

Health Information Strategy Action Committee

Action Zone 5 - eLabs

Preliminary Scope and Approach

This document has been developed in consultation with the sector and portrays the scope, principles, key enablers and implementation approach for this Action Zone at a point in time. It should be used as a reference to inform and guide business and technical decision making for initiatives related to this Action Zone.

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Vision

Diagnostic laboratory test ordering and reporting information is easily accessed and shared on a secure and timely basis.

Strategy

Standards-based, electronic systems are established to enable all appropriate health practitioners, laboratories and patients to appropriately and securely order laboratory tests, monitor the associated processes and securely access and share diagnostic laboratory test information.

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About this document

Action Zone document structure

The 2005 Health Information Strategy for New Zealand (HIS-NZ) identified 12 Action Zones as areas where effort should be focused over the next three to five years.

A '**Preliminary Scope and Approach**' (PS&A) document has been prepared for each Action Zone. The PS&A documents build the case for change, including benefits the sector can expect to achieve and suggest an approach to implement the change.

Each individual PS&A document should be read in conjunction with the "HIS-NZ Implementation Approach" (a PowerPoint presentation). It describes common themes that have emerged from the PS&A work, the key enablers that are necessary to support a common approach to information management, and the priority areas where HISAC and the Sector can assist with implementing the Action Zones.

Action Zone 5: eLabs

Action Zone 5, 'eLabs', is a Sector-wide approach to improving the quality of and access to, information about laboratory testing.

The scope of Action Zone 5 is limited to laboratory testing and excludes other forms of testing, such as radiology and endoscopy.

Constraints

This document focuses on community laboratories. The needs of other stakeholders will be addressed during a later engagement stage.

Acknowledgements

This document was influenced by the contributions of the health professionals listed in Appendix B and previous studies and papers as referenced in Appendix D.

Context

This document contains	This document does not contain
An overview of current information-based laboratory processes	Detailed definition of current state processes
A high-level definition of an 'ideal' eLabs system	Detailed system or process design
A summary of high-level requirements for eLabs	Detailed definition of user requirements
Identification of high-level standards required for eLabs	Detailed definition of the required standards
Components to be used in the evaluation of options during the next phase of Action Zone development	A set of evaluation criteria and options
An initial view of how progress with eLabs can be made across the health sector	A detailed implementation plan or cost benefit analysis

Executive Summary

Current situation

Laboratory testing process

The core laboratory testing process consists of:

- Health practitioners creating test orders and referring them to laboratories;
- Laboratories carrying out tests on samples; and
- Laboratories recording and reporting results to health practitioners.

Additionally, payment claims are sent by laboratories to HealthPAC and recorded in a data warehouse.

Laboratories and most health practitioners operate a variety of IT systems. Order forms and test results are transmitted as HL7 Version 2.1 structured content messages and PDF files through the health network.

Issues with the existing process are summarised below.

IT systems

The disparate systems used within the Sector hold information in different formats. This, together with limitations around the way records are transferred between systems, means that fields in patient records generally are not updated automatically in real time.

Challenges are exacerbated by a lack of decision support functionality and comprehensive coding standards and order sets to support test ordering.

The effects are that:

A patient's laboratory test records may be spread over systems in general practices, hospitals and laboratories and there is no way of presenting health practitioners with a complete patient record;

Test orders have to be transcribed from paper forms into laboratory systems, giving rise to data errors; and

There is little automated quality control to help practitioners select tests on a 'right first time' basis.

These issues waste time and resources and militate against an end-to-end process capable of improving efficiency and patient care.

Data access

Access to historical data across multiple organisations is largely limited to HealthPAC reports. There are no cross-Sector on-line reporting mechanisms.

Security and privacy issues

The current process gives rise to concerns over security and privacy issues, largely because of its dependence on paper forms.

Existing projects

Some of the many system development initiatives under way within the Sector fit within the ambit of 'eLabs'. Developments are in the areas of clinical decision support systems and electronic transfer of records and repositories. None of these developments are being undertaken on a Sector-wide basis.

Uncoordinated development (of what could be eLabs components) wastes money within the Sector and is unlikely to result in an effective, comprehensive, nationwide solution.

Moving eLabs forward

Future model

The ideal future eLabs model is one in which all laboratory-related information is stored, transmitted and accessed electronically.

This means health practitioners and laboratory staff having access to network-enabled IT systems and requires the introduction of consistent standards, processes and supporting systems.

Within this model:

- Practitioners would use an eLabs system embedded within their existing systems and incorporating decision support functionality. The system would create orders from a standard, code-driven schedule;
- Orders would be transmitted, probably via some form of repository or 'post office'¹, to a laboratory. The Health Network would be 'upgraded' to allow data-field records to be transmitted, based on messaging standards;
- A laboratory system might receive orders automatically or pick them up from the repository/post office, probably by scanning a bar code from a paper form. The orders would automatically populate the laboratory systems' patient records;
- Laboratory staff would record results against their system's patient records;
- Results would be sent to practitioners in a standard format for automatic update to their systems;
- Practitioner systems would acknowledge receipt of the result; and
- Practitioners would be able to check whether significant tests had taken place.

The overall 'system' would maintain a store of historical data for use (within privacy and security rules) by patients, practitioners and researchers.

Conceptual Design

At a technical level, eLabs will be an interacting set of telecommunications networks and IT applications (such as practitioner, laboratory and decision support systems).

The technology solution should be set within Action Zone 12 (the 'Anchoring Framework') but the overall solution must:

- Guarantee security and disaster-recoverability of patient data;
- Work on an 'always on' model (that is, participants' systems always running and connected to a Network);
- Continue to operate if individual components are turned off or unavailable.

These systems would operate through a series of technical and interoperability standards that would allow connectivity with systems used through the Sector.

Some of these systems currently exist, some are under development (often in more than one place) and some may have to be acquired. Their main components are discussed below.

Connections

Figure 1, below, illustrates the interoperability and connecting components needed to make the eLabs concept work.

¹ A 'post office' would hold records temporarily prior to routing them to a specific organisation. A 'repository' would do the same job but retain the records in a permanent store.

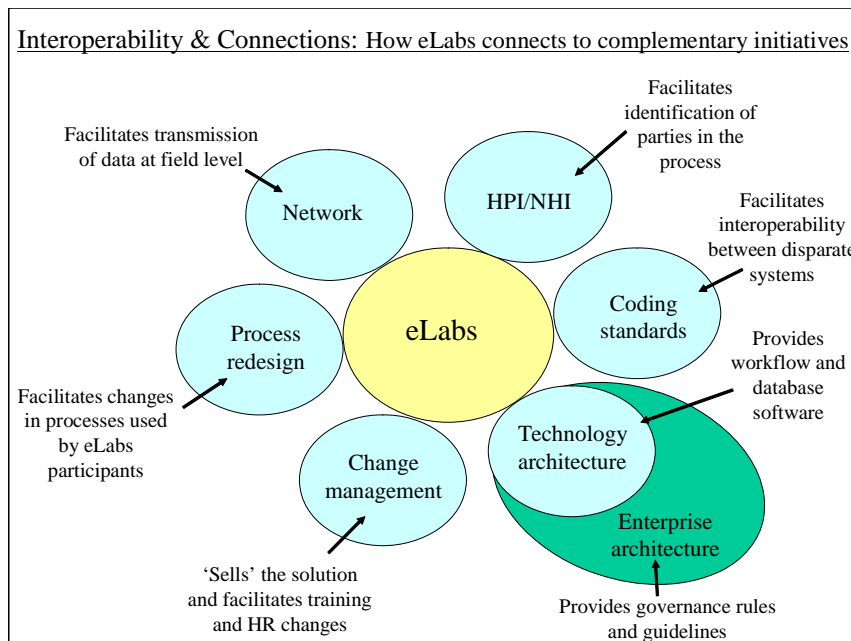


Figure 1: eLabs - interoperability and connections

Coding standards

Standards and codes will be needed in the following areas:

- On-line laboratory test order schedules;
- Inclusion of relevant NHI and HPI data on all transactions;
- An HL7 (or similar) communications interface;
- A standard 'menu' comprising laboratory test terminology standards and schedules;
- Standard laboratory codes. (While HISO has decided that the LOINC subset NZPOCS will be used in New Zealand, its implementation and the role to be played by standards such as SNOMED), needs to be addressed; and
- A two-dimensional bar code capable of carrying identifier and test data, if required, on paper orders.

