From Dr Sarah Wollaston MP, Chair

The Rt Hon Jeremy Hunt MP
Secretary of State for Health
Department of Health

12 May 2016

Dear Secretary of State

I have been contacted in my capacity a Chair of the Health Committee by a solicitor who has acted on behalf of a number of patients who were seriously injured following failed treatment by outsourced healthcare providers, including the recent Vanguard/Musgrove Park cataract case in Taunton and the Independent Sector Treatment Centre initiative introduced in 2003.

My correspondent has noted the answers to a number of recent Parliamentary questions tabled in the wake of the Vanguard/Musgrove Park cataract case, but has raised concerns with me about the arrangements both for ensuring that providers to whom services are outsourced are competent to carry out the work which is contracted, so that patient safety is not compromised (as it appears to have been in the Vanguard/Musgrove Park case), and for ensuring that appropriate indemnity arrangements are in place so that the cost of any failures on the part of the outsourced provider do not have to be picked up by the NHS.

I understand from the information which my correspondent has sent me that responsibility for both these issues lies with the Trust, or clinical commissioning group, which contracts with the outsourced provider. In the Vanguard/Musgrove Park case, the Trust concerned clearly failed on the first point (ensuring that the outsourced provider was competent), and has been unable to tell my correspondent whether it has succeeded on the second (ensuring that it is able to recover the cost of rectifying the provider’s mistreatment).

I am not seeking information specific to the Vanguard/Musgrove Park case, which I understand the Trust itself has investigated, and shared its learning from. However, the case does appear to raise some wider issues on which I seek your reassurance.

First, what monitoring and support does the Department, or NHS England, undertake of local trusts’, and clinical commissioning groups’, contracting with outsourced providers? Whilst responsibility both for ensuring the competence of the contractor, and for making arrangements for the reimbursement of the NHS in the case of a necessity to rectify the contractor’s mistakes, lies with the contracting local Trust or CCG, I would expect either
the Department or NHS England (or both) to take a close interest in the arrangements which are being made. In particular, I would expect both to want to ensure that local trusts and CCGs are putting patient safety at the forefront of their minds throughout the process of putting outsourcing arrangement in place.

Secondly, I would be grateful for your reassurance about the lines of accountability in cases where problems arise for patients in such circumstances. In the Vanguard/Musgrove Park case, I understand that the Trust contracted with Vanguard, which then subcontracted with another company which provided clinical staff, which in turn subcontracted to a third company for provision of equipment. In such circumstances, it is very easy for responsibility for any failures to be avoided. **What arrangements does the Department expect local trusts or CCGs to have in place when services are outsourced to contractors, or subcontractors, to ensure that accountability is clear, so that those responsible can be held to account for any failures, and patients are able to direct complaints about unsatisfactory service provision appropriately?**

I look forward to your reply. I would appreciate receiving a reply by Thursday 26 May.

Yours sincerely

Dr Sarah Wollaston MP
Chair of the Committee
Thank you for your letter of 12 May on contracted healthcare providers. Following consideration of my response, you may also wish to contact NHS England directly if you would like more detail on the support they provide to Clinical Commissioning Groups (CCGs).

As you are aware, CCGs are responsible for securing the provision of services to meet the health needs of their population, and we expect them to do so. CCGs should therefore commission services from the provider that they feel offers the best services for the local population in line with the legislative framework, and as part of this, the Department expects CCGs to hold providers to account. As contract holders, CCGs have levers to hold providers to account for poor performance. In the first instance, this can involve local meetings between commissioner and provider to try and resolve problems, but can escalate to financial sanctions and even early termination of the contract. Nationally, we have put a duty of candour in place on all providers to speak up when things go wrong.

In response to your first question regarding monitoring of trusts and CCGs and what support is provided to them, I should emphasise that it is the responsibility of CCGs to monitor their contracts, and that of trusts to meet their contractual and regulatory obligations. However, NHS England does provide a range of support to CCGs to increase their commissioning capabilities. NHS Improvement and the Care Quality Commission (CQC) have a similar role in relation to trusts.

As the independent regulator of health and adult social care providers in England, the CQC has a key responsibility in the overall assurance of safety and quality of health and adult social care services. Under the Health and Social Care Act 2008 (the 2008 Act) all providers of regulated activities, including NHS and independent providers,
have to register with CQC and follow a set of fundamental standards of safety and quality below which care should never fall.

The CQC assesses providers against the fundamental standards of safety and quality. A CQC inspection asks five questions of every service and provider; are they safe, effective, caring, well led and responsive to people’s needs.

