Scottish Clinical Biochemistry Managed Diagnostic Network
User Point of Care Testing (POCT) National Questionnaire Report

1. Executive Summary

1.1 Introduction

In early 2010 the Scottish Medical and Scientific Advisory Committee (SMASAC), recognised the need to produce up to date guidance for NHS Scotland on Point of Care testing (POCT). They therefore established a short-term working group to address these issues which reported in 2011 and made recommendations for implementation by NHS Boards in Scotland[1].

To comply with these recommendations, in March 2012 the Chair of The Diagnostic Steering Group wrote to the CEOs of all Scottish NHS Boards advising that they undertake a comprehensive audit to identify all POCT being undertaken in their area. The aim was to determine the degree of regulation being applied to the introduction and maintenance of these services, and the value for money which they offer.

The Scottish Clinical Biochemistry Managed Diagnostic Network (SCBMDN) assisted boards with this request by coordinating a POCT user survey of all Scottish Health Boards. In November 2013 the survey was coordinated across the country by using local laboratory SCBMDN members, in each health board region, to contact their POCT service providers and request that they complete an on-line questionnaire (Survey Monkey). The survey was closed in April 2014 and the responses collated to provide a single national report.

1.2 Findings

The detailed findings are outlined in the results section below, however, in summary –

i. 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.

Assuming that these questionnaire responses are typical of POCT practices across the Scottish health care setting, then it is likely that > 3.5 million POC tests are performed each year, with more than 2 million of these performed in primary care. This, therefore, represents a huge investment for NHS Scotland and every effort should be made to maximise the clinical and cost effectiveness of these services. However, within the existing service model, the restricted use of POCT data does not appear to represent best value for money. In addition, the reported lack of adherence to good clinical governance practice, reported in this questionnaire, is presently a significant concern in terms of risk to patient care. Looking to the future, and given the direction of travel indicated in the 2020 Vision, the number and repertoire of POCT services is likely to increase further and, therefore, alternative models of POCT service delivery should be examined to address these concerns.

1.3 Recommendations

In addressing the findings of this user questionnaire, it is important not only to address the current POCT concerns but also address those likely to arise in the future. Many of the clinical governance failures highlighted in this report are identical across the ten participating Health Boards and the different POCT services. Fortunately, the solutions are also generically applicable and the following recommendations are suggested to improve clinical governance of POCT services and offer improved value for money -

i. Utilise laboratories' experience in the application of process driven quality management techniques and introduce a new model of service delivery, utilising open connectivity and data management solutions with the appropriate laboratory staffing requirement to manage all aspects of clinical governance. This will address the current and future POCT management and governance concerns.
ii. Establish an overarching POCT Committee in each Health Board, integrated within the board risk management and clinical governance frameworks and with responsibility for managing and regulating applications for new POCT services.
iii. Value for money would also be a key focus for the POCT Committee with all future POCT developments requiring detailed business cases along with clinical and cost effectiveness evidenced.
iv. Utilise connectivity solutions to enable POCT results to be recorded within PMS and SCI store, thereby increasing the clinical and economic value of the result to NHS Boards.

2. Results

2.1 POCT Services: Number and Workload

354 completed questionnaires were returned from the ten health board across Scotland: 186 from primary care users and 168 from secondary care users. The responses covered thirty-five different POCT tests. Figure- 1 shows the number of responses from primary and secondary care users in each of the ten boards.

