "outside the scope" of healthcare decision making:
 - Transportation
 - Employment
 - Basic necessities: housing, food, electricity

2016 Top Case Management Issues

Inability to afford transportation expenses	10.0%
Co-pay assistance – pharmaceutical	6.0%
Inability to afford rent/mortgage	5.5%
Co-pay assistance - facility/doctor visits	4.7%
Inability to afford utility/shut off notice	4.1%



Transportation Challenges

- About 20% of PAF patients report round trip to their medical appointments takes between 2 to 4 hours
- About 40% report being usually to always overwhelmed by the time and effort it takes to get to treatment
- Roughly 1/3 report that is somewhat to very difficult to travel to and from appointment, and only 30% of those patients attribute that challenge to distance
- Roughly 40% reported skipping trips to drop off or pick up prescriptions due to transportation challenges

Impact on Employment

Thinking about the last 12 months, has this illness impacted your employment in any of the following ways? Please select all that apply. (n=1,285)

Yes, I lost my job due to this illness	12.30%	
Yes, I lost income due to the inability to work full time	21.25%	
Yes, I was unable to perform at my normal performance levels	25.14%	-62 %
Yes, I was or am unemployed for reasons not related to this illness, and I am finding it difficult to find a job now due to this illness	3.74%	
No, this illness had minimal impact on my job	8.02%	
No, I was already retired or not employed	27.24%	

How to Operationalize the Triple Aim

- How do we build a healthcare system that is capable of that level of precision?
- Does the "system" decide on behalf of patients when the triple aim has been reached through standards of care?
- Does the triple aim mean that the standard of care should be personalization?
- What is the patient's role in helping to determine what is the right care for them at certain points of time?

Two Competing Camps?

Eliminate unnecessary variation in care by creating tools and policies that standardize care and/or minimize opportunities for individual characteristics to influence care decisions.

Transactional cost = utilization review.

Cost containment through efficiency and economies of scale

Allowing for appropriate variation in care by creating tools and policies that facilitate opportunities for individual characteristics to influence care decisions.

Transactional cost = taking time to personalize the care plan.

Cost containment through effectiveness and utility maximization

What do patients want?

(n=1,349 low income cancer patients; 90% in treatment in last 12 months; unpublished PAF survey data)

How important is it to you that your treatment be highly personalized to the unique characteristics of your cancer?

>83% said extremely important

How important is it to you that you receive the standard of treatment for most patients diagnosed with the same or similar cancer as yours?

>57% said extremely important

If you had to choose...?

>96% said highly personalized treatment

2016-2017 Patient Advocate Foundation Quantitative Market Research

Conditions of Interest

Cancer

- Multiple Myeloma (n=162)
- Breast (n=350)
- Other cancers (n=250)
 - Prostate
 - Lung
 - Colorectal
 - Leukemia & Lymphoma

