

A Regional Strategy towards a Clinical Laboratory Decision Support System

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Abstract

Whilst diagnostic laboratory testing represents a significant cost item (in excess of \$200 million in 2004-05 financial year) in New Zealand healthcare expenditure, little is known about the effectiveness of tests ordered on post test diagnostic probabilities for the clinical problems that health practitioners are required to manage. There is increasing pressure on District Health Boards to improve the demand side (from test orderers and consumers) and supply side (community laboratory services) management to reign in the escalating costs and improve appropriateness (and diagnostic predictability) of test orders. The impending expiry of the national laboratory contract has highlighted the absence of a regional laboratory strategy and robust, reliable information that would assist in the formulation, implementation and evaluation of such a strategy and its longer term outcomes. Diagnostic Electronic Clinical Decision Support (ECDS) has been identified in the international literature as a tool that has the potential to address this information deficit for both supply and demand side laboratory market management. This paper documents the considerable benefits that judiciously implemented ECDS would offer to laboratory services funding, planning and delivery for the Auckland Metro Region. A recommended first step towards preparing a business case for Auckland Metro diagnostic ECDS development would include an inventory of regional diagnostic ECDS resources in consultation with the stakeholders responsible for those resources.

Key Words

Electronic decision support, clinical laboratory service provision, supply and demand management

1. Introduction

Diagnostic laboratory tests form a key component of the 'Check-Plan-Do' of the clinical care cycle. It is estimated that in excess of \$200 million will be spent on diagnostic laboratory testing in New Zealand in this current financial year and the rate of expenditure continues to accelerate at a rate that is of concern to health funders and planners. Of equal (if not greater) concern is the lack of accurate and direct evidence that increased uptake of laboratory tests improves the post-test probability of diagnosis in common clinical situations and therefore patient care outcomes¹.

Community laboratory services in the Auckland Metro Region are funded by Auckland District Health Board (ADHB), Counties Manukau District Health Board (CMDHB) and Waitemata District Health Board (WDHB) with ADHB as lead District Health Board (DHB) for non-DHB laboratory providers. The DHBs entered into a service agreement with a number of community laboratories of which a privately owned company, Diagnostic MedLab (DML), provides the great bulk of community laboratory services. The contract for community laboratory services in the Auckland Region is due to expire within the next two years. Decisions on the future laboratory contracting process (at strategic and operational level) therefore need to be made such that future laboratory services will be provided in cost-effective ways.

Thus, the Auckland Metro DHBs are facing two major problems – the demand (test order by prescribers) side and supply sides of the laboratory management equation. Appropriate decisions can only be made if accurate data about test orders and cost effectiveness are available. There is robust peer-reviewed evidence highlighting the usefulness of electronic decision support systems (EDS) on improving healthcare demand side management¹.

This paper aims to examine a number of issues or problems pertinent to both the demand side and supply side of diagnostic test services in the Auckland Metro Region within the context of the Regional Information Services Strategic Plan² (RISSP), and to explore how EDS can contribute to resolve these problems.

2. The Demand Side Problem of Laboratory Services

In a landmark Harvard Business Review article³ it was asserted that poor quality information about relevant market signals to consumers, funders and providers was an internationally recognised problem in the health care industry. Laboratory test orderers in particular tended to treat laboratories like “black boxes” with little or no knowledge/concern about many characteristics of the tests except the test results. Of particular concern is the dominance of the “third-party payment” mentality. The cost of laboratory testing is considered ‘free’ to patients and doctors. As a consequence, both doctor and patient can act as if the cost of the test ordered was zero. The resultant minimal constraints lead to a natural tendency to over-servicing. There is evidence that attempts to supply test-orderers with the dollar cost of tests on order forms have had some impact on test ordering. However the current design of the New Zealand clinical diagnostic laboratory system including its current laboratory remuneration schedule has not been rigorously investigated since 1974⁴. The ad-hoc adjustments to schedule pricing cannot therefore be considered a true reflection of the current costs of laboratory testing.

Recent empirical New Zealand research has confirmed the need to seek alternatives to price signalling as a tool for efficient provision of diagnostic laboratory testing. France⁵ concludes that competitive contracting, as a means of price control for diagnostic laboratory services should be abandoned.

To fulfil the perfect information criteria to ensure an efficient laboratory market test orderers need information about the downstream benefits for improved disease outcomes and ultimately improved patient health outcomes to make rational choices over time. To quote from a recent evidence based medicine literature review carried out on behalf of the Australian Commonwealth Department of Health and Ageing.

“.....our literature review showed that evidenced-based information on the majority of pathology tests is sadly lacking.”

