



# AI & HEALTH CARE: A FUSION OF LAW & SCIENCE

REGULATION OF MEDICAL DEVICES WITH AI

MAY 2021

This report was first drafted by Michael Da Silva in collaboration with the participants of the second AI & Society workshop for AI & Health Care: A Fusion of Law & Science.

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## CIFAR

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AI & HEALTH CARE:

# FUSION OF LAW & SCIENCE WORKSHOP

CIFAR EVENT  
**26 FEBRUARY 2021**  
(ONLINE VIA ZOOM)

Artificial Intelligence (AI) could radically change the Canadian healthcare system and is already in the process of doing so.<sup>2</sup> Stakeholders in industry, academia, and government offer different accounts of how AI will impact the system. Some predict that AI will yield clear benefits by, for instance, reducing human error, mitigating human biases, and/or giving providers the ‘gift of time’ to work with complex patients and provide more compassionate care.<sup>3</sup> Others suggest that AI will present new challenges by, for instance, introducing widespread harms through the use of unsafe AI tools, violating privacy rights, or exacerbating existing issues related to bias and discrimination.<sup>4</sup> These possibilities are not mutually exclusive. Neither are they inevitable. Rather, whether AI presents a net positive or a net negative for the Canadian healthcare system is partly a function of regulatory decisions. Onerous regulations could stifle innovation, but light (or no) regulation could harm AI tool users — and lead to public pushback that itself produces onerous regulations.<sup>5</sup> Fully addressing these concerns requires attending to a host of existing laws and regulations — including constitutional protections, legislation/regulations, case law, and “soft” law like professional ethical codes and research ethics codes — and analyzing

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whether they are sufficient to protect patients from harms that may emerge from AI technologies as well as scoping out possible alternatives. The first CIFAR meeting on [\*AI & Health Care: A Fusion of Law & Science\*](#) began this analysis of the landscape.

The second event, *Regulation of Medical Devices with AI*, continued the research team's work by focusing on a narrower issue: medical device regulation. Researchers and innovators with expertise in law, ethics, policy, medicine, and computer science met to address a central question: How should Health Canada regulate medical devices with AI? Health Canada possesses clear regulatory authority over medical devices and conducts safety analyses to determine which medical devices will be authorized for use in Canada.<sup>6</sup> It is in the process of changing its approach to the regulation of medical devices, partly due to a concern with how to regulate AI.<sup>7</sup> This is, accordingly, an important and timely case study in the regulation of AI in healthcare. The interdisciplinary scholars who were convened for this workshop collaborated to help guide Health Canada in its efforts to regulate in ways that can leverage AI's benefits. Having representatives from Health Canada in attendance helped to further ensure that the insights and recommendations made were timely and well-informed.

# COMPARATIVE ANALYSIS: CANADA, THE U.S.A., AND NEW ZEALAND

The event began with presentations on how AI is – and should be – regulated in three countries by legal scholars with expertise in the regulation of AI and/or of medical devices. They were intended to provide a better understanding of how medical devices are regulated and to compare regulatory options in order to identify possible best practices in comparator states.<sup>8</sup>

## A. CANADA (MATTHEW HERDER, LAW, DALHOUSIE UNIVERSITY SCHULICH SCHOOL OF LAW)

First, Matthew Herder provided an overview and analysis of the regulation of medical devices with AI in Canada.

Herder noted that the *Food and Drugs Act* and *Medical Devices Regulations* raise two key questions about the regulation of medical devices with AI: (1) Is this technology a ‘medical device’ and thus subject to Health Canada’s regulatory powers? and (2) If so, how should the technology be ‘classified’ into one of four categories of devices under the *Regulations*?

With respect to the first question, Herder noted that ‘device’ has a broad definition in the *Act*, referring to “instrument, apparatus, contrivance, or other similar article, or an *in vitro* reagent” used in disease diagnosis, treatment, mitigation, or prevention; bodily restoration/modification/correction; pregnancy diagnosis or pre- or postnatal care; and the prevention of conception “in human beings” and also fits under the category of “therapeutic product.”<sup>9</sup> Given this broad definition, Herder suggested the second question is more pressing.

With respect to the second question, Herder noted that the four categories track different levels of risk (with Class I encompassing lowest risk and Class IV encompassing the highest). He then noted that classification sets the bar for evidence and how devices are regulated. Higher risk devices will need to meet a higher evidentiary bar before Health Canada will permit their sale. He noted that Class I devices were not subject to any pre-market review and that one does not require a ‘Medical Device Licence’ to trade in such devices. Only an ‘Establishment Licence’ is required to import or sell a Class I product. Class II-IV devices must demonstrate some positive evidence of safety and effectiveness to be licenced for sale, but the level varies. Herder noted that evidence for Class III and IV devices needs to be submitted prior to market authorization, but Class III evidence can rely on summaries

of studies used to validate the device while only Class IV licence applications required detailed information about the studies; moreover, only Class IV licencing application requirements explicitly mention software studies.<sup>10</sup>

Herder then noted that the definition of ‘device’ could apply to AI and that the classification scheme could be used to address devices with AI, but much depends on regulators’ interpretation of the *Act* and *Regulations*. A recent guidance document on ‘Software as a Medical Device’ [SaMD] provides a broad definition of SaMD that could capture many devices with AI but regulatory exclusion criteria under same could limit Health Canada’s regulatory ambit.<sup>11</sup> This raises questions about whether certain kinds of AI fall under Health Canada’s authority. Assuming that AI tools are under that authority, a guidance document provides examples of how they may be classified; yet none of the examples are Class IV devices, which raises questions about what detailed information Health Canada receives and, in turn, the extent to which it can validate the underlying software.<sup>12</sup> Depending on the precise information and types of studies that are required, the regulator’s ability to analyze many devices with AI prior to their going on the market may be limited.

