

CARE Fertility Quality Account

April 2017 -
March 2018





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Welcome to CARE Fertility

CARE FERTILITY GROUP - The largest provider of assisted conception services in the UK

CARE was founded in 1997 by Professor Simon Fishel, Mr Ken Dowell and Mr Simon Thornton to provide fertility services to self-funding and NHS patients. Since then CARE has helped thousands of couples to have a family. CARE is the UK's largest independent provider of assisted conception treatment, and is the proud operator of eight main clinics in Nottingham, Birmingham, Sheffield, Northampton, Manchester, London, Tunbridge Wells and Dublin. CARE also has a number of satellite clinics linked to these main clinics that provide local access to consultations and treatment cycle monitoring.

Our clinics provide a comprehensive range of treatment for the investigation and management of fertility problems and are regulated by the HFEA and Care Quality Commission. Our staff have specialist skills and knowledge and are committed to providing a high quality level of service to our patients.

At CARE we aim to provide the highest quality service to NHS funded couples who meet the eligibility criteria set out by their CCG. Individualised patient care and satisfaction is our primary focus.

Patient safety is our highest priority and our robust recruitment processes and training programmes ensure that staff are competent and fully trained in all aspects of service provision.

Patient feedback and involvement is extremely important to us, we also rely on other measures of safety and clinical effectiveness which we use to satisfy ourselves that treatment is evidence based and delivered by appropriately qualified and experienced healthcare professionals.

CARE Fertility has been at the forefront of major research breakthroughs in the field of assisted conception for several decades, and our work published in scientific and medical journals on a regular basis.

Statement on Quality from CARE Fertility's Chairman

Welcome to the 2017-18 CARE Fertility Quality Account which describes how we performed this year against our quality and safety standards. It also looks forward and sets out our plans for quality improvements in the forthcoming year.

The account aims to provide a balanced view of what we are good at and our priorities for improvement. In addition, our quality priorities for the coming year (2018-19) as agreed with the CARE senior management team, are outlined within this report. At CARE we are dedicated to achieving the best chance of pregnancy for our patients. In all of our clinics, our experienced teams provide a discreet, professional and caring service, delivering clear, concise information to our patients.

To maintain our position as the UK's leading independent fertility health care provider, CARE will continue its commitment to research, developing new procedures to assist those who seek our help, and in a manner sensitive to local

regulation and social requirements in all the geographic locations in which we operate. This report details:

- The clinic's priorities for improvement in 2018-19.
- Statements relating to the quality of services provided by CARE.
- What others say about us.
- How CARE has performed over the past year on key indicators of quality.

To the best of my knowledge, as requested by the regulations governing the publication of this document, the information in this report is accurate.

Nigel Robertson, Chairman
CARE Fertility Group



Quality Priorities 2018-19

On the basis of local senior management group discussions; whole team contributions via clinical governance and quality meetings and discussions with Board members, CARE Fertility has identified the following priorities for quality improvement.

	Quality objective	Strategy for achieving the objective
Clinical Effectiveness	To maintain clinical outcomes: Clinical success rates are a direct measure of the effectiveness of treatments provided by CARE. Research and patient feedback supports a conclusion that this is a significantly important metric for our patients.	Monthly review of success rates; monthly trend analysis using HFEA benchmarking data; implementation of root cause analysis if adverse trends identified, implementation of corrective and preventative actions as required.
Patient Safety	Multiple births are considered by the fertility regulator to be the single biggest risk to the health of mothers and babies.	As above.
	Aim to ensure that risks of OHSS are minimised.	All severe OHSS cases recorded on DATIX, reported to the HFEA and trends analysed to identify any opportunities for learning. OHSS rates reported monthly in KPI matrix and reviewed at local and group clinical governance review meetings. Should adverse trends be identified, implementation of corrective and preventative actions as required.
Patient Experience	Improving customer service experience by ensuring prompt response to telephone enquiries.	Implementation of a group enquiry management system.
	This was identified as a priority on the basis of customer feedback and analysis of telephone response rates.	Monitoring of local response times and patient feedback to identify effectiveness of call responses.
	Improving patients' experience of access to information and communications. This was identified as a priority to adapt the service to evolving patient expectations.	Development of an electronic platform for sharing information and communications with patients that can be accessed from a range of electronic devices.

