SCBMDN Shared Services Discussion Document

Scottish Clinical Biochemistry
Managed Diagnostic Network

V1.0, September 2015

Executive Summary

The Shared Services Agenda presents a number of challenges to clinical biochemistry services, namely:-

- Current clinical services have been established in a response to demand and in line with available resource
- Whilst some specialist clinical services are nationally commissioned, most are locally owned, with a variety of cross-boundary agreements in place
- Historical solutions have not been whole-systems focused
- Clinical biochemistry is one of several laboratory-based disciplines and any future model would require cross-disciplinary development
- Whilst SCBMDN has had several successes; its ability to influence does not extend to mandating change, which has led to further disparity in service provision
- Evidencing compliance through accreditation visits is more challenging for clinical staff in smaller NHS Boards

As many of the challenges infer, the current service provision does not easily lend itself to a national whole-systems approach to service improvement. There are many areas of interest, such as demand optimisation, where there is clear understanding of the need for change; however there is no consolidated route to progress this. Within the current configuration, to create a culture where such challenges can be responded to, a shift is required in how change is enabled. SCBMDN makes the following recommendations:-

1. Those recommendations for standardisation made by the networks are promoted as national priority/ policy to the boards via the Diagnostic Steering Group or other empowered body.
2. The work plan of the network is aligned to national priorities and, where resource are required for implementation of consensus approaches, standard business cases are developed to be endorsed and recommended to the NHS Boards.
3. A work stream is developed to investigate the optimal service requirements of varying sized primary and secondary care units to enable definition of a distributed service model that ensures the availability of the right repertoire testing within the right time frame.
4. A multidisciplinary work stream is established to identify technological approaches to enable an economic and safe service delivery of optimal repertoires at satellite/primary care/rural remote locations.
5. Opportunities for consolidation of specialist testing associated with paediatric services are explored with a particular focus on removal of duplication and increasing overall resilience.

6. Clinical Biochemistry services are Consultant led 24/7 services. Recognising the crucial role in the provision of expert clinical advice, a shared on-call system should be explored, with a particular focus on providing more comprehensive support in the out of hours period for smaller NHS Boards. It should be noted this will require shared systems for data access in order to be operable.
7. Mechanism for supporting a flexible approach to procurement that enables delivery of local solutions to multi-disciplinary service delivery that enable compliance with national standardised approaches as identified by the SCBMDN to enable reduction of variation across Scotland.
8. Cost and volume of between lab requesting, for all disciplines, should be audited and the business case for potential service provision to be focussed within Scottish laboratories scoped. Key performance indicators for testing should be agreed and assessed in terms of feasibility by a distributed national service.
9. A business case should be developed for all Scottish laboratories to be linked to the National Pathology Exchange (NPEx) service.
10. An approach is developed and adopted to enable construction of a detailed "Scottish Atlas of Variation" of use diagnostic services similar to the Atlas of Variation developed for use in England (http://www.rightcare.nhs.uk/index.php/atlas/diagnostics-the-nhs-atlas-of-variation-in-diagnostics-services/).
11. To deliver reduction of waste and variation national recommendations should be developed or adopted to enable optimal use of resources to enable delivery of evidence based best practice.
12. A national framework should be developed to enable a multidisciplinary whole systems approach to service demand optimisation to enable focussed investment in diagnostics. The structure should enable a bottom up and top down approach to identification and development of targets for demand optimisation.
13. A national infrastructure should be developed to enable sharing and adoption of demand optimisation initiatives that have proven value.
14. Diagnostics services should deliver a Scottish formulary of diagnostic testing and promote uniform adoption to enable standardisation of terminologies, codings, units, reference intervals to enable interoperability, new approaches to use of data and deliver demand optimisation.
15. Time should be invested in exploring increasing the equity of services provided across the country and reducing the variation in the processes used in communication of results of examinations. This will be echoed in "Communication of Critical Results", due to be published in 2016, by the Royal College of Pathology.
16. A diagnostic specialities e-Health group should be formed and identified as key stakeholders by the national e-Health groups; they shall be required to review existing and future needs around data, information and knowledge

management to produce a national strategy for delivering a resilient infrastructure for diagnostics that improves efficiency and effectiveness enables interoperability and fits with national e-Health strategies within the context of the currently evolving health care model. The strategy should evolve to enable the development, delivery and benefits of investment in diagnostics rather than define and inhibit. Serious consideration should be given to the implementation of a common Laboratory Information Management System (LIMS) across NHS Scotland to enable improved Board to Board cross working and communications.

17. Current and future workforce models for delivery of diagnostics data, information and knowledge management and technology should be undertaken; this should be appropriately focussed on development and delivery of increased levels of skills and knowledge within existing, and proposed workforce structures, in newer information and communications systems (e.g. web technologies and mobile devices).
18. Lab services should provide significant input to the development of a primary care portal.
19. A flexible model should be developed for delivery of a defined core or extended examination repertoire to enable delivery of optimal service levels for secondary care units of varying size and to support of a weekend primary care service. Novel approaches to configuration should be considered to enable potential workforce issues and the requirement/potential to deliver cross disciplinary workloads.
20. Biochemistry services provide a broad range of services that impact on the patient journey. A model which has a secure foundation, yet allows a range of expertise to be available across the country should be agreed as the optimal model.
21. Diagnostic services should be configured nationally and locally to support increasing volumes of POCT and that mechanism should be found to invest in the required infrastructure to enable clinical and information governance issues to be addressed. Schemes should be accreditable to ISO 22870 standards.
22. That technological advances in POCT should be exploited alongside other technologies to enable multi-disciplinary delivery of core workloads in small workload volume units 24/7 (e.g. biochemistry, haematology, coagulation and bacteriology (e.g. molecular approaches for hospital acquired infection purposes).
23. An infrastructure should be developed at national level that enables a reduction of the overhead associated with compliance with regulation and accreditation standards. Mechanism should be specifically identified to support the smaller more remote units to address their challenges they face in achieving the required standards.
24. Alternative approaches to the Keele benchmarking system are developed to enable meaningful comparisons of key performance indicators across boards

and that processes are developed to enable meaningful evaluations of effectiveness at local and national levels.

25. A national approach to work force planning should be developed in the context of the favoured model of delivery of services.

There are alternatives to the current model of clinical service provision, and options for more radical change to deliver the vision of shared services. The task of implementing such a change should not be underestimated, in terms of contractual difficulties, governance and accountability, staff buy-in and agreement on optimal pathways.

Four options are proposed to realise this aim:-

A. Continue as is with Diagnostic Steering Group overseeing the activities of the MDNs as they try to achieve consensus.
B. An enhanced version of the current model:
    1) The current model, but with enhanced ability to mandate clinical service change. It is expected this could only be achieved through authority devolved from the NHS Board Chief Executives Group
    2) The current model with devolved authority as above, giving national oversight of diagnostic services however with an enhanced proportion of national specialist services.
C. A national diagnostics service, where all budget is top-sliced from NHS Boards and services are provided through a series of service level agreements with NHS Boards for local or multi-Board services.
D. Nationally tendered service, where a series of agreements is in place for the provision of services, some of which will be service level agreements with NHS Boards; others will be agreements with private sector.

It is of course feasible to combine a number of these options in a variety of different ways.

These options, and their relative merits, are presented in the paper as a starting point for discussion. It is recommended that a formal options appraisal exercise should be undertaken on these and any other identified options, including a full risk analysis, prior to proposing a preferred option.

What may, perhaps, be needed is a road map that can support the system in transitioning from the existing model, alongside implementation of the recommendations above, to a new model. Consideration of lessons learned from other areas, where significant change has already been tested, should be factored into planning.

Document control

Key personnel

Title:	SCBMDN Shared Services Discussion Document
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Approver:	SCBMDN Shared Services Short Life Working Group
Owner(s):	SCBMDN Steering Group

Version history

Version	Date of revision	Summary of changes	Changes marked
0.00	15/08/2015	First draft presented by WAB	No
0.01	17/08/2015	Proposed changes by LB	Yes
0.02	17/08/2015	Proposed changes reviewed WAB	Yes
0.03	20/08/2015	Final formatting changes prior to issue to group	No
0.04	26/08/15	First implementation of changes as discussed at the SLWG	Yes
0.05	31/08/15	Further changes as above and changes from v0.04 accepted	No, see v0.04
0.06	03/09/15	Comments noted during SLWG discussion	Yes
0.07	08/09/15	Changes accepted	No
0.08	17/09/2015	Changes as proposed in discussion with the SCBMDN Steering Group on 16th September	Yes
0.09	22/09/2015	Changes in response to feedback from Dr Bartlett	Yes
0.10	22/09/2015	Accepting changes as above	No
0.11	06/10/2015	Changes proposed by Liz Blackman	No

Distribution

Name	Organisation
Liz Blackman	NSS
SCBMDN Shared Services Short Life Working Group	Various
SCBMDN Steering Group	Various

