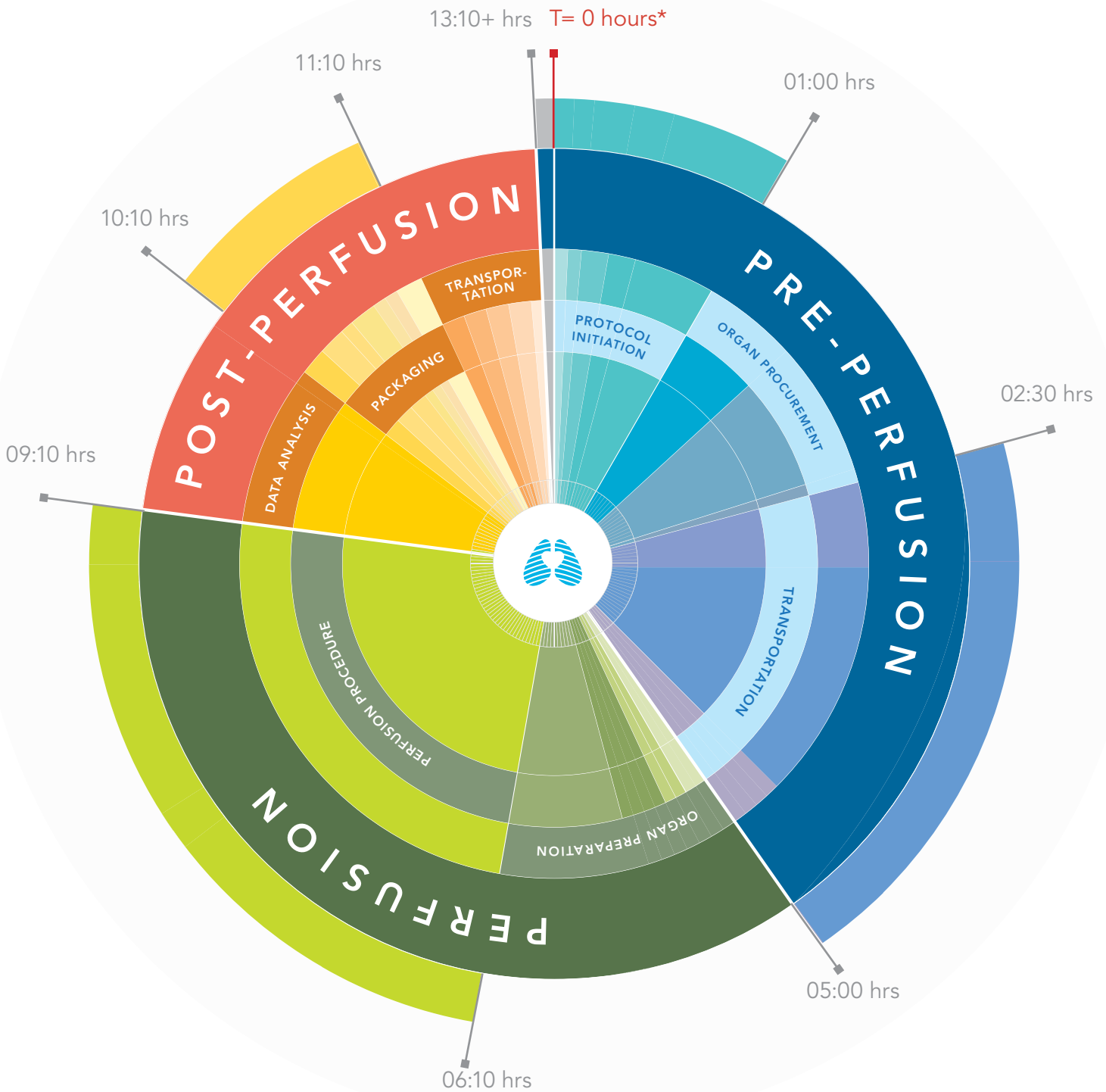
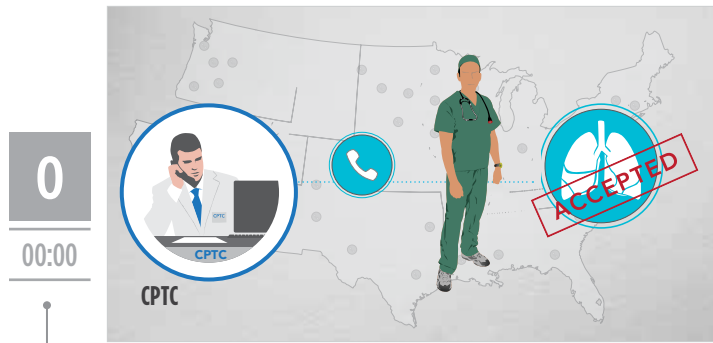


