

**PHILIPPINE SOCIETY OF MEDICAL ONCOLOGY (PSMO)
CONSENSUS RECOMMENDATIONS IN THE MANAGEMENT OF PANCREATIC
CANCER DURING COVID-19 PANDEMIC IN THE CORONAVIRUS DISEASE 2019
(COVID-19) ERA**

**Section of Medical Oncology
Jose R. Reyes Memorial Medical Center
2020**

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I. Background

- Patients with cancer are at increased risk for poor outcomes from the on-going COVID-19 pandemic and are considered high-risk group.
- Limited data suggests close to 40% rate of adverse events, complications, and even death from COVID-19. At the same time, pancreatic cancer is a very aggressive disease and even with treatment, outcomes remain poor.
- Therefore, taking care of Pancreatic cancer patients with the on-going pandemic can be very challenging and decision to treat or not to treat becomes almost impossible.

Rajvi Patel, Wasif Saif. Pancreatic Cancer During COVID-19 Pandemic: Treat or Not to Treat? Northwell Health Cancer Institute & Donald and Barbara Zucker School of Medicine, Hofstra, NY, USA JOP. 2020 ; 21(2): 27–28.

II. Objectives

- To provide local guidance on the management of Pancreatic Cancer in the COVID-19 era
- To protect the pancreatic cancer patients who are part of the vulnerable population and at the same time not to compromise their survival or disease control.

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III. Guidelines/ Recommendations

A. ESMO's tiered framework:

- **Tier 1 (High Priority):** patient's condition is immediately life-threatening, clinically unstable, and/or the magnitude of benefit qualifies the intervention as high priority (ex: significant overall survival gain and/or substantial improvement in the quality of life (QoL));
- **Tier 2 (Medium Priority):** patient's situation is non- critical but delay beyond 6–8 weeks could potentially impact overall outcome and/or the magnitude of benefit qualifies for intermediate priority;
- **Tier 3 (Low Priority):** patient's condition is stable enough to allow services to be delayed for the duration of the COVID-19 pandemic and/or the intervention is non-priority based on the magnitude of benefit (e.g. no survival gain with no change or reduced QoL).

B. Initial Consults and Diagnostics:

B.1. Outpatient

- How do we prioritize Outpatient visits for the management of pancreatic cancer?

OUTPATIENTS VISIT PRIORITIES FOR THE MANAGEMENT OF PANCREATIC CANCER		
HIGH PRIORITY Patients with newly diagnosed resectable cancer : convert as many visits as possible to telemedicine appointments and schedule a multidisciplinary assessment in order to plan surgery	MEDIUM PRIORITY Established patients with new minor to moderate problems or symptoms — convert as many visits as possible to telemedicine appointments	LOW PRIORITY Postoperative patients with no complications
Potentially unstable patients (complications in the post-surgery recovery period: anastomotic leak, bleeding, acute	Follow-up visits considering patients at high risk of relapse	Established patients with no new issues

pancreatitis, fistulae, pneumonitis; jaundice; acute abdominal pain consistent with upper or lower intestinal occlusion; symptomatic ascites)		
Patients newly diagnosed with non-resectable (locally advanced) or metastatic cancer and symptoms such as jaundice, pain, weight loss		Survival follow-up visits out of clinical trials

- Hospitals and oncology care units should be provided at the entrance with triage areas, assessing the presence of symptoms of potential COVID-19 infection and measuring body temperature of outpatients and healthcare professionals. In case of suspicion, COVID-19 testing should be carried out according to national health system guidelines.

Catanese S, Pentheroudakis G, Douillard J-Y, et al. ESMO Management and treatment adapted recommendations in the COVID-19 era: Pancreatic Cancer. ESMO Open 2020;**5**:e000804. doi:10.1136/esmoopen-2020-000804

B.2. Telemedicine

- Should we consider Telemedicine in lieu of face to face consultations during Covid-19 Pandemic?
 - Telemedicine (web-video consulting or telephone calls) should be considered, whenever feasible, the first-choice instrument, minimizing travelling and hospital visits, but maintaining a sufficient contact between healthcare professionals and cancer patients, with their physical and psychological needs.
 - A face-to-face consultation may be replaced by a video consultation in order to assess performance status and general medical conditions.

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B.3. Diagnostic Imaging

- How do we prioritize diagnostic imaging for the management of pancreatic cancer?
 - Imaging tests should be maintained or postponed according to their importance and the impact on the choice of treatment strategy.

