comment

"Vacancies are a policy risk, but I've still to see a credible workforce plan" **DAVID OLIVER**
"Is the health secretary's salaried GP plan a route to re-privatisation?" **HELEN SALISBURY**
PLUS When staff are told to do the impossible; Javid's "reform trust" proposal

TAKING STOCK Rammya Mathew

Difference between a doctor and a family doctor

My 1 year old daughter has been unwell for the past four days with diarrhoea and vomiting. She's been struggling to keep any fluids down. I've naturally been worried about her and, as I write this, I'm wondering when I should get her seen by someone who can provide a more objective medical opinion.

I've been holding back because she doesn't look overly dehydrated, and although four days is longer than the expected course of viral gastroenteritis, it's still most likely going to be that. She will, most likely, get better soon.

The slightly longer version of the story is that she started nursery last week and as a result had already been suffering from separation anxiety, so even before this bout of illness we hadn't been getting much sleep at home. I also felt extraordinarily guilty about her having to spend 10 hour days in nursery since I started back at work in general practice. The fact that she's become so unwell has only added to the guilt.

To top it off, I started a new job at the same time, so alongside the changes in our home life I've been trying to settle into a new role and get to know my new colleagues. Fortunately, I've had the support of my family, but the stress of having to organise childcare at the last minute and leave a sick child at home is not something to be dismissed.

When I was thinking about whether to take her to see our GP, it struck me that the difference between being a doctor and being someone's family doctor is spending those extra minutes hearing the long story. Anyone could eyeball her, do a few basic observations, and pretty quickly conclude that she isn't unwell enough to require hospital admission.

But as family doctors we're naturally curious and take an interest in our patients and their families. It's the quality of these relationships, along with the trust that we build over time with our patients, that makes GPs unique and irreplaceable, giving validity to our counsel.

Anyone who still believes that general practice is just about coughs, colds, and viral illness is missing the bigger picture. We deal with complex disease, but more importantly we deal with the complexity of people, as well as the wider circumstances that influence their health and vice versa.

GPs hold one of the few remaining pastoral roles that many people still routinely engage with in modern society, and it's incredibly short sighted for anyone to undermine the role of the family doctor—be that through policy or put-downs. I think I now know who I'll be calling in the morning.

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It's incredibly short sighted for anyone to undermine the role of the GP

OPINION Esther Choo

We're asked to do the impossible, then abandoned to our failures

The single worst stressor on healthcare workers is the gap between what their patients need and what they can deliver

News media have been insistently describing the omicron variant as "mild," but that is scarcely a consolation in parts of the world where covid hospitalisations have surged to January 2021 levels. In the US, the National Guard has been called in to relieve overwhelmed hospitals in at least 10 states. Similarly, in London, the military has been deployed to NHS hospitals.

In a recent Kaiser Health News podcast about the response to the latest covid surge, the host, Julie Rovner, posed a question: "Is there a possibility that our health system just stops functioning or grinds to a halt?" A second journalist was optimistic: "We've been through this several times and so I think we'll make it through this one."

I heard in the comment a familiar, complacent confidence in the emergency healthcare system—a social service that is predictably and thus forgettably always there. Like public health itself, you don't hear about emergency care that functions well: for most people, it stays comfortably buried in the subconsciousness, only rising to the surface if they or a family member need us.

But the current crisis should dispel the illusion that any aspect of emergency care is guaranteed. In the US, unprecedented staff attrition has markedly reduced the number of available beds hospitals have. The pandemic has caused serial delays in primary and other kinds of outpatient care, pushing people to the point of health crises.

Ever present inequities

With omicron, the volume of patients presenting for care has been crushing, with waiting times for emergent care becoming intolerable in many places. The kinds of inequities that surface whenever anything is in short supply are ever present. In stark terms, crisis standards of care and triage algorithms assure that some patients will be refused needed care, even in emergencies, and harms will follow—especially for those made vulnerable by illness or societal structures.

For healthcare workers, the single worst stressor is the feeling of being lost in the increasingly vast gap between the care they want to deliver and what they can provide. Yet for many people, hearing that emergency care is overwhelmed is an abstraction that doesn't alter individual, societal, or medicolegal expectations for care. What then are we doing but asking staff to do the impossible, and abandoning them to the certainty of failure?

Running an acute care system always requires creative problem solving, but we've reached the point where every short term effort to fix a problem triggers another elsewhere. We cancel outpatient procedures and non-emergent treatments in one surge, only for those patients to become sicker and in need of more care. We make shifts longer to accommodate staffing shortages, but that further taxes exhausted workers, leading to more staff losses. We recruit bank workers at generous rates, and demoralise existing staff.

It feels like a grim, everlasting game of hot potato. Even the very work of grappling with the impossibilities adds to the problem. Whether staffing shortages or boarding or allocation of scarce resources, each issue requires a solution devised by committees and taskforces, which necessarily comprise the same people trying to keep their heads above water in hospitals and clinics.

Healthcare workers are facing all these stressors, all at once, in sustained fashion,

OPINION Richard Vize

Instead of gimmicks, the NHS needs a workforce plan

The reported plan by health and social care secretary Sajid Javid to introduce "academy-style" hospitals risks triggering organisational chaos in the NHS while failing to address any of its underlying problems.

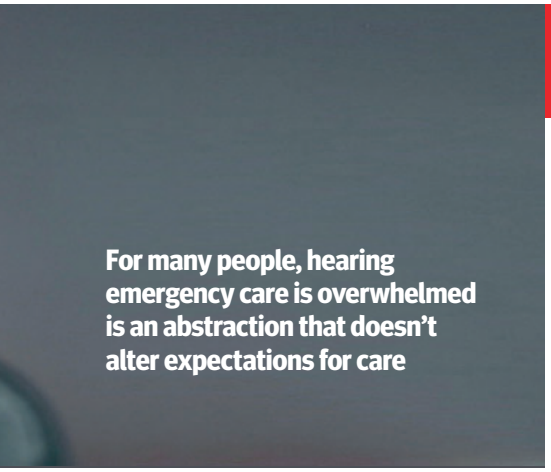
According to the *Times*, barely six months after his cabinet return Javid plans to force failing hospitals to become "reform trusts," similar to academy schools, to address wide variations in performance. It's possible hospital chains will be run by leading NHS managers, or even outside sponsors.