Progress against priorities 1-5 is reported on a bi-monthly basis to the CARE Corporate Quality team and where applicable key issues are reported to the Board of Directors.

Progress in the delivery of priorities 4 and 5 will be monitored and reported by the project management team at CARE Board level.

Statements of Assurance

This section of our Quality Account provides the mandatory information for inclusion as determined by the Department of Health regulations and reviews our performance over the last year between April 2017 and March 2018 but reported in June in line with guidance.

Review of NHS Services Provided 2017-18

During 2017-2018 CARE Fertility provided fertility treatment to NHS funded patients under the terms of a number of CCG contracts. CARE Fertility provides fertility services for 91 CCGs, and NHS England funded patients for the armed services and PGD.

CARE Fertility has reviewed all the data available to them on the quality of the NHS services provided. The income generated by the NHS services reviewed in 2017-2018 represented c.15% of the total income generated by CARE Fertility.

Clinic	NHS Cycles	
	April 2016 - March 2017	April 2017 - March 2018
Nottingham	300 (20%)	366 (20%)
Northampton	272 (26%)	343 (27%)
Manchester	306 (16%)	296 (14%)
Sheffield	245 (28%)	254 (26%)
Tunbridge Wells	438 (50%)	45 (4%)
Birmingham		5 (2%)
TOTAL	1561 (25%)	1309 (17%)

Participation in Clinical Audit

National Audit - During 2017-18 no national clinical audits and no national confidential enquiries covered NHS services that CARE Fertility provides. As a result CARE Fertility did not participate in National Clinical Audits.

Local Audits - CARE Fertility is committed to providing a robust audit system which evaluates key aspects of the Group and individual Clinic systems and processes. The audit schedule ensures conformance to national regulatory requirements such as the HFEA Code of Practice and Care Quality Commission Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The audit schedule runs from January to January over a 2 year period. During 2017-18 CARE clinics completed 15 audits resulting in changes to practice where any non-compliance was identified.

Audit	Completed
Surrogacy	February 2017
Patient records	March and November 2017
Counselling	March 2017
Infection Control	April 2017
PGS and embryo testing	April 2017
Provision of information	May 2017
Welfare of the child	June 2017
Multiple Birth Review	July 2017
Legal Parenthood	July 2017 and January 2018
Controlled drugs	October 2017
Confidentiality	November 2017
Medicines Management	December 2017
Staff recruitments and competencies	March 2018

Participation in Clinical Research

All patients (including NHS patients) have an opportunity to consent to the donation of embryos that are not wanted for treatment to HFEA licensed, research ethics committee approved research programmes. These embryos are marked for research purposes within patient's electronic records.

Use of the CQUIN payment framework

A proportion of CARE Sheffield, Manchester, Northampton and Nottingham's income in 2017-18 was conditional on achieving quality improvement and innovation goals agreed between Clinical Commissioning Groups and Associates and any person or body they entered into a contract, agreement or arrangement with for the provision of NHS services, through the Commissioning for Quality and Innovation payment framework

Statements from the Care Quality Commission (CQC)

The Human Tissue Authority (HTA), the Human Fertilisation and Embryology Authority (HFEA) and Care Quality Commission (CQC) have agreed on the ways that they will work together to ensure the safety of people who use services.

Two joint working agreements called a memorandum of understanding (MoU) have been developed to ensure that all bodies will:

- Share information about services that fall under the remit of all three bodies.
- Respect each organisation's independence.
- Continue to explore ways to develop more effective and efficient ways to work together to promote quality and safety.

To view the two joint working agreements please visit:

Working with the Human Tissue Authority and the Human Fertilisation and Embryology Authority | Care Quality Commission

Statements from the Human Fertilisation and Embryology Authority (HFEA)

The Human Fertilisation and Embryology Authority (HFEA) regulate all UK fertility clinics and projects involving research with human embryos. To ensure all patients receive high quality care throughout their fertility journey the HFEA licence, inspect and set standards.

