NHS
East of England
Clinical Senate

Herts Valley Clinical Commissioning Group

Report of the clinical review panel held on 08 May 2018

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Glossary of abbreviations used in the report

CCG	Clinical Commissioning Group
CQC	Care Quality Commission
Concordia	Concordia Ambulatory Care Ltd
ECG	Electrocardiogram
Echo	Echocardiogram
HVCCG	Herts Valley CCG
QA	Quality Assurance (process)
WHHT	West Hertfordshire Hospitals NHS Trust

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1. ADVICE REQUEST, BACKGROUND AND SCOPE OF THE REVIEW

1.1 The East of England Clinical Senate was requested to undertake a retrospective review of the actions taken by Herts Valley Clinical Commissioning Group (HVCCG) following some concerns from the local acute Trust and some GPs in respect of the community 24-hour Electrocardiogram (ECG) and Echocardiogram (Echo) service. The service provider in question - Concordia Ambulatory Care Ltd - was no longer the service provider.

Background

1.2 Concordia Ambulatory Care Ltd (Concordia) won an open market procurement to provide a community 24-hour Electrocardiogram (ECG) and Echocardiogram (Echo) service aimed to provide quick direct access for General Practice in the Herts Valley Clinical Commissioning Group (HVCCG) area. Following formal procurement, the service commenced on 1 June 2016.

1.3 In September 2016 a contract performance query notice was served to Concordia and then withdrawn in October when HVCCG was satisfied with Concordia's assurance plan.

1.4 The CCG received a number of clinical concerns from the cardiology department and Medical Director at West Hertfordshire Hospitals NHS Trust (WHHT); a few concerns were also received from GPs. Twelve of the clinical concerns were independently investigated by Dr Jim Newton, an eminent cardiologist based in Oxford.

1.5 An audit was designed and undertaken to identify safety failures with the analysis and interpretation of 24-hour ECGs and Echos. If failures were identified they were assessed against the Duty of Candour definitions given by

CQC[1]. The purpose of the audit was to demonstrate whether patients had suffered any harm. The audit was undertaken by Dr Newton - he examined 135 patient investigations which included a selection of tests from every technician.

Scope and aim of the review

1.6 The scope of this review is regarding the action taken by HVCCG and to identify whether or not any additional investigation or actions should have taken place to provide assurance of the service and in light of the outcome of that, whether there should have been any recall of patients and if there should be any further action taken to address any identified shortcomings.

1.7 This was a review of actions taken not a further audit.

2 METHODOLOGY & GOVERNANCE

2.1 Clinicians with the appropriate expertise from within the East of England Clinical Senate were identified as suitable and invited to be panel members (Appendix 2). They signed conflict of interest and confidentiality agreements and were provided with the background evidence.

2.2 Terms of reference for the review were drafted although these were not formally signed off due to changes within HVCCG. (Dr David Buckle who was the lead for this review retired from the CCG prior to the panel being held, although he was able to dial into the call on 8 May 2018).

2.3 The clinical review panel took place, by teleconference, on Tuesday 8 May 2018. The panel requested further information and this was provided by HVCCG and circulated to panel members for response by email. A draft report

[1] CQC Regulation 20: a requirement that healthcare professionals must be open and honest with their patients (or their legal representative) when something could have gone wrong with their treatment or care and has the potential to cause, harm or distress.

was sent to the members of the panel for review and confirmation of accuracy and approved by the Chair of the clinical review panel.

2.4 The final report will be submitted to the East of England Clinical Senate Council for it to ensure that the clinical review panel met and fulfilled the Terms of Reference for the review and is then submitted to the commissioning body. The report will be submitted to Senate Council at its next meeting in December 2018.

2.5 East of England Clinical Senate will publish this report on its website as agreed with the sponsoring organisation, Herts Valley CCG.

3 SUMMARY OF KEY FINDINGS

Key findings:

3.1 The panel agreed that whilst the literature review provided a helpful overview, the remaining information put forward did not provide absolute clarity in terms of dates, when the audit was undertaken, (how much was prospective and how much was retrospective), and what was and what was not part of the contract query process, prior to the service resuming.

3.2 Whilst the panel found from evidence that there had been issues with mobilisation of the service from award of contract, the detail of these issues was not fully provided. However, the panel understood that the service provider was working in the context of having started the service with an unexpected backlog of around 500 patients and a 350% increase in referrals above what was expected and that this was neither planned nor commissioned for. The panel was advised that the British Society of Echocardiography recommendation were 45 minutes for each scan and reporting an agreed that any service provider would have significant challenge in meeting appropriate quality targets whilst also managing demand under such circumstances.

