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Clinical 3D printing: A protected health information (PHI) and compliance perspective

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ABSTRACT

Advanced manufacturing techniques such as 3-dimensional (3D) printing, while mature in other industries, are starting to become more commonplace in clinical care. Clinicians are producing physical objects based on patient clinical data for use in planning care and educating patients, all of which should be managed like any other healthcare system data, except it exists in the "real" world. There are currently no provisions in the Health Insurance Portability and Accountability Act (HIPAA) either in its original 1996 form or in more recent updates that address the nature of physical representations of clinical data. We submit that if we define the source data as protected health information (PHI), then the objects 3D printed from that data need to be treated as both (PHI), and if used clinically, part of the clinical record, and propose some basic guidelines for quality and privacy like all documentation until regulatory frameworks can catch up to this technology. Many of the mechanisms designed in the paper and film chart era will work well with 3D printed patient data.

1. Background

An orthopedic surgeon 3-dimensionally (3D) prints a reconstructed CT scan model of a comminuted fractured humerus so that he can custom fit a steel plate to repair the fracture. The surgeon bends the plate to the model deriving a perfect fit, has the plate sterilized, and implants the plate; after surgery, the surgeon disposes of the model knowing the hospital radiology systems will store the 3D reconstruction. The patient returns with malunion of the bone, and on further imaging it is noted that the plate in fact does not fit the contour of the bone precisely. On Quality Improvement (QI) investigation, the surgeon reprints the model and the plate does not fit the reproduced model.

1.1. Regulatory background

We will discuss both quality of output and privacy as with most clinical documentation, these cannot be separated when considering a complete element in the medical record. In most countries in the world, health data is legally considered private and secure, which in the United States is covered by the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH). The definition of Protected Health Information (PHI) under HIPAA, is broadly defined as any information whether oral or recorded that relates to the past, present or future condition of an individual. A subset of PHI is Individually Identifiable Health Information (IIHI) which adds that there exists a reasonable basis for re-identifying the patient. The HIPAA rules do mention the data being transmitted or stored in "any medium" but this is generally assumed to mean documents, results and reports, whether written on paper or stored electronically.

There are also regulations concerning retention of medical records to document the provision of medical care. In the United States, the Center for Medicare and Medicaid Services (CMS) covers this under a series of regulations, along with state regulations. At a minimum CMS requires 6 years of retention of medical records in most cases under 42 CFR 164.316(b)(2). In addition, under 42 CFR 422.504 [d][2] [iii] CMS does not specify media formats of medical records, but they need to be in original form or a legally reproduced form, so that they may be reviewed and audited with methods to prove they have not been altered. There is no mention specifically around 3D models produced for clinical care, as to their privacy, fitness for purpose, reproducibility, auditability, security and whether they are part of the medical record.

Finally, the Health Information Technology Standards Panel, charged with advising ONC about HITECH implementation, suggested that standards be selected based on fitness for purpose [36] including privacy and security standards. Audit trail requirements for Meaningful

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Use do not include 3D print rendering or tracking of 3D objects as opposed to other clinical data. A reasonable approach would be to include rendering of 3D printed objects in standard electronic record audit trails, similar to the manner used for paper records and radiology physical films. In addition, there is no guidance from ONC on quality of produced objects, whereas there are legibility standards for paper records under CMS rules, even including handwritten signatures.

1.2. 3D printing background

Three-dimensional (3D) printing, a form of *additive manufacturing*, produces physical objects from digital files [1]. Additive manufacturing was initially primarily focused on producing product prototypes for automotive and aerospace industries. The technique has recently started to become more commonplace in the healthcare sector both in industry and in direct clinical care [2,3].

Early 3D printers, called rapid prototypers, were based on a complicated and expensive technology termed Selective Laser Sintering (SLS) and Stereotactic Lithography (SLA). These printers still typically cost in excess of $100,000 and require industrial engineers to manage although SLA printers have come down to consumer prices; today many high-quality consumer and small-business level devices are now available.

In the 1980s the manufacturing industries created an international standard called G-Code (RS-274) [4], as the standard control language for all computer controlled manufacturing devices, such as 3D printers, CNC milling machines, NC Lathes among others in one of the most successful standardized communication protocols. In 2005 a project termed the RepRap Project (self-Replicating Rapid prototyper) was started in the UK to design a low-cost consumer level 3D printer, based on G-Code, capable of reproducing itself [5]. This project, along with several other key technological advances, brought high-powered 3D printing down to consumer price levels which are now available for $200–$2000 [6]. These printers can print in a very wide array of plastics, from Poly-Lactic Acid (PLA), Acrylonitrile butadiene styrene (ABS), PolyEther Ether Ketone (PEEK), Nylons, and Thermoplastic polyurethane (TPU), among many others. Several of these plastics, such as several nylons, carry FDA acceptance for medical usage.

