

Form for assessment of our duties under: Section 14Z2: Patient and Public Participation Section 244: Duty to consult local authority

<p>Introduction</p> <p>Clinical Commissioning Groups have a duty under Section 14Z2 of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning.</p> <ul style="list-style-type: none"> This form is a tool to help commissioners identify whether there is a need for patient and public participation in their commissioning activity, and if required help them plan for a level of participation which is 'fair and proportionate' to the circumstances. The form must be completed at the start of the planning process for any commissioning activity and before operational commissioning decisions are taken which may impact on the range of commissioned services and/or the way in which they are provided. Completed forms may be used as evidence in the event of a legal challenge. Please retain a copy within your local system. 	
<p>Step 1 – Title of the plan/proposal/project/commissioning activity and a brief description (including key objectives where appropriate). <i>Possible examples - procurement of a new service, proposals for service change, national policy development or an operational commissioning decision which affects services, e.g. closure of a GP practice.</i></p>	
<p>Location: e.g. CCG, area</p>	<p><i>5 CCG areas of South Yorkshire and Bassetlaw – Sheffield CCG, Doncaster CCG, Bassetlaw CCG, Rotherham CCG and Barnsley CCG</i></p>
<p>Title and Brief Description of Proposal:</p>	<p><i>Speculative proposal for patient engagement on the introduction of Avastin into ophthalmology services as a choice of treatment for patients with Wet Age-related macular degeneration (wAMD). Avastin is an unlicensed treatment for wAMD.</i></p> <p><i>The ICS is currently undertaking a piece of work to ascertain how Avastin could be supplied to the ICS in order to become a treatment option. Patient engagement will only take place if this supply route can be determined and signed off.</i></p>
<p>Key Objectives of the Proposed Activity:</p>	<p><i>To engage with the patient population to ascertain if introduction of Avastin as an unlicensed treatment option would be supported.</i></p> <p><i>To engage with the patient population to gain information on the type of information that would need to be given to patients in order for them to make an informed choice to choose Avastin or other treatment options.</i></p>
<p>Step 2 – Is there likely to be an impact on patients and the public? <i>To assess impact you should consider the overall population and groups/individuals within that population who are likely to be affected.</i></p>	
<p>If the plans, proposals or decisions are implemented, do you think there will be:</p> <p>(a) An impact on how services are delivered? X Yes</p> <p>Please explain your answer and provide further details:</p> <p><i>Patients with a diagnosis of wAMD will be able to access the existing service and continue current treatments regardless of whether Avastin is introduced as a treatment option or not. However,</i></p>	

service delivery may change to accommodate the increase in demand on ophthalmology services anticipated over the next 5-10 years. This is likely to happen regardless of introduction of Avastin.

- (b) An impact on the range of health services available?
X Yes No

Please explain your answer and provide further details:

Introducing Avastin as a treatment option expands the range of treatments which a wAMD patient can choose from. As part of this work, there are ongoing discussions about other ways in which ophthalmology services can be delivered to make them more sustainable and meet predicted future demand.

- (c) Any other impact that you can envisage at this point in time? Please describe.

Some wAMD patients already receive Avastin as an off-label product. These patients will not need to be reconsented, however, they may experience a change in how their treatment is delivered as ophthalmology services change to meet increasing patient need. This is likely to happen regardless of introduction of Avastin.

*If you have answered yes to (a), (b) or (c), it is highly likely that the Section 14Z2 duty applies. Note: the duty **always** applies to planning of commissioning arrangements (regardless of impact).*

Does the Section 14Z2 duty apply to the activity? Yes No

Please explain briefly why you have answered yes or no to the above:

Introducing Avastin as an option increases the number of treatments on offer to patients with wAMD and patients will still be able to choose from existing treatment options. The ICS needs to engage with patients to ascertain if introduction of an unlicensed product as a treatment option would be a. acceptable to patients and b. what kind of information patients need in order to make an informed choice between licensed and unlicensed treatments.

Please note that if you have determined that Section 14Z2 does not apply to this particular activity it is good practice to retain a copy of the form should a challenge be made at a later date.

