NHS
Yorkshire and the Humber
Clinical Senate

Free and full independent and impartial clinical advice

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Your Ref:

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1 March 2018

*Via email to:*
Jane Ellerton
Head of Strategic Commissioning
North Lincolnshire CCG

Dear Jane

**Senate Review of Ophthalmology Clinical Assessment and Treatment Service Specification**

Thank you for the opportunity to review your proposals for a Clinical Assessment and Treatment Service (CATS) to be procured by North Lincolnshire, North East Lincolnshire and East Riding Clinical Commissioning Groups (CCGs).

The objectives of the clinical review are to provide the CCG with an independent clinical view of the proposed service set out in the service specification. It is your intention to include our findings in a report to each CCG Commissioning Committee and to use the advice to finalise the scope of the specification. The members of the clinical review panel who reviewed the proposals through email and teleconference discussion are listed within the Terms of Reference enclosed with this letter.

The questions you asked us to consider are

- Is the service scope set out in the attached CAT service specification clinically safe to be delivered within a community based, consultant led service?
- Where the Clinical Senate panel feels that elements of the specification are not suitable for community based delivery we would like to understand the rationale for this.

The members of the panel shared their comments by email and broadly discussed their findings in a teleconference on 6th December. Our understanding of the documents was supplemented with a helpful discussion with you on 20th December.

I hope this letter provides a constructive summary of our comments and advice.

**Is the service scope set out in the attached CAT service specification clinically safe to be delivered within a community based, consultant led service? Where the Clinical Senate panel feels that elements of the specification are not suitable for community based delivery we would like to understand the rationale for this.**

1. The Senate is in agreement with the premise of developing a community service for ophthalmology. We recognise your concerns with the capacity of the existing hospital service, including the quality concerns raised by the CQC, and the need to find a solution for those issues. We are not clear how the proposals in this model fit with the wider acute services review and it would be helpful to understand this further. We are aware from discussion with you that there is already a community service working well in North East Lincolnshire and you feel there is opportunity to build on the successes of that service. The Senate supports the proposal for a community service to be part of the solution to the current capacity and quality issues with the hospital service. We have a number of concerns however with the ambitious scope of the community service as it is currently described and the current lack of detail on the governance, staffing, the supporting IT and data transfer.

2. Currently therefore the Senate advises that the service scope may not be clinically safe to be delivered within a community based, consultant led service and we hope that the following detail clearly sets out the rationale for this. We do however support the premise of a community service and we recommend that our comments are used to revise the specification to address those points of concern.

## Geography

3. Through our discussions with you we clarified that this specification is for a service commissioned by North Lincolnshire, North East Lincolnshire and East Riding CCGs who commission the hospital eye services (HES) delivered at hospital sites in Scunthorpe, Grimsby and Goole and which are all part of North Lincolnshire and Goole NHS Foundation Trust.

## The Breadth of Conditions

4. The Senate panel have concerns about the breadth of services included within the CAT service and recommend that commissioners reduce the list of services. As currently described the community service seems to be largely replicating a Hospital Eye Service in a community setting rather than working in partnership with the existing HES. Our reasons for recommending a reduced list of conditions are primarily due to:

- The inclusion of some emergency conditions which require immediate treatment and cannot wait for a 48-hour triage;

- The questionable benefit of including some of these conditions due to the requirement for expensive equipment to diagnose and treat those conditions and the compatibility of that equipment with HES;

- The potential impact on the stability of the HES.

5. Each of these issues is discussed in more detail in the sections below.

***Emergency Conditions***

6. The panel expressed concern about the inclusion of a number of conditions which due to their complexity and high risk require the need to assess the patient that same day or the next making them unsuitable for the proposed 48 hour triage. These include:

- R3 retinopathy;
- Iritis;
- Corneal Ulcer (this requires a more comprehensive description. Does this relate to acute presentation? Medical management of acute red eye would be a more appropriate definition for the service provided to avoid overlap with the Minor Eye Conditions (MEC) service);
- Acute angle closure;
- Maculopathy - this implies you are commissioning an intravtireal injection service. We recommend that more detail is needed to clarify whether this is the case or if it is the intention to only screen out those that don't need treatment. This has the potential to create additional appointments for patients who could have been seen just once and treated by the HES;
- Age Related Macular Degeneration (AMD) – the consensus from the panel is that new patients should see a consultant retina specialist as it is a very significant decision to start treatment. Follow up under allied health professionals under direct or indirect supervision of a consultant retinal specialist is reasonable (with access to an intravitreal injection suite, pharmacy support, Optical Coherence Tomography (OCT) machine, Eye Clinic Liaison Officer (ECLO), Low Vision Aid (LVA) clinic and regular audit). There are currently examples in the UK where AMD is managed in this way in a community provider setting.

