Chapter 11

ROBOTS AND ARTIFICIAL INTELLIGENCE IN HEALTH CARE

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A. INTRODUCTION

Robots and artificial intelligence ("AI") will infiltrate the health care system before the next edition of this book is published. Machines will not only assist, but in many circumstances, will substitute for humans as caregivers, medical service providers, diagnosticians and expert decision-makers. In so doing, they will generate a number of novel issues for Canadian health law and policy. The appropriate application of existing law, the need for new laws and the formation of wise policy choices require our early attention in order to ensure beneficial uses of robots and AI.

Robots are already automating various physical tasks traditionally carried out by health care professionals, such as: lifting; suturing; delivering goods; administering medications; monitoring vital signs; tracking patients; and assisting with mobility. Kinova, a Montreal-based robotics firm, has developed robotic arms that increase the mobility and independence of wheelchair users.[1] The Smart Tissue Autonomous Robot ("STAR") is already outperforming human surgeons at suturing incisions.[2] Transcending the physical, AI is achieving measurable success in carrying out various intellectual tasks in the fields of psychotherapy, medical diagnostics and decision-making — elements of health care that, historically, were within the exclusive domain of human clinical experts. For example, IBM Watson — a cognitive supercomputer

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1 "Get the Most from Your Robot" Kinova Robotics, online: http://www.kinovarobotics.com/assistive-robotics/knowledge-center/.

2 Larry Greenemeier, "Robot Surgeon Successfully Sews Pig Intestine", *Scientific American* (May 4, 2016), online: https://www.scientificamerican.com/article/robot-surgeon-successfully-sews-pig-intestine/.

designed to glean meaningful information from countless sources of structured and unstructured medical information[3] — is able to diagnose lung cancer with a success rate of 90%, significantly outperforming human doctors' 50% success rate.[4] After scouring more than 20 million journal articles (an impossible task for human experts), Watson was recently praised for correctly diagnosing a rare form of leukemia in a patient whose doctors had misdiagnosed her.[5] Health benefits are not limited to sophisticated supercomputers. PARO, a small "social robot" in the form of a baby seal that responds to human touch and noises, was shown to improve the well-being and social interaction of elderly patients who were exposed to it.[6]

These early successes prefigure the anticipated impact that robotics and AI will have in the coming decades on the health care system, its many industries, professionals and caregivers, as well as the patients and family members subject to their use. At the same time, various features of robots and AI will create emerging challenges for health care, requiring careful reflection about the appropriate bounds of delegating human tasks and decision-making to machines. In addition to their potentially huge impact on labour markets, robots and AI will force us to rethink several traditional legal and moral concepts, including liability, responsibility and redress. Thus, as we march down the road to automation, it is worth taking stock of the various robots and AIs currently deployed and under development in the health sector. Doing so will help us identify, anticipate and better understand some of the social, legal and policy challenges that these technologies are generating.

Part B of this chapter offers a survey of notable robots and AI currently used in health care, as well as some that are on their way to commercialization. Following this description of the technological landscape, Part C examines sociotechnical considerations that must be confronted by health policy as it grapples with the complex interactions between humans, robots and AI. This sets the stage for Part D, which is devoted to an exploration of key legal considerations that arise, highlighting the need for various reforms of legal doctrine and regulatory structures. As robots and AI are an emerging rather than established component of health care delivery, this chapter seeks to provoke, challenge and inspire readers to think critically about what is sure to be one of the most pressing sets of issues in Canadian heath law and policy debates over the next two decades.

3 For example, scientific journal articles, hospital records and even doctors' notes.

4 Ian Steadman, "IBM's Watson is Better at Diagnosing Cancer than Human Doctors" *Wired* (February 11, 2013), online: http://www.wired.co.uk/article/ibm-watson-medical-doctor.

5 Bernie Monegain, "IBM Watson Pinpoints Rare Form of Leukemia After Doctors Misdiagnosed Patient", *Healthcare IT News* (August 8, 2016), online: http://www.healthcareitnews.com/news/ibm-watson-pinpoints-rare-form-leukemia-after-doctors-misdiagnosed-patient.

6 Cristina A. Costescu, Bram Vanderborght & Daniel O. David, "The Effects of Robot-Enhanced Psychotherapy: A Meta-Analysis" (2014) 18:2 Rev. General Psychol. 127.

B. A SURVEY OF ROBOTS AND AI USED IN THE HEALTH SECTOR

This Part provides a survey of various categories of robots and AI used in the health care setting. Although the level of uptake and impact of the technologies described below remains uncertain, this snapshot will help foreshadow the social, legal and regulatory issues discussed in Parts C and D.

1. SURGICAL ROBOTS

Surgical robots are perhaps the most well known robots in use in the medical sector.[7] Robotic surgery is proliferating in medical centres eager to position themselves as leaders in cutting-edge treatment. At the same time, questions remain about the effectiveness and overall cost benefit of robot-assisted surgery.[8] Intuitive Surgical's "da Vinci" is the undisputed industry leader and has been employed in more than a million successful surgeries on patients requiring hysterectomies or prostate removal.[9] A human surgeon remotely operates the da Vinci. Trading proximity for precision, the surgeon uses computer assisted vision, joystick-like controls and advanced 3D imaging technology to guide the da Vinci's robotic arms through small incisions in the patient's body.[10] The system's control algorithms enhance the surgeon's expert abilities by filtering out hand tremors and allowing for more complicated and precise movements than would be possible by human hands alone.[11] While these control algorithms are the catalyst to better-than-human surgical capability, they simultaneously mediate the doctor's relationship with her own expertise, as a kind of third party whose operations are beyond the surgeon's control. For example, the integrity of a surgery could be undermined by a bug in the algorithm or "biases" in the software that presume certain machine responses are appropriate when they are not. Tele-surgery could also be hacked.[12] The technological challenge is to find ways to allow the machine to correct for human imperfection while, at the same time, allowing the human operator to maintain control in the case of a machine malfunction. This is a more general aim of "co-robotics" — humans and machines working symbiotically to achieve results that neither could achieve alone.

As indicated, with the da Vinci and similar tele-operated surgical systems, the surgeon is meant to dictate the procedure and its outcome. The robot merely

7 Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

8 Robots have botched more than 100 surgeries, generating significant litigation. *Ibid.*

9 *Ibid.*

10 *Ibid.*

11 Sulbha Sankhla, "Robotics Surgery and Law in USA – a Critique" (2013), online: Social Science Research Network https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2425046.

12 "Security Experts Hack Teleoperated Surgical Robot", *MIT Technology Review* (April 24, 2015), online: https://www.technologyreview.com/s/537001/security-experts-hack-teleoperated-surgical-robot/.

assists the surgeon in carrying out her task. More recent innovations, however, have generated robots that are meant to perform autonomously, *i.e.*, the robots carry out procedures from start to finish without human intervention. Significant research and development on autonomous surgery is underway. For less complicated procedures like laser eye surgery, knee replacements and hair transplants, automated surgeries of these sorts are now possible.[13] Already, much progress has been made in autonomous soft tissue surgery. The STAR robot described in the introduction can stitch a pig's small intestines using its own computer vision, tools and AI to carry out the procedure without human help.[14] It is already performing with greater precision than human surgeons. As autonomous robotic surgery continues to advance and success rates continue to increase, there will be increasing pressures on surgeons to relinquish control to the machines.