Projected EVLP Timeline

**Times shown are approximate; actual times will vary based on logistics and case specifics.*





The process begins when an organ procurement organization (an OPO) generates a match run list for suitable organs from a deceased donor. The OPO utilizes DonorNet to electronically notify transplant centers and make offers to the different transplant centers' potential recipients. Allocation continues until a recipient is located which may take only 2 or 3 notifications, but sometimes up to 20 or 40. In about 25% of the cases, lungs are placed for transplant.



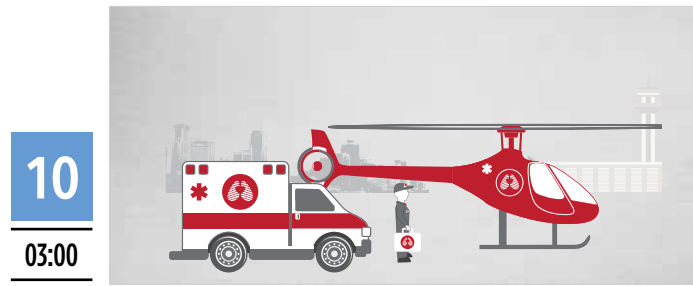
Next, the case is initiated in our CMX system. Referral information includes UNOS ID number, date and time of referral, participating OPO, transplant center, and the physician at TGH who will be participating in the case. The blood type, chart, and authorization/disclosure form are received for review by the EVLP specialist at LB-1, at which time the procedure room is assigned.



The LB-1 procedure room is prepped, and all case consumables are put in place by the clinical staff following the CMX checklist.



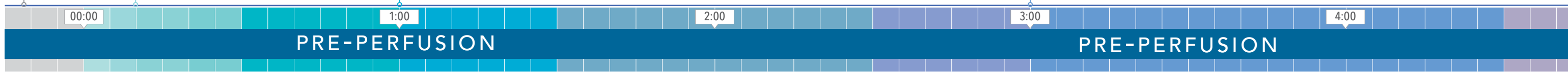
An IT specialist establishes a video conferencing link for collaborative online meeting during the case.



Transport arrives at the local airport and the lungs are transferred to the aircraft.



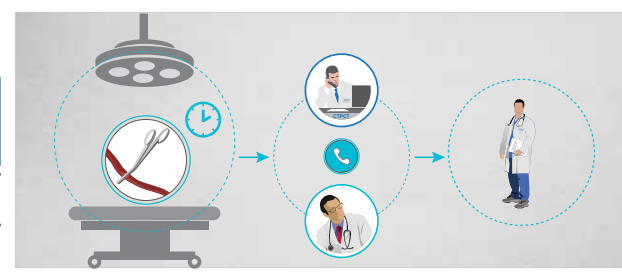
Ongoing: Communication continues between the primary EVLP specialist and the medical transport provider, including flight status and updates on the ground medical transport status.



If a transplant surgeon at one of our participating trial centers accepts a lung but considers it marginal, they'll direct it to the LB-1 facility for EVLP. The details of the case are communicated, including demographics, surgery time, reason for EVLP, and organ quality.



With the estimated time of arrival at LB-1, the CMX alerts security of the incoming ground medical transport.



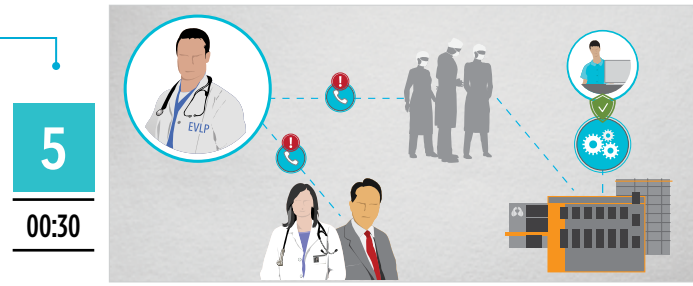
The donor cross clamp time is communicated to the primary EVLP specialist.