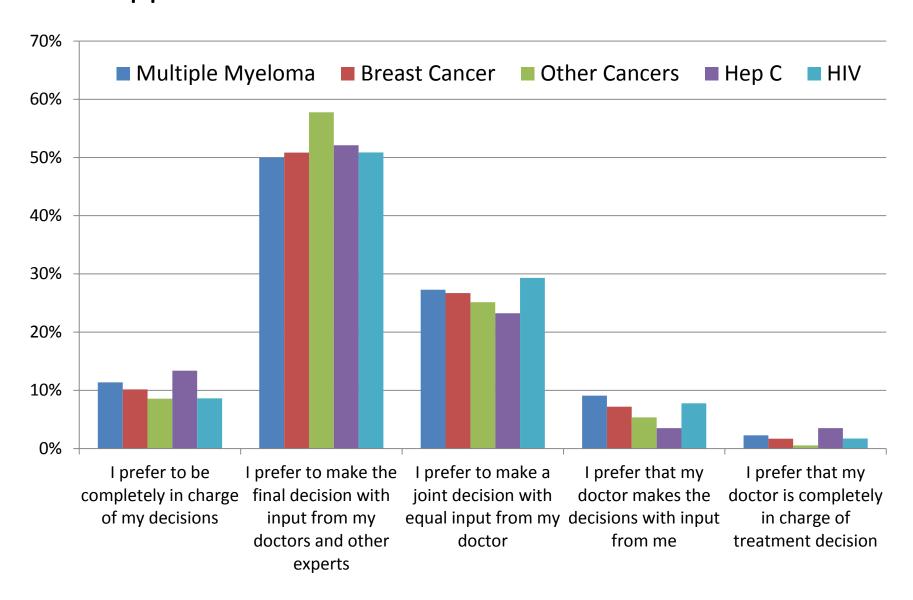
Chronic Conditions

- Inflammatory Arthritis
- Cardiovascular Disease

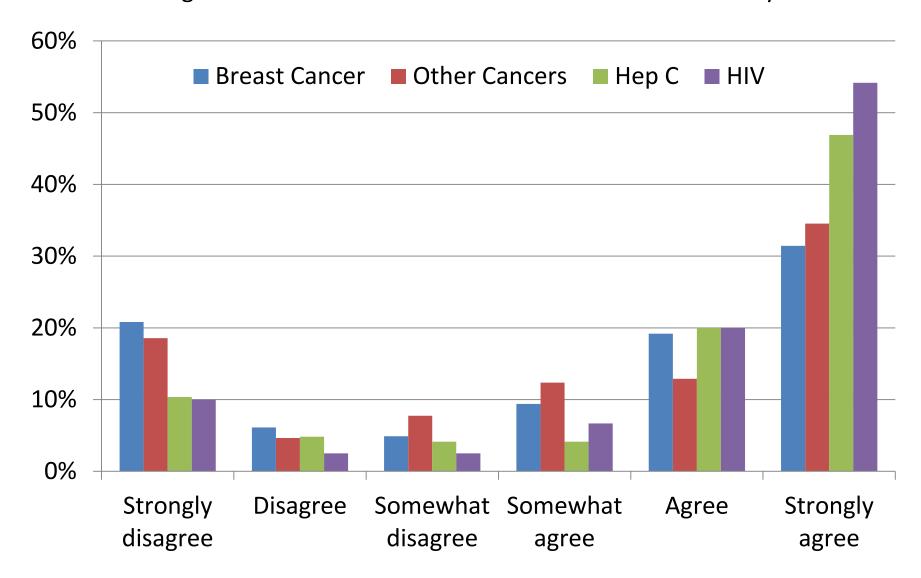
Virology

- Hepatitis C (n=175)
- HIV (n=175)

Which of the following best describes your preferred approach for decisions related to medical care?



To what extent do you agree with the following statement: Knowing the cost I am going to pay out of my own pocket for my care is important when it comes to making decisions about what treatments I should take for my disease.



Multiple Myeloma: Side Effects

- Have you experienced any of the following side effects in the past 12 months and how significant was the impact?
- List of events that were reported by >50% patients on therapy and then lists those SEs that were moderate/severe in impact and ranked from most to least.

ORAL

- 54% Feeling tired all the time
- 39% Forgetfulness
- 37% Difficulty sleeping
- **37%** Pain
- **31%** Sleeping too much

INFUSED

- 40% Feeling tired all the time
- 39% Pain
- 33% Difficulty sleeping
- 33% Forgetfulness

Breast cancer: Oral vs Infused Drug Side Effects

Self-reported as most severe for oral drugs (n=114)

- 34% Bone and/or joint pain
- 29% Fatigue
- 34% Hot flashes

Self-reported as most severe for infused drugs (105):

- 49% Hair loss
- 29% Fatigue

2017 Qualitative Insights into Patient Values

Another Triple Aim?

Three things that came up in every interview

- **Respect**—seeing and treating each person as an individual, not making assumptions or judgments
- **Listening**—having a genuine two-way discussion, not just dictating treatment or "hearing without actually listening."
- The Personal Connection—wanting a relationship, or at least to be acknowledged on a personal level by the doctor or provider



Roadmap to Consumer Clarity in Health Care Decision Making



Support for this project was provided by the Robert Wood Johnson Foundation. The views expressed here do not necessarily reflect the views of the Foundation.

