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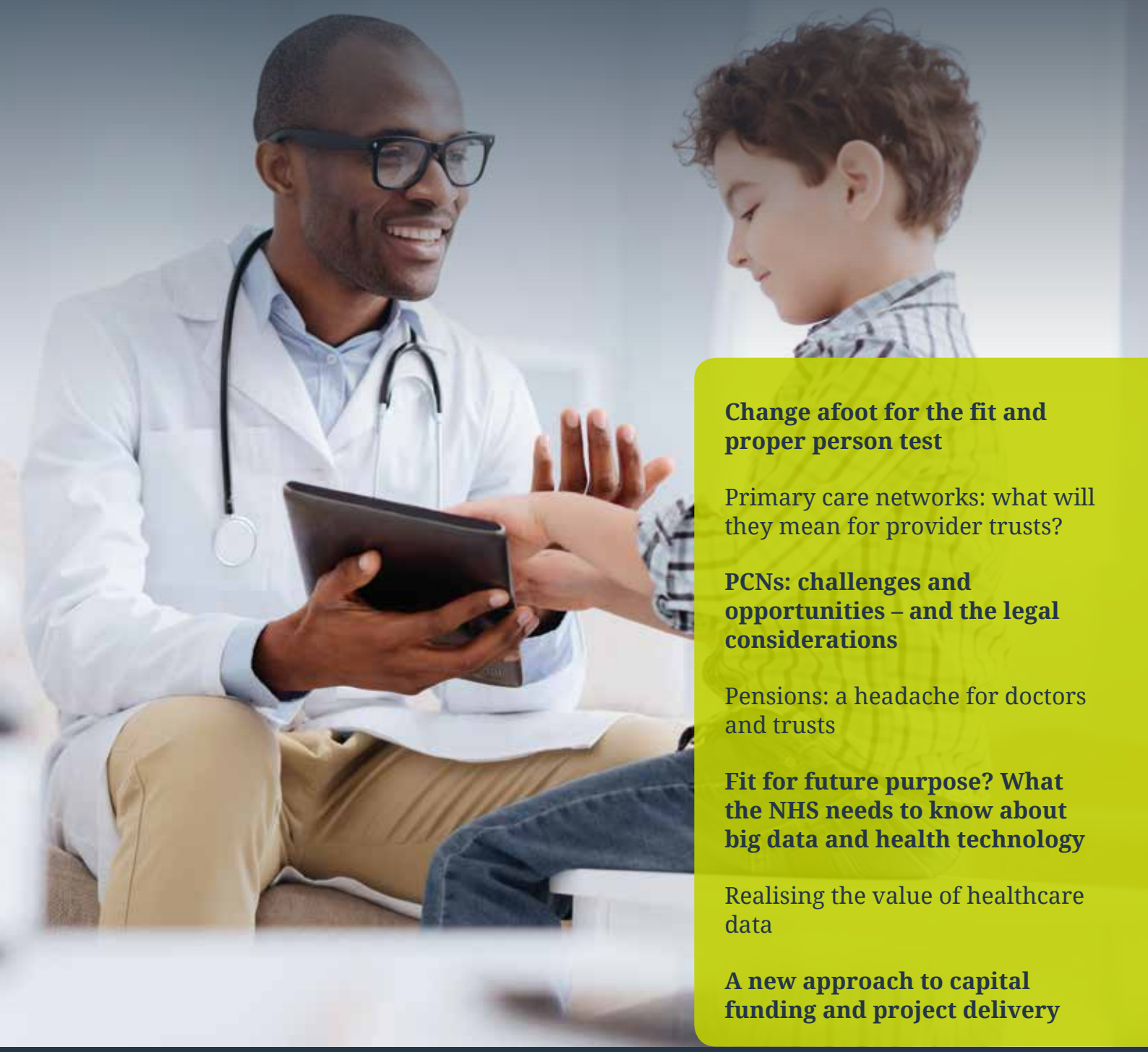
Healthcare Newsbrief



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Welcome

Welcome to the autumn edition of Hempsons' healthcare newsbrief – produced to coincide with the NHS Providers' annual conference in Manchester in October. We are hoping to meet many of you on our stand and to hear about the issues which matter to you.

We know the Kark review of the fit and proper person test has been a key concern for many boards. Hempsons partner, Andrew Davidson looks at what is proposed and asks whether its recommendations resolve some of the problems.

Many of you will be thinking about some of the changes in the NHS's structure which are beginning to have an impact. Primary care networks are groupings of practices covering populations of 30,000 to 50,000. Trusts will increasingly have to work closely with them and many boards are wondering what opportunities and challenges they will present. We have two articles exploring this – one written by Miriam Deakin, NHS Providers' director of policy and strategy, and the second by Hempsons partner, Alison Oliver, on the legal issues.

Pensions are another big concern for boards as many will be aware of consultants rejecting extra hours or responsibilities, or even retiring early, because of the impact of tax owed on their future pensions. This is an exceptionally complex area where the government is consulting on changes but trusts are coming under pressure to find their own solutions. Andrew Davidson assesses the two main ways in which trusts can help – and finds them both problematic.

You will all have heard of big data and what its use could mean for the treatment and identification of illnesses. But the massive datasets held by the NHS could also have significant value – EY look at how this could be monetarised and our own Chris Alderson looks at what would need to be in place before this could be progressed.

Finally, partners Crispin Pettifer and Oliver Crich look at an existing mechanism used by trusts which could help wider areas – such as integrated care systems – access capital for rebuilds and refurbishments. At a time when little capital is reaching the NHS, this could help plans to improve care which involve some element of building work or repurposing get off the ground.