Contents

1.0 The Challenge

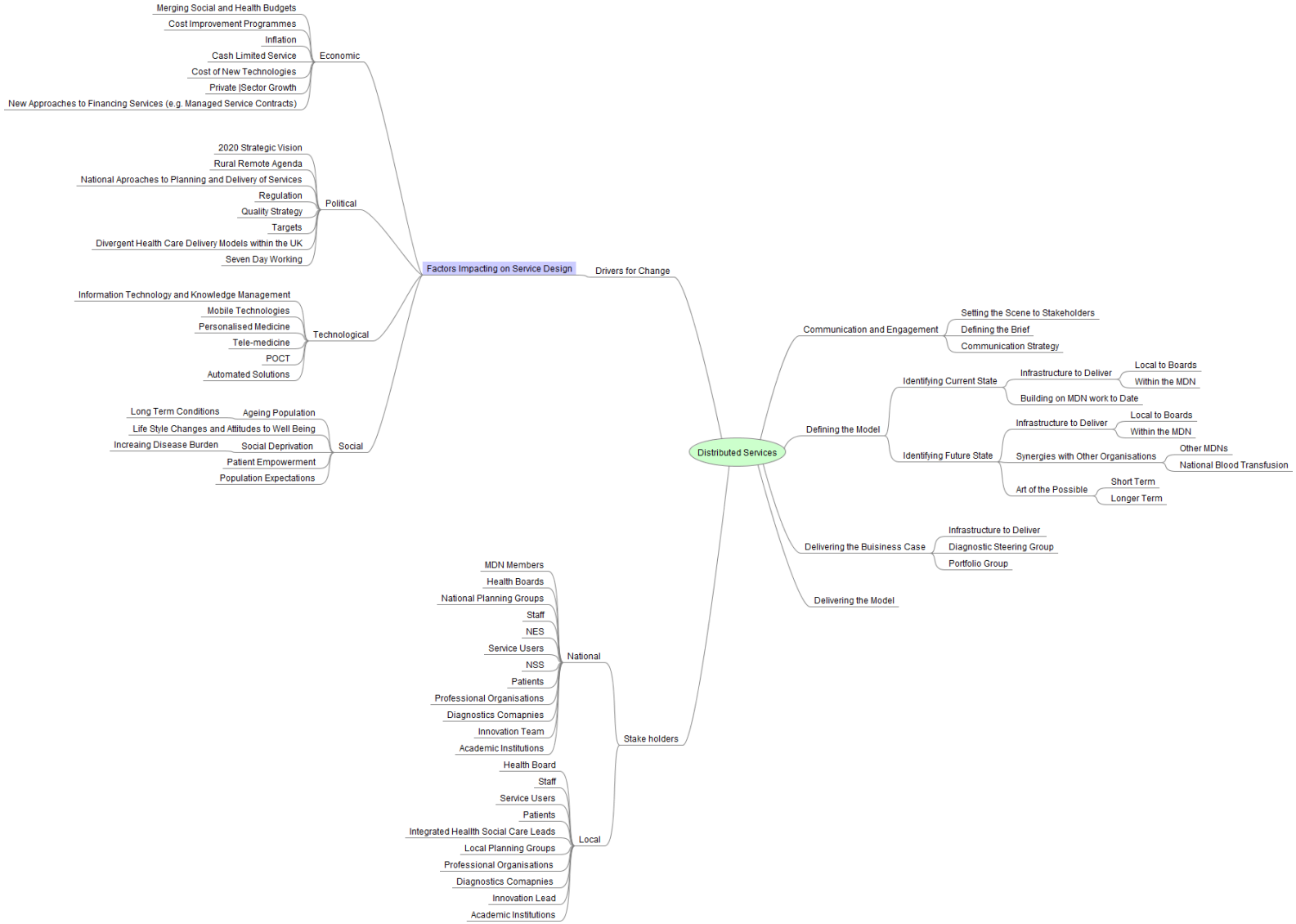
To deliver an effective laboratory medicine service to the population of Scotland that service must be able to provide the right repertoire of testing, within the right context within an appropriate time frame. The outputs from those services underpin delivery of modern health care systems and have been stated to represent involvement in 80% of patient interactions.[i] It follows that the quality and equality of health care delivery to the population of Scotland is dependent upon the provision of a dynamic service model for laboratory medicine that is contextually configured to meet the needs of patients within urban, rural and remote locations. A whole systems understanding is required to enable design and delivery of a national shared/distributed service model for laboratory medicine provision that meets national and local requirements within the Triple Aim framework.[ii] Future service delivery models will continue to operate within complex and continuously evolving environments with many drivers for change (Figure 1). Quality standards and competencies for the clinically led medical laboratories within the model are further identified within the challenging ISO15189 standard. Compliance with these standards demands a user focus and ensures that the services are equipped to deliver the necessary clinical focus from within an appropriately configured infrastructure with embedded systems and processes to deliver the necessary quality of service.

The existing models for laboratory medicine service provision within the 14 territorial Scottish NHS Boards reflect a long history of development at the forefront of technology within a complex and changing environment. Medical laboratory services are delivered, and in the main are operated and funded, by the individual Boards in order to meet local requirements. Some specialist services are commissioned nationally by National Services Scotland (NSS) and delivered by individual Boards while others have evolved as a consequence of local requirement, professional expertise and interest supported by cross charging. The larger boards (e.g. Greater Glasgow and Clyde and NHS Lothian) have historically delivered larger volumes of the more complex services or focus for specialist workloads. The service delivery models are thus complex and demand-led. Structure at a local level has been determined by local requirements and resource availability. Further complexity arises in that local implementation of services that would deliver national benefit, but require resource at Board level, requires individual agreements within the Boards and delivery of local business cases if they do not fall within a national service delivery model. The success of business cases will be subject to varying pressures and priorities locally and the whole systems impact of proposals may not be fully understood where departmental budgets are ring-fenced. The impact of this is that variation is perpetuated and may for example result in delays or failure to introduce new diagnostic tests of proven efficacy in many locations, leading to an inequality of

service provision with whole system impacts in terms of outcomes, patient flow and capacity.

Clinical Biochemistry is one of several Consultant (medical or scientific) led laboratory medicine disciplines residing within a variety of organisational management structures within the Boards (e.g. Pathology, Laboratory Medicine, Diagnostics, and Blood Sciences). Locally Biochemistry services share infrastructure with other disciplines and demonstrate varying degrees of integration both in technical delivery and management of services. This further layer of complexity has to be considered when attempting to design a national model for delivery of any individual laboratory speciality and consequently provides a driver within the design process for a holistic overview all specialities to be taken in any national planning process. A national model for an all-specialities service provision would need to be designed to deliver Triple Aim objectives at a national level and at the same time remain focussed upon how this might impact local requirements.

Figure 1: Distributed Services Mindmap



The complexity and challenges of the current model for delivery of Clinical Biochemistry services are recognised at a national level by the Scottish Clinical Biochemistry Managed Diagnostic Network (SCBMDN). The network approach has enabled development of consensus agreement and views through a number work streams. Individual projects have been delivered by network members that would benefit the whole system if implemented nationally (e.g. adoption of HbA1c as a diagnostic test for diabetes). However, there is no formal governance structure to drive the adoption of consensus initiatives uniformly across the network, to promote approaches within the constituent Boards, or for the constituent Boards to ratify and deliver initiatives. As stated earlier local implementation of developments at Board level for those initiatives requiring funding requires local business cases. The success of business cases will be subject to varying pressures and priorities locally on existing resources and compromised by silo budgeting and thinking within affected services. The impact of this is that variation in service provision and failure to deliver best practice is perpetuated. This will deliver an inequality of service provision and improvement depending on engagement and prioritisation within each location.

HbA1c as a diagnostic test for diabetes.

Diabetes is an increasing problem across the world and has a strong relationship with lifestyle. It is a major financial burden on NHS, treating the disease and its complications (the leading cause of blindness, kidney failure and amputations in the UK). Many patients have diabetes for a considerable time prior to diagnosis, and present with established complications: earlier diagnosis and treatment are key to reducing morbidity and mortality, as well as overall costs. The UK has adopted previous WHO guidance for diagnosing diabetes. In 2011 updated WHO diagnostic guidelines [1] recommended using HbA1c for diagnosis, where appropriate, in place of glucose measurements and oral glucose tolerance testing. The HbA1c test is currently in routine use in NHS Scotland for monitoring of diabetes. A new diagnostic algorithm, based on the presence of two or more risk factors, was published in the UK in 2012 by the UK Department of Health Advisory Committee on Diabetes [2], and adopted in England and Wales, and is now incorporated into the 2014 Quality Outcomes Framework for Primary Care. This new algorithm is easier for Primary Care clinicians to manage, as the patient does not require to fast, facilitating testing at the initial consultation, yet there are significant clinical, technical and funding issues in adopting this guidance. In addition to increased number of HbA1c tests (considerably more expensive than a glucose test), it is likely that significantly more patients will be tested, with an estimated doubling of the workload for laboratories (a conservative estimate). More patients will be diagnosed with an opportunity for earlier intervention, as well as monitoring of those deemed at high risk of diabetes.

The SCBMDN have worked with other stakeholders towards an agreed consensus that HbA1c should be adopted as the test of choice in diagnosis of type 2 diabetes would allow guidance to be developed, creating consistency between requestors and helping to ensure appropriate use of the test.

