

# Trauma Registry Data Standards

## Implementation Timeframe Best Practices

*Technical Implementation Best Practices  
for the Trauma Registry Industry*

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## 2 Introduction

### 2.1 Driving Purpose – *Constantly Evolving Data Standards*

In the dynamic world of the modern trauma registry system, Registry Data Standards must constantly evolve at every level (e.g., national, state, regional, local). Data standards work to provide the information needed for evidence-based improvement to patient's care.

Currently, within the trauma industry, there are no industry-wide accepted technical best practice guidelines related to Registry Data Standard change implementation timeframes. The increased practice of routine modifications to industry data standards, with the desire for timely adoptions, has brought the industry to see the need for clear communication and industry recognized expectations related to change implementation.

The industry is all too familiar with the routine question “What changes are coming?” This leads to additional questions such as:

- Are these changes complete/final?
- When is the expected implementation date?
- When will the systems be updated?

Often there are additional impacts which are often not fully addressed, such as:

- How does this impact the data collection process?
- Are there educational components to these changes?
- Who else is dependent or impacted by these changes?

### 2.2 Document Vision - Industry Involvement and Feedback

We want your input! This document helps all stakeholders to formulate a realistic and reasonable implementation plan by providing a process and plan template. This document is a dynamic shared document intended to strengthen our industry as a whole by empowering and considering every individual. To achieve this, *what you should do is help this vision by:*

- Getting the word out by freely distributing this document to your System, network, and peers.
- Using these guidelines on your current and next change implementation.
- Providing feedback to a TVA vendor through your leadership groups.
- Sharing the TVA video and announcement board links (see Section 6.)

### 2.3 Best Practices Objective

The TVA seeks to provide a consistent set of industry best practices to assist all trauma stakeholders in establishing realistic time frames (at all stages/phases) to address the need for constantly evolving data standards. The TVA has assembled a TVA Implementation Timeframe Work Group of industry stakeholders from state, national, collaborative, hospital, and registry vendor groups. This team has met on several occasions via workgroup calls to discuss and identify various common tasks

and impacts of registry data set changes that affect and impact implementation timeframes across all registry stakeholders.

This document is the culmination of the activities of the Work Group to establish a set of best practices. The main purpose of these best practices is to improve the overall process of routine change and the associated timeframes needed by various stakeholders who are invested in implementing trauma registry data standards.

The details of these best practices address the following items:

- Identifying the standard items influencing implementation timeframes (e.g., documentation, distribution, education and implementation modifications).
- Establishing standard change release timelines for trauma-related data dictionary modifications and implementation.

## 2.4 Swimlane Chart

Based on the feedback of participants in the TVA Implementation Timeframe Work Group, the concept of establishing a Swimlane Chart for each revision cycle of a registry data standard has emerged as a key best practice. The details of the Swimlane Chart are described more fully in Section 4 of this document, along with the best practices associated with defining, documenting, and communicating a Swimlane Chart (Section 3).

This approach brings a consistent project management and planning discipline to the trauma registry industry that will benefit all stakeholders.

## 2.5 Terminology/Glossary

A main goal of the TVA is to establish consistent practices across the country for efficient trauma registry technical implementations. To assist in this process, we have established a consistent terminology that is used throughout this document. We encourage stakeholders to use this terminology throughout the industry to provide additional consistency and clarity. Terms are listed in alphabetical order.

- **Change Log** – Refers to a revision history that should be maintained for each Data Dictionary revision cycle. It will typically have numerous items associated with each revision cycle.
- **Data Dictionary** – A document that is readable by an end user that describes the clinical and operational definitions of a registry data standard. The document typically contains a page for each data element, organized in a logical fashion (such as the phase of care). It also includes additional technical details needed by software developers, including items such as response codes for fields that have drop-down menus, data types, and other information needed to establish a well-defined Submission File Format. It should include the Validation Rules for a trauma registry System.
- **Inclusion Criteria** – Refers to the specific set of criteria upon which patients are included in a trauma registry for a System. It is important for all stakeholders to understand the qualifying criteria so that only appropriate patients are submitted to the System trauma registry. Sometimes referred to as “the definition of a trauma patient.”

