NICE advice

Remote ECG interpretation consultancy services for cardiovascular disease

Medtech innovation briefing
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Summary

- The **technologies** described in this briefing are remote electrocardiogram (ECG) interpretation consultancy services. They are used for assisting in diagnosing and decision-making for people with cardiovascular disease.
- The **innovative aspects** are that with remote ECG interpretation, a person does not need to travel to hospital for a consultation with a cardiologist, potentially providing quicker and more accurate diagnoses.
- The intended **place in therapy** would be to replace referrals to secondary care for interpreting ECGs from people with suspected cardiovascular disease.
- The **main points from the evidence** summarised in this briefing are from 4 UK pilot studies including 26,320 adults and children in primary care. The studies show that remote ECG interpretation consultancy services may reduce the number of unnecessary referrals to secondary care and reduce costs for the NHS.
- **Key uncertainties** around the evidence or technology are that the economic benefits are not yet clear and there is a lack of evidence for clinical outcomes. Published evidence of clinical utility is only available for 1 out of 6 services in this briefing.
- The **cost** of the services in this briefing ranges from £3 to £195 per report (excluding VAT). The **resource impact** may be cost saving because of reductions in secondary care referrals.

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The technology

An electrocardiogram (ECG) is a recording of the electrical activity of the heart and is used to diagnose cardiovascular disorders. Remote ECG interpretation consultancy services provide expert analysis of ECGs to support clinical decision-making. The services can receive and interpret ECGs – along with other information – using telephone and digital methods. This briefing describes 6 services that are available in the UK (see table 1).

There are 3 main types of ECG:

- **12-lead ECG**: the standard diagnostic test used in primary care for a number of cardiovascular disorders. Ten electrodes are placed on the skin of the chest and limbs to measure the electrical activity of the heart from 12 angles. The signal is recorded for about 10 seconds.
- **Holter/ambulatory ECG**: a monitor is worn for a period ranging from a day to a week, to record heart activity. The number of leads varies between manufacturers.
- **Loop/event monitoring**: captures unusual heart activity over longer periods, in some cases up to 4 years.

An ECG of any type can be interpreted by a trained health professional or by dedicated software. The services in this briefing all offer interpretation by expert staff at remote locations. The ECG is transmitted from a primary care centre to the service provider. This can be done automatically from devices supplied by the services (see regulatory information). Alternatively, ECGs may be uploaded to the internet using a software platform or webpage, or sent by email.

A cardiac technician, cardiac nurse, consultant cardiologist or specialist consultant cardiologist such as an electrophysiologist interprets the ECG. Recordings from Holter, loop and event monitors can be interpreted live. The signal can be continuously transmitted to allow the interpreter to monitor activity in real time.

The interpreter returns a report with their ECG interpretation or recommendations to the patient's primary care clinician within an agreed timeframe. All 6 of the services in this briefing can receive ECGs recorded using any existing device. Three of the services are also able to supply third-party devices.

Five of the 6 services in this briefing are based in the UK. Smart Telecardiology is based in India and offers interpretation worldwide. The UK-based services all support transmission using the N3 broadband network (with an NHS.net email address).

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Table 1 summarises the remote ECG interpretation services included in this briefing. Other similar technologies may be available but are not included (for example, if they were not identified, or the company chose not to participate).

Table 1 Summary of included remote ECG Interpretation services

Company	Transmission	Interpretation	Proposed reporting time	Devices	Modality
MEOMED	NHS email, dedicated software upload.	Instant report* or consultant cardiologist's or electro-physiologist's written patient care plan with level of urgency. Offers live feedback between GP and consultant cardiologist after report is returned.	Under 24 hours; average 2 hours.	None.	12-lead, Holter, loop/ event.
Primary Diagnostics	NHS email, dedicated software upload.	Technician's written report – if a consultant cardiologist's expertise is needed, the ECG can be passed on to a service such as MEOMED.	Under 24 hours.	None.	12-lead, Holter, loop/ event.
Broomwell Healthwatch	Automatic by telephone, or digitally with NHS email.	Specialist nurse's or cardiologist's reports – quality control performed by consultant cardiologists.	Verbal report returned 'immediately' and a full written report within 15 to 20 minutes.	Supplies/ leases third-party devices.	12-lead, Holter, loop/ event.