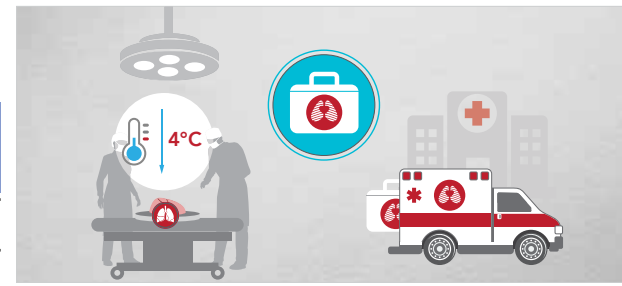
When the flight arrives at the airport local to LB-1, the lungs are transferred to the ground medical transport.



If the donor and lungs meet the inclusion criteria for the clinical trial, our specialist works with the supplying OPO to coordinate transportation to LB-1, including air and ground medical transport.



The entire team of EVLP specialists, QA lead, and EVLP technicians proceed to LB-1. IT performs system checks. The medical director and general manager are alerted for remote monitoring of the case.



The lung is explanted and packaged according to OPTN policies and loaded onto ground medical transport.



As soon as ground medical transport is en route to LB-1, the sterile field is established and the EVLP specialist scrubs in.

14

05:00



The lungs are received at LB-1 and checked in. This includes confirming the UNOS number and that the correct organ is going to the assigned procedure room.

At this point the CMX automatically sends out a notification to the participating centers including the OPO, the transplant center, LB-1 clinical staff, and the medical advisory team at Toronto General Hospital.

17

05:05



A back table evaluation takes place, noting organ condition.

19

05:30



The perfusion circuit is set up, primed and brought to room temperature.

21

06:10



Perfusion continues over a 3-6 hour period, with ongoing CMX documentation and assessment steps.

These include bronchoscopy, X-rays and blood gas analysis, both on a scheduled and as needed basis.

5:00

6:00

7:00

8:00

9:00

PERFUSION

PERFUSION

15

05:05



The lungs are moved to the procedure room and packaging is inspected. Pictures are taken of the internal and external labels, then blind verification of the UNOS number, and blood type are completed in the CMX.

18

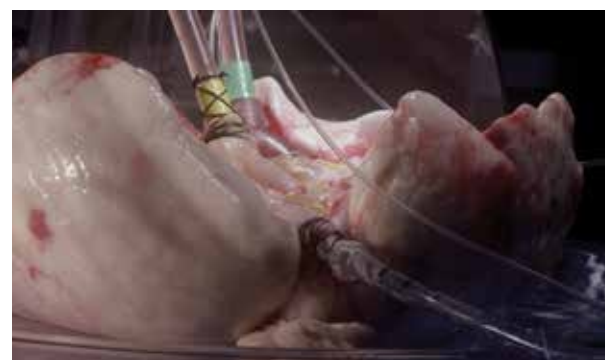
05:10



Cannulation, intubation, and back table flush are performed. A pre-EVLP biopsy is taken.

20

06:10



Then lungs are transferred to the procedure table. Pressure lines are zeroed. The perfusion pump is started and cannulas are connected to the perfusion circuit, which starts the EVLP procedure clock.

22

06:10



Throughout this period, the IT specialist in our command center facilitates visual and data communication with Toronto General Hospital and the transplant surgeons.

16

05:05



The lungs are removed from the shipping container and moved to the sterile field.

23

At the 3-hour mark of perfusion, the collective team makes an initial assessment of the lungs.

09:10

If the transplanting surgeon decides to transplant, the primary EVLP Specialist facilitates transportation.

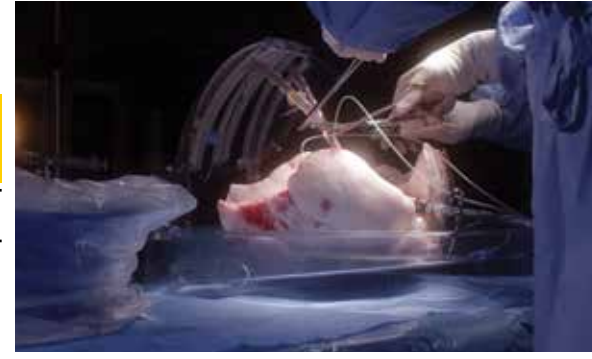
24

After all data is collected, the case is locked and a disposition email is automatically sent to the TGH surgeon, the transplant surgeon, and finally to the OPO, which confirms transfer of custody to the transplant center.