Herder also described a new ‘Advanced Therapeutic Products’ pathway for approving ‘novel devices,’ which could include devices with AI.<sup>13</sup> Yet he noted that details on how this pathway will be used remain scarce.

Herder stressed that Health Canada’s safety-based regulation should attend to concerns about discrimination since there are also safety-related issues. He noted that while some believe that AI can help address systemic racism, algorithmic bias is also well-documented. He further noted that this could have health impacts if, for instance, devices are based on data from one population and used on members of another population. Herder worries that regulators may miss these concerns if they do not have details on software validation for

lower risk devices. These concerns could be part of ‘risk’ analyses generally, but it is not clear that under current rules they must be. The ‘Advanced Therapeutic Products’ pathway could be designed in a way that addresses discrimination and bias. Including marginalized groups in the ‘consultations’ envisioned in the development of that pathway could be key to ensuring that they are addressed.

## **B. THE U.S.A. (NATHAN CORTEZ, LAW, SMU DEDMAN SCHOOL OF LAW)**

Second, Nathan Cortez discussed the regulation of medical devices by the U.S. Food and Drug Administration [F.D.A.]. Cortez noted that there have been two main pathways by which devices can get to market in the United States. The ‘Pre-market Approval’ pathway includes intensive pre-market scrutiny for safety and efficacy.<sup>14</sup> By contrast, the ‘510(k)’ clearance pathway focuses on whether the device is “substantially equivalent” to one already on the market.<sup>15</sup> More than 98% of devices are cleared through this less intensive pathway. Per Cortez, demonstrating the substantial equivalence of a device does not directly demonstrate its safety and efficacy. Most AI and machine learning software is not regulated by F.D.A. in any case and enforcement of the regulations is rare even with respect to the products that are regulated.

Cortez noted that the F.D.A. is nevertheless increasingly paying attention to AI, releasing many guidance documents and developing its Digital Health Center of Excellence. He explained that the guidance documents suggest that AI will be treated using a risk-based classification scheme similar to the one in Canada (which has also been used in the U.S.A. for some time). Like Canada, the U.S. approach is partly indexed to international standards, so overlap between the countries is unsurprising. For instance, both adopt an international classification system for SaMD that considers the device’s level of risk and intended use.<sup>16</sup> The classification determines how rigorous review will be. Yet Cortez noted that the F.D.A. is also abandoning the pre-market/post-market dichotomy in favour of a ‘lifecycle approach’ to regulation. Cortez thinks this makes sense since any device should be safe and effective throughout its lifecycle. Yet Cortez has worries about the F.D.A.’s pilot ‘precertification’ program, which provides companies that have established safety records with streamlined review processes for all their medical devices in exchange for increased post-market scrutiny. It could be beyond the F.D.A.’s statutory authority and may not best protect safety if company-level factors are not better predictors of safety than individual product-level factors.<sup>17</sup>

Cortez also noted that the F.D.A. has long considered whether medical software allows time for “competent human intervention.” Yet, Cortez emphasized, automation bias leads people to trust technology even when they should not, so the presence of a human ‘intervener’ is not a realistic way to differentiate products to regulate and products to exempt from oversight.

According to Cortez, the F.D.A. has emphasized the importance of analytical and clinical validation for medical devices with AI (viz., focusing on how AI actually impacts care) and is increasingly emphasizing the value of transparency and auditability. Cortez believes this is wise. A lifecycle approach to regulation requires opening up any ‘black boxes’ in AI tools.

Cortez also discussed a new de novo authorization pathway (via section 513 of the *Food, Drug, and Cosmetic Act*) for products that do not warrant full pre-market approval but also do not have existing predicates (viz., no comparators are on the market).<sup>18</sup> This pathway not only clearly requires explaining how the device is supposed to work but requires that companies set out a ‘Pre-Determined Change Control Plan’ explaining how a machine learning AI-based device, for example, can be expected to change over time and the improvements the companies will produce to help properly guide these changes. The control plan provides a baseline against which purported ‘innovation’ can be judged during the lifecycle. It establishes specific expectations against which one can judge whether the device is doing better or worse than expected.

Overall, Cortez believes that the F.D.A. is doing a good job at keeping up with the rapid pace of innovation. Non-binding guidance documents are being produced quickly and can help ensure proper accountability, and Cortez discussed several cases where the F.D.A. was able to make quick, justifiable determinations on how to regulate specific devices. The F.D.A. is also working with innovators to develop industry-wide standards (“Good Machine Learning Practices”) that could eventually serve as ‘best practices’ like those used for other manufactured goods.