We hope you will find something to interest you in this newsbrief. If you are at the conference, I hope you have an enjoyable time and I know the Hempsons team is looking forward to meeting you. Alternatively, if you are reading a hard or electronic copy after the conference please feel free to contact the authors to discuss any of the issues raised.

GRAHAM LEA,
MANAGING PARTNER
g.lea@hempsons.co.uk

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Change afoot for **the fit and proper person test**

Key points

- The fit and proper person test has been widely criticised and the government commissioned a review of how it operates.
- Tom Kark QC came up with seven recommendations, only two of which the government has accepted so far –
  i) accepted standards of competence for directors and
  ii) a database of their details.The other five are still being consulted on.
- Trusts can take some action now to prepare for changes, but much has still to be decided.

The fit and proper persons test (FPPT) for NHS directors has been in place for nearly five years – but has found few supporters.

Last year the government commissioned a review of how it was working out in practice. Tom Kark QC delivered the review in February 2019 and made seven recommendations. Almost immediately the government announced that they would accept the first two recommendations and would consider the others. Baroness Harding is currently leading a consultation on the remaining recommendations.

In the executive summary of the report Kark says that he found "…few fans" of the FPPT as currently applied.

Some regard it as:

"…simply a distraction or a tick box exercise, just another hoop to go through…Essentially it does not ensure directors are fit and proper for the post they hold, and it does not stop the unfit or misbehaved from moving around the system."

His recommendations are aimed at remedying some of the defects in the FPPT.

Background

The FPPT was introduced by Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the regulations) on 27 November 2014 for NHS provider organisations.

The FPPT applies to directors and those performing functions of directors. It is enforced by the Care Quality Commission (CQC).

The regulations state that directors **cannot** be:
- On the DBS held barred list.
- An undischarged bankrupt.
- Responsible for, involved in or privy to **serious mismanagement** or **serious misconduct**.

The regulations also state that directors **must**:
- Have necessary qualifications, skills and experience for the role.
- Be of "good character".

The Kark recommendations

Kark recommended:

1. Separate review of FPPT in social care.
2. The development of core standards of competence (accepted).
3. Set up a central database of information about directors (accepted).
4. Mandatory references for all directors.
5. FPPT should be extended to all commissioners and arm's length bodies (ALBs), including NHSI and NHS England.
6. Disbar directors for serious misconduct.
7. Remove the phrase 'privy to' from the FPPT.

In addition, he recommended that the wording of the FPPT be amended.

At present the regulations state that the obligation has been breached where:

"A director has been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying out a regulated activity or providing a service elsewhere, which if provided in England, would be a regulated activity."

Kark recommends that the word "privy" is removed on the basis that it is unclear what it adds to the definition. We expressed concerns about this element of the definition when it was introduced in 2014 because it appeared to us to be needlessly wide and could, as Kark suggests, adversely affect a director who had been only marginally aware of misconduct or mismanagement in a former role.

Kark did not have time to consider the FPPT in the social care sector but recommended that a separate review be undertaken.

Standards of competence

Kark recommends the development of a "core competencies" model. NHS organisations will be required to show the CQC that their directors are competent with reference to this model.

Kark has suggested these competencies:

- Governance including:
  - board
  - clinical
  - financial.
- Patient safety and medical management.
- The importance of learning from whistleblowing and 'speaking up'.
- Complying and encouraging compliance with the duty of candour.
- The protection, security and use of data.
- Awareness of current information systems.
- Equality and diversity.
- Nolan principles.

Kark has not gone as far as to recommend a "gateway" or accreditation approach that would require directors to undergo formalised training or assessment. He has recommended that NHS organisations have in place ways to assure themselves (and ultimately the CQC) of their director's competence with regard to the specific competencies.

This will be the subject of further guidance rather than any amendment to the existing regulations.

It would greatly assist NHS organisations if the guidance could set out, in some detail, not just what the core competencies are but also how employers can assure themselves that they have been achieved in each case.

The CQC will consider whether an NHS organisation has complied with this obligation as part of their well-led inspection.

We anticipate that appraisals, 360 degree assessments and individual personal development plans will be useful in this regard.

National director database

NHSI will hold a database of information about NHS directors. This will be accessible by potential employers. Kark intended this recommendation to minimise what he described as the "revolving door" of directors leaving one organisation under a cloud only to reappear in another NHS organisation later.

Kark suggests that the database should include the following information about each director:

- Name.
- Current employer.
- Job description of current employment.
- A full employment history and explanation of gaps.
- History of training and development undertaken.
- Available references from previous employers.
- All relevant appraisals and 360 reviews.
- Any upheld disciplinary findings.
- Any upheld grievance findings.
- Any upheld whistleblowing complaint.
- Any upheld finding pursuant to any trust policies or procedures concerning employee behaviour.
- Any Employment Tribunal judgment relevant to the director's history.
- Any settlement agreements relating to work in any health-related service.
- Criminal convictions.
- Whether the director is or has ever been disqualified or disbarred as a director.

There has been some debate about whether putting this database together will be a "massive task" or "not overly onerous" (both views are expressed to Kark and mentioned in the report).

Full details on how the database is to be created and maintained have yet to be published but we do not underestimate the scale of the task and expect it to take some time before it is fully operational.

Directors will be able to rely upon their rights as data subjects under the GDPR, not just to see the information stored but also to rectify any mistakes. NHSI may also introduce its own process for checking the data.

The other recommendations

It remains to be seen whether Kark's other recommendations will be accepted and implemented.