***Children's Care***

7. It is noted that in section 3.2.1 and 4.4 it states that CCGs are seeking advice on the inclusion of people under the age of 18. The Senate panel are agreed that the majority of children's care would benefit from a less hospital based and more sympathetic environment and that this service could be adequately managed in a community setting with smooth transfer onto Specialist Ophthalmology Service for surgical intervention as necessary. It is noted that there are existing pathway models for shared care for children in other services and further details can be provided to commissioners if this would be helpful.

***Equipment and Compatibility with HES***

8. If the procurement results in a different provider in a different location from the HES this introduces the potential for a "seam" between services and commissioners will be aware of

the need to ensure that there is no delay in onward referral or duplication of tests.

9. In our discussion with you, you acknowledged the complexity of the equipment issues and the range of advice there is on this issue. The Senate advises that it is the breadth of services you have currently included in the community service that is complicating the issue of equipment. The current list would necessitate lasers, intravitreal injection suites, ultrasound, photography, OCT machines and angiography equipment and this brings with it the issues of compatibility with the HES equipment and the risks of duplicating tests. If the provider and HES purchase different makes of OCT or Field machine they may be incompatible or at the very least it will be difficult to import the data and back it up in both systems.

10. We discussed with you the value of including some of these conditions within the CAT scope as they greatly increase the complexity of the community service whilst not necessarily reducing the burden of work in the hospital service. Our recommendation is to reduce the scope of the specification to the higher volume routine work like glaucoma, macular degeneration, diabetes related conditions and cataracts. This would have the maximum impact on reducing the volume of work in the HES and considerably simplify the list of required equipment. Commissioners are also recommended to specify particular brands of machine to improve the compatibility with the HES equipment and additional detail can be provided if required.

11. We recommend that more detail on the diagnostic equipment is provided within the specification. We do not feel that the current list (although it is stated as not exhaustive) gives sufficient guide as to the service requirements, and recognition of the cost effectiveness of this, and makes no reference to addressing the compatibility issues. Commissioners are recommended to include wording in the specification that makes it clear that the provider must ensure appropriate equipment to meet the needs of the service and that this equipment is compatible with the HES equipment to enable data transfer and avoid duplication of tests.

12. The following is a list of equipment that the panel advises is necessary for a comprehensive eye clinic and that is deemed to be missing from current specification. This may be helpful to commissioners.

- Ophthalmic ultrasound which is essential for any ophthalmic service.
- Autofluorescence imaging*
- Fluorescein and (Indocyanine green) ICG angiography*
- Mydriatic examination including OCT angiography and choroidal imaging*
- (*the above are now standard care for investigating a new patient with retinal disease - they are delivered as a one-stop for new patients within HES where indicated- if they cannot be provided (and correctly interpreted) the patient will require a further unnecessary follow-up within HES to complete the full set of baseline diagnostics.
- B-scan
- Corneal topography

- Orthoptic assessment
- Visual field analysis ( to include neurological and glaucomatous field assessments)
- Optic nerve OCT or other imaging for glaucoma
- Ishihara colour vision
- Gonioscopy
- Exophthalmometry
- Indirect ophthalmoscopy with scleral indentation

***The Stability of the HES***

13. Commissioners are aware of the need to balance the development of the community service with the need to maintain an effective HES. The Senate has concerns that this balance is not achieved within the specification as it currently written. The specification states that emergency surgery or inpatient related diseases are to be the only conditions managed by HES which misrepresents the broad spectrum of ophthalmic diseases that are managed in HES of which only a small minority need either emergency surgery or inpatient care.