Assessment of the potential costs to the boards is circa £3M as some boards will need to invest in analytical capacity to meet workloads. The cost of this under the current model of service delivery will need to be met through individual business cases to each board. There is no foreseeable timeframe for the delivery of this initiative across Scotland.

The laboratory medicine services provided within Scotland are generally of high quality with all required or aspiring to accreditation via various bodies including MHRA and the UKAS (successor to CPA). Those systems are underpinned by the international ISO 15189 mentioned earlier, leading to comprehensive rigorous assessments of individual services within each Board. ISO 15189 specifies requirements for quality and competence in medical laboratories and enables medical laboratories to develop their quality management systems and assessment of quality. Compliance carries a significant resource overhead which is difficult for small organisations with limited resources to deliver. This is becoming an increasingly challenging goal for many services. New models of service delivery will be expected to deliver services to the recognized accreditation standards and will require adoption of processes that enable availability of resource to deliver quality and competence standards that are uniform across the larger and smaller services within Scotland.

Development and convergence of technologies within specialities, shared requirements for infrastructure and developments in data, information and knowledge management technologies across specialties provides opportunities for delivery of new service models for laboratory medicine. The traditional boundaries between the disciplines are blurring with opportunities for delivering high volume cross disciplinary workloads on large automated platforms in central locations and lower volume work at other sites on small robust platforms and point of care instruments. Technological development and new workforce models combined with opportunities for dissemination of the data via information technology to those with the expert knowledge at other locations delivers opportunities for improving efficient and effective shared services that allow scalable infrastructures matched to locational needs. The level of sophistication in the automated delivery systems provided by large *in-vitro* diagnostic providers and the legislation covering delivery of the equipment and reagents is such that there is a greater reliance on multi-national companies to deliver accreditable production systems to meet the requirements of the NHS. These developments again deliver drivers for change in workforce structure as far as production is concerned delivering efficiencies and generating resource to focus on the quality and effective use of ever increasing workloads. Role extension of existing staff types and development of roles including more expertise in robotics and biomedical engineering may be required. The ISO 15189 standard requires that medical laboratories should have a much greater focus on the user requirements and thus impact of services. Delivery of this requires the focus of more senior technical, scientific and medical personnel on quality issues and with the user interface locally and nationally, to improve effectiveness in context. The increased focus on delivery of health care in the community, rather than secondary care, will also require the development of community-focused roles with supporting infrastructure for delivery of point of care testing demand optimisation. These issues provide a challenge to adapt and uniformly deliver new service delivery models

within the pressurised resource envelope enclosing the current services across Scotland.

The brief from the shared services initiative is to consider the art of the possible; in terms of proposing a shared service configuration that will deliver a model that supports the evolving model of health care delivery in Scotland up to 2020 and beyond. A national clinical strategy is under development that will necessarily be high level and permissive to enable development of local clinical strategies within the new framework of integrated health and social care. If it is accepted that form of service delivery should follow function, then this will impact upon laboratory services configuration. Once the model for delivery of those services is identified then workforce planning is possible using the “Six Steps” approach. These issues further complicate the challenge to deliver necessary change as the services have to develop alongside an evolving strategy and delivery plan to a final form whilst servicing existing arrangements.

2.0 A current view from the network perspective: the art of the possible within the current evolutionary framework.

2.1 Governance and Finance

The SCBMDN is one of a number of networks managed through National Services Division's National Network Management Service. It currently provides a focus and a forum for laboratory professionals to get together to discuss common themes and, at times, help introduce national initiatives. As pointed out earlier, while consensus is achievable around issues that may address issues of variation, impact on waste and prevent harm; the existence of individual autonomous Health Boards provides significant barriers to enable effective and consistent roll-out of laboratory procedures and policy in all situations. This limits attempts to try and bring into play a consistent standard for laboratory repertoires, test name nomenclature, units of measurement and guidance for laboratory practice.

In order for a shared services approach across Scottish Laboratory Medicine Services to succeed, it is vital that a suitable governing structure is put in place that enables decisions made across the Diagnostic Networks to filter through to definitive action and change at each Health Board level. Without this, it will remain extremely difficult to drive any form of change or consistency of approach along the shared services model. It is acknowledged however, that the establishment of a shared services portfolio board and a portfolio management office may be able to act as a mechanism for suitable initiatives put forward by the MDNs to be implemented within Health Boards; although the exact mechanism whereby any degree of mandatory status within the current model could be achieved remains unclear. It may therefore be possible to impose proper clinical governance to the level that is necessary for a shared services model to succeed in this context. A possible route for this under the existing structure would be to use the Diagnostic Steering Group as a body to ratify national approaches with direct communication of requirements to be delivered to the Boards as an expectation.

Recommendation One: *Those recommendations for standardisation made by the networks are promoted as national priority/ policy to the boards via the Diagnostic Steering Group or other empowered body.*

This approach will be difficult in situations where substantial resource is required to enable delivery as each of the Boards fund their own services in the main with conflicting priorities and consequent demand from silo-ed budgets. In the current model there is no national flexibility. The network has considered the approach of delivering a standard business case to be submitted by network members to their individual Boards (e.g. HbA1c business case). This leads to at least 14 iterations of process with no guarantee of uniformity of response. However this approach

combined alignment of the SCBMDN agenda to national initiatives and priorities with the NHS Scotland Clinical Strategy might enable production of business cases for service change/improvement that are again endorsed by the DSG with some expectation of implementation by Boards.

Recommendation Two: *that the work plan of the network is aligned to national priorities and where resource are required for implementation of consensus approaches a standard business cases are developed to be endorsed and recommended to the Board.*

The culture needs to be developed that encourages a whole systems view with the Diagnostic Steering Group providing a forum to enable the cross disciplinary discussions of issues and to identify commonalities, issues and priorities within an evolving health care delivery model.

2.2 Further consolidation

Considerable consolidation of laboratory services has already taken place within most Boards over the past 20 years. Notably within NHS Greater Glasgow & Clyde there has been recent significant change and investment in infrastructure. Changes in service delivery and configuration have not necessarily taken into account the potential impacts on services in other Boards. There has been a tendency towards concentration of services into central sites delivering challenges to serving remote sites. Hub and spoke approaches present challenges in terms of delivery of appropriate repertoire and 24/7 services. New technologies to enable delivery of cross disciplinary workloads that involve use of advanced point of care delivery and remote management of systems and processes (e.g. remote blood product issue, remote monitoring of quality control and validation) provide opportunities for new approaches to delivery at satellite/rural remote location. Any attempt to further consolidate Clinical Biochemistry services necessarily needs to consider the local needs within health boards, including turnaround times, with the ease and cost of performing such services against the complexity and cost of transporting samples large distances. The evolvement of a market-led approach to health care, with commissioning and consolidation of pathology services in England, has provided useful observations in recent years. It is notable that any attempts to form large networks have not been viewed as successful, with many services having been left in disarray and significantly overspent from forecasted budgets. Similar thoughts to consolidate services across Wales and Northern Ireland to that of a single service have also been resisted.

Within the current model it should be possible to identify a minimum service requirement for local services of varying complexity and to explore how differing technological approaches to service delivery might enable delivery of the correct repertoire of testing within the correct time frame to meet local requirements. Using the conceptual approach that complexity is layered such that a large tertiary referral hospital provides general hospital facilities, but is likely to have a critical mass of

resource to enable delivery of more complex support services to the locality and wider.

Recommendation Three: *that a work stream is developed to investigate the optimal service requirements of varying sized primary and secondary care units to enable definition of a distributed service model that ensures the availability of the right repertoire testing within the right time frame.*

Recommendation Four: *that a multidisciplinary work stream is established to identify technological approaches to enable an economic and safe service delivery of optimal repertoires at satellite / primary care/rural remote locations.*

The view is expressed by some that within the current model there is very limited scope for further consolidation of Clinical Biochemistry services across Scotland. An exception was identified in the area of specialist testing associated with paediatric services, where much thought needs to be given as to whether duplication of particular services is justified in both Glasgow and Edinburgh.

Recommendation Five: *Opportunities for consolidation of specialist testing associated with paediatric services are explored with a particular focus on removal of duplication and increasing overall resilience.*

There is a need to consider the approaches to be adopted by other disciplines in this context. Newer automated facilities provide cross disciplinary workloads (haematology, coagulation, viral serology, antimicrobial assays, and immunological assays). Economies of scale and efficiencies of process can be delivered across bigger automated platforms utilising reflexive and reflective testing. Inefficiencies in existing service delivery need to be identified and reinvested into a model of service delivery that is effective.

The provision of expert clinical advice on a 24/7 basis will provide challenges in consolidated models and a distributed services model given issues around medical and scientific workforce. Developments in information and communication technologies might enable wider geographical/cross board delivery of clinical advice within and out with core working hours. The need to explore the delivery of shared on call systems for clinical advice has been proposed by network members.[1]

Recommendation Six: *Clinical Biochemistry services are Consultant led 24/7 services. Recognising the crucial role in the provision of expert clinical advice, a shared on-call system should be explored, with a particular focus on providing more comprehensive support in the out of hour's period for smaller NHS Boards. It should be noted this will require shared systems for data access in order to be operable.*

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1 Initial SCBMDN work identifying metabolic work may not require rationalisation; however this should be explored with IMD Scotland.

