SCHOOL OF APPLIED SCIENCES AND TECHNOLOGY

BACHELOR OF APPLIED

INFORMATION SYSTEMS TECHNOLOGY

IT Trends and Medical Imaging

BAIS 4991

Submitted: 7/30/2021

A survey of AI, Cloud Storage and Web Based Workflows for PACS

1 ABSTRACT

This report will briefly discuss trends in the medical industry, special considerations, and a comparison of SaaS for Imaging solutions and their IaaS/PaaS partners primarily in the United States of America. Areas of focus include shifting to cloud-based vendor-neutral archives for storage, web-based/API workflows, and Artificial Intelligence. Special considerations include the legal/security needs of private health data primarily. The main vendors discussed include Change Healthcare, IBM and Ambra. Based on the research done, if AI is a focus, IBM offers a more robust ecosystem. In the case that storage speed and scalability are of concern, Change's Enterprise Network should be considered. Otherwise, Ambra offers the most complete cloud solution offering both its PACS and VNA as cloud-native applications.

2 TABLE OF CONTENTS

3 INTRODUCTION

This paper research paper will be a brief survey of major considerations of the medical industry at large, three major trends in the medical imaging solutions, a comparison of three major vendors in space, as well as some notable contenders. The three considerations include legislation such as HIPAA, industry standards such as HITRUST and application protocols such as DICOM amongst others. Trends discussed include cloud-based storage, Web-Based workflows and Patient Access, and Artificial Intelligence. The three major vendors compared will be Change Healthcare, Ambra Healthcare, and IBM. Notable omissions in the space include Philips, Fujifilm, and Hyland.

4 CONSIDERATIONS OF MEDICAL IT INDUSTRY

Just like regular IT, Medical IT handles data; however, the data handled by the medical industry requires special consideration from a legal standpoint and by extension, privacy. Furthermore, much like the greater industry, some standards and protocols are in place to ensure that applications and information are interoperable and meet the legal and ethical requirements set forth by legislation. For American vendors and likely others, compliance is very important. Failure to comply may result in crippling fines. For example, St. Joseph Health, a large non-profit network, was served a 2.14 million USD fine for its publicly searchable Public Health Information of 31,800 individuals(HIPAA Journal, 2016). As such, IT solutions in healthcare are compliant with both legislation and other industry standards.

4.1 LEGISLATION

One of the most important pieces of legislation is HIPAA and amendments to it such as HITECH. Similar pieces of legislation exist in North America such as Canadian "Personal Information Protection and Electronic Documents Act" (PIPEDA) and Mexican "Federal Law for Protection of Personal Data in Possession of Individuals" and NOM-2024. However, for brevities sake, this paper will discuss primarily HIPAA given that most cloud providers and vendors are American-based companies. Other government regulators that should be considered are the Federal Drug Administration as they deal with the certification of Diagnostic Viewers. Other standards government-mandated standards include Federal Information Processing Standards Publication 140-2 (FIPS PUB 140-2)

4.1.1 HIPAA

There are three major rules that HIPAA covers, those being the Security Rule, Privacy Rule and Breach Notification rule("Official 2021 HIPAA Compliance Checklist," 2021). The Security Rule is a standard required to protect healthcare data. Healthcare data or Personal Health Information (PHI) is defined as any identifying information about an individual known. This may include identifying information such as health numbers, medical conditions, family medical history, plans or services rendered for the conditions, and coverage. To that end, Digital Imaging and Communications in Medicine (DICOM) formatted images would be considered PHI as it includes patient demographics as part of its metadata. The protection of data includes data that is at rest and in transit.

4.1.1.1 Security Rules

Per the HIPAA Journal, HIPAA outlines three areas of concern when dealing with Security Rule and Privacy rules. Those are Technical safeguards, Physical safeguards, administrative safeguards which address different aspects of the CIA ("Official 2021 HIPAA Compliance Checklist," 2021).

4.1.1.1.1 Technical Safeguards

As the name implies, technical safeguards are concerned with the technological tools and protocols used to protect PHI. To address CIA, electronic PHI (ePHI) in transit or at rest leaving the premises of an organization must meet National Institute of Standards and Technology (NIST) standards of encryption. For data in transit, there are two ways of securing data, TLS, or VPNs. For TLS enabled protocols, NIST recommends TLS 1.2 as the minimum with 1.3 as the preferred recommendation (McKay & Cooper, 2019, p. 33). Older protocols should not be used as they are known exploits such as POODLE and DROWN which can easily decrypt and access data such as ePHI and or passwords to access ePHI (Beattie, 2016; Thenault, 2014). Certificate requirements include recommendations for Elliptic Curve Digital Signature Algorithm, RSA signatures, Elliptic Curve Diffie-Hellman certificates. RSA or ECDSA signature certificates being the minimum. Elliptic Curve Diffie-Hellman must have P-256 or curve P-384 as minimum(McKay & Cooper, 2019, p. 9). Depending on the type of certificates used, cipher suite minimums start from AES_128(McKay & Cooper, 2019, p. 14).

For data at rest, the recommendation by NIST is to use FIPS-approved algorithms for encryption. NIST AES being the suggested algorithm due to its strength and speed. However, other algorithms are also permissible(Scarfone et al., 2007, pp. 4–4). Furthermore, centralized, highly

available, and highly secure key management systems for key generation, use, storage, recovery, and destruction must be in place. Access to these keys must be highly restricted and must use one or more methods of authentication; however, if the authentication involves integration with existing solutions such as Active Directory, or RADIUS, multi-factor authentication is required. How these keys are secured is up to the implementor. Keys can either be logically secured via encryption or physically stored in Trusted Platform Modules (TPM) or tamper-resistant cryptographic tokens(Scarfone et al., 2007, pp. 4-4,4-5,4-6). From an integrity standpoint, the HMAC-SHA, Cipher-based Message Authentication code (CMAC) and Cipher Block Chaining-Message Code (CCM) is the primary recommendations(Scarfone et al., 2007, pp. 4–4).

Other notable requirements within the technical category include the need for audit controls and logging. The Compliancy group citing the Department of Health and Human Services (HHS) guidelines states that includes the monitoring and auditing of user logins into the application, access to ePHI, and manipulation of ePHI (Compliancy Group, n.d.) Trails to capture unsuccessful attempts to access the system or access data should also be logged. Other logging included are firewalls, level of access, and anti-virus logging. Logs should also be kept for a minimum of six years; However, some states, provinces and territories may have additional requirements.

4.1.1.1.2 Physical Safeguards

Physical safeguards must also be in place which includes similar requirements of access, controls and policies for mobile device access and workstations that might have access to the data. The two required aspects of the physical safeguards are policies for the use/positioning of workstations and Policies and procedures for medical devices. This may include, locking down of mobile devices to a secure location when not in use, locking of the mobile device itself or its

screen when not in use, always keeping the mobile device on the persons, and restrict the use of the device that may be used to access PHI to a single person. When disposal or reuse of devices, all stored information on the device must be thoroughly deleted (HealthIT.gov, n.d.).

4.1.1.1.3 Administrative Safeguards

Per the HIPAA Journal, Administrative safeguards are mostly policies and procedures that are an ongoing process to ensure protections and steps that can be continuously taken to ensure ePHI are secured. Multiple aspects make up administrative safeguards but there are four requirements. This includes conducting risk assessments, risk management policies, contingency plans, and restriction of third-party access and reporting of security incidents. Conducting risk assessments and Risk management policies involves an appointed security officer's continuous assessment of where and how ePHI can be exposed which can then be addressed in a contingency plan. Policies for sanctions for employees that fail to comply with HIPAA must also be part of this management policy. Contingency plans must allow for critical business continuity whilst maintaining CIA for ePHI(“Official 2021 HIPAA Compliance Checklist,” 2021, pt. Administrative Safeguards).

4.1.1.2 Privacy Rules, Breech Rules and HITECH Amendments

Other rules include privacy rules and breach rules. The privacy rule is concerning policies in place to ensure authorized access to data. Notable specifics include the rights to obtain access, copies and make corrections to said information. These requests for information must have a response within 30 days. If data is to be shared, Notice of Privacy Practices (NPPS) must be provided, and written permission is obtained for purposes of research, marketing, or fundraising. Any external connections or exchanges of information that may contain ePHI require the signing

of a Business Associate Agreement of Covered Entity between Covered Entities(Rights (OCR), 2008). Finally, any third-party access must be restricting and if required as part of conducting business, a Business Associate Agreements (BAA) must be signed between involved parties that may have access to ePHI. The Breach Rule is where if there is a potential exposure of PHI, all affected parties should be notified within a reasonable time ("Official 2021 HIPAA Compliance Checklist," 2021, pt. HIPAA Breach Notification Rule). HITECH amendment also increased the penalty of HIPAA violations as well the prohibition of the sale of PHI without authorization (Practical Law, n.d.).

