The lowdown

Health news and analysis to inform and empower NHS staff and campaigners

Health and Care Bill is "a wasted opportunity" – Justin Madders MP gives an insider's view

Justin Madders is Shadow Minister for Secondary Care, Workforce and Patient Health and is one of the 17 MPs (5 are Labour) involved in the line by line scrutiny of the Health and Social Care Bill in its committee stage, before it returns before the house on 22 November.

A pandemic, a burnt out workforce, record waiting times – pressure in every part of the system. The NHS is stretched to its absolute limit and beyond, yet against this background the Government have put forward the Health and Care Bill which represents yet another reorganisation of the NHS that fails to tackle the underlying causes of the challenges both health and social care face.

In simple terms, the Bill removes competitive tendering for clinical services (but not all NHS funded services); it replaces Clinical Commissioning Groups with bigger ICBs (which are expected to delegate to 'place-based' units of some sort); it replaces market structures with heavy top down management by a much enhanced NHS England. The big winners as always are the large acute trusts.

The Bill may end the waste and cost of pointless tendering introduced under Andrew Lansley, but it does not end privatisation even of clinical services.

The claims about the Bill favouring integration of services are largely rhetorical and clearly even the Government don't believe they will be delivered as they have already begun to trail another White paper on integration.

Most worrying was the inadequate response to the issue of workforce planning. The provision was universally criticised – but has still so far remained.

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During consideration in the Commons Public Bill Committee, numerous amendments were proposed but none were carried. Tory MPs voted down our efforts to ensure representation on NHS decision-making boards for mental health, social care, public health, staff and patients, and safeguard near-patient services from further outsourcing.

They also blocked our attempts to remove controversial powers for the Secretary of State to intervene in local service reconfigurations from the Bill.

Instead, there were many assurances and promises of further discussions and thought. Some Government amendments are expected before the Bill goes to the next stage and concerns remain, especially about the possibility for private sector interests to influence commissioning of NHS funded services by having a role on ICBs, and for contracts with the private sector to be agreed without any proper oversight.

The new organisations are weak on clinical leadership and on staff, public and patient involvement. Who decides what is no clearer. There is also the focus on acute care and the big Trusts – potentially leaving primary care, mental health, community care, social care, public health outside the key decision-making bodies.

The argument often advanced for rejecting Labour amendments that may have dealt with some of the concerns was that local systems should have 'flexibility' to shape services, but this argument was totally undermined by the provisions in the Bill giving many further powers for the Secretary of State and for top down intervention.

The Bill is about reorganising the NHS, not about improving care or the integration of care – and not about improving wellbeing or tackling unacceptable inequalities. It is a huge missed opportunity.

The structures in the Bill which are already largely in place may not last long, do not do enough to fix the mess made by the Tories' previous reorganisation, and are frankly a distraction at a time when the NHS is facing the biggest crisis it has had in its proud history. Staff and patients deserve better than this.

Kent campaigners fight on for stroke services

Health campaigners in Kent have declared they will fight "tooth and nail" the government decision to endorse a reconfiguration which will mean halving the number of stroke units in Kent, lengthening journey times and delays in treatment.

Campaign group Save Our NHS In Kent (SONIK), which has been campaigning for years to save stroke units in east Kent called an emergency protest outside Margate's QEQM hospital on November 6.

The three remaining specialist stroke centres will eventually be in Dartford, Maidstone and Ashford – with units at Margate, Medway and Canterbury closing, leaving much of East Kent with 60 minute journeys to a Hyper Acute Stroke Unit (HASU) – assuming the ambulance services can deliver even that much.

Larger areas would face 45 minute journeys to a HASU – far higher than the 30 minute maximum journey for all patients that was specified when stroke services were centralised in London ten years ago, when ambulance services were under less pressure.

However stroke services in Kent are currently in disarray with no HASU yet established in the county. Staffing shortages have led to the "temporary" closure of stroke units at Tunbridge Wells Hospital and Medway Hospital during the pandemic, leaving services for East Kent concentrated in Canterbury.

Even with the go-ahead now is estimated it will take until at least 2024 before the new replacement unit can be operational at William Harvey Hospital in Ashford.

Meanwhile ambulance response times in Kent (and across the country) have worsened dramatically since the initial plan for the service redesign was submitted for ministerial approval over two years ago, questioning the viability of the proposed 2-hour maximum "call to needle" time.