To find out more information about what the HFEA says about each CARE clinic and our latest inspection reports please visit:

www.hfea.gov.uk/choose-a-clinic

Statement on Data Quality

CARE Fertility did not submit records during 2017-18 to the Secondary Uses Service for inclusion in the Hospital Episode Statistics: this is not a relevant requirement for this service.

CARE Fertility does submit comprehensive data on every cycle of fertility treatment undertaken to the specialist fertility regulator, the HFEA. This data is validated and subject to audit by the HFEA to confirm accuracy and quality. Data quality is a significant priority and allows accurate evaluation of clinical success rates both by CARE and the HFEA. The HFEA provides access to non-identifying information for secondary users, and can also supply identifying data to both research organisations (if the patient consents) and to children born from donation.

Our Information Governance policies continue to inform our standards of record keeping which support and evidence the delivery of care and treatment. Records are regularly monitored for accuracy, completeness, and legibility providing timely identification of quality issues and any remedial steps required.

Information Governance Toolkit attainment levels:

The Information Governance Toolkit is a performance assessment tool produced by the Department of Health. It is a set of standards that organisations providing NHS care must complete, to ensure that all personal and confidential data we handle is protected and held safely and securely in line with the law and central guidance.

We must achieve level 2 or above on all requirements to be graded satisfactory and a trusted organisation.

CARE Fertility's Group Information Governance Assessment Report overall for 2016-2017 was 66% and it was graded satisfactory with no improvements indicated. We are now working towards next year's compliance.

Infection Prevention and Control

CARE have a specific Infection Prevention and Control policy which informs the infection prevention and control activities required to maintain an effective clinic wide Programme for the prevention of clinic-acquired infection and the containment of infection brought into the CARE Fertility group by patients, staff or visitors.

CARE have an Infection Prevention Control committee who meet twice yearly to develop, promote and implement infection control practices corporately across the CARE group. At each clinic there is also an infection prevention and control Nurse to provide advice and guidance to staff, attend the committee meeting and oversee relevant audits.

Infection	2017/2018
MRSA positive blood culture	0
MSSA positive blood culture	0
E. Coli positive blood culture	0
Clostridium difficile hospital acquired infections	0



Review of Quality Performance 2018-19



Patient safety

In 2017 CARE Fertility transferred all incident reporting to the DATIX system. Comprehensive training to ensure all staff are confident in what and how to report incidents was provided on the introduction of DATIX. Root Cause Analysis (RCA) training was provided for key staff with further training being planned for 2018/19. To enhance staff knowledge two Human Factors workshops were provided in September 2017 which received positive feedback.

Sharing learning across the organisation is key to improving quality of care for our patients. Where a serious incident has occurred a shared learning tool is circulated to all Clinics to highlight the lessons learned and recommendations identified following investigation.

To promote learning and development of our staff a new eLearning platform and Learning

Management System "CARE Learning Lab" was launched in January 2017. All mandatory training required for working at CARE is available on the CARE Learning Lab including:

- Conflict Resolution
- Equality Diversity and Human Rights
- Fire Safety
- Infection Prevention and Control – Clinical
- Infection Prevention and Control – Non Clinical
- Health, Safety and Welfare
- Information Governance
- Moving and Handling
- Patient moving and Handling
- Safeguarding Adults
- Safeguarding Children

We have robust governance procedures and identify opportunities for improvement from all sources including audit, incidents, feedback and complaints.

April 2017 - March 2018 (%of Total Number of NHS Cycles)				
Clinic	Severe OHSS	Never Events	HFEA reportable incidents	Total Numbers of incidents
Nottingham	0% (0)	0% (0)	2.5% (9)	29
Northampton	0% (0)	0% (0)	1.5% (5)	22
Manchester	0% (0)	0% (0)	1.0% (3)	27
Sheffield	0% (0)	0% (0)	3.1% (8)	28
Tunbridge Wells	0% (0)	0% (0)	11.1% (5)	31
Birmingham	0% (0)	0% (0)	0.0% (0)	1
TOTAL	0% (0)	0% (0)	2.3% (30)	138

Source: Incident reporting system DATIX

Clinic	Number of NHS patient Complaints
Nottingham	0
Northampton	0
Manchester	1 (partially upheld)
Sheffield	0
Tunbridge Wells	0
Birmingham	0
TOTAL	1

