Patient, Caregiver and Physician Perspectives on Participating in a Thoracic Rapid Tissue Donation Program

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Abstract

Objective—The collection of posthumous tissue from advanced stage lung cancer patients is beneficial to medical science. Recruiting living patients to a Rapid Tissue Donation Program (RTD) poses several psychosocial challenges and little is known about perceptions of joining this type of program. This study qualitatively examined perceptions of advanced stage lung cancer patients (n=14) participating in a lung cancer RTD program, their NoK (n=11), and physicians (n=6) at the Thoracic Oncology Clinic at H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida USA.
Methods—Semi-structured interviews were conducted with participants and interview transcripts were analyzed using the constant comparison method.

Results—Majority of patients joined to give back to research, discussed participation with family members, and desired for family to receive information about the use of the tissue after their death. All participating NoK were supportive of their family member’s decision. Physicians described the program as running smoothly, but provided suggestions for process improvements.

Conclusion—Participants joined with intention to give back to research community and families were supportive of loved one’s participation in RTD. Physicians agreed with overall process.

Practice implications—Key factors for a successful RTD program is tailoring to institutional and individual needs.

Keywords
rapid tissue donation; rapid autopsy; cancer; ethics; patient recruitment; qualitative

1. Introduction

Precision medicine is an important tool in the treatment of cancer, particularly lung cancer. [1] Precision medicine relies on results of blood analyses and tissue samples, merged with personal clinical information to determine factors associated with treatment response and clinical outcomes. [2] In the treatment of cancer, a major challenge in the application of precision medicine is the limited amount of tissue available from patients with advanced disease and refractory disease. Rapid tissue donation (RTD), also known as rapid autopsy, warm autopsy, or posthumous tissue donation, is the procurement of ‘fresh’ tissue (primary tumor and metastases) within 24 to 48 hours after death of a cancer patient. These tissues provide an opportunity for genomic and proteomic research to improve understanding of: drug resistance, especially in the context of targeted therapy and immune therapy; [3] heterogeneity of advanced cancer, including differences between primary tumor and metastatic lesions [4] and; refractory cancers. [3]

Publications on posthumous tissue collection programs are increasing in popularity, [5, 6] but to our knowledge, none have discussed the donors perceptions about participating in such programs. Improved understanding of their perceptions could lead to greater gains in knowledge, increase enrollment of patients, allow more centers to create RTD programs, and potentially allow consortia of RTD centers. While there are benefits to medical science with the collection of posthumous tissue, recruiting living cancer patients to participate poses several challenges, [7] as has been shown in other rapid autopsy programs. A warm autopsy program for idiopathic pulmonary fibrosis identified critical areas to focus on in program development, namely: listening to the patient; ensuring the decision is based on free choice; and involving the family early in the discussions. [7] Another rapid autopsy program for Alzheimer’s research and brain tissue also identified the need to involve the family, but suggested the use of nurse clinicians to participate in the research and maintain close contact with patient donors. [8] However, formative research at our institution indicated patients preferred to work directly with their physician, while nurses were not comfortable being involved in RTD discussions. [9] Discomfort from the healthcare team is not uncommon as
some staff may be uncomfortable broaching the topic feeling it sends a negative message to the patient. [10, 11]

Additionally, while program participation may be desired by the patient, family and loved ones may be unwilling due to the logistics or personal beliefs about tissue donation. [5] If next of kin (NoK) disagree with the patient's decision, there may be a legal obstacle to following the patient's wishes since NoK “own the body” post death. [12, 13] For the purpose of this study, NoK was used when referring to patients' family members, companions, and loved ones.

Our previous formative research examining patients, their loved ones, hospice members, pathologists, funeral homes, and health care provider’s perceptions of a hypothetical RTD program found strong support. [9, 11] Additionally, feedback from these sources was used to develop educational materials, talking points for physicians as well as a detailed process for program implementation. [9]

This study examined the patient's perceptions regarding participation as well as the psychosocial and procedural concerns of patients who consented to the lung cancer RTD program at H. Lee Moffitt Cancer Center & Research Institute, their NoK, and the physicians who discussed it with them. Our goal was to use these data in real time by immediately changing any aspect of the recruitment or consent process with which patients, NoK, or their physicians had a concern.