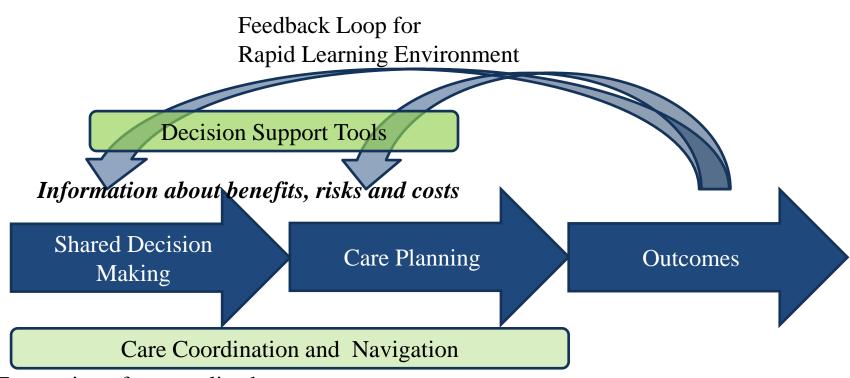


Co-Creation of Care Principles

- What matters most will **vary** from patient to patient and will change over time.
- What matters needs to be **reassessed on a regular** basis.
- Patients and caregivers need **timely, usable information** about the costs, benefits and risks of their care.
- All patients are capable of making shared decisions about their care, regardless of their health and social status, or health literacy.
- All patients expect and deserve respect and benefit from a collaborative, cooperative relationship.

Identifying the Key Activities

- Shared decision making (SDM)
- Decision support tools (DST)
- Care plan
- Care coordination and navigation
- Quality measurement (QM)
- Patient reported outcomes (PROs)



Expression of personalized goals, needs, and preferences and matched against

Treatment options personalized to benefits, risk, and costs

- Adjusted for certain variables that may impact appropriate treatment selection.

Development of a goal concordant care plan that includes identification of social support and care navigation needs

Data collection and sharing to track adherence and progress - Patient Reporting on QoL, Functional status, Health status and safety.

- Care coordination and navigation especially for high cost and high needs patients

Shared Decision Making

- The sources of information shaping the decision should be both the patient and the provider.
- Patients need preparation for how to be part of the decision making process.
- Providers need training about how to do it in a way that patients want.
- Must assess the patient's preferences ahead of clinical visit so the provider knows key information about the patient's attitudes and goals.
- Need a standardized approach for scale and replicability for ongoing SDM.

Care Plan

- The SDM process should create the personalized discussion that automatically leads to a care plan that aligns with patient/family-determined goals
- This includes identification of social support, navigation, and other care needs.
- Patients should be able to track their progress, provide data and feedback related to their care goals, and interact with their care team.

Data and Measurement

- Outcomes should include the health experiences and metrics most relevant to patients.
- Data feedback loops change behavior.
- PROs should allow a patient to report and track their progress, side effects, and other factors critical to patients and share them with their clinicians.
- PRO data can be used to generate aggregate information about benefits, costs, and risks that helps increase clarity to consumer decision making for those upstream (i.e., rapid learning environment for both patients and providers).

Bridge the Gap: Achieve Person-Centered Care

WHAT MATTERS TO THE PATIENT

- Change in functional status or activity level
- Role change
- Symptoms, especially pain
- Stress of illness on family
- Loss of control
- Financial burden
- Concerns about stigma of illness
- Conflict between wanting to know what is going on and fearing bad news

WHAT'S THE MATTER WITH THE PATIENT

Diagnosis and disease-directed treatment PLUS:

- Symptom management and services supporting well-being, functioning, and overall QOL
- Care planning and coordination across multiple specialists, subspecialists and settings

Evaluation of key clinical outcomes

Skilled communication and coordinated team-based services

Value-based quality care

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Just Ask the Patient Sara van Geertruyden Executive Director, Partnership to Improve Patient Care



Inspiring Good Patients and Good Shoppers Paul Hain Regional President, Blue Cross Blue Shield of Texas





Just Ask the Patient Roadmap to Patient Engagement

October 16, 2017
Sara van Geertruyden
Partnership to Improve Patient Care





Introduction

- Sara van Geertruyden
 - Executive Director, Partnership to Improve Patient Care (PIPC)
 - Public Policy, Patton Boggs LLP, 2003-2010
 - Legislative Assistant, Senator John Breaux, 1996-2003