3.3 The panel heard that the Quality Assurance (QA) process described in the evidence ('Response to Cardiology Audit') included complaints handling, a governance log system, incident handling, supervision and a monthly audit. The panel felt this was a robust process that should have been able to handle any concerns or risks appropriately under normal circumstances but was not sure from the evidence whether it was in place at the time of the contract award or from the time of the contract performance query, or implemented at an even later date. (*NB Clinical Senate was subsequently advised by Concordia Ambulatory Care Ltd that it had agreed at the start of the contract to audit 5% of appointments as part of a quality assurance process.)*

3.4 The panel agreed that due to an element of subjective interpretation, even to the highest standard, a degree of discrepancy in reporting was expected in such a service; absolute diagnostic certainty in 100% of cases could not be expected. The panel agreed that the rate indicated in the report was not out of keeping with what one would expect from a well-run service. This view was also supported by the document provided which gave an overview of the evidence.

3.5 The panel agreed that the errors quoted were not significant in number nor were they of a higher than acceptable rate for a cardiology service given the subjectivity of the reporting. Furthermore the panel agreed unanimously that this did not raise any particular patient safety issues or a need to suggest a recall of any patients.

3.6 The panel was advised that Dr Andrew Wragg, Vice President of Clinical Standards at British Cardiovascular Society (Consultant Cardiologist, Director of Quality and Safety St Bartholomew's Hospital) had been provided with the evidence for comment in his capacity in the British Cardiovascular Society. Dr Wragg had commented that:

> *"Just commenting on the documents, I do not think they raise any serious concerns about the quality of the service. The diagnostic test results with regard to accuracy do not appear*

higher than expected and the response from the provider I think is reasonable, comprehensive and does not appear to leave any fundamental questions about the quality of the service unanswered".

3.7 The panel agreed that although appropriate investigations appeared to have been undertaken in response to the concerns, the panel felt that it was assured that appropriate actions had been put in place in response to the audit and investigations.

3.8 The panel requested that the CCG provide further evidence to demonstrate this including

- Clarity on dates and the timeline.
- The nature of the contract query notice and subsequent actions implemented.
- Confirmation as to whether there was a requirement for a tested Quality Assurance process and procedure included in the service specification?
    - What was the QA procedure in place when the contract was awarded?
    - The CCG's response to the audit and actions implemented.
    - The current service provider, performance levels and whether any backlog still exist and, if available, the current level of error reporting.

3.9 Some further information was provided although all of the panel's requests were not met in full; it is acknowledged that the information provided was relevant to the scope of the review. Importantly, HVCCG confirmed that a Quality Assurance process and procedure was defined in the service specification.

3.10 Although outside the scope of the review, the panel advised that for future service provision for similar services, Concordia Ambulatory Care Ltd ensured appropriate Quality Assurance processes were carefully considered, and

described, including prospective audit with detailed documentation on appropriate actions to be taken in relation to audit data.

3.11 Whilst recognising the difficulty of developing such standards, the panel suggested that it would be helpful if quality standards for such services, describing acceptable error rates and appropriate QA processes, were available and agreed that the British Society of Cardiology would be best placed to develop such standards.

3.12 Whilst not a formal recommendation, the panel suggested that HVCCG ensured that, for future tendering processes for similar services, even more focus was placed on ensuring appropriate QA processes are carefully described ad include prospective audit and appropriate actions related to audit data.

4 RECOMMENDATIONS

The panel agreed the following recommendations:

Recommendation 1

4.1 The panel agreed that the evidence provided did not indicate a patient safety issue and therefore recommended there was no reason to suggest recalling any patients for repeat investigations or any need to carry out a further audit.

Recommendation 2

4.2 The panel recommended that HVCCG ensures as accurate demand estimates as possible are built into future procurement of services and the mobilisation and initial capacity building of new service providers is carefully considered and built into an appropriate lead in time.

End.

