

Point of Care Testing Environment Survey Report

June 2016

Abstract

Moving diagnostic tests to the point of care is a growing sector that has the potential to alter substantially when and where patients are treated. This survey of point of care coordinators from acute hospitals shows that, while there is a positive future for point of care testing, this is not always reflected in the service that exists presently within secondary care.

POCT ENVIRONMENT SURVEY REPORT

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Executive Summary

Moving diagnostic tests to the point of care (POC) has the potential to alter substantially the delivery of care to patients, allowing timely diagnosis of patients at the bedside, in general practice, or in the community. POC testing is an area of *in vitro* diagnostics (IVD) that has been gaining momentum over recent years and is now recognised as having a major role to play in redesigning services around the needs of the patient.

Commonly, however, recognition of the value of a technology or service does not necessarily translate into rapid and successful adoption due to a variety of reasons, such as financing, resourcing, implementation barriers, infrastructure limitations, or cultural resistance. And so, it was felt that the IVD industry needed to gain a clearer understanding of the current POC landscape across the UK. By gaining such an insight, it will then be possible for industry to help address some of the issues that restrain the adoption of existing technologies, while ensuring that the development of new products is aligned with the needs of both patients and the end users.

By surveying the POC coordinators who are responsible for driving and coordinating this growing service within the UK, it is apparent that, while there is certainly a positive future for POC testing, this is not reflected in the disjointed service that exists presently. Substantial variation in terms of service offering, resource and support exists, meaning that patients certainly have inconsistent access to POC testing across the UK.

Background

The British In Vitro Diagnostics Association (BIVDA) is the national industry association for the manufacturers and distributors of IVD products in the UK, currently representing more than 95% of the industry in the UK, over a hundred organisations, ranging from British start-up companies to multinational corporations. As well as providing a range of support services for its members, BIVDA pursues a strategy of raising the awareness of the clinical and cost utility of diagnostics in the provision of effective healthcare in the UK.

A range of different working parties, focusing on specific topics significant to members, allow industry colleagues to come together to identify and tackle challenges that are common to the industry. The POC Working Party meets quarterly and aims to improve uptake of POC devices by raising the profile of such diagnostics, discussing common issues internally and with external stakeholders, and developing possible solutions to these challenges. In 2015, the group decided that it should carry out analysis of the current POC testing landscape in order to gain a greater appreciation of the nature and scale of POC services across the UK, and some of the problems faced by providers that are likely to slow progress in this exciting area.

As a starting point, it was decided that the group should question POC coordinators within secondary care, rather than those involved in POC testing in a primary care setting, due to the logistical challenges a primary care survey would present. On behalf of the POC Working Party, BIVDA produced a short survey of POC coordinators that was sent by members to their POC co-ordinator contacts and was also posted on the Association of Clinical Biochemists POC forum. A question by question summary of the findings forms the basis for this report on the current POC environment in the UK.

Results

After eliminating inappropriate respondents, there were 101 respondents to the survey who contributed to the discussed findings. The results for each question are summarised below:

Questions 1 & 2 established personal information in order to ensure that the same person did not complete the survey more than once, asking for name, organisation and job title. This, therefore, also allowed the respondent locations to be mapped and various job titles to be aggregated, as shown below.



Respondents were based at Trusts across the whole of UK, as well as two respondents who were from the Republic of Ireland, meaning the results of the remainder of the survey reflect the national situation rather than being specific to one or two particular regions. All but three of the respondents were employed by an NHS Trust.

Job Titles

POC Coordinator x37
Deputy HCS Service Manager & Trust POCT coordinator
POCT Countywide Manager
POCT Lead x7
Principal Clinical Biochemist and Clinical Lead for POCT
POCT Manager x17
Screening Laboratory & POCT Manager
POCT Officer
POCT Specialist
POC Testing x2

Biomedical Scientist (BMS1-7/Senior) x14

Consultant Biochemist
Principal Biochemist
Senior Clinical Biochemist

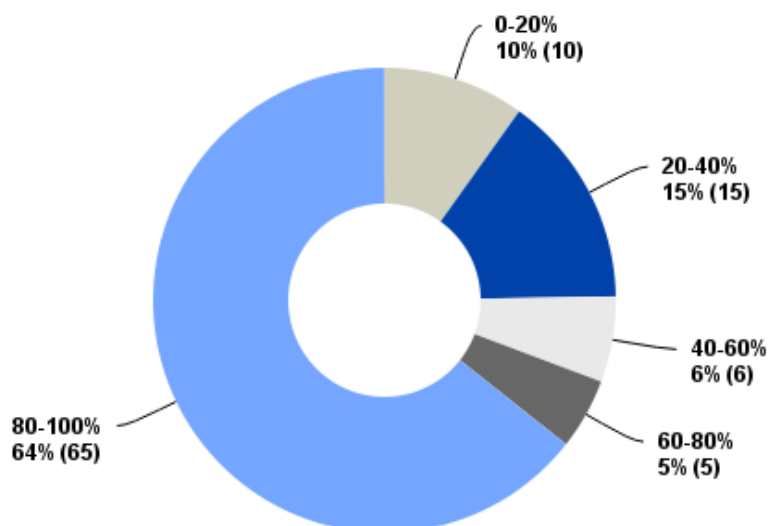
Clinical Scientist x2
Consultant Clinical Scientist x2
Senior Clinical Scientist
Senior Medical Scientist

Associate Practitioner
Health Improvement Practitioner
Laboratory Sector Manager (Specialist/POCT)
National Pathology IT Programme Lead
Pathology Quality Manager
Section Manager
Service Delivery Manager
Testing Facilitator

Slight differences between the job titles given by respondents meant that it was not always straightforward to separate respondents into certain groups. The list above, however, attempts to group together certain respondents, although there were also several 'unique' job titles given. This indicates that the named role of POC coordinator/manager, whilst in place in around half of Trusts, is not well established across the UK, which likely reflects an inconsistent national POC service where POC responsibilities sit within different roles in different Trusts.