A spokesperson for SONIK said: "Everyone knows that surviving a stroke is critically dependent on how close you are to an emergency unit. The halving of our stroke units in Kent from six to just three is going to put people's lives at risk. We have fought this appalling decision every step of the way and we will not give up now. We will fight it tooth and nail."

"We've had judicial reviews, petitions, debates. We've presented local NHS bosses with overwhelming evidence of the lethal dangers of this move. Our only recourse now is protest."

John Lister

NHS diagnostics losing out to the private sector

- **Independent providers are receiving substantial public funds to help shift the backlog in diagnostics, amidst fears of long term arrangements**
- **NHS radiology staff are understaffed by 33% and equipment is failing**
- **Review says private sector use should be a stop gap, alongside calls to divert public funds away from firms and towards the NHS**

Headline-grabbing short-term funding for local partnerships with independent providers, rather than long-term investment in staffing and capital equipment for the public sector, increasingly appears to be the government's preferred approach to easing the crisis in diagnostic services..

The government's latest initiative – trumpeted by health secretary Sajid Javid as a major boost to the diagnostics sector, and part of the 'levelling up' agenda – came last week with a relatively paltry 'injection' of £248m to digitise scan and test results, designed to speed up diagnoses, enable earlier treatments and reduce waiting lists.

The move – accompanied by another dig at the primary care sector, as the funding will also back the launch of a referral tool to 'help' GPs reduce 'inappropriate' test requests – was greeted with little enthusiasm by the BMA, whose spokesperson suggested solving workforce issues first was essential to making the best use of any new technology.

That stance has been echoed by others in the diagnostics sector – in July the National Breast Imaging Academy reported that staff shortages had led to several breast units closing – and is supported by the most recent census by the Royal College of Radiologists (RCR), published in April.

Staff shortages

This survey found that the NHS' radiologist workforce is now under-staffed by 33 per cent and needs at least another 1,939 consultants to meet safe staffing levels and pre-covid levels of demand – and that the shortfall was predicted to hit 44 per cent by 2025. More than half (58 per cent) of senior radiologists responding said they didn't have enough staff to keep patients safe, and the RCR calculates there are just nine radiologists per 100,000 people, compared with an average of 12 per 100,000 across Europe, with the shortfall leading to diagnostics being outsourced overseas.

And last month RCR president Dr Jeanette Dickson told charity Breast Cancer Now that, "Breast imaging and treatment services were massively under-resourced even before the pandemic hit. Now, screening teams are trying to fit two years' worth of appointments into one to catch up with a backlog of millions, while struggling with long-standing staff shortages and woefully substandard facilities… Ultimately, we cannot get away from the need to invest in people. The NHS needs more imaging and oncology staff to ensure future breast cancer patients get the care they deserve."

A potentially much bigger windfall than Mr Javid's £248m – perhaps for the independent diagnostics sector as much as for the NHS, although exactly how the cash will rain down on recipients is as yet unclear – was announced in last month's budget.

According to one newspaper report, more than a third – that's £2.3bn – of chancellor Rishi Sunak's £6bn package of support for the NHS will go towards setting up 56 community diagnostic hubs (CDHs) England, taking the total number to 100, to help clear the tests backlog in time for a 2024 general election.

But as is often the case with funding announcements for the NHS, there is some confusion over numbers. Pulse Today reported at the beginning of October that 40 new CDHs would open across the country by next March, as part of a £350m plan already being funded from NHS England's (NHSE) existing budget. And earlier this year, in July, news emerged of NHSE's call for bids to run 150 new CDHs would come within a £10bn framework contract tender.

Capacity problems

Whatever the numbers, however, CDHs are being positioned by NHSE and the government as the solution to the backlog crisis in the diagnostics sector. Although the CDH concept was piloted in ten areas back in 2018, it gained considerable traction following publication of the NHSE-commissioned review of diagnostic services last October. This review – a leaked version of which was reviewed in The Lowdown following publication by news site HSJ – was led by Professor Sir Mike Richards and offered a useful breakdown of what was required to bring the diagnostics sector back up to speed after the pandemic.

Noting a marked increase in breaches of the six-week diagnostic standard over the previous two years, matched by a substantial rise in the outsourcing of imaging requirements, the review called for a major expansion of capacity – in both workforce and scanner provision – as soon as possible, but recommended the increased use of independent sector facilities only during what it termed the 'recovery phase'.

