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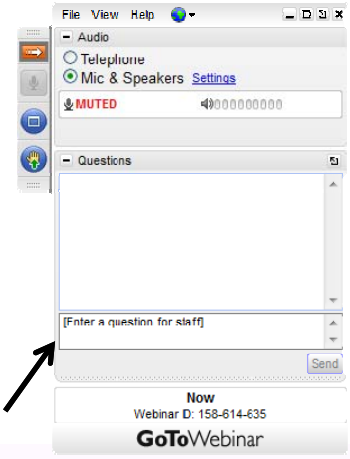
VALUE-BASED HEALTH CARE
Identifying Benefits for Patients, Providers & Payers

How to Ask A Question



Type your question in the 'Questions' area

VALUE-BASED HEALTH CARE
Identifying Benefits for Patients, Providers & Payers

7th Annual Research Symposium

- October 16, 2017
- Preconference to AMCP Nexus
- Dallas, TX

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Download Research Symposium Report

- www.amcp.org/amcp-foundation/resources/proceedings/
- Executive Summary distributed with Jan. 2018 *Journal of Managed Care & Specialty Pharmacy*

VALUE-BASED HEALTH CARE
Identifying Benefits for Patients, Providers & Payers

Speakers

- John J. Doyle, Dr.P.H., SVP & Managing Director, IQVIA (Moderator)
- Ruth Daniel, Senior Analyst, Southwest Airlines
- Clifford Goodman, PhD, Senior Vice President, The Lewin Group
- Alan Balch, PhD, CEO, Patient Advocate Foundation

VALUE-BASED HEALTH CARE
Identifying Benefits for Patients, Providers & Payers

Overview

Realizing Value-based Healthcare Leveraging *RWE to Align Stakeholders*

John J. Doyle, Dr.P.H.
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Identifying Benefits for Patients, Providers & Payers

Real world insights are fueling the health care system transformation from volume, to value, to outcomes

Patient
- Need to maintain health
- Benefit/risk tradeoffs
- Affordability of care

Rx & Dx Manufacturer
- Incentives to develop evidence
- Reimbursement commensurate with value
- Reward for innovation

Laboratory
- Better, faster, cheaper
- Staff resource requirements and turn around
- Managing with a budget

Policymaker
- Balance of quality and cost
- Societal considerations
- Health system statutes and guidelines

Payer & HTA
- Balance of quality and cost
- Evidence-based care
- Provision of appropriate care to appropriate populations
- Balancing care across the population

Provider & Hospital
- Provision of appropriate care
- Provision of reimbursed services
- Financial efficiency & viability
- Managing with a budget

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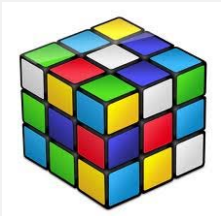
How do we solve for multiple health care stakeholder needs simultaneously when generating evidence?

Current



One-dimensional, people-driven, supply-side organized

Future

Multi-dimensional, data-driven, demand-side organized

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New approaches are needed to align stakeholders

Traditional approach	New approach
Assumptions and Models	Evidence Based
Variable, Reactive	Predictable, Proactive
Siloed	Integrated
Risk Avoidance	Risk (& Benefit) Sharing

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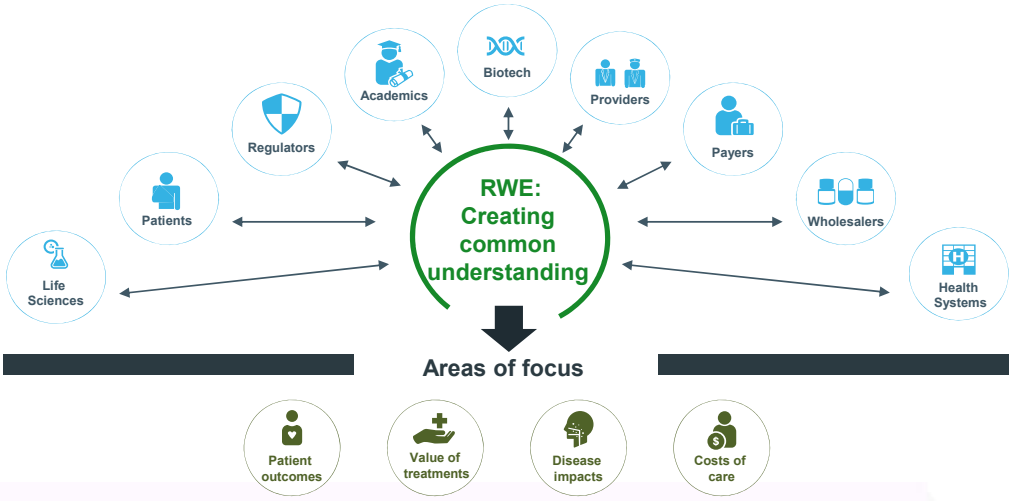
RWE as needed connective thread



