



**Point-of-Care: the demise of
high throughput screening?**

A workshop hosted by Cambridge Consultants

Cambridge Consultants recently hosted a 24-hour workshop for leaders in the diagnostics industry. The aim of the workshop was to examine the central question of 'Point-of-Care: the demise of high throughput screening?'

Guests came from a variety of backgrounds, which ranged from the front-line clinicians through to diagnostic companies developing new tests and devices. All held senior positions within the industry, and we would like to thank each of them for their excellent contributions to the workshop and for helping to make the event both informative and enjoyable.

To kick-start the workshop, delegates were given the opportunity to get to know each other over an informal dinner. Afterwards, serial entrepreneur John Snyder delivered an excellent and thought-provoking speech on the way the hi-tech industry uses human networks to produce novel solutions that deliver significant competitive advantage and, ultimately, wealth creation. Our aim at this stage of the event was to deliberately challenge the perceived 'status quo' by showing an example of best practice from a completely different, yet highly motivated industry. The mixed views from the audience suggest that many of John's points may have hit home.

The following day was organised into two distinct sessions. In the morning, the group examined the Point-of-Care market and addressed the issue as to whether it was set for growth or bust. In the afternoon, the delegates turned their attention to whether new technology would be critical to any market change.

Between these two sections, Joan Pearson from Leeds General Infirmary kindly gave up her valuable time to present her view of what was happening in today's healthcare market under the heading 'Point-of-Care and the Emergency Room – a clinician's view'.

This report reflects the views of our guests and we have made every effort to reflect the consensus of view as accurately as possible. We trust that you will find this report interesting and useful.

Naturally, we welcome your comments.

Participants

Helen Beckingham	Stirling Medical Innovations
Will Colon	Oxford Biosensors
David Evans	British Biocell Holdings
Gordon Forrest	Atlas Genetics
Alun Griffith	Lifescan Scotland
Malcolm Luker	Hypoguard
Nick Major	Genzyme Diagnostics
Fabrizio Mastrantonio	A. Menarini Diagnostics
Albert Nazareth	Church & Dwight
Joan Pearson	Leeds General Infirmary
Julian Pieters	Atonomics
Chris Price	University of Oxford
Antonio Sanesi	A. Menarini Diagnostics
Eckhard Schwenner	pes diagnosesysteme
David Wilson	Genzyme Diagnostics
Malcolm Yeudall	Stirling Medical Innovations
George Zajicek	Axis-Shield

Hosts

Charles Tavner
Andrew Diston
Tim Clay
David Ellis
Simon Burnell
Richard Snell
Patrick Pordage
Laura Rule

The Status Quo

Point-of-Care diagnostic testing is a diverse label that covers many forms of diagnostic tests. The group agreed that considering Point-of-Care testing (POCT) as a single market was naive and that there are radically different pressures between regions, users and healthcare regimes. Furthermore, POCT exists in fragmented pockets without gradual transitions. Instead we need to think about, and approach, the different markets in very different ways.

What are the major sectors? The group considered the regions of the US and Europe. Defensive medicine dominates the US so that liability rather than wealth generation drives behaviour. Although reimbursement encourages physicians to be adopters of POCT, concerns over liability arising from accuracy and precision means that they often request a final confirmatory central test in order to rest responsibility with the laboratory.

Conversely, Europe's adoption of POCT is driven by perceived clinical benefits, centralised purchasing and budget distribution. But the rate of uptake of POCT varies considerably between country. At one extreme, centralisation in the UK's NHS means that government policy, and voters' influence on it, creates slow uptake. Here cost control and evidence of cost benefit is a very important part of any case for the increased use of POCT. However, in countries like Sweden and Germany a more decentralised healthcare system means that POCT uptake is moving much faster. Physicians and patients are more aware of POCT and smaller inertia allows more rapid adoption. One delegate suggested that 80% of Sweden's diagnostic tests will be made by POCT in the near future.

Within these geographical regions POCT divides into a number of subsets. These can be summarised as professional and non-professional applications with each market having its own subdivisions.

Professional POCT, like existing cardiology tests and hospital diabetes testing, currently accounts for 42% of the market and is carried out in two major locations;

- Primary testing in the doctors surgery
- Secondary testing in the hospital emergency room

Professional testing is subject to similar downward cost pressures to other healthcare spending. Therefore POCT needs to provide evidence of clinical benefits to be embraced. POCT still suffers from a lower perception of quality than laboratory testing with healthcare professionals. This is compounded by the difficulty of demonstrating quality control with a more distributed network. POCT manufacturers need to produce evidence that demonstrates how the reduced number of handling steps in the POCT process improves the total accuracy over that of its laboratory equivalent. This can often be the case even though the laboratory instruments have higher accuracy than their POC equivalents. This kind of clear evidence will be vital to convince conservative policy makers and physicians to make a change. This requires careful studies to demonstrate cost benefit and overcome current silo budgeting.

