UNIFIED INTERIM GUIDELINES OF THE PHILIPPINE SOCIETY OF NEPHROLOGY AND THE PHILIPPINE SOCIETY FOR TRANSPLANT SURGEONS FOR KIDNEY TRANSPLANTATION DURING THE COVID-19 PANDEMIC

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I. INTRODUCTION

With the recent suspension of the enhanced community quarantine in several regions of the country, there is a persistent clamor to gradually resume elective surgical services including those of solid organ transplantation, which is also a life-saving procedure for patients with end-organ failure. The COVID-19 pandemic however, remains a persistent health concern. With cases now approaching 30,000 nationwide, the hospitals' policies and resources remain focused on the treatment, control and eradication of the coronavirus.

In the midst of this, kidney transplant (KT) candidates remain hopeful that they can be transplanted soon in order for their quality of life and long-term survival to improve. However, we are also concerned because these same patients are highly susceptible to opportunistic infections and may contract the coronavirus infection in its most severe form, given their immunosuppressed state.

Therefore, in order for a safe and effective resumption of transplant clinical practices to remain feasible, we need to balance our patients' requirements for transplantation against the ongoing health crisis. Our ultimate objective is to maintain a high quality service in organ transplantation, while minimizing virus transmission and cross-infection among donors and recipients, and to all transplant physicians and other related allied health professionals. These interim guidelines are being set in order to help provide for a safe transition to the "new normal" of practice of transplant surgery and medicine.

II. GENERAL RECOMMENDATION ON DIAGNOSTIC, PERSONAL PROTECTIVE EQUIPMENT (PPE), FACILITY AND REGIONAL PRACTICE

A. COVID Awareness

1. Know your national, regional and local epidemiologic profiles on the SARS-COV2 infection by getting updated on the incidence and prevalence rates of COVID-19.
2. Be aware of any government or specific hospital mandates on the timing of resuming transplant practices in your area and institution.
3. It is generally recommended that a sustained reduction of new COVID-19 cases for at least 14 days in your area of practice is needed before deciding to resume transplantation.

B. Diagnostic and testing capabilities for SARS-COV2 Infection

1. Ensure availability of Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) testing kits for patients and hospital staff.
2. GeneXpert system, when available, is a helpful tool in hastening the documentation of SARS-COV2 infection and can facilitate the timely screening of potential donors and KT candidates.
3. Rapid Antibody Testing is not recommended as a screening tool because it cannot diagnose active COVID infection reliably. Both IgM and IgG appear late in the course of the disease.

C. Personal Protective Equipment (PPE)

1. Know your local availability of PPE and develop a regular supply chain with stored inventory of at least a month.
2. Develop policies and procedures including instructional materials for proper donning/doffing of PPE.
3. Be aware of the guidelines on the rational use, extended use, reuse and reprocessing of PPEs.

D. Local Facility Capacity

1. Know your local facility's capacity (rooms, beds, ICU, ventilators) including OR capacity to provide regular disinfection and sterilization services.
2. Consider also engineering issues (retrofitting and conversion of operating room suites to negative flow ORs for transplant surgery, installation of HEPA filters) and possibly assignment of designated OR suites exclusively for transplantation purposes.

III. GENERAL RECOMMENDATION ON TRANSPLANT CANDIDATES

A. Pre-emptive Kidney Transplantation

1. Pre-emptive KT candidates should resume their pre-transplant preparation and be given access to transplantation in order for them to avoid the complications and high mortality risk resulting from chronic dialysis.
2. This is more relevant at this time of the pandemic because the indefinite suspension of their access to transplantation during the extended community quarantine may mean transitioning to chronic hemodialysis.
3. These KT candidates are unique subsets of patients who have marginal renal function but are not clinically decompensated (no signs and symptoms of uremia).
4. They may not manifest life-threatening symptoms that warrant emergent therapy but they are considered to benefit the most from KT.
5. The long-term survival of a pre-emptive KT recipient is higher compared to their counterparts who remain on dialysis because the former are spared of the sustained chronic ill-effects of dialysis which include progressive cardiovascular disease and renal osteodystrophy.
6. A contemplated pre-emptive KT should follow the recommended risk stratification and prioritization protocol as described in Section III-C of this guideline.

