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Healthcare Newsbrief

Psychiatric injury in the NHS: prevention is better than financial remedy

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Welcome

Welcome to this latest edition of Hempsons' healthcare newsbrief – timed to coincide with one of the biggest events in the healthcare executives' calendar, the annual NHS Confederation conference.

Healthcare policy is always a challenging area to write about and this year the election, with its uncertain result, has made it even more so. As we went to press, it appeared that the general thrust of NHS policy would continue unchanged with a Conservative-led government remaining in power. However, please excuse us if things have changed in the last few days before publication!

In this issue, we look at some of the big issues facing the NHS – issues which won't go away regardless of which government is in power. The NHS has a vast estate. Not all of which is always used to capacity. Michael Dulhanty looks at Sir Robert Naylor's recommendations for how the NHS could save money and match its estate more closely to its needs. Every board member needs to be aware of this and think what the review could mean for their trust.

Ross Clark looks at the move towards GP practices either formally merging or working more closely together. This has been partly prompted by the difficulties of recruitment and retention in general practice – and a desire to make GPs' lives easier – but also by the vision of sustainability and transformation plans (STPs) of groupings of GPs covering up to 100,000 patients.

Jamie Foster looks at the potential development of accountable care systems and organisations. These could transform how healthcare is organised in England but it will take some time for STPs to move towards them. NHS England has identified some frontrunners which are in a position to start this journey.

One very real concern for boards is what happens what childbirth goes wrong and what their organisation's liability is. In some sad cases, it is not just the baby which suffers harm – the mother and others witnessing the birth can also be affected psychologically. Richard O'Keeffe and Mirabel Williams look at the implications of a recent court ruling for trusts.

Finally, James Lawford Davies looks at the evolving technology of gene editing and how this is regulated in England. Many are fearful of the potential offered by this development but there is a strong legal framework around both research and treatment in this area.

We hope you enjoy reading this newsbrief – and your time at the Confed17 conference if you are there. Please drop into see us on stand A8 in the Arena Hall.

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Psychiatric injury in the NHS: prevention is better than financial remedy

The NHS is facing increasing claims for injuries suffered at birth which leave babies with lifelong disabilities. But difficult births can also be a traumatic experience for the mother and for others who witness it. This article looks at the implications of this for NHS trusts.

If negligent treatment causes a baby to be born apparently dead and to undergo prolonged vigorous resuscitation, it is understandable that the baby will be entitled to compensation. If the mother suffers psychiatric harm as a result of witnessing the trauma to her baby, should she be compensated as well? Things get more difficult when claims are put forward by her partner and her mother, or indeed friends and others who visit the ward. What about those who view videos made by the father in the hope of recording a happy event?

There is no doubt that these things are all very distressing and may result in the witness developing conditions that can be formulated by modern psychiatrists and so characterised as psychiatric damage. However, here the law has recognised the danger of floodgates opening and so has devised control mechanisms to avoid claims for compensation being brought by every bystander who witnesses an unpleasant event.

The recent case of *RE (a minor by her mother and Litigation Friend LE) & ors v Calderdale and Huddersfield NHS Foundation Trust* is rich in learning points for potential defendants in the context of obstetrics. Mr Justice Goss awarded compensation to the mother and the grandmother who witnessed the birth of a 'flat' or apparently lifeless baby. RE's mother delivered at Calderdale Birthing Centre on 22 April 2011. There was a 19 minute interval between the delivery of the purple swollen head and the white lifeless body. The baby did not draw her first breath until 12 minutes after delivery and, during that time, the mother and grandmother who witnessed the resuscitation believed she was dead. Both sustained post-traumatic stress.

A claimant victim of psychiatric injury who has been at no risk of physical injury themselves must seek to recover as a 'secondary victim', and must satisfy the control mechanisms set out by the House of Lords in *Alcock v Chief Constable of South Yorkshire Police* [1991] UKHL 5 the claim brought by the victims of Hillsborough. They must

- be in a close and loving relationship with the other injured party
- must directly perceive the death, injury or risk of it
- being proximate in time and space to that event or its immediate aftermath
- the event must be so sudden and shocking that it is foreseeable that it will cause psychiatric harm to someone of reasonable fortitude.