- **Registry Data Standard** – Refers to the set of resources that define a collection of data points (e.g., Data Dictionary, Inclusion Criteria, Change Log) and associated technical specifications (e.g., Submission File Format, XSD, Sample Submission File) that are required for a trauma registry System to implement a consistent data collection and aggregation function across its participating hospital sites.
- **Sample Submission File** – Refers to a resource provided by the System to other stakeholders involved in the technical implementation. It includes data for one or more sample trauma registry patients represented in the required upcoming revision cycle Submission File Format for a Registry Data Standard.
- **Submission File Format** – Refers to the format of a data file used to submit trauma registry data to a registry System. The most common technical submission file format is XML; however, in some instances, other types of file formats may be used.
- **Swimlane Chart** – Refers to a Gantt chart style document that illustrates the various tasks that each stakeholder group must perform in a coordinated and interdependent fashion to implement a change to a Registry Data Standard throughout an entire System. This document describes attributes of a Swimlane Chart and associated best practices for developing one for each System. (See Sections 2.3 and 4 for additional information).
- **System** – Refers to a trauma registry at any level of aggregation. For example, a System could refer to a state, regional, hospital, county, collaborative, national, or any other desired aggregation of trauma data. Each System typically has a set of stakeholders responsible for the overall planning, administration and associated resources, such as the Data Dictionary and related artifacts.
- **Validation Rules** – Refers to specific data edits that must or should be satisfied for trauma registry data to be considered valid for data submission to the System. These are typically documented in a section of the Data Dictionary and may have different levels of severity associated with them. The TVA recommends the adoption of multiple validation levels as utilized in resources such as the current National Trauma Data Standard. Having a clear and concise definition of edit checks helps ensure overall quality and consistency of trauma registry data.
- **XML** – Refers to one specific type of computer data file, most often used as a Submission File Format. The structure of XML is often conveyed through the provision of an XSD and/or a Sample Submission File.
- **XSD** – This is a special, technical resource that defines an XML structure that system developers can use to help them understand and implement a specific XML Submission File Format. It is also helpful to have a Sample Submission File to further assist implementers.

## 3 Best Practices

### 3.1 Best Practice #1 – Swimlane Chart (Planning and Preparedness)

It is the best practice of any agency responsible for creating and maintaining a Registry Data Standard to fully plan and prepare for ongoing change needs related to the growth of the Registry Data Standard.

Highlights of the planning phase include:

- Ensuring effective communications among all stakeholders.
- Allowing for early technical and clinical input from expert stakeholders, during draft and design phases.
- Allowing for necessary timelines for all phases.
- Establishing reasonable and rational timelines for each revision cycle.

To implement this important phase, the TVA and additional stakeholders recommend the creation and publication of a “Swimlane Chart” for each revision of the registry data standard. (See 4.1 – Swimlane Chart Example). Details of this best practice include:

- Identify all stakeholders. At a minimum this will include stakeholders from the System itself, as well as the System Vendor, Hospital Registry Vendor(s), and Hospitals.
- Interview each stakeholder to identify the Tasks they must perform and realistic Timeframes required by the stakeholder for timely, efficient, and accurate implementation.
- Document the Tasks and Timeframes in the Swimlane Chart that reflect the necessary interdependencies of each stakeholder upon the others in a logical “flow.”
- Establish a deadline for each stakeholder phase to complete their Tasks that supports not only each of their independent Timelines, but also all of the interdependencies needed by the System stakeholders as a whole.
- Establish the final policy deadlines for the System (e.g., data collection cutover date, data submission cutover date, etc.) based on the overall Swimlane Chart.
- Publically communicate the Swimlane Chart and all associated deadlines and policy decisions.

In short, the TVA has identified the Swimlane chart as a compact, single, and easily understood “tool” for meeting the highlights articulated above in a consistent manner across the country. This helps everyone plan and prepare for the rapid and constant change that has become a required reality of the modern trauma registry environment.

## 3.2 Best Practice #2 – Pre-Release Collaboration

A revision cycle to a Registry Data Standard requires the input and coordination amongst all the varied stakeholders supporting an overall trauma registry System. Prior to the release of a “final” Data Dictionary and associated resources for the given cycle, it is valuable and important for System leadership to support as much collaboration as possible.