Question 3: How much of your time is spent on your point-of-care (POC) role?

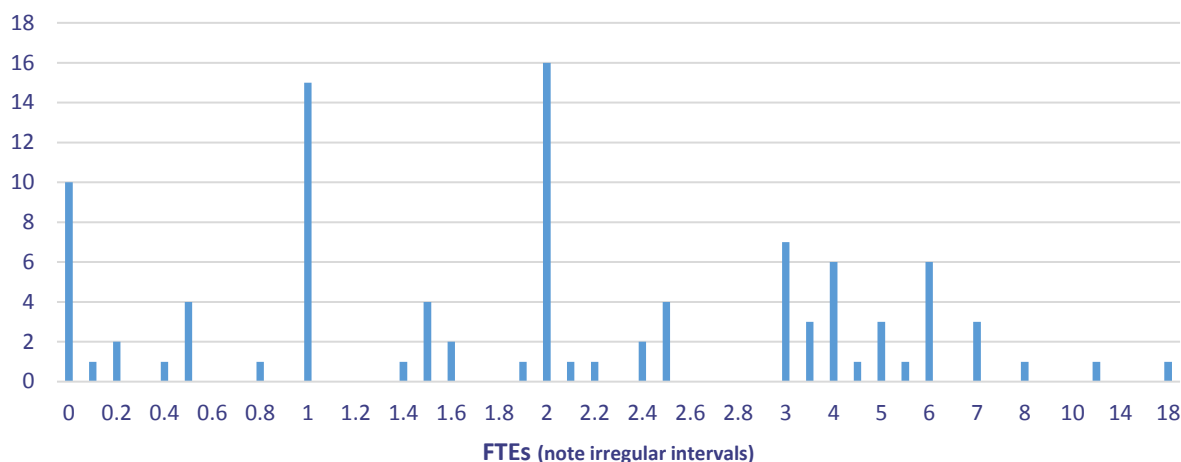
[0-20%; 20-40%; 40-60%; 60-80%; 80-100%]



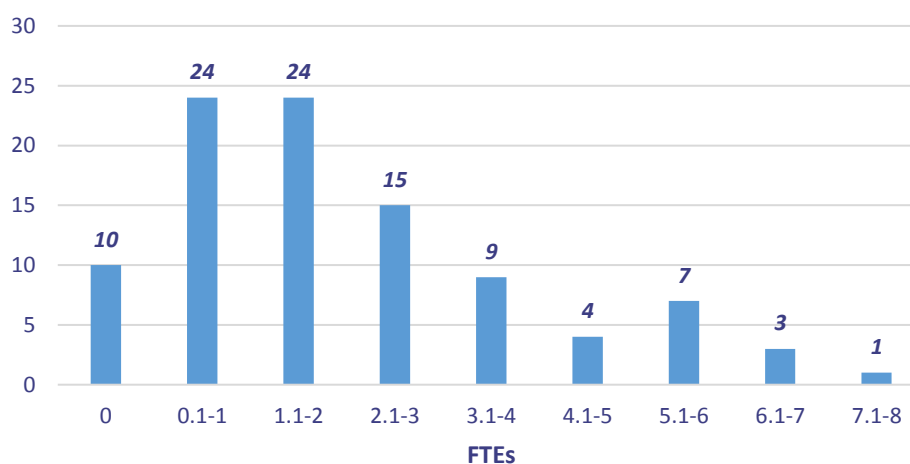
This survey indicates that around two-thirds of the respondents spent over 80% of their time on their POC role. This is encouraging as it gives the impression that POCT is a service that is given dedicated support in a large number of Trusts. Equally, however, over a quarter of respondents indicated that they spend less than half of their time on their POC role, suggesting they are trying to support a POC service on top of their 'normal' duties.

Question 4: How many full-time equivalents (FTEs) are involved in POCT within your organisation?

Number of FTEs - All Values



Number of FTEs - Grouped Data



Answers to this question were given in free text form to allow respondents to be as precise as they felt appropriate. A few answers indicated that the number of FTEs was due to increase, but the graph was based on the number of FTEs involved in POCT at the time of response. Naturally, these results are not necessarily representative of all secondary care providers in the UK as POC is not available from all providers – these findings are only reflective of those Trusts that had POC coordinator respondents.

As can be seen, over half of all respondents indicated that fewer than two FTEs are involved in POCT within their organisation. Furthermore, around 10% of respondents implied that there is no employee within their organisation in a dedicated POC role or, alternatively, no additional support to the POC coordinator themselves. It is recognised that the question is slightly ambiguous in regards to what an 'involvement in POCT' means exactly. These findings do suggest, however, that while POCT may be in place in various organisations, it is not supported with a significant amount of resource at this time. It is possible, however, that the POC coordinator may also have support in other departments from POC 'champions', which would not necessarily be represented by the number of FTEs given in answer to this question.

