PHILIPPINE SOCIETY OF DIGESTIVE ENDOSCOPY

A Member of Asia Pacific Society of Digestive Endoscopy (APSDE)

PSDE Clinical and Procedural Guidance for the Resumption of Semi-Urgent and Elective Procedures at the GI Endoscopy Unit in the Time of COVID-19.

The latest directive from the Office of the President of the Philippines is the extension of Enhanced Community Quarantine (ECQ) in high risk areas such as the National Capital Region (NCR). On the other hand, General Community Quarantine (GCQ) is enforced in areas considered to be moderate and low risk to COVID-19. This document is provided in anticipation of the relaxation of ECQ and GCQ and the eventual resumption of semi-urgent and elective procedures at the GI Endoscopy Units across the country. Please note that these are recommended for implementation only AFTER THE COVID-19 CRISIS has been deemed resolved or resolving.

The contents and statements in this document are an interpretation of the best available published information and expert opinion, and is intended to supplement relevant recommendations from the Department of Health (DOH) and the Inter-Agency Task Force (IATF). Please also consider recommendations applicable to your unit, based on resources and your institution's infection control strategies.

Philippine Society of Digestive Endoscopy
May 4, 2020

BACKGROUND

- As of May 3, 2020, a total of 9,223 patients have been diagnosed with COVID 19 in the Philippines, with a mortality rate of 6.6%
- The 25th Inter-agency Task Force (IATF) recently released a document on the "Guiding Principles of COVID-19 RESPONSE". We consider the following:
    - One (of four) major strategies to address the over-all objective of ECQ (reduce human-human transmission) is to DETECT and ISOLATE infected individuals. This is done by ENHANCING TESTING CAPACITY and ENHANCING ISOLATION CAPACITY.
    - Testing of individuals is needed to establish a good estimate of transmission and infection rates. These rates are best described via CASE DOUBLING TIME (CDT).
    - Reducing transmission rates means that the health system will be better able to cope (ie., ICU and regular bed capacity, ventilator machines, personal protective equipment) with the number of affected individuals requiring care. This data is described via CRITICAL CARE UTILIZATION RATE (CUR).
    - Both CDT and CUR allow for the determination of risk level for COVID-19 for particular localities. RISK LEVEL classification determines aggressiveness of response.
- Current international and local guidelines on endoscopy unit operations in the time of COVID-19, recommend that semi-elective and elective procedures be withheld in response to high transmission rates, limited capacity for RT-PCR testing, and the need to comply with rational use

and conservation of PPE. These recommendations are consistent with recommendations of the IATF and the DOH.

- Community restrictions while considered essential have resulted in the delay of many necessary, albeit elective, medical procedures. Although considered non-urgent at the beginning of ECQ, many disease conditions have also unfortunately developed and deteriorated from the delay of medical treatment.
- While current recommendations are in effect, there is a need to prepare for the anticipated relaxation of ECQ and GCQ. Once community risk level is determined to be low, and after considering possible LIMITATIONS of risk stratification (ie, testing not readily available especially outside NCR leading to possible inaccuracy of CDT and CUR; significant number of asymptomatic COVID-19 positive individuals), units must be ready to accept patients without delay.
- The Department of Health recently released data on the number of affected health workers. As of date, there are 1,758 healthcare workers diagnosed with COVID 19 (1 out of 5) and already 34 have died. This highlights the need to continue educating HCWs regarding COVID-19, and providing them access to appropriate personal protective equipment (PPE). Aside from this, appropriate diagnosis and triaging must be put in place to avoid minimizing HCW exposure to affected individuals unnecessarily.
- Several studies have attempted to determine the percentage of asymptomatic COVID-19 positive individuals. The results show that symptom-based screening will miss several cases which may range anywhere from 5% to 80% in any given population. In the Philippines, the DOH reports 1,056 asymptomatic patients, 14.8% of tested individuals.
- Healthcare workers are integral to an effective healthcare system and should therefore be given enough support to remain in the workforce for as long as possible. Testing should be made readily available to these workers to avoid unnecessary confinement and isolation, to document asymptomatic infection and also to prevent inadvertent transmission to patients.
- Personal protective equipment is key in protecting healthcare workers. PPE (based on biosafety levels) requirements are prescribed based on community risk level, patient symptoms and exposure, as well as type of procedure performed to ensure protection of both patient and medical worker.
- Other practices that reduce transmission and cross-contamination such as physical distancing should be incorporated in the plan of every unit.
- An effective referral system must be put in place for those with little access to appropriate facilities and PPEs.