2. Methods

Figure 1 describes the logistical steps of the RTD process. The study received approval from Chesapeake IRB (Columbia, MD) and a waiver of written informed consent was granted.

2.1 Sample

Participants and physicians were recruited at the Thoracic Oncology Clinic at H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida.

2.2 Patient and NOK Interviews

From September 2015 to January 2016, nineteen lung cancer patients were recruited to participate in the RTD program. The average age at enrollment was 66 years, 53% (n=10) were female, 68% (n=13), 100% (n= 19) were white, had adenocarcinoma, 21% (n=4) small cell lung cancer, and 11% (n=2) squamous cell carcinoma. The majority, 84% (n=16), were former smokers (Table 1). Two patients declined to participate in RTD and also declined the interview.

A total of 25 participants, patients (n=14) and NoK (n=11), were interviewed. Demographic data for NoK were not collected. Three RTD participants declined the interview and two participants died before they could be interviewed (Table 1). The majority of interviews occurred within one week of the RTD discussion and three occurred within four weeks. These interviews lasted between 10 and 60 minutes.
Using a semi-structured interview guide, vetted by Thoracic Program patient advocates, social work staff, and program leaders [9] we conducted interviews with eligible patients and their NOK in real time, contacting them immediately after they had a discussion with their physician. The content of the guide for patients and NoK focused on their perspectives regarding the overall RTD process, positive and negative aspects of the program, and suggestions for improvement (Figure 2). The interview guide for physicians consisted of similar questions (Figure 3). Interviews were conducted by the lead author and a study coordinator, in person or by phone, with patients and NoK. Participants received a $25 gift card for participation in the interview.

2.3 Physician Interviews

We interviewed each physician (n=6) involved in discussing RTD with their patients. Eligibility for the physician interviews included oncologists in the Thoracic Oncology Program at H. Lee Moffitt Cancer Center & Research Institute, who agreed to discuss RTD with patients. Physician interviews lasted 10 to 30 minutes, were conducted over the phone, and compensation was not provided. To maintain anonymity we do not report physician demographics. Physicians provided feedback about the need for any improvements or changes in the process.

2.4 Analysis

All interviews were audio-recorded, transcribed and coded for key themes based using the constant comparison method. [14] Initially the code book was created based on the a priori themes from the interview guides (responses to specific questions). Two coders worked from a preliminary code book, which was then narrowed to a final code book once discrepancies between coders were resolved and definitions of each code were created. We used a $\kappa$ score to achieve an inter-rater reliability of .90. [15]

3. Results

3.1 Patient/NoK

3.1.1 Decision to Participate—During the interview, participants were asked reasons why they decided to join the RTD program (Table 2). All participants had multiple reasons for joining. The majority of patients stated they wanted to contribute to cancer research and “give back” to the medical research process and research community, which they felt had helped them throughout their illness. About half of the patients were organ donors prior to their diagnosis and saw the program as an opportunity to fulfill this commitment in another way, due to their inability to donate organs because of the cancer diagnosis. A few patients were motivated to join because they saw it as a way to help other patients and families who might be diagnosed with cancer in the future.

3.1.2 Potential Concerns—Patients and their NoK were asked if they had any concerns about RTD. Most did not have significant concerns and had an overall understanding of the program (Table 2). However, some participants, both patients and caregivers, had a variety of questions about the process, such as: the amount of tissue that is removed during the retrieval, the length of time between the retrieval and the return of the deceased, the death
notification process, and if the retrieval would interfere with final funeral arrangements (Table 2).

3.1.3 Disclosure of Decision—Patients were asked if they had discussed their participation in the program with other family members and their reactions to this decision (Table 2). Most participants noted their decision had been discussed with their spouses, children, and other members of their extended family. A few decided not to notify or discuss their decision with any family members until later or when they felt it was the right time to do so. No respondents had any concerns about the way or the timing with which they were approached by their physician or the consent process.

