Substantial development or variation of health services in Medway – protocol for consultation by NHS bodies with Overview and Scrutiny Committees

1. Introduction

This protocol establishes a framework for consultation by NHS bodies with Medway Council’s Overview and Scrutiny Committees (OSCs) on proposals under consideration for any substantial development of the health service in or affecting the community in Medway or any proposal to make any substantial variation in the provision of such services. The protocol has been discussed with the Strategic Health Authority, NHS Medway (the PCT), Medway NHS Foundation Trust, Kent and Medway NHS and Social Care Partnership Trust, the South East Coast Ambulance Trust and the Local Involvement Network (LINK).

2. Duties placed upon NHS bodies to consult

Each local NHS body has a duty to consult the relevant OSCs set up by Medway Council on any proposal it may have under consideration for any substantial development of the health service in or affecting Medway or on any proposal to make any substantial variation in the provision of such services. This is additional to any discussions that NHS bodies will have with the Council, as distinct from the OSCs about service developments, especially where they link to services provided or commissioned by the Council. The duty to consult relevant OSC Committees is also additional to the duty placed upon NHS bodies to consult and involve patients and the public.

The NHS body will discuss any proposals for service change with the relevant OSC committee at an early stage as part of the Committee’s work programming process in order to agree whether or not the proposal is substantial and at this point there will be discussion about how consultation with the OSC will be undertaken. The local NHS body will make it clear when the consultation period will end and will allow sufficient time for the OSC to consider the matter and reach a view. Government guidance on consultations states that full consultation should last for a minimum of 12 weeks although it is recognised that in some circumstances the consultation period may have to be shorter.

In Medway, responsibility for the overview and scrutiny of health and social care services for adults rests with the Health and Adult Social Care OSC. Responsibility for overview and scrutiny of health and social care services for children rests with the Children and Adults Overview and Scrutiny Committee. The Health and Adult Social Care OSC has principal responsibility for matters bridging services for children and adults.

3. Identifying who is the consulting body

Where an NHS Trust plans to vary or develop services locally it will discuss the proposal with the relevant Medway OSC to determine whether the proposal is substantial. If the outcome of the discussion is that the proposal is a substantial development or variation the Trust must consult the OSC.
Where a NHS Foundation Trust intends to vary its authorisation and the variation would result in a substantial variation of goods and services provided by the Trust to NHS patients and commissioned locally by PCTs, it must consult relevant OSCs. If an OSC considers it should refer the issue referral would be to MONITOR (the independent regulator of Foundation Trusts) and not to the Secretary of State.

NHS Medway (the PCT in Medway) is responsible for consulting on the planning and commissioning of services for the local population. However another “lead” PCT may be responsible for consultation on any substantial variation or development where a number of PCTs commission services from an acute or other type of NHS Trust.

Guidance from the Centre for Public Scrutiny (CfPS) suggests that PCTs should have mechanisms in place to ensure that joint consultation takes place where there is no lead commissioning PCT, or if a proposal relates to services across more than one PCT. The relevant OSCs in Medway will rely on NHS Medway to ensure that this happens. This could involve coordination of the consultation by a Strategic Health Authority.

It is important for the OSCs to have a clear understanding of which body will be responsible for considering the responses to consultation and taking the final decision on a substantial service development or variation.

4. Gathering Information about potential proposals for “substantial” change

NHS bodies will be requested to make information about planned reconfiguration activity available to the relevant OSCs at their meetings clearly identifying service developments and variations on which OSCs will be consulted either formally (because they are “substantial”) or informally. This will enable each Committee to create capacity within work programmes to respond to forthcoming consultation and to respond to issues that arise during the year.

5. Defining a "substantial" variation or development

A “substantial variation or development” of health services is not defined in regulations. Department of Health guidance and good practice indicate that in deciding whether a proposal is substantial, the following issues should be considered:

- Changes in accessibility of the service. For example, both reductions and increases on a particular site or changes in opening times for a particular clinic. There should be discussion of any proposal which involves the withdrawal of in-patient, day patient or diagnostic facilities for one or more speciality from the same location.

- Impact of the service on the wider community and other services, including economic impact, transport and regeneration.