They are:

- **Mandatory references** – Kark recommends that, as in other sectors such as the financial services sector, all NHS organisations should be obliged to give "full, honest and accurate" mandatory references for directors when they seek work in another NHS organisation. He expresses concern that directors are often given "vanilla" references as part of settlement packages and that this is of limited use to prospective NHS employers. Kark recommends that the content of such mandatory references should be determined by NHSI but sets out (in Appendix 3 to the report) some suggested contents including information about any FPPT concerns that the employer has.
- **Extending the FPPT** – Kark recommends that the FPPT should be extended to all commissioners and ALBs such as NHSI and NHS England. There are some enforcement issues associated with this recommendation because, at present, the CQC is the enforcer of the FPPT and they have no power over commissioners/ALBs. We would not expect this to be an overwhelming difficulty to overcome and, as Kark has suggested, NHSI and NHS England could voluntarily adopt FPPT now if they so choose.
- **Disbarring directors** – in order to reduce the "revolving door" effect Kark suggests setting up a body to disbar/disqualify directors who are proven to have been guilty of "serious misconduct". He suggests that this body might be called the Health Directors' Standards Council (HDSC). Sensibly he suggests that there might be a limitation period of five years for complaints except in exceptional circumstances.

Baroness Harding is taking forward consultation on these additional recommendations and it is unclear whether they will be implemented. We expect it to be made clear by the time the Workforce Implementation Plan has been published. The Interim People Plan, published on 3 June this year, makes a brief reference to Kark but provides no further details on implementation.

Pressures on NHS directors

Section three of the Kark Report sets out his summary of other reports of relevance to the FPPT. Kark refers to the Kings Fund report on leadership in the NHS (2018) and its findings that leadership vacancies were widespread and that a culture of blaming individuals for failure was making leadership roles less attractive. The report identified a high level of regulatory burden and a constant pressure to report "upwards" to national bodies. It also identified how regulatory or political interventions to remove leaders for failing performance or financial targets suggested that individuals were sometimes held to account for systems failings.

In our experience it has rarely been harder to perform the role of a director in the NHS. The issues identified by the Kings Fund report are major contributors towards the "leadership churn" referred to by Kark.

The operational and financial pressures on NHS directors are significant and are unlikely to reduce in the short to medium term.

In addition, recent developments have added to the pressures upon NHS directors. We identify just a few below:

- **Pensions** – recent changes to the tax treatment of pensions have led to the well-publicised concerns that clinicians are leaving or reducing their NHS commitments, but the same rules apply to NHS directors. The Department for Health and Social Care have said that there is no evidence that NHS managers are leaving the NHS. That may be true but the changes add to existing pressures on NHS directors.
- **Potential for prosecution** – earlier this year the CQC prosecuted a care home manager for a failure to observe fundamental standards. The prosecution opened a discussion about s.91 of the Health and Social Care Act 2008. This provision allows the CQC, in principle, to prosecute directors personally for a failure to comply with fundamental standards. Although we would expect this provision to be rarely used by the CQC it is an example of another pressure on NHS directors.
- **Exit payments** – although not yet in force (and we have been waiting since 2015) the government still intends to impose a cap of £95,000 on public sector exit payments. This will undoubtedly have an adverse impact on NHS directors when they leave their employment and could lead to earlier than planned departures once the date for implementation has been fixed.
- **Severance payments** – NHS organisations are restricted in the severance payments they can make to NHS employees, including directors. Directors are aware that, unlike the private sector, a smooth exit is unlikely to be accompanied by an ex gratia payment unless approved by NHSI/HMT.

What to do now

We recommend that NHS organisations consider now how they can best comply with the accepted Kark recommendations (and think ahead in relation to the other recommendations).

We suggest that you:

- Review how you currently record director competencies – are your records complete and up to date? Are there any gaps in training/experience?
- Ensure appraisals/360 degree assessments are up to date.
- Review whether you have sufficient information to provide to NHSI for the database.

ANDREW DAVIDSON, PARTNER AND HEAD OF EMPLOYMENT NORTH
a.davidson@hempsons.co.uk

Andrew supports employers in the health, social care and private sector on employment law issues. Andrew has a national reputation for his work in handling concerns about doctors (under the MHPS framework), dealing with discrimination issues, employment tribunal claims and TUPE in particular and he has considerable expertise across healthcare employment law. He regularly provides training for clients on a wide range of employment law and HR issues and is a regular speaker at national conferences. He was recently on the Panel, alongside Chris Hopkins of NHS Providers, for a webinar on the Fit and Proper Person Test.

Primary care networks: what will they mean for provider trusts?

The director of policy and strategy at NHS Providers, Miriam Deakin said:

"The announcement of primary care networks (PCNs) in the long term plan (LTP) marks a significant shift for the health and care sector – and for trusts. The expectations placed on PCNs are considerable and range from acting to "finally dissolve the historic divide between primary and community health services", to addressing challenges in general practice, to acting as the building blocks on which integrated care systems (ICSs) will function successfully."

While there is recognition in NHS England/Improvement that PCNs are not the answer to everything, and can't be given too much to do too quickly, it is clear that the approximate 1,260 PCNs across the country are expected to become the principal mechanism to achieve changes in how neighbourhood-level health and care will be delivered across the country.

There are clear opportunities and challenges ahead for providers as PCNs develop. First and foremost, trust leaders see the opportunity for a population based approach to healthcare based on a shared local understanding of the needs of the population, and of the collective resource at play. Hopes for better integrated local services for local populations, including through more integrated multi-disciplinary teams, rightly run high.

