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Radiological Society of North America (RSNA) 3D Printing Special Interest Group (SIG) clinical situations for which 3D printing is considered an appropriate representation or extension of data contained in a medical imaging examination: abdominal, hepatobiliary, and gastrointestinal conditions

David H. Ballard 1*, Nicole Wake 2, Jan Witowski 3, Frank J. Rybicki 4, Adnan Sheikh 5 and RSNA Special Interest Group for 3D Printing Abdominal, Hepatobiliary, and Gastrointestinal Conditions Voting Group

Abstract

Background: Medical 3D printing has demonstrated value in anatomic models for abdominal, hepatobiliary, and gastrointestinal conditions. A writing group composed of the Radiological Society of North America (RSNA) Special Interest Group on 3D Printing (SIG) provides appropriateness criteria for abdominal, hepatobiliary, and gastrointestinal 3D printing indications.

Methods: A literature search was conducted to identify all relevant articles using 3D printing technology associated with a number of abdominal pathologic processes. Each included study was graded according to published guidelines.

Results: Evidence-based appropriateness guidelines are provided for the following areas: intra-hepatic masses, hilar cholangiocarcinoma, biliary stenosis, biliary stones, gallbladder pathology, pancreatic cancer, pancreatitis, splenic disease, gastric pathology, small bowel pathology, colorectal cancer, perianal fistula, visceral trauma, hernia, abdominal sarcoma, abdominal wall masses, and intra-abdominal fluid collections.

Conclusion: This document provides initial appropriate use criteria for medical 3D printing in abdominal, hepatobiliary, and gastrointestinal conditions.

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Background
In 2018, the Radiological Society of North America (RSNA) Special Interest Group on 3D Printing (SIG) published initial guidelines for medical 3D printing appropriateness [1]. These appropriateness guidelines included a number of organ or system-based appropriateness criteria; however, they did not include indications for abdominal, hepatobiliary, and gastrointestinal 3D printing. Medical 3D printing has been gaining popularity in new areas of clinical practice and is now performed for a variety of abdominal indications [2]. However, there is no consensus on which abdominal, hepatobiliary, and gastrointestinal scenarios and indications can most benefit from 3D printing. The purpose of this work is to provide evidence-based appropriate use criteria for abdominal, hepatobiliary, and gastrointestinal indication for medical 3D printing.

Methods
The SIG initiated writing groups for appropriateness of performing 3D printing from medical imaging for various clinical conditions. This present work provides the literature search and strength of evidence to introduce the appropriateness of abdominal, hepatobiliary, and gastrointestinal 3D printing for clinical utilization, research, scientific, and informational purposes. Related work previously published and not covered in the present work includes genitourinary and abdominal vascular conditions, which were presented in the initial appropriateness guidelines [1]. This work is loosely modeled after the American College of Radiology (ACR) Appropriateness Criteria® [3], in that the guidelines committee uses an evidence-based approach at scoring. Consensus among members is used when there is a paucity of evidence. Strength of evidence is determined by literature review.

The SIG Guidelines Chairperson oversees the ratings via a vote among Special Interest Group members at in-person meetings. The results of the ratings follow the following 1–9 format (with 9 being the most appropriate):

1–3, red, rarely appropriate: There is a lack of a clear benefit or experience that shows an advantage over usual practice.
4–6, yellow, may be appropriate: There may be times when there is an advantage, but the data is lacking, or the benefits have not been fully defined.
7–9, green, usually appropriate: Data and experience shows an advantage to 3D printing as a method to represent and/or extend the value of data contained in the medical imaging examination.

Clinical scenarios were organized by organ systems. An exhaustive PubMed literature search was performed through October 2018, a strength of evidence analysis was performed, and an appropriate use criteria document was generated. The supporting evidence was obtained through structured PubMed searches, as detailed in the Appendix 1. For each category, from the pool of total results, the number of publications considered “included results” was initially curated by a single author with expertise in 3D printing and abdominal imaging (DHBP) then substantiated by consensus of coauthors with expertise in 3D printing. For the present study, only anatomic models were included for evaluation. The following categories were excluded because they were considered outside the project scope: virtual and augmented reality, 3D printed implants, 3D printed instruments and surgical guides, bioprinting, and bioactive printing. Abdominal 3D printing review articles were recorded, but not considered in determining final appropriateness ratings. All final components of this section were vetted and approved by vote of Special Interest Group members face-to-face at the 2018 Annual Meeting of the Radiological Society of North America (November 27, 2018, Chicago, IL, USA). Afterwards, a 2-week period for comments by SIG member was posted on the SIG’s members-only online forum. In addition, all included studies [4–49] were graded with a strength of evidence assessment according to ACR Appropriateness Criteria Evidence Document [50].

