Executive Summary
Additive Manufacturing (3D Printing) is currently being used to produce a variety of medical devices including implants, hearing aids, guides for surgery and training, and custom prosthetic and orthotic devices. The focus of brief is on currently deployable and in some cases commercially-available AM healthcare products. Therefore, newer and more research-oriented AM processes such as bio-printing is not discussed. *It is our argument that AM innovations can provide enhanced treatment options for personalized healthcare, but that the successful extension of AM innovations into mainstream medical practice requires deeper attention to the social context of production and use.* Two example projects are discussed.

Background
As part of our ongoing research exploring emerging technologies and social change, the Semaphore Research Cluster has explored AM and its current and potential role in health care. This work has been cross-disciplinary, involving public health care partners such as the University Health Network, Toronto General Hospital and Toronto Rehabilitation Hospital, and the George Brown College Prosthetics and Orthotics training program. Other partners include private companies such as Autodesk Inc. and Boundless Orthotics, and other University units including the Faculty of Medicine and Departments of Occupational Science and Occupational Therapy and the Institute of Biomaterials and Biomedical Engineering.

Overview of AM and health care
While many different Additive Manufacturing (AM) technologies are currently being explored within the health sciences, the largest current use of these technologies is in the production of medical devices including orthopaedic implants, hearing aids, surgical guides and models, and, to a lesser degree, prosthetics and orthotic devices. Reasons for the use of AM include:

1. A need to produce complex topographies or materials that cannot be manufactured using other techniques,
2. A need to produce objects ‘on demand’ due to limited storage space or other procurement issues,
3. A need to create custom, patient-specific devices or objects.

In most other cases, more traditional manufacturing technologies such as injection molding, sheet metal fabrication, or subtractive milling are more scalable fabrication choices. Such forms of fabrication are typically faster, more cost-effective, and less energy-intensive than AM.
An example of a commercially-available AM produced device with complex topology or material needs is (1) Stryker’s Posterior Lumbar Cage orthopaedic implant (‘http://www.stryker.com/builttofuse/’). This titanium implant is used as part of spinal fusion treatments and includes a specially-designed porous microstructure that encourages in-growth of bone and biological fixation. This structure is only manufacturable using additive techniques.

An example of a medical device produced using AM in order to overcome procurement or storage issues is (2) 3D4MD - Dr. Julielynn Wong’s finger splint, printed using the Made in Space Additive Manufacturing Facility aboard the International Space Station. The production of the splint is part of Dr. Wong’s testing of AM as a way to overcome storage limitations in long-term space missions – instead of carrying all potentially necessary medical equipment, devices can be printed on-demand.

An example of a class of commercially-available AM produced devices that are custom and patient-specific is (3) custom fitted hearing aides, many of which are now printed (http://www.materialise.com/en/cases/hearing-aid-industry-will-never-be-same-again). In this process, a hearing aide specialist takes an impression of the patient’s ear canal which is then digitally scanned and uploaded to a manufacturer. This scan is used to generate a digital model, customized to the patient and optimized to contain the necessary electronic components. The model is printed in a batch with many others and, following post-processing and component installation, is then sent to the hearing aid specialist for patient training and fitting.

Example Projects
Two projects have extended from our research (see bibliography below) and have resulted in more sustainable public interventions. These are illustrative in that they focus on the use of AM in the production of custom, patient-specific models or devices and make use of inexpensive and commodity forms of AM.

The Advanced Perioperative Laboratory (APIL)
APIL was developed in 2016 by research partners at Toronto General Hospital and the Faculty of Medicine, University of Toronto. Dr. Massimiliano Meineri, an Associate Professor in Anaesthesia, and Dr. Azad Mashari, a lecturer in Anaesthesia leverage advanced AM knowledge from Semaphore to produce custom and patient-specific models for surgical training and planning. Current projects include (1) AM production of variable-difficulty bronchoscopy training systems – printed airways to support the training of medical personnel; (2) 3D Printed heart phantoms for use in Trans-Esophageal Echocardiogram (TEE); (3) patient specific lumbar and thoracic spine phantoms for the training of ultrasound-guided epidural procedure.
The main purpose of the above research and associated AM production is to resolve issues associated with preventable medical error (the third leading cause of fatalities in the US, Ziv et al., 2000; Rodriguez-Paz et al., 2009; James et al., 2013) through skill-based training and identification. APIL is supported by the University Health Network (UHN) and a generous grant from Lynn and Arnold Irwin.