PIPC

- Chaired by Tony Coelho, former Congressman, author of ADA, patient with epilepsy
- Members are organizations representing patients, providers, researchers and industry
- Coalition began to advance legislation creating the Patient-Centered Outcomes Research Institute (PCORI)
- Supports policies toward a patient-centered health system





Evolution of "Patient-Centered"

- Don Berwick, 2009: "leaving choice ultimately up to the patient and family means that evidence-based medicine may sometimes take a back seat."
- Triple Aim includes patient experience
- PCORI created in 2010 to change the culture of research to better respond to patient needs, outcomes, and preferences.
- FDA focus on patient experience, PFDD
- Development and use of patient-reported outcome measures





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Key Considerations

- The range of endpoints, care outcomes and treatment goals that matter to patients;
- Factors that influence differences in value to patients within populations;
- Differences in perspectives and priorities between patients, caregivers, people with disabilities, consumers and beneficiaries;
- How patients want to be engaged in their health care and treatment decisions, and characteristics of meaningful shared decision-making to support this.





Key Challenge for Achieving Patient-Centeredness

Quality-Adjusted-Life Years





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How are QALYs Developed?

- Traditionally, survey instruments are designed to assess how much patients value different health conditions or "states."
 - Often population-based surveys to assess how persons would value their lives in a particular state of health or what they are willing to trade to treat a hypothetical health condition or symptom.
- It is methodologically difficult to measure patient preferences
 - There are a multitude of survey instruments and methods to measure QALYs.
 - Research has shown various surveys and methodologies yield wildly different results.
 - Surveys to construct a single, average measure of patient preference does not reflect the wide heterogeneity of patient preferences.

Calculating the QALY: 45 Year Old Patient with Tuberculosis (TB)

Value of perfect health	1.0
Value of health while	0.726
suffering from TB	
Duration of health condition	6 months
QALY	0.36

QALYs are calculated as a combination of the value of a particular health status as measured by surveys, duration of condition, and discount rate (Sassi, 2006).





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Challenges Posed by QALYs

Ethical Implications

- Value "perfect health" over pre-defined "less than perfect" states of health.
- Potential for discrimination against people with serious conditions and disabilities.
- At odds with the movement toward personalized medicine and patient-centered outcomes.

Current Use

- Health technology assessment (HTA) organizations use QALYs to assess "value" of interventions.
 - Egs. Cost effectiveness analyses used in some state Medicaid programs
- The Institute for Clinical Economic Review's (ICER) Value Assessment Framework and the Second National Panel on Cost-Effectiveness endorse the use of QALYs in valuing healthcare interventions.
 - Provides a reference to insurers, the Veterans Administration, and other payers for coverage decisions that impact clinical decision-making.

Public Policy Response

- In 1992, HHS rejected Oregon's prioritized list for Medicaid citing the potential for violating the ADA due to use of QALYs.
- ACA explicitly prohibits PCORI from using the cost-per-QALY to determine effectiveness, and further restricts use in Medicare to determine coverage, reimbursement, or incentive programs.
- In 2016, CMS proposed using QALYs to make value judgements as part of the Medicare Part B Drug Payment proposal, opposed by stakeholders and rescinded.





Culture of Patient-Centeredness

- Formalize pathways to provide a meaningful voice to patients in the creation and testing of alternative payment models (APMs);
- Ensure value and quality definitions driven by value to patients;
 - Egs. Patient-reported outcomes measures
- Foster informed choices from the range of clinical care options
 - Shared decision-making
 - Accessible, understandable evidence to achieve personal treatment goals.
- Avoid a singular focus on cost-containment and protect against a "one-size-fits-all" approach to patient care.
 - Patient-centered care avoids costly readmissions, non-adherence, etc.
- Support access to new medical advances.





How Do We Get There?

