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## Editorial

## The laboratory information system functionality assessment tool: Ensuring optimal software support for your laboratory

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In June 2012, the Association of Pathology Informatics (API) convened a 1 day. Strategic Summit conference in Pittsburgh, Pennsylvania, USA, to discuss the future role of laboratory information systems (LISs) as Electronic Health Records (EHRs) are being deployed on an increasingly broad basis across the U.S., some of which include an integrated LIS. Additionally, some of these EHR deployments involve the pursuit of an enterprise-wide solution (EWS) with all of the software components of the EWS provided by a single vendor in an ostensibly unified single software application framework. Such an EWS may suppress consideration of other LIS solutions available in the market, some of which are considered best-of-breed (BoB). BoB, in the context of this communication, is defined as any stand-alone LIS with optimum functionality as compared with the field of equivalent competing systems. An EWS strategy, from the perspective of lab professionals, is only optimal if and when its integrated LIS functionality performs at or beyond the level of performance of established BoB solutions. This selection strategy is necessary because choosing a BoB LIS lowers the overall cost of laboratory tests and attracts higher quality personnel, who relish working in the most modern laboratory environment that is achievable.

The Strategic Summit was organized to better understand the effects that the growing popularity of EHRs and the pursuit of the EWS by hospital and healthcare executive will have on the LIS industry, laboratories served by LISs, and laboratory professionals in general. In order to frame this discussion, a series of panelists and faculty were invited to the Summit on a competitive basis to address a predetermined set of questions to an invitation-only audience of pathologists, industry representatives, and laboratory executives. One of the nagging questions that begged addressing in the minds of the faculty and audience was how to define and measure LIS functionality in order to obtain a clearer understanding of the value proposition offered by the BoB LISs available in the market.

A clear take-away lesson from the Strategic Summit was that laboratory professionals needed a tool to assess and quantify the functionality of their current LISs in order to call attention to the need for an upgrade of a current LIS or drive its replacement. In addition, such a tool could also be used to assess the functionality of an LIS integrated into the software suite "offered" to a hospital by an EHR vendor. In this latter case, lab professionals might be facing a significant loss of functionality over their currently installed LIS, in the name of system integration at the enterprise level. We put the word offered in quotes here because there is often intense, combined financial and political pressure from the EHR vendor and hospital executive for lab professionals in the hospital to accept an enterprise-wide "primary vendor strategy," where the LIS is a component of the overall EWS software suite.

For the Chief Information Officer (CIO), such a strategy avoids the need for the integration of a "foreign" LIS that then needs to be integrated with the EWS software suite. However, such promises are illusory, because



## J Pathol Inform 2014, 1:7

the primary vendor solution may still be based upon disparate architectures that are themselves integrated by the vendor into a more monolithic construct. Experience shows that such integrative exercises carried out by single vendor solutions can be far inferior to locally executed integration. Hence, there is, in fact, no guarantee that a primary vendor will carry out integration in a manner that exceeds the level of integration that is possible with thoughtfully implemented BoB solutions.

To achieve a greater understanding of LIS functionality, the API appointed a working group to develop a "toolkit" to help laboratories assess their current LIS functionality as well as serve as a guide to functionality that would be expected by an LIS replacement, sometimes on the basis of an EWS strategy. Further and by corollary, the toolkit could also be used to highlight functionality that would be lost by LIS replacement and requiring the purchase of additional software at additional cost.

After nearly a year of effort, the availability of the "toolkit" developed by the API working group was announced at the American Society for Clinical Pathology (ASCP) Annual Meeting in September, 2013, in Chicago. The announcement was made as part of a plenary session presented by the API as part of the API's inaugural participation in the ASCP annual meeting. Whether used to reject a proposal of an inadequate LIS integrated with an EHR by hospital executives or as a justification for the replacement or upgrade of a current LIS, the announcement of the availability of the toolkit (available at no cost on the API web site) has had a significant impact on the practice of pathology informatics in the USA (http://pathologyinformatics.org/toolkit).

The LIS Functionality Assessment Toolkit (LIS-FAT) consists of four sections: (1) A narrative overview of the rationale for the development of the toolkit and how to use it; (2) Approximately 850 LIS functionality statements covering most general and specific laboratory units; (3) A set of LIS scenarios that can be used to guide on-site LIS demonstrations; and finally; (4) A work sheet that can help laboratory's assess the total cost of ownership (TCO) of an LIS. TCO is an important calculation in relation to a new LIS because of the additional software purchases that will be required when an immature or inadequate LIS is deployed. Such additional purchases are necessary to achieve BoB functionality and, obviously, will add to the total cost

of the system. Not only is it license fees to provide the additional functionality lost, but also the cost for hardware and LIS staff support moving forward. Taken as a whole, the four components of the toolkit can assist lab professionals to select an optimal system but can also assist them in defending against poor system selection by those who may not have an adequate and detailed understanding of laboratory workflow and operations.

We believe the LIS-FAT will help laboratories develop a meaningful dialogue with their hospital organizational leadership about the need for fully functional LIS as opposed to those that are a merely" good enough" system. How can a "good enough' LIS suffice if it lacks a transfusion management module! How can laboratories perform adequately without support for the microbiology laboratory? How will you integrate and manage data across all of the various hospital laboratories when your LIS lacks a common database platform and in tandem requires the use of multiple third party integration engine data transformation nodes? These are problems that lead us back to the earliest days of the LIS development, most of which were already thoroughly addressed by the workflow solutions and software architecture intrinsic in modern BoB LISs.

To date, there have been over 1500 visits to LIS-FAT web site. While that may sound low in an Internet world of billions of hits and downloads, in the relatively small world of clinical and anatomic pathology that is LIS, we believe this is a significant amount of activity. Moreover, the availability of LIS-FAT is only now being understood and acted upon. Advertising has been mainly through web sites, e-mail, and word of mouth. Thus, we expect "hits" to continue to grow as more and more laboratorians are faced with the problem of LIS replacement, particularly with enterprise solutions that may significantly compromise laboratory efficiency. Such a latter outcome is totally unacceptable in this era of healthcare reform and pressure to reduce costs in all hospital units.

Just as Bruce Schnier, an internationally recognized IT security expert, stated in his recent publication concerning the Snowden-informed vulnerabilities in the very fabric of the Internet, we too as laboratorians entrusted with ensuring the highest standards of clinical laboratory medicine, need to "take back" the LIS from those who threaten the 40 or more years of progress we have experienced and leading to the current state of the art. Inaction is not an option.