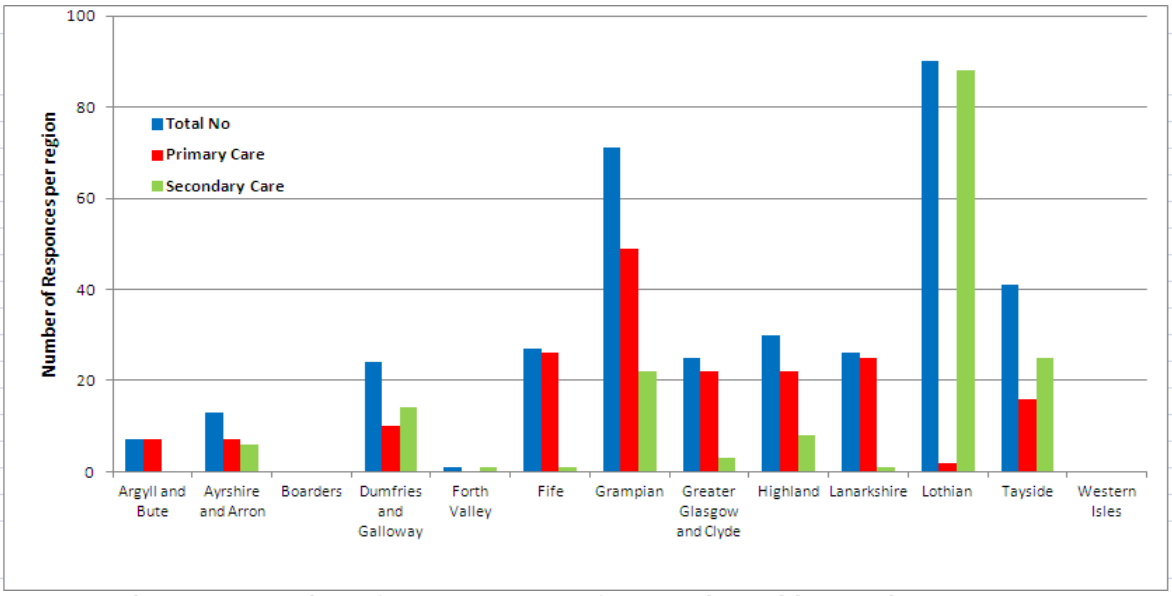

Figure – 1 Number of user responses from each Health Board

All thirty-five separate POCT services reported by users for each of the ten boards are listed in appendix-1. There are some ubiquitous services, such as blood glucose, urinalysis and blood gas testing which are present in all ten health boards, but also some POCT services unique to particular health boards, such as the NT-proBNP POCT services within NHS Grampian primary care practices.

Those POCT services that were present in five or more health boards are summarised in table -1 below along with their service distribution across primary and secondary care locations. In total, the user responses cover more than one thousand separate POCT services: 617 in primary care locations and 390 in secondary care locations with an estimated workload of over 650,000 tests per annum.

Assuming that these questionnaire responses from participating services are typical of POCT practices across the Scottish health care setting and knowing the number and list sizes of GP practices across Scotland[1] and the number and size of hospitals in Scotland, then an estimate of > 3.5 million POCT tests are performed each year in Scotland with more than 2 million performed in primary care. By way of comparison, this test workload is on a par with the annual workload of an average sized DGH hospital laboratory in Scotland [2] and illustrates the importance of these POCT services to patient care and the necessity for ensuring the good clinical governance of these services. Financially, it represents a huge investment for NHS Scotland and thus every effort should be made to ensure the clinical and cost effectiveness for these services.

POCT Service	No of Health Boards with this service	Total Number of locations with POCT	Total number of Primary care locations	Total number of Secondary care locations
Blood Glucose	10	301	143	158
Urine Analysis/ Dipsticks	10	170	120	50
INR	8	89	81	8
Urine HCG	10	96	78	18
Urine Ketones	9	61	47	14
Blood Ketones	8	55	26	29
Blood Gas	9	62	7	55
ESR	6	37	37	0
Urine DOA	7	10	6	4
FOB	5	14	9	5
D-Dimer	3	12	10	2
Haemoglobin	6	9	3	6
cTnI	4	9	6	3
Urine M-albumin	5	9	9	0
UE	5	6	2	4
FBC	5	6	4	2

Table -1 POCT Services present in 3 or more Health Board Regions and their split between primary and secondary care locations

2.2 Governance of POCT Services

The user responses from this questionnaire has revealed a wide range of POCT services in use throughout Scotland; however, a focus on the most commonly reported POCT services will be used for a more detailed examination of the adherence by users to good clinical governance practices. Figure -2 reveals the reported user compliance of blood gas, blood glucose, blood ketones, INR and urine HCG with the following eight markers of good clinical governance practice -

i. Regular internal quality control (IQC) testing – which is essential to ensure, in real time, that the individual operator is performing the test satisfactorily and that the device is operating optimally.
ii. Regular participation in an external quality assurance (EQA) programme – recommended for retrospective and independent assessment of performance compared to a peer group.
iii. Regular service and maintenance of POCT equipment – an essential component of quality assessment.
iv. Laboratory oversight of POCT service and EQA performance – critical to ensuring that POCT results are comparable to central laboratory results (units and cut off values) to avoid misinterpretation by users and also provide advice and general assistance including interpretation of EQA reports.
v. Recording patient results permanently in the electronic patient record (EPR) – recording the results accurately, securely and in a retrievable format to help in the prevention of medical errors.
vi. Regular staff training in POCT – essential to address staff turn-over issues in wards, OP clinics and GP practices. New staff must be brought to an agreed standard of proficiency by practice and instruction and certified to perform the test by a designated trainer.
vii. Competency assessments for POCT staff operators – regular (annual) assessment of proficiency required in order that users retain their certification.

viii. Written protocols for action required in event of an abnormal result, erroneous result or poorly performing device – essential that users know what steps are required when things go wrong and not take inappropriate action that may endanger the patient.