Finally, Cortez highlighted the importance of international coordination on the regulation of medical devices with AI. He noted that the U.S.A., like Canada, is involved in many international agreements that seek standardization and harmonization of device regulation. He suggested that consensus standards could help guide both innovators and their regulators.

**C. NEW ZEALAND** (COLIN GAVAGHAN, LAW,  
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Finally, Colin Gavaghan noted that regulations are in a state of “flux” in New Zealand. The *Medicines Act 1981* and the regulator charged with implementing it, Medsafe, are primarily focused on ‘medicines’ and take an exceptionally light regulatory touch to devices. There is no pre-market review of medical devices in New Zealand. Devices simply need to be registered in the Web Assisted Notification of Devices database.<sup>19</sup> Post-market review of medical devices only occurs when a problem is brought to the attention of the Director-General of Health.<sup>20</sup>

There are, however, movements towards more regulation of medical devices. The proposed *Therapeutic Products Bill* and attendant regulatory scheme would divide therapeutic products into four categories, including a devices category.<sup>21</sup> While the bill does not explicitly discuss ‘software’, a consultation document states that medical devices with software would be captured by the regulatory scheme.<sup>22</sup> Those seeking to trade in devices would need to establish the “quality, safety and efficacy or performance of the product,” that the product meets basic standards, that its benefits likely outweigh its risks, and that the applicant meets certain criteria.<sup>23</sup> Whether discrimination and bias will play a role in evaluating safety risks remains to be seen.

Gavaghan further noted that New Zealand imports most of its devices and thus relies on foreign assessments for a lot of safety and quality reviews. This may present a regulatory tension when even government documents have stressed that all tools should be fit for the population of New Zealand and yet most foreign reviews are done on foreign populations.

How these issues are resolved could depend on details about the new regulator envisioned for the scheme that are also presently unclear. A further challenge, Gavaghan noted, is that some uses of AI in healthcare may straddle two previously distinct regulatory streams: one concerned with the safety of devices, and another concerned with the performance of human practitioners. Some of the latter could become increasingly relevant as AI in healthcare comes to assume more patient-facing roles (e.g., ‘chatbots’ like Woebot, billed as “the future of mental health”<sup>24</sup>). Healthcare professional regulations and consumers’ rights documents require cultural competence and non-discrimination in healthcare that could attend to some bias-based concerns.<sup>25</sup> Is a devices regulator likely to be equipped to apply similar standards to healthcare AI?

New Zealand has also recently adopted a more general ‘Algorithm Charter,’ to which most government departments – including the Ministry of Health – are signatories. This could lead to more ‘soft’ regulation of AI tools that could encompass their use in medical devices.<sup>26</sup>

# COMMENTARIES

The comparative legal analyses were followed by brief commentaries by AI innovators on how regulation could impact their work and what they would look for in a regulatory scheme.

First, [Joelle Pineau](#) (Computer Science, McGill University/MILA/Facebook AI Research Montreal/CIFAR) noted that innovators often enter these discussions calling for less regulation in order to permit experimentation, but she feels that there is a need for greater clarity on the rules and more reflection on what they should be. Pineau stated that this appears to be a time of regulatory experimentation and is a time to work together to get appropriate regulations. The key will be to balance the need for a regulatory structure and the need for innovation.

Pineau suggested that a form of review emphasizing post-market evaluation is appropriate for the kind of machine learning AI that is most likely to challenge existing regulatory frameworks. In this context, data comes through experience with the device. Attending to this data over time will permit us to improve the quality of our AI tools and our regulations thereof.

Pineau noted that, while the algorithm in a machine learning tool may change over time, it is easier for humans to change an algorithm when needed than it is for them to change a hardware device, and regulation should account for this. She also noted the importance of clearly defining what qualifies as a 'change' that should trigger requirements in reporting, auditing, etc. Requiring that innovators submit to an entirely new review after each tweak would be an unnecessary burden.

Second, [Anna Goldenberg](#) (Computer Science, University of Toronto/ The Hospital for Sick Children/ SickKids Research Institute/Vector Institute/CIFAR) began by noting that many of the most exciting developments in health-related AI are by start-ups and that we must be sure that regulations do not favour large companies at the expense of these smaller innovators. Goldenberg suggested that the 'Advanced Therapeutic Products' pathway needs to take start-up culture into account and the U.S.A. may provide a model of how to do so. She suggested that start-ups need light regulatory pathways to account for fast-moving developments.

Goldenberg expressed skepticism about the need to open any 'black boxes' to ensure proper regulation, instead suggesting that regulators should focus on how to interact with the black box and what we can expect from it. She also suggested that innovators are addressing concerns about bias and about what will happen as AI learns over time. She mentioned that it is unclear whether continual auditing is possible, but not permitting effective AI on the market where continual auditing is not possible can raise distributive justice issues. It is unfair not to let patients get the best advice, for example, where an AI tool is more likely to provide it.

