Agenda – Health, Social Care and Sport Committee – Fifth Senedd

Meeting Venue:
Video Conference via Zoom
Meeting date: 13 January 2021
Meeting time: 09.00

For further information contact:
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In accordance with Standing Order 34.19, the Chair has determined that the public are excluded from the Committee's meeting in order to protect public health. This meeting will be broadcast live on senedd.tv

Informal pre-meeting (09.00-09.30)

1 Introductions, apologies, substitutions and declarations of interest

(09.30)

2 Welsh Government Draft Budget 2021-22: Evidence session with the Minister and Deputy Minister for Health and Social Services

(09.30-11.40) (Pages 1 – 73)

Vaughan Gething MS, Minister for Health and Social Services
Julie Morgan MS, Deputy Minister for Health and Social Services
Dr Andrew Goodall, Director General for Health and Social Services and the NHS Wales Chief Executive – Welsh Government
Albert Heaney, Deputy Director General, Health and Social Services Group – Welsh Government
Alan Brace, Director of Finance – Welsh Government

Research Brief
Paper 1 – Welsh Government Draft Budget 2021-22

3 Paper(s) to note

(11.40)

3.1 Letter from the Auditor General for Wales regarding the procurement and supply of PPE during the COVID-19 pandemic

(Pages 74 – 79)

3.2 Letter from the Minister for Health and Social Services regarding the successor arrangements for the major health condition delivery plans

(Pages 80 – 81)

3.3 Letter from the Minister for Health and Social Services regarding the LCM for the Medicines and Medical Devices Bill

(Pages 82 – 88)

3.4 Letter to ADSS Cymru following the evidence session on 9 December 2020

(Pages 89 – 90)

3.5 Additional information from ADSS Cymru following the evidence session on 9 December 2020

(Pages 91 – 93)

4 Motion under Standing Order 17.42 (ix) to resolve to exclude the public from the remainder of this meeting

(11.40)

5 Welsh Government Draft Budget 2021-22: Consideration of evidence

(11.40-12.05)

6 Forward work programme

(12.05-12.30) (Pages 94 – 127)

Paper 7 – Forward work programme

Paper 8 – Common Framework for Food Compositional Standards and Labelling

Paper 9 – Public Health Protection and Health Security Framework

Agenda Item 2

Document is Restricted

Health, Social Care and Sport Committee

Date: 13th January 2021
Venue: Senedd Cardiff Bay
Title: Scrutiny of Health and Social Services Draft Budget 2021-22

1. Purpose

The Committee's Chair wrote to both the Minister for Health and Social Services and the Deputy Minister for Health and Social Services on 18 November 2020 inviting them to give evidence on their Draft Budget proposals and asking them to provide a paper in relation to the Draft Budget.

2. Introduction

This paper provides information for the Health, Social Care and Sport Committee on the Health and Social Services (HSS) Main Expenditure Group (MEG) future budget proposals for 2021-22 and also provides an update on specific areas of interest to the Committee.

3. Budget Overview

	2021-22
Revenue	**£m**
2020-21 DEL Baseline as@ Final Budget	8256.527
Baseline Adjustments	(2.296)
MEG allocation	420.576
COVID	10.000
MEG to MEG Transfers	(2.863)
Revised DEL as @ Draft Budget 2021-22	**8681.944**
Capital	
Indicative Baseline Budget	366.528
MEG allocation	16.000
Revised DEL as @ Draft Budget 2021-22	**382.528**
Overall Total HSS MEG	**9064.472**

The table above does not include Annual Managed Expenditure (AME), which is outside the Welsh Government's Departmental Expenditure Limit (DEL).

Details of all transfers are shown in Annex A to this paper.

4. Approach to Budget proposals

This budget has been set at a time when our health and social care sectors are facing an extremely challenging winter period in early 2021. The NHS is treating around 2,000 patients in hospitals suffering from the effects of coronavirus, while cases are continuing to grow. At the same time, the NHS has recently embarked on the largest mass vaccination programme in its history, with the hope of ensuring population coverage by the middle of 2021. When the acute phase of the pandemic recedes during 2021, the NHS will then need to focus on responding to the long term harm that the pandemic has caused, in terms of increased waits for routine care, the impact on chronic conditions, and the impact that the pandemic and the necessary restrictions have had on mental health.

There still remains significant uncertainty of the course of the pandemic, so in this budget we have concentrated on protecting our NHS for the long term, and continuing to invest in our vision of an integrated health and care system as set out in our long term plan for health and social care, *A Healthier Wales*. We intend to make further allocations in the Final Budget to ensure the NHS has the resources it needs to continue the response to the pandemic into next financial year.

The Health and Social Services MEG contains the core revenue and capital funding for NHS Wales, as well as funding to support social care and supporting children. With a focus on protecting the health and social care sector we are investing an extra £430.6m revenue funding in the health and social care system and £16m capital funding.