Results
Table 1 provides evidence-based guidelines, supplemented by expert opinion when there was a paucity of peer-review data, to define and support the use of 3D printing for patients with abdominal, hepatobiliary, and gastrointestinal conditions. The citations included in forming the appropriateness criteria and the strength of evidence assessment are presented in Appendices 1 and 2 respectively.

Discussion
Hepatobiliary
The majority of intrahepatic masses requiring resection in adults includes hepatocellular carcinoma and isolated or few intrahepatic metastases, such as colorectal metastasis [51]. Anatomic models have been used in preoperative planning for surgical resection of hepatic masses [19, 21, 52]. Specifically, 3D printed anatomic models may be helpful in the resection of hepatic tumors through demonstrating the relationship of the tumor in regards to its location within hepatic segments, invasion or proximity to major hepatic or portal veins, arteries, and bile ducts. Printed models can help in choosing the optimal resection plane and may be useful in selecting patients at risk of posthepatectomy liver failure. Additionally, anatomic models have been used for both liver transplant donor and recipients [20].

Biliary obstruction has benign and malignant etiologies including strictures, extrinsic compression, stones, and biliary malignancies. Symptomatic patients or those with
laboratory derangements of obstructive jaundice or liver dysfunction may benefit from endoscopic stones and sludge removal, dilation, and stenting in select cases [53]. For biliary endoscopy, previous work show 3D printed anatomic models being used primarily in training applications [29, 30]. 3D printing has been used in the development of novel biliary stents [54]. Laparoscopic cholecystectomy is among one of the most common operations performed by general surgeons, which may be performed in an acute setting for

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Rating</th>
<th>Rating driven by literature appraisal or expert opinion</th>
<th>References</th>
<th>Study quality</th>
<th>Number of patients (combined)</th>
<th>Number of patients in largest series (reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRA-HEPATIC PATHOLOGY</strong></td>
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<tr>
<td>Intra-hepatic masses</td>
<td>8</td>
<td>Both literature appraisal</td>
<td>4-28</td>
<td>Category 2: 4 studies Category 3: 5 studies Category 4: 16 studies</td>
<td>151 patients</td>
<td>32 patients (19)</td>
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<tr>
<td>- Surgical management</td>
<td>4</td>
<td></td>
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<tr>
<td>- Percutaneous management</td>
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<td>Biliary pathology</td>
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<tr>
<td>- Hilar cholangiocarcinoma</td>
<td>5</td>
<td>Literature appraisal</td>
<td>6, 15, 19, 29-31</td>
<td>Category 2: 1 study Category 3: 3 studies Category 4: 2 studies</td>
<td>48 patients</td>
<td>32 patients (19)</td>
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<td>- Stenosis, benign and malignant</td>
<td>3</td>
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<tr>
<td>- Biliary stones (simple and complex)</td>
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<tr>
<td>- Simple</td>
<td>3</td>
<td>Expert opinion</td>
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<tr>
<td>- Complex</td>
<td></td>
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<tr>
<td>Gallbladder pathology</td>
<td>1</td>
<td>Expert opinion</td>
<td></td>
<td></td>
<td></td>
<td>No results from literature search and inclusion criteria</td>
</tr>
</tbody>
</table>

| **PANCREATIC DISEASE** | | | | | | |
| Pancreatic adenocarcinoma | 5 | Literature appraisal | 32-40 | Category 3: 4 studies Category 4: 5 studies | 13 patients | 10 patients (37) |
| Pancreatic mucous or cystic neoplasms | 3 | Literature appraisal | 40 | Category 4: 1 study | | |
| Pancreatitis | 1 | Expert opinion | | | | No results from literature search and inclusion criteria |

| **SPLENIC DISEASE** | | | | | | |
| Splenic trauma | 3 | Literature appraisal | 35, 40 | Category 3: 1 study Category 4: 1 study | 22 patients | 12 patients (40) |

| **GASTROINTESTINAL TRACT PATHOLOGY** | | | | | | |
| Gastric pathology | 3 | Literature appraisal | 30, 41-43 | Category 3: 3 studies Category 4: 1 study | No patients – endoscopy and laparoscopic simulators | |
| Small bowel pathology | 1 | Expert opinion | | | | No results from literature search and inclusion criteria |
| Colorectal cancer | 5 | Literature appraisal | 44-47 | Category 3: 2 studies Category 4: 2 studies | 30 patients | 22 patients (45) |
| Perianal/perirectal fistula | 4 | Literature appraisal | 48 | Category 4: 1 study | 3 patients | 3 patients (45) |