IMAGING PRIORITIES FOR THE MANAGEMENT OF PANCREATIC CANCER		
HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Symptomatic patients (intestinal occlusion, jaundice) should be rapidly assessed and properly treated in order to stabilize their QoL and prevent rapid life-threatening deterioration of their health status.	For tumor Restaging after surgical treatment taking into account that adjuvant curative treatment should be started until up to 12 weeks after resection.	Routine radiologic follow-up assessments and radiologic response evaluations , in the neoadjuvant and first line setting, can be postponed if patients are clinically stable, not complaining of new symptoms, and

		laboratory values are not getting out of range.
A total body CT with contrast should be performed in order to confirm the clinical suspicion of pancreatic cancer (CT scan, followed by EUS in the case of non-metastatic disease) and assess the disease stage.		
Established patients with new problems or symptoms from treatment		
clinical variations consistent with progressive disease, or urgent need of response evaluation		

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B.4. Multi-Disciplinary Team

- Should we consider Multidisciplinary team discussions (MDT) during COVID-19 pandemic?
 - Every tailored medical and surgical decision during the COVID-19 pandemic, in respect to current national and international guidelines, should be derived from a multidisciplinary experts' consultation, balancing the pros and cons of every evidence-based therapeutic option to determine the best treatment course for the patient.
 - It is strongly advised to hold dematerialized meetings when possible based on video or teleconferencing even if the doctors practice in the same establishment.
 - A remote multidisciplinary team consultation is urgent in order to plan oncological surgery as soon as possible, provided hospital ICU and surgical resources are available.
 - The immune-depressive but potentially curative pancreatic cancer resection still retains a high priority to be evaluated in a multidisciplinary team consultation, discussing available resources in the pandemic, life expectations, and complications associated with an eventual SARS-CoV-2 infection.

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C. Treatment

C.1. Treatment and COVID-19

- Among cancer patients who develop COVID-19 infection during treatment, what do we consider?

- Defer further systemic treatment (if feasible) until patient has ≥ 1 negative test
- Conduct proactive palliative and end-of-life conversations as soon as possible especially for patients with late-stage disease or with co morbid conditions

COVID-19 rapid guideline: delivery of systemic anticancer treatments. NICE guideline [NG161] Published date: 20 March 2020.

Ueda, M., Martins R. Managing Cancer Care During the COVID-19 Pandemic: Agility and Collaboration Toward a Common Goal J Natl Compr Canc Network 2020 Mar 20;1-4. doi: 10.6004/jnccn.2020.7560

C.2. Surgery

- How do we prioritize pancreatic patients for surgical procedures?

Priorities for pancreatic cancer: surgical oncology and image-guided surgical procedures		
HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Resectable cancers (primary or after neoadjuvant treatment) including resectable cystic lesions with suspicion of malignancy	Hepatojejunostomy (or hepatogastrojejunostomy in case of gastric obstruction) in case of biliary obstruction and recurrent cholangitis in patients with non-resectable localized or metastatic disease, good PS and life expectancy >3 months	
Borderline cancers in patients not fit for neoadjuvant treatment	Duodenal stent and/or PEG tubes in case of gastroduodenobiliary obstruction in symptomatic patients in Best Supportive Care	
Endoscopic placement of biliary stent in case of biliary obstruction in non-resectable or metastatic cancers		
Endoscopic placement of biliary stent in case of biliary obstruction: in resectable cancers with active cholangitis and bilirubin >250 μmol , or non-resectable localized cancers assigned to neoadjuvant or palliative treatment		
Post-surgery complications (anastomotic leak, bleeding, acute pancreatitis, fistulae)		
Histologic assessment: CT scan or EUS guided in case of urgent therapeutic consequences such as curative resection or symptom relief		

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- Among patients with borderline resectable or resectable disease where upfront surgery is unlikely to be performed because of lack of operating theatre, should we consider neo-adjuvant hypo-fractionated (5-fraction) RT or chemoradiotherapy (CRT) as bridge to surgery?
 - We should consider neo-adjuvant hypofractionated precision RT or CRT concurrent with capecitabine (Mon-Fri) (modified from PREOPANC). These hypofractionated regimes would carry the theoretical advantage of reducing hospital visits, and concurrent capecitabine is minimally immunosuppressive.

