



**The future of diagnostics:
a consumer driven world?**

A workshop hosted by Cambridge Consultants

Cambridge Consultants recently hosted an exclusive 24-hour workshop for leaders in the diagnostics industry. Following on from the success of the previous year's event, which focused on the role of POCT and its relationship to the central laboratory, this year the workshop set about examining the central question of 'The future of diagnostics: a consumer driven world?'

Guests came from a variety of backgrounds, and all held senior positions. We would like to thank them for their excellent contributions to the workshop.

The findings presented in this report are drawn together from the output of the day's guided workshops. Following short, provocative presentations from our staff, guests came together in two working parties and spent the morning looking at the market for consumer-based testing, and discussing the factors that will influence the growth of the sector. In the afternoon, the group turned its attention to the technology that would be critical to any market change.

The workshop was further enhanced by two presentations from Professor Kim Pettersson, from the University of Turku, who shared his thoughts on technological approaches to POCT, and Dick Powell, from design agency Seymourpowell, who examined the critical role of good design in creating a successful consumer product.

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.

Guests at this event were deliberately chosen because they hold senior positions within the European diagnostics industry. We will be repeating this workshop in the autumn in North America in order that we can compare and contrast the results.

We believe this report is just the start of the debate on the role that the consumer will have on the future of diagnostics. Naturally, we welcome your comments and views.

Participants

Mike Addison	Procter & Gamble
Gordon Forrest	Atlas Genetics Ltd
Fabio Gennari	BioMerieux Italia S.p.A
Eric Hecker	Roche Diagnostics GmbH
Aman Khan	Unipath Ltd
Malcolm Luker	Philips - Healthcare Incubator
Fabrizio Mastrantonio	A.Menarini Diagnostics
Per Matsson	Phadia AB
Kim Pettersson	University of Turku
Julian Pieters	Atonomics A/S
Chris Price	University of Oxford
Grenville Robinson	Lifescan Scotland Ltd
Antonio Sanesi	A.Menarini Diagnostics
Gordon Sanghera	Oxford Nanolabs Ltd
Ian Yeeles	Abbott Point of Care

Hosts

Ben Arlett
AJ van Bochoven
Simon Burnell
Tim Clay
Andrew Diston
David Ellis
Patrick Pordage
Laura Rule
Richard Snell

In store now

The diagnostics industry has been tempting the healthcare professional with promises of convenient, accessible and reliable diagnostics for years; they are still waiting. Consumers have fared little better with offerings largely limited to glucose monitors, pregnancy tests and bathroom scales. With the consumer revolution gathering pace in many other areas of our lives, how will consumers drive growth in this market?

While there are many predictions for the size and growth of the in vitro diagnostics market, it is clear that sales for glucose monitors dominate in the over-the-counter segment. The global in vitro diagnostics sector was estimated to be \$32 billion in 2005 and will grow by 41% to \$45.6 billion by 2010. The professional point of care market sector accounts for 12.5% of the total, with non-glucose over the counter tests accounting for just 2% of the total in vitro diagnostics market.

The growth of non-glucose over-the-counter tests developed slowly with only 60 applications for 510(k) registrations between 1982 and 1999. However, in the last seven years there have been an additional 80 applications of non-glucose tests, indicating a significant growth in this market. Originally, over-the-counter tests were developed to replicate those being offered by the central laboratory (e.g. clinical chemistry tests), but more recently they have been developed for lifestyle testing: drugs of abuse, STI, cholesterol, fertility and allergy, for example. Although the underlying drivers behind these changes are complex, it is clear that firstly, there appears to be no slowing of the number of tests being developed for the over-the-counter market and secondly, new unmet market areas are being targeted.

It is predicted that cardiovascular disease will overtake infectious diseases and malnutrition as the world's leading cause of death and disability. With the possible exception of China, cholesterol and blood pressure levels have also soared worldwide. Obesity, no longer restricted to highly developed countries, is also skyrocketing. There are clear opportunities for the diagnostics industry to make an impact on people's lives but to achieve this there are hurdles to be overcome.