For POCT blood gas and INR services, users reported a high level of compliance in most, but not all, of the clinical governance markers. However, with the exception of regular performance of IQC, POCT services for Blood glucose, blood ketones and urine hCG report very poor adherence to good clinical governance practices (see Fig -2).

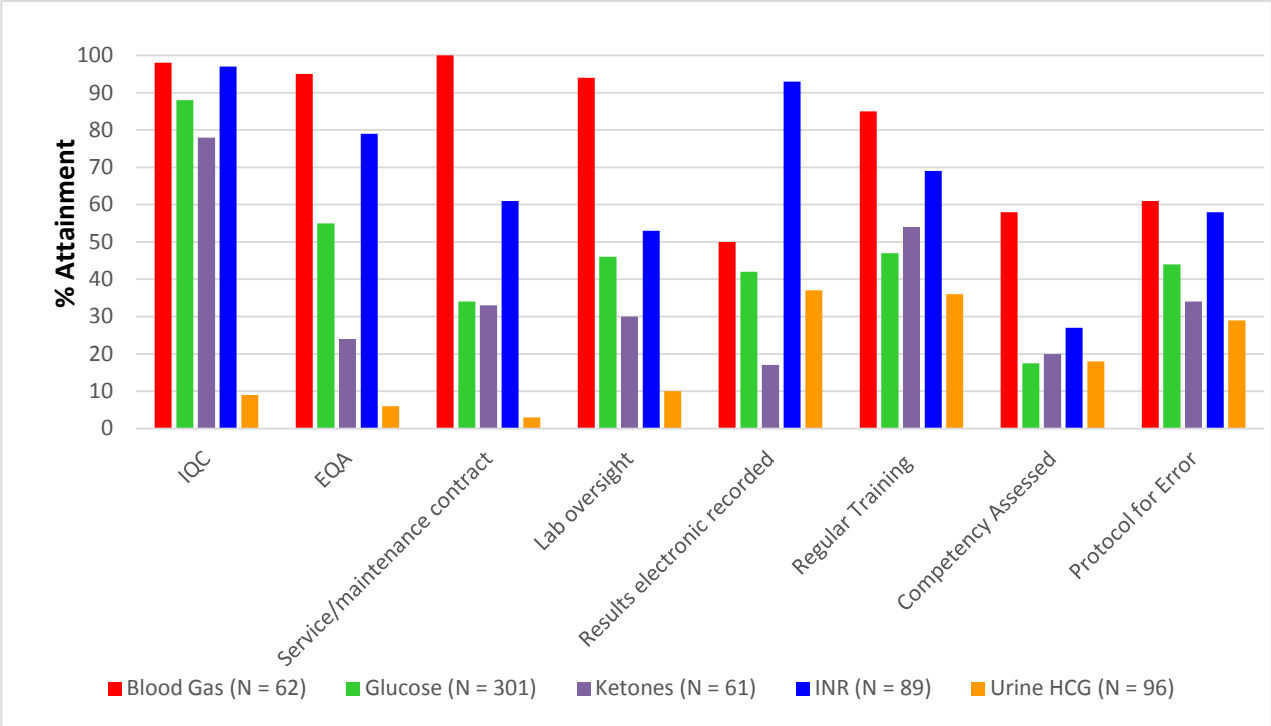

Fig -2. Percentage of POCT services meeting key governance criteria (N = 367)

In an effort to better understand the underlying reasons behind these governance failures, the level of attainment of the eight governance criteria above were examined in more detail to determine -

- Any regional differences across the ten Health Board regions.
- Any differences depending on where the POCT services were located, i.e. between primary and secondary care locations.
- Any differences depending on whether or not the POCT services were afforded laboratory oversight.

2.2.1 Regional Differences

When POCT services for blood gas, glucose, ketones, INR and urine HCG were compared across the ten health board regions, no one health board demonstrated consistently higher or lower attainment levels for the eight markers of clinical governance.

Table -2 (below) shows the attainment for POCT blood glucose services of the eight key governance markers for each health board region compared to the mean attainment level. This finding is representative of the other POCT services in that no one board manages to attain higher compliance than the mean attainment level for more than four out of the eight key governance markers.