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Employer/Payer Perspective

Ruth Daniel
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Southwest Airlines
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Challenges

- Soaring drug costs
- Limited visibility into medical plan drug spend
- Limited resources and expertise
- Preserve member experience

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Solutions

Utilization Management
Prior Authorization, Step Therapy, Quantity Limits

Exclusive Specialty Pharmacy
Maximize unit cost discounts

Specialty Drug Management Tools

Preferred Therapies
Maximize Manufacturer Rebates

Site of Care
Drug administration through most cost-effective channel

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Solution: Pharmacy

Oncology Split-Fill Program

Overview

- Includes 19 oral oncology drugs
- First fill limited to 2-week supply
- Patient charged 50% copay
- Care team pharmacist or nurse contacts patient assesses side effects & tolerance

Advantages

- Offers additional patient contact, care management
  - Assesses patients for side effects/adverse events
  - Assists patients with difficult to tolerate drugs
- Minimizes financial risk to patient (50% copay) and Southwest (50% plan paid) as a result of early discontinuation for difficult to tolerate drugs

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Solution: Medical

Injectable Outpatient Chemotherapy Prior Authorization Program

Overview

- Prior Authorization using eviCORE Healthcare, online authorization tool
- Offers all available cancer treatment regimens
- Uses National Comprehensive Cancer Network (NCCN) guidelines
  - Assesses treatment regimen including combination of chemotherapy drugs & sequencing appropriate for diagnosis

Advantages

- Ensures patients receive most appropriate treatment regimen upfront
- Requests which meet NCCN guidelines granted immediate approval
  - All other requests competed within 3 business days
- All requests reviewed by medical oncologists
- Timely peer to peer reviews with medical oncologists for exceptions
- Immediate coverage answers
- Evidence-based alternative treatments recommended immediately

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Solution: Medical

Site of Care (SOC) Redirection

Overview

- Specialty drugs administered in outpatient hospital incur costs 3-4 times higher than when administered in physician office or through home infusion
- Adult patient getting Remicade at a children's hospital paying 559% ASP
- Claims paying at $28,000 vs. $5,500, total plan paid $266,960
- Medical Vendor has programs in place to redirect patients on Remicade & similar drugs to more cost-effective sites
- Implementing 1/2018

Advantages

- Ensures specialty drugs billed through medical benefit are administered at most cost-effective sites
  - Criteria applied through prior authorization process for select specialty drugs

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Solution: Consultants

DATA	COLLABORATION	EXECUTION
• Artemetrx Specialty Diagnostic provides integrated, detailed view across pharmacy and medical claims to identify trends, cost drivers, outlier claims and savings opportunities	• Partner with broker and vendors to explore available programs and develop strategies to improve outcomes and achieve savings	• Work together to implement solutions

Summary

- Specialty drug management is key to achieving optimal drug therapy benefits while containing costs.
  - Use evidence-based protocols to ensure member access to the most appropriate treatments
  - Use criteria to identify the appropriate patients for drug therapies and not create barriers to care
  - Use processes to direct physician-administered drugs to the most cost-effective site of care
- Southwest has engaged partners to
  - Ensure appropriate use of specialty drugs
  - Preserve the member experience
  - Minimize financial risk to members and Southwest.

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Health Plan/Provider Perspectives

Clifford Goodman, PhD
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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," "indication-based pricing," etc.)

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A Value-Based Payment Mechanism of Particular Interest: Value-Based Contracting (VBC) …

- What are the main challenges/barriers/hurdles of VBC?
- What do these stakeholders seek in VBC?

