

E13/S(HSS)/a

**2013/14 NHS STANDARD CONTRACT  
FOR COMPLEX CHILDHOOD OSTEOGENESIS IMPERFECTA SERVICE**

**PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION**

<b>Service Specification No.</b>	E13/S(HSS)/a
<b>Service</b>	Complex childhood osteogenesis imperfecta service
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

**1. Population Needs**

**1.1 National/local context and evidence base**

All the data available from five published randomised controlled trials (RCTs) indicate an approximate 50% (range 38-62%) reduction in fracture frequency for children with osteogenesis imperfecta (OI) receiving bisphosphonates in a specialised care setting.

Multiple observational studies of pamidronate (given intravenously in cycles typically at 3-4 month intervals) have been undertaken that document improved grip strength, mobility and increased size and restoration of shape of previously crush fractured vertebrae; only limited RCT data is available but reduction in fracture rates are similar to those obtained with risedronate (see below). Consistent with the use of intravenous bisphosphonates in adult osteolytic conditions (metastatic disease, myeloma), there is substantial relief of bone pain. Children and parents also consistently report improved endurance for everyday tasks following infusions. This improvement diminishes and bony aches and pains increase as the time for the next dose of treatment approaches. It is likely that in the majority of cases, the initial therapeutic approach will be undertaken using intravenous bisphosphonates.

A study has been undertaken and published examining the effects of different doses of risedronate in children with moderate and severe OI (Bishop N et al. J Bone Miner Res. 2010 Jan;25(1):32-40) that showed a 45% decrease in fracture frequency for the two year period of the study compared to the two years prior to study entry. This work was undertaken in three UK centres (Sheffield, Birmingham and Glasgow) that all provided a specialist care setting for the children with additional therapy input. It was likely, in the view of the reviewers, that some of the benefit seen in terms of reduced fracture frequency was due to the specialised care setting.

Unpublished data from the largest trial of bisphosphonates in children with OI yet undertaken (POISE study; n=141) recruiting largely moderately affected children (two thirds had had six or fewer fractures prior to trial initiation) showed a similar fracture rate reduction of 47%. Similar to previous studies, this multicentre study enrolled children with OI in the setting of specialised clinical services including physio- and occupational therapy. Health economic evaluation of the multidisciplinary intervention has not been undertaken, but the impact on costs to the NHS of reducing fractures alone in this group is estimated at £19,868 annually.

The factors cited above combine to create a situation in which physiotherapy and occupational therapy interventions are both more feasible and result in increased benefits. Such therapies improve muscle strength, the range of joint movement and the range of activities undertaken. All these factors contribute to improved maintenance of bone mass and improved bone architecture, thereby reducing the risk of fracture in the short term, and of scoliosis and skull deformity in the longer term. The designated providers are committed to clinical audit of therapy interventions to further clarify the role of therapies and the benefits of these interventions.

## **2. Scope**

### **2.1 Aims and objectives of service**

The aim of the service is to provide a multidisciplinary approach to the diagnosis and management of infants and children aged 0-16 years with severe, complex or atypical osteogenesis imperfecta (SCA OI) to reduce the associated morbidity and mortality and to achieve optimal outcomes.

Strengthening bone tissue, reduction of fracture risk, rebuilding of crush fractured vertebrae and relief of bone pain are all outcomes reported from the institution of bisphosphonate therapy in a setting of comprehensive multidisciplinary care.

The service will be delivered through a 'Hub and Spoke' model incorporating the delivery of three levels of service. The four Level 3 'Hubs' are the nationally designated provider trusts: Birmingham Children's Hospital NHS Foundation Trust, University Hospitals Bristol NHS Foundation Trust, Great Ormond Street Hospital for Children NHS Trust (GOSH), and Sheffield Children's NHS Foundation Trust. These centres will, together, be responsible for the care of all infants and children with SCA OI in England. Patients and families will have the choice of which Level 3 centre they choose to attend.

Each designated Level 3 provider will sub-contract some services related to outreach clinics and service delivery to Level 2 centre or Level 1 centre provider trusts in their region. The specific role and responsibilities at each level are described in this specification (see section 2.1).

