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A matrix for a LIMS with a strategic focus ☆

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.bstract

This article focuses on the impact that a laboratory information management system (LIMS) should make on both a .boratory and an organisation but rarely does. To be effective a system should deliver benefit to both the laboratory .vironment and the organisation. But how should this be designed? To overcome this problem a matrix is proposed, which ′ill allow any LIMS to be developed with a strategic focus. The matrix can be used either as an aid to system nplementation and deciding which applications the LIMS should interface with. Alternatively, the matrix can be a means of valuating the effectiveness of existing applications and to chart their further development. The aim is to give analytical hemists, managers and computer scientists a tool to enable any LIMS to reach its true potential.

eywords: Laboratory information management systems; LIMS; Strategic matrix

. LIMS in analytical laboratories

The major function of most analytical laboratories the creation and presentation of information quickly) make decisions. A LIMS is one of the major .boratory automation tools at the disposal of analyt- al chemists to help achieve this aim [1]. Although a IMS does not undertake analysis, a LIMS can be ivotal in integrating both the laboratory operations nd the laboratory itself within an efficient organisa- .ion. A LIMS can provide a laboratory with the neans to automate the processes of information cre- .tion and presentation, as well as being the platform for information dissemination to clients and senior management.

However, this is not always the case. A large number of systems fail to meet initial expectations which implies that LIMS are not fully understood [2]. To help overcome this, a LIMS model was proposed [2,3] that enabled the requirements of a system to be visualised conceptually [3,4]. It has been adopted, modified and used as the basis of the LIMS concept model in the ASTM LIMS Guide [5]. However, the LIMS model focuses on identifying and visualising the user functions within the laboratory environment and less on the strategic siting of a system.

To overcome this problem, a previous article proposed a matrix for the development of a LIMS with a strategic focus [6]. It introduced the concept of an operational, logistic and strategic LIMS. The matrix is formed by plotting these three types of LIMS against the scope of laboratory and organisational

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tasks that can be undertaken by such a system. The purpose of this article is to develop the matrix further and discuss the impact that a logistic and strategic LIMS can make within an organisation.

2. A LIMS has two targets

A LIMS is unlike any other piece of laboratory automation equipment available to the analytical chemist. It can provide benefits both within the laboratory and outside it. Thus a LIMS has two targets: (i) the laboratory: the information generator; (ii) the organisation: the information user.

The problem is how to site and implement a system so that it hits both targets effectively.

Fig. 1 shows an outline of the functions that a LIMS should undertake. The diagram shows a LIMS sited at the interface between a laboratory and an organisation. Samples are generated in the organisation and logged into the LIMS, the samples are analysed within the laboratory and data are produced and reduced within the LIMS environment to information which is transmitted back into the organisation. Fig. 1 represents the ideal siting of the LIMS: both the organisation and the laboratory benefit. The line dividing the organisation and the laboratory show the system is of equal benefit to both.

However, there are two other implementations that are possible with a LIMS, which result in a different position of the interface between the laboratory and organisation. Fig. 2 shows the more common implementation, this is probably typical of the majority of early implementations of LIMS in the 1980s. The main functions carried out by the system are the same as previously but the emphasis of the implementation is different. The boundary between the organisation and the laboratory has moved up and the benefit of the LIMS is almost exclusively that of the laboratory with little payback for the organisation. Here the LIMS is a toy for the laboratory that few others are allowed to play with. The system is built from the bottom up but with no consideration for anyone outside of the laboratory.

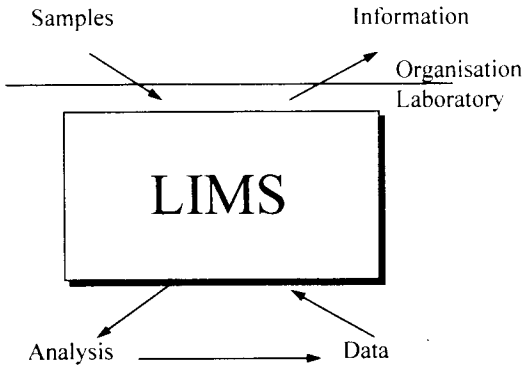

Fig. 2. A bottom–up implementation of a LIMS. The laboratory benefits but the organisation does not.

