Severity of Harm Category Designation Survey Results

Hopital Pontchaillou, Rennes, France: L. Peltier
Heilig Hart Ziekenhuis, Lier, Belgium: S. Van Aelst and B. Peeters.
Bio-Rad Laboratories, Marnes-la-Coquette, France: J. Raimbourg
Bio-Rad Laboratories, Irvine, U.S.A.: J. Yundt-Pacheco

Background

ISO standard 14971 – Application of Risk Management to Medical Devices and CLSI guidance EP23 – Laboratory Quality Control Based on Risk Management both use a Severity of Harm model to designate maximum acceptable probability of patient harm (risk) based on the severity of the consequence to the patient.

When designing a risk managed quality control program for the clinical diagnostic laboratory, the starting point is to select a Severity of Harm category for each analyte being tested. As each Severity of Harm Category (Negligible, Minor, Serious, Critical, Catastrophic) can be mapped to a corresponding maximum acceptable probability of patient harm from erroneous results (0.01, 0.001, 0.0001, 0.00001, 0.000001). The laboratory can then design quality control strategies that have a predicted probability of patient harm below this maximum for a risk managed quality control program.

Unfortunately, there is little guidance on setting Severity of Harm designations, and they are by nature, subjective. To remedy this, we conducted a survey of laboratory professionals, asking them to rate the Severity of Harm for 20 routine analytes to begin establishment of an international consensual classification which can be used to improve patient risk management.

Methods

An international survey was conducted in clinical diagnostic laboratories to solicit Severity of Harm designations for 20 routines analytes by the question:

"How would you rate the severity of patient harm if a clinician would interpret incorrect reported results from these analytes?" Nota bene: As we understand that an erroneous result could generate different severity of harm depending on clinical context and error depth, we advise you to consider the most unfavorable situation that can occur in your lab activity.

The available ratings were described as:

Negligible	Inconvenience or temporary discomfort
Minor	Temporary injury or impairment not requiring professional medical intervention
Serious	Injury or impairment requiring professional medical intervention
Critical	Permanent impairment or life-threatening injury
Catastrophic	Patient death

In addition, some demographic information was requested such as:

- Country of activity
- Degree / Credentials
- Principal medical lab department
- Type of laboratory

All responses were curated to ensure complete demographic data and that all responders were Clinical Laboratory Professionals.

Results

A Total of 261 respondents from 42 countries completed our survey. After collegial curation the answers of 243 respondents from 40 countries were used to define patient severity of harm from an erroneous clinical lab result. Most respondents come from Europe (70%). Table 1 details the distribution of respondents' countries of origin.

Table 1: Distribution of respondent's country origin

Europe		**Middle East**	
Austria	4	Bahrain	1
Azerbaijan	2	Israel	1
Belarus	1	Jordan	3
Belgium	5	Kuwait	4
Denmark	1	Oman	1
France	39	Qatar	1
Germany	28	Saudi Arabia	6
Greece	3	UAE	16
Hungary	3	**Total**	**33**
Italy	32	**Africa**	
Kazakhstan	2	Algeria	1
Romania	3	Cameroon	2
Russia	12	Egypt	4
Serbia	1	Ethiopia	1
Spain	25	Ghana	1
Sweden	1	Kenya	13
Switzerland	5	Morocco	1
Ukraine	2	South Africa	6
United Kingdom	3	Tunisia	1
Total	**172**	**Total**	**30**
Asia		**North America**	
Pakistan	5	Canada	2
Philippines	1	**Total**	**2**
Total	**6**		