4.1.2 FDA

FDA compliance is also required by PACS as it is considered a medical device by the FDA and failure and/or recalls related to PACS can have a severe impact on patient safety. Components of a PACS system, such as viewer, require 501(k) clearance from FDA to be considered diagnostic(US Food & Drug Administration, n.d.). There have been some recent changes to FDA regulations. PACS including the storage and display of images used to be considered a medical device. However, recent changes to the language have excluded these functions as part of the device. Rather, only the software functions such as image manipulation, and enhancement are considered a medical device called Medical Image Management and Processing System(*PACS Are Now MIMPS, Says the FDA - LUMEDX*, n.d.). For this research, and given the change is recent, FDA 501(k) certification should still be the benchmark.

4.2 INDUSTRY STANDARDS

There are a variety of general industry standards that are in place to ensure that services dealing with sensitive data to ensure that companies meet both legal and technical controls necessary to conduct business. Many of which generally align with legislation such as HIPAA and similar legislation. Notable ISO standard examples include ISO 27001, ISO 27017, ISO 27018, and ISO 29100. Other relevant standards include SOC 2/3, and HITRUST Cybersecurity Scorecard.

ISO 27001, ISO 27017, and ISO 27018 concern specifications for an information security management system (ISMS), cloud security, and cloud privacy respectively. ISO 27001 specifically provides a model to ascertain an organization's information risk management process, which aligns nicely with HIPAA's Administrative safeguards section of its Security Rule and Privacy Rules (ISO, n.d.-a). An extension of IOS 27002, ISO 27017 is an international standard for security controls for the cloud in relation to ISO 27001(ISO, n.d.-b). This aligns with the technical requirements of security rules for access controls. ISO 27017 is concerned with a model in which to implement privacy requirements set forth by ISO 29100. ISO 29100 covers a variety of topics that involve the consent and limitation of the collection of retention of and disclosure of information. Furthermore, it discusses measures of accountability, transparency and compliance with the former (PECB, 2015).

SOC 2/3 certification was developed by the American Institute of CPAS (AICPA). It describes 5 key needs when dealing with customer data. Those are privacy, security, confidentiality, processing integrity, and availability(Vidich, 2021b). These areas have some overlap of technical solutions that help ensure meeting those needs; however, key points include

the need for access controls, two-factor authentication encryption, network firewalls, performance monitoring, disaster recovery, security incident handling and quality assurance(Imperva, n.d.).

HITRUST's Cybersecurity Framework Scorecard (CFS) is another certification developed to demonstrate an organization's compliance with NIST Cyber Security Frameworks. Per their website, the CSF is "[t]he foundation of all HITRUST programs and services," which, "provides organizations with a comprehensive, flexible, and efficient approach to regulatory compliance and risk management"(HITRUST Alliance, n.d.). This includes governing policies and documentation to handle access controls, authorization, information exchange, monitoring, procurement of IT and maintenance, cryptographic controls, security of file systems, security incident management, privacy practices, auditing, business continuity management amongst other topics (Leutwyler, 2020, pp. 4–7).

4.3 PROTOCOLS

Interoperability with major established application protocols include Digital Image and Communication in Medicine (DICOM) and Health Level 7(HL7) are a basic requirement for solutions dealing directly with PACS and or EMRs. The following section will provide a brief overview of the said protocols and the roles that they play.

4.3.1 DICOM

DICOM was established by NEMA. Per *DICOM PS3.1 2021B – Introduction and Overview*, DICOM is "the standard for communication and management of medical imaging information and related data," which "facilitates interoperability of medical imaging equipment"(DICOM, 2021, p. 11). Specifically, it concerns specifications for network communications, commands, file format, and filesystem structures for storage between PACS and medical imaging equipment or modalities. The following section will describe a high-level overview of DICOM.

DICOM communications operate on a server-client model with the server known as a Service Class Provider and a user known as the Service Class User which is further identified using unique Application Entities (AE) Title. DICOM's well-known port assigned by IANA is 104 TCP/UDP for unencrypted traffic, with 2762 TCP/UDP for DICOM with TLS encryption(ExtraHop, 2016). DICOM service is used by SCU and SCPs during an association after a TCP/UDP connection is formed. Common commands include A-ASSOCIATE, A-RELEASE, C-STORE, C-MOVE, C-FIND and C-ECHO.

Each of these commands is conjoined into a Service-Object Pair (SOP) class representing types of these services in relation to objects during DICOM communication. Both the SCU and SCP must accept the Service-Object Pair class before a DICOM association is formed. Each of the SOP classes has a universal Identifier (UID) which is represented by a series of numbers separated by decimals. An example would be Computed Radiology Image storage, whose SOP Class UID is 1.2.840.10008.5.1.4.1.1.1 (*B.5 Standard SOP Classes*, n.d.).

DICOM communications are initiated by an SCU via an A-ASSOCIATE-RQ followed by either an A-ASSOCIATE-RJ for rejection or A-ASSOCIATE-AC for accepting of the association by the SCP. Rejections are dependent on whether the AE Title is allowed to issue the command to the receiving device or if the Service-Object Pair Class is acceptable. This is followed by C-STORE, C-MOVE or C-FIND commands depending on the reason for the connection. C-STORE for an SCU such as a modality to store images into PACS, C-MOVE for requesting images from PACS by a modality, C-FIND for requesting of scheduled studies in PACS, and C-ECHO for testing DICOM association. When the service is completed, the SCU will send an A-RELEASE-RQ to terminate the connection. SCP will in turn reply with an A-RELEASE-AC

DICOM imaging objects (or Data Sets) associated with the SOP Classes passed also have multiple DICOM elements that contain meta-data. Each DICOM element is made up of a DICOM tag, value representation, value length and a value. A value tag is formed by 2 sets of four hexadecimal numbers often separated by a comma for readability. The first of numbers refer to the DICOM group number and the second group consists of the element number. This tag identifies what the data element represents. Value representation defines the type of data. This may include primitive data types such as string and integer or non-primitive such as DICOM Person Name (PN). Value length defines the size of the data stored in the element. The value is the actual data.

Elements can describe met-a data such as modality, patient name, ordering physician, image UID, patient birthday date, source modality and other identifying information. See the following example acquired from Rip Tutorial (*DICOMweb*, n.d.):

```
10001000 504E0C00 454C454D 414E535E 4A4F484E
```

This translates into a human-readable format of:

```
0010,0010 PN 12 Elmans^John
```

The first octet, 0010,0010, is the DICOM tag, the first 0010 being the group number and the second 0010 refers to the element number. In this case, 0010,0010 identifies the data in this element to be the patient's name. The second octet is split between the value representation and the value length. The PN represents the data type DICOM person's name. The length, in this case, is 12 bytes. Finally, the value is Elmans^John, which is the actual data in the element which we know is the patient's name, John Lemans.

While full compliance with DICOM is not required, there are minimums described by NEMA in PS3.4, which includes the services, several SOP classes such as Digital X-Ray Storage SOP Classes amongst other requirements. Extension of the DICOM standard with custom SOP classes called Private SOP classes are permitted but may not be supported by all vendors in the space.

4.3.2 HL7

HL7 is the protocol used for data exchange and interoperability of electronic health systems including radiology information systems (RIS), hospital information systems (HIS) and PACS. Messages that are sent using HL7 include patient demographics, patient admission, discharge, and transfer. Other messages include scheduling, ordering of procedures, test results, physician consultations, billing and material inventory, patient referrals and health record archiving. When dealing with PACS, the common message types are ADT for admissions, discharge, or transfers, ORM which is for orders for studies into PACS, and ORU, which are for reports. Message types can be further broken down into triggers. For example, common triggers for ADT^A01 for patient admissions, ADT^A02 for transfers, ADT^A03 for discharge, ADT^A04 for registration. For orders, the more common triggers are O01 which is for sending an order. ORU^R01 is for sending order results(Lyniate, n.d.).