In recent years the courts have applied these control mechanisms restrictively. For example, in *Wild and another v Southend University Hospital NHS Foundation Trust*, Mr Wild sought compensation from Southend Hospital

after being present both when the doctors diagnosed death in utero, and when the body of his dead son was delivered the following day. The hospital admitted negligence in relation to the claimant's wife and settled her claim. However, Mr Wild's claim as a secondary victim failed because he did not satisfy the *Alcock* test:

- it was not enough for the claimant to have been witness to the manifestation of the consequences of the defendant's negligence, i.e. the retrospective discovery that the baby had died in the womb
- this did not equate with actually witnessing a horrific event leading to a death or a serious injury.

The judge there applied the case of *Taylor v Novo*, where the claimant's mother had been injured at her workplace through the negligence of a fellow employee. She had apparently made a good recovery, but she suddenly collapsed and died at home three weeks later. Her daughter did not witness the accident, but she did witness her mother's death and suffered post-traumatic stress disorder as a consequence. She pursued a claim for damages against her mother's former employer. Lord Dyson MR said that it would be incomprehensible to allow the claimant to recover for witnessing the death of her mother three weeks after an accident, when she would not recover damages if Mrs Taylor had died at the time of the accident and the claimant had arrived on the scene shortly after the immediate aftermath. If her claim succeeded, why bar those who witness the death decades after the negligent events?

Lawyers in the RE case argued that the mother and foetus were one legal person up to the point of delivery. If physical injury to the foetus was also physical injury to the mother that would avoid the control mechanisms, because she could recover for consequential psychiatric injury as a 'primary victim', the psychiatric damage being merely something to be assessed as a consequence of her physical damage.

In *RE* it was found that the hypoxic injury to the foetus was sustained after the head had crowned. The defendant said that this meant the injury was sustained ex utero and that the mother should be treated as a secondary victim. The judge held that the foetus remains a part of the other until wholly expelled from her body and highlighted that the relevant moment for assessing whether the mother and foetus are separate legal entities is when the negligence occurs rather than when the injury is sustained. It may be possible to think of cases in which the negligence is in utero but the injury to the child only apparent after it is born, for which RE may be an important authority. If so, it will be difficult for defendants to escape liability for psychiatric injury to mothers whose delivery involves a negligent birth injury.

However, the situation should be different for birth partners and other family members, like the grandmother in *RE. Liverpool Women's Hospital NHS Foundation Trust v Ronayne* is the most recent Court of Appeal case and Tomlinson LJ held that the event which causes the psychiatric injury must be horrifying by objective standards and by reference to persons of ordinary susceptibility. The claimant had seen his wife being treated in intensive care for septicaemia and peritonitis as a result of a negligently misplaced suture during a hysterectomy. She was receiving four types of intravenous antibiotics and her face and body were swollen, as the husband described it, 'like the Michelin man'. Tomlinson LJ found that this experience lacked the elements both of suddenness and being objectively horrifying. He stated that '*A visitor to a hospital is necessarily to a certain degree conditioned as to what to expect, and in the ordinary way it is also likely that due warning will be given by medical staff of an impending encounter likely to prove more than ordinarily distressing*'.

One can see the point, since but for such a restrictive approach hospitals would have to be extremely cautious in permitting visitors to most ITUs. It was argued for the defendant in *RE* that there is no such thing as what claimant's counsel had called a 'Mary Poppins' delivery, being 'practically perfect in every way'. Labour and delivery are inherently anxious, traumatic and exceptional events. However, despite Court of Appeal authority that assessments as to the exceptionality of events and their sudden, horrific nature, should take into account the clinical context where that is present, Mr Justice Goss found that '*there was no conditioning for what came*' and that the events of RE's delivery and resuscitation were '*sufficiently sudden, shocking and objectively horrifying*' for the secondary victim claim to succeed.

Individual judges will inevitably take different views of what is objectively horrifying. If secondary victim claims cannot be excluded from the clinical context except in exceptionally horrifying circumstances, then potential defendants must prepare to deal with such claims more commonly.

The law does not allow anyone to exclude liability for personal injury – section 2(1) of the Unfair Contract Terms Act 1977 – and so potential defendants can no more exclude liability to birth partners and other family members than they can control claims from the patients themselves. What clinicians can do is to give proper warning to those attendees of difficult clinical situations, of what they are letting themselves in for. If they are warned that they may be confronted with a chaotic and life-threatening situation, it should, in light of the decision in *Ronayne*, be difficult to establish that what they went on to witness was a 'sudden shock'.

