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PART 2

Avoiding Liability in Telemedicine: HIPAA & Informed Consent

That you are a responsible covered entity under HIPAA and a fiduciary for the privacy of your patients' PHI do not decrease with telemedicine. In fact, it is a setting in which you want to be very careful, particularly if working from home, where family will be present and habits may become lax. Your primary obligation is to make sure no unauthorized individual encounters PHI in any form.

However, the Office of Civil Rights (OCR) will waive penalties for HIPAA violations that would otherwise accrue due to this issue during the COVID-19 crisis. The intention is to open a telehealth option to practitioners who were not set up for such but who find themselves with patients in need of any telehealth diagnostic or treatment, even if not directly related to coronavirus.

The OCR extended permissible use to non-public-facing apps such as Skype, Google Hangouts video, and Zoom, that only allow intended parties to participate. A Business Associates Agreement is not required.

The standard during this waiver is one of good faith. If PHI is intercepted during transmission but the practitioner followed the OCR's guidance, there will be no penalty. Note, however, that states often have stricter regulations, and the federal waiver does not affect these.

Increased access also carries the important responsibility of informed consent. Many states specifically require that it be done and documented before engaging in a telehealth visit. In most such states, verbal consent is allowed, but consent must be obtained in writing in some. Regardless, the more certain the proof of consent, the better.

You should first inform the patient that this method is limited as compared with an in-person evaluation and is also potentially not secure. You should then get an affirmative consent to continue. If possible, build the consent form into the software so that the patient is required to assent before the virtual visit. If that is not possible, create a standardized e-mail with the consent and have the patient return it before you start. A verbal consent, if permissible, should be carefully documented.

You must apply all encryption and privacy modes available from your end. Increasing usable systems to ones that are inherently less secure is predicated on you doing what you can to minimize the risk of a breach, and it is this that the OCR will look to in determining a "good faith" use of the waiver. If a relative or friend or caregiver will be involved to help the patient with the televisit, make certain that you have a release that allows them access to PHI. Remember that the waiver on non-HIPAA compliant systems will only last during the emergency.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.

Establishing a Hyperthermic Intraperitoneal Chemotherapy Program in Gynecologic Oncology

Hyperthermic intraperitoneal chemotherapy (HIPEC) is emerging as a viable treatment option for patients with advanced epithelial ovarian cancer. Investigators have published a guide of recommendations to help clinicians implement a HIPEC program for their institution.

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In recent studies, hyperthermic intraperitoneal chemotherapy (HIPEC) has been evaluated for use at the time of cytoreductive surgery in patients with both primary and recurrent epithelial ovarian cancer. In a 2018 *New England Journal of Medicine (NEJM)* study, researchers assessed patients with advanced stage ovarian cancer who were randomized to receive either interval debulking or interval debulking plus HIPEC. "In this study, patients receiving interval debulking and HIPEC experienced an improvement in overall survival of 1 year," explains Anthony B. Costales, MD. "Since improvement in overall survival has been a void in ovarian cancer, this study represents a significant landmark."

Since the 2018 *NEJM* study was published, there has been an uptick in the implementation of HIPEC for epithelial ovarian cancer throughout the United States, according to Dr. Costales. "However, many clinicians and institutions attempting to implement this approach may be doing so for the first time," he says. With this in mind, Dr. Costales and colleagues published a review in *Gynecologic Oncology* that provided guidance and recommendations based on their extensive experience with HIPEC at the Cleveland Clinic.

"Our review article is important because research shows that implementation of HIPEC for epithelial ovarian cancer in the US is increasing dramatically," Dr. Costales says. "The Society of Gynecologic Oncology (SGO) surveys healthcare providers every 5 years to analyze trends in treatment. HIPEC was not mentioned 5 years ago in the SGO survey, but the most recent survey found that approximately 45% of clinicians are now offering HIPEC."

Key Highlights

According to the review article, establishing a HIPEC program requires a committed effort. "Given our experience with the procedure, we highlighted many aspects to consider when implementing this program, specifically personnel and training, patient selection, safety, and specific chemotherapy considerations," says Dr. Costales. The study team offered evidence-based strategies for preoperative care and preparation, team and equipment requirements, and HIPEC protocols. They also provided insights on anesthesia and surgical considerations as well as postoperative considerations, specifically ICU admissions.

The review noted that establishing a HIPEC program requires building a multidisciplinary team and educating each member on several important aspects of the procedure (Table). Chemotherapy-certified personal protective equipment and a HIPEC pump, which is connected to inflow and outflow catheters placed within the peritoneal cavity, are required equipment. During HIPEC, 3-6 L of a hyperthermic perfusate—composed of an isotonic crystalloid vehicle and the chemotherapy of choice—should be infused through the peritoneal cavity with a goal temperature of 41-43°C.

Prior to infusing HIPEC, surgical teams are recommended to communicate with anesthesia and pharmacy members. Patients receiving HIPEC with cisplatin, furosemide and mannitol should be administered 1 hour before chemotherapy to ensure adequate diuresis. Sodium thiosulfate may be considered to protect the kidneys. A multiagent premedication protocol before HIPEC infusion should be considered to reduce hypersensitivity reactions, renal toxicity, and postoperative nausea.

Optimizing Implementation

"The recommendations from our review are generalizable to institutions nationwide and internationally," says Dr. Costales. "For women with epithelial ovarian cancer, HIPEC is best served at large academic medical centers, because these patients may require a brief ICU stay following the procedure. Additionally, close patient monitoring is paramount, especially for electrolyte levels and fluid management." Continuous patient monitoring and proactive management of abnormalities that arise during HIPEC is imperative to decrease patient morbidity and mortality.