5 TRENDS

The following sections will discuss trends and advancements in the general IT industry that can be leveraged to improve patient care, scalability, and accessibility to healthcare resources. Those areas are storage, telehealth, and artificial intelligence.

5.1 CLOUD-BASED STORAGE

Per Fortune Business Insight, the cloud storage market size was estimated to be about USD 61.15 billion and experienced a 24.7% growth when compared to the year-on-year growth between 2017 and 2019 when compared to 2020 with further growth is expected (Market Data Forecast, 2021). As such, this is a key area in which PAC's solutions, particularly Vendor Neutral Archives, have taken advantage of the key benefits of cloud storage.

Cloud storage reduces the upfront capital expenditure for upgrades and reduces the administrative overhead of maintaining these complex SAN and NAS solutions. Unlike purchasing appliances and subsequent supporting infrastructures such as rack space, power, cooling and personal needed to maintain the former, cloud storage solutions operating on a pay-as-you-go pricing model. Sites maintaining strictly private clouds adds a high level of complexity that can easily be abstracted away using cloud-based storage. Reducing the capital expenditures, also enable smaller clinics to take advantage of this level of availability that would otherwise be difficult to replicate with on-premises managed infrastructure.

Storage solutions for PACS data archival via Vendor Neutral Archiving (VNA) solutions offered directly by companies are increasingly cloud-based or cloud hosting. More traditional hosted solutions such as IBM offer a whole suite of software on top of their existing IaaS solutions with in-house experts to help consult with deployment. Other vendors in the space have partnered with IaaS to provide SaaS VNA have major public partnerships with existing software vendors. For example, Google has a major partnership with major vendors such as Change Healthcare with their Enterprise Imaging Network archiving.

Cloud storage enables a level of scalability that cannot be matched by traditional solutions. At any given time, the amount of storage can be scaled up or down depending on demand. Traditional archiving systems employed in healthcare solutions such as PACS relied on hierarchical storage models that used a combination of magnetic drives as well as tape for longer-term storage. Although the use of tapes has fallen out of favour as the capacity per dollar of magnetic storage has improved, traditional on-premises solutions are still bottlenecked by the additional administrative overhead of maintaining complicated storage solutions.

Cloud storage can easily be distributing or replicate data to disparate datacenters where legally permitted or based on security policies, thereby increasing the availability of data. For example, an earthquake in a single geographical location may cause a data center in that location to go down. However, because there is a mirror elsewhere that is not affected by the said earthquake, users can still connect and ensure business continuity. Furthermore, handling of encryption of data at rest is in part handled by IaaS and SaaS providers. Many cloud vendors offer data at rest encryption built into their storage solutions and along with the subsystems needed to ensure appropriate access.

Given these benefits availability and scalability, movement to cloud storage solutions is a natural path of progression for VNA solutions and this is reflected in the increasing number of traditional vendors offering deployments of VNA into the public cloud.

5.2 Web-Based Workflows and Patient Access

Throughout the late 80s and early 90s, several advancements and standards were developed by the industry for the digital storage of imaging. By 1993, DICOM was created with network support, which truly allows teleradiology to be possible("What Is Teleradiology?," n.d.). However, DICOM and HL7 were and still are niche relative to more widely used application protocols such as HTTP. Modern extensions to traditional healthcare-specific protocols such as DICOM and HL7 have been implemented to leverage the gains and improvements to web-based protocols such as HTTPS and RESTful APIs. For DICOM, the DICOMweb has been implemented with this in mind including equivalent services such as query (QIDO-RS), Retrieve (WADO-RS), (STOW-RS)(*DICOMweb*, n.d.).

For example, extraction of metadata from traditional DICOM required parsing of binary data. Let us go back to the example provided by Rip Tutorial below expressed in hex:

```
0010,0010 PN 12 Elmans^John
```

As it is found in traditional DICOM objects expressed in hexadecimal.

```
10001000 504E0C00 454C454D 414E535E 4A4F484E
```

More commonly found in the industry is to store metadata in XML or JSON which is human readable and therefore lowers the barrier of entry for development and parsing of data. The DICOMWeb equivalent would be as follows:

```
"00100010": {
              "vr": "PN",
              "Value": [
                  {
                      "Alphabetic": {
                          "Family": [
                              "Elmans"
                          ],
                          "Given": [
                              "John"
                          ]
                      }
                  }
              ]
```

Examples of the benefits of DICOMWeb over traditional DICOM communications noted by Genereaux et al. are the use of industry-standard security and acceleration appliances that are optimized for HTTP traffic rather than specialized devices specifically for DICOM. Other examples cited are the possibility of relying less on specialized tooling and applications to be installed locally for image viewing. Unlike traditional DICOM, more commonly found image formats such as JPEG, GIF, PNG can be read without plugins in browsers without said plugins. By using DICOMWeb, images can be transferred using those traditional formats and meta-data can be transferred using XML. This allows viewers to run entirely in a browser, making it more portable and accessible from a variety of devices including mobile devices as well as minimizing the IT overhead of managing base installs (Genereaux et al., 2018).

Likewise, Fast Healthcare Interoperability (FHIR) is the extension of traditional HL7 enabling modern data formats such as XML, JSON and RDF formats which are human-readable and familiar to developers outside of the healthcare industry. In terms of modes of data exchange, FHIR also supports more traditional event-based messaging as found with traditional HL7v2 and v3, but also other modes such as the sending of documents and or exchanges via RESTful API (*What Is HL7?*, n.d., p. 7). This culminates in the interoperability of more device types that were otherwise traditionally excluded such as mobile devices, apps, and wearables.

For example, the popular Apple Watch and Apple Healthcare on iOS support FHIR for communicating data to EHRs (*Healthcare - Health Records*, n.d.). Other examples include Microsoft's Cloud for Healthcare that includes APIs that employ FHIR to transforming and provide analysis of data (*Azure API for FHIR(r) | Microsoft Azure*, n.d.). Another notable benefit of HL7 FHIR is the inclusion of SMART App launch Frameworks that enables apps to launch from inside or outside the user interface of EHR systems. Specifically, it enables authentication of

requests to access FHIR resources using OAuth 2.0 compliant servers (*SMART App Launch Framework*, n.d.).

This level of accessibility to healthcare information is increasingly important as seen with COVID-19 pandemic. APIs or built-in features in HIS/RIS that enable users to readily access their medical health information or consult with their providers electronically via patient portals as we will see in the later sections. These APIs also enable the creation of purely web experiences for image and study viewing that otherwise required installation of standalone viewers on systems as also discussed later. Overall, these advancements in interoperability have the potential of increasing accessibility and quality of healthcare by introducing more points of information gathering through on persons IoT devices such as wearables and other smart devices.

5.3 Artificial Intelligence

With the power of machine learning and Artificial intelligence, vendors and organizations can leverage the readily available compute that can be made available in the cloud for technologies such as Computer Assisted Detection (CAD), providing providers with actionable insights to improve healthcare outcomes. Although there is some pushback from radiologists and members of the industry, the use of AI in CAD is making major strides in terms of clinical adoption as well as improving medical outcomes.

Per Bill Siwicki on Healthcare IT News citing the American College of Radiology states that "clinical adoption of AI by radiologists has gone from none to 30% from 2015-2020"(*Mass General Brigham and the Future of AI in Radiology*, 2021). An example provided by Dr. Keith in Swiciki's during his interview was on CT scans. Unlike more expensive MRI scans, CT scans read

by radiologists alone are typically not able to detect blood clots that may cause strokes. Beyond just aiding in detection CAD, AI can be used for analytics and improving other workflows. Other examples include the use of AI to help triage the most suspicious images to more experienced radiologists and less suspicious cases to less experienced radiologists as well as reduce human biases that can lead to incorrect interpretation of images (*Pictures into Numbers*, 2020).

6 VENDORS

This section will introduce some of the major players in PACs with cloud-based modules in their solution stack. These include Change Healthcare, Ambra Healthcare, and IBM.

6.1 CHANGE HEALTHCARE

Change Healthcare was established in 2005 as Emdeon before it rebranded in 2015 following the purchase of its namesake ("Change Healthcare," 2021c). It is heavily involved in on-premises Radiology and Cardiology PACS and related solutions. More recently, Change has partnered with Google to introduce a cloud solution called Enterprise Imaging Network (Bloomberg Business, 2019). Enterprise Imaging Network is comprised of four major parts, with Enterprise Imaging Network Viewer, Enterprise Imaging Network Analytics, and the Enterprise Imaging Network Archive. Enterprise Imaging Network Archive is the primary component of the solution handling long-term storage of images with support for any imaging systems. Enterprise Imaging Network Viewer allows for collaborative viewing of images and reports. Enterprise Analytics provides

interactive dashboards and performance metrics. Image Share promises sharing of images for patients and other relevant third parties (Change Healthcare, 2021b).