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Express Diagnostics	NHS email.	SCST-accredited data analyst's report with pathway recommendation.**	Same day; up to 10 days.**	Supplies/ leases third-party devices.	12-lead, Holter.
ECG On-Demand	Automatic – digitally with NHS email or webpage upload.	SCST-accredited cardiac physiologist's written report with level of urgency. Quality control performed by consultant cardiac electro-physiologists.	Within 24 hours or 'immediately' on request. Average turnaround 2 hours.	Supplies/ leases third-party devices.***	12-lead, Holter/ event.
Smart Telecardiology	Webpage upload or dedicated online platform.	Technician's or cardiologist's downloadable report.**	4 to 48 hours, depending on geographical location and depth of interpretation.	None.	12-lead, Holter, loop/ event.

Abbreviations: ECG, electrocardiogram; SCST, Society for Cardiological Science and Technology.

* If ECG is normal and no patient information is provided.

** Depending on the customer's needs.

*** Loaded with (Glasgow) interpretation algorithms. The algorithms identify potentially abnormal ECGs, and the practice can decide to transmit only identified ECGs or transmit all ECGs.

Innovations

Remote ECG interpretation consultancy services may provide diagnostic reports quicker than with standard care. Interpretation takes between 15 minutes and 2 days and does not need a person to travel to hospital for an appointment. This may be particularly useful for specific populations, such as those who live in rural areas, people who work offshore and prisoners.

Interpreting ECGs often needs in-depth knowledge and continuous practice, so ECGs that are challenging to interpret are frequently referred to secondary care. Using remote ECG

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interpretation services may reduce the number of unnecessary referrals to secondary care and the number of misdiagnoses.

Current NHS pathway or current care pathway

A standard 12-lead ECG should be offered to:

- adults when atrial fibrillation is suspected (see NICE's guideline on atrial fibrillation)
- people aged 16 and over if they have experienced a blackout (see NICE's guideline on transient loss of consciousness)
- adults with recent onset chest pain, in certain instances (see NICE's guideline on chest pain of recent onset).

Other types of ECG may be taken in the above circumstances, if a 12-lead ECG is inconclusive.

After taking an ECG, the practitioner can either: interpret the results and treat the person themselves; refer the person to an NHS consultant; or refer the person for emergency treatment. A referral to an NHS consultant cardiologist or electrophysiologist can take between 2 and 18 weeks and the patient must travel to hospital.

Automated ECG interpretation services are related technologies that use algorithms to interpret ECGs that are automatically uploaded to cloud networks or virtual private networks (VPNs).

Population, setting and intended user

GPs or nurses in primary care take ECGs from people with suspected cardiovascular disease. Remote ECG interpretation would replace a referral to an NHS consultant cardiologist or electrophysiologist in secondary care. A GP, nurse or healthcare assistant would record the ECG and then transmit the results to a remote location for interpretation. The consultancy service would then send a report back to the GP or nurse, with a recommendation for treatment.

Training may be needed for GPs to learn how to transmit the recorded ECGs and receive the reports.

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Costs

Technology costs

Table 2 Cost of remote ECG interpretation consultancy services

Company	Cost (excluding VAT)	Additional information
Broomwell Healthwatch	**12-lead ECG service:** £14 to £30 per report. **Arrhythmia service – 24-hour tape (Holter):** £30 to £50 per report.	Price depends on speed of response and level of advice.
MEOMED	**Cardiologist 12-lead ECG service**: between £22 and £30 per report. **Arrhythmia service – (Holter):** £65 per report.	Price varies depending on the usage for a practice per annum.
Primary Diagnostics	About £65 per analysis.	Price varies depending on the usage for a practice per annum.
ECG On-Demand	**12-lead ECG service:** £14 to £25 per report or a fixed monthly fee of £77 per 1,000-practice population, irrespective of the number of tests done. **Holter analysis:** 24 hours: £45 per report 48 hours: £70 per report 72 hours: £95 per report 7 days: £120 per report. **Consultant cardiologist e-consultation:** £42 per report.	Holter analysis prices are based on the duration of the ECG is recording.
Smart Telecardiology	Fees for 12-lead ECG interpretation start at £3 for a technician's report and £8 for a cardiologist's report.	Price depends on client location, reading cardiologists, turnaround time for reports and practice working hours.

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Express Diagnostics	**12-lead ECG service:** £10 to £25. **Holter analysis:** £25 to £195.	Price depends on turnaround time and recording time for Holter recordings.
Abbreviation: ECG, electrocardiogram.		

Costs of standard care

The standard care in the NHS for ECG interpretation is referral to either emergency care or a cardiology outpatient unit. The unit cost per attendance for a hospital emergency department is £138 and for a cardiology outpatient appointment is £156 (Department of Health and Social Care 2016).