Goldenberg noted that part of the bias problem stems from innovators' inability to access representative data. Privacy regulations can limit access to representative data, which makes it hard to make representative AI. She suggested that we cannot evaluate whether AI needs to be representative without first discussing whether innovators can even get the data in the first place.



# BREAKOUT SESSIONS<sup>27</sup>

The commentaries were followed by three simultaneous breakout sessions in which participants discussed how Health Canada should regulate medical devices with AI in order to balance the demands discussed earlier. Rapporteurs then summarized the findings as part of a debriefing session. Each breakout session covered a wide variety of issues. The following is a stylized representation of the findings that focuses on some core thematic concerns in each session.

## BREAKOUT #1

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The first breakout group focused on (1) the importance of lifecycle regulation, including (2) reporting requirements as well as (3) the importance of attending to privacy and bias concerns.

### I. LIFECYCLE REGULATION

There was broad agreement that a lifecycle approach to the regulation of medical devices was appropriate and that it should be indexed to the level of risk raised by the device. While most participants agreed that pre-market and post-market review were important, there was also broad agreement that any regulation model cannot be 'one-size-fits-all.' The safety and testing needs for Class I devices are and should be different from those of Class IV devices. Most felt that overly burdensome requirements could undermine incentives for innovation in Canada. Some were also concerned that lifecycle review could be costly for regulators and innovators.

One concern was that any regulatory model could face challenges keeping up with the deluge of information and safety review requests. Some felt that this augured in favour of self-certification, though this is already in place in the current system and so would not cut down on existing or new review procedures. Limiting additional post-market review to cases where there are "serious" changes to the device could help address some concerns; what qualifies as a serious change could be in the legislation and in the specific product licence (as is envisioned in New Zealand). At minimum, the rules for when information must be provided need to be easily understood.

In addition to lifecycle regulation, there was a comment that there needs to be unity across the many layers of regulation. One proposal was an expert group that would inform Health Canada and the professional colleges, for two prominent examples, about how medical devices with AI are meant to be used and how they are regulated and evaluated for safety.

Another discussion focused on liability for use of devices on the market. Some participants held that liability should accrue to manufacturers in cases of intended use and users in cases of off-label use, but no strong conclusions were reached on liability or how Health Canada's decisions impact it.

## II. REPORTING REQUIREMENTS

Most participants in this group felt that reporting requirements should be a component of any lifecycle review process, but there was some debate about who should be responsible for reporting and when. Some proposed clinical or even patient reporting as an adjunct to manufacturer reporting. Some were concerned that it is difficult to identify adverse events in the AI sector and that this may present a challenge for establishing when such an event ought to be reported.

## III. PRIVACY AND BIAS

Many felt that any 'safety'-based analysis should take a broad view of the potential 'harms' that could be caused. For instance, a device used in a diagnostic setting that misdiagnoses a patient could cause undue mental anguish and have financial implications (re: e.g., insurance). Privacy implications may also constitute harms and this should be part of the regulatory process. There was broad recognition that privacy rules may be outdated and may not reflect changing attitudes towards privacy – though Canadian privacy laws are being reformed at present. One point of contention was whether even deidentified data could be misused (by, for instance, being sold to third parties who repurpose it to re-identify people) and how to regulate against such 'harms.' There was some skepticism about consent-based approaches to privacy-related issues.

Bias was also seen as a potential safety issue. Concerns were raised about whether to allow devices trained on non-representative data to enter the market. Some felt that restricting access would bolster equality while others felt it would cause undue suffering for those in the population on whom the data was trained. Several thus felt that data representativeness concerns were better addressed through best practices documents, professional rules, or human rights law, rather than safety review.

## BREAKOUT #2

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The second breakout group began with a general discussion of the need to balance innovation and safety. There was discussion of the fact that many Canadian innovators go to the U.S.A. to get their initial approval and then come back to Canada. Some attributed this to regulatory restrictions and/or a slow regulatory process in Canada while others noted that the larger economy of the U.S.A. means that innovators will always want to get approved there first. Both sides of that debate eventually agreed that a need for innovation cannot come at the expense of safety, so the conversation shifted to strategies to promote and ensure safety. Part of this analysis focused on the importance of coordinating safety measures with other regulations and the possible need for intergovernmental cooperation to adequately catch all regulatory issues. Some felt that a lack of federal action could put undue pressure on provinces to act in areas under their own jurisdiction. Others noted that each level of government has its own responsibilities and must focus on those. When the group narrowed in on Health Canada's role in regulating the safety of medical devices with AI, it discussed several issues including (1) the unique issues requiring regulatory reform, (2) the importance of proper classification, (3) the appropriate balance of pre-market and post-market review, and (4) the need to address bias and privacy concerns as an integral part of safety analyses at the pre-market and post-market review stages.

## I. UNIQUE ISSUES REQUIRING REFORM

There was a discussion about whether and when a new regulatory pathway was required. Some felt that devices with AI did not raise new levels of risk or areas of use and so classifying devices with AI under the existing regulatory pathway should not be a problem. The key should be to reform the existing classifications to ensure proper pre- and post-market review appropriate to each class. Others felt that AI raised truly novel concerns that justify the development of the new pathway.

