

Care Fertility Quality Account

April 2022 - March 2023





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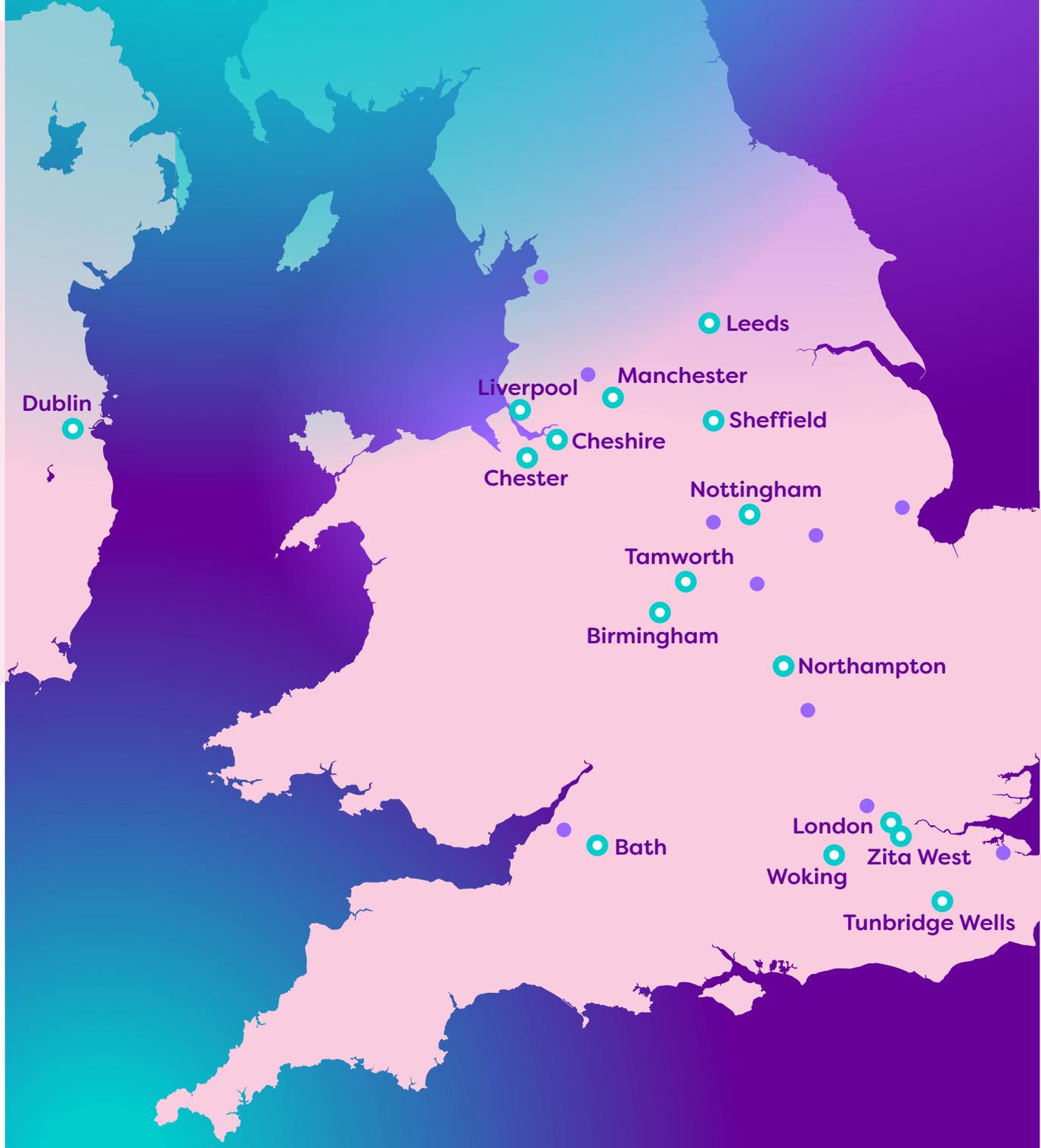
- Main Care Clinics
- Satellite Clinics

International

IVF Life group
Alicante, Spain
San Sebastian, Spain
Madrid, Spain



REACH Fertility
Charlotte,
North Carolina, USA



Welcome to Care Fertility

Care Fertility Group - The largest provider of assisted conception services in the UK

Care Fertility is an international fertility group, focused on innovation, clinical excellence and market leading patient proposition with strong success rates. Over the last 25 years, Care Fertility scientists and clinicians have driven many of the innovations in the field of IVF and our continuous clinical improvement is supported by and recognised through international collaborations and publications. Our current work on time-lapse imaging and artificial intelligence is shared internationally.