B. Deceased Organ Donation

1. We recommend the temporary suspension of all deceased organ donation retrieval procedures for the following reasons:
    a. Although current molecular screening tests such as the Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) is an accepted screening for presence of SARS-COV2, the speed with which result of RT-PCR as of the present time can be available, is not ideal in a potential deceased organ donor.
    b. The risk of coronavirus transmission during organ retrieval to the surgical team and to the recipient is still uncertain.
    c. The outcome of a potential SARS-COV2 transmission to a recipient is also yet to be determined.
    d. The logistical requirements for organ procurement have become more challenging because of current travel and working restrictions.
    e. The lack of diagnostic capacity of RT-PCR to test the general population for SARS-COV2 infection limits our ability to assess the suitability of deceased organ donors.
2. Deceased donor organ procurement may be resumed once a more reliable and rapid diagnostic test for detection of the SARS-CoV2 infection is available.
3. In areas with no reported cases of COVID-19, deceased donor KT may be considered as long as limitations mentioned above are addressed accordingly.

C. Living Kidney Donation

1. For purposes of prioritization, the KT candidates should be classified according to two clinical categories based on their co-morbidity and immunological risks:

   a. Patient is considered LOW/STANDARD risk if ALL of the following are present:

      (1) Low to intermediate cardiac risk
      (2) No prior cardiac intervention in the past 6 months (i.e. angioplasty, coronary artery bypass surgery)
      (3) Negative CDC and flow cross-match
      (4) No CMV mismatch (i.e. +D/-R)
      (5) Panel Reactive Antibody (PRA) screening <20%
      (6) Negative donor-specific antibodies (DSA)
      (7) HLA mismatch </=3 or DR matched
      (8) Pre-emptive transplant or first transplant

   b. Patient is considered HIGH risk if any of the following is present:

      (1) Deceased donor kidney transplant
      (2) Re-transplants
      (3) PRA screening ≥20%
      (4) Positive for DSA
      (5) CMV (+D/-R) mismatch
      (6) Requiring desensitization
      (7) HLA Mismatch >3 or DR mismatched
      (8) Negative CDC but flow cross-match (+)

2. Based on these categories, we recommend prioritizing low/standard risk patients in the first few months post ECQ as we acquire more knowledge about coronavirus infection in transplantation.

3. In certain situations where clinical harm is likely to occur if transplantation is delayed for several weeks (e.g. patients with serious dialysis access issues with available living donors,) the pre-KT work-up should be expedited, followed by emergent transplantation in order to avoid the risk of death while on dialysis. They should be prioritized regardless of risk category.

4. High risk patients are generally not prioritized at this time because they may require prolonged hospitalization and a more intensive immunosuppression which may make them more vulnerable to infection, such as SARS-COV2.

IV. PRE-KT WORK-UP

A. Standard Work-up for Donors and KT Candidates

1. Aside from the standard pre-KT work-up, screening and clearance for recipients and donors, a comprehensive clinical assessment, based on a thorough history-taking and physical exam should be done to assure that both the potential donor and the transplant candidate are free of any transmissible infection, specifically, SARS-CoV2.

2. Although transmission of SARS-COV2 from donor to recipient has not been reported, the following are recommended in order to minimize its occurrence:

   a. Mandatory testing of both donor and recipient should be done with the use of RT-PCR.
   b. Donors with history of or suggestive of SARS-COV2 infection should be avoided.
   c. Only RT-PCR NEGATIVE donors and recipients will be allowed to proceed with donation and KT.