| **VISCERAL TRAUMA** (excluding vascular conditional managed endovascularly, fractures, and genitourinary trauma) | | | | | | |
| Visceral trauma | 1 | Expert opinion | | | | No results from literature search and inclusion criteria |

| **MISCELLANEOUS ABDOMINAL CONDITIONS** | | | | | | |
| Hernias | 2 | Literature appraisal | 49 | Category 4: 1 study | No patients – laparoscopic simulator | |
| Abdominal, abdominal wall, or sarcomas | 2 | Expert opinion | | | | No results from literature search and inclusion criteria |
| Retropertitoneal sarcomas | 4 | Expert opinion | | | | No results from literature search and inclusion criteria |
| Abdominal wall masses | 2 | Expert opinion | | | | No results from literature search and inclusion criteria |
| Intra-abdominal fluid collections | 1 | Expert opinion | | | | No results from literature search and inclusion criteria |

Table 1: Appropriateness Ratings for Abdominal, Hepatobiliary, and Gastrointestinal Indications. The “Rating driven…” column denotes if the primary decision for the condition’s rating was decided primarily through results and discussion of the literature search or expert opinion (the latter was largely reserved for conditions with no or few supporting studies). The “Study quality” column reflects the graded strength of evidence assessment according to ACR Appropriateness Criteria Evidence Document (individual ratings available in Appendix 2). The highest/most robust level of evidence is ‘Category 1’ and the lowest is ‘Category 4.’ No studies qualified for Category 1, but multiple did qualify for Category 2.
acute cholecystitis or electively for symptomatic chole-
lithiasis and other indications [55]. Percutaneous chole-
cystostomy is a percutaneous approach for management
of acute cholecystitis, often performed in those who are
critically ill or poor candidates for general anesthesia
[56]. The gallbladder may infrequently be a site of pri-
mary malignancy, prompting cholecystectomy (often
open and radical) in the absence of metastasis. Specific
applications of 3D printed anatomic models related to
the gallbladder have not been published through the ex-
tent of our literature search.

Pancreas and spleen
Pancreatic cancer is the fourth leading cause of cancer
death in the United States and typically carries a poor
prognosis with a 3% 5-year survival rate [57]. Resections
of pancreatic tumors are challenging operations with
high rates of morbidity [58]. To this end, 3D printed
anatomic models to delineate tumor anatomy may be of
use and have been published in cases series for pancre-
atic cancer applications [34–37].

There are a number of mucinous and serous pancre-
atic neoplasms, some of which may be indicated for sur-
gical resection [59]. One educational series fabricated a
3D printed anatomic model for a pancreatic tail mucin-
ous neoplasm, although this was not used in the pa-
"nent's preoperative planning [34].

Pancreatitis is an inflammatory response of the pan-
creas most commonly due to alcoholism and obstruction
of the pancreatic duct. This condition is a clinical diagno-
sis by symptomatology and laboratory derangements. Im-
aging can be used to help confirm the diagnosis or assess
for complications. Complications requiring percutaneous,
endoscopic, and infrequently surgical management in-
clude infected peripancreatic fluid collections, walled off
pancreatic necrosis, and other less frequent etiologies [60].
Specific applications of 3D printed anatomic models re-
lated to pancreatitis or its complications have not been
published through the extent of our literature search.

Elective splenectomy is often performed for
hematologic conditions, as part of larger operations (typ-
ically cancer adjacent cancer resections), or, rarely, due
to splenic masses with indications for resection. There
have been two cases series involving 3D printed anato-
ic models [36, 40], one of which was used in the
process of patient consent [40].

Gastrointestinal
The incidence of gastric cancer has decreased worldwide
with improved detection and treatment of Helicobacter
pylori and availability of endoscopy. However, gastric
cancer remains a morbid diagnosis and cause of cancer
death [61]. Peptic ulcer disease is a prevalent condition,
often treated medically and occasionally further
characterized with endoscopy [53]. Published uses of
anatomic models in gastric pathology largely encompass
simulation of endoscopy or surgery [41, 42].

Small bowel tumors are relatively uncommon, most
commonly due to adenocarcinoma, gastrointestinal strom-
tal tumor, carcinoid tumor and lymphoma. These may
present with abdominal pain, small bowel obstruction,
or without symptoms [62]. In North America, small
bowel obstruction most commonly occurs due to post-
operative adhesions. Other causes include incarcerated
hernias, strictures, and malignant obstruction [63]. Spe-
cific applications of 3D printed anatomic models related
to small bowel pathology have not been published
through the extent of the literature search.