Investment in NHS Wales

In 2021-22 we will invest a further **£385 million** revenue funding in our NHS, taking total NHS revenue funding to over **£8.4 billion.** This provides long term stability to the NHS to continue the delivery of quality health services, ensuring access to the services people need and delivering good health outcomes.

Our core spending plans for the NHS continue to be based on the evidence contained in the 2014 Nuffield Trust and 2016 Health Foundation reports on the levels of investment required to maintain core safe services, updated to incorporate the additional investment in pay awards for our highly valued NHS staff not covered by these reports.

As well as funding core cost growth in NHS Wales, we will invest in transforming the delivery of health services and in new technologies. This includes new investments in precision medicine, including in Advanced Therapeutic Medicinal Products and genomics, and continuing to invest in education and training of the future NHS workforce.

The experience of the COVID pandemic has highlighted the need for increased investment in health protection. We will provide an extra £10m to Public Health Wales to support the transformation of Health Protection Services in Wales. Building on the investments we have

already made into modernising and increasing capacity in the Public Health Wales microbiology service, this will ensure Wales has a leading edge health protection service for the long term.

We will also invest a further £25m in taking forward the vision set out in *A Healthier Wales*. We will continue our investment in preventative programmes and prioritise digital programmes. These will include national data, digital wards, prescribing and eye care and we will continue to explore further digital transformation and targeted support to maintain essential services. During the pandemic the use of technology has been accelerated across Wales, not only by embedding new ways of working but by improving access to healthcare advice from homes. These new ways of working are providing services out of the hospital setting and show how digital technology can empower patient care.

Capital

The NHS capital budget for 2021-22 will increase by £16m to £383m, and will be invested in infrastructure to support the delivery of sustainable and accessible high quality services and to take forward the transformation of healthcare provision. This funding represents a 4% increase over the baseline budget for 2020-21.

Capital investment next year will include the continuing redevelopment and modernisation works at Prince Charles Hospital along with the completion of the neonatal works at Glangwili Hospital.

At an all Wales level, this budget also provides for national programmes focusing on priority investments across imaging and diagnostic equipment, decarbonisation, mental health, hospital infrastructure as well as supporting digital and informatics developments.

Funding linked to decarbonisation initiatives for 2021-22 will focus on a range of areas including LED lighting and renewable energy installations. Schemes that can deliver significant carbon reductions will be targeted through joint working with the Welsh Government Energy Service and the Carbon Trust.

As well as schemes within the acute sector, the capital budget includes the continued investment in the delivery of a pipeline of primary and community care projects as part of the implementation of the Taking Wales Forward commitment to invest in a new generation of integrated health and care centres.

Commentary on Actions and detail of Budget Expenditure Line (BEL) allocations

The detailed budget published on December 21st set out our spending plans for the HSS MEG by BEL. An analysis and explanation of the budget changes is set out in Annex A.

5. Local health boards' financial performance

My Written Statement on 6 July set out the financial performance of NHS organisations at the end of the 2019-20 financial year. It also set out the action I have taken to remove the burden of future repayment of cash support and deficits from those organisations that are not in financial balance, to support their future plans as they emerge from the pandemic.

COVID has inevitably impacted on the financial performance of NHS organisations in 2020-21. It is important to note that the funding model Welsh Government have maintained for NHS Wales, based on the evidence set out in the Nuffield Trust (2014) and Health Foundation (2016) reports, is that financial sustainability of NHS Wales is achievable through a combination of annual real terms growth funding and annual delivery of NHS efficiency of at last one percent each year. The need for the NHS to respond at pace to the significant impact of COVID has meant that normal efficiency programmes were inevitably paused, and this will have an impact on NHS underlying positions going forward.

Recognising that decision-making had to be undertaken at pace during March and April to put in place the necessary interventions, my officials took rapid action at the beginning of the emergency period to ensure that sound processes of financial governance and management were secured from the outset by NHS organisations. The Director General of Health and Social Services issued Accountable Officer and financial guidance to Chief Executives on 30th March outlining key considerations in taking urgent decisions in a pandemic environment, in line with the standards of ‘Managing Welsh Public Money’.

Officials, with support from the Finance Delivery Unit, established additional financial monitoring arrangements early in the financial year to ensure that the impact on baseline NHS financial plans could be captured and carefully monitored. A detailed analysis of direct cost impacts, efficiency delivery impacts and offsetting resource savings was developed. Financial monitoring processes have sat alongside the quarterly planning processes, ensuring that they validate the financial planning assumptions underpinning the operational and workforce plans.

In addition, bespoke and specific financial reporting exercises were introduced across the system to key interventions, including workforce, PPE, Test, Trace and Protect, Field Hospitals and the mass vaccination programme. This included developing rapid detailed modelling and detailed reporting in key areas such as PPE where systems were not in place prior to the pandemic at the required breadth and scale.

The response also required significant repurposing of the capital programme. This has resulted in c.£104m of the programme being directed towards schemes including the early opening of the Grange University Hospital, the additional testing laboratory and equipment for Public Health Wales and digital enabling investments across Wales. The £33m additional 400 bedded surge

capacity on the University Hospital of Wales site has been fully supported from a capital perspective through Strategic Budgeting.