There was broad recognition that 'closed' AI systems could easily fit under existing regulations but there were concerns about how to regulate 'open' 'learning' systems. The ability for medical devices with AI to change and present new risks over time arguably challenges existing systems. Some also suggested that automation bias may present a risk of a different magnitude from those seen in other devices and that this could justify a new pathway with closer attention to bias.

## II. THE IMPORTANCE OF CLASSIFICATION

The group noted that the level of pre-market scrutiny for medical devices – with or without AI – differed across the different classes and discussed whether AI raises challenges for different schemes. One concern was that a lack of transparency on how Health Canada makes these determinations makes it hard to know how medical devices with AI are being slotted into existing categories and thus whether they are being subject to adequate evidentiary standards on pre-market review. It was noted that there is a need to know how Health Canada addresses AI to be able to evaluate what is working – and when they should alter their approach. This point was also made with respect to the impact of classification on post-market review. There was some debate as to whether different classes face different levels of post-market scrutiny and whether they should.

Machine learning may challenge classifications by requiring re-classification over time. The group shared a concern that Joelle Pineau raised in her plenary remarks regarding the need for a clear standard for when changes trigger re-evaluation of a device's fitness for market. Yet whether this re-evaluation would be de novo pre-market review or a form of post-market review was contested. There was a general view that minor changes should not trigger review as such frequent reviews would burden innovators and regulators and could create issues for patients. At the same time, most recognized that this admission cannot be a blanket excuse not to conduct post-market review.

### III. THE APPROPRIATE BALANCE OF PRE-MARKET AND POST-MARKET REVIEW

While most members of the group agreed that pre-market and post-market review are both necessary to ensure device safety, there was debate about what this means. There was a concern that lowering pre-market review standards could let goods on the market too quickly and that it would be hard to get them off the market after the fact. Others noted that many risks related to machine learning AI cannot be predicted in advance and can only be identified through the operation of the AI. Even proponents of strong pre-market review noted that this would augur in favour of post-market review as the most important safety valve. Many agreed that experimentation may be necessary and that witnessing machine learning AI ‘in practice’ could be useful not only for evaluating AI but for learning about how best to regulate it. Yet there was a strong counterpoint suggesting that giving up on very strong pre-market review could inhibit the ability to ever do proper safety review – or even collect the data necessary to do it. At minimum, this contingent suggested that an adherence to post-market review as the primary mechanism for safety review would need to ensure that review is independent and avoids regulatory capture.

A further topic of discussion was whether regulation needs to be tied to a match of conditions of pre- and post-market evidence or if evidentiary standards could change over time. This led to a discussion about the need for clearer indication of what the evidentiary standards should be at either stage. Group members noted that the level of evidence required to find that a device is ‘beneficial’ differs from that required to show that it is ‘safe’ and that we should consider which should be our proper target. Others questioned whether it was fair to download the risk of assessing evidence to Health Canada given that many experts do not understand the evidence at present. Some noted that the evidentiary standards are still being developed for the field. Yet some standard is likely needed for regulatory purposes. Group members noted that the lack of evidentiary standards contributes to physician hesitancy to use AI. There was also a discussion about whether the evidence required for the ‘validation’ of Class III devices suffices for determining whether the device could produce biased outcomes at the pre-market stage of analysis.

### IV. BIAS AND PRIVACY AS SAFETY ISSUES

There was a broader discussion of how bias and privacy should be treated as safety concerns and incorporated into Health Canada’s safety analyses. There was near-unanimity on this point with respect to bias and more controversy as to whether privacy breaches created direct harms. With respect to bias, however, there were questions about whether Health Canada should attend to bias as a societal risk or as an individual risk. Algorithmic bias can have health impacts at the population and individual levels, but these impacts can have different origins. Which impacts are relevant to ‘safety’ is important to determine when trying to decide how bias should be regulated.

One possibility that was discussed as a means of addressing bias-related concerns was to require pre-market testing and post-market auditing of devices with AI. A device could, for instance, be tested using a new data set prior to being approved for the market and only approved if it does not produce biased results. It could alternatively or additionally be audited over time against certain bias standards. It was noted that a broad continuum of levels of auditing is possible between AI that never changes and continually updating AI. There could be a requirement for bias auditing – and for reporting the results to Health Canada. Yet this requires determining where and when a regulator should be able to intervene and requires the regulator to take a clear stance on what equity-based issues it wants to address, including building them into testing and/or auditing procedures. This is technically possible. One group member stated that the hard part is not designing the audit(s), but whether, when, and how we want to conduct the audit(s). One possible problem with this approach identified by another group member is that one cannot identify all bias-related issues a priori. Even post-market auditing may not catch these biases for some time. Inequities will be able to persist until they are identified. This approach could nonetheless minimize bias.

