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In 2001, the Institute of Medicine lamented that the American healthcare system was failing to take advantage of emerging information technologies (IT) and Internet-based platforms:

> IT has barely touched patient care. The vast majority of clinical information is still stored in paper form. Only a fraction of clinicians offer e-mail as a communication option to patients . . . Few patients benefit even from very simple decision aids, such as reminder systems, which have been shown repeatedly to improve compliance with practice guidelines. Many medical errors, ubiquitous throughout the health care system, could be prevented if only clinical data were accessible and readable . . . The pace of change is unacceptably slow.[1]

Fifteen years later, such technology is changing healthcare resources˘ accessibility even across borders.[2] For instance, researchers in southern California are using smart phones to track migrant workers and monitor whether they are adhering to a treatment regimen for tuberculosis.[3] Direct observed therapy is the most effective means of ensuring adherence, yet is often cost-prohibitive because it requires a clinician to observe patients taking their medication.[4] Additionally, such therapy would be even more

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1. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHASM 176 (2001) [hereinafter QUALITY CHASM].

2. Jyoti Schlesinger et al., Health and Mobility: Realizing the Power of Mobile Technology, 7 PERFORMANCE 1, 4 (2015).

3. Debra Kain, UC San Diego and Verizon Team to Improve Tuberculosis Care, UC SAN DIEGO: UC SAN DIEGO NEWS CTR. (Dec. 4, 2012), http://ucsdnews.ucsd.edu/pressrelease/uc_san_diego_and_verizon_team_to_improve_tuberculosis_care.

4. See S.E. Weis et al., Treatment Costs of Directly Observed Therapy and Traditional Therapy for Mycobacterium Tuberculosis: A Comparative Analysis, 3 INT. J. TUBERCULOSIS & LUNG DISEASE 976, 977 (1999) (requiring clinician and the patient to meet either at a clinic, a workplace, or other agreed-upon place in order for the clinician to observe the patient following the regimen); see also Peter Cegielski & Mark Lobato, Preventing and Controlling Tuberculosis Along the U.S.-Mexico Border, CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WKLY. REP. (Dec. 19, 2000) (explaining that researchers should

expensive for a population that may cross the border daily between San Diego and Tijuana.[5] But by using video capabilities and text messaging on cell phones, clinicians were able to follow an initial group of patients and achieve a high rate of medication adherence and patient satisfaction.[6] More importantly, this seemingly simple intervention is potentially scalable and adaptable both to other conditions and regions.[7]

This anecdote illustrates just one example of the promise of accessible and exchangeable health data: for years, proponents argued that the open exchange of health data would help consumers make better health decisions, patients engage in their care, practitioners avoid costly mistakes and duplicate tests, and the government evaluate services for actual value.[8]

But to many critics, much of the promise of health information is still unfulfilled. As one critic noted, out of the `hundreds of apps out there promising to keep you on a healthy diet, have you exercise regularly, and make sure you are a happy person every day of the year,_ most will have little utility or efficacy in improving health.[9]

Further, there is a great need to share data to improve the delivery of care and to reduce medical errors. Over a decade after the Institute of Medicine published Crossing the Quality Chasm,[10] health systems still are not communicating with full interoperability, or the ability to `talk_ to each other and share data.[11] Increased operability would allow providers to share data

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monitor participants carefully to ensure compliance with an anti-tuberculosis drug regimen).

5. Dov Michaeli, A Small Example of the Real Power of Mobile Health, THE DOCTOR WEIGHS IN (Dec. 5, 2012), https://thedoctorweighsin.com/a-small-example-of-the-real-power-of-mobile-health/.

6. Richard Garfein, RD/TB Institute Lecture on Video Directly Observed Therapy (VDOT) for Monitoring Tuberculosis Treatment Adherence (Aug. 12, 2015), http://action.lung.org/site/DocServer/Dr._Garfein_VDOT_Lecture_for_RD-TB_Durham_8-12-15_draft.pdf?docID=35881; see also Michaeli, supra note 5 (using a smartphone camera to communicate with nurse regarding medication adherence resulted in a 99% adherence rate).

7. Kain, supra note 3; see also WORLD HEALTH ORG., MAXIMIZING MOBILE 1, 51 (2012) (`Currently, applications focusing on individuals are mainly geared to developed countries, where purchasing power and education are higher._) [hereinafter WORLD HEALTH ORG.].

8. Health Information Exchange: What is HIE?, OFF. NAT˘L COORDINATOR FOR HEALTH INFO. TECH., https://www.healthit.gov/providers-professionals/health-information-exchange/what-hie (last visited Sept. 12, 2016) [hereinafter Health Information Exchange].

9. Michaeli, supra note 5.

10. QUALITY CHASM, supra note 1, at 176.

11. OFF. NAT˘L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP˘T HEALTH & HUMAN SERVS., REPORT TO CONGRESS: REPORT ON HEALTH INFORMATION BLOCKING 1, 4 (April 2015), https://www.documentcloud.org/documents/2461137-onc-report-to-congress-on-health-information.html (`Current economic and market conditions create business incentives for some persons and entities to exercise control over electronic health information in ways that unreasonably limit its availably and use._); see also Patrick Caldwell, We˘ve Spent Billions to Fix Our Medical Records, and They˘re Still a Mess. Here˘s Why, MOTHER JONES (Oct. 21, 2015), http://www.motherjones.com/politics/2015/10/epic-systems-judith-faulkner-hitech-ehr-interoperability (discussing vendor issues and the government˘s inability to police them).

on adverse events and help reduce medical errors, which a recent study estimated are the third leading cause of death in the United States.[12] Surveys have found that physicians believe that electronic medical records do make information more accessible and have great potential in quality, but they have been frustrated with the types of products available and their functionality.[13] Even so, digitizing health information and helping patients to access and understand their own health information remains beneficial. For example, recent renewed interest in telehealth stems from innovations in telecommunications and mobile technologies because such innovation has improved monitoring and created convenient options interaction between patients and providers.[14] Due to the worldwide availability of mobile phones, mobile health can reach both the developing and the industrialized worlds, and everywhere in-between.[15] New mobile devices help consumers track different aspects of their health, from diet to daily steps, to even sleep patterns.[16] Although much attention has focused on practitioners˘ frustrations meeting federal meaningful-use requirements,[17] the federal investment in health IT has helped to ensure that doctors, hospitals, and many safety-net providers are wired with electronic medical records.[18]

Like much of our healthcare system, our regulations around health IT are messy and fractured. Policymakers struggle to keep up with new technological advances that are allowing more patient-data to be collected

12. Martin Makary & Michael Daniel, Medical Error´ The Third Leading Cause of Death in the U.S., THE BMJ 2 (May 3, 2016), http://www.bmj.com/content/353/bmj.i2139.

13. Mark Friedberg et al., Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy, RAND HEALTH iii, xvi (2013), http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf.

14. Jeremy Storm, Affordable Telehealth For Everyone, AM. TELEMEDICINE ASS˘N. (Oct. 8, 2015, 7:12 PM), https://thesource.americantelemed.org/blogs/jeremy-storm/2015/10/08/affordable-telehealth-for-everyone; see also Memorandum from Bernice Reyes-Akinbilege, to the Senate Special Comm. on Aging 3 (Sept. 12, 2014) (on file with Congressional Research Service), http://www.aging.senate.gov/imo/media/doc/CRS%20Selected%20Telehealth%20and%20Telemedicine%20Funding%20FY 2012%20FY 20141.pdf [hereinafter CRS Memorandum].

15. Schlesinger et al., supra note 2, at 4; WORLD HEALTH ORG., supra note 7, at 51.

16. WORLD HEALTH ORG., supra note 7, at 51.

17. Rajiv Leventhal, Physicians Pinpoint Frustrations with EHRs in Published Commentary, HEALTHCARE INFORMATICS (Aug. 18, 2016), http://www.healthcare-informatics.com/news-item/ehr/physicians-pinpoint-frustrations-ehrs-published-commentary (citing Donna M. Zulman et al., Evolutionary Pressures on the Electronic Health Record Caring for Complexity, 316 J. AM. MED. ASS˘N 923, 923¯24 (2016)).

18. Karen DeSalvo & Vindell Washington, By the Numbers: Our Progress in Digitizing Health Care, HEALTH AFFAIRS BLOG (Sept. 29, 2016), http://healthaffairs.org/blog/2016/09/29/by-the-numbers-our-progress-in-digitizing-health-care/ (noting that federal investments in health IT have exponentially increased the use of EHRs from 10 percent of hospitals and 17 percent of physicians in 2009 to nearly all hospitals and approximately 80 percent of physicians).

and stored, while continuing to deal with longstanding issues like interoperability.[19] Different federal agencies each play a role in regulating health information itself and the mechanisms that collect, transmit, and utilize this data.[20] This diffusion across the federal government means that providers must follow multiple agencies for policy updates: for example, within the United States Department of Health and Human Services (HHS), the Office of the National Coordinator sets interoperability standards and certifies health information technology,[21] the Health Resources and Services Administration provides grants to rural providers and technical assistance centers,[22] and the Office of Civil Rights monitors violations of patient privacy;[23] outside HHS, the Federal Trade Commission plays a role in ensuring the safety of mobile health applications,[24] and both the Federal Communications Commission[25] and the United States Department of Agriculture fund telehealth and infrastructure to connect rural providers with providers in other parts of the country.[26] Thus, a provider that wants to communicate with its patients electronically will face different compliance issues depending on the modes of electronic communication, the types of devices that the patient uses to communicate, and how information gleaned from such communications will be secured and treated.