Failure to comply with some of the fundamental standards is an offence and, under the 2008 Act, CQC has a wide range of enforcement powers that it can use if the provider is not compliant. This includes:

- issuing a warning notice;
- imposing, varying and removing conditions of registration;
- issuing a monetary penalty notice for prescribed offences;
- prosecuting for offences;
- suspending registration; and
- cancelling registration.

In response to your second question on accountability, CCGs are accountable to NHS England, and NHS England is in turn responsible for ensuring that the health services which both it and CCGs commission are high quality and deliver value for money. Although the Department ultimately holds NHS England to account for its commissioning activity, it has no role in individual contracts.

CCGs and NHS England, when commissioning Foundation Trusts, NHS Trusts as well as independent sector providers and others, to deliver non-primary care clinical services, must do so using the NHS Standard Contract published each year by NHS England. The NHS Standard Contract requires the provider of clinical services to put in place and maintain in force (and/or procure that its sub-contractors put in place and maintain in force) at its (or their) own cost (and not that of any employee) appropriate indemnity arrangements.

In situations where providers operating under an NHS Standard Contract wish to subcontract (“outsource”) clinical services to another provider, the Standard Contract makes clear that this can only happen with the commissioner’s consent (which can include consent to the specific proposed terms of the subcontract). The ‘lead’ provider also remains fully responsible to the commissioner for the performance of the subcontractor.

NHS England provides a model form of subcontract – which ‘flows down’ the relevant provisions from the main NHS Standard Contract into a subcontract template. However, its use is not mandatory.
Where performance concerns are identified, NHS England has the ability to exercise formal powers to either provide an enhanced support to a CCG, or in rare circumstances to intervene where it believes that a CCG is failing or is at risk of failing to discharge its functions.

Patients have the right to make a complaint about any aspect of NHS care, treatment or services, however it is contracted, and this is firmly written into the NHS Constitution. If a patient would like to make a complaint about healthcare they received, they can do so either to the organisation that provided the healthcare or the organisation that commissioned that NHS service. Concerns can also be raised by contacting regulatory bodies, such as the CQC.

I hope this reply is helpful.

JEREMY HUNT
From Dr Sarah Wollaston MP, Chair

Simon Stevens  
Chief Executive  
NHS England

Letter by email to

9 June 2016

Dear Simon

You may be aware of the attached correspondence which I have had with the Secretary of State. The response from the Secretary of State suggests that I should contact NHS England for more detail on the support which you provide to CCGs. There are two points on which I would be grateful for a response from you.

I understand from the Secretary of State’s letter that the NHS Standard Contract requires the provider of standard services to put in place and maintain in force (and/or procure that its sub-contractors put in place and maintain in force) appropriate indemnity arrangements; and that NHS England provides a model form of sub-contract which ‘flows down’ the relevant provisions from the main NHS standard contract into a sub-contract template. However, I also understand from the Secretary of State’s letter that the use of the model form of sub-contract is not mandatory. Further, the Secretary of State has not specified what “appropriate” indemnity arrangements are in this context. The specific point I raised in my letter was to ask whether arrangements are in place to ensure that the cost of any failures on the part of the outsourced (sub-contracted) provider do not have to be picked up by the NHS. Are you able to reassure me that any trusts which sub-contract clinical work must have in place arrangements to ensure that the NHS can recoup the cost of treatment for patients which becomes necessary as the result of a failure on the part of the sub-contractor, such as that which occurred in the Vanguard/Musgrove Park case?

My second question is more general. I appreciate, as I said in my original letter to the Secretary of State, that responsibility both for ensuring the competence of the sub-contractor, and for making arrangements for the reimbursement of the NHS in the case of a necessity to rectify the sub-contractor’s mistakes, lies with the contracting local Trust or CCG. Nonetheless, again as I said in my letter to the Secretary of State, I would expect NHS England to take a close interest in the arrangements which are being made. What monitoring does NHS England undertake of outsourcing, or sub-contracting, of NHS clinical services, to ensure that any systemic problems are picked up and measures put in place to resolve them? In that context you might like to comment particularly on how
NHS England ensures that local trusts and CCGs are in a position to ensure that the providers with which they sub-contract are competent to carry out the work which is being sub-contracted, which clearly was not so in the Vanguard/Musgrove Park case.

It would be helpful if you could reply by Monday 27 June.