3.1.4 Recognition of Donation—Patients were also asked how they felt about their family receiving information about the use of their tissue after their death, in what format they would like them to receive it, and if they were interested in public acknowledgement of their donation (Table 2). Most patients and NoK stated they would like for their family to receive information about the types of studies using their tissue and they would prefer for their family to be notified via a newsletter. When asked about wanting public acknowledgement, most patients stated they would like to be publicly recognized; however, a few did not and two had no opinion. All NoK were supportive of any public or non-public recognition desired by their loved one.

3.1.5 Perception of Materials—In addition to the physician-led introduction to the program, a brochure describing the process and goal of RTD was developed (Figure 4). During the interview, participants were asked about their opinion on the visual aspects and the content on the brochure. All patients and most caregivers had positive reactions to the look and content of the brochure and found it a very informative document about the program (Table 2).

3.2 Physician Responses

All physicians were pleased with the RTD protocol and process and did not have any recommendations for changes. The majority said the first time they had a discussion with a patient they were slightly “uneasy” but subsequent discussions became easier. No physicians reported any negative encounters during the RTD discussion. The challenges for the majority of the physicians related to incorporating the identification of eligible patients into their busy practice schedules. Several suggestions were offered including having the team notify their nurses with a list of eligible patients with upcoming appointments and having the RTD brochures in the patients’ file. Table 3 provides a list of representative quotes.

4. Discussion and Conclusion

4.1 Discussion

In this study we examined patient, NoK, and physician perceptions as well as the psychosocial implications of joining a RTD program. Our results showed patients are motivated to participate to give back to medical research and when they learn they can no longer be organ donors. Patients and NoK had limited concerns about the program.
end we are pleased that our formative research [11] guided us in designing a sound approach to recruitment resulting in satisfaction with the process. While some participants had unanswered process questions they were not considered “concerns.” This underscores the need to create a list of key points to review in the consent process. In our case, most questions asked by participants were already in the consent form, however since it was clear patients did not retain some of these pieces of information, we developed follow-up packets of information for patients and their NoK. These follow up packets contained the signed consent form, a list of telephone numbers and email address to reach someone from the RTD program for questions, and a contact list and flow chart of the steps that should take place when the patient dies.

While most patients discussed their decision with their NoK, some did not, which poses a potential challenge. While multiple studies have examined organ donation in healthy individuals such as the Genotype-Tissue Expression Project (GTEx) [16-17], a substantial difference between this type of donation and that of people with cancer who are aware that their treatments may not be curative. Our results may be better compared to posthumous decisions about organ donation, where the request is made after the patient’s death. [18] Rodrigue, Cornell and Howard examined factors influencing organ donation decisions between donor and nondonor families. [18] Their findings showed the NoK of the deceased were more likely to allow organ donation when their loved ones had made their intentions to donate known while they were alive and when they perceived the timing of the request as optimal. Similar findings were seen in a 3 year longitudinal study of bereaved families, where the wishes of the patient were a key factor but also positive and negative events that occurred during the patients hospital stay, had influence on decision making. [19]

With this knowledge, it is imperative to carefully consider how the decision making process for patients with end-stage disease and their families may be different than those making choices about organ donation, or similar programs, and adjust recruitment procedures accordingly. Our study and others that examined attitudes towards “rapid autopsy” or posthumous tissue donation have shown there is a high degree of willingness (at least hypothetically [20, 21]) to participate, but programs should be tailored to the needs of the culture of the institution, the clinicians, patients and NoK.