2. EXOSKELETONS

The co-robotic ideal described above is no more evident than in the recent development of wearable robotic systems used to rehabilitate, restore and enhance human mobility. Lower-body robotic exoskeletons like the Ekso are being used for gait rehabilitation of stroke and spinal cord injury patients.[15] The magical interplay between the Ekso's AI/algorithms and its robotic hardware allows physically disabled patients to move without human help, increasing independence, accelerating strength development and reducing the physical toll on human rehabilitation therapists.[16] This fascinating merger of humans and machines is not limited to the therapy setting. People with mobility disorders are now using exoskeletons quite successfully as alternatives to wheelchairs. The ReWalk Personal and the Indego Personal have met the safety standards required by the FDA for all-day use at home and in the community.[17] As these machines are more broadly adopted — like canes, crutches and electric wheel chairs — co-robotics will become further normalized.

Like many robotic technologies in development, it is possible to tweak exoskeletons initially designed to restore human function in a therapeutic context in ways that ultimately augment human function beyond typical human performance capabilities. Consequently, physically assistive wearable robots are also being created for able-bodied users to enhance their strength and mobility. In the health care setting, medical applications such as Cyberdine's The HAL

13 Tanya M. Anandan, "Robots and Healthcare Saving Lives Together", *Robotics Online* (November 23, 2015), online: http://www.robotics.org/content-detail.cfm/Industrial-Robotics-Industry-Insights/Robots-and-Healthcare-Saving-Lives-Together/content_id/5819.

14 Azad Shademan *et al.*, "Supervised Autonomous Robotic Soft Tissue Surgery" (2016) 8:337 Science Translational Medicine 337ra64, online: http://stm.sciencemag.org/content/8/337/337ra64.

15 Gurney Khera, "Exoskeletons to Revolutionise Rehabilitation" (2015) 22:8 Australian Nursing Midwifery J. 17.

16 *Ibid.*

17 Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

have been developed to enable smaller framed health care workers to safely and easily lift and move patients without strain.[18] Although such applications have very practical benefits, it is important to realize that the commercial development of non-therapeutic exoskeletons creates the possibility of a shift away from traditional restorative medicine, in favour of an enhancement-based approach, the aim of which is to make those who can afford it better-than-well.[19] Although this vision smacks of Dr. Tony Stark's "Iron Man",[20] it in fact raises serious policy considerations associated with resource allocation in the health care system.

3. PROSTHETICS

Prosthetics raise similar concerns. The possibility of prosthetics as enhancements emerged at least a decade ago when Oscar Pistorius, a paralympic-cum-olympic athlete was subject to scrutiny by the International Association of Athletics Federation.[21] At issue was whether "the fastest man on no legs" was "too-abled" when running on his Ossur bionic legs.[22] Although Pistorius (an elite athlete endorsed by Nike to the tune of $2 million per year) could easily afford several pairs, the same is not true of the broader community of amputees, many of whom might also prefer performance enhancing rather than merely therapeutic prosthetics. The health care system will continue to feel pressure as more people demand enhancement-quality hip and knee replacements and the like.

There have been significant technological advances in prosthetics in past decades. For amputees, smart robotic prosthetics, like the DEKA Arm System, that can be controlled through EMG signals sensed in the amputee's own muscles are now being developed.[23] Similar systems are being developed for

18 Jason Falconer, "Cyberdyne Wants to Offer Robot Suit HAL in the U.S." *IEEE Spectrum* (December 9, 2014), online: http://spectrum.ieee.org/automaton/robotics/medical-robots/cyberdyne-to-offer-robot-suit-hal-in-the-us.

19 Ian Kerr & James Wishart, "'A Tsunami Wave of Science': How the Technologies of Transhumanist Medicine are Shifting Canada's Health Research Agenda" (2008 Special Ed.) Health L.J. 13.

20 Archie Goodwin, *et al.*, *The Invincible Iron Man* 1:1 (New York: Marvel Comics, 1968).

21 Ian Kerr, "Oscar Pistorius' New Normal" (January 6, 2008), Ian Kerr (blog), online: http://www.iankerr.ca/blog/2016/6/21/oscar-pistorius-new-normal; Gregor Wolbring, "Oscar Pistorius and the Future Nature of Olympic, Paralympic and Other Sports" 5:1 SCRIPTed J.L. Tech. Soc'y 139. To be clear, Oscar Pistorius is no hero. After a protracted legal battle, Pistorius was sentenced to six years imprisonment in July of 2016 for the murder of Reeva Steenkamp at his home in Pretoria on February 14, 2013.

22 Jeré Longman, "An Amputee Sprinter: Is He Disabled or Too-Abled?" *New York Times* (May 15, 2007), online: http://www.nytimes.com/2007/05/15/sports/othersports/15runner.html; Josh McHugh, "Blade Runner" *Wired* (March 1, 2007), online: https://www.wired.com/2007/03/blade/.

23 Developed by the Defense Advanced Research Agency ("DARPA"). Erico Guizzo, "Dean Kamen's 'Luke Arm' Prosthesis Receives FDA Approval" *IEEE Spectrum* (May 13, 2014),

prosthetic hands.[24] These systems will use implanted electrodes to measure prosthesis control signals from muscles and motor nerves, and will provide sensory feedback to the amputee via electrodes implanted in sensory nerves.[25] This will allow for a more "natural" human control of the prosthetics and better integration with the body.

Currently, most smart prosthetics use Bluetooth and other device-based connectivity rather than wireless networks to support these interactions. Soon, however, cloud computing and the so-called "Internet of Things" will drive robotic devices of this sort. Much in the same way that the Internet currently uses various software protocols to link communications devices, our expanding networks will increasingly permit the connection of bodies and other physical objects. These objects will be embedded with electronics, software, sensors, processors and actuators, allowing novel forms of cybernetic interactions between biological and non-biological entities.

Many of today's exoskeletons and prosthetics are already internet-enabled and this tendency towards greater connectivity is sure to increase. This will, of course, raise a series of issues relating to privacy and information security. Devices with wireless capabilities are prone to being hacked, and protocols and standards will be required to minimize the possibility of such interference. As discussed below, Vice President Dick Cheney realized this need in 2007 when he became worried that his heart implant would be subject to a denial of service attack.[26] The application of data protection and privacy laws will also have to be refined in response to the enormous amounts of health data transmitted between such devices, our bodies, device makers and health care providers. These issues are not novel, but the sheer magnitude of data and the serious consequences of breaches will require careful attention.

4. ARTIFICIAL ORGANS

Although the commercialization of artificial organs sounds like science fiction,[27] a wide range of robotic devices are already assisting and replacing human organs. For example, blind patients are receiving retinal implants like the Argus II, which uses a video camera and retina-stimulating electrodes to convey shapes and motion.[28] Profoundly deaf individuals may choose to receive cochlear implants ("CIs") that directly stimulate the inner ear via surgically implanted

online: http://spectrum.ieee.org/automaton/biomedical/bionics/dean-kamen-luke-arm-prosthesis-receives-fda-approval.

24 Douglas Weber, "Hand Proprioception and Touch Interfaces (HAPTIX)", online: DARPA http://www.darpa.mil/program/hand-proprioception-and-touch-interfaces.

25 *Ibid.*

26 Dan Kloeffler & Alexis Shaw, "Dick Cheney Feared Assassination Via Medical Device Hacking: 'I Was Aware of the Danger'" *ABC News* (October 19, 2013), online: http://abcnews.go.com/US/vice-president-dick-cheney-feared-pacemaker-hacking/story?id=20621434.

27 *Repo Men*, online: IMDb http://www.imdb.com/title/tt1053424/.

