Regulation Matters:
a CLEAR conversation

Episode 20: Lessons from Cases Involving Intentional Harm to Patients

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Line Dempsey: Welcome once again to our podcast, Regulation Matters: a CLEAR conversation. Again, I'm your host, Line Dempsey. I am the Chief Compliance Officer with Riccobene Associates here in North Carolina. I'm on the CLEAR board of directors, as well as the current chair of the National Certified Investigator Training committee and Vice Chair of the annual conference program committee with CLEAR.

As many of you may know, the Council on Licensure, Enforcement and Regulation, or CLEAR, is an association of individuals, agencies and organizations that comprise the international community of professional and occupational regulation. Our podcast is a chance for you to hear about the latest and greatest in that community. And today I am joined by some presenters for a session in the administration, legislation and policy track at the upcoming CLEAR Annual Educational Conference this September in Minneapolis.

We'd like to give you a sneak peek of what's in store for this session. And that session in particular is called "Rare Events with Catastrophic Impact: Lessons from Cases Involving Intentional Harm to Patients." I welcome Laura Kinkartz with Weirfoulds LLP, Christine Braithwaite with the Professional Standards Authority in the UK, and David Benton with the National Council of State Boards of Nursing. We're glad have you with us today. Welcome.

Guest speakers: Thank you, glad to be here.

Line: Excellent, well again, I really appreciate you guys joining me today. Since we have three speakers, I'll kinda call out maybe a first question to Lara, then maybe each of you can respond to the same question. First, Lara, why should we be concerned about healthcare providers who intentionally harm or kill their patients, other than the obvious, but isn't it extremely rare?

Lara Kinkartz: Well, it is extremely rare, but it's actually not as rare as you might assume. Here in Ontario, the Long-Term Care Homes public inquiries just released its final report and recommendation on July 31. And this is a public inquiry that was called to look into the offenses committed by Elizabeth

Wettlaufer. And she was a nurse who worked in Ontario's long-term care system and was convicted of murdering eight patients in her care and attempting to kill or seriously harm six others. And just while our inquiry was underway between 2017 and 2019, two more healthcare workers were arrested for intentionally killing their patients, one in the UK and one in Japan. And while the long-term care homes inquiry was going on here in Ontario, it actually heard evidence about the literature and research that's been done into healthcare workers who intentionally kill their patients, which the literature actually dubs these people "healthcare serial killers".

And what's surprising is that there are actually documented cases going back to the 1800s. And since 1970, there have been 90 convicted healthcare serial killers in the Western world, including Europe, the US, and now in Canada with Elizabeth Wettlaufer. And just from those 90 people, they've been convicted of killing 450 patients and assaulting or causing serious bodily harm to 150 others. But when we step back, the total number of suspicion deaths that have been attributed to these people is actually closer to 2600, which is a fair number of patients. So, is it rare? Absolutely. But as we've just seen here in Ontario, the magnitude of the harm caused when one of these cases does come up is enormous, not only for the victims and their loved ones, obviously, but also to the public trust in the healthcare system and in healthcare regulators.

Christine Braithwaite: Hi, and this is Christine. I would just like to echo that. I would agree that it's not as rare as we would like. For example, here in the United Kingdom between 2000-2005, we had six public inquiry reports into the actions of people who caused intentional harm. But I think instead of looking at the number, we really just do need to stay focused on the scale of the impact. For example, in the UK here, we had a man called Clifford Ayling, who worked as a clinical assistant in obstetrics and gynecology and also was a general practitioner. Over period of about 30 years, the concerns about his sexual behavior towards women he was examining started to emerge in the early 1970s, and he wasn't convicted of it until 2000. He had multiple victims in multiple locations, and although there were twelve counts of assault on ten patients, there were another fourteen cases left to lie on file. And I think if you read the inquiry report, you can see that actually the magnitude of the harm that was caused was highly likely to have been much more extensive than that. If we look at one of the famous cases in the UK, the Harold Shipman case, he was convicted of fifteen murders, but he was estimated to have committed somewhere in the region of 250. We also had another gynecologist, Rodney Ledward; he was subject to complaints from 550 women and was found to have botched 418 operations. And he was actually under investigation a second time at the time of his death for sexual abuse as well.