(Harvey and Visser, 2002¹)

Harvey and Visser¹ conclude that most diagnostic tests are evaluated using methods subject to considerable bias and poor study design, which often results in an over-estimation of the accuracy of pathology tests. For many tests there is too little information about how to use them, and when this has been examined it demonstrates significant lack of agreement.

There will always be some pressure on the prescribers to order laboratory tests, be it as a defence against litigation by the health care practitioner or due to demand from consumers (patients). Effective and successful demand side management relies heavily on evidence-based answers to questions such as:

1. Do the tests ordered increase or decrease post test diagnostic probabilities for the clinical problems that health practitioners are required to manage, particularly for those conditions which are vague and most importantly for general practice, where practice circumstances are necessarily uncertain?
2. For New Zealand, what is the disease prevalence at the national, regional, DHB and PHO levels? – Information that is critical for determining the usefulness of a laboratory test in any given patient encounter.

Few systematic reviews of diagnostic tests have been found to meet evidence-based standards because of methodological flaws¹. In most circumstances it has been suggested we may need to start afresh with new, better, and more directed research. An accurate clinical data repository can assist in the provision of this vital knowledge, with the use of data-mining approaches to provide both useful answers to clinical queries raise and help formulate effective and reliable demand side management policy. Some form of evidence-based decision support will be an essential prequel to the formulation of a solution to the third party over-servicing tendency.

3. The Supply Side Management Problem of Laboratory Services

Community Laboratory Services in the Auckland Region are funded by ADHB, CMDHB and WDHB with ADHB as lead DHB for non-DHB based providers. The total annual expenditure for laboratory tests has been increasing over time at an accelerating rate. There is also the perception (although unsubstantiated by any empirical data) that considerable unused laboratory testing capacity exists, particularly in the area of automated equipment. This perception raises the question of whether greater scale of economy can be achieved by better supply side management, for example, by more rational allocation of segments of the laboratory test market. A planned and therefore interventionist approach such as this would signify the departure from a pure market approach in favour of more government regulation to address this market failure.

Economic policy is the means by which scarce resources are allocated between competing requirements in the most efficient manner. It is important to separating policy aims and objectives from the means by which those aims are carried out. A rejection of either state or market as an economic tool is does not serve the interests of the individual or society at large It cannot be too strongly stressed that the choice of appropriate mix between market and state

intervention is should wherever possible be on an empirical basis, and one made after the aims of any economic policy have been determined.

It is particularly important that the market not be rejected out of hand as a means by which part or all Northern Region Diagnostic Laboratory as a means for diagnostic laboratory service provision, given that New Zealand is a Western social democracy currently governed by a left of centre political party that campaigns on the merits of state intervention in the health care sector.

On the other hand, it is important that a repeat of excesses due to deregulation ensuing from the reforms instituted by the Lange Labour Government and concluded under the Bolger-led minority National Government recur because of an inappropriate reliance on market forces. For example according to France⁵ the change towards market controls not only destroyed assets of the existing centrally controlled laboratory system (co-operative arrangements between centres and sectors, attractive career structures, a research and development-oriented culture), but greatly increased expenditure on laboratory testing 'with no clearly demonstrable evidence of health gain'. Additional costs, the transaction costs of contracting, have added to the price-per-test borne by the taxpayer but, sadly, it would seem, to no advantageous end.

The invisible hand theorem holds that the market is the most efficient means of allocating resources if and only if a number of assumptions called the standard assumptions hold, in which case no state intervention is required on efficiency grounds. Where one or more of the standard assumptions fails it is necessary in each case to consider which type or types of state intervention: regulation, finance or public production.

Currently a privately owned company, Diagnostic MedLab (DML), provides the great bulk of community laboratory services for the Auckland Metro Region with remaining service coverage provided by Southern Community Laboratory (SCL) for and the DHB provider laboratories approximately. DML and SCL have specimen collection and transport services. The DHB provider laboratories are currently dependent on DML for the collection and transport of community specimens.

The contract for community laboratory services in the Auckland Region is due to expire within the next two years. Decisions on the future laboratory contracting process (at strategic and operational level) need to be made such that:

1. Services delivery be maintained.
2. Service costs can be properly managed within the context of anticipated growth in demand.
3. Resources allocation and demand for services are properly managed so that demand and supply are appropriately aligned.
4. Relevant workforce skill mix and appropriate infrastructure are maintained.