The review made much the same points as the BMA and RCR did a year later, suggesting workforce issues were a major constraint on the sector. It also highlighted the fact that England lags far behind the OECD averages for scanners – a situation only made worse by many NHS trusts having to rely on charity efforts to buy large diagnostic equipment, and by the sort of equipment performance issues uncovered during a Channel 4 documentary last month.

Ageing equipment

The Dispatches production team revealed that CT and MRI scanners older than ten years, potentially putting patients' health at risk, are still being used by about a third of hospital trusts, despite an NHSE report published last year that recommended that all imaging equipment aged ten years or older be replaced. The programme makers found that coroners were concerned about the shortage of radiology staff, as well as poor CT and MRI scans. More worryingly, they also found 48 reports over the past five years that mentioned a lack of scans and/or radiology staff in relation to the death of a patient.

Unfortunately, Professor Richards' recommendation that cash- and equipment-rich independent sector facilities should not have a role long-term in the NHS' diagnostics capability looks increas-

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Private hospitals vs NHS: study is not the full picture

- **Research that shows better outcomes for private hospitals is missing the key depth to be definitive.**
- **The data shows that NHS patients treated in private hospitals are wealthier, older, fitter and more are white.**

Healthcare Markets magazine was predictably delighted to largely reprint a recent press release from Birmingham University on research showing that NHS operations delivered in private hospitals appear to involve "shorter hospital stays and fewer readmissions than in NHS hospitals.".

Especially congenial to the private sector magazine are the assurances from Birmingham Uni's Professor Richard Lilford, that despite "plausible concerns" regarding the safety of elective surgery in the independent sector:

"Taken in the round, our findings provide a measure of reassurance that independent sector healthcare providers [IHSPs] are providing an acceptable service."

However, keeping the door open for further research projects funded by the National Institute for Health Research (NIHR) the Prof went on to note that:

"our results stop short of total reassurance, and ongoing

scrutiny of a richer set of outcomes and further investigation of practice is required in both the NHS and the independent sector."

Indeed the initial project may have sifted through 3.5million episodes of care between 2006 and 2019, but it asked very few questions, and made no attempt to explain or evaluate the results they found, even though the clues are in plain sight.

It finds length of stay in hospital for all 18 common surgical procedures analysed was longer for patients treated in NHS hospitals than those treated in the private sector.

Why should this be the case? Is it not certainly linked to the fact that, especially since the launch of "independent sector treatment centres" in the mid-2000s, with specific protocols defining which patients were and were not appropriate, patients have always been screened to ensure the NHS sent only the least complicated cases, and those with support at home, to private hospitals?

The study notes that while "Reimbursement levels are the same irrespective of which type of organisation provides treatment," patients treated in the private hospitals tend to be whiter, healthier and wealthier [and we might add less expensive] than the NHS casemix. They had:

"fewer underlying conditions; lived in more affluent areas; and tended to be White (or had no ethnicity recorded) than those treated in NHS hospitals."

In other words the private sector has continued to cherry-pick the easiest patients to treat and discharge, leaving the NHS to cope with a much more complex and demanding caseload.

According to the report data 3.2m of the operations were in 734 NHS hospital sites and 468,000 operations in 274 private hospitals. Each relatively much smaller private hospital therefore averaged just 1,708 patients over the 13-year period compared with 4,364 per NHS site. However, while the private hospital sites involved are listed (some of them more than once if they changed ownership), no detail is given on how as many as 734 NHS units were identified, compared with around 170 acute trusts.

More important, there is no comparison of staffing levels to allow any assessment of the amount of post-operative support given to patients.

The report states that nearly 40% of patients treated in independent sector hospitals were discharged on the same day after a total hip replacement, "compared with less than 5% of patients treated in NHS hospitals, who stayed an average of 5 days."

With no further information on the circumstances of these patients and the availability of community-based services to support them on discharge from hospital, it's impossible to draw any conclusions from this – other than that wealthier fitter people are more likely to be mobilised more quickly, and to have reliable support in place at home, than poorer, less healthy ones.

Moreover the study only tacitly admits that when things go wrong, the NHS has to carry the can – whether or not the patient had their operation in a private or NHS hospital. It states blandly that "patients in independent sector hospitals were more likely to be transferred to another hospital as an emergency." But the press release cited by Healthcare Markets does not clarify that all emergency care is provided by the NHS, even though the full report does admit:

"Many ISHPs lack the full range of services, including intensive care, required for management of an emergency case. Thus, given an emergency, a patient in an ISHP is more likely to be transferred than an equivalent patient in the NHS who is already likely to be in the institution of last resort."

