HCCA Virtual Research Compliance Conference 2020

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Session R17, June 2nd 1:15 – 2:15 CDT

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Protecting Research Participants Financially: Making SENSE of Patient-CENTric Research When Patients Lack CENTS

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Today's Presentation:

Session Itinerary:

- Benefits of Clinical Trials Research & Challenge of Enrollments
- Insurance Coverage and Identification of "Routine Costs"
- Research Financial Hardship Program

Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials

Sumit R. Majumdar, MD, MPH; Matthew T. Roe, MD, MHS; Eric D. Peterson, MD, MPH; Anita Y. Chen, MS; W. Brian Gibler, MD; Paul W. Armstrong, MD

Background: Barriers to institutions participating in clinical trials include concerns about harms and costs. However, we hypothesized that patients treated at hospitals participating in trials would have better outcomes than patients treated at nonparticipating hospitals. We tested this hypothesis in 494 CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the American College of Cardiology/American Heart Association Guidelines) hospitals treating 174 062 patients with non–ST-segment elevation acute coronary syndrome.

Methods: Hospitals were classified into tertiles by percentage of patients concurrently enrolled in non–ST-segment elevation acute coronary syndrome trials. Outcomes were use of composite guideline-indicated care and in-hospital mortality. Multivariate regression was used to examine the association between hospital trial participation and outcomes.

Results: Overall, 4590 patients (2.6%) were enrolled in trials, ranging from 0% (145 hospitals) to low-enrollment tertile (1.0%; interquartile range [IQR], 0.5%-

increased with increasing tertiles of trial participation: 76.9% (IQR, 71.8%-81.3%) vs 78.3% (IQR, 73.2%-82.4%) vs 81.1% (IQR, 76.2%-84.1%) (adjusted $P = .008$). Hospitals that participated in trials had higher adjusted guideline adherence than nonparticipating hospitals (low enrollment, 0.8% greater [95% confidence interval [CI], −0.9% to 2.6%]; and high enrollment, 2.5% greater [95% CI, 0.5%-4.5%]). In-hospital mortality decreased with increasing trial participation: 5.9% vs 4.4% vs 3.5% (adjusted $P = .003$). Patients treated at hospitals that participated in trials had significantly lower mortality than patients treated at nonparticipating hospitals (low enrollment adjusted odds, 0.9 [95% CI, 0.8-1.0]; and high enrollment adjusted odds, 0.8 [95% CI, 0.7-0.9]).

Conclusions: The CRUSADE hospitals enrolled less than 3% of their patients with non–ST-segment elevation acute coronary syndrome into trials, and one-third never participated in trials. Compared with hospitals that do not participate in trials, those hospitals that do participate in trials seem to provide better care and to have lower mortality.

JAMA Internal Medicine, 2008; 168(6):657-662

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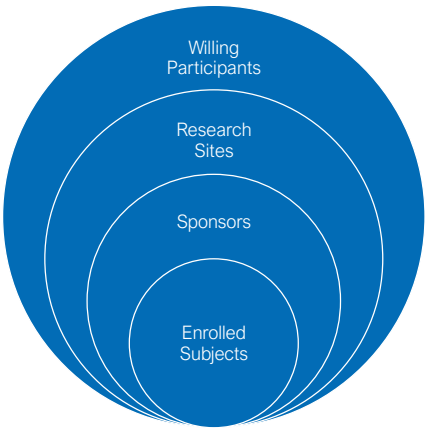
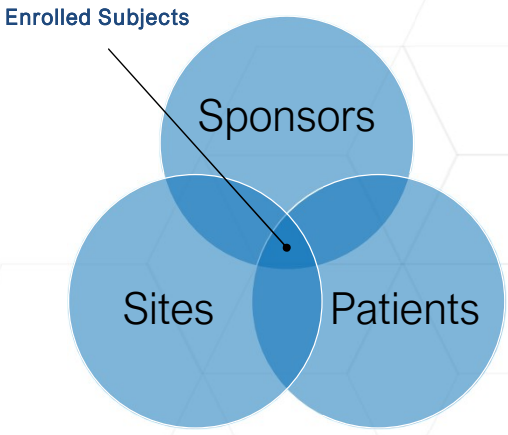
Research Utopia vs. Research Reality





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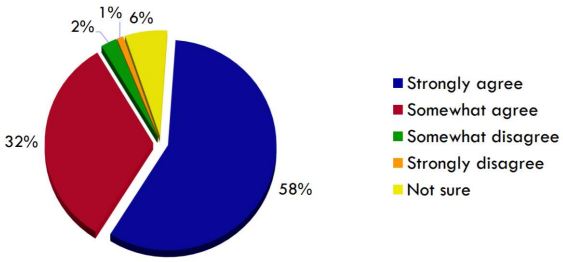
Why Do Patients Participate in Clinical Trials Research?