6.2 AMBRA HEALTHCARE

Headquartered in New York, Ambra Healthcare is a full cloud PACS solution in that all its components, except for an on-premises appliance. This is in contrast to Elastic Compute Cloud, Elastic Block Store and Amazon S3 Glacier with Amazon being its premier partner in the cloud outside of the USA in places such as Canada, stating that " AWS cloud would be the best technology to meet our needs" (*Ambra Health Case Study – Amazon Web Services (AWS)*, n.d.). They normally spin their own data centers in the US but are also expanding their presence on AWS within the US. Ambra healthcare has cloud deployments for VNA, PACS and image exchange solutions. Noted users of the application include Johns Hopkins Medicine, Standford Children's Health, Spectrum Health, and Memorial Hermann.

6.3 IBM

Much like Change, IBM's approach is more of a hybrid approach to its PACS stack. IBM still maintains its on-premises Merge PACS systems for direct ingestion from modalities much like Change Healthcare. They however offer a cloud-based suite of products called iConnect which includes an archiving system called IBM iConnect Enterprise Archiving, and iConnect Access for a zero-footprint viewer as well as the use of Watson AI for CAD and workflow optimizations for its on-premises solutions, Merge PACS. Of note, iConnect Enterprise Archive is, unlike the other

two vendors, openly has the choice of supporting via Red Hat OpenShift or VMware with data being hosted on IBM's cloud solutions or even Azure S3 Blobs.

7 COMPARISON OF VENDORS

The following sections will compare the three vendors in areas in terms of their abilities to leverage advancements made in the general IT world and how well they maintain the compliance and security needs of the industry.

7.1 SECURITY AND COMPLIANCE

This subsection will primarily cover security regarding data at rest and in transit, as well as compliance with industry standards and subsequently legal compliance with FDA or HIPAA/HITECH.

7.1.1 Standards Compliance

For the most part, all the discussed solutions and their partners are HIPAA/HITECH compliant. Change Healthcare Enterprise Imaging Network (EIN) is vetted and certified by HITRUST certification, SOC2 Type 1 report, ISO 27001 and Manual penetration testing(Change Healthcare, 2021a, p. 2). Google, Change's primary partner is also certified for HITRUST CSF, and ISO 27001 and SOC1/2/3 amongst others (Google Cloud, n.d.). IBM also has similar accreditation for ISO 27001, SCO2/3 and HITRUST(IBM, 2021a, 2021b). If Microsoft is chosen for the storage platform, Microsoft is also accredited for 27001, SCO1/2/3 and HITRUST

CSF(Vidich, 2021a). Ambra's official documentation is limited with regards to its compliance; however, major partner University of Birmingham Hospital suggests that Ambra is fully compliant with HIPAA and HISTRUST, and SOC 2 compliant (UAB Medicine, 2021). Regarding the web-based viewers, iConnect Access and Ambra Health's ProViewer are FDA-approved for diagnostics but only on desktops (Ambra Healthcare, n.d.-c, n.d.-b; Watson Health, 2021). Change describe their zero-footprint reference viewers as diagnostic but make no mention of FDA approvals (Change Healthcare, 2020a, p. 1).

7.1.2 Security

For Data in transit, Change Healthcare only uses a well-protected HTTPS-based API that is monitored for instances of malicious behaviour and fraud and only authorized client applications via on-premises gateways are allowed and all suspect connections are automatically ejected(Change Healthcare, 2021a, p. 1). Much like Change, Ambra offers an on-premises gateway that can be used to connect on-premises modalities and devices all securely via HTTPS/TLS securely to Ambra's cloud PACS and VNA(Ambra Healthcare, 2020a, p. 7). IBM's security for data in transit is less clear and they make no mention of on-premises appliances or gateways; however, they do mention in their cloud architectural documentation for their object stores that that data in transit is protected via HTTPS and TLS(*Data Security Architecture*, n.d., sec. Object Store Encryption). As mentioned previously, iConnect also supports the use of Microsoft's storage which also supports TLS (Myers et al., 2021). IBM, AWS, Microsoft and Google also provide and/or support services for certificate management included revocation as recommended by NIST(Amazon Web Services, n.d.-d, n.d.-e; *Data Security Architecture*, n.d., sec. Certificate Management; *Encryption in Transit in Google Cloud*, n.d., sec. Increasing the use of HTTPS).

Given that Ambra specifies which AWS products it employs, determination of security practices or assurances can be made based on said products. Those being S3 Glacier and Elastic Block(*Ambra Health Case Study – Amazon Web Services (AWS)*, n.d.). S3 Glacier employs, AES 256-bit symmetric keys for data at rest, and traffic is done over HTTPS via specific regional endpoints in Central Canada, two in US West and two points in US East. Data in the Elastic Block Store is secured on a per-volume basis, with each volume secured using a unique volume key and Amazon's EBS encryption. Key management is handled by AWS. For Elastic Compute, encryption is often handled by SaaS vendors but integration with AWS KMS for key management or native file system solutions such as dm-crypt, LUKS and others can also be used (Amazon Elastic Compute Cloud, n.d., sec. Default KMS Key for EBS encryption).

Data at rest is encrypted via AES-256 per Change and Google's statements(Change Healthcare, 2021a, p. 1). Google also goes into detail with regards to the uses of several layers of encryption including splitting data into chunks and each chunk is encrypted with unique keys at the file system level(Google, 2020, sec. Layers of Encryption). Its key management system is redundant and globally distributed and access is controlled using access control lists to ensure that chunks of data are accessed only by authorized applications (Google, 2020, sec. Encryption at the storage system layer).

Data at rest for IBM has several options. For IBM's solutions, object stores have three types of encryptions as well as integrity protocols specified. Those are RC4-128 with MD5-128 hash, AES-128 encryption with MD5-128, and AES-256 encryption with SHA-256 Hash with the former two enabled for cloud object storage(*Data Security Architecture*, n.d., sec. Data Integrity, Object Store Encryption Using IBM Cloud Object Store). Key management is handled by IBM Cloud key services which allow customers to bring their key or have IBM handle key management

for you(*Data Security Architecture*, n.d., sec. IBM Cloud Key Protect). Azure data encryption also supports AES-256 and SHA-256 hashing for integrity (Microsoft, 2014, 2020)

End-user access and authentication are handled via the on-premises gateways using OpenID and OAuth for all 2.0 APIs. secured using two-factor authentication (Change Healthcare, 2021a, pp. 1–2, 2021b, p. 12). For authentication, Ambra healthcare offers SAML which allows for exchanging of authentication of its application to identity providers as well as two-factor authentication for local accounts. IBM is strangely quiet on this matter but given their claim to have similar levels of compliance as Ambra and Change, they likely have integrations like Change and Ambra.

7.1.3 Concluding Statements on Security and Compliance

For the most part, each vendor meets the requirements for confidentiality via their encryption levels for data at rest and data in transit, all of which meet NIST requirements for TLS and encryption at rest. Something of note is that IBM and Microsoft are much clearer in terms of the protocols in place to validate data integrity. Conversely, Change and Ambra are both very clear as the methods of authenticating into their applications. Furthermore, each solution discussed does claim compliance with ISO, SCO and HITRUST and therefore meets auditing and other requirements in the preceding sections. As such, it would simply be a matter of confirming with each solution what they do to ensure integrity in the case of Ambra and Change, and what are the means of authentication for IBM iConnect Suite. Concerning viewers, it appears that only Change is missing FDA approval for their Enterprise Viewer; however, they do note that cloud-based versions of their Radiology and Cardiology Diagnostics viewers are in development(Change Healthcare, 2021b, p. 16). Another area of concern not mentioned would be availability. To note,

while most vendors promise 99.99% availability. Real-world numbers might not reflect that. For example, Google registered a downtime of 361 hours in 2019 with Amazon logging 338 hours. In comparison, Microsoft Azure had over 1934 hours of outage (Linkeit, n.d.).

7.2 STORAGE

When evaluating how EIN, iConnect and Ambra compare when it comes to storage performance, evaluation can be based on their IaaS partner's advertised performance. Having said that, Google and EIN take a significant take the lead with chart-topping raw performance and larger per-disk sizes.

