



# RQIA Provider Guidance 2016-17

## Independent Health Care

### Fertility Services and Assisted Conception

[www.rqia.org.uk](http://www.rqia.org.uk)

# What we do

The Regulation and Quality Improvement Authority (RQIA) is the independent body that regulates and inspects the quality and availability of Northern Ireland's health and social care (HSC) services. We were established in 2005 under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to drive improvements for everyone using health and social care services.

Through our programme of work we provide assurance about the quality of care; challenge poor practice; promote improvement; safeguard the rights of service users; and inform the public through the publication of our reports. RQIA has three main areas of work:

- We register and inspect a wide range of independent and statutory health and social care services.
- We work to assure the quality of services provided by the HSC Board, HSC trusts and agencies - through our programme of reviews.
- We undertake a range of responsibilities for people with mental ill health and those with a learning disability.

We inspect and report on the following four domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well led?

RQIA registers and inspects a wide range of health and social care services. These include: nursing, residential care, and children's homes; domiciliary care agencies; day care settings/centres; independent health care; nursing agencies; independent medical agencies; residential family centres; adult placement agencies; voluntary adoption agencies, school boarding departments and young adult supported accommodation (inspected only).

# The four domains



# How we will inspect

We will inspect every Independent Hospital –In Vitro Fertilisation establishments at least annually. Our inspectors are most likely to carry out an announced inspection, however from time to time we may carry out an unannounced inspection.

During our inspections we will inspect and report on the following four domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well led?

When we inspect an In Vitro Fertilisation establishment, we aim to:

- Seek the views of the people who use the service, or their representatives
- Talk to the management and other staff on the day of the inspection
- Examine a range of records including care records, incidents, complaints and policies
- Provide feedback on the day of the inspection to the manager on the outcome of the inspection; and
- Provide a report of our inspection findings and outline any areas for quality improvement where failings in compliance with regulations and/or standards are identified

Our inspections are underpinned by:

- The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments July 2014

# What we look for when we inspect

To help us to report on whether the care is safe, effective and compassionate and whether the service is well led, we will look for evidence against the following indicators. The evidence listed for each indicator provides examples of what may be reviewed and should not be considered exhaustive.

## Is care safe?

**Avoiding and preventing harm to service users from the care, treatment and support that is intended to help them.**

### Indicator S1

There are, at all times, suitably qualified, competent and experienced persons working in the service in such numbers as are appropriate for the health and welfare of service users.

### Examples of Evidence

#### Staffing

- There are sufficient numbers of staff in various roles to fulfil the needs of the establishment and patients
- There is an induction programme in place appropriate to the role
- A system is in place to ensure all staff receive appropriate training to fulfil the duties of their role including professional body CPD recommendations and RQIA mandatory training
- A system is in place to ensure staff receive annual appraisal and records are retained
- There are arrangements in place for monitoring the registration status for all clinical staff (e.g. GMC, NMC)
- There are arrangements in place for monitoring the professional indemnity of all clinical staff who require individual indemnity cover
- All practitioners have the necessary training, qualifications, experience and expertise to safely and competently undertake the treatments and services they offer

#### Recruitment and Selection

- Staff have been recruited in line with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005
- There is a written policy and procedure for staff recruitment
- Staff personnel files are in keeping with 19 (2) Schedule 2
- Enhanced AccessNI checks received prior to new staff commencing work

**Indicator S2**

The service promotes and makes proper provision for the welfare, care and protection of service users.

**Examples of Evidence****Safeguarding**

- Staff are knowledgeable about and have a good understanding of safeguarding
- Policies and procedures are in place (to include; safeguarding champion, definitions of abuse, types and indicators of abuse, onward referral arrangements including contact information and documentation)
- Within three months of commencing employment, staff complete training and can demonstrate knowledge of safeguarding principles
- Safeguarding training or refresher training is provided as per minimum standards
- All suspected alleged or actual incidents of abuse are fully and promptly referred to the appropriate agencies in accordance with written procedures and records maintained
- Awareness of the new regional guidance issued in July 2015 entitled 'Adult Safeguarding Prevention and Protection in Partnership'
- The establishment has a current licence with The Human Fertilisation Embryology Authority (HFEA) which is subject to regulatory review

**Indicator S3**

There are systems in place to ensure that unnecessary risks to the health, welfare or safety of service users are identified, managed and where possible eliminated.