Dr. Costales cautions that more research is needed for many aspects of HIPEC. "An ongoing clinical trial from the Netherlands is assessing HIPEC in the upfront setting," he says, "and we eagerly anticipate data from this study. We also need to establish if there is a role for consolidation HIPEC and in secondary or greater debulking procedures. In addition, questions remain on how PARP inhibitors change the landscape of HIPEC for treating ovarian cancer. We look forward to having these unanswered questions addressed in future research."

Table The Multidisciplinary Team & Education Requirements

Establishing a HIPEC program requires building a multidisciplinary team and education on several key factors.

The Multidisciplinary Team	Required Education
• Gynecologic oncologists	• HIPEC protocols
• Anesthesiologists and intensivists	• Toxic waste and spill management
• Nursing	• Personal protective equipment
• Perfusionists	
• Pharmacists	

Source: Adapted from: Chambers LM, et al. *Gynecol Oncol.* 2020 Jul 2;S0090-8258(20)32302-7.

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Be an Upstander, Not a Bystander

By Aasna Shaukat, MD, MPH

I am a female immigrant gastroenterologist from Pakistan, practicing in Minneapolis. Having lived in this country for 22 years and married to a white man, I generally feel that I fit in pretty well. A couple weeks ago at work, I walked into a procedure room and introduced myself to a 66-year-old white male on whom I was about to perform a procedure. There were three other people in the room—a nurse and two techs. I explained the procedure in my usual cheerful voice and asked, "Do you have any questions?" like I always do at the consent process.

The patient said, "Yes, I do. Where's your burqa?" I was quite taken aback and wondered if I misheard.

Me: "I'm sorry. What did you say?"

Patient: "I said, where's your burqa?"

Me, confused: "Sir, why would I have a burqa?"

Patient: "Don't women like you wear one to cover themselves?"

Me (more confused): "What do you mean women like me?"

Patient: "Well, aren't you from Pakistan or Afghanistan? Aren't you Muslim?" I was at a loss for words and desperately wanted to end the conversation."

Me: "Let's not talk about me but about your procedure. Any questions about the procedure?"

The patient replied, "no," and we went ahead with the procedure and the rest of the day.

The incident bothered me all day and the following many days. I couldn't quite put a finger on what it was and brushed it aside and stopped thinking about it. In the wake of recent events, it dawned upon me that it wasn't the patient's comments that bothered me. It was the fact that no one standing in the room witnessing the conversation stepped in. Not during the conversation, and not after. Considering I've worked with my colleagues every day and in the same place for the last 12 years, I felt strangely betrayed.

Stories like this happen every day and are sadly more common than we realize. There will always be racist, insensitive, inappropriate comments by people across life. It's how we react to them that will shape our lives. Most individuals have asked how they can help. Well, start by being an upstander and not a bystander. That will mean the world to us people of color and immigrants.

And let's start teaching and training students in medical school, nursing, and technical schools how to identify and stand up to inappropriate comments. It may take us a few generations to make seismic changes, but we must start now.

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Cervical Intraepithelial Neoplasia & Cancer Risk

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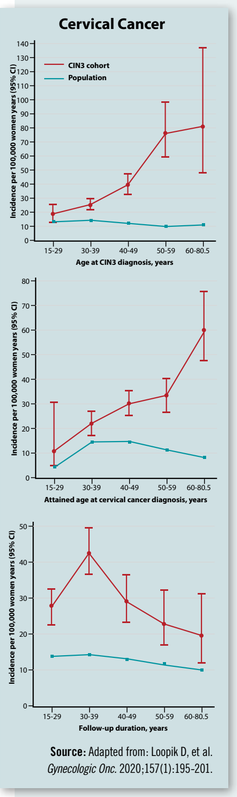
Prior research indicates that women who are treated for cervical intraepithelial neoplasia (CIN) remain at increased risk of developing cervical cancer when compared with women with normal cytology results or women in the general population. However, several are limited by small study populations, use of different CIN grades, or lack of information on post-treatment follow-up.

To estimate the risk of cervical cancer in women with a history of CIN grade 3 (CIN3) and review the compliance with post-treatment follow-up, my colleagues and I conducted a retrospective cohort study in 80,442 women with a CIN3 diagnosis between 1990 and 2010, with cases of recurrent CIN3 and cervical cancer identified until 2016.



Source: Adapted from: Loopik D, et al. *Gynecologic Onc.* 2020;157(1):195-201.

After a median follow-up of 15.8 years and 1,278,297 person years, 1,554 women (1.9%) developed recurrent CIN3 and 397 women (0.5%) cervical cancer. Women with CIN3 had a twofold increased risk of cervical cancer when compared with the general female population. This risk was highest between 5 and 9 years of follow-up (Figure). Increased risk of cervical cancer was seen at up to 20 years, but this seems to be mostly attributable to ageing. Women with recurrent CIN3 had a nine-fold increased risk of developing cervical cancer, while women aged 50 and older at CIN3 diagnosis had a seven-fold increased risk. Women older than 60 had a sixfold greater incidence of cervical cancer, suggesting that women treated for CIN3 are in need of an adjusted long-term follow-up program, as well as that screening only until age 60 is insufficient.

With 37% of women who developed cervical cancer not completing the advised post-treatment follow-up, further research is needed to optimize follow-up strategies and to investigate if women treated for CIN3 may benefit from adjuvant high-risk HPV vaccination.