



C a r d i o C h e k P A

C a s e S t u d y

**Practicing  
Physician Utilizes  
Efficient & Accurate  
Point-of-Care  
Cholesterol Testing**



## Solutions Brief

### Customer Profile

In the United Kingdom, primary health care is distributed by the National Health Service (NHS), which is free for all patients and is financed by the government via taxation. A nationwide network of General Practitioners (GPs) is available for patient appointments, varying from a single doctor's office to small clinics with several doctors, nurses, other support functions and advisors.

### Business Situation

An integral part of the healthcare system in the UK is preventative care for heart disease. On a world-wide basis, an estimated 17 million people die of Cardiovascular Diseases, particularly heart attacks and strokes, every year according to estimates from the World Health Organization. The corresponding figure for the UK is close to 200,000 deaths per year (British Heart Foundation). A patient's cholesterol level is normally defined as one of five major risk factors associated with heart disease. In the current system, the process involves sending a blood sample to a laboratory or recommending the patient to visit a laboratory. The true cost of the analysis includes not only the expense of the test in the laboratory, but also costs for transportation of the blood sample to the laboratory, administration fees and a follow up visit to the physician.

## Dr. Jane Barnard Tests a Hand-held Device for Monitoring Cholesterol Levels

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### Equipment review

The importance of cholesterol levels in cardiovascular disease is well known and, as the public becomes more aware of the significance of cholesterol to general health, so the demand for checks is increasing.

There are various situations where cholesterol testing in-house would be very useful. It can save on sending samples to the laboratory and allows for early intervention, via dietary changes, in those you may have previously declined to test with a lab sample. It also allows for simple re-checking afterwards.

It is quick and convenient and, as we've experienced while testing the CardioChek PA machine, the patients love the fact they get an instant result. They are often less pleased about the actual figure.

Relatives of patients with known cardiovascular disease or hyperlipidaemia can also be simply and accurately screened with this machine, and it would be a useful addition to any well-man or well-woman screening clinic you may offer.



### Reliability of readings

Point-of-care testing machines do have a higher variability than lab testing, but CardioChek's results have less than 10 per cent variability, which meets the accuracy guidelines established by the National Cholesterol Education Program of the National Institutes of Health.

The general advice, however, if you get several high readings and are considering prescribing a statin is to get a fasting laboratory sample first.

To ensure you obtain accurate results in-house, I think the training provided with this machine is essential. It takes half an hour, is offered free by the manufacturer and extends to as many staff as you require. It is clear and comprehensive and will definitely improve your skills at skin-prick testing. It also, more importantly, enables you to avoid the factors that can sometimes affect results.

I would also suggest you use the capillary pipettes as recommended in the manual. Having had a go without one, there was definitely more room for error.

A system is now being implemented in the UK that will give GPs additional control over their budgets. One of the effects of this is that GPs and their staff will now have the ability to use point-of-care systems in combination with the existing system of sending blood samples to a laboratory. GPs in the UK are now challenged with the task of finding reliable and accurate point-of-care systems in order to aid in the testing of cholesterol for patients at risk for heart disease.

Dr. Jane Barnard, MB BS, DCH, MRCP, was asked to review a comprehensive cholesterol screening panel.

### **Solution**

The CardioChek PA point-of-care instrument, by Polymer Technology Systems, Inc., is a diagnostic analyzer for point-of-care professional testing of cholesterol and other cardiac risk factors.

Dr. Jane Barnard is now using the CardioChek PA point-of-care instrument in her practice. The CardioChek PA cholesterol test system is used extensively in pharmacies in the UK as a screening tool.

### **Business Benefits**

The CardioChek PA cholesterol test system allows physicians to easily and accurately test the cholesterol levels of their patients and provide feedback in the same visit. It is efficient, much more cost-effective than a laboratory test, and avoids the need for follow-up calls to obtain results.



### **Ease of use**

Having said all that, we were all thoroughly impressed with the machine's simplicity and speed. Readings come up within one to two minutes - just enough time in which to do a BP reading - and up to 30 are stored. If you are testing more than one parameter, you can scroll through the results.

As well as total cholesterol, the machine can be programmed to use strips that measure HDL, triglycerides, LDL, TC/HDL ratio and glucose.



### **The verdict**

It was a pleasure reviewing this machine, which is easy to use, gives instant, accurate results, and avoids the need for sending repeat samples to the lab.

And although a number of our patients - and indeed some of our staff - are now on low-cholesterol diets, this can only be of benefit to them in the long term.