Who is the consumer?

Healthcare providers have been the traditional customers for the diagnostics industry, with their own set of unique challenges from complex funding routes to government policy and data management (particularly with the advent of the electronic patient record). Change within healthcare providers often occurs at a glacial pace and so the requirements dictated by these providers are slow to emerge. Unlike the traditional diagnostics market place, the evolving over-the-counter market is more like the market for fast moving consumer goods, the requirements being driven by the end user – the consumer.

The question of who is the consumer for these new over-the-counter tests was debated. Up to now the healthcare providers have, by and large, been both the customer and consumer for diagnostics tests. However, in this evolving diagnostics market it is clear that the diagnostics companies have a number of customers (retail outlets, distributors, healthcare providers) but just one consumer, the patient. During the discussion, the group concentrated on the concept of the patient being the consumer and exercising their choice regardless of who actually pays the bill.

The market place for these new tests is global. Diagnostics companies would be wise to understand cultural and demographic differences when developing new products.

A consumer driven world?

Independent of which country we live in, the role that medical diagnostics play is similar in so far as they are used reactively to identify, monitor and aid treatment. This, coupled with trends in decentralised healthcare practices, passes the burden of care to clinics and community healthcare providers. As healthcare spending of developed countries is predicted to grow, significant efforts are being made to reduce this burden. Opportunities exist to identify disease states earlier and reduce the total cost of disease management.

As the developed world continues to expand, the population is living longer and becoming richer. Disposable incomes are continuing to grow and indications are that we are becoming more conscious of our health and the quality of our life. Opportunities exist for diagnostics companies to take a share of this increase in disposable income.

There are clear consumer benefits for the range of well established over-the-counter tests such as those for pregnancy. The group's view of the underlying reasons behind the limited growth in non-glucose over-the-counter market products was that:

- There is an absence of a clear benefit for some emerging tests
- Consumer awareness is poor
- Underlying technologies are not simple or robust enough for routine consumer use
- There is limited support from clinicians for consumer testing
- The outcome from diagnostics has not always been actionable

The majority of diagnostics companies present indicated they were skeptical about the size of the 'worried well' market, so often talked about. Their belief is that it will be hard to persuade people who are not experiencing symptoms to spend money on tests. Yet we have seen a growth in health shops offering a range of wellness tests, some of which have little scientific grounding. There is a growing and unmet need for reliable tests with, to date, consumers only being offered a few tests that have clinical acceptance. An example of consumer drive is the success of nutraceuticals which have been a revolution in the food market. From a saturated market section, food additives have offered consumers a route to healthy living. The clinical benefits are hotly debated but in spite of this motivated consumers worldwide are taking action to reduce health risks.

The relationship between the patient, the clinician and the healthcare system has evolved as patient access to knowledge via the internet has increased. As patients become better educated they may become increasingly dissatisfied with the service that they are receiving. Consequently, they are more likely to look to alternative options where they have an ability to choose for themselves.

Market factors

There are many factors that will drive a consumer to want to test themselves at home. There is also a huge difference in consumer experience between remote testing (in a physician's office, pharmacy or sending in a sample) and where the consumer can take it home:

- Privacy, or the feeling of privacy, is guaranteed. This is particularly important when testing for STIs
- The offer of immediacy of test results
- The convenience of not having to make an appointment
- The availability of tests through a range of outlets

The group discussed the 'form and feel' of consumer medical devices and were split on whether the products should have a medical feel. Through extensive user studies consumer demands for glucose systems are well understood. As a result, these systems are now available in a range of complexities and colours to suit the individual. In addition, the user experience is enhanced further with significant support available through the internet. More specifically, diagnostics company websites are becoming definitive resources for information on disease states. Interestingly, it would appear that glucose systems have managed to change user perception by re-branding themselves to the brink of being fashionable, rather than something to be hidden.