Everything about this plan is flawed. It shows that a decade after Andrew Lansley's disastrous attempt to use market mechanisms to drive NHS improvement, this government has forgotten all the painful lessons of the cost, political damage, and impact on services of ill conceived top-down reorganisations driven by whim, not evidence.

Rather than showboating, Javid needs to work out how to recruit more staff

The experience of academy schools tells us that reform trusts would undermine the push for integration by weakening links to other local health services and local government. The idea could postpone yet again the moment when primary care and community services get the investment needed to improve prevention and early diagnosis and move services closer to the people who need them.

Many of the trusts likely to be in Javid's sights are those that have been struggling for decades. They have not been in difficulty for so long because of a statistically improbable succession of poor leadership teams, but because of underlying factors such as dysfunctional local health economies, the pressures of serving



For many people, hearing emergency care is overwhelmed is an abstraction that doesn't alter expectations for care

added to feelings of obligation and guilt. Take care of yourself, rest, we tell each other. But there is no rest to be had.

I worry those learning to practise medicine will normalise this state of healthcare or internalise the sense of futility that caring for patients is currently imbued with. I worry the exigencies will melt into collective amnesia and relief at having blown past this crisis.

I've worked the same shift for six years. The pandemic has decimated what was a stable, familiar crew. Some colleagues went to other parts of the system, some retired early, a few pursued advanced degrees, and some were caught between work and the responsibilities of caring for relatives. One died from suicide (I can barely stand to write that).

What people don't see is how we're there, until we're not. Or how we're there, but so diminished you might not recognise us.

Esther Choo, emergency physician, Oregon Health & Science University

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If you're struggling, you're not alone. In the UK and Ireland, Samaritans can be contacted on 116 123 or email jo@samaritans.org

deprived communities, difficulties attracting key staff, and a lack of capital investment.

Instead of such gimmicks, Javid needs to tackle the fundamental problems that hobble NHS performance such as underfunded social care and community health services leaving people stranded in hospital, a lack of investment in equipment and buildings, a disillusioned primary care service that is unable to meet demand, and the shortage of acute and intensive care beds.

The plan the NHS needs from Javid more than any other is a workforce plan. Instead of showboating to his backbenchers, he needs to work out how this government is going to train and recruit sufficient nurses, doctors, midwives, therapists, and many more so that the NHS can meet current and future demand.

Richard Vize, Public policy journalist and analyst

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ACUTE PERSPECTIVE David Oliver

GPs as employees won't solve pressures

There's a communications tactic in politics of "flying a kite," where nascent proposals are strategically placed in sympathetic media outlets to start a discussion, gauge reaction, or soften us up in advance. We also see diversionary "squirrel" policy announcements, designed to distract the press and public.

Last month we saw both, in the form of stories based on an ongoing internal review of the NHS commissioned by England's health secretary, Sajid Javid. First, a story in the *Times* described hospital models akin to school academies, operating as semi-autonomous entities. The *Times* then wrote last week of "GPs nationalised in Javid plan to reduce hospital admissions." The leaked proto-plan was that GPs would be encouraged or offered the chance to move to salaried employment by hospital trusts.

Why? Because politicians believe that the independent contractor model of GP partnerships makes it harder for ministers to pull levers to deliver their performance objectives and that direct line management would somehow help reduce pressure on hospitals. I think that it's misguided and doomed to fail.

Changing GPs' contracts won't create more GPs. Since 2015 we've seen a slight fall in full time equivalent GPs, while hospital consultants have grown. In that time the GP workload has grown significantly. They see far more daily patients than counterparts in comparable nations.

The modest increase in junior doctors entering GP training won't compensate for the older GPs retiring or reducing hours because of burnout, worsening morale, or a desire to restore some work-life balance. Workforce gaps are another major policy risk, but I've still to see a credible workforce plan.

I can't see how new employers for some salaried GPs, or hospital takeovers, would meaningfully affect pressures on hospital beds. Acute admissions to beds are in patients who, having been seen by specialists in emergency and acute medical specialties, are deemed sick enough to require hospital admission, or where no alternative community health and social care services are rapidly available.

The social and community healthcare crisis is another major problem for Javid but also one with no solutions in sight. Reviews of the reasons for admissions have shown numerous factors at play, well beyond general practice, and studies on interventions to reduce admission have modest benefits at best. Yet some evidence suggests that continuity of primary care in helping people to live with long term conditions can modestly reduce acute illness episodes. Making GPs work for trusts won't deliver that. Adequately resourced and staffed general practice just might.

Many doctors chose general practice partly because they weren't on the payroll of a large organisation. Hospitals' expertise isn't in primary care. That lies with GPs. And a GP's role is more than "keeping people away from hospital."

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I think the proposal is misguided and doomed to fail

PRIMARY COLOUR Helen Salisbury

Javid's plan for salaried GPs

In general practice we're becoming wearily accustomed to learning about the next proposed upheaval in our working lives by reading about it in newspapers. This week we read in the *Times* about the health secretary's suggestion that hospital trusts should run GP surgeries, turning primary care into a fully salaried service.

Since the NHS's creation in 1948 GPs have operated as private contractors rather than being its direct employees. Over the years the contract has become more complex and arcane, and arguably less fair. There are many reasons why GPs might welcome a salaried service. If we didn't run as private businesses, perhaps we wouldn't need to worry about fixing leaky roofs or recruiting nurses or receptionists. Someone else could organise the vaccination clinics and worry about who will staff the unpopular extended hours shifts. We'd be free to focus on looking after the patients under our care, rather than being distracted by the business of running a practice.

But the main problems facing primary care would not be solved. Even if we had confidence that trusts would manage us better than we manage ourselves, this change would not fix the GP shortage. We don't have enough GPs: there are more in the pipeline, but the existing ones are burning out, retiring early, or emigrating to places with better working conditions more quickly than we can replace them. Some GPs have opted for salaried contracts where they're more likely to be able to control their hours, but many, both salaried and partners, are working 12 hour days to cover for missing colleagues. I'm not sure the health secretary realises that if we were all paid for the actual hours worked, the bill would be significantly higher than it is now.