Gov Marker Health Board	IQC	EQA	Service Contract	Lab oversight	Electronic record	Training offered	Competence assessed	Protocol for Errors
Argyll & Bute	↓	↓	↓	↓	↑	↑	↓	↓
Ayrshire & Arran	↓	↑	↓	↓	↓	↑	↑	↓
Dumfries&Galloway	↑	↓	↑	↑	↑	↓	↓	↓
Fife	↑	↓	↑	↓	↑	↑	↓	↓
Grampian	↑	↓	↑	↓	↓	↓	↑	↑
G.Glasgow & Clyde	↑	↓	↓	↓	↑	↑	↓	↓
Highland	↓	↓	↑	↓	↓	↑	↑	↑
Lanarkshire	↑	↓	↓	↑	↑	↑	↑	↓
Lothian	↑	↑	↓	↑	↓	↓	↓	↑
Tayside	↑	↓	↓	↑	↑	↑	↓	↓

Table –2 Comparison of Governance attainment level for each health board relative to the mean attainment level for POCT Blood Glucose Services
(↑ = higher than mean attainment level. ↓ = lower than mean attainment level)

Similarly, Figure -3 shows the percentage attainment of key governance markers for POCT blood glucose services across ten Scottish Health Boards and whilst some boards report excellent attainment in some governance markers (e.g. >80% users regularly performing IQC) they equally report very poor attainment in others (e.g. <20% of users have annual competency assessments).

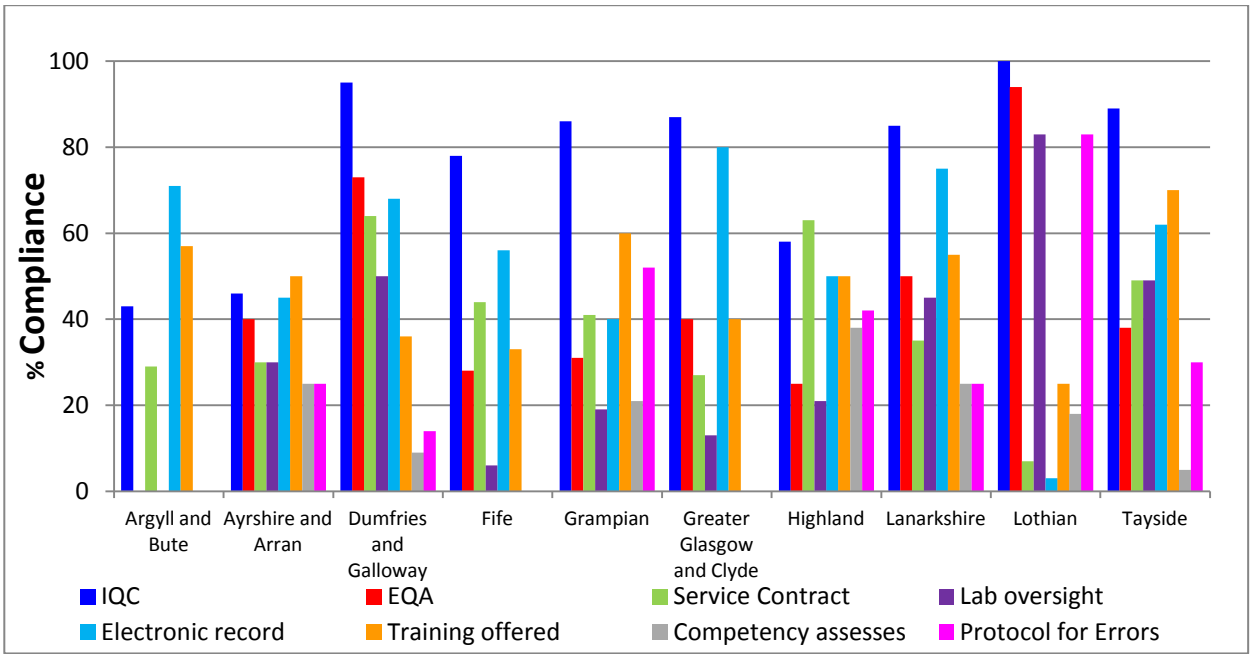

Fig -3. Percentage attainment of key governance markers for POCT blood glucose services across ten Scottish Health Boards.

2.2.2 Differences between Primary and Secondary Care POCT services.

A comparison of governance attainment levels between Primary and Secondary Care locations for POCT services was undertaken for blood gas, glucose, ketones, INR and urine HCG. Examples of the attainment level for each of the eight governance markers for INR and Blood Ketone services are shown in Figures 4 and 5 respectively.