Trusts are also well positioned to offer skilled support services to PCNs which they may be too small to provide themselves economically. These could include HR, data analysis and even access to legal advice. This may be an ad hoc support or a formal contract. The offer of back office support can be a transactional agreement, or a means to start to build a relationship between PCNs and the trust with a more meaningful partnership in mind, or to make best use of available estate to support integrated care (by offering PCNs access to trust sites for example, or co-locating services).

While our members welcome opportunities to work collaboratively with primary care via PCNs and other routes, they are mindful of some of the challenges to be overcome in ensuring the success of PCNs.

Many trusts are concerned that work they have done on building relationships and reshaping services around local groups of GPs has to be revised to fit into pre determined PCN footprints. This could represent extra work for trusts, and primary care partners who have actually made the most progress towards new integrated models of delivery. It is also worth highlighting that effective collaboration between secondary and primary care is not confined to the PCN model. A number of trusts already have productive partnerships with primary care, either via a structural solution (in which a trust acquires local GP practices), or through a trust's engagement with a local federation or super practice. Ensuring that the national policy drive to roll out PCNs does not deter other innovative, local solutions to integrate care will be key.

Although the introduction of PCNs does incentivise primary care colleagues to organise at greater scale, the sheer number of PCNs which each trust has to relate to is also a challenge in itself. This will be particularly difficult for trusts covering large geographical areas such as those providing mental health services, community trusts and the ambulance sector. This whole new approach will rely on building new and trusting relationships which may take considerable time to establish.

As PCNs look to develop new models of care and recruit staff, trusts are also keen to ensure they do not end up competing for staff. One area where this could happen is with paramedics, where ambulance trusts are already seeing paramedics in high demand from other parts of the NHS. There may be opportunities to mitigate this by developing innovative career pathways across PCNs, developing a more flexible multi disciplinary approach, or by allowing staff to 'passport' between local organisations.

Finally, it's worth noting that PCNs will face their own challenges. The clinical director role will be crucial but is likely to be filled by practising GPs with limited time to spare. As PCNs will cover small populations, there will also be a limited pool of GPs they can call on to become actively engaged. Much will depend on the capacity and capability of PCNs to engage with provider trusts, and on the quality of local relationships.

The community network (led by NHS Providers and NHS Confederation) recently published a briefing on the relationships between trusts and PCNs: 'PCNs: A Quiet Revolution'.

PCNs: challenges and opportunities – and the legal considerations

Key points

- PCN members collectively will take on a range of clinical services through directed enhanced services added to their existing contract.
- There will be opportunities for community providers to work with PCNs and offer them services.
- Providers should be aware of the legal aspects of entering into agreements with these new bodies.

Primary care networks – background

A central element of the NHS England Long Term Plan is the introduction of primary care networks (PCNs).

PCNs are intended to help dissolve the historic divide between primary and community healthcare services and to act as building blocks for integrated care systems.

PCNs comprise general medical practices which typically have a combined patient population of around 30,000 to 50,000 patients (although there is some flexibility over these numbers). The practices each sign up to the Network Directed Enhanced Service Contract (Network DES) and enter a network agreement which sets out how they will collectively deliver the Network DES services. In addition, PCNs are expected, over time, to have other "non-core" members to ensure integration of primary healthcare, social and community care and mental health services.

PCN activities

In the current contract year, the only clinical service under the Network DES is the provision of extended hours appointments. More services will be added in the next two contract years.

Funding is also being provided for additional roles. In the current year, there is funding for clinical pharmacists and social prescribing link workers. Future years will bring funding for physician associates, first contact physiotherapists and community paramedics.

Nature of the network contract

The Network DES is a bolt on to the general practice core contract. For this reason, the Network DES contract is between the commissioner and the individual practices rather than between the commissioner and the PCN (which is not a legal entity). There is understandably some nervousness on the part of practices as they are each reliant on other practices in the PCN (or third party providers where the Network DES provision is sub-contracted) in order to fulfil their collective obligations under the Network DES – a failure in performance of one practice could undermine the success of the PCN as a whole and render member practices jointly liable.

Aims of PCNs

The key aims of PCNs are:

- Better, more personalised care for patients, closer to home.
- Better coordinated support for individuals with complex conditions.
- Stronger support for patients to play a greater role in decisions about their own health.
- Building capacity and resilience of providers.
- A more stable workforce and multi-disciplinary working.
- Enabling "triple integration" – of primary and community care, physical and mental health services and health and social care.
- Driving up consistency in quality and outcomes.
- Increased focus on prevention, self-care and population health management.

Challenges and requirements for PCNs to succeed

PCNs are required to put in place organisational and clinical governance arrangements, which typically include establishing a governing body comprising practice representatives. Every PCN receives funding which is earmarked for a clinical director who is expected to play a key role in driving the PCN's strategy and development and ensuring integration with the wider healthcare system.

PCNs are new organisations and their member practices have limited capacity for additional work over and above their core service provision. There was pressure on practices to form PCNs before the 1 July 2019 Network DES commencement date and, as a result, many of the PCNs have not had the opportunity to give proper consideration to their governance arrangements, how they will work together to deliver clinical services or employ additional workforce. Many of the clinical directors are new and relatively inexperienced in strategic leadership roles. PCNs do not as yet have dedicated premises and the implications of sharing premises and staff are yet to be thought through and resolved by many PCNs. All of this could make it difficult for PCNs to achieve their aims.