How we share data across borders is even more in flux not only due to barriers around interoperability but also around ensuring the privacy and security of patients˘ and consumers˘ health data.[27] As more health data is

19. See Richard Adler, Rethinking Communications Regulation, THE ASPEN INSTITUTE (2013), https://assets.aspeninstitute.org/content/uploads/files/content/upload/Rethinking-Communications-Regulation.pdf (discussing the challenges facing policymakers in regards to making new IT communications regulations); see also WORLD ECONOMIC FORUM, THE GLOBAL INFORMATION TECHNOLOGY REPORT (Soumitra Dutta & Be¿at Bilbao-Osorio, eds., 2012), http://www3.weforum.org/docs/Global_IT_Report_2012.pdf (outlining interoperability at a global level).

20. See CRS Memorandum, supra note 14 (discussing selected telehealth and telemedicine activities).

21. About ONC, OFF. NAT˘L COORDINATOR FOR HEALTH INFO. TECH., https://www.healthit.gov/newsroom/about-onc (last updated May 12, 2016).

22. Telehealth Programs, HEALTH RES. & SERVS. ADMIN. (2015), http://www.hrsa.gov/ruralhealth/telehealth/.

23. About Us, OFFICE FOR CIVIL RIGHTS, U.S. DEP˘T HEALTH & HUMAN SERVS., http://www.hhs.gov/ocr/about-us/index.html (last visited Nov. 18, 2016).

24. Press Release, Fed. Trade Comm˘n, FTC Releases New Guidance For Developers of Mobile Health Apps (Apr. 5, 2016) (on file with the author) https://www.ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps.

25. The Connect2HealthFCC Task Force, FED. COMMC˘NS COMM˘N (2016), https://www.fcc.gov/about-fcc/fcc-initiatives/connect2healthfcc/general/connect2healthfcc-task-force.

26. Distance Learning and Telemedicine Grants, U.S. DEP˘T OF AGRIC., http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants (last visited Nov. 18, 2016).

27. THE GLOBAL INFORMATION TECHNOLOGY REPORT, supra note 19, at v.

moved online, many Americans have expressed concern about breaches.[28]

Data generated in the health, financial, and commercial sectors has huge implications for our economic interests both domestically and globally.[29] Such information can have as much economic value as other goods and services[30] even across borders.[31] The free flow of data nationally and internationally allows for international financial transactions, remote monitoring of supply chains and equipment, and for improved diagnostic and imaging services.[32] How do we approach health information˘s regulation and use in comparison to other nations? How do we regulate data˘s exchange across borders? How do other countries view such data˘s exchange with us?

This paper will look at the regulation of health information both domestically and with a specific focus on Canada, one of our largest trading partners, for several reasons. Our nations share a common border, speak a common language, and have a long history of regulatory collaboration in many areas. Often, regulatory schemes harmonized between our two nations pave the way for further harmonization efforts internationally.[33] Thus, overcoming the challenges with data exchange across our northern border may yield opportunities that can be harnessed elsewhere.[34]

I. GATHERING DATA

The growth of health IT allows clinicians to capture patient data instantaneously. In the United States, federal investment into health IT for physicians and hospitals has led to a dramatic increase in digitized health

28. Ashley Kirzinger et al., Kaiser Health Tracking Poll: August 2016, KAISER FAMILY FOUND. (Sept. 1, 2016), http://kff.org/global-health-policy/poll-finding/kaiser-health-tracking-poll-august-2016/.

29. See generally Expanding U.S. Digital Trade and Eliminating Barriers to U.S. Digital Exports: Hearing before Subcomm. on Trade, H. Comm. on Ways & Means, 114th Cong. 7-8 (2016) (statement of Robert Atkinson, President, Information Technology and Innovation Foundation) [hereinafter Expanding U.S. Digital Trade].

30. Id. at 4˘5.

31. ORG. FOR ECON. CO-OPERATION & DEV., PRIVACY GUIDELINES 1, 19 (2013) (`Innovations, particularly in information and communication technologies, have impacted business operation, government administration, and the personal activities of individuals._) [hereinafter OECD PRIVACY].

32. Expanding U.S. Digital Trade, supra note 29, at 5˘7.

33. For an overview of regulatory cooperation between the United States and Canada, see WILSON CTR., CANADA-U.S. HEALTH SUMMIT 2015, 12˘19 (2016), http://pages.wilsoncenter.org/rs/219-MVU-643/images/Canada-U.S._Health_Summit_Summary_Report.pdf [hereinafter CANADA-U.S. HEALTH SUMMIT 2015]; see also CAN.-U.S. REGULATORY COOPERATION COUNCIL, JOINT FORWARD PLAN (2014), https://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada-rcc-joint-forward-plan.pdf (outlining future regulatory plans between the United States and Canada).

34. See generally CANADA-U.S. HEALTH SUMMIT 2015, supra note 33.

data.[35] Additionally, patients and consumers are also increasingly able to record their own personally-generated health data through wearable devices or mobile health applications on smart phones, tablets, and similar technology.[36] The question then becomes what to do with these increasing sources of data, which could have tremendous public health uses if analyzed correctly.[37] As discussed below, countries try to balance domestic and international data exchanges˘ economic interests and public health benefits with individuals˘ privacy and security concerns. Consequently, businesses and researchers must think through the economic costs of complying with different countries˘ rules as well as of analyzing large sets of health information.[38]

A. Clinically-generated data

In 1991, the Institute of Medicine reported that `computer-based patient records are an :essential technology˘ for health care, and that electronic records should be the standard for medical and all other records related to health care._[39] When used successfully, electronic health records (EHRs) capture clinical data about patients, providing information for clinicians to improve the patient˘s health and building a foundation for researchers to measure numerous factors to improve health at a community level.[40] EHRs

35. Margaret Rouse, Health IT (Health Information Technology), TECHTARGET, http://searchhealthit.techtarget.com/definition/Health-IT-information-technology (last updated June 2016); see also Brian Schilling, The Federal Government Has Put Billions into Promoting Electronic Health Record Use: How Is It Going?, THE COMMONWEALTH FUND: QUALITY MATTERS ARCHIVE (June/July 2011), http://www.commonwealthfund.org/publications/newsletters/quality-matters/2011/june-july-2011/in-focus.

36. Katy Human, Maximizing Your Health Data, GENOME, http://genomemag.com/maximizing-your-health-data/#nav-search-box (last visited Sept. 12, 2016); Michaeli, supra note 5; see generally Apps and Wearables in Healthcare: What works?, MOBILESMITH (2015), https://www.mobilesmith.com/wp-content/uploads/2015/09/Apps-and-Wearables-in-Healthcare-What-Works-MobileSmith-2015.pdf [hereinafter Apps and Wearables].

37. David Bates et al., Big Data in Health Care: Using Analytics to Identify and Manage High-Risk and High-Cost Patients, 33 HEALTH AFFS. 1123, 1129 (2014).

38. OECD PRIVACY, supra note 31, at 20 (`The potential uses of personal data have increased tremendously as a result of the wide range of analytics that can provide comprehensive insights into individuals˘ movements, interests, and activities._); Janine Hiller, Healthy Predications? Questions for Data Analytics in Health Care, 53 AM. BUS. L.J. 251, 251-52 (2016).

39. QUALITY CHASM, supra note 1, at 171.

40. Although many use the terms electronic medical records and electronic health records interchangeably, some, including the federal government, define them differently. Lauren E. Sweet & Deborah Lea Moulaison, EHR Data and Metadata Challenges, 1 BIG DATA 245, 246˘47 (2013); see generally Peter Garrett & Joshua Seidman, EMR vs. EHR´ What is the Difference?, HEALTH IT BUZZ (Jan. 4, 2011), https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/; What is an Electron Medical Record (EMR)?, OFF. NAT˘L COORDINATOR FOR HEALTH INFO. TECH., https://www.healthit.gov/providers-professionals/electronic-medical-records-emr (last visited Sept. 11, 2016);

have the potential `to reduce errors, improve patient care, facilitate clinical coordination, and monitor care quality._[41]

In the United States, health IT investment lagged in the healthcare system until the Health Information Technology for Economic and Clinical Health Act (HITECH) was passed.[42] HITECH exponentially increased the adoption of EHRs by providing incentives through Medicare and Medicaid for physicians, hospitals, and certain other providers to invest health information technology.[43] At the same time, HITECH required meaningful use of such technology as a condition of payment, and providers who fail to meaningfully use EHRs are subject to a Medicare payment penalty.[44]

B. Patient Generated Information

In addition to clinician-generated data collection, more health data is coming from patients and consumers themselves.[45] Rapidly evolving technology, such as wearable devices and mobile health applications,[46] allow

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Katherine Drabiak-Syed, Granular Control of EHRs to Overcome Fragmented Disclosure Law, 10 INDEP. HEALTH L. REV. 39, 40–41 (2013) (`The information contained in an EHR gives providers a comprehensive reference of the patient's full medical history so providers may make more efficient and informed decisions during the course of care such as whether to order a test of procedure, whether a particular medication would counteract with any of the patient's current medications or drug allergies, and cross reference relevant information in the patient's medical history. The aggregate information and its availability to providers decrease the number of tests to which the patient is subjected and lowers the risk of potentially problematic drug responses. EHR systems also offer the potential to provide clinical decision support to physicians by checking patient medication interactions, providing test recommendations, or offering suggestions for treatment options based on best practices guidelines._).

41. Drabiak-Syed, supra note 40, at 40–41.

42. HITECH Act Enforcement Interim Final Rule, U.S. DEP'T HEALTH & HUMAN SERVS. (2009), http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/.

43. Ashish Jha et al., Use of Electronic Health Records in U.S. Hospitals, 360 NEW ENG. J. OF MED. 1628, 1628 (2009); see generally American Recovery & Reinvestment Act of 2009, Pub.L. No. 111–5 í 13001 (2009); Andy Slavitt & Karen DeSalvo, EHR Incentive Programs: Where We Go Next, THE CMS BLOG, https://blog.cms.gov/2016/01/19/ehr-incentive-programs-where-we-go-next (last visited Nov. 11, 2016) (`We've come a long way since then with more than 97 percent of hospitals and three quarters of physician offices now wired._); see also New Survey Shows Nearly All U.S. Hospitals Using Certified Health IT to Manage Patient Care, HEALTHCARE SCENE NEWS (May 31, 2016), http://www.emrandehrnews.com/tag/karen-desalvo/ (noting a nine-fold increase in hospitals' adoption of EHRs since 2008).