2.3 Further issues to consider around shared services within the current framework

2.3.1 Procurement

Currently, individual laboratory services go out to procurement associated only within their own NHS Board area. These are often multi-disciplinary in scope and vary in size complexity. The financial framework for delivery is based on a managed service contract arrangement with a single provider, with many third party providers contracted within. Such contracts are usually for periods of time, up to 10 years in length and deliver benefits in terms of VAT reclaim. The process is highly complex and requires increasing levels of legal and contractual input from not just local NHS Board Procurement Officers, but also the Central Legal Office in Edinburgh. The contracts drawn up, which can have as many as 100 third party providers contained within, are highly tailored for the demands of the clinical services served by the laboratories within each Health Board. There would appear to be a strong opinion within the profession that there would be very minimal economies of scale savings made by expanding such managed service contracts beyond individual NHS Boards. Indeed, this may likely make the process overly complex and increase the likelihood that the procurement would not succeed and would be open to significant legal challenge. In addition, because of the nature of the contracts involved, it is likely that larger procurements would decrease levels of competition amongst the commercial companies who may decide to bid for such work, and this in itself may drive up the cost and decrease the drive for innovation.

An approach to delivering benefit within the current framework may be a better supportive mechanism set up to aid individual laboratory services that are going through procurement processes. This would need to include appropriate contractual and legal advice on the procurement issues, but may also allow a mechanism for more formal sharing of procurement documentation between individual NHS Boards. There would also be the opportunity to ensure that common service standards and requirements, as deemed appropriate by the Managed Diagnostic Networks, could be consistently made integral to all procurement tenders.

Recommendation Seven: *Mechanism for supporting a flexible approach to procurement that enables delivery of local solutions to multi-disciplinary service delivery that enable compliance with national standardised approaches as identified by the SCBMDN to enable reduction of variation across Scotland.*

2.3.2 Regional/Supra-regional services

All Clinical Biochemistry laboratories currently send away samples to regional centres for work that is too specialised or not cost-effective to carry out in their own departments. Much of this work is sent to Specialist Centres in Glasgow and Edinburgh (some of which are already funded by NSS), however it also remains the

case that many samples are still sent south of the border to English laboratories. Some of these are available in Scottish labs with capacity to take on the workload at an economic cost, while for others it may be possible to set many of these services within Scottish laboratories to enable all the work to remain in NHS Scotland. Currently, no central data is collected on what tests are sent to English laboratories and this should be explored to establish whether the demand across the country warrants an NHS Scotland service, thus ensuring investment in our own infrastructure and control over quality.

Recommendation Eight: *Cost and volume of between lab requesting, for all disciplines, should be audited and the business case for potential service provision to be focussed within Scottish laboratories scoped. Key performance indicators for testing should be agreed and assessed in terms of feasibility by a distributed national service.*

It is acknowledged that much time and effort is spent on the process of sending samples from one laboratory to another – this involves double requesting, double inputting, and opens up the risk for transcription errors at both ends. It would be important that all the laboratories within NHS Scotland worked together to improve this system and to achieve the goal of a seamless electronic transfer of patient and laboratory data. In the absence of a common laboratory information system, the National Pathology Exchange (NPEx) would seem an appropriate vehicle for allowing this to take place. Currently, there is only one laboratory in Scotland (NHS Grampian) that is fully signed up with the NPEx system in place. They can, however, only currently communicate and use this facility with laboratories that they send samples to in England.

Recommendation Nine: *A business case should be developed for all Scottish laboratories to be linked to the National Pathology Exchange (NPEx) service.*

2.3.3 Demand Optimisation

There has been much discussion in recent years regarding appropriate utilization of laboratory tests, with particular focus on the so called wastage element of this. However, there is also significant under utilisation in some testing areas, meaning that patients are being missed out or disadvantaged. The NHS England atlas of variation highlighted huge variations in requesting rates amongst general practitioners across England. It is likely that such variation also exists across Scottish Primary Care. There are national projects coming on line from within the professional bodies, including the Royal College of Pathologists, aimed at both defining guidance on demand optimisation initiatives, but also the establishment of minimum retesting intervals across all pathology disciplines. There is much to be gained within a shared services model if a common consistent approach to the delivery and monitoring of demand optimisation interventions can be delivered.

Recommendation Ten: An approach is developed and adopted to enable construction of a detailed "Scottish Atlas of Variation" of use diagnostic services similar to the "Atlas of Variation" developed for use in England *(http://www.rightcare.nhs.uk/index.php/atlas/diagnostics-the-nhs-atlas-of-variation-in-diagnostics-services/).*

Recommendation Eleven*: To deliver reduction of waste and variation national recommendations should be developed or adopted to enable optimal use of resources to enable delivery of evidence based best practice.*

Demand optimisation necessarily addresses variation and waste. On a micro scale this might be considered in the context of a single test and delivery of the benefits of that test by ensuring that test is applied in the appropriate context to deliver a desired outcome. On a macro level it needs to be considered in terms of optimised application of appropriately configured services within the whole system to deliver desired outcomes at a population level. The concept therefore needs to be embedded throughout the health care system challenging existing silo-ed thinking around resource allocation and management. Those charged to deliver diagnostic services must understand and demonstrate the impacts of investment in existing and new systems of working and technological developments across the whole health care system. Demand optimisation should not be silo focussed, but organisationally viewed to enable identification of opportunities for both investment and disinvestment with virement (e.g. investment in new test such as procalcitonin and calprotectin). This approach requires engagement nationally within a framework that will enable cross silo view of demand optimisation to enable a much broader view of the concept of demand optimisation. The SCBMDN and other networks should engage with the National Health Care Sciences Delivery Plan to progress demand optimisation and ensure that measures adopted and proven to be successful at Board level are documented, shared and adopted.

Recommendation Twelve: *A national framework should be developed to enable a multidisciplinary whole systems approach to service demand optimisation to enable focussed investment in diagnostics. The structure should enable a bottom up and top down approach to identification and development of targets for demand optimisation.*

Recommendation Thirteen: *A national infrastructure should be developed to enable sharing and adoption of demand optimisation initiatives that have proven value.*

Procalcitonin measurements: whole system benefits from investment in diagnostics.

Antibiotic stewardship is an increasingly important area of focus and concern within the NHS and other healthcare systems internationally. Direct cost of antibiotics, impacts of antibiotic treatments on bed stays, and over usage of antibiotics leading to antibiotic resistance all deliver resource pressures on health care systems and deliver risks for patients. Unintended and avoidable outcomes for patients may result from unnecessary administration of antibiotics include acute kidney injury.

An outcome based business case developed within NHS Tayside identified that making pro-calcitonin assays available to the intensive care unit enabled antibiotic stewardship and other benefits to the unit. An evidence based protocol applied to patients within a 12 bedded unit delivered an estimated 38 antibiotic free days per month and a reduced spend of £750.00 per month on drugs. Benefits accruing include:

- Reduced bed stays, within and outwith ICU
- Enabling clinicians to make informed decisions as to start and stop antibiotic therapy delivering antibiotic stewardship
- Direct costs associated with prescribing and administering intra venous antimicrobial interventions
- Reduction of exposure to antibiotic side effects, reduction of selection pressures that might lead to emergence of antibiotic resistant strains.

The business case to make the test available to ICU, medical and surgical HDU totalled £85,000. This cost would not be recouped by save in antibiotic spend, but clearly offset by estimated impacts on bed stays within those high cost areas and other benefits in terms of patient safety and potential improved outcomes. Thus, investment in diagnostics is having benefit elsewhere in the system delivering opportunities for virement of savings or invest to save opportunities as a consequence cost avoidance in other areas.

This project was proposed by a laboratory medicine specialist and executed by a multidisciplinary team consisting of laboratory scientists, hospital infection specialists, and intensivists taking a whole systems outcome based approach. The initiative has flow and capacity impacts and therefore impacts on demand (bed occupancy).

Other examples of how investing lab diagnostics to impact on demand for service would be the introduction of calprotectin assays to manage the demand on endoscopy services from primary care.

2.3.4 Data, Information and Knowledge Management systems

Modern Diagnostic services cannot be delivered without the aid of information technology. Delivery of safe and effective services relies on accurate flows of data, information and knowledge. The overall impact of services on patient care, and the health care economy, depends on how well they are utilised and their outputs applied. Failure to apply investigations available through diagnostic services in the correct context and at the right time, or failure to apply the report generated appropriately at the point of care represents a failure of the system and reduces the value of investment in skills and resources within those services. This failure carries penalties for the patient and other parts of the organisation. Delivery of an effective value for money service requires therefore a fit for purpose infrastructure to deliver a well thought out information and knowledge management strategy.