Dr. Barnard is a GP in Yateley, Hampshire, United Kingdom.



### **About the CardioChek PA cholesterol test system**

For more information about the CardioChek PA cholesterol test system, please visit: [www.cardiochekpa.com](http://www.cardiochekpa.com)



### **About GP magazine**


GP magazine is the leading weekly publication for family doctors and is distributed to the majority of GPs in the UK. For more information about GP magazine, please visit: [www.healthcarerepublic.com](http://www.healthcarerepublic.com)

## Q & A with Dr. Jane Barnard

 **Q: How did you come across the CardioChek PA cholesterol test system?**

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**A:** It was introduced to me via GP Magazine. The journal was keen to get an equipment review performed on the machine to assess its usefulness. I was then asked to write up my review which would be published for other GPs to enable them to have a colleague's opinion on how the machine functioned, its usefulness, and ease of application within a GP surgery. This would hopefully enable other GPs to make a more informed decision about the purchase of the CardioChek PA cholesterol test system. Prior to this I was aware of point-of-care testing for glucose and urine samples and had also heard about the possibility of point-of-care testing for INR's, but I was not aware of the development of a machine for accurately assessing cholesterol in the GP surgery, so was very excited to be able to carry out the review.

 **Q: What features do you like best about the CardioChek PA cholesterol test system?**

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**A:** It is very simple and easy to use, which is so important for a busy GP. It is quick and allows for testing at opportune moments as well as for routinely booked appointments. *Opportunistic testing makes things easier for the patient, who can avoid the need for a second appointment, and enables the doctor to seize the occasion to test patients who may not come back for a blood test at a later date. Another invaluable advantage is that the doctor or nurse is able to offer some preventative advice there and then.*

The machine's accuracy is an important factor, as it gives readings within 10% variability (which has FDA approval), and it meets the accuracy guidelines established by the National Cholesterol Education Program (NCEP) of the National Institutes of Health (NIH). This is a significant advantage, as it is most important that practitioners have faith in the machine they are using and the accuracy of its readings. The CardioChek PA cholesterol test system also enables the GP to not just check a cholesterol level, but also monitor HDL and other parameters, thus enabling the use of methods like the Framingham scale to establish a cardiovascular disease risk for the patient.

 **Q: How does this product make in-house testing easier for your patients (rather than sending the results to the lab)? How does it make testing easier for you?**

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**A:** *Patients can have the test performed during a routine appointment, it is a simple finger prick test and the patient only has to wait while the machine processes the sample. They can be given the results immediately and appropriate advice can be given about the result. This makes things much easier for the patient as they avoid a second visit to the surgery or hospital laboratory for a blood test, with yet a third visit to the surgery to review the results. It also avoids the anxiety of waiting for a result from the laboratory that follows the performance of a test. With the time constraints on GP appointments (about 10 minutes on average), if the patient*

presents with another problem, it may be difficult to have the time to perform the test and then discuss the result and give advice. In such circumstances the patient might be asked to come for another appointment to have the test performed. Even this scenario avoids a third visit to the surgery for the results. In my practice, our health care assistant can perform the test and uses guidelines on how to deal with the result and what advice to give the patient. This avoids another GP appointment, and there is the added safeguard that if the findings fall outside the guidelines, the patient is directed back to the doctor.

For the doctors in our practice, using the CardioChek PA point-of-care instrument has enabled us to perform tests immediately and address any problems found. It is quicker than a laboratory test and avoids the extra results that need to be reviewed from hospital-based testing. There is also a consequent reduction in the number of telephone enquires staff have to take from patients chasing up test results. *Another important consideration is that because we are doing some tests in the practice, we are sending fewer tests to the hospital-based laboratory, so reducing the pressure on that facility and avoiding the extra costs involved with sending samples for laboratory analysis.* The fact that a finger prick is easier and simpler than taking a sample of venous blood is a further advantage.



**Q:** What is your opinion of the accuracy of the CardioChek PA cholesterol test system?

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**A:** Accuracy is a vital issue, and when I reviewed the equipment I looked into this area in detail. One thing that became clear was that adequate training was essential. We learnt this lesson because when the machine first arrived, the doctors and staff attempted to use the machine without any formal instruction, and some readings were reported as errors or were clearly inaccurate. I am sure this was due to poor technique, and after we had undergone the formal training, results were dramatically more consistent. Although the technique is essentially simple, performing the test in the proper manner is key to obtaining accurate results. I am also convinced that the using the pipettes led to greater accuracy, and would recommend their use at all times.