IMPORTANT DEFINITIONS

Table 1. COMMUNITY RISK LEVEL AS DETERMINED BY CDT* and CUR**

Risk Level	Low	Moderate	High	High	Low
Indicator	>30 day CDT and <30% Critical care Utilization Rate (CUR)	7-30 day CDT or 30-70-% CUR	<7 day CDT or >70% CUR	7-30 day CDT and 30-70% CUR	>30 day CDT and <30% CUR following Deceleration phase

*Case Doubling Time

**Critical Care Utilization Rate

Table 2. PERSONAL PROTECTIVE EQUIPMENT AND BIOSAFETY LEVELS

	LEVEL 4	LEVEL 3	LEVEL 2
Coveralls	√	√ (or impermeable gown)	√ (or impermeable gown)
Impermeable gown	√		
Surgical cap	√	√	√
N 95 mask	√	√	√
Scrub suit	√		
Goggles	√	√	√
Face shield	√	√	
Double gloves	√	√	√ (or single gloves)
Dedicated shoes	√		
Shoe covers	√		

Table 3. CASE DEFINITIONS

Urgent/Emergency	Semi-Urgent	Elective
• Acute GI bleeding • Foreign body necessitating extraction • Acute cholangitis • Obvious tumor and high suspicion of cancer requiring diagnosis • Endoscopic guided feeding tube placement	• ERCP for biliary cancers • ERCP for Symptomatic bile duct stones • Endoscopy for cases with only low suspicion of cancer • Evaluation of esophagogastric injury after ingestion of caustic substance	• Endoscopy for screening of early CA • All surveillance and follow up endoscopy • Diagnosis and therapy for non-cancer disease • EUS for diagnosis of benign conditions • ERCP for asymptomatic bile duct or PD stones, change of stent, surveillance post ampullectomy

With the expected influx of patients and procedures, the necessary steps to minimize transmission of SARS-CoV-2 virus in endoscopy centers are given. The Society provides recommendations of the highest standard, and doctors and staff are encouraged to exert all effort in applying these recommendations to their own centers.

- In accordance with the current PSDE Clinical and Procedural Guidance for the GI Endoscopy Unit in the Time of COVID-19 (3rd Update), the preparation and resumption of semi-urgent cases (Table 1) may be considered once there are:

(1) sustained reduction in the rate of new COVID 19 cases in the region resulting in low community transmission risk, as determined by the IATF and the DOH
(2) adequate PPE supply for the staff for at least 8 weeks
(3) adequate supply of COVID 19 (RT-PCR) test kits for patients and staff with acceptable turnaround time of test results
(4) appropriate and adequate endoscopy unit operations and workflow required for the prevention of transmission in place
(5) the hospital is capable of providing adequate service to all patients requiring hospitalization, regardless of community health situation

- Elective cases may resume at full capacity when the terms required for the resumption of semi-urgent cases are fulfilled and the following conditions are likewise met:

(1) no new cases of COVID-19 have been diagnosed for at least 2 weeks.
(2) there is normal (12 weeks) reserve of PPE supply

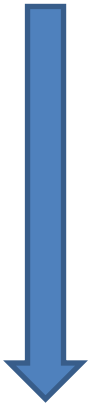
GENERAL CONSIDERATIONS

- Before considering partial opening of any endoscopy unit, the following must be observed:
  - Ensure that all equipment and peripherals are in good working condition
  - Check availability of all necessary equipment and accessories in the unit. Make sure suppliers are open and available to deliver the required instruments when needed
  - Communicate and ensure that other specialties, important referral units and ancillary services are open and accepting referrals when needed (ex. pathology, radiology, surgery departments)
  - Establish an appropriate triage system. Only scheduled patients will be allowed in the unit. All initial consults and inquiries should be entertained over phone or teleconsultation.
  - Staff should undergo retraining and dry-runs to ensure smooth work flow once unit operations resume.

SCHEDULING OF SEMI-URGENT AND ELECTIVE CASES

- Semi-urgent cases must first undergo thorough endoscopy unit team discussion to determine urgency and appropriateness of endoscopic procedure.
- Elective cases must be postponed until the SARS-CoV-2/COVID-19 crisis is resolved
- Schedule cases at least 2 hours apart to allow for diffusion of aerosols and full disinfection of endoscopy suite. Consider full unit operating hours during weekends and holidays until backlog of procedures are reduced
- Ensure staff availability with at least one nurse assist and one technician (wash) for each procedure while observing 8-hour shifts to minimize fatigue related oversight

- Prioritize scheduling of procedures according to the following conditions and indications (from highest to lowest priority):