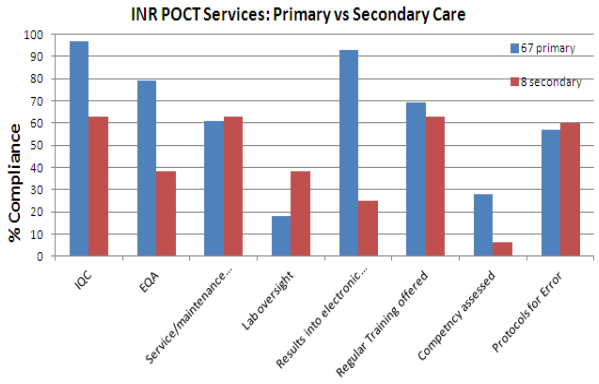

Fig -4. Percentage attainment of key governance markers for POCT INR Services in Primary and Secondary Care

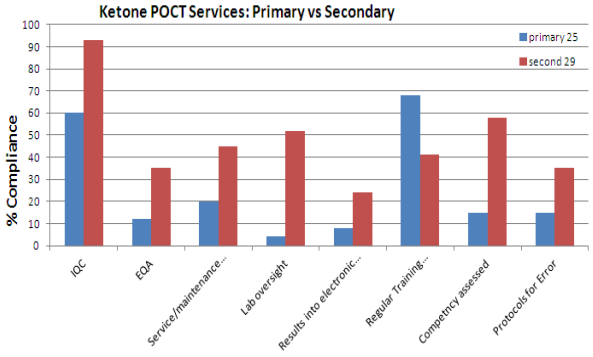

Fig -5. Percentage attainment of key governance markers for POCT Ketone Services in Primary and Secondary Care

INR POCT services in primary care locations attained higher attainment levels than services in secondary locations in five of the eight governance markers (fig -4). In contrast, secondary care Blood Ketone POCT services attained higher attainment levels in seven of the eight governance markers compared to Blood Ketone POCT services provided in primary care locations (fig -5).

Figures 6 and 7 show a comparison in the attainment level for each of the eight governance markers located in primary and secondary care locations for Blood Glucose and Urine HCG POCT services.
Secondary care blood glucose services demonstrate higher levels of attainment for IQC, EQA and laboratory oversight but lower levels of attainment for regular training, competency assessment and protocols for dealing with errors compared to primary care (fig -6).
For urinary HCG testing both primary and secondary care locations demonstrate extremely poor attainment levels for the all of the governance markers with the exception of recording patient results in primary care (fig -7).

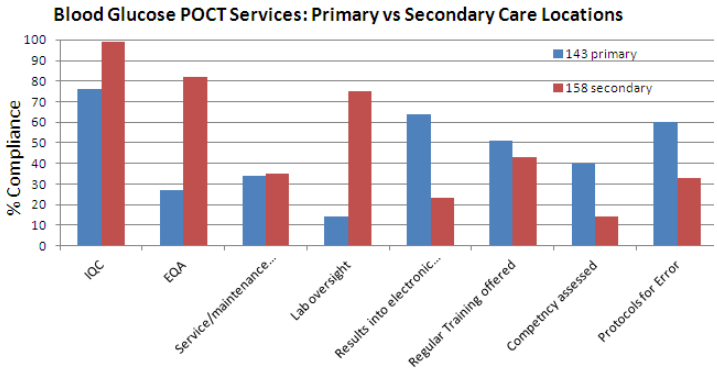

Fig -6. Percentage attainment of key governance markers for POCT Blood Glucose Services in Primary and Secondary Care

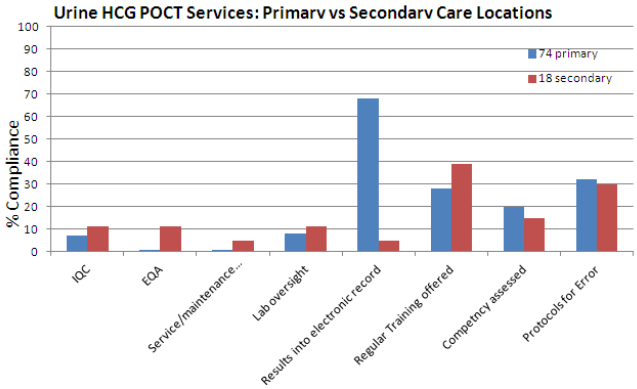

Fig -7. Percentage attainment of key governance markers for POCT Urine HCG Services in Primary and Secondary Care

Thus, there are examples of higher, lower and equal attainment of good governance practice for POCT services in both locations and whether the POCT service were delivered in primary care locations or in secondary care locations does not appear to influence the user compliance with good clinical governance practices.