Implementation approach

Key Actions to achieve the eLabs strategy may occur in phases. The shape and timing of phases would depend on the architectural model advanced under Action Zone 12, the Anchoring Framework.

Implementation may require the development of interfaces to and amendment of existing health practitioner and laboratory systems.

Some new technology may also be needed. No assumption is made in this document about how such technology will be acquired. It is likely that it will come from existing or future initiatives run by specific organisations in the Sector.

Key Action phases

Figure 2 is an *example* of how phases could be organised. In this example:

- Phase 1 is based on the use of bar codes (on paper orders), capable of identifying health practitioners and patients and providing details of test orders. The bar codes would be scanned into laboratory systems;
- Phase 2 could automate the transmission of test order information between practitioners' systems and laboratory systems, with data transmitted via some form of regional repository;
- Phase 3 could see the transmission of data fields such that 'receiving' IT systems could be updated automatically;
- Phase 4 could see the introduction of functionality that allows

authorised parties access to historical data derived from repositories. Further phases could introduce advanced functionality, depending on the overall technology direction set in Action Zone 12.

The definition of the appropriate standards would occur as a parallel activity over phases 1 to 4.

Figure 2 below illustrates how the different phases might look.

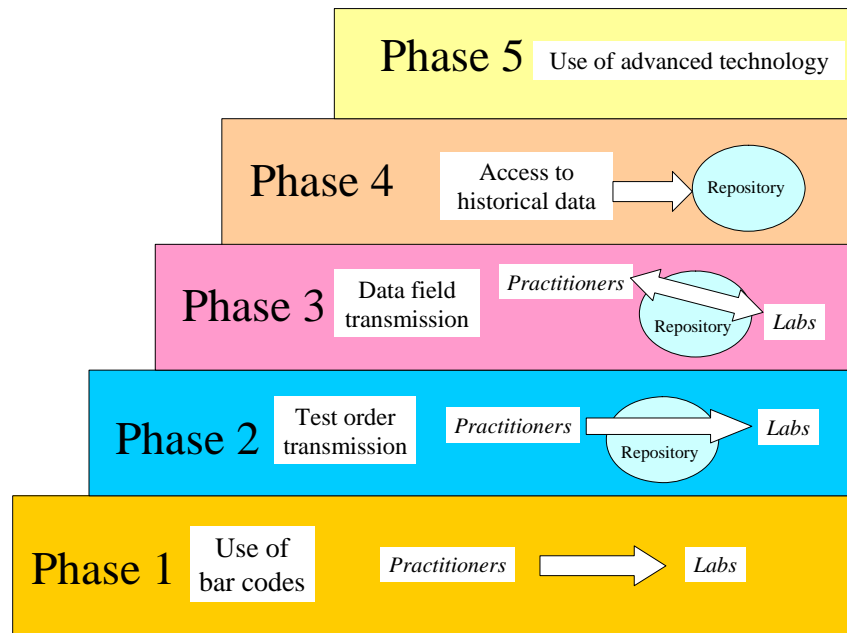


Figure 2: eLabs Key Action implementation phases

Stakeholder Benefits

An eLabs system would primarily bring benefits to laboratories, by reducing costs and errors, which mainly result from order forms and samples becoming separated. Health practitioners would derive benefits from reduced errors.

Further benefits will result from the inclusion of testing information as part of an 'eHealth' system, as the aims of HIS-NZ are realised.

Gains from improved efficiency will benefit the government by improving its return on health investment.

Next steps

'Evolution not revolution'

The introduction of eLabs may be an evolutionary process. Participants will be able to take up new functions in phases and the overall timing will depend on the availability of technological components for deployment.

Progressing eLabs

The steps needed to progress the eLabs Action Zone are:

1. Circulation of this report and a request for Sector support;
2. Definition of an eLabs application architecture, based on Action Zone 12 and including evaluation and selection of those eLabs system components that can be sourced from current Sector systems and projects;
3. Preparation of a costing model and a business case for any eLabs components that require funding;

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4. Formation of an eLabs development steering committee; and
 5. Initiation of an eLabs project that encompasses technology, standards development (via HISO), clinical and business process redesign and change management.
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1 What Happens Today

1.1 Current situation

Introduction

eLabs is based on:

- 'Workflow' (a term which can refer to IT software and/or a set of steps within a process) which:
 - Routes documents between people and teams;
 - Records, tracks and schedules activities; and
 - Delivers prompts and alerts to users.
 - Enables on-line data analysis by regional and national bodies for purposes of clinical research, planning and funding.
-

Workflow

The laboratory testing process primarily covers:

- The creation of test orders by a health practitioner (usually during a patient consultation);
- Referral of the orders to a laboratory; and
- Recording and reporting of results by the laboratory.

Currently, the process is a mixture of manual and IT-supported processes, which varies from place to place. A typical process for community laboratory testing is:

- A GP enters test details into a Practice Management System (PMS)²;
 - The PMS prints a laboratory test request form (probably featuring a bar code) which is usually given to the patient;
 - The laboratory test request form is presented to the laboratory by the patient or is faxed or posted to a laboratory collection centre;
 - A nurse or technician (located in a GP surgery, hospital ward or laboratory) takes a sample from the patient;
 - A laboratory nurse or technician transcribes information from the request form into the Laboratory Information System (LIS);
 - The sample is analysed in the laboratory;
 - Test results are entered into the LIS and despatched on paper or electronically, via the HealthLink system to the GP's PMS;
 - Results are copied if necessary to other practitioners and (usually on paper) to residential care facilities;
 - The laboratory creates a report of completed tests and sends a payment claim for subsidised tests to HealthPAC for payment; and
 - Details of all claims are added (by the Ministry of Health's IT group) to a laboratory data warehouse, 'LabHouse'.
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Data Access

A need for access to laboratory-related data can come from:

- Checks by health practitioners or laboratory staff on tests performed for specific patients (including tests that might have been ordered by other practitioners and locums); and
 - 'Data analysis' by parties interested in using databases to derive information about health trends, performance of specific health initiatives and so on.
-

² Practitioners use a variety of systems, including PMSs in GP surgeries and Clinical Information Systems (CIS) in hospitals. A minority of GPs have no IT system.

In addition, there could be opportunities to allow patients in self-management programmes to have limited access to their records.