44. American Recovery & Reinvestment Act of 2009 í 4101, 42 U.S.C.A. í 1396b (West 2009). For a discussion of Medicare payment penalties in relation to EHRs, see CTRS. FOR MEDICAID & MEDICARE SERVS., EHR INCENTIVE PROGRAM 19–25 (2015), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/FAQs_Apr_2014.pdf.

45. Michaeli, supra note 5.

46. Apps and Wearables, supra note 36 (noting half of all smart phone users have used a health app on their phone).

both patients and consumers to self-assess their own health and self-identified needs or conditions.[47] Thus, patients and consumers can utilize technology to interact with their healthcare providers.[48] This industry shift has led to what has been characterized as an unprecedented era of patient engagement in healthcare decision-making.[49]

In the United States, both policymakers and industry stakeholders have encouraged integration of patient-generated data into EHRs.[50] Through meaningful-use requirements, the federal government has encouraged the use of patient portals and other patient-facing applications in hope of engaging patients more with their providers.[51] These incentives were aimed at physicians in effort to change physicians˘ behavior, and the nature of patient-physician relationships and interactions.[52] Surveys have found that patients are interested in interacting with their healthcare provider through email and interactive technology.[53] While federal regulators have stated that the final regulation will be revised for physicians in light of a change the new Medicare law, the Medicare and CHIP Reauthorization Act (MACRA),[54] it is unlikely that Centers for Medicare and Medicaid Services (CMS) will walk back from proposals to make EMRs more accessible to patients.[55] Further,

47. OECD PRIVACY, supra note 31, at 32 (`Over the past few years, individuals have transcended the role of passive `data subjects_ to become actively involved in creating, posting and sharing personal data about themselves, friends, relatives and others, over a vast array of information outlets including social networking services, rating systems and geo-location based applications._).

48. Id.

49. Debra Ness et al., How Person-Centered Is Your Health Care Organization?, HEALTH AFFS. BLOG (Aug. 30, 2016), http://healthaffairs.org/blog/2016/08/30/how-person-centered-is-your-health-care-organization/; Susan Denzter, Rx For The `Blockbuster Drug_ Of Patient Engagement, HEALTH AFFS. 202 (Feb. 2013), http://content.healthaffairs.org/content/32/2/202.full.

50. Sweet & Moulaison, supra note 40, at 246 (`EHRs are intended to be shared between healthcare providers and even be accessible to patients._).

51. CTRS. FOR MEDICARE & MEDICAID SERVS., THE MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PROGRAMS: STAGE 2 TOOLKIT 14 (2013), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_Toolkit_EHR_0313.pdf [hereinafter STAGE 2 TOOLKIT].

52. Id.

53. One survey of patients˘ understanding of online communications with their physicians found that slightly over half either did not know whether their physician had a patient portal or knew that there was no patient portal. Cameron Graham, Study: How Patients Want to Communicate with Their Physician, TECHNOLOGY ADVICE (Aug. 13, 2014), http://technologyadvice.com/blog/healthcare/study-patient-portal-communication-2014/; 2016 Connected Patient Report, SALESFORCE 1, 2 (2016), https://www.salesforce.com/assets/pdf/industries/2016-state-of-the-connected-patient-pr.pdf (`The report found that people primarily interact with their physicians through in-person visits, phone calls and emails, but are open to virtual care treatment options enabled through technology._).

54. Medicare Access and CHIP Reauthorization Act of 2015, Pub.L. No. 114¯10 (2015).

55. Joseph Conn, Final Stage 3 EHR Rule Is Out, But HHS Signals More Changes Ahead,

much of MACRA uses reimbursement to encourage more patient interaction.[56]

Additionally, the growth of mobile applications and devices˘ growth has extended another source of patient-generated data to providers.[57] For example, health-related mobile applications available in the Apple App Store nearly quadrupled in one year.[58] Analytic tools can also notice trends in online searches, allowing for public health officials to respond to emerging issues.[59] Although many Americans are concerned about data privacy and security,[60] smart phones˘ and other mobile devices˘ ubiquity makes mhealth a convenient means of measuring and storing one˘s own data.[61] One survey found that more people´ particularly younger people´ are willing to share their personally-generated data with their physician or even with their insurer.[62] With an estimated 30 percent of smart phone users using health applications, this technology provides a new way to gather data that is more convenient than a visit to a physician˘s office.[63]

MODERN HEALTHCARE (Oct. 6, 2015), http://www.modernhealthcare.com/article/20151006/NEWS/151009952; see generally Medicare Access and CHIP Reauthorization Act of 2015, Pub.L. No. 114¯10. MACRA consolidates several Medicare incentive programs, including the meaningful use program, into a single `merit-based incentive payment system._ Sec. 101(b)(1) of Pub.L. No. 114¯10. This new merit-based incentive will continue to encourage the meaningful use of electronic medical records. Kavita Patel et al, How the money flows under MACRA, BROOKINGS (July 12, 2016), https://www.brookings.edu/research/how-the-money-flows-under-macra/ (`MIPS consolidates three existing programs that dictate physician bonuses or penalties for Medicare physicians and other providers. . .into a new system that creates a composite score based [in part] on. . .Meaningful use of electronic health records (EHRs) False_).

56. See Medicare Access and CHIP Reauthorization Act of 2015, Pub.L. No. 114¯10 í 101(c) (2015) (discussing clinical practice improvements to engage patients that will be used to evaluate payments to clinicians).

57. WORLD HEALTH ORG., supra note 7, at 51. The use of mobile technology for health purposes is often referred to as `mhealth._ Definitions of mHealth, HEALTH INFO. AND MGMT. SYS. SOC˘Y (Jan. 5, 2012), http://www.himss.org/definitions-mhealth.

58. WORLD HEALTH ORG., supra note 7, at 51.

59. Id. at 41.

60. Kirzinger, supra note 28.

61. WORLD HEALTH ORG., supra note 7, at 3, 50.

62. SALESFORCE, supra note 49, at 14¯15. Surveys have found that consumers have different views depending on what they will receive in return and how the information is collected. Insurance Customers Speak Out, INSURANCE NEXUS (Mar. 10, 2016), http://www.insurancenexus.com/customer/insurance-customers-speak-out (discussing surveys on consumers˘ attitudes toward sharing health data with insurers in exchange for incentives); Consumer comfort with sharing health data in exchange for insurance discounts varies from 26 -42% depending on connected fitness device owned, PARK ASS˘N (Aug. 12, 2015), https://www.parksassociates.com/blog/article/chs-2015-pr6 (finding consumers˘ willingness to exchange data for an insurance premium discount varied depending on the type of device used (ranging from 42% from digital pedometer, 35% from a smart watch owners, to 26% from a sleep-quality monitor)).

63. WORLD HEALTH ORG., supra note 7, at 51.

II. USING DATA

Being able to gather data is one step toward improving health´ data needs to be aggregated and shared in order to truly harness its power to shape health by spotting trends not visible at an individual patient level.[64] At a global level, harnessing even greater data can help identify trends regardless of whether the payer is public or private and provide important tools for research, public health, and preparedness.[65] But, for such public health and research efforts to be successful, there needs to be greater harmonization between different nations˘ requirements for the collection and utilization of health information.[66]

A. Research collaborations

Health data has a broad range of uses. [67] For example, health data can be used for medical research, population health, and healthcare delivery systems improvement.[68] Interest in techniques such as data mining[69] and `big data_ analytics[70] may help improve health quality and lead to advances in population health by identifying key trends.[71] When available, EHRs provide `longitudinal, comprehensive, and interoperable_ data and serve as a `repository of electronically maintained information about an individual˘s

64. Hiller, supra note 38, at 251 (`Big data, analytics, and predictive algorithms are poised to play a large part in the transformation of health-care delivery in the United States, determining who will benefit and, unfortunately, who may suffer from its insights. Health-care reform depends on cost savings derived from the application of sophisticated data analytics to the ever-expanding mass of data collected from and about individual patients._).

65. See generally A New Era for the Healthcare Industry, Cloud Computing Changes the Game, ACCENTURE (2016), https://www.accenture.com/us-en/~/media/Accenture/Conversion-Assets/DotCom/Documents/Global/PDF/Technology_2/Accenture-New-Era-Healthcare-Industry-Cloud-Computing-Changes-Game.pdf.

66. Rebecca Li et al., Global Clinical Trials: Ethics, Harmonization & Commitments to Transparency, 5 HARVARD PUB. HEALTH REV. 1, 6 (2015) (`The more that clinical trial regulations differ from country to country, the more difficult it will be to establish common approaches to current pressing ethical issues._).

67. BEN GOLDACRE ET AL., WHO CONSULTATION ON DATA AND RESULTS SHARING DURING PUBLIC HEALTH EMERGENCIES: BACKGROUND BRIEFING 18 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf (`There are also numerous policy initiatives around data sharing in science more broadly, outside of emergency settings._).

68. Id.

69. Bill Palace, What is data mining?, http://www.anderson.ucla.edu/faculty/jason.frand/teacher/technologies/palace/datamining.htm (last visited Nov. 11, 2016) (defining data mining as the `process of analyzing data from different perspectives and summarizing it into useful information . . . that can be used to increase revenue, cuts costs, or both_).

70. Joachim Roski, Creating Value in Health Care through Big Data: Opportunities and Policy Implications, HEALTH AFFAIRS 1115, 1116 (2014) (attempting to define the term `big data_).