For many partners, one compensation for the long hours and responsibility is autonomy: we can arrange appointment systems to suit our patients, and we can decide how many and what sort of staff we work with. If that freedom was lost many experienced GPs wouldn't stay.

Paradoxically, it's possible to see this suggested nationalisation as a route to the eventual re-privatisation of general practices. One fear is that, once under the control of hospital trusts, US-style health maintenance organisations covering both hospital and community care would be a natural conclusion, which may be far more attractive to private investors. We'd need reassurance that any new model would provide a universal, tax funded, cradle-to-grave personal service, embedded in the community and offering continuity of care.

On first reading, this proposal looks like a distraction from the main problems of workforce and premises—and a way to antagonise a group of professionals Sajid Javid needs to work with, not against.

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This change would not fix the GP shortage

LATEST PODCAST

Publish or perish?

At medical school, doctors in training already feel the pressure to publish. This episode of Sharp Scratch delves into the world of academic publishing, covering how to get better at writing, predatory journals, and the changing landscape of publishing.

Nikki Nabavi, medical student and former editorial scholar at *The BMJ*, talks about what editors are looking for in manuscripts:

"If you've had a rejection, it doesn't mean that you've written something that's objectively bad. It just means that this journal wasn't the right home for it. The other important thing that editors are considering is 'why is this person the appropriate author?' This can be a really difficult hurdle for students because nine times out of 10 they're not the expert on the topic so they've got to justify they're the right person to write about it. It could be that you have an expert co-author. It could be that you really struggled to learn how to do this particular thing and now you've got a good way of teaching other people about it."

Joseph Ross, co-founder of the preprint service medRxiv and research editor at *The BMJ*, describes the importance of finding value and joy in academic medicine, and not just subscribing to a culture that sees publications and citations as trophies to decorate a CV:

"I always find it very sorrowing to think that people are engaged in research just as a means of collecting points. The point is to make the healthcare system work better for our patients and for us as healthcare workers. What I always hope is that people are engaging in research with the goal of learning something that can then be one more little brick in the wall to make it stronger."

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Edited by Kelly Brendel, deputy digital content editor, *The BMJ*

ANALYSIS

Waiving covid intellectual property rights: stop worrying about profits

Luke Hawksbee and colleagues argue that policy makers should prioritise public health over private monopolies in the debate around global access to vaccines and treatments

PAUL QUEZADA-NEIMAN / ALAMY

Most experts agree we should vaccinate as many people on the planet against covid-19 as quickly as possible; where they disagree is how to do it. At the heart of many debates has been the issue of intellectual property rights: should companies that developed vaccines against covid-19 be required to make their knowledge available to others who can produce these vaccines? Or would a waiver of intellectual property rights or other reforms to the current intellectual property system jeopardise future innovation?

This debate rose high on the global policy agenda after President Joe Biden showed support for a temporary waiver on vaccine intellectual property rights. He has now been backed by the US Senate and joined by others ranging from the World Health Organization to the UK's Independent Scientific Advisory Group for Emergencies, Médecins Sans Frontières, and even the pope. Yet, half a year later, some European countries remain obstinately opposed, and the head of the World Trade Organization has warned negotiations were "stuck." Meanwhile, the Covax scheme seems designed to preserve existing market mechanisms and power dynamics.[2]

The argument against reforming the intellectual property system is that intellectual property rights are necessary to compensate for the financial risks that the drug industry takes on when investing in the research and development needed to develop new products. In the case of covid-19 vaccines, the amount of risk facing drug companies is debatable because governments provided a substantial share of research and development funding and bought large quantities of the vaccines in advance.[3] Do those governments deserve a "return" on their investment in the form of lower prices or greater access to the vaccines for poor people worldwide to increase global immunity, for example? Or is waiving intellectual property rights a form of state theft that might imperil future research vital for public health?

KEY MESSAGES

- The largest drug companies make higher profits than the largest companies of any other sector
- The incentive structure of for-profit pharmaceutical research results in major threats to global public health being neglected
- The industry fears that a waiver on intellectual property rights would harm future profits by undermining the monopoly power on which they rest
- Intellectual property rights for covid-19 products should be suspended as part of an intensive effort to reduce variant emergence and end the pandemic

Governments provided a substantial share of research and development funding for vaccines

Predictably, the drug industry has held that a waiver would reduce the profits that incentivise new drug development. Emergence of the omicron variant, however, shows the risks of the status quo: maximising vaccination is not only a moral necessity but also a potential bulwark against the evolution of other variants that might be even more contagious, virulent, or immune evasive. Moreover, we argue that a waiver would not threaten future drug development, primarily because the link between profits and innovation is tenuous, and public sector contributions are already a major driving factor in much of the innovation that most benefits public health.

The drug industry's consistently high profits

The industry's arguments would be stronger if there was evidence that it would be unable to attract investors—thus undermining its ability to fund research and development—if its profits were threatened. But this does not seem to be the case. The Fortune 500, a list of the largest corporations in the US (determined by revenue, that is total annual income) has been published annually since 1955. This allows us to calculate net profit margins: the percentage of the revenue a company receives that is surplus to covering its spending on items such as research and development or marketing, and is either paid out to shareholders, saved in company coffers, or used to buy back its own shares.

A calculation of average net profit margins shows that the drug industry has long been the most profitable sector, exceeding even the energy and financial industries (figs 1 and 2). From 1954 to 1999, its mean profit margin was already more than double the average of other sectors; since the turn of the century, this has ballooned to more than triple.

In short, even if drug companies lost a fifth of their profits they would still outperform 75% of other sectors, and losing nearly a third of their profits would leave them earning no less than the average industry.[6] Remember: these profits are, by definition, left over after paying for research and development.