10:10

26

10:20



Cannulas are clamped and the inflated lungs are disconnected and moved to the back table. The EVLP procedure clock is stopped.

28

10:55



LB-1 clinical staff then prints the CMX perfusion record for inclusion in the shipping container.

30

11:10



Lungs are loaded into ground medical transport, and the transplant center is advised of departure from LB-1.

31

11:10

Task List	Tasks Completed: 1/1	Task List (Cont.)	Tasks Completed: 1/1
EVLP Perfusion	Completed	Perfusion A-Flow 01:00	Completed
EVLP Substrate Removal	Completed	Scan and Upload Consent Chart	Completed
IT Preparation/Transfer to	Completed: 1/1/15	Contact 10 Stead Damages H&I	Completed
Case Record Creation	Completed	Vital Data Entry 02:00	Completed
Transplant Consent Received	Completed	Contact 10 Stead Damages H&I	Completed
Designate Operating Room	Completed	Vital Data Entry 03:00	Completed
Designate Primary Case Specialist	Completed	Contact 10 Stead Damages H&I	Completed
Designate Case Physician	Completed	Vital Data Entry 04:00	Completed
See Cross-Check Table	Completed	Contact 10 Stead Damages H&I	Completed
Define Transport	Completed	Vital Data Entry 05:00	Completed
Define Center Metrics	Completed	Contact 10 Stead Damages H&I	Completed
Validate Procedure Steps in CMX	Completed	Vital Data Entry 06:00	Completed
Configure Video System, Send Test Video	Completed	Contact 10 Stead Damages H&I	Completed
Identify Items for Inventory	Completed	Vital Data Entry 07:00	Completed
Custom Instrument Count	Completed	Contact 10 Stead Damages H&I	Completed
211/212/213/214/215/216/217/218/219/220/221/222/223/224/225/226/227/228/229/230/231/232/233/234/235/236/237/238/239/240/241/242/243/244/245/246/247/248/249/250/251/252/253/254/255/256/257/258/259/260/261/262/263/264/265/266/267/268/269/270/271/272/273/274/275/276/277/278/279/280/281/282/283/284/285/286/287/288/289/290/291/292/293/294/295/296/297/298/299/300/301/302/303/304/305/306/307/308/309/310/311/312/313/314/315/316/317/318/319/320/321/322/323/324/325/326/327/328/329/330/331/332/333/334/335/336/337/338/339/340/341/342/343/344/345/346/347/348/349/350/351/352/353/354/355/356/357/358/359/360/361/362/363/364/365/366/367/368/369/370/371/372/373/374/375/376/377/378/379/380/381/382/383/384/385/386/387/388/389/390/391/392/393/394/395/396/397/398/399/400/401/402/403/404/405/406/407/408/409/410/411/412/413/414/415/416/417/418/419/420/421/422/423/424/425/426/427/428/429/430/431/432/433/434/435/436/437/438/439/440/441/442/443/444/445/446/447/448/449/450/451/452/453/454/455/456/457/458/459/460/461/462/463/464/465/466/467/468/469/470/471/472/473/474/475/476/477/478/479/480/481/482/483/484/485/486/487/488/489/490/491/492/493/494/495/496/497/498/499/500/501/502/503/504/505/506/507/508/509/510/511/512/513/514/515/516/517/518/519/520/521/522/523/524/525/526/527/528/529/530/531/532/533/534/535/536/537/538/539/540/541/542/543/544/545/546/547/548/549/550/551/552/553/554/555/556/557/558/559/560/561/562/563/564/565/566/567/568/569/570/571/572/573/574/575/576/577/578/579/580/581/582/583/584/585/586/587/588/589/590/591/592/593/594/595/596/597/598/599/600/601/602/603/604/605/606/607/608/609/610/611/612/613/614/615/616/617/618/619/620/621/622/623/624/625/626/627/628/629/630/631/632/633/634/635/636/637/638/639/640/641/642/643/644/645/646/647/648/649/650/651/652/653/654/655/656/657/658/659/660/661/662/663/664/665/666/667/668/669/670/671/672/673/674/675/676/677/678/679/680/681/682/683/684/685/686/687/688/689/690/691/692/693/694/695/696/697/698/699/700/701/702/703/704/705/706/707/708/709/710/711/712/713/714/715/716/717/718/719/720/721/722/723/724/725/726/727/728/729/730/731/732/733/734/735/736/737/738/739/740/741/742/743/744/745/746/747/748/749/750/751/752/753/754/755/756/757/758/759/760/761/762/763/764/765/766/767/768/769/770/771/772/773/774/775/776/777/778/779/780/781/782/783/784/785/786/787/788/789/790/791/792/793/794/795/796/797/798/799/800/801/802/803/804/805/806/807/808/809/810/811/812/813/814/815/816/817/818/819/820/821/822/823/824/825/826/827/828/829/830/831/832/833/834/835/836/837/838/839/840/841/842/843/844/845/846/847/848/849/850/851/852/853/854/855/856/857/858/859/860/861/862/863/864/865/866/867/868/869/870/871/872/873/874/875/876/877/878/879/880/881/882/883/884/885/886/887/888/889/890/891/892/893/894/895/896/897/898/899/900/901/902/903/904/905/906/907/908/909/910/911/912/913/914/915/916/917/918/919/920/921/922/923/924/925/926/927/928/929/930/931/932/933/934/935/936/937/938/939/940/941/942/943/944/945/946/947/948/949/950/951/952/953/954/955/956/957/958/959/960/961/962/963/964/965/966/967/968/969/970/971/972/973/974/975/976/977/978/979/980/981/982/983/984/985/986/987/988/989/990/991/992/993/994/995/996/997/998/999/1000	Completed		

