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RADIATION ONCOLOGY
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CLARITY PSO
A Patient Safety Organization

RO-ILS THEME REPORT:

COVID-19
DISRUPTIONS TO PROCESSES

PATIENT SAFETY WORK PRODUCT

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COVID-19 Disruptions to Processes

As the COVID-19 pandemic continues, radiation oncology practices across the nation have not been spared from the challenges of continuing to treat patients, while also enacting strategies to mitigate the spread of the virus. While common prevention strategies entail the postponement of treatment, significant numbers of patients requiring radiation therapy cannot be delayed. During the early stages of the outbreak, most practices adapted some "work from home" strategies for staff, where feasible. Telework continues to be a common strategy, even in areas where stay-at-home orders are lifting. The intention is to reduce the practice's foot traffic and subsequently reduce the risk of exposing staff and patients to the virus. Patients with cancer, often immunocompromised and/or older, are a particularly vulnerable population for COVID-19[i]. Disruptions to staffing levels and methods of communication and collaboration are not without their own quality and safety risks. Ideally, process and staff changes should be carefully considered and planned for in advance. Unfortunately, the speed with which the pandemic spread throughout the U.S. did not allow many practices the time to fully plan for such significant changes to normal operating procedures.

With this in mind, RO-HAC searched the RO-ILS national database for events related to COVID-19 to identify learning opportunities. Events reported to RO-ILS during the first couple of months of the outbreak where the practice included COVID-19 were identified and reviewed by RO-HAC. The following three case examples summarize how the pandemic can create or contribute to an error pathway.

CASE 1: MISSING TREATMENT PLAN

A patient participating in a research study arrived for radiation treatment and staff discovered that there was no prepared treatment plan in the EHR. At that time, staff determined that the patient's simulation had been postponed due to a team member's interpretation of the site's COVID-19 restrictions placed on study patients. It was subsequently recognized that radiation therapy was exempt from COVID-19 restrictions, but the patient was never scheduled for a restart.

Upon detailed inquiry, it was concluded that the patient would not require additional radiation treatment given the study protocol. The study used blood analysis results to determine whether radiation should be given or withheld, and these results were delayed due to COVID-19. The decision to withhold radiation was not clearly communicated with the patient and appointments were not fully cancelled. While there was ultimately no direct patient harm, the patient was inconvenienced and increased their chance of viral exposure by unnecessarily being in the practice.

The process of managing radiation treatment and coordinating care for patients is extremely complex, especially when patients are on research trials. The additional disruption from a COVID-19 response plan can significantly increase the probability of missteps in the overall process. Additionally, many practices have limited research staff during the pandemic, which may further add to this confusion. This case highlights the importance of clear communication with colleagues and the patient and the importance of asking for clarification when warranted. This is especially important for care coordination across different specialties (e.g., medical oncology, surgical oncology) and when ensuring the necessary information (e.g., histology, lab results, imaging) is available to make clinical decisions. Fortunately, it seems this disruption to the normal care process was of minor impact but it is not difficult to imagine how a similar error could lead to delay of essential care for a patient.

CASE 2: FAILURE TO ACQUIRE PATIENT CONSENT

The attending physician was working off-site and an urgent simulation was requested. Because of the disruption of the normal workflow processes, the patient was not consented. A same day treatment was scheduled and, fortunately, the treating staff noticed the missing consent prior to treatment. Consent was subsequently obtained and treatment proceeded without incident.

This represents a similar theme observed multiple times in the preliminary review of COVID-19 events in the RO-ILS national database. Disruptions to standard workflow processes affect the normal flow of operations and procedures, ultimately leading to confusion and potential missteps. This situation underscores how prospective risk analysis can be helpful; for instance, to prevent this sort of event, several radiation oncology practices have developed an electronic consent process, where two physicians certify the patient's consent without a physical signature from the patient. Alternatively, other practices have initiated a two-step consent process through which a verbal consent is acquired by one physician, which is followed up with written/signed documentation when the patient arrives on site. Both scenarios may increase the risk for error due to a new and potentially more complex process. When consent happens is also an important consideration. Ideally, the presence of consent should be verified before simulation. Placing this step further upstream decreases the chances that this would be missed and not caught by subsequent quality assurance steps. Fortunately, all instances reported thus far have been of low severity and impact.

CASE 3: INAPPROPRIATE SIMULATION POSITION

A patient that would have typically been treated with 3-D CRT was now to be treated with IMRT given new COVID-19 precautions and local practice guidelines. However, the physician's simulation order for the patient indicated 3-D CRT treatment. The patient underwent simulation with a set-up position appropriate for 3-D CRT. However, given the need for IMRT treatment, patient had to be re-simulated in a different position.