Profits do not safeguard global public health

Perhaps high profits could be justified on the grounds that drugs companies provide the innovations most needed to improve and protect public health. But it is far from clear that they are focused on the most needed new products. Only around 2–3% of new drugs represent important breakthroughs and

around 9–11% offer a modest advantage over existing treatments.[7 8] Conversely, other crucial research is neglected: for instance, despite the urgent need for products to counter the threat of antimicrobial resistance, development pipelines are largely empty and the few new products have relied on public sector support rather than market forces.[9] But hasn't the drug industry been critical for rapid development of covid vaccines?

Over the past two decades, viral outbreaks, including SARS-CoV-1 in 2002 and MERS-CoV in 2012, raised fears of a global pandemic—in retrospect they could be considered "dry runs" for the emergence of SARS-CoV-2 in 2019. Although effective covid vaccines were developed at record speeds, and might have benefited from some of the scientific work in the wake of these previous viral outbreaks, vaccine development scientists have described how they struggled to obtain support for earlier work against betacoronaviruses.[10] To a large extent, even the current vaccine rollout was dependent on public sector and third sector support (though exact figures are disputed).

Some experts have suggested that a single vaccine could protect against future variants of SARS-CoV-2 and many or all other betacoronaviruses—including ones we have not encountered yet.[11-14] This idea had been proposed well before 2019. But the drug industry was reluctant to dedicate sufficient resources until a new virus was on our doorstep.

This should come as no surprise, given that the industry's dominant business model in the current intellectual property rights system is to develop patented drugs and generate the highest sales possible before the patent runs out, not necessarily to meet the greatest medical or public health need. There is no financial justification for a private sector company to invest in products for which there is no apparent market, including new antibiotics (which cannot be sold in vast numbers without provoking bacterial resistance) and drugs for neglected tropical diseases (which generally affect poor people in poor countries). A basic conflict exists between seeking profit for shareholders on the one hand and investing in medicines for underserved communities or getting ahead of the epidemiological curve on the other. The same incentive structure also explains why the industry has arguably adopted a "wait and see" approach to pandemic threats,[15] why companies have often shown unwillingness to donate vaccines, cut prices, or waive intellectual property rights, and why they have prioritised the highest bidders when allocating scarce vaccines.[16]

Industry fears reduced future profits

The pandemic is characterised by our inability to roll out products fast enough—under such circumstances an intellectual property rights waiver should not materially harm profits, as any vaccine or treatment produced by competitors would most likely be sold in addition to the originating company's sales rather than replacing them. The main problem is not minimising price (as it might be under more normal circumstances) but rather maximising supply: there is enough of a market for all current producers and more. We would therefore expect no material fall in covid-19 related profits for companies whose intellectual property rights are waived. Moreover, given 65 years of consistently high profits, investors are unlikely to abandon pharmaceutical innovation because of loss of intellectual property rights in the exceptional circumstances related to covid-19.

So why are companies insistent that strong intellectual property rights must remain in place even for vital vaccines they cannot produce enough of during a global public health crisis? One reason is that many of the covid vaccines on the market or in development incorporate new generic vaccine platforms that—with relatively simple changes—could yield not only further vaccines but treatments for other diseases.[17-21] A letter being circulated among US legislators warns that a waiver would allow China to "profit from our innovation," beating the US to develop products based on the new platforms.[22]

This might explain why certain leading companies are so keen to monopolise not only intellectual property rights, but also the productive capacity and, perhaps even more importantly, the knowledge, or "trade secrets," needed to produce the vaccines. Pfizer's chief executive officer noted the

The main problem is not minimising price, but rather maximising supply

"dramatic potential" of the mRNA technology and stated, "We are now ahead and we plan to maintain the gap" in future development.[20] By collaborating with BioNTech, Pfizer can say that now "we have our own expertise developed." Little wonder that Pfizer is so reluctant to help competitors obtain for free the same knowledge.

We also think the industry fears a waiver would change the nature of the discourse of pharmaceutical policy, potentially leading to price controls or reduced intellectual property rights in key markets such as North America, which accounted for 49% of global pharmaceutical sales in 2018.[23]

This is not the first time drug companies have prioritised intellectual property rights in the face of a public health crisis endangering the lives of millions. Drugs effective against HIV were identified by 1996, yet poorer countries were priced out of the market for years. At that time, roughly 4.5 million South Africans (20% of the population) had HIV, but only 90 people were receiving antiretroviral therapy (ART).[24] In 1997, South Africa passed a law to import generic ART drugs that are vastly more affordable to enhance access to treatment. In response, 39 drug companies collectively sued South Africa.[25] Eventually the companies conceded, and with the help of additional international funding, huge progress has been made in rolling out affordable ART drugs: four million South Africans were receiving ART by the end of 2017. This flexibility around patent rights for ART did not cause a collapse in drug company profits, and research and development spending rose steadily across this period.