So there's the impact in terms of the patient and obviously all of the families too, but the other area I think that it's important for regulators to be focused on is, what's the impact of that on colleagues? There are several impacts on those who are working alongside people who cause intentional harm. Firstly, they tend to be aware that something is wrong within the system, so either consciously or unconsciously, they react by maybe monitoring the person a bit more and also having to or trying to ameliorate their impact, so whether that's by undertaking actions to try and correct something that they think they've done wrong.

But there are also what's termed in the literature "bonds of transgression." Let's say you have a consultant, as Rodney Ledward was, in a senior position who's working alongside junior doctors and others - they start to cover for one another, again consciously and unconsciously. Ayling and Ledward, interestingly, worked together actually for a short period of time. The other thing that is talked about a lot in the literature and certainly exercises the judges and others when they're leading the inquiries is what sometimes is called a "conspiracy of silence." An alternative view of that is to view it not as a conspiracy of silence and not as a deliberate getting together of health professionals in order not to allow the truth to come forward, but actually it's a form of cultural censorship in which there's a kind of unspoken but tacit acceptance that we don't talk about these types of things. And often health professionals feel themselves to be put in a very ethically and morally difficult position, and they suffer themselves all sorts of emotional reactions. So, one nurse, for example, in an inquiry when asked why she hadn't said anything said 'Because I'm a coward,' and living with those kind of feelings is not easy for people either.

So there is that. And we've done some work, quite a lot of work now, in the UK trying to understand why it is, from a psychological perspective, various health practitioners get themselves in trouble under fitness to practice panels. And Professor Rosalind Searle published a very interesting report, which if you haven't seen I would commend you, which she called "Bad Apples, Bad Barrels, Bad Cellars." And what Ros says essentially from regulators' perspective is that, yes, it's important to think about the traits, but it's also important to think about the context in which they're working. And with the bad barrels, she suggested there are two types of bad barrels - what she calls ”corrupting barrels,” and then there are what she calls “depleting barrels.” And the corrupting barrels are the ones where people adopt the bad behaviors, deliberately in some cases. So if people are working within a climate in which sexual abuse is prevalent for example, they're more likely, if they're so inclined, to feel that it's okay for them to do that too. And then there's depleting barrels, which is where people kind of become exhausted and drained by everything that's going on around them, and their standards slip and they engage in poor practice too. So it's important to focus on the scale of impact.

Line: Well, that's understood. David, I'd like hear your thoughts. Although now I'm starting to think it may be not that extremely rare, probably more often than people die of shark attacks.

David: Well, let's start with some facts first of all. First of all, research in this topic is relatively recent, and the research that is available, there's not a huge amount about it. If you think about the number of individuals that are being identified compared to the number of services that are offered, we are actually talking about a very small percentage. But as my colleagues have indicated, the impact of this is really catastrophic, not just for the individuals but their families, for the systems that these individuals often work in, and of course their colleagues that are part of that.

I think part of the problem that we are seeing is that patients are sicker, and in today's society, families are much more fragmented and therefore, often individuals are receiving treatment in isolation from their normal peer supports. So the ability to recognize patterns and to identify at an early stage that particularly vulnerable patient is problematic. The intensity of healthcare these days is so great that the time that people have in institutions is often very short, and therefore the ability to simply spot

that particular practitioner is always on duty when one of these events, a death, occurs, for example, is becoming much more complex in terms of just pattern recognition itself. And therefore we need to be much more agile and vigilant in terms of actually thinking about these things. Obviously the majority of managers in the health services wherever they may be, whether they be in community settings or in large hospitals, are unlikely to come across such an event, and indeed regulators themselves will probably only see one or possibly two of these cases in their entire career. So this does actually mean that we need to think about how do we prepare people to be ready to deal with this when such an incident would occur.

