A Longitudinal and International Survey of Transplant Centers during the COVID-19 pandemic (LIST-COVID-19)

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Outline

1. Synopsis

Title	A Longitudinal and International Survey of Transplant Centers during the COVID-19 pandemic
Short title	LIST-COVID-19
Design	Prospective, longitudinal and international study (3 surveys to be administered over 2 years)
Participants	Transplant professionals and leadership
Planned sample size	500
Planned study period	2 years
Objectives	a) To document and compare transplant trajectories and volumes across centers during the COVID-19 pandemic • Compare them by country/jurisdiction, COVID-19 incidence, solid organ transplant • Identify real-time challenges to transplantation and access to transplantation, and propose mitigation strategies b) To capture and report current transplant practices and immunosuppression management across transplant centers c) To assess the associations of health system-related factors, transplant volumes, access to transplantation, transplant practices and immunosuppression management d) To longitudinally follow this data and investigate how each changes over the next two years

2. Scientific Background and Literature Summary

a) **The COVID-19 pandemic has impacted and overwhelmed health care systems globally** and was declared a pandemic by the World Health Organization on March 11, 2020. [1] As of May 2 2020, 3.5 million people are confirmed to be infected with SARS-CoV-2; over 240,000 have died. [2]

b) **Patients waiting for a transplant are being indirectly affected by this pandemic**, [3-5] as several centers have had to reduce or stop their transplant activity. [6-8] Reasons for this are summarized in table 1. [7,9-18] Living donations are being cancelled to avoid exposure of healthy donors to the hospital. [16]

c) **In patients with end-organ failure, a solid organ transplant is a lifesaving procedure;** over 200 Canadians die annually while waiting for a transplant. [19]. Preliminary Italian data shows a 25% reduction of recovered organs has already occurred during the first 4 weeks of the COVID-19 outbreak. [14] However, the proportion of this impact on current transplant volumes and the anticipated decline in the upcoming year is not known. This may vary by organ, due to the fact that some organs are considered less emergent. For example, due to the availability of dialysis, patients with kidney failure may be disproportionately affected. [9,17]

Table 1: Factors affecting transplantation volume

Donor related
- Donor screenings
- Limitations of current diagnostic tools
- Unavailability of timely testing results
- Risk of SARS-CoV-2 transmission
- Community transmission
- Logistics of donor procurement

Recipient related
- Lack of clarity on immunosuppression management
- Drug interactions
- Unclear prophylaxis and treatment options
- Unavailability of timely testing results
- Donor transmission

System related
- Resource utilization
- ICUs overwhelmed
- Resources being re-directed
- Low manpower
- Risks to health care workers
- Availability of personal protective equipment
- Scarce medical resources

COVID-19 related
- Lack of treatments
- Nosocomial and community related
- Lack of research and evidence
- Preventative measures to avoid community spread
- Severity, extent, trajectory and duration of the pandemic is uncertain

d) **The effect of COVID-19 on transplantation volumes may vary significantly across countries, health system and jurisdictions**. However, this might not be as intuitive as one would expect. On one hand in "resource-rich" countries, patients may have better access to medications, viral testing, clinical trials, and other resources, but the health system varies significantly and not all patients will have insurance. In addition, incidence of COVID-19 significantly impacts donor availability and thus transplantations. The latter is especially true if transplant activities depend more on deceased donation than living donation. [14] Quebec and Spain perfectly exemplify this. Spain is a leader in deceased donation and has the best donor rates in the world, [20,21] but it also has the second-highest confirmed cases of COVID-19. [2] Similarly, in Quebec kidney transplant activity is predominantly from deceased donor (80-85% versus 50-70% in rest of Canada), [19] but Quebec also has the highest number of COVID-19 cases and deaths in Canada. [2] Both factors will influence transplantation in these regions. Thus, the impact COVID-19 on transplantation will vary by country, health system and jurisdiction but the true scope of this problem is unclear.