APPENDIX 1: Terms of Reference for the review

East of England Clinical Senate

Independent clinical review of the

08 May 2018

Terms of Reference

CLINICAL REVIEW: TERMS OF REFERENCE

Title:

Sponsoring bodies:

Terms of Reference agreed by:

Signature

NOTE – DUE TO Dr Buckle's retirement, these ToR were not formally signed off by HVCCG

Dr David Buckle, Medical Director Herts Valley CCG

and

Signature 

Dr Bernard Brett, East of England Clinical Senate Chair, on behalf of East of England Clinical Senate

Date: 19 April 2018

Clinical review panel members

Dr Bernard Brett, Panel Chair	Consultant in Gastroenterology at Norfolk and Norwich University Hospitals NHS FT.
Dr Stuart Harris	Consultant, Cardiologist and Electrophysiology & Clinical Director, Basildon & Thurrock
Dr Patrick Heck	Consultant Cardiologist and Electrophysiologist Clinical Lead for Cardiac Rhythm Management, Royal Papworth
Dr Stephen Hoole	Consultant Interventional Cardiologist | Honorary Senior Visiting Fellow, University of Cambridge
Simone Meldrum	Cardiac Rehabilitation Specialist Nurse, Community Cardiac Rehabilitation Team West Suffolk Community Services
Dr Henri Oki	GP, Essex. Clinical Senate Fellow
Natalie Sales	Chief Cardiac Physiologist, Clinical Measurements Dept, James Paget Hospital

Background to the review

Concordia Ambulatory Care Services won an open market procurement to provide a community 24hr ECG and Echocardiogram (Echo) service aimed to provide quick direct access for General Practice in the Hertfordshire Valley CCG area. The service commenced on 1st June 2016.

In September 2016 a contract performance query notice was served to Concordia and then withdrawn in October when Herts Valley Clinical Commissioning Group (HVCCG) was satisfied with Concordia's assurance plan.

The CCG received a number of clinical concerns from the cardiology department and Medical Director at West Hertfordshire Hospitals NHS Trust (WHHT) and a few concerns were also received from GPs. Twelve of the clinical concerns were independently investigated by Dr Jim Newton, an eminent cardiologist in Oxford.

An audit was designed and undertaken to identify safety failures with the analysis and interpretation of 24hr ECGs and Echos. If failures were identified they were assessed against the Duty of Candour (DoC) definitions given by CQC. The purpose was to demonstrate whether patients had suffered any harm. The audit was undertaken by Dr Newton and he examined 135 patient investigations which included a selection of tests from every technician.

Scope and aim of the review

The scope of this review is on the action taken so far and the aim is to identify whether or not any additional investigation or actions should take place to provide assurance of the service.

Clinical Senate is asked to respond to the following question:

Does the evidence demonstrate that the

i. **appropriate investigations and actions had been undertaken to provide assurance of an appropriate level of safety for patients and**
ii. **provider had in place an acceptable Quality Assurance process to ensure the best outcome for patients?**

Based on the evidence submitted, Clinical Senate is asked to provide advice and recommendations; this should include, but not be limited to:

i. Any areas of clinical risk the CCG should give careful attention to during development of specifications for future commissioning and

ii. Any additional considerations the Trusts should make during the development of the service specifications for future commissioning and subsequent implementation plans; this might include, for example, the approach to clinical engagement, impact assessment and risk management.

- Clinical effectiveness and quality assurance.
- Patient safety and management of risks.

The clinical review panel is not expected to advise or make comment upon any issues outside of this service.

Questions that may help the panel in assessing the benefit and risk of the proposals include (but are not limited to):

- Is there evidence that the service will improve the quality, safety and sustainability of care (e.g., sustainability of cover, clinical expertise)?
- Do the proposals reflect up to date clinical guidelines and national and international best practice e.g. Royal College reports?
- Cooperation and collaboration with other sites and/or organisations?

The clinical review panel should assess the strength of the evidence base of the case for change and proposed models.

Timeline

The clinical review panel will be held on the 8 May 2018 by teleconference.

Reporting arrangements

The clinical review panel will provide a report to the Clinical Senate Council which will ensure the panel met the agreed Terms of Reference, agree the report and be accountable for the advice contained in the final report.

Methodology

The review will be undertaken by a teleconference.

Report

A draft report will be made to the sponsoring organisation for fact checking prior to publication.

Comments/ correction must be received from the sponsoring organisation within **ten working days**.

Final report will be submitted to Clinical Senate Council (on 20 September 2018) to ensure it has met the agreed Terms of Reference and to agree the report. The final report will be submitted to the sponsoring organisation following the Council Senate Council meeting.

Communication and media handling

Communications will be managed by the sponsoring organisation. Clinical Senate will publish the report once the service change proposal has completed the full NHS England process. This will be agreed with the sponsoring organisation.