Education

Information is key. As consumers we are becoming more aware of our surrounding environment through the media channels available to us. Specific demographic groups are being educated very differently about their health options. Younger groups are typically targeted through magazines, the middle-aged sector through the internet and the more elderly through traditional channels such as pharmacies, health clinics and community care centres. With a growing level of cardiac related problems, a campaign was recently launched in the United States to promote the awareness of cholesterol, blood pressure and glucose levels. The 'Know Your Number' scheme was the start of an education campaign which is quickly growing. Schemes such as Health 2.0, supported by companies like Microsoft and Google, continue the theme. What is interesting is that these campaigns and schemes are not driven by healthcare providers or diagnostics companies but instead by consumer groups, non-profit organisations and large IT companies.

But it is not just the consumers that need education, the diagnostics companies and the healthcare providers should not be forgotten. Successful consumer products have a story which runs alongside them and why should diagnostic products be any different? Two examples were presented: the SIAscope™ and cholesterol testing.

Stores which sold skincare products are now introducing diagnostics systems to help sell consumers the correct products. The SIAscope, originally developed to measure melanin, haemoglobin and collagen for detecting melanoma, is being used to detect skin tone. From the results, consumers are able to select the most appropriate skincare products.

Cholesterol testing has been available for some time. When these tests were originally introduced, the user could take little action other than modify their diet or exercise. The sale of statins is now openly available and is being offered to consumers based on the result of the cholesterol test. Consumers want to be able to action the results they get from the test and, as

such, diagnostics companies need to consider this when developing systems. Simply providing a result is only one element that is required of a diagnostic system. An entire infrastructure needs to be in place to support the consumer. A mindset change is required by diagnostics companies when developing new tests.

Technology

From the outset of the discussions, the group was unanimous on the need for simplicity and reliability. The tests of the future need to be reliable and foolproof and the validity of the result must be beyond question. The necessary clinical sensitivity is taken as a given. A number of standard technologies have emerged and over time have become robust and their performance extended.

Whilst companies strive to generate new technologies which offer increased sensitivity and lower sample volume, we debated if this is the correct approach to achieve the simplicity and reliability goals. There was disagreement from the delegates about whether the diagnostics industry is creating technologies for the next generation of diagnostics or whether they are seeking to make incremental improvements on the technologies of today. In a consumer driven world, the technology which underpins the measurement is utterly irrelevant to the consumer, provided that it is trustworthy, e.g. through accreditation. With so many diagnostics companies struggling to bring increasingly advanced and complex technology to the consumer it may come as a shock to them that there is far more to the story than just making a measurement.

Successful consumer tests require a very low blood sample volume or indirect measurement to increase compliance. Traditional sampling methods can be painful and intrusive, often resulting in users either avoiding the test or testing irregularly. Alternative sources of sample are available, for example, saliva, sweat and urine. Indeed direct measurement may also be possible, all of which could be used to improve compliance.

Technology is being used to increase compliance with some computer games,



which are coupled with glucose meters, offering access to new levels if children comply with their therapy. SMS reminders are also being used by one healthcare trust as a reminder to help patients improve compliance. It is clear that in order for the next generation of diagnostic tests to be successful, the issue of compliance must be addressed. This sends a clear message to the diagnostics industry: tests must be simple and preferably integrated seamlessly into our everyday routines, if they are to succeed.

Interpretation of the results is another area to which delegates thought attention should be given. The group felt that consideration should be directed to the format in which the result is presented. Diagnostic testing falls into the four areas of prognosis, screening, disease identification and monitoring, and the presentation of results in each case will be different. In the case of Type II diabetes, users

are given the direct concentration of their glucose levels. Diabetics have been trained to make the interpretation and are able to act on their glucose levels. In all cases the result of the test should be presented in a way that will allow easy interpretation and appropriate action.

Service and connectivity are critical for future devices. Arguably, the success of devices such as the iPod only became truly successful once iTunes became widely available. This model is not unique and is replicated across a number of industries. Consumers are driving mobile phone providers to constantly add functionality to their devices, web and e-mail access, for example. Issues still to be addressed in diagnostics include how results will be handled and stored, and who will be the custodian of the information. The internet is already allowing knowledge and access to tests which previously could not have been reached. Information about disease states and medical conditions can be found with ease but the validity of the information cannot be guaranteed.