Not the solution

If these missing questions are asked it becomes far clearer that far from being part of the solution to the current growing NHS crisis, the private sector is part of the problem. Its very existence and periods of growth have depended upon gaps and weaknesses in the NHS, and its expansion as supposedly "additional" beds and capacity can only take place at the expense of draining the available limited pool of NHS-trained staff.

Even if the whole of the bed capacity of acute sector private hospitals were to be somehow procured ,it only amounts to 8,000 beds – just 8% of the latest, reduced total of NHS acute beds in England, and less than half of the 16,000 acute beds that compared with pre-pandemic in 2019 are either still standing empty or filled with Covid patients on the latest figures.

If the NHS could access the necessary capital and staff, and was focused on reopening the unused beds, it would be far more productive to expand capacity that way than to divert staff from already busy teams in the main hospitals to conduct operations some miles away in small-scale private hospitals.

In practice all 8,000 private acute beds will never be available to the NHS unless the private hospitals are nationalised. The companies that own them can make so much more money from privately insured and self-pay patients driven to desperation by NHS waiting lists, they will never see full dependence on the treating NHS patients at tariff prices as a profitable option.

As for the Birmingham Uni research? The best that can be said is "could do better"..

John Lister

NHS success in fighting cervical cancer

The NHS's vaccination programme to prevent cervical cancer, begun in 2008, is now leading to a dramatic reduction in cervical cancer in women, with rates of disease down 87% in women in their 20s, who would have been given the vaccine at age 12 to 13.

The study, published in The Lancet and funded by Cancer Research UK, shows the potential for the human papillomavirus (HPV) vaccine in combination with cervical cancer screening to reduce cervical cancer to the point where almost no-one develops it and many lives will be saved. At present, across all age groups, around 850 women die from cervical cancer each year, according to Cancer Research UK.

Michelle Mitchell, Cancer Research UK's chief executive said: "It's a historic moment to see the first study showing that the HPV vaccine has and will continue to protect thousands of women from developing cervical cancer."

The study, conducted by researchers based at King's College London, the UK Health Security Agency (UKHSA), and the National Cancer Registration and Analysis Service (NCRAS) run by NHS Digital, looked at all cervical cancers diagnosed in England in women aged 20 to 64 between January 2006 and June 2019.

The researchers estimated that by June 2019, there were around 450 fewer cases of cervical cancer and 17,200 fewer cases of pre-cancerous changes to cells (known as CIN3) than expected in those vaccinated against HPV in England.

The amount of protection produced by the vaccine is dependent on the age the vaccine was given. The vaccine reduced cervical cancer incidence by 34% in those who received it aged 16 to 18, by 62% if aged 14 to 16 and by 87% in those who were vaccinated aged 12 to 13. The vaccine is most effective when given between the ages of 11 and 13 when someone is less likely to have been exposed to HPV.

The study was the first to focus on the UK vaccination programme and to analyse the effectiveness of Cervarix, developed by GlaxoSmithKline, the first HPV vaccine used in the UK programme. Cervarix is a bivalent vaccine protecting against infection with HPV types 16 and 18, which are responsible for around 80% of cervical cancers.

In 2012, the UK's HPV vaccination programme moved from Cervarix to Merck & Co's Gardasil, a quadrivalent vaccine, which protects against four types of HPV (6, 11, 16, 18). In the 2021/22 academic year, Gardasil will be replaced by Merck & Co's Gardasil 9. This new vaccine protects against nine types of HPV, covering more than 95% of cervical cancers, and around 90% of genital warts.

In July 2018, the vaccination programme was extended to boys aged 12 to 13 years, as the vaccine also offers protection against other HPV-related cancers, including head and neck cancers, and anal and genital cancers. Since the 2019 to 2020 school year, both 12- to 13-year-old boys and girls have been eligible for the HPV vaccine.

Studies have shown that the vaccine protects against HPV infection for at least 10 years, although protection is expected to last for much longer.

Unfortunately, the pandemic disrupted the vaccination programme in 2020 and official figures show that only 54.4% of boys and 59.2% of girls in England got the HPV vaccine in 2019/20, compared with a rate of 88.0% in girls in the previous academic year. Experts are urging parents to make sure their children catch up on missed vaccinations, although 12 to 13 are the ideal ages, the beneficial effects are great for older children as well.