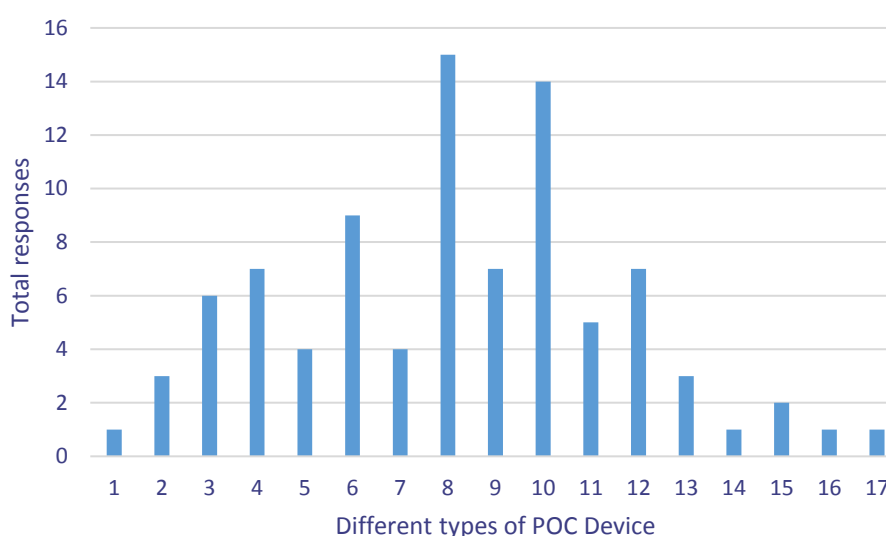
Question 5: Is there a dedicated POC team within your organisation?

70% of respondents said that there was a dedicated POC team within their organisation. This is again encouraging and correlates with the number of people who stated that they spent most/all of their time on their POC role.

It is suggested that this is one area that could be probed further, in order to gain more of an understanding about POC teams in the NHS. Possible questions could be around:

- desire for a dedicated POC team amongst those currently without one
- make-up of the POC team
- challenges for the POC team

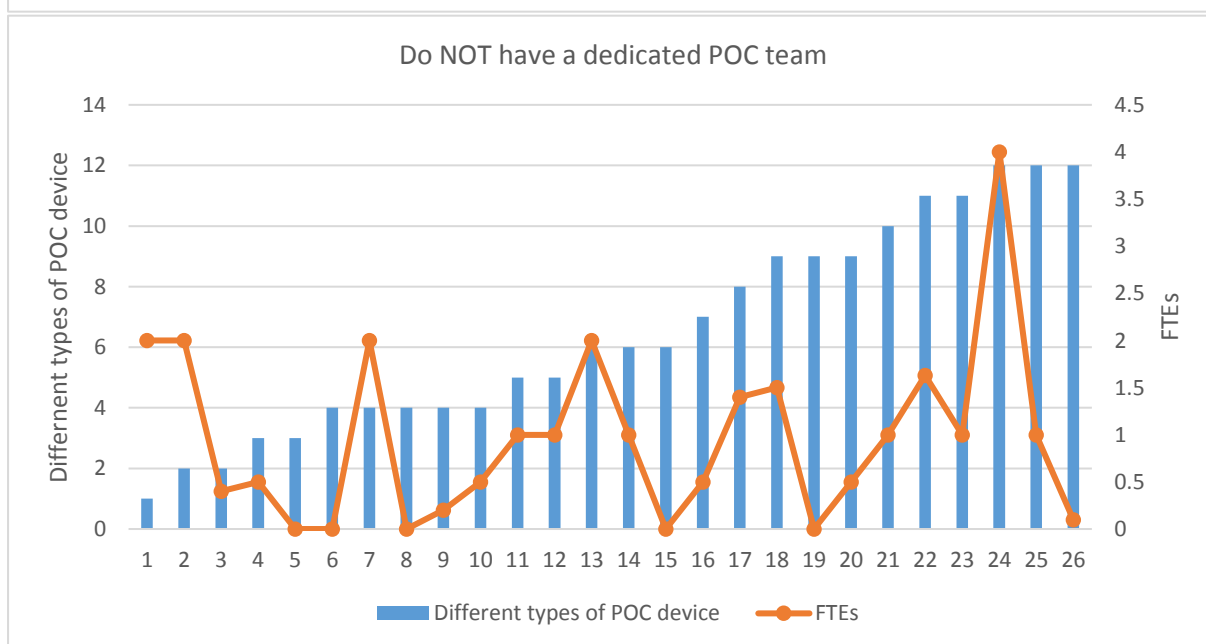
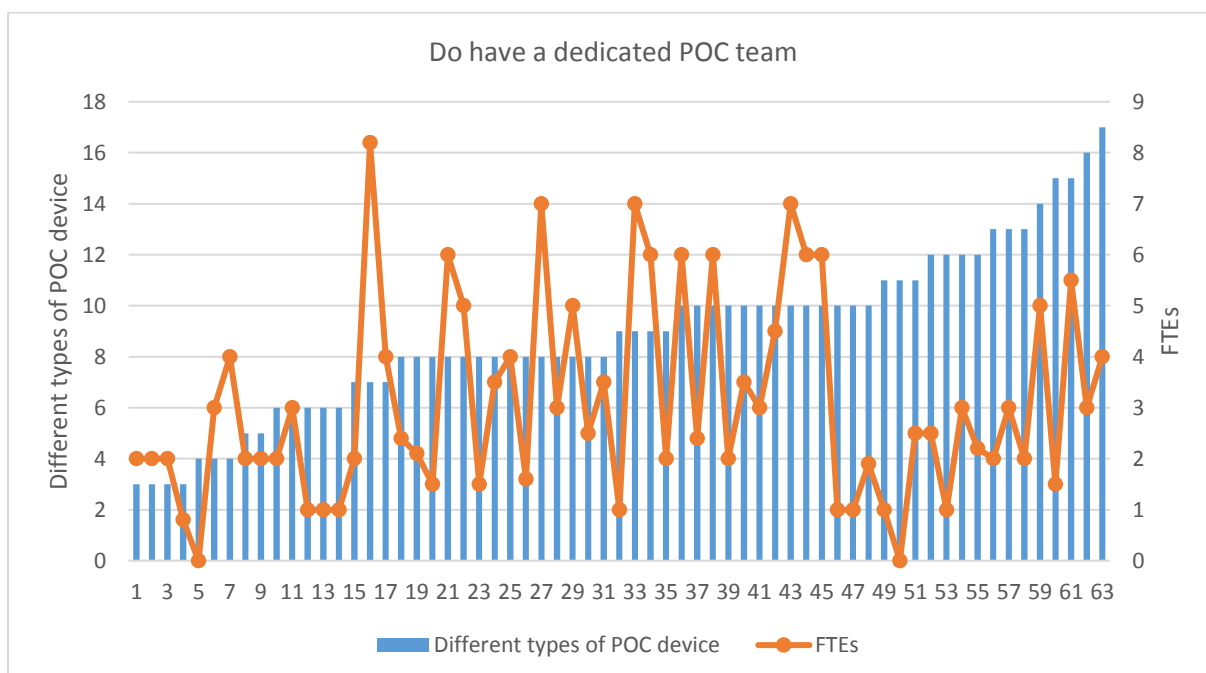
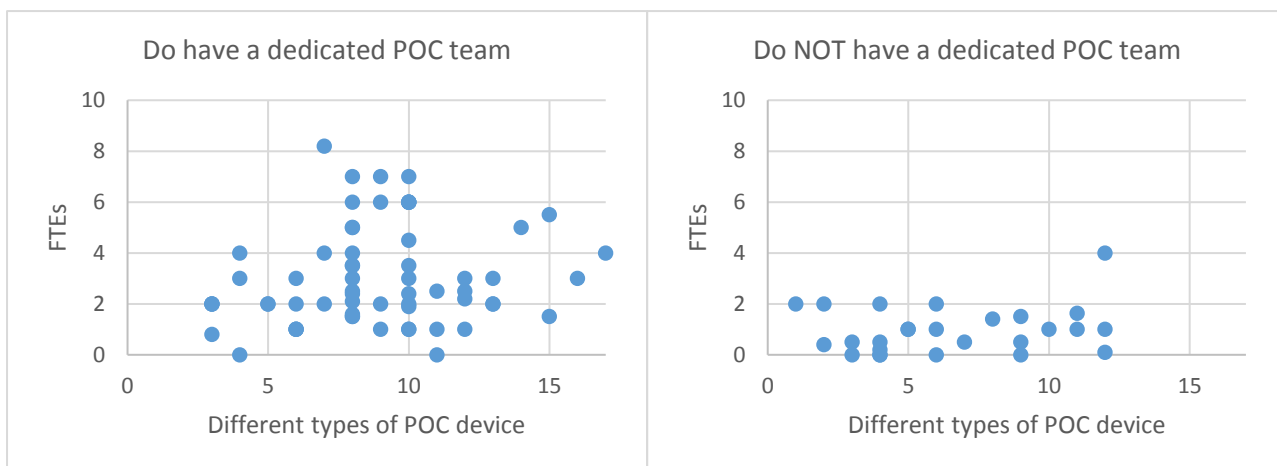
Question 6: How many different types of POC device do you/your team support?