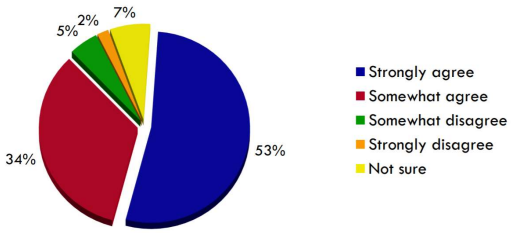
- Advance the science of medicine. (Zogby Analytics 2017)
- Improve nation's health. (Zogby Analytics 2017)
- Advanced treatment options closer to home.

(Alliance for Aging Research Team 2017)

Do you agree or disagree that clinical trials are important to advancing science?



Do you agree or disagree that clinical trials are important to improving our nation's health?



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So Participants are Lining up to Enroll in Research?

- Ummm….not exactly.
- 11% of research sites conducting a study fail to enroll a single participant.
- 9 out of 10 trials require original enrollment timeline to be **doubled** to meet accrual goal.
- US pharma companies' clinical trials account for $7B of their budget per year.
  - ~40% of research budget is patient recruitment costs: $1.89B per year
- Only ~6% of patients with a chronic illness will ever participate in a clinical trial.

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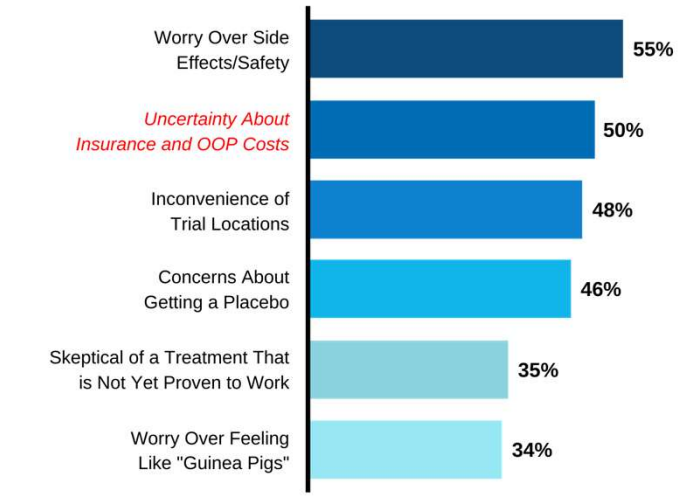
Barriers to Clinical Trial Participation Among Americans

Percentage of Respondents Citing Barrier

n=1,511



Source: "Why Don't Patients Enroll in Clinical Trials?", Advisory.com, Ashley Riley, 10/17/16

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Clinical Trials Research Coverage by Insurance Type

- Medicare (Traditional): NCD 310.1 and Chapter 14 of Medicare Benefit Policy Manual allows for charges associated with routine care, administration of investigational drug/device, and diagnosis/monitoring/treatment of complications to be billed as "routine costs"
- Medicare Advantage: Routine costs for drug studies billed to traditional Medicare; investigational device trial charges billed to – and covered by – Medicare Advantage plans.
- Commercial Insurance: Carriers have varying policies on participation in clinical trials research for fully insured population.
  - Affordable Care Act requires coverage of routine costs of care when participating in clinical trials "…with respect to cancer, or other life-threatening disease or condition."
  - Self-insured employers – typically, larger entities with > 100 employees – are not subject to state mandates, including those that might be more prescriptive than the ACA.
- Medicaid: Varies by State

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Patient Out of Pocket ("OOP") Considerations

1. Deductible
   Amount of money a patient will pay BEFORE insurance coverage kicks in.
   **HDHP plans now cover approximately 1/3 of workers with employer sponsored health insurance.*
   ***Medicare annual deductible (2019):*
   Part A = $1,364
   Part B = $135.50
2. Co-payment
   A set rate paid for a service each time it is consumed.
   *ex: $25 for each physician visit
3. Co-Insurance
   Co-insurance is the % of charge a patient will pay **after** the deductible has been met.
   *Commercial varies by plan design
   **Medicare Part D "donut hole" = 25% once drug costs reach $4,020 until $6,350
4. Lifetime Maximum Benefit
   ACA legislation has eliminated lifetime maximum benefit for **essential services** (emergency care, hospitalization, etc.), however non-essential services can cease to be covered once the limit is reached.
   *Cancer care and associated imaging can have large impact on reaching the max.