Highlights of the collaboration phase include:

- Ensuring clinical experts provide necessary input into the Data Dictionary.
- Ensuring details of the Data Dictionary are “harmonized” with other larger-scope registry initiatives, such as at a state or national level.

- Ensuring the technical experts who are responsible for implementing changes at the System level and hospital level have an opportunity to weigh in on the technical impacts of proposed changes to the Data Dictionary.
- Allowing end users to weigh in on the potential impacts of efficiently collecting accurate data.

To implement this important collaboration phase, the TVA and its Work Group members recommend the following best practice activities:

- Provide draft versions of resources such as the Data Dictionary (or, at the very least, a list of proposed revisions to the Data Dictionary) to all System stakeholders prior to finalizing them (i.e., “lockdown”).
- Provide ample timeframes for stakeholders to review and provide meaningful clinical, technical, or operational feedback on the proposed revisions.
- Create technical resources for the evaluation of the proposed Registry Data Standard, such as Sample Submission Files, XSDs, or other similar technical artifacts.
- Incorporate overall feedback into the preparation of final deliverables (see Best Practice #3) and share with all stakeholders including hospitals, vendors, etc.

### 3.3 Best Practice #3 – Final Deliverables/Lockdown

There are a set of resources, such as a Data Dictionary and other associated artifacts, required to implement an effective revision cycle to a Registry Data Standard. The TVA and its Work Group members recommend establishing a consistent set of resources that will be provided by each System as part of each revision cycle.

Highlights of this deliverable phase include:

- Providing a final set of technical resources (by the due dates published in the Swimlane Chart) that all System stakeholders can use to implement the needed technical, educational, and other operational components of an overall trauma registry System. The word “final” is particularly important to reduce the risk of “rework” by System stakeholders that would otherwise have to occur if artifacts were released piecemeal and/or changed after they are intended to be “locked down.”
- Effective communication and publication of all deliverables to all System stakeholders.

**Standard Deliverables** - To implement this important deliverable phase, the TVA and its Work Group members recommend the creation and publication of the following documents for the trauma registry System (which should be made available to all System stakeholders):

- **Data Dictionary** (Change Log, Inclusion Criteria, Validation Rules)
- **Submission File Format** (XSD, Sample Submission File)

A version of each of the above-mentioned resources should be provided for each revision cycle of a Registry Data Standard, along with a Swimlane Chart (Tasks, Timeframes, Due Dates). It is recommended that revision cycles be no more frequent than annual to allow ample time for

realistic timeframes and the important input, planning, and implementation activities across a System by all of its many and varied stakeholders.

### 3.4 Best Practice #4 – Deployment and Education

As a key component of the technical and clinical revisions to a Registry Data Standard, it is important to plan and allow for activities related to the deployment of necessary software updates, as well as many facets related to end user education and adoption of the changes.

Highlights of this logistical phase include:

- Ensuring that all IT resources at vendor and hospital levels have ample time to coordinate necessary deployment and change control processes required by each organization.
- Ensuring that end users are adequately trained by System leadership on clinical and operational changes to the Data Dictionary.
- Ensuring that end users of hospital trauma registry software are properly trained in any clinical or technical revisions needed to implement a Data Dictionary update.
- Ensuring that end users are properly trained on any new, or revised, data submission procedures required to submit their trauma registry data to the System.
- Ensuring that all of these activities have ample planning and implementation timeframes.

To implement this important logistical phase, the TVA and its Work Group members recommend the following:

- Conduct Data Dictionary orientation sessions by System leadership to stakeholders.
- Train users on software registry products, per the recommended direction of the applicable registry vendor(s).
- Plan and prepare within each hospital (or ideally via a coordinated group of trauma registrars within the System) to revise data abstraction or other internal processes as required.
- Schedule associated installation activities related to software deployment, per the recommended timeframes and processes established by the applicable trauma registry vendors.