The wording of this question – in particular the use of the word ‘type’ – was designed to prevent respondents from giving the total number of different devices, which would, particularly in the case of blood glucose meters for example, be very large and not particularly informative. Four answers are not included in the above table as they were in excess of 20. In hindsight, we have realised that the question can still be interpreted in two ways – whether device means separate instruments or simply different assays on the same instrument. As such, these findings should be treated with a degree of caution.

The graph above clearly shows a normal distribution, with an average of around eight different types of device supported by the POC coordinator/their team, assuming that the respondents included above interpreted the question as intended. Industry colleagues agreed that a ‘normal’ range of 4-12 types of device supported by most Trusts is about what would be expected.

In addition to the distribution shown above, it was thought to be important to analyse the relationship between the number of different types of device supported within an organisation and the number of FTEs employed in a POC role/whether there is a dedicated POC team – this is shown below.

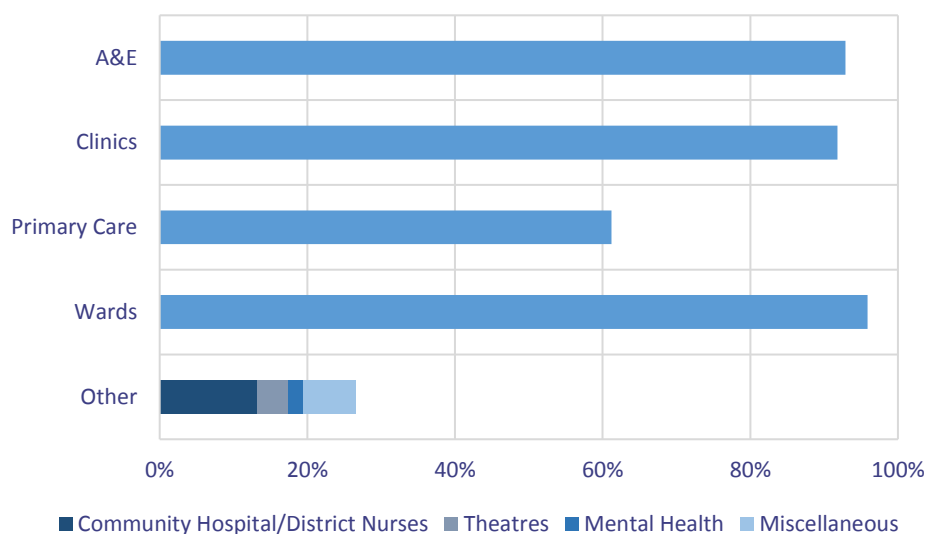


It would be reasonable to assume that there would be some form of correlation between the number of different types of device and the number of FTEs employed in a POC role, since a greater variety of tests will likely require a greater amount support in terms of staff time. Furthermore, it would be expected that the greater the number of different product types, the greater the necessity for a dedicated POC team.