Source: CARE complaints system

Clinical Effectiveness

HFEA validated data: The clinical pregnancy rates for patients treated at CARE as verified by the Human Fertilisation and Embryology Authority are shown below:

CARE Group - Fresh Cycles, patients own eggs			
Clinical pregnancy rate per embryo transferred (July 2015 to June 2016)			
Age group	Number of embryos transferred	Clinical pregnancy rate	HFEA National Rate
<35	1822	44%	33%
35 - 37	1000	30%	26%
38 - 39	664	24%	19%
40 - 42	694	15%	12%
43 - 44	112	8%	6%
>44	39	0%	2%
All Ages	4544	31%	25%
Source: Latest HFEA published results July 2015 - June 2016			

CARE Group - Fresh Cycles, patients own eggs			
Multiple Live Birth rate per embryo transferred (July 2014 to June 2015)			
Age group	Number of embryos transferred	Clinical pregnancy rate	HFEA National Rate
<35	1992	4%	4%
35 - 37	1083	5%	3%
38 - 39	739	2%	2%
40 - 42	965	1%	1%
43 - 44	133	4%	4%
>44	16	0%	1%
All Ages	5085	3%	3%
Source: Latest HFEA published results July 2014 - June 2015			

CARE Group - Fresh Cycles, patients own eggs			
Live Birth rate per embryo transferred (July 2014 to June 2015)			
Age group	Number of embryos transferred	Live Birth rate	HFEA National Rate
<35	1992	36%	29%
35 - 37	1083	26%	22%
38 - 39	739	19%	16%
40 - 42	965	8%	8%
43 - 44	133	4%	4%
>44	16	0%	1%
All Ages	5085	24%	21%
Source: Latest HFEA published results July 2014 - June 2015			

These success rates provide evidence of the high quality of treatment provided by CARE Fertility. Comparative data published and verified by the HFEA shows that CARE are number 1 and 2 of the 79 UK fertility clinics.

www.carefertility.com/why-care/success-rates

NHS patient data (CARE local validated data)

CARE Group - Fresh Cycles, patients own eggs		
Clinical pregnancy rate per embryo transferred (April 2017 to March 2018)		
Age group	Number of embryos transferred	Clinical pregnancy rate
<35	327	49%
35 - 37	126	30%
38 - 39	49	31%
>40	41	20%
All Ages	543	41%

Source: CARE Clinical Information System (CIS) KPI data

CARE Group - Fresh Cycles, patients own eggs		
Live Birth rate per embryo transferred (April 2016 to March 2017)		
Age group	Number of embryos transferred	Clinical pregnancy rate
<35	403	39%
35 - 37	120	32%
38 - 39	47	19%
>40	42	12%
All Ages	616	34%

Source: CARE Clinical Information System (CIS) KPI data

Patient Experience

Patients are at the centre of the service we provide and CARE Fertility places a high value on patient feedback and strives to act on all feedback to ensure any opportunities for improvement are taken.

All patients are asked to provide feedback post consultation and again post treatment. These responses are then reported and reviewed on a monthly basis.

During 2017 – 2018 patient satisfaction post consultation was ranked as excellent or very good in 90% of responses. Patient satisfaction post treatment was ranked as excellent or very good in 96% of responses. 99% of patients said they would recommend our service to friends or family post treatment.

NHS Patient Questionnaire Responses		
Clinical pregnancy rate per embryo transferred (April 2017 to March 2018)		
Post Consultation Questionnaires	NHS - CARE 16/17	NHS - CARE 17/18
Patient Satisfaction (Excellent/Very Good)	92%	90%
Friends and Family Score (Extremely likely/likely to Recommend)	96%	97%
Post Treatment Questionnaires	NHS - CARE 16/17	NHS - CARE 17/18
Patient Satisfaction (Excellent/Very Good)	94%	96%
Friends and Family Score (Extremely likely/likely to Recommend)	98%	99%

Source: CARE Patient Questionnaire survey data

We believe we have an open and transparent culture and aspire to listen to and act on all feedback – positive and negative. To improve the management of patient complaints and concerns our current system will be replaced with the Datix module during 2018. Implementation of the Datix system for complaints and concerns will allow easier identification of themes and trends and support triangulation of data with incident reporting.