Our clinics provide a comprehensive range of treatment for the investigation and management of fertility problems and are regulated by the Human Fertilisation and Embryology Authority (HFEA) and Care Quality Commission. Our staff have specialist skills and knowledge and are committed to providing an excellent level of service and care to all our patients.

In each clinic we have a dedicated Quality Manager who oversees all matters quality related. They in turn form the Care Group Clinical Governance team to share best practice and ensure cohesion across the clinics.

At Care we provide this quality service and care to NHS funded patients who meet the eligibility criteria set out by their Integrated

Care Board (ICB). Individualised patient care and satisfaction is always 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 confirm that treatment is evidence based and delivered by appropriately qualified and experienced healthcare professionals.

Inclusivity is at the core of Care's culture, with a brand promise of Family is for everyone, and we continue to build a culture where everyone belongs and empathy is shown for all patient groups.

Care Fertility has links with various academic institutions and leads the field in training of specialist staff. We have established a Master's degree in clinical embryology in collaboration with Liverpool John Moore's University.

We currently have 22 clinics in the UK that provide services to NHS funded patients.



Our Values

Our Values

Every
step
matters

We **care**
about
everyone

Determined
to do
our best



Care



“Care Woking has been amazing from day one. From telephone consultations to embryo transfer, everyone has been very supportive and friendly. Always available to answer any questions. You all do a great job in helping couples conceive. Thank you all.”

(NHS North East Hants & Farnham)

Statement on Quality from Care Fertility's Chief Executive

Welcome to the 2022-23 Care Fertility Quality Account which explains how essential quality assurance is to Care Fertility and looks forward to our plans for further quality improvements in the forthcoming year.

At Care we are dedicated to achieving the best chance of pregnancy for our patients by providing safe, effective and personalised treatment. This is supported by our Quality Management System across the Group and the continuous quality improvement supported by the representation of quality managers in each clinic.

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.

We continue to be regulated by our governing body, the Human Fertilisation & Embryology Authority (HFEA), with each clinic maintaining a rigorous inspection and certification process.

Care is proud to engage and invest in the National Scientist Training Programme (STP). We currently have 18 people on this programme being trained across Care's UK clinics – which have all been assessed and accredited for this training. In addition, we have recently launched our own Master's degree in partnership with Liverpool John Moore's University, and our first cohort will graduate this summer.

This year has seen some important technological advancements and associated awards for our team. Following the development of a machine learning solution to assess embryo development more reliably and reproducibility than manual methods, we were awarded both the National Technology Award for Healthcare and an Achievement Award from the Royal College of Pathologists.

This Quality Account details:

- The clinic's priorities for improvement in 2023-24.
- Statements of assurance relating to the quality of services provided by Care.
- What others say about us.

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

David Burford
Chief Executive Officer
Care Fertility Group



“ All of the staff were lovely, supportive and kind! The centre is lovely and I felt at ease through my procedures! ”

(NHS Dorset CCG)