	Symptomatic patients requiring diagnosis and treatment (ex. Recurrent mild rectal bleeding, persistent diarrhea, symptomatic bile duct stones, acute mucosal injury secondary to caustic ingestion)
	Confirmation of diagnosis in suspected cancer patients
	Non-urgent diagnostic and therapeutic procedures (ex. EMR, ESD, Polypectomy, change of biliary stents) for non-cancer disease
	Cancer and disease surveillance
	Cancer screening (ex. Screening colonoscopy)

- Schedule and book procedures only after satisfactory pre-procedure screening interview via teleconsultation. The conditions on patient screening (Pre-procedure Patient Screening) must also be met:

  PRE-PROCEDURE PATIENT SCREENING

  1. All patients should be asked regarding travel history, close contact with confirmed case, and symptoms worrisome for COVID-19. Documentation using an appropriate *screening form* (Appendix A) should be used. Any "YES" answer will automatically disqualify a patient for elective procedure scheduling
  2. Patients must undergo usual pre-procedure cardio-pulmonary clearance as deemed necessary prior to scheduling.

PATIENT SELECTION AND INSTRUCTION

- All patients with cases deemed semi-urgent and elective MUST agree to undergo RT-PCR testing at least 72 hours before the planned procedure.
  - Those tested positive shall be referred for COVID-19 care and procedures shall be deferred until the infection has resolved.
  - RT-PCR Test results and community risk level shall be considered in determining appropriate PPE to be used by doctor and staff
  - If an institution cannot test all patients for COVID19 prior to endoscopy, ***it is the Society's recommendation to assume that all patients are infected (SUSPECT) and the endoscopist should wear recommended LEVEL 4 PPE***

COMMUNITY RISK LEVEL	URGENT	SEMI-URGENT	ELECTIVE
HIgh Risk	Test (+) L 4 PPE Test (-) L 4 PPE	Test (+) Defer Test (-) Defer	Defer
Moderate Risk	Test (+) L 4 PPE Test (-) L 4 PPE	Test (+) Defer Test (-) conditional/L4	Defer
Low risk	Test (+) L 4 PPE Test (-) L3 PPE	Test (+) Defer Test (-) L3 PPE	Test (+) Defer Test (-) L3 PPE

- Febrile patients and those with malaise, cough and/or diarrhea are sent to ER for further management
- Any patient with known recent contact or possible exposure to (1) a person diagnosed with COVID-19 or (2) a person with recent travel to an area or country significantly affected by COVID-19 should be advised a minimum of 14 day quarantine prior to testing and scheduling
- If there is questionable and/or unconfirmed exposure despite negative RT-PCR and absence of symptoms, patients should *undergo Chest CT scan to rule-out early asymptomatic disease* and be required Infectious Disease Service clearance.

ENDOSCOPY UNIT REGISTRATION AND ADMISSION

- Waiting area should have enough space of at least 6 feet between persons to avoid droplet inhalation.
- Establish a queuing system for patient registration and inquiries
- Only patients with appointments should be entertained. No walk-in patients.
- All patients and companions (only one responsible adult should be allowed) should be subjected to mandatory non-contact temperature check and be made to wear a surgical (or higher grade) mask prior to entering the unit
- Provide alcohol-based sanitizer upon entry into the unit
- In addition to routine informed consent form, ensure that patient or family member signs an "*Informed Consent Form for Digestive Endoscopy During Current COVID-19 Crisis*" (Appendix B)
- Patients should be led to a patient dedicated changing room (separate from staff changing room)

ENDOSCOPY ROOMS

- Limit number of operational endoscopy rooms to preserve supplies of PPE's
- Depending on current health situation, the following should be observed:
    1. With new cases of community transmission still documented, procedures are performed by only highly trained endoscopists with the minimum required support staff

to limit procedure time and exposure (ie, limit GI Fellow involvement, minimize repeated entry/exit into the endoscopy room)

2. For low-risk communities, semi-urgent and elective procedures may be performed by trainees (GI Fellow) provided that a highly trained endoscopist/mentor is present to observe and assist

- Only essential appliances and devices in the endoscopy rooms should be in the endoscopy room
- Patient must be maintained in a mask during lower GI endoscopy procedures
- All procedures are *encouraged* to be performed in a negative pressure room
- In the absence of a negative pressure room, the procedure should be performed in a well ventilated room with windows that allow for cross-ventilation
- Full disinfection of all surfaces of endoscopy room after every case. Change all beddings and pillows after each procedure
- Reports may be done in a separate clean room by different set of staff supervised by endoscopist