2.2.3 Impact of Laboratory Oversight

User responses were examined to determine whether the provision of active laboratory oversight of POCT services influenced the levels of attainment of the eight clinical governance markers.
For those POCT services present in three or more health boards, table -3 lists the user responses to the question on the provision of laboratory oversight.

	Yes, Lab Oversight	No Lab Oversight	Lab Oversight Unknown
Blood Gas	51	10	1
Blood Glucose	138	130	32
Blood Ketones	15	39	Nil
INR	26	43	13
Urine HCG	8	82	6
Urine Ketones	3	58	Nil
ESR	1	33	3
Urine DOA	1	8	1
FOB	1	12	1
D-Dimer	1	9	2
Haemoglobin	5	2	2
cTnI	1	8	Nil
Urine M-Alb	1	7	Nil
U/E	5	1	Nil
FBC	5	1	Nil
Total	***262***	***443***	***61***

Table -3 POCT Services with and without Laboratory oversight

These responses indicate that for the majority of the POCT services reported in this questionnaire (66%) there is no provision of laboratory oversight.
Figures 8 to 11 (below) illustrate the difference in the percentage attainment level of key governance markers for those POCT services with and without laboratory oversight reported by users for glucose, ketone, INR and blood gas services. Note, that as lab oversight has been removed as a comparator then only the compliance of the seven remaining markers is compared. Notably, those POCT services where users reported the active provision of laboratory oversight demonstrated higher levels of attainment of the eight clinical governance markers compared to those services that reported no laboratory oversight. This was the case for all 7 markers for blood ketone services, 6 out of 7 markers for INR and blood gas services and 5 out of 7 markers for blood glucose services. In some of the POCT services where laboratory oversight was provided users reported the use, by labs, of central data management systems to remotely monitor the governance of POCT services. These systems have been shown to support laboratories in the application of process driven quality management techniques to ensure that high clinical governance standards are consistently achieved and maintained across multiple clinical areas and remote sites.

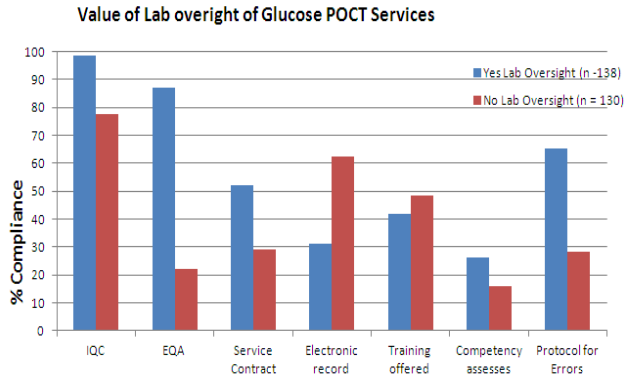

Fig -8 Percentage attainment of key governance markers for POCT glucose services with and without lab oversight of services

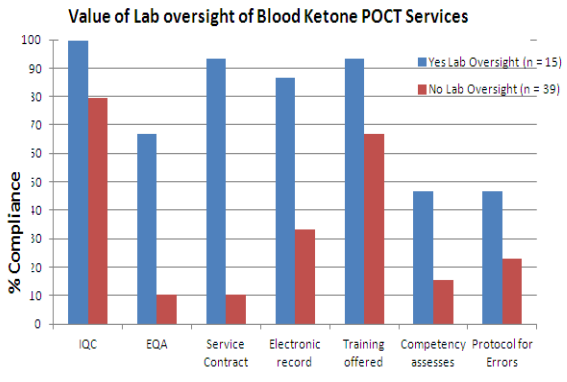

Fig -9 Percentage attainment of key governance markers for POCT ketone services with and without lab oversight of services

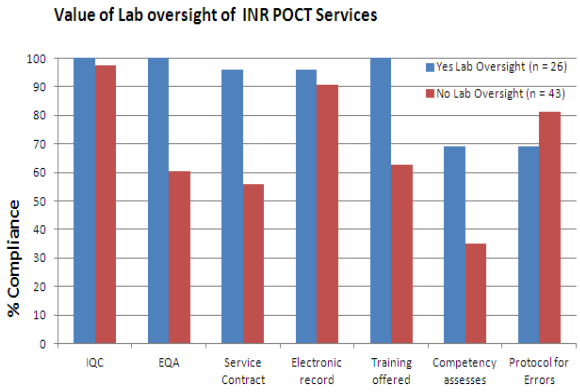

Fig -10 Percentage attainment of key governance markers for POCT INR services with and without lab oversight of services