A change in outlet

In considering the available resources to alleviate the growing financial burden, governments in the UK, USA and some central European countries are encouraging pharmacies to be an outlet for diagnostic testing. The general view from the group was that Italy and the UK are the more fertile ground as there is a pharmacy network which is supported by highly trained and underutilised pharmacy staff. This is expected to be further accelerated by the review of the UK's independent dispensing legislation, the results of which are about to come into effect and give pharmacies more control and power. Integration of the pharmacy into the healthcare system is inextricably linked with the referral model and dependent upon regulation. The roll-out of over-the-counter testing in pharmacies is likely to increase consumers' acceptance, but the full benefit can only be achieved if the pharmacies can expand beyond their traditional limited client base.

Supermarkets have been very successful

at widening their access to different demographic groups. The services they offer are continually extending from car and home insurance to internet shopping and in-store pharmacies. These services exist for pure commercial reasons and they are successful. When diagnostics companies consider the range of outlets, they should be cognisant of their ever expanding options.



What's in store for the future?

In a world driven by consumerism, the stakeholders are not just different from the traditional healthcare infrastructure, they are so fantastically different that they share almost no common ground. Classically, we have been able to segment medical diagnostics by the arena in which it has been used, i.e. clinical laboratory, point of care or over-the-counter. Thereafter the global markets for these traditional diagnostics are well understood, largely driven by culture and wealth. Consumer markets are radically different. These very different consumer market pressures make product migration between professional and consumer diagnostics markets difficult. Diabetes and pregnancy testing are currently the only professional diagnostics that have successfully transitioned into non-professional applications. These areas are well understood and the clinical utility defined.

Market creation is an art form. Global consumer companies across the world spend billions of dollars creating and maintaining markets. In this new market it is not clear that diagnostics companies alone will succeed in developing successful products.

A growing number of markers are being identified which are thought to be useful in the diagnosis of a range of diseases. In order to determine their clinical utility, clinical trials and outcome studies are required. The accurate design of outcome studies is complex, costly and takes a significant amount of time. This requires resource that the majority of diagnostics companies simply do not have access to. As such, and unlike the pharmaceutical industry, the diagnostics industry has not typically funded outcome studies. The result of this is that companies often develop speculative tests in the hope that someone else will demonstrate their clinical utility. How will the consumer ever get access to new tests unless there is a mindset change? Today, there are still very few diagnostics companies with both the diagnostic and marketing expertise to develop these products and compete in a consumer goods market. One solution is to link the pharmaceutical industry together with the diagnostics industry.



It is difficult for the diagnostics industry to see beyond the present situation and the barriers to entry for new platforms are immense. As the pharmacy becomes more integrated into the healthcare model there is an opportunity for the diagnostics industry to engage with them. The emergence of the pharmacy-based consultation room is one example of where this is starting occur. As such, pharmacists stand to gain a slice of this market. However, it is not clear how the patients and pharmacists will push to bring new technologies to the market. One suggestion was made that, with mature areas such as diabetes, one single diagnostics company could manage this particular market by becoming a turnkey provider.

The delegates examined the future within the four main areas of diagnostics:

Screening

It is believed that screening for future disease prevalence is of benefit to a healthcare system as it may help to reduce the overall cost of treatment for a patient through earlier diagnosis. There are a range of tests where the consumer would benefit from early diagnosis: Coeliac disease, Type II diabetes, rheumatoid arthritis, blood pressure, STIs and Hep. A. It was thought that there is sufficient support through consumer groups for consumers to undertake these tests themselves. Recently, a product offered by University Diagnostics to screen for a breast cancer gene was advertised with great success in a women's magazine. Here, a diagnostics company was providing the consumer with a service not offered by the mainstream healthcare system. Interestingly, a view by the diagnostics group present was that screening will never make an over-the-counter test as the consumer would be better served by going to a clinician, a view contradicted by those representing the consumer driven markets. Is the diagnostics industry view too conservative?