Given these challenges and the emphasis on integration, PCNs will need to work effectively with other providers of community services if they are to achieve their aims. There are inevitably some challenges to be overcome, not least around geography – PCN boundaries are not necessarily entirely consistent with the boundaries of other providers.

Opportunities for community service providers

There are various opportunities for community providers to support and work collaboratively with PCNs, including:

- Assisting with workforce and employment arrangements for the new roles which PCNs are expected to provide.
- Supporting the development of governance and decision-making arrangements which enable input from other parts of the system.
- Sitting on the PCN governing body.
- Designing clinical governance arrangements.
- Providing financial, organisational and back office support.
- Contributing to service delivery arrangements.
- Training clinical directors and other members of the PCN governing body.
- Sharing premises.

Community providers could fulfil these roles in a variety of capacities, including as:

- Non-core members of the PCN.
- Sub-contractors of clinical services.
- Providers of management/organisational support.
- Employers of PCN workforce.
- Landlords or licensors of premises space.

Legal considerations

There are obviously a number of legal considerations when working with PCNs. These include:

- Non-core members of PCNs will be expected to sign up to the PCN's network agreement. Community providers should review carefully the terms and conditions applicable to non-core members in the network agreement. In particular, they should ensure that they are not responsible for PCN liabilities other than those that they specifically agree to take on.

- If acting as a sub-contractor of clinical services, providers should ensure that their rights and obligations are properly defined and that the sub-contract clearly spells out any obligations of the PCN practices on which their service delivery is dependent. They should bear in mind that the applicable service standards are those under the primary care contract rather than the NHS standard contract under which community providers are more used to providing services. The primary care contracts have specific requirements for sub-contracting, including that the head contractor must notify the commissioner prior to sub-contracting services.
- As provider of management/organisational support, there should be a contract for service provision which clearly sets out what providers are to deliver and on what terms. As for a clinical sub-contract, it should spell out any obligations of the PCN practices on which service delivery is dependent.
- As employer of PCN staff, there should again be a contractual arrangement setting out the terms on which providers will employ staff. Matters to consider include:
  - Who is responsible for recruitment and selection – will the PCN have a say?
  - Who will meet the employment costs – will the PCN fund 100 per cent or just a proportion of the costs?
  - Where will the staff be based?
  - What policies and procedures apply to the staff when working in or for PCN practices?
  - Who is responsible for determining work priorities, training and supervision?
  - Who is responsible for grievance and disciplinary matters?
  - Who is liable for employment claims and redundancy costs?
- As a landlord or licensor of premises, providers will need to ensure that there is an appropriate lease, sub-lease or premises licence in place. They should ensure the rights and obligations of the parties are clearly documented and that they are able to terminate the arrangements if required. They will also need to ensure that they have any necessary consents to grant the occupation rights that they are granting.
- Be mindful that the PCN is not a legal entity, so any contracts should be with the individual practices rather than with the PCN.
- Although not strictly a legal issue, some service provision might be a VATable supply and obtaining tax advice is recommended.

ALISON OLIVER, PARTNER
a.oliver@hempsons.co.uk

Alison is a partner in the corporate team focusing mainly on the GP and dental sectors. She helps GP and dental practices and multi-practice healthcare organisations, including GP federations, find practical legal solutions to the unique and complex challenges that they face. Alison has particular expertise in partnership and company law, NHS primary care and community services contracts and regulations, healthcare joint ventures, organisational governance, dispute resolution and practice sales, mergers and acquisitions.

Pensions: a headache for doctors and trusts

Key points

- Highly-paid NHS staff may need personalised advice on their pension positions.
- Trusts are under pressure from consultants to consider alternatives which reduce the risk of large tax bills.
- There could be legal ramifications from some of the proposed solutions so trusts need to tread carefully.

NHS pensions have been a major concern for boards over the last few months, as many consultants have turned down extra work or even reduced clinical commitments because of the impact of the increased income on their pension-related tax bills.

Like others in the public sector, NHS staff on higher salaries can face significant tax bills for future pension benefits if they exceed their pension annual allowance – which will range from £10,000 for the highest earners to £40,000 for those on more modest sums. Tax will be payable if the accrued increase in future pension multiplied by 16 exceeds an individual's annual allowance.

Consultants whose income increases significantly – for example from taking on a clinical director role – or whose income is irregular, from additional work such as sessions to clear waiting lists, are exceeding their annual allowance and facing tax bills in the tens of thousands. This is causing some consultants to consider leaving the NHS pension scheme and others to restrict their clinical commitments.

Hempsons has been asked to advise several trusts about suitable ways forward. Our advice is that consultants and others – such as executive directors – worried by these tax issues should look at the bigger longer-term picture. The NHS scheme offers excellent benefits and most people would be best advised to remain in it: this may still be the case for some of those facing a large tax bill. Personalised advice will be needed to help them reach a decision on what to do.

The government has been consulting on possible changes to the scheme and has indicated these could be in place by April 2020. One suggestion has been to allow a 50-50 option where employees can opt out of pension contributions for 50 per cent of their income. While this has not met with a warm reception from some doctors, it may provide a partial solution to the issue – albeit that the employee will lose out on some pension benefits as a result.

Some trusts, however, are under pressure from their consultant body to develop a local solution and this may continue if any government action is delayed or not viewed as adequate. Proposed schemes usually are of two types.