**Nia Technologies**

Nia is a non-profit startup focused on developing and deploying software and hardware technologies to support orthopaedic clinics in Low and Middle Income Countries. Additive Manufacturing assists clinics in addressing a complex issue in LMIC contexts, namely, the lack of access to affordable prosthetics and orthotics. Nia’s 3Dprintability toolchain allows trained prosthetists and orthotists to produce orthopaedic devices in hours rather than days, making it possible to serve more patients. The software and hardware that Nia deploys involves the following; (1) an iPad with an attached 3D scanner running Nia’s scanning software, (2) a laptop running Nia’s custom design tool OrthoGen and Canfit, prosthetic and orthotic design software produced by Vancouver-based Vorum, Inc., and (3) Two Lulzbot Taz5 3D printers using Nylon filament. The results from this toolchain are (4) definitive trans-tibial prosthetic sockets attached to commodity components; and (not pictured) Ankle-Foot Orthoses, braces used to assist patients with walking.

Nia is currently completing the largest ever clinical trial of Additive Manufactured prosthetic and orthotic devices, including over 200 patients at four clinics in three different countries – Uganda, Tanzania, and Cambodia. The results of this trail are forthcoming, but appear to validate the strength and quality of AM devices. Nia’s technical partners include the Semaphore Research Cluster, Faculty of Information, University of Toronto, CBM Canada, Autodesk Research, and Vorum, Inc. Nia’s medical partners include CORsU Hospital, Uganda, CCBRT and TATCOT, Tanzania, CSPO hospital and the Exceed network, Cambodia, and Boundless Orthotics, Toronto. Nia is currently supported by Grand Challenges Canada, CBM Canada, Google Foundation, Autodesk Foundation, and the Jericho Foundation.
Implications and Recommendations

1) Currently available Inexpensive AM technologies can be well utilized in healthcare.
In both the above examples, currently available inexpensive AM technologies are used to positive effect. The printers used in both the APIL and Nia Technologies include ~$3000 Lulzbot Taz5/6 FDM printer and the ~$4000 Form2 SLA printer. Both are small and easily operated in clinical or office settings. While more limited in the materials they can print than expensive ‘professional’ printers, their ease-of-use and ongoing operational costs are more appropriate to a typical hospital or clinic. Equally, their capital costs encourage the use of multiple devices. For example, APIL currently operates six printers, allowing for the simultaneous printing of multiple patient models. Additional printers can be purchased to add additional capacity upon need. Similar logics apply to the Nia Technologies clinical use.

2) AM technologies can be used to provide patient-specific healthcare solutions.
In both the above examples, AM is used to produce patient-specific care options based on medical imaging (APIL) or 3D scanning. As one of Nia’s clinical partner’s once remarked, ‘medical care is standardized but patients are not.’ AM can help overcome this issue by allowing for the production of devices custom fit to the body, as in the Nia example, or models derived from patient’s own medical imaging data, as in the APIL examples.

3) Current AM technologies are very capable, but poorly integrated into current healthcare practices, training, and institutions.
Some of the most difficult work involved in producing and scaling the interventions described above involves the integration of these novel technologies into current medical practice. While some of this work is design and technology-focused, much of it requires a deeper understanding of the social, economic, and organizational structure of clinical infrastructure, organizations, training, and funding.

Recommendation
Based on the above implications, there is an opportunity to use currently available inexpensive AM technologies to provide more customized direct and indirect patient care. The main limiting factor in the deployment of AM solutions is in the need to better analyze, understand, and intervene successfully in current healthcare infrastructures. Such work requires technical and medical knowledge, but also methods and processes for analyzing social factors and context-specific organizational issues. The necessary skillsets are therefore multi-disciplinary and require educational processes and sources of funding that cross the current divisional differences of advanced University education and funding.
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