Monitoring laboratory data across manufacturers and laboratories—A prerequisite to make "Big Data" work

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Abstract:

The Percentilerproject provides quasi real-time access to patient medians across laboratories and manufacturers. This data can serve as "clearinghouse" for electronic health record applications, e.g., use of laboratory data for global health-care research.

Methods:Participants send their daily outpatient medians to the Percentiler application. After 6 to 8 weeks, the laboratory receives its login information, which gives access to the user interface. Data is assessed by peer group, i.e., 10 or more laboratories using the same test system. Participation is free of charge.

Results:Participation is global with, to date, > 120 laboratories and > 250 instruments. Up to now, several reports have been produced that address i) the general features of the project ii) peer group observations; iii) synergisms between "The Percentiler" and dedicated external quality assessment surveys. Reasons for long-term instability and bias (calibration- or lot-effects) have been observed for the individual laboratory and manufacturers.

"The Percentiler" project has the potential to build a continuous, global evidence base on in vitro diagnostic test comparability and stability. As such, it may be beneficial for all stakeholders and, in particular, the patient. The medical laboratory is empowered for contributing to the development, implementation, and management of global health-care policies.

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Introduction:

Laboratory data has the potential for substantially aiding the development, implementation, and management of public healthcare policies. It can create public awareness of the importance of maintaining a healthy lifestyle as well as reacting early to signals of health problems. As such, it can indirectly contribute to reduce the burden of healthcare expenses. The drive to focus on improved exploitation of laboratory data typically comes from financial

pressures, such as the steady increase in health-care expenses in the US during the last 20 years. Such expenses now represent 17.6% of the gross domestic product and nearly $600 billion more than the expected benchmark for a nation of the size and wealth of the US (Miller,2011). An additional impetus to transform the laboratory landscape comes from the information technology (IT) revolution, offering, among others, the opportunity to create reliable and accessible "Big Data" (Stepman, et al, 2012).

In an attempt to illustrate this limitation and more importantly to do something about it, we describe "The Percentiler" project, which is part of our overarching "Empower" project introduced elsewhere (G.L. Horowitz,2014). In essence, it provides quasi real-time access to patient medians across laboratories and manufacturers. This data can serve as a "clearinghouse" for potential future EHR applications, such as the retrieval of laboratory data for epidemiological or toxicological research on national or global scale, long-term follow-up of chronic diseases, or linking laboratory data to mortality risk (Solinger, 2013).

Participants and participation process:

Participating laboratories are globally distributed. They range from medium-sized to big hospital laboratories, but also include private laboratories. When a laboratory declares its intention to join, we provide it with the information about the IT requirements for sending data, together with a request for a test e-mail. One of our project team controls the test-mail, maps the data and verifies error-free transmission into our database. If successful, we continue this verification for a while before giving the definitive Percentiler e-mail address. Subsequently, data transfer either occurs automatically and on a daily basis (depending on the Laboratory Information System (LIS)) or is done in manual batches. After sending data for 6 to 8 weeks, the participating laboratory receives its login information, which gives access to the graphical presentation of its data via a user interface.

Data :

We collect instrument-specific daily medians calculated from outpatient results of 20 commonly measured analytes in serum or plasma: albumin, alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), calcium, chloride, C-reactive protein (CRP), creatinine, γ-glutamyl transferase(GGT), glucose, inorganic phosphorus (phosphate), lactate dehydrogenase (LDH), magnesium, potassium, sodium, total-bilirubin, total-cholesterol, total-protein, urea, and uric acid (urate).

Data coding and transfer to a database :

Data coding comprises 7 attributes each separated by "semicolon": laboratory identification (Lab ID); date (e.g., 02/01/2014); instrument identification (Instr ID); code for outpatients (e.g., OUT); test name (e.g., CA for calcium); test unit (e.g., mmol/L); median (e.g., 2.35). The laboratories can retrieve these attributes directly from the LIS and adopt the used mnemonics. **The only requirement is for the laboratories to organize the data in a table according to the format below:**

- Lab ID;02/01/2014;InstrID;OUT;CA;mmol/L;2.35
- Lab ID;02/01/2014;InstrID;OUT;NA;mmol/L;141
- Lab ID;02/01/2014;InstrID;OUT;CL;mmol/L;102.5

Database:

The software for data downloading from the e-mail, transfer into a MySQL database, and the development of "The Percentiler" application and user interface was programmed by Bruno Neckebroek (Zwijnaarde, Belgium). Data from the individual laboratories are "mapped" by the STT/UGent project team to common analyte names, units, and instrument names and other technical details.