Most patients wanted some form of recognition (e.g., a remembrance wall) for their contribution as well as for their NoK to receive information about how their tissue was used and the progress of studies using their tissues. The brochure (Figure 4) was seen as a useful tool to help patients better understand the RTD program, to encourage new participants and serve as a follow-up to discussions patients had with their physician about becoming a donor. Since patients and NoK responses varied considerably in what type of posthumous information they wanted to receive and how to receive it, it is important to offer options for each family if permissible. A recent report based on work from the Children's Oncology Group [22] makes several recommendations about the return of results. The recommendations include (among others): reporting results from each aim of the study using a bio specimen with a lay summary of these results adjusted for low health literacy, notifying participants that results may be presented at public meetings such as scientific conferences, and publishing results on a study website, accessible to participants.
Finally, the physicians in this study were pleased with the RTD program, their role in it, and had no concerns. Their suggestions about how to improve the notification process of eligible patients was easily met by copying their nurses in weekly emails, and having electronic RTD brochures available.

There are several limitations to this study. We were unable to interview patients who declined to participate in RTD although they were approached for an interview; thus, we have no perspective from patients who were not interested in participating. Another limitation is that this is a single institution study and our physician and patient perspectives are perhaps unique to the institution. A limitation we discovered of the RTD program is that we did not develop our consent form to allow families to receive any specific information about results of studies in which their loved one’s tissues were used. We send individual letters thanking the family for participating in the program after the death of their loved one and provide general information on the types of research being conducted (e.g., tissue staining for evaluation of the cancer morphology).

4.2 Conclusion

This is one of the first studies to examine the perceptions about participation in a rapid tissue donation program. To date, nine consented patients have died and successful tissue retrievals have been completed. The results of these cases will be in a forthcoming manuscript.

4.3 Practice implications

This study shows the feasibility of creating RTD programs, with the provision that input and assessment of satisfaction from all involved are required prior to development and continually examined during program implementation. NoK are very supportive and willing to fulfill their loved ones’ wishes, independent of their own thoughts on the subject; making this a key factor in the success of programs like RTD. Another important aspect of maintaining this type of program is to work closely with treating physicians to identify, not only eligible patients, but patient who are coping well with their disease status and talking about end of life decisions. Using these screening practices can reduce the distress and discomfort of a patient who will become alarmed during the presentation of the offer and is not likely to consider participation anyway.

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Acknowledgments

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References


Patient Educ Couns. Author manuscript; available in PMC 2018 April 01.


Figure 1. RTD Process
**General RTD Experience**

1. Describe for me where you are in your thinking about the RTD program. Have you decided whether or not to join?
   a. If yes, describe for me how you decided to join/not join the RTD. Tell me the entire story.
      i. What was the main reason you decided to or not to join?
2. Who have you talked to about your decision?
   a. What did they say (probe pro or con for the RTD participation)
   b. Do you plan to talk to anyone else?
3. List all the strengths of the program, if any, in your opinion.
4. List all the weaknesses, if any, in your opinion.
5. Or how do you feel about your family receiving information about the use of your tissue/ or how your tissues were used?

**Brochure**

1. Did you receive the brochure?
2. If yes, what were your thoughts?
3. Are there any confusing words? Images?
4. Does it provide all the information you need?
5. What else is needed? Is it helpful?
6. Does your family/caregiver have a copy?

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Figure 2. Patient/NoK Interview Guide
1. What has been your experience so far in discussing RTD with your eligible patients?
2. How is the process working for us to send you notifications of eligible patients?
3. Have you had any negative encounters with patients or NoK/companions?
4. Is there anything about the process you would change or do differently?

Figure 3. Physician Interview Guides
Figure 4. Rapid Tissue Donation Brochure
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Table 2