The rarest alternative implementation is presented in Fig. 3. This is the top–down approach, where senior management or, worse, the IT group has decided that a LIMS will be implemented. There has been little consideration for the laboratory, only the

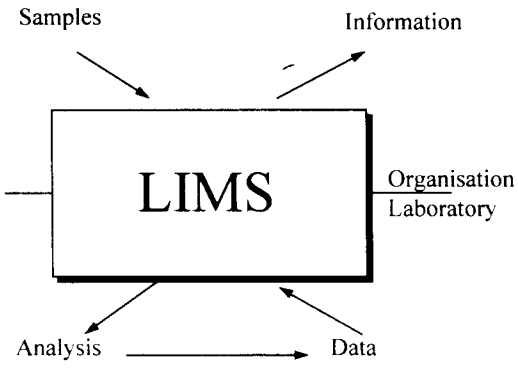

Fig. 1. The ideal implementation of a LIMS. The interface between the laboratory and the organisation shows that the LIMS benefits both.

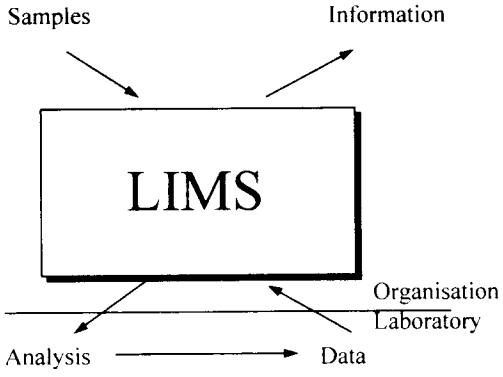

Fig. 3. A top–down implementation of LIMS. The emphasis is on the organisation allowing the laboratory staff to develop their own data handling solutions independently of the LIMS.

organisation. The analysis and data gathering functions of a LIMS have been ignored, which allows the staff the latitude and the excuse to develop their own alternative local processing solutions. This system requires additional work by the staff to ensure its success in addition to the normal analytical function. The likelihood of failure with such a system is much higher than with the other two forms of implementation.

As can be seen when comparing the three alternatives, there is a balance to be found between the needs of the organisation and the laboratory. The interface between the two must be carefully defined; however, the initial implementation should be towards the analytical laboratory, the information generator. Automating the information generator is the key to success for the whole LIMS.

The importance of the LIMS matrix, described in the following section, allows that dividing line to be drawn accurately before starting the project and manage the implementation of a system.

3. Construction of the LIMS matrix

The matrix axes consist of LIMS type plotted against function in the laboratory or organisation. Each will be outlined below.

3.1. Three types of LIMS

There are three types of LIMS: operational LIMS, logistic LIMS and strategic LIMS [6]. The functions and aims of these systems are described in more detail.

Operational LIMS

This is a basic system that automates analytical processes in the laboratory. This system increases the efficiency of a laboratory but the impact is only local. A computer system in this category would normally be concerned with the operation control of a laboratory and would automate functions such as sample entry, work list generation and report preparation. Another way of looking at this system is usually the automation of the status quo (see Section 5 on organisational integration and LIMS). Such a system is probably typified in Fig. 2.

Logistic LIMS

In addition to the functions of an operational LIMS, a logistic LIMS provides users, especially managers, with the information necessary to undertake their work. Such systems generate control information. Ultimately, this information improves the effectiveness of a laboratory.

