May 29, 2015

Karen B. DeSalvo, MD, MPH
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

RE: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

Dr. DeSalvo,

RTI Surgical Inc. is a leading global surgical implant company providing surgeons with safe biologic, metal and synthetic implants. RTI's implants are used in sports medicine, general surgery, spine, orthopedic, trauma and cardiothoracic procedures and are distributed in nearly 50 countries. Our company is accredited in the U.S. by the American Association of Tissue Banks (AATB) and is a member of the Advanced Medical Technology Association (AdvaMed).

I am writing in response to the Office of the National Coordinator for Health Information Technology's (ONC) 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications proposed rule. Specifically, we are writing in response to proposals that would incorporate the US Food and Drug Administration's (FDA) Unique Device Identifier (UDI) into the certification criteria. RTI Surgical strongly supports this proposal and encourages ONC to finalize it as part of the 2015 Edition given the importance of collecting medical device use by UDI and methods for adverse event reporting; to detect, track, and manage problem devices; and, to conduct and contribute to medical product safety surveillance.

To that end, we draw your attention to a related area of critical interest to RTI Surgical that we strongly urge you to consider including when finalizing the certification criteria; that is, **the ability to capture a tissue identification number (TIN) to assist with tracking and tracing human cell, tissue, or cellular or tissue-based product (HCT/Ps) from a donor to a recipient.** Tissue processors are required assign each individual HCT/P product a distinct identification code.[1] This distinct identification code, herein referred to as a tissue identification number (TIN), facilitates the linkage between HCT/Ps and a donor. The ability to track and trace HCT/Ps from a donor to a recipient is a serious, ongoing public health concern largely hindered by a lack of appropriate standardized identification standards and a mechanism by which to collect, store and share HCT/P data for public health, clinical and research purposes. For HCT/Ps regulated as devices, the FDA requires the TIN to be included within the production identifier (PI).[2] However, for 361 HCT/Ps (which are not regulated as

[1] § 1271.290(c). http://www.gpo.gov/fdsys/pkg/CFR-2007-title21-vol8/pdf/CFR-2007-title21-vol8-sec1271-290.pdf

[2] "A *production identifier* that more precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, the date of manufacture, and, for human cells, tissues, or cellular and tissue-based products (HCT/Ps) regulated as devices, the distinct

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devices), many tissue processers, including RTI Surgical, are opting to utilize the labeling conventions supported by the UDI final rule for their 361 HCT/Ps, as described further below. Therefore, for those 361 HCT/Ps, we urge you to ensure that such label information, including the TIN, which is included within the PI, can also be appropriately captured.

HCT/Ps are used in more than a million medical and dental procedures per year, including wound care management, hernia repair, orthopedic and sports medicine procedures, bone and gum grafting and repair, among many others. Most of these services are routinely performed on Medicare and Medicaid beneficiaries in hospitals, ambulatory surgery centers (ASC), dental practices, podiatric practices, and other medical facilities. In total, the use of HCT/Ps account for a significant volume of spending in federal health programs. However, **HCT/Ps regulated solely as 361 products[3] are not covered under the UDI regulations, as these products are not "medical devices."[4]** As a result, ONCs proposed revisions to the certification criteria would not benefit the public when it comes to the vast majority of implanted HCT/Ps.

Given our longstanding concerns, we have engaged in a dialogue with federal agency and Congressional leaders to devise a long-term solution. And, while simultaneously working to develop a comprehensive solution, RTI Surgical has been working toward implementation of UDI-compliant tracking of its non-device HCT/Ps.

We provide background on our efforts to facilitate a solution to this problem, below.

Facilitating Solutions

Legislative Efforts

In the 113th Congress, Congressman Phil Roe introduced the Biological Implant Tracking and Veteran Safety Act of 2014 (H.R. 4374). As introduced, the bill directs the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants (including HCT/Ps) by the Department of Veterans Affairs, and for other purposes. RTI was instrumental in developing the legislation, working directly with the Veteran's Affairs Committee and other Congressional staff.

The legislation was reintroduced in the 114th Congress on February 20, 2015, as H.R. 1016, and on April 21, 2015, the House Veterans Affairs Subcommittee on Oversight and Investigations by voice vote (with no verbal objections) voted the legislation out of the Subcommittee for referral to the full Committee.