71. ACCENTURE, supra note 65, at 14.

lifetime health status and health care._[72] In turn, data analysts and researchers can use such data to improve the delivery of care by looking at the effectiveness and cost of specific interventions and treatments.[73] Such efforts to refine payment and delivery systems are possible regardless of payer source because all payers´ private and public´ share an interest in reducing costs while ensuring access to care and quality services.[74]

Additionally, policymakers, industry stakeholders, and researchers continue to collaborate with respect to how sharing data across borders can reduce costs in the drug approval process.[75] Data exchanges could reduce costs and improve the efficiency of clinical trials occurring in different countries.[76] If different countries harmonized formats for how clinical trials must be conducted as well as how the resulting data must be submitted, pharmaceutical companies might not need to conduct duplicative trials and could submit data more quickly and easily to multiple regulators, thus reducing the approval time for new drugs to come to market and into the hands of patients.[77] The purported costs of running clinical trials has increased so much that many pharmaceutical companies and foundational sponsors are looking outside the United States and Europe to run these trials.[78] Assembling clinical trial data from different countries can be complex depending on each country˘s rules for conducting a trial and securing patients˘ data as well as how sophisticated that country˘s IT infrastructure is.[79]

Greater use and exchange of health data can enhance these harmonization efforts and the drug development process. Data derived from EHRs can be another means of collecting information to help supplement clinical trials:

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72. Drabiak-Syed, supra note 40, at 40.

73. Sweet, supra note 4040, at 246; Roski, supra note 70, at 1115.

74. CANADA- U.S. HEALTH SUMMIT 2015, supra note 33, at 10.

75. Thomas Bollyky et al., Bridging the Gap: improving clinical development and the regulatory pathways for health products for neglected diseases, 7 CLINICAL TRIALS 719, 721 (2010); see also Li, supra note 66, at 5 (`Clinical trial data transparency that ensures fair and responsible access to data to enable further research and progress._).

76. Sharona Hoffman & Andy Podgurski, The Use and Misuse of Biomedical Data: Is Bigger Really Better? 39 AM. J. OF L. & MED. 497, 507¯08 (2013) (`Observational studies are often less costly and time-consuming than experimental research, especially when researchers obtain the required data from existing databases._); see Bollyky, supra note 75, at 721. (`[N]ational and international requirements for data monitoring and record keeping have increased in complexity. . . .[N]ow frequently comprise a third to two-thirds of total clinical trial cost._).

77. Betty Kuhnert, ICH at 20: An Overview, 3 GLOBAL FORUM 17, 17 (April 2011).

78. Li, supra note 66, at 1¯2 (`[O]ne publication cited a $600M cost savings per year (assuming 60,000 trial participants) through shifting 50 percent of late phase trials from the U.S. and Europe to less costly locales such as India and South America._).

79. Hoffman & Podgurski, supra note 76, at 506¯07.

> If the researchers aim to show whether a specific treatment achieves the desired benefits, they may reasonably choose to conduct a randomized clinical trial to ensure that uncontrolled variables that influence outcomes, such as age or drug interactions, do not confound the study. However, observational studies may be needed to determine whether the results of randomized clinical trials that involved only a few thousand patients can be generalized to the patient population at large and to realistic treatment situations rather than carefully controlled ones. Furthermore, observational research based on medical records will often be sufficient to determine a treatment˘s adverse effects.[80]

Indeed, as a domestic example, an FDA advisory group on diabetes recommended approval of a continuous-glucose-monitoring device that relied on simulation data based on a small set of actual clinical data.[81] While several members of the advisory group raised concerns about the use of this type of data, an FDA official suggested that, if approved, there could be a requirement to conduct post-market surveillance of the device to ensure patient safety and compliance with recommended guidelines.[82] Thus, this reliance on data´ both as part of the approval process and to supplement surveillance efforts once a device has gone to market´ could be precedential in future drug approvals.

Through efforts dating back to 1980, countries have attempted to find ways to `strengthen collaboration and exchange information_ through international organizations, such as the International Conference of Drug Regulatory Authorities, the World Health Organization, and regional negotiations.[83] The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has developed a global standard `for the design, conduct, recording, and reporting of trials._[84] Because ICH standards are guidelines, not regulations,[85] they allow for differences between countries as to how this standard is applied.[86] Often, these differences reflect the result of cultural norms and

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80. Id. at 507.

81. Miriam Tucker, FDA Panel Supports Dexcom CGM for Insulin Dosing in Diabetes, MEDSCAPE (July 22, 2016), http://www.medscape.com/viewarticle/866492.

82. Id.

83. Kiichiro Tsutani et al., Harmonizing East Asia: The Evolution of DIA Japan and Its Impact on East Asia 43 DRUG INFO. J. 325, 325˘26 (2009); see also Li, supra note 66, at 3˘4 (discussing the development and efforts of the Multi-Regional Clinical Trials Center at Harvard University to encourage uniform standards for multi-national clinical trials); Fran´oise Augier de Cr¶miers, The Birth of the ICH E3 and How it Led to the CTD, 3 GLOBAL FORUM 19, 19˘20 (April 2011).

84. Kuhnert, supra note 77, at 17.

85. Id. (`The guidelines are guidelines and not regulations; thus, they are intended to be used in combination with regional requirements_).

86. Bollyky, supra note 75, at 721; see also Kelly Davis, Biopharmaceutical

country-specific issues.[87]

B. Public health preparedness

The flow of health data from providers to public health agencies can identify public health emergencies such as food-borne illnesses, disease outbreaks, and environmental concerns.[88] Additionally, the Internet and mhealth provide public health services, such as online databases, that can help patients research topics that they either do not feel comfortable asking, or do not have the time to ask a health provider in-person.[89] Although analyzing what these searches mean will require more sophisticated tools to properly filter data, they demonstrate an emerging use of patient-generated data for public health purposes.[90]

Similarly, recent outbreaks have demonstrated the need to share public health data between countries, particularly in a global economy.[91] Researchers have attempted to make information, including proprietary information for drug development, available for public health use to combat Ebola and now Zika.[92] Failing to do so can have both economic and political

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Manufacturing: The Challenge of Global Regulatory Compliance, 32 PHARM. TECH. 60, 62 (June 2008) (explaining that regional disparities still exist as a result of different governmental structures, cultural norms, and business environments which lead to distinct interpretations and implementation of international guidelines).

87. Beth Ann Fiedler & Robert Bebber, An International Regulatory Clinical Trial Comparative, 7 INT'L J. PHARM. & HEALTHCARE MKTG. 199, 205-06 (2013) (discussing Japanese cultural resistance to informed consent as part of clinical trials); see also Marc Saner & Gary Marchant, Proactive International Regulatory Cooperation For Governance Of Emerging Technologies, 55 JURIMETRICS J. 147, 148 (2015) (`regulations differ among jurisdictions only when there are explicit reasons such as existing differences in cultural, social, ethical, political, legal, or physical environments._).

88. LEGAL ISSUES RELATED TO SHARING OF CLINICAL HEALTH DATA WITH PUB. HEALTH AGENCIES, P'SHIP FOR PUB. HEALTH LAW 7 (2016), http://www.astho.org/Public-Policy/Public-Health-Law/Legal-Issues-Related-to-Sharing-Clinical-Health-Data-with-Public-Health-Agencies/.

89. WORLD HEALTH ORG., supra note 7, at 51 (noting the most popular search was for chlamydia, demonstrating the privacy of the Internet).

90. See Beth Mole, New Flu Tracker Uses Google Search Data Better Than Google, ARS TECHNICA (Nov. 11, 2015), http://arstechnica.com/science/2015/11/new-flu-tracker-uses-google-search-data-better-than-google/ (discussing the challenges Google faced when it attempted to predict flu outbreaks based on large data sets and common Google searches about flu trends).

91. Christopher Dye et al., Data Sharing In Public Health Emergencies: A Call To Researchers, BULL. OF THE WORLD HEALTH ORG. 158 (2016); see Jean-Paul Chretien et al., Make Data Sharing Routine to Prepare for Public Health Emergencies, 13 PLOS MED. 1, 1 (Aug. 16, 2016), http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1002109.pdf (`The recent outbreaks caused by Ebola and Zika viruses highlighted the importance of medical and public health research in accelerating outbreak control and prompted calls for researchers to share data rapidly and widely during public health emergencies._).

92. Chretien et al., supra note 91, at 2.

consequences: for example, health leaders criticized the Chinese government for its secrecy and its failure to adequately respond to the SARS outbreak.[93] The Canadian response to SARS was also criticized for a lack of protocols between provinces and an aged surveillance system.[94]

Given the porous border between the United States and its neighbors, and the amount of traffic and trade, health information is necessary to prevent or respond to outbreaks and protect both public health and regional economies.[95] The federal government and states along national borders have cultivated their understanding of this challenge by collaborating with Canadian and Mexican counterparts to share such information.[96] For example, the Pacific NorthWest Border Health Alliance, representing northwestern states and western provinces, has held forums to examine topics such as emergency licensing of health professionals across state lines and across the U.S.-Canadian border.[97] The purpose of these agreements is to help resolve `[d]ifferences in epidemiological case definitions, communication systems and personnel licensure . . . in order for provinces/territories and states to enhance cross-border public health emergency preparedness and response._[98]

However, organizations such as the World Health Organization and the Chatham House have observed that generally, there still are complex `legal, political, economic, technical, motivational, and ethical_ barriers preventing

93. Yanzhong Huang, The SARS Epidemic and Its Aftermath in China: A Political Perspective, LEARNING FROM SARS: PREPARING FOR THE NEXT DISEASE OUTBREAK 116, 125-26 (Stacey Knobler et al. eds., 2004). Some even estimated that the Chinese economy lost nearly a percentage point from its 2003 gross domestic product. Id.