This does not appear to be true, however. As the graphs above show, there is very little correlation between the number of different types of device supported and the FTEs involved in POC delivery within an organisation. Furthermore, whilst the five organisations with the greatest number of different POC devices all had a dedicated POC team, it is not true that organisations without a dedicated team only support a very low number of different product types. This is concerning as it suggests that the procurement of a number of different POC devices is not necessarily supported by adequate resources. Without sufficient support, it is not possible to guarantee that POC devices are being controlled, maintained, and utilised to their full potential.

The one link that can be made is that organisations with more than two FTEs involved in POCT have a dedicated POC team to support the service, with one exception, rather than having a number of employees involved in POC who do not work together as part of a team.

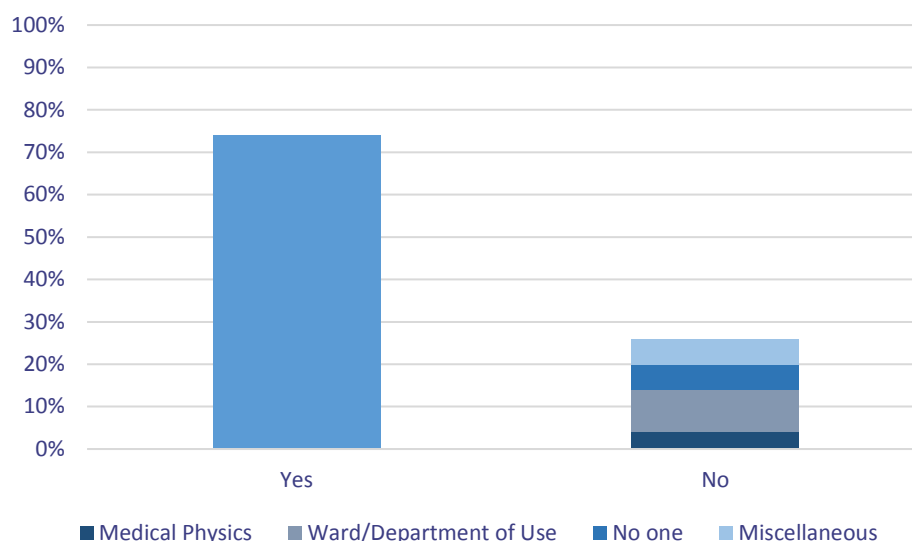
Question 7: Where are the POC devices located? Please select all that apply
[A&E; wards; clinics; primary care; other]



POC devices appear to be spread across all the options given in the question, with certain further locations repeated throughout the survey as indicated. Primary care is noticeably lower than the other three given locations, although this may reflect the fact that most respondents are POC coordinators within a hospital setting. Furthermore, clinics can be interpreted as both those within hospitals and in primary care (e.g. sexual health clinics), which may reduce the 'primary care' number further. The use of POC devices in laboratories was also not revealed by this question.

It has been suggested that a further survey could explore POC in primary care in more detail, by establishing where exactly POC devices are found most commonly in a primary care setting, as well as directing the survey to individuals more directly involved in primary care.

Question 8: Does your team have responsibility for all POC devices within your organisation?



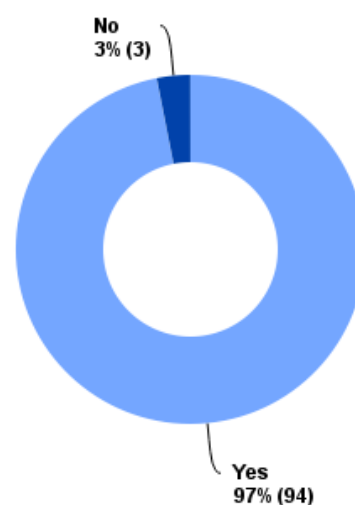
The finding that almost 75% of respondents stated that their team has responsibility for all POC devices reflects the number of respondents who are part of a dedicated POC team. Furthermore, it once again correlates with the number of people who stated that they spent most/all of their time on their POC role. These three questions seem to be consistent and support the logical idea that an established POC team contains full time POC employees who are responsible for all the POC devices within an organisation. The results may also reflect whether POC is seen as an all-encompassing service that involves a variety of tests across a whole hospital or Trust, or whether specific POC tests are used and governed by specific departments.

Whilst this was a straightforward yes/no question, the comments are revealing in that they indicate that POCT is a fragmented service in many organisations (around a quarter of cases). Responsible parties for the POC devices included medical physics (4) and individuals in the wards/departments where the device is used (10). In particular, the fact that six respondents stated that no one was responsible for the POC devices is concerning.