The post procedure checklist is initiated in CMX to close out the case.

10:00

11:00

12:00

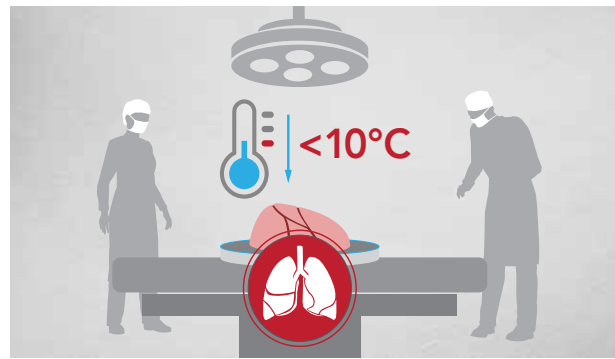
13:00

POST-PERFUSION

POST-PERFUSION

25

10:10



Over an approximately 10 minute period, the lungs are cooled from normothermic to less than 10° Celsius.

27

10:25



The lungs are then flushed with Steen™ and stored in cold preservation solution. The EVLP specialists remove the cannulas. The EVLP specialists staple the trachea and perform a post-EVLP biopsy.

*Steen™ is investigational in the USA and is included in the IDE.

29

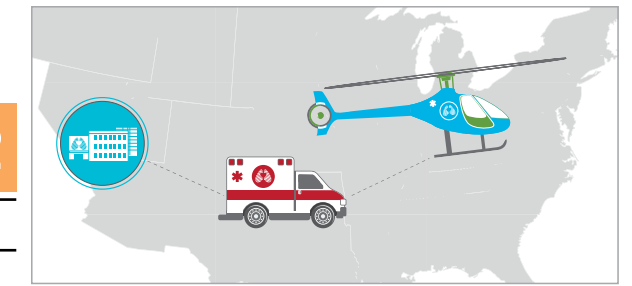
11:00



The organ is then packaged according to OPTN policy. Pictures are taken of internal and external labels. Original tissue typing materials are included in the packaging with the original donor chart and perfusion record. The organ is then brought to the loading dock by LB-1 clinical staff for transport.

32

11:40



Ground medical transport arrives at the airport and the lungs are loaded on the flight to the transplant center.

33

13:10



The lungs arrive at the destination airport and are transferred to ground medical transport. Finally, the lungs reach the transplant hospital and are transferred to custody of the hospital staff by the ground medical transport personnel.