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Editor's Corner

Who owns the right to repair?

I recently participated in an effort led by members of the health technology management community in North America about what is becoming to be known as "the right to repair" movement. This is not just a healthcare equipment issue but rather it origin is from outside the healthcare industry and spread throughout many industries including information technology (computers), consumer electronics (phones), agricultural products, appliances, automotive and more. The debate is about the principal question: Why do consumers not have the right to access parts, tools, or guides (service manuals) for the equipment that they own? Holding back information or placing replacement parts as inaccessible to consumers/owners or an independent equipment service providers takes away the owner's property rights. The right to repair coalition maintains programs aimed to change that by raising awareness including within the healthcare technology management field. The coalition's website post a quotation, under their medical technology tab[1], that "In some developing countries, up to 50% of the medical equipment is unusable at any given time. In some hospitals, up to 80% of their medical equipment is inoperative …" World Health Organization. To access service information, you and many others are probably familiar with, and perhaps even used, the Frank's Hospital workshop site[2] to find needed information not otherwise provided for repairing your medical equipment.

This coalition's website posts Frank's story as follows: "Frank Weithoener is a well-regarded biomedical repair technician in Tanzania. He identifies five major barriers to medical device repair in developing countries:

1. No spare parts for repairs and maintenance
2. No technical manuals
3. Poorly trained biomedical technicians
4. No technical support from the manufacturers
5. Lack of awareness of the advantages of preventive maintenance

Since manufacturers weren't supporting the repair of their products, Frank decided to do it himself. He runs a website[2], dedicated to training technicians. Unfortunately, Weyer, General Electric, and other manufacturers regularly send him legal threats and take-down notices demanding that he stop teaching people to repair life-critical medical equipment." The US FDA issued a report on the topic in May 2018[3] summarizing, in part, that "the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices" and that "The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system." However, this did not address the questionable access to manuals and spare parts. Others, including an Apple Inc. co-founder, Steve Wozniak, stated during an interview with one of the supporters of this movement in part[4] "if you know what you're doing and you're doing certain steps that other solved…why stop the self-repair community?" Even politicians engage with this debate, like US Senator Mr. Ron Wyden and US Representative Y. D. Clarke who together introduced a bill in the Senate of the US tilted "Critical Medical Infrastructure Right-to-Repair Act of 2020"[5] attempting to alleviate medical equipment repairs during COVID-19 crisis.

However, as medical equipment is used at times in life critical conditions, we must ask the question: who is competent to service such important technology. This led me to search for an answer to the question what is a competent clinical engineer? I visited variety of sources and came across an article *A day in the life of a clinical engineer system supervisor*[6] where "this sophisticated technology requires constant assessment, management and maintenance to deliver on that promise" points to the public expectations that the equipment will improve

providers' ability to manage their patient's conditions and raise their care outcomes.

During my search I used terms such as how to become an engineer where the Quora website that states its mission is "to share and grow the world's knowledge", showed as a response one of the titles that asked: Can anyone become an engineer, or do you have to be born into it with natural skills?[7]. An interesting angle that I wonder if it suggests that it is possible that engineers' DNA set us apart? Hopefully, they are not serious about that. Another source adds the suggestion that soft and interprofessional skills must be part of clinical engineering education program[8,9]. So, while I believe in the principal of right to repair, I also strongly recommend that clinical engineers should seek demonstration of their competency through credentialing program. In a recent article *Is Clinical Engineering an occupation or profession?*[10], where I am included as one on the list of international authors, it states in part: "Clinical engineers also need to recognize, like other professions that when establishing defined requirements to enter the professional practice, there needs to be consensus about and adopting clinical engineering practice criteria. This includes domain boundaries, establishing a minimum qualifications criterion for entering clinical engineering practice in healthcare, a commitment for compliance with life-long continuing education, adherence to ethical behavior, service stewardship to their communities, and rules for self-governing. Adoption of these cannons will gain wider recognition and elevate the professional standing they desire."

Did you experience any of the obstacles when looking for service manuals or access to replacement parts or software keys to equipment apps? Would you agree with me that, since we are concerned with patients' lives, the Right to Repair movement should modify their poster to reflect that it's argument should be about the Right to Repair by Competent Workers. Let me know your opinion.

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