## 4 Swimlane Chart

### 4.1 Swimlane Chart

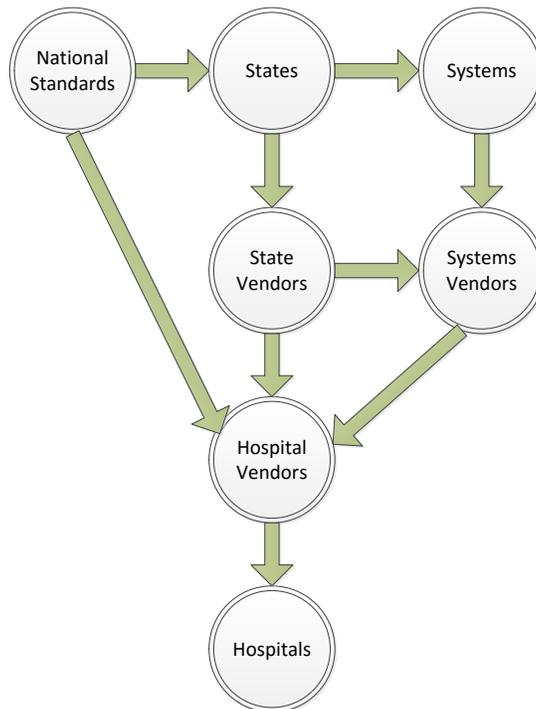
A key planning resource and best practice recommended by the TVA is that each trauma registry System establishes a Swimlane Chart for each revision of its Registry Data Standard. This section contains an example Swimlane Chart, as well as a typical type of “process flow” that illustrates the interdependencies that must be addressed in the creation of a realistic overall plan.

The following is an example Swimlane Chart for a trauma registry System. Each “lane” represents a set of phased tasks to be performed by a given stakeholder. Ample time is given for each Task associated with a given lane. Associated documentation should include a bullet list of the types of activities to be performed at each such phase.

2016 Q1														2016 Q2														2016 Q3														2016 Q4														2017 Q1													
Jan				Feb				March				April				May				June				July				Aug				Sept				Oct				Nov				Dec				Jan				Feb				March													
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	1	2	3	4	5	6	7	8	9	10	11	12	13	14				
NTDS Early Concept Release Review																																																																					
																												DD and Change Log Review																																									
																												XSD Change Log and Initial Validator Review																																									
																												***DD and Validator Current Version Changes***																																									
																												System Design, User Input and Development																																									
																												Beta Testing and Packaging																																									
																												Update Distribution, Education and Support																																									

## 4.2 System Process Flow Map

Many stakeholders are involved in the implementation of an overall trauma registry System. When implementing a revision to a trauma Registry Data Standard, there is an impact on all of the stakeholders, which must be carefully planned to allow each stakeholder to: (i) have ample time to perform their necessary Tasks; and (ii) allow for the prior definition of any dependent Tasks from other stakeholders.



## 4.3 Standard Swimlanes

The following standard swimlanes have been identified as a best practice to implement a Registry Data Standard revision across all the stakeholders of a typical System:

Stakeholder	Standard Swimlane	Typical Activities / Best Practices
National	National Data Dictionary Release	Best Practice #2 (Pre-Release Collaboration)  Best Practice #3 (Development of Data Dictionary and Submission File Format)

System (State, Region etc.)	System Data Dictionary Release	Best Practice #1 (Swimlane Chart)  Best Practice #2 (Pre-Release Collaboration)  Best Practice #3 (Development of Data Dictionary)
System Vendor	System Submission File Format Release	Best Practice #3 (Development of Submission File Format)
Hospital Vendor	Registry Software Release	Software Design, Development, and Testing
System	System Data Dictionary Orientation	Training and Orientation
Hospital	Hospital Registry Adoption and Implementation	Documentation, Training, and Orientation
Hospital Vendor / Hospital	Registry Software Deployment	Testing and Installation
Hospital Vendor	System Download Release	Software Design, Development, and Testing
Hospital Vendor / Hospital	System Download Deployment	Testing and Installation

To prepare a Swimlane Chart for a given release of a Registry Data Standard, System leadership should use Best Practice #1 to identify needed Timeframes and Tasks for each of the above standard Swimlanes that are specific to the System. For example, this could address specific regulatory, financial, or other required stakeholder activities. Once the reasonable and required Timeframes are established and known for each Swimlane, an overall Swimlane Chart can be prepared that will allow ample time for each stakeholder to complete their tasks.