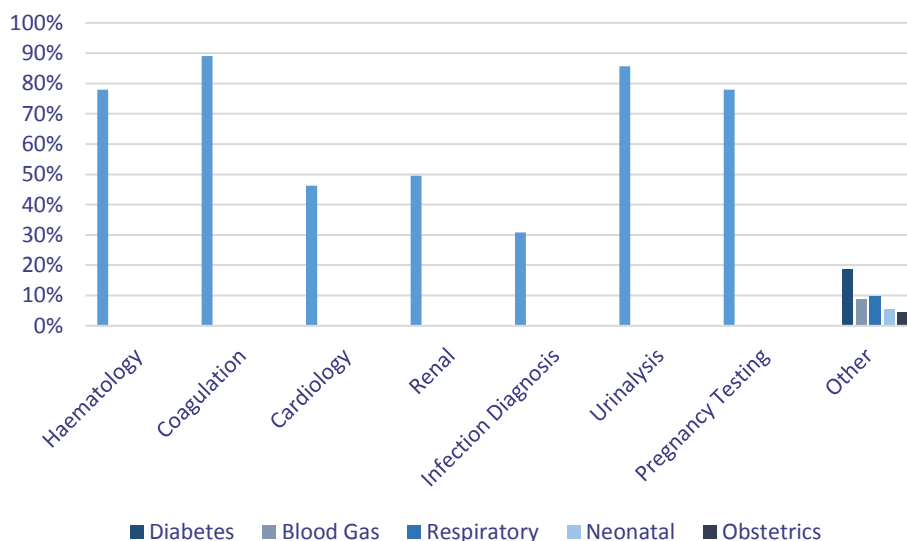
Question 9: Is the POC service affiliated with a hospital laboratory?

Whilst almost all the POC coordinators said that their POC service is affiliated with a hospital laboratory, the exact nature and extent of this affiliation, and particularly the situation regarding accreditation, varied across the comments.

These findings suggest that POCT lends itself to accreditation. Question 8, however, shows that a significant proportion of POC coordinators do not have oversight of *all* the devices within their organisation, and, as a result, laboratories may not feel comfortable incorporating POCT into their accreditation. Indeed, this may be reflected by the fact that only 10 sites had applied for POC accreditation as of September 2015. Looking at the findings of Q8 and 9 together, therefore, raises a question about the possible need for a stand-alone ISO accreditation for POC.



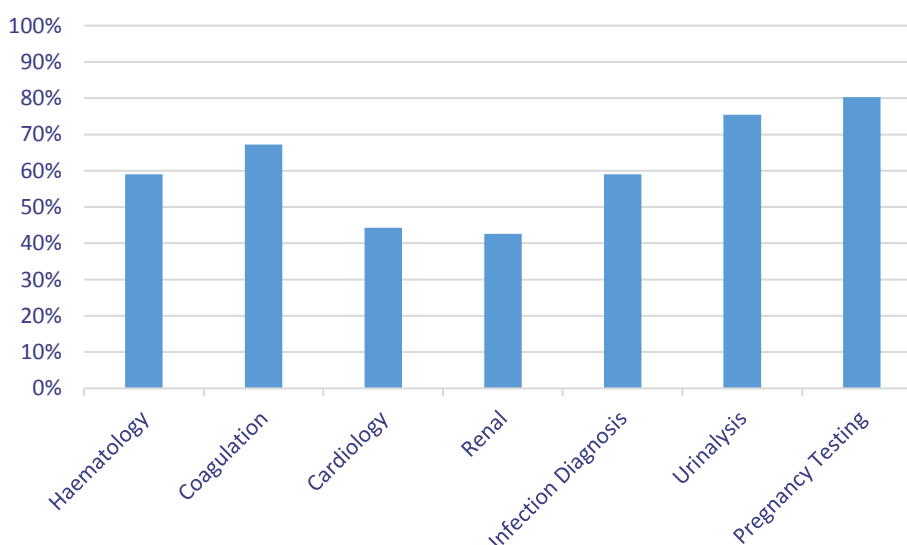
Question 10: What therapy areas are covered by POCT within your organisation? Please select all that apply [haematology; coagulation; cardiology; renal; infection diagnosis; urinalysis; pregnancy testing; other]



POC devices are available in a wide range of different therapy areas; indeed, the range of POC devices only increases every year. These findings suggest that most Trusts do take advantage of this range of products by offering a POC service in several of the different therapy areas covered.

Common therapy areas from the comments have then been grouped together in the 'Other' section. Further therapy areas that were mentioned include oncology, GI, and specifically HIV testing. It is also important to note that the therapy areas listed from the 'Other' section may well have scored even more highly if they were included as an option of their own – the provided options are not necessarily the most commonly supported areas.

Question 11: What therapy areas would you like to be covered by POCT within your organisation? Please select all that apply [haematology; coagulation; cardiology; renal; infection diagnosis; urinalysis; pregnancy testing; other]



After initial discussions with some BIVDA members, it became clear that this question could have been interpreted in three different ways:

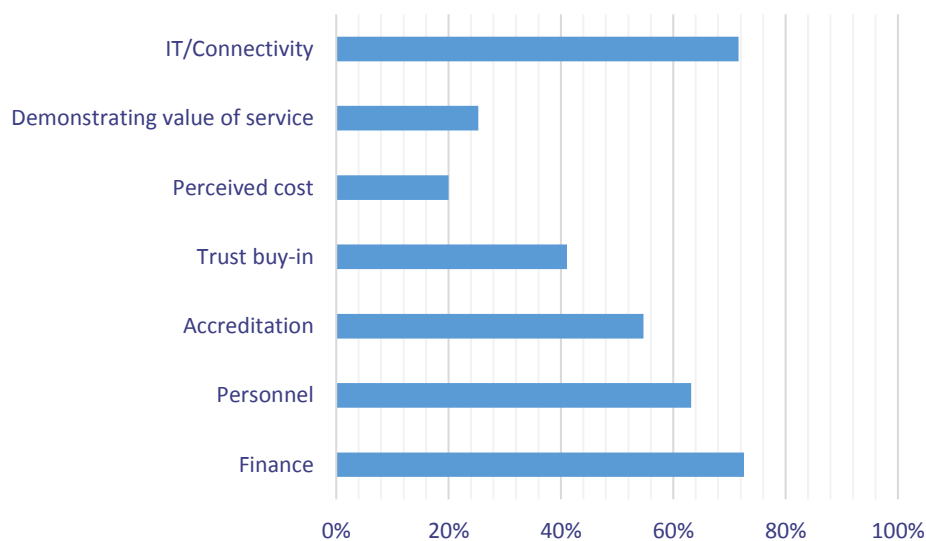
- 1) What therapy areas do you not cover that you would like to cover?
- our intention for the question
- 2) What therapy areas would you like to continue to cover?
- 3) What therapy areas would you like to be under your **control** that are not currently?
- it was suggested that this interpretation may be particularly relevant for urinalysis and pregnancy testing