More flaws are exposed in ‘integrated care’

- **No shared understanding of what integration means**
- **Pilots achieved “only mixed results” and made little progress on unplanned hospital admissions, although staff reported improved communication.**
- **Little engagement with GPs, and the impact on patient experience was “mixed”, they reported improved organisation but being less likely to see a doctor or nurse and less involvement in decisions.**

While we challenge the flawed provisions of the Health and Care Bill, it’s also important to recognise that NHS England’s claim the Bill is all about creating “integrated care” is founded on bogus assumptions.

Not only will the new system NOT be integrated (all the existing divisions – between commissioners and providers, primary care and secondary care, acute care and mental health, health and social care, NHS quangos and elected local government – remain intact, with outsourced contracts and private providers still in place with no end in sight) but the model of ‘integrated care’ itself has been shown again and again to be flawed.

The relentless drive towards a fresh top-down reorganisation of the NHS in England, to leave decision-making in the hands of just 42 so-called ‘Integrated Care Boards’ (ICBs), with little if any accountability to the local communities they cover, began without evidence – and has continued despite the evidence.

Too many senior managers, policy experts and academics have nailed their colours firmly to the mast of ‘integrated care’ as a supposed magical key to more effective and efficient health services – despite the lack of NHS staff and resources, the necessary bold reform to replace the current largely privatised and dysfunctional social care system with a national care and support service, and the wider policies needed to address widening health inequalities.

None of them now really dares to point to the uncomfortable truth.

This is the real takeaway message from a new study (**‘Integrated Care in England – what can we Learn from a Decade of National Pilot Programmes?’**) published in the International Journal of Integrated Care.

The authors are five British academics, a management consultant, and the head of evaluation of RAND Europe. All of them have been involved in funded projects over the past 10 years to establish or investigate and evaluate the three national

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pilot programmes on integrated care in England, the earliest going back to 2008.

Their combined report seeks to bring together and evaluate the outcomes of these projects: and it's clear from the summary that there is precious little good news to celebrate:

"There was little stable or shared understanding of what 'integrated care' meant, resulting in different practices and priorities. An increasing focus on reducing unplanned hospital use among national sponsors created a mismatch in expectations between local and national actors. … Pilots in all three national programmes made some headway against their objectives but were limited in their impact on unplanned hospital admissions."

The authors, apparently aware that many similar findings can be found in the growing array of studies and reports on "integrated care" opted nonetheless to focus narrowly on the experience of the three national schemes – and ignore the warning signs on all sides that most of the techniques being adopted are failing to deliver much, if any benefit.

Their report makes it obvious that the schemes being evaluated varied hugely "in terms of their scale of operation, the priorities emphasised, patient groups targeted, interventions implemented and types of organisations involved."

It appears they shared only two things: all of the schemes were lumped into the general bag of "integrated care" – and they shared the "general expectation among programme sponsors, usually shared by pilots themselves, that integrated care would result in a reduction in the level of unplanned hospital admissions." However this has not been achieved.

Integrated Care Pilots, the first of the national schemes, launched in 2008 with "some funding" and support from management consultants, actually led to a significant ***increase*** in unplanned hospital admissions, along with "reductions in elective inpatient and outpatient care." And a reduction of 9% in overall costs of hospital care for patients who were individually case managed ran alongside an increase in numbers of them requiring unplanned admission.

Obviously transforming patients from electives into emergencies was not one of the objectives of the pilots.

The impact on the patient experience is politely summed up as "mixed:" in fact patients were less likely to be able to see the clinician of their choice and less likely to have their opinions and preferences taken into account.

Integrated Care and Support Pioneers, beginning from 2013, with "relatively modest financial support" and closer scrutiny by NHS England, apparently delivered "a modest impact on unplanned admissions," aka limiting the increase in demand to below the average – but only for one year, and not in all pilots. Data are only now, years later, being collected on the patients' experiences.

New Care Model Vanguards were launched in 2015 with "comparatively lavish amounts of additional funding." They "slowed the rise in unplanned admissions," but achieved "no overall reduction in bed-days," and some of the sites had higher than average unplanned admissions beforehand. No systematic study had been made of patient experience, and evaluations by individual Vanguards schemes were of "mixed" quality.