Obstetricians tell us that labour is an inherently shocking event, particularly for those who have not experienced it before. As one put it:

'Babies frequently come out looking like "a stunned mullet" and ladies often do think their babies are dead when they do not start to cry right away.' It used to be worthy of comment if the father was present at the birth, and although the current fashion is now that the reverse is true we do very little to prepare them for the unexpected. In many cases it is not very useful having even a single birth partner present and it is well-known that men can suffer psycho-sexual problems after witnessing their partners give birth. Multiple birth partners, however, is invariably too much and often quite intrusive.'

NHS trusts can, within reason, adopt appropriate policies to control the number and role of those who attend, provide they make clear what the stipulations are in advance. However, it is hard to see how a hospital could restrict the presence of family members on the basis that they might be upset by the negligence of the staff.

The level of damages for these sorts of claim is not huge, but the pool of potential claimants is vast. Preventative measures may be cost-effective. In a recent trial the court was told by an experienced psychiatrist, Dr Trevor Turner, that cognitive behavioural therapy (CBT) can help with adjustment disorders, but more than 5-10 sessions will make little or no difference in respect of PTSD. CBT can currently be accessed on the NHS with a referral from the GP. Hospitals could offer referrals to family members who have witnessed a particularly shocking scene, and this may occasionally reduce awards where that offer is not taken up.

Prevention is better than cure and is certainly better than financial remedies. If policies within the NHS can be adapted to anticipate this sort of harm it may both improve care and reduce clinical claims.

Key points

- this recent decision suggests that claims for psychiatric injury resulting from witnessing traumatic clinical negligence incidents may be successful in more cases than had previously been thought.
- trusts should consider whether providing more information to mothers, birth partners and other attendees before a delivery or offering counselling after a traumatic birth could reduce incidence of such harm and reduce the value of claims.

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Accountable care in the NHS

Next Steps of the Five Year Forward View (March 2017) sets out plans for the transition of the NHS to population-based integrated health systems. This will be achieved by the evolution of Sustainability and Transformation Partnerships (STPs) into 'accountable care' models. Next Steps defines two types of accountable care models:

- **Accountable Care Systems (ACSs)**
- **Accountable Care Organisations (ACOs).**

Before exploring what is meant by the ACS and ACO, it is worth considering what is meant by 'accountable care' in general terms. Accountable care models evolved in the United States from existing integrated care systems. They are more easily defined by a series of common characteristics than by a fixed definition – a commonly held definition of accountable care is a model which brings together a variety of provider organisations to take responsibility for the cost and quality of care for a defined population within an agreed budget (for example a whole population budget).

NHS England views the development of accountable care models as an evolution into ACSs and then ultimately into ACOs. An ACS will allow STP partners to work together to integrate care and develop collective responsibility for resources and population health. An STP that develops into an ACS is also expected to get greater control and freedom over the health system in their area, working closely with local government. Whereas becoming an ACO will be the end objective in the evolution of STPs in some areas, where commissioners will contract with a single organisation for the great majority of health and care services in an area.

NHS England rightly acknowledges that one size does not fit all and STPs are continuing to develop at different speeds with different arrangements for STP leadership and accountable care.

We have co-produced with NHS Providers a guide about accountable care which identifies seven key steps for STP partners considering putting in place accountable care models. We summarise these steps below:

Step 1: **Phasing**
NHS England recognises that the transition to accountable care is complex and requires careful management of risk. In particular, ACOs are likely to take time to establish given they will be dependent on the award of whole population budgets under long term contracts. As a result, staged implementation will be necessary, starting with the evolution of existing care models and organisational structures towards ACSs.

Step 2: **Partners**
STPs may decide that their area is suited to one accountable care model or a number of different models. Early clarity about the key partners in each model will be essential. Some partners will be obvious, such as commissioners, GPs and acute and mental health trusts. Others will be less obvious, such as voluntary sector and private sector partners responsible for delivery of NHS and local authority funded care.

Step 3: **Governance**
Some of the most substantial risks to developing accountable care models lie in transition as STP partners seek to coordinate decision-making, since STPs are not legal entities in their own right and have no powers to make decisions. Partners need to consider carefully how to put in place effective structures to facilitate decision-making. And in due course, they need to consider how decisions will be made in the accountable care models that partners put in place – for example, they need to consider whether leadership by a single organisation will make decision-making easier and reduce governance risks.

Step 4: **Contracting**
NHS England anticipates that accountable care models will operate under accountable performance contracts. These contracts are likely to be based on the existing and evolving suite of contracts produced by NHS England for new care models. They will be long term contracts which incorporate new payment models such as whole population budgets, improvement schemes and gain/loss share agreements. In time, commissioners may be able to award a single accountable care contract to an ACO, but until then partners will need to operate through a network of different contracting arrangements including existing contracts and new contracts.