Disease identification

Disease identification will gain some acceptance if there is a clear action that the patient can implement themselves. If the patient does not have to go to the healthcare provider as a consequence of the test then there is an added benefit. An example of a test where the consumer may be able to diagnose and treat themselves is osteoporosis which could be linked to nutria-supplements added to the consumer's diet. In the example of conditions such as *Strep. A* or meningitis, speed of diagnosis is a key benefit.

Disease monitoring

There is a clear case for the use of disease monitors if testing is required on a regular basis. Aside from the potential clinical benefit, if the test does not need clinical supervision it will reduce work load from the clinician (e.g. glucose or congestive heart failure). However, evidence of compliance with blood glucose is so poor that regulatory bodies may be unwilling to let other monitoring tests onto the market unless there is no alternative.

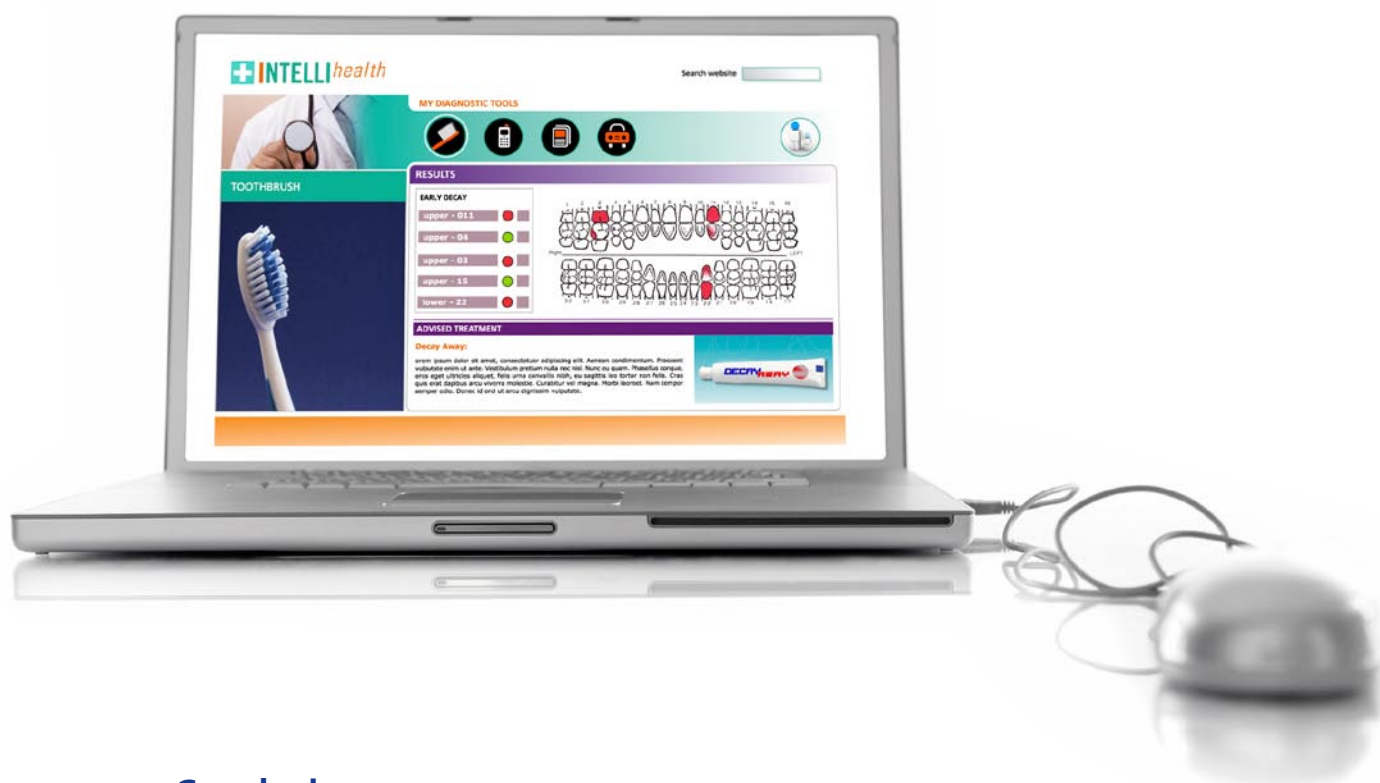
Prognostics

The technology exists to allow consumers to identify future likelihood of disease and severity but in the short term it is not clear who is willing to pay. Will patients demand these technologies and will they be prepared to pay for them? Will they integrate them into their lives? In order for success the industry must demonstrate a clear economic benefit.

All these areas have different drivers, but for consumer diagnostics to take off there has to be some clear advantage to the consumer. Selling consumer healthcare products introduces a new set of marketing challenges to diagnostics companies, more closely linked to those seen in the fast moving consumer goods sector. What will make a product attractive to the consumer?

The user must still have some actionable benefit such that they perceive a reason for doing the test. As many of the large consumer goods companies sell solutions, there is a potential risk of being seen to have a vested interest by co-developing diagnostic products that subsequently support the sale of their own goods. This may be further compounded if the pharmaceutical industry is involved, as regulators and consumers are naturally wary. Ultimately the diagnostic tests need to identify a complete story selling a benefit to the consumer. Brand awareness and brand loyalty will play a big part in this and companies either need to build consumer awareness of their brand or use high street brands to generate confidence in new tests and sell products.