Priorities for Quality Improvement 2022-23

	Quality objective	Strategy/Measurement for achieving the objective
Clinical Effectiveness	To maintain clinical outcomes:	This will always remain our primary quality objective as clinical success rates are a direct measure of the effectiveness of treatments provided by Care. Research and patient feedback support that this is a significantly important metric for our patients.
Patient Safety	Multiple births are considered by the fertility regulator to be the single biggest risk to the health of mothers and babies.	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.
	To ensure that risks of Ovarian Hyper Stimulation Syndrome (OHSS) are minimised.	All severe/critical OHSS cases recorded on Datix, reported to the HFEA and trends analysed to identify any opportunities for learning. OHSS rates reviewed at local and group clinical governance and quality meetings. Should adverse trends be identified, implementation of corrective and preventative actions as required.
	Adoption of the Patient Safety Incident Response Framework (PSIRF).	PSIRF sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety. During 2023/24 we will be updating our policies to incorporate PSIRF and providing training to our staff.
Patient Experience	Development and implementation of patient experience audits.	Understanding our patients experience throughout their treatment journey is key to us providing the best care. During 2023/24 we will be enhancing our audit programme by developing and conducting specific patient experience audits.
	Digital Transformation project.	Our Digital Transformation project is designed to support Care's vision of the world's leading patient-centric fertility provider. We aspire to offer the best clinical care and outcomes alongside the best customer service, support and care to achieve this aim. We aim to use technology to: <ul style="list-style-type: none"> • Improve success rates through combining the latest AI technologies with our database. • Develop a new clinical system from the ground up, built around the needs of our teams (and in consultation with our teams) and created through partnerships with expert third parties. • Launch a new website with revised branding and modern functionality, e.g., chatbots, online booking, and tailored content.

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 2022 and March 2023 but reported in June in line with guidance.

Review of NHS Services Provided 2022-23

During 2022-23 Care Fertility provided fertility treatment to NHS funded patients under the terms of a number of ICB contracts.

Care Fertility provides fertility services for 29 ICB's, and NHS England funded patients for the armed services together with Preimplantation Genetic Diagnosis (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 2022-23 represented c.16.5% of the total income generated by Care Fertility.

Total number NHS patients	NHS cycles (% total cycles)	
	April 2021 - March 2022	April 2022 - March 2023
Nottingham	348 (13.9%)	541 (20.8%)
Northampton	243 (9.8%)	318 (12.5%)
Manchester	628 (14.8%)	544 (17.7%)
Sheffield	300 (19.3%)	288 (18.4%)
London	10 (0.4%)	24 (1.0%)
Tunbridge Wells	320 (17.2%)	324 (18.9%)
Birmingham	3 (0.2%)	41 (2.3%)
Bath	289 (15.7%)	276 (15.8%)
Chester	547 (39.3%)	531 (39.3%)
Tamworth	32 (3.6%)	21 (2.5%)
Woking	400 (23.2%)	388 (22.0%)
Leeds	-	1140 (30.7%)
TOTAL	3110	4436

“From our very first visit the level of care and support from the whole team has been superb. We feel so confident in the quality of care from each and every team member.”

(NHS Nottingham and Nottinghamshire CCG)

Participation in Clinical Audit

National Audit

There were no national clinical audits that were relevant to fertility services and therefore Care could not participate in the national programme.

Local Audits

Care Fertility has a robust audit calendar 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. It is an HFEA requirement that all aspects of practice in a licensed clinic are audited at least once every two years

Audits are performed using an audit tool format which is reviewed on an ongoing basis or if new/ revised guidelines or regulations are introduced.

Our current audit schedule consists of the following audits:



Our current audit schedule consists of the following audits:

Adverse Incidents
Annual Consumable and Equipment Traceability
Annual Witnessing
Complaints Management
Compliance with Donor consent
Confidentiality
Consent
Controlled drugs
Counselling
Donor recruitment
Extended Storage
Import and Exports
Infection, Prevention & Control
Laboratory Process Validation
Legal Parenthood
Liquid Nitrogen Safety and Handling
Medical Gas Safety and Handling
Medicines Management
Multiple Birth review
Patient Records
Perioperative pathway
PGT-A and embryo testing
Perioperative pathway
Procurement, processing and transport of gametes and embryos
Provision of information
Research and Training
Satellite Clinics
Screening
Sedation
Staff recruitment and competencies
Storage of gametes and embryos
Surrogacy
Third Party Agreements
Welfare of the Child

Audit reports and outcomes are discussed at local and group Clinical Governance and Quality meetings to highlight any areas of non-compliance, the actions being taken and good practice shared. Completion of actions are monitored by the local Clinical Governance and Quality manager through the Datix system.