On other levels, too, the pilot projects have failed to deliver, and highlighted the lack of any real drive to integrate services. Despite reports from all of the schemes of problems sharing data between organisations, for example, "there is little compelling evidence that national NHS organisations did much to address such barriers."

And despite the obvious importance of linking with GPs to ensure services out of hospital can integrate with hospital care, some so-called 'Primary and Acute Care Systems' had "little engagement with local primary care."

Sites in all three programmes "complained that insufficient resources were hampering their activities – whether a lack of funding or available workforce." If the pilots are having these problems with extra funding, it bodes poorly for the national roll-out of "integrated care".

The upshot is that the failed pilots have also yielded few, if any, wider lessons on how integrated care might be made to work:

"No single programme has been able to distil key, generalisable 'lessons' that have then been applied subsequently. Indeed, successive programmes did little to build on one another in their conception nor to synthesise learning as they progressed."

Part of the reason at least must be the failure to deliver what has become the key objective of reducing the need for hospital beds:

"The evaluations have shown that even a modest curbing in the upward trend of unplanned admissions is not guaranteed, takes a long time, may not always be sustained, and may arguably not prove to be value for money."

So why are these lessons not being learned? Partly there is the reluctance of large numbers of NHS managers to admit that they cannot make the new models deliver: instead their reports roll out reams of bluster and evasion.

One expert at such bluster is Boris Johnson's advisor on new models of care Samantha Jones, who annoyed local MPs by "walking away" from her post as CEO of West Hertfordshire Hospitals trust after just two years in 2015, to lead Simon Stevens' "New Care Models Programme" for NHS England. After less than two years presiding over this shambles she again stepped down, to become an 'independent' consultant, and six months later signed up as UK chief executive of American health corporation Centene from January 2019.

Ms Jones is one of many who will not be keen to draw attention to the failures of the new systems for fear it might undermine their own credibility. But there is evidence a-plenty that "integrated care" as implemented in England and elsewhere falls well short delivering the expected results.

But it should come as no surprise. Back in 2012 an analytical paper in the BMJ co-authored by one of the new report authors, Professor Martin Roland, questioned one of the central tenets of 'integrated care': that hospital admissions could be reduced (and costs cut) by improving primary care interventions, especially aimed at those of high risk (whose chronic health problems often lead to them being perjoratively dismissed by NHS bureaucrats as "frequent flyers").

Among the bevy of myths dispelled by this study was the illusion that high risk patients account for most admissions, or that case management of such patients could save money:

"most admissions come from low risk patients, and the greatest effect on admissions will be made by reducing risk factors in the whole population. […]

"[…] even with the high risk group, the numbers start to cause a problem for any form of case management intervention – 5% of an average general practitioner's list is 85 patients. To manage this caseload would require 1 to 1.5 case managers per GP. This would require a huge investment of NHS resources in an intervention for which there is no strong evidence that it reduces emergency admissions."

Four years ago the National Audit Office also warned of the lack of evidence to show integrated care could deliver the promised improvements in patient care.

In early 2019, the Public Accounts Committee (PAC), commenting on the move to commissioning of services by Integrated Care Systems across much larger areas, noted the dangers of reducing the number of bodies commissioning services:

"… as CCGs become responsible for commissioning services across larger populations there will be a tension between commissioning at a larger scale while maintaining an understanding of the health needs of local populations."

Last year The Lowdown reviewed an article from the US journal Milbank Quarterly that also exposed the weakness of targeting the small number of patients with complex medical and social needs who "account for a large proportion of health care costs." The article went on to debunk claims that such action to tackling individual cases could impact on social determinants of health:

"Red flags also have been waving for many years regarding the limits of trying to address the upstream, social drivers of health through individual-level interventions aimed at complex patients."

The author, Paula Lantz, drew the wider conclusion – also relevant in England – that addressing wider 'social determinants of health' and health inequalities can not be successfully done by targeting individual cases:

"Reduced health inequities are not going to result from better care transitions from hospital to home or from tertiary care that attempts to connect patients to beleaguered social safety nets. Achieving health equity requires that we strengthen public policy and community investments to ensure education, economic, social and political resources, opportunities, and well-being over the life course, and that we prioritize evidence-based primary and secondary prevention interventions aimed at populations and communities."

As discussed in The Lowdown last month, the once left of centre IPPR ("The Progressive Policy Think Tank") also published a new critical report Solving the Puzzle – Delivering on the promise of Integration in Health and Care, and from the right wing the Thatcherite Centre for Policy Studies has also published a report questioning the evidence that "integrated care" can deliver any improvement in outcomes for patients.