94. HEALTHCANADA, LEARNING FROM SARS: RENEWAL OF PUBLIC HEALTH IN CANADA, 28-29 (2003).

95. GOLDACRE ET AL., supra note 67, at 8-9 (`Such issues can arise due to fears over restrictions on outward migration, or discouraging tourism and trade, as well as worries about the economic or political implications of a public health emergency. It has been reported that obstacles to information sharing contributed to delays in responding to SARS CoV in 2003, and similarly to delays in responding to cholera outbreaks._).

96. See, e.g., PAN BORDER PUBLIC HEALTH PREPAREDNESS COUNCIL, PBPHPC AT A GLANCE (`comprised of health department/ministry representatives from the three regional border health collaboratives (Eastern, Great Lakes, and Pacific NorthWest); four unaligned provinces and states (Alberta, Manitoba, and North Dakota); and the Canada and United States federal government._)), http://www.pbphpc.org/ (last updated Feb. 25, 2015); U.S. BORDER HEALTH COMM'N, http://www.borderhealth.org/ (last visited Dec. 12, 2016); see also An Updated Overview of the Great Lakes Border Health Initiative, GREAT LAKES BORDER HEALTH INITIATIVE, http://www.michigan.gov/mdhhs/0,5885,7-339-71548_54783_54875-170665',00.html (last visited Sept. 13, 2016); Home, PACIFIC NORTHWEST BORDER HEALTH ALLIANCE, http://www.pnwbha.org (last visited Sept. 13, 2016).

97. PACIFIC NORTHWEST BORDER HEALTH ALLIANCE, STRATEGIC PLAN 2015-2020 (Oct. 8, 2015), http://www.pnwbha.org/wp-content/uploads/2016/09/2015-2020-Strategic-Plan-Approved-100815.pdf.

98. Who we are, PAN-BORDER PUB. HEALTH PREPAREDNESS COUNCIL, http://www.pbphpc.org/?page_id=5 (last visited Sept. 13, 2016).

public health data sharing globally.[99] Critics note that much data sharing only comes in response to a public health emergency rather than creating `enduring systems or cultures for sharing information_ that others can readily access if such an emergency reoccurs.[100] Further, one reviewer noted that often there is no plan on what to do with data collected or shared in an emergency, which can raise ethical issues.[101]

Critics urged that such long-term systems focus more on ensuring that countries can share data through `an internationally agreed framework_ rather than focusing on standardizing data.[102] Some note that data standardization requirements may be difficult and costly for low- and middle-income countries to implement and might not be necessary for data exchange:

> We thought, if all the countries could harmonize their disease surveillance systems reporting could be enhanced, and then we quickly discovered each of these countries, or most of them, already have pretty good systems in place and we˘re not going to replace them with the neighbouring system . . . So we˘re no longer trying to say countries should have the same systems . . . but we want them to be able to communicate with each other more readily.[103]

In other words, even if there are barriers to the direct exchange of data, such increased communication´ either among lower-income countries or between them and high-income countries´ has great value for public health because low- and middle-income countries can learn from what worked and what were costly failures elsewhere. Understanding some best practices around how to collect and use data for public health purposes can help countries anticipate and prepare for emergencies.

III. REGULATION OF HEALTH DATA: ARE COUNTRIES READY TO SHARE?

As the ways data can be gathered continue to evolve rapidly, technology

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99. Jussi Sane & Michael Edelstein, Overcoming Barriers to Data Sharing in Public Health: A Global Perspective, CHATHAM HOUSE 18 (2015).

100. GOLDACRE ET AL., supra note 67, at 15 (`Every time there˘s a new outbreak and it˘s a new pathogen, then people that have never had to experience how you do this start learning from the bottom up. . . and they end up making all the mistakes that we keep making of the last 15 or 20 years._).

101. Sane & Edelstein, supra note 99, at 17; see also Chretien et al., supra note 91, at 3 (discussing how researchers who included `Zika virus genome sequences in a public database felt they were not credited appropriately when another group used those sequences for a paper published 2 weeks later._).

102. GOLDACRE ET AL., supra note 67, at 16 (`There really is a need for some move towards a global consensus on governance of data sharing so that various players, not only the public, but certainly even the researchers who collect the data in the first place are protected and fairly treated._).

103. Sane & Edelstein, supra note 99, at 7.

is changing the way that law and policy regulate the use of health data.[104] Given the challenges to sharing health data within a country, these challenges can be more complex for sharing across borders.[105] Even between countries as closely aligned as the United States and Canada,[106] cultural and political differences can slow or even prevent the flow of data for critical health needs.[107] Here, trust works on several levels; each country needs to be able to trust that its partners will protect sensitive health data[108] and will not hide data for fear of economic consequences.[109]

The American approach to privacy differs from other countries; Americans look at privacy sector by sector,[110] whereas other countries take a holistic view of data privacy, regardless of the type of data.[111] Further, reactions to American surveillance techniques and authorizations, such as the USA PATRIOT Act,[112] have led to Canadian provinces prohibiting Canadian health information from being stored in American-based data storage.[113]

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104. See infra Part III.

105. OECD PRIVACY, supra note 31, at 30 (`Transborder flows of personal data, to Member countries or non-Member countries, present risks, which data controllers must address._).

106. Fact Sheet: United States-Canada Relationship, WHITE HOUSE (Mar. 10, 2016), https://www.whitehouse.gov/the-press-office/2016/03/10/fact-sheet-united-states-%E2%80%93-canada-relationship; see also CANADA-US HEALTH SUMMIT 2015, supra note 74 (noting partnership between Canada and the United States to advance the Global Health Security Agenda); see also Oliver Kim & Dani Peters, Health is not Always Local: Beginning a Cross-Border Health Dialogue, HEALTH AFFS. BLOG (Mar. 22, 2016), http://healthaffairs.org/blog/2016/03/22/health-is-not-always-local-beginning-a-cross-border-health-dialogue/ (`At both the federal and the state/provincial levels, regulatory and surveillance systems are communicating with one another, on a frequent basis, for public health purposes._).

107. Sane & Edelstein, supra note 99, at 18.

108. OECD PRIVACY, supra note 31, at 30 (`Some data flows may require close attention because of the sensitivity of the data or because the receiving jurisdiction may lack either the willingness or capacity to enforce privacy safeguards._).

109. See, e.g., Huang, supra note 93, at 116¯17; see also Tom Leonard, Swine flu: Wall of Silence in Mexico˜s Cancun Holiday Resort, DAILY TELEGRAPH (Apr. 29, 2009), http://www.telegraph.co.uk/news/health/swine-flu/5245411/Swine-flu-wall-of-silence-in-Mexicos-Cancun-holiday-resort.html.

110. BARRY FURROW ET AL., HEALTH LAW 171¯73 (2d ed. 2000).

111. Vadim Schick, Data Privacy Concerns for U.S. Healthcare Enterprises˜ Overseas Ventures, 4 J. HEALTH & LIFE SCI. L. 173, 178 (2011) (`In contrast [to American law], many foreign data privacy regimes, including the laws reviewed in this section, are privacy laws of general application, which apply to all personally identifiable information, including, but not limited to, health-related data._); see also Elana Rivkin-Haas, Electronic Medical Records and the Challenge to Privacy: How the United States and Canada are Responding, 34 HASTINGS L.J. 177, 194¯95 (2011).

112. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT Act) Act of 2001, Pub. L. No. 107¯56, 115 Stat. 272.

113. See infra III.B.2.

A. United States

Many Americans are concerned about health privacy, particularly as more data becomes available electronically.[114] In the United States, the security and privacy of health data is governed mainly by two federal laws. First, the Health Insurance Portability and Accountability Act (HIPAA)[115] provides the foundation for health privacy in the United States.[116] Under HIPAA, HHS promulgated two major rules on the privacy and security of health data: the Privacy Rule regulates when `covered entities_[117] and `business associates_[118] can disclose `personal health information_ (PHI),[119] and the Security Rule regulates how covered entities secure such data.[120] Covered entities include health plans, healthcare clearinghouses, and healthcare providers that transmit health information in electronic form.[121] HIPAA also applies to a covered entity˘s business associates, individuals, or businesses that help the covered entity perform certain functions or activities that require the use or disclosure of PHI.[122] PHI can include names, medical record numbers, social security numbers, and medical record information.[123]

Under the Privacy Rule, covered entities may use and disclose PHI without an authorization for uses such as `treatment, payment, or health care

114. See, e.g., Schick, supra note 111, at 178.

115. Health Insurance Portability and Accountability (HIPAA) Act, Pub. L. No. 104¯191, 110 Stat. 1936 (1996).

116. For a greater discussion of state privacy laws, see Drabiak-Syed, supra note 40, at 47 and following (`States vary with regard to how they define terms such as medical record or medical information, to whom this information can be disclosed, for what purposes, what an individual˘s consent to disclose this information must contain, and the nature of exceptions for disclosure without consent._); Sane & Edelstein, supra note 99, at 4, 8 (`In the United States public health laws regarding data sharing vary from state to state, and in some instances, while the law provided opportunities for data sharing, these were restricted by health department policies that had not been updated to reflect new legislation._); see also Janlori Goldman, THE STATE OF HEALTH PRIVACY (2d ed. 2002), https://www.cdt.org/files/pdfs/The%20State%20of%20Health%20Privacy%20(Volume%201).pdf.

117. 45 C.F.R. í 164.104 (2013).

118. 45 C.F.R. í 160.103 (2014).

119. Id.

120. 45 C.F.R. í 164.306 (2013).

121. 45 C.F.R. í 164.104; Are you a covered entity?, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jun. 21, 2016, 6:31 PM), https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.html.

122. Summary of the HIPAA Privacy Rule, U.S. DEP˘T HEALTH & HUMAN SERVS., http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (last visited Nov. 20, 2016) [hereinafter HIPAA Privacy Rule]; see also Business Associates, U.S. DEP˘T HEALTH & HUMAN SERVS., http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/ (last visited Oct. 16, 2016).