STAFF PROTECTION

- Mandatory temperature-check with non-contact thermometer for everyone at the beginning of the workday and prior to entering the endoscopy unit
- Any staff showing fever, fatigue, dry cough, diarrhea or contact history with COVID-19 infected patients should be identified, referred to infection control committee and treated appropriately
- Staff must change into scrub suits once in the unit. Masks should be worn at all times.
- All forms of jewelry (watches, rings, necklaces, earrings etc.) must be removed
- Standard hand hygiene should be practiced by the staff before and after each procedure
- Dedicated donning and doffing areas for the staff and patients is recommended
- Staff should undergo training on proper donning and doffing of PPE. A safety officer must be available to ensure strict adherence to proper doffing technique
- Used and contaminated PPE must be disposed of in appropriate medical infectious waste bin and following institutional infection control policies. Hands and exposed areas should be immediately washed and disinfected. Surgical masks are required in all areas of the unit
- Shower areas must be available and easily accessible for immediate washing in case of breach of barrier and contact or contamination. All incidents of splash or contact contamination must be recorded and reported to the institution's infection control committee
- Establish a protocol for post exposure support and treatment for affected staff

PERSONAL PROTECTIVE EQUIPMENT

- ***The Society maintains that the endoscopists and staff wear proper PPE and encourage a "NO PPE no Endoscopy policy"***
- Regular monitoring of supply and use of PPE should be done to adjust endoscopy service and protect the staff
- For staff NOT in direct contact with the patient: Surgical or N95 mask, gloves, isolation gown
- For Endoscopist and staff in direct contact with the patient:

    - For COVID 19 negative patients: Standard PPE: Hair cap, goggles or face shield, surgical mask OR N95 mask, gloves, impermeable/water proof gown, shoe covers/booties. If there are no available impermeable gowns, impermeable aprons must be used on top of isolation (water resistant) gowns

    - For suspected, probable or confirmed COVID 19 patients: Enhanced/ Level 4 PPE: Medical cap or hood, face shield and goggles, N95 mask, coveralls, impermeable gown on top of coveralls, booties and double gloves. If there are no available impermeable gowns, impermeable aprons must be used on top of isolation (water resistant) gowns

RECOVERY BAY

- The recovery bays should provide privacy and enough space of at least 6 feet between patients, to avoid droplet inhalation and for monitoring and care
- Patient mask must be placed back on if it was removed during procedure
- No watchers or family members will be allowed In the recovery area
- Provide patients discharge instructions and instructions for follow-up teleconsultation after 14 days post procedure or earlier if with problems

SCOPE/ACCESSORY PROCESSING AND DISINFECTION

- Standard disinfection and reprocessing of endoscopic instruments should always be practiced
- Accessories must be disposed of immediately in the appropriate medical infectious waste bin and following institutional infection control policies.
- Accessories MUST NOT BE REUSED.