Agency Efforts

In May 2013, RTI Surgical met with staff in the Office of the National Coordinator for Health It (ONC) to discuss the challenge of HCT/P track and trace and foster collaboration among our organizations to identifying solutions. We suggested the potential for leveraging ONC's Electronic Health Record (EHR) Certification Criteria and the Centers for Medicare and Medicaid Services (CMS) "meaningful use" criteria, as included in its Medicare and Medicaid EHR Incentive Program, to capture and track HCT/P data and information, similar to pending requirements that would capture medical device data via the UDI.

We also urged ONC to support a Challenge Grant that would identify and pilot an option for addressing this issue, which would ultimately help inform a more permanent solution. We prepared a Challenge Grant application, as well as identified other interested stakeholders, including the Department of Defense

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identification code required in § 1271.290(c) (21 CFR 1271.290(c))." https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system.

[3] http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm

[4] 21 CFR § 821.3 (n) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device. http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf

(DOD)/Veteran's Administration (VA) Interagency Program Office (IPO), the American Podiatric Medical Association (APMA), and the ADA, who supported the concept. Some months later we learned that a high-level working group inside the Office of the Assistant Secretary for Health (OASH) intended to address policy around biologics and tissue safety, and therefore, the Challenge Grant could not be pursued by ONC.

Standards Development

In April 2013, we approached the ADA's Standard Committee on Dental Informatics (SCDI), an American National Standards Institute (ANSI) accredited standards developing organization (SDO), with broad concerns about the ability to track and trace HCT/Ps. Spurred by our mutual concern, the ADA embarked on a standards development activity that could assist in facilitating HCT/P track and trace issues in dentistry. Specifically, the SCDI formed Working Group 11.8 on Track and Trace for Implantable Devices and Biologics (including HCT/Ps regulated as medical devices) among other products used in dentistry. From this workgroup, Technical Report (TR) 1081 was drafted to address dental products regulated as medical devices and covered under the FDA UDI regulations.

It is our understanding that the ADA SCDI approved a proposal submitted by RTI Surgical to develop a complementary TR that would address HCT/Ps not covered under TR 1081. TR 1089, Track and Trace for HCT/Ps, is currently being drafted for review and consideration by Workgroup 11.8. Once completed, the TRs could be recognized by the federal government, adopted by vendors, and appropriately scaled and applied more broadly to other health care settings, including hospitals, ASCs, and podiatric surgery practices, among others.

Proposed 2015 Edition Certification Criteria

Implantable Device List (170.315(a)(20)) and Common Clinical Data Set (CCDS) Modifications

The ONC's emphasis on improving patient safety and public health by facilitating the capture of UDI data in Certified Electronic Health Record Technology (CEHRT) provides important momentum to accomplish track and trace for HCT/Ps. To that end, **we <u>strongly</u> urge ONC to update the Common Clinical Data Set (CCDS) and modify the proposed "implantable device list" to facilitate capture and exchange of TIN data.** TIN data collected via CEHRT should be easily exported or transmitted to clinical data registries and other health information technologies for clinical and other research or study, as well as searchable by TIN in the event of a recall or for other purposes.

In addition, **we urge ONC to reconsider its proposal to ***<u>not</u>*** require health IT to facilitate the capture of the UDI (and TIN) at the point of care.** There must be consistency in collecting UDI and TIN data, or its value toward improving patient safety and other goals will be greatly diminished; therefore, capture of UDI and TIN data at the point of care must be a requirement. If it is not a requirement, a multitude of providers that use HCT/Ps, including hospitals, spine surgeons, orthopedic surgeons, sports medicine surgeons, foot and ankle surgeons, podiatrists, and dentists will likely incur significant additional costs if they are to request their EHR vendor to provide a separate or stand-alone mechanism for UDI and TIN data collection.

Notwithstanding the above, we believe the inclusion of TIN as part of the UDI-related certification criteria proposals is critical for other reasons.

1) The overwhelming majority of providers (and EHR vendors) are largely unaware of the distinction between implanted 361 HCT/Ps and HCT/Ps that are regulated medical devices, as outlined in the UDI final regulations. Providers will likely attempt entering TIN data in to the UDI field, assuming the field is also for TIN capture.
2) Many tissue banks (and growing majority) have adopted a UDI-like label for their 361 HCT/P products (see attached AATB April 2015 Survey: UDI Implementation). This is primarily due to the fact that many tissue banks also manufacture HCT/Ps that are regulated as medical devices, and from a business

standpoint, it makes sense to use "like" labeling for all of their products.