- CMMI issued a Request for Information on a "New Direction" for Developing APMs
 - Comments Due November 20!
- Health Care Payment and Learning Action Network (LAN)
 - Push APM Measures that Reflect Outcomes that Matter to Patients
- Oppose Use of QALYs to determine access and coverage
 - No patient is average
- CMS Quality Payment Program and enhanced use of PROMs
- Support Patient-Centered Outcomes Research





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Patient Perspectives Panel Q&A

Alan Balch CEO, Patient Advocate Foundation



Sara van Geertruyden Executive Director, Partnership to Improve Patient Care



Paul Hain Regional President, Blue Cross Blue Shield of Texas





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Provider Perspectives on Consumer Priorities in Value-Based Care

Assessing Value: One Size Does Not Fit All **Bobby Dubois** Chief Science Officer and Executive Vice President, National Pharmaceutical Council



Finding, Counting and Proving Value Van Crocker President, Healthagen Outcomes, Aetna





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Assessing Value: One Size Does Not Fit All

Robert Dubois

Chief Science Officer and EVP, National Pharmaceutical Council





Value Assessment Debate: Pluralistic approach: one size can't fit all

October 16, 2017



There Are Many Value Frameworks

















Only One Has Gained Much Traction

















This Is Problematic: The market requires varied approaches to value assessment*

Stakeholder priorities for factors that contribute to value vary across:

- Health condition
- 2. Subgroups within a patient population
- 3. Stakeholder groups



*Guiding Practices for Patient-Centered Value Assessment-National Pharmaceutical Council's



Many Factors Influence Value

- 1. Survival life extension
- 2. Quality of life improved functioning
- 3. Adverse events change in number of side effects
- **4. Treatment requirements** mode and frequency of administration of treatment
- 5. Patient out-of-pocket costs
- 6. Total payer costs
- 7. Availability of test to determine if drug will work



Conclusion

Stakeholder priorities for factors that contribute to value vary across:

- 1. Health condition
 - Among patients
- 2. Stakeholder groups
 - Patients vs. physicians
 - Patients vs. payers

Value assessment needs to be tailored.



Value assessment needs to be tailored: ...message varies by stakeholder

Payers:

- Different value frameworks consider different factors (in different ways); it is important to consider the range of different values that exist for a treatment choice (i.e., sensitivity analysis)
- Patient preferences vary; important to understand how this variation impacts the value of a treatment choice (and corresponding access to coverage).
- consider multiple frameworks or ones that enable preferences to vary
- Out-of-pocket costs are a key element to patients



Value assessment needs to be tailored: ...message varies by stakeholder

Providers:

- what you value may differ from what your patients value
- Patients have different preferences and will assess value differently
- Important to elicit preferences (e.g., survival, function, impact of out-of-pocket costs)

Industry: collect preference information and show how and when it differs



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Finding, Counting, and Proving Value – Reducing Uncertainty in VBC **Conversations**

Van Crocker

President, Healthagen Outcomes, Aetna





Finding, Counting, and Proving Value – Reducing Uncertainty in VBC Conversations







First, a Note on Healthagen Outcomes

> We are a division of Aetna BUT...

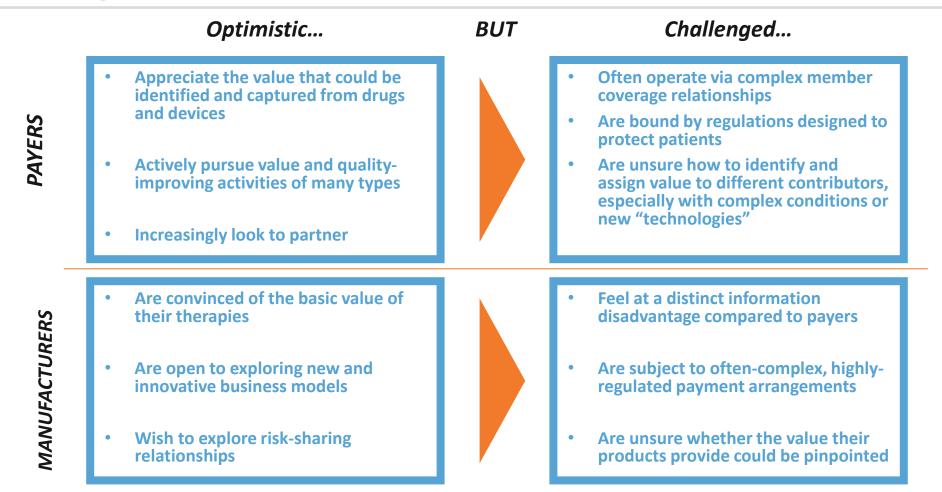
We do not set medical or pharmacy POLICY