At CARE we understand that fertility treatment may often be emotionally draining and patients sometimes need to make difficult decisions about treatment options that could have significant emotional impact. As a result of this all CARE patients are given the opportunity to receive fertility support counselling with our professionally qualified counsellors during their treatment.

CARE have a support co-ordinator who has developed in conjunction with the clinics the 'CARE Together Support Package'. The aim of the support package is to establish additional support structures for our patients in a commitment to making their fertility journey easier. Support is provided in a variety of ways including in clinic and online support meetings, organised Walk 'n' Talk events which allow patients to connect with others going through fertility treatment and a Buddy – peer to peer support system.

“ I often see patients who ask about ways to cope with their treatment, we believe that talking it through in a supportive environment may help you find some answers... ”
CARE Counsellor

“ After each 'Walk and Talk' I feel like I can see clearer and have the strength to keep plodding on with treatment. It makes me thankful that I chose CARE as they clearly value the 'oh so important' mental health aspect of dealing with the challenges of infertility. ”

CARE Patient

“ After feeling so isolated, the opportunity to meet people in a similar situation was appreciated. ”

CARE Patient



What our patients say



“ Even though we were using NHS CARE treated us like we were the only people involved, everything that happened was talked through and was done in a professional manner, the whole process from start to finish was very comfortable and despite it being a stressful time emotionally CARE was a place where stress didn't exist, thank you all for the service you provide, you never know we could be seeing you all again, a massive thank you ”

CARE Patient, Nottingham

“ What is a difficult situation has been made so much easier by all the team at CARE in Tunbridge Wells. Everyone has been so friendly and kind. I was very anxious about egg collection and the lovely nurses made me feel at ease and looked after me during the procedure. Thanks for your excellent care ”

CARE Patient, Tunbridge Wells

“ Excellent customer service by all staff at CARE. From the moment you walk in to the moment you leave all of the staff can't do enough for you to make sure you are kept up to date, are comfortable and at ease.

The nursing team are very friendly, knowledgeable and their willingness to help with a smile on their face is second to none. The embryologist, Amy, was superb and kept us up to date with progress on a daily basis which certainly put us at ease every day and even phoned us on transfer day.

Special mention also to the Consultant who is the nicest man you will ever meet and is great at making you feel relaxed, comfortable and knowing that he

really knows what he is doing! Well done to everyone at CARE Sheffield for making us feel special and valued through this difficult but exciting time! ”

CARE Patient, Sheffield

“ Every step of our treatment so far has been amazing. For a set of treatment which is distressing and traumatic enough, the team have all made it feel so much more bearable. It feels like I am coming to see family and am very welcomed, everyone knows who I am when they see me, (that may be because I have been with them for 18 months now) but even at the start I was recognised and instantly felt the warm from all the team.

Thank you all for the support and care- we have really appreciated every second, and while I hope this transfer is the last so I don't have to come back after the scan, it has nothing to do with the team as I will miss you all once we leave your care. ”

CARE Patient, Northampton

“ The nursing team are so friendly and welcoming with fantastic knowledge ”

CARE Patient, Birmingham

“ Having had previous IVF treatment at another NHS IVF clinic we have been very pleasantly surprised by the standard of care we have received at CARE Manchester. All though I am unable to comment on the outcome of our treatment at this time the standard of care we have received from the beginning of our time at the clinic has been excellent. Staff are very friendly and you feel as though you matter as an individual and are well cared for which is important when you are going through something as emotionally challenging as infertility treatment.

After a very difficult start to our IVF journey with many challenges along the way myself and my husband would like to thank the staff at CARE for their help and dedication to our treatment. I do not

believe this cycle would have been possible without our lovely consultant going out of her way to make sure our treatment was suited to our individual needs. Something that wasn't easy and we greatly appreciate everything she has done. Having arrived at CARE feeling very despondent with the health care system we are pleased to say that regardless of the outcome of this cycle our confidence has been restored and we hope to keep perusing our dream to start a family.