For Ambra, Amazon's storage endpoints for S3 Glacier can be found in Ohio, North Virginia, Northern California, Oregon, Centra Canada as well as AWS GovClouds located on East and West coasts for a total of 7 locations (Amazon Web Services, n.d.-c, sec. Service Endpoints). Elastic block storage (EBS) endpoints are in the same locations in the US and Canada (Amazon Web Services, n.d.-a, sec. Service Endpoints). Amazon S3 Glacier and S3 Glacier storage are automatically distributed across a minimum of three geographically separated locations within an AWS region(Amazon Web Services, n.d.-b). Other advertised features include digital preservation and integrity checks on data, self-healing systems and promises up to 1-5 minute retrievals for expedited retrievals(Amazon Web Services, n.d.-b). EBR is Amazon's higher performance tier of storage which offers up to 60 Gbps bandwidth or 260K IOPS, with the option for Snapshotting. EBS volumes are automatically encrypted as are any volume backups made. Per volume, size ranges from 4-64TB for EBS storage(Amazon Web Services, n.d.-b).

Given that EIN Archive is built upon Google Cloud, the geographical availability of the data handled be extrapolated from Google's data centers. In North America, there are 8 data centers for its cloud archive storage locations with Google explicitly stating that all regions are at least 100 miles apart(Google, n.d.-b). In the west, there are four locations, Oregon, Los Angeles, Salt Lake City, and Las Vegas (Google, n.d.-b). In the east, there are data center locations in Montreal, South Carolina, and North Virginia(Google, n.d.-b). There is one central North American Server in Iowa (Google, n.d.-b). More traditional persistent disks are available in these locations if more performance is needed. In terms of performance, Google claims a read and writes of 60,000 IOPS for its block storage at the low end with an upper limit of 2.4 million IOPS for Local SSD NVME storage options. Persistent disk size can be up to 64TB in size (Google, n.d.-a). Google much like Amazon features automated replication of data across zones (Google Cloud, n.d., sec. Regional Persistent Disk automatically replicates between zones).

Although there is no documentation regarding iConnect's exact deployment for storage it would be a good exercise to examine equivalent storage solutions used by Ambra on AWS. IBM block storage offers increments of 48,000 IOPS maximum storage at increments of 12TB, snapshots and replication, concurrent access, high availability and durability (*IBM Cloud Block Storage - Features*, 2021). Data centers are located in Dallas, San Jose and Washington DC for the US with Canadian Locations are located in Toronto and Montreal. (*IBM Cloud Docs*, n.d., Chapter Block Storage Locations) Object storage advertised tiers, standard, cold, vault, archive, accelerated archive (warm archive) are offered in Toronto region, US East and US-South regions which consist of multiple data centers in those general geographical regions(*IBM Cloud Object Storage - Resiliency Options*, n.d.). There are multiple tiers to Microsoft's blob storage. Those are premium performance, hot tier, cool tier, and archive tier. Performance ranges from single-digit

millisecond response times to hours (Microsoft, n.d.-a). Current locations include Iowa, Virginia, Illinois, Texas, Wyoming, California, Washington and Arizona, Toronto and Quebec City (Microsoft, n.d.-b).

As suggested, Google and EIN maintain a top position in terms of both speed and scalability. From a speed standpoint, Change and Google feature the most performance storage. Persistent per disk sizes are tied between Change and Ambra with the largest per disk size. From a geographical availability standpoint, Google, Microsoft, and Amazon are quite close on paper with data centers on both coasts and central Canada. Conversely, IBM's offerings are limited to the southern USA, Eastern USA, and Central Canada.

7.3 Protocol Conformance, Accessibility and Cloud Viewer Features

Overall, each vendor maintains conformance with traditional implementations of the protocols. However, IBM has limited documentation regarding the more web-based standards. Change Healthcare's EIN Archive support traditional DICOM and HL7, as well as being FHIR compliant(*FAQ*, n.d.; Hagland, 2021). Conversely, while IBM's iConnect Suite has an extensive DICOM conformance statement, there is limited documentation when it comes to FHIR implementation in their PACS Systems(Watson Health, 2019, pp. 126–141). Like EIN Archive, Ambra Healthcare support both traditional HL7 messaging through its on-premises gateway as well as via FHIR (Ambra Healthcare, 2020b, p. 7; *V3 Services Public API*, n.d.). Traditional DICOM connections are also supported to its Ambra Gateway running on Windows supports the common DICOM commands with API support for DICOMWeb(Ambra Healthcare, 2020a, p. 4; *V3 Services Public API*, n.d.).

Image Streaming enables Change Healthcare Radiology Solution Workstations to directly access studies on archives bypassing the need for migration from the archive into the local cache(Change Healthcare, 2021b, p. 11). Change Healthcare Enterprise viewer supports the use of DICOMweb for querying and retrieval of images from both Change Healthcare and other vendor's DICOM-enabled solutions(Change Healthcare, 2020a). In terms of device support, Windows 7-10 and macOS devices are supported with Google Chrome, IE11, Edge and Safari browsers with Mobile device support including IOS and Android Devices(Change Healthcare, 2020a, p. 2). If need be, connectivity can be locked down to Citrix Virtual apps or virtual desktop infrastructure (Change Healthcare, 2020a, p. 1). Conversely, Enterprise Viewer supports SMART on FHIR which enables launching and authenticated the Enterprise Viewer via EMR links securely from demilitarized zones (Change Healthcare, 2020b, p. 2). Image Share can also be used for automated or directed sharing of images with anyone outside or inside the network via DICOM, DICOMweb, HL7 or other APIs (*Change Healthcare Imaging Share™*, n.d.).

Likewise, Ambra's ProViewer also supports access via Firefox, Chrome, Microsoft Edge, Internet Explorer, Safari, IOS, and Android. (Ambra Healthcare, n.d.-b) . Ambra image and report sharing is also made easy with Epic MyChart integration, access via a standalone patient portal or by secure email (Ambra Healthcare, n.d.-d). iConnect Access also allows access to data without real-time collaboration capabilities for up to 10 users and integration with web-based portal patient portals can be enabled ease of access for patients to their data(*IConnect Access | IBM*, n.d.).

While Patient accessibility is equal, Change EIN and Ambra healthcare's solutions provide overall better protocol compliance. Both Ambra and Change EIN archives and viewers support DICOM, DICOMWeb, FHIR and Hl7 whereas IBM is notably missing built-in support for FHIR.

If integration with products FHIR products such as Apple Healthcare or Microsoft's Cloud for Healthcare additional research and investigation may be required when considering iConnect.

7.4 Artificial Intelligence

All three of the vendors advertise integrations with AI solutions to varying levels, partners are hosted on-premise and cloud. Some of the more highlighted/notables are described in the following section. Overall, nearly all solutions leverage AI and the cloud to deliver their respective objectives which include CAD and or intelligent triaging and workflow improvements.

Change Healthcare leverages machine-learning technology Zebra-Med solutions to "uncover actionable insights for healthcare providers" and aid in detection in a variety of workloads. (Change Healthcare, n.d., 2017) This includes direct integration with viewer and study lists to help detect and triage workloads for asymptomatic coronary artery disease, vertebral compression fractures, increased detection of compression fractures amongst others (Zebra Medical Vision, n.d.-a, n.d.-b, n.d.-c, n.d.-d, n.d.-e). Deployments of appliances can be on-premises but also on the cloud in AWS(Zebra Medical Vision, n.d.-e).

IBMs Patient Synopsis leverages IBM Watson and IBM Health Cloud to help identify, aggregate and display contextually relevant information for studies for reading physicians(Watson Health, n.d.). Merge CADStream strengths include breast MRI aided detection and cancer detection(*Merge CADstream - Overview*, 2021). IBM Watson Imaging Clinical Review helps highlight and juxtapose clinical disparate diagnoses for further analysis. IBM also has an AI marketplace for 3rd party vendors that are cloud-ready and can be used to integrate with Merge

PACS workflows. Vendors include maxQ, VIDA, LVivo, cvi42, and vascuCAP(*Imaging AI Marketplace - Catalog*, 2020).