The table below illustrates four layers of business operation of a diagnostics service. While each layer has a different role within the overall organisation of a laboratory, the functional integration of each of the matrix components is key to the system's overall success. In practical terms this means that information and knowledge systems need to meet the multi-disciplinary practice needs of service providers and users, while also having the capability to address the key business issues shown in the table. Systems and processes developed, need to be robust, resilient, and flexible enough to support existing services and able to develop rapidly to support local and national initiatives. Delivery of an effective strategy will depend upon people, processes and availability and appropriate use of technology. Web technology and system interoperability will provide many opportunities to increase the effectiveness of services by enabling faster, or real time, dissemination of information and knowledge rich interfaces. The E-health agenda has a major focus here and consequently there needs to be a significant degree of co-ordination of relevant activities and developments within Diagnostics to the benefit of the whole system to maximise the impact of diagnostic services.

Historically the diagnostics services have been forward thinking in the use of IT. They have however evolved approaches to development, delivery and support of many different systems in ways that may well be perceived as ranging from co-ordinated, structured and pro-active, to idiosyncratic and reactive. This has happened as a result of developments taking place within separate departmental structures, with the result that there are significant pockets of knowledge that are essential to the delivery of the overall service that reside in a small number of people. Merging of Departments, with the blurring of the distinctions between disciplines, the introduction of new systems that figure significantly in the wider E-health agenda (e.g. in localities and nationally) and moves towards web based systems is changing the environment within which the Diagnostics services staff with “IT” responsibilities operate and how they need to operate. It is important to note

that the support overhead for newer systems is increasing at a time when a greater focus is required on developing the functionality of intermediate and executive systems as described in Table 1.

At Board level there are varying degrees of ownership of key systems by laboratory staff and E-health structures and varying degrees of involvement in strategic planning around e-Health. The increasing drive towards electronic ways of working, and the aspiration of a purely electronic patient record requires alignment of strategies, common functionality across organisational boundaries within and between Boards and consequently interoperability. The current level of inter-operability that exists between Scottish laboratories and their ability to share and transfer laboratory information electronically is particularly low. Each Health Board Laboratory Service has been allowed, over the years, to set up their own individual laboratory information system (LIMS) using test names, units of measurements, and reference intervals that are unique to them. Similarly, even when so-called national roll outs of reporting systems such as Trakcare were introduced, this did not meet with universal uptake, and in any case, each NHS Board was again allowed to define the attributes for common tests in their own personal and unique way. Overall, this means that it is not possible for laboratories to easily share and combine information data related to patients' tests results currently across NHS Board boundaries in Scotland. As well as being a significant patient safety issue when patients or doctors move Health Boards, it also limits the ability for the pooling of information for clinical audit work or research purposes. This barrier therefore to the use of "big data" will remain in place until this situation is resolved through exploration of the rationalisation of IT systems to improve interoperability between NHS Boards.

Nationally, within NHS England, there has been an attempt to develop a National Laboratory Medicine Catalogue. This is aimed at providing a single mechanism for naming all laboratory tests within the laboratory medicine repertoire, as well as units of measurement and reference intervals where possible. There is still some way to go in this process, however there is clearly an opportunity for NHS Scotland to adopt this at an early stage and ensure its roll out through all areas which will include laboratory information systems, order communications systems, downstream clinical databases, and GP/secondary care electronic records systems. Again, a shared services model with the proper mandate and clinical governance arrangements would be vital in order for such a scenario to move forward in a sensible and consistent manner. Selection of the correct examination procedures with subsequent application of the results to maximum effect delivers value from the system and delivers improved patient safety. Evidence based approaches to communication of results will lead to improved effectiveness and equity of care.

Recommendation Fourteen: *Diagnostics services should deliver a Scottish formulary of diagnostic testing and promote uniform adoption to enable*

standardisation of terminologies, codings, units, reference intervals to enable interoperability, new approaches to use of data and deliver demand optimisation.

Recommendation Fifteen: *Time should be invested in exploring increasing the equity of services provided across the country and reducing the variation in the processes used in communication of results of examinations. This will be echoed in "Communication of Critical Results", due to be published in 2016 by the Royal College of Pathology.*

Recommendation Sixteen: *A diagnostic specialities e-Health group should be formed and identified as key stakeholders by the national e-Health groups; they shall be required to review existing and future needs around data, information and knowledge management to produce a national strategy for delivering a resilient infrastructure for diagnostics that improves efficiency and effectiveness enables interoperability and fits with national e-Health strategies within the context of the currently evolving health care model. The strategy should evolve to enable the development, delivery and benefits of investment in diagnostics rather than define and inhibit. Serious consideration should be given to the implementation of a common Laboratory Information Management System (LIMS) across NHS Scotland to enable improved Board to Board cross working and communications.*

There is often a significant resource within Diagnostics service workforce focussed on IM&T that needs to be developed to enable effective delivery of the business operations outlined in the above table. In addition there is a need to enable delivery of information and knowledge management strategy for the diagnostics that is that is compatible with Boards and NHS Scotland's E-health agenda. There is significant IM&T expertise, skill and knowledge within the Diagnostics departments that could be made available to aid progression the E-health agenda. It is fair to say that much of this resource is in the form of health care professionals that have developed IT skills. Knowledge, skills and infrastructure not present within that group of individuals to enable the newer approaches to delivery of IM&T services on an enterprise wide basis are present with e-Health departments. It therefore would appear sensible to review the current approach to delivery and development of the various systems used in Diagnostics to enable identification of a model that will facilitate the use of staff and other infrastructure to enable the most efficient and effective delivery of the business processes outlined above. Sight must however not be lost of the need to provide and cultivate specialist local professional knowledge required to enable optimal systems configuration and operation to support service delivery and development. Diagnostics IM&T staff may benefit significantly from closer more integrated working across disciplines and with laboratory IT specialist staff where they exist with staff within and between Boards e-Health departments. Closer working and alignment of laboratory IT and E-health may enable better planning of services, alignment of strategies and resource requirements and opportunities for development of staff.

It has been stated that modern diagnostics services should be considered as specialised information and knowledge management services. Today's environment requires skills that are matched to the developments employed for data management and in newer information and communication systems. The latter will form interactive interfaces with rich in functionality required to support the user of diagnostic services of varying knowledge and ability. The need to enable safe accurate and effective use of medical laboratory services in primary/community care may require the development of an appropriate portal with significant input from laboratory medicine specialists. This reinforces the need to develop appropriately developed levels of knowledge of and skills in these areas within the diagnostics services or e-health workforce structures.

Recommendation Seventeen: *Current and future workforce models for delivery of diagnostics data, information and knowledge management and technology should be undertaken; this should be appropriately focussed on development and delivery of increased levels of skills and knowledge within existing and proposed workforce structures, in newer information and communications systems (e.g. web technologies and mobile devices).*

Recommendation Eighteen: *Lab services should provide significant input to the development of a primary care portal.*

Layer	Description	Clinical Functions	Management Functions	Information Content
4	Executive Systems	Clinical Decision Support Clinical Audit Risk Analysis	Performance Monitoring Planning Quality Management Document Control	Knowledge
3	Intermediate Systems	Ward/GP Requesting Clinical Reporting R&D Support	Workload Statistics Contracting Supplies Quality Assurance statistics Scottish Government returns	Aggregate information
2	Operational Systems e.g. Traditional LIMS & Workstations	Analytical Control Reporting POCT Networks	E-mail Word Processing Web Browsing	Operational Data
1	Network / Infrastructure	Servers / PCs Network / Printers/voice & image management User Groups Liaison with other IM&T and KM groups, Board E-Health, National groups. Information Governance		Infrastructure

Table 1

2.3.5 Seven Day Working

Diagnostics currently provide 24 hour cover seven days per week where clinically necessary. Currently Depth and breadth of repertoire of examinations available at

particular locations vary according to the clinical service requirements at any particular location. The potential impact on diagnostic services cannot be fully determined until the model of care is defined by SGOH Seven Day Working Task Force. There are currently variable approaches to out of hours and weekends and this is likely to be the case depending on the clinical configuration of the locality being served. Different localities may be better equipped to provide much larger core multidisciplinary workloads with fewer staff via large robotic systems at this point in time. The same workloads might prove difficult to deliver and unnecessary in smaller units. A flexible model for delivery a core or extended repertoire might be agreed to define a minimum service level for units of varying size and to support a weekend primary care service.

Staffing a seven-day delivery of wider out of hours and weekend repertoires with increased volume will deliver challenges to the current model of service delivery. An extended critical mass of HCPC registered laboratory staff with support workers will be required to deliver reconfigured services in the absence of alternative technological approaches. Those approaches might include use of POCT systems managed by laboratory staff, but operated by health care workers; or enabling smaller number of HCPC registered professionals to remotely manage via IT links systems with much greater analytical capability located in laboratories at several locations but operated by non registered laboratory staff.