Resources

The East of England Clinical Senate will provide administrative support to the review panel, including setting up the meetings and other duties as appropriate.

The clinical review panel may request any additional existing documentary evidence from the sponsoring organisation. Any requests will be appropriate to the review, reasonable and manageable.

Accountability and governance

The clinical review panel is part of the East of England Clinical Senate accountability and governance structure.

The East of England Clinical Senate is a non-statutory advisory body and will submit the report to the sponsoring organisation.

The sponsoring organisation remains accountable for decision making but the review report may wish to draw attention to any risks that the sponsoring organisation may wish to fully consider and address before progressing their proposals.

Functions, responsibilities and roles

The **sponsoring organisation** will

i. provide the clinical review panel with the appropriate evidence and background including the data audit.

The sponsoring organisation will provide any other additional background information requested by the clinical review panel.

ii. respond within the agreed timescale to the draft report on matter of factual inaccuracy.
iii. undertake not to attempt to unduly influence any members of the clinical review panel during the review.
iv. Arrange and bear the cost of suitable accommodation (as advised by clinical senate support panel) for the panel and panel members

Clinical Senate Council and the sponsoring organisation will

i. agree the Terms of Reference for the clinical review, including scope, timelines, methodology and reporting arrangements.

Clinical Senate Council will

i. appoint a clinical review panel this may be formed by members of the Clinical Senate Council and Assembly, external experts, and / or others with relevant expertise. It will appoint a Chair of the review panel
ii. endorse the Terms of Reference, timetable and methodology for the review
iii. consider the review recommendations and report (and may wish to make further recommendations)
iv. provide suitable support to the panel and
v. submit the final report to the sponsoring organisation.

Clinical review panel will

i. undertake its review in line the methodology agreed in the Terms of Reference
ii. follow the report template and provide the sponsoring organisation with a draft report to check for factual inaccuracies.
iii. submit the draft report to clinical senate council for comments and will consider any such comments and incorporate relevant amendments to the report. The panel will subsequently submit final draft of the report to the clinical senate Council.
iv. keep accurate notes of meetings.

Clinical review panel members will undertake to

i. Declare any conflicts of interest and sign a confidentiality agreement prior to having sight of the full evidence and information
ii. commit fully to the review and attend all briefings, meetings, interviews, and panels etc. that are part of the review (as defined in methodology).

iii. contribute fully to the process and review report

iv. ensure that the report accurately represents the consensus of opinion of the clinical review panel

v. comply with a confidentiality agreement and not discuss the scope of the review nor the content of the draft or final report with anyone not immediately involved in it. Additionally they will declare, to the Chair of the clinical review panel and the Head of Clinical Senate, any conflict of interest that may materialise during the review.

APPENDIX 2: Clinical Review Panel Members

Dr Bernard Brett, Panel Chair	Consultant in Gastroenterology at Norfolk and Norwich University Hospitals NHS FT.
Dr Stuart Harris	Consultant, Cardiologist and Electrophysiology & Clinical Director, Basildon & Thurrock
Dr Patrick Heck	Consultant Cardiologist and Electrophysiologist Clinical Lead for Cardiac Rhythm Management, Royal Papworth
Dr Stephen Hoole	Consultant Interventional Cardiologist, Honorary Senior Visiting Fellow, University of Cambridge
Simone Meldrum	Cardiac Rehabilitation Specialist Nurse, Community Cardiac Rehabilitation Team West Suffolk Community Services
Dr Henry Okoi	GP, Essex. Clinical Senate Fellow
Natalie Sales	Chief Cardiac Physiologist, Clinical Measurements Dept, James Paget Hospital

Expert Advice to the panel

Dr Andrew Wragg, Vice President of Clinical standards at British Cardiovascular Society, (Consultant Cardiologist, Director of Quality and Safety St Bartholomew's Hospital)

Panel Member biographies

Dr Bernard Brett
Consultant in Gastroenterology at Norfolk and Norwich University Hospitals NHS FT.
Clinical Senate Chair

His clinical interests include Bowel Cancer Screening (he has been an accredited bowel cancer screening colonoscopist for the last 10 years), Therapeutic Endoscopy and ERCP. Bernard has held several senior management posts including that of Medical Director, Responsible Officer, Deputy Medical Director, Divisional Director, Director of Patient Flow and Appraisal lead.