Yours sincerely

Dr Sarah Wollaston MP
Chair of the Committee
8 July 2016

Dear Sarah

Thank you for your letter of 9 June 2016, in which you raised questions about the arrangements for commissioning and sub-contracting of clinical services.

Your first question was whether any trusts which sub-contract clinical work must have in place arrangements to ensure that the NHS can recoup the cost of treatment for patients which becomes necessary as the result of a failure on the part of the sub-contractor.

Under the NHS Standard Contract, which must be used when commissioners contract with any provider for services other than primary care, there is a specific provision (at General Condition 11.2) under which a commissioner may recover costs and losses which it incurs as a result of the provider’s (or its sub-contractor’s) clinical negligence (through a claim being made by or on behalf of a patient for the breach of a duty of care to that patient) or breach of contract (for example, a failure to deliver services in accordance with good clinical practice). Losses recoverable would include, where appropriate, the cost of putting right operations that had been incorrectly performed. There would obviously be a requirement to demonstrate negligence or breach of contract (as appropriate) by the provider or its sub-contractor.

In respect for a NHS Trust or Foundation Trust reclaiming such costs from a subcontractor, this will depend in part on the terms of the subcontract between them. Where the Trust has put in place the model subcontract published by NHS England, then General Condition 11.2 will effectively apply as between lead provider and subcontractor – so the lead provider will be protected and can reclaim its losses from the subcontractor.

Sub-contracting of clinical services by providers happens in such a wide variety of circumstances and in relation to such a wide variety of services that it has not been considered sensible to enforce use of a particular form of sub-contract. However, any alternative local subcontract, properly drafted, should pass down the indemnity obligation, and it is the responsibility of the lead provider to ensure that it does so.

However, even if a sub-contract does not include a specific indemnity along the lines of General Condition 11.2, if the sub-contractor has failed to deliver services in accordance with the terms of its sub-contract, the lead provider would be

High quality care for all, now and for future generations
entitled to seek to recover from the subcontractor the costs and losses which it has incurred as a result of that failure. This could be done on the basis of the contractual principle that, where there is a breach of contract, the injured party may claim, as damages, any sums which may be required to put it in the position it would have been in had the breach not occurred – which would include, for example, the cost of rectifying poorly performed clinical services.

It is also worth noting that the terms of a contract or sub-contract will not affect the rights of any patient to seek and recover damages from the provider or subcontractor in respect of clinical negligence on its part.

Your second question was about monitoring of outsourcing, or sub-contracting, of NHS clinical services, to ensure that any systemic problems are picked up and measures put in place to resolve them.

As you know, under the current statutory framework, it is primarily for the Care Quality Commission (CQC), through its national inspection regime, to license and monitor the quality and effectiveness of clinical services provided by different providers (whether NHS or non-NHS bodies and whether acting as lead provider or subcontractor). CQC inspections are an important means of identifying patient safety issues at specific providers, and we expect CCGs and trusts to take CQC reports fully into account in their local procurement and commissioning processes.

Through the NHS Standard Contract and model subcontract, we provide the contractual tools which enable commissioners and trusts to monitor and assure quality of care locally – along with detailed guidance on their use. Under the Standard Contract, subcontracting of any service by the provider is subject to the prior approval of commissioners, and commissioners may insist on seeing and approving the terms of the proposed subcontract as a condition of giving that approval. More broadly, the Contract and model subcontract:

- require providers to run services in line with recognised good practice and to comply with national standards on quality of care – the NHS Constitution, for instance, and the Fundamental Standards of Care regulations;
- require providers to adhere to national guidance on specific service areas, such as infection control, safeguarding, the care of dying people and the duty of candour;
- require the provider to demonstrate that it is continually reviewing and evaluating the services it provides, taking into account patient feedback, complaints and surveys, Patient Safety Incidents and Never Events, learning lessons and implementing improvements; and
- provide processes through which commissioners (or lead providers) can intervene to ensure that high-quality care is delivered – by requiring regular submission of monitoring information, requiring Remedial Action Plans to address service deficiencies, and ultimately by suspending services temporarily or terminating them permanently.
We expect CCGs and Trusts to use these tools and guidance effectively in fulfilling their statutory functions to commission and provide safe, high-quality care.

Yours sincerely,

Simon Stevens
CEO, NHS England
Dear David

You may be aware of my correspondence with, first, the Secretary of State, and then with the Chief Executive of NHS England, concerning sub-contracting, or outsourcing, in the NHS. I enclose the relevant correspondence, which is I hope self-explanatory.