In the light of the impending the service contract expiry, a number of important questions need to be considered. Is the market the most appropriate means by which laboratory services should be provided in the Auckland Metro Region? Another way of phrasing this question is therefore do "standard assumptions" of the invisible hand theorem hold for the provision of laboratory services in the Auckland Region? Should this be the case, the market would be the most appropriate means laboratory services should be provided in Auckland? Or, if the success of Pharmac's pharmaceutical purchase policy offers any guide, is state-intervention a more effective mechanism to extract greater efficiency while holding down the costs?

Currently no accurate data are available to assist in formulation of a robust fiscal and service provision policy that can best manage supply side issues and most importantly, help resolve the tension between demand and supply management.

4. Auckland Metro Laboratory Work Stream: Proposal and Work Plan

A number of Laboratory Workstreams overseen by the Regional Funding Forum and project managed by the NDSA were established in response to the risks perceived by laboratory test funders, and in particular because of an increase in the rate of laboratory test ordering in the new millennium. The current status of some of these workstreams is summarised in Table 1.

Should price-based competition based on the entry of the Auckland Metro DHB provider laboratories into the community diagnostic services market be identified as the means by which the DHB funding teams chose to reduce costs and increase efficiency in laboratory test service delivery two major barriers to competition need to be addressed:

- DHB provider labs lack a means of collecting, storing and transporting specimens collected in the primary sector.
- DHB provider labs lack a means of providing primary care providers real-time electronic access to laboratory test results.

The following associated demand-side workstreams will be of particular value in addressing these barriers to competition.

- Regional Éclair Laboratory data repository now in phase one business case formulation will provide a means by which authorised users will be able to access patient-centred integrated laboratory test reports regardless of where the test was performed.
- MoH/HISO sponsored national Logical Observation Identifier Names and Codes (LOINC) laboratory test project. A national standard for common laboratory test codes and electronic transmission formats is essential for the efficient operation of the planned Regional Éclair Laboratory data repository.
- New Zealand HL7 users group (NZHUG).

Table 1 Current Auckland Metro Regional Laboratory Work Streams

Cost/volume monitoring	Aim	Status
Laboratory Utilisation/ Population Based Funding Formula budget, forecasting and reporting project	laboratory test ordering modelling and forecasting tool that generates reports incorporating, DHB patient domicile analysis by age and gender, ethnicity, and indices of deprivation	Routine reports available for DHBs. Reporting format under development at the level of PHOs and individual GPs
Supply Side Workstreams	Aim	Status
Regional Modification of National Community Laboratory Contract (“risk share”)	Manage volatility in community laboratory expenditure in the Auckland Region by sharing any increase spend above and beyond a population adjustor between the funder (ADHB as lead DHB and the provider (DML)	Current risk share arrangement expires within the next two years
Associated Demand Side Workstreams	Aim	Status
Demand Management/Best-Practice Electronic Clinical Decision Support (ECDS)	Improve patient care by ensuring clinicians have one-stop easy access to individual patient-centered EBM based best practice guidelines based on the local disease prevalence and to assist with real-time patient work-flow management	NDSA Review of Auckland CDS current state in progress. Watching brief on expected Australasian initiative
Regional Éclair Laboratory Data-Repository	Improve patient-centered integrated test reporting, particularly for tests carried out in different laboratories	Business case currently being prepared by an external project manager
Privacy Impact Assessment (PIA) for Regional Éclair Laboratory Data-Repository	Ensure that the requirements of the Privacy Act and Health Act are fulfilled and resourced on an ongoing basis for the Regional Repository	Stakeholder contributions to PIA being collated by NDSA under the oversight of the DHB legal advisers
National HISO* MoH Sponsored Diagnostic Laboratory LOINC [#] project	Increase awareness of and uptake of an internationally standardized laboratory test unique identifier to facilitate shared laboratory information initiatives (e.g. Regional Éclair Repository Project)	National project managed by HISO with the goal of establishing a national LOINC standard is in progress
Community Laboratory Diagnostic Test Duplication and Eligibility	To ensure only eligible New Zealand resident receive publicly funded community laboratory tests. To reduce harm and cost associated with un-necessary laboratory test ordering	Dependent on progress of the progress with the Region Laboratory Data-Repository and LOINC projects

Given the impending expiry date for the current contract between the Auckland DHBs and DML, it is essential that a range of options and recommendations to guide future community laboratory contracting be available for by November

2004. To this end a Laboratory Services Strategy workshop bringing together the relevant Metro Auckland stakeholders was convened.

A key direction provided by this strategy meeting was that the focus of the regional laboratory workstreams should be seen as market supply and demand side management tools supporting a regional laboratory strategy. These workstreams are to be re-focused by a regional working group representing stakeholders in the funding and provision of laboratory services in the Auckland Metro Region.