## **Strategic goals:**

- to create a cohesive national clinical service that delivers an improved availability of services in an equitable fashion across England;
- to enable collaboration in service development and research between the 4 designated Level 3 Centres;
- to achieve wide recognition for England as an international centre of excellence for both the clinical care and research of SCA OI.

Clinical goals are reflected in the specific outcome measures by which the success of the service are to be judged:

- reduction in fracture frequency;
- reduction in incidence of progressive scoliosis i.e. scoliosis progressing beyond 30 degree Cobb angle;
- reduction in incidence of basilar invagination.

The incidence of fractures in OI varies according to disease severity, age and growth rate, being higher when intrinsic bone turnover and activity is increased. Based on both published and unpublished data we would expect to reduce fracture frequency by between 45-50% relative to that expected for untreated patients based on historical data; we would also expect to demonstrate a continuing reduction over time in the number of fractures suffered throughout childhood to age 16 i.e. at the point of transition to adult services.

It is expected that a Quality of Life (QOL) measure currently in development will be available for use within the next three years.

## **Organisational outcomes**

Organisational goals are those which will demonstrate progress towards a cohesive and effective service at both the national and regional levels:

At national level :

- establishment of a single interconnected data system common to all four designated centres;
- six monthly meetings between the Level 3 centres;
- evidence of the development and updating of best practice and clinical guidelines;
- research;
- national clinical day annually – to involve Level 3 and Level 2 centres plus patient representatives;
- advertising of service;
- the Sheffield OI service coordinator will take on a national co-ordinating role on behalf of the four nationally designated centres.

At supra- regional level (Level 3 centres):

- clear and accountable leadership and management structures;

- effective sub-contracting relationships where required;
- outreach services in place;
- meetings for Level 2 and 1 centres to provide education, disseminate information and discuss problems;
- clinical multi-disciplinary team (MDT) meetings will be held as is clinically appropriate to deliver the stated aims and objectives of the service;
- operational management meetings will be held as is appropriate to deliver the stated aims and objectives of the service;
- availability of relevant evidence-based protocols and guidelines to other centres involved in the care of children with CSA O;I
- regular performance reporting.

The service will also be subject to generic key performance indicators (KPIs) in common with other providers within the NHS.

At both levels there will be demonstrable progress towards the implementation of all agreed standards with a year-on-year action plan.

## **2.2 Service description/care pathway**

The care pathways for the children fulfilling the criteria for entry to the service are detailed in the accompanying process maps and supporting information. An operational policy for the national service is being drawn up.

### **Description of disease/condition**

The fundamental defect in the majority of OI sufferers lies in one of the two genes encoding type I collagen, the major structural protein of bone and ligaments. Whilst in mild forms of OI the primary problem is a lack of adequate amounts of normal type I collagen, in the more severe forms of the condition the collagen that is produced is both inadequate in amount and defective in structure and material quality. The bone substance itself is over-mineralised with respect to the amount of collagen fibre, resulting in a material that is less able to absorb and dissipate energy than normal bone. It is therefore brittle. The overall effect on the skeleton is to produce bones that are architecturally inadequate for everyday loads and which break and deform readily.

All the bones of the skeleton are affected, so that vertebrae suffer crush fractures that lead to shortening of the vertebral column and are predisposed to significant scoliosis and kyphosis. This results in a small chest of abnormal shape with associated cardiorespiratory compromise. Softening of the base of the skull with protrusion of the odontoid peg may result in brain stem compression.

Out with the bones, the ligaments stretch more easily, allowing dislocation and subluxation of joints, requiring the use of muscle strength to maintain normal joint alignment. This joint hypermobility still significantly affects the quality of life as it results in ready fatigability of many muscle groups, so that mobility and the performance of the ordinary tasks of everyday living are impaired. All affected

individuals suffer from bone and muscle pain.

Diagnosis of OI is based on clinical criteria, referring primarily to the Silience classification (types I-IV) with occasional children diagnosed with rarer types (e.g. types V-XII). The diagnosis of these rarer forms is partly based on clinical features, but also on bone biopsy analysis (types V and VI) and genetic testing. Types VII, VIII and IX have defects in the genes CRTAP, LEPRE1 and PPIB respectively. Most cases of types I-IV are due to defects in the genes COL1A1 and COL1A2. Some children do not fit clearly within the standard classification and have no detectable mutation in any commonly tested gene. In terms of severity of disease: types III and V-IX are severe; type I is generally mild; and type IV encompasses a range between types I and other types. Additional forms of OI have described in the last 12 months due to mutations in the genes FKBP10 (which may be the same as Type VI but this is unclear at present), SERPINH1 and OSX/SP7. Other children have a clear OI phenotype, apparent recessive inheritance, and no identified mutation; these would also fall within the atypical group (see below).