123. HIPAA Privacy Rule, supra note 122.

operations,_[124] certain public health activities,[125] and when the individual health information has been `de-identified._[126] For a covered entity to disclose PHI for other purposes, the covered entity may need to seek the patient˘s authorization[127] or offer him an opportunity to agree or object.[128] Under HIPAA˘s Security Rule, covered entities and business associates must follow standards to `ensure the confidentiality, integrity, and availability of all electronic_ PHI and `protect against any reasonably anticipated threats or hazards_ or unpermitted disclosures.[129] Further, covered entities and business associates must `implement policies and procedures to prevent, detect, contain, and correct security violations._[130]

Second, HITECH subsequently modified federal privacy rules, while simultaneously encouraging greater data sharing through an investment in EHRs.[131] As aforementioned, through meaningful-use requirements, the federal government encourages health providers eligible for incentives to share health data not only among other eligible providers but also public health agencies and other providers that are ineligible for incentives.[132] Such data sharing should improve public health, clinical research, and payment and delivery reforms.[133]

To balance individual privacy with this explicit encouragement to share health data, HITECH includes several new privacy protections. First, HITECH expands the definition of a business associate[134] and clarifies that business associates must comply with both HIPAA regulations on data security[135] and the new HITECH privacy protections.[136] Further, business associates can be held liable for their failure to comply with the Privacy Rule.[137] HITECH also required individuals to be notified of breaches, or the

124. 45 C.F.R. í 164.502 (2013).

125. 45 C.F.R. í 164.512(b) (2016).

126. 45 C.F.R. í 164.514 (2013).

127. 45 C.F.R. í 164.508 (2013) (discussing an authorization and the core elements needed for a valid authorization).

128. 45 C.F.R. í 164.510 (2013).

129. 45 C.F.R. í 164.306 (2013).

130. 45 C.F.R. í 164.308 (2013).

131. Kara Johnson, HITECH 101, ABA YOUNG LAWYERS DIV., http://www.americanbar.org/groups/young_lawyers/publications/the_101_201_practice_series/hitech_101.html (last visited Oct. 16, 2016).

132. See STAGE 2 TOOLKIT., supra note 51.

133. See Roski, supra note 70, at 1116.

134. American Recovery and Reinvestment Act of 2009 í 13408, 42 U.S.C.A. í 17938 (West 2009) (including patient safety organizations, state health information organizations, and subcontractors); 45 C.F.R. í 160.103.

135. American Recovery and Reinvestment Act of 2009 í 13401, 42 U.S.C.A. í 17931 (West 2009).

136. Id.

137. Id.

impermissible disclosure or use of protected health information, by a covered entity or its business associates.[138] Second, HITECH also gave individuals more control over their health information by improving their right to see who has obtained copies of their records, as well as requiring them to be notified in the event of a data breach.[139]

B. Canada

Health IT adoption is growing in Canada, but challenges remain. As a commonwealth form of government, Canada faces certain procedural obstacles in moving towards a digital health system.[140] For example, Canada has one of the most trusted relationships with the United States, but Canada˘s reaction to foreign legislation, which has bearing on data exchange, has impeded intergovernmental exchange of health information.[141] However, concerns over the PATRIOT Act demonstrate how important trust is to the free exchange of data.

1. Health IT Utilization in Canada

Like other countries, the Canadian healthcare system is encouraging robust health IT use to improve quality and patient care.[142] Health IT use in Canada nearly doubled from 2009 to 2015 through investments by the provinces, territories, and the federally-chartered Canada Health Infoway.[143] The board of Canada Health Infoway represents both the national government as well as the provincial and territorial governments,[144] and this structure has helped reduce some potential variation across the country.[145]

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138. HITECH Breach Notification Interim Final Rule, U.S. DEP˘T HEALTH & HUMAN SERVS., http://www.hhs.gov/hipaa/for-professionals/breach-notification/laws-regulations/final-rule-update/HITECH/index.html (last visited Nov. 18, 2016).

139. 42 U.S.C.A. íí 17932, 17935, & 17937; see also Johnson, supra note 131.

140. See Sara Allin and David Rudoler, The Canadian Health Care System, 2015, in ELIAS MOSSIALOS ET AL., EDS, INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS 27 (2015) (`Provinces and territories are responsible for developing their own electronic information systems, with support from Canada Health InfowayFalse_), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2016/jan/1857_mossialos_intl_profiles_2015_v7.pdf.

141. See USA PATRIOT Act of 2001, Pub. L. No. 107˘56, 115 Stat. 272 (2001).

142. See OFFICE OF THE INT˘L COORDINATOR FOR HEALTH INFO. TECH., HEALTH IT ENABLED QUALITY IMPROVEMENT: A VISION TO ACHIEVE BETTER HEALTH AND HEALTH CARE (2013), https://www.healthit.gov/sites/default/files/HITEnabledQualityImprovement-111214.pdf.

143. Riley Denver, Family Doctors See Improvements for Patients, But Canada Still Lags Peer Countries on Most Measures, CANADIAN INST. FOR HEALTH INFO. (Jan. 28, 2016), https://www.cihi.ca/en/cmwf/media_release_commonwealth_2015.

144. Board of Directors, CAN. HEALTH INFOWAY, https://www.infoway-inforoute.ca/en/about-us/about-canada-health-infoway/board-of-directors (last visited Nov. 2, 2016).

145. Joshua Vest, Health Information Technology in the International Context, in 12

However, this national strategy does not dictate what technology or vendors can be used.[146] This limited variance has led to some challenges with information exchange, but Canada Health Infoway has found more positive than negative experiences among physicians.[147]

The Canadian investment has had a dramatic effect on patient care for those physicians who utilize EHRs. Nearly four out of five physicians with EHR generate a computerized list of patients by diagnosis in contrast with just one out of five among physicians without EHR, and six out of ten physicians with health IT could determine which patients were overdue for routine tests or preventative care compared to just one out of ten for physicians without.[148] Further, three out of five Canadian physicians believe health IT has contributed to `the quality of patient care throughout the healthcare system, _ and four out of five believe that health IT has helped to reduce medical errors.[149] Similarly, the general Canadian public is supportive of public investments in health IT and sees positive benefits.[150] Such positive reactions are key factors in spurring on the adoption of health IT.[151]

Even still, two recent surveys found that Canada˘s utilization is lower than similarly situated industrialized countries.[152] Canadian physicians were less likely than their counterparts in other surveyed countries to be able to use their health IT systems for population health or patient care management, and only about two in five Canadian physicians routinely used health IT for at least two or more of common patient care tools such as prompts about drug interactions or dosages, reminder notices for overdue care, or automated prompts for guideline-based interventions and/or screening tests.[153]

HEALTH INFORMATION EXCHANGE: NATIONAL AND INTERNATIONAL APPROACHES 7˘8 (Nir Menachemi & Sanjay Singh eds., 2012).

146. Id. at 7.

147. See Sukirtha Tharmalingam et al., The Value of Connected Health Information: Perceptions of Electronic Health Record Users in Canada, BMC MED. INFORMATICS & DECISION MAKING 1, 6˘8 (2016).

148. CAN. HEALTH INFOWAY, Canadian Physicians Can Improve Patient Care with Advanced EMR Use (Jan. 28, 2016), https://www.infoway-inforoute.ca/en/what-we-do/news-events/newsroom/2016-news-releases/6752-canadian-physicians-can-improve-patient-care-with-advanced-emr-use [hereinafter Canadian Physicians].

149. Canada˘s Healthcare IT Dilemma, ACCENTURE 3 (2013), https://www.longwoods.com/articles/images/Accenture-Canada-Healthcare-IT-Dilemma.pdf [hereinafter Canada˘s Healthcare IT].

150. See Shelagh Maloney, What Canadians Think, CAN. HEALTH INFOWAY 1, 4˘6 (June 2, 2015), http://www.e-healthconference.com/pastpresentations/2015/201571419700/2848Maloney_eHealth_What_Canadians_Think1.pdf.

151. Id.

152. Id.; see also How Canada Compares, CAN. INST. OF HEALTH RESEARCH (Jan. 2016), https://www.cihi.ca/sites/default/files/document/2015-cmwf-chartpackenrev-web.pptx [hereinafter How Canada Compares].

153. How Canada Compares, supra note 152, at 46˘47.

Additionally, investments in health IT have not focused on engaging patients.[154] According to one survey, Canadian provinces had focused their public investments into infrastructure and interoperability, `which do not have an obvious impact on everyday patient experiences,_ over patient-focused conveniences such as making health information accessible to patients and online prescribing and `scheduling appointments._[155] Further, there are variations between the Canadian provinces on rates of adoption.[156] While health ID adoption in all Canadian provinces and territories ranked below the average of all industrialized countries surveyed, certain provincial adoption rates (i.e., Alberta, British Columbia, and Saskatchewan) ranked close to the average.[157] In contrast, the largest province of Ontario was behind the average.[158]

Unlike the United States but similar to other countries, Canada˘s privacy laws are of general application, not specific to health care or health data.[159] First, the Canadian Privacy Act regulates public actors˘ roles and responsibilities in regards to personal information.[160] Second, the Personal Information Protection and Electronic Documents Act (PIPEDA) regulates private actors˘ ability to collect and utilize personal information.[161] Additionally, Canada Health Infoway also plays a role in the regulation of data through its role as a funder and a technical expert to `the provinces and territories to foster and accelerate the development and adoption of pan-Canadian electronic health information systems._[162]

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154. Id.

155. Canada˘s Healthcare IT, supra note 149, at 3; see also Allin, supra note 140140, at 23 (noting that among general practitioners, `only 6 percent reported that [their] patients can request appointments online_); Harnessing the Potential of Mobile Health Apps , CBC NEWS (June 27, 2016, 3:33 PM), http://www.cbc.ca/news/health/m-health-1.3654795.