28 Sarah Lewin, "8 Must-Have Implants for the Cyborg Patient", *IEEE Spectrum* (June 5, 2015), online: http://spectrum.ieee.org/biomedical/bionics/8-musthave-implants-for-the-cyborg-patient.

electrodes. Newer CIs, in addition to transmitting environmental sounds, use wireless connectivity to stream audio directly from cell phones, TVs and whatever other devices the patient desires.[29]

It is also possible to automate the regulation of bodily functions via devices. Medtronic, for example, has developed such an application for diabetics[30] — an "artificial pancreas" that monitors and automatically adjusts blood-glucose levels, eliminating "peaks and valleys" to improve health outcomes.[31] Similar feedback mechanisms are used in internal cardiac defibrillators ("ICDs"), such as the one implanted in Dick Cheney. ICDs can monitor cardiac rhythms, "shocking" the heart back into normal rhythms when life-threatening irregularities are detected.[32] Some of these assistive devices, for example, ventricular assist devices, are performing so well that they are no longer merely "bridges" to a transplant but, instead, allow patients to return to a relatively full life.

Artificial organs, like other implantable technologies, give rise to hacking, information-security and failure concerns. They also raise novel issues for health law and policy by virtue of their location inside the human body. With artificial organs, patients' bodies are now being driven by life-sustaining software that resides inside of them but is entirely beyond their control. The software is most often proprietary, meaning that some company owns it (usually treating its source code as a trade secret). The patient's use of the device is strictly regulated by the terms of an end user licence agreement ("EULA"). As a result, manufacturers are able to adopt the controversial business models used for mass-marketing consumer goods known as "planned obsolescence" and "vendor lock-in" (think Apple's iPhones and iPads). By regularly requiring software updates, or by developing new hardware that is not forward/backward compatible, EULAs permit the possibility of serious injustice.[33]

Will a patient's damaged bionic knee be replaced if her lifestyle did not comport with the User Manual? Will the warranty for a cochlear implant be void if the CI is plugged into peripheral devices made by competitors? While courts have yet to make any such pronouncements, existing Terms of Service agreements provide clear answers to these questions (respectively: "no" and

29 Cochlear, "Cochlear Implants", online: http://www.cochlear.com/wps/wcm/connect/au/home/discover/cochlear-implants.

30 Medtronic, online: https://www.medtronicdiabetes.ca/; Philip E. Ross, "Diabetes Has a New Enemy: Robo-Pancreas" *IEEE Spectrum* (May 27, 2015), online: http://spectrum.ieee.org/biomedical/bionics/diabetes-has-a-new-enemy-robopancreas.

31 Philip E. Ross, ibid.

32 Jason Millar, "Technology as Moral Proxy: Autonomy and Paternalism by Design" *IEEE Technology and Society Magazine* 34:2 (June 2015) 47, online: http://ieeexplore.ieee.org/document/6893388/.

33 Ian Kerr, "Repo Men Are Coming: Body EULAs, Privacy and Security of the Person" (speech delivered at the University of Waterloo, October 10, 2012), online: https://crysp.uwaterloo.ca/speakers/20121010-Kerr.

"yes").[34] These one-sided, take-it-or-leave-it contracts are becoming the rule, and device manufacturers the rule-makers. Consumer protection legislation will not provide an easy cure. Law reform in the health sector is necessary to protect patients who are dependent on these devices and yet do not own or control the software that drives them.

5. Pharmacy and Hospital Automation Robots

Robots are also driving changes in hospitals and pharmacies. In an effort to cut costs, hospitals are taking cues from the manufacturing sector and using robots to increase efficiency. Autonomous delivery robots are being used for intra-hospital deliveries of medicine, meals, linens and equipment, freeing up time for nurses and support staff to take on other tasks.[35] Delivery bots like TUG, RoboCourrier and HOSPI, are programmed to intelligently navigate hospital corridors and avoid obstacles.[36]

Robots are also encroaching on the traditional role of pharmacists as large robotic systems like Script Pro, Robot RX and RIVA are able to autonomously compound and dispense drugs.[37] These machines can increase the number of prescriptions that can be completed in a day and reduce human error in those tasks.[38] Scientists and engineers are working on automating other complex and specialized medical procedures like embryo vitrification — a highly technical and cumbersome operation in the processing of embryos that are then frozen for subsequent IVF procedures.[39] Robots are also being designed to replace health care workers performing needle-based procedures. The Veebot system is being developed to fully automate venipuncture procedures used to draw blood from patients and could help reduce many needlestick injuries common among health care workers. Another emerging class of robots in this category is disinfection robots — devices that can eliminate human error during the disinfection process (*e.g.*, surgical and other reusable medical equipment) and thus reduce infections.[40] While the introduction of robots into hospitals and other care facilities may result in greater overall efficiency, it also generates new risks. Robots have the capacity to do physical harm. They might one day also have the capacity to eliminate entire categories of the health care workforce.

[34] Terms of Service for the Ossur bionic knee and the Advanced Bionics cochlear implant are on file with the authors.

[35] Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

[36] Tanya M. Anandan, "Robots and Healthcare Saving Lives Together" *Robotics Online* (November 23, 2015), online: http://www.robotics.org/content-detail.cfm/Industrial-Robotics-Industry-Insights/Robots-and-Healthcare-Saving-Lives-Together/content_id/5819.

[37] Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

[38] *Ibid.*

[39] Jun Liu, *et al.*, "Automated Vitrification of Embryos: A Robotics Approach", *IEEE Robotics & Automation Magazine* 22:2 (June 2015) 33, online: http://ieeexplore.ieee.org/document/7066930.

[40] Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

6. Social Robots

Many robots used in health care will have social attributes, interacting with patients to provide companionship, therapy and an extended ability to monitor vital signs and other health-related functions. As robots become better able to mimic human facial gestures, voices, expressions, language and emotions, people will increasingly develop social bonds with them.[41] This, in turn, will establish the kind of trust necessary for the delegation of certain tasks and decision-making previously carried out by human caregivers and doctors. Robots are already being designed to optimize interaction with dementia and autism patients, providing the optimal level of social engagement to facilitate learning, companionship and, in some cases, increasing the capacity for independence among those patient populations.[42]

Another strategy for imbuing robots with sociality involves telepresence. Telepresence robots are semi-autonomous robots that can be remotely operated but can also carry out some operations on their own. The purpose of these robots is to give a sense of presence both to the teleoperator and those co-located with the robot. These robots use telecommunications to monitor health and provide support services to out-patients and others in need of care, without tethering them to an institution. The physical embodiment of these robots usually includes a body made of plastic and metal and a "face" (usually a screen that projects the face of the distant operator). The Giraff, a European-made telepresence robot targeted at elderly populations, uses a variety of smart home sensors to measure patients' blood pressure changes and detect when they fall down.[43] It also has a Skype-like interface to connect the patient with caregivers and relatives.

Social robots do not need all of these bells and whistles. Some of the most effective social robots to date are much simpler machines. Perhaps the most well-known of these is PARO, a socially assistive companion robot that resembles a baby seal. PARO is, in essence, an animated "stuffie" that uses tactile, light, auditory, temperature and posture sensors to perceive people and react to its environment.[44] PARO provides therapeutic support in much the same

[41] Kate Darling, "Extending Legal Protection to Social Robots: The Effects of Anthropomorphism, Empathy, and Violent Behavior Towards Robotic Objects" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016); Brian R. Duffy, "Anthropomorphism and the Social Robot" *Robotics and Autonomous Systems* (2003) 42:3 177.

[42] Cynthia Breazeal, *Designing Sociable Robots* (Cambridge, MA: MIT Press, 2003); Heike Felzmann, *et al.*, "Robot-Assisted Care for Elderly with Dementia: Is there a Potential for Genuine End-User Empowerment?" (Paper delivered at The Emerging Policy and Ethics of Human-Robot Interaction conference, Portland, OR, March 2, 2015) [unpublished], abstract online: http://www.openroboethics.org/hri15/wp-content/uploads/2015/02/Hf-Felzmann.pdf.

[43] Robotic Business Review, *Healthcare Robotics to the Rescue: Life-Changing Encounters with Machines* (Framingham, MA: EH, 2016).