We would definitely recommend CARE Manchester to friends and family. ”

CARE Patient, Manchester



Statement of assurance NHS East Midlands Commissioning Groups

Care Nottingham, Care Sheffield and Care Northampton hold NHS Standard Contracts with NHS East Midlands Commissioning Groups for provision of NHS funded IVF/ICSI treatment. East Midlands CCGs commission one cycle of IVF/ICSI treatment for patients who meet eligibility criteria, and Arden GEM Commissioning Support Unit (AGCSU) has responsibility for managing and monitoring the quality and performance of services provided by the 3 CARE Clinics based in the East Midlands.

There are a number of ways in which AGCSU review and monitor the performance and quality of the services commissioned from CARE Nottingham, CARE Sheffield and CARE Northampton. This includes a quality dashboard and quality schedule which is monitored on a quarterly basis and acts as an early warning sign of any quality issues. Regular quality and contract review meetings are held which include reviews of incidents, complaints, concerns and patient satisfaction and also helps to review the accuracy of the information being presented in order to formulate opinion about the quality of services provided to patients.

The Clinic Directors, Quality Leads and all staff can be commended for their continued efforts to improve patient safety and experience of the organisation.

CARE Sheffield and CARE Nottingham underwent a comprehensive HFEA inspection and the reports have been shared with Commissioners. There has been no Never Events reported by CARE Fertility and no reported post-treatment infections.

There are very few formal complaints about NHS Funded IVF treatment, and any concerns about treatment are handled in a quick, prompt and caring manner. Consistent participation in undertaking the Family and Friends Test has been demonstrated, with excellent response results, 99% of patients saying they would recommend the service to friends and family post treatment.

Commissioners have been pleased to see that CARE Sheffield has improved parking facilities as well as refurbishment in a number of areas, and Fire Safety checks were completed swiftly following a request to review fabrication safety in all buildings where NHS patients attend.

IG Governance and data security has also been continually improved across the 3 CARE organisations within East Midlands, and the use of the DATIX system has helped to support more robust reporting to Commissioners. AGCSU will continue to work closely with CARE Nottingham, CARE Sheffield and CARE Northampton to ensure high quality services are provided.

How to provide Feedback on the Account

CARE Fertility welcomes feedback on the content of its Quality Account and suggestions for inclusion in future reports.

Comments should be directed to:

Janine Elson Group Medical Director	Nigel Robertson Chairman
CARE Fertility John Webster House Lawrence Drive Nottingham Business Park Nottingham NG8 6P	CARE Fertility John Webster House Lawrence Drive Nottingham Business Park Nottingham NG8 6P

Statement of Directors' responsibilities in respect of the Quality Report

The Directors are required under the Health Act 2009 and the National Health Service (Quality Accounts) Regulations 2010 as amended to prepare Quality Accounts for each financial year.

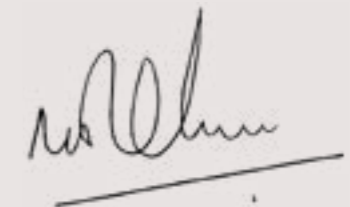
In preparing the quality report, Directors are required to take steps to satisfy themselves that:

- The content of the Quality Report meets the requirements set out in the NHS Guidance
- The content of the Quality Report is not inconsistent with internal and external sources of information including:
 - Clinic/Board minutes and papers for the period April 2017 to March 2018
 - Papers relating to quality reported to the Board over the period April 2017 to March 2018
- Feedback from the HFEA

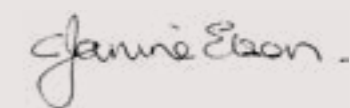
- Feedback from CQC
- Quarterly Quality Reports submitted to the Corporate Quality Team
- The performance information reported in the Quality Account is reliable and accurate

The Quality Report is robust and reliable, conforms to specified data quality standards and prescribed definitions, is subject to appropriate scrutiny and review; and the Quality Report has been prepared in accordance with Monitor's annual reporting guidance.

The directors confirm to the best of their knowledge and belief that they have complied with the above requirements in preparing the Quality Report.



Nigel Robertson, Chairman



Janine Elson, Group Medical Director



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