Recommendation Nineteen: *A flexible model should be developed for delivery of a defined core or extended examination repertoire to enable delivery optimal service level for secondary care units of varying size and to support of a weekend primary care service. Novel approaches to configuration should be considered to enable potential workforce issues and the requirement/potential to deliver cross disciplinary workloads.*

Recommendation Twenty: *Biochemistry services provide a broad range of services that impact on the patient journey. A model which has a secure foundation, yet allows a range of expertise to be available across the country should be agreed as the optimal model.*

2.3.6 Point of Care Testing

Points of care testing (POCT) technologies have developed significantly in recent years enabling delivery of in vitro diagnostics by health care professionals. The sophistication of the technologies available is resulting in wider repertoires of testing available outside of conventional laboratories across primary and secondary care. The availability of POCT enables delivery of results of testing that enable informed decisions within time frames that enable positive impacts on patient care and thus outcomes, patient flow and capacity.

Findings from the SCBMDN POCT Survey 2013

Three hundred and fifty four (354) completed questionnaires were returned from ten health boards across Scotland: 186 from primary care users and 168 from secondary care users. Two health boards did not participate in the questionnaire process and one health board submitted only a single user response.

ii. Users reported on one thousand and thirty-one (1031) individual POCT services across ten health boards, covering thirty-five different POCT tests, with an estimated annual POC workload of ~650,000 tests.

iii. Of the 1031 POCT services 61% of these resided in primary care locations and 39% in secondary care locations.

iv. POCT services are highly valued by users because they help avoid the need for central laboratory testing, saved in repeat patient appointments and guided users in the management and treatment of their patients.

v. There are large numbers of services, across all health board regions and across both primary and secondary care locations, where user reported adherence to good clinical governance practice is poor. The consequent concern, therefore, is the ability of these POCT services to subsequently deliver the high quality of service necessary to minimise the risk to patient care.

vi. Across all the Health Boards and across primary and secondary care locations, a consistent marker for demonstrating higher levels of compliance with good clinical governance practices was the provision of laboratory oversight.

vii. Within the current service model, the management of POCT data is limited and essentially resides within the service silo where it is produced. Patient results cannot be shared within or between primary care locations and this limits the value of the test result significantly in comparison to laboratory produced results which are available within PMS and SCI store.

A recent survey by the SCBMDN and the SMVMDN identified the current extent of POCT schemes within the Boards and further highlighted the Clinical and information governance issues. It was observed that there was a positive relationship between laboratory oversight of schemes and compliance with good clinical governance schemes. The view is that POCT will not only enable patients to be dealt with outside of the standard hospital setting, but also, in other more acute areas, allowing a faster turnaround in their subsequent diagnosis and management. Such developments in point of care testing have been hindered in recent years due to stagnation in the laboratory silo budgets and the resulting inability for the laboratory to provide proper input, guidance and overseeing functions for such services. It is no surprise therefore, that many point of care services have been rushed through without laboratory involvement and exist with minimal or no governance or quality arrangements. A shared service model with appropriate governance may allow this situation to be better resolved. It would however require loosening of the laboratory silo budget within each Health Board to enable laboratories to fund and support such services.

POCT is recognised as one of the major work streams within the National Health Care Science Delivery Plan with objectives set for the Boards. There is a need for a co-ordinated approach to POCT to ensure appropriate investment in schemes that deliver value and which comply with governance requirements. There is requirement for investment in infrastructure to ensure data are captured in patients records and quality of systems are POCT managed and a need to develop strong links between laboratory specialists and community based delivery systems to enable safe and effective delivery of POCT services that deliver value from the investment in them. The health economics of POCT schemes need to be critically assessed prior to their introduction with appropriate virement of finance to support a national infrastructure.

Recommendation Twenty-One: *Diagnostic services should be configured nationally and locally to support increasing volumes of POCT and that mechanism should be found to invest in the required infrastructure to enable clinical and information governance issues to be addressed. Schemes should be accreditable to ISO 22870standards.*

Recommendation Twenty-Two: *That technological advances in POCT should be exploited alongside other technologies to enable multi- disciplinary delivery of core workloads in small workload volume units 24/7 (e.g. biochemistry, haematology, coagulation and bacteriology (molecular approaches for hospital acquired infection purposes).*

2.3.7 Quality and Accreditation.

Compliance with regulation and accreditation standards delivers an increasing overhead to laboratories with smaller boards struggling to comply. MHRA and UKAS standards are rigorous and those labs achieving the recognised level of accreditation or regulation are compliant with international standards (e.g. ISO 15189) and deliver safe and appropriately resourced services. Meeting these challenges in the 14 NHS Boards is resource hungry and results in duplication of effort. Shared infrastructures, commonality of approaches to analytical systems introduction and usage systems, competencies equivalence and many other convergences which could be achieved through a shared service approach would reduce the quality overhead and enable compliance of smaller units with fewer staff.

Recommendation Twenty-Three: *An infrastructure should be developed at national level that enables a reduction of the overhead associated with compliance with regulation and accreditation standards. Mechanism should be specifically identified to support the smaller more remote units to address their challenges they face in achieving the required standards.*

2.3.8 National Laboratory Dashboard

In the current model each of the Board based lab services, in all disciplines, are able to undertake comparisons of elements of their service structure and delivery via participation within Keele Benchmarking. While the majority of Scottish laboratories

annually submit information for publication in the Keele benchmarking system, it is clear that this process is complex and is limited in terms of the conclusions that can be drawn. It also carries a significant overhead in terms of delivery. The recent pathology quality assurance review carried out for NHS England has recommended that a National Pathology Dashboard be formulated for NHS England. The aim of this dashboard would be to provide key summary and benchmarked statistics on a regular basis for use locally within a Health Board organisation, but also for national comparative purposes. This is something that a shared services model could develop for laboratories within Scotland. It would enable summary forecasts to be made on aspects of not only budgets, staffing, EQA, accreditation and revalidation rates, but also focus on outcome statistics such as turnaround times for key diagnostic tests or 24/7 repertoires.

While benchmarks of this type will enable some valuable comparisons to enable identification variance across Boards and a few key performance indicators, they do not necessarily give and meaningful measure as to whether investment in a local service is effective.

Recommendation Twenty-Four: *Alternative approaches to the Keel benchmarking system are developed to enable meaningful comparisons of key performance indicators across boards and that processes are developed to enable meaningful evaluations of effectiveness at local and national levels.*

2.3.9 Workforce

Following a workforce planning meeting that occurred between SCBMN steering group members and NSD on 5th March 2014, a decision was taken to facilitate a workforce data collection exercise in advance of the proposed changes to providing "Round the Clock Care" which will have implications for diagnostic services. This exercise was consistent with earlier discussions that have taken place within the Network that concluded more intelligence was required around the current and future proposed models for delivery of service to enable definition of a workforce planning.

A questionnaire was constructed requiring respondents to address the following questions.

1. What is the size of your Laboratory?
2. What are your Current and Future Drivers?
3. Briefly describe what is working well in this model
4. Briefly describe what is not working well in your current model
5. Are there any plans in place to change your service delivery model?
6. If so who/why /what are the key drivers for this change?
7. What would your ideal service delivery model look like and why?
8. What do you think needs to be put in place to nationally to support the delivery of your ideal model of service delivery?

Clearly the development of a work force plan using Six Step[iii], or any other methodology, requires that we have a defined service model. The environment in the various boards across Scotland provides a high degree of complexity and variation in approach to service provision. Population density and geography have a major impact on service requirement and design. This diversity results in difficulties in future workforce planning locally and nationally to deliver what is believed to be needed for the safe provision of existing models and futures service delivery models.

It is clear that current service delivery models have evolved to meet local needs with a requirement to deliver equity of service to the population as a whole. A common theme within the response to the questionnaire is one of continuing service improvement in response to various drivers for change, often involving significant redesign, and a predominant progression towards a Blood Sciences model. This latter evolution is proving challenging in terms of achieving levels of integration of the individual disciplines and development of environments that enable best use and development of generic skills. An issue at board level and nationally for the services is therefore one of provision of a workforce that is able to efficiently and effectively deliver core services while maintaining specialist services and knowledge within units of varying size. The scale of the operation may in fact deliver an effective driver for delivery of true multidisciplinary services with the pressure to succeed being much greater in those smaller labs serving rural and remote areas with smaller workloads and smaller numbers of staff.

Hub and spoke models of service delivery have/or are being developed with newer analytical technology and information and communication systems now affording different opportunities to manage workloads out of hours or in the community. The newer high throughput tracked analytical systems provide massive multi-disciplinary capacity in the core lab services and deliver economy of scale from centralisation of workloads. Increasing efficiency should enable refocusing of staff resource into other areas of the service. It should be noted that a common driver for change identified in the responses was identified as delivery of financial targets. This may lead to pressure to reduce staff numbers and grades to meet financial targets rather than as opportunities to release resource to reinvest in other elements of current or developing service.

Out of hours working was identified as providing challenges by respondents in various Boards. There is impact on core staffing levels during the day as a consequence of the need to comply with working time directives. The need to deliver 24/7 services at both hub and spoke labs carries a high cost and delivers sustainability issues. Some Boards are now delivering service during the day at spoke labs and resorting to point of care testing out of hours or transport of work to core labs.

