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

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**Background:** Benefits to institutions participating in clinical trials include: increased trials and costs. However, we hypothesized that patients enrolled at high-performing hospitals are less likely to enroll than those enrolled at lower-performing hospitals. We used the National Cancer Institute's (NCI) Cancer Registry for patients treated at participating hospitals. We found that patients treated at high-performing hospitals are more likely to have a good outcome than those treated at lower-performing hospitals. The NCI Cancer Registry includes information on patient outcomes, such as survival rates and complications. We found that patients treated at high-performing hospitals had a lower risk of mortality than those treated at lower-performing hospitals. Conclusion: Patients treated at high-performing hospitals had a lower risk of mortality than those treated at lower-performing hospitals. Overall, our findings support the importance of participating in clinical trials and the potential benefits for patients.
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?

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree
- Not sure

53% 58% 32% 2% 1%

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

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree
- Not sure

53% 34% 9% 2% 7%

5

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.
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 \textit{routine costs}.

- **Medicare Advantage:** \textit{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 \textit{routine costs} of care when participating in clinical trials \textit{“...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:** \textit{Varies by State}
# 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.*
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

To determine if the study sponsor or the patient/insurance will pay for each item or service required by the study.

- Each item should have one payer – EITHER the patient or the sponsor
- Major compliance problem = double billing

Where is all this going?

Quick Recap:

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

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

Uncertainty About Insurance and OOP Costs [50%]

✓ 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)?
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

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
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

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

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*For families/households with more than 8 persons, add $4,480 for each additional person
Source: https://aspe.hhs.gov/poverty-guidelines
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?

Wrapping Up

Questions?
Comments?

Thank you!

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