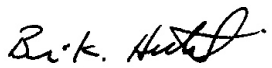
3) Tissue banks continue to press the FDA to include 361 HCT/P data as part of the Global Unique Device Identification Database (GUDID), to which ONC's proposed modifications would require a link to in order for CEHRT to retrieve device description information attributable to UDIs captured by providers. Providers entering TIN data into the UDI field would not be able to access "device description" information from GUDID, as the present database does not include 361 HCT/P description information, which would continue their confusion given some HCT/Ps would have this data, and others (316 HCT/Ps) would not.
4) EHR vendors are likely to assume that the UDI field is also for TIN capture, as TIN and UDI characteristics are nearly identical. As a result, vendors will misinform their customers that TIN data collection functionality exists, when in fact, it may not (unless the vendor is aware of this distinction and makes this functionality available, which is unlikely).

Conclusion

RTI has long supported the development of a comprehensive, standardized tracking system for all HCT/Ps (361 HCT/Ps and those regulated as a medical device). Not only would this data be useful for public health, clinical and research purposes, it would also improve our efforts to connect donor families with recipients. Making these important connections enhances the value of donation as well as reduces the potential for exploitation.

We appreciate the opportunity to comment on proposed modifications to the ONC's certification criteria, and would like to follow-up with relevant ONC staff on this important issue as part of an in-person meeting. Please contact Wendy Crites Wacker at wwacker@rtix.com or 386-418-8888 x4220 with any questions and to set up a time for us to meet with you to discuss options for ensure all HCT/Ps can be tracked from donor to patient.

Sincerely,



Brian K. Hutchison
President and CEO
RTI Surgical Inc.

CC:
Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services

American Association of Tissue Banks®

AATB TPG, LLC

April 2015 Survey: UDI Implementation

FDA's UDI Rule. In 2013, the Food and Drug Administration (FDA) released a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use. The final rule requires device labelers to include a unique device identifier (UDI) on device labels and packages, except where the rule provides for an exception or alternative. Each UDI must be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology.

The UDI is a unique numeric or alphanumeric code that consists of two parts:

> (1) a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
>
> (2) a production identifier (PI), a conditional, variable portion of a UDI that, for a human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as devices must include a distinct identification code (which is an alphanumeric code that relates the HCT/P to the donor).[1]

All UDIs are to be issued under a system operated by an FDA-accredited issuing agency. Currently, the FDA has accredited three different issuing agencies – (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA.[2] Despite the different issuing agencies, given the specific requirements of the UDI, each specific device (including those HCT/Ps regulated as devices) will have a unique UDI.

Further, the **FDA has confirmed the position that all three issuing agencies are appropriate for HCT/Ps**. On August 13, 2014, in response to a UDI Help Desk submission seeking clarification on this point, FDA noted that "manufacturers of HCT/Ps must comply with the tracking and traceability requirements contained in 21 CFR 1271.290, which means that they must assign and label each HCT/P with a 'distinct identification code' that they can use to trace back to the donor and to all records pertaining to the HCT/P. This requirement may be met through the use of a serial number (which is available as a form of production identifier under the GS1, HIBCC, or ISBT 128 UDI systems), lot number (also available under GS1, HIBCC or ISBT 128 UDI systems) and/or donation identification number (ISBT128 only). Therefore, any of these UDI systems may be used for an HCT/P that is regulated as a device."

UDI Application to Tissue Devices. For HCT/Ps regulated as devices, the vast majority of such products are implantable devices. As such, the labels and packages of those devices produced on or after September 24, 2015 must bear a UDI.[3] Such devices generally include corneal lenticules, preserved umbilical cord vein grafts, human collagen, femoral veins intended as ArterioVenous shunts, demineralized bone with handling agents (e.g., glycerol, sodium hyaluronate, calcium sulfate, gelatin, collagen), and bone-suture-tendon allografts.[4]

In addition, tissue banks may also work with xenografts (animal-derived grafts), including porcine heart valves, bovine or porcine acellular dermis and bovine bone. Implantable xenografts have a similar timeframe for implementation. ICCBBA nomenclature is not appropriate for xenografts, given that xenografts are not of human origin. Further, The

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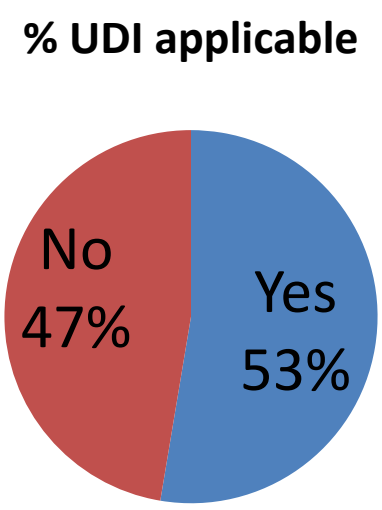
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm
[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm
[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm
[4] http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm

Joint Commission (TJC) tissue safety handling requirements tend to cover not only conventional tissue but also xenografts, given the broader definition of the term "tissue."