14. The community service cannot operate effectively without robust secondary care support to provide easily accessible urgent and emergency eye care and the Senate advises that the community service currently described will potentially destabilise the HES. Hospital eye service needs sufficient volume and breadth of cases to ensure consultants are seeing enough cases and trainees are getting exposure to a variety of conditions. There needs to be enough outpatient and elective work to justify the number of consultants required to staff a 24hr on-call rota and be attractive for recruitment. The proposed community service may result in out of hours on call being no longer feasible and it would be very difficult to support trainee ophthalmologists and recruit new consultants to such a reduced clinical environment. A HES also has research commitments that it will need to fulfil.

**The Relationship with the HES**

15. The panel agreed that there is not enough detail about the definition of those diseases referred onto the Specialist Ophthalmology Service and there are many ophthalmic conditions that are missing leaving it unclear under which service they will fall. The specification would benefit from greater clarification to fully understand the remit of the CAT service.

16. There is no mention of inflammatory eye disease (Uveitis), inherited ocular diseases, retinal vascular diseases other than diabetic retinopathy, other chorioretinopathies eg Central Serous Chorioretinopathy (CSC), myopic related diseases, adult strabismus, neuro-ophthalmology (emergency and elective), orbitopathies including thyroid eye disease, corneal degenerations and dystrophies, vitreo-retinal diseases other than emergency care and paediatric ophthalmology. These all need specialist input and whilst the specification states that "the specialist Ophthalmology service will manage patients with high risk and complex conditions" we are in agreement that greater clarity is needed on what is meant by

that statement.

17. The specification also does not provide any detail on the sharing of clinical records other than acknowledging the requirement for "seamless and timely transfer of data". There is a high risk that data will be lost or unavailable at the point of care resulting in care being compromised due to the incompatibility between the CAT and HES system. An example given is that of a patient managed within CATS for iritis who then presents late on a Sunday night at the hospital with a dense vitritis.

18. The Senate recommends that commissioners need to give further detail on when to escalate from the community to hospital setting. For each condition there are circumstances that would need to be seen in a hospital setting and the criteria for escalation is not defined within the specification. We understand from discussion with you that this detail will be addressed in discussion with the providers at a later date but the Senate remains concerned that the procedures are currently omitted and the out of hours arrangements remain unclear. The specification would benefit from further explanation on the timescale for onward referral.

**The Consultant Led Service and Skills and Competencies of Staff**

19. In our discussion with you it was confirmed that the proposed service will have a consultant on site every day delivering care and directly accountable for a team of optometrists, nurse injectors and technicians for example. There may be more than one consultant if the volume of work demands this. We did not discuss with you where the additional consultant staff would be sourced from. The Senate recommends that the consultant led service needs improved definition within the specification as it is currently unclear if the consultant is delivering the care or only offering oversight. The confirmation of an on-site consultant does open up the opportunities to have an expanded list of services which are safe to be delivered within the community setting but the previously raised points about the emergency conditions, equipment and impact on HES remain.

20. With regard to the skills and competencies of staff you have confirmed that you expect potential providers to expand on this as part of their response to the specification. The Senate recommends that the specification needs to include further detail to support the commissioner in these discussions. In our view it is insufficient to only state that the service will be delivered by appropriately skilled clinician.

21. We recommended that the specification states that every patient has a named consultant responsible for their care and that the specification makes it clear that the consultant is responsible for the team that delivers the care to the patient. Consultants would certainly need to be reassured that any colleagues working within the CATS schemes had the appropriate qualifications. Consultants may be unwilling to be accountable for a service with the uncertain level of expertise currently reflected within the specification. Success of this scheme is highly dependent on robust training and clear protocols both of which remain unclear within the specification.

22. In our telephone conversation with you we discussed the College of Optometrists certificates and the framework produced by the Clinical Council of Eye Health Commissioning which has qualifications for optometrists in glaucoma care for example. We recommended reference to the certification schemes in the specification. Our panel advises that there is

very little post-basic training currently available which will mean that specialist training and competency achievement will have to be delivered locally and will take 6 months to a year to complete. In discussion with potential providers commissioners will need to ensure that the development process is in place so that there are the staff ready to take on the work when the new service is launched.