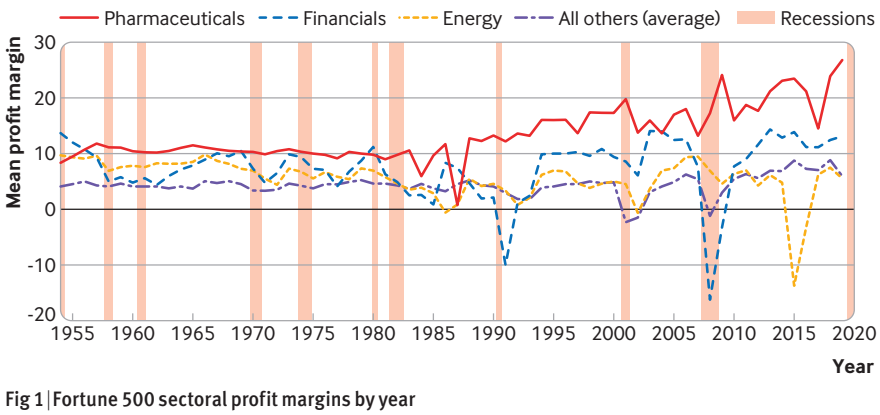

Fig 1 | Fortune 500 sectoral profit margins by year

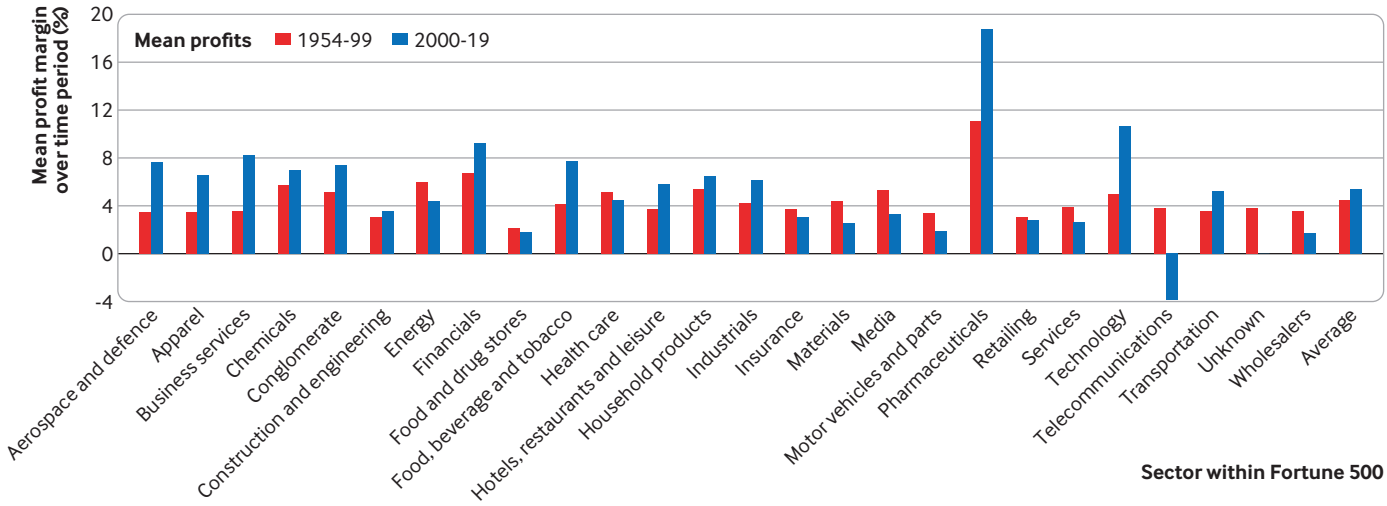

Fig 2 | **Fortune 500 sectoral profit margins before and after 2000**

Roles for public and non-profit institutions

The idea that society can only reap the benefits of medical innovation if intellectual property monopolies provide the drug industry with extraordinary profits is no longer plausible. Record profits did not lead to the research we needed after SARS or MERS nor to solutions to antimicrobial resistance or neglected tropical diseases, and they have never guaranteed access to drugs or vaccines for the many millions of poor people around the world. There is no reason to think that profit seeking will provide the proper incentives to safeguard global health in the future, either. Rather, the incentive structure underlying research and development needs to be reformed through more public led and mission oriented research, where rewards are disconnected from the current size and affluence of the market served.[26]

Thankfully, there are existing models of medical research that prioritise public health over private profit, on which we could base future innovation. The Drugs for Neglected Diseases Initiative has shown that non-profit organisations can bring new products to market at relatively low cost: from its creation in 2003 to the release of its current strategic plan in early 2021, well under a billion dollars was sufficient to develop eight new treatments for neglected diseases.[27] This stands in marked contrast to the drug industry's frequent—but controversial—claims that it costs upwards of $2bn to bring a single new product to market.[23 28] The Drugs for Neglected Diseases Initiative also negotiated liberal intellectual property agreements designed to maximise access to these drugs, working with partners in both industry and academia.[27]

This is not solely an ethical issue but also a question of risk management

State funded and managed organisations like the US National Institutes of Health or, in future, the EU's Health Emergency Preparedness and Response Authority, could have a greater role in drug development. This aligns with proposals for a new European pharmaceutical strategy.[29] Governments could acquire promising early stage drugs and biologics (or the companies developing them) or could commission trials of promising but otherwise neglected therapeutics.

Such activities could form part of innovative hybrid and network based initiatives that contribute vital research outside the traditional model of monopolising intellectual property rights and are not driven by anticipated profits but by public health priorities. Examples of such groups include Open Source Malaria—established by a non-profit private-public partnership—and WHO's Global Influenza Surveillance and Response System, which shares data and advice that contribute to effective flu vaccines.[30 31] Other alternatives that rebalance the risks and benefits to public and private sector actors, such as prizes for successful innovations and sharing of profits with governments providing research and development funding for successful products, have also been proposed.[32 33]

Although there is growing acceptance that private, profit driven, intellectual property protected approaches to drug discovery, development, and marketing are not working for people, change will only come about with political will that can overcome the combination of lobbying and inertia that maintains the status quo.

As a first step, intellectual property rights for covid-19 vaccines should be waived, and necessary knowledge and technology should be transferred. This should be expanded to cover other covid-19 products such as therapeutics and should also be part of a wider programme including pricing policies, tackling bottlenecks of raw materials, dealing with unequal distribution of doses between countries, accelerating research into broadly protective coronavirus vaccines, and strengthening delivery systems, drawing on, for example, the experience of the Global Fund.

Even if leading companies do see their profits drop as a result of these measures, we cannot place profits before human health and life, especially as profits would have to collapse catastrophically to jeopardise future innovation. This is not solely an ethical issue but also a question of risk management, as suggested by the emergence of the omicron variant. We urge an intensive effort to waive intellectual property rights on covid-19 vaccines, vaccinate the entire world, end the pandemic, and prepare for the next one.

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Lawrence King professor of economics, University of Massachusetts, Amherst

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LETTERS Selected from rapid responses on bmj.com

LETTER OF THE WEEK

Care home staff need long term support

In their trial of a programme to prevent falls in older people, Logan and colleagues show that training care home staff with written guidance has a short lived effect (Research, 11 December). A persistent effect can be achieved only by nurturing and sustaining staff over the long term.

The approach mirrors FallSafe, a trial to prevent inpatient hospital falls, in which a care bundle was given to staff to implement, with falls prevention training for ward staff. It was successful because of the work of the paid "falls champions" on the wards and the team of people they enthused, not because of the care bundle and the initial training. We are not told what support falls champions were given in this trial—that support, not the training and guidance, may have been the actual intervention.