The one thing that is sure if you have to deal with one of these cases as a regulator, is that there are additional costs to the system. There are huge stresses on the leadership of the organization and in terms of dealing with the media and preparing for this, you just simply cannot be well enough prepared because there's always something that will put you on the spot at some point. So yes, it is relatively rare, relative to the care that is delivered globally; but when it happens, it is a catastrophic event for all.

Line: Certainly. Well, I guess, let me ask this, and maybe I'll direct to Christine first and then you guys can each kind of weigh in. Are there processes that regulators can put in place to help minimize the chances of actual intentional harm occurring?

Christine: To minimize the chances of intentional harm occurring, I think, is difficult for a regulator beyond setting a standard that they would do normally, and beyond making sure that the training that people provide in the training places and so on are good. And I think the reason why it's quite difficult for a regulator to do that, is that they don't have control over the workplace. I'll move on later to consider how people work together. But I think that's the main thing because what you see when you look across these particular type of cases is that the perpetrators tend to be working in environments in which there are staff shortages, there is a lack of supervision, there are all sorts of pressures on the system, which means quite often that the contribution that the person makes is seen as being very valuable and that helps to bolster people's confidence in them and allows them to get away with the kind of things that they do. So I think the amount of direct influence that a regulator has over intentional harm is quite difficult for them.

I think that having a good relationship and good channels of communication between regulators and between the workplaces in which registrants are is helpful because it starts to make it easier for people to have conversations, and begin to say, 'So I'm a bit worried about this, can we talk this one through and you tell me whether I'm right to be concerned' and let staff to bring in all sorts things about how and when you use soft intelligence. And I think regulators need to think about that.

And I think one of the things that has really come through from this, and I take David's point absolutely about the difficulty, is you're probably only gonna maybe come across one or two of these cases in the course of your career. But it's about the mindset of staff who are investigating and that's about really developing a very inquisitive mindset and not taking things at face value. I remember a police trainer saying once upon a time that when they train the police, they teach them ABC, which

means "assume nothing; believe nobody; and check everything."

And I think that helps in relation to this. And it's a good discipline to have not just in relation to spotting these really high level intentional harm cases, but I think it's also simply good discipline in terms of investigating any kind of cases, particularly whether and when things like incompetence and so on are happening. But if you have that mindset from the start, you're more likely to be open to the possibility of intentional harm and more likely to be prepared to think the unthinkable.

David: So I would like to build on that. Christine identified the importance of the relationship to the regulator and the employer, but I would like to stress the importance of the fact that regulators need to work together on some of these issues as well so that there's a consistency of message. We know that healthcare is increasingly a team-based activity; therefore ensuring that there are discussions between the different health regulators as part of consistency of message, so that there is less confusion and a faster flow of information, is also important.

We know that regulators now are increasingly collaborating, together; they are coming out with joint statements. And this is, as I said, a rare event, and therefore, there is some real value in collaborating together and pooling intelligence and information so that there can be joint standards set on some of these issues, because invariably there will be other disciplines involved as part of the investigation anyway. And therefore, a consistency of approach is really important. Regulators also need to work very closely with their staff to educate them to be vigilant and to consider these things as part of their process. That's not to over-react, but to really have a systematic approach to this in a way that does really validate everything that's happening there and think that the impossible could in fact happen, therefore not to reject it out of hand, but to really investigate it in a very structured way.

If you do have a case that you are suspicious of, then I think regulators also need to have a very clear fast-track procedure to deal with these serious allegations, to know who they need to talk to, not just within the healthcare system, but also within the criminal justice system as well; because the detection of this can come from different angles, and knowing who the various actors are that have an interest in this so that you really have a very streamlined approach that actually progresses the inquiry as quickly as possible and prevent further harm happening.