As an overall summary it is fair to state that all the Scottish biochemistry services have similar objectives in that they wish to support delivery of patient centred and

effective health care. It is clear that one model of service delivery will not fit all NHS Boards, but there are commonalities and interdependencies. The many common drivers for current and future service design (Figure 2) will impact heavily on local workforce planning that may have knock on effects for other Boards. This may impact on availability of training places, for instance, and also upon delivery of specialist services. A need was identified by respondents for more joined up thinking around workforce planning on a national level that is truly linked to a defined models of service delivery tailored to the various Boards requirements. If Blood Sciences is to be the preferred service delivery model in Scotland for the future, then the following represent a response to question eight in the survey identifying national needs from several Boards that also generally encapsulates those of others in this context:

- A clear Scottish perspective on scientific staff training for people entering the professions in Blood Sciences
- Support to develop externally validated training and competency schemes for cross-training of staff
- Leadership development for senior staff in laboratories
- Adequate resources to train and develop staff – currently staffing levels do not provide enough slack to allow timely training
- Workforce planning. Support for training. Mechanisms to enable a more holistic approach to national delivery of appropriately configured services.
- National programme for training of Clinical Scientists across Scotland and consistent career structure
- Review of specialist laboratory services to ensure these can be sustainably delivered for the Scottish population
- Mechanisms to deal with geographical difficulties with recruitment
- Education of Chief executives and senior management team as to the value of collaborative developments between clinical and diagnostic services

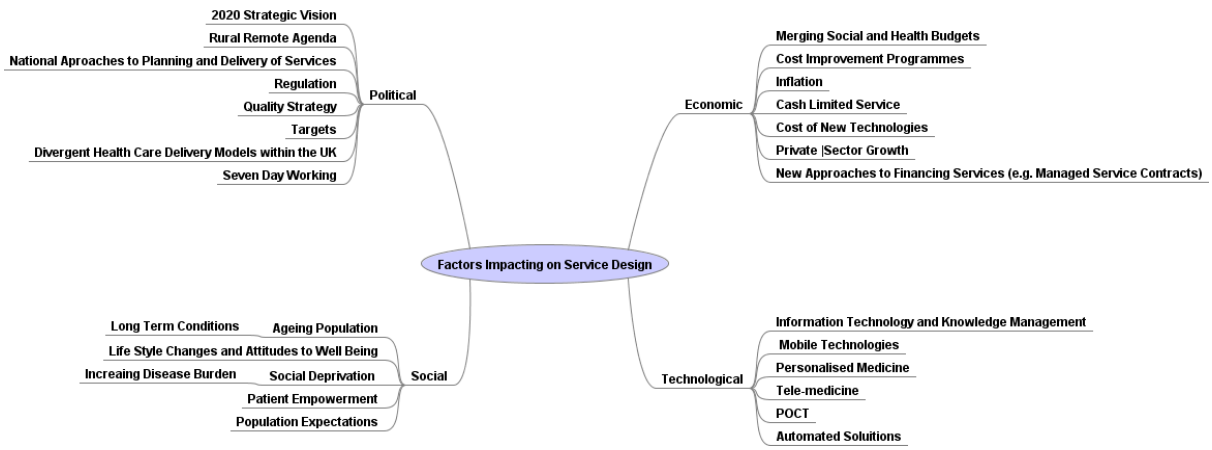
In the current state issues of resilience, recruitment and retention and geographical mobility of staff groups were identified as issues by respondents requiring a national focus. The impact of Agenda for Change issues and pay protection were cited by a number of respondents as being a significant cause for concern at this time.

In terms of an overall assessment of current state, many Boards are moving to, or have a desire to, move towards a Blood Sciences model of service delivery as a future service delivery model. This evolution is taking place within a complex environment (see PEST below Figure 2) and is confounded further by silo-ed developments within the Boards varying as a consequence of different weightings being applied to the drivers for change influencing the design of the future state. Clearly national directions as defined by 2020 Vision and 24/7 service delivery require more joined up thought around future models of service delivery and workforce planning at a national level. Respondents have identified these two national initiatives as areas that will impact on service models and this will provide

challenges in terms of design and delivery at every level. The need for patient focus, the increasing burden in delivering the current and future quality agenda and of increasing complexity of regulation and accreditation will provide further challenges particularly to smaller units. Opportunities in terms of technological advances and improvement in information and knowledge management provide opportunities of service redesign that will enable some of these challenges to be addressed and burden proportionately shared, but the full advantages of such developments may require organisational change enable the delivery of benefit. Response would suggest that some Boards feel quite vulnerable at the moment and it has been suggested by one at least that an obligate network might enable many of their local concerns to be addressed through more formal links with a bigger diagnostics operation. Focusing on the latter point; there has been a lot of investment in real estate and technology for Biochemistry in Scotland linked to local planning which delivers benefits of economies of scale locally that may lead to increasing diversity of approaches nationally. This silo-ed approach to improvement needs to be addressed as it impacts on future resilience of the service delivering inequities within the service provision nationally. There is a clear need identified to develop national approaches on issues of common concern around planning of workforce for all professional groups. In any future state there will be requirement for new roles, extension of roles and change of focus towards more community based activities. A more holistic approach to service design and delivery in the context of national planning will be required to meet the challenges ahead.

Recommendation Twenty-Five: *A national approach to work force planning should be developed in the context of the favoured model of delivery of services.*

Figure 2. PEST: analysis factors impacting on service design



3.0 The art of the possible: A radical view

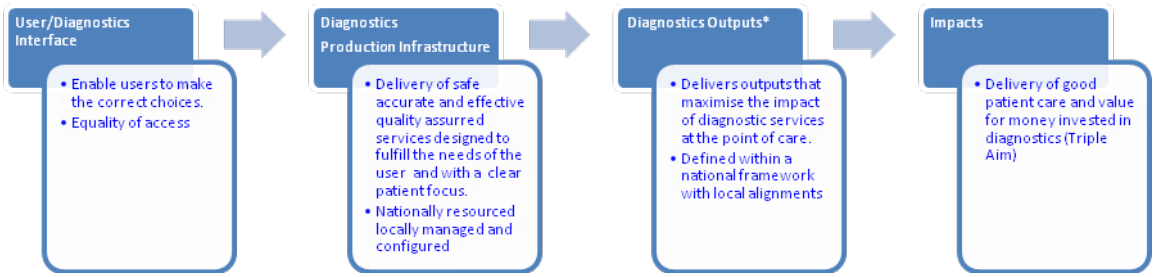
The previous section proposes potential ways of developing a national approach to service delivery based on consensus working across Boards under the current model. The approach is conservative and does not identify a governance structure to enable mandatory change to deliver benefits of standardised approaches at a national level. The absence of such a governance structure has delivered a significant barrier to moving forward initiatives by the SCBMDN. Much has been achieved, but progress has been impeded by the fact that decisions of the network are not binding, and the fact that any initiatives requiring resource for implementation require multiple business cases. While there is clearly a need to enable a degree of flexibility in the design and delivery of services within Boards to support local clinical configurations and strategies, the question arises as to the relative benefits of bespoke services operating outside a national framework in this way; compared to that of a service delivered under a national framework, with some modifications to meet local needs. Arguably a national service model with a defined strategy and budgetary responsibilities might be better equipped to deliver a more resilient and robust model that delivers efficiencies and increased effectiveness. National approaches will enable alignment of service delivery to NHS Scotland requirements by enabling top down and bottom up lines of communication to achieve the required linkage throughout the system to address the Triple Aim.

The concept of delivering a nationally managed Diagnostics service will prove to be controversial to those working within the current model/system and fraught with difficulties in terms of delivery. However, the question must be asked as to whether there is any other way to address the sustainability issues or to enable the required transition to support proposed changes to healthcare in Scotland and to deal with the demands on service that are arising from the drivers that are forcing that change. The organisational complexity is set to increase within NHS Scotland as a consequence of the integration of health and social care and formation of the Integrated Joint Boards. Those boards will have control over funding that will impact on diagnostics services as a consequence of prioritisation within new agenda.

The delivery of diagnostics needs to be considered and managed holistically. The services need to be robust, resilient, efficient, effective and enabled to rapidly translate best evidence, technology and practice into patient focussed care. This can only be achieved via an accessible delivery model that is serviced by an able and empowered workforce working within an infrastructure delivering diagnostic outputs that have impact and thus value (Figure 3). Clinical biochemistry is only one of a number of laboratory medicine specialties in diagnostics specialties and cannot be considered in isolation because of the blurring boundaries between disciplines arising from convergence of technologies, sharing of infrastructure, the existence of a common interface with users in terms of input and outputs and the development of

delivery systems that are driving multidisciplinary approaches to the management of combined services. The Four Box model shown in Figure 3 is therefore applicable to all disciplines and can be populated with items to be managed within evolving management structures at a national and local level. It also applies to non-laboratory services again with commonalities. The use of electronic ordering interfaces and adoption of problem, symptom or pathway approaches to ordering tests requires shared functionality.

