

Improving Patient Access to Cancer Clinical Trials (IMPACT) Study at Abramson Cancer Center (ACC)

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Crystalyn's Story

Sanity

The hospital became our second home.
And you know what
Being on isolation sucks.
You just wanna go outside
Look people in their eyes
Shake hands
Give hugs
Just reach out and... touch,
The outside of the door
And just walk across the floor,
And when I got the chance to leave,
I put one foot in front of the other,
And stepped out to breath.



VIP Crystal Trevillion with Lazarex's Founder Dana Dornsife

Policy

- As Founder, Chief Mission and Strategy Officer of Lazarex, Dana was involved in new FDA guidance language ‘giving the green light to reimburse patients for travel expenses to clinical trial sites’
- Advocates at the state level for laws that **reinforce** the FDA guidance clarifying that patients can be reimbursed for travel expenses related to clinical trial participation

DATE INTRODUCED

April 6, 2017

PRIME SPONSOR

Senator Dinniman

DESCRIPTION AND PURPOSE OF BILL

Senate Bill 576 enacts the Cancer Trial Access for Pennsylvania Patients (TAPP) Act clarifying that the reimbursement of certain expenses of cancer clinical trial patients does not constitute impermissible inducements.

The bill provides that all sponsors of cancer clinical trials shall inform potential patient-subjects of the following:

- Reimbursement for travel and ancillary expenses is available to all enrollees based on financial need;
- Coverage of these expenses is done to eliminate financial barriers to enrollment in order to retain patient-subjects in the clinical trial; and
- Family, friends or chaperones that attend the cancer clinical trials with the patient-subject are eligible for reimbursement for travel and ancillary expenses.



Lazarex IMPACT Program

□ What is the IMPACT Program?

- A program established 10 years ago that covers **out-of-pocket travel** (e.g., mileage, tolls, airfare) **and lodging expenses** (e.g., hotel rooms, AirBNB) associated with cancer treatment clinical trial participation for financially eligible patients
 - **Eligibility is based on household income** and reimbursement is based on a sliding scale

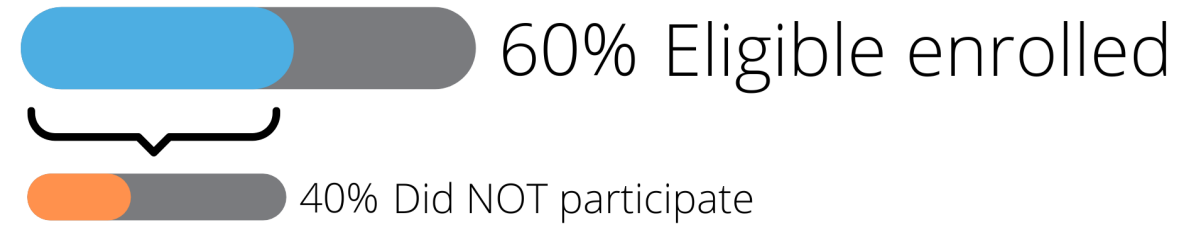


Preliminary Studies

Pilot Study:

- **29% increase in clinical trial participation**
- **200% increase in minority participation**

Follow-Up Study:



Study Aims

- In patients with cancer who are **eligible for a cancer treatment clinical trial** at the Abramson Cancer Center we will **identify barriers and facilitators of:**
 1. **Enrollment** in the IMPACT program
 2. **Participation** in the IMPACT program
 - A. Submission of **receipts** for reimbursement
 - B. Submission of **travel logs** for reimbursement

Methods

- Clinical Research Coordinators identify eligible patients and **refer them to IMPACT program**
Eligibility Criteria:
 - I. ALL adult patients with cancer being **considered for a therapeutic clinical trial**
 - II. Household income **does not exceed 700%** of the most recent HHS Poverty Guidelines
- ACC IMPACT Team administers **recruitment questionnaire by phone**
 - If confirmed eligible, complete IMPACT program application over the phone & send to foundation
- **4-6 weeks** after foundation approves, ACC IMPACT Team administers the **first of two** qualitative **interviews by phone** that are recorded and transcribed
 - 30 item questionnaire that includes, REALM-SF, COST-Q
- **3-4 months later**, ACC IMPACT Team administers the second qualitative interview **by phone** that are recorded and transcribed
 - 30 item questionnaire that includes satisfaction survey

Analysis

- NVivo (12)
 - store, organize, and analyze data
- Sample size:
 - Up to 100 interviews
 - Recruitment informed by **thematic saturation**
- **Grounded Theory** to guide analysis/coding
 - Coding categories reflect the content of data collected rather than the questions of the interview and often use concepts or vocabulary borrow from respondents

Preliminary Results - Enrollment

Barriers of and Facilitators to Enrollment in the Lazarex Cancer Foundation IMPACT Program