The vision of the future, discussed amongst the group, was one where the clinician is moved to that of a referral role. In this model, the consumer has a healthcare system which is integrated seamlessly into their life. By using simple devices integrated in everyday objects, a range of measurements can be taken. This issue of compliance is overcome as measurements are taken automatically. For example, the integration of a thermometer into your mobile phone, or a hydration monitor into your PC mouse. Interfacing the data with a remote management centre, through an internet portal, the consumer can be advised to test, with specific tests being sent by mail where needed. Using complex data analysis, trends can be assembled and disease states spotted before they become untreatable. When a problem arises the consumer is referred by the remote centre when trends or symptoms dictate.



Conclusion

With continued growth and a range of new tests being developed, change in the diagnostics industry is to be expected. This workshop intentionally focused on the over-the-counter products with the consumer being the patient, from which debate followed. Consumer driven market pressures are very different from those experienced by the traditional diagnostics industry. In this market the traditional offerings of a result from a diagnostic test will simply not suffice. To drive a new generation of diagnostics testing, the clinical utility of the device must be demonstrated, along with the functional performance and the integration being demanded by the consumer. In order to provide the consumer with the whole story, the next generation of diagnostics may need to be jointly developed by a consortium from the pharmaceutical, diagnostics and consumer industries. Whilst there is uncertainty about how this market will develop, it is clear that a mindset change within the diagnostics industry will be required. Only then will the resource, capability and consumer requirements of this model be fully provided for. The market - and subsequent rewards - if someone were to take this bold step, and get this combination right, could be enormous.

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 nearly 300 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 medical technology, industrial and consumer products, automotive, transport, energy and wireless communications.

Medical technology is a central strength of our business. Within the industry we specialise in four areas, namely diagnostics, drug delivery, medical and surgical devices, and wireless medical technologies. Within these areas our work ranges from concept development through to turnkey 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:

Simon Burnell, [Head of Diagnostics](#)
Simon.Burnell@CambridgeConsultants.com

Andrew Diston, [Head of Medtech](#)
Andrew.Diston@CambridgeConsultants.com



info@CambridgeConsultants.com
www.CambridgeConsultants.com

Cambridge Consultants Ltd
Science Park
Milton Road
Cambridge
England CB4 0DW

Tel +44 (0)1223 420024
Fax +44 (0)1223 423373

Cambridge Consultants Inc
101 Main Street
Cambridge MA 02142
USA

Tel +1 617 532 4700
Fax +1 617 737 9889