Ambra Healthcare has tight integration with companies such as CureMetrix, and Keya Medical(Ambra Healthcare, n.d.-a). CureMetrix's cmTriage and cmAssist also run in AWS and are used to improve breast imaging workflows(CureMetrix, n.d.-a). cmTriage is an FDA-cleared tool that helps automatically identify suspect cases and prioritize readings based on its findings and triage to specialties as required(CureMetrix, n.d.-b). cmAssist "leverages AI to help radiologists identify, mark and score regions of interests on screening and diagnostic mammography" and flags and identifies suspicious images using a neuScore that quantifies the suspiciousness of an image(CureMetrix, n.d.-a). Curemtrix claims an improvement of detection of 27% and 69% fewer false markings.

Curacloud, now subsidiary of Keya Medical, product CuraRAD-ICH is a model trained and provides seamless workflow integrations for detecting and triaging Intracranial Hemorrhage (ICH) that can cause strokes. The CuraRAD-ICH makes claims to sensitivity and specificity of up to 90.6 and 93.1 percent. By triaging and prioritizing identified cases, earlier detection decreases mortality of up to 50 percent if detected in 24 hours from 35-52% over a 30-day range. CuraRad-ICH can be deployed in either cloud or on-premise and the AI model was trained from 3800 head CT scans from the US and China, as well as 523 imaging facilities across the states via a convolutional neural network and convolutional recurrent neural network architecture(*CuraRad-ICH - Keya Medical*, n.d.).

Overall, while Change and Ambra boast important relationships with Ai vendors, IBM has a larger variety and in-house products that could potentially be better integrated with products like

Cadstream and its more traditional Merge solutions. Furthermore, they have the added benefit of leveraging the general development of Watson in providing as well as their computing cloud platforms for tight integration. That is not to say that Change or Ambra's AI partnerships are not substantial, but it is nonetheless something to consider.

8 NOTABLE OMISSIONS

The following are some notable contenders that also provide a similar suite of products.

8.1 FUJIFILM

Although there is limited information on Fujitsu, Fujitsu could be a contender with its cloud offerings. Along with its traditional on-premises deployments but also offer cloud-specific solutions in three different flavours. Those flavours being "Hosting", "Storage and Archiving" and "Disaster Recovery". With "Hosting", Fujifilm's entire suite of products and other third-party integrations such as Powerscribe 360, would run under an IaaS model(Fujifilm, n.d., p. 4). In its "Synapse Cloud Services Storage and Archiving" model, Fujitsu would be primarily operating as a vendor-neutral archive with links to an on-premise PACS system in which the on-premise PACS can access data fluidly as it would an on-premise archive(Fujifilm, n.d., p. 5). Finally, the "Disaster Recovery" model operates more like a backup or snapshot of their synapse systems on-premise(Fujifilm, n.d., p. 6). Details on their cloud implementation are otherwise limited. Fujifilm's Synapse solution also promises tight integration with its own Fujifilm REiL AI CAD platform. Notable features include REiLI include Autonomy Segmentation, Computer-Aided

Detection and workflow supports(*REiLI | Fujifilm*, n.d.). Regarding its viewer, it is web based and can run in browsers.

8.2 Hyland Enterprise Imaging

Hayland Acuo VNA solution supports cloud deployment although it is unknown as to who they are partnered with for such a deployment. However, It is noted that Hyland is partnered with its Onbase platform with Amazon(Amazon Web Services, n.d.-f). Provided Acuo deployment is also on AWS, expect similar performance and compliance from storage as Ambra Healthcare. Hyland's VNA supports traditional protocols such as HL7 and DICOM. Hyland's NILREAD is a zero-footprint reader that supports traditional DICOM, FHIR and DICOMWeb and HL7 protocols as well as real-time collaboration(Hyland Healthcare, 2021, pp. 1–2). Furthermore, NilREAD supports server-side rendering to negate the need for powerful workstations(*NilRead Enterprise Viewer | Access and View Images From Anywhere | Hyland*, n.d.). Another notable feature is the use of NilRead for Patient portals, much like IBM, Change and Ambra(*NilRead Enterprise Viewer | Access and View Images From Anywhere | Hyland*, n.d.).

8.3 Philips Clinical Repository and Viewer

Philips is also a notable contender in the space. They provide SaaS and cloud-based versions of its Enterprise Imaging Suite including products such as a cloud-hosted Vendor Neutral Archive with support for HL7 and DICOM(Philips Healthcare Information Solutions, 2019, p. 6) They also boast a web-enabled diagnostic viewer for radiology and mammography with integration with variety CAD vendors (Philips Healthcare Information Solutions, 2019a, p. 3). On the other

Cardiology viewer is a zero- footprint much like iConnect, EIN Viewer and Ambra ProViewer(Philips Healthcare, n.d., sec. Cardiology). However, there is limited information regarding what CAD vendors are supported and points of comparison for cloud storage.

9 CONCLUSION

In conclusion, most vendors offer compliance with legal and industry standards such as HIPAA and HITRUST amongst others; however, of the three main vendors discussed, IBM appears to have the least clarity when it comes to its offerings when it comes to protocol compliance. Where IBM has an advantage, is in the AI department. It is also fair to note that IBM also has RIS/HIS solutions available with cloud deployment expertise that can be leveraged for other aspects of the organization. Although Ambra's entire solution is cloud-based, Change has the benefit of being an established player in the imaging field with its on-premises products. In the case that Change Radiology and/or Cardiology products are already in place in the organization, migrations to future cloud versions of its Diagnostics Viewers solutions might ease the transition for end-users. Another consideration for Change Healthcare is the storage performance. As mentioned in previous sections, Google provides the strongest performance and equal per-volume scalability when compared to its AWS. However, if a cloud or otherwise solution is required immediately, Ambra is something that should be considered.

10 BIBLIOGRAPHY

Amazon Elastic Compute Cloud. (n.d.). *Amazon EBS encryption* -. Retrieved July 25, 2021, from https://docs.aws.amazon.com/AWSEC2/latest/UserGuide/EBSEncryption.html

Amazon Web Services. (n.d.-a). *Amazon Elastic Block Store endpoints and quotas*. Retrieved July 25, 2021, from https://docs.aws.amazon.com/general/latest/gr/ebs-service.html

Amazon Web Services. (n.d.-b). *Amazon S3 Glacier*. Amazon Web Services, Inc. Retrieved July 25, 2021, from https://aws.amazon.com/s3/glacier/

Amazon Web Services. (n.d.-c). *Amazon S3 Glacier endpoints and quotas* -. Retrieved July 25, 2021, from https://docs.aws.amazon.com/general/latest/gr/glacier-service.html

Amazon Web Services. (n.d.-d). *AWS Certificate Manager*. Retrieved July 25, 2021, from https://docs.aws.amazon.com/acm/latest/userguide/acm-concepts.html

Amazon Web Services. (n.d.-e). *Encrypting Data-at-Rest and -in-Transit*. Retrieved July 25, 2021, from https://docs.aws.amazon.com/whitepapers/latest/logical-separation/encrypting-data-at-rest-and--in-transit.html

Amazon Web Services. (n.d.-f). *Partner Hyland Software, Inc.* Retrieved July 27, 2021, from https://partners.amazonaws.com/partners/001E000001hNv40IAC/Hyland%20Software%2C%20Inc.

Ambra Health Case Study – Amazon Web Services (AWS). (n.d.). Amazon Web Services, Inc. Retrieved July 25, 2021, from https://aws.amazon.com/solutions/case-studies/ambra/

Ambra Healthcare. (n.d.-a). *Ambra Health Expands AI Adoption of Radiology Services Through New Solution Directory Partners*. Retrieved July 26, 2021, from https://www.prnewswire.com/news-releases/ambra-health-expands-ai-adoption-of-radiology-services-through-new-solution-directory-partners-301127111.html

Ambra Healthcare. (n.d.-b). *Ambra Health ProViewer | Overview*. Retrieved July 26, 2021, from https://insights.ambrahealth.com/proviewer

Ambra Healthcare. (n.d.-c). *DICOM Web Viewer*. Retrieved July 25, 2021, from https://ambrahealth.com/products-and-services/dicom-web-viewer/

Ambra Healthcare. (n.d.-d). *Patient Sharing*.

Ambra Healthcare. (2020a). *Ambra Gateway Guide*.

Ambra Healthcare. (2020b). *HL7 Guide*.