1. Pension flexibility where employees opt out of the NHS pension scheme and are given back all as additional salary (or a proportion – of the employers' contribution). This is superficially attractive as it can be cost neutral for the employer (once extra NI contributions are accounted for) and attractive to the employee. However, there are two issues. One is that by offering it only to those at risk of pension-related tax bills, trusts could face claims for indirect discrimination. Those benefiting from it will generally be older than other employees and may be disproportionately male: it may be possible for younger, female employees to argue they are being indirectly discriminated against by not being allowed

the same flexibility. Trusts could potentially justify this by citing the negative impact on recruitment and retention, and therefore clinical services, if they don't take this action – but this may not be demonstrable in all cases. The second concern is that pensions law prohibits "inducements" to leave a scheme. The extra income could be seen as an inducement (particularly if the employer only refunds half of the contributions) as they would then benefit financially.

2. Contracting clinical work to limited liability partnerships (LLPs) set up by consultants. This has been suggested by a number of consultants and considered by some trusts. The LLPs would carry out clinical work under a service level agreement but consultants would have the option of withdrawing their money at some time in the future when the tax regime is more favourable (this could even be after retirement). The issue for trusts is that they would need to ensure a watertight legal agreement which ensured the necessary clinical work was carried out – and drawing up a service level agreement would be a lengthy process. Even if this was done, there is a risk that HMRC could view the arrangement as one set up to avoid tax: this could result in tax having to be paid regardless.

Another consideration for the government may be a recent ruling on the fire fighters' and judges' pension scheme. In June the government was refused permission to appeal to the Supreme Court after the Court of Appeal ruled that changes to the schemes in 2015 (which allowed older employees to remain in an existing scheme while younger members had to transfer) were discriminatory on grounds of age, race and equal pay. Similar provisions apply in many public sector schemes, including the NHS. The government has said it will look at how this can be remedied across the public sector: it has already indicated this could cost around £4bn a year.

ANDREW DAVIDSON, PARTNER AND HEAD OF EMPLOYMENT NORTH
a.davidson@hempsons.co.uk

Andrew supports employers in the health, social care and private sector on employment law issues. Andrew has a national reputation for his work in handling concerns about doctors (under the MHPS framework), dealing with discrimination issues, employment tribunal claims and TUPE in particular and he has considerable expertise across healthcare employment law. He regularly provides training for clients on a wide range of employment law and HR issues and is a regular speaker at national conferences.

Fit for future purpose?

What the NHS needs to know about big data and health technology

Key points

- Steps are now being taken centrally to adopt a co-ordinated approach to using NHS data and new technologies to unlock improvements in health care.
- Guidance is still high level, but more detailed work is expected.
- A strong legal and ethical framework will form the core of these requirements.
- The commercial value of the data should not be underestimated – particularly bearing in mind the investment in NHS infrastructure that has made such projects feasible.

Last year we covered the legal framework for governance arrangements to enable "Big Data" and machine learning–driven AI projects to take place using NHS data while still maintaining appropriate ethical safeguards for the use of that data. Since then, we have seen such projects climb up the political agenda, as both the potential for healthcare improvement and the value of such projects have become more widely known.

We take a look at the developments in this area and the changes we are likely to see in the future.

As anyone with more than a passing interest in the secondary uses of health data will be aware there is an initially baffling number of official sources of advice and guidance on the information governance issues relevant to its use with new technologies. The fragmented nature of this guidance was exemplified by media coverage of a 'new' ban on exclusive data sharing arrangements in the NHS, introduced in July 2019, despite this already being existing government policy. (Admittedly it was tucked away at page 46 of the December 2018 'Industrial Strategy – Life Sciences Sector Deal 2'!)

It is therefore not surprising that there is a lack of a common understanding of the principles to be applied, even within the NHS economy. These problems are magnified when dealing with the big tech, data and pharma companies who are not used to working with NHS data in this way and have little institutional experience or knowledge of the limitations on using patient data for purposes outside direct care. This can result in unintended consequences, such as those arising out of the Royal Free/Deep Mind "Streams" project.[1]

Everybody involved needs central, authoritative and accessible guidance to be produced. Thankfully some steps in this respect are being taken.

[1] See, for example ICO press release 31 July 2019

In July, there was a flurry of activity from the Department of Health and Social Care (DHSC) which sets out a road map of how such data projects are likely to be governed in the future. As well as updating its Code of Conduct for Data Driven and Health and Care Technology, the DHSC published the guidance "Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation". This outlines the plans for NHSX to take the lead on strategy and guidance in this area. Five guiding principles for NHS data projects are outlined. In summary these are:

1 Any use of NHS data must have the explicit aim to improve the health welfare and/or care of NHS patients, or improve the operation of the NHS.

2 The importance of NHS data as a resource must be reflected in ensuring fair terms for the use of NHS data for their own organisation and the NHS as a whole.

3 The arrangements should not inhibit or restrict the ability of the NHS as a whole, including a reiteration on the prohibition on exclusive data access deals.

4 Public trust is vital, so transparency and communication are necessary.

5 All existing national, legal, regulatory, privacy and security obligations should be met, including the National Data Guardian's standards.

The guidance also outlines plans for NHSX to set up a National Centre for Expertise for data agreements and projects, publishing guidance, standards and templates. Such work will undoubtedly be invaluable, but at present much of the published information is a high-level indication of future projects rather than direct practical solutions, and in relation to these data projects the devil is very much in the detail.