For those to be served by the national service the definitions of severe, complex and atypical OI are as follows:

Individuals up to the age of 15 years and 364 days meeting the following criteria:

#### Severe OI:

- neonates with OI who have multiple long bone fractures;
- children/infants with OI who have one or more of the following:
  - six or more vertebrae crush-fractured/deformed (more likely to progress to scoliosis according to published data);
  - multiple limb deformities resulting in corrective surgery for more than one long bone and attendant frequent OT/PT input;
  - intractable bone pain despite intravenous bisphosphonate therapy.

#### Complex OI:

Children/infants with OI who:

- have cranio-cervical malformations such as hemivertebrae / fusion, creating risk of resulting in altered CSF flow;
- have basilar invagination, creating risk of resulting in neurological symptoms;
- have scoliosis requiring corrective surgery, or likely to progress to requiring corrective surgery (Cobb angle  $\geq 30^\circ$ );
- undergo Ilizarov or similar corrective surgery;
- experience complications of bisphosphonate therapy e.g. osteonecrosis of the jaw (not yet reported in any child).

#### Atypical OI:

Children/infants who have two or more of the clinical features of OI including:

- fractures;
- hypermobility;
- growth failure;
- typical facies.

Plus at least one atypical feature:

- unusual facies;
- craniosynostosis;
- arthrogyrosis;
- cystic bone disease;
- hypertrophic callus formation;
- lack of response to bisphosphonate therapy.

- or recognised features of those disorders classified as OI types V-XII, or with a clear recessive pattern of inheritance, Bruck syndrome, Cole-Carpenter syndrome or Caffey's disease.

The service will be delivered by four nationally designated provider trusts:

- Birmingham Children's Hospital NHS Foundation Trust
- Great Ormond Street Hospital for Children NHS Foundation Trust
- Sheffield Children's NHS Foundation Trust
- University Hospitals Bristol NHS Foundation Trust

These four organisations will be the Level 3 centre providers who, together, are responsible for the service as a whole. The Level 3 centre providers will be supported by co-ordination from the 'lead centre' – Sheffield Children's NHS Foundation Trust.

Level 3 centres will receive referrals, conduct the initial assessment, and make the diagnosis in referred infants and children, then establish a plan and initiate intervention with medical and/or other therapies as required (see process maps in section 3.1). Some children will be referred in the neonatal period. Others will be referred at a later stage when they meet the criteria for SCA OI (see section 1.2). The service will receive referrals for any children who meet the criteria provided they are aged less than 16 years. The service will retain responsibility for some children who remain under its care beyond 16 years if appropriate and part of planned transition but all individuals will be discharged into the care of a suitable adult physician by the age of 18 years. The number of patients transferring out of the SCA OI service into adult care will be recorded on a monthly basis.

Level 2 shared care centres will be those with an existing cohort of children who fulfil the criteria for the SCA OI service, and other children with OI who do not meet the criteria. Treatment in these centres will occur under the auspices of paediatricians who have tertiary level expertise in dealing with metabolic bone disease. Such centres will be able to monitor treatment both biochemically and radiologically. The full range of services offered by NHSEngland SCA OI service will be available through the Level 3 centre with delivery either at the Level 3 centre or locally in the form of out-reach, as appropriate.

Treatment in Level 1 shared care centres may occur under the auspices of paediatricians who will not necessarily have any specialist knowledge of OI. They will not be expected to take responsibility for the monitoring of the effects of treatment or for monitoring patients in clinic beyond basic biochemical monitoring and their usual clinical role. No routine radiological monitoring would be expected to be undertaken

in these centres (see below).