B. Screening for SARS-COV2 infection for donor and KT Candidates

1. As previously stated in Section II-B, RT-PCR is the recommended screening test for SARS-COV2 infection. Rapid Antibody Test is NOT recommended as standard screening.
2. The FIRST nasopharyngeal and oropharyngeal swab is recommended to be done at the start of the work-up and to be repeated at least 3 days before KT.
3. Both recipient and donor must be monitored for symptoms of COVID-19 and/or exposure to confirmed COVID-19 patients in the last two weeks preceding the date of the contemplated KT. Self-quarantine (when not on hemodialysis) or reverse isolation is recommended to avoid infection.
4. For the recipient, we suggest doing a chest x-ray at the start of work-up and chest x-ray OR plain chest CT scan at least 3 days before KT.
5. For the prospective kidney donor, chest X-ray should be done at the start of work-up and at least 3 days before the surgery.
6. The choice of doing Chest X-ray or Plain CT scan should be based on attending physician's clinical evaluation.

C. Informed consent

1. Both recipient and donor must be informed of the risk of acquiring COVID-19 infection at any time during the pre-transplant evaluation and even after kidney transplantation.
2. The attending physician must inform the potential transplant recipient of the risks and benefits of kidney transplantation, the advantages and disadvantages of postponement of transplantation and that of remaining on dialysis during this pandemic period.
3. Potential transplant candidates should be informed that as a consequence of immunosuppression, they have an increased risk of acquiring opportunistic infections, particularly COVID-19 in the time of pandemic. The importance of reiterating the risk of post-transplant infections has never been more important at this time of the pandemic.
4. The transplant candidate must be well informed of the potential sequelae of post-transplant COVID-19 infection including the possible risk of graft loss, return to dialysis and mortality.
5. The designated donor must not be under any form of coercion, intimidation or mitigating circumstance that might force him to proceed with organ donation during this pandemic period.
6. The potential kidney donor should also be informed of the following:
    a. The importance and need of the recipient for transplantation during this pandemic period.
    b. The risk of developing postoperative COVID-19 infection and its sequelae.

D. A Health Declaration Form (which includes history of COVID exposure, signs and symptoms of COVID infection and recent OPS/NPS swab RT-PCR testing) must be signed by all concerned parties:

1. All health care personnel participating in the transplant and donor processes
2. All transplant candidates and their designated donors
3. All accompanying persons of both recipient and donor

E. Timing of KT of transplant candidates who recovered from COVID infection.

1. There is no current data on the timing of KT of prospective recipients or donors who recovered from COVID-19. Hence, no recommendation can be made at this time.

V. PERI-OPERATIVE MANAGEMENT

A. Induction Therapy

1. Corollary to the prioritization of low risk recipient, use of monoclonal antibody is recommended.
2. As always the risk of infection, particularly SARS-COV2 infection should be discussed prior to induction therapy.

B. PPE Requirement inside the Operating Room (OR)

1. The recommended minimum level of PPE for both the donor and transplant surgical teams is Level 3, as defined in the guidelines for the Rationale Use of PPEs by the Philippine College of Surgeons.
    a. These include surgical scrubs, surgical cap, goggles or face shields, N95 masks, sterile gowns, gloves and shoe covers.
    b. These should be worn by all personnel including the anesthesia team, all participating nurses, surgeons and assists.
    c. The use of proper PPEs shall be in accordance with the respective institutional guidelines.
2. Alternative options include the use of the following:
    a. Half or full-face elastomeric masks
    b. Face shields should be worn on top of magnifying loupes
    c. Powered air-purifying respirators (PAPR) are not necessary but may be used:
        (1) These are industrial grade re-usable respirators which were not routinely used and tested in the surgical setting.
        (2) Their initial use require some investment because of their high costs.
        (3) These need specific disinfection or sterilization methods which should be followed strictly as specified by the manufacturers.
        (4) Although there may be some potential advantages for their use, especially for aerosol-generating procedures, they currently not recommended for routine use and should be only used at the discretion of the transplant personnel.