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 allocated for research purposes with the patient’s full consent.

Use of the CQUIN payment framework

A proportion of Care Tunbridge Wells income in 2022-23 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 Fertilisation and Embryology Authority (HFEA) and Care Quality Commission (CQC) have agreed to work together to ensure the safety of people who use services but to minimise regulatory burden. As a result of the memorandum of understanding between HFEA and CQC a number of Care clinics have de-registered with CQC. Only Care Manchester, Northampton, London, Chester and Birmingham remain registered.

“Care have been fantastic throughout my treatment. This was my first cycle and I had no idea what to expect, but all of the staff I encountered were professional, compassionate and friendly. Information regarding my treatment (scan results, blood test results, etc) was conveyed quickly clearly and my partner and I felt fully supported throughout. I would definitely recommend care Tunbridge Wells to friends and family.”

(NHS Dorset CCG)

“The kindness, positivity, smiles and care of the staff came through and really supported us and put us at ease (especially when I was a little nervous). We are really thankful for all the support we have received! Thank you!”

(NHS Chorley and South Ribble CCG)

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, inspection calendar and Code of Practice.

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

<https://www.hfea.gov.uk/choose-a-clinic/>

Statement on Data Quality

Care Fertility did not submit records during 2022-23 to the Secondary Users 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.

Data Security and Protection Toolkit attainment levels:

Care Fertility takes its responsibilities towards personal data very seriously. It recognises GDPR, Data Protection Act 2018, Common law for Confidentiality and the HFE Act 1990 requirements for personal data. Care is also required to complete the Data Security and Protection Toolkit - an online self-assessment tool that is used by organisations to measure and publish their performance against the National Data Guardian’s ten data security standards.

Care goes much further, and as part of a continuous improvement process, Care works to bring “Data Protection by design and default (GDPR Article 25), into everything we do, with key risks identified by an active corporate risk log, and controlled an ongoing data security improvement plan which is subject to Board level scrutiny. The continuous improvement process is also shown through the Toolkit submission: as well as every mandatory item reaching the required standard, Care also submits an increasing amount of non-mandatory items Toolkit requirements each year.

Infection Prevention and Control

Our Infection Prevention and Control Policy sets out a clinic-wide programme of activity designed to prevent clinic-acquired infection and the containment of disease that may be introduced to our premises by patients, employees or visitors.

Our Infection Prevention Control committee meets bi-annually to develop and implement infection control measures across the business. An infection prevention and control lead nurse from each clinic attends this committee meeting and provides advice, training and guidance on infection control within their clinic.

Healthcare Associated Infections

INFECTION	2021/2022
MRSA positive blood culture	0
MSSA positive blood culture	0
E. Coli positive blood culture	0
Clostridium difficile hospital acquired infections	0

Safeguarding

Care Fertility takes a broad community approach to establishing safeguarding arrangements.

Prevention Strategies include:

- Mandatory training module for completion by all staff
- Having effective policies and procedures in place which are disseminated to staff
- Listening to the voice of the adult, family, carers and provider staff
- Empowering service users to recognise and report safeguarding and quality concerns
- Promote and implement the principles of the Mental Capacity Act (2005)
- Using safe recruitment processes
- Monitoring incidences and data for patterns and trends

Freedom to speak up

Care have a specific freedom to speak up and raising concerns (whistle blowing) policy which details how staff can speak up and the support they will be provided with. Care has a dedicated Freedom to Speak Up Guardian who has been given special responsibility and training in dealing with whistleblowing concerns.

All staff are required to complete the Care mandatory eLearning module Freedom to Speak Up (Whistleblowing). The eLearning module covers the following areas:

- What is whistleblowing
- Who can raise a concern
- Roles and Responsibilities
- How to raise a concern
- Raising concerns with an outside body

Any whistleblowing events, the outcome of their investigation and what actions have resulted are reported to the Board on an annual basis.