We had similar results in Oxfordshire in 2006. There was no sustained change in behaviour. Training was problematic, with 34 first languages and high turnover of staff, forever too busy to attend training. After an interval, falls became just another priority and the guidance was filed away.

The outcome was the formation of the Oxfordshire Care Home Support Service in 2010, with 22 full time staff, consisting of physical and mental health nurses, physiotherapists, and occupational therapists, led by a consultant geriatrician. They support 118 local care homes to manage the complex cases of residents, including falls prevention, dementia management, end of life support, drug reviews, manual handling, mobility and positioning advice, hydration and nutrition, and the ability to access rapid input from psychiatry and other specialties, and to signpost to other services.

Independent audits show Oxfordshire performs well on any metrics concerning care homes—mortality, hospital admissions, days spent in hospital, falls, and fractures. The service is now part of the county's regular healthcare landscape.

Adam Darowski, consultant geriatrician and clinical lead; Antoinette Broad, advanced clinical practitioner, community services; Kristel Silvester, clinical lead; Paula Hughes, falls specialist, Oxford

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PREVENTING FALLS IN RESIDENTIAL CARE

Promoting health in care homes

Logan and colleagues found that a complex intervention was associated with a significant reduction in falls among older adults living in long term care (Research, 11 December).

Falls prevention is one of many health problems that care home staff deal with. In addition to the health issues of residents, the care home sector has wider, long standing problems—underinvestment, understaffing, poor employment conditions, and difficulty recruiting and retaining staff.

Care homes provide opportunities for promoting the health of all those who live and work there. As a workplace, care homes can tackle occupational health problems and general health promotion. But they need more support to maximise the focus on promoting all aspects of health. This could be facilitated by public health specialists if they were provided with sufficient resources.

We would like to see "health promoting care homes" established, empowering and firmly promoting the health of residents and all the staff.

Michael Craig Watson, trustee; Sylvia Tilford, trustee, Institute of Health Promotion and Education

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FINANCIAL INCENTIVES FOR HEALTH

Financial incentives should be standard

Berlin and colleagues found that increasing financial incentives had positive effects on smoking abstinence in a randomised controlled trial of pregnant smokers (Research, 4 December).

Financial incentives should be part of standard practice to support general health for all populations. An institutional approach should be taken to create scalable and sustainable financial innovations embedded in large health policy platforms. In the US, health savings accounts cover more than 30 million workers, providing tax benefits and additional incentives to motivate positive health behaviours (such as annual physical examinations). Nearly a million newborns a year are automatically enrolled in state child development accounts in the US, and financial incentives improve the behavioural and mental health of participating families. Conditional cash transfer programmes in developing countries could be used to accommodate financial incentives for health.

More efforts should be invested in general policy platforms supporting financial incentives for health.

Shu Fang associate professor, Beijing; Jin Huang professor, St Louis

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OVERACTIVE BLADDER IN WOMEN

The female bladder is not a territory to be claimed

We challenge the recommended referral of overactive bladder in women to urology (10-Minute Consultation, 4 December).

Urogynaecologists can provide the listed "urological" investigations and have the additional skills to manage pelvic organ prolapse, which improves overactive bladder symptoms in women who have both conditions. They can also improve quality of life by tackling the commonly coexisting sexual dysfunction, vulvo-vaginal atrophy, and incontinence.

We urge GPs to identify any gynaecological symptoms or signs when assessing for overactive bladder and, if symptoms don't improve after physiotherapy and medication, to refer to urogynaecology. GPs should consider referral to urology if the patient has persistent bladder or urethral pain or recurrent or persistent unexplained urinary tract infection.

The female bladder is not a territory to be claimed in a war between specialties, and ultimately a collaborative multidisciplinary approach might be best, including urologists, urogynaecologists, physiotherapists, colorectal surgeons, and physicians.

Sarah Wali, specialty trainee year 6 obstetrics and gynaecology; Claudine Domoney, consultant in obstetrics and gynaecology, London

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EDITORIAL

Automatic registration for UK trials

A welcome development, not a panacea

Public registration of studies before they start (prospective registration) is an effective way to reduce publication and other reporting biases in healthcare research. Such biases can result in misleading findings, waste resources, and even harm patients.[1 2]

Publicly declaring hypotheses and methods before results are known is hardly new, but the potential to improve transparency and reproducibility has not been fully realised. Registration of certain clinical trials has been mandatory for several years in the US, EU, and UK, and the Declaration of Helsinki stipulates that every study with human subjects must be registered in a publicly accessible database before recruitment begins.[3-5]

Compliance with these legal and ethical obligations has steadily improved, but violations are still common, with academic and public institutions lagging behind commercial organisations.[6 7]

Policy framework

In response, the UK's medical research regulator, the Health Research Authority (HRA), has published a new policy framework to "make transparency the norm" and announced plans for all UK clinical trials to be automatically registered after NHS ethics approval under a partnership with the ISRCTN registry, starting with drug trials from January 2022.[8 9] This will make the ISRCTN an invaluable national portal guaranteeing access to information on all UK clinical trials and if successful could be an example for regulators and registries worldwide. Automatic registration should also reduce the problematic practice of registering trials only after they've started, or even finished.[12]

The HRA should consider expanding automatic registration to all research approved by an NHS ethics committee

Prospective registration permits comparisons between a study's prespecified aims and methods and those reported in published papers, but it does not guarantee that such checks occur. Furthermore, the HRA acknowledges that resource constraints limit its ability to ensure all registered trials are subsequently published.[8] Even when discrepancies between registered protocols and published trials are identified, journals and authors often fail to acknowledge them.[13] To realise the full value of registration, trial sponsors must ensure that registered information remains up to date and includes a link to the final study results.

Complementary approach

A separate preregistration initiative, registered reports, could also help improve transparency and reduce reporting biases. These reports allow authors to submit their research question, hypotheses, and methods to a journal for peer review, and to start collecting data only when their study has been accepted in principle for publication.