e) **The prevalent transplant population is immunosuppressed and at higher risk for adverse outcomes**. While the overall mortality rates in patients with COVID-19 are reported to be 2-3%, [16,22] in transplant recipients these numbers range from 4-28%. [23-26] Also, transplant recipients have higher rates of

pneumonia, acute respiratory distress syndrome and ICU admissions when compared with the general population. [23]

f) **Transplant recipients need immunosuppression but how best to manage these medications in asymptomatic and symptomatic patients are not known.** Current management and treatment practices are anecdotal and suffer from reporting bias. [27-46] Transplant recipients may need induction immunosuppression perioperatively that causes significant T-cell depletion and maintenance immunosuppression thereafter to prevent rejection. Immunosuppression is considered a risk factor for adverse outcomes as it can increase susceptibility to infection. [13] However, some have proposed that immunosuppressive drugs could be protective against COVID-19. [47,48] Thus, there is wide heterogeneity in managing transplant recipients with COVID-19 and [8,13,27-46] sharing of experience worldwide is being called upon to provide a foundation for clinical care. [16] Some online registries have been created that entail voluntary reporting of the data, [25,26] but physicians at the epicenter of this pandemic may not have the time to report their patients and their outcomes.

g) **Lastly, the higher impact of the COVID-19 pandemic on vulnerable populations is a growing concern.** [49-51] Race, sex, gender and socio-economic status are known to decrease access to transplantation and negatively impact transplant outcomes. [52-61] The pandemic will, thus, inadvertently affect these vulnerable populations and their access to transplantation even more but how exactly these factors vary by country, health system and region is not known.

3. Objectives

a) To document and compare transplant trajectories and volumes across centers during the COVID-19 pandemic
   - Compare them by country/jurisdiction, COVID-19 incidence, solid organ transplant
   - Identify real-time challenges to transplantation and access to transplantation, and propose mitigation strategies

b) To capture and report current transplant practices and immunosuppression management across transplant centers

c) To assess the associations of health system-related factors, transplant volumes, access to transplantation, transplant practices and immunosuppression management

d) To longitudinally follow this data and investigate how each changes over the next two years