Patient Safety

Incidents are logged by category on our Datix system and reported quarterly to the Board. Our Datix dashboard is a live 'at a glance' tool designed to enhance transparency across our clinics and inform local action where negative trends are identified. Datix allows any member of staff across the business to report an incident and record any immediate or remedial action taken. Once an incident is reported Quality Managers review the information ensuring that the severity and categorisation of the incident have been correctly assigned. In addition, they ensure that any proposed actions have been completed, lessons learned identified and shared.

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.

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

“ Each member of staff has been so welcoming and they have all explained everything clearly and in detail. We are very happy with the way we have been treated so far. ”

(Doncaster CCG)

Clinic	Severe OHSS	Never Events	HFEA reportable incidents	Total number incidents
Nottingham	0.0% (0)	0.0% (0)	0.6% (3)	34
Northampton	0.0% (0)	0.0% (0)	1.6% (5)	113
Manchester	0.2% (1)	0.0% (0)	1.7% (9)	50
Sheffield	0.0% (0)	0.0% (0)	0.7% (2)	27
London	0.0% (0)	0.0% (0)	0.0% (0)	2
Tunbridge Wells	0.3% (1)	0.0% (0)	1.5% (5)	36
Birmingham	0.0% (0)	0.0% (0)	0.0% (0)	1
Bath	0.4% (1)	0.0% (0)	2.9% (8)	22
Chester	0.0% (0)	0.0% (0)	0.6% (3)	85
Tamworth	0.0% (0)	0.0% (0)	4.8% (1)	76
Woking	0.0% (0)	0.0% (0)	0.3% (1)	28
Leeds	0.0% (0)	0.0% (0)	0.4% (5)	120
TOTAL	0.1% (3)	0.0% (0)	0.9% (42)	594

Source: Incident reporting system DATIX

“ Everyone makes you feel cared about and important - an out of this world experience full of care and support. ”
 (NHS Northamptonshire CCG)

Care Clinical Governance model



Patient Experience

Patients are at the centre of the service we provide and Care Fertility places a high value on patient 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 quarterly basis.

We believe we have an open and transparent culture and aspire to listen to and act on all feedback – both positive and negative. Complaints, and concerns are logged by category on our Datix system and reported quarterly to the Board. Our Datix dashboard is a live ‘at a glance’ tool designed to enhance transparency across our clinics and inform local action where negative trends are identified.

During 2022 - 23 95% (671) of NHS patients who completed our post treatment questionnaire reported they would be likely or extremely likely to recommend Care to others.

“ Really lovely staff. Made us feel at ease. We are feeling supported. ”
 (Derby & Derbyshire CCG)

During 2022 - 23 95% (671) of NHS patients who completed our post treatment questionnaire reported they would be likely or extremely likely to recommend Care to others.

We believe we have an open and transparent culture and aspire to listen to and act on all feedback – both positive and negative.

Clinic	Total number of NHS patient complaints
Nottingham	4
Northampton	0
Manchester	6
Sheffield	0
London	0
Tunbridge Wells	3
Birmingham	0
Bath	3
Chester	4
Tamworth	1
Woking	0
Leeds	14
TOTAL	35

Source: Care complaints system

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 of Care patients are given the opportunity to receive implications counselling prior to commencing treatment. Patients also have access to fertility support counselling with our professionally qualified counsellors during their treatment journey.

Ensuring our patients feel supported throughout their treatment journey is very important to us. Patients are asked to rate the level of support they received during their treatment. During 2022 - 23, 93% (680) of NHS patients who completed our post treatment questionnaire reported the level of support they received during their treatment as excellent, very good, or good.