Azure API for FHIR(r) | Microsoft Azure. (n.d.). Retrieved July 25, 2021, from https://azure.microsoft.com/en-us/services/azure-api-for-fhir/

B.5 Standard SOP Classes. (n.d.). Retrieved July 29, 2021, from http://dicom.nema.org/dicom/2013/output/chtml/part04/sect_B.5.html

Beattie, D. (2016). *The DROWN Attack Vulnerability*. https://www.globalsign.com/en/blog/drown-attack-sslv2

Bloomberg Business. (2019, December 1). Four Leading Providers Join Change Healthcare and Google Cloud in Next-Generation Enterprise Imaging Initiative. *Bloomberg.Com*. https://www.bloomberg.com/press-releases/2019-12-01/four-leading-providers-join-change-healthcare-and-google-cloud-in-next-generation-enterprise-imaging-initiative

Change Healthcare. (n.d.). *Smarter Healthcare: How Artificial Intelligence and Machine Learning Are Rewriting the Rules*. Change Healthcare. Retrieved July 26, 2021, from https://www.changehealthcare.com/insights/smarter-healthcare-with-artificial-intelligence-machine-learning

Change Healthcare. (2017). *Change Healthcare Teams with Zebra Medical Vision to Bring Artificial Intelligence to Medical Imaging*. https://www.prnewswire.com/news-releases/change-

healthcare-teams-with-zebra-medical-vision-to-bring-artificial-intelligence-to-medical-imaging-300562429.html

Change Healthcare. (2020a). *Enterprise Viewer FAQ*.

Change Healthcare. (2020b). *Enterprise Viewer Update June 2020 Brochure.pdf*. https://www.changehealthcare.com/content/dam/change-healthcare/sales---marketing-content/provider-clinical/enterprise%20imaging/enterprise-imaging/brochure/enterprise-viewer-update-june-2020-brochure/Enterprise%20Viewer%20Update%20June%202020%20Brochure.pdf

Change Healthcare. (2021a). *EIN Security FAQ*.

Change Healthcare. (2021b, April). *Change the Future of Enterprise Imaging*.

Change Healthcare. (2021c). In *Wikipedia*. https://en.wikipedia.org/w/index.php?title=Change_Healthcare&oldid=1032444062

Change Healthcare Imaging Share™. (n.d.). Change Healthcare. Retrieved July 26, 2021, from https://www.changehealthcare.com/solutions/enterprise-imaging/imaging-share

Compliancy Group. (n.d.). *What Are HIPAA Audit Trail and Audit Log Requirements*. Compliancy Group. Retrieved July 25, 2021, from https://compliancy-group.com/hipaa-audit-log-requirements/

CuraRad-ICH - Keya Medical. (n.d.). KeyaMedical. Retrieved July 26, 2021, from https://www.keyamedical.com/curarad-ich/

CureMetrix. (n.d.-a). CmAssist. *CureMetrix*. Retrieved July 26, 2021, from https://curemetrix.com/cm-assist/

CureMetrix. (n.d.-b). *CmTriage*. Retrieved July 26, 2021, from https://curemetrix.com/cm-triage-2/

Data security architecture: Overview - IBM Cloud Architecture Center. (n.d.). Retrieved July 25, 2021, from https://www.ibm.com/cloud/architecture/architectures/data-security-arch/

DICOM. (2021). *DICOM PS3.1 2021b—Introduction and Overview*. http://dicom.nema.org/medical/dicom/current/output/pdf/part01.pdf

DICOMweb. (n.d.). DICOM. Retrieved July 25, 2021, from https://www.dicomstandard.org/dicomweb

Encryption in Transit in Google Cloud. (n.d.). Google Cloud. Retrieved July 25, 2021, from https://cloud.google.com/security/encryption-in-transit

ExtraHop. (2016, June 20). *An Introduction to DICOM*. ExtraHop Community Forums. https://forums.extrahop.com/t/an-introduction-to-dicom-digital-imaging-and-communications-in-medicine-extrahop/1363

FAQ. (n.d.). Data Access and Interoperability. Retrieved July 26, 2021, from https://developers.changehealthcare.com/dataaccessandinteroperability/docs/clinical-document-collector-api-faq

Fujifilm. (n.d.). *Synapse Cloud Services eBrochure*. Retrieved July 27, 2021, from https://f.hubspotusercontent00.net/hubfs/402806/synapse-cloud/Synapse%20Cloud%20Services%20eBrochure.pdf

Genereaux, B. W., Dennison, D. K., Ho, K., Horn, R., Silver, E. L., O'Donnell, K., & Kahn, C. E. (2018). DICOMweb™: Background and Application of the Web Standard for Medical Imaging. *Journal of Digital Imaging*, *31*(3), 321–326. https://doi.org/10.1007/s10278-018-0073-z

Google. (n.d.-a). *Block storage performance*. Google Cloud. Retrieved July 25, 2021, from https://cloud.google.com/compute/docs/disks/performance

Google. (n.d.-b). *Bucket locations*. Retrieved July 25, 2021, from https://cloud.google.com/storage/docs/locations

Google. (2020). *Encryption at rest in Google Cloud*. Google Cloud. https://cloud.google.com/security/encryption/default-encryption

Google Cloud. (n.d.). *Cloud block storage data protection*. Google Cloud Blog. Retrieved July 29, 2021, from https://cloud.google.com/blog/products/storage-data-transfer/cloud-storage-data-protection-that-fits-your-business/

Google Cloud. (n.d.). *Cloud Compliance—Regulations & Certifications*. Retrieved July 25, 2021, from https://cloud.google.com/security/compliance/offerings

Hagland, M. (2021, July 22). *Innovator Awards: Apervita, Change Healthcare Recognized in the Vendor Space*. Healthcare Innovation. https://www.hcinnovationgroup.com/clinical-it/article/21231533/innovator-awards-apervita-change-healthcare-recognized-in-the-vendor-space

Healthcare—Health Records. (n.d.). Apple (CA). Retrieved July 25, 2021, from https://www.apple.com/ca/healthcare/health-records/

HealthIT.gov. (n.d.). *How can you protect and secure health information when using a mobile device?* Retrieved July 25, 2021, from https://archive.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device

HIPAA Journal. (2016, October 19). St. Joseph Health to Pay OCR $2.14 Million to Settle HIPAA Case. *HIPAA Journal*. https://www.hipaajournal.com/st-joseph-health-pay-ocr-2140500-settle-hipaa-case-3638/

HITRUST Alliance. (n.d.). *One Framework, One Assessment, Globally*. HITRUST Alliance. Retrieved July 25, 2021, from https://hitrustalliance.net/product-tool/hitrust-csf/

Hyland Healthcare. (2021). *NILRead v5.0 Feature Descriptions*. 3.

IBM. (2021a, June 11). *Cloud Industry Compliance Programs*. https://www.ibm.com/cloud/compliance/industry

IBM. (2021b, June 25). *Cloud Global Compliance Programs*. https://www.ibm.com/cloud/compliance/global

IBM Cloud Block Storage—Features. (2021, June 8). https://www.ibm.com/ca-en/cloud/block-storage/features

IBM Cloud Docs. (n.d.). Retrieved July 25, 2021, from https://cloud.ibm.com/docs/BlockStorage?topic=BlockStorage-selectDC

IBM Cloud Object Storage—Resiliency Options. (n.d.). Retrieved July 25, 2021, from https://www.ibm.com/ca-en/cloud/object-storage/resiliency

IConnect Access | IBM. (n.d.). Retrieved June 26, 2021, from https://www.ibm.com/products/iconnect-access

Imaging AI Marketplace—Catalog. (2020, November 26). https://www.ibm.com/products/imaging-ai-marketplace/catalog

Imperva. (n.d.). SOC 2 Compliance. *Learning Center*. Retrieved July 25, 2021, from https://www.imperva.com/learn/data-security/soc-2-compliance/

ISO. (n.d.-a). *ISO/IEC 27001—Information security management*. ISO. Retrieved July 25, 2021, from https://www.iso.org/isoiec-27001-information-security.html

ISO. (n.d.-b). *ISO/IEC 27017:2015*. ISO. Retrieved July 25, 2021, from https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/04/37/43757.html

Leutwyler, N. (2020). *HITRUST CSF v9.4.2*. https://hitrustalliance.net/csf-license-agreement/

Linkeit. (n.d.). *Comparing the cloud giants: Uptime and reliability*. Retrieved July 25, 2021, from https://www.linkeit.com/blog/comparing-the-gigants-of-cloud-uptime-and-reliability

Lyniate. (n.d.). *HL7 Messages*. Retrieved July 25, 2021, from https://www.lyniate.com/knowledge-hub/hl7-messages/