Currently, the processes are:

- Patients wanting information must generally try to obtain it from their practitioners: there are few online channels³;
 - Practitioners and/or laboratory staff may be able to provide information by accessing their own IT systems and in some cases, IT systems operated in other regions. The information won't necessarily represent a patient's entire testing history;
 - Aggregation of data for analysis purposes is performed within DHBs and the 'LabHouse' data warehouse.
-

1.1.1 Current systems

Introduction

In addition to cross-Sector systems, a number of specialist systems are used within the laboratory process. These are described in the following paragraphs.

Laboratory Information Systems (LIS)

LISs deployed in hospital and community laboratories manage order registration, specimen processing and report generation. They are designed specifically for use in high volume laboratory processing environments and interface with robotic specimen 'analysers'.

The main LIS vendors in New Zealand are:

- Sysmex: the Delphic LIS system is used in hospital and community labs. In its 'Multilab' guise, it can be used as a regional system, allowing parts of the testing process to be performed in different locations;
- Affinity LAB's Détente system which, in New Zealand, is only used in hospitals;
- Lab Solutions, a system only used in community laboratories;
- IBA Health;
- Triple G, a hospital and community laboratory system; and
- Galen, a hospital-only system.

There are also some 'home-grown' systems.

National Cervical Screening Programme (NCSP) Register

The NCSP Register, operated by the Ministry of Health's National Screening Unit (NSU), holds information on cervical smear tests and biopsy results for women enrolled in the programme. It provides programme management features, including a back-up system to check that women have received follow-up investigation and/or treatment following an abnormal test result.

The Register system is being redeveloped to allow the (currently) eight laboratories, which process smear tests to submit results through an electronic interface. The system will check transactions (issuing an error code if necessary) and update the register. Test orders will be recorded and results matched against orders.

The new system is based on an Oracle database with a workflow and rules engine. Expected to be operational from July 2007, it will be consistent with the eLabs strategy.

³ BPAC NZ is currently promoting www.labstestonline.org for the provision of basic information.

New Zealand Cancer Registry

The New Zealand Cancer Registry is a population-based register of all primary malignant diseases diagnosed in New Zealand, excluding squamous cell and basal cell skin cancers.

Data is used in research, monitoring and evaluating cancer-screening programmes. Tumours are classified using the WHO International Statistical Classification of Diseases and Related Health Problems (ICD), and the WHO International Classification of Diseases for Oncology (ICD-O).

The NSU is currently tendering for replacement of the existing system.

Other initiatives and projects

In addition to the systems referenced in this document, many development initiatives are under way within the Sector. Typical of these initiatives are⁴:

- BPAC's development of a clinical decision support system;
- 'Testsafe', an eLabs system operated by Health Alliance Ltd. for the Auckland, Counties Manukau and Waitemata DHBs. The system uses a regional laboratory tests repository based on Éclair (from Sysmex Delphic Ltd);
- HealthLink's Quantum ordering system, which allows GPs to order tests from community laboratories;
- An eLabs interconnectivity project run in Auckland by East Health Services Limited and Diagnostic Medlab Limited; and
- The New Zealand Health IT Cluster-sponsored 'Microsoft Collaborative Health Showcase'.

Many of the country's DHBs are implementing or planning regional results repositories, which could be assessed and incorporated into the eLabs system.

1.2 Areas for Improvement

Introduction

The eLabs Action Zone will take advantage of opportunities presented by technology in order to enhance patient care and reduce administration and compliance costs.

This will involve overcoming challenges inherent in the existing process, which are summarised in the following paragraphs.

Systems

The challenge arises from a lack of interoperability between the disparate systems used within the Sector and the fact that the systems hold information in different formats.

An individual's electronic laboratory test records may be spread over systems in general practices, hospitals, laboratories and HealthPAC's claim information database. There is no easily accessed 'common view' of all this information.

Some initiatives, such as Health Alliance's 'Testsafe', are automating the transmission and sharing of laboratory testing information. Elsewhere, however, lack of interoperability between systems prevents primary and secondary care organisations from sharing laboratory testing information. 'Audit gaps' and a lack of 'quality loops' between systems are barriers to the coordinated management of patient care.

This affects practitioners, patients and anyone interested in demographic-type information.

The impacts are:

⁴ This list is not exhaustive.

- Health practitioners who can't access a patient's laboratory test/result history may order repeat tests, wasting time and money⁵;
- Patients presenting at hospitals could be kept in a ward overnight while repeat tests are performed;
- Delays in obtaining test results could affect patient care; and
- Opportunities to use demographic information for research purposes are limited.

A solution will provide interoperability between all IT systems involved in the Sector's laboratory processes and make patients' test information accessible to interested parties, subject to security, ethics and privacy rules.

End-to-end patient processes

The challenge is that the lack of interoperability between systems also stops primary and secondary care organisations from sharing laboratory testing information.

This affects all parties in the process.

The impact is that 'audit gaps' and a lack of 'quality loops' between systems are barriers to the coordinated management of patient care:

- Practitioners estimate that between 5 and 30 percent of patients lose forms or neglect to 'follow through' and have tests done. There are no automated ways to advise practitioners, who find it impossible to check 'non-adherence'⁶ issues manually; and
- Although test results are generally transmitted electronically to GPs and hospital specialists, other practitioners, such as midwives, experience delays in getting results.

An associated issue is that some lab orders (as many as 30 percent, according to a manager in one laboratory) are copied to someone else, e.g. to get second opinions from specialists or to inform family planning groups.

A solution will connect all systems in the end-to-end process in such a way that information can be shared as appropriate, systems can be updated automatically and doctors can be advised if patients don't follow through when significant tests aren't performed as ordered.

Decision support systems

The challenge is a lack of integrated, electronic, clinical decision support systems to assist health practitioners with test ordering.

This affects practitioners, laboratory staff and (indirectly) patients.

The impact is that current systems don't help practitioners to select appropriate tests in response to specific patient conditions and:

- Laboratories waste time and effort detecting shortcomings and calling practitioners to correct or clarify orders; and
- Opportunities to enhance patient care (for example, by ensuring that all appropriate tests are performed) can be missed.

A solution will incorporate optional DSS functions in PMSs and hospital ordering systems (and possibly LISs, if laboratories want to use the system). The DSS could:

- Pre-populate data fields on an online order 'form';

⁵ No statistics are available for the number of tests that are needlessly repeated. Laboratory managers vary in their opinions on this subject, with some saying that the number is low and others maintaining that the incidence of unnecessary repeat tests (and the associated costs) is very high.

⁶ This raises an (as yet, unresolved) issue of legal liability: if practitioners know (or should have known) that patients are missing vital tests, could they be held responsible in law?

- Provide a choice of standard order sets;
- Prompt practitioners to select tests (depending on information entered into the practitioner's system about a patient); and
- Caution against inappropriate tests.

This sort of system will only work if it's 'smart'. E.g.:

- It should be up to the user to decide whether to use it. (It will be most valuable when a health practitioner is dealing with a rare or unusual condition);
- It needs to be able to 'zero in' on likely tests rather than require the user to select from the 3,000 or so tests currently available;
- It might also need to take account of the way a practitioner has treated a specific patient in the past when making its 'recommendations'; and
- It must not attempt to force the practitioner to take a particular course of action.

