PTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
April 6, 2021
Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair
Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 04/06/2021 to discuss the following agenda items:

1. Policy Review: SARS-CoV-2 Lower Respiratory Testing for Lung Donors
2. SARS-CoV-2 Summary of Evidence Suggested Revisions Review

The following is a summary of the Committee's discussions.

1. Policy Review: SARS-CoV-2 Lower Respiratory Testing for Lung Donors

The Committee chair reviewed feedback from the Lung and OPO committees, additional data, as well as potential policy language to require SARS-CoV-2 testing in a lower respiratory specimen for potential lung donors.

Lung Committee Feedback:

- Strongly support policy change
- Ok with "lower respiratory specimen" instead of BAL to increase
- OK with results pending at initial organ offer but NOT supportive of OPO being able to bypass lung programs that request pending results be returned before final acceptance
- Think change would increase lung utilization because many programs declining otherwise good organs because lack of testing

OPO Committee Feedback:

- All OPOs moving towards doing this testing
- Some hospitals can't get BALs but tracheal aspirates ok
- Turnaround issues still, but committee as a whole supports results prior to transplant and likely recovery but not feasible to have prior to allocation
- Bypassing lungs would only occur under extreme circumstance
- Supportive of policy change
- Implementation timeline: consider OPOs being able to turnaround tests

Data Review:

Lower respiratory tract SARS-CoV-2 testing for lung donors has risen in recent weeks, from about 25% of all deceased donors at the beginning of January to 60% the week of March 22nd.

Proposed policy language:

- Definition of lower respiratory specimen: A sample taken from the respiratory system within the trachea or below. Sputum, tracheal aspirate, bronchial suction, bronchial wash, bronchoalveolar lavage (BAL), and lung biopsy are considered lower respiratory specimens.
- Required testing: Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)
- Test timing requirement: Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available prior to lung procurement.

Discussion Questions:

- Is policy warranted given the potential impact on patient safety? What happens if another transmission happens and policy is not pursued?
- Should the results be required prior to OPO organ offer? Prior to lung procurement?

Summary of discussion:

Members were in agreement that the gap in number of lung donors being tested by lower respiratory tract (LRT) specimen is concerning, even though it is decreasing. They also were in agreement that requiring results prior to organ offer is less feasible than prior to procurement. They also agreed that there is no evidence to requiring LRT testing for non-lung organs at this time, and so this testing should only be required if lungs are being evaluated for transplant.

Members discussed what would happen if the LRT test resulted positive for the lungs. They weren't sure that anybody would want the positive lungs, so weren't concerned about potential for reallocation at this point in those circumstances.

Members agreed that they would like comparative data on the sensitivities of various lower respiratory specimen types, but that it does not exist at this point. One member was concerned that by simply stating "lower respiratory test", the policy implied that all lower respiratory tests are the same level of sensitivity. One UNOS staff member brought up that the DTAC can propose a specimen type change during the retrospective public comment in August, if there is any data by then. This doesn't "lock" DTAC into a specimen type in the long term.

One member was concerned about the timing of specimen results, and that it could lead to decreased utilization of DCD lung donors. He expressed that he would be more comfortable if results were allowed post-procurement, since the lungs could be on ex-vivo lung perfusion (EVLP) until the results were available.

Members wanted to know whether or not testing would change in DonorNet. They were concerned that OPOs might be "locked out" if a result is required at a certain time, or that OPOs might not be able to use the full functionality. Staff confirmed that this policy change would not necessitate a change in programming, and that staff also recommended against changes in DonorNet so as to avoid unintended consequences.

The Committee chair brought up that the goal of the policy is to balance between patient safety and lung utilization. 10% of donors are DCD donors, but the OPO committee pointed out that they don't feel like this testing would be a barrier to procurement and that the barrier has been shrinking. The Committee will also closely monitor the policy for any unintended consequences. In addition, another donor-derived transmission would be extremely detrimental to the system.

One member brought up that 40% of lung donors are currently being transplanted without LRT testing, and lung programs are willing to take these organs without LRT testing. The OPO committee feels that

the lungs are being turned down or discarded, but 40% are still being utilized. The Vice Chair pointed out that the analysis should also look at number of donor organs, not just percent, as a decrease in organ acceptances for lungs without LRT could skew the data and not show true utilization.

UNOS staff clarified that there are multiple options, including special public comment, and that emergency policy actions are not the only method for more expedient policy actions. Committee members agreed that time is of the essence, and even a delay of a few months could be highly detrimental.

Members would like to receive monthly monitoring reports for any potential unintended consequences, especially in regards to lung utilization.

Vote: 14 yes, 0 no, 1 abstained.

Next steps:

The proposed emergency policy will be sent to the Executive Committee for review.

2. SARS-CoV-2 Summary of Evidence Suggested Revisions Review

The Committee chair reviewed

Major suggested edits:

- Add review of CDC data to information sources
- Clarify the definitions of upper and lower respiratory tract specimens
- Change wording on lower respiratory testing for SARS-CoV-2 in lung donors, that it is anticipated to significantly decrease the risk of unrecognized infection. Include additional sources on upper versus lower respiratory testing, currently validated assays for lower respiratory specimen testing, and CDC-investigated potential donor-derived transmission events
- Add language about potential changes in allograft quality related to COVID-19 infection
- Add information on potential peri-operative risks following recovering from COVID-19

Summary of discussion:

Members agreed that there needed to be additional information on the risk of peri-operative complications in living donors who were recently recovered from COVID-19. They felt the study cited was extremely powerful, and wanted to ensure to disseminate the information to protect living donor safety. Members were not in agreement about the exact phrasing of this particular addition, and needed to discuss further. Members did not have concerns with any of the other suggested edits.

Next steps:

Members will discuss further and vote on changes by email.

Upcoming Meetings

- April 26, 2021, 12 pm EST, Teleconference
- May 4, 2021, 3 pm EST, Teleconference
- May 24, 2021, 12 pm EST, Teleconference

Attendance

- **Committee Members**
  - Ann Woolley
  - Charles Marboe
  - Debbie Levine
  - Gary Marklin
  - Heather Stevenson-Lerner
  - Helen Te
  - Jason Goldman
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Marian Michaels
  - Meenakshi Rana
  - Raymund Razonable
  - Ricardo La Hoz
  - Saima Aslam
  - Stephanie Pouch
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **CDC Staff**
  - Ian Kracalik
  - Pallavi Annambhotla
- **FDA Staff**
  - Brychan Clark
- **UNOS Staff**
  - Abigail Fox
  - Cassandra Meekins
  - Courtney Jett
  - Darby Harris
  - Emily Womble
  - Laura Cartwright
  - Leah Slife
  - Liz Robbins Callahan
  - Matt Prentice
  - Nicole Benjamin
  - Rebecca Murdock
  - Roger Brown
  - Sandy Bartal
  - Tina Rhoades
- **Other Attendees**
  - DongHeun Lee