Market Data Forecast. (2021, April). *Cloud Storage Market Size and Growth Analysis | 2021-2026*. Market Data Forecast. http://www.marketdataforecast.com/

Mass General Brigham and the future of AI in radiology. (2021, May 10). Healthcare IT News. https://www.healthcareitnews.com/news/mass-general-brigham-and-future-ai-radiology

McKay, K. A., & Cooper, D. A. (2019). *Guidelines for the selection, configuration, and use of Transport Layer Security (TLS) implementations* (NIST SP 800-52r2; p. NIST SP 800-52r2). National Institute of Standards and Technology. https://doi.org/10.6028/NIST.SP.800-52r2

Merge CADstream—Overview. (2021, March 5). https://www.ibm.com/products/merge-cadstream

Microsoft. (n.d.-a). *Access tiers for Azure Blob Storage—Hot, cool, and archive*. Retrieved July 25, 2021, from https://docs.microsoft.com/en-us/azure/storage/blobs/storage-blob-storage-tiers

Microsoft. (n.d.-b). *Data residency in Azure*. Retrieved July 25, 2021, from https://azure.microsoft.com/en-ca/global-infrastructure/data-residency/

Microsoft. (2014). *Microsoft Azure Data Protection*. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjswKnw4f_xAhWE_p4KHYrCATYQFjAJegQIBRAD&url=https%3A%2F%2Fgo.microsoft.com%2Ffwlink%2Fp%2F%3FLinkID%3D2114156%26clcid%3D0x409%26culture%3Den-us%26country%3DUS&usg=AOvVaw2rr6_nsMoYZTg7t0N3y2-U

Microsoft. (2020, August 13). *Azure Data Encryption-at-Rest—Azure Security*. https://docs.microsoft.com/en-us/azure/security/fundamentals/encryption-atrest

Myers, T., Robbins, M. F., Gara, R., Jake, Wren, B., sihegde, & Coulter, D. (2021, July 7). *Enforce a minimum required version of Transport Layer Security (TLS) for incoming requests—Azure Storage*. https://docs.microsoft.com/en-us/azure/storage/common/transport-layer-security-configure-minimum-version

NilRead Enterprise Viewer | Access and View Images From Anywhere | Hyland. (n.d.). Retrieved July 27, 2021, from https://www.hyland.com/en/healthcare/enterprise-imaging/nilread

Official 2021 HIPAA Compliance Checklist. (2021). *HIPAA Journal*. https://www.hipaajournal.com/hipaa-compliance-checklist/

PACS are now MIMPS, says the FDA - LUMEDX. (n.d.). Retrieved July 25, 2021, from https://www.lumedx.com/pacs-are-now-mimps-says-the-fda

PECB. (2015, 17). *ISO 29100 How Can Organizations Secure Its Privacy Network?* https://pecb.com/whitepaper/iso-29100--how-can-organizations-secure-its-privacy-network

Philips Healthcare. (n.d.). *Diagnostic tools & reporting solutions*. Retrieved July 27, 2021, from https://www.usa.philips.com/healthcare/resources/landing/enterprise-imaging/diagnostics#triggername=close_mammography

Philips Healthcare Information Solutions. (2019a). *Breast Imaging*.

Philips Healthcare Information Solutions. (2019b). *Clinical Repository*.

Pictures into numbers. (2020, September 2). Watson Health Perspectives. https://www.ibm.com/blogs/watson-health/pictures-into-numbers/

Practical Law. (n.d.). *Health Information Technology for Economic and Clinical Health (HITECH) Act*. Retrieved July 25, 2021, from https://ca.practicallaw.thomsonreuters.com/3-501-7466?transitionType=Default&contextData=(sc.Default)&firstPage=true

REiLI | Fujifilm. (n.d.). Fujifilm. Retrieved July 27, 2021, from http://reili.fujifilm.com/

Rights (OCR), O. for C. (2008, May 7). *Privacy* [Text]. HHS.Gov. https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

Scarfone, K. A., Souppaya, M. P., & Sexton, M. (2007). *Guide to storage encryption technologies for end user devices* (NIST SP 800-111; 0 ed., p. NIST SP 800-111). National Institute of Standards and Technology. https://doi.org/10.6028/NIST.SP.800-111

SMART App Launch Framework. (n.d.). Retrieved July 25, 2021, from https://hl7.org/fhir/smart-app-launch/

Thenault, O. (2014, October 15). *Poodle Vulnerability in SSL 3.0*. GlobalSign GMO Internet, Inc. https://www.globalsign.com/en/blog/poodle-vulnerability-in-ssl-30

UAB Medicine. (2021). *Ambra UAB Compliance GuideV2*.

US Food & Drug Administration. (n.d.). *Display Devices for Diagnostic Radiology—Guidance for Industry and Food and Drug Administration Staff*. 14.

V3 Services Public API. (n.d.). Retrieved July 25, 2021, from https://access.dicomgrid.com/api/v3/api.html

Vidich, S. (2021a, July 19). *Azure, Dynamics 365, and other Microsoft online services compliance offerings—Azure Compliance*. https://docs.microsoft.com/en-us/azure/compliance/offerings/

Vidich, S. (2021b, July 19). *System and Organization Controls (SOC) 3—Azure Compliance*. https://docs.microsoft.com/en-us/azure/compliance/offerings/offering-soc-3

Watson Health. (n.d.). *IBM Watson Patient Synopsis*. Retrieved July 26, 2021, from https://www.ibm.com/downloads/cas/3ZK0OOPW

Watson Health. (2019). *IBM Connect Enterprise Archive 12.0 DICOM Conformance Satement*.

Watson Health. (2021). *Universal viewing and image exchange with real-time collaboration*. https://www.ibm.com/downloads/cas/DAKVGWVZ

What is HL7? Definition and Details. (n.d.). Retrieved July 25, 2021, from https://www.paessler.com/it-explained/hl7

What is Teleradiology? A Definition of Services & History. (n.d.). *EVisit*. Retrieved July 25, 2021, from https://evisit.com/resources/what-is-teleradiology/

Zebra Medical Vision. (n.d.-a). *Bone Health Solution*. Retrieved July 26, 2021, from https://www.zebra-med.com/bone-health-solution

Zebra Medical Vision. (n.d.-b). *Cardiac Solution*. Retrieved July 26, 2021, from https://www.zebra-med.com/cardiac-solution

Zebra Medical Vision. (n.d.-c). *Chest Solution*. Retrieved July 26, 2021, from https://www.zebra-med.com/chest-solution

Zebra Medical Vision. (n.d.-d). *Mammo Solution*. Retrieved July 26, 2021, from https://www.zebra-med.com/mammo-solution

Zebra Medical Vision. (n.d.-e). *Neuro Solution*. Retrieved July 26, 2021, from https://www.zebra-med.com/neuro-solution

11 APPENDIX

11.1 RESEARCH COMMENTS

The scope of the project changed significantly over time. Initially, it was scoped to the entire healthcare IT industry and cloud, but that proved to be a bit too broad. I then narrowed it down to cloud in PACS and EHRs. Finally, I changed directions to trends for imaging solutions which, depending on the vendor, only consists of VNAs, Viewers and AI. The main vendors discussed also changed over time. Initially, I had IBM, Change, and Fujifilm. However, there was very limited information regarding Fujifilm, and it made comparing it to the others untenable. Overall, it often it was difficult to acquire information on the vendors without going through several hoops such as signing up for newsletters as well as paywalled ISO standards.

In terms of time, it could have used more time for researching the other vendors that were mentioned. While some like Fujifilm were difficult to find information at all, Hyland and Philips had a lot more marketing which made it difficult to filter out. Possibly with enough time, I could be able to extract enough information to make a fairer comparison. In terms of other things, I would have liked to add, more diagrams. Diagrams would help explain and visualize the

topology of the solutions that the vendors have. As such a future addition to this research paper could be to flesh out the other vendors and provide a comparison to the other three vendors.

11.2 Validity of Document

From: Quan, Lance <lance.quan@changehealthcare.com>
Sent: Thursday, July 29, 2021 4:06 PM
To: Gabriel Kwan <me@gabrielk.ca>
Subject: RE: (External Email) Internship - Research Project Comments

Hi Gabriel,

Thanks for allowing me to read your paper! It is very well consolidated into the context of CHC and our space. Good thought was put into the market as well and enjoy knowing actually a lot more of the industry outside what CHC is offering.

Lance Quan
Support Manager, Customer Success Operations