It seems the only people not getting the message are the NHS bosses with fingers in their ears, eyes shut and singing la la la to avoid the warnings that they are riding a dead horse.

John Lister

Antiviral approved by MHRA as effective against Gamma, Delta, and Mu variants

On 4 November, the UK became the first country in the world to approve Molnupiravir, an oral antiviral treatment for Covid-19. Molnupiravir, developed by US companies Merck & Co and Ridgeback Biotherapeutics, was approved by the UK Medicines and Healthcare products (MHRA) for the treatment of mild-to-moderate Covid-19 in adults with a positive Covid-19 diagnostic test and who have at least one risk factor for developing severe illness. In the UK the planned trademark is Lagevrio.

Approval of the drug could provide much needed respite to NHS hospitals struggling to cope with the number of Covid-19 patients being admitted. In clinical trials its use in Covid-19 patients was found to reduce hospitalisations by around 50%.

In October 2021, the UK government secured 480,000 doses of the Merck & Co drug. The UK will start to roll out molnupiravir for use on the NHS through a drug trial later in November in vaccinated people. The drug has so far been tested only in unvaccinated people.

Drug approval was based on results of the MOVe-OUT trial, a phase 3 trial, that recruited patients across the globe, including counties in South America, Europe, Asia, the UK and the USA.

The trial, which was placebo-controlled, tested the drug in non-hospitalised adult patients with laboratory-confirmed mild-to-moderate Covid-19. Patients in the study were unvaccinated and had at least one risk factor associated with poor disease outcomes (e.g., heart disease, diabetes). Patients were enrolled on the trial and randomised to either placebo or drug treatment within five days of developing symptoms. The primary objective of MOVe-OUT was to assess the efficacy of molnupiravir compared to placebo as determined by the percentage of participants who were hospitalised and/or died from the time of randomisation through to day 29.

The study included patients who had Delta, Gamma and Mu variants of Covid-19, which accounted for nearly 80% of the viral variants that had been sequenced at the time of the interim analysis of the study.

Merck & Co reported interim phase 3 results in October 2021. Molnupiravir (800 mg twice daily for five days) was found to have reduced the risk of admission to hospital or death by around 50% in non-hospitalised adults who had mild to moderate Covid-19 and were at risk of poor outcomes when the drug was given within five days of onset of symptoms. At day 29 no deaths were reported in the molnupiravir group, while eight were reported in the placebo group. Recruitment to the trial was then stopped on the advice of the independent data monitoring committee because of the positive results.

Availability crucial

In contrast to the developers of the Covid-19 vaccines, Merck & Co is making the drug widely available throughout the world. The company has entered into a licensing agreement with the Medicines Patent Pool to increase broad access in low- and middle-income countries, plus non-exclusive voluntary licensing agreements with Indian generic manufacturers.

These agreements will accelerate availability of molnupiravir in more than 100 low- and middle-income countries, many in Asia and Africa, following approvals or emergency authorisation by local regulatory agencies. The availability of the drug at a cheap cost could help economically disadvantaged countries as they struggle to get their population vaccinated. The drug has a short and simple treatment regimen – four pills, twice a day for five days.

Molnupiravir is the first oral antiviral to be approved for Covid-19. It is simple to administer with tablets twice a day. In contrast, remdesivir, the first antiviral approved for Covid-19 has to be administered by IV and is not very effective – it speeds up recovery but does not save lives. Remdesivir is also very difficult and costly to produce; it is not a drug that could be used in economically disadvantaged countries.

A day after molnupiravir approval, Pfizer announced results for its oral antiviral Paxlovid, with a late-phase trial showing that Paxlovid reduces the risk of hospitalization or death by 89% if administered within three days of symptom onset. Paxlovid could possibly be approved in the UK early in 2022. Paxlovid is a combination of PF-07321332 and ritonavir; the latter is an antiviral already approved for the treatment of HIV. As a result of these positive results the trial, known as EPIC-HR, was stopped and Pfizer has sought emergency use authorisation from the FDA. Albert Bourla, Chairman and Chief Executive Officer of Pfizer, called the trial results "a game-changer in the global efforts to halt the devastation of this pandemic." The UK government has bought 250,000 doses of Paxlovid.