Once advocates of POCT have overcome the central barriers of cost and quality they must address a series of practical concerns such as connectivity, training and role changes to increase adoption in the professional environment.

The other major sector, non-professional POCT or homecare, makes up 58% of the market and divides into two subgroups;

- Chronic disease management, e.g. home diabetes care
- Opportunistic personal management, the 'worried well', e.g. pregnancy

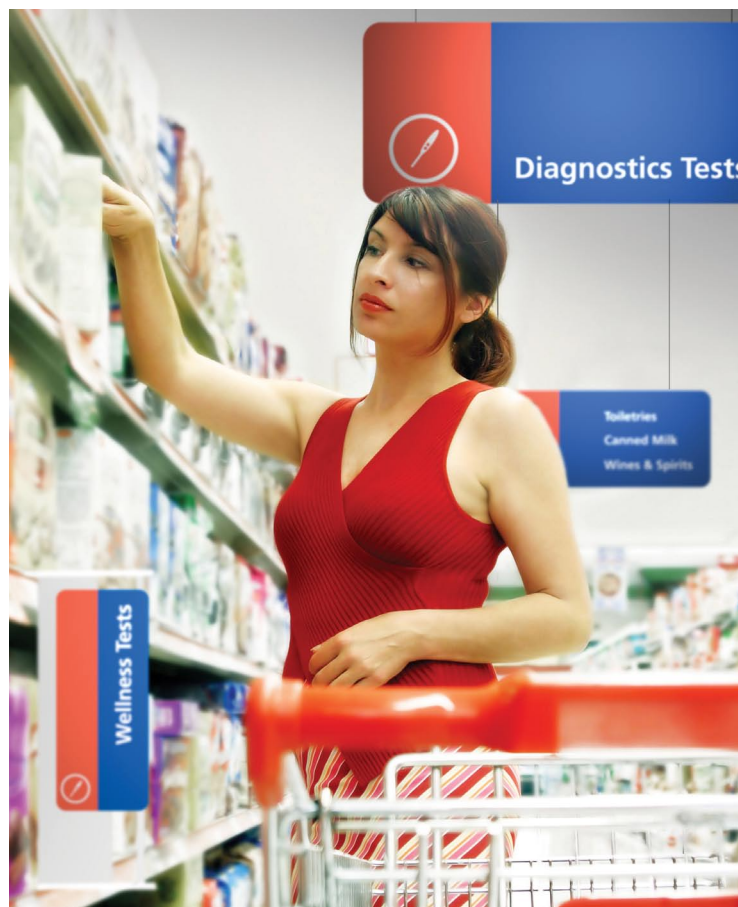
Because patients are directly meeting some, if not all, of the costs of these consumer devices, the commercial pressures are much closer to fast moving consumer goods. Whilst regulatory hurdles and physician support are vital, direct advertising, user experience and product innovation will define product success. This will need a radically different approach to the one taken for the professional market.

These very different pressures make migration between these markets difficult. Diabetes and pregnancy testing are currently the only professional tests that have successfully transitioned into non-professional applications. There are very few companies with both the diagnostic and marketing expertise to develop these products and compete in a consumer goods market.

POCT's global sales figure of \$6.8 billion per annum in 2003, approximately one third of the global IVD market, illustrates its importance. However, use of POCT is fragmented and driven by different factors in different markets. The single unifying advantage of POCT is speed;

- Where there is a need for fast intervention (cardiology, diabetes)
- Where people have a strong desire to know sooner (pregnancy, STD)

Ultimately governments and individuals will pay for POCT. However, diagnostics companies need to provide evidence to educate institutions and individuals to combat what one delegate referred to as the "Gulf of Ignorance" and demonstrate what is possible and illustrate the clinical and financial benefits of POCT.



■ *Are supermarkets soon to become the primary provider of diagnostic tests?*

Future of POCT

Market predictions estimate a 9% compound annual growth rate in POCT taking it to a \$10 billion market by 2010. The group discussed some of the changes that will create this growth.

The 'worried well'

The developed world is taking an increasing interest in its health. US healthcare expenditure has grown from 12% of GDP in 1990 to 15% in 2005, and currently shows little sign of slowing. This growth is fuelled by a culture of fear, reluctance in government to curtail state costs, and an enthusiasm amongst consumers to spend their own money on healthcare. An increasing part of consumer expenditure is with over-the-counter products, of which diabetes and pregnancy testing are examples. Many companies are investing in developing new tests like these. However, selling consumer healthcare products introduces a new set of direct marketing and manufacturing challenges to diagnostic companies. These are closer to those seen in fast moving consumer goods or pharmaceutical sales in the US. Accordingly, many diagnostic companies will have to form strategic alliances to successfully market if they intend to operate in this growing area.