C. Surgical technique for living donor nephrectomy

1. Laparoscopic donor nephrectomy (LDN) may be done in consideration of the following:
    a. As opposed to traditional open surgery, the benefits of LDN are well established and includes less postoperative pain, faster convalescence, shorter length of hospital stay and better cosmesis.
    b. The advantages of LDN translate to a lesser risk of exposure to nosocomial infection and also less change of developing pulmonary complications.
    c. In order to obtain the maximal benefits derived from LDN, only experienced laparoscopic surgeons should perform this procedure.
    d. Safety precautions on the control of fumes related to the application of pneumoperitoneum and use of energy-based sealing devices should be observed in order to minimize the potential ill-effects of aerosolization.
2. In the absence of experienced laparoscopic donor surgeons, an open donor nephrectomy may be opted.
    a. Only surgeons experienced in open donor nephrectomy should be assigned to undertake this procedure.

VI. IMMEDIATE POST-OPERATIVE MANAGEMENT

A. PPE Requirement of the Transplant Team in the Postoperative Period

1. The recommended minimum level of PPE for both the donor and transplant surgical and medical teams is Level 3.
    a. These include surgical scrubs, surgical caps, goggles or face shield, N95 masks, sterile gowns, gloves and shoe covers.
    b. These are necessary in order to avoid any transmission of potential SARS-COV2 infection from the health care personnel to the transplant recipient.
    c. Reverse isolation protocol should be strictly observed at all times.

B. Monitoring for Signs and Symptoms of COVID-19.

1. A repeat nasopharyngeal and oropharyngeal swab testing and chest X-ray are recommended if the patient develops signs and symptoms that are suggestive of COVID-19.

VII. INFECTION CONTROL IN TRANSPLANT FACILITY AND HOUSEHOLD PREPAREDNESS

A. Health Care Workers (HCW)

1. Determine the minimum effective OR workforce and ensure its availability through proper coordination among staff and physicians.
2. Specialized personnel (transplant coordinators and nurses) should be assigned exclusively to attend to transplantation services and should never be assigned to areas taking care of COVID-19 patients.
3. All transplant personnel should be educated and trained on the proper use of PPEs as well as on all the necessary precautions that are needed to prevent SARS-COV2 transmission among patients and HCWs.
4. Doctors, nurses and all health care personnel should be honest about their own status and be tested or quarantined as deemed necessary based on their exposure or symptoms. No potentially infected staff should participate in the transplant procedure.
5. All participating personnel in the KT should be symptom-free and have SARS-COV2 negative swab result within 2 weeks before participating the surgery.
6. All transplant personnel should sign a Health Declaration Form as described in Section IV-D.

B. Accompanying Person/Caregiver/Watcher/ Any Person Who Will Stay With The Transplant Recipient and Donor

1. We suggest only one designated watcher/caregiver to assist the recipient or donor during hospitalization.
2. We suggest screening for SARS-COV2 infection by doing swab test and chest x-ray at least 3 days before assuming his role as an accompanying person.
3. If a private duty nurse is available, we suggest to avoid any accompanying person in the room, especially with the recipient.
4. All accompanying persons should sign a Health Declaration Form as described in Section IV-D.

VIII. TELEMEDICINE AND FACE-TO-FACE CONSULT

A. At any point during the donor and recipient evaluation, at least one face-to-face consultation is recommended in order to make a comprehensive clinical assessment of both patients.

B. Telemedicine is preferred to minimize “face-to-face” consults and physical contact between the physician and the patient.