[44] Erico Guizzo, "Paro the Robotic Seal Could Diminish Dementia", *IEEE Spectrum* (May 22, 2009), online: http://spectrum.ieee.org/robotics/home-robots/paro-the-robotic-seal-could-diminish-dementia.

way as animal therapy: reducing stress, promoting relaxation and stimulating interaction between patients and caregivers.[45]

7. BIG DATA ANALYTICS

Today's medical information technologies are generating truly staggering quantities of unstructured data, ushering in an era of information overload. From FitBits and medical imaging to electronic patient records and peer-reviewed scientific studies, it has become impossible for health care professionals to analyze all of the relevant data in a way that gleans useful, actionable information. Neuroimaging alone is estimated to generate 10 petabytes of data in 2017, (the equivalent of 3.3 billion pictures on an iPhone). The amount of data generated globally tends to double every 12-14 months.[46] Even with the aid of conventional computing techniques, this information overload presents an intractable problem. Thankfully, sophisticated AIs such as IBM Watson are finally starting to make a serious dent in the big data problem.

As we have seen, Watson already outperforms human diagnosticians. Like other big data analytics AIs, Watson is essentially a sophisticated computer program. However, its design differs from conventional computing approaches in a way that raises unique legal and ethical challenges: it uses *machine learning* to excel at its diagnostic tasks. Watson is programmed to "ingest" vast quantities of unstructured medical data and related medical literature, and "learns" how to perform a diagnosis under the directed tutelage of human expert diagnosticians who train it using question-answer pairs and reinforcement learning.[47] Once the human experts declare that Watson has reached a certain level of proficiency at the task, it is deemed expert enough to go into production. Just like human experts, Watson undergoes periodic "training updates", reading the latest curated sets of information, and answering more questions under supervision designed to test its new knowledge. Compared to conventional computer programs, Watson is less like a tool, and more like a medical student — always learning new medical information and occasionally making discoveries that would astonish an attending supervisor.

An important feature, and benefit, stemming from machine learning-based AIs like Watson is their ability to outperform human experts, often by gleaning new insights or performing actions that surprise even their designers and expert trainers. This *unpredictability by design*, sometimes referred to as "emergent behaviour",[48] has been observed fairly consistently in widely reported public

[45] Robotics Business Review, *Healthcare Robotics: 2015-2020 Trends, Opportunities & Challenges* (Framingham, MA: EH, 2015).

[46] Ivo D. Dinov, "Volume and Value of Big Data Healthcare" (2016) 4:3 J. Medical Stat. Info., online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4795481/.

[47] IBM Watson, "IBM Watson: How it Works" (October 7, 2014), online: https://www.youtube.com/watch?v=_Xcmh1LQB9I.

[48] Ryan Calo, "Robotics and the Lessons of Cyberlaw" (2015) 103:3 Cal. L. Rev. 513.

displays involving machine learning-based AIs, including Watson's debut on Jeopardy![49]

In addition to its growing success as a diagnostician, Watson is also being trained to help people navigate complex health institutions, identifying personalized treatments by analyzing patient and genomics data, and improving cancer treatment recommendations.[50] Watson's early successes are only the beginning. Google has plans to enter the world of health care AI with its own DeepMind technology.[51] As we discuss below, the need for big data analytics are changing the role of human experts in the world who will need to grapple with the complexities of working alongside their emerging AI counterparts.

C. SOCIOTECHNICAL CONSIDERATIONS

In addition to those discussed in Part B, robots and AI raise or amplify a number of traditional medical ethics issues, including: disagreements about treatment decisions; access to health care for vulnerable populations; medical error; informed consent; and substitute decision-making. Though these issues are important and worthy of mention, this section focuses instead on three particular sociotechnical considerations that arise alongside an increased interaction between humans, robots and AI in the health care setting: (i) Sociotechnical Influence; (ii) Social Valence; and (iii) The Paradox of Evidence-Based Reasoning.

1. SOCIOTECHNICAL INFLUENCE

It is well known that technology can have a significant influence on the people who use it. It can introduce new modes of thought and action, while simultaneously eliminating others.[52] Robots and AI can potentially influence traditional modes of medical practice by shifting the manner in which health care practitioners understand evidence, engage in scientific reasoning, and execute decision-making processes and protocols. As IBM Watson demonstrated

[49] Jason Millar, "The Momentous Advance in Artificial Intelligence Demands a New Set of Ethics", Opinion, *The Guardian* (March 13, 2016), online: https://www.theguardian.com/commentisfree/2016/mar/13/artificial-intelligence-robots-ethics-human-control. See also Ian Kerr & Jason Millar, "Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 102.

[50] Laura Lorenzetti, "Here's How IBM Watson Health is Transforming the Health Care Industry" *Fortune* (April 5, 2016), online: http://fortune.com/ibm-watson-health-business-strategy/.

[51] Search results for "google deepmind health", Google, online: https://www.google.ca/search?client=safari&rls=en&q=google+deepmind+health&ie=UTF-8&oe=UTF-8&gfe_rd=cr&ei=WJa3WICUMqOC8QfusYn4Bg.

[52] Luciano Floridi, *The Fourth Revolution: How the Infosphere is Reshaping Human Reality* (Oxford: Oxford University Press, 2014); Ian Kerr "Digital Locks and the Automation of Virtue" in Michael Geist, ed., *From Radical Extremism to Balanced Copyright: Canadian Copyright and the Digital Agenda* (Toronto: Irwin Law, 2010) 247.

when it discovered the right leukemia diagnosis in a case that had stumped doctors for months, AIs may well become agents of change, capable of suggesting novel interpretations or approaches previously unconsidered.[53] As some scholars have described it, the implementation of health technology is a "process of mutual transformation in which the organization and the system transform each other".[54] Since this can lead to good or bad outcomes, it will be important to better understand these transformative processes in order to inform and implement the most beneficial modes of robot and AI policy.

Consider, for example, a very different technological transformation that led to a tragic outcome with a system called the Therac-25. After use of this popular radiation therapy machine was well-established, a malfunction of the machine's radiation sensors resulted in massive radiation overdoses to six patients. The operators trusted the "all is normal" messages that the machine delivered — even after observing clinical symptoms to the contrary. The trust that operators had developed for the Therac-25 caused them to disregard contradictory evidence.[55] This example illustrates the need for designers, health professionals, practitioners and policy makers to reflect critically on the mediating influence that technologies are capable of exerting when determining how best to integrate them into well-established health care practices. Among other things, there is a need to be careful not to over-trust robots and AI or to unduly project onto these machines superior intelligence, reliability or objectivity.[56]

Even if robots and AI one day outperform human clinicians and health care practitioners in tasks and decision-making, it will still be important to develop checks and balances that ensure more than just beneficial outcomes. We must avoid the risk that robots and AI are treated like oracles of previous times that humans unquestioningly relied upon to their detriment.[57] In related contexts such as autonomous vehicles or autonomous weapons, laws and policies under consideration would require "meaningful human control" of those systems by keeping humans in the decision-loop. Canadian health law and policy will eventually need to confront similar considerations for health care workers and their patients.

[53] For a discussion on Knowledge Discovery in Databases, see Mireille Hildebrandt, *Smart Technologies and the End(s) of Law* (Northampton, MA: Edward Elgar, 2015) at 31-35.

[54] Zahra Niazkhani, *et al.*, "Evaluating the Medication Process in the Context of CPOE Use: The Significance of Working Around the System" (2011) 80:7 Int'l J. Medical Informatics 490 at 491.

[55] Joan Ash, *et al.*, "Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors" (2004) 11:2 J. Am. Medical Informatics Ass'n 104 at 110.