In his reply to my letter of 9 June, Simon Stevens notes that “under the current statutory framework, it is primarily for the Care Quality Commission (CQC), through its national inspection regime, to license and monitor the quality and effectiveness of clinical services provided by different providers (whether NHS or non-NHS bodies and whether acting as lead provider or subcontractor)”. That comment came in response to my question about monitoring of outsourcing/sub-contracting of NHS clinical services, to ensure that any systemic problems are picked up and measures put in place to resolve them. The Secretary of State’s response also refers to the role of the CQC.

In the light of Simon’s response, and that from the Secretary of State, my question for you is, does the Care Quality Commission undertake work which would enable it to pick up any systemic problems with the outsourcing/sub-contracting of NHS clinical services? It is clear that the responsibility for individual outsourcing arrangements lies with the local trust or CCG which decides to enter into them, and it is for those individual trusts or CCGs to ensure that the necessary arrangements are in place for—above all—patient safety, and for the reimbursement of any costs in the event of the failure of the arrangements. Nonetheless, it seems to me that it is important that there should be a mechanism to ensure that any systemic problems are identified and addressed—to “join the dots”, as it were, of any instance of similar problems arising at different places involving different trusts or CCGs. The responses from the Secretary of State and from Simon Stevens seem to indicate that neither the Department of Health nor NHS England provide that mechanism themselves: the response from Simon Stevens seems to imply that the responsibility lies with the CQC.

It would be helpful to have a response to this letter by Friday 2 September.

Yours sincerely

[Signature]

Dr Sarah Wollaston MP
Chair of the Committee
Dear Sarah,

Thank you for your letter of 28 July 2016, in which you asked whether the Care Quality Commission (CQC) undertakes work which would enable it to pick up any systemic problems with outsourcing/sub-contracting of NHS clinical services. I note the responses you have already received from the Secretary of State and Simon Stevens.

At the CQC, we make sure that health and care services in England provide people with safe, effective and high-quality care.

To do this effectively, it is really important that people tell us about their experience of care. This helps us to decide where, when and what to inspect. When we look at quality of care, we look at what matters most to people, based on five key questions - Is it safe? Is it effective? Is it responsive to people’s needs? Is it caring? Is it well-led? We monitor, inspect and rate the quality of care of providers and tell them where they need to make any improvements in their standards of care. If they do not meet the legal requirements, known as Fundamental Standards, we take action to make sure they improve.

All organisations providing health or adult social care services are required under the Health and Social Care Act 2008 (the 2008 Act) to register with CQC, regardless of the type of organisation they are or how the care is contracted or commissioned. Where we identify concerns in quality of care of services being provided we are able to take enforcement action as outlined in the response from the Secretary of State.

CQC’s remit is limited to the assessment of the provision of services and it does not have the legal remit to assess commissioners of services. However, if a provider of care services is also engaged in outsourcing services, we may look at how the organisation works with those service providers and how it monitors any services it outsources. This would form part of our assessment of how well-led the provider is and is not intended to identify any systemic problems with the outsourcing/sub-contracting of NHS clinical services. The 2008 Act allows us to take enforcement action only where we have concerns related to the quality of care provided rather than the commissioning or sub-contracting of services.
We have set out in our Guidance to Providers how we inspect services provided by a third party. The guidance can be found at: http://www.cqc.org.uk/sites/default/files/20150327_acute_hospital_provider_handbook_march_15_update_01.pdf.

A provider will often have an arrangement in place where a third party organisation provides part or all of a service, often on the provider’s premises. Where this is the case, it is essential that the services work effectively with those provided by the third party.

The inspection team will not inspect or rate the third party service as part of the provider’s inspection. However, they will consider the care pathways between the service and the provider’s own services as part of their inspection. Our reports will explain where a third party provider is delivering part or all of a core service and who that third party provider is.

When planning the inspection we will consider whether it would be helpful, for the public and people using services, if we inspected the third party service at (or close to) the same time.

Therefore, we would always inspect the third party provider in their own right and we may undertake the inspections at the same time. Any issues identified with the care offered by the third party provider would not be reflected in the ratings of the provider who has outsourced the services.

Where concerns about the quality of care are identified during the course of our inspections we will alert the commissioners of or the organisation contracting out those services, where appropriate, to the concerns we have and what action we are proposing to take to ensure they are aware. It is also in their interests to consider any concerns raised with respect to contracting arrangements which may be in place.

Thank you again for writing and I hope you find this response helpful.

Yours sincerely,

David Behan
Chief Executive