Step 5: **Funding**
Delivering integrated services for an accountable care footprint will ultimately require whole population based funding. NHS England has indicated its intention to put in place such arrangements and

indeed whole population based funding is already in place in a small number of locations. Moving to new payment models will be complex and may need to be phased in over time.

Step 6: **Organisational form**
An accountable care model can take many different organisational forms ranging from loose alliances or partnerships in which organisations retain their own autonomy but agree to collaborate to fully integrated networks of hospitals and other providers. An ACO is likely to involve a greater degree of organisational integration than an ACS. There is no 'right answer' to the question of which organisational form best suits a particular model – the much-quoted 'form follows function' really is true here.

Step 7: **Enablers**
Finally, partners need to consider the key enablers that will be required to deliver accountable care, as identified by *Next Steps* – workforce, safer care, technology and innovation.

For further details about the key considerations for each of these steps please see 'A seven step guide to accountable care' available on our website.

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The regulation of gene editing in the UK

Introduction

We love to regulate in the UK. We have a long history of developing novel regulations governing numerous areas of society, and healthcare in particular has kept statutory draftsmen busy for decades. The UK has not shrunk from regulating novel (and sometimes controversial) therapies and technologies. It was one of the first jurisdictions in the world to develop a comprehensive framework for the regulation of IVF and embryo research, and UK law addresses human cloning, pre-implantation genetics, stem cell research, and gene therapy – amongst many other areas.

One highly controversial area which has been the subject of regulatory scrutiny in recent months is the use of gene editing techniques in human embryos. Whilst gene editing is not a new discovery, the recent development of techniques such as CRIPR-Cas9 enable the genome to be edited cost effectively at precise locations in specific ways. The use of such technologies in human embryos gives rise to significant legal and ethical dilemmas for policy makers and legislators and this article briefly considers the UK regulatory framework which applies to research in this field, together with some of the potential challenges based in EU law.

Gene editing in human embryos

The creation, storage and use of human embryos outside the human body is tightly regulated in the UK under a legislative framework designed in the 1980s and implemented through the Human Fertilisation and Embryology Act 1990. The same act also regulates all research involving human embryos. The use of embryos in treatment and research must be conducted under a licence granted by a statutory regulator, the Human Fertilisation and Embryology Authority (HFEA) and unlicensed research or treatment (or activity outside the terms of a licence) is a criminal offence.

The HFEA grants separate research and treatment licences.

Gene editing: research

With some very limited exceptions, the 1990 Act does not regulate the use of specific techniques in research: there is no statutory provision regarding gene editing in human embryos for research in the legislation, nor is there any prohibition of such research. Instead, the regulations focus on the purpose of proposed research projects. Applications for a HFEA research licence must demonstrate that the proposed project is "necessary or desirable" for one of a number of statutory purposes, which include (for example):

- increasing knowledge about or developing treatments for serious diseases or serious medical conditions
- increasing knowledge about the causes of any congenital disease or congenital medical condition
- increasing knowledge about causes of miscarriages
- developing methods for detecting presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
- increasing knowledge about the development of embryos
- promoting advances in the treatment of infertility.

In addition, the licence application must explain why it is necessary (not merely desirable) to use human embryos, as opposed to another source of material. The applicant must also show evidence of ethics approval from a recognised research ethics committee.

If these requirements are fulfilled, the HFEA may grant a licence permitting research involving human embryos. The HFEA has recently followed this statutory process in granting a research licence to the Francis Crick Institute in London permitting the use of CRISPR/Cas9 in human embryos for the purposes of developing treatments for serious disease, increasing knowledge about the development of embryos, and promoting advances in the treatment of infertility.

It is a condition of all HFEA research licences that embryos used or created under the licence cannot be used in treatment. It follows that, if a gene editing technique is applied to an embryo pursuant to a HFEA licence, that embryo could not lawfully be implanted: indeed, to do so would constitute a criminal offence.

It is also an offence to keep or use an embryo after 14 days from creation or from the appearance of the primitive streak (if that appearance is earlier than the 14 day period). There is therefore a statutory limit on the duration of research, though there have been recent calls for this 14 day limit to be extended.