[56] *Ibid.*

[57] Elena Esposito, "Digital Prophecies and Web Intelligence" in Mireille Hildebrandt & Katja de Vries, eds., *Privacy, Due Process and the Computational Turn* (Abingdon, U.K.: Routledge, 2013) 121.

2. SOCIAL VALENCE

One novel form of sociotechnical influence is that robots and AIs tend to have "social valence".[58] The popular image of robots, after all, is not one of prosthetics, artificial organs or hospital automation; it's of mechanical people. True to the popular imagination, social robots are often designed to promote "anthropomorphism" — the psychological tendency to treat inanimate objects as though they have human qualities — thus blurring the line between human and instrument. "Anthropomorphic design" increases our tendency to blur that line. Some human-robot interaction experts believe that this suggests a "new ontological category" of beings.[59] Robots are not persons but neither are they merely toasters. Our tendency to think of robots as possessing some form of agency is gaining currency. Anthropomorphic design appears to be useful in psychology research, where pediatric patients are often willing to trust "psychotherapy" robots to a greater degree than human adults, suggesting that robots might be better at providing therapeutic interventions with certain patient populations.[60]

Although anthropomorphic design is already providing obvious therapeutic benefits with robots like PARO, it is important from a policy perspective to continue to ask the question: "when is it appropriate to substitute machines for human caregivers?" Although robots may provide vital and effective support, they are not a panacea to the problems generated by an aging population. Likewise, it is important to appreciate how easily anthropomorphic design can be used to influence perceptions of trust and the underlying trustworthiness of technologies, opening the door to manipulation by those who develop or employ the robot. As the sociality of these machines becomes more sophisticated, Canadian health law and policy will need to pay attention to the risk of manipulation through the use of social and companion robots — especially when they are interacting with vulnerable populations.

Of course, machines need not be anthropomorphic to generate social valence. Consider the seemingly simple ICD used to shock a potentially deadly cardiac arrhythmia into a normal heartbeat. After receiving painful and unexpected shocks from this small implanted device, some recipients report fears that their device might "decide" to shock them again, while others see their

[58] Ryan Calo, "Robotics and the Lessons of Cyberlaw" (2015) 103:3 Cal. L. Rev. 513.

[59] Peter H. Kahn, *et al.*, "The New Ontological Category Hypothesis in Human-Robot Interaction" (Conference proceedings from 6th International Conference on Human-Robot Interaction, Lausanne, 2011) 159, online: http://ieeexplore.ieee.org/document/6281274/.

[60] Including youth and the elderly, and patients with dementia and autism. See Sooyeon Jeong, *et al.*, "Deploying Social Robots in Pediatric Hospitals: What Needs to be Considered?" (Paper delivered at The Emerging Policy and Ethics of Human Robot Interaction conference, Portland, OR, 2 March 2015) [unpublished], online: http://www.openroboethics.org/hri15/wp-content/uploads/2015/02/Hf-Jeong-et-al.pdf.

ICDs as their protectors.[61] Researchers describe this perceived agency as stemming from the ICD recipients' perception that the device has them in a state of persistent surveillance. Like the prison guards in Foucault's famous Panopticon, the ICD is perceived to exert a constant though unverifiable power over its host, the consequences of which come unexpectedly and swiftly whenever the recipient's heart steps out of line.[62] Other researchers have gone even further, making a strong case for understanding the ICD as a moral proxy — an entity that makes a number of deeply moral decisions on the patient's behalf by virtue of its design.[63] In an increasing number of cases, there are good reasons for understanding the robot as having its own ontology.[64] For example, it may one day make more sense for judges assessing liability to treat an AI as an expert rather than merely as a tool used by experts. But we can also slip into careless thinking about the ontological nature of robots and AI and thereby come to entrust them with tasks and decision-making though they are in fact unreliable or unsafe. We saw this in the case of the Therac-25.

3. The Paradox of Evidence-Based Reasoning

Evidence-based reasoning will be a key practice in ensuring that robots and AI are functioning safely and appropriately, and will also be an important safeguard in our critical reflections about the more general sociotechnical influence that robots and AI have on the health care system. Perhaps the central role that evidence-based reasoning will play, however, is to assist with policy determinations about whether, or under what circumstances, it is appropriate and permissible to delegate human tasks or decision-making to a robot or an AI in the first place. The question of whether to substitute machines for humans in any given instance requires an evidence-based perspective: "if there is good evidence to suggest that a particular action produces the most favorable outcome, then that action is the most justifiable one."[65] Similarly, if the evidence demonstrates that a robot is better at producing beneficial outcomes and is equally cost-effective, then it becomes more difficult to reject use of the robot. Evidence-based reasoning provides a normative pull.

61 Anne Pollock, "The Internal Cardiac Defibrillator" in Sherry Turkle, ed., *The Inner History of Devices* (Cambridge, MA: MIT Press, 2008) 98.

62 *Ibid.*

63 Jason Millar, "Technology as Moral Proxy: Autonomy and Paternalism by Design" *IEEE Technology and Society Magazine* 34:2 (June 2015) 47, online: http://ieeexplore.ieee.org/document/6893388/.

64 For example, there are pragmatic legal reasons for treating IBM Watson as an "expert". Ian Kerr & Jason Millar, "Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 102.

65 David L. Sackett, *et al.*, "Evidence-Based Medicine: What It Is and What It Isn't" (1996) 312 Brit. Med. J. 71 as cited in Ian Kerr & Jason Millar, "Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 102 at 116.

Although the requirement of evidence seems straightforward and obvious, it becomes much more complicated with robots and AI. As we described above in discussing Big Data Analytics, IBM Watson and other AIs employ machine learning. This means that these AIs have the ability to do things that they were not explicitly programmed to do. This novel form of agency allows AIs to change and adapt their operations when exposed to new data, transcending their own programming. Consequently, the developers of such programs will not always be able to predict, foresee, or immediately comprehend what the AI will do in the future. As long as the AI is functioning well and its evidentiary track record is successful, this is of little concern. Problems will arise, however, when things go wrong. This is because general responsibility, accountability and liability standards require explanations when harms result.

Thus, even in situations where the robot or AI has a vastly superior performance record compared to a human expert, and there is good reason to delegate the task or decision-making to the machine, there is now a new problem when it comes to assigning responsibility or liability when things go wrong. Unlike our more traditional product liability regimes — where the product can be characterized as "defective" owing to the manufacturer's negligence, which in turn can be understood to have caused the harm — in the case of machine learning (and possibly other AI techniques) there is no equivalent defect. This is because the AI was not explicitly programmed to perform in any one particular way. Developers of AIs will in many cases be unable to provide a traditional causal explanation of the AI's behaviour based on their programming inputs. The complexity of the massive informational inputs combined with the machine's ever-shifting learned behaviours break the traditional causal links between the programmers' inputs and the system's behaviour. It would likely be equally or more difficult to demand an account from the health care administrators and professionals who adopted the AI.

Here we are confronted with a paradox: the normative pull leading to a decision to delegate to the robot or AI — namely, evidence-based reasoning — generates a system in which we now have no straightforward evidentiary rationale for explaining the outcome generated by the AI. This will create significant problems in the assessment of liability. Ironically, medical malpractice law may escalate this paradoxical result. In areas where AIs outperform human health care providers without mishap, the looming threat of negligence law will pressure hospitals and other health care providers to adopt these technologies, generating an AI monoculture where exclusive AI decision-making undermines the further attainment of human medical knowledge. This could become a very serious problem and is but one of the many legal considerations that robots and AI will require.