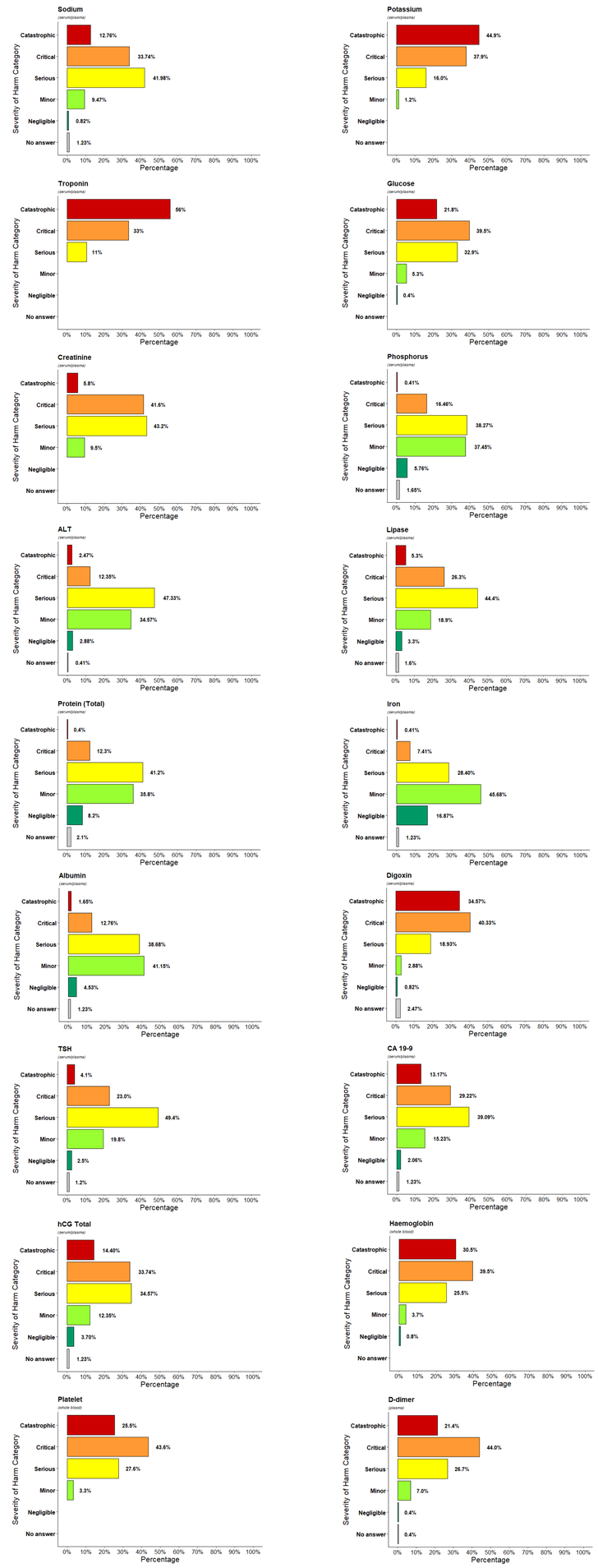
Download

Take Survey

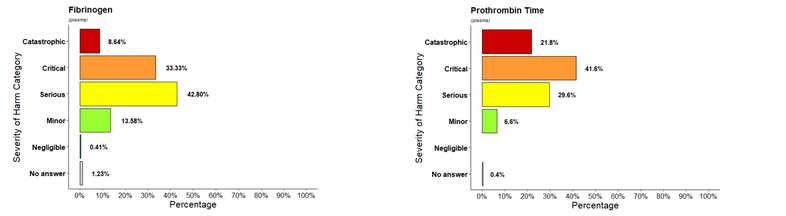
Results

The results of severity of harm rating category designation are presented below individually for the 20 routine clinical lab tests in the survey. The analytes are mainly clinical chemistry (14) with 3 coagulation, 2 hematology, and 1 pharmacology parameters. The survey respondents category designation is presented in percentage and bar plots graphs and are presented here the same order as in the survey. The matrix of each analyte is specified in the graph.