**Examples of Evidence****Management of Patients Undergoing Fertility Treatment**

- There are a range of treatment protocols in place for the management of patients receiving assisted conception services which have been developed and agreed by all professionals within the establishment
- There are systems in place to regularly review protocols and discuss patient outcomes
- There is a protocol for the prevention and management of ovarian hyper stimulation syndrome (OHSS) which is evidence based and in line with best practice guidelines
- There are written protocols in place for the close monitoring of patients in order to avoid unnecessary complications including multiple pregnancy
- There are up-to-date protocols setting out the number of embryos placed in a woman in any one cycle that comply with the HFEA's code of practice
- There are procedures for indelible labelling of material for individual patients to ensure the unique identification of a patient's material and records at all stages of treatment
- There are clinical meetings involving the nurses, doctors and members of the embryology team to discuss the management of patients

**Resuscitation**

- Medicines required for resuscitation or other medical emergencies are clearly defined and are regularly monitored.
- These medicines are readily accessible in suitable packaging and available for use at all times.
- Accessible records are maintained relating to the regular monitoring of medicines required for resuscitation or other medical emergencies
- Equipment for resuscitating patients is in line with the Resuscitation Council (UK)
- Resuscitation equipment is checked and restocked to ensure all equipment remains in working order and suitable for use at all times. Checks are carried out daily by a designated person and recorded
- Resuscitation equipment is cleaned and decontaminated after each use
- Policy and procedural guidance, in relation to resuscitation are in place
- Management of resuscitation is included in staff induction and update training is provided annually
- Staff have knowledge and understanding of managing resuscitation and other medical emergencies

**Infection Prevention Control and Decontamination Procedures**

- The environment is clean and clutter free
- Infection prevention and control (IPC) policies and procedures are in place in keeping with regional guidance
- Records of training, which meet GMC, NMC recommendations are retained
- Staff have knowledge of infection prevention and control measures in line with best practice including the decontamination of equipment commensurate with their role and responsibilities
- The risk of cross infection to patients, staff and visitors is minimised by single use equipment or decontamination of reusable medical devices and equipment in line with manufacturer's instructions and current best practice
- There are written guidelines for staff on making referrals for advice and support to infection control nurses, microbiology services and public health medical staff who have expertise in infection prevention and control
- There is information available for infection prevention and control for patients, their representatives and staff
- Exploration of any issues identified during inspection

**Indicator S4**

The premises and grounds are safe, well maintained and suitable for their stated purpose.

**Examples of Evidence**

- There are dedicated rooms for specific purposes such as egg collection, production of semen specimens, treatment area for undertaking clinical procedures and laboratories for embryology procedures
- The room used for egg collection for in-vitro fertilisation is close to the laboratory where fertilisation is to take place
- There are secure designated areas with access by authorised personnel only for the atmospheric temperature controlled storages of gamete and embryos
- The establishment is clean, clutter free, warm and pleasant
- There are no obvious hazards to the health and safety of patients and staff
- There are arrangements in place in relation to maintaining the environment (e.g. servicing of lift/gas/boiler/fire detection systems and fire-fighting equipment, fixed electrical wiring installation)

# Is care effective?

The right care, at the right time in the right place with the best outcome.

## Indicator E1

The service responds appropriately to and meets the assessed needs of the people who use the service.

### Examples of Evidence

#### Management of Patients

- Patient care records are contemporaneous and clearly outline the patient journey
- Patient records include a record of consultation with the medical practitioner, consultation with other health care professionals, signed consent forms, patient care plans, patient treatment plans, embryology records, patient medical regime and other relevant records
- There are clinical meetings involving the nurses, doctors and members of the embryology team to discuss the management of patients
- The registered manager provides a weekly Director's report to the Board of Directors, outlining the number of patient treatment cycles undertaken and any other issues

#### Records

- Arrangements are in place for maintaining and updating clinical records
- Record keeping is in accordance with legislation, standards and best practice guidance
- A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection
- Records are securely stored – electronic/hard copy
- The established is registered with the Information Commissioners Office (ICO)
- There are systems in place to audit the completion of clinical records and an action plan is developed to address any identified issues
- Staff displayed a good knowledge of effective records management

## Indicator E2

There are arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals.