Following the training, but before using the CardioChek PA point-of-care instrument as the sole means of determining cholesterol levels, we performed a small in-house audit. We decided to check the accuracy of the machine on patients who were booked for routine venous sample cholesterol checks. We asked them to consent to an additional finger prick test with the CardioChek PA cholesterol test system at the same time as the venous sample was taken. No one objected and the patients were all very pleased as they obtained their results instantly. We were encouraged by the results of this audit and no samples exceeded the claimed 10% variability. *To summarise, in my opinion, the machine has good accuracy provided the practitioner has been taught how use it properly.*

 **Q: Did you find the product easy/difficult to use?**

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**A:** *The CardioChek PA cholesterol test system is very easy to use. My mention of the essential nature of training might make it sound as if it is a complicated device, but this is not the case. The training provides knowledge of the little tricks and techniques required to obtain the best finger prick sample, introduce it to the machine quickly and appropriately, and with just the right amount of blood. However simple any equipment appears to be, it is still important to know how to use it properly!* The design of the CardioChek PA point-of-care instrument and its controls make navigating its functions straightforward. There is a scrolling screen, the use of which is self-explanatory, and once the results have been generated, if more than one parameter has been tested it is possible to quickly scroll through all the findings.

 **Q: What is the importance of regular cholesterol testing?**

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**A:** The National Institute for Health and Clinical Excellence (NICE) updated their guidance on cholesterol testing and monitoring in May 2008. The advice now given is that for primary prevention, there is no target level for total or LDL cholesterol. However, if a patient is found to have a 20% or greater 10-year risk of developing CVD (based on Framingham 91 10-year risk equations and clinical judgement), they should be offered 40mg of simvastatin. A repeat lipid profile is not necessary, but the advice is to review management according to clinical judgement and patient preference. Liver function tests are recommended within 12 weeks of starting statins, and again at one year. From a personal perspective, I feel regular checking of cholesterol levels reassures patients (as most are aware it is a very important risk factor for developing cardiovascular disease), reinforces the importance of continuing the dietary and any medical intervention, and allows for any alteration in medication if required. If a patient is found to have a raised cholesterol level but has a relatively low risk on the Framingham scale, then I would still want to measure follow-up cholesterol levels along with blood pressure.

With secondary prevention (such as in patients with established coronary heart disease, diabetes mellitus, or a history of stroke or transient ischaemic attacks) the guidance from NICE is that monitoring is advised with the aim of achieving a total cholesterol of below 4 mmol/L. In the United Kingdom, our Quality and Outcomes Framework (QOF) recommends that in patients requiring secondary prevention, the aim should be to achieve a level below 5 mmol/L.

 **Q: Are you currently using the CardioChek PA point-of-care instrument on your patients? Are other medical professionals in your practice using it?**

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**A:** Yes and Yes. Due to the current time constraints in consultations mentioned earlier, the GPs in my practice perform a few tests during the course of normal clinic time, but the CardioChek PA cholesterol test system is mainly used by our health care assistant. We are currently establishing a cardiovascular risk register, and one of the required parameters is the cholesterol level. We will soon be informing patients that they can book in for a routine cholesterol check to be performed on-site with the CardioChek PA cholesterol test system.

By using the point-of-care testing for this screening, it is quick and easy for the patient, can be performed at any time of day, avoids a sudden influx of results being sent from the laboratory, and the patient can have a BP measurement at the same time (if one hasn't been performed recently). We are then able to calculate their cardiovascular risk using the Framingham scale and be in a position to act accordingly. It is important to state that we do still send some cholesterol samples for laboratory testing, as the NICE guidelines state that before offering medication for lowering cholesterol, fasting total cholesterol, LDL, HDL and Triglyceride levels are required.

 **Q: Will you continue to use the CardioChek PA cholesterol test system in the future?**

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**A:** *Yes, definitely. It has been an incredibly useful addition to the practice; there is always going to be a need for cholesterol checking, and I think demand for this is only going to increase.*

 **Q: Why did you choose the CardioChek PA cholesterol test system over competing/similar products?**

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**A:** This machine was introduced to me via the GP magazine, and as we had been trained on this machine and found it easy to use we did not consider any alternatives. However I have since looked at some of the other machines on the market, including the Cholestech LDX, which took longer to get results, looked bulkier, and was a much more expensive machine. The Accutrend Plus system appeared quite competitive in terms of speed, size, ease of use and cost, but it is less versatile in that it does not perform LDL or HDL tests. The expense of the test strips is a factor that must be considered when buying a point-of-care cholesterol machine, but the cost of these seems much the same across all available products.



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