This new-look DSS system will also depend for its success on consistent standards, some of which are referenced as general requirements in this document. Additionally, patient records will need to include consistent codes to allow decision support systems to apply rules and make decisions about them. (E.g. a consistent way to represent patient weight or chest pain.)

The use of the HL7 Clinical Document Architecture (CDA) might be appropriate, as well as the coding standards for clinical states such as ICD9 and 10 and SNOMED.

Double entry of data

The challenge is that, although most GPs can print test orders from their PMSs, there is no automatic transmission of soft copy orders to laboratories. Laboratories re-enter information manually from the hard copy test orders (which are usually in a variety of formats) into their own systems.

This affects laboratory staff and (indirectly) patients.

The impacts are:

- The process is inefficient and prone to transcription errors, estimated by one GP as occurring in one to two percent of cases;
- Errors tend to occur in patients' details, such as dates of birth, and GP identifiers; and
- An associated issue is that forms and samples sometimes get separated.

These impacts waste the time of laboratory staff and health practitioners.

A solution will involve doctors selecting tests using standardised terminology via a DSS (refer above). This system will facilitate:

- Tests being sent directly to a laboratory or to an online repository/'post office'; and
- Laboratories picking up test orders electronically (with an automatic update of the LIS data).

Note that laboratories will probably still want to have a paper record sent with a sample for testing, to help identify the sample.

Standards

The challenge is a lack of standards and common approaches in the laboratory testing process, including:

- Common 'language', test order forms and communication protocols;
 - An electronic laboratory test schedule or catalogue; and
 - Lack of agreement about whether clinical data repositories should be
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held at local, regional or national levels.

HISO has set standards in three areas but they are yet to be implemented. Standards for microbiology, cytology and anatomic pathology are yet to be addressed.

This affects all parties.

The impact is that solutions to the other problems listed here cannot be implemented.

A solution will involve all systems used within the testing process communicating to common standards.

Data access

The challenge is that there is inadequate and untimely system-based reporting on all aspects of laboratory testing in terms of clinical quality and population health. ('LabHouse' only contains charging data sent from laboratories to HealthPAC and does not meet Sector requirements for easy access to all relevant testing data.)

This affects local, regional and national bodies (such as DHBs, PHOs and MoH).

The impacts are:

- The Sector is limited in its ability to target resources to those most in need;
- Health practitioners are unable to access population-based information, such as percentages of people in particular segments who are getting cholesterol tests and how this compares with national norms; and
- The potential for getting the best health outcomes from finite health resources is reduced.

A solution will involve test-related data being loaded to a database as soon as possible after it is created and then made available to authorised parties for data analysis purposes.

Security and privacy issues

The challenge is that the quality of current processes for security, privacy and disaster recovery planning gives rise to concern. E.g.:

- Communication of test orders and (to a lesser extent) results is largely paper-based, and thus inherently insecure;
- IT systems are currently being managed by staff within health practitioners' offices as an adjunct to their normal tasks. This raises questions over the quality of processes, such as:
 - Security and privacy enforcement (such as the quality and currency of firewalls, anti-virus and anti-spyware agents); and
 - Disaster recovery planning.

These issues, while not strictly part of eLabs, have the potential to impact adversely on all systems, including eLabs.

This affects all parties in the process.

The impact is that current and future systems could be placed at risk.

A solution will incorporate the means to secure IT systems wherever they are used.

In practice, the best level of security can only be achieved through professional system management. One way to achieve this could be by implementing all systems on a 'thin client' architecture.

This could require a major change to existing systems. For the foreseeable future, the Sector may need to operate on a 'next best' model. This model may be a 'code of practice' or operating instructions to be provided to IT

system users.

Lack of nationwide approaches

The challenge is that uncoordinated development of eLabs components wastes money within the Sector and is unlikely to result in an effective, comprehensive, nationwide solution.

Currently, various organisations are developing eLabs components such as decision support and workflow systems. These organisations usually operate on a regional basis, although a 'mini eLabs' system is currently under development for the National Cervical Screening Register.⁷ Elsewhere, work is being done on the development of clinical decision support systems, for example within Dunedin's Best Practice Advocacy Centre (BPAC).

This affects all parties.

The impact is a loss of opportunities to develop eLabs in as short a period as possible, as cost-effectively as possible.

A solution will involve a single, nationwide approach to developing an end-to-end eLabs system. This approach could include the development of specific components by individual organisations.

Funding

The challenge is that changing existing systems to accommodate eLabs requirements may be expensive. (One community laboratory estimates that adding a single data item to their system could cost as much as \$100,000.)

This affects all parties.

The impact is that eLabs will not succeed without adequate funding.

A solution will involve a funding model that covers all system (and other) changes required to implement eLabs.

⁷ This development – due to become operational in mid-2007– is being carried out by the NSU.

2 Achieving the eLabs strategy

2.1 Key Features of the Strategy

The Strategy

The eLabs strategy is:

Standards-based, electronic systems are established to enable all appropriate health practitioners, laboratories and patients to appropriately and securely order laboratory tests, monitor the associated processes and securely access and share diagnostic laboratory test information.

Introduction

Achieving the eLabs strategy will involve all laboratory-related information being stored, transmitted and accessed electronically. This will result in health practitioners and laboratory staff having access to network-enabled IT systems and will require the introduction of consistent standards, processes and supporting systems.

The introduction of eLabs will be an evolutionary process. Participants will be able to take up new functions as and when it suits them and overall timing will depend on when technological components are ready for deployment.

Practitioners

For practitioners who order laboratory tests and receive results, eLabs should be embedded within their PMSs or CISs to:

- Create orders via a clinical decision support system and 'reference' data. The 'reference' data should include relevant NHI and HPI information and a schedule of available tests rendered via a 'smart checklist' function. The 'smart checklist' should show specific tests, based on information entered into the system, rather than the full list of around 3,000 tests available in New Zealand;
- Transmit an electronic order to a repository and/or directly to a laboratory (probably with a paper copy accompanying the sample);
- Alert the practitioner if a result is available from a previous (recent) test;
- Allow dialogue with laboratory staff who might wish to query details of the order or suggest additional tests;
- Capture results and transmit them back to the PMS/CIS, with automatic updating of fields within patients' records; and
- Allow practitioners to check whether significant tests (that is, tests that, if missed, could have a serious effect on a patient's wellbeing) have taken place.
- Paper copies of order forms could feature a two dimensional bar code⁸ which:
 - Uses NHI and HPI 'serving mechanisms' to identify patients and practitioners; and
 - Specifies the test(s), which need to be performed.

The process should allow for test samples to be taken somewhere other than in a laboratory and delivered to the laboratory. The process should also allow patients to select a laboratory or sample station of their choice (although patients in some regions have little choice).

⁸ A 'two-dimensional' or '2-D' bar code stores information in the horizontal dimension – a set of stripes like those on supermarket products – and the vertical dimension. In the latter, the vertical 'bars' host symbols, which store information. The paper document containing the bar code should also bear the patient's printed name as a double-check that test orders are correctly matched to specimens.

Laboratory staff

For laboratory staff who process tests and record and transmit results, eLabs should eventually operate within their LIS and allow them to:

- Pick up test orders either from a physical form (such as a bar code) or from an electronic repository or 'post office'. 'Picked' orders should automatically populate a patient record within the LIS (that is, add/update information for each data item within the record);
- Record results against their LIS-based patient records;
- Send results automatically to practitioners in a standard format (directly or through a repository);
- Check that results have been received; and
- Route automatic requests for payment to HealthPAC.