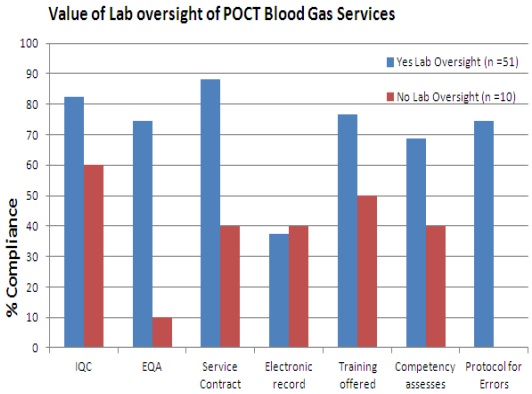

Fig -11 Percentage attainment of key governance markers for POCT blood gas services with and without lab oversight of services

3. Discussion

Guidance on the management and governance of POCT services from a number of reputable organisations, including the Royal College of Pathologists[4], MHRA[5], Clinical Pathology Accreditation (CPA)[6] and the Institute of Biomedical Science[7] have been available for a number of years. These documents informed the SMASAC report recommendations in 2011 which, in turn, prompted the Chair of The Diagnostic Steering Group to write to the CEOs of all Scottish NHS Boards advising that this audit of POCT be undertaken.

Adherence to good clinical governance is essential in order to deliver high quality POCT services that are fit for purpose and the SCBMDN coordinated this POCT user survey, of all Scottish Health Boards, with the aim of determining the degree of governance applied to the introduction and maintenance of POCT services, and the value for money which they offer.

Thus, the reported lack of adherence to good clinical governance practice reported in this questionnaire is a significant concern and, given the potential impact that this could have on patient care, user responses were examined further to determine an explanation for this finding with the aim of identifying possible solutions.

On comparing the individual compliance of each Health Board no region had a consistently higher or lower reported gap in their adherence to the eight markers of clinical governance for any particular POCT service.

The location where the POCT services were provided and delivered did not consistently determine the level of compliance with good clinical governance practices: examples of good and poor compliance were reported in both primary care and secondary care locations.

However, across all the Health Boards and across all locations, a consistent marker for demonstrating the attainment of high levels of compliance with good clinical governance practices was the provision of laboratory oversight. Those POCT services where users reported the active provision of laboratory oversight consistently demonstrated higher levels of attainment of the eight clinical governance markers compared to those services that reported no laboratory oversight. This is particularly evident for those POCT services for Blood Gas, Blood Glucose, INR and Blood Ketones. In addition, the use of central data management systems, by laboratories, to remotely monitor the governance of POCT services, greatly aided the application of process driven quality management techniques that ensured that high clinical governance standards were consistently achieved and maintained across multiple clinical areas and remote sites.

As highlighted by user responses to this questionnaire, the current repertoire of POCT services is very large and given both the pace of technological developments and the direction of travel indicated in the 2020 Vision, the number and repertoire of POCT services, particularly in the community setting, is likely to expand further. Currently, laboratories are not adequately resourced to deliver the required level of oversight to all the POCT services covered in this report and to try to do so using the existing model of service delivery would be prohibitive in terms of staffing resource. A new model of service delivery, utilising open connectivity and data management solutions (and a more modest staffing requirement) to help manage the governance aspects of training, competency assessment, IQC, EQA, flagging of abnormal results etc, should be developed.

There is also an issue with respect to the management of POCT data: users reported that a high proportion of the POCT results produced were transcribed manually into either paper or electronic patient records. For example, glucose results recorded into secondary care patient case notes or within the patient journal in the GP practice Vision system in primary care. This process represents a significant risk in potential transcriptional errors particularly given the large number of testing performed (approximately 3.5 million tests per year). The lack of centrally recorded results limits the clinical value of the test result to the organisation since it cannot be communicated to, and understood by, other clinicians across different parts of the organisation (eg between primary and secondary care). A potential solution is to utilise open connectivity and data management solutions. This would allow the interfacing of multiple POCT services to both Laboratory Information Systems (LIS) and PMS. This would enable the electronic identification of patients, creation of electronic orders and the secure transmission of results to both SCI store and PMS. Given appropriate investment, this change in the service delivery model is achievable across all Health Boards in Scotland.

4. Conclusion

In addressing the findings of this user questionnaire, it is important not only to address the current POCT concerns but also address those likely to arise in the future. Many of the clinical governance failures highlighted in this report are identical across the ten participating Health Boards and the different POCT services. However, those examples where adherence to good clinical governance has been consistently achieved across all the Health Board regions, including both primary and secondary care sectors, have shown that laboratory oversight has been key.