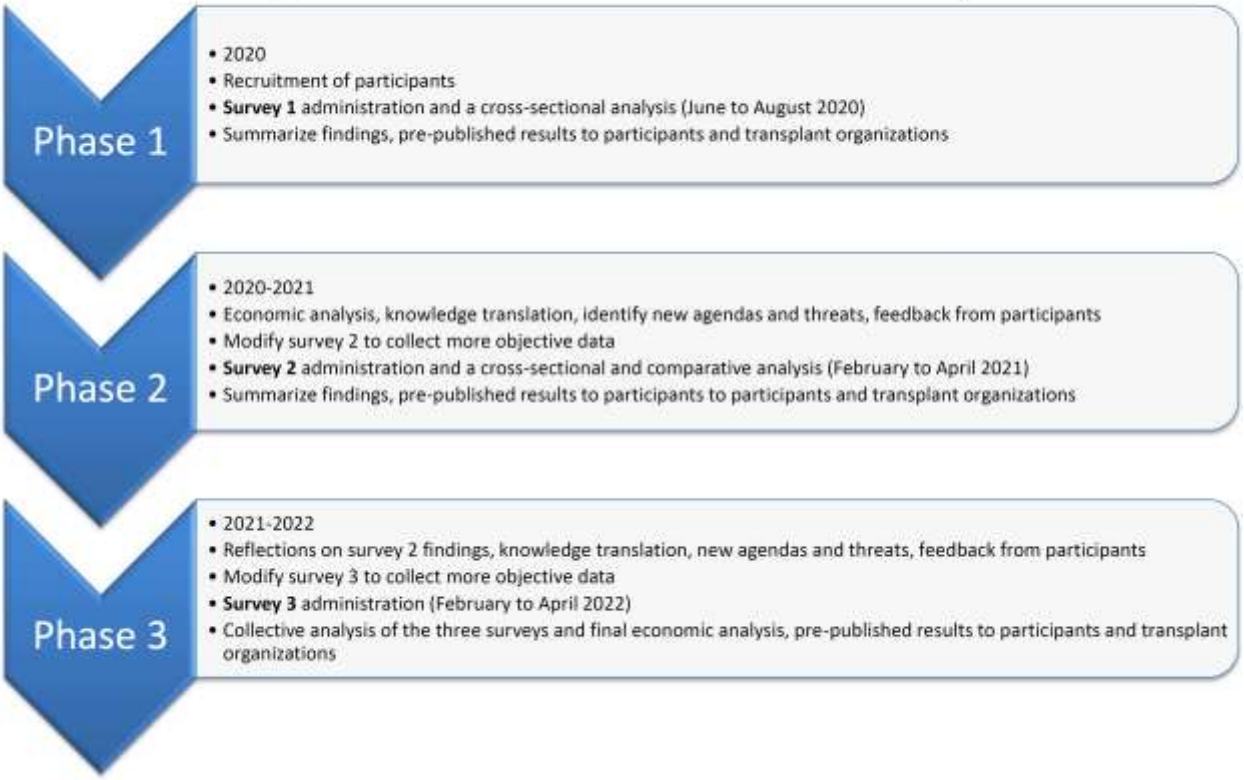
4. Methods

a) ***Approach and timeline***: The LIST-COVID-19 is a prospective, longitudinal and international study. Data will be collected in real-time as the pandemic evolves via three separate surveys conducted 6-12 months apart. The outline and timeline are presented in Figure 1.

b) ***Survey design*****:** Survey-1 has been designed using an iterative process that involved two transplant nephrologists, two transplant surgeons, one health services researcher and (TBD))(Appendix 1). The scope of the survey questions were 1) current and previous transplant volume 2) current immunosuppression practices in symptomatic and asymptomatic recipients 3) current treatments and prophylaxis practices 4) observed outcomes 5) current and anticipated threats to transplant volumes 6) anticipated risks to vulnerable populations. For content we conducted a thorough review of the transplant literature being reported in real-time by the Transplantation Society (TTS), the Canadian Society of Transplantation, and the American Society of Transplantation, surrounding COVID-19 and used information from Webinars and discussion boards created by these national and international societies. For methodological guidance on survey creation, we sought the works of Boynton, Gillham, and

Oppenheim. [62-64] We ensured questions are clear, simple and neutral. [65] We reviewed all items for relevance, redundancy and wording. To minimize bias due to predisposition towards socially acceptable answers, i.e. social acceptability bias, we formulated the questions to be as neutral as possible. [66] Minimal demographic data is being collected as personal questions have been shown to deter participation. [67,68] To reduce the risk of acquiescence bias, where applicable, the Likert scale was used. [69] The follow-up surveys will be administered using the same set of questions 6-12 months later, but we will request more granular and objective data. If any new threats and agendas emerge that were not envisaged before, they will be added to the second survey. Survey three will be modified similarly.

Figure 1: Outline and timeline of the LIST-COVID-19 study



c) ***Study population*:** We are using purposive sampling to determine our study population i.e. a sample that can be logically assumed to be representative of the population of interest. [70,71] This is the transplant professionals and leadership at each transplant center and this method is argued to be an appropriate recruitment strategy for longitudinal studies. [71] To minimize recruitment bias, several sources are being used to develop this list. A sample of transplant centers in the U.S. and Canada has already been created from previous work of Dr. Segev and for Canada we are using the Canadian Society of Transplantation platform. [8] For other countries, we will use a well curated list of centers and directors developed by the TTS and (TBD). Each participant will be requested to fill out the survey once, or identify someone else at their center. No exclusionary criteria will be applied.

d) ***Recruitment*:** Our recruitment goal is 500. To ensure we achieve a heterogeneous sample and minimize the risk of selection bias we agreed on meeting the following quotas. At least 30% of the participants should represent non-kidney transplant organs. At least 50 different countries should be represented of which at least 30% must be from low- or middle-income countries and at least 30% should be from the top 10 countries with the highest incidence of COVID-19. If needed, we will increase our

recruitment goal to meet these quotas.

e) ***Survey administration*****:** The surveys will be administered electronically using the Qualtrics XM platform and responses will be stored in a password protected Qualtrics database accessible to the research assistant. An internet link to the questionnaire will be sent to each participant via email which contains an anonymous ID. Surveys will be self-administered as this has been shown to minimize examiner and social desirability bias and increase response rates. [69,72,73] We will send out two additional email reminders, one week apart, and request an alternate individual should the participants be unable to complete the survey. To increase the response rate and minimize attrition rate, we will offer five $100 gift certificates following each survey cycle to participants via a raffle draw.