1. Several online platforms may be utilized for this purpose.

2. This will also reduce the number of hospital visits and potential exposure to patients with COVID-19 or SARS-COV2 infection, which could occur at any point, during travel or within the hospital premises.
3. The requisitions for laboratory work-up and radiologic imaging studies may be sent through emails and other virtual platforms.
4. The interpretation of these results is preferably done online through these same platforms.
5. The pre-transplant evaluation shall be discussed by a multidisciplinary team of doctors which may include the attending nephrologist, transplant surgeon, infectious disease specialist and other physicians (as needed) to determine the suitability for transplantation.
6. Post-operative surveillance may be done in coordination with the transplant surgeon and the attending nephrologist and with other specialists as needed.
7. At least one face-to-face consult is also recommended postoperatively for both the recipient and the donor. This is necessary in order to assure that there are no gaps in clinical evaluation for potential postoperative complications.

C. A comprehensive history taking should include the following:

1. Elicit from the patient possible exposure to a COVID-19 patient.
2. Signs and symptoms (cough, fever, sore throat, difficulty of breathing, loss of taste or smell, diarrhea) suggestive of COVID-19.
3. Asymptomatic patients who had recent exposure to a COVID-19 patient must be advised to obtain RT-PCR and chest x-ray, and do self-quarantine for 14 days as prescribed by local and national health guidelines.
4. Symptomatic patients should be advised to seek help from designated health facilities for acute treatment.
5. The transplant candidate should always be informed regarding his or her increased vulnerability to COVID-19 as a result of continuous immunosuppression.
6. We recommend that the patient sign a written declaration/commitment form stating the absence of symptoms and exposure.

IX. MANAGEMENT OF POST-KT WITH COVID INFECTION

A. Clinical Features

1. Based on published case series, the clinical signs and symptoms of COVID-19 among kidney transplant recipients are similar to general population. Around 75-100% presented with pneumonia on chest x-ray during hospitalization.
2. There are however varying degrees of disease severity and mortality rates.
3. KT recipients require prolonged immunosuppression and may be anticipated to have more intense and prolonged shedding of virus, thus potentially increasing the risk of transmission to contacts including health care workers.

B. Diagnostic modalities

1. The mainstay of diagnostic testing is the use of RT-PCR to detect presence of virus in the respiratory tract swab samples.
2. If the clinical suspicion is high and the test is negative, the test may be repeated after 48 hours. While repeat testing is pending or if repeat testing is not available, then it is reasonable to manage the patients as having COVID-19.
3. We recommend doing chest X-ray as part of the diagnostic test. In a symptomatic patient where chest X-ray is negative, a plain chest CT scan is recommended.
4. Always remember that not all pneumonic processes are due to COVID-19 (even if the patient is RT-PCR positive). A complete clinical evaluation is necessary to rule out other differential diagnoses.

C. Treatment

1. The most common primary intervention is immunosuppressive dose reduction or temporary cessation. As with other infections, a balance between controlling infection and maintaining graft function should be taken into consideration.
2. At present most of the therapeutic regimen used for the treatment of COVID-19 are experimental or off-label. We strongly recommend obtaining informed consent prior to their use.
3. The different types of drug interactions between these medications used to treat COVID-19 and the patients' maintenance medications especially immunosuppressive drugs should always be considered. Please refer to Table 1 in the appendix for this purpose.
4. Prompt consultation with an Infectious Disease Specialist (IDS) is recommended. Treatment should be in accordance with the accepted protocols for the treatment of COVID-19 patients.

Comment: The current available clinical data on COVID-19 in kidney transplantation are all based on case series and expert opinions. We will update these interim guidelines as new evidences become available.