23. The Senate also recommends that commissioners give consideration to the need for the clinical team within a CATS service to have broad expertise across all ophthalmic sub-specialities to ensure they have the competencies to deal with the full range of diseases and avoid the need for repeat visits for patients. This is directly relevant to one of the proposed outcomes which is to "ensure that duplicate testing of patients is avoided".

**Governance**

24. On reading the specification the Senate raised a number of questions about the accountability and governance of the service. This is answered in part through the clarification that the consultant will be on site and accountable for the clinical team.

25. In our discussion with you it was confirmed that you intend to develop the governance framework in the discussions with the providers. The Senate recommends however that commissioners include greater detail within the specification on the proposed governance of the service and this needs to include the provision of out of hours care and the integration with the Specialist Ophthalmic Service to ensure clinical safety. It is noted that 24 hour ophthalmic cover is proposed. Although there is only a small amount of overnight work those clinicians covering overnight do need the competence to deal with emergency situations where a 48 hour triage just isn't suitable.

26. The Senate also questioned whether the potential providers will be asked to provide previous audit data of clinical outcomes for all sub-specialities within ophthalmology that they are expected to manage. We recommend that new providers should also be able to clearly document their audit tools/governance systems including incident/Duty of Candour/ Serious Incident reporting tools and their quality assurance systems. CATS centres regardless of the type of professional staff involved need to follow the HES/NHS model of governance/training/educational and audit facilities and there is currently no mention of this within the specification.

**Exclusion for Temporary Residents**

27. The Senate raised concerns with the current wording of section 4.4 within the specification which states that this service will exclude patients who are not registered with the relevant CCG. This raised concerns for the treatment of holiday makers who have an acute presentation. In discussion with you it was confirmed that the patient would attend A&E and access ophthalmology services through that route. The Senate notes that there is an on call ophthalmology service if referral to the next available clinic does not provide quick enough access to manage the condition. You confirmed that if a temporary resident attends a GP then they will be granted temporary residency and able to access the CAT service. In order to make this clearer we recommended a change in wording to section 3.2 1 to expand the urgent access to seeing a specialist ophthalmic consultant.

**Learning from Other Models**

28. In our discussion of this specification Senate panel members shared examples of good practice from other parts of the country. Examples given include Great Yarmouth outreach clinicians which are led by trained staff with good supervision and system interface, and the consultant led community service under Any Qualified Provider (AQP) in Leeds. Panel members have offered to share these models and in discussion you confirmed that this would be helpful. Leeds CCG have offered for you to attend the next Leeds CCG/Leeds Teaching Hospitals Trust (LTHT) Consultant Led Ophthalmology Delivery Network (CLODN) meeting.

**Other Comments**

29. On page 6 the specification states that "patients presenting at A&E with ophthalmic problems will be initially seen in A&E. Where ongoing care is required, but can be provided as an outpatient, the patient will be referred by A&E into the CAT service. Patients presenting at A&E who require emergency surgery or inpatient stay will be referred to the HES service." The Senate advises that A&E doctors have insufficient training to correctly identify which patient is complex or straightforward and therefore decide which patients need surgery and inpatient admission. The expertise of the ophthalmologist is required for this. A&E doctors are trained to decide which patients need an opinion from an ophthalmologist and in the experience of the panel the A&E doctors pass any patients complaining of visual symptoms or ocular signs straight onto HES without further investigation/triage.

30. The specification states that it is "Providers responsibility to liaise with a GP". Successful triage depends on the detail about the eye condition and also detail about the patients general co-morbidities. Frequently the first information comes from a community optician generating the referral whilst general medical history may come from the GP. If the provider is independent to the main hospital Trust obtaining a general medical history will necessitate direct GP contact and the GP may not be able to provide this information within 48 hours. This brings into question who would be accountable if a delay takes place because the GPs can't produce this information within 48 hours.

31. The specification refers to the direct listing of surgical procedures within secondary care. The Senate panel raised concerns on the lack of clarity on the surgical review and the process for obtaining consent and suggests that this is made clearer in the specification.