The system will allow laboratory staff to lodge electronic queries, e.g. if they think further tests should be carried out, to the practitioners' system. The system must, however, prevent one organisation from gaining unauthorised access to another's system.

Patients

The eLabs system could enable patients in self-management programmes to access their own test records on-line, subject to authentication and security rules.

Researchers

eLabs should provide access to all tests carried out anywhere in the country. Access by organisations for research purposes should be subject to appropriate authentication, ethics and security rules.

Access by researchers to individual data records, especially those that identify patients, would be tightly controlled.

National Cervical Screening Program processing (NCSP)

Under an eLabs regime, laboratories should be able to:

- Download 'their' test orders from the NCSP register;
- Access patients' smear histories on-line from the NCSP register (unless patients exercise their rights to 'opt out' of the process); and
- Examine the test code for each test and if appropriate, route the result to the NCSP register.

Result messages will be received and uploaded into the NCSP, using the NHI to identify the patient.

If there are issues with the test result data or the patient details, the data entry operator will be able to contact the laboratory or the smear taker to resolve them.

NZ Cancer Registry processing (NZCR)

HL7 formatted files will be collected from the NZCR mailbox for processing by an operator who will upload the file. The file will be verified automatically using the NHI.

2.2 Conceptual Design

Introduction

Much of the technical design for an eLabs 'system' (leaving aside the current health practitioner and laboratory systems) will arise from design work in Action Zone 12, the Anchoring Framework. Action Zone 12 should comprise a communications system that can store transactions (probably in some form of logical repository) and route them between application systems.

In their Initial View for Action Zone 12, HISAC commits the Sector to develop and implement a framework for the identification, prioritisation, coordination and oversight governance of development of key enablers for information sharing and interoperability within the health and disability

Sector, including (but not limited to) standardised architectural and data models, business processes, information technologies and usage principles and policies.

These Key Features, relating to the flow of health information around the Sector, include:

- The Health Information Hierarchy, which is a model for shared distributed health information, including principles and conceptual architectures for information capture and sharing;
- Health Event Summaries, related to individuals' and patients' health care events, are the starting point for improved information sharing across the Sector;
- The Interoperability Framework defines the standards, policies and information specifications enabling meaningful, secure, consistent, reliable and cost effective capture and sharing of information.

The combination of systems will allow messages to be passed between properly-authorised people and organisations and will:

Transmit messages in a standardised, field-based format, probably using a version of HL7;

Check that events happen as expected and (possibly) raise alarms in appropriate exception conditions; and

Store information in historical records for access by authorised people and organisations as and when required.

The main additional system requirement for eLabs will be a decision support system.

Some of these systems currently exist, some are under development (often in more than one place) and some may have to be acquired.

Taken as a whole, the various systems will allow testing-related messages to be passed between authorised people and organisations in the Sector.

Components of the potential design solution are discussed below.

Workflow

The eLabs strategy is one in which the workflow process, from test ordering through to reviewing of results, operates electronically. The system should require a minimum of manual intervention and its standards-based approach should promote accuracy.

In addition to the general Key Features, above, the overall system should:

- Provide health practitioners with on-line access to patients' past results (including those from other practitioners in primary and secondary care);
- Advise a practitioner if a current/valid test result is already available;
- Match specimens to orders via a barcode;
- Allow variations, including the use of paper-based orders. In the case of paper orders:
 - Electronic versions of the order should still be sent to the repository and/or laboratory;
 - Paper orders could contain 2-D barcodes; and
 - Laboratories will scan bar codes into their systems in order to download orders from a repository or 'post office'.

There should also be links between eLabs and the other solutions implemented through the HIS-NZ Action Zones. E.g. pharmacists may use the ePharmacy system to check that certain lab tests have been done before they dispense certain drugs.

**Data storage/
access/analysis**

Data generated in the overall eLabs process should be available to multiple parties. Users will, depending on their access privileges, have a 'local', 'regional' or 'national' view of data. Features of the system will include:

- Sector organisations and practitioners will have access to relevant results for patients, irrespective of who ordered the tests;
 - Funding agencies, purchasers and planners will have (appropriate) access to well-structured data for management reporting and research; and
 - DHB-based analysts will be able to review regional results repositories using NHI, HPI and LOINC/NZPOCS-style codes in order to conduct research and identify 'outliers'. (See Appendix E for an explanation of LOINC and NZPOCS codes.)
-

Repository/'post office'

In essence, a 'post office' holds records temporarily prior to routing them to a specific organisation. A 'repository' does the same job but retains the records in a permanent store.

Some sort of 'repository' or 'post office' will be needed where the destination of a test order is not known, e.g. in a region where there are multiple laboratories. Where orders are always sent to one laboratory, a repository might not be necessary, but the laboratory system will need to store incoming test orders until they are ready for processing.

A repository model could:

- Identify patients and practitioners by reference to their NHI and HPI records;
- Store patients' complete laboratory result histories;
- Allow health practitioners and health workers access to all test results of all patients, within a set of rules for the management of personal information. The latter would include security, ethics and privacy rules and allow for all accesses to be logged and recorded;
- Provide input data to decision support systems; and
- Make event summaries available to health practitioners and possibly, patients in self-management care programmes.

eLabs data should be available for analysis at local, regional and national levels. The system should facilitate longitudinal access to individual and aggregated patient records within an agreed privacy, authentication and security framework, for both clinical care and (with safeguards against patients being identified) for health planning.

These concepts are 'logical' in that they describe how a system might appear to a user. The actual design of a post office/repository structure will need to be addressed.

The 'national versus regional' repository issue is not necessarily restrictive to eLabs' conceptual design. If the physical implementation involves regional repositories, eLabs will 'expect' an automatic link to operate so that repositories can be accessed as if they were one logical entity.

Other features

A future eLabs system should have embedded, automatically updated test terminology standards (appropriate to New Zealand) and a schedule to facilitate test ordering and reporting.

The system should also feature:

- On-line reviewing and monitoring of test ordering and reporting;
 - Provision for participants to opt for paper-based documents at any point within the process;
 - Electronic receipting of authenticated test orders at laboratories with
-

(optional) confirmation to the health practitioner that a test order has been received by a specific laboratory.

Technology features

In addition to the technology architecture to be provided from Action Zone 12, a future eLabs system must provide disaster-recoverability of patient data. It must also work on an 'always on' model (that is, participants' systems always running and connected to a network) but continue to work correctly if a component is unavailable.

Refer to Appendix C for a summary of IT system 'building blocks' for eLabs.

2.3 Standards & Policies

Introduction

Implementation of eLabs will depend on the use of standards by all parties throughout the process. The standards will ensure that:

- Systems can communicate with each other;
 - Processes can be made as error-proof as possible; and
 - Data can be accessed and used irrespective of where it is held.
-

Identifiers

The NHI and HPI will be standard requirements in the eLabs process.

Codes and schedules

Standards and codes will be needed in the following areas:

- On-line laboratory test order schedules; and
 - Standard laboratory order/test and result codes. HISO has decided that the LOINC subset NZPOCS will be used in New Zealand. Implementation of NZPOCS (and the role to be played by standards such as SNOMED) will need to be addressed.
-

Messaging

The eLabs system will require an HL7 version to be specified and NZ-specific standards for message segment and field content to be implemented for:

- A laboratory order message standard; and
- Test results and coding.