Review of Quality Performance 2022/23

	Quality Priority	What we said we would do	What we achieved
Clinical Effectiveness	To maintain clinical outcomes: This will always remain as a quality objective as clinical success rates are a direct measure of the effectiveness of treatments provided by Care. Research and patient feedback support that this is a significantly important metric for our patients.	<p>Monthly review of success rates;</p> <p>Any 'red flag' markers to be investigated at clinic level and reported back to Group.</p> <p>Alignment of lab processes across all clinics.</p> <p>More sophisticated and interactive reporting mechanism being implemented.</p>	<p>Overall Clinical Pregnancy rate per embryo transferred for NHS patients (all ages fresh IVF/ICSI own eggs) April 2022 to March 2023 was 33.4%.</p> <p>Clinical Pregnancy rates, along with a suite of clinical outcomes and laboratory indicators, are reviewed on a monthly basis by individual clinics using our new reporting platform: Power BI. This allows clinics to interact with a variety of metrics and compare their outcomes within the Group.</p> <p>Any key performance indicators (KPIs) that fall below the target continue to trigger an investigation and improvement plan. These are discussed and reviewed at monthly Clinical Governance meetings and Quarterly Performance Reviews.</p>
Patient Safety	Multiple births are considered by the fertility regulator to be the single biggest risk to the health of mothers and babies.	<p>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.</p>	<p>The HFEA launched a campaign to reduce the high multiple birth rate following IVF with an overall goal to reduce the national multiple birth rate to 10% which was achieved for the first time in 2017.</p> <p>Overall Multiple Birth rate for NHS patients April 2022 to March 2023 was 2.2%, compared to 1.9% the previous year.</p> <p>Individual clinics monitor their multiple birth rates via Power BI on a monthly basis.</p>
	To ensure that risks of Ovarian Hyper Stimulation Syndrome (OHSS) are minimised.	<p>All severe/critical OHSS cases recorded on Datix, reported to the HFEA and trends analysed to identify any opportunities for learning.</p> <p>OHSS rates reviewed at local and group clinical governance and quality meetings.</p> <p>Should adverse trends be identified, implementation of corrective and preventative actions as required.</p>	<p>3 cases of severe OHSS (0.1% of all NHS cycles) were reported 2022 - 23. All were reported to the HFEA and investigated. No adverse trends were identified.</p>
Patient Experience	Telephone Call Handling Project	<p>Following patient feedback, we are committed to improving the management of telephone calls across the Care group. Following review of the management of initial enquiries we successfully implemented the General Enquiry Management (GEM) Team in May 2018. We want to extend this to better manage all incoming patient calls to Care.</p>	<p>The Care Patient Admin Liaison Service (Carepals) has now successfully launched across all our clinics.</p> <p>Carepals was created with a simple but clear vision:</p> <p>'To have a team who take overall responsibility for the patient journey and are passionate about improving patient experience.'</p>

Sustainable Care

Care is committed to planning towards a sustainable future. Our approach to sustainability is to work towards interweaving it into our operational processes and is fundamental to ensuring that we positively impact our staff, our patients and the communities where we work and that we contribute to the development of local and national sustainability agendas.

Care's strategy for 2022/23 will be to continue to:

- Improve Care's Carbon Footprint
- Increase recycling
- Introduce the use of solar panels and our electric car scheme
- Reduce the plastic we use across the business
- Identify opportunities for improving sustainability across the Care group

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:

David Burford CEO

Care Fertility, John Webster House, Lawrence Drive, Nottingham Business Park, Nottingham NG8 6PZ

Debra Bloor Group Director of Governance

Care Fertility, John Webster House, Lawrence Drive, Nottingham Business Park, Nottingham NG8 6PZ

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 2022 to March 2023
 - Papers relating to quality reported to the Board over the period April 2022 to March 2023
 - Feedback from the HFEA
 - Feedback from CQC
- 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.

Debra Bloor
Group Director of Governance

David Burford
Chief Executive Officer

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REACH Fertility

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Centres for Assisted Reproduction Limited (no. 03328039), Care (Sheffield) Limited (no. 04145167), Care Fertility (Northampton) Limited (no. 03083989), Care Fertility (London) Limited (no. 08529488), Centre for Reproductive Medicine Limited (no. 03295082), South East Fertility Clinic Limited (no. 06546136) and Care Fertility Group Limited (no. 05423241) are wholly owned subsidiaries of Care Fertility Holdings Ltd (no. 08102663). These companies are registered in England and have a Registered Office at John Webster House, 6 Lawrence Drive, Nottingham Business Park, Nottingham, NG8 06PZ. Care is a trading name for Centres for Assisted Reproduction Ltd.