**Conclusion**

32. In conclusion the Senate supports the premise of a community service for ophthalmology services and agrees that there is opportunity here to provide a convenient and high quality service for patients with the potential to provide an effective solution to the current challenges within the hospital eye service.

33. You asked the Senate whether the service scope set out in the CAT service specification is clinically safe to be delivered within a community based, consultant led service and our advice is that currently it may not be if the community provider is different to the HES

provider The safety of the community service is dependent on the competency of its staff, the IT interface, its governance and accountability procedures and its relationship with the HES, which needs to be sustainable. We recommend that all these areas need further consideration within the specification. Many of these safety concerns would be mitigated if the community provider is the same as the HES provider creating a seamless pathway for escalation to secondary care. If this is the way forward commissioners will need to evaluate the benefits of investing in expansion of the existing service compared to the creation of new community pathways and their impact on limited resources.

34. Of key concern to the Senate is the ambitious scope of services included within the current description of the community service. We advise that this scope includes some emergency conditions unsuitable for 48-hour triage and the range of conditions would necessitate expensive equipment for diagnosis and treatment. We question the value of their inclusion as they would not greatly reduce the capacity issues of the hospital service. If under different providers the broad scope of the service would also potentially destabilize the hospital eye service and the community service cannot operate effectively without this robust secondary care. Commissioners need to balance the development of the community service with the need to maintain an effective HES and our advice is that this balance is not achieved within the current specification.

35. Thank you for the opportunity to work with you on this proposal and I hope our comments are helpful to you in your further development of the specification of a community service.

Yours sincerely

**Chris Welsh**
**Senate Chair**
**NHS England – North (Yorkshire and the Humber)**

NHS
Yorkshire and the Humber
Clinical Senate

# CLINICAL REVIEW

# TERMS OF REFERENCE

**TITLE: Community Ophthalmology Services, Northern Lincolnshire CCGs**

**Sponsoring Organisation:** North Lincolnshire CCGs

**Terms of reference agreed by:** Jane Ellerton, Head of Strategic Commissioning at North Lincolnshire CCG and Joanne Poole, Senate Manager, Yorkshire and the Humber Clinical Senate
**Date:** 29th November 2017

## 1. CLINICAL REVIEW TEAM MEMBERS

**Clinical Senate Review Chair**: Steve Ollerton, GP and Clinical Leader for Greater Huddersfield CCG.

**Citizen Representatives**: At Senate Council discussion

**Senate Review Clinical Team Members:**

| Name | Job Title |
|---|---|
| Richard Allen | Head of Optometry at Colchester Hospital University and Independent Prescriber Qualified Optometrist |
| Roopesh Arjan | Optometrist, Lowestoft, Suffolk |
| Ben Burton | Consultant Ophthalmologist, James Paget University Hospital |
| Ella Bowers | Ophthalmic Nurse, Nottingham |
| Stephen Clark | Chair, West Yorkshire Eye Network and Clinical Advisor, Optometry |
| Louise Downey | Consultant Ophthalmologist, Hull and East Yorkshire Trust |
| Edward Doyle | Consultant Ophthalmologist and Clinical Director (SW Senate) |
| Stephen Winder | Consultant Ophthalmic Surgeon Sheffield Teaching Hospitals |

## 2. AIMS AND OBJECTIVES OF THE REVIEW

**Question:** Is the service set out in the CAT service specification clinically safe to be delivered within a community based, consultant led service?
Where the Clinical Senate panel feel that elements of the specification are not suitable for community based delivery, please explain the rationale for this.

**Objectives of the clinical review (from the information provided by the commissioning sponsor):**
The clinical review advice provided by the Senate will be used to finalise the scope of the service specification by 4th January 2018. The advice will also be reported to the CCG Commissioning Committee alongside the public and supplier engagement findings.

**Scope of the review:** The Clinical Senate will focus their review on the above 2 questions based on the information provided in the documentation. The clinical panel will supplement their understanding of the model through discussion with commissioners.

## 3. TIMELINE AND KEY PROCESSES

**Receive the Topic Request form**: 10th November 2017

**Agree the Terms of Reference**: by end November 2017

**Receive the evidence and distribute to review team**: Evidence received on 13th November and distributed to the panel on 27th November. Delay due to the sourcing of the clinical panel.