Resource consequences

It is estimated that 34.7 ECGs per 1,000 patients are recorded annually in GP practices (Wolff et al. 2012). Assuming that a GP practice sends all recorded ECGs to a service for interpretation, then the likely use is about 35 ECGs per 1,000 patients.

Table 3 NHS use of interpretation consultancies

Service	NHS use	Training
Broomwell Healthwatch	States that its services are currently used by around 70 CCGs in the UK.	Provided free of charge.
ECG On-Demand	States its service is used by CCGs, NHS trusts, GP alliances, and NHS healthcare providers such as mental health trusts and HMP.	
MEOMED	Performed 3 pilot trials in Brent CCG, Liverpool CCG and Vale of York CCG.	
Primary Diagnostics	Has provided its service to Suffolk CCG for the past 6 years.	
Express Diagnostics	States that its services are currently used by 20 CCGs.	
Smart Telecardiology	Not currently in use.	

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Abbreviations: CCG, clinical commissioning group; ECG, electrocardiogram; HMP, Her Majesty's Prison Service.

As long as the services are compliant with NHS communication networks such as the N3 network or health and social care network, no changes to current infrastructure are needed.

No published reports on the resource consequences of adopting the technology were found. Broomwell Healthwatch provided the results of 3 audits of pilot studies performed in Lancashire and Cumbria, Greater Manchester and Greater Birmingham. Cost savings were estimated based on secondary care referrals that were prevented in 61 to 65% of the cases. In Greater Birmingham, 1,934 audit forms were returned and the estimated cost savings were £97,672. In Greater Manchester, 2,377 secondary care referrals were prevented out of 3,732 ECGs, leading to estimated cost savings of £358,927. MEOMED also provided the results of a number of pilot studies (see table 5). It estimated that its service could save a 60-practice CCG between £730,000 and £1.816 million per year.

Regulatory information

Table 4 shows the regulatory status of the remote electrocardiogram (ECG) interpretation consultancy services included in this briefing. Telehealth services operating in England must be registered with the Care Quality Commission (CQC). The CQC inspects these services and reports on the quality of care provided.

Some of the services included in this briefing supply or lease medical devices from third parties. These devices are regulated under the Medicines and Healthcare products Regulatory Agency's (MHRA) medical devices directive and must carry a CE mark.

Table 4 Regulatory information

Company	CQC registration	Medical device and CE mark
Broomwell Healthwatch	Registered 19 May 2011. Last inspection report 28 March 2013.	• HeartView 12L and HeartView 12i (Aerotel Medical systems Ltd). Class IIa. • LifeCard (Spacelabs Healthcare Ltd). Class IIa.

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MEOMED	Will register with the CQC when work begins (registration not needed before starting contract).	Intend to register with the CQC when work begins.
Primary Diagnostics	Will register with the CQC when work begins (registration not needed before starting contract).	Intend to register with the CQC when work begins.
ECG On-Demand	Registered 28 October 2015. No inspection reports to date.	• eMotion Faros 90, 180 and 360 (Mega Electronics Ltd). Class IIa. • Cardioline TouchECG with HD+, ECG100+, ECG200+ (Cardioline SpA). Class IIa.
Express Diagnostics	Registered 30 December 2010. Last inspection report 5 September 2013.	• LifeCard (Spacelabs Healthcare Ltd). Class IIa. • eMotion Faros 90, 180 and 360 (Mega Electronics Ltd). Class IIa.
Smart Telecardiology	Not registered.	No information available.

Equality considerations

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People aged 65 or over are more likely to have cardiovascular disorders. Age is a protected characteristic under the Equality Act 2010.

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Clinical and technical evidence

A literature search was carried out for this briefing in line with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Four studies including 26,320 participants are summarised in this briefing. All 4 are pilot studies, 3 relating to Broomwell Healthwatch and 1 to MEOMED and all were done in the UK. One is an abstract reporting the results of a large pilot study (n=25,346) over 4 years.

Using these services resulted in improvement of appropriate referrals and this was found to be cost saving. The average time to receive results was around 2 hours.

Table 5 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Broomwell Healthwatch and MEOMED were the only services for which there is publicly available information. These services report results from pilot studies in the NHS and focus on assessing the clinical utility of the service.

The primary outcome for all of the studies is the proportion of changes to care plans. The potential utility of the service can be shown by evaluating differences between the remote service's recommendation and the care pathway prescribed by the practitioner.