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Policy & Regulatory Hurdles to VBC

- Medicaid Best Price rule
- Medicare Part B Average Sales Price (ASP)
- FDA restrictions on communications from manufacturers to health plans, payers, others (e.g., timing of communications, discussion of off-label uses)
- Federal Anti-Kickback Statute (AKS) and Stark Law
- 340B Program ceiling prices

Proposed fixes/work-arounds for these hurdles include various waivers, safe harbors, pilot/demo programs, legislative proposals

Note: Pharma/bio manufacturers tend to express more concern about these hurdles than do health plans/payers/providers

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FDA Restrictions on Communications from Manufacturers to Health Plans, Payers (1)

- Limit manufacturers' sharing of information/promotion about investigational (pre-approval) therapies
  - Health plans would prefer to have such information in time to influence premium setting and related benefit offerings a year or more prior to drug launch
- Limit discussion/information exchange regarding health care economic information and off-label use of approved drugs
- Limit options for certain outcomes (i.e., outcomes not included in label) to be incorporated into VBC
  - Even so, health plans can decide to cover specific off-label uses
- As noted above, pharma/bio manufacturers are especially mindful about adhering to these restrictions to avoid legal challenges

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FDA Restrictions on Communications from Manufacturers to Health Plans Payers (2)

- Existing and pending legislation provides some leeway:
  - FDAMA 114 (Section 114 of the Food and Drug Administration Modernization Act)
  - 21st Century Cures Act (Section 3037)
  - Medical Product Communications Act of 2017 (introduced March 2017, under committee review)
  - Pharmaceutical Information Exchange (PIE) Act (HR 2026; supported by AMCP, in House Energy & Commerce Committee)
- Guidance helped promote some additional sharing potential, but many companies still reviewing passage of legislation that could help.

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Operational Challenges to VBC

Health plans, payers, providers tend to be more concerned about operational challenges

- Selection of outcomes that are feasible to assess
- Data collection and analysis burden, especially for:
  - data beyond what is routinely collected
  - multiple simultaneous VBCs
- Data infrastructure of sufficient capacity/efficiency/timeliness; medical vs. pharmacy benefit data silos
- Implementation costs (with expectation of worthy ROI)
- Insufficient staff capacity/expertise to manage VBCs
- Limitations/concerns about access to personal health information
- Time horizon mismatches (e.g., contract period vs. clinical episode; beneficiary churn)
- Portfolio (multiple therapy) deals that may “shut out” certain individual therapies

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Health Plans, Providers, Payers Seek …

- Ability to demonstrate/promote that they seek value for beneficiaries
- Legitimate/clinically meaningful outcomes
- Outcomes for which data are feasible to collect, esp. from routine sources
- Waivers, safe harbors, guidance, pilots/demos, revised regs to enable various VBC approaches
- More case examples/evidence in the public domain about VBC successes
- More wrap-around services, other support (e.g., to improve compliance) from manufacturers to support/enable VBC
- Feasible and sufficient ROI expectations (e.g., supported by pilot/test of VBC)
- Continued innovation in value-based models

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Delivering Value that Matters to Patients

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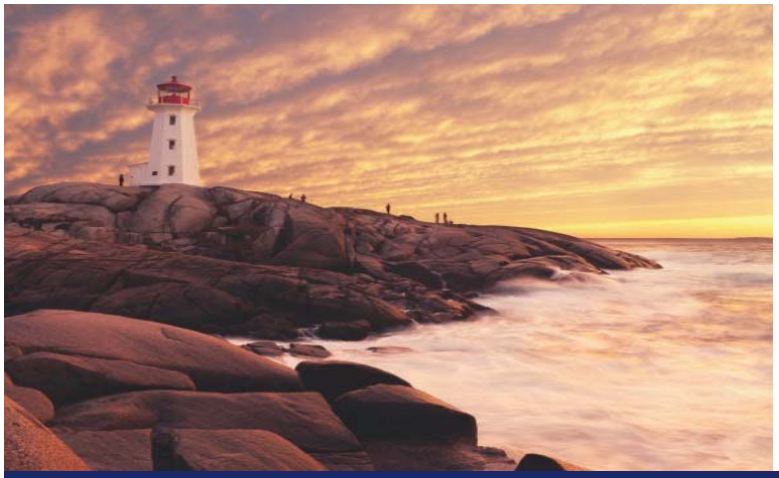

OUR MISSION

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.