**Teleconferences:** The first Clinical Panel teleconference scheduled for late 6th December. The teleconference with commissioners scheduled for 20th December.

**Draft report submitted to commissioners**: 22nd December was the original request date and extended to 12th January due to the delay in arranging the commissioner teleconference due to commissioner annual leave and Christmas holidays. Report will be by Chair's letter.

**Commissioner Comments Received**: within 10 working days of the draft report being received

**Senate Council ratification**; at the January Council meeting

**Final report agreed:** end January

**Publication of the report on the website:** to be agreed with commissioners

## 4. REPORTING ARRANGEMENTS

The clinical review team will report to the Senate Council who will agree the report and be accountable for the advice contained in the final report. The report will be given to the sponsoring commissioner and a process for the handling of the report and the publication of the findings will be agreed.

## 5. EVIDENCE TO BE CONSIDERED

The review will consider the following key evidence:
Ophthalmology Clinical Assessment and Treatment Service - Service Specification (commissioners also provided the service specification for the Specialist Ophthalmology Service to demonstrate how the services link but this specification is not for review)
The review team will review the evidence within this documentation and supplement their understanding with a clinical discussion.

## 6. REPORT

The draft clinical senate report will be in the form of a letter from the Chair. It will be made available to the sponsoring organisation for fact checking prior to publication. Comments/ correction must be received within 10 working days.
The report will not be amended if further evidence is submitted at a later date. Submission of later evidence will result in a second report being published by the Senate rather than the amendment of the original report.
The draft final report will require formal ratification by the Senate Council prior to publication.

## 7. COMMUNICATION AND MEDIA HANDLING

The final report will be disseminated to the commissioning sponsor, provider, NHS England (if this is an assurance report) and made available on the senate website. Publication will be agreed with the commissioning sponsor.

## 8. RESOURCES

The Yorkshire and the Humber clinical senate will provide administrative support to the clinical review team, including setting up the meetings and other duties as appropriate.
The clinical review team will request any additional resources, including the commissioning of any further work, from the sponsoring organisation.

## 9. ACCOUNTABILITY AND GOVERNANCE

The clinical review team is part of the Yorkshire and the Humber Clinical Senate accountability and governance structure.
The Yorkshire and the Humber clinical senate is a non-statutory advisory body and will submit the report to the sponsoring organisation.
The sponsoring organisation remains accountable for decision making but the review report may wish to draw attention to any risks that the sponsoring organisation may wish to fully consider and address before progressing their proposals.

## 10. FUNCTIONS, RESPONSIBILITIES AND ROLES

The **sponsoring organisation** will

i. provide the clinical review panel with agreed evidence. Background information may include, among other things, relevant data and activity, internal and external reviews and audits, impact assessments, relevant workforce information and population projection, evidence of alignment with national, regional and local strategies and guidance. The sponsoring organisation will provide any other additional background information requested by the clinical review team.
ii. respond within the agreed timescale to the draft report on matter of factual inaccuracy.
iii. undertake not to attempt to unduly influence any members of the clinical review team during the review.
iv. submit the final report to NHS England for inclusion in its formal service change assurance process if applicable

**Clinical senate council** and the **sponsoring organisation** will:

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

**Clinical senate council** will:

i. appoint a clinical review team, this may be formed by members of the senate, external experts, and / or others with relevant expertise. It will appoint a chair or lead member.
ii. endorse the terms of reference, timetable and methodology for the review
iii. consider the review recommendations and report (and may wish to make further recommendations)
iv. provide suitable support to the team and
v. submit the final report to the sponsoring organisation

**Clinical review team** will:

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

**Clinical review team members** will undertake to:

i. commit fully to the review and attend all briefings, meetings, interviews, and panels etc. that are part of the review (as defined in methodology).
ii. contribute fully to the process and review report
iii. ensure that the report accurately represents the consensus of opinion of the clinical review team
iv. comply with a confidentiality agreement and not discuss the scope of the review nor the content of the draft or final report with anyone not immediately involved in it. Additionally they will declare, to the chair or lead member of the clinical review team and the clinical senate manager, any conflict of interest prior to the start of the review and /or materialise during the review.

**END**