There is an increasing understanding of the value of NHS data in purely commercial terms as indicated in EY's accompanying article on 'Realising the value of healthcare data'. A direct translation from commercial database sales to NHS data is not possible, as the protections for NHS data will mean that there will always have to be some purpose limitation and controls over data shared. Even within such constraints the commercial value of NHS data is potentially immense, with the ability to provide linkages between primary and secondary care over a lifetime, and at a scale and population diversity not currently replicable anywhere else in the world,

Whether and how that value should be realised raises complex ethical and practical questions. For many the idea of commercial exploitation of NHS data will be redolent of selling patient data for profit or might be seen as impeding medical research. However, just as is the case with the pharmaceutical industry, progress may only realistically be possible within a commercial environment. With appropriate safeguards the benefits of interrogating mass de-identified databases can be realised while still maintaining the core NHS principle of protecting individual privacy. While making data available without charge may seem more in line with the spirit of the NHS, it is worth bearing in mind that this incredibly fruitful information source is only available to be analysed as a result of billions of pounds of investment of public funds. This may provide reassurance that there is a strong moral case that it is only fair and just that the NHS seeks a return on this investment, particularly when the data is used in commercial projects.

There may be lessons to be applied from the purchasing of medicines. Even the president of the United States is aware the NHS is able to secure a better deal from its medicines suppliers by bargaining on behalf of the NHS as a whole. Likewise, central negotiations for commercial data deals will result in better overall value for the NHS than individual local bespoke agreements.

We are still very much in the early days of what has the promise to revolutionise healthcare. However, there are clear indicators of how future guidance is likely to be shaped and so those responsible for planning Big Data projects should bear in mind the following points.

- Health data should not be commoditised – it should not and cannot simply be sold.
- Ensure there is a proper ethical and legal framework applied to the use of even de-identified data.
- Be transparent about who is working with your data and how it is being used. If the potential users of data are unknown, you need to have a clear and transparent idea of the types of user and types of project that will be involved.
- Regulation of this area is likely to be tightened in the future, so what is currently good practice is likely to be mandatory as time goes on. Similarly, previous projects may not necessarily meet current standards and so may have limited precedent value.

CHRIS ALDERSON, PARTNER
c.alderson@hempsons.co.uk

Chris is a leading information lawyer and advises a wide range of local, national and international health and third sector organisations on information law and legal and practical aspects of the data protection and freedom of information legislation. Chris has expertise in the particular ethical rules governing the use of health data, and especially in the developing area of using information derived from health records with AI techniques to discover improved treatments. He has advised the NHS on a lead Test Bed project involving a major pharmaceutical company, and also advises digital health companies developing such products.

Realising the value of **healthcare data**

Unlocking the power of healthcare data to fuel innovation in medical research and improve patient care is at the heart of today's healthcare revolution. When curated or consolidated into a single longitudinal data set, patient-level records will trace a complete story of a patient's health, wellness, diagnosis, treatments, medical procedures and outcomes. Healthcare providers need to recognise patient data for what it is: a valuable intangible asset desired by multiple stakeholders, a treasure trove of information.

Among the universe of providers holding significant data assets, the UK's NHS is the single largest integrated healthcare provider in the world, its patient records covering the entire UK population from birth through to death. There are two primary approaches to quantifying the value of data:

1. A market-based approach, calculating the implied "per record" valuation multiples of comparable data assets or valuation multiples of companies with significant patient data assets.
2. An income-based approach, which quantifies value based on the economic benefit to be generated from the curated data set.

Applying these approaches, we estimate that the 55 million patient records held by the NHS today may have an indicative market value of several billion pounds to a commercial organisation. We estimate also that the value of the curated NHS data set could be as much as £5bn per annum and deliver around £4.6bn of benefit to patients per annum — generated through potential operational savings for the NHS, enhanced patient outcomes and creation of wider economic benefits to the UK, generated through 'big data', artificial intelligence and personalised medicine.

The curated NHS data set is an intangible asset with a current valuation of several billion pounds and a realisation of £9.6bn per annum in benefits that could be unlocked following the generation of insights.

There will be a significant process and technology cost associated with aggregation, cleaning, curating, hosting, analysing and protecting the transformation of these raw data records into a consolidated longitudinal patient-level data set. The costs associated with this data transformation require further research and clearly could impact data set valuation. To ensure success the NHS and the UK government will need to partner with companies that can help unlock these valuable patient insights.

It is critical that the analyses and innovations adhere with medical ethics and research regulations. Patients have to be informed and need to be confident that their data is being used for their own and public good, and that their privacy and rights are safeguarded.

Ultimately, analysis and insights generated from this unique NHS data set can help the UK Government achieve its health priorities on prevention, care and costs, place the NHS and the UK at the forefront of health care innovation, and make the NHS the envy of the world.

To find out more please see EY's report 'Realising the value of health care data: a framework for the future' https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf

A new approach to **capital funding and project delivery**

Key points

- Strategic estates partnerships (SEPs) have helped around a dozen trusts to access capital and deliver projects expertise since 2010.
- The SEP model can be extended to cover health economies or integrated care systems with one trust acting as a host for the benefit of the entire economy or system in question.
- Like SEPs, these local development partnerships (LDPs), work best for a series of smaller builds or refurbishments, supported by land or property disposals or redevelopments.
- The LDP can be used by a wide range of public sector health and care organisations, so it can help them to work together to develop the more suitably-located, efficient and modern facilities they need to actually achieve the aims of integrating health and social care. The LDP creates a bigger, long-term, opportunity for private sector partners and investors.

Accessing capital funding for projects big and small has been a major concern for trusts over the last few years – and despite some money being made available, capital funding remains an issue.

Yet many trusts are sitting on unused land or property which could be leveraged to develop improved facilities. This might take the form of disposal to release capital or a major refurbishment to adapt estates for new uses. In the current climate many trusts are struggling even to access funding for much-needed maintenance. Hempsons has developed an innovative way for a variety of organisations within a health economy to work together in a way which secures expertise and releases capital funding to bring projects to fruition.