UDI Application to Conventional Tissues. For conventional HCT/Ps or those regulated as 361 HCT/Ps, the UDI final rule does not apply. However, many tissue banks (as described more fully below) are voluntarily applying the UDI processes to conventional tissue. Conventional tissues include bone (including demineralized bone), ligaments, tendons, fascia, cartilage, ocular tissues (such as corneas and sclera), skin (include acellular dermal matrix), pericardium, vascular grafts (veins and arteries), pericardium, amniotic membrane, minimally manipulated heart valve allografts, hematopoietic stem cells derived from peripheral or umbilical cord blood, etc.[5]

AATB Survey. To better ascertain how tissue banks are opting to implement the UDI, the American Association of Tissue Banks (AATB) performed a survey of its members in April 2015. Of the 125 accredited tissue banks, the AATB sent the survey to the 38 U.S.-based tissue banks who are accredited for processing tissue other than reproductive tissue. This summary data includes information from all 38 tissue banks (100% response rate).

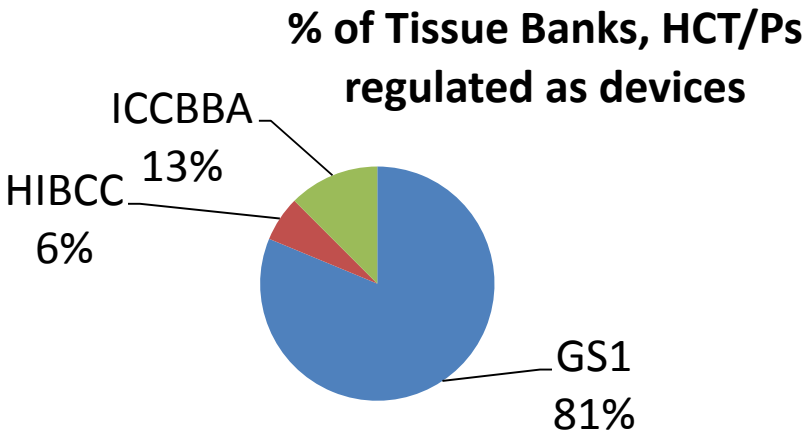
Issuing Agency Selection for Tissue Devices. As outlined in the pie chart below, of the 38 tissue banks, 18 (47% or nearly half) noted that the UDI was not applicable to them because they do not process tissue regulated as a device.



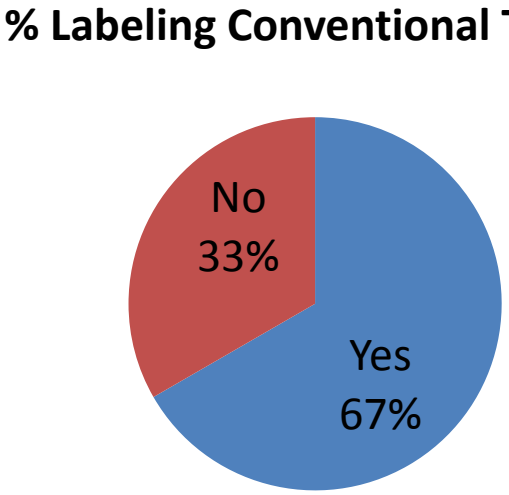
Of the 20 tissue banks that process HCT/Ps regulated as devices, four selected more than one issuing agency. One selected all three, while the three remaining picked two (one chose both GS1 and HIBCC, while the other two chose both GS1 and ICCBBA). Of the 16 who selected only one issuing agency, there was not unanimity on the appropriate issuing agency, as outlined in the table and chart below.

[5] http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm

Issuing Agency for HCT/Ps regulated as devices	% of Tissue Banks	N
GS1	81%	13
HIBCC	6%	1
ICCBBA	13%	2
Total		16

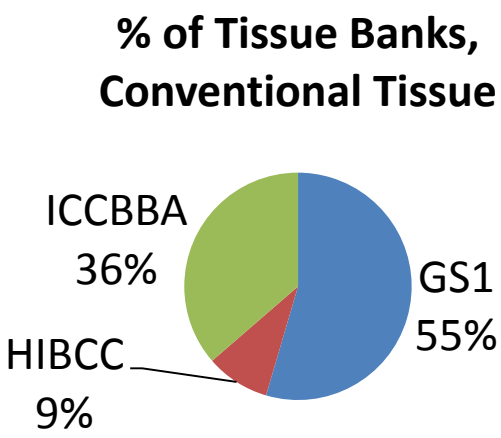


Issuing Agency Selection for Conventional Tissues. As outlined in the pie chart below, of the 38 tissue banks, only 2 tissue banks (5%) noted that they did not process conventional tissue. Of the remaining 36 U.S.-based tissue banks who process tissue, as outlined in the pie chart below, the majority (67%; 24 tissue banks) are planning to label their conventional tissues using the UDI system coding approach.