### Examples of Evidence

- A range of audits, including clinical audits, are undertaken routinely and actions identified for improvement are implemented into practice

**Indicator E3**

There are robust systems in place to promote effective communication between service users, staff and other key stakeholders.

**Examples of Evidence****Patient Information and Decision Making**

- The establishment has written information available for prospective patients regarding the services provided, how to access these and the costs of treatment. This information is written in plain English and when required is available in an alternative language or format
- There is a range of information leaflets on each procedure carried out by the establishment and given to patients on consultation to enable them to make informed decisions regarding their treatment
- During the consultation period the procedures, risks, complications and expected outcomes are discussed with each individual patient
- There is a comprehensive range of standard operating procedures protocols and clinical guidelines in place. These guidelines relate to all areas of the provision of safe, effective patient centred care and adhere to the HFEA Code of Practice and other national best practice guidelines
- All publicity materials used by the establishment conforms to the guidelines of the GMC and the code of the NMC
- There is a written policy and procedure for ensuring that written information provided to patients seeking treatment includes risk and safeguarding confidentiality
- There is a website for the establishment that provides information on the services available
- Arrangements are in place for effective communication with other relevant healthcare professionals regarding patient care
- A system is in place for breaking bad news to patients
- There is an open and transparent culture that facilitates the sharing of information
- Patients are aware of who to contact if they want advice or have any issues/concerns
- Staff meetings are held on a regular basis and minutes retained
- Staff can communicate effectively
- Learning from complaints/incidents/near misses is effectively disseminated to staff

# Is care compassionate?

**Service users are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.**

## **Indicator C1**

There is a culture/ethos that supports the values of dignity and respect, independence, rights, equality and diversity, choice and consent of service users.

### **Examples of Evidence**

#### **Dignity, Respect and Rights**

- Staff can demonstrate how confidentiality is maintained
- Staff can demonstrate how consent is obtained
- Discussion with staff and observation of interactions demonstrate patients are treated with dignity and respect
- There is a suitable location for private consultation
- There are arrangements in place to assist patients with a disability or who require extra support
- There is a policy and procedure on confidentiality
- Patient's modesty and dignity is respected at all times
- Patient's rights to make decisions about care and treatment are acknowledged and respected
- Patients and visitors are treated and cared for in accordance with legislative requirements for equality and rights
- The service facilities and layout of the establishment are designed to ensure the need for privacy and protection of confidentiality of people seeking treatment is met
- Patients are reassured by the certificate of registration displayed in a conspicuous place

## **Indicator C2**

Service users are listened to, valued and communicated with, in an appropriate manner.

### **Examples of Evidence**

- There are arrangements in place for involving patients to make informed decisions
- There are arrangements for providing information in alternative format/interpreter services if applicable

#### **Counselling**

- Counselling and support is offered to all patients before, during and after treatment
- There is information for patients on local and national counselling and support organisations
- There are clear referral arrangements to specialist genetic counselling, when required

## **Indicator C3**

There are systems in place to ensure that the views and opinions of service users, and or their representatives, are sought and taken into account in all matters affecting them.

### **Examples of Evidence**

#### **Patient Consultation**

- Patient consultation (patient satisfaction survey) about the standard and quality of care and environment is carried out at least on an annual basis.
- The results of the consultation are collated to provide a summary report
- The summary report is made available to patients
- An action plan is developed to inform and improve services provided, if appropriate
- RQIA staff/patient questionnaire responses support the outcome that compassionate care in place

# Is the service well led?

**Effective leadership, management and governance which creates a culture focused on the needs and the experiences of service users in order to deliver safe, effective and compassionate care.**

## **Indicator L1**

There are management and governance systems in place to meet the needs of service users.