Figure 1

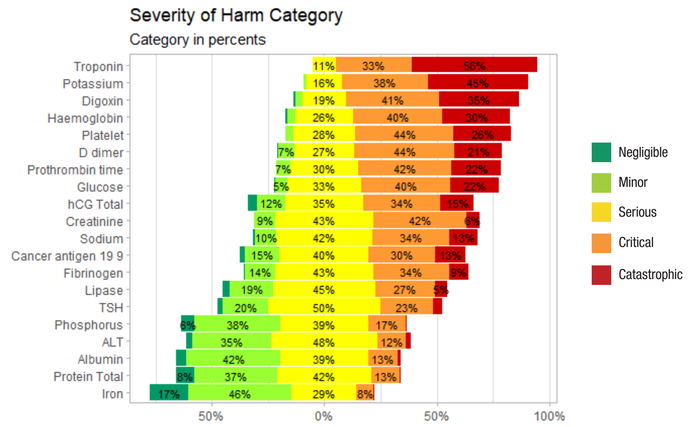


Results



The results of severity of harm rating category are summarized in a Likert graphic type in Figure 1. Analytes are ordered by the combined Critical and Catastrophic responses. No answer category was removed.

Figure 2: Likert graphic of severity of harm rating category



The graphic presents the results of severity of harm rating category designated by the 243 curated respondents in percentage.

The severity of harm principal rating category is summarized in Table 1 and listed in alphabetical order within the severity of harm designation.

Table 2: Severity of harm principal rating category

Analyte Type	Analyte	Severity of Harm Category Disignation
Clinical Chemistry	Potassium *(serum/plasma)*	Catastrophic
Clinical Chemistry	Troponin *(serum/plasma)*	Catastrophic
Clinical Chemistry	Glucose *(serum/plasma)*	Critical
Clinical Chemistry	ALT *(serum/plasma)*	Serious
Clinical Chemistry	CA 19-9 *(serum/plasma)*	Serious
Clinical Chemistry	Creatinine *(serum/plasma)*	Serious
Clinical Chemistry	hCG Total *(serum/plasma)*	Serious
Clinical Chemistry	Lipase *(serum/plasma)*	Serious
Clinical Chemistry	Phosphorus *(serum/plasma)*	Serious
Clinical Chemistry	Protein (Total) *(serum/plasma)*	Serious
Clinical Chemistry	Sodium *(serum/plasma)*	Serious
Clinical Chemistry	TSH *(serum/plasma)*	Serious
Clinical Chemistry	Albumin *(serum/plasma)*	Minor
Clinical Chemistry	Iron *(serum/plasma)*	Minor
Coagulation	D-dimer *(plasma)*	Critical
Coagulation	Prothrombin Time *(plasma)*	Critical
Coagulation	Fibrinogen *(plasma)*	Serious
Hematology	Haemoglobin *(whole Blood)*	Critical
Hematology	Platelet *(whole Blood)*	Critical
Pharmacology	Digoxin *(serum/plasma)*	Critical

The table presents the principal severity of harm rating category designated by the 243 curated respondents.

Discussion:

We noted that the principal selected level of severity of harm are consistent with medical practice. The principal chosen category was "Serious" (10 times) followed by "Critical" (6 times). Surprisingly, the "Negligible" level was never designated as the main category and the total of negligible responses was very low (2.67%). Finally, we found that in a few analytes, the survey respondents were almost evenly split between two categories (i.e.: hCG Total, Phosphorus, Creatinine).

Limitations: Even though the survey was carried out internationally, it lacks representativeness insofar as most of the respondents are from Europe (70%) with four countries accounting for 51% of respondents (France, Italy, Germany and Spain). In addition, there are no participants from the USA, UK, Australia or South America.

Perspectives: In order to reduce the limitations observed in this survey, the data collection process is still active to increase the number and geographic diversity of the respondents. By reducing these limitations, we hope to be able to propose a consensus classification that is recognized and used by the scientific community of clinical diagnostic laboratories. With this new data we also hope to be able to determine statistically whether the demographics of the respondent's influence the severity of harm level of the analytes.

Conclusion:

To the best of our knowledge, this is the first attempt to define and graduate a patient harm introduced by an erroneous lab result. While severity of harm designations are specific to the local clinical system, guidance can be provided by collecting the opinion of a wide variety of clinical laboratory professionals. This provides support for the clinical diagnostic community in building risk managed quality control programs. It represents the first step to build a lab management quality process based on patient risk from lab error.