Lara: Yeah, I completely agree with what Christine and David have said. And they've both alluded to the importance of ensuring that a regulator's staff, and in particular its investigations staff, are alert to the possibility that an incident could be the result of intentional harm. Because I think that is something that many of us don't even think of. And so if investigators are alert to some of the risk factors that have been associated with known cases, that can be a good starting place. So for example, have colleagues expressed suspicion or concern? Has the healthcare worker changed jobs frequently? Are you dealing with a case involving patients that are particularly vulnerable - very young, very old, cognitive impairment? Has there been a pattern of unexpected deaths or an unexpected deterioration of patients' health conditions? And in particular, has that been happening on shifts where the health care professional you're looking at tends to be working alone or with less supervision, like on the night shift? So obviously those are not foolproof, but they are factors that have been associated with many

previous cases that investigators should be aware of, just so that they know that these are factors that sometimes come up in these cases.

I think one thing that can be tempting is to try to profile people and to say, 'Well if you have a healthcare worker that fits this certain profile, we need to pay attention to them because they're more likely to harm patients.' But the research shows there's not really any easy way to determine ahead of time which healthcare professional may go on to deliberately harm their patients. So there isn't a consistent profile across the healthcare professionals who have been convicted of intentionally harming or intentionally killing their patients. So for example, profiling at the registration stage isn't gonna be all that useful. But what Christine and David have both touched on, and it was one of the major lessons that came out of the inquiry into Elizabeth Wettlaufer here in Ontario, was the importance of ensuring all those in the healthcare system - so, regulators, employers, and the healthcare professionals themselves - need to be aware that it's possible for a healthcare professional to intentionally harm their patients.

And if that is something that you're aware of as a possibility, then you're more likely to pick up on it if the worst case scenario happens and it does come up. Another thing that can be helpful, although it's not always practical, is if you are dealing with the system where there's an ability to collect data about death or sudden changes in condition, there have been cases in the past where some of these people have been caught because of significant spikes and deaths associated with their shift. With that said, it tends to be large healthcare employers who have the ability to gather data and analyze trends like this, like large public hospitals; it doesn't tend to be the regulators themselves, but if that is something that's possible, that can be helpful.

Line: Well, that's interesting. Let me go to David now. Obviously, you can revoke a license or the ability to practice, but are there any other things that regulators can do specifically in the healthcare system to help protect patients from these, for lack of a better term, "rogue" practitioners?

David: Well, I think one of the things that we need to think about is, how do we learn from other high-risk industries in terms of how they mitigate risk? And there was a publication that came out quite a while ago now - it's almost 20 years ago - from the then-Chief Medical Officer of the United Kingdom called "An Organization with a Memory." And that was really about systems failures and how different parts of the system tolerate levels of risk. And then when it all comes together, this is when these catastrophic events can occur because there's a set of consequences that are put in play.

And I do believe that looking at not just within the healthcare regulatory family, but actually looking more widely, as to how we can mitigate some of these catastrophic events can be helpful. Certainly the recommendations that came up from the expert group on "An Organization with a Memory" - many of them are very, very relevant to how you mitigate this situation of potential serial killers. It's about the way the information flows; it's about early detection; it's about a culture of reflection and learning. And I think that's part of what we need to do as well. So not just simply look internally, but actually look externally as to what we can learn from others.

Certainly as a community of regulators, as I said, it's a very rare event and therefore the importance of us all sharing our experiences, once obviously the process has been followed, is important because we can learn from the experiences of others. We can learn from the mistakes of others, and to acknowledge the things that we might want to do differently to avoid either delay or upset that can be caused in some of these very emotionally charged discussions.

I think the other thing that we also need to remember is that as a regulator, as the chief executive or the executive officer of a regulatory body, it's a very lonely job. And therefore having an established network of trusted peers that you can actually turn to at these times for both confidential model and advice in terms of how you might deal with some of these things, acting as a sounding board is also an important point to consider. Now, obviously, there are potential difficulties with that because if you're in the middle of an investigation, you cannot share the detail, but the ability to reflect on some of these issues and actually think this through ahead of time - how did it work for you when this happened? - again, is I think an important point in preparing and getting ahead of these issues.

Lara: Yeah, I agree. And to build on that, to the extent the regulators have involvement in developing best practices or guidelines for those in the sector, I think that's a real opportunity to spread awareness, to emphasize the importance of good processes and, as David said, to improve information sharing.