Gene editing: treatment

The 1990 Act has withstood the test of time remarkably well in a fast-paced area of scientific and clinical development. In 2008, however, it was amended to bring the legislation up to date. At the same time, Parliament introduced a new approach to the regulation of IVF treatment which relies upon the concept of 'permitted' gamete and embryos[1]. An embryo is a permitted embryo if *"no nuclear or mitochondrial DNA of any cell of the embryo has been altered"*. Under section 3 of the 1990 Act (as amended), only a permitted embryo may be transferred to a woman. It therefore follows that, if the DNA of an embryo has been altered through the application of a gene editing technology, the embryo could not be a permitted embryo and could not be lawfully used in treatment. Additionally, there is a further restriction in Schedule 2 of the 1990 Act which states that a HFEA treatment licence *"…cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo"*. Through this somewhat circuitous route, UK law prohibits the use of germ line gene editing as a reproductive technology, and this position could only be altered through a change to primary legislation, requiring further Parliamentary debate.

The European context and eugenics

As the above extracts illustrate, UK legislation is generally drafted in objective and unemotional terms. Whilst there may be underlying principles and ideals, these are seldom articulated in the legislation itself. This is largely true of the 1990 Act in its approach to the regulation of embryo research and reproductive technologies, including reproductive genetics. By contrast, other European countries have adopted legislation which seek to prohibit germline interventions and 'eugenic' practices, and certain European Union legislation features similar terminology. The EU Clinical Trials Directive, for example, prohibits trials which *"…result in modifications to the subject's germ line genetic identity"*, and it has been suggested that this might prevent clinical trials in the EU involving the application of gene editing technologies to human embryos. The directive, however, concerns clinical trials *"on medicinal products for human use"*, whereas gene editing in an embryo involves the application of a process or technique. Furthermore, editing the DNA of an embryo does not create a *"product"*, still less a *"medicinal product"*.

Similarly, the Charter of Fundamental Rights of the EU includes the right to the *"integrity of the person"* which includes a prohibition of *"…eugenic practices, in particular those aiming at the selection of persons"*. It has been argued that this prohibition could extend to gene editing technologies. As with the Clinical Trials Directive, however, the concern is misplaced. This prohibition was included in the charter on the recommendation of the European Group on Ethics in Science and New Technologies to address (amongst other things) "*Eugenics … [which] may also involve genetic manipulations on human beings such as the modification of the germ line in view of enhancement, without any therapeutic aim"* (my emphasis). This touches on an important distinction which is lacking from many legislative and policy instruments which seek to regulate in this field, namely the distinction between the therapeutic and non-therapeutic application of a technology.

In the UK, the use of genetic technologies (such as preimplantation genetic diagnosis and mitochondrial donation may only be licensed for use in a therapeutic context where there is a significant risk that a child will otherwise inherit a serious genetic disorder. In the event that the editing of embryonic DNA is made lawful in the UK in the future, it is very likely that similar restrictions will be imposed.

[1] Section 3ZA of the 1990 Act, as added by the Human Fertilisation and Embryology Act 2008

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Conclusions

The UK regulatory landscape for gene editing requires careful navigation. Whilst sometimes complex, however, it provides a mature, comprehensive and facilitative environment for research and therapy. The UK framework operates to protect patients from unregulated, untested treatments and ensures that both researchers and clinics are licensed and regularly inspected, thus reassuring the public, media and parliamentarians that the field is properly monitored.

Such a robust framework is particularly valuable when it comes to the application of gene editing technologies to human embryos. In circumstances where UK law is comprehensive and clear in its application to gene editing, there is no need to implement a moratorium on the use of this technology in embryos, as has been advocated in certain quarters. The strength of this framework is reflected in the successful history of the regulation of preimplantation genetics and mitochondrial transfer in the UK. This success, however, was built upon a vital foundation of open and accessible dialogue between researchers, clinicians, policy makers and the public, and it is to be hoped that a similar transparency will be maintained around gene editing research as it continues to develop.

Naylor in a nutshell

What you should know about Naylor's vision for the future of NHS estates

The man – who is Sir Robert?
It's fair to say that Sir Robert's NHS credentials are second to none. He's the former chief executive of UCLH Foundation Trust, and the former chair of the London NHS Chief Executives Group.

He's currently the national advisor to the government on NHS property and estates, and is referred to informally as '*the estates tzar*'.

The mission – what has Sir Robert been asked to do?
Last year Sir Robert was asked by the government to review the NHS estate and advise on how it could be better managed.