Table 1
The functional scope of a LIMS

Functional area	Scope
Laboratory operations (LO)	To automate and structure work
	The automation of the basis laboratory operations such as sample entry, work list generation and results entry
	Work rationalisation
Monitor and control (MC)	To evaluate performance
	The monitor and control of the laboratory operations by such processes as approving results, the use of quality control schemes and the checking of transcription errors
	Provide standards, measures, and information for performance evaluation and feedback
Laboratory management (LM)	Support intellectual processes
	Organising and managing the laboratory functions and operations
	Project and work planning
Reporting and communications (RC)	To augment human communication
	Here are the means to transmit results or reports and communicate with the clients of the laboratory
Analytical decision making (AD)	To aid and speed decision making
	Providing quality information in a timely manner and the right format to make decisions
	Supporting processes in production, development or research
Organisational integration (OI)	Facilitate intra and inter organisation transactions
	Integrating with other functional groups in the corporation and between organisations

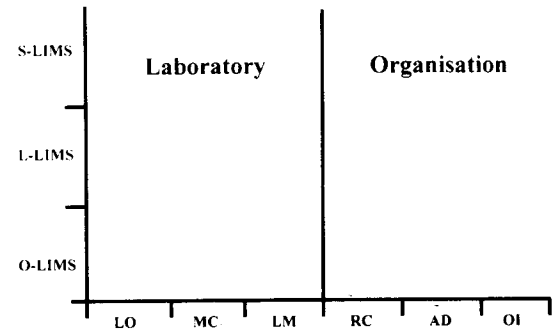

Fig. 4. An outline of the LIMS matrix. S-LIMS, L-LIMS and O-LIMS are strategic, logistic and operational versions of LIMS. The horizontal axis functions are laboratory operations (LO), monitor and control (MC), laboratory management (LM), reporting and communications (RC), analytical decision making (AD) and organisational integration (OI).

Strategic LIMS

The aim of a strategic LIMS is to integrate information and applications from different functional areas. From this information it may be possible to reshape operations. A strategic LIMS has the greatest impact on the business by increasing the competitiveness of the laboratory.

Properly designed, a logistic or strategic LIMS will achieve the correct balance shown in Fig. 1. However, too great an emphasis at the start of the project is likely to produce the system shown in Fig. 3.

3.2. The system scope

Where does a laboratory begin and end? Clear definition of these two points helps to determine the scope of a LIMS. The six areas of system scope that define the matrix are laboratory operations, monitor and control of operations, laboratory management, reporting and communications, analytical decision making and organisational integration [6]. This is the maximum scope of a LIMS. These comprise the horizontal axis of the matrix. The functions carried out by each of these areas are outlined in Table 1.

3.3. Matrix construction

The matrix can now be formed as a three by six block and is depicted in Fig. 4. There is a division between the first three items of the system scope. Laboratory operation, monitor and control and laboratory management are concerned with functions inside the laboratory. Organisational functions are represented as reporting and communications, analytical decision making and organisational integration.

The individual components of the matrix are shown in Fig. 5. This is still an outline of the functions of a LIMS within each cell. The author would welcome suggestions for additional functions within the matrix.

Considering all of the functions in Fig. 5, one can see that the main functions of the laboratory are outlined in the lowest three cells of the matrix (Operational LIMS: Laboratory operations, Monitor

Strategic LIMS	Integrate with client operations	Compare requests with capacity	Resources based on workload	Integrate with document management software	Decision support system integration	EDI & CANDA Rapid commercialisation
Logistic LIMS	Integrate laboratory operations	Automate regulatory compliance	Monitor test use	Electronic reports to clients	Highlight out of specification results	Remote on-line inquiry
Operational LIMS	Automate existing operations	Monitor and approve results	Sample status Billing	Paper reports to clients	Display results v specification	Remote printing of results Client/lab E-mail
	Laboratory Operations	*Monitor and Control*	*Laboratory Management*	*Reporting and Communications*	*Analytical Decision Making*	*Organisational Integration*

Fig. 5. Detailed functions of the LIMS matrix.