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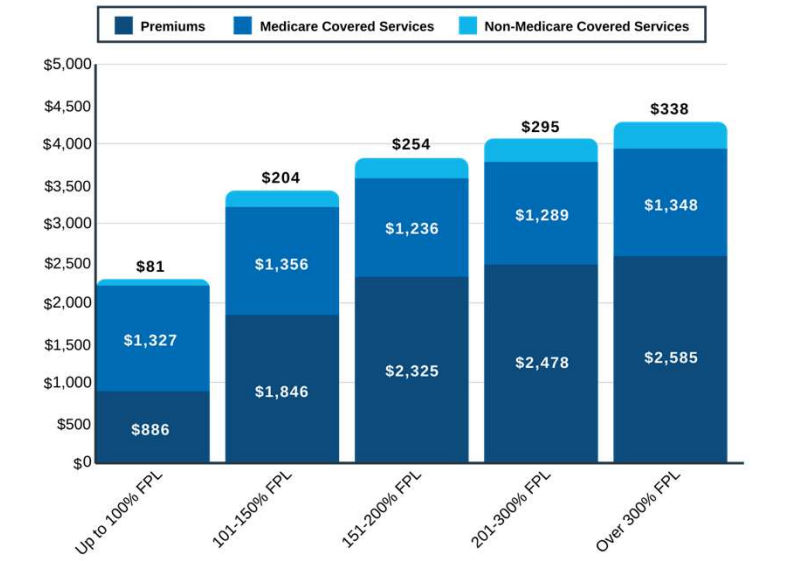
Out-of-Pocket Spending on Services and on Premiums by Income Level



Source: Medicare Beneficiaries' Out-of-Pocket Spending for Health Care, Claire Noel-Miller, AARP Public Policy Institute, December 2013, Issue 88

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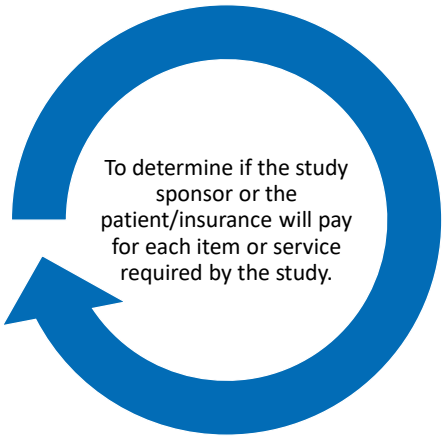
Medicare Coverage Analysis: Identification of Routine Costs

- Review Medicare coverage rules/regulations
  - Clinical Trial Policy (NCD 310.1)
  - Medicare Benefit Policy Manual
  - National and Local Coverage Determinations
- National Guidelines related to the disease and/or intervention
- Therapy risks/side effects and monitoring of these risks/side effects
- Review items that the sponsor is paying for in the budget



- Each item should have one payer – **EITHER** the patient or the sponsor
- Major compliance problem = <u>double billing</u>

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Where is all this going?

<u>Quick Recap</u>:

✓ Benefit to science of medicine – and patients – from clinical trials research.

✓ Significant concern from would-be participants regarding coverage and costs.

✓ Research entity with an adequate research billing compliance program will be able to identify services identified as "routine costs" which will be billed to insurance

? What if potential participants are unable to cover routine costs (or denied services)?