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APPENDIX

TABLE 1. Potential Importance of Drug–Drug Interactions Between Immunosuppressive Drugs and Investigational COVID-19 Treatments and Recommendations With Grading in Brackets

	(Hydroxy)chloroquine	Lopinavir/Ritonavir (Kaletra)	Darunavir (Prezista)	Darunavir/Cobicistat (Rezolsta)	Favipiravir, Remdesivir, Tocilizumab (Investigational)
Tac					
Risk level	Moderate—major	Major	Major	Major	No information available
Outcome	QT-interval prolongation.	Increased Tac concentrations; may result in an increased risk of Tac toxicity	Increased Tac concentrations; may result in an increased risk of Tac toxicity	Increased Tac concentrations; may result in an increased risk of Tac toxicity	
Our recommendations	QT interval monitoring (required)	Consider a Tac dosing regimen of 0.5–1 mg once weekly and close TDM (highly recommended)	If RTV boosted: Consider a Tac dosing regimen of 0.5–1 mg once weekly and close TDM. If unboosted: Close TDM (highly recommended)	Consider a Tac dosing regimen of 0.5–1 mg once weekly and close TDM (highly recommended)	
CsA					
Risk level	Moderate	Moderate-major	Major	Major	No information available
Outcome	Increase the concentration of CsA may result in an increased risk of CsA toxicity	Increased CsA concentrations; may result in an increased risk of CsA toxicity	Increased CsA concentrations; may result in an increased risk of CsA toxicity	Increased CsA concentrations; may result in an increased risk of CsA toxicity	
Our recommendations	QT interval monitoring (required)	Consider a CsA dosing regimen of 25 mg every 1–2 days and close TDM. ! possible delay in Tmax (highly recommended)	If RTV boosted: Consider a CsA dosing regimen of 25 mg every 1–2 days and close TDM and close TDM. Possible delay in tmax if unboosted: Close TDM (highly recommended)	Consider a CsA dosing regimen of 25 mg every 1–2 days and close TDM. ! possible delay in tmax (highly recommended)	
EVR					
Risk level	None—low	Major	Major—not recommended	Major—not recommended	No information available
Outcome		Increased EVR concentrations; may result in an increased risk of EVR toxicity	Increased EVR concentrations; may result in an increased risk of EVR toxicity	Increased EVR concentrations; may result in an increased risk of EVR toxicity	
Our recommendations	QT interval monitoring (required)	Consider weekly dosing interval and close TDM (highly recommended)	If RTV boosted: Consider weekly dosing interval and close TDM. If unboosted: Close TDM (highly recommended)	Consider weekly dosing interval and close TDM (highly recommended)	
SRL					
Risk level	None reported	Major	Major	Major	No information available
Outcome		Increased SRL concentrations; may result in an increased risk of SRL toxicity	Increased SRL concentrations; may result in an increased risk of SRL toxicity	Increased SRL concentrations; may result in an increased risk of SRL toxicity	
Our recommendations	QT interval monitoring (required)	Consider weekly dosing interval and close TDM (highly recommended)	If RTV boosted: Consider weekly dosing interval and close TDM. If unboosted: Close TDM (highly recommended)	Consider weekly dosing interval and close TDM (highly recommended)	
MPA					
Risk level	None	None	None	None	No information available
Our recommendations		Close TDM (suggested)	Close TDM (suggested)	Close TDM (suggested)	
Prednisolone					
Risk level	None	Major	Moderate—major	Moderate—major	No information available
Outcome		Increased steroid concentrations and decreased plasma cortisol; may result in development of Cushing syndrome	Increased prednisolone concentrations	Increased prednisolone concentrations	
Our recommendations	QT interval monitoring (recommended)	Monitor patient (in) tolerance and biochemical parameters for dosage adjustment (suggested)	Monitor patient (in) tolerance and biochemical parameters for dosage adjustment (suggested)	Monitor patient (in) tolerance and biochemical parameters for dosage adjustment (suggested)	

Tac, tacrolimus; CsA, ciclosporin; EVR, everolimus; SRL, sirolimus.[98–100]

Adapted from: Pharmacologic Treatment of Transplant Recipients Infected with SARS-CoV-2: Considerations Regarding Therapeutic Drug Monitoring and Drug-Drug Interactions by Laure Elens, PhD, Loralie J. Langman, PhD, et al. in Therapeutic Drug Monitoring 2020;00:1-9

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