The fact that the answers for questions 10 and 11 add up to more than 100%, which would not occur if option 1 was the interpretation made by all respondents, suggests that it is likely to be a combination of these possibilities. It is also possible that there are some services that are covered by the POC coordinator that they do not want to cover (e.g. services, such as haematology and coagulation, that should be moved out into primary care), but this information cannot be obtained from the answers to this question.

Generally, the answers to this question mirror the answers to question 10, with the exception of 'Infection Diagnosis', which appears to be a therapy area not currently widely covered that POC coordinators would like to see covered within their organisation. It is suggested that these findings could feed into the NHS Supply Chain framework as it reflects what customers want, allowing industry to focus on the devices that would be of most use within Trusts. It is important to note that rapid progress is being made in developing novel POC tests in previously unsupported specialisms, such as oncology, even though none of the options provided in this question are particularly innovative.

There were no common comments for this question, although answers such as 'I cover too many already', 'Cannot support other areas with current resources', and 'in Primary Care (but lack of primary care funding)' are a good indication of some of the problems faced by POC coordinators in some organisations.

Question 12: What are the challenges you face regarding POCT? Please select a maximum of 3 challenges [finance; personnel; accreditation; Trust buy-in; perceived cost; demonstrating value of service; IT/connectivity; other]



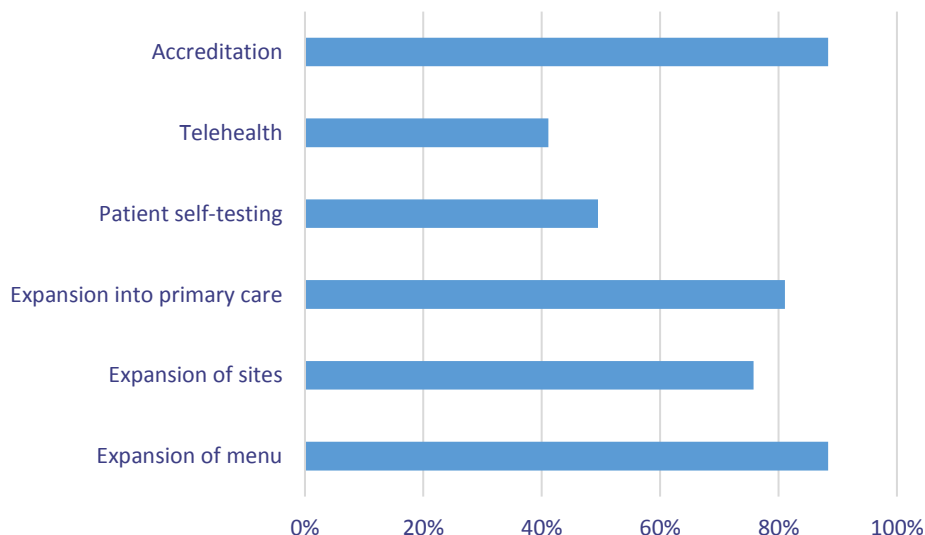
It is interesting to note the difference in the proportion of respondents who believed that 'Finance' was an issue compared to those who thought that 'Demonstrating value', 'Perceived cost' and 'Trust buy-in' are a main challenge. These results may indicate that whilst the value, reasonable cost and potential benefits to their organisation is recognised, there is simply not the money available to fund the POCT that they would like to see or funding is tied up in budget silos. Alternatively, whilst the 'Trust buy-in' is present in general, the POC coordinator may be unable to convince the finance team to invest. It is encouraging, however, that perceived cost is low amongst the POC coordinator community.

These answers may, however, reflect the audience that was targeted in this survey. By surveying POC coordinators, it is the 'converted' who are being questioned. Furthermore, POC coordinators would not necessarily be involved in demonstrating value, therefore, it may be beneficial to survey different demographics (e.g. finance, IT) and compare the findings to this initial survey. Such a survey may provide a clearer insight into whether industry needs to adapt the way they interact with POC coordinators to help resolve challenges they are facing.

Again, the comments generally built upon the results shown above, however, some specific comments that may be of interest were:

- 'Quality of results from POCT device e.g. D Dimer'
- 'We are already accredited but it is changing to ISO15189 so more to do'
- 'Lab feeling threatened by POCT'
- 'All of the above are challenges - as well as unregulated expansion'

Question 13: What do you see in the future for POCT? Please select all that apply
[expansion of menu; expansion of sites; expansion into primary care; patient self-testing; telehealth; accreditation; other]



Again, most answers to this question were reasonably popular. Accreditation is clearly a concern for most POC coordinators, whilst the popularity of the 'Expansion of menu' option provides a definite indication of potential growth in the sector.