Category	Barriers identified by interview	Facilitator identified by interview
Enrollment	ACC Clinical Research Team (6) Unaware of IMPACT (6) Difficult to Trust (7) First contact (10) Happened post-start of treatment (4) Needs to be earlier (6) Patient (3) Difficulty Navigating Resources (2) Difficulty contacting (1)	ACC Clinical Research Team (18) Explained IMPACT (4) First contact (6) Shared proof of income docs (1) ACC IMPACT Team (15) Assist with enrollment (6) Clarity (2) Explaining IMPACT (5) First Contact (3) Enrollment Process Clarity (2) Conciseness (3) Easy (4)



Preliminary Results - Participation

Barriers of and Facilitators to Participation in the Lazarex Cancer Foundation IMPACT Program

Category	Barriers identified by interview	Facilitator identified by interview
Participation	Reimbursement lag time (2)	ACC Clinical Research Team (1)
Travel Log Submission	Access (1)	Reminders (1)
	Not provided (1)	Clarity (4)
	Technology need (5)	Easy (10)
	Busy (2)	Gets easier with time (1)
	With treatment (2)	Options how to submit (2)
	Format (4)	Someone to do for patient (1)
	Example confusing (2)	
	Per type (1)	
	Limited space (1)	
	Ineligible Expenses (4)	
	Over approved amount (1)	
	Retroactive reimbursement (3)	
Receipt Submission	Busy (5)	Clarity (2)
	With treatment (4)	With eligible receipts (1)
	Gathering Receipts (5)	Easy (7)
	EZ Pass (3)	Options how to submit (1)
	Ineligible Expenses (2)	Someone to do it for patient (1)
	Retroactive Reimbursement	
	Approval amount low (1)	
	Technology Need (4)	
	Internet (2)	
	Scanner (2)	
	Uncomfortable with process (3)	
	Confusing (1)	
	Don't know where to start (2)	

Conclusions

- There are many multiple barriers to enrollment and participation in the IMPACT program that can be addressed at the patient, site, and foundation level.

Future Directions

- Consensus coding meetings
- Create recommendation products
 - Using suggestions from interviews
- Present to sponsor - Lazarex Cancer Foundation



Lessons Learned

- "Just because the system is broken doesn't mean it has to stay that way"
 - The role we play in this
- Qualitative studies can help us with answering questions such as "What is X and **how** does X vary in different circumstances, and **why**?" Rather than "how many Xs are there?"

Thank you!



iMPACT!

Improving Patient Access
to Cancer Clinical Trials

Lazarex
CANCER FOUNDATION
www.lazarex.org



Penn Medicine

ABRAMSON CANCER CENTER





COST (Comprehensive Score for financial Toxicity)		Not at all	A little bit	Some- what	Quite a bit	Very much
Patient –Reported Outcome Measure						
1	I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment.	0	1	2	3	4
2	My out-of-pocket medical expenses are more than I thought they would be.	0	1	2	3	4
3	I worry about the financial problems I will have in the future as a result of my illness or treatment.	0	1	2	3	4
4	I feel I have no choice about the amount of money I spend on care.	0	1	2	3	4
5	I am frustrated that I cannot work or contribute as much as I usually do.	0	1	2	3	4
6	I am satisfied with my current financial situation.	0	1	2	3	4
7	I am able to meet my monthly expenses.	0	1	2	3	4
8	I feel financially stressed.	0	1	2	3	4
9	I am concerned about keeping my job and income, including work at home.	0	1	2	3	4
10	My cancer or treatment has reduced my satisfaction with my present financial situation.	0	1	2	3	4
11	I feel in control of my financial situation.	0	1	2	3	4

Behavior _____

Exercise _____

Menopause _____

Rectal _____

Antibiotics _____

Anemia _____

Jaundice _____



2. Are you enrolled in cancer treatment trial at Abramson?
 - a. If yes: Proceed to question #3
 - b. If no: Why not?
3. Were you contacted by the Lazarex Cancer Foundation?
 - a. If yes: Were you approved for financial reimbursement by the IMPACT Program?
 - i. If yes: Continue to question #4
 - ii. If no: Is there anything we can do to help you enroll in the program?
 - b. If no: I'm sorry to hear that. Are you still interested in enrolling in the IMPACT Program?
What is the best number to call you? What is the best time of day to contact you?
(NOTE: Pass along information to appropriate personnel and reschedule Interview #1)
4. How likely is it that you would have **enrolled** in a clinical trial without the help from the IMPACT Program? (5 very likely, 4 somewhat likely, 3 neutral, 2 somewhat unlikely, 1 very unlikely)
5. What suggestions do you have that would make it easier for patients to **enroll** in the IMPACT program?
6. Have you begun submitting your **travel logs** to Lazarex? (may need to note that this is the printable worksheet where you input how many nights of lodging, how many miles, how much spent on parking, etc.)
 - a. If yes: What suggestions do you have that would make it easier for patients to submit their **travel log** to Lazarex? (Long pause...)
 - b. If no: Is there anything we can do to help you submit your **travel log** to Lazarex? (NOTE: Make note of ways patient needs assistance)
7. Have you begun submitting your **receipts** to Lazarex? (may need to note that this refers to the process of gathering receipts and attaching to travel log)
 - a. If yes: What suggestions do you have that would make it easier for patients to submit their **receipts** to Lazarex? (Long pause...)
 - b. If no: Is there anything we can do to help you submit your **receipts** to Lazarex? (NOTE: Make note of ways patient needs assistance)

8. What general suggestions do you have about the IMPACT Program that we have not mentioned yet?
9. Are there barriers besides financial ones that prevent you from **enrolling** in a clinical trial?
10. Is there anything else we should know that would make **enrolling** in a clinical trial easier?