So in terms of awareness, we've already talked about the need to make sure people are aware that intentional harm is something that needs to be considered. And so when it comes to a regulator's role, if you're a regulator that helps develop or deliver ongoing professional development content, you can play a role in encouraging that awareness by, for example, incorporating discussions about intentional harm into learnings about professionalism or assessing risk or other relevant topics like that.

And it's also important to ensure that healthcare professionals and employers understand their reporting obligations. So for example, here in Ontario regulated health professionals have to report when there's evidence that a patient has been sexually abused by another healthcare professional; but when it comes to non-sexual abuse, that may be something that under the standards you need to report, but it's not a mandatory reporting obligation under the legislation. And so there's often some confusion about, do I have to report this? To whom do I report it? So I think just doing something as simple as clarifying to the professionals you regulate what you expect them to report and when can go a long way.

And then in terms of processes, most cases involving intentional killing by healthcare professionals have involved the use of medications as a weapon. So one thing, a regulator can do is put out guidelines that encourage a strong approach to analyzing medication errors, so for example, by encouraging use of an incident analysis framework that involves the consideration of intentional harm. And that just makes it more likely to pick up on cases like this at an earlier phase.

Another thing we heard a lot about during the inquiry into Elizabeth Wettlaufer was the importance of

encouraging a just culture philosophy when it comes to medication errors. And that's an approach that doesn't seek to blame the person involved when they make a medication error, but it views errors as a learning opportunity. And the research shows that this increases instances of self-reporting and reporting of errors by colleagues. So when everyone understands that reporting is expected, it's a positive thing, it increases the odds that an employer and the regulator will learn of errors that may be caused intentionally.

Christine: So, I think there are just two things that I'd like to pick up on here. So the first, in terms of what regulators might do to work with others within the health system, I think it's important for them to work with system regulators to address the contextual factors. We know from the literature that while traits are an important component, the contextual factors can actually moderate their prevalence. So ideally I suppose I would see a system in which professional regulators are working alongside system regulators and vice versa. So the system regulators are checking the kind of factors that we know impact on health professionals' ability to meet and apply the standards, but also to reduce the opportunity for intentional harm to take place.

The second aspect is actually to increase patient agency. So we've done some work recently looking at what is the role of a patient in maintaining their own safety rather than them just simply having to rely on health professionals to keep themselves safe. What is it they can do themselves to help them to improve that? And I think that takes some work with patient organizations to help look at ways to do that.

We know that we heard from David that actually the likelihood is, you say, that people are being treated in places for short periods of time, maybe not with their family members around, so what happens when they don't have anybody else there to advocate for them? How will that system be put in place? And what could be done to address the sort-of power imbalance and the asymmetry of influence? In the case of Clifford Ayling for example, he was often targeting young women; he was targeting women many of whom it was their first experience of childbirth and they didn't know what to expect; they didn't know what was gonna happen with regard to the health procedures. And you can see this time and time and again, in inquiries in which patients are kind of self-critical and doubt themselves as to 'Well, maybe that's just normal medical procedure. Maybe I shouldn't make a fuss about it.' And that of course can be reinforced by the reactions of some other health professionals around them when those health professionals are also finding it difficult to think that their colleague could possibly be doing the unthinkable. So I think that's another focus for regulators to think about and probably one we haven't thought about to any very great extent. But it is definitely one that we should be focusing on in the future.

Line: Absolutely. Well, let's finish with one final question, I guess. If a worst case scenario happens where maybe a regulator does learn that one of its registrants or licensees has intentionally harmed or killed a patient or patients, what can regulators do to help navigate increased public scrutiny that often results from something like this, as I would imagine?

Lara: Well, I think one maybe obvious thing, but it's important, is to work with your communications

team to reassure the public that they're safe. Because as we talked about at the beginning, one of the really serious effects of a case like this, is when it does happen, it really shakes the public trust in the system. And given that we're all in the business of protecting the public, reassuring the public that they're safe is one of the top priorities.

The other thing you'll probably have to do is to devote resources to cooperating with any law enforcement investigations that are going on and coordinating that process to make sure that you're doing what you need to do, but you're not interfering with any criminal investigation that's going on at the same time.