We do not negotiate medical device or pharmacy CONTRACTS

> We provide Analytical and Clinical Development Services to Manufacturers in Healthcare



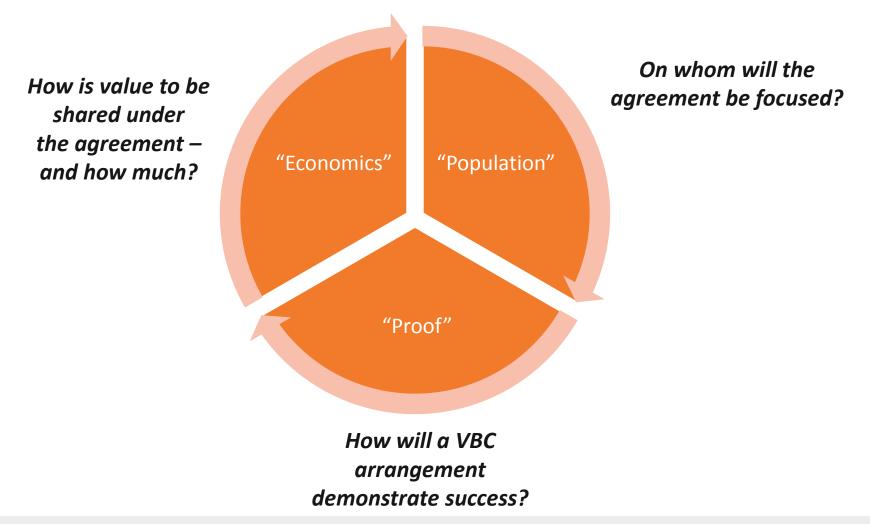
Similar Perspectives and Challenges are Faced by Payers and Manufacturers



THE RESULT: Payers and Manufacturers are agreeable <u>in concept</u> about pursuing value-based arrangements, but tentative and even isolated <u>in practice</u>

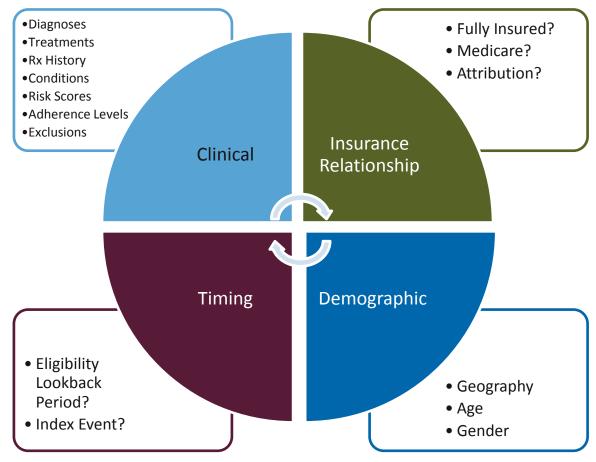


To Address These Challenges, Open Questions About Value-Based Arrangements Must be Systematized





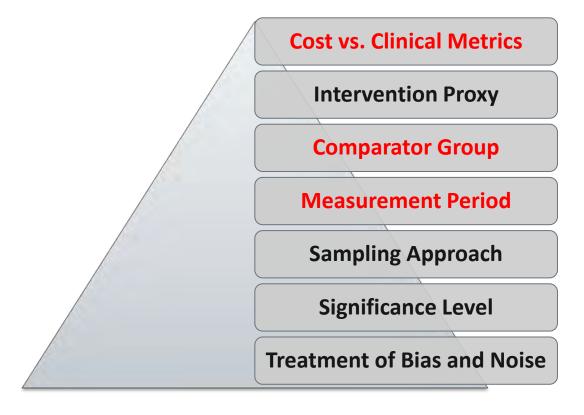
<u>Q1: Population</u> – On Whom Will the Arrangement Focus? – Illustrative Parameters and Examples