- Number of patients/service users affected. Changes may affect the whole population (such as changes to accident and emergency) or a small
group (patients accessing a specialised service). If change affects a small group it may still be regarded as substantial, particularly if patients need to continue accessing that service for many years (for example, renal services). There should be an informed discussion about whether this is the case and which level of impact is considered substantial.

- Methods of service delivery eg moving a particular service into a community setting from an acute hospital setting.

National guidance encourages OSCs and NHS bodies to agree a method of evaluating the need for formal consultation. In line with guidance issued by the Department of Health, CfPS and the Independent Reconfiguration Panel (IRP). Medway OSCs will expect the relevant NHS Trust to **notify the relevant OSC of every proposed service development or variation and to take into account the guidance set out above and the questions set out in Appendix 1 when evaluating whether or not a proposed service development or variation should be defined as "substantial" and thereby subject to formal consultation with the relevant OSC. Appendix 1 provides a clear indication of where it is likely that the relevant OSC would challenge a decision not to define a change as "substantial". The template at Appendix 2 will be used by the NHS bodies to ensure that relevant information is consistently supplied to the OSCs.**

6. Changes that result from national policies for service modernisation

When significant changes are proposed about how NHS organisations are structured, they do not automatically constitute substantial variations or developments. Changes that either alter the delivery of management or administrative functions of NHS bodies, or the number of NHS bodies, are not substantial variations or developments as outlined in the exemptions within the relevant Regulations. OSCs will be consulted along with other stakeholders in these circumstances and the power of referral to the Secretary of State is not available.

However where proposals involve specific changes to service delivery, which impact upon patients, carers and the public in Medway, NHS Trusts will be expected to enter into discussions to identify whether the issue is substantial and to consult OSCs as set out in this protocol.

Likewise, the establishment and development of an Independent Treatment Centre (ITC) is not initially a substantial variation or development as it is the establishment of a new service provider. However if the commissioning PCT proposes changes to services received by patients as a consequence of the establishment of an ITC it should discuss the proposals with the OSC to agree whether or not these proposals are substantial.

7. Handling disagreements about what is “substantial”

If the relevant NHS body and the OSC cannot agree whether an issue is "substantial" the NHS body will provide the OSC with information and reasons why they consider the issue is not substantial and the OSC may seek views from other NHS bodies **such as the SHA**. If it proves impossible to reach an agreement, the
OSC and NHS body may ask the Independent Reconfiguration Panel for informal advice on whether the issue should be regarded as substantial.

If agreement still cannot be reached and the OSC believes the issue is substantial it may refer the matter to the Secretary of State on the basis of inadequate consultation. At this point it would be for the Secretary of State, and then potentially the Courts, to determine whether it is substantial.

8. Scrutiny of specialised services

The commissioners of NHS services that are highly specialist and provided across a large geographical area are required to consult all OSCs that consider any proposed variations or developments to be substantial. The Medway OSCs will rely on NHS Medway to alert them to any proposed change to specialised services where the proposed change affects Medway residents. NHS Medway will identify the body responsible for consultation with OSCs across the area affected. This may be a commissioning group established through a number of PCTs, a specific Trust or a national commissioning group.

When Medway OSCs are consulted directly by a NHS body outside Medway about changes to specialised services, or invited to be part of a joint OSC involving several other local authorities, the relevant Overview and Scrutiny Coordinator will seek a view from NHS Medway and the Medway LINK so that PCT and LINK advice about potential local impact is taken into consideration by the relevant Medway OSC in its response or in its contribution to the work of a joint committee.

9. Joint Overview and Scrutiny Committees

Where there are proposals for substantial variation or developments to services affecting more than one OSC area the consulting NHS body has a duty to consult all the OSCs affected. In these circumstances the law requires the affected local authorities to establish a joint committee for the purpose of responding to the consultation. In some circumstances affected OSCs may delegate the power to respond to one OSC.

In line with CfPS guidance the NHS body leading the consultation should provide sufficient information about the proposal, the evidence used to require the action proposed, and the anticipated impact of the variation or development upon existing and future patients and carers to each of the affected OSCs at an early stage. It is important for sufficient time to be allowed for OSCs to decide whether the proposal would be substantial for the people within its local authority area or not.