Laboratories are very experienced in the application of process driven quality management techniques to ensure that high clinical governance standards are consistently achieved and maintained across their services. However, using the current model of service delivery, it is not possible to expand the degree of laboratory oversight required to all POCT services without incurring significant supporting staff costs. An alternative model of service delivery is required that will require a more modest level of staffing resource in addition to the costs of interfacing and supplying the necessary connectivity solution.

Laboratories, by utilising their process management skills and utilising available open connectivity solutions, can work with suppliers to manage the process of training, competence assessment, IQC, EQA, flagging of abnormal results and also recording all POCT results into the host PMS and SCI databases. This method of service delivery provides a practical and systematic solution to the current and future clinical governance difficulties facing POCT services. Laboratories and the connectivity solutions together provide the host organisations with the management, oversight and transparency required for the educational/training, risk management, clinical audit and clinical effectiveness components of clinical governance under one operational structure. Importantly, with the connectivity solution enabling POCT results to be recorded with PMS and SCI store, the clinical and economic value of the result to NHS Boards is multiplied several fold as it can be freely communicated to all clinicians across different parts of their organisation.

Finally, it is recommended that an overarching POCT Committee be established, in each Health Board, integrated within the board risk management and clinical governance frameworks and with responsibility for managing and regulating applications for new POCT services. This is particularly important given the future expansion of POCT and an overarching approach to considering the justification of clinical need, and the expected benefits to the organisation of proposed POCT developments will be required. Value for money would also be a key focus for this committee with all future POCT developments requiring detailed business cases along with clinical and cost effectiveness evidence. This level of oversight will deliver economies of scale, offer managed service contract opportunities and prevent duplication of services/ effort therefore generating potential savings to NHS Boards. This committee will also be responsible for setting high standards of clinical governance for POCT services across the organisation and ensuring that the responsibility and accountability for these services are transparent from the outset.

5. References

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5. Management and Use of IVD Point of Care Test Devices: DB2010(02). MHRA Device Bulletin: February 2010.

6. Additional Standards for Point of Care Testing (POCT) Facilities. Clinical Pathology Accreditation (UK) Ltd: 2010.

7. Institute of Biomedical Science, Point of Care Testing (Near-Patient Testing) Guidance on the Involvement of the Clinical Laboratory, IBMS Professional Guidance. www.ibms.org/publications

Appendix -1

POCT Serviced Provided in Each Scottish Region															
	Argyll and Bute	Ayrshire & Arran	Borders	Dumfries & Galloway	Forth Valley	Fife	Grampian	GG&C	Highland	Lanarkshire	Lothian	Tayside	Western Isles	Tot No of practices or wards who offer this test	POCT offered in how many regions
PTH												1		1	1
Syphilis										1				1	1
Norovirus										1				1	1
Rotavirus										1				1	1
Infuenza										1				1	1
HIV and HBV										1				1	1
Y. Vaginalis										2				2	1
Gonorrhoea										2				2	1
NT-proBNP							8							8	1
Fibronectin									1			1		2	2
Amylase										2		1		3	2
Cholesterol										2		1		3	2
RSV					1			1		1				3	3
CK							1			2		1		4	3
Bilirubin							1			2		3		6	3
D-Dimer					1		10					1		12	3
Lactate		2						1		1		2		6	4
HbA1c							2		1	2		2		7	4
cTnI		1			1		6					1		9	4
UE		1						1		2	1	2		7	5
FBC		1						1	1	2		2		7	5
Urine Microalbumin	1					1	3			2	1			8	5
Coagulation Screen							4	1		2	3	1		11	5
FOB	1				1	1	11			1				15	5
Haemoglobin		1					1	1		2	2	3		10	6
ESR	2					1	28	1	4	2				38	6
Urine DOA				1	1		1	1	2	2	1			9	7
Urine Analysis				2	1	1	9			2	1	13		29	7
Blood Ketones				9		1	11	1	3	3	7	20		55	8
INR	6	6		3		14	39		17	3		6		94	8
Blood Gas		3		3	1		3	4	3	1	15	17		50	9
Urine Ketones	3			13		3	13	13	5	11	1	5		67	9
Urine HCG	5	2		5		6	15	3	18	13	2	15		84	10
Urine Dipsticks	5	6		15	1	13	43	18	23	20	5	23		172	11
Blood Glucose	7	13		22	1	18	58	15	24	20	87	37		302	11
Total Services														1031	