Colorectal cancer is the third most common cause of
cancer death in the United States [57]. Treatment strategies
vary considerably according to anatomic location, staging,
among other factors [64]. 3D printed anatomic models have
shown some utility in delineating relevant surgical anatomy
for resection of colorectal cancer [45, 46].

Anorectal fistulae and abscesses are abnormal tracts
and collections about the anus and rectum that occur
with greater frequency in patients with Crohn disease
[65]. Frequently, pelvic MRI may be obtained to deline-
ate anatomy for treatment planning. In one feasibility
series, 3D printed models were used to demonstrate
anatomy of anorectal fistulae [48].

Visceral abdominal trauma
Blunt and penetrating abdominal trauma may result in
life-threatening visceral trauma requiring resuscitative
efforts and exploratory laparotomy. With current 3D
printing technology, the time needed to segment and
print anatomic models is currently too lengthy for use in
traumatic conditions requiring immediate treatment.
Accordingly, our literature search yielded no relevant re-
"ults regarding the use of 3D printed anatomic models
in visceral abdominal trauma.

Miscellaneous abdominal conditions
Elective hernia repair is among the most common oper-
ations performed by general surgeons [66]. Diagnosis is
often by physical examination and imaging infrequently
plays a part in diagnosing hernias. However, although
anatomic models have not been published for preopera-
tive planning of hernias, 3D printing has facilitated a
training system in one published series [49]. 3D printing
technologies have been used in the design of novel surgi-
cal meshes [67, 68].

Sarcomas are aggressive tumors, often locally advanced
at the time of diagnosis. They may occur anywhere in the
body. In the abdomen, sarcomas may be retroperitoneal,
"ntra-abdominal, or affect the abdominal wall [69]. Al-
though 3D printed anatomic models could potentially be
helpful in planning surgical approaches, our search yielded no results for abdominal sarcomas. One case series described anatomic models used for treatment planning in a mediastinal/intrathoracic sarcoma [70].

Abdominal wall masses are most frequently benign and include fibromatosis (desmoid tumor) and endometriosis. Malignant causes are most frequently metastases or sarcomas [69, 71]. Specific applications of 3D printed anatomic models related to abdominal wall masses have not been published through the extent of our literature search.

Intra-abdominal fluid collections with indications for drainage are frequently managed with image-guided percutaneous drainage [72]. There is often acuity in time to drainage, which may account for the lack of publications related to 3D printed anatomic models delineating intra-abdominal fluid collections. Accordingly, our literature search yielded no results.

Limitations
Limitations of this work include its lack of objective data collection and inferential statistics. Although such an analysis would be desirable, it is not practical with most published abdominal, hepatobiliary, and gastrointestinal applications due to the small number of publications and patients. One exception is 3D printing in liver surgery, which does have a previously published systematic review [73]. PubMed search terms, as highlighted in Appendix 1, were based on prior search terminology from previously published guidelines [1] and used ‘3D printing’ or ‘rapid prototyping’ to capture 3D printing-related publications; it is possible some publications may have been missed without using additional terms such as ‘three dimensional printing’ or ‘three-dimensional printing’. The RSNA 3D Printing SIG is comprised of physicians (primarily radiologists), imaging scientists, biomedical engineers, and other 3D printing experts, the voting group did not have direct input from general surgeons, gastroenterologists, or collaboration from a surgery or gastroenterology professional organization. Future iterations should aim for such collaboration.

Conclusion
This document provides initial appropriate use criteria for 3D printing in abdominal, hepatobiliary, and gastrointestinal conditions. Adoption of common clinical standards regarding appropriate use, information and material management, and quality control are needed to ensure the greatest possible clinical benefit from 3D printing [1]. With accruing evidence for value in 3D printing, recently implemented category III Current Procedural Terminology codes, and the upcoming ACR registry for 3D printing [74], it is anticipated that this consensus guideline document, created by the members of the RSNA 3D printing Special Interest Group, will provide a reference for clinical standards of 3D printing. The document will be periodically refined, based on expanding clinical applications and growing medical literature.

Supplementary information
Supplementary information accompanies this paper at https://doi.org/10.1186/s41205-020-00065-6.

Additional file 1: Appendix 1. Literature search
Additional file 2: Appendix 2. Strength of Evidence

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Authors’ contributions
Every author listed above has been involved in design, data collection, interpretation, as well as manuscript drafting and editing. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
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