156. How Canada Compares, supra note 152, at 45; see also Canadian Physicians, supra note 148148 (`Alberta, British Columbia and Ontario continue to have the highest adoption rates in Canada. Quebec, Manitoba and Saskatchewan experienced the highest increases in EMR uptake by primary care physicians since 2012._).

157. How Canada Compares, supra note 152, at 45.

158. Id.

159. See FURROW ET AL., supra note 110110 (discussing American regulation of health privacy); see also Schick, supra note 111, at 178 (`In contrast [to American law], many foreign data privacy regimes, including the laws reviewed in this section, are privacy laws of general application, which apply to all personally identifiable information, including, but not limited to, health-related data._).

160. Privacy Act, R.S.C., 1985, c. P˘21 (Can.).

161. Personal Information Protection and Electronic Documents Act, S.C., 2000, c. 5 (Can.).

162. Rivkin-Haas, supra note 111, at 198 (`This comprehensive system will likely help address some privacy issues resulting from electronic transmission of sensitive information by creating a uniform approach to security and privacy expectations; but it may not adequately safeguard secondary uses or aggregation of personal data._).

2. Barriers to Cross-Border Exchange between the US and Canada: The PATRIOT Act as a Case Study

In 2001, the United States enacted the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (`PATRIOT Act_) to increase law enforcement capabilities in response to the terrorist attacks on September 11 of that year.[163] Section 215 of the PATRIOT Act expanded the authority of the Federal Bureau of Investigation to seek:

> an order requiring the production of any tangible things (including books, records, papers, documents, and other items) for an investigation . . . to protect against international terrorism or clandestine intelligence activities, provided that such investigation of a United States person is not conducted solely upon the basis of activities protected by the first amendment to the Constitution.[164]

This provision raised great controversy as certain agencies of the United States federal government argued this provision authorized the government to obtain bulk data from telephone companies.[165] Public opinion turned against the PATRIOT Act after a whistleblower leaked that data collection included information on millions of Americans related to who they called who, when, and for how long.[166]

In addition to creating significant debate and controversy within the United States, Section 215 also provoked significant controversy in Canada

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163. See USA PATRIOT Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001) (codified at 50 U.S.C.A. § 1861(a)(1) (West 2001)).

164. USA PATRIOT Act, Pub. L. No. 107-56 § 215(a)(1) (2001). Note that Section 215 was amended when Congress reauthorized much of the PATRIOT Act in 2015; under the reauthorization, called the USA FREEDOM Act, P.L. 114-23, the federal government could not continue mass phone data collection but instead could seek permission from a federal court to obtain information from phone companies about targeted individuals; see Harley Geiger, Q&A on the USA Freedom Act of 2015, CTR. FOR DEMOCRACY & TECH. (Apr. 28, 2015), https://cdt.org/blog/q-a-on-the-usa-freedom-act-of-2015/; see also Erin Kelly, Senate Approves USA Freedom Act, USA TODAY (June 2, 2015), http://www.usatoday.com/story/news/politics/2015/06/02/patriot-act-usa-freedom-act-senate-vote/28345747/ (discussing the 2015 reauthorization of the PATRIOT Act and changes to Section 215).

165. Harley Geiger, Issue Brief: Bulk Collection of Records under Section 215 of the PATRIOT Act, CTR. FOR DEMOCRACY & TECH. (Feb. 10, 2014), https://cdt.org/blog/issue-brief-bulk-collection-of-records-under-section-215-of-the-patriot-act/.

166. Id.; Compare Lydia Saad, Americans Generally Comfortable With Patriot Act, GALLUP (Mar. 2, 2004), http://www.gallup.com/poll/10858/americans-generally-comfortable-patriot-act.aspx (finding `a more than 2-to-1 balance of opinion against the idea that the act goes too far_) with Lauren Walker, Poll: Majority of Americans Want the PATRIOT Act Reformed, NEWSWEEK (May 18, 2015), http://www.newsweek.com/poll-majority-americans-want-patriot-act-reformed-332991 (finding that after ten years, `80 percent of respondents are :concerned˘ that the government is `collecting and storing Americans˘ personal information,_ while 18 percent are not._).

about the security of data on Canadian citizens held in the United States.[167] For some Canadian businesses, assuring customers that their data remained in Canada, and not stored in the United States was seen as a competitive advantage.[168] Despite an opinion from the Canadian Attorney General determining that the PATRIOT Act posed `minimal_ risk, this political controversy resulted in four provinces enacting legislation that restricted data exchange, including health data, between these provinces and the United States.[169]

The effect of these provincial laws was very dramatic because these laws affect a wide range of public services that constitute about a third of the Canadian economy.[170] For instance, in these provinces, Canadian physicians could not consult with their American counterparts effectively on cases if it involved sharing medical images across the border, and American medical imaging and diagnostic equipment manufacturers could not service their equipment remotely because a technician would have temporary access to Canadian patient data.[171] In order to fulfill a health benefits contract with British Columbia, the American company MAXIMUS had to create three subsidiaries to achieve arm˘s length distance and place the shares of its subsidiary˘s stock in trust with the threat of loss of the stock, and a financial penalty if the data held by MAXIMUS˘s subsidiary was breached.[172] The Information Technology Association of Canada described this province˘s data law as `the most stringent public sector privacy laws in the world´ creating an invisible wall beyond which personal information cannot be moved._[173]

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167. FRED CATE, PROVINCIAL CANADIAN GEOGRAPHIC RESTRICTIONS ON PERSONAL DATA IN THE PUBLIC SECTOR 1˘3 (2008); Timothy Banks, Cloud Computing and the USA Patriot Act: Canadians Implications, INTERNET & E-COMMERCE LAW IN CAN. 20, 22˘23 (July 2012).

168. Robert Gates, Privacy, Power Concerns Drive Canadian Data Center Growth, TECHTARGET (Feb. 18, 2016), http://searchdatacenter.techtarget.com/news/4500273368/Privacy-power-concerns-drive-Canadian-data-center-growth; see Shane Dingman, Microsoft Opens Cloud Services to Select Canadian Clients with New Data Centres, THE GLOBE & MAIL (Mar. 14, 2016), http://www.theglobeandmail.com/technology/microsoft-opens-cloud-services-to-select-canadian-clients-with-new-data-centres/article29225256/ (referencing an opinion by the president of Microsoft˘s Canadian division that many business feared storing their data outside Canada because of provincial restrictions on storing public data in the United States); Brian Jackson, Canadian firms shy from cloud because of Patriot Act, ITBUSINESS.CA (May 20, 2010), http://www.itbusiness.ca/news/canadian-firms-shy-from-cloud-because-of-patriot-act/15164 (noting that many Canadian firms are basing their decisions on information storage in part on fear of the PATRIOT Act).

169. CATE, supra note 167, at 3˘8 (discussing the laws passed in Alberta, British Columbia, Nova Scotia, and Quebec).

170. Id. at 13.

171. Id. at 14˘15.

172. Id. at 16˘17.

173. Id. at 13.

Given these economic hardships, critics opined that the provincial restrictions were an overreaction to the PATRIOT Act.[174] After all, most countries do allow for access to data in the context of law enforcement and national security, and several legal observers believed the threat of the PATRIOT Act was minimal to Canadian data housed in the United States.[175] But even if the actual risks of seizure under the PATRIOT Act are minimal, Canadians˘ perception of the law˘s risk became a barrier to data exchange because of the differences between how Canadians believed their data would be treated if held in the United States.[176] This trend shows that trust is a key component in ensuring that data can flow freely between countries.[177]

IV. RCC AS A PATHWAY FORWARD: REGULATORY HARMONIZATION

As data exchange becomes more critical to managing countries˘ public health and economies, identifying early any political and legal `flash points_[178] like the PATRIOT Act will also become increasingly important. Resolving these domestic issues in the context of trade negotiations or global diplomacy is unlikely, but such discussions may help ease tensions, restore trust, and find possible solutions.[179]

Looking at the Canadian-American relationship also is useful because our countries have a formal process for regulatory harmonization.[180] The Regulatory Cooperation Council (RCC)[181] offers a way for government

174. See Banks, supra note 167, at 22 (noting that since 1990, Canada and the United States have `agreed to assist the other with the investigation, including seizure of records, of criminal activity_); see J.V.J. van Hoboken, A.M. Arnbak & N.A.N.M. van Eijk, Cloud Computing in Higher Education and Research Institutions and the USA Patriot Act, INST. INFO. LAW, UNIV. OF AMSTERDAM (Nov. 2012).

175. CATE, supra note 166, at 23.

176. Id. at 3, 23.

177. See supra Part III.

178. See infra note 182.

179. See generally Birgit Matthiesen, Trust, In So Many Words, 37 CAN.-U.S. L.J. 365 (2012).

180. Christopher Sands, Restoring Respect for the Law in Canada-U.S. Commerce: The Regulatory Cooperation Council So Far, 37 CAN.-U.S. L.J. 319, 326 (2012).