## **Examples of Evidence**

### **Governance Arrangements**

- The registered provider/manager monitors the quality of services and undertakes a visit to the premises at least six monthly and produces a report of their findings (where appropriate)
- There are arrangements in place for policies and procedures to be reviewed at least every three years
- Policies are centrally indexed and retained in a manner which is easily accessible by staff
- Arrangements are in place to review risk assessments (e.g. legionella, fire, COSHH)
- The registered provider/manager ensures the establishment delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards
- There are clear clinical governance structures in place

### **Complaints**

- The practice has a complaints policy and procedure in accordance with the relevant legislation and DHSSPS guidance on complaints handling
- Records are kept of all complaints and these include details of all communications with complainants, the result of any investigation, the outcome and the action taken
- Information from complaints is used to improve the quality of services
- Staff know how to receive and deal with complaints
- Arrangements are in place to audit complaints to identify trends and enhance service provision

### **Incidents**

- The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA
- Incidents are effectively documented and investigated in line with legislation
- All relevant incidents are reported to RQIA and other relevant organisations in accordance with legislation and procedures

### **Audits**

- There are procedures to facilitate audit including clinical audit
- Results of audits are analysed and actions identified for improvement are imbedded into practice

**Indicator L2**

There are management and governance systems in place that drive quality improvement.

**Examples of Evidence****Quality Improvement**

- There is evidence of a systematic approach to the review of available data and information, in order to make changes that improve quality, and add benefit to the organisation and patients
- **Quality Assurance**
- Arrangements are in place for managing relevant alerts
- Arrangements are in place for staff supervision and appraisal
- There is collaborative working with external stakeholders e.g. GP, multi-professional team
- Audits of incidents are undertaken and learning, outcomes are identified and disseminated throughout the organisation
- The registered provider/manager has arrangements in place for dealing with managing identified lack of competency and poor performance for all staff including those with practicing privileges, and reporting incompetence in line with guidelines issued by DHSSPS and professional regulatory bodies
- The registered provider/registered manager ensures that professional registration and revalidation requirements are met

**Indicator L3**

There is a clear organisational structure and all staff are aware of their roles, responsibility and accountability within the overall structure.

**Examples of Evidence**

- There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities of all areas of the service
- Staff are aware of their roles & responsibilities and actions to be taken should they have a concern
- The registered person/s have understanding of roles and responsibilities under legislation
- Patients are aware of roles of staff within the establishment and who to speak with if they want advice or have issues/concerns
- The registered provider/manager is kept informed regarding the day to day running of the establishment

**Practising Privileges**

- There is a written agreement between the medical practitioner and the establishment that sets out the terms and conditions of granting practising privileges. Practising privileges agreements are reviewed at least every two years
- There is a written procedure that defines the process for application, granting, maintenance and withdrawal of practising privileges

**Indicator L4**

The registered person/s operates the service in accordance with the regulatory framework.

**Examples of Evidence**

- The Statement of Purpose and Patient Guide are kept under review, revised when necessary and updated
- Insurance arrangements are in place - public and employers liability
- Registered person/s respond to regulatory matters (e.g. notifications, reports/QIPs, enforcement)
- RQIA certificate of registration is on display and reflective of service provision

**Indicator L5**

There are effective working relationships with internal and external stakeholders.

**Examples of Evidence**

- There is a whistleblowing policy and procedure and staff are aware of this
- Arrangements are in place for staff to access their line manager
- There are arrangements in place to support staff (e.g. staff meetings, appraisal & supervision)
- Discussion with staff confirmed that there are good working relationships and that management are responsive to suggestions/concerns
- There are arrangements for management to effectively address staff suggestions/concerns

# Inspection reports

Our inspection reports will reflect the findings from the inspection. Where it is appropriate, a Quality Improvement Plan (QIP) will detail those areas requiring improvement to ensure the service is compliant with the relevant regulations and standards. Where either no requirements or recommendations result from the inspection this will be reflected in the report.

It should be noted that inspection reports should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in a service. The findings reported on are those which came to the attention of RQIA during the course of the inspection. The findings contained within inspection reports do not exempt the service provider from their responsibility for maintaining compliance with legislation, standards and best practice.

Once the inspection report is finalised and agreed as factually accurate, it will be made public on RQIA's website.



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