Peer review before study commencement could reduce bias and unjustified flexibility in analyses, and emerging evidence suggests that registered reports help to improve standards of transparency, reporting, and study rigour.[15 16] Clinical trials are particularly well suited to this approach. By reviewing protocols before trials start, and guaranteeing publication when they are complete, use of registered reports could improve the availability, quality, and timeliness of results and reduce the pressure to use poor research practices to generate significant results. Unfortunately, medical research has been slower to adopt registered reports than other disciplines, such as psychology. Few medical journals currently offer this option.[17]

The pandemic has shown our reliance on observational and modelling studies to inform major policy decisions and the problems caused by failure to report key study details.[18] The HRA should consider expanding automatic registration to all research approved by an NHS ethics committee, with reasonable exceptions. For studies that do not require ethical review, host institutions, journals, and funders could promote preregistration and registered reports to help reduce the risk of biased findings entering the healthcare literature or valuable findings being withheld.

Progress has been made in improving transparency and controlling biases in research, particularly in clinical trials, but serious gaps remain. The robust system of transparency established for clinical trials should be applied to other study types. Making this happen will require continued engagement with stakeholders as they work to raise standards. The public, which both funds and benefits from healthcare research, must be able to trust the results.

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Kelly E Lloyd, doctoral student, Leeds Institute of Health Sciences, University of Leeds
Nicholas J DeVito, doctoral researcher, University of Oxford

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Peter Michael Hacking

Consultant radiologist Royal Victoria Infirmary, Newcastle upon Tyne (b 1929; q Cambridge/Middlesex Hospital Medical School, London, 1953; MD, DRMD Eng, FRCR), died after a general decline secondary to Parkinson's disease and related postural hypotension on 25 November 2021

Peter Michael Hacking moved with his family to Newcastle upon Tyne, where he started his training at the Royal Victoria Infirmary. He was appointed a consultant in 1962, and as administrator in charge in 1977. He was active in the Royal College of Radiologists, published extensively, and finally retired in 1990. He and his wife, Helen, moved to Oxfordshire. They enjoyed the cultural life of Oxford and attended performances in Stratford-upon-Avon, and at the National Theatre and the Royal Opera House in London. They also visited most of the important historic archaeological sites and international art centres around the world. Peter leaves Helen, three children, five grandchildren, and two great grandchildren.

Nigel Hacking

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Richard Higginson

GP (b 1939; q Middlesex Hospital, London, 1962), died from Parkinson's disease on 6 November 2021

Richard Higginson started his career as a GP by joining a small practice in Billericay, Essex. After several years, he moved to Worcester with his family to become joint senior partner at the Bullring Surgery in the St John's area of the city. He became the sole senior partner and saw the practice expand from one site to three. Richard was medical officer for Worcester County Cricket Club's home matches. His interests included a lifelong love of rugby and making model railways and trains. He also enjoyed sailing, having built his own yacht. He bore the effects of Parkinson's disease with complete stoicism over the last couple years of his life and was finally at peace, quietly in his sleep. He leaves his wife, Catherine; two daughters; and four grandsons.

Sarah Watson

Cite this as: *BMJ* 2021;375:n2973

Alison Paice Hill

GP and medical director NHS North West London (b 1947, q Guy's Hospital Medical School, London, 1971; FRCGP, MRCP, BSc, MA medical anthropology), died from non-small-cell lung cancer on 3 July 2021

Alison Paice Hill did a groundbreaking piece of mid-career research on difficult consultations in general practice. She moved from a successful trajectory in national medical politics to roles focused on enabling better care by resolving misunderstandings between doctors and patients. Posts at Southampton University Medical School, Barts/London Medical School, the King's Fund, and the Department of Health's NHS genetics team followed, before she returned to clinical practice in inner city Kilburn and became medical adviser and finally medical director NHS North West London. She died 23 months after her diagnosis and leaves her three children and four stepchildren.

George Freeman

Cite this as: *BMJ* 2021;375:n2971

William John Pryn

Director of army surgery, consulting surgeon to the British army, and consultant surgeon Royal Hospital Chelsea (b 1928; q Guy's Hospital, London, 1951; OBE, FRCS, OStJ), died from heart failure and chronic renal failure secondary to valvular heart disease on 8 November 2021

William John Pryn ("Bill") trained as an army surgeon in the Royal Army Medical Corps. He rose up the ranks to major general. His career took him around the world. He contributed to surgical practice by publishing the first description of the dartos pouch procedure for the treatment of undescended testes in small boys, which is now standard practice throughout the world. Bill was appointed as Queen's Honorary Surgeon in 1981 and retired in 1986. He embraced his hobbies of game shooting, fly fishing, and golf. He leaves his first wife, three children, two stepchildren, 14 grandchildren, and numerous great grandchildren.

Bob Pryn, Steve Pryn

Cite this as: *BMJ* 2021;375:n2968

Robert Newton Smith

Consultant physician and medical director in the pharmaceutical industry (b 1934; q Birmingham 1958; MD, FRCP, FFPM), died from frailty of old age on 17 September 2021

Robert Newton Smith ("Bob") met his future wife, Doreen, a schoolteacher, while he was doing national service in the Royal Army Medical Corps in Cyprus. On return, they moved to Sheffield, where he held clinical and academic posts. He moved into the pharmaceutical industry in 1976, initially as director of clinical research at Roche in Basel, Switzerland, and then as medical director at Glaxo back in the UK. He was involved in drug development, sat was on the founding committee of the Faculty of Pharmaceutical Medicine, and was the first editor of the journal *Pharmaceutical Medicine*. He had a happy retirement with Doreen, enjoying his grandchildren and travelling before illness in his later years. He leaves Doreen, two sons, and four grandchildren.

Jane Rogers

Cite this as: *BMJ* 2021;375:n3078

Wendy Leigh Thomson

Medical director (b 1930; q St Mary's Hospital Medical School, London, 1954; DObst RCOG), died from cerebrovascular disease on 22 December 2019

Wendy Leigh Thomson (née Jefferson) did her pre-registration jobs at St Mary's. After several post-registration jobs in and around London and a radiology post in Oxford, in 1968 she became a principal in general practice in High Wycombe, where her husband had been appointed as a consultant physician. In 1972, she became medical adviser to Johnson & Johnson Limited UK. Her responsibilities lay in clinical research, mostly associated with the development of new consumer products. In 1975 she joined Ortho-Cilag Pharmaceutical, a subsidiary of Johnson & Johnson USA, as medical director. She retired in 1988, and was able to pursue her interests of travel, music, art, and the theatre. Wendy leaves her three children and seven grandchildren.