The government's hope in carrying out the review was that Sir Robert would be able to identify an opportunity to raise up to £2 billion from the sale of surplus NHS estate assets, with up to 26,000 homes being built on land disposed of by the NHS by 31st March 2020.

So how did Sir Robert get on?
Well quite well, putting it mildly. In fact, it's fair to say that Sir Robert has knocked the government's target right out of the ball park. Sir Robert has identified an opportunity to generate up to £5.7 billion in revenue and up to 40,000 homes from the sale of surplus NHS land.

Wow! That is impressive. So how does Sir Robert think this can be done?
This is where you need to pay attention, as Sir Robert has made 17 recommendations in his report. If you want to see them all, you can access a full copy of the report on the government's website at: www.gov.uk/government/publications/nhs-property-and-estates-naylor-review.

To help to simplify things, Sir Robert has grouped his recommendations under three key themes:

1. support national strategic planning and local delivery
2. encourage and incentivise local action
3. funding and national planning

Here are my thoughts regarding each of Sir Robert's key themes:

Theme one: supporting national strategic planning and local delivery
This revolves around the creation of a "*powerful new NHS Property Board*" which intends to "*bring together [the currently] fragmented NHS property capabilities into a single organisation.*"

The Board would have a national remit but Sir Robert does not want it to be overly centralised – it would have a regional structure to facilitate local delivery of the overarching, national strategy.

The Board's focus would be to work with the 44 STPs to develop each STP's local estates strategy for the disposal of its surplus assets. The object would be to maximise the revenue released by each STP from its surplus estate.

Theme two: encouraging and incentivising local action
So, the Board would work with each STP to develop their local estates strategies. But what about the implementation of the strategies by the STPs – how would Sir Robert make this happen?

Essentially by brandishing a stick – to punish underperforming STPs – and a large carrot – to reward STPs that dispose of land in accordance with their approved estates strategies.

The stick: The board would set benchmark targets against which each STPs performance in disposing of its surplus estate is to be measured. The board would ensure STPs' targets are "*sufficiently stretching*" and, crucially, Sir Robert goes on to add "*...STPs which fail to develop sufficiently stretching plans...should not be granted access to capital funding...*" [my emphasis]. I suspect that would make STPs sit up and take notice!

The carrot: However, it's not all bad news for STPs. Sir Robert also proposes that STPs which dispose of land in accordance with their approved strategies would:

(i) get to retain the sale proceeds for themselves (the proceeds won't be whisked off back to the Treasury!)

(ii) in addition, receive a "2 for 1" payment from the Treasury whereby central funds are used to effectively double the STPs' sale proceeds. This is indeed a bold attempt by Sir Robert to inject momentum into STPs' disposal strategies, particularly as the "2 for 1" offer is only likely to be available to STPs for a limited period.

Theme three: funding and national planning
Sir Robert's point here is that substantial capital investment is needed to deliver NHS service transformation, pursuant to properly executed STP plans.

By *"substantial capital investment"*, Sir Robert is of the view that a total of *"around £10 billion"* is likely to be required in the medium term. He identifies three sources of revenue which could provide the required £10 billion as being: "*property disposals, private capital and HM Treasury*."

Or to put it more simply, Naylor has identified a medium term funding gap of £10 billion but believes up to £5.7 billion of this can be met via the disposal of surplus NHS estate.

Will Sir Robert's recommendations be accepted and implemented by the government?
Of course nobody knows for sure. However, during a recent televised interview, the BBC's Andrew Neil asked Theresa May how the Conservatives plan to pay for their promise of "*the most ambitious programme on investment and buildings and technology the NHS has ever seen*."

Mrs May's answer? "*We're backing the proposals in the Naylor report*."

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Generating revenue from NHS intellectual property

Next steps on the NHS Five Year Forward View (March 2017) acknowledges that technology underpins all of the current major NHS work programmes. Strategies include the adoption of new technologies, digitising hospitals and increasing online access to services. As a result, NHS bodies will be required to become more innovative and to embrace innovation as an integral part of their activities.

This will undoubtedly help to deliver the vision of the Five Year Forward View, but will also present some interesting opportunities for NHS bodies to generate new revenue streams from assets that may potentially have been under-utilised to date – their intellectual property.

What is IP?

The term "intellectual property" or IP is used to describe a specific set of intangible assets that are generated through intellectual effort and creative activity. It typically covers patents, trademarks, copyright, designs and databases. It is often used as a broader term to include know how and confidential information as well, although these are not, strictly speaking, IP.