Mukherjee S, Jones C et al. Considerations for Treatment of Pancreatic Cancer Within the United Kingdom During the COVID-19 Pandemic (published online 03/04/2020 – version 3.0)

Versteijne E, Suker M, Groothuis K et al. Preoperative Chemoradiotherapy Versus Immediate Surgery for Resectable and Borderline Resectable Pancreatic Cancer: Results of the Dutch Randomized Phase III PREOPANC Trial. *J Clin Oncol* 2020 (published online Feb 27 2020)

- In the case of acute overutilization of resources of the healthcare system, and when surgery postponement is unavoidable, should we consider addition of an extra neoadjuvant chemotherapy cycle?
 - Neoadjuvant therapy can be extended in order to delay elective surgery as long as patient is tolerating treatment and showing response

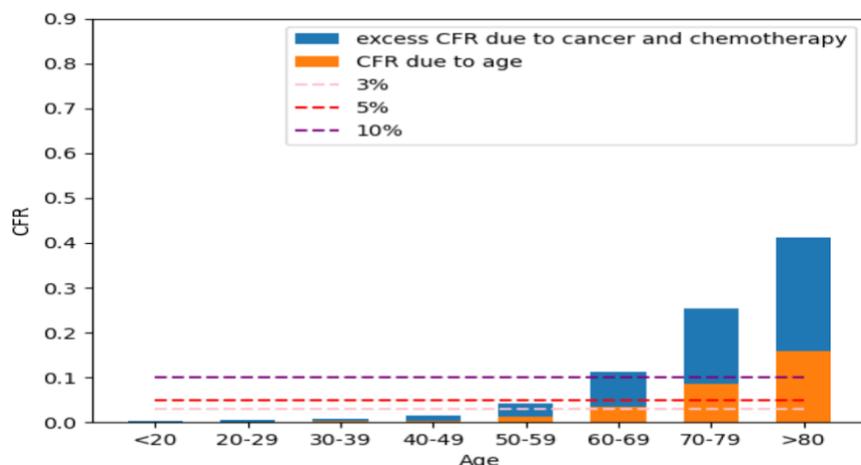
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C.3. Systemic Chemotherapy

C.3.1. Chemotherapy Provisions during COVID-19

- Should we consider the use of models to inform decisions relating to chemotherapy provision during the COVID-19 outbreak?
 - In a modelling exercise, Williams et al identified potential harms in patients undergoing chemotherapy during the COVID-19 outbreak.



Optimistic model case fatality rates in patients with cancer infected with SARS-CoV-2, by age.

Dashed lines represent common levels of benefit from chemotherapy in percent. (Williams et al, 2020).

Age	Cases	Deaths	CFR(%)	CFR with Chemotherapy (%)
0-9	480	0	-	-
10-19	672	1	0.086	0.23
20-29	4158	7	0.017	0.45
30-39	8453	19	0.22	0.6
40-49	10121	39	0.39	1.0
50-59	12547	144	1.15	2.9
60-69	11181	374	3.34	7.9
70-79	7001	592	8.46	16.9
>80	3995	639	15.99	15
Not reported	565	18	-	-
Total	59173	1833	3.10	7.6

Table 2. Estimated case fatality rates by age group with chemotherapy

Williams M, Calvez K, Mi E et al. Estimating the risks from COVID-19 infection in adult chemotherapy patients. <https://doi.org/10.33697/ajur.2019.003>

Mukherjee S, Jones C et al. Considerations for Treatment of Pancreatic Cancer Within the United Kingdom During the COVID-19 Pandemic (published online 03/04/2020 – version 3.0)

C.3.2. Adjuvant Chemotherapy Candidates

- Who are the potential candidates for adjuvant regimen and what other strategies do we consider to simplify chemotherapy regimens to decrease the frequency of clinic visits as well as to decrease risk of neutropenia in patients with pancreatic cancer during the COVID-19 pandemic?
 - Adjuvant mFOLFIRINOX may be considered in fit younger patients where incremental benefit of post-operative chemotherapy can be justified despite increased risks posed by COVID. Factors that may favor intervention would include young age (<60 years) with no comorbidity, particularly if there is poor prognostic features on histology.
 - Use of adjuvant chemotherapy in older patients (>70 years) or those with comorbidities is likely to confer considerable risk, and should be avoided.
 - Decision regarding adjuvant therapy in patients aged 60-69 years should be considered carefully.
 - If following discussion with patient, adjuvant treatment is favored, consider delay of 12 weeks post surgery prior to commencing therapy to tide over the peak of the pandemic.
 - Patients must be carefully counselled regarding increased risks of death or severe complications if they were to contract COVID during treatment.
 - For patients on oral therapy, physicians should provide drug supply for 2 or 3 courses with home monitoring and using telemedicine for toxicity management.
 - Use low dose fixed dose capecitabine 1000 mg twice daily on days 1 to 21 of 28 days for patients who are on oxaliplatin, irinotecan, and gemcitabine combinations.
 - Switch weekly schedule to bi-weekly schedule for gemcitabine/cisplatin, gemcitabine/oxaliplatin, or gemcitabine/capecitabine.
 - Omit bolus 5-FU to reduce risk of neutropenia.
 - When possible and if applicable, 5FU maintenance can be considered in the form of capecitabine.
 - Biweekly gemcitabine-capecitabine
 - Adopting to short infusion time for few drugs based on pharmacology

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Cancer Services Prioritization Guidelines for COVID-19. Hellen Diller Family Comprehensive Cancer Center.