In the setting of resource constraints and the pandemic, radiation oncologists have rapidly adopted different treatment techniques and protocols, such as hypofractionation, in an effort to minimize the risk of infection. The speed with which new clinical guidance was developed and published to help aid decision making speaks to the strength of the field[ii]. However, treatment changes, especially adapting new treatment techniques, significantly alters the normal process of care and may lead to mistakes. Although a re-simulation is unlikely to result in real harm, it does inconvenience the patient, waste resources, involves additional imaging dose and can lead to treatment delays. To prevent this sort of event, practices can consider developing unique COVID disease-specific templates to be used when ordering a simulation. Adherence to guidelines increases over time[iii] and therefore mishaps are likely to decrease with experience. The presence of a draft prescription indicating technique would help the therapists evaluate the adequacy of treatment positioning and immobilization. With many staff members working remotely, cross coverage is more common. Having physician physical presence at the simulation is important, but is most helpful when the physician on site is familiar with the treatment being planned. Practices need to prudently review upstream and downstream processes and make sure everything aligns.

As can be seen from the above examples, the pandemic can lead to additional risk of disruptions to quality care in radiation oncology practices and general health care. It is prudent to consider what practices can do to proactively mitigate what is likely to be an extended disturbance of typical processes.

STRATEGY #1

If the first step to addressing a problem is to recognize that one exists, then one important and valuable, yet simple, strategy can be to **become sensitized to the potential for error during disruptions**. Safety mindfulness is felt to be effective. If staff are on heightened alert for disruptions, and their potential for impacting the safety and quality of the care delivered, then practices *will be* less vulnerable to and more likely to avoid deviations from intended treatment.

STRATEGY #2

Practices should assess and maintain **stability through consistent processes, wherever possible**. Even with staff working remotely, it is important to maintain all safety practices and policies for patients being treated, such as peer review. Practices should discourage deviations from standard policies that can be maintained during the pandemic. Maintaining processes reinforces routine during a crisis. In order to ensure consistent communication patterns and documentation, practices should support staff working remotely by providing access to systems they require to do their work (e.g., cloud access).

STRATEGY #3

When modifications are necessary, it is important to **be mindful of changes and counterbalance risks**. For example, one common strategy during this pandemic has been to "reduce non-essential" treatments, staff, etc. The well-intentioned nature of this statement is understood, but it could be argued that few, if any, of the employed staff or cancer care interventions are 'non-essential'. As such, for staff, this becomes a discussion of which staff need to be on-site. But the risks associated with reducing on-site staffing numbers must also be carefully considered, along with the subsequent disruption to normal processes and safety barriers. In addition to optimizing remote work such that the same safety processes can be followed, coverage remains essential and cross-coverage risks should be assessed. The presence of standard policies and procedures enables for safer cross-coverage. Only local staff can accurately characterize the nature and balance of these risks for their practice, but it is prudent to consider the interplay of both risk and benefit in such scenarios and manage accordingly. When change is required, special care is necessary to communicate unambiguously all expectations.

STRATEGY #4

A fourth strategy addresses the long-term need to **prepare for major disruptive scenarios**. While a global pandemic is a rare occasion, there are numerous other disasters that can and do significantly impact cancer care. These could be natural catastrophes such as hurricanes, earthquakes, wildfires or flooding. While institutions typically have disaster plans at the system (e.g., hospital) level, it is important that plans be discussed and practiced at the radiation oncology practice level. This is reinforced by radiation oncology accreditation programs; for example, APEx standard 9 is dedicated to emergency preparation and planning. In the wake of Hurricane Maria, experts from Puerto Rico and mainland United States developed emergency preparedness suggestion broken down into four steps: prepare, communicate, operate and compensate (PCOC)[iv]. Each of the four categories are accompanied with checklists that outline dozens of steps practices could take to help minimize treatment delays during a disaster.

As some practices begin treating more patients, there may be other factors to prepare for. Given the overall disruption to the health care system, the number of cancer screenings, surgeries and other patient visits have plummeted, but will eventually rebound. Therefore, practices may be inundated with patients in the future given those postponements, in addition to the previously scheduled but delayed patients. Practices will need to balance the importance of treating many patients quickly with other risks. While addressing an increase in patient volumes, practices will need to ensure staff have adequate time to accurately perform their duties whether planning a patient's treatment course, performing QA or conducting peer review. It is also plausible that even as practices begin to move away from the more extreme COVID-19 related changes, some amount of telework will remain. It will be important, then, to stay wary of and protect against newly revealed communication and workflow challenges.

RO-ILS appreciates that with the constantly changing COVID-19 related environment (e.g., added pressures, staffing challenges) reporting events to RO-ILS may not be considered a top priority. However, users are encouraged to continue reporting events to the program. RO-HAC will continue to monitor, analyze and provide learning from incoming events.

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ii. American Society for Radiation Oncology. COVID-19 Clinical Guidance. ASTRO website. Updated May 20, 2020. Accessed July 6, 2020. https://www.astro.org/Daily-Practice/COVID-19-Recommendations-and-Information/Clinical-Guidance

iii. Chagpar R, Xing Y, Chiang Y, et al. Adherence to Stage-Specific Treatment Guidelines for Patients With Colon Cancer. *J Clin Oncol*. 2012 30(9):972-9.

iv. Gay HA, Santiago R, Gil B, et al. Lessons Learned From Hurricane Maria in Puerto Rico: Practical Measures to Mitigate the Impact of a Catastrophic Natural Disaster on Radiation Oncology Patients. *Pract Radiat Oncol*. 2019 9(5):305-321. https://www.practicalradonc.org/article/S1879-8500(19)30079-7/fulltext