Some types of IP, such as patents and registered trademarks require registration in order to gain protection, but others such as copyright and some types of design right do not, with the right arising automatically when the work in question is created. Each requires a different strategy to ensure that effective protection is obtained and maintained.

The type of IP that may be created within an NHS body varies dramatically and we have seen a huge range from training materials and software which attract copyright protection, to patentable inventions and distinctive brands that are registered as trademarks.

How can revenue be generated from IP?

In all cases identifying, capturing and appropriately protecting IP are just the first steps on the road to realising the value in that IP. NHS bodies should now be looking at what can be done to maximise the return on their innovation investment through exploitation of their IP.

It may be that the best value is realised by simply using the IP within and for the benefit of the NHS alone. However, the potential revenues that can be gained by commercial exploitation should not be ignored.

NHS IP can be licensed out to third parties, either for further R&D, to facilitate the manufacture and sale of products in other non-NHS markets, to permit services to be offered under a proprietary brand or, increasingly, to allow exploitation overseas. Licensing terms require careful consideration to ensure that the IP is properly protected, maintained and enforced, to ensure the scope of rights granted to any third party is clear and to provide appropriate mechanisms for payment of royalties and other fees to be implemented.

There are many possible approaches and the licence agreement must be tailored to the relevant circumstances. Care must also be taken to follow the guidance in the 2002 Department of Health document "The NHS as an Innovative Organisation" which, although it is now 15 years old, still stands and provides a competent framework for managing and exploiting IP within the NHS. For example, it contains a useful checklist of the typical contents of a licence agreement between an NHS body and a commercial organisation.

The guidance also contains information on how to manage the risks on a variety of commercial exploitation projects. It acknowledges that licensing is just one route to market. Exploitation can also take the form of an outright sale or assignment of IP or the setting up of a spin out company which takes the IP, either by way of licence or assignment, and exploits it in return for fees, a revenue share, royalties and/or shares in the company itself.

All of these project structures can be highly effective means of exploiting NHS IP and generate a return for the organisation which can, in turn, be used to further benefit patients and the NHS generally.

NHS bodies need to consider their statutory powers to generate income from IP, including approvals that may be required and whether they have the power to invest in spin out companies.

What steps should NHS bodies take next?

Given the increasing focus on technology and innovation within the NHS and the increasing number of commercial organisations keen to engage with the NHS in order to access and use its IP, it is a prime time for NHS bodies to:

- carry out a review of their potential IP generating activities to ensure that IP is being captured and protected adequately
- update their IP policies which should establish an appropriate internal structure which ensures that all IP is identified and assessed properly
- examine how staff are empowered and incentivised to innovate within the organisation
- review their existing IP portfolio to determine whether all rights are being appropriately maintained and whether all potential exploitation options have been explored
- review and update any existing licence arrangements.

IP can be a complex area and legal support is often essential. If you require any further information please contact **Gill Hall** on **0191 230 6056** or email **g.hall@hempsons.co.uk** or **Nabil Asaad** on **01423 724102** or email **n.asaad@hempsons.co.uk**

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Gill has 20 years of experience advising public and private sector organisations on intellectual property and IT issues. Gill's IP practice covers advising on the identification, protection and exploitation of all types of IP including patents, trade marks, copyright and designs.

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Nabil works across the Corporate & Commercial and IP teams assisting with all aspects of commercial and IP work for clients.

Primary care at scale

GP practices across the country were just getting to grips with the implications of the Five Year Forward View when the publication of Sustainability and Transformation Plans ("STP's") transformed expectations of the level and scale of integration expected in the new models of care.

The Five Year Forward View identified two principal models particularly relevant to primary care; the Multi-disciplinary Community Provider ("MCP") and the Primary and Acute Care System ("PACS"). Broadly, MCP's are "bottom-up" models, with care organised and developed at community level around GP practices with out of hospital secondary care services being delivered in the primary care environment, whereas PACS are "top-down" models where the acute sector takes responsibility with hospitals acting as hubs, delivering care into the community.

However, STP's have a much broader reach and look at the integration of primary, secondary, social, community, mental health and voluntary care in a large single provider entity, most commonly referred to as an Accountable Care Organisation ("ACO"). The difficulty for GP practices is the scale of integration that is suggested by the STP's and required for a fully integrated ACO model. This suggests clustering of GP practices, typically on a CCG footprint but often across multiple CCG boundaries, to form groupings with populations in excess of 100,000 patients. That is a scale that most GP Practices have not contemplated before.