C.3.3. Localized and Locally Advanced Pancreatic Cancer (LAPC)

- How do we prioritize the systemic treatment of pancreatic patients with localized and locally advanced disease?

Priorities for pancreatic cancer: medical oncology in localized and locally advanced disease		
HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Initiation of neoadjuvant or adjuvant treatment not yet initiated	Adjuvant treatment to be initiated, if patient condition after surgery has not recovered (to be postponed only within 12 weeks from surgery)	Follow-up imaging and restaging studies in asymptomatic patients, taking into account pathological stage
Completion of neoadjuvant or adjuvant treatment that has already been initiated	In case of elderly patients with cardiovascular or other comorbidities not fit for a triple regimen, evaluate risk/benefit ratio of a mono-chemotherapy	
Continuation of treatment in the context of clinical trial		

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- What treatment options do we consider for Locally Advanced Pancreatic Cancer (LAPC) during COVID-19 Pandemic?
 - Decision regarding starting upfront chemotherapy (particularly FOLFIRINOX) vs upfront RT/CRT will have to be clinical decision in discussion with patient, considering age and co-morbidities, risks of the regimen itself and likelihood of contracting COVID.
 - Consider dose reduction and prophylactic GCSF in patients receiving FOLFIRINOX.
 - Upfront capecitabine based CRT (median OS 14.3 months) or hypofractionated (5-fraction) radiotherapy (13.9 months) may be less immunosuppressive options with reasonable outcomes, and may allow us to defer the onset of additional chemotherapy till after COVID-19 peak.
 - Where CRT is being considered, a hypofractionated course (45Gy/15 fractions with capecitabine) would be preferred to minimize hospital visits.
 - An alternative regimen of hypofractionated precision RT alone (25-35Gy/5 fractions) may also allow holding off immunosuppressive chemotherapy for a period of time in patients considered to be of

particularly high risk of death or severe complications of COVID-19, or in exceptional circumstances, to ease excessive pressure on NHS resources.

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Kim HS, Yi SY, Jun HJ et al. Definitive Chemoradiation Therapy With Capecitabine in Locally Advanced Pancreatic Cancer. *Anticancer Drugs*. 2010 Jan;21(1):107-12

Herman J, Chang D, Goodman K et al. Phase 2 Multi-Institutional Trial Evaluating Gemcitabine and Stereotactic Body Radiotherapy for Patients With Locally Advanced Unresectable Pancreatic Adenocarcinoma. *Cancer* 2015 Apr; 121(7), 1128-37.

C.3.4. Advanced and Metastatic

- How do we prioritize the systemic treatment of pancreatic patients with advanced/metastatic disease?

Priorities for pancreatic cancer: medical oncology in disease advanced/metastatic disease		
HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
First line chemotherapy in patients fit for a combined regimen likely to improve survival and quality of life outcomes in metastatic disease	In case of asymptomatic or paucisymptomatic elderly patients consider with caution the risk/benefit ratio derived from monotherapy treatment	Follow-up imaging and restaging studies in asymptomatic patients
Continuation of treatment in the context of a clinical trial	Consider with caution starting or prosecution of second line treatment according to the patient's condition	Antiresorptive infusional therapies (zoledronic acid, denosumab) should be rescheduled with a longer interval (every 3 months), except in the case of hypercalcaemia.

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- What do we consider prior to initiating first-line systemic therapy for metastatic pancreatic cancer during COVID-19 pandemic?
 - Consider palliative chemotherapy in highly selected patients who are most likely to benefit
 - Consider dose reduction and use of prophylactic gCSF.
 - Consider early imaging to assess response to systemic anti-cancer therapy to enable early treatment discontinuation if not achieving benefit.
 - Patients who have achieved partial response, consider break from chemotherapy (with imaging follow-up).

Mukherjee S, Jones C et al. Considerations for Treatment of Pancreatic Cancer Within the United Kingdom During the COVID-19 Pandemic (published online 03/04/2020 – version 3.0)

- Should we consider initiating second-line systemic therapy for metastatic pancreatic cancer during COVID-19 pandemic?
 - Second-line systemic therapy for metastatic pancreatic cancer should not be initiated.