And the other thing I'd say is that if it is one of those cases that leads to a public inquiry, that often requires significant resources. And if a regulator's involved in that, they may need additional staff support dedicated to that process because public inquiries tend to be very long, they tend to be very resource-intensive, and you may need additional support for that.

Christine: And I think I would add to that the importance of having liaison people in two ways. One is, I think it's important, particularly where it be multiple incidents, that there is a chief investigator appointed within the regulator who oversees the multiple incidents if there are multiple incidents, so that the connections between those cases aren't lost in any way. And also to think about whether or not there may be other cases that haven't come to light yet or whether it might cause the regulator to need to think about whether there are other health professionals whose actions might also need to be looked at, given what I said earlier about bonds of transgression.

And then the second thing I think that is really critical, is to support patients and witnesses well and make sure that they are really kept well-informed throughout the whole process. Ideally they should be given a main person within the regulator, with whom they can get in touch both proactively and in response to any communication from the regulator too. Those two things are really important in terms of helping to maintain and to re-build trust.

And I have one final point. And that's for the regulator themselves to make sure that they're being open and transparent and honest. And so if a regulator has made a mistake or is being slow in dealing with something like that, it's really important that the regulator models the behavior they expect of their registrants and that it's up-front about that.

David: I want to amplify a little bit about the points I made in relation to communication. The last thing that you want to do is to go and get media training in the middle of all of this. You really need to be prepared. And therefore, one of the things that I would certainly advocate for is, that whoever your spokesperson is, that they are regularly updated in terms of their media skills as part of a proactive approach. Not all regulators have the authority to speak publicly; some are part of agencies. And therefore, knowing how communication flows within your own agency and knowing who the spokesperson will be is also really important, and the type of briefing that they will need to make the point. If you're not able to obviously do it yourself, you need to make sure that those key points are given into the hands of whoever the person is that is actually going to be speaking to the public on the

media as part of this process as well.

I think obviously be as transparent as possible, but there are often things that cannot be said at a particular point of time, but be really clear about that - why you're not actually giving information at that point of time and make it clear that once it is possible to do that, you will come back to them - and certainly do it.

I think the other thing that can often happen when there is more than one or more than a couple of cases is the public themselves start to think about their loved ones that have perhaps passed and wonder whether or not their family member could have been the victim as well. And therefore thinking about not just psychological support for those that have been directly affected by this, but think about how you have mechanisms in place as a helpline or whatever. It potentially gives you additional information that you may need to investigate, but also you're prepared to actually handle that issue as well.

And one of the things that I think it is always very good to do is really, in the media training sessions, get the worst case scenarios really pushed so that you're ready to deal with those. There's nothing worse than just simply saying 'No comment.' It really does vexate the media, the public as well. It's a mechanism that often loses confidence, and therefore having ways of dealing with those really tricky questions ahead of time will enable you to get your message across, reassure the public, and deal with this in a professional and effective manner.

Line: Well, very good. Well, I wanna take a moment just to thank Lara, Christine, and David for your time and being a part of this podcast. I think it's always a great opportunity to share and learn from each other. And with this being one of the sessions for the AEC this September, I actually look forward to checking out that and hearing a little bit more about it. So again, thank you for speaking with me today.

And I also want to thank our listeners. We'll be back with another episode of Regulation Matters: a CLEAR conversation very soon. Please subscribe to our podcast on Podbean, iTunes, Apple Podcast, Google Podcast and Google Play, Stitcher, Spotify or TuneIn. So there's a lot of different areas for you to be able to hear this. If you enjoyed this podcast, please leave a rating or a comment in the app. That helps us improve our ranking and make it easier for new listeners to find us. Feel free to visit our website at www.clearhq.org for additional resources as well as the calendar of upcoming training programs and events. Finally, I'd like to thank our CLEAR staff, specifically Stephanie Thompson, our content coordinator and editor for this program. I'm Line Dempsey, and I hope to be speaking to you again very soon.

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