Dr Stuart Harris BSc (Hons) MBBS FRCP FHRS
Consultant Cardiologist & Electrophysiologist, Essex Cardiothoracic Centre, Basildon & Thurrock Hospital

I qualified in Medicine at St Bartholomew's Hospital Medical College in 1995, and subsequently trained in Cardiology and Cardiac Electrophysiology in London and Edinburgh. I was appointed as a Consultant Cardiologist with a subspecialty interest in cardiac electrophysiology and arrhythmia management in April 2005 at St Bartholomew's Hospital and King George Hospital, Ilford. A Barts I was part of a team of four Consultants providing interventional electrophysiological and complex pacing services for a population of 3.2 million people. Within Barking, Havering and Redbridge NHS Trust I provided a general Cardiology service as well as leading in the development of local arrhythmia services including a specialist arrhythmia clinic, a nurse-led rapid access palpitation clinic and the local implantation of cardiac defibrillators. I was also the arrhythmia lead for the North East London Cardiac Network.

I was subsequently appointed as a Consultant Cardiologist and Electrophysiologist at the Essex Cardiothoracic Centre in July 2007 to lead the development of arrhythmia services for Essex, a population of 1.7 million people. I was appointed as the Clinical Director (Chief of Service) for Cardiothoracic Services at Basildon University Hospital in 2013.

I have been an elected Council member of the British Heart Rhythm Society since 2014 where I was Editor of the Newsletter and involved in writing clinical standards documents for the implantation and follow-up of CRM devices in adults and the standard for Interventional Electrophysiological Study and Catheter Ablation in Adults.

Dr Patrick Heck

Dr Heck completed his undergraduate training in medicine at Cambridge University (Gonville and Caius College) in 1997 and later graduated from clinical school at Oxford University in 2000. After completing his junior doctor training, Dr Heck undertook his specialist training in Cardiology in Cambridge before completing a period of post-graduate clinical research for he was awarded a Doctor of Medicine (DM) from Oxford University in 2010. He then completed an 18-month Electrophysiology Fellowship at the Royal Melbourne Hospital, Australia, one of the world's leading centres in cardiac electrophysiology.

His areas of major interest are ablation of all cardiac arrhythmias, including atrial fibrillation and ventricular tachycardia. Additionally, he is interested in complex device implantation (ICDs and CRT) and is trained in the device extraction.

Dr Stephen Hoole

Dr Hoole qualified in medicine with distinction from Christ Church, University of Oxford, and subsequently trained in cardiology in Nottingham, London and Cambridge. He completed a doctorate in the Department of Cardiovascular Medicine, University of Cambridge, where he

investigated cardioprotective strategies to improve PCI outcomes. He was shortlisted for the Thomas J. Linnemeier Spirit of Interventional Cardiology International Young Investigator Award for this work. He was awarded an NIHR Clinical Lectureship in cardiology by the University of Cambridge and completed his training with an interventional fellowship in Vancouver, Canada.

Dr Hoole was appointed as a consultant interventional cardiologist in January 2012 and leads interventional cardiology research in Cambridge.

He was accepted into the 2013-2015 Society of Cardiovascular Angiography and Interventions Emerging Leader Mentorship (SCAI-ELM) program as one of 12 national and international SCAI-ELM fellows.

Dr Henry Okoi

Working in Thurrock as a GP since October 2006. He is a GP Trainer and a GP Appraiser in Essex and also a member of the South Essex Local Medical Committee (LMC).

He is a member of the Governing Body of the Thurrock CCG where he also serves as the lead for Medicines Management and Optimisation. Henry leads a team tasked with enhancing efficient and effective use of medicines and is also a member of the Basildon area Medicines Management Committee.

He holds a Master's degree in Healthcare Leadership and Senior NHS Leadership Award by the NHS Leadership Academy Elizabeth Garrett Anderson Programme and is a Clinical Senate Fellow.

Natalie Sales

A Clinical Cardiac Physiologist for 17 years working within the James Paget Hospital NHS Trust. Natalie specialises in Adult Echocardiography and has been scanning for approximately 13 years, becoming an accredited member of the British Society of Echocardiography in 2010.

In attendance at the panel

Dr David Buckle (retired) Director of General Practice Development / Medical Director Herts Valley CCG (by telephone)

Clinical Senate Support Team:

Brenda Allen	East of England Clinical Senate Project Officer
Sue Edwards	East of England Head of Clinical Senate, NHS England

APPENDIX 3: Declarations of Interest

All panel members were required to declare any interests. All panel members claimed to have no a) Personal pecuniary interest b) Personal family interest c) Non-personal pecuniary interest or d) Personal non-pecuniary interest.