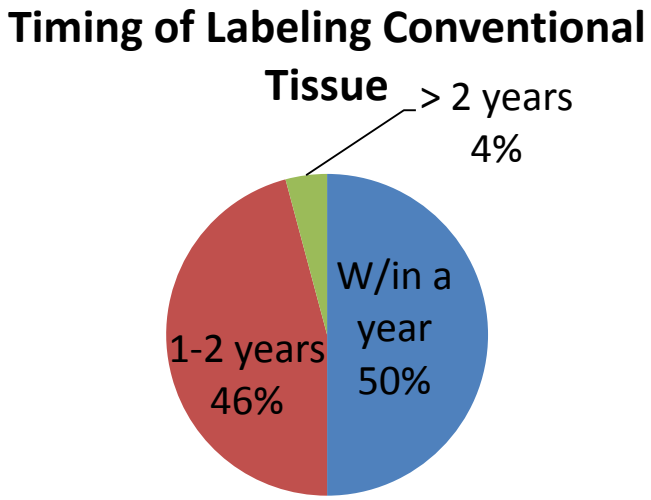


Of the 24 tissue banks that are planning to label their conventional tissues, two chose more than one issuing agency -- one tissue bank plans to use all three issuing agencies while one other plans to use HIBCC and GS1. Of those that selected only one issuing agency (total of 22 tissue banks), as outlined in the table and chart below, there was not unanimity on the appropriate issuing agency.

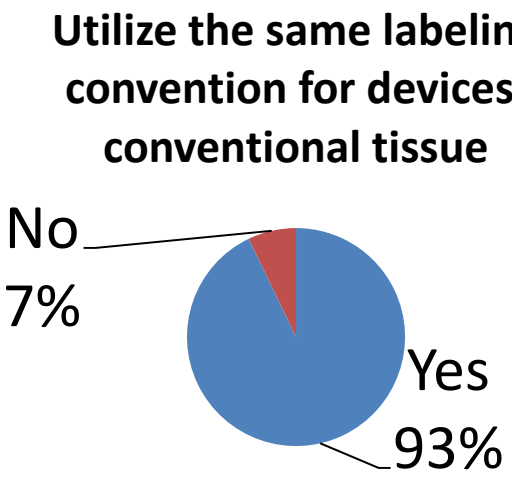
Issuing Agency for conventional or 361 HCT/Ps	% of Tissue Banks	N
GS1	55%	12
HIBCC	9%	2
ICCBBA	36%	8
Total		22



Given that the UDI timeframe does not apply to conventional tissues, the AATB also inquired as to when the tissue banks planned to implement the UDI specified labeling convention. As outlined in the pie chart below, of those 24 tissue banks that plan to label their conventional tissue, the vast majority plan to issue it within 2 years (96%).



Concordance Between Systems. To gain a better understanding of whether tissue banks were opting to alter the selection of the issuing agency depending on the tissue classification (e.g., utilizing at least two issuing agencies – one for devices and one for conventional tissue), we examined the concordance between the selection of the issuing agency for HCT/Ps regulated as devices and conventional tissue. Of the 38 tissue banks, 14 (37%) plan to label both their HCT/Ps regulated as devices and conventional tissue, nearly all (13 tissue banks; 93%) plan to maintain the same issuing agency or agencies for both the devices and conventional tissue.



Cost. While not directly addressed by the most recent survey, cost factors may be a consideration for tissue banks in their selection of the issuing agency. In general, ICCBBA is a more expensive option for tissue banks. For more information regarding the cost implications, visit AATB's comparison of the various issuing agencies.[6]

[6] http://aatb.org/aatb/files/ccLibraryFiles/Filename/000000000880/UDI%20Systems%20Comparison%20Report%20for%20Tissue%20Banks%20-%20Dec%2020%202013.pdf?utm_source=News+Release+-+UDI+Systems+Comparison+Report+for+Tissue+Banks&utm_campaign=7th+World&utm_medium=email