D. LEGAL CONSIDERATIONS

1. LIABILITY FOR ROBOTS AND AI

It is extremely likely that delivering care using robots or AI will in some instances cause harm. Establishing liability in such cases will present novel legal issues. For example, in the case of AI medical diagnostics discussed above, negligence claims against the AI will require determination of who (or what) counts as a medical expert, and decisions about how to deal with robot evidence in situations where it is unlikely that a human expert understands how or why the robot did what it did.[66] For now, as discussed in the two subsections that follow, accountability will likely be an issue only for doctors and hospitals using AI or robots, rather than for the AI or robots themselves. As noted above, this is because traditional product liability law is likely inapplicable in the case of robots and AIs designed to be autonomous or have emergent characteristics.

Liability for medical malpractice is grounded in negligence law. A successful claim requires that the defendant be found to owe a duty of care to the plaintiff. Could a robot owe a duty of care to a patient? Or could its manufacturers or developers? As explained above, the development of a trust relationship is the underlying strategy in the emerging field of social robotics. Indeed, it is the functional glue in human-robot interaction. It is therefore possible to imagine, one day, proof of a sufficient relationship between human and machine that could lead to a duty of care being ascribed to the robot, its manufacturer or the software developer. That day, however, is still far off in the distance.

Even if we reach a point where we treat robots as though they owe duties of care, the standard of care aspect of the negligence claim would give rise to strange and difficult questions about whether robots and AIs are even capable of apprehending and following standards of care — requirements that usually apply only to members of an interpretive community.[67] Such considerations lead us back to some of the foundational questions briefly mentioned above — is a robot or AI to be understood as an instrument, a person or some intermediate form of agency?[68] Along these lines, one might also ask: could robots or AIs owe duties or be expected to adhere to standards of care, as are other inanimate entities like hospitals? Conversely, are robots capable of being rights-bearing

66 Kerr & Millar, *ibid.*

67 Ian Kerr & Carissima Mathen, "Chief Justice John Roberts is a Robot" (Paper delivered at the We Robot 2014 Conference, Miami, April 5, 2014) [unpublished], online: http://robots.law.miami.edu/2014/wp-content/uploads/2013/06/Chief-Justice-John-Roberts-is-a-Robot-March-13-.pdf; Benjamin Alarie, *et al.*, "Regulation by Machine" (Paper delivered at the 30th Conference on Neural Information Processing Systems, Barcelona, 5-10 December 2016) [unpublished], online: http://www.mlandthelaw.org/papers/alarie.pdf.

68 Ian Kerr, "Spirits in the Material World: Intelligent Agents as Intermediaries in Electronic Commerce" (1999) 22:2 Dal. L.J. 190.

entities, or are there ever pragmatic reasons for treating them as such?[69] As anthropomorphic lines continue to blur the distinction between robot and person, these may one day become actual legal and policy issues in the health care context. For now, such considerations are speculative and fanciful. They are interesting, but also distracting. The remainder of this Part focuses instead on more mundane but crucial legal considerations that need to be resolved in the short term.

2. LIABILITY FOR PHYSICIANS USING ROBOTS AND AI

Medical negligence claims against a doctor can be of two very different sorts. The first sort is the more typical case where it is alleged that the physician was negligent in delivering care. The second involves cases where the physician failed to obtain the patient's informed consent to the proposed medical treatment or intervention. The lawsuits against doctors using the da Vinci robot mentioned previously, provide a clear example to the first sort of lawsuit. But robots and AIs can also be implicated in cases where the physician failed to obtain the patient's informed consent. In such cases, the general duty of care that physicians owe to patients includes a duty to disclose to the patient all material information relating to the proposed treatment.[70] In the context of untested or experimental therapies, a higher level of disclosure is required than for established therapeutic treatments.[71] An important policy consideration, therefore, is whether the use of robots or AIs, in cases where their operations are autonomous or their outcomes are emergent, should be understood as experimental. If so, their use would attract the more onerous standard of disclosure. In such instances, physicians would, for example, be required to disclose not only that they are consulting robot diagnosticians but also to fully inform patients of the robot's diagnosis and recommended course of treatment. This would include disclosure of options the physician may have chosen not to pursue. Similar considerations would arise with autonomous robots used to carry out surgical or other care-related procedures. Cases where there is a discrepancy in approach or outcome between the doctor and robot could undermine trust between physicians and patients regarding the best course of treatment.[72]

As suggested above, another important question that will arise relates to the standard of care applicable when physicians use robots or AI in the course of

69 Kate Darling, "Extending Legal Protection to Social Robots: The Effects of Anthropomorphism, Empathy, and Violent Behavior Towards Robotic Objects" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 213.

70 *Reibl v. Hughes*, [1980] S.C.J. No. 105, [1980] 2 S.C.R. 880 (S.C.C.); *Hopp v. Lepp*, [1980] S.C.J. No. 57, [1980] 2 S.C.R. 192 (S.C.C.).

71 *Halushka v. University of Saskatchewan*, [1965] S.J. No. 208, 52 W.W.R. 608 (Sask. C.A.); *Weiss v. Solomon*, [1989] J.Q. no 312, 48 C.C.L.T. 280 (Que. S.C.).

72 Ian Kerr & Jason Millar, "Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 102.

treatment. The current approach is tempered when it comes to assessing whether an emerging technology is part of the required standard of care or not. As Picard and Robertson have explained, "doctors need not employ the very latest tools or techniques to meet the standard of care, but neither can they ignore them once these have found their way into common use."[73] AI and health care robots certainly have not yet found their way into common use and, as such, a physician who chooses to use them now will risk challenges in establishing the reasonableness of such decisions.[74] Thus a certain level of caution is required in the initial decision whether to use robots and AI, though this may be less significant in hard medical cases, where even the best diagnostician or surgeon is up against significant uncertainty or unlikelihood of success.

Of particular interest is whether courts will ever hold physicians liable for relying on their own skill, judgment and experience over recommendations made by a machine or a medical procedure carried out by a machine. Technologies that threaten the skill or discretion of professional practitioners have always raised alarm bells. To take a historic example, in 1932 the British Columbia Court of Appeal had to decide whether a practitioner who failed to use x-ray results to inform his diagnosis breached the required standard of care.[75] In the words of the court:

> There is no suggestion of any unskillfulness or want of care on his part except that of his failure to advise an X-ray. The two eminent specialists called for the defendant at the trial approved of the defendant's diagnosis and stated that X-ray ought not to be advised in cases where the surgeon is convinced by the use of the usual tests that that course was unnecessary. It has not surely come to this that if the cause of the trouble is not apparent to the eye of the surgeon or physician he must advise an X-ray or take the consequences to his reputation and to his pocket for not having done so. Is the X-ray to be the only arbitrator in such a case and are years of study and experience to be cast aside as negligible?[76]

The luxury of nearly a century of hindsight provides an established line of evidence-based reasons to the contrary. For starters, x-rays have clearly become a technology of common usage. By current standards, it is practically inconceivable for a physician not to consult an x-ray or some other form of

[73] Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed. (Toronto: Carswell, 2007) at 224.

[74] *Zimmer v. Ringrose*, [1978] A.J. No. 932, 89 D.L.R. (3rd) 646 (Alta. T.D.), aff'd [1981] A.J. No. 596, 124 D.L.R. (3rd) 215 (Alta. C.A.), leave to appeal refused [1981] S.C.C.A. No. 200, 28 A.R. 92 (S.C.C.); *Cryderman v. Ringrose*, [1977] A.J. No. 759, [1977] 3 W.W.R. 109 at 118 (Alta. Dist. Ct.), affd [1978] A.J. No. 1007, 3 W.W.R. 481 (Alta. C.A.). See also *Baills v. Boulanger*, [1924] A.J. No. 76, [1924] 4 D.L.R. 1083 at 1100 (Alta. C.A.), where the court held that as the properties of a quartz lamp were not fully understood, it was incumbent of the doctor to use the greatest care possible in its use. See also *Misericordia Hospital v. Bustillo*, [1983] A.J. No. 270 (Alta. C.A.).