The Good News: "Retrospective Analysis" is a Well-Known
Tool for Evaluating Populations



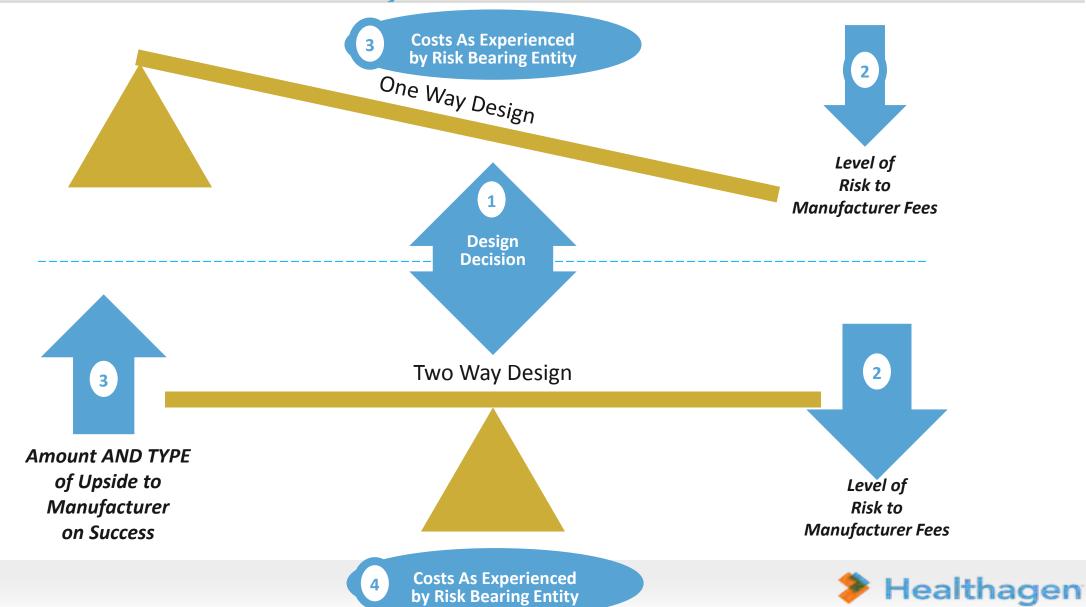
Q2: Proof – How Will Success be Measured? – Illustrative Parameters



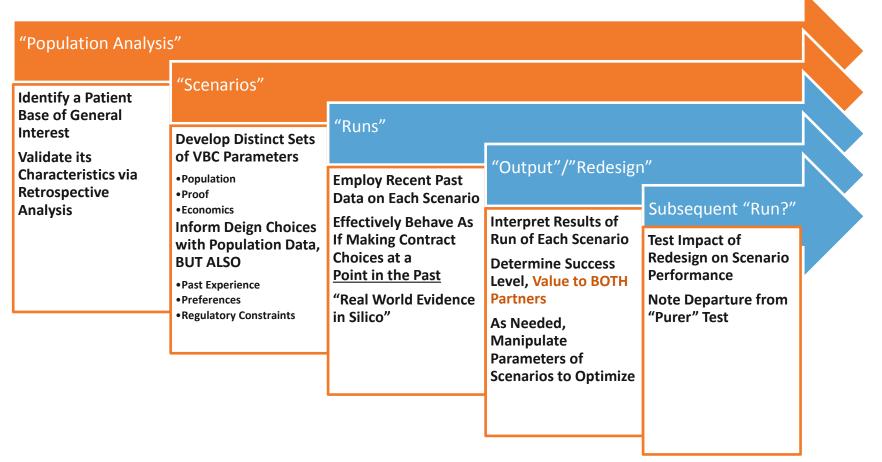
Statistical and Technical Considerations Often Have a Huge Impact on Arrangement Designs



Q3: Economics – How Will Value be Shared by the Manufacturer and Payer?



A Systematic Approach: The "Value Prototyping" Process



The Objective: "Pretend" that you are entering into a VBC in the PAST, and see how you did...