PSDE, Working Committee on COVID-19 Safety

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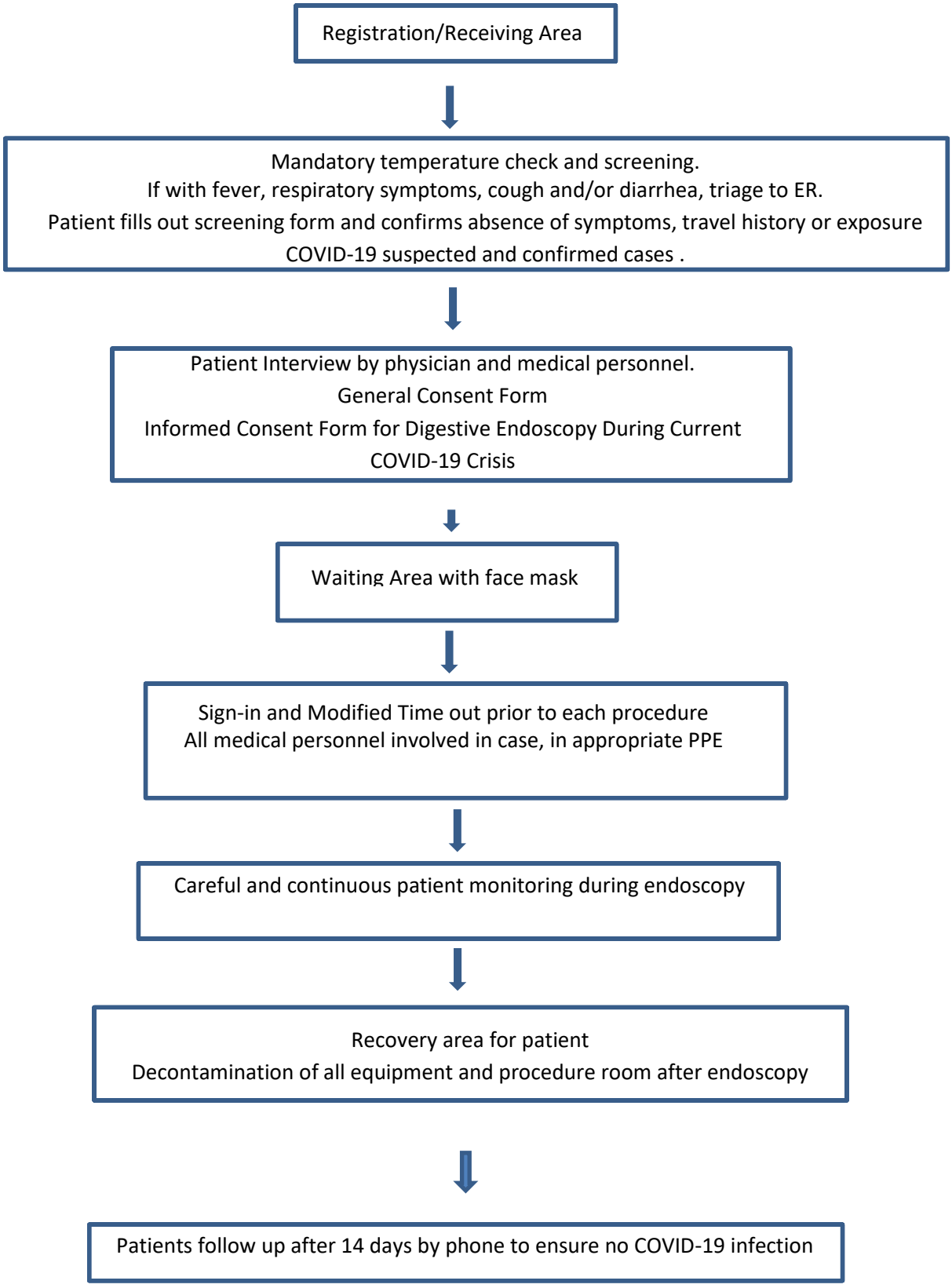
DIAGNOSIS AND TREATMENT WORKFLOW IN ALL ENDOSCOPY UNITS DURING SARS COV2 CRISIS



APPENDIX A

Screening Form

Please answer the following questions truthfully.

1. Are you experiencing any of the following symptoms: fever, diarrhea, nausea, vomiting, abdominal discomfort, cough, sore thorat, runny nose or nasal congestion? _____

2. Have you travelled abroad or to any high-risk COVID-19 area within the last 14 days? _____

3. Within the last 14 days, have you had any contact or possible exposure to a person who has recently travelled to a country affected by SARS-CoV-2/COVID-19 ? _____

4. Have you been diagnosed with COVID-19 previously?

I hereby declare that all the information I have provided are true and correct to the best of my knowledge.

_____

Signature over Printed Name, Date & Time

DATA PRIVACY CONSENT and CONFIDENTIALITY:

By signing this form, the Patient voluntary and unconditionally consents to the collection, processing, and storing of all Personal Data disclosed in this form, in accordance with the Data Privacy Act of 2012, and its implementing rules and regulation. Please be rest assured that any information or Personal Data disclosed by the Patient in this form shall remain strictly confidential and will be held by the hospital and the doctor solely for the purpose of diagnosis and treatment.

APPENDIX B

Informed Consent Form for Digestive Endoscopy During Current SARS-COV2 (COVID-19) Crisis

The doctor has explained that I have the following condition:

_____
_____
_____.

This condition requires the following procedure/s which is/are deemed necessary:

_____
_____.

I agree to the above procedure to be performed on myself. I understand that COVID-19 Crisis is on-going. I am fully aware that my procedure/s need to be done during this time and cannot be delayed or postponed for a long period, or wait until the crisis is resolved . I understand that despite the utmost care being taken by the entire medical team in preventing the spread of infection, the risks of contamination/exposure to COVID-19 are greatest given the current national health situation. I submit myself to the care of my physician _____ and current health team.

_____

Signature over Printed Name, Date & Time

DATA PRIVACY CONSENT and CONFIDENTIALITY:

By signing this form, the Patient voluntary and unconditionally consents to the collection, processing, and storing of all Personal Data disclosed in this form, in accordance with the Data Privacy Act of 2012, and its implementing rules and regulation. Please be rest assured that any information or Personal Data disclosed by the Patient in this form shall remain strictly confidential and will be held by the hospital and the doctor solely for the purpose of diagnosis and treatment.