The results of the Paxlovid study suggest the drug is more effective than Merck's drug, but the trial results may not be directly comparable. Like Merck, Pfizer has said it will offer cheaper prices for Paxlovid to developing countries.

The Ritonavir component of Paxlovid is no longer covered by patents and is already made by companies that make generic drugs.

Although both Merck and Pfizer will make the drugs available cheaply in many countries, a major problem in many low to middle income countries will be testing – both drugs need to be administered early in the infection which means testing needs to be easily accessible and with a quick turnaround of results.

Another issue is the possibility of the development of resistance. Most if not all previous antiviral drugs have seen resistance develop and treatments often comprise a cocktail of drugs, such as those given for HIV and hepatitis. Any virus variant that is less susceptible to the way molnupiravir or Paxlovid acts to prevent viral replication could survive and become dominant and drive the evolution of a resistant variant.

Well-tolerated

On the positive side, the short period of time that both drugs are administered – for just four to five days – will help as there is only a short time for resistance to develop. In addition, short treatment times mean that people are much more likely to take the full course of treatment; not taking the full course means virus left in the body with even slight drug resistance can multiply and become dominant. Both Pfizer and Merck have said that the drugs were well-tolerated in the study population and side effects were mild.

Merck has highlighted that in the trials molnupiravir demonstrated "consistent efficacy" across the Gamma, Delta, and Mu variants of the virus, which suggests that existing strains of the virus have not yet succeeded in developing resistance against the drug.

There is still much to be investigated around the use of both these oral antivirals and how they will perform in a real world setting. How do they work in vaccinated people? Do they prevent viral transmission? How can a combination of vaccine and drugs be used to clamp down on outbreaks of disease? Despite the number of unanswered questions and the need for more trials, the approval of these drugs is very welcome and could signal a turning point in the global fight against Covid-19..

Sylvia Davidson

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ingly unlikely to be adopted, as private equity starts to bolster the outsourcing market and enable independents to partner NHS trusts to run CDHs on a more permanent basis.

A Royal College of Pathologists survey, featured in the Richards review, found that 45 per cent of histopathology labs were having to outsource work because of staff shortages, and just last month the RCR predicted that the NHS could waste £420m by 2030 if it continues with expensive outsourcing and overseas recruitment to plug the UK's shortage of radiologists and clinical oncologists.

And earlier this month the FT reported that the NHS is outsourcing analysis of patient scans as far afield as Australia, amid an acute shortage of radiologists in the UK. It quotes experts in Australia and New Zealand who claim about 14 per cent of scans are now being outsourced, up from five per cent six years ago. Management consultancy LEK says this figure rises to 80 per cent for out-of-hours services.

According to the RCR, 91 per cent of trusts and health boards sent a proportion of their scan workload to 'tele-radiology' companies in 2020, spending £206m, but a spokesman for the college told the newspaper that although private-sector involvement was currently vital to managing immediate demand, "more and more outsourcing to external suppliers is not the cure for insufficient radiologists on the ground".

There are currently ten tele-radiology providers in the UK, says the FT, all using NHS-trained radiologists working from home. In September one such company put out a press release headlined, "Tele-radiology start-up Hexarad tackles medical imaging crisis." Founded in 2016 by a group of NHS consultant radiologists, adopting what it describes as an "intelligent outsourcing" business model, Hexarad clearly seems confident of expanding its market, having recently closed a £2.3m funding round, which included a £1.7m growth capital investment from private equity and infrastructure investment manager Foresight Group.

With a major expansion of the CDH concept now underway, however, outsourcing isn't the only way the independent sector is increasingly moving into NHS community diagnostics – public-private partnerships are taking off too, on the back of CDHs.

Last month saw the launch of the Rutherford Diagnostics Centre in Taunton – run by Rutherford Diagnostics Ltd, a subsidiary of Rutherford Health, in a five-year partnership deal with Somerset NHS Foundation Trust, and the company plans four more CDHs under a £55m agreement with "infrastructure investor and developer" Equitix, whose CEO in the accompanying press release described the Taunton facility simply as an asset being added to his company's investment portfolio.

There will undoubtedly be other such partnerships emerging over the next six months as more CDHs are established across the UK, potentially favouring the independent sector in much the same way as the 'mega lab' Lighthouse diagnostics project – covered extensively by The Lowdown over the past 12 months – has already appeared to have done.

So it's worth keeping an eye on whose diagnostic pockets Mr Sunak's £2.3bn Budget bonus ends up in.

Martin Shelley

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