

Dear Trauma Registry Clients -

June 23, 2017

As you have recently heard from ACS, they are in the process of transitioning to new internal systems for their proprietary, fee-based NTDB and ACS TQIP® database programs. Their recent correspondence outlines the good news that there is a relatively little impact for the remainder of 2017 on participants and vendors since ACS will continue to use the existing 2017 XML format, which all of the vendors have already successfully implemented under our prior work and collaborations. The only time-sensitive item advocated by us for 2017, as your vendor, is your registration for the FREE Vendor Validator™ on www.TraumaCloud.com as previously communicated by us. Hundreds of you have already successfully registered on the Trauma Cloud™ and will receive ongoing support for the Vendor Validator™ from your vendor without any further action on your part.

For 2018, however, the transition work required is not yet known and could have a substantial impact on us. Potentially, work could be required by CDM, DI, and Lancet to provide a solution for delivering data to NTDB and ACS TQIP® in new XML formats that will be defined by ACS. ACS has indicated that it will not be levying any additional ACS surcharges or fees on participants of CDM, DI, Lancet, or other software packages. However, at the same time, ACS has indicated to us that it will not be subsidizing or funding any of our work for the 2018 revisions. Therefore, any costs would be vendor costs for vendor work that might be required by vendors to conform to the technical requirements of this ACS transition in an unfunded but mandated environment. While ACS may take the position that this is “simply a cost of doing business in our industry,” we do not concur. These are proprietary, fee-based initiatives of a private organization that take considerable technical efforts to support. That said, we do wish to help all of you, and you will see the generous offer that we are able to make to our industry in support of ACS.

Lest you think that this 2018 transition is the “normal course of annual revisions,” as a statement of fact, please note that 2018 marks the first year that the XML formats required by ACS will not be designed by a hospital trauma registry vendor. Since the inception of NTDS, a hospital trauma registry vendor, and in fact, one serving the majority of NTDB and TQIP participants, has designed the XML, and has maintained an open, free support channel available for feedback from all vendors, including CDM and Lancet. A hospital-registry-vendor-designed XML is important to us and the hospital and state trauma registry clients that we serve, to minimize impact on our programming of customized systems, minimize mappings, and avoid the breaking of backwards compatibility for your local trauma registry data, reports, queries, and interfaces. All of the work was previously provided “behind the scenes” for you by us (as your registry vendor). In supporting ACS compliance, we simultaneously designed the XML from both the hospital vendor perspective as well as to meet the clinical requirements of the NTDS Data Dictionary published each year. As part of our prior collaboration with ACS, they adopted the vendor XML as their compliance requirement for NTDB and ACS TQIP®.

Starting in 2018, based on decisions of the College, the vendors and the College may not be collaborating to the extent we previously did on the XML and submission methods for NTDB and ACS TQIP®. Though the vendors will continue to provide the same annual revisions to the XML format that we have historically performed, the ACS has indicated to us its intention to not use this format, and that ACS will be providing (mandating) that data submissions occur in a 2018 XML format to be defined by its new vendor. Once these new XML formats are published and made available to us, we can make assessments as to their impact on our clients. Fortunately, however, we have been collaborating as vendors to position you for no-additional-cost “Continuity Options” that you will have the option of selecting. By pooling our resources and donating tools and our expertise to the industry, we will be able to extend a variety of options to you for meeting your NTDB and ACS TQIP 2018 compliance, while lowering cost impacts and promoting interoperability and your freedom of choice as consumers. Please see the attached information sheet for an overview of the options that will be available to you for meeting your 2018 compliance. These options are our way of helping support all of our reason for being here in this industry -- to help improve outcomes and save lives. We are proud to help advance and support this collective mission of you, us, and especially the American College of Surgeons.

Sincerely, Your Trusted Trauma Registry Partners

Jody Summers
Clinical Data Management

John F. Kutcher, Ph.D.
Digital Innovation, Inc.

Leon Bowman
Lancet Technology

2018 Compliance Options – Joint Vendor Roadmap

For meeting your 2017 compliance requirements, you can continue to use the same Export Software in your registry software to provide data in the required 2017 formats. ACS will be providing instructions for you to perform the necessary uploads for the remainder of 2017.

For 2018, there will be an impact on the vendors to transition to new 2018 XML formats (and to support new submission methods if you do not elect our primary recommended options for you to simply continue using the current systems that we own and have been providing to the College up until this transition). Previously the XML formats were designed by hospital registry vendors in collaboration with the ACS and distributed by the ACS as industry standards. Now, from our perspective, the ACS process is reversed, as ACS will be providing new XML formats that the vendors will need to support, designed outside of the hospital vendor community (who incidentally serve 98% of TQIP Participants as of the most recent TVA survey in Sep 2016). The vendors will continue to maintain our vendor XML format for 2018 and beyond as a free industry resource of the public benefit TVA to help avoid cost increases, support continued ACS and State compliance, and expand interoperability -- just simply under a new name (the "ITDX"). The ACS will provide its alternative offshoot of the past vendor-designed XML, designed by its new vendor, which will be used as the standard for data drop off for NTDB and ACS TQIP® data submission.