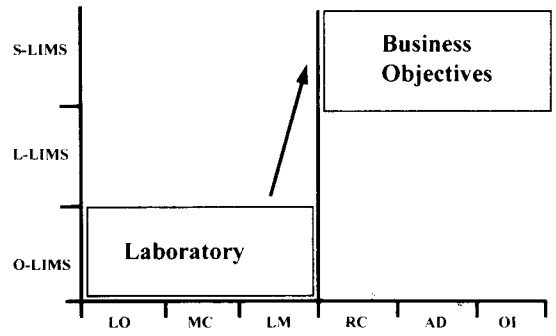

Fig. 6. The LIMS matrix, illustrating where some LIMS are implemented for the benefit of the laboratory and the business objectives where the best payback will be obtained.

and control and Laboratory management). This represents the basic laboratory operation and is indicative of the data domain discussed previously [2]. This is shown in Fig. 6 as the box labelled 'Laboratory'.

Ideally, the major impact of any computer system, including a LIMS, should be strategic. The organisation uses the information used generated by the analytical laboratory and this can be considered as the information domain [2]. The maximum impact of a LIMS is in the top right-hand side of the matrix. It consists of the strategic LIMS cells of results and communications, analytical decision making and organisational integration, and is marked 'Business objectives' in Fig. 6. It should be the aim of every LIMS to aim for the top right-hand area of the matrix.

However, it should be stressed that not every LIMS will be developed to the full extent of the matrix. There will, inevitably, be some duplication with other computer applications that have been implemented or are being implemented within an organisation. The aim, therefore, is to develop the matrix around business objectives and a good financial justification to make the system pay for itself in a reasonable time period. One way to do this, and make the economical use of resources, is to link the implementation of the LIMS with existing applications to provide the functionality described in the matrix. The development of a LIMS within a pharmaceutical environment has been shown in an earlier publication [6]. Here the LIMS was linked through a communications network to a document management software package that can itself be developed to produce computer assisted new drug applications (CANDAs) which will fulfill the requirements of the matrix.

4. Matrix views

Similar to the ability to use views to gain an insight into the contents of a data base, the same concept can be used to gain an insight into the matrix and its impact. We will consider two main views in this section. The first is the vertical view through laboratory operations and a horizontal view across the logistic LIMS cells.

4.1. Vertical view of laboratory operations

The vertical view through the laboratory operations cells of the matrix will see how this changes from the operational LIMS to the strategic LIMS. The lowest left hand cell of the matrix represents the core of the analytical laboratory: the inventory of assay methods and instrumental techniques. The operational LIMS would generally automate these processes and techniques. Business rules would be incorporated into the system such as who was allowed to create, modify or delete methods within the LIMS, how many replicates were needed for each analysis. Samples would be logged in and work sheets would be produced for each analytical run. All functions are the usual LIMS functions within the analytical laboratory.

At the logistic LIMS level, the matrix is looking for integration of laboratory operations. This would be the linking of analytical instruments to the LIMS for electronic transfer of results, samples would be bar-coded and would have their location monitored as they move through the laboratory. The various applications used for analysing data and producing results would be integrated into the LIMS environment and would not be stand-alone applications requiring re-entry of data.

At the strategic LIMS, the system should be integrating with client operations. Possible examples of this could be the clients logging onto the system to initiate sampling within their areas. The system would print bar-coded labels for the samples from printers within the clients area. The samples would

be submitted to the laboratory for analysis and logged into the system via the bar code. An alternative scenario in a production environment could be the analytical laboratory developing robust methods for the production staff to operate and use the LIMS as a means of collating and disseminating the results. The LIMS would be the medium for the laboratory staff to monitor the performance of the analytical methods and alert them if a method were getting out of control.

4.2. Horizontal view of a logistic LIMS

Looking along the matrix cells at the logistic LIMS level would give us a view of a system that has integrated laboratory operations as described above. The monitor and control cell requires automated regulatory compliance, this would also include compliance with a quality scheme such as ISO 9000. There would be audit trail facilities as standard and the establishment of chain of custody from the time the sample arrived into the laboratory to when it was disposed or returned to the client. Automated regulatory compliance is a term which means that the documentation required to meet the quality standards that the organisation is working to is generated by the system automatically. This would include receipt of samples and documentation of exceptions.