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C.3.5. Performance Status and Chemotherapy

- Should we consider giving chemotherapy in patients with reduced performance status who are either on first line or beyond first line treatment?
 - All other regimens with a modest activity should be considered with caution due to their minor benefit that are not comparable with the risks associated with a possible infection of SARS-CoV-2 in chemotherapy-treated cancer patients.
 - A drug-free period in asymptomatic patients might be the most appropriate option.
 - The best supportive care approach should be encouraged, even more so during this pandemic.

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C.4. Radiation Therapy

- What do we consider in giving palliative radiation during COVID-19 pandemic?
 - Consider reducing fractionation and use single fraction approaches
 - Consider to seek alternative non-radiotherapy based approaches to disease palliation.

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C.5. Ancillaries

- Should we still administer corticosteroids as anti-emetic premedication and as pain relievers?
 - The existing literature about the treatment of COVID-19 patients does not provide conclusive evidence for or against the use of corticosteroids. The prescription of Dexamethasone use should be limited, as appropriate, to reduce immunosuppression.

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- Should we consider prophylactic use of cytokine G-CSF (granulocyte colony-stimulating factor) to minimize neutropenia-associated risks?
 - The lack of data does not allow for definitive statements, but we should keep in mind that the severe neutropenia percentage of combined regimens commonly used in pancreatic cancer care are around 38% with gemcitabine-based chemotherapies in curative and palliative lines and around 30% and 45% with mFOLFIRINOX in the adjuvant and metastatic settings, respectively. The rate of febrile neutropenia associated with combined chemotherapy is around 5%. We should consider secondary prophylactic support with G-CSF to minimize the risks associated with febrile neutropenia.

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- Should we consider venous thromboembolic prophylaxis?

- Consider appropriate venous thromboembolic prophylaxis to prevent venous thromboembolism, since these events are very frequent in pancreatic cancer patients and are associated with a poorer outcome and rapid deterioration in case of COVID-19 infection.

Frère C, Bournet B, Benzidia I, et al. [Venous thromboembolism and pancreatic cancer]. *J Med Vasc* 2018;43:246–54.

Wang T, Chen R, Liu C, et al. Attention should be paid to venous thromboembolism prophylaxis in the management of COVID-19. *Lancet Haematol* 2020;7:S2352302620301095.

D. Survival and Follow-up

- What do we consider among patients on survival follow-up?
 - Consider postponing scheduled visits, only if feasible, and/or convert to telemedicine according to the patient's desire.
 - If existing recommendations offer follow-up range (such as 3-6 months), consider delaying scheduled intervention to longest recommended frequency duration (for example, 6 months if range is 3-6 months).

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ASCO Guidance for COVID-19 Patient Care

E. Prognosis

- What is the prognosis of pancreatic cancer patients who develop COVID-19 infection?
 - We have very limited data for patients with cancer who develop COVID-19 infection. In a retrospective analysis including 1,572 COVID-19 cases, authors identified 18 patients with cancer. Patients with cancer were observed to have a higher risk of severe events (intensive care unit admissions requiring mechanical ventilation or death) compared with patients without cancer, 39% versus 8% respectively. Moreover, 75% (3 out of 4) patients who underwent chemotherapy or surgery in the past month had a higher risk of clinically severe events compared to 43% of patient who did not receive chemotherapy or surgery. Therefore, it is very important for medical oncologists to strongly weight risks versus benefits of continuing cytotoxic treatments for PC patients with the on-going pandemic.

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Liang W, Guan W, Chen R, Wang W, Li J, Xu K, et al. Cancer patients in SARS-CoV-2 infection: a nationwide analysis in China. *Lancet Oncol* 2020; 21:335–337. [PubMed: 32066541]

Patel R, Park J, Shah A, Saif MW. COVID-19 and Cancer Patients. *Cancer Med J* 3:40–48.

F. Research

- Should Cancer research be continued during the CoVId-19 pandemic?
 - The US Food and Drug Administration and the European Medical Agency have produced special guidance for the conduction of clinical trials during the COVID-19 pandemic. Paramount is the overall well-being and best interests of the trial participants. Physical visits should be converted to phone or video visits whenever possible, and laboratory, imaging or diagnostic tests should be allowed to be done at a local certified laboratory. Starting a new clinical trial or accrual of new trial participants in an ongoing trial should be

critically evaluated, with consideration of a postponement of trial activation, or a temporary halt or a slowing down of recruitment.

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