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Emerging Solution: Research Financial Hardship Program ("RFHP")

RFHP Typical Characteristics

- Can be administered by a Sponsor, Site, or independent Foundation
- Research participant applies for assistance with assistance from Study CRC
- Assistance based on financial need
- Payments for clinical services at established, fair market value
- Applicable to uninsured or *under-insured* individuals

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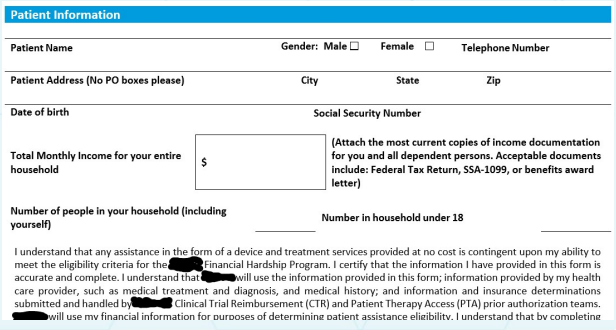
RFHP Source: Study Sponsor

- Typically organized around specific clinical trial or investigational product(s)
  - Ex: for participants in the CHAMPION HF study, or studies on investigational device ABCXYZ
- Patient application and supporting documents (tax return, SA-1099, W2, etc) sent to Sponsor for qualification determination
- Funding backed by Sponsor organization
  - Could be positive or negative consideration
- RFHP administration handled by Sponsor
- Additional contract amendment(s) likely



Patient Information

Patient Name | Gender: Male ☐ Female ☐ | Telephone Number

Patient Address (No PO boxes please) | City | State | Zip

Date of birth | Social Security Number

Total Monthly Income for your entire household | $ | (Attach the most current copies of income documentation for you and all dependent persons. Acceptable documents include: Federal Tax Return, SSA-1099, or benefits award letter)

Number of people in your household (including yourself) | Number in household under 18

I understand that any assistance in the form of a device and treatment services provided at no cost is contingent upon my ability to meet the eligibility criteria for the [redacted] Financial Hardship Program. I certify that the information I have provided in this form is accurate and complete. I understand that [redacted] will use the information provided in this form; information provided by my health care provider, such as medical treatment and diagnosis, and medical history; and information and insurance determinations submitted and handled by [redacted] Clinical Trial Reimbursement (CTR) and Patient Therapy Access (PTA) prior authorization teams. [redacted] will use my financial information for purposes of determining patient assistance eligibility. I understand that by completing

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RFHP (Alternative Source): Independent Foundations

- Organized around disease categories (i.e. Parkinson's Disease, Epilepsy, Leukemia, etc.)
- Opportunities to apply for assistance beyond research-related expenses.
- Smaller Foundations with limited funds
  - When the $$$ is gone, it's gone

LEUKEMIA & LYMPHOMA SOCIETY®

The Leukemia & Lymphoma Society Co-Pay Assistance Program
Covered and Non-Covered Expenses

Expenses covered by the Co-Pay Assistance Program:

- Medications associated with blood and marrow stem cell transplantation
- Blood cell boosters/erythropoietin-stimulating agents
- Blood transfusions
- Chemotherapy
- Intravenous preparation and or maintenance procedures
- Iron chelation therapy
- Kyphoplasty
- Photopheresis/UV light therapy
- Prescription drugs related to the covered diagnosis
- Public or private insurance premiums
- Radiation therapy
- Radioimmunotherapy (RIT)

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RFHP Source: Research Site, Health Care Entity, or Aligned Foundation

- Flexibility in RFHP setup
  - Open to multiple therapeutic areas/studies
  - Variety of care expenses qualify (IP, OP, Rx)
  - RFHP determination on thresholds (1.5-6x)
- Opportunity to establish streamlined administration process
  - Approval Committee: Research, Finance, & Compliance
  - Can set fund to pay at research rates
- Variety of funding sources based on organizational preferences
  - Donations to Foundation
  - Fundraising Events
  - Contributions from study sponsors

2020 Poverty Guidelines for the 48 Contiguous States and the District of Columbia	
Persons in Family/Household	**Poverty Guideline**
1	$12,760
2	$17,240
3	$21,720
4	$26,200
5	$30,680
6	$35,160
7	$39,640
8	$44,120

*For families/households with more than 8 persons, add $4,480 for each additional person

Source: https://aspe.hhs.gov/poverty-guidelines

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Advanced Discussions (Internal)

1. Coordination of multiple RFHP?
2. FPL multiplier for eligibility…consistency?
3. Donations from Sponsors: $$ available beyond their trials!
4. Hard coding revenue stream from Study to fund? (1-5% of total revenue?)
5. Discussion with HRPP on RFHP; disclosed in ICF?

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Wrapping Up

Questions?
Comments?

Thank you!

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