Messaging protocols must allow information to be passed and stored at the data field level.

System use

A set of standards and guidelines for use of the system, including interfaces with vendor systems, should be developed.

Other standards and policies

eLabs will depend on use of laboratory test terminology standards and schedules.

Requirements for standards to govern security, privacy and so on will be outlined.

2.4 Linkages to other action zones

Introduction

The eLabs implementation will occur within the overall Action Zones context. The other Action Zones can be divided into categories:

1. Enabling and Information Anchoring Action Zones (1, 2, 3, 11, 12) contribute to the technology framework that will eventually be implemented for HIS-NZ.
 2. Action Zones 4 through 10 provide functional solutions to improve
-

patient care and operational efficiency.

3. Action Zones 7, 9 and 10 deliver care and collect information for national purposes, including analysis and research.

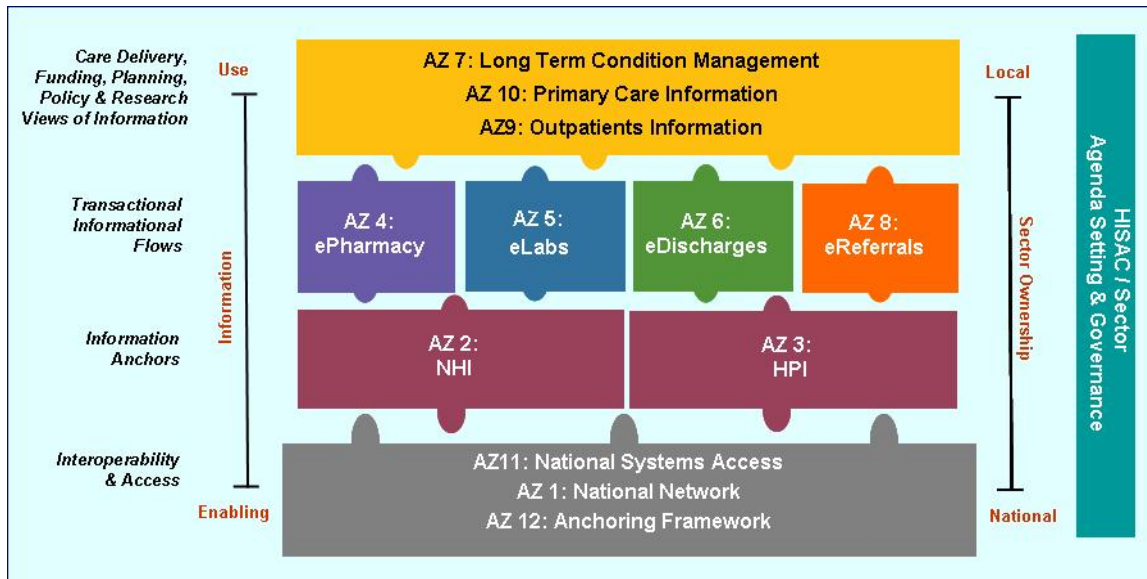


Figure 3: Action Zone 'jigsaw' diagram

Action Zones 4-10

These Action Zones will be implemented through a combination of:

- Standards;
- Existing systems deployed in the Sector;
- Information and Communications Technology (ICT) projects (which may be existing or new Sector initiatives and may involve the development of new IT/network systems or the modification of existing systems); and
- Change management/process redesign projects (such as changes to the way doctors order tests).

All Action Zones should share technology solutions wherever possible.

Cost benefit analyses will be addressed in later stages, as the technical solutions become more clearly defined.

Enabling and Information Anchoring Action Zones

Action Zone 12 (refer to the section on Conceptual Design) will establish much of the infrastructure required for eLabs, work on the following Action Zones will also affect implementation:

- The National Network Strategy (Action Zone 1), National Systems Access (Action Zone 11) and the Anchoring Framework will address these issues:
 - What standards and mechanisms will apply for messaging between organisations?
 - What (if any) data repositories will be needed (locally, regionally or nationally)?
- The NHI Promotion (Action Zone 2) and HPI Implementation (Action Zone 3) initiatives will facilitate all Action Zones by providing a 'serving mechanism' to identify and authenticate patients and health practitioners.

3 Key Actions

Introduction

Action Zone implementation will occur in phases. At a technical level, in the case of eLabs, it will be based on the acquisition of some new technology and interfaces to and amendment of existing health practitioner and laboratory systems⁹ Refer also to Appendix C.

The development of the necessary standards will be achieved involving HISO.

It is difficult to say how each of the eLabs implementation phases will look until more analysis is performed (during later stages of Action Zone development). What follows is a proposed version of how eLab phases could be organised. This model may differ from the final version.

Phase 1

eLabs phase 1 could be based on the use of 2-D bar codes on paper orders. The bar code could be used to store identification data, such as NHI and HPI and specified tests.

Phase 1 could function as follows:

- Practitioners would enter test order information into their IT systems as at present;
- The systems would print order forms as at present, with the addition of the 2-D bar codes; and
- Paper forms would be delivered to laboratories, as at present and laboratory staff would scan the 2-D bar codes directly into their systems.

This approach would bring benefits in terms of:

- Avoiding the need for laboratory staff to enter data manually; and
- Reducing 'dual-handling' errors; and
- Reducing the NHI discrepancies¹⁰.

Phase 1 would incur some costs. Implementing phase 1 would require changes to:

- Practitioners' IT systems, to allow them to print forms containing the 2-D bar code; and
 - Laboratories' systems, to allow them to scan data from 2-D bar codes directly into their systems. Laboratories would also need to acquire scanners to read the bar codes. The purchase of readers could be expensive as the devices can cost \$1000 each. The largest of the country's laboratories would need to buy up to 80.
-

Phase 2

Phase 2 could automate the transmission of test order information between practitioner and laboratory systems. Data in this phase could be transmitted as an EDI/PDF record, as in the existing Healthlink record. Transmission may be via a repository.

'Copy to' requirements for test orders could be met in this phase by, e.g. a repository system intelligently forwarding orders to 'copied in' practitioners and then 'remembering' what it did so that it can also copy results. Users would need discretionary rights over how any copying mechanism is applied.

⁹ No assumption is made in this document about how new technology will be acquired. It is likely that it will come from existing or future initiatives run by specific organisations in the Sector.

¹⁰ Most discrepancies originate in general practices. One major laboratory estimates that up to 100 NHI discrepancies can be encountered every day. Each can take as long as three hours to resolve.

Phase 3

Phase 3 could involve the introduction of networking technology that would allow data fields to be transmitted to and from laboratories, e.g. a test 'record' transmitted from a PMS to a LIS would contain a patient's NHI, the HPI and codes to identify the tests being ordered. This would allow data fields within the 'receiving' IT system to be updated automatically.

Phase 4

Phase 4 could involve the introduction of functionality that would allow authorised parties access to a store of historical test data. This could be some sort of 'logical' national database comprising linked regional repositories.

The eLab system, as a result of these phases, could be represented as in Figure 4.