Laboratory management is concerned at this level with monitoring test use. Many laboratories accept requests for sample assays without questioning the rationale for the analysis or finding out if the information generated is ever used. The purpose of this cell is to question the analyses requested and monitor how the results are used. Is the laboratory generating the right information and offering the methods that the clients want? It is managing the client as much as managing the future direction of the laboratory with anticipating the services it will offer. The information from the LIMS, via a retrospective search of the data base, will allow managers to follow up work that was done and how the results were used. Depending on the implementation of the whole system, this could be done electronically via feedback loops or manually.

The cells of reporting and communications, analytical decision making and organisational integration cover the functions whereby reports generated by the system are transmitted via the network, out of specification results are highlighted and the clients can have remote access for on-line query of the data base. The aim of these first two cells is to transmit the report to the client effectively and highlight aberrant results, which allows the client to focus immediately on problem areas. Some of the options available to implement this section are covered in more detail under the financial justification and risk assessment in the next section.

These views of the matrix are based on straight lines. However, not all systems will be implemented in straight lines and the views of individual systems will be based on functions required by an organisation and laboratory.

5. The matrix: financial justification and risk assessment

During presentation of this material at the 8th LIMS Conference, it was observed independently by both R.C. Collins [7] and J.H. Golden [8] that the matrix can be used to justify the spend on a LIMS on a cell by cell basis. The costs for each cell in the matrix can be calculated and the benefits quantified. This cost justification can be used to justify each cell of the matrix to senior management. It will enhance the efficient use of resources and avoid duplication of functions within an organisation.

However, this idea can be taken further. Fig. 7 shows as the LIMS is developed out of the operational level to the logistic and strategic levels and also into the organisation there is increasing benefit

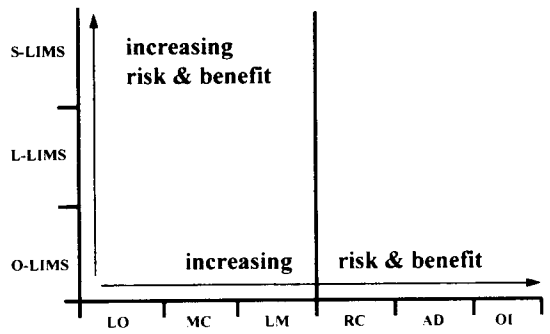

Fig. 7. The LIMS matrix, showing increasing risk and benefit the further the implementation moves outside of the laboratory.

but there is also a corresponding increase in the risk of the project. Therefore a combined cost justification and risk assessment can be made for each matrix cell.

Let us look at two examples of this approach. In the logistic LIMS level of the matrix corresponding to the organisation, communication is electronic, there is the ability to highlight out of specification results for the client for decision making, and to help organisational integration, clients can access their results remotely. Ideally, these first two functions will help communicate results to the clients and enable them to make effective decisions. The third will enable the client to access the LIMS to see the progress of their samples and avoid the need to phone the laboratory to enquire about progress. All functions are desirable to integrate the laboratory and the organisation. However, senior management is looking for a cost–benefit justification and an outline of the risks involved. Imagine two companies, one where information technology is well established and the second where use is not as successful as management would wish.

Scenario one would envisage an organisation with an existing network linking all functional groups. This is a key component for organisational integration and provides the medium to move information [1]. This organisation is relatively sophisticated in its use of IT with e-mail and on-line diaries available and used regularly. The main communications component, the network, is already installed. Therefore the cost–benefit justification will only require expenditure for the customisation of reports and the linkage of the LIMS with the e-mail system to transmit a report to the client, a relatively minor cost component. To highlight out of specification results, more programming would be required to place an asterisk to highlight an out of specification result. The final cell in this level of the matrix, requires external read-only access via the network to the LIMS data base. Security levels would be set up within the LIMS to prevent unauthorised users from changing results and roaming around the data base; this may require a customised data base view for each client or client group. With a network in place and working, the approach to implementation might be to authorise the communication cell and the organisational cell to proceed, with the ability to highlight out of specification results being implemented in the first place with the asterisk option. The risk assessment would be based upon a number of factors [9] but would be low. The reasons are that there should be little impact on the ways of working as the staff already tend to work using the network facilities. The use of the matrix builds on the use of information technology and requires relatively little capital investment to be made.