Level 3 centres will maintain the responsibility for the on-going care of some children with SCA OI although cycles of bisphosphonate therapy will be delivered in Level 2 and Level 1 shared care centres as well as in Level 3. These other centres will be sub-contracted to provide for the safe administration of bisphosphonates locally in line with the arrangements outlined in this service specification. Each patient should be offered an appointment to see their Level 3 MDT once every six months and may include review at a Level 2 centre in an outreach clinic where the clinical load in that centre justifies an outreach clinic. Arrangements will be tailored to the needs of the child and family. For instance, a typical arrangement once established in a relatively uncomplicated older child with SCA OI would consist of 3 monthly visits to the shared care centre (Level 1) for bisphosphonate administration with appropriate biochemical monitoring as required by the Level 3 centre with regular review by the Level 3 team in the aforementioned biannual clinics. Therapy needs that cannot be met solely through input at these clinics will be addressed through out-reach work by the Level 3 team and liaison and support of local therapists and/or through more frequent visits to the Level 3 centre, as appropriate. There will be a greater degree of involvement of the Level 3 team for those children who are younger and who have greater needs; it is likely that much if not all of the care in the first year of life will be delivered via the Level 3 centre, given the need for frequent therapy input. The process of devolving care locally is likely to be slower and more gradual in such cases.

### **Description of Level 3 centre and its activities**

In each Level 3 centre there will be a dedicated multidisciplinary team (MDT), the minimum requirement for which is as follows:

- named lead paediatrician
- named lead orthopaedic surgeon
- clinical nurse specialist
- physiotherapy
- occupational therapy
- psychology
- specialist social work input
- speech and language therapy (SALT)
- play specialists

### **Core interventions**

The core interventions are captured in the activity currencies and these costs are covered by the commissioning arrangements. The core activities are listed below:

- out-patient first attendance;
- out-patient follow-up attendance;
- intensive therapy days;
- in-patient admission;
- genetic test.

Most of these activities will take place within the Level 3 centre but there will be a

significant amount of peripatetic work that will generally be counted as “intensive therapy days”.

Peripatetic work will be undertaken by each Level 3 MDT where and when needs dictate. It may not be required for every child. This peripatetic work will usually take place in either the referring hospital (may be shared care hospital), the home or in schools. It will typically be undertaken by therapy staff but, on occasions (such as with early input to newborn infants with severe OI), there will be involvement of the clinical nurse specialist and other team members.

### **Indications for peripatetic involvement.**

In referring hospital:

- critically ill infant or child with severe, complex or atypical OI where there is a clear clinical need
- need for early assessment and input for severely affected infant prior to seeing the child in the centre.

Home visits:

- need to assess provision of aids to daily living, including mobility aids that cannot be undertaken in a clinical setting
- need to assess the suitability of accommodation and requirement within the same for adaptations.

School Visits:

- need for on-site assessment and advice to ensure that the appropriate provisions are made for the child within the school environment including education of school staff.

### **Other activities**

The Level 3 MDT will facilitate access to (but not directly provide) appropriately trained and experienced input from:

- orthopaedics – in respect of surgical interventions;
- neurosurgery - in respect of surgical interventions;
- radiology – for imaging that is not required for monitoring SCA OI treatment and for monitoring and/or screening for basilar invagination and scoliosis;
- clinical genetics (except in respect of atypical OI);
- orthotics;
- dentistry.

The costs of these services and individuals in relation to the management of SCA OI are not covered by the commissioning arrangements. Most of the above services will be provided in Level 2 or 3 centres, but some will be provided in a Level 1 setting. Specific services which **are** encompassed within the service specification are broken down below according to broad areas of activity:

- highly specialist equipment and aids
- specialist radiology



Qualifications required of all relevant staff are documented in the service standards (appendix 1)

### **Description of Level 2 and Level 1 centres and their activities**

Level 2 or Level 1 centres will be sub-contracted by their respective Level 3 centre. Level 3 centres will ensure that Level 2 or Level 1 centres are able to meet the terms and conditions of any sub-contract including meeting the standards and requirements of each level set out below (See appendix 1 for details and section 2.1)

Level 2 and Level 1 centres must be able to agree an appropriate sub-contracting arrangement with their respective Level 3 organisation to allow pass through payment.

Level 2 Shared Care Centres will also be expected to provide facilities to enable:

- environment and facilities for the safe administration of bisphosphonates
- radiological monitoring of patients
- biochemical monitoring of patients
- hosting of outreach clinics by the respective Level 3 centre
- co-operation with all governance requirements.