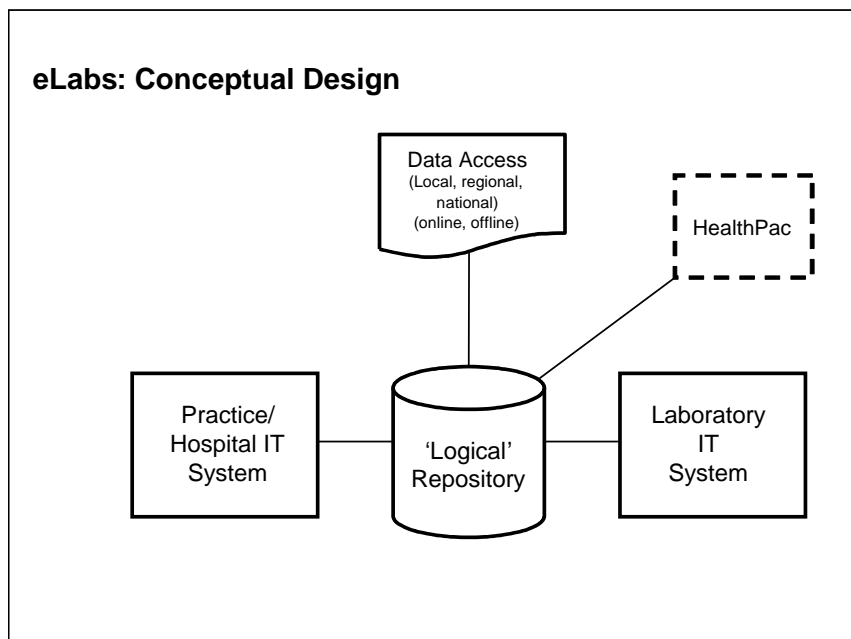


Figure 4: eLabs Conceptual Design

Change management

Some issues specific to eLabs, mainly concerning data ownership and patient/public representation, will need to be addressed. These arise out of the complexities involved in sharing clinical details, e.g. whether tests for sexually transmitted infections ordered by a Family Planning Clinic should be shared with a GP.

eLabs implementation will need to address these issues.

4 Stakeholder Benefits

4.1 Benefits

Moving eLabs forward

The diversity in the Sector's capability and use of information systems has been represented with the 'thermometer' diagram, below.

eLabs will initially lift the capability of Primary Care and Secondary Care organisations towards the Target Future State.

Improvements in the areas of Long Term/Residential Care or Community Organisations will probably be achieved in phases 3 onwards.

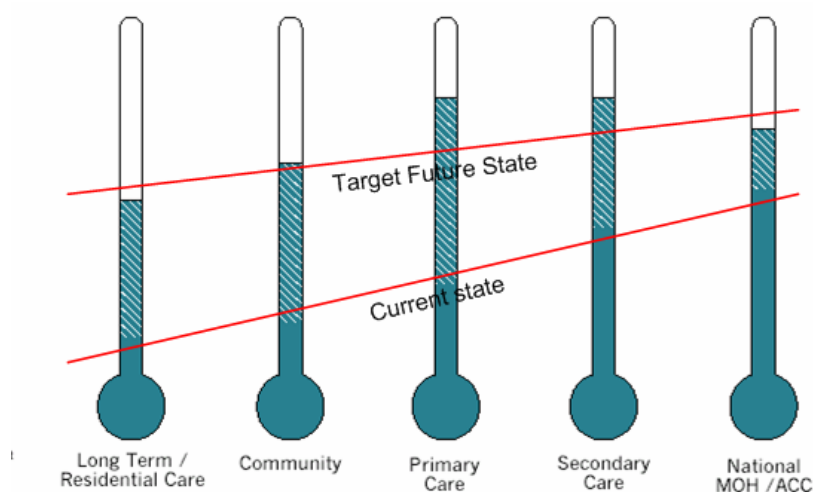


Figure 5: Health Sector information use 'thermometer' diagram

Patients

The benefits to patients and people in care will include:

- Reduced risk of incorrect laboratory tests being undertaken and reported on through the use of standard laboratory test codes;
- Being able to recall laboratory test histories when seeing a different health practitioner;
- Being able to have laboratory tests undertaken and reported on by any laboratory collection depot;
- Having laboratory test results available more quickly through more efficient processes;
- Needing fewer laboratory tests because health practitioners will have better access to the results or earlier tests
- Ability (through self-management programmes) to examine their test records on line and take more responsibility for their own medical well-being;
- Eventually patients could have their key medical records available internationally.

Health practitioners

Health practitioners who order laboratory tests will benefit through:

- Easier updating of information in their PMS and CIS systems (subject to their examining the record, if they want to, before the update occurs);
- Better access to decision support mechanisms when ordering laboratory tests, reviewing results and ensuring that tests have been performed;

- Better tracking of work performed by locums, through the HPI codes;
- Saved time as a result of a reduced 'paper chase' and fewer transcription errors;
- Fast access to patients' test histories, including tests that were ordered by other practitioners;
- Identification of significant 'non-adherence' instances (that is, patients not getting tests done);
- Reduced likelihood of patients suffering medical misadventure;
- Improved 'customer satisfaction'; and
- Better back-up of vital data.

The benefits of eLabs increase when the system's features are added to those envisaged under the other Action Zones. A key aim of Programme EPIC will be to provide health practitioners with a comprehensive view of a patient's treatment.

National Screening Unit (NSU)

NSU will benefit from:

- Having access to more accurate and timely information; and
- The removal of time-consuming, staff-intensive processes associated with manually based patient identification.

The result will be improved staff productivity and possibly a reduction in staff numbers and costs.

Laboratories

Laboratories will benefit through:

- Better quality assurance across the test ordering process;
 - Standardisation of test terminologies;
 - Improved authentication of health practitioners;
 - Easier input of test orders to LISs;
 - Easier reporting of results;
 - Improved 'customer satisfaction';
 - Reduced costs: one community laboratory has estimated a saving of up to 30 FTE positions if 95% of orders are electronic;
 - More efficient business processes; and
 - Better collaboration on patient care between community and hospital laboratories
-

IT system vendors

Vendors will benefit through a clearer understanding of the Sector's technological direction and the standards with which their software and services have to comply.

Funding and payment-related organisations

These organisations will benefit through:

- Better value for money resulting from improved efficiency within the process and fewer lost/misplaced records;
 - Better quality assurance, security and accuracy of data;
 - Better decision-making informed by better access to data; And
 - Less wastage from ordering duplicate tests.
-

The New Zealand government

eLabs offers the government opportunities to improve the welfare of its citizens, reduce costs and get better value for its Vote Health expenditure.

Any movement towards electronic storage of patient data will help protect the nation in the event of pandemic and/or bioterrorism.

Other organisations	Organisations responsible for the delivery of health and health care results through population-based strategies will benefit through improved quality and reduced costs across the Sector.
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4.2 Indicators of success

Introduction	Although it is currently too soon in the Action Zone process to define Critical Success Factors (and measures), the following paragraphs describe the general 'indicators' that will demonstrate that the eLabs Action Zone strategy is being achieved.
Patients	The main indicator of success will be better 'customer satisfaction' with the process.
Health practitioners	The main indicators of success will be saved time for practitioners and better levels of 'customer satisfaction' reported by their patients.
Laboratories	The main indicators of success will be: <ul style="list-style-type: none">• Saved time and higher levels of productivity;• Reduced operating costs; and• Improved 'customer satisfaction' reported by their customers.
Funding and payment-related organisations	The main indicators of success will be a better return on investment in the laboratory testing process.
The New Zealand government	The main indicator of success will be a healthier populace. The main indicators of success will be improved confidence in the health system from citizens and a better return on investment from Vote: Health.