What does all of this mean to you? Ultimately, you will have multiple options for how your data makes its way from your local customized or individualized trauma registries into NTDB and ACS TQIP® in a manner that conforms to all ACS-defined clinical and technical specifications. The "detail" will be HOW this is performed. It would be helpful for you to review our video entitled "The Anatomy of Compliance" to understand the software building blocks that we, as a vendor community, have provided to support you, our valued clients, and ACS, our esteemed colleague. In support of ACS initiatives, we have cumulatively invested millions of dollars in software, which we collectively refer to as "The Vendor Infrastructure" over the past decade. Based on decisions made by ACS, and decisions to be made by you as our clients, we will be able to determine how much of the Vendor Infrastructure we can continue to use and provide to you at no additional cost for 2018 compliance vs. how much of this infrastructure you will require that we rewrite to an alternate method to new technical standards which presently are not published and that we did not design.

In summary, the options we have designed for you can be described as follows:

- **Option 1 - Seamless Continuity** - To be clear, this option will only be available if it is the will of the American College of Surgeons. In this option, the vendors would continue to operate a data submission site for CDM, DI, Lancet, and any other interested clients at the existing website that would utilize all of the existing software in place for you to validate, export, and submit your data. We could also continue ongoing access to your historical PDF reports if ACS consents. The vendors have offered to continue to operate a data submission portal that would automatically validate and produce data files in the exact technical formats required of the ACS and QuintilesIMS for 2018 submission compliance. Since this option uses the existing software from the same vendors on the same secure, HIPAA-compliant servers that have been used for NTDB and ACS TQIP® submission prior to the transition, this has a minimal impact on us as vendors. Accordingly, CDM, DI, and Lancet are pleased to announce that not only will we fund 100% of the costs of operating the continuation of this Aggregator, we are also all willing to commit to making the 2018 revisions to our Export Software and the ITDX XML for 2018 at no additional charge to our clients. To be clear, this option requires the consent and collaboration with ACS and is a proposal that we have made jointly to ACS and are waiting on a final definitive response. We respect whatever decision ACS feels is best for ACS regarding Option 1. We have been hesitant to advance Option 2 or Option 3 since they would not be necessary should Option 1 be selected. Under Option 1, your data will still be submitted to the new system provided by ACS and QuintilesIMS for inclusion in NTDB and/or TQIP and will give you any and all such capabilities of those systems. The Vendor Systems serve the purpose of helping to get your data to these new systems in a way that we believe is vastly less impactful to all stakeholders.

- **Option 2 - Maximal Technical Continuity** - This is the same as Option 1, except that it does not require ACS consent. In this event, since your submission to the vendor-provided Aggregator that you have always used for NTDS submissions to NTDB or ACS TQIP® would not fall under a master HIPAA umbrella with the College (as it did up until this transition), you would need to establish a HIPAA compliance strategy. We would work with our State and System Leaders on approaches to minimize the administrative burden of this one-time hurdle, as well as leverage the hundreds of existing BAA agreements many of you already have with us as your trusted registry vendors.
- **Option 3 - Technical Impact** - In the event Option 1 is not possible, and you are unable or unwilling to take us up on our generous offer to fund Option 2, then we will be in a position of needing to build or support changes to some or all of the Vendor Infrastructure for you. In this event, each vendor will independently assess the efforts involved and provide time or cost impacts. We cannot perform this planning or assessment work until ACS and QuintilesIMS provides us with the 2018 technical requirements for NTDB and ACS TQIP® compliance. The vendors have collaborated to design some technical approaches that can help utilize ITDX and the Trauma Cloud® to help minimize some of this potential time or cost impact. We can finalize specific variations and proposals for Option 3 once we have the technical information needed to do so from ACS and QuintilesIMS.

So, what should you do next to prepare for 2018 compliance? In a word, “wait.” There's nothing that we can advise you to do at this time until a definitive decision is made on Option 1 and until information is provided to us for Option 3. We are in a position to rapidly proceed with all of you on Option 2, and we want you all to rest assured that both Option 1 and Option 2 will entail zero additional cost for meeting your 2018 compliance. However, since Option 2 is not without its administrative impact, we are giving a few more weeks to see if Option 1 can be achieved.

Yes, waiting is a concern to us. But transitions of this nature are significant, and it's understandable that our vendor perspectives may not be the top priority. We stand ready, willing, and able to support you through this transition with these options. We believe you will be impressed with the added value and capabilities our generosity and collaboration will afford to you. It is our way of helping support all of our reason for being here in this industry -- to help improve outcomes and save lives. We are proud to help advance and support this collective mission of you, us, and especially the American College of Surgeons.