## BREAKOUT #3

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The third and final breakout group also highlighted (i) the importance of strong post-market review, including regular auditing or reporting requirements. They noted that enforcement mechanisms, like recalls, should be used. Many members of the group stressed that Health Canada must provide clear guidelines that innovators can understand. The breakout group also discussed issues surrounding (ii) bias and (iii) industry involvement in regulation as well as general issues surrounding AI and (iv) liability and (v) healthcare provider autonomy.

### I. POST-MARKET REQUIREMENTS

The group stressed the importance of not assuming that AI in medical devices will always be 'locked' AI. Many suggested that post-market review is important for addressing AI that continuously learns, especially where 'black box' issues may arise. Regular auditing and reporting requirements are important for addressing these concerns, though they need to be enforced to serve their role.

There was also broad agreement that this post-market review need not come at the expense of strong pre-market review. Some participants noted that it is much harder to get an item off the market – as it might have been integrated with the workflow and previous resources would have been redirected elsewhere – than to keep one from going on the market in the first place. Moreover, significant harms can occur before an unsafe item is taken off the market. This led some to question the value of the U.S. Food and Drug Administration's pilot precertification program.

The group debated the possible value of labelling requirements as a way of understanding the potential benefits and risks of the use of AI. One suggestion was requiring AI tools to include an interface indicating the confidence level of the prediction because physicians cannot be expected to be aware of or remember it for every AI tool. Moreover, some believed the general public might not understand the probabilistic nature of AI tools. Questions about labelling for intended populations of use relate to the discussion of bias.

### II. BIAS

There was broad agreement that bias issues can be safety concerns and that regulators should address bias risks as part of safety evaluations. Yet no tool for addressing bias was viewed as wholly unproblematic. Labelling requirements for AI devices designed for specific populations may address some safety-related issues, for instance, but cannot address concerns about the benefits of AI only accruing to some populations. One line of discussion focused on the possibility of ensuring that AI in devices is based on data that is at least representative of the population most likely to use the device, if not representative of the population as a whole. The group seemed to view bias and privacy as appropriate elements of safety review and yet took different approaches on how to address tensions between representativeness and privacy.

One difficulty highlighted in the discussion is that even if we had representative data, there needs to be a way to motivate innovators to work on devices that would benefit marginalized populations. Safety review alone may not be able to address benefit distribution concerns. Insurance reimbursement rules may be more important than safety on this front.

Some participants were concerned that those worried about access to representative data were insufficiently attentive to the history and continuing reality of discrimination motivating the reluctance to provide data. They suggested that historical examples of harms to marginalized groups from both a lack of regulation and inapt regulations should guide future analysis. One simply cannot ignore the historical and current examples of exploitation of minority populations.

### **III. INDUSTRY INVOLVEMENT IN REGULATION**

There was spirited discussion about the appropriate role of industry in the development of regulations. While most recognized that industry insight is key to ensuring that regulations are fit for purpose, there were also broad concerns about regulatory capture. Striking the right balance will be difficult but remains important. Governments should not be afraid of regulating technology companies or they will run the risks of letting industry take advantage of these gaps and operate in these grey areas. Yet regulations completely divorced from practical realities are unlikely to have their intended impact.

One related, but analytically severable, concern was that the company-level safety inspection in the American pilot precertification program only benefits particular kinds of companies. There were worries that these would favour large companies, rather than start-ups, and that there may be insufficient motivation for company-level scrutiny since even traditionally powerful enterprises with good records can produce unsafe devices and we should analyze those. There were, however, debates about whether small companies would in fact be disadvantaged.

### **IV. LIABILITY**

Discussions about both safety and liability raised general questions about how to allocate liability for harm – both in general and for privacy breaches. If safety reviews are not alive to bias or privacy concerns, discrimination and privacy laws do not adequately address them, and companies indemnify themselves against liability for anything under contract law, the possibility of a regulatory gap remains. The extent to which Health Canada can address a gap was debated but the need for some law to appropriately allocate responsibilities was clearly highlighted.

### **V. PHYSICIAN AUTONOMY**

There was some debate as to whether the use of AI tools could undermine healthcare providers' autonomy and the role that this should play in Health Canada's regulation of medical devices. There was broad recognition that Health Canada's regulations should be understood as part of a broader set of regulations, including professional rules and regulations. While automating workflow, for instance, may undermine healthcare provider autonomy along one axis, there was debate on whether this was an issue given that AI tools make more efficient and accurate decisions – and this concern is not directly related to device safety.

# CONCLUSION

**International and domestic regulation of medical devices with AI is in a process of change. Different devices present different challenges. While countries take varied approaches to their regulation, at least Canada and the U.S.A. are seeking a harmonized international approach. Close attention to the potential challenges of proper safety review is wise in this context.**

The interdisciplinary and international research team at the *CIFAR AI & Health Care: A Fusion of Law & Science* workshop on *Regulation of AI with Medical Devices* analyzed three countries' approaches and discussed a range of regulatory and ethical issues raised by those approaches. Unsurprisingly given the complexity of the issues, the group did not reach consensus on how medical devices with AI should be regulated, but a series of themes emerged across the sessions.