Key elements of this regional strategy will comprise:

- Inter-sectoral regional collaboration, coordination and governance e.g. DHB provider labs/community labs, referrer/provider, specimen transport/collection
- Test appropriateness – duplication, cost-effectiveness, schedule reform
- Alignment of clinical responsibility and financial accountability e.g. improving clinical outcomes
- Cost-transparency and information sharing
- Pathologist/technologist training and retention issues
- Quality improvement initiatives e.g. benchmarking

5. The Promise offered by Laboratory Electronic Decision Support

There is evidence that a significant proportion of pathology tests ordered fail to contribute to the diagnosis and/or treatment of individual patients while some cause patients harm¹. A systematic literature review including that of key preceding Australian reviews and research was performed. This review literature reiterated the value of a creating a sustainable mechanism to authoritatively distil the plethora of medical scientific papers, meta-analyses and consensus statements into practical, concise and consistent best-practice guidelines to assist health practitioners and consumers. The literature review also showed that the increasing use of computers in clinical practice is creating a unique opportunity to provide best-practice information at the point of clinical care, when decisions are being made such as tests ordered or drugs prescribed. There is good evidence that such decision support systems can substantially reduce inappropriate and/or unnecessary ordering (and prescribing), diminish errors and improve practice.

5.1 How ECDS supports demand side management

ECDS can contribute to improvements in the management of the quality of test utilisation i.e. both over and under utilisation by

- The provision of real time evidence-based/best practice-based guidelines through the PREDICT type of electronic decision support system to help GPs determine the most appropriate (and cost effective) tests to order without compromising the equity of access or quality of care provided to patients and by reducing harm from un-necessary testing
- Increasing the accurate utilisation of the patient NHI as the unique identifier for all electronic laboratory requests and referrals. The NHI can then be used to validate the patient's demographic data to determine whether the patient is eligible for free test or a fee needs to be charged for the service. This removes the gate-keeper responsibility from the test orderer.
- Facilitating accurate service utilisation and test order pattern data for quality audits, data mining and feedback information to the test orderers.
- Facilitating continuous quality improvement (CQI) initiatives such as the use of statistical process control charts (SPC)

5.2 How ECDS supports supply side management

ECDS has the potential to facilitate the automated collection, collation, analysis and reporting of the quantitative information essential for supply side management. Accurate monitoring of market signals for example real time test cost, prices and capacity to increase test output is essential for determining whether any market is operating efficiently and therefore requires no intervention by a regulatory or funding authority.

Should a market be deemed efficient, regulatory and funder monitoring remains important as markets have the potential to become inefficient, often requiring intervention to restore and/or maintain efficient operation. Real-time, cost-efficient accessing of clinical, financial and infra-structural information relevant to monitoring the market is an important contribution that can be made by ECDS.

In reality, laboratory markets vary in their degree of efficiency both on the basis of geography and of time. The mix of market and regulation is therefore critical and can only be optimised if robust and reliable information is available. In addition, because economics is not an experimental science, funders and planners require a means of establishing what

effect any proposed intervention will have, what the magnitude of that intervention should be, what effect other market drivers e.g. other interventions, will have in a quantitative manner with an estimate of certainty i.e. simulation modelling. ECDS has the potential to support this modelling approach by:

- Providing accurate, robust and real-time information to construct and test an appropriate system model
- Provide a real time distillate of the evidence-base to formulate novel model rules
- Inter-facing with knowledge discovery statistical approaches e.g. data mining (drill-downs and extracting implicate rules), Bayesian approaches, neural networks and support vector machines, formulate previously unknown model rules and provide sophisticated data extracts
- Constructively managing the relationship of fixed/marginal costs and economies-of-scale to maximise benefits without unduly distorting the market

6. Building the Laboratory EDS Business Case

Obtaining resources and sign-off for any clinical support system requires a robust, rigorously staged and transparent business case with a high benefit cost ratio framed within the context of the regional IS strategy (RISSP).

The RISSP² is the Auckland Metro IT strategy approved by the CEOs of the Auckland Metro DHBs and aims to improve health outcomes for the people of Auckland through appropriate information exchange. The RISSP is underpinned by the seven principles of the New Zealand Health Strategy⁶ (2000), the MoH strategic formulation that translates the New Zealand Health and Disability Act (2000) into a framework of action for the DHBs. The foundation of any diagnostic ECDS business case in the Auckland Metro Region is therefore the demonstration that this business case adds value to the key projects that have been selected to implement the RISSP. The RISSP key projects that diagnostic ECDS would add value to include:

- *Chronic Care Management*, involving the implementation and enhancement of a consistent and integrated regional chronic care management solution incorporating ECDS tools and allowing people to access their own information.
- *Clinical Audit*, involving the implementation of support tools (*such as ECDS*), providing access to patient records, capturing additional clinical information, and reporting on clinical outcomes and the effectiveness of clinical processes.
- *Clinical Data Repository*, involving the development of a regional clinical data repository architecture that will allow logical integration of patient records and clinical images
- *Clinical Notes* (clinical forms and database solution) to allow clinicians to capture specific clinical data, integrated with patient management systems and the clinical data repository.
- *e-Prescribing* involving the implementation of an e-prescribing system that delivers the right medication to patients, reduces medication errors and the overall cost of pharmaceuticals.
- *Mental Health* involving the creation of a single mental health patient record accessible by patients; coordinate care between primary health care, community organisations and secondary care providers; incorporate clinical decision support tools and support a mobile workforce.
- *Order Entry*, requiring a regional computerised physician order entry (CPOE) system, incorporating clinical decision support tools.
- *Primary Health Care Information Services* that would allow easier and cheaper access to information technology for primary and community/NGO health care providers by exploring the possibility of facilitating a shared information services capability.

Having established that there is a strategic basis for formulating an Auckland Metro Regional business case for diagnostic ECDS the subsequent step is the choice between the two fundamental approaches to building an ECDS business case

1. Top-down approach in which a business case is constructed to fulfil the requirements of a multi-disciplinary stakeholder consensus informed by a systematic and comprehensive review of the published literature. The draw-backs to this approach include the cost, difficulty of implementation e.g. only two or three large academic centres in the USA have come close to going live with such a system and the opportunity-cost of not leveraging on similar international developments, particularly those of the sponsored by the Commonwealth Government of Australia.
2. Bottom-up approach in which the starting point is a regional inventory of available ECDS resources accompanied by focussed stakeholder consultation and a focussed literature review. Such an approach has the advan-

tages of ensuring pre-existing ECDS resources are aligned and utilised in the most efficient manner possible, maximum advantage is made of possible trans-Tasman linkages and that a workbook and templates prepared by the Healthcare Information Management Systems and Society, USA, (HIMMS) are available as Internet downloads for no charge⁷. HIMSS is actively encouraging user feedback and partnership as part of the ongoing development of their inventory work book, providing an opportunity for forging Auckland Metro Links with centres of international excellence.

It is recommended that the “bottom-up” approach be using the HIMSS workbook and templates as a first step in the development of a diagnostic ECDS business case for the Auckland Metro Region because ECDS resource that a project management team is not aware of cannot be costed. In addition, without a catalogue of existing resource there is a significant danger of systems duplication with the ensuing wastage of scarce resources and blunting of strategic IT focus.

On completion of an inventory, preliminary stakeholder consultation and review of relevant literature and with the assistance of trans-Tasman and USA collaborators a formal cost-benefit and resource impact assessment then becomes possible. The convening of project management team with designated sponsor, manager, reporting line, deliverables, key performance indicators, risk assessment/mitigation strategy and suggested post-implementation review then become a logical next step.

7. Conclusion

The planning, funding and delivery of high quality, cost-effective diagnostic laboratory services in the is becoming of increasing importance for the high priority by Auckland Region Metro DHBs due in part to the need to address DHB budget deficits and free-up scarce health care resources to address the health priorities identified by the New Zealand Strategy⁶ (2000). To this end the Auckland Metro DHBs have sponsored a number of both supply and demand side laboratory management workstreams project managed by the NDSA.

The impending expiry of the national laboratory contract has highlighted the absence of a regional laboratory strategy and robust, reliable information that would assist in the formulation, implementation and evaluation of such as strategy and its longer term outcomes. Diagnostic ECDS has been identified in the international literature as a tool that has the potential to address this information deficit for both supply and demand side laboratory market management.

In addition ECDS has been identified as critical to a number of key projects identified in the Auckland Metro Regional Information Services Strategy Plan² (RISSP). Advocates for increased utilisation of diagnostic ECDS in the Auckland Metro Region advocate within the IT governance framework authorised by the Auckland Metro DHB CEOs. Parallel ECDS international developments, particularly those sponsored by the Australian Department of Health and Ageing (DOHA) provide a serendipitous foundation upon which considerable economies of scale could be leveraged provided a robust business case with a large benefit-cost ratio can be made to the senior managers of the Auckland Metro DHBs.

This paper has established the considerable benefits that judiciously implemented ECDS would offer to laboratory services funding, planning and delivery for the Auckland Metro Region. It is therefore recommended that the first step towards preparing a business case for Auckland Metro diagnostic ECDS development should be an inventory of regional diagnostic ECDS resources in consultation with the stakeholders responsible for those resources.

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