Figure 3. Four box model: Delivery of Diagnostics



3.1 What could a national service model look like?

The model would need to address the issues identified in earlier section of this paper. The main issue is around the governance structure and funding arrangements to enable delivery of a national model. There may be a number of options which may stand alone or work as hybrid models:

A. Continue as is with Diagnostic Steering Group overseeing the activities of the MDNs as they try to achieve consensus.
B. An enhanced version of the current model:
    1) The current model, but with enhanced ability to mandate clinical service change. It is expected this could only be achieved through authority devolved from the NHS Board Chief Executives Group
    2) The current model with devolved authority as above, giving national oversight of diagnostic services however with an enhanced proportion of national specialist services.
C. A national diagnostics service, where all budget is top-sliced from NHS Boards and services are provided through a series of service level agreements with NHS Boards for local or multi-Board services
D. Nationally tendered service, where a series of agreements is in place for the provision of services, some of which will be service level agreements with NHS Boards; others will be agreements with private sector.

In each option a national group would be required to deliver oversight; with the technology available to deliver both high degrees of centralisation of laboratory

services and a more distributed service with increasing volumes of POCT. All options require joined up strategies around IT and robust logistic solutions.

All options will prove challenging to deliver; and, as was pointed out in section 2 of this document, attempts to deliver national models elsewhere in the UK have identified difficulties that would need to be overcome, particularly around IT and transport logistics. Options may include elements of outsourcing, which has been attempted on varying scales and met with varying degrees of success. Lessons learned from other centres should be thoroughly explored.

Option A presents the current model, a National Managed Diagnostic Network, which reports into the National Specialist Services Committee via the Diagnostic Steering Group. Status Quo provides a route for national networks to recommend change to the NHS Board Chief Executives via NSSC; however this has not been tested as a way to mandate whole-systems change and it is thought this approach will be both time consuming and lead to piecemeal responses to many of the 25 recommendations identified within this paper. The HbA1c project described earlier identifies some of the potential issues with this approach. The question arises as to whether this approach is flexible and responsive enough to enable reactive and transformational change required within a rapidly evolving healthcare system.

The B options enhance the current model; effectively giving it greater powers to affect change. In B1, devolved authority would be required (presumably from the NHS Board Chief Executives' Group); allowing the network to mandate change and set standards across NHS Scotland. B2 builds on this however in addition to the national oversight and change vehicle as described in B1, there would be identification of additional national specialist services which would be commissioned through the usual channels. This would concentrate expertise in certain subject matters in specific labs, allowing general services to be managed locally.

Option C is the most radical, potentially the most challenging to implement but also if successful the most likely to result in a model capable of providing equitable, high quality services. Funding would be top sliced from NHS Board budgets for the provision of a nationally managed diagnostic service. This type of approach has been attempted in other health care systems within the UK and it is critical that the benefits and disbenefits arising from those initiatives are fully assessed as part of a balanced risk assessment of this option.

Option D may become of increasing interest as some of the diagnostic companies move towards delivery of managed pathology contracts as opposed to managed service contracts. The term tendered in this context being defined as commissioning work from a third party provider which may be another NHS provider or a commercial partner. The challenge here is to maintain the equality and diversity of service within an affordable cost envelope. Sufficient professional oversight would be needed in this model to deliver the required degree of flexibility, ensuring its ability to be

reactive to emergent issues as the model of care evolves and to enable adoption of new advances in the field. How to deliver the clinical advice layer to enable the delivery of clinical governance and clinical effectiveness is a critical question to be addressed in these models.

Option B2 and D may provide an approach enabling transfer of risk and delivering efficiencies while affording transfer of resource into the gate keeping, demand optimisation and effectiveness agenda. The national group charged with commissioning these options would own the strategy with operational groups at a national and local level over those items to be found in the four box model (Figure 3) less focussed on the production elements of service delivery. In option D those with national and local oversight would continue to own strategy, oversee quality and issues such as demand optimisation via operational groups.

Whichever option is adopted to deliver the required service to users will require a transitional approach to service delivery that will be challenging. There have already been attempts in England, Wales and Ireland to progress the options proposed or variants of them. It is important at this stage that those initiatives are not written off as unworkable in Scotland without undertaking a critically appraisal of what worked well and what did not for those health care systems.

The critical question to be addressed is whether the risks surrounding the current status quo in the delivery of service within the evolving health care system in Scotland outweigh those potentially associated with delivery of a radical new approach. This assessment needs to be taken across all laboratory medicine disciplines given the interdependencies.

As noted above, there has been varying experience of these options in England, Ireland and Wales and information on the success and failure of these experiences should be sought and fed into a major options appraisal of these options, prior to recommending a preferred route.

4. Conclusion

The options provided may not be exhaustive and represent a starting position for further discussion. The objective is to consider the art of the possible in terms of a model for delivery of lab services to underpin the delivery of a health care system evolving under considerable demands and pressure on its resources. The current model for diagnostics service provision is highly complex and pressurised. The current drivers for change deliver at the same time additional pressures and opportunities for services to evolve more efficient and effective delivery models matched to local needs to support the delivery of a national strategy. There are opportunities also to build on and learn from the experience of other health care systems within the UK that have attempted to, or have delivered, effective or distributed service models.

The interdependencies that exist with the other diagnostic services have not been fully explored in this document. The governance issue will be common across disciplines. Sharing of ideas across the diagnostic networks is an essential next step in order to identify the final models for option appraisal. New technologies and scalable solutions with varying degrees of centralisation may identify radically different models for distributed delivery of diagnostics to NHS Scotland. Such solutions will challenge current professional and speciality specific barriers and may involve significant transformational change. Any radical model identified as best fit for the future state may present us with a difficult and painful implementation, but this may need to be endured to enable the transformation to the required Triple Aim focussed services, operating at the forefront of technology and medical evidence, within the future health care delivery model.

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[i] http://www.england.nhs.uk/wp-content/uploads/2014/01/path-qa-review.pdf

[ii] http://www.qihub.scot.nhs.uk/media/581636/nhsscotland%20qi%20hub%20-%20triple%20aim%20final.pdf

[iii] https://www.ewin.nhs.uk/storage/southcentral/toolbox/e1d93a6f96313335274bd128aef71a20.pdf

5.0 Appendix

5.1 SCBMDN Steering Group Representation

Dr Julia Anderson, SCBMDN Scientific	NHS Dumfries and Galloway
Mr James Allison, Service Clinical Director	NHS Grampian
Dr Bill Bartlett, Consultant Biochemist	NHS Tayside
Mrs Liz Blackman, Senior Programme	NHS National Services Scotland
Mr David Cameron, Head of Technical	Institute of Biomedical Scientists, NHS
Miss Robina Collins, Programme Support	NHS National Services Scotland
Dr Bernie Croal, Clinical Director	NHS Grampian
Dr Anne Cruikshank	NHS GG&C
Mr Geoffrey Day	NHS Shetland
Dr Kevin Deans	Association for Clinical Biochemistry & Laboratory Medicine, NHS Grampian
Mr Frank Finlay, Clinical Lead	NHS GG&C
Mr Ian Gilbert, Clinical Laboratory Manager	NHS Western Isles
Mr Ian Godber, Consultant Clinical Scientist	NHS Lanarkshire
Dr Kim Heathcote, Consultant Clinical	NHS Dumfries & Galloway
Dr Mark Holliday ,Consultant Chemical	NHS Forth Valley
MS Shelia Kowalczyk	NHS Forth Valley
Ms Gillian Lowe	NHS Fife
Dr Suzanne MacKenzie, Consultant	NHS Ayrshire & Arran
Ms Janice McNicol	NHS Lanarkshire
Mr Nick Mitchell, Laboratory Manager	NHS Dumfries & Galloway
Dr John O'Donnell, Consultant Clinical	NHS Borders
Ms Rebecca Pattenden, Principle Biochemist	NHS Lothian
Ms Colleen Ross, Consultant Clinical	NHS GG&C
Dr Mr Ian Rothnie, Laboratory Manager	NHS Grampian
Mr David Smith, Blood Science Manager	NHS Highland
Mrs Alexandra Speirs, Network Programme	NHS National Services Scotland
Dr Cathie Sturgeon, Consultant Biochemist	NHS Lothian
Mr Gordon Taylor, Scientific Consultant	NHS Ayrshire & Arran
Dr Marie Van Drimmelen, Clinical Lead,	NHS Highland
Dr Philip Wenham, Consultant Biochemist	NHS Fife

5.2 SCBMDN Shares Services Working Group Representation

Mr James Allison, Service Clinical Director	NHS Grampian
Dr Julia Anderson, SCBMDN Scientific Manager	NHS Dumfries and Galloway
Clare Adams, Portfolio Manager	NHS National Services Scotland
Dr Bill Bartlett, Consultant Biochemist, SCBMND Lead Clinician	NHS Tayside
Mrs Liz Blackman, Senior Programme Manager	NHS National Services Scotland
Dr Bernie Croal, Clinical Director	Royal College of Pathologists, NHS Grampian
Mr Ian Godber, Consultant Clinical Scientist	NHS Lanarkshire
Dr John O'Donnell, Consultant Clinical Biochemist	NHS Borders
Mr Maurizio Panarelli, Consultant Clinical Biochemist	NHS GG&C
Dr Anne Pollock, Consultant Clinical Biochemist	NHS Highland
Ms Colleen Ross, Consultant Clinical Biochemist	NHS GG&C