Level 1 centres will be expected to enable the administration of cycles of bisphosphonate therapy locally under a shared care agreement with the respective Level 3 centre. Local responsibilities in these cases will include:

- environment and facilities for the safe administration of bisphosphonates
- biochemical monitoring of patients
- cooperation with all governance requirements.

### **Diagnostics**

Genetic testing and review of bone biopsies performed for diagnostic purposes will be undertaken in Sheffield Children's NHS Foundation Trust, where expert analytical facilities are in place. These items are counted as separate currencies and are costed within the commissioning arrangements.

### **Genetics**

Molecular analysis and reporting of results will be done by appropriately skilled staff based in the Molecular Genetics Department at Sheffield Children's Hospital for samples from all four designated centres.

### **Histology**

Preparation, histologic analysis and reporting of results will take place at the Royal Hallamshire Hospital. Results should be available within ten weeks of the sample having been received by the Department of Histology.

### **Services not covered by the commissioned arrangements**

- surgical interventions (except insertion of central lines to deliver iv bisphosphonate therapy);
- management of orthopaedic problems e.g. correction of deformity;
- management of neurosurgical complications;
- routine management of fractures by the Emergency Department and orthopaedic services;
- local and community physiotherapy services including those located in shared care centre organisations;
- provision of wheelchairs, adaptations and non-specialist aids;
- pain management;
- routine clinical psychology e.g. needle phobia;
- genetic counselling for OI cases that are not atypical;
- genetic testing for OI cases that are not atypical;
- general paediatric outpatients and management;
- general paediatric inpatient stays and management;
- transport;
- Intensive Care Unit ( ICU) /High Dependency Unit (HDU) admissions.

### **Patient and public involvement and communications**

The Brittle Bone Society will act as a reference group for the designated centres for the review of changes in the service and of communication plans. The views of patients, carers and staff will be regularly and formally sought and the results made openly available. Patients, carers and support groups will be regularly updated with appropriate information on issues of clinical governance and the results of local and national audit. The providers will work with NHS England to ensure sufficient considerations are given to communications

### **Governance**

Appropriate governance arrangements will be put in place for both clinical and research activities (see standards document – appendix 1).

### **Risk management**

Care delivered by the SCA Childhood OI service providers must be of a nature and quality to meet the care standards, specification and agreement for the service. It is the trust's responsibility to notify the commissioner on an exceptional basis should there be any breaches of the care standards. Where there are breaches any consequences will be deemed as being the trust's responsibility.

Patients must be managed in line with the specification and care standards. Any deviation from these which has not been approved by NHS England is at the trust's risk both clinically and financially. It is the trust's responsibility to inform the commissioners of any such non-approved deviations on an exceptional basis.

Where a patient's presentation challenges the assumptions that underpin the specification, service standards and contractual arrangements it is the trust's responsibility to inform the commissioners on an exceptional basis, prior to any

treatment (except for emergency treatment) so that the implications of the patient's requirements can be considered. This does not affect situations where the Individual Funding Application process applies.

### **Service model and Care Pathways**

The care pathways for the children fulfilling the criteria for entry to the service are detailed in the process maps and supporting information. An operational policy for the national service is being drawn up.

### **Days/hours of operation**

There is no capacity in this service specification for care to be routinely delivered outside normal working hours. Contact details for the respective Level 3 centres will be provided to patients. Existing general out of hours arrangements will be defined by local arrangements.

### **Discharge Criteria & Planning including any transition arrangements**

Discharge from the service will take place following review in a transition clinic where practicable. Typically, discharge will take place due to age/maturity and occur between the ages of 16 and 18 years.

Patients will be discharged to an adult service consultant with an interest in osteoporosis. A comprehensive written summary of the patient's history and care under the service will be provided by the relevant Level 3 centre to the consultant taking over care within one month of the patient having been discharged from the SCA OI service. It is each Level 3 centre's responsibility to ensure that they have developed relationships with clinically appropriate adult NHS providers to facilitate transition of these patients

Once a child has been accepted into the SCA OI then they will not be completely discharged from the SCA OI national service until they have been transitioned to adult services.

### **2.3 Population covered**

This service specification covers patients registered with an English General Practitioner, resident in the European Union and eligible for treatment in the NHS under reciprocal arrangements.

Patients from Scotland, Wales and Northern Ireland are not part of this commissioned service and the trust must have separate arrangements in place.