Theranostics

Another area for growth incorporates the use of the rapid diagnostic information available from POCT to directly drive therapy. Theranostics, the convergence of diagnostics and drug delivery, is currently carried out in the physician's head based on many years of training. To develop a closed-loop system using a test to diagnose and deliver drug presents considerable regulatory challenges. Again, diagnostic companies will need to form alliances with pharmaceutical companies if they are to have any hope of creating these solutions.

One of the criticisms levelled at professional POCT is that it transfers a large amount of activities to the physician. In combination with pushing more testing into the home, we expect to see pharmacists becoming the new primary professional provider, reducing the burden on physicians. Ultimately, with the move of pharmacists into the supermarket, this could see an extensive range of diagnostics tests available on their shelves. This will create all the associated problems of untrained individuals in possession of critical healthcare data.

Hub and Spoke

The complex requirements for diagnostic testing mean that POCT will never provide all of the answers. Furthermore within POCT there will be professional and non-professional solutions with significant diversity in each area. The group expected a 'Hub and Spoke' model to develop for diagnostics. This model has each laboratory at the centre carrying out calibrations, confirmatory tests and more esoteric tests that are uneconomical at Point-of-Care. Each laboratory is then linked to many physicians or pharmacists carrying out the majority of screening at the Point-of-Care. In turn, each healthcare professional may have many patients carrying out home care tests to indicate when a consultation is necessary. This means that there is a place for both laboratory testing and POCT, although the relative numbers would suggest a gradual shift in the balance of power from the laboratory to the primary healthcare provider and POCT.

Education

All of these changes require users to know what tests are possible and which are appropriate. This requires education. There is alarming evidence of errors being made even by healthcare professionals with the current POC technologies. Furthermore, many do not know the capabilities and limitations of these tests. Therefore, if the diagnostics industry wants to promote the changes described above, it needs to undertake an evidence-based education programme so that professional and non-professional users can correctly operate and interpret current tests, as well as select new tests.

Naturally, the future of diagnostics is complex. The challenges it faces are analogous to those when trying to provide an integrated transport network. It is, after all, something nearly all users want, but the way that various individuals behave with conflicting interests and priorities, often stops such a system from ever emerging. Diagnostics already have isolated pockets of a hub and spoke infrastructure. Like transport, however, the major challenge is to educate users on capabilities if we are to successfully integrate these isolated pockets and begin to fill in the gaps.



■ Will chemistry remain at the core of future diagnostic tests?

Integration or Innovation?

What do these changes mean to where companies should invest their research and development budgets? Is technology a barrier? Typically physicians are unable to define whether current performance is satisfactory. This makes it very difficult to judge whether current 'wet chemistry' is sufficient to meet our needs.

One group at the event argued that "the chemistry is cracked", performance is adequate and that the challenge lay in the sample preparation and data management. The group felt that existing wet chemistry met the accuracy demands and that challenges lay in integration, namely;

- Increasing the tests on panels
- Integrating the IT output

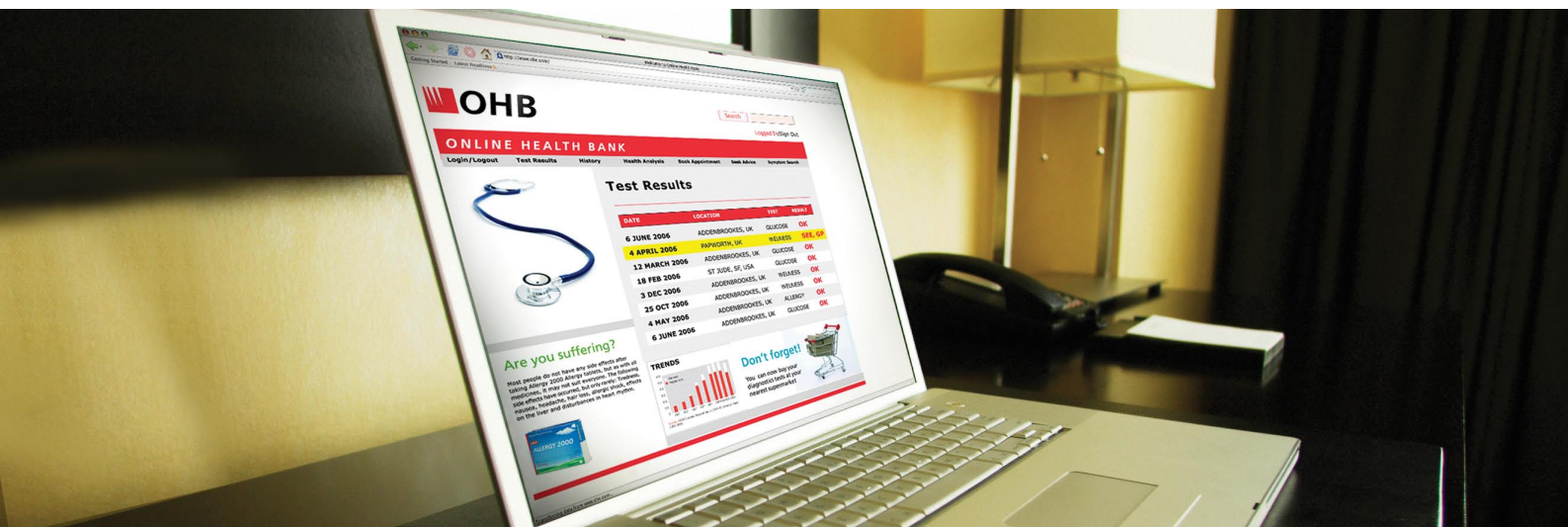
This would drive us to invest in development rather than research to perfect;