In contrast, scenario two envisages an organisation where information technology implementation is not always successful. A network is not in place throughout the organisation and requires investment. Here the cost–benefit justification and risk assessment are changed dramatically to implement exactly the same functions. A higher capital investment is required to put in place the network. There may be the need to retrain or hire staff to run the network. Users would need to change their ways of working to use the system effectively, thus increasing the risk to the success of the whole project. Here the prudent approach would be to implement an operational level of the LIMS matrix: hard copy reporting first and concentrate on getting the LIMS working within the laboratory. As a future phase of the project, a network investment to the client groups could be justified on a piece by piece basis.

This illustrates the combined use of cost justification and risk assessment that should be applied to the use of the matrix. It also requires an assessment to be made of the use of information technology and the maturity of staff within an organisation.

6. Organisational integration and LIMS

The use of information technology crosses functional boundaries: robots and other automation equipment are justified and used locally, however the impact of a LIMS is far greater as shown by the matrix. A LIMS has the ability to influence groups outside of the laboratory. This is shown in Fig. 8.

The operational LIMS has its impact mainly within the laboratory with little influence in the rest of the organisation. As discussed earlier in this article, this is the typical implementation seen in the 1980s. The logistic LIMS has its main impact on the functional groups that work closely with the laboratory. They

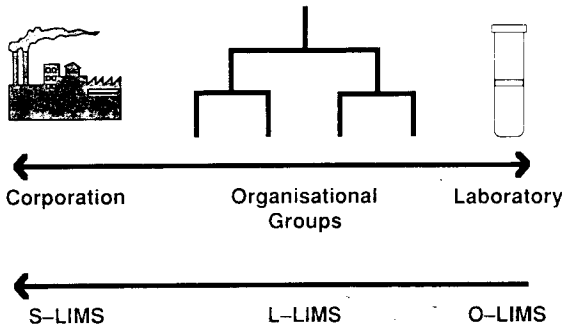

Fig. 8. The impact of operational, logistic and strategic LIMS.

are linked increasingly by electronic means which is fully realised with the strategic LIMS. The strategic LIMS has its greatest impact on the organisation as well as providing benefits to the laboratory and the client groups served by the laboratory.

The implementation of a LIMS with increasing logistic and strategic elements means that there will be greater impact on the organisational structure. In instances where this occurs, a question arises: which processes should be automated? Most LIMS automate the current ways of working. These have evolved over time, but may not be efficient or cost effective. Examples may be the way samples are received by the laboratory via multiple log books or several signatures are required to authorise a report. It may be prudent when considering such a system to consider re-engineering or redesign of the laboratory operations prior to automating them. This is a higher risk approach, but it can improve the overall efficiency of the laboratory and its client groups and may be better than simply automating the status quo.

The other element in the equation is the impact of the LIMS on the existing organisational structures. It may be that organisational changes are required when implementing either a strategic or logistic LIMS. If this has not been anticipated or thought out, this can make a high risk factor [9]. To avoid project failure due to this cause, an assessment of the impact of the system on the existing organisational structures is essential.

7. Conclusions

The aim of the LIMS matrix is to enable cost-effective laboratory information management systems to be designed and implemented. Furthermore, being able to visualise the overall scope allows definitive boundaries to be drawn and prevent creeping functionality inherent in so many systems. The matrix allows the full vision of an implementation that is achievable over time to be designed and phased.

However, the key to success in implementing a LIMS is not the technology but how successful you are in persuading people to change their ways of working.

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