Evaluation of Each Candidate Value-Based Arrangement Design or "Scenario"

- 1. Was "Proof" Achieved?
- 2. Did "Proof" Indicate "Success," and if so, HOW MUCH?
- 3. Does Achieved Result Improve Economics for Manufacturer?
- 4. Does Achieved Result ALSO Benefit Risk Bearing Entity?
- 5. Other Considerations (e.g., Regulatory)



Conclusion: Prototyping Can Be a Valuable Contribution to "Closing the Value Uncertainty Gap"

- Many arrangements are never entered into, or never even PROPOSED because Payer or Manufacturer are uncertain about:
 - The VALUE in question
 - The amount of RISK being taken
- Value Prototyping can reduce the uncertainty of potential arrangements without actually WAITING or CONTRACTING

Although de-identification and other analytical constraints may limit Prototyping scope, great clarity can still be added to many Payer/Manufacturer conversations



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Payer Perspectives on Value Transparency in Health Care: A Roadmap for Consumer Engagement
Caroline Steinberg

Vice President of Programs, Network for Excellence in Health Innovation

An Employer's Balance in Managing
Clinical Decisions
Kembre Roberts
Manager for Employee Wellness, Southwest
Airlines





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Transparency in Health Care: A Road Map for Consumer Engagement

Caroline Steinberg

Vice President of Programs, Network for Excellence in Health Innovation (NEHI)





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Transparency in Healthcare:

A Priority Roadmap for Consumer Engagement





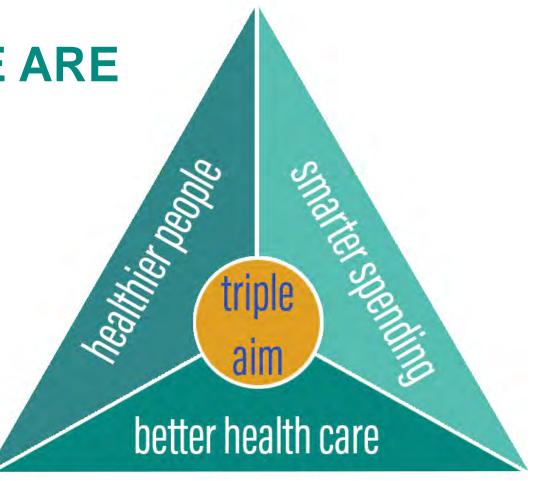


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NEHI: WHO WE ARE

- A national nonprofit, nonpartisan organization
- Composed of stakeholders from across all key sectors of health and health care
- We advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent







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Focus:

Choosing a Health Plan

Choosing a Provider

Choosing a Treatment Option







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Key Questions

- What are the most critical information needs of consumers?
- How well are current tools and resources meeting these needs?
- What can policy-makers and other stakeholders do that would result in meaningful improvements to transparency initiatives to better support consumer decision-making?





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Consumer Information Needs

Choosing a Plan	Choosing a Provider	Making a Treatment Decision
Estimated total annual costs	Expected episode cost reflecting plan negotiated rates and cost sharing	Range of medically viable options
Network composition	Summary quality rating:	Potential risks and benefits
Network depth	 Patient safety 	Process for ensuring coverage
Drug formularies	Patient experience	Comparative out-of-pocket costs
Consumer experience ratings	 Outcomes 	Potential burden on patient and family members
	 Adherence to evidence- based practices 	





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Top Five Messages: #1

Consumers face many knowledge gaps as they try to navigate the health care system. Arguably the most critical is a lack of understanding that they have choices, and that these choices can make a significant difference in terms of cost, quality, and outcomes.

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Top Five Messages: #2

Very few consumers are using even the good tools that are available.





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Top Five Messages: #3

Health care decisions that are based on inaccurate or incomplete data can be hazardous for patients.







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Top Five Messages: #4

One of the most trusted sources of information is the consumer's physician or other caregiver, but these individuals are not currently trained, rewarded, or equipped with the necessary information to help their patients.

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To be attractive and useful to consumers, tools must be actively promoted at the time of decision-making, and information should be accurate, specific, and personalized to the individual's preferences, characteristics, and treatment goals.







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An Employer's Balance in Managing Clinical Decisions

Kembre Roberts

Manager for Employee Wellness, Southwest Airlines





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Consensus Priorities
Cliff Goodman
Symposium Moderator and Speakers





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