PAF Patient Advocate Foundation | patientadvocate.org |

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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

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2016-2017
Patient Advocate Foundation
Quantitative Market Research

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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)

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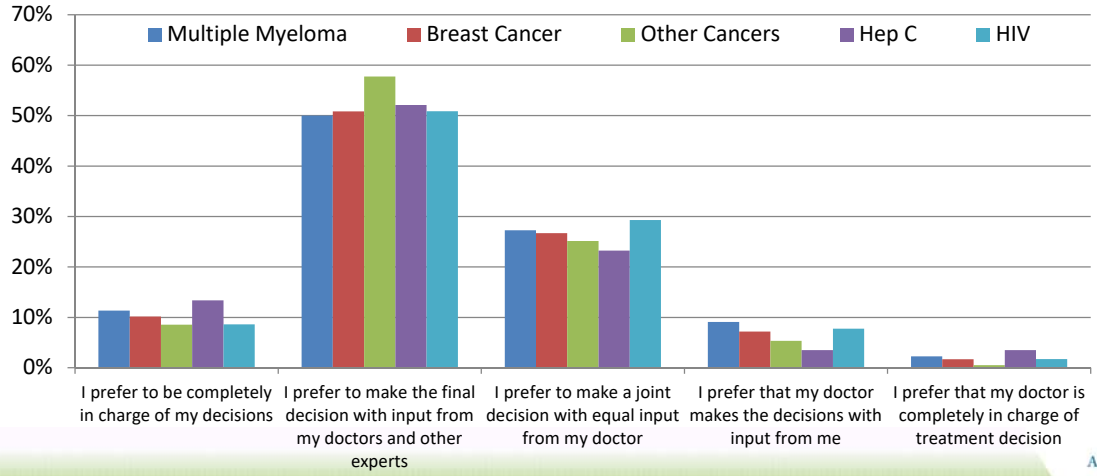
Which of the following best describes your preferred approach for decisions related to medical care?



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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?

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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

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Roadmap to Consumer Clarity in Health Care Decision Making

Robert Wood Johnson Foundation

PAF Patient Advocate Foundation
Solving Insurance and Healthcare Access Problems | since 1996

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.

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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.

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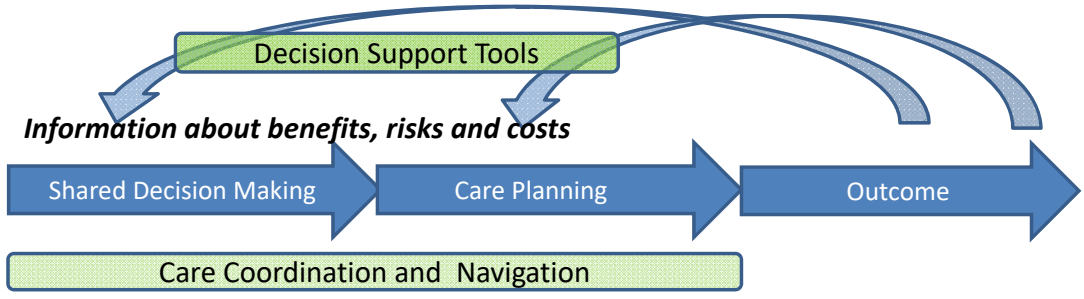
Feedback Loop for Rapid Learning Environment



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

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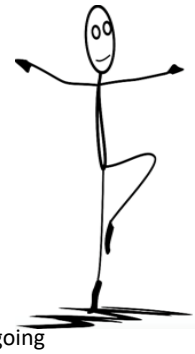
Bridge the Gap: Achieve Person-Centered Care

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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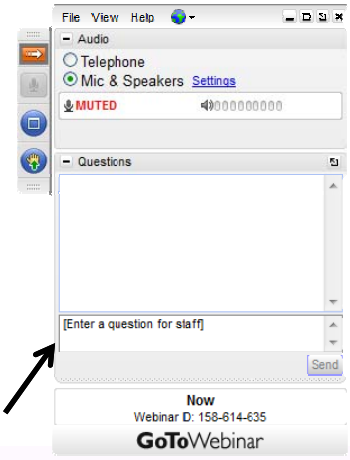
How to Ask A Question



Type your question in the 'Questions' area

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Thank You!

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