Appendix A Stakeholder Engagement

The following stakeholders were among those consulted during the investigations that led to this document.

Primary Care

Harry Pert
Harley Aish
Sandra Hicks
Hywell Lloyd
Ram Vara
Various other GPs

Community laboratories

Dave Aarons and various members of staff, Diagnostic Medical Laboratory
Sam Chan, Chairman of the IT Sub-committee of the New Zealand Association of Pathology Practices (NZAPP)

DHBs

Ross Boswell, Counties Manukau
Danny Wu, Counties Manukau
Chris Dever, Canterbury

HISAC/Others

Paul Cressey, chairman HISAC
Tony Cooke, Hutt Valley DHB
Andrea Pettet, Health IT Cluster
Brendan Kelly, Senior Advisor, MOH
Murray Tilyard/BPAC, plus around a dozen members of BPAC and interested Dunedin-based individuals
Brett Hawthorne and Louise Robertson (National Screening Unit)
A meeting of the CIO Forum was also attended in May.

Appendix B eLab's IT System 'Building Blocks'

System-based 'building blocks'

The infrastructure system 'building blocks' for eLabs are:

- Some form of workflow mechanism capable of interfacing with existing PMS/CISs and LISs in order to action and monitor all transactions;
 - Network and messaging technology to facilitate XML/HL7-like transfer of data records. (Specific data fields must be held within messages so that they can be used to populate corresponding fields in PMS/CISs and LISs);
 - A 'logical' data store capable of storing current and historical data in a state-of-the-art DBMS; and
 - Report-generating tools to access and format data extracted from the 'logical' repository.
-

Practitioners' IT systems

Modifications to PMS/CISs will be needed in order to:

- Incorporate a clinical decision support module capable of applying agreed clinical guidelines and advising the practitioner on appropriate tests;
 - Apply a standardised on-line schedule for test ordering;
 - Access centralised NHI and HPI files via serving mechanisms¹¹;
 - Transmit electronic orders that either:
 - Identify the laboratory that will perform the tests, or;
 - Print a bar coded paper order that will allow another laboratory to 'pick' the electronic order when contacted by a patient;
 - Receive standardised results records;
 - Review results and the status of tests in the repository; and
 - (At the practitioner's discretion) receive and display lists of test orders that haven't been actioned after a certain period.
-

Modifications to laboratory information systems

Systems will need to be modified to:

- Scan a repository and pick up test orders destined for the specific laboratory; and/or
- Store incoming test orders in a 'post box'; and/or
- Scan a bar-coded test order (or enter data manually as a fallback) to select orders from a repository or 'post office'.

The systems will also need to:

- Retrieve NHI and HPI details;
 - Apply a national test codes standard; and
 - Output results messages to GP and funding systems via a repository, using coding standards.
-

Modifications to claims processing systems

Modifications to claims processing systems will be needed to update rules for Private Care tests and incorporate the use of the HPI in laboratory claims.

NZCR and NCS systems

The eLabs project team should liaise with the NSU to assess whether these systems will need modification.

¹¹ This assumes that practitioners' systems can update patients' NHI details (EG address changes).

Appendix C Bibliography and references

Many papers, documents and other points of reference were used in the preparation of this document but particular reference was made to:

- The HIS-NZ strategy, the basis of the underlying strategic approach
- The 2003 report 'Feasibility Study, E-Labs', commissioned by the Ministry of Health and written by Michael Furlong
- The Health IT Cluster's February 2006 report "E-Laboratory: Clinical Data Repository Options"
- The eLabs 'Indicative Scope' and 'Initial View' documents developed by HISAC.

Appendix D Overview of standards

This Appendix expands on the PS&A's summary of standards related to eLabs. *Note that the Health Provider Index (HPI) and National Health Identifier (NHI) are key standards for eLabs but are being addressed in other HIS-NZ Action Zones.*

Orders/Results Coding

The main coding standards relating to laboratory results are:

- SNOMED - Systematized Nomenclature of Medicine, a division of the College of American Pathologists Medical Society. SNOMED is the preferred clinical terminology standard for the UK and Australia and provides comprehensive lists of terms to describe the care and treatment of patients. The codes enable computer systems to capture and retrieve patient information in clinical language.
- SNOMED has been commonly used in New Zealand, over many years, for the coding of histological diagnoses and coding associated with laboratory results of cervical screening tests;
- LOINC - Logical Observation Identifiers Names and Codes, provided by Regenstrief Foundation, a not-for-profit organisation operated in conjunction with the Indiana University School of Medicine. LOINC is used by various countries, including Germany and Switzerland. A subset of the full LOINC code set (which contains around 32,000 codes) is more suitable for use in New Zealand (as only around 3,000 tests are performed in this country), hence...
- NZPOCS - the NZ Pathology Observation Code Sets, a subset of LOINC which HISO has decided will be used in New Zealand;
- READ (now defunct) - Clinical Terms distributed by the British NHS Information Authority on behalf of the UK Department of Health. READ has been widely used in the primary care sector but the NHS Terminology Service has discontinued the maintenance of Read Codes in favour of SNOMED Clinical Terms (SNOMED CT) in the Care Records Service; and
- LIS Coding – LISs typically have built-in (non-sector standard) test codes

There is a school of thought in New Zealand that LOINC is a more suitable standard for laboratory testing than SNOMED. The latter is thought to have limitations from an orders/results perspective.

LOINC provides standard names and codes for identifying individual laboratory results (such as Haemoglobin and Serum Sodium concentration) and is specifically designed for coding observation report messages for data transmissions.

LOINC licensing is free but requires that the codes be not changed without approval of the managing body. New Zealand does have country specifics, which may be catered for by agreed 'interpretations' of existing LOINC codes or by additional codes.

Messaging

Health Level 7 ('HL7') is a messaging standard for the electronic transfer of health care data. Results messages sent by community laboratories to GP systems conform to a variation of the HL7 2.1 standard facilitated by HealthLink.

eLabs – an example from Wales

<http://www.ehiprimarycare.com/news/item.cfm?ID=2507>

GPs and nurses across Wales are to switch to using printed labels and barcodes when they send test samples to the lab for analysis.

Hand-written request forms and labels will be phased out over the next six months under an initiative from Informing Healthcare Wales, the Welsh

Assembly Government programme set up to modernise the NHS.

Informing Healthcare says the labelled samples are easier for staff at the pathology laboratory to understand, with no smudging or illegible scripts to decipher. Patients benefit as appointment times are shorter, the information provided to the lab is accurate and requests are processed more efficiently.

Ian Kelsall, chairman of Informing Healthcare, commented: "This is a simple idea that works well and delivers major benefit to staff and patients."

Informing Healthcare has funded new label printers and specialist label software for the country's 500 GP practices, following a trial at 10 surgeries in the Rhondda Cynon Taff area, and at eight practices using the Barry Blood Service.

The information printed on the labels, which includes details, such as the patient's NHS number and name and the GP's address is taken directly from the GP's computer system.

One practice manager commented, said: "Our nurses love it and they would not want to go back to hand-writing labels."

Other comments included: "The labels really help to speed up appointments in phlebotomy (blood test) clinics" and, "We are fitting 50% more patients into the allotted clinic time."

Informing Healthcare says the new system, supplied by Codegate Ltd, will also help to improve data quality.