Satisfaction Questionnaire

Likert Scale (1 to 5 – 1 = strongly disagree, 3 = neutral, 5 = strongly agree)

1. The Abramson Cancer Center IMPACT Coordinator that assisted me was very knowledgeable about the IMPACT Program.
2. The Lazarex Foundation Coordinator that assisted me was very knowledgeable about the IMPACT Program.
3. I am satisfied with the information I received from the Abramson Cancer Center coordinator about the Lazarex Foundation IMPACT Program.
4. I am satisfied with the assistance I received from the Abramson Cancer Center coordinator when enrolling in the IMPACT Program.
5. I am satisfied with the Abramson Cancer Center coordinator's ability to address my questions/ and or concerns.
6. Compared to before enrolling in the Lazarex IMPACT program, I am feeling less overwhelmed by costs related to travel and lodging associated with participating in a clinical trial.
7. I still have concerns about the travel and lodging costs associated with participating in a clinical trial.
8. I knew who to call when I had a question about the Lazarex IMPACT program.
9. I understand how the reimbursement the Lazarex foundation IMPACT program was determined.
10. The Lazarex IMPACT program eliminated the barriers of travel and lodging costs related to participating in a clinical trial.
11. I am satisfied with the monthly reimbursement maximum that was approved for me by the Lazarex Foundation.
12. I am satisfied with the travel log required for reimbursement by the Lazarex Foundation.
13. I am satisfied with the travel log required for reimbursement by the Lazarex Foundation.
14. I am satisfied with the time the Lazarex foundation takes to reimburse costs.
15. I am satisfied with the overall Lazarex IMPACT program.



Results: Current Enrollment of the IMPACT Program

▶ We are partnered with **13 different disease teams**

- Lymphoma
- Breast
- CCI/CAR-T
- GYN Oncology
- Developmental Therapeutics
- GI Oncology
- Melanoma
- Multiple Myeloma
- Neurosurgery
- BMT/Cell Therapy & Transplant
- Thoracic
- GU
- Otorhinolaryngology - Head & Neck

▶ **New partnerships** being explored with:

- Rad Oncology
- Penn Presbyterian Medical Center
- Pennsylvania Hospital

▶ Have screened for FRP eligibility from patients across **72 cancer therapeutic clinical trials**

▶ **170 (and counting!) patients** referred to the IMPACT team

▶ Over **26 interviews** conducted, to date

Eligibility for the IMPACT Program

2022 HHS Federal Poverty Guidelines

# Household Members:	Total Adjusted Gross Household Income up to 400% FPG	Total Adjusted Gross Household Income between 401% - 550% FPG	Total Adjusted Gross Household Income between 551% - 700% FPG	MUST PROVIDE INCOME INFORMATION:**
1.	\$51,520	\$51,521 - \$70,840	\$70,841 - \$90,160	Acceptable proof of income: First two pages of signed copy of income tax return OR If you do not file a tax return, a copy of your most recent pay stub, unemployment check, or SSI, SSD, or public assistance benefit notification. If you are not currently employed please send a signed letter stating your current financial situation. <i>(Please cross out social security number)</i>
2.	\$69,680	\$69,681 - \$95,810	\$95,811 - \$121,940	
3.	\$87,840	\$87,841 - \$120,780	\$120,781 - \$153,720	
4.	\$106,000	\$106,001 - \$145,750	\$145,751 - \$185,500	
5.	\$124,160	\$124,161 - \$170,720	\$170,721 - \$217,280	
6.	\$142,320	\$142,321 - \$195,690	\$195,691 - \$249,060	
7.	\$160,480	\$160,481 - \$220,660	\$220,661 - \$280,840	
8.	\$178,640	\$178,641 - \$245,630	\$245,631 - \$312,620	
Eligibility %	100%	75%	50%	
Monthly Maximum:	Up to \$1500	Up to \$1125	Up to \$750	

Program implemented 2020

At Abramson Cancer Center

PAST 2.5 MONTHS

\$141,000

**AMOUNT APPROVED
FOR REIMBURSEMENT**

AMOUNT APPROVED

Amount approved by foundation for monthly maximum reimbursement across 2.5 months

\$7,200

**AMOUNT REIMBURSED TO
PATIENTS**

REIMBURSED

Amount patients submitted receipts for and got deposited into prepay visa cards

