Stanford Cancer Institute

Financial Burden for Low-Income Trial Participants: Patient Travel Reimbursements

NCI Designated Comprehensive Cancer Center

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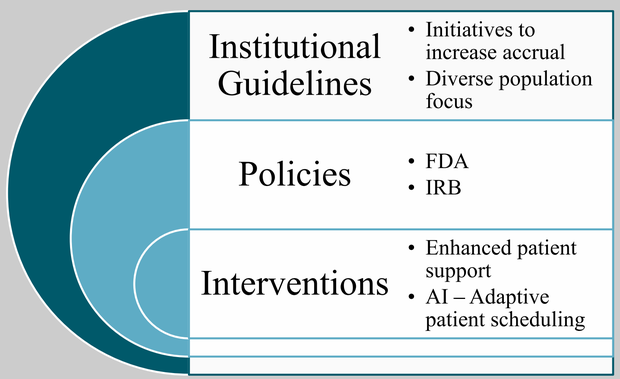
Background

Clinical Trial retention has negative correlation with patient burden, especially patient's financial burden. Financial sensitivity results in underrepresentation of low-income population in clinical trials.

- **FDA** cautions against payments that are coercive or present undue influence
- **NIH** warns for payments that cause undue inducement.
- **IRB** should determine that the risks are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(20]. IRB generally accepts procedure specific incentive payments for invasive procedures.
- **IRS**: Payment for study participation over $600 is taxable income for IRS purposes. Rare disease exception of $2,000 per year

Methods

We looked at the different policies and published research regarding patient financial burden. We also took a look at existing interventions to provide enhanced patient navigation support. We gathered time taken to reimburse patients and looked at third party vendors providing these services.



Balance between Compensation and Reimbursements

What is allowable and ethically appropriate?.

Compensation: Incentive cash/gift card/check payment or other rewards provided to research participants in exchange for time, effort, inconvenience, potential risks, and/or to provide incentive to participate

Reimbursement: Payment for expenses incurred by research participants due to study participation like travel, food, hotel, parking fees, childcare, lost wages.

"Appropriate" compensation:

- Respect for time to participate
- Mitigate inconvenience of participants
- Prorate compensation with participation
- IRB restrictions
- Funding availability
- Not coercion or undue influence
- No token gifts - can be considered as bribe

Reimbursements:

- Air travel or gas mileage
- Hotel/Air BnB charges
- Parking and Tolls
- Meals
- Caregiver / Parents coverage
- Out of pocket expenses
- Ground Transportation

Ethical Consideration vs Cost Burden of Participation

- ❖ Higher Incentives are associated with higher risk perception
- ❖ Monetary incentives help better participant retention
- ❖ Participation biases based on higher socio economic levels

Hidden Costs

- Lost wages
- Childcare
- Time to participate
- High deductibles on SOC
- Cost of additional testing
- Temporary relocation near study center

IRB Considerations

- ❖ Incentive appropriateness
  - ❖ How much
  - ❖ For what? (time, inconvenience, discomfort, etc.)
- ❖ Voluntary informed consent and undue influence
- ❖ Fairness
- ❖ Method and timing of disbursement

Conclusion

It is critical to consider patient hidden costs and potential reimbursement to reduce patient financial burden associated with clinical trial participation. Patient navigation and patient supportive roles in healthcare system re essential to assist patients, address risk perception, trial accrual and retention. Health policy changes are needed to compensate low-income trial participants

Recommendations

- ➢ Patient focus: Timely reimbursements
- ➢ Compensation to subjects which cover patient's time (lost wages) and other inconveniences are essential to recruit subjects from low-income categories
- ➢ Enhanced Patient Support Services
  Support staff being available to navigate the patient experience plays a key role in recruitment and retention.
- ➢ Staff incentives for recruitment
- ➢ Using AI to minimize appointment time burdens and adaptive patient scheduling
- ➢ Reduction of long wait times
- ➢ Clinical Trial Design to shorten duration