### **2.4 Any acceptance and exclusion criteria**

The service is accessible to all patients under 16 with severe, complex or atypical OI

as described in this specification regardless of sex, race, or gender.

Providers require staff to attend mandatory training on equality and diversity and the facilities provided must offer appropriate disabled access for patients, family and carers.

When required the providers will use translators and printed information must be available in languages appropriate to the patient.

The provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation

### **Referral criteria, sources and routes**

Referral into the service will be according to the criteria for the definition of severe, complex and atypical OI in children under the age of 16 years. These definitions are listed in section 1.2.

Referrals can come from primary, secondary or tertiary care but there will be a process of triage by the MDT. This will be undertaken at regular weekly meetings. Referrals not fulfilling the criteria for SCA OI may be seen under the standard tariff or directed toward another provider.

### **Exclusion criteria**

Patients who are not included according to the definitions of SCA OI or who are 16 years or over at the time of referral will not be accepted under the umbrella of the SCA OI service. Screening will consist of a process of triage by the MDT that will be undertaken at regular weekly meetings.

Response time and prioritisation - the service will meet national waiting time guidelines and targets

## **2.5 Interdependencies with other services**

### **Whole System Relationships and Interdependencies**

The patients covered by this agreement will be receiving care from other health providers and service out with specialist teams. Key stakeholders include:

- universal and primary care services e.g. GPs, health visitors etc
- hospital services including ICU, general medical staff, general nursing staff, radiology department, trauma and orthopaedic staff, support and administrative staff
- local physiotherapy and occupational therapy services
- wheelchairs and orthotics providers
- local dietetic services
- local speech and language therapies

- local ophthalmology services
- interpreter services

### **Relevant networks and screening programmes**

The British Paediatric and Adolescent Bone Group (Medical Practitioners)  
 Skeletal Dysplasia Group  
 Brittle Bone Society  
 Osteogenesis Imperfecta Foundation (Europe)  
 Paediatric OI National Team (Nurses and Therapists)  
 National Osteoporosis Society  
 Arthritis Research UK-MCRN Clinical Studies Group

## **3. Applicable Service Standards**

### **3.1 Applicable national standards e.g. NICE, Royal College**

The nationally designated SCA OI providers must be fully integrated into their trust's corporate and clinical governance arrangements.

The commissioners and service will conduct a formal Joint Service Review at least every six months.

The service will be provided in accordance with current legislation, official guidance and good practice, including (without limitation) Good Clinical Practice and Good Healthcare Practice and shall comply with the standards and recommendations:

- contained in the Statement of National Minimum Standards;
- issued by any relevant professional body and agreed between the parties;
- arising from any audit and Incident and Patient Safety Incident reporting.

The service will also comply with the standards and recommendations from time to time:

- issued by the National Institute of Clinical Excellence (or any successor) and agreed and in writing between the commissioner and provider;
- issued by the UK National Screening Committee and the National Specialist Commissioning Advisory Group (or any successor of them) and agreed and in writing between the commissioner and provider;
- issued by any relevant professional body and agreed in writing between the commissioner and provider.

The Agreed Premises for delivery of the service will at all times:

- be suitable for the performance of the services;
- comply with any applicable Law and Good Healthcare Practice relating to health and safety;
- be sufficient to enable the services to be provided at all times and in all respects in accordance with this agreement;
- be well maintained, and kept in excellent decorative order in compliance with

- the Patient Environment Action Team (PEAT) parameters;
- be cleaned in compliance with PEAT and National Standards of Cleanliness.

### **Clinical Audit**

The designated centres will agree an annual programme of audit with commissioners and will present these at review meetings

## **4. Key Service Outcomes**

### **Quality Performance Indicator**

- reduction in fracture frequency;
- reduction in incidence of progressive scoliosis i.e. scoliosis progressing; beyond 30 degree Cobb angle;
- reduction in incidence of basilar invagination.

### **Quality & performance standards**

The providers will provide agreed performance monitoring data on a monthly basis. Where any elements of this deviate from the agreed plan, the service will provide a brief explanation accompanying the submission of the report. The commissioner may wish to follow this up and request further information to inform any necessary actions that will be agreed between the service and commissioners in the context of the terms and conditions of the agreement.