The fact that ‘Telehealth’ and ‘Patient self-testing’ were comparatively low possibly again reflects the fact that the survey was completed by POC coordinators whose role will not be influenced significantly by development in these areas. This fact is emphasised by comments such as ‘Patient self-testing should be a remit of its own’ and ‘POCT by healthcare professionals has different governance requirements from patient self-testing’. It is suggested that what POC coordinators and pathology managers see and want is likely to be very different.

The question could also be built upon since it is unclear whether respondents interpreted the question as *their* future or *the* future for POCT, and to what timeframe ‘the future’ related i.e. two years or ten years.

Conclusions

Point of care testing is a growing sector that has the potential to alter substantially when and where patients are treated. This initial survey shows that there is a positive future for POCT, but this is not consistently reflected in the service that exists presently. The idea that POC is growing and of increasing importance does not appear to be reflected in the support and resource available across the UK, although there are clearly a number of Trusts that have fully embraced POCT in terms of the number and range of utilised devices, and so, support their POC team appropriately. There appears to be an appetite for a range of POC devices across different therapy areas, utilised in a variety of locations across the Trust, but these ambitions can only be matched if a robust POC service that considers financing, resource, governance and accreditation is developed. The IVD industry looks forward to working with key stakeholders in this exciting area to harness this potential so that the UK can become a world leader in the utilisation of POC devices and realise the benefits that they offer to both patients and the NHS as a whole.

Next Steps

BIVDA would greatly appreciate any comments. This may clear up some ambiguity by revealing how respondents interpreted certain questions, allowing the conclusions based on the results of these questions to be validated or revisited.

BIVDA will be looking to build upon these initial findings in a variety of ways. One way of gaining an even clearer understanding of the POC environment in the UK would be to carry out a second survey. The audience and purpose of a potential second survey is outlined below – any comments or suggestions from initial respondents would be greatly appreciated.

Possible follow-up survey:

- second survey of original respondents targeting specific aspects of this initial survey to provide greater detail
- survey of a different group within the secondary care setting (such as finance or IT) to establish their perspective on POCT and the challenges they associate with the sector
- survey of POC in primary care specifically, since identifying problems within the community in order to relieve the burden currently placed on hospitals will come with a number of different obstacles and challenges

Appendix

Organisation List

Abertawe Bro Morgannwg University Health Board **x3**
Aneurin Bevan University Health Board
Ayrshire and Arran Health Board
Barnsley NHS Foundation Trust
Barts NHS Trust
Betsi Cadwaladr University Health Board
Belfast Health and Social Care Trust
Brighton and Sussex University Hospitals NHS Trust
Buckinghamshire Healthcare Trust
Calderdale & Huddersfield NHS Foundation Trust
Central Manchester Foundation Trust
Cork University Hospital (IRE)
Countess of Chester NHS Foundation Trust
County Durham and Darlington Foundation Trust
Cwm Taf University Health Board **x2**
Doncaster and Bassetlaw Hospitals Foundation Trust
Dorset County Hospital NHS Foundation Trust
Dumfries & Galloway Royal Infirmary
East Kent Hospitals University NHS Foundation Trust
East Sussex NHS Trust
East Lancashire Hospitals Trust
Epsom and St Helier Hospital
Frimley Health
Gateshead Health NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
Great Western Hospital Swindon
Harrogate and District NHS Foundation Trust **x3**
Royal Free Hospital
Homerton University Hospital
Hywel Dda University Health Board
Imperial College Healthcare NHS Trust
Kingston Hospital NHS Foundation Trust
London Borough of Redbridge
London North West Healthcare NHS Trust
Leeds Teaching Hospitals Trust (Bradford Site)
Midland Regional Hospital (IRE)
Milton Keynes University Hospital NHS Foundation Trust
North Cumbria University Hospitals NHS Trust
NHS Fife

NHS Greater Glasgow and Clyde
 NHS Grampian
 NHS Lothian
 NHS Wales Informatics Service
 Norfolk and Norwich University Hospitals NHS Foundation Trust
 North Lincolnshire and Goole NHS Foundation Trust
 North Tees & Hartlepool NHS Foundation Trust **x2**
 Northampton General NHS Trust
 Northumbria Healthcare NHS Foundation Trust
 Nuffield Health
 Oxford University Hospitals NHS Foundation Trust **x3**
 Path Links
 Kettering General Hospital
 Pennine Acute NHS Trust
 Peterborough City Hospital
 Plymouth Hospitals NHS Trust
 Derriford Combined Labs, Plymouth
 Princess Royal Hospital Telford
 Queen Elizabeth Hospital, Gateshead
 Raigmore Hospital, NHS Highland
 Royal Cornwall Hospital **x2**
 Rotherham General Hospital
 Royal Brompton & Harefield NHS Foundation Trust
 Royal Derby Hospital
 Salisbury NHS Foundation Trust
 Sheffield Teaching Hospital NHS Foundation Trust
 South Tees Hospitals NHS Foundation Trust
 St. Mary's Hospital, Isle of Wight
 Stockport NHS Foundation Trust
 Surrey Pathology Services **x2**
 The Mid Yorkshire Hospitals NHS Trust
 Torbay & South Devon Healthcare Trust
 University Hospitals Birmingham NHS Foundation Trust **x2**
 University Hospitals of North Midlands
 University Hospitals of Morecambe Bay NHS Foundation Trust
 Viapath, Bedford Hospital
 Viapath LLP **x2**
 Warrington and Halton Hospitals NHS Foundation Trust
 West Suffolk Hospital
 Whittington Health
 Worcestershire Acute Hospitals NHS Trust
 York Hospital