Some of the core themes that emerged through the presentations and breakout sessions include:

- Potential safety issues arise at all stages of the device lifecycle.
- Any new regulatory pathway should accordingly ensure appropriate pre-market and post-market safety reviews.
- Indexing pre-market review requirements to risk and intended use is wise, but there needs to be adequate information to provide thorough safety validation for all higher-risk tools.
- Increased post-market review need not come at the expense of decreased pre-market review.
- Post-market reporting requirements are a good step in increased post-market review but must be enforced.

- One cannot rely on manufacturer reporting alone for good post-market review.
- Bias- (and, perhaps, privacy-) related concerns should be part of safety reviews.
- Safety review regulations must be understood against the backdrop of a wider range of regulations, but there is a risk of regulatory gaps where the appropriate authorities do not address the full range of concerns, including those related to safety, privacy, and bias, within the confines of their respective jurisdictions.

There was also no consensus that these were the core ethical issues, let alone about how to address them. Several participants have written about some of the themes elsewhere and reached different conclusions on them. Yet there was remarkable overlap in identifying the issues and several intriguing solutions were proposed above. The organizers hope Health Canada will find it useful to consider the workshop themes when deciding how to regulate devices with AI.



## ENDNOTES

- 1 *Nb.* Professor Ian Kerr played a central role in organizing the event proposal prior to his death in 2019. Céline Castets-Renard (Law, University of Ottawa/Université Toulouse Capitole en France) co-organized an earlier event.
- 2 For a good introduction to these issues, see Ian Kerr, Jason Millar & Noel Corriveau, “Robots and Artificial Intelligence in Health Care” in Joanna Erdman, Vanessa Gruben & Erin Nelson, eds, *Canadian Health Law & Policy*, 5th ed (Toronto: LexisNexis Canada, 2017) 257. Some were discussed at our prior event, which formed the basis of *AI & Health Care: A Fusion of Law & Science – An Introduction to the Issues* (CIFAR, 2021), online: <<https://cifar.ca/wp-content/uploads/2021/03/210218-ai-and-health-care-law-and-science-v8-AODA.pdf>> [Introduction] and in a report by the CIFAR AI for Health Task Force, *Building a Learning Health System for Canadians – Report of the Task Force on Artificial Intelligence for Health (AI4Health)* (Toronto: CIFAR, 2020) <<https://cifar.ca/wp-content/uploads/2020/11/AI4Health-report-ENG-10-F.pdf>>. For other representative reports, see Royal College of Physicians and Surgeons of Canada, *Task Force Report on Artificial Intelligence and Emerging Digital Technologies* (Ottawa: Royal College of Physicians and Surgeons of Canada, 2020); Canadian Medical Association, *The Future of Technology in Health and Health Care: A Primer* (Ottawa: Canadian Medical Association, 2018).
- 3 These oft-discussed benefits are helpfully summarized in Eric Topol, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again* (New York: Basic Books, 2019), which uses ‘gift of time’ language. See also *Introduction*, *ibid*, which also provides citations for concerns related to healthcare provider errors and/or biases.
- 4 See e.g., Sara Gerke, Timo Minssen & I Glenn Cohen, “Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare” in Adam Bohr & Kaveh Memarzadeh, eds, *Artificial Intelligence in Healthcare* (Cambridge: Academic Press, 2020) 295 (also highlighting concerns related to informed consent). Consider also questions about liability when interacting with AI in e.g., Ian Kerr & Vanessa Gruben, “Als as Substitute Decision-Makers” (2019) 21 Yale JL & Tech Special Issue 78 and A Michael Froomkin, Ian Kerr & Joelle Pineau, “When Als Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning” (2019) 61 Ariz LR 33. For an introduction to and analysis of how Canadian law addresses some of these issues, see Colleen M Flood & Catherine Régis, “AI & Health Law in Canada” in Florian Bariteau-Martin & Teresa Scassa, eds, *Artificial Intelligence and the Law in Canada* (Toronto: LexisNexis, 2021) 203.
- 5 *Introduction*, *supra* note 1. This point also appears in e.g., Nicolas P Terry, “Appification, AI, and Healthcare’s New Iron Triangle” (2018) 20(2) Journal of Health Care Law and Policy 117; Trishan Panch, Heather Mattie & Leo Anthony Celi, “The ‘Inconvenient Truth’ About AI in Healthcare” (2019) 2 npj Digit Med 77.
- 6 The primary authority to regulate and primary regulations on medical devices are the *Food and Drugs Act*, RSC 1985, c F-27 [FDA] and the *Medical Devices Regulations*, SOR 98-282 [MDR]. These documents technically provide regulatory authority to the Minister of Health, but that authority can be delegated by statute. It is delegated to Health Canada, whose Medical Devices Directorate plays the primary regulatory role. See e.g., Government of Canada, “Medical Devices Directorate” (2020), online: <<https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/medical-devices-directorate.html>>.
- 7 See e.g., Health Canada, *Health Canada’s Action Plan on Medical Device Devices: Continuously Improving Safety, Effectiveness, and Quality* (Ottawa: Health Canada, 2018), online: <<https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/medical-devices-action-plan.html>>; Government of Canada, “Health and Biosciences Sector Regulatory Review Map” (2020), online: <<https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review/roadmap.html>>; Government of Canada, “Guidance Document: Software as a Medical Device (SaMD): Definition and Classification” (2019), online: <<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html>> [SaMD].
- 8 A systematic comparison would invoke the methods of comparative law research, which specifies guidelines for case study selection that would likely require attending to more countries. These countries were selected partly due to the expertise of members of the research group but also because of their shared language and common law history and Canada and the U.S.A.’s historical connections and current agreements on device regulation. The facts that (a) the U.S.A. has one of the most developed regimes for medical device regulation while New Zealand has one of the least developed and (b) all three countries are revising their rules also at least suggested aptness for comparison.