Data analysis/user interface :

The database is fully accessible to the STT/UGent project team, who investigate laboratory and peer group data for bias and trends. Critical observations are communicated in the first instance to the laboratories concerned. They are also shared with instrument vendors, and regularly, with the whole group of participants. It is important to note that the identity of the laboratory is not disclosed to a third party under any circumstances. The assessment of the stability of laboratory testing is done against desirable bias limits from biological variation, at least for the analytes for which state-of-the-art performance allows this (S.L. Braun, 2004).

Results:

1. **Laboratory bias:**
   To date, assessment of laboratory bias is done with caution as only the Cobas peer group target is calculated from sufficient instruments. In addition, more experience needs to be gained about the potential influence of population effects. Nevertheless, some grossly deviating results have been reported by individual laboratories. The discrepancies were confirmed by sample exchange experiments.
2. **Pre-analytical effects**
   Pre-analytical effects are seen in certain private laboratories. Follow-up determined that this is due to a considerable delay between sample collection and processing. For potassium, this led to high values in winter and normalvalues in summer. The opposite pattern was observed for LDH medians.

Recommendations:

The project may improve the physician/laboratory interface because communication is about patient results and not, for example, about trends observed for quality control samples. At the same time, it helps physicians to develop realistic expectations about inevitable variability of laboratory data. Ultimately, interoperable and stable laboratory data facilitate and improve care that physicians can offer to their patients.

The project is beneficial for the society, and finally for the patient. The data can serve as a "clearinghouse" for potential future EHR applications. This is particularly important when laboratory data are intended for use in epidemiological or toxicological research on a national or global scale. Continuous evidence for test comparability and stability is of paramount importance for long-term follow-up of chronic diseases (diabetes, thyroid-, kidney- and cardiovascular disease) and linking laboratory data to mortality risk.

Of course, the monitoring of patient data also has limitations: the greater the test volume and the more careful the selection of outpatient results, the greater the utility of the data. In addition, monitoring is most effective at the median level because "outer percentiles" (for example, 2.5th or 97.5th percentiles) exhibit a significantly higher population variation than do central tendencies such as the median.

Conclusion:

The Percentiler" project has the potential to build a continuous, global evidence base on in vitro diagnostic test comparability and stability. As such, all stakeholders could profit from it, that is, laboratories, manufacturers, physicians, society, and naturally the patient. The medical laboratory, in particular, may be empowered for future tasks, such as contribution to the development, implementation, and management of global health-care policies.

References:

- K. Van Houcke, P. Rustad, H.C. Stepman, *et al.*, Calcium, magnesium, albumin, and total protein measurement in serum as assessed with 20 fresh-frozen single-donation sera, ClinChem, 58 (2012), pp. 1597-1599.
- H.C. Stepman, U. Tiikkainen, D. Stöckl, *et al.*, Measurements for 8 common analytes in native sera identify inadequate standardization among 6 routine laboratory assaysn, ClinChem, 60 (2014), pp. 855-863.
- G.L. HorowitzmAssessing accuracy on the front lines: a pragmatic approach for single-donor proficiency testing, ClinChem, 60 (2014), pp. 806-808.
- B. Solinger, S.I. Rothman, Risk of mortality associated with common laboratory tests: a novel, simple and meaningful way to set decision limits from data, available in the Electronic Medical Record, ClinChem Lab Med, 51 (2013), pp. 1803-1813.
- K. Goossens, K. Van Uytfanghe, L. Thienpont, Trueness and comparability assessment of widely used assays for 5 common enzymes and 3 electrolytes
- ClinChimActa, 442 (2014), pp. 44-45.
- W.G. Miller, G.R. Jones, G.L. Horowitz, C. Weyka mp.,Proficiency testing/external quality assessment: current challenges and future directions, ClinChem, 57 (2011), pp. 1670-1680.
- S.L. Braun, K. Ciolek, W. Vogt., Early detection of the selectivity loss of the Cobas Integra analyzer

chloride ion-selective electrodeClinChem, 50 (2004), pp. 1272-1273.

- H.C. Stepman, D. Stöckl, V. Stove, *et al.*, Long-term stability of clinical laboratory data: sodium as benchmark, ClinChem, 57 (2011), pp. 1616-1617.
- S.K. Van Houcke, H.C. Stepman, L.M. Thienpont, *et al.*, Long-term stability of laboratory tests and practical implications for quality management
- ClinChem Lab Med, 51 (2013), pp. 1227-1231.