Medical applications for 3D printing are expanding rapidly [1,7]. This technology caters to the demands of personalized medical care due to its ability to produce patient customized medical devices based on individual patients (a version of precision medicine). Medical additive manufacturing is defined as “the manufacture of dimensionally accurate physical models in human anatomy derived from medical image data using a variety of additive manufacturing technologies” [7]. Over the last decade, a growing number of physicians and hospitals have embraced 3D printing, which has opened new avenues for manufacturing across multiple medical specialties.

1.3. Clinical 3D printing

The application of 3D printing technology is expanding rapidly, particularly in the field of surgery. 3D printed models have been used for anatomical training, surgical training, and accurate operative planning within a variety of surgical specialties such as Plastic and Reconstructive surgery [6–11], Orthopedic surgery [12–16], Craniofacial and Maxillofacial surgery [17–21] (Fig. 2), Cardiovascular surgery [3,22–25], and Neurosurgery [26–32] (Fig. 2), and for creating surgical guides in oncologic, plastic & reconstructive along with dental surgeries. In addition to educating students, trainees and surgeons, recent studies have reported the role of 3D printing in patient education and improved patient consent [33,34]. The visual 3D model can play an important role in the consent for complex surgical cases as the 3D model allows the surgeon to anticipate intra-operative difficulties and selection of the optimal surgical approach.

In addition to printing traditional materials such as plastics and metals, there are also “bio-printers” which are 3D printers that print either cellular or extra-cellular products, to produce living tissue directly, or scaffolds for living cells [35] which can be used in transplantation. There is the additional challenge here that the object printed may be implanted into a patient. In addition to the issues of PHI and compliance, there is the challenge of how one documents the manufacture of a living object, which like any transplant may be derived from one or more patients; these models may also present a biosafety and bio-compatible storage challenge as well.

2. Discussion

A typical workflow that a clinician might perform is to take a 3D image set, such as a CT-scan, and using the imaging software produce a 3D reconstruction, often with some model cleanup; this model is then exported into a CAD/CAM (Computer-Aided-Design/Manufacturing) system, which will produce the G-Code required to print out this model for the clinic which is then printed (Fig. 3). This model might be of a patient’s tumor, to use in patient education towards informed consent, education of trainees, surgical route planning or ultimately device fitting.

Patient specific models need to be managed like any other healthcare system “data,” except that it exists in the “real” physical world, this includes ability to audit access, usage and provenance. All readers will agree that the original CT scan of the patient is both PHI/IIHI and part of the medical record. When radiologists perform 3D reconstruction of CT scans for operative planning, that is stored in the Picture and Archiving System (PACS) for the practice, and that is also considered PHI and IIHI. If you believe that the CT scan and reconstruction are both PHI and IIHI along with part of the record, you must consider a physical representation of these data as PHI, IIHI, and part of the record. Simply transforming 3D images on the screen to 3D plastic models on a desk did not change the content of that data, any differently than printing the CT out on film did. We submit that these objects need to be treated as PHI, possibly IIHI, and part of the clinical record. And with the premise of their being part of the record, standards need to exist for quality, reproducibility, retention, auditability and privacy. The PACS software typically performs audit trail management, and in the x-ray film days there was often a librarian who used a paper log to record access to printed films.

This model in our example is possibly re-identifiable if it distinctly physically resembles the patient, as a tumor is often printed with surrounding body structures. For example, a head and neck tumor might have part of the face reproduced (Figs. 1 and 2) at realistic resolution. This represents PHI under the general understanding of what PHI and IIHI are, but there is no section of HIPAA that directly addresses this, either to affirm that this is in fact PHI/IIHI or not. In addition, if the object in this case is used for arriving at informed consent or in the case of surgical planning or device fitting, it should be documented as part of the medical decision-making process. In written or digital examples (such as an imaging test) these are documented either explicitly or implicitly in the medical record; however, it is unlikely that any current medical center treats these 3D-printed objects as PHI or part of the medical record under both HIPAA and documentation regulations.

The privacy regulations all have the notion of transformation of the storage form of medical records, such as hand-written notes being scanned into digital form, digital data being shown on a screen or printed out. No one would consider the zeros and ones that make up a CT scan as being different than the visual representation of the CT scan or even if printed onto film. Under that premise, the transformation of voxels (3D pixels) of a CT scan becoming 3D bits of plastic in the same configuration, should be considered the same data. Theoretically one could place the printed model back into the CT scanner and essentially re-derive the source data.

Since these printers produce objects with a wide array of materials (some can print in multiple materials in the same model [2]) the