10. Variations in services provided by NHS Foundation Trusts

The rules governing consultation by NHS Foundation Trusts with OSCs are different to those covering other NHS bodies. NHS Foundation Trusts must consult the relevant OSC if they propose to apply to MONITOR to substantially vary the provision of protected goods or services in Medway. Protected goods or services are those goods and services provided to NHS patients and commissioned locally by PCTs.
Medway’s OSCs will have regard to CfPS guidance which says an application by a Foundation Trust could be considered “substantial” where the application asks to provide additional or reduced services compared to the current services provided. If the OSC is not satisfied with the level or timing of consultation or where it considers that the proposed application would not be in the interests of health services in Medway it may report to MONITOR in writing. There is no power of referral to the Secretary of State in relation to NHS Foundation Trusts.

11. **Changes in independent healthcare provision**

The powers and duties associated with health overview and scrutiny apply to all services provided by or for the NHS and include independent providers in primary care eg GPs, dentists, pharmacists. For NHS commissioned services and independent sector providers who are contracted to provide NHS services the commissioning body is responsible for any consultation with OSCs. The OSC may invite a representative from the provider to supply information and attend meetings but cannot require attendance as these organisations are not subject to the requirements placed upon NHS bodies in relation to health scrutiny.

12. **Identifying and using expert witnesses**

In line with CfPS guidance Medway OSCs may call witnesses who can provide a specialist, objective or independent view of the issues when gathering evidence for their response to NHS proposals. Consideration will be given to drawing on advice and evidence from a range of organisations including service user groups, the LINK, professional organisations, academic institutions and the NHS.

13. **Responding to consultations and preparing a response**

Where time permits the relevant OSC will respond to the consulting NHS body by the given deadline with its comments and views in writing and will explain the process it has followed, the evidence it has considered and identify any witnesses that have contributed. The written response will summarise any areas of disagreement between the OSC and NHS body and include recommendations and suggestions for reaching a consensus.

The OSC may request a report on the outcome of all the consultation undertaken by the NHS body on the proposed service variation or development in order to take a view on how the consulting body has responded to the views it has received to ensure that the final decision is in the interests of local people.

14. **Receiving the NHS response**

At the end of the consultation an OSC may conclude that the consultation has not been adequate or that the proposal is not in the interests of the local health service in Medway. If local resolution cannot be reached the OSC may refer the issue to the Secretary of State or in the case of a Foundation Trust to MONITOR where they are not satisfied:

- with the content of consultation or the time allowed
• that the reasons given for not carrying out adequate consultation are reasonable

• that the changes are in the interests of the health service in Medway.

Referral will be a last resort after every effort has been made to reach agreement locally, noting that the Strategic Health Authority has expressed its willingness to contribute to any discussion to resolve a local dispute about the scale of change or its impact. The relevant OSC will notify the NHS body if it is minded to make a referral and provide a copy of the referral.
Appendix 1

Definition of a health service development or variation as "substantial" and therefore subject to consultation with relevant Overview and Scrutiny Committee (OSC) - Checklist for NHS bodies and OSCs

It is a matter for the lead NHS body to decide if a proposed service variation or reconfiguration is “substantial” and therefore subject to formal consultation with the relevant Overview and Scrutiny Committee (OSC). OSCs will wish to understand why a change is being proposed and what the intended and likely outcomes will be for patients and the public in Medway.