- <sup>9</sup> FDA, *supra* note 6, s 2. The definition of “medical device” there excludes those who bring about their result by “solely by pharmacological, immunological or metabolic means or solely by chemical means.” The definition of “therapeutic product” excludes “natural health products,” which are subject to a different regulatory regime.
- <sup>10</sup> This framework is outlined in MDR, *supra* note 6. The *Standards Council of Canada Act*, RSC 1985, c S-16 lets the Standards Council of Canada set standards for each class. These standards – and the classes – are indexed to norms established by the International Accreditation Forum and the International Medical Device Regulators Forum.
- <sup>11</sup> SaMD, *supra* note 7.
- <sup>12</sup> See Government of Canada, “Guidance Document: Software as a Medical Device (SaMD): Classification Examples” (2019), online: <<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance/examples.html>>.
- <sup>13</sup> For details, see e.g., Government of Canada, “Policy and Program Initiatives: Novel Regulatory Approaches” (2019), online: <<https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review/policy-program-initiatives-novel-regulatory-approaches.html>>; Health Canada, “Discussion Paper: Agile Regulations for Advanced Therapeutic Products and Clinical Trials” (2019), online: <[https://www.sac-oac.ca/sites/default/files/resources/healthcanada\\_atp\\_discussionpaper.pdf](https://www.sac-oac.ca/sites/default/files/resources/healthcanada_atp_discussionpaper.pdf)>.
- <sup>14</sup> *Food, Drug, and Cosmetic Act*, 21 U.S.C. ch. 9 § 360 et seq, s 515ff [FDCA].
- <sup>15</sup> *Ibid*, s 510(k).
- <sup>16</sup> On the U.S.A., see e.g., U.S. Food and Drug Administration (USFDA), *Digital Health Innovation Action Plan* (2017), online: <<https://www.fda.gov/media/106331/download>>; U.S. Food and Drug Administration (US FDA), *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback* (2020), online: <<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>>; USFDA *Developing the Software Precertification Program: Summary of Learnings and Ongoing Activities – September 2020* (2020), online: <<https://www.fda.gov/media/142107/download>>. On the international standards, see e.g., International Medical Device Regulators Forum, “Software as a Medical Device (SaMD): Key Definitions” (2013), online: <[www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf)> and International Medical Device Regulators Forum, “Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations” (2014), online: <[www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf)>.
- <sup>17</sup> The pilot program is discussed in the U.S. sources in *ibid*.
- <sup>18</sup> FDCA, *supra* note 14, s 513.
- <sup>19</sup> *Medicines (Database of Medical Devices) Regulations 2003*, SR 2003/325.
- <sup>20</sup> *Medicines Act 1981*, s 38.
- <sup>21</sup> A document issued for consultation, which ended in December 2018, is available online at <<https://www.health.govt.nz/system/files/documents/publications/therapeutics-products-bill.pdf>>.
- <sup>22</sup> Ministry of Health, *Therapeutic Products Regulatory Scheme: Consultation Document* (2018), online: <[https://www.health.govt.nz/system/files/documents/publications/therapeutic-products-regulatory-scheme-consultation-document\\_dec18.pdf](https://www.health.govt.nz/system/files/documents/publications/therapeutic-products-regulatory-scheme-consultation-document_dec18.pdf)>. More recent regulatory development were not publicly available at press.
- <sup>23</sup> *Ibid* at e.g. 28-29, 58-59.
- <sup>24</sup> For more information on this example, see the official website (2021), online <<https://woebothealth.com>>.

- <sup>25</sup> See e.g., Medical Council of New Zealand’s *Good Medical Practice* document (2016, online <<https://www.mcnz.org.nz/about-us/publications/good-medical-practice/>>), which includes requirements “to establish and maintain trust with your patients” (para 14), to “[m]ake sure you treat patients as individuals and respect their dignity and privacy” (para 15), and to “[b]e courteous, respectful and reasonable” (para 16). See also the *Code of Health and Disability Services Consumers’ Rights*, ss 5(1) being Sch to *Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996*, SR 1996/78, which states that “Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided.”
- <sup>26</sup> For details on the *Algorithm Charter for Aotearoa New Zealand*, visit <<https://www.data.govt.nz/use-data/data-ethics/government-algorithm-transparency-and-accountability/algorithm-charter/>>.
- <sup>27</sup> Sylvain Bédard, Jennifer Chandler, Karen Eltis, and Muhammad Mamdani also attended parts of the workshop.