There is no direct within-study comparison between the services in this briefing. There are also no comparisons between the services and other technologies, such as automatic interpretation services. In the evidence included in this briefing, there was no follow-up of outcomes to ensure that care pathway recommendations made by the service resulted in improved clinical outcomes. There are also no comparisons of results between different clinical commissioning groups or regions of the UK.

Table 5 Summary of Evidence

Paynter (2008)

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Study size, design and location	32 people with chest pain or transient loss of consciousness in a 6-week pilot study in Bridgwater Community Hospital, Somerset, UK.
Intervention and comparator(s)	Broomwell Healthwatch compared with automatic referral to acute trust.
Key outcomes	16% of ECGs had abnormalities not detected by practitioner (that were identified by Broomwell Healthwatch).
Strengths and limitations	The study did not report any power calculation. This was a single-centre pilot and so is not representative of other types of practice, such as GP surgeries. No economic information is reported and outcomes are limited to descriptions of the prescribed care plan.
Albouaini et al. (2009)	
Study size, design and location	24,541 12-lead ECGs and 805 1-lead ECGs, in a 4-year pilot study in the Greater Manchester and Cheshire Cardiac Stroke Network, UK.
Intervention and comparator(s)	Broomwell Healthwatch compared with standard care.
Key outcomes	In 15,698 people with symptoms (from 24,541 12-lead ECGs), 87.5% were recommended for treatment in primary care; 6.5% were recommended for secondary care and 6% recommended for emergency care. In people with symptoms from lead-I ECGs, 96% were recommended for treatment in primary care. All ECGs were reported within 2 hours of their receipt. The prevention rate of secondary care referrals was 65.8% of the total cases (95% confidence interval 61.6 to 65.8%) and the extrapolated gross savings were calculated to be over £300,000.
Strengths and limitations	The study included a large number of ECGs, over 4 years, in multiple GP surgeries. Only the abstract is freely available, so there is no detail on the study methodology.
Weatherburn et al. (2009)	

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Study size, design and location	A total of 373 ECGs from people aged 8 to102 years, in a 6-month pilot study in Lancashire and Cumbria (NHS Northwest), UK.
Intervention and comparator(s)	Broomwell Healthwatch compared with standard care.
Key outcomes	There were 76 changes made to care pathways. In total, 14 unnecessary referrals to secondary care were avoided and 18 people who the practitioner planned to only see in primary care were referred to secondary care.
Strengths and limitations	The study included results from 8 GP surgeries and 2 walk-in centres and included people with a wide age range. Rates of use varied between practices so economic outcomes are not given.
MEOMED Ltd Process Improvement Audit, Hall et al. 2015	
Study size, design and location	569 people from 3 CCGs (see table 3) in the UK.
Intervention and comparator(s)	MEOMED compared with standard care.

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Key outcomes	Using the MEOMED service, 78% fewer patients were referred to secondary care when compared to the standard pathway. A total of 37% of all patients – and 61% of all people with abnormal ECGs (256 from a total of 569) – had their condition managed in primary care, based on MEOMED's management plan. In the patients that the GP would have initially cared for in primary care, MEOMED recommended, within 2 hours, that 29% be referred to secondary care. In addition, 24 unnecessary referrals were prevented in a group of 30 patients that the GP would have referred to secondary care, based on patient history alone. A total of 5% of all patients were referred to secondary care by MEOMED, based on patient history alone. The average cost saving for a 60-practice CCG was estimated to be: • £730,000, compared with a technician-led ECG service • £1,816,000 compared with a standard hospital service.
Strengths and limitations	The study included multiple practices across 3 CCGs. The report was written by employees of MEOMED in collaboration with Trustech (NHS Northwest innovation organisation).

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field. The comments received are individual opinions and do not represent NICE's view.

All 4 experts were aware of, or had used, the remote electrocardiogram (ECG) interpretation services described in this briefing. Two experts believed that the services were not being widely used in the NHS, while the other 2 were unsure or did not comment.

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Level of innovation

Two experts believed that the services were novel, while another thought they were not. One expert believed the services were only a minor iteration of current care that had not been superseded.

One expert thought that some of these services were innovative because patient reports could be written and interpreted by experienced clinicians who had access to patient history. Two experts felt that non-commercial interpretation services available in their local hospital coronary care unit by trained clinicians offered competition to the services reported in this briefing because, in their opinion, they were either faster, free or better. One expert mentioned that some services developed in hospital had a system to immediately assess if ECG changes were new or pre-existing. They believed that this gave their service an advantage over the commercial services in this briefing. On the contrary, 1 expert had to stop using a commercial service because their local trust chose to provide their own in-house service instead. They felt that the commercial service was better than the service provided by the local trust because it had a faster turnaround time and less variability in reporting. One expert mentioned open access services for Holter monitors as a similar technology but added that they were often poorly supervised and did not take patient history into account.