- Sample preparation; the input to the chemistry, and
- Data management; the output from the chemistry

This means we need an IT infrastructure that would allow diagnostic instruments to interface with each other as well as the central patient records. The initial group reaction was that this was simple and "just software". However, a closer examination of some of the challenges illustrates the scale of the undertaking in such areas as;

- Agreeing unified standards
- Integrity and reliability
- Security
- Training

Creating a system for the UK alone would be incredibly challenging with 60 million 'clients' and 1.1 million staff in the NHS. Therefore achieving global standards and approaches seems unlikely. Computing giants, like Microsoft, are able to bulldoze the market because of their size and global domination. Bayer is attempting to do this with its closed source Rapidlink® system. However, with a low barrier to entry, POCT diagnostic companies are typically not big enough to drive this kind of standardisation. Companies like Menarini take a different approach by using open source systems like NetCare to try and create standardisation. Will this ever work? Could – or should - legislation be used to drive integration?



■ *Health account / bank account – will medical data ever be as accessible as that which is already widely used today in personal banking?*

The second group started down a similar path, agreeing that accuracy levels achieved in today's POCT was sufficient. Again they initially focused on IT. However, whilst they agreed that significant advances could be made using current chemistry, innovation focussed at the core of the process could reduce the inherent complexity of analyte preparation and radically change diagnostics. Technologies like microarrays, NMR, mass spectrometry, surface technology, nanoparticles and biosensors might fundamentally change diagnostics.

This presents a serious dilemma for the diagnostics industry.

A technology breakthrough that replaced wet chemistry would require major research investment. The more tangible improvements around IT are a development problem, albeit a large one.

With no breakthrough technology imminent, maybe the correct strategy is to invest in IT and sample preparation development, whilst keeping a watching brief on start-ups that could deliver the breakthrough. As long as diagnostic companies are quick to recognise the impact of a proven replacement to wet chemistry they will be able to integrate it into their business and stay ahead of the competition.

Whilst it is easy for many industries to believe that they are truly adopting a 'watching brief', it's worth remembering that electricity and the subsequent development of the refrigerator put thousands of 'ice-men' down America's coastline quickly out of work in an industry that thought it was safe. They failed to react quickly enough. There is no reason to believe that diagnostics is any less immune from just such a breakthrough innovation.

About Cambridge Consultants

Cambridge Consultants has, for over 45 years, enabled its clients to turn business opportunities into commercial successes, whether launching first-to-market products, entering new markets or expanding existing markets through the introduction of new technologies. We develop breakthrough products, create and license intellectual property, and provide business consultancy in technology critical issues for clients worldwide.

With a team of over 200 engineers, scientists and consultants, in offices in Cambridge (UK) and Boston (USA), we are able to offer solutions across a diverse range of industries including healthcare, industrial and consumer products, automotive, transport, energy and wireless communications.

Healthcare remains a central strength for our business. Within the industry we specialise in three traditional key areas, namely diagnostics, drug delivery, medical devices and surgical tools, and a fourth, high-growth, area of wireless medical technologies. Within these areas our work ranges from concept development through to turn-key device development, and encompasses skills including product design, analysis, low cost electronic design, regulatory affairs and programme management. Further information about our work in these areas can be found on our website.

As part of our ongoing commitment to the diagnostics market, we would be pleased to hear your reactions on the subject of where the industry is going.

For further information or to discuss your comments, please contact either

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