H A Thomson

Cite this as: *BMJ* 2021;375:n2967

OBITUARIES

Peter Pharoah

Public health professor whose research eradicated iodine deficiency related cretinism in Papua New Guinea

Peter Oswald Derrick Pharoah (b 1934; q St Mary's Hospital Medical School, London, 1958; MSc Lond, MD, FFPHM, FRCPCH, FRCP), died from dementia on 23 October 2021

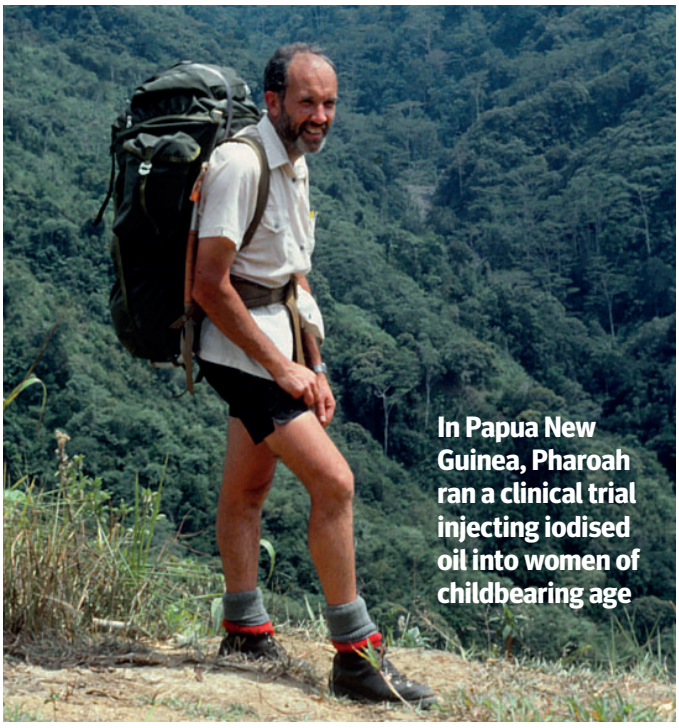
Peter Pharoah, emeritus professor of public health at the University of Liverpool, was born in Ranchi, India, to Oswald Pharoah and Phyllis (née Gahan), who were both teachers. As a young child, he attended schools in Lovedale and Sanawar, India. On losing his father at the age of 7, Pharoah moved with his mother and brother to England in 1948. He continued his education at Palmer's School in Grays, Essex, where he excelled at academic subjects as well as sport.

Pharoah met his future wife, Margaret (née McMinn), who was also training as a doctor, at the Royal Free Hospital Medical School. They both qualified in 1958 and were married in 1960. Junior posts in several London hospitals followed, but in 1963 Pharoah's career changed direction when he moved to Papua New Guinea with his young family to become the medical officer in Rabaul, a beautiful settlement until it was destroyed in 1994 by falling ash from a volcanic eruption. District medical officer posts in Mount Hagen, Wewak, and Goroka followed.

Endemic cretinism in Papua New Guinea

According to his son, Paul Pharoah, a cancer epidemiologist at the University of Cambridge, "My father's research in an inaccessible highland region, the Jimi Valley, established that the arrival of Australian administrators in the late 1950s coincided with the onset of endemic cretinism.

"Administrators paid villagers with salt, and the villagers stopped making a highly iodised salt sourced from remote volcanic rock pools. Severe iodine deficiency in the population resulted and, believing it might be the source of cretinism, my father ran a clinical trial injecting iodised oil into women of childbearing age. Clinical trials, particularly in such difficult terrain, were rare at the time. The intervention prevented cretinism in the women's children and suggested severe iodine deficiency in the mother produces neurological damage during fetal development. Legislation was then introduced to ensure only iodised salt could be imported, and endemic goitre and cretinism disappeared from the highlands. My father's doctoral thesis based on this research was described by examiners as 'reading like a novel.'"



In Papua New Guinea, Pharoah ran a clinical trial injecting iodised oil into women of childbearing age

With Papua New Guinea's independence, Pharoah returned to the UK in 1972 to study at the London School of Hygiene and Tropical Medicine, where he achieved an MSc two years later and was appointed senior lecturer. In 1979 he moved to the University of Liverpool as professor of public health; in 1997 he became emeritus professor. He published widely on cerebral palsy and the factors determining its long term prognosis, using his globally recognised database to forecast the life expectancy of children with the condition in many legal cases.

"Vanishing twins" study

Sally Sheard, professor and head of the department of public health, policy, and systems at the University of Liverpool, recalled, "Peter was head of the department of public health from 1979 until 1997 and worked on several large epidemiological studies, some that continued into retirement. I arrived in 1994 as a postdoctoral researcher, and he was an inspirational figure. He had a great and evident sense of humanity, in his research and his interactions with colleagues. He always had a smile, or as Margaret Whitehead says, a twinkle in his eye.

"In 1999 Peter's 'vanishing twins' study showed that as many as one in 20 started life as one of a pair of twins, but that many were not detected as such during pregnancy. His research concluded that if a child has a twin that dies in utero, the surviving child has an increased risk of cerebral palsy or heart defects.

"He also set up the largest cohort in the world of very low birthweight babies, which provided the most robust estimates of expectation of life for children with a range of health conditions. For much of his time at Liverpool, Peter was also editor of the *International Journal of Epidemiology*.

"In retirement he continued to self-fund his research and a small team. Peter was the epitome of a great academic: collegiate, inquisitive, inclusive, and, above all, kind. He has left a great legacy through his research, through the generations of staff he mentored, and the students he helped train."

His later research focused on a variety of health conditions that affect young children, including heart defects and low birth weight. He initiated a major study into the causes of perinatal mortality.

In 2020, shortly before their diamond wedding anniversary, Margaret, died. Pharoah leaves their four children and 12 grandchildren.

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