Three-dimensional printing in a pandemic: panacea or panic?

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Patience and well designed studies are important for balancing opportunity and risk in uncertain times

Even before they had to deal with the COVID-19 pandemic, clinicians were negotiating the infiltration of three-dimensional printing (3DP) into several aspects of medicine. This development probably began with the invention of stereolithography by Charles Hull in 1983.[1] The technology has found broad application in engineering and manufacturing, particularly for computer-aided design of machine parts. Its principles were also relevant to related aspects of clinical medicine, beginning with the production of reference biomodels from imaging data, and later in virtual surgical planning. It did not take long for the workflow that provided these services in the clinical environment to expand into other areas.

More recently, 3DP and related solid imaging technologies have provided clinicians with patient-specific implants (endovascular stents, plates and screws, surgical guides) made from a range of biocompatible materials, devices for drug delivery (implantable devices for monitoring and managing epilepsy, or for delivering chemotherapeutic agents and antibiotics), high fidelity training models, biofabricated tissue replacements (bone, cartilage, fat, and — in the future — solid organs), external prostheses, and ancillary devices such as face shields, respirators,[2] and, as described in this issue of the *MJA*, nasal swabs.[3]

A recent review of surgical applications of 3DP found that the technology was both efficacious and cost-effective for manufacturing biomodels for surgical planning and teaching applications.[4,5] It is not difficult to see that developing models for training and teaching can, in turn, improve patient outcomes. However, the usefulness of 3DP surgical guides or implantable devices is less clear, and is probably only beneficial in complex cases; but what constitutes a complex case is difficult to define.[4] In any case, a well managed 3DP workflow for educational purposes can support direct clinical applications. As the routine clinical use of 3DP has not matured in medical disciplines other than surgery, evidence of its clinical utility outside this area is limited. It should also be noted that the costs and capability of the technology are changing more rapidly than are the processes for its assessment.

This leads to the question of regulation. It is tempting to regard regulatory processes as impediments to progress, particularly in the middle of a pandemic, but every stage of the 3DP workflow is subject to control processes. For the clinical use of

implants, for example, they include the acquisition and storage of imaging data as DICOM files, software for segmenting and manipulating images, manufacturing to relevant ISO standards and according to conformity assessment procedures,[6] and Food and Drug Administration (United States), Therapeutic Goods Administration (TGA; Australia) and CE marking (European Union) approvals processes and certification.

Changing any part of the 3DP workflow, including the method of manufacture or the design of the 3D-printed object, voids previous approvals. There is risk of regulatory slippage in the well intentioned desire to privately manufacture personal protective equipment in the face of threatened or real shortages. For example, protective visors were manufactured for frontline health care workers by non-clinical third parties in Brisbane earlier this year.[7] However, face shields, masks and gowns are TGA class 1 medical devices and therefore not exempt from regulatory considerations. For any such device, this should include robust internal validation against the accepted gold standard and subsequent testing by an accredited National Association of Testing Authorities (NATA) facility to assess conformity with Australian standards. As is currently the case for face shields, there may be no accredited NATA facility in Australia. Once testing has been completed, a risk analysis should be performed to ensure that the device satisfies specific claims regarding its performance. It may then be listed as a device on the Australian Register of Therapeutic Goods and granted a certificate of conformity. It may be necessary to engage a commercial partner with expertise in regulatory procedures to negotiate this process, which should be overseen throughout by the clinical governance infrastructure of the relevant health care institution.

While the intention behind manufacturing home-made protective equipment may be admirable, the demand for personal protective equipment must be balanced against the risk of the device not fulfilling its intended purpose, particularly when this could have been avoided by regulatory review.

The distance between technology and the regulatory approvals processes that oversee them has been substantial for some time, but the COVID-19 pandemic has brought this problem into sharper focus. We commend the authors of the article about

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3D-printed nasal swabs in this issue of the Journal, not just for an innovative idea but for their efforts in generating evidence regarding both the usefulness and safety of their swabs.[3] Patience and well designed comparative studies, supported by clinical trials, are important for balancing opportunity and risk in uncertain times.

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2 Ballard DH, Trace AP, Ali S, et al. Clinical applications of 3D printing: primer for radiologists. *Acad Radiol* 2018; 25: 52–65.

3 Williams E, Bond K, Isles N, et al. Pandemic printing: a novel 3D-printed swab for detecting SARS-CoV-2. *Med J Aust* 2020; 213: 276–279.

4 Vitali J, Cheng M, Wagels M. Utility and cost-effectiveness of 3D-printed materials for clinical use. *Journal of 3D Printing in Medicine* 2019; 3: 209–218.

5 Langridge B, Momin S, Coumbe B, et al. Systematic review of the use of 3-dimensional printing in surgical teaching and assessment. *J Surg Educ* 2018; 75: 209–221.

6 Australian Department of Health, Therapeutic Goods Administration. Manufacturing medical devices and IVDs. Sept 2017. https://www.tga.gov.au/node/4425 (viewed July 2020).

7 Bowling M. Catholic colleges printing thousands of face shields for frontline healthcare workers. *The Catholic Leader* (Brisbane), 8 Apr 2020. https://catholicleader.com.au/news/iona-college-plans-to-print-13000-face-shields-for-frontline-healthcare-workers (viewed July 2020). ■