Representative Quotes from Patients and Caregivers

<table>
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<th>Theme</th>
<th>Participant Representative Quotations</th>
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| Decision-making     | Patient: “I think it's just a fact that we can't be organ donors. And I'm an organ donor so it was like, okay, I can't be an organ donor anymore. So what do I do now?”  
                      Patient: “…my purpose for getting involved is to be able to contribute in any way towards the study of cancer…”  
                      Patient: “Well, if taking tissue from my body helps someone else that might have cancer presently or might have it in the future, if it helps to develop a cure or a medicine that will cure them, it's worth it”  
                      Patient: “At the beginning I was a little bit hesitant just because I thought that involved removing my whole lungs”  
                      Patient: “No, I don’t think so. As long as I'm totally dead, I don't have concerns. I'm sure the people know how to do it…”                                                                                                           |
| Overall understanding| Patient: “As much as I have been told, yes, I am. It's my understanding that upon my death, you are going to have, I guess, if it's local, identifiers and they will let you know that I am deceased at this point and someone comes in and takes samples”  
                      Patient: “I just have more questions about who will - when I'm dying - who contacts my daughter or who do we contact or that kind of stuff?”  
                      Patient: “How would this interfere, change, or alter from the time you're deceased to when if your family wanted to have a church funeral, how long would this take?”  
                      Caregiver: “I’m just curious, how does it work? How many samples do you typically take?”  
                      Caregiver: “All I told the doctor was, 'you take the tumors and give me the ashes back and I will be happy’”                                                                                                             |
| Disclosure of decision | Patient: “They feel okay. I explained to them what it was about, and they said you're not going to notice anything. It's just going to be a small removal of tissue. So, they are concerned, but they are okay with it.”  
                      Caregiver: “I think the choices are hers and that's her decisions to make them and I think it's great that she wants to do that. I support whatever decision she makes.”  
                      Caregiver: “Basically she goes: are you okay if I give my body to science after I die? I was like: sure, I don't care; you're dead.”                                                                                      |
| Recognition         | Patient: “if they wanted to do it in a general way, or specifically - you know, then that the tissue has been useful for drug medication that is in investigation, you know, I think that would be good.”  
                      Caregiver: “I think that would be nice because I have a sense that our children would have an interest in that, particularly if it pertained to anything genetic that could impact them and their children.”  
                      Patient: “Yeah, but I think if you gave a letter to the family that you're thinking about your parent, your loved one, whatever it is, you want to thank them, that they're trying, they contributed.”  
                      Patient: “Well, I don’t know. Just - why? I’m done, I’m dead, I’m gone, but dying - I don’t know, I just - that seems like you’re - it’s like you’re writing a magazine article and publishing it after I'm dead. And I really don't have any interest in that. Or a newspaper article or something like that. 'Here’s so and so and so and so. We chopped him up today.’”  
                      Patient: “I think it's a good idea, because if it's posted up in the lobby, there are a lot of patients waiting. There is decision about a number of matters. And I think it would be good to - they would see this program, and maybe be interested in it as well, so.”                                                                 |
<p>| Brochure            | Caregiver: “I think it is good to have a handout because people don't know that you do it [RTD] and they should know it.”                                                                                                                                                   |</p>
<table>
<thead>
<tr>
<th>Theme</th>
<th>Physician Representative Quotations</th>
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<tbody>
<tr>
<td>Program discussion</td>
<td>“I was nervous the first time, but it went so well I never worried about it again”</td>
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<tr>
<td></td>
<td>“I’ve had some great interactions with my patients on this topic. Sometimes the spouses may not be on board at first, but they really defer to the patient.”</td>
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<td></td>
<td>“It’s always easier if the patient brings it up first, and many of them do – they ask how they can give back or they ask about body donation.”</td>
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<td>Identifying eligible patients</td>
<td>“There is nothing wrong with the process that I know of, it’s just not part of my routine yet. I forget or I get busy in clinic.”</td>
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<td>“I probably don’t get every eligible patient if I’m having a busy clinic day, if I can’t devote the right amount of time to this I won’t do it.”</td>
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<td></td>
<td>“I appreciate what you folks do to prep us, the rest is on me”</td>
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<td>Negative encounters</td>
<td>“Nothing negative has happened and I don’t expect it to, I am selecting the right patients under the right circumstances and I have good relationships with them or I wouldn’t bring it up.”</td>
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<td>“Not one negative issue that I know about… Did someone complain?”</td>
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<td>Changes to process</td>
<td>It would help if my nurse were copied on notifications so he or she could star them on my patient list for the day</td>
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<td>“I’d like to have the brochure more readily accessible, an electronic version if possible”</td>
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