Step 3 – Describe any existing arrangements to involve patients and the public which are relevant to this plan/activity and/or provide relevant sources of patient and public insight? *Examples could include patient and public views by patient and public voice (PPV) partners; surveys; intelligence on patient and public views from partners including other commissioners, Healthwatch and voluntary and community organisations.*

Please briefly complete each question below:

- (a) What arrangements/mechanisms are already in place to involve the public which are relevant to this activity? (These may be local, regional, or national):

There are no known mechanisms in place to involve the public in discussions about Avastin introduction at a national or local level.

- (b) How will the insight available to you help to inform your decision?

Insight gained through the process of communicating and engaging with the public will help to inform any decisions made about introducing Avastin, method of introduction, and how patients should be offered choices within services. Insight will also help the ICS to identify further opportunities to research or questions to answer to ensure public confidence in use of Avastin if introduced.

Please note that consideration of existing arrangement and patient and public insight will help inform any additional arrangements required under step 4.

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Step 4 – Are additional arrangements for patient and public involvement required for this activity and in particular how will you ensure that ‘seldom-heard’ groups, those with ‘protected characteristics’ under the Equality Act, and those experiencing health inequalities are involved? (In due course, it may be appropriate to develop a full communications and engagement plan).

a) If yes, provide a brief outline of your approach and objectives for any additional patient and public participation:

The comms and engagement team will support the workstream in patient and public involvement, including methods to ensure hearing from a range of voices, including seldom-heard groups, people with protected characteristics and those experiencing health inequalities. There is ongoing clinical and pharmaceutical engagement by the ICS workstream with leads across organisations, though there may also be a need for wider staff engagement.

b) Have you considered the following:

Seldom-heard groups

Yes No

Nine Protected Characteristics

Yes No

Health Inequalities

Yes No

c) Briefly describe how your proposed participation will be ‘fair and proportionate’, in relation to your commissioning activity?

The introduction of Avastin does not reduce other choices available to patients and affects a relatively small proportion of staff and patient population.

d) At this stage whilst there is no legal requirement to engage a decision has been taken that this is best practice.

Step 5 - Planning for impact and feedback

(a) Provide a brief outline of how the information collected through patient and public participation will be used to influence the plan/activity.

The communications and engagement team will support the workstream to set up methods with which to collect information through patient/public or employee engagement.

Information collected about opinions of introducing Avastin will be considered when planning ophthalmology services. Information about how to inform patients of their right to choose a treatment and the positives and negatives of Avastin could also be used to plan the process by which patients will be given a choice, consented and reviewed.

(b) How will the outcomes of participation be reported back to those involved? (refer to your communications and engagement plan, if appropriate):

The communications and engagement team will support the workstream to feedback outcomes to participants. Participants that request specific feedback will be given it.

(c) How will you assess the ongoing impact of the change on patients and the public after it has been completed?

Impact of the change will be collected through patient experience data and outcome data of receiving different treatments options.

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s244 (2013 Health Scrutiny Regulations) duty to consult local authorities

The regulations state that an NHS body must consult the local authority where they have under consideration any proposal for a substantial development or variation in the provision of the health service in the area of that local authority (2013 Health Scrutiny Regulations 23[1]).

Date this 14z2 form was taken to the JHOSC: <to be completed at JHOSC meeting>

The JHOSC believe that this is a substantial development or variation in the provision of health services from the perspective of the local authority and therefore require that they are formally consulted on this matter (please tick):

Yes: <to be completed at JHOSC meeting>

No: <to be completed at JHOSC meeting>

Please explain? <to be completed at JHOSC meeting>

If the JHOSC have asked to be formally consulted then formal public consultation will also take place.

If the JHOSC have not asked to be formally consulted, do they feel that this change is significant enough to warrant formal public consultation, or would direct engagement/ involvement of affected patients be the appropriate course of action? (please tick):

Formal public consultation: <to be completed at JHOSC meeting>

Engagement/ involvement of affected patients: <to be completed at JHOSC meeting>

Once this form is completed please retain a copy for your records.