

Medical Devices

SECTION EDITOR



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Editorial

May 2020 was set to be a busy month for medical device writers in Europe. The EU Medical Device Regulation (MDR) was to take effect on May 26, and we were anticipating lively discussions on the final MDR preparations with our fellow writers at the 50th EMWA conference. For this issue, Cherry Malonzo had

originally intended to provide you with a recap of the Medical Device Expert Seminar Series (ESS) from the conference in Prague. That is until the coronavirus pandemic arrived in Europe, the EMWA conference was cancelled, and even the implementation of the MDR was postponed. With no ESS to report on, Cherry proposed to reach out to our medical writing colleagues to hear how they

are coping with this unprecedented situation, both personally and professionally. In this issue, we can share with you three of the responses from colleagues weathering the COVID-19 lockdowns in England, Germany, and Switzerland. I hope you are all staying safe, healthy, and sane in these challenging times.

Kelly



Medical writers under lockdown

When the coronavirus lockdowns were put in place across the globe in a span of a few short weeks, it felt as though we had all been thrown into the set of a bad movie. Suddenly, we all found ourselves re-orienting our entire existence to the new normal, learning to find the best means to cope with the circumstances (and with each other). Regardless of location, it is not hard to relate to the following accounts and reflections of our colleagues Jane, Claudia, and Payal.

Cherry Malonzo Marty
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Jane Edwards, England

I have two types of a rare autoimmune disease, vasculitis, which means that my immune system attacks my blood vessels and causes inflammation. The first type is granulomatosis with polyangiitis (GPA), which affects my small blood vessels, leaving lasting damage to my kidneys, eyes, nose, and ears. The second type is large vessel vasculitis, Takayasu Arteritis (TAK), which has caused inflammation in the main aortic root and arch.

The COVID-19 pandemic has created a crazy time, and it is extremely difficult for those of us with underlying health issues. I am used to being isolated after 8 years of being ill, but I now find myself surrounded by people 24 hours a day.

Having an energised husband, an emotional teen, and a very bouncy dancing 9-year-old in the house is leaving me exhausted. But I am also glad to have them all close and to be able to do fun things together. We have been shooting netball hoops in the garden, playing Jenga, and doing a YouTube Joe Wicks PE podcast some mornings.

The whole of the UK is on lockdown, and people should not leave their homes except for essential shopping, daily exercise, and critical medical appointments. We have a list of key workers, including medical staff, who are also allowed to travel to and from work. I work for BSI Notified Body as the Global Head of Communications, and a significant number of the team were already partly working from home, so

the adjustment has been gentle.

Because of my level of prednisolone and the fact that I have Rituximab infusions every 4 months, I am considered high-risk and advised to go into "shield" mode by the UK government. We are advised not to leave the house for any reason, and to enact "social distancing" inside the house with our family. My whole family has been social distancing for about 20 days. The advice is to stay 3 feet from the family, but because we have been cut off, we have decided that we will not do this, partly because we live in a quiet area and can avoid people. I am not advising anybody else about what they should do, we must look at our own situation.

I have found it beneficial to just stop using all

social media. I couldn't cope with all the comments from people, whether they were claiming to be experts, making light of the situation, or having a dig at those who were taking it seriously or conversely ignoring the warnings. This has helped me to almost ignore the situation. I have stopped watching the news, except for listening to the government briefing just once a day. I believe the hard part of this situation is to remain positive and try to keep a routine, both for work needs and family time. Maintaining the balance will be how we survive this difficult time.

Jane Edwards

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Claudia Frumento, Germany

To be honest, being a freelance medical writer who works from home, I was not expecting my life to change much under the self-imposed coronavirus quarantine. I wake up at around 7 am, enjoy breakfast, read the newspaper, start working in my pyjamas, and at some point, when my dog (Greco) gets nervous, I get dressed and go for our daily walk in the woods.

But after only 2 weeks, I realised there were changes. There were some changes that I might have expected first in a few years, with retirement: my husband is also at home now, every single hour of the day, every single day and night! It is not that I don't love him, but he uses MY phone (ringing all the time), he uses MY office, and he uses MY printer. By the way, my husband is working very closely with the health authorities of the country and he is ALWAYS in conference calls using MY phone line, and MY calls are diverted or are lost in the corona ether.

Our poor dog Greco does not understand why he can't doze any more in his preferred corner of the office and bark once in a while when a rabbit comes into the garden. Before

coronavirus he used to bark at the footballs that came in flying from the playground. Now he gets all confused when he finds me working downstairs in the living room.

But the real problems start around dinner time when my husband finally comes downstairs. The new "corona news" discussed during the endless conference calls are described in detail over dinner. If I had managed to forget about it during the day, it all comes over me again. The fear, the "German angst", what this virus is going to do to us all, why we are part of that high-risk group that is dying like flies in other countries, why men seem to die more than women, why this will have a tremendous negative impact in the economy! The only thing that has not yet been discussed at high health authority levels is why Germans and most Europeans seem to have a fixation on toilet paper in times of crisis!

Yesterday, I issued an ultimatum to my husband: think of something nice to discuss during dinner, simply one topic that is not related to corona. He answered with a smile: how about the Netflix series *The Crown** or the *Walking Dead*?

*corona = crown in Spanish

Claudia Frumento

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Payal Bhatia, Switzerland

It was a Sunday morning when I heard from my employer that I would be working from home. With COVID-19 picking up pace, this arrangement was a big relief. But was it? Several questions started sprouting up in my mind: Was it too late? How bad will things get? How long will the lockdown last? Should we stock up groceries? What if the daycare is closed? Even if daycare is not closed, should we continue sending our 4-year-old? And on and on I went.

Now, almost 4 weeks later, I can say that it was fear. Not the fear of dying from the virus, but the fear of the unknown. The fear coming from the uncertainty that surrounded (and still does) the circumstances and our ability (or inability) to deal with them. The fear of not making the right decisions and the fear of losing it all with the lockdown. But our doubts have started to settle, and we are managing to sail through, just like everyone around the world is. We continue to send our daughter to daycare, and my husband and I have found peace by dividing our home into separate office zones. I took the office room, not because I am mean, but because I work 2 days from home in my 4-day work week and it just seems easier to continue with the status quo. He has set up his office in the dining room. We communicate more than usual to ensure we do not have overlapping meetings but schedule our lunch together. Sharing domestic work is no longer relegated only to the weekends.

Speaking of weekends, keeping our child entertained is a challenge. My go-to activities so far have mainly included teaching my daughter to write, inventing silly stories and songs almost the entire day, letting her tune into audio stories every now and then, reading to her even more, taking walks in the barren forest in the neighbourhood, hosting imaginary birthday parties (and dressing up for them), cleaning out closets and cabinets, baking, and preparing our terrace for spring. My sanity comes from organisation around the house, good nutrition, mindfulness, reading, and keeping myself well-informed – but not overinformed. Besides that, I am staying hydrated, using the stairs at least once a day, and trying hard to practice minimalism in everyday life. By staying home, we are all doing our part. Let's hope it's enough!

Payal Bhatia

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EU MDR implementation postponed

The European Commission has adopted a proposal to delay implementation of the EU MDR by 1 year, to May 26, 2021.^{1,2} The delay is intended to ensure essential medical devices remain available and allow medical device manufacturers to prioritise efforts to fight the COVID-19 pandemic. While the MDR date of application will move to 2021, the planned implementation of the in vitro Diagnostics Regulation (IVDR) remains unchanged with application from May 26, 2022. The proposal received the full support of the European

Parliament and the Council needed through an accelerated co-decision procedure to become effective before the original May 26, 2020, MDR implementation date.

References

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