The model, called a local development partnership (LDP) uses an existing, proven vehicle which around a dozen trusts across the country have successfully procured, operated and adopted – a strategic estates partnership – to progress capital projects across a wider geographical footprint that is aligned to the relevant health economy or system. It builds on the successful features of existing LIFT, LABV (local asset-backed vehicles) and SEP models in the health and care sectors and it is specifically designed to meet the current challenges facing project delivery.

SEPs have been used in the NHS since 2010. A SEP is basically a partnership to cover the strategic development of a trust's estates. It's not the same as a private finance initiative arrangement – a trust entering into a SEP does not offer the chosen provider any exclusivity and is not required to commit to a massive new hospital (or any other development necessarily). Instead, a SEP is a flexible long-term partnership which allows trusts to work within a framework covering a wide range of activities and allowing them to access additional capital.

Potential new projects and services are developed from an initial concept stage through a tried and tested approval process, that enables trusts to decide whether to go ahead on a project-by-project basis. Trusts go through an OJEU procurement process to find a partner and set up a SEP in the first place, but do not have to go out to procurement each time they work with the partner to deliver an individual project within the scope of the SEP.

Up until now, SEPs have been used by individual trusts to address their own estates needs. The model is already attractive to trusts looking for extra capacity and support for their strategy, estates and facilities teams. However, Hempsons believes that the SEP model can be adapted successfully to work across a wider health economy by using one trust as the lead to host and administer the joint venture vehicle, creating an LDP. Others can then use this LDP to develop and, if appropriate, deliver new estates related projects or services. LDPs could be created across integrated care systems and there could be opportunities for other partners such as local authorities and even the third sector to become involved.

Such an arrangement needs to be scoped appropriately from the outset and to use a firm and well established legal structure. Hempsons has previously advised several organisations setting up SEPs, including throughout all stages of the procurement process and during the lifetime of the arrangement.

The capital spending within the SEP or LDP structure will still count towards the Department of Health and Social Care's capital departmental spending limit (CDEL) – which may mean that organisations will need to dispose of an asset to raise the money or to create the headroom to invest in a new one, whilst remaining within the overall permitted capital expenditure envelope. However, local health economies may not need to wait for the CDEL rules to loosen before making real progress. The SEP/LDP model is an iterative one that delivers small projects and service improvements just as well as it delivers the more eye-catching multi-storey car parks, retail developments and intermediate care units.

One of the potential benefits of an LDP structure is that in some cases organisations may want to collaborate with other NHS organisations, to undertake developments that would otherwise be impossible to deliver on their own. For example, this could enable trusts to structure asset ownership and occupations in new more more flexible ways; or they may be able to sequence their projects, potentially using money released by one trust's asset disposal to kickstart a project in another, with both organisations (and the local economy/system) benefitting from the new project that is delivered in the long term.

Private sector partners will bring skills in developing these projects and finding appropriate funding. LDPs may also be more attractive to the private sector than SEPs because they will potentially be bigger in monetary terms and cover a wider geographical area with an increased pipeline of potential projects over at least a ten-year timeline.

The LDP approach is likely to work well for smaller projects and service improvements which can be considered and developed on a case-by-case basis. It is less likely to work for very large new builds. But these smaller developments will also mean that organisations are less exposed to the risks of a builder going bankrupt: there is little prospect of a second Carillion, where a provider insolvency could result in bills of hundreds of millions to get the development underway again. Shorter, smaller projects also allow the supply chain to be re-evaluated as each one is developed and tested. It also means that the value for money of each project can be fully evaluated before proceeding with that individual project.

The non-exclusive nature of the LDP means that if the relevant new project or service will not deliver satisfactory value for money, there is no obligation to proceed with it or to use the LDP to deliver it at all. If needs have changed since the original estates strategy was conceived, it is also possible to go back to the drawing board and develop an alternative – and still deliver it through the LDP.

If you are exploring how up-coming projects can be delivered in your health economy, an LDP is worth considering. It will offer extra options without restricting access to other service delivery routes, frameworks, partners and investors.

If you would like more information or to discuss LDP model further, please do not hesitate to contact the authors.

CRISPIN PETTIFER, PARTNER AND HEAD OF PROJECTS AND CONSTRUCTION
c.pettifer@hempsons.co.uk

Crispin is a partner in Hempsons' corporate commercial team and Head of Hempsons' projects team, a role that involves leading on construction and projects.

OLIVER CRICH, PARTNER
o.crich@hempsons.co.uk

Oliver is a partner in Hempsons' corporate commercial team, a role that involves advising public and private sector clients on a variety of health and social care matters. He advises on high value and complex commercial contracts, transactions and projects. He is an expert in public procurement law, including in relation to procurement disputes.

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About Hempsons

Hempsons is a leading national law firm specialising in health and social care, practitioners, real estate, charities and social enterprise sectors across the UK. Our highly experienced lawyers provide a number of cost-effective solutions for a range of private and public healthcare organisations, from employment law through to clinical negligence.

We aim to achieve our clients' objectives and provide support down to the last detail whether the issue is big or small, challenging or simple. We work with over 200 NHS organisations including NHS trusts, foundation trusts and commissioning bodies, with services delivered by a team of over 130 specialist healthcare lawyers. A significant number of our employees hold dual qualifications, combining medical, dental or nursing qualifications with their legal credentials.

You can find details of our lawyers and their specialisms on our website.

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