#### 4.4 Swimlane Tools

The TVA provide sample Swimlane Charts and other tools to assist trauma registry Systems in rapidly and efficiently developing Swimlane Charts for each revision of their Registry Data Standard. Effective communication and planning of the realistic timelines associated with building a Swimlane Chart will provide significant and valuable benefits to all stakeholders within the trauma registry System.

## 5 Goals of Best Practice Implementations

### 5.1 Registry Data Standard Change Optimization

The actions needed to create a Swimlane Chart will help a system clearly identify their current process flow. However, this is just a solid starting point in the journey of optimizing the processes to meet each system’s unique needs. Systems should then progress with determining ways to improve and further optimize their system’s change processes.

## 5.2 Process Optimization Goals

The goals of process optimization and TVA Best Practices are:

- Meet Registry Dataset compliance requirements with timeliness and accuracy.
- Minimize unnecessary work, resources and costly rework.
- Higher stakeholder involvement and transparency.
- Higher quality with lower cost.

You can achieve these goals for your System by implementing the TVA best practices and involving all your System stakeholders, including hospitals and vendors.

## 5.3 Process Optimization Techniques

There are many optimization techniques used in the process management industry, from formal to informal, all which begin with a clearly identified process before being able to begin accurately optimizing a system. Each system is free to choose the techniques that are unique to their circumstances.

## 5.4 Global Optimization

Nearly every Trauma Registry System now coordinates core aspects of their registry with national standards and initiatives. Accordingly, there was a strong consensus from members of the TVA Work Group that a lead time of 9 to 12 months is, in general, the needed time to implement change on a national scale measuring from the final published national requirements. The TVA Best Practices help explain the many interdependencies in the industry, so that all stakeholders can better understand the impacts of their deliverables on the others and the associated timeframes required for implementation. The Process Flow map (Section 4.2) illustrates the domino effect that is in play, meaning that Global Optimization is enhanced as more lead time and advanced communication is provided for the implementation of national standards throughout all stakeholders.

## 5.5 Risks of Not Utilizing TVA Best Practices

When you utilize the TVA Best Practices, rest assured you already have “buy in” of every major trauma registry vendor in your change process. When a solid starting point and collaboration is not used by a System the risks are:

- Stakeholder frustration and dissatisfaction
- Missed deadlines and implementation dates
- Preventable rework caused by poor process management
- Higher costs with questionable quality

The TVA Best Practices help you avoid these risks and achieve success.

## 6 References

This section provides references to publically available documents that may be helpful during the reading of this best practices document:

- TVA Introductory Video: This is a brief video presentation describing the mission and formation of the Trauma Vendor Alliance to benefit the trauma registry industry.

[Click Here](http://www.screencast.com/t/xq66Y110t93) - <http://www.screencast.com/t/xq66Y110t93>

- TVA Announcement Board: This is a freely available announcement board that the TVA uses to provide and distribute information to the trauma registry industry.

[Click Here](https://groups.google.com/forum/#!forum/tva-announcement-board) - <https://groups.google.com/forum/#!forum/tva-announcement-board>

## 7 Acknowledgments and Contributors

The TVA has assembled an Implementation Timeframe Work Group to provide significant input and feedback into this document. The TVA Implementation Timeframe Work Group includes significant stakeholder representation from all of the following types of groups:

- All national trauma registry vendors
- State trauma registry leadership
- National trauma registry leadership
- PI collaborative leadership
- Major national hospital system leadership

We would like to thank all of the contributors. It is the intent of the TVA to have an inclusive process that welcomes input from any organizations of the above types (or others) that wish to provide input. The TVA will publish revisions to documents when there is sufficient feedback or interest to do so. All TVA resources and documents may be freely used by all members of the trauma registry industry and will be made available via the TVA Announcement Board and other public resources as they become available. Please feel free to distribute any TVA resources within your System or to any interested stakeholders responsible for the implementation of trauma Registry Data Standards.

## 8 Revision History

- **Release Version 1.0 – August 10, 2016** – Prepared in collaboration with a TVA work group comprised of representatives from all major Trauma Vendors with National, State, Hospital, and Collaborative registry systems.