Medical Image Integrity Issues International Data Security and Thoracic Screening

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Disclosures

- Editor of the DICOM Standard (NEMA contract)
- NCI FNL Leidos Essex sub-contractor (SME DICOM, de-identification)
- NCI Imaging Data Commons (IDC) sub-contractor
- Consult with various equipment manufacturers regarding DICOM

Scope

- Images
 - digital CT scans, chest X-Rays, whole slide (pathology), …
 - images are (pixel) data + metadata
- Metadata includes
 - image file "headers" structural, identifying, descriptive
 - "associated" clinical data (spreadsheets, CSV, databases)
 - structured fields and unstructured text (including burned in)
 - annotations (patient, study, series, image, ROI, pixel, ...)
- CIA "triad" confidentiality, integrity, availability
- FAIR findable, accessible, interoperable, and reusable
- Availability/Accessibility standard format and protocols (DICOM)



https://www.ec-mea.com/wp-content/uploads/2019/11/CS_TriadGraphic-01-1024x900-e1574600971693.png



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Digital Imaging and Communications in Medicine

CIA – Confidentiality

- In what context
 - active clinical data
 - needs to be identifiable
 - protected from access beyond clinical team
 - operational use as data
 - for processing by algorithm used clinically
 - for on-study patients in clinical trial
 - "transiently" de-identified/anonymi[sz]ed to those beyond clinical team
 - research (other than clinical trial)
 - internal or external, academic or commercial
 - "permanently" de-identified/anonymi[sz]ed (usually)
- What protection
 - encryption in transit (network) and at rest (physical media, cloud)
 - de-identification/pseudonymi[sz]ation/anonymi[sz]ation

CIA – Integrity

- In what context
 - active clinical data
 - needs to be identifiable and appropriately described (w. quality control)
 - patient, staff, device, technique, anatomy, ...
 - operational use as data
 - "transiently" de-identified/anonymi[sz]ed
 - preserve operational integrity modality/anatomy/device re. algorithm
 - research (other than clinical trial)
 - "permanently" de-identified/anonymi[sz]ed (usually)
 - preserve research utility including unanticipated secondary re-use
 - retain as much as possible at "reasonable" re-identification risk threshold
- What protection
 - reliable transport, storage, ... usually deemed sufficient in practice
 - integrity checks (hashes, signatures, ...) unusual, unnecessary, expensive

Overall Security Considerations

- An organizational, not just a technical problem
- People, hardware, software, ...
- Many attacks by insiders (incompetent, compromised, malicious, ...)
- Actual vs. perception, regulatory presumption of harm, reassurance
- Networks expanding, remote access increasing
- "Zero Trust" same inside as outside (convenience impact)
- Organization/system is "complex" therefore vulnerable
- New is not necessarily better ... just unexplored risks
- Beware of purported panaceas ("blockchain", NFTs, ...)
- Healthcare is not banking don't oversimplify analogy

De-identification/pseudonymi[sz]ation/anonymi[sz]ation

- Definitions & requirements vary
 - by jurisdiction, over time, ...
- "Absolute" (random noise) vs "reasonable"
- Tolerance for re-identification risk
 - hard to define, quantify, establish
 - site, region, regulator, court, ...
- Threat model
 - what are we trying to protect, from whom, under what constraints
- Approaches
 - "rule-based" (structured data or elements in unstructured data)
 - statistically determined ("expert determination", "SDC")



Computer Science > Cryptography and Security

[Submitted on 18 Mar 2023 (v1), last revised 1 Apr 2023 (this version, v2)]

Report of the Medical Image De-Identification (MIDI) Task Group -- Best Practices and Recommendations

David A. Clunie, Adam Flanders, Adam Taylor, Brad Erickson, Brian Bialecki, David Brundage, David Gutman, Fred Prior, J Anthony Seibert, John Perry, Judy Wawira Gichoya, Justin Kirby, Katherine Andriole, Luke Geneslaw, Steve Moore, TJ Fitzgerald, Wyatt Tellis, Ying Xiao, Keyvan Farahani

This report addresses the technical aspects of de-identification of medical images of human subjects and biospecimens, such that reidentification risk of ethical, moral, and legal concern is sufficiently reduced to allow unrestricted public sharing for any purpose, regardless of the jurisdiction of the source and distribution sites. All medical images, regardless of the mode of acquisition, are considered, though the primary emphasis is on those with accompanying data elements, especially those encoded in formats in which the data elements are embedded, particularly Digital Imaging and Communications in Medicine (DICOM). These images include image–like objects such as Segmentations, Parametric Maps, and Radiotherapy (RT) Dose objects. The scope also includes related non–image objects, such as RT Structure Sets, Plans and Dose Volume Histograms, Structured Reports, and Presentation States. Only de-identification of publicly released data is considered, and alternative approaches to privacy preservation, such as federated learning for artificial intelligence (AI) model development, are out of scope, as are issues of privacy leakage from AI model sharing. Only technical issues of public sharing are addressed.

Comments: 131 pages

Subjects: Cryptography and Security (cs.CR); Computer Vision and Pattern Recognition (cs.CV); Image and Video Processing (eess.IV) Cite as: arXiv:2303.10473 [cs.CR] (or arXiv:2303.10473v2 [cs.CR] for this version) https://doi.org/10.48550/arXiv.2303.10473

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http://tinyurl.com/DICOM15AnnexEDeid http://wiki.nci.nih.gov/display/MIDI/2023+Medical+Image+De-Identification+Workshop

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Best Practice #1 - Everything & quantify risk

 "Thorough de-identification by removal or replacement of all known direct and indirect identifiers and sensitive information, in all collection descriptions and supporting data, structured and unstructured text data elements, pixel data, and geometric and bitmapped overlays, is required for public sharing. Direct identifiers should always be removed. A realistic collection-specific expert statistical analysis should be performed to quantify residual re-identification risk with respect to a pre-determined risk threshold, to justify retention of selected indirect identifiers or sensitive information, potentially with modified risk-reduced values, to preserve re-use utility. Any such risk analysis needs to consider any other publicly available information about the subject, and is only valid at the point in time at which it was done; consideration should be given to the potential for an increase in risk over time."

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Additional concerns in an AI-enabled world

- Greater demand for data access training, inference, QC, regulator
- Data has a different "value" now
- Reproducibility, generalizability (subjects, exposure, protocols, machines, ...)
- Models are data too may also be privacy leak
- In-house AI means in-house foreign code security risk
- Greater IT complexity to support it inherently less secure
- Beyond in-house review capability/expertise
- Al in the cloud (OTS providers, no on-premise HPC, network cost, but trust?)
- Provider audit, security penetration tests need extending to imaging, AI, research, de-identification, ...
- Al as a de-identification tool, and as a re-identification tool

"Trust no one."

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