At the same time, there are continuing and growing pressures on primary care, most noticeably the combination of the succession crisis with the common demographic in practices, where a significant proportion of partners are close to retirement age.

There is no doubt that the pressures in primary care with the expectation of primary care at scale under the STP's have been the key drivers for the establishment of Super Partnerships (and the term is used widely but we would define it as a merger of 10 or more practices), including most notably Our Health Partnership ("OHP") in Birmingham which has recently expanded to include just under 50 Practices with a patient population in excess of 300,000. Even though the Super Partnership model can provide for a system of delegated authority, whereby the partners of a merging practice can retain autonomy over the running of and decisions made in connection with that practice, this is often a step too far too soon for many partners.

As a result, we have seen a marked increase in mergers of practices and in the number of practices involved in each merger. Traditionally we would see mergers involving two or three practices but now mergers of between five and ten practices are common.

For those partners who are reluctant to consider a "smaller scale merger" such as this, we have seen a marked growth in closer working arrangements and cluster or neighbourhood agreements, where practices work more closely to sustain and support each other. This is often an important first step in gaining confidence in each other to then move towards considering a merger.

However, the pressures driving towards primary care at scale are increasing, and practices also face the concern that, if they do not have a collective voice, they will not have a significant voice or influence within the ACO's that are forming around them.

Practices do not necessarily need to merge to achieve this voice and can nominate a group of representatives within their locality to represent practices collectively within the ACO discussions. However, the time will come, and for some it will be a (lot) sooner than they may anticipate, when ACO's are taking on single contracts for all out of hospital care and will be looking for a single primary care organisation to take a sub-contract to deliver many of these services.

Accordingly, partners need to understand the implications of the STP in their area, keep track of where the STP is with the development of an ACO (or any alternative provider model) and ensure that primary care is involved in those discussions and is structured together at scale to be able to deliver primary care and other out of hospital services collectively across their locality.

The growth in mergers, and the number of practices involved in each merger, is resulting in some innovative and exciting new structures for merged partnerships. In general there seems to be an appetite for a move away from ownership and profit sharing by the few to the many, so that all staff have the potential to become partners and where employee share models (the “John Lewis model” is often discussed as the aspiration) is being seen as the best means of providing rewarding career structures, increasing staff retention and loyalty and, ultimately, improve the overall performance and securing the future of the practice. However, returning to STP’s and the drive from the centre to create large scale single provider organisations in the form of ACO’s, scale really is the issue.

Accordingly we have no doubt that we are going to continued growth of Super Partnerships and a rapid increase in mergers of five to ten practices, which will then continue to grow in size as neighbouring practices seek to join them.

Many mourn the passing of the traditional sole practitioner and small partnership models, but the evolving models of primary care at scale can offer levels of autonomy found in those models but with the security of being within a much larger, single, partnership. These new models can also enable clinicians, and others within primary care practices, to focus on what they enjoy doing best (there is room for the general practitioners and the GPSI’s in these new broad churches) whilst, and here is the real benefit that most seek today, releasing them from other duties to have more time to focus on what they enjoy doing best and in getting a bit of their personal life back. Now, that can't be a bad thing, can it?

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Ross acts for GP practices, doctors, dentists and orthodontists advising on the sale, acquisition or merger of medical and dental practices and partnerships or in joint ventures entered into by them (whether contractual or through an appropriate corporate vehicle).

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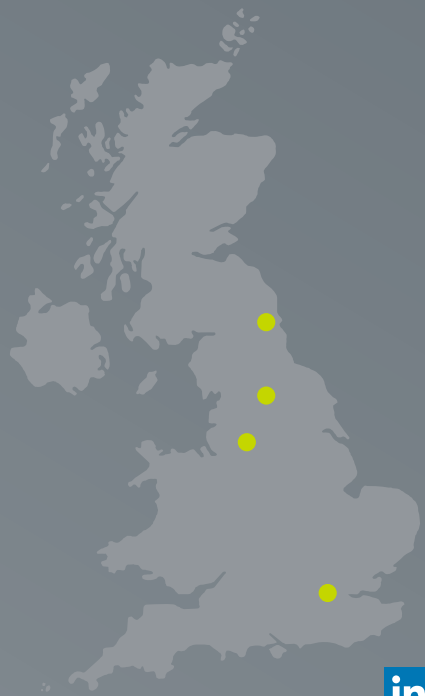

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