Potential patient impact

All of the experts agreed that avoiding unnecessary hospital visits was a potential patient benefit. Three experts also agreed that high-risk cardiac symptoms could be identified earlier than with standard care and this would allow for earlier prevention or treatment to begin. However, 1 expert also expressed concern that such services may be used improperly in people with symptoms that need clinical review, such as acute chest pain or unexplained syncope. One expert mentioned that some of these services may provide the added reassurance to patients because the results would be reviewed by highly trained clinicians.

The experts stated various types of patients would particularly benefit from these services including: people with low-risk symptoms (history of vasovagal syncope, palpitations or hypertension); people with a pre-existing ECG abnormality because a comparison to a current ECG might prevent an unnecessary referral or because ECGs taken from Holter monitors are more likely to be misinterpreted in primary care; older people or those with mobility issues because there would be a reduced need for them to travel to hospital.

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Potential system impact

All of the experts agreed that a potential reduction in non-emergency referrals to secondary care specialist clinics would be a benefit to the health or care system. One expert said this reduction could lead to cost savings in regions where links to secondary care are poor. Another expert added that less money would need to be spent on secondary care and more could be allocated to primary care. Two experts thought that cardiac interpretation services could increase costs for their region but another expert thought that there could be cost savings if cardiologist resources were used more effectively by reducing unnecessary outpatient appointments. They added that this may also lead to better resource allocation in secondary care.

Three experts felt that little to no change to current infrastructure would be needed to use these technologies and that when needed they would presumably be provided by the companies. One expert believed that advanced ECG interpretation skills would be needed for clinicians to use any of the technologies.

Two experts expressed some concerns about the resource impact from adopting these technologies. One thought that the interpreter would need to take a holistic view and take clinical history into account for best management. They also felt that the most important element of such services was the skill set of the interpreter. The other expert reiterated that such services should not be used alone in managing high-risk symptoms and expressed worry that some practitioners could become overly reliant on these services. A third expert highlighted that primary care services would be expected to take responsibility for clinical decision-making if not referring patients onward for additional specialist follow-up. No safety concerns or regulatory issues were raised surrounding the use of these technologies.

General comments

One expert mentioned that his knowledge of ECG analysis had improved after using an ECG interpretation service. Another expert felt that establishing local, non-commercial telemetry services should be attempted before using commercial providers. The expert acknowledged that some regions may not manage to establish close collaborations with their local hospital to successfully use non-commercial services. None of the experts had an opinion on how the services will adapt to the end of the N3 network but stressed the importance of continued data security. One expert expressed suspicion of services that provide diagnostic guidance without assessing clinical presentation.

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Three of the experts felt that the technology would be an addition to standard care, rather than a replacement. One added that the services could be a replacement for outpatient referral where links to local cardiology services are poor. The fourth expert agreed, stating that the technology would replace the need to refer every patient for an initial outpatient appointment.

Two experts identified information technology-related difficulties, such as network and transmission problems, as the only practical issues with the services. One expert was not convinced by the published research because of industry involvement and limited real-world cost information. The expert felt that a pilot trial for an individual healthcare organisation would provide more useful data as results may vary across different locations. One expert thought that the services should agree to make audits of their performance available to purchasers. This would be particularly informative if the results included hospital referral rates and patient outcomes.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Jonathan Watt, consultant cardiologist, Raigmore Hospital, NHS Highland, member of the British Cardiovascular Intervention Society. No relevant conflicts of interest.
- Mr Charlie Bloe, clinical ward manager, NHS Highland, member of SHARP (Scottish Heart and Arterial disease Risk Prevention). Mr Bloe is the clinical lead and managing director for a private healthcare education company and provides regular tuition to healthcare professionals on electrocardiogram (ECG) interpretation.
- Dr Richard Schilling, professor of cardiology, Barts Health NHS Trust, member of the British Heart Rhythm Society. No relevant conflicts of interest.
- Dr M C Patel, GP, Brent Clinical Commissioning Group. Dr Patel is a shareholder in Harness GP Cooperative Ltd and chair of Harness Board. His patients were included in an NHS England Regional Innovation-funded audit.

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