[75] *Moore v. Large*, [1932] B.C.J. No. 73, 46 B.C.R. 179 (B.C.C.A.).

[76] *Ibid.*, at 182-183 (B.C.R.).

imaging in her diagnosis of a broken bone.[77] Only time will tell whether it will be equally inconceivable to imagine a medical diagnosis or a surgical procedure to be made by a human alone without the help of a robot or AI. History may very well repeat itself: like the x-ray machine, the appropriate use of robots and AIs may need to be litigated in court many times before similar human biases and prejudices give way to seeing it as a standard component of treatment.

3. Liability for Institutions Using Robots and AI

(a) Vicarious Liability

One way of imposing institutional liability is through the device of vicarious liability — holding hospitals or other care facilities liable for the actions of their employees.[78] The question of whether a robot could ever be considered in law an employee will re-invigorate a number of the foundational questions discussed previously and would have tremendous implications in the fields of labour and economics that go beyond the scope of this chapter. That said, one could easily imagine the development of targeted legislation that stipulates strict or vicarious liability for a robot or AI when used in certain ways by hospitals or other care facilities. One could imagine, for example, holding hospitals liable for sending a patient home with a faulty exoskeleton that causes injury, or as a result of an autonomous robotic procedure run amok.

Whether to carve out such liability regimes is in fact part of a broader set of legal and policy considerations concerning the appropriate scope of liability for hospitals and other care facilities. The traditional view, which still holds much currency today, is that hospitals remain primarily responsible to provide a location and support staff for physicians to practice.[79] However, fundamental changes to our health care system mean that "the hospital is no longer merely a place where a doctor treats patients, but [...] a sophisticated facility designed to provide a plethora of services from a wide variety of health professionals."[80]

Indeed, the provision of care services in the coming decades is more likely to be distributed among a wide array of care locations — including the home. As care robots begin to populate these other spaces, will it still be reasonable to maintain the claim that a care facility is a mere location where competent human personnel provide treatment? When a patient receives tele- or virtual care, should she not expect safe and reliable medical treatment, irrespective of

[77] *Parkin v. Kobrinsky*, [1963] M.J. No. 86, 43 D.L.R. (2nd) 519 (Man. C.A.); *Lee v. O'Farrell*, [1988] B.C.J. No. 3071, 30 B.C.L.R. (2nd) 130 (B.C.S.C.); *Larson v. Lucky*, [2005] B.C.J. No. 1266, 2005 BCSC 829 (B.C.S.C.).

[78] Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed. (Toronto: Carswell, 2007) at 476.

[79] *Bateman v. Doiron*, [1991] N.B.J. No. 714, 8 C.C.L.T. (2nd) 284 at 290 (N.B.Q.B), affd [1993] N.B.J. No. 598, 141 N.B.R. (2nd) 321 (N.B.C.A.).

[80] Lorian Hardcastle, "Governmental and Institutional Tort Liability for Quality of Care in Canada" (2007) 15 Health L.J. 401 at 402.

whether it is delivered by fleshy or mechanical hands? Courts seem already to have recognized this in principle:

> The provision of a wide range of medical services is thus an integral and essential part of the operation of a modern, general hospital. This is so regardless of the way in which the hospital has structured its relationship with the professional personnel who provide those services. … It is medical care that is sought by the patient; and it is proper medical care that should be provided. The primary responsibility for the provision of this medical care is, in my opinion, that of the hospital, and the hospital cannot delegate that responsibility to others so as to relieve itself of liability.[81]

It would therefore seem wrong-headed if a hospital or other institution could escape liability in such situations simply by delegating the medical task to a robot rather than a human.

(b) Direct Duties

Another possible source of institutional liability comes via duties owed directly by health care institutions to their patients. Among other things, these include the duty to: (i) provide proper facilities and equipment; (ii) provide proper instruction and supervision; and (iii) establish systems necessary for safe operations.[82]

As we have seen, choosing proper equipment does not necessarily mean implementing the state of the art. A decision to delegate to an AI before proven reliable, or a decision not use a robot once it has become standard practice to do so, would obviously be problematic. The more difficult challenge is how to interpret an institutional duty to instruct and supervise in the case of robots. It is clear that hospitals have a duty to provide instruction, direction and supervision to their staff.[83] Although, this seems perfectly reasonable in the case of human health providers, what, if anything, would be expected for robotic health providers who are substituted for tasks previously carried out by humans? While the success of many robotic prosthetics, artificial organs and assistive devices depend entirely on the intervention or oversight of human "supervisors", there are many robots that a hospital would have little or no control over in terms of its operations. Machine learning AIs and autonomous robots operate independently, with minimal human input. Recall IBM Watson, an AI is:

[81] *Yepremian v. Scarborough General Hospital*, [1980] O.J. No. 3592 at para. 182, 28 O.R. (2nd) 494 at 497 (Ont. C.A.).

[82] Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed. (Toronto: Carswell, 2007) at 460.

[83] *Murphy v. St. Catharines General Hospital*, [1963] O.J. No. 822, 41 D.L.R. (2nd) 697 (Ont. H.C.J.); *Till v. Walker*, [2000] O.J. No. 84 (Ont. S.C.J.); *Martin v. Listowel Memorial Hospital*, [1998] O.J. No. 3126 (Ont. Gen. Div.).

> … designed to surprise. Though software is written in comprehensible lines of code, software functions that parse and operate on massive, constantly changing data sets, deliver results that no programmer can fully anticipate.[84]

If the programmers' ability to predict Watson's behaviour is necessarily diminished by virtue of Watson's underlying design, how reasonable is it to expect that hospital staff could be able to supervise or instruct its use? Is the fact that a well-functioning robot cannot be supervised always a reason against allowing its use in a hospital? The duty to instruct and supervise remains unclear in the context of task delegation to sophisticated robots and AIs.

It is also unclear whether a hospital's duty to establish systems necessary for its safe operations will require the inclusion or exclusion of certain robots and AI. As Hardcastle has noted, "cases imposing a duty to establish safe systems are limited in number, and the courts have only imposed this type of liability in the clearest of cases."[85] In some of these cases, courts have demonstrated a more sophisticated understanding of health care in terms of the integration of complex systems. For example, in *Lachambre v. Nair*[86] the court recognized that health care is a multifaceted enterprise requiring institutional coordination, stating: "where a patient in a hospital is treated by more than one specialty, the hospital owes a duty to ensure that proper coordination occurs and that the treatment program operates as a unified and cohesive whole."[87] Presumably, this sort of reasoning would require the integration of health care and information technology professionals in the delivery of health care services that involve robots. Will this duty to develop safe systems require the integration of roboticists and computer scientists? What about cloud computing services, which are sure to drive the next generation of robot and AI applications?

As growing numbers of AI applications increasingly interact with potentially millions of other medical devices, discussions about "safe systems" will increasingly include consideration of the IT infrastructure on which they are built. How much responsibility should a hospital have in ensuring that proper IT systems are built? In the context of manufacturer responsibilities, section 18 of the *Medical Device Regulations*[88] attempts to anticipate this reality by requiring that: "a medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system."[89] However, if robotic devices require dynamic, unpredictable and constant connections with a number of other

[84] Ian Kerr & Jason Millar, "Delegation, Relinquishment and Responsibility: The Prospect of Robot Experts" in Ryan Calo, A. Michael Froomkin & Ian Kerr, eds., *Robot Law* (Cheltenham, U.K.: Edward Elgar, 2016) 102 at 108.

[85] Lorian Hardcastle, "Governmental and Institutional Tort Liability for Quality of Care in Canada" (2007) 15 Health L.J. 401 at 422.