f) ***Data collection and analysis*****:** The data collected in the study will provide longitudinal trajectories and comparisons but it is designed with sample sizes large enough to allow for cross-sectional comparisons during each step. Descriptive statistics will be used as appropriate to describe survey responses. For our primary analysis, we will compare the responses between countries, organs and COVID-19 incidence as reported by the Johns Hopkins COVID Map data and perception of the participants. [2] An appropriate regression model or Fischer's exact test will be used. A health econometric analysis of how health system-related factors influence some of the risks and challenges to transplant will be done with the support of the Canadian Donation and Transplantation Research Program. This will be done to determine the effect of country's economic activity (gross domestic product (GDP) and gross national income), health system (healthcare costs as a percentage of GDP, % of healthcare costs paid by government), health financing (universal vs. non-universal insurance system, government-funded vs. private-funded vs. public – private funded), health workforce/capacity (number of physicians per capita, number of hospital bed per capita) on the response to each question. Following survey 3, a collective and comparative analysis will be done to report trends and outcomes and how the above mentioned factors and proposed mitigation steps modified them. For Canada and the U.S. a sub-analysis will be conducted by province/jurisdiction.

5. **Significance and Impact:**

According to the WHO's, Global Observatory on Donation and Transplantation data, in 2017, 139,024 organs were transplanted across the world that included organs from 37,447 deceased donors. [74] A single deceased organ donor can donate several organs and save up to eight people. However, decreased availability of donors will significantly decrease transplant volumes and patients will die waiting for a transplant. In Canada alone, over 4,000 people are waiting for an organ transplant. [19] Thus, the pandemic has created a true emergency not just for health systems and patients with COVID-19 but also for those with end-organ failure who will die without an organ. Evidence is needed to inform mitigations steps and develop clinical guidelines to minimize the impact of COVID-19 and future pandemics on transplantation. Our project is of the highest impact as it will collect real-time evidence and propose real-time mitigation strategies to support the rapid response to COVID-19 at a global stage. In addition, immunosuppression management decisions are anecdotal and there is an immediate need to systematically gather data to inform clinical guidelines, research priorities, and clinical practice. We will assess how socio-economic factors may influence the outcomes of transplant recipients with COVID-19 and access to transplantation in the upcoming year. This can influence the development of services to those who require it the most. Data gathered and summarized results following each survey, will be disseminated to all participants and directly reported to transplant leadership. Our longitudinal design will address, and compare ongoing responses. In the midst of this pandemic, it is critical to improve international coordination and communication and to learn more from the experiences of others. Our study is designed to gather data from centers across the world and is perfectly aligned to amplify existing national and international networks.

6. Data Management and Safety

a) Potential risks and benefits

This is a prospective but observational study without any intervention. Participants' responses will be de-identified and only a collective analysis will be done and reported by country/region. No risks or direct benefits to the participants are recognized. Participation is voluntary and participants may withdraw from the project at any time. We will send them the pre-publication results.

b) Data management and confidentiality

The surveys will be administered electronically using Qualtrics XM platform. The responses will be stored in a password protected Qualtrics database accessible by only one research team member. Following data collection, participant information procured in the course of this study will be de-identified and a collective analysis will be performed. Only this collective analysis will be disseminated. If clarification is needed on written surveys, only those who consented and provided their email will be contacted. The study data will be stored for seven years by the researcher responsible for the study.

c) Informed consent

Informed consent will be implied if participants complete the survey. Participants will be told that participation is voluntary and that they may withdraw from the project at any time.

7. Anticipated Timeline

As outlined in figure 1, this study will be conducted over two years.

8. Study funding

To be determined.

9. Obligations and ethical requirements

The study will be conducted in accordance with the International Conference on Harmonization Guidelines for Good Clinical Practice, the principles of the Declaration of Helsinki and the Tri-Council Policy Statement (2014). The Research Ethics Board (REB) at the McGill University Health Center will evaluate this study. The investigators will conduct the study in compliance with the protocol and any changes to the protocol will require written REB approval prior to implementation.

10. Publications

Upon completion of the study, the results will be submitted for publication/s to peer-reviewed journal/s. There is no commercial sponsorship involved, and therefore there is no potential conflict of interest that could delay publication.

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