<table>
<thead>
<tr>
<th>Key questions for NHS bodies</th>
<th>Circumstances in which the relevant OSC may challenge a decision not to designate a change as “substantial” and not to formally consult</th>
</tr>
</thead>
</table>
| 1. What is the reason for the proposed service development or variation? | • Failure to brief the OSC on the proposed change and the range of options considered  
• Perception of change being driven by financial considerations over and above benefits to patients |
| 2. How extensive, inclusive and adequate is the consultation process? | • Lack of evidence of adequate consultation with patients and the public in planning and developing the proposals for change  
• Lack of evidence of adequate consultation with other key stakeholders (such as voluntary sector and social services)  
• Lack of evidence of account being taken of patient, public and stakeholder views in the development of the proposed change  
• Strong opposition to change as consequence of patient and public consultation |
| 3. How will access to services be affected? | • Lack of evidence of assessment of impact of change on Medway patients, their carers and the public  
• Lack of evidence that local health needs assessments or health equity audits have been taken into account  
• Particular communities will experience greater adverse effects of change than others and in particular vulnerable people (now and in the future)  
• Absence of transitional arrangements to ensure no loss of access during period of change |
| 4. What demographic assumptions have been made in formulating the proposals? | • No evidence that demographic projections have been taken into account  
• Failure to address future patient flows and/or catchment areas for services  
• Disagreement about assumptions made on catchment areas for new national or regional centres of excellence and future patient flows particularly for specific groups of patients eg children, people with particular conditions |
<table>
<thead>
<tr>
<th>Key questions for NHS bodies</th>
<th>Circumstances in which the relevant OSC may challenge a decision not to designate a change as “substantial” and not to formally consult</th>
</tr>
</thead>
</table>
| 5. What provisions are being made for the effects on patient flow of initiatives around choice and commissioning? | • Insufficient indication of whether the proposed change will generate a significant decrease or increase in demand for a service arising from patient choice, payment by results and practice based commissioning  
• Absence of contingency plans for financial “cushioning” if any additional capacity in the proposals is not taken up |
| 6. What is the clinical evidence on which proposals are based? | • Insufficient information to satisfy OSC that the proposal will lead to just as good or preferably improved outcomes and experiences for Medway patients supported by robust clinical evidence  
• Absence of local evidence that the proposals will lead to good clinical outcomes for patients/evidence of disagreement between clinicians  
• Likelihood that particular groups will be less well off even where the majority will have better outcomes  
• Lack of evidence about how the proposal will contribute to achievement of national and NHS priorities/targets in Medway |
| 7. How will the proposed reconfiguration contribute to joint working? | • Failure to consider how patient pathways across health and social care will improve to provide a more “seamless service” as a consequence of the change. |
| 8. How will the proposal help the NHS achieve its health improvement goals and reduce inequalities? | • Lack of information about how the proposed change will contribute to NHS Medway’s achievement of targets relating to health improvement and reduction in health inequalities  
• The proposal has the capacity to increase inequalities for any groups of the population |
| 9. What infrastructure will be available to support redesigned or reconfigured services? | • Failure to consider transport and infrastructure issues in the context of sustainable transport policies, public transport routes and frequency of transport services |
Health Overview and Scrutiny

Health Service development or variation - assessment form

In order that the relevant Health Overview and Scrutiny Committee can assess whether it agrees that a proposed service change or development is “substantial” please provide the following details.

A brief outline of the proposal with reasons for the change and timescales

Extent of consultation
(a) Have patients and the public been involved in planning and developing the proposal?
(b) List the groups and stakeholders that have been consulted
(c) Has there been engagement with the Medway LINK?
(d) What has been the outcome of the consultation?
(e) Weight given to patient, public and stakeholder views
Effect on access to services
(a) The number of patients likely to be affected
(b) Will a service be withdrawn from any patients?
(c) Will new services be available to patients?
(d) Will patients and carers experience a change in the way they access services (i.e., changes to travel or times of the day)?

Demographic assumptions
(a) What demographic projections have been taken into account in formulating the proposals?
(b) What are the implications for future patient flows and catchment areas for the service?

Can you estimate the impact this will have on specific groups?
(a) What will be the impact on children?
(b) What will be the impact on people with disabilities?
(c) What will be the impact on older people?
(d) Has an equalities impact assessment been carried out of this proposal?
Choice and commissioning
(a) Will the change generate a significant increase or decrease in demand for a service arising from patient choice, payment by results and practice based commissioning?
(b) Have plans been made for “financial cushioning” if additional capacity is not taken up?
(c) Is the proposal consistent with World Class Commissioning and reflected in NHS Medway commissioning plans?

Clinical evidence
(a) Is there evidence to show the change will deliver the same or better clinical outcomes for patients?
(b) Will any groups be less well off?
(c) Will the proposal contribute to achievement of national and local priorities/targets?

Joint Working
(a) How will the proposed change contribute to joint working and improved pathways of care?
Health inequalities
(a) Has this proposal been created with the intention of addressing health inequalities and health improvement goals in this area?
(b) What health inequalities will this proposal address?
(c) What modelling or needs assessment has been done to support this?
(d) How does this proposal reflect priorities in the JSNA?

Wider Infrastructure
(a) What infrastructure will be available to support the redesigned or reconfigured service?
(b) Please comment on transport implications in the context of sustainability and access

Do you believe the outlined proposal is a substantial variation or development?

Is there any other information you feel the Committee should consider in making its decision?