181. Promoting International Regulatory Cooperation, Exec. Order No. 13609, 77 Fed. Reg. 87 (May 1, 2012). Federal Register: The Daily Journal of the United States. Web. 4 May 2012. With the transition from an Obama administration to President-elect Donald Trump, it remains to be seen how US-Canadian relationships will change, but several pundits believe that strong trade relations will continue between the two countries. Compare David Burke, Donald Trump presidency may not endanger Canada-U.S. free trade, CBC NEWS (Nov. 9, 2016), http://www.cbc.ca/news/canada/nova-scotia/trump-election-trade-nafta-1.3843128 (posting an interview with a Canadian scholar who notes that much of the trade between the two countries is `locked in through World Trade Organization rules_) with Laura Dawson, What Trump Means for Canadian Prosperity, WILSON CTR. CANADA INST. (Nov. 9, 2016), https://www.wilsoncenter.org/article/what-trump-means-for-canadian-prosperity ( `Canada is in a better position than other countries. While Trump has threatened to build a wall against

regulators and stakeholders´ such as industry and business interests and consumer advocates´ to collaborate and strategize with respect to regulatory harmonization, and develop workable plans to identify key `flash point_ policies prior to the promulgation of regulations.[182] In 2011, then-Canadian Prime Minister Stephen Harper and United States President Barack Obama announced the creation of the RCC, under which Prime Minister Harper would provide a forum for regulators and interested stakeholders to harmonize existing regulations and help prevent potential conflicts in future regulations, easing cross-border trade and increasing the potential for economic growth and development.[183]

The RCC works by matching federal regulatory agencies from each country together to identify regulations that could be harmonized.[184] Often, stakeholders identify areas where American and Canadian regulations could be aligned, and the RCC hosts periodic stakeholder sessions to solicit input for potential harmonization initiatives.[185] Through the RCC, both countries˘ regulators can work together to harmonize conflicting regulations and standards, making it easier for companies to conduct business on both sides of the border.[186] Reducing regulatory burdens should also reduce costs as companies only have to meet the same or similar regulatory requirements, thus making products more affordable for consumers and freeing up capital for investment.[187]

While the RCC has branched into health, it has not yet focused on regulatory harmonization around issues surrounding the exchange and use of health data. [188] The RCC could play a major role in harmonizing policies around health data, mobile health, electronic medical records, and similar health information exchanges, but there are structurally limitations in how

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Mexico and impose punitive tariffs against China, he has limited his remarks about the Canadian border and trade to : not our biggest problem.˘_).

182. CAN.-U.S. LAW INST., Welcoming Remarks, 37 CAN.-U.S. L.J. 289, 295 (2012).

183. Press Release, Office of the Prime Minister, PM and U.S. President Obama Announce Shared Vision for Perimeter Security and Economic Competitiveness between Canada and the United States (Feb. 4, 2011), http://news.gc.ca/web/article-en.do?m=%2 Findex&nid=587999 [hereinafter Shared Vision].

184. U.S.-CAN. REGULATORY COOPERATION COUNCIL, A New Era in U.S.-Canada Regulatory Partnership (Jan. 30, 2012), http://trade.gov/rcc/rcc-summary.asp.

185. See, e.g., U.S.-CAN. REGULATORY COOPERATION COUNCIL, Stakeholders & Senior Officials Meetings Agenda (May 4, 2016), http://trade.gov/rcc/documents/final-agenda-E.pdf.

186. Press Release, The White House, Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation (Feb. 4, 2011), https://www.whitehou se.gov/the-press-office/2011/02/04/joint-statement-president-obama-and-prime-minister-harper-canada-regul-0.

187. Id.

188. Canada-United States Regulatory Cooperation Council Joint Forward Plan August 2014, GOV˘T OF CAN. (Apr. 15, 2016), https://www.tbs-sct.gc.ca/ip-pi/trans/ar-lr/rcc-ccmr/cjfp-rppc-eng.asp [hereinafter Joint Forward Plan].

the RCC is set up that may make this process difficult.

A. WHERE THE RCC COULD HELP

In terms of health, the RCC has predominantly focused in the pharmaceutical, device, and cosmetic space `to reduce unnecessarily duplicative activities and further leverage each other˘s regulatory capacities and scientific expertise, and to improve efficiencies and timeliness of product regulatory assessments._[189] High-profile initiatives for the RCC include implementing a common electronic submission gateway at both Health Canada and the Food and Drug Administration (FDA) for the approval of new drugs; developing common labeling for routine over-the-counter drugs; and sharing inspection reports for drug and cosmetic manufacturing facilities `rather than having to conduct unnecessarily duplicative inspections in the other country._[190]

An emerging area for regulators to come together under the RCC umbrella is regulating the use of mhealth. Both Canadian and American regulators are looking at the issue of when to regulate mobile health applications with the United States further along: the FDA has issued guidance[191] and tools for app designers,[192] and the Office of Civil Rights has issued guidance on when HIPAA applies to mobile health applications.[193] There also is growing interest in finding ways to harness data collected through mhealth, as it is largely patient-generated, as well as finding ways to share such data with EHRs and other clinician tools.[194] This interest touches on privacy and security, as well as on policy issues that can be addressed by national regulators.

Thus, the RCC contains many of the key factors that could help with the

189. Joint Action Plan for the Canada-United States Regulatory Cooperation Council, GOV˘T OF CAN. (Apr. 15, 2016), https://www.tbs-sct.gc.ca/ip-pi/trans/ar-lr/rcc-ccmr/japrc-paccc-eng.asp [hereinafter Joint Action Plan].

190. THE WHITE HOUSE, UNITED STATES-CANADA REGULATORY COOPERATION COUNCIL JOINT ACTION PLAN 15 (Dec. 2011), https://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf.

191. CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES (July 29, 2016), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf.

192. Mobile Health Apps Interactive Tool, FED. TRADE COMM˘N (Apr. 2016), https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool.

193. Health App Develops: Questions about HIPAA?, OFFICE FOR CIVIL RIGHTS (Feb. 11, 2016), http://hipaaqsportal.hhs.gov/a/pages/helpful-links.

194. See Heather Landi, Harnessing the Power of Mobile, HEALTHCARE INFORMATICS (Feb. 9, 2016), http://www.healthcare-informatics.com/article/harnessing-power-mobile?page=2.

share of data between the United States and Canada.[195] Given the economic and cultural ties between the two countries, and the fact that President Obama and the Prime Minster Harper jointly announced the RCC, many of the barriers that typically impede data exchange are absent.[196] Indeed, the potential development of a common electronic submission gateway for drug and device approval would be an important step forward in the use of cross-border health data exchange.[197] Whereas one commentator noted that frequently there is a `lack of perceived benefits among policy-makers leads to restricting the data that goes out of a country,_[198] the RCC is built on the premise of information sharing.[199]

B. Where the RCC cannot help. . . but might provide impetus

Not all data issues can or will be solved by the RCC at the country level. As discussed earlier, some of the data sharing issues are at the provincial, not national, level in Canada.[200] Overcoming these provincial challenges may be politically or procedurally difficult in a commonwealth. For example, the provinces drive many regulatory decisions in Canada around interoperability and data privacy, and the RCC process relies on bringing together federal, not state or provincial, regulators together to harmonize national standards and regulations.[201] Further, Canada Health Infoway, the Canadian health IT agency, is not actually a government agency, but rather, a federally-funded non-profit organization that provides technical assistance and funding for health IT decisions´ it can help drive policy through funding decisions but it does not have regulatory authority.[202] Thus, if the RCC wanted to harmonize interoperability standards between the United States and Canada, it would be difficult because there is no natural Canadian regulatory agency[203] that is equivalent to the American Office of the National Coordinator.[204]

Yet, having the RCC engage in some aspect of health data exchange, such

195. Sane & Edelstein, supra note 99, at 6.

196. Id. at 18.

197. JOINT ACTION PLAN, supra note 189 (discussing efforts under `Health and Personal Care Product and Workplace Chemicals_); Zachary Brennan, FDA, Health Canada Look to Implement Common Electronic Submission System, (Aug. 9, 2016), http://www.raps.org/Regulatory-Focus/News/2016/08/09/25554/FDA-Health-Canada-Look-to-Implement-Common-Electronic-Submission-System/.

198. Sane & Edelstein, supra note 99, at 12.

199. Joint Action Plan, supra note 189.

200. See, e.g., CATE, supra note 167.

201. See Joint Forward Plan, supra note 188.

202. About Canada Health Infoway, CAN. HEALTH INFOWAY, https://www.infoway-inforoute.ca/en/about-us (last visited Dec. 12, 2016).

203. Allin & Rudoler, supra note 140, at 23.

204. See About ONC, supra note 21.

as mhealth, would bring much needed attention to an issue that has some roots at a provincial level but requires national coordination to be successful. Beginning talks at a top-down high level could set the stage for internal dialogue within Canada as a political `jawboning_ exercise[205] to push provincial governments and other stakeholders to come together around developing policy around the exchange of health data. Given that the RCC was established by the highest level of political leadership in the U.S. and Canada, and is made up of high-level government officials from key regulatory agencies, the RCC could use its influence to call for action in this area even if it lacks the ability to take such action itself.[206]

V. CONCLUSION

Like many legal and policy issues, the exchange of health data boils down to a matter of trust, whether between a patient and her physician, or between countries. The Canadian provincial reaction to the PATRIOT Act is a clear example: the Canadian provinces did not trust American servers and cloud storage would keep their citizens˘ information secure from unwarranted intrusion by our federal government. Addressing these political and cultural concerns through mechanisms such as the RCC are necessary to overcoming these barriers to data exchange.[207]

When a new administration assumes office in January 2017, the new President will have the opportunity not only to rebuild this trust with Canada to allow the free flow of health information, but also to work together to ensure the security and privacy of this information. Allowing the flow of data for public health preparedness, medical research, and delivery system reform will help improve health care in both countries.

205. MICHAEL MILAKOVICH & GEORGE GORDON, PUBLIC ADMINISTRATION IN AMERICA 255 (Katherine Hayes et al. eds., 10th ed. 2009); see also Jason Millman, HHS Jawboning doesn˘t Faze Insurers, POLITICO (May 8, 2012), http://www.politico.com/story/2012/05/jawboning-by-hhs-doesnt-scare-insurers-076066 (discussing attempts by HHS to `jawbone_ insurers into accepting lower rates).

206. Shared Vision, supra note 183.

207. Sane & Edelstein, supra note 99, at 11 (`:You cannot have data sharing without political buy-in.˘_).