[86] *Lachambre v. Nair*, [1989] S.J. No. 98, [1989] 2 W.W.R. 749 (Sask. Q.B.).

[87] *Ibid.*, at 768 (W.W.R.).

[88] SOR/98-282 [hereinafter "*Regulations*"], made under the powers granted in s. 30(1) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27.

[89] *Regulations*, s. 18.

devices, is it reasonable to expect that manufacturers or hospitals be in a position to know all of the potential impacts of its interactions with the performance of the system? At this time, it is far from evident whether this duty and the requirements of section 18 will be enforceable in the context of robotic systems likely to emerge in hospitals in the coming years.

4. REGULATING ROBOTS AND AI AS MEDICAL DEVICES

The final legal consideration in this chapter focuses on the regulation of robots and AI as medical devices. This approach to regulating medical devices is pre-market, seeking to ensure that their interactions with people and their bodies are proven safe and effective before such devices are allowed to go to market.[90] The *Food and Drugs Act* and the *Regulations* govern most medical technologies employed in Canadian health care. Section 2 of the *Food and Drugs Act* defines a "device" as:

> … an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them … for use in (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals, (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals, (c) diagnosing pregnancy in human beings or animals, (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or (e) preventing conception in human beings or animals … .[91]

From this definition one immediately sees that the current regime may not cover many of the medical enhancement devices discussed in Part B, which are not therapeutic in nature. Likewise, while the current regime works for traditional hardware-based medical devices driven by pre-programed software,[92] it is not well-suited for devices whose operations are autonomous or emergent by virtue of machine learning and other AI techniques. Such devices — by their very nature — will make it impossible to comport with section 20 of the *Regulations*,

[90] Schedule 1 of the *Regulations* provides rules for classifying devices into four increasing risks levels: Class I, II, III and IV. The categorization is generally proportionate to the intended purposes of the device, the type of contact that the device is making with the patient and the degree of harm that could arise should the device fail.

[91] *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 2.

[92] Currently, the risk classification of software as a medical device is dependent on the manufacturer's intended use for the product. There are generally two classes of medical device software. Class I software are those intended to be used to view images, or other real time data for the purposes of aiding in treatment or diagnosis of a patient; and Class II software which are devices generally characterized by their ability to directly aid in the treatment or diagnosis of a patient and/or that can replace a diagnostic or treatment decision made by a physician. Health Canada, Notice, "Software Regulated as a Class I or Class II Medical Device" (Ottawa: Health Canada, 2010) at 2, 4, online: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.pdf.

which specifically states that: "if a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated." As we have seen, it is possible with complex AI that software performance is not always capable of validation in the traditional sense. Either these laws will require reform, or else many beneficial health innovations in the years to come will not be allowed to go to market.

The larger point is that this regime is not meant to protect beyond basic safety and efficacy in the narrowest sense. For example, the *Regulations* are not sufficiently flexible to ensure the safety and efficacy of robots and AI that learn and adapt as they go. Further, the current regime does not address any of the ethical or sociotechnical concerns enumerated above. This is in part because the regime is premised on the idea that medical devices are purely mechanical. As we have seen, the introduction of emergent characteristics and social valence will move us far beyond this realm:

> We are slowly accepting the … idea that we are not Newtonian, stand-alone, and unique agents. Rather we are informational organisms, mutually connected and embedded in an informational environment, which we share with other informational agents, both natural and artificial, that also process information logically and autonomously. We shall see that such agents are not intelligent like us, but they easily outsmart us, and do so in a growing number of tasks.[93]

We stand on the precipice of a society that increasingly interacts with machines, many of which will be more akin to agents than mere mechanical devices. If so, our laws need to reflect this stunning new reality. Treating machines imbued with artificial intelligence merely as tools reduces them to something quite other than what they are; it strips them of a legitimate descriptive richness in order to fit them into comfortable metaphors which suggest established categories of liability even though those categories may no longer be fitting. By doing so, we sacrifice accuracy for tradition, precision for metaphor. Although this makes regulation appear more straightforward, it actually undermines the safety and efficacy that such laws were initially designed to achieve.

E. CONCLUSION

The rise of robots and AI in health care is part of a larger effort to leverage technology in order to meet increasing demand and provide more accessible and efficient health care services. As we have seen, our current social, legal and policy frameworks are insufficient to deal with a number of issues that will arise.

Canadian health law and policy can either support the development of beneficial robots and AI or impede it. Moving forward, decisions about the

[93] Luciano Floridi, *The Fourth Revolution: How the Infosphere is Reshaping Human Reality* (Oxford: Oxford University Press, 2014) at 94.

uptake, permissible use and regulation of robots and AI in the health care setting will require some careful juggling — multiple balls in the air but only two hands to guide them. There will always be the risk of under- and over-regulation, either of which could impact human flourishing. It is therefore crucial to develop clear social, legal and policy frameworks that minimize risks, so that hospitals and the broader public might enjoy a range of benefits that could only be delivered by a co-robotic health care system.

Chapter 12

GENETICS AND THE LAW

Ubaka Ogbogu

A. INTRODUCTION

The Human Genome Project concluded in 2003 with the publication of the complete set of genes that exist in the human body.[1] The Project enabled a new era in genetics (the scientific study of genes and how they control and affect living things), characterized by a virtual explosion of refinements, advancements and applications of the knowledge resulting from the Project. Genetics has had and continues to have a transformative impact on health care. Advances in genetics have been applied to a wide variety of health care purposes, such as the diagnosis, prevention and treatment of disease, the development and administration of pharmaceuticals that are tailored to genetic makeup or characteristics, and screening for genetic factors that cause or contribute to rare and neglected diseases.[2]

As the march towards an era of genetic medicine gains momentum, questions have emerged about the consequences for individuals and society, and regarding the ethical and legal implications of applying genetics to health care.[3] Some of these questions are unique to genetics, others cast old dilemmas in a new light, or are concerned with social and policy implications that have not been fully or clearly articulated.

Past editions of this book have dealt with the nature and legal status of genetic information and the key policy dilemmas surrounding uses of genetic information in health and related contexts.[4] This chapter builds on and updates

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1 National Human Genome Research Institute, "All About the Human Genome Project (HGP)" (October 1, 2015), online: https://www.genome.gov/10001772/; Mark P. Sawicki, *et al.*, "Human Genome Project" (1993) 165:2 Am. J. Surgery 258.

2 R.N. Battista, *et al.*, "Genetics in Health Care: An Overview of Current and Emerging Models" (2012) 15:1 Public Health Genom. 34; ACMG Board of Directors, "Scope of Practice: A Statement of the American College of Medical Genetics and Genomics (ACMG)" (2015) 17:9 Genet. Med. 1; Bruce R. Korf, "Genetics in Medical Practice" (2002) 4:6 Genet. Med. 10S; Munir Pirmohamed, "Pharmacogenetics and Pharmacogenomics" (2001) 52:4 Brit. J. Clin. Pharmaco. 345; Kym M. Boycott *et al*, "Rare-Disease Genetics in the Era of Next-Generation Sequencing: Discovery to Translation" (2013) 14:10 Nat. Rev. Genet. 681.

3 For useful overviews of such ethical and legal implications, see Ellen W. Clayton, "Ethical, Legal, and Social Implications of Genomic Medicine" (2003) 349:6 N. Engl. J Med. 562; Kathy L. Hudson, "Genomics, Health Care, and Society" (2011) 365:11 N. Engl. J Med. 1033.

4 See Bartha Maria Knoppers & Geneviève Cardinal, "Genetics and the Law" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds, *Canadian Health Law and Policy*, 2nd ed (Markham, ON: Butterworths, 2002) 433; Ian Kerr & Timothy Caulfield, "Emerging Health