Within Welsh Government, my finance team have worked closely with finance and budgeting officials from other portfolios and with Welsh Treasury and central finance staff. Senior health officials have attended weekly internal finance and budgeting meetings which have ensured robust communications across Welsh Government and ensuring consistent advice to Ministers. In addition, health officials have worked with Welsh Treasury officials to engage with UK Government departments to understand the financial implications of policy development within England on Wales, and to secure appropriate consequential funding.

We have also ensured that the NHS Wales approach is in line with other nations, through regular dialogue and sharing of approaches and assumptions with colleagues in NHS Scotland, Scottish Government, the Northern Ireland Executive and the Northern Ireland Health and Commissioning Board.

Despite the need for a significant and rapid operational response to the emergency, we have maintained a focus on financial performance throughout the duration and looking forward to the end of the financial year. The additional funding announced by ministers in August has allowed us to stabilise the financial position, taking account of the planned deficits that were being managed through the planning process prior to the pandemic. With the inevitable caveat that we cannot predict with any certainty how the pandemic will continue over the next few months, our current assessment is that the funding that has now been allocated in the First and Second Supplementary Budgets will be sufficient to manage the ongoing NHS response to the year end.

6. Future delivery of health care

Details of how Welsh Government is supporting the delivery of more routine care, and addressing the backlog of treatment which is a consequence of the pandemic.

Through a programme of annual investment in performance, we saw year on year improvement in volumes of long waiting patients from 2016 to the lowest point in 6 years in March 2019 (8,985 patients waiting over 36 weeks). A combination of reduced staffing capacity due to the implications of tax changes in 2019/20, and, more significantly, the reduction in capacity because of the pandemic, has seen this trend reverse sharply. By September 2020, the number of patients waiting over 36 weeks had increased by 159,959 since March 2019, with just under 169,000 patients now waiting over 36 weeks.

To put this into perspective, the reduced capacity in 2019 because of tax changes and some COVID impact led to an additional 19,309 patients waiting over 36 weeks. The COVID

pandemic as of September 2020 has resulted in an additional 169,000 patients waiting over 36 weeks.

The significant backlog created in these eight months is likely to continue to grow to March 2021, and beyond. The continued growth being due to both the constraint in capacity, caused by necessary measures to reduce the risk from COVID, and referrals returning to normal levels. Priority for the available resources is urgent patients (including cancer), and those identified as at immediate risk from further waits. This targeting of resources results in minimal impact on routine waits and growth of the backlog in long waiters. The current inability to increase resources significantly, in particular staff, and the estate, constrains the NHS's ability to increase capacity at pace to make any real impact on reducing the backlog.

Addressing the backlog will require a balance between the clinical priority of the patient, the need to treat our long waiting patients as soon as possible, and an awareness of the capacity constraints, particularly staff who have been so hard pressed in dealing with the COVID pandemic. For this reason, we plan to address the backlog through a phased approach over four years, with a mixture of local, regional and national solutions. The option to reduce the recovery period will depend on the available delivery solutions identified as deliverable for Wales.

Significant progress in redesigning services models has commenced during COVID in line with *A Healthier Wales* and the primary care strategy to support movement of services appropriately to the community, promote self- management and joint working between primary and secondary care.

Cancer Services

In line with the Essential Services framework, Health boards have tried to maintain cancer services during the pandemic and have responded extremely well to innovative approaches such as embracing virtual appointments, straight to test and the implementation of FIT testing.

The number of referrals dipped considerably at the start of April (by around 70%) and are now back to normal levels. The evidence suggest that patients have been reluctant to come forward, consequently, cancer referrals are around 18,000 less (October 2020) than we would expect. Assuming that around 25% of these have received treatment elsewhere or no longer require treatment, it is estimated that there are at least 13,500 people with suspected cancer that may be referred at some point in the near future. It is clear, that this number coupled with increasing backlogs at health boards due to diagnostic pressures will take considerable time to clear. Our best estimate is that operating at normal capacity it may take 132 weeks to see and review the additional volume of patients, which we believe is unacceptable. Therefore, we intend to

develop and implement a three-year plan incorporating diagnostic and treatment transformation. We intend to confirm funding for this plan for 2021-22 before the start of the new financial year.

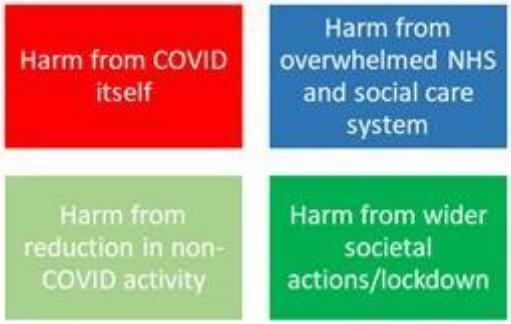
7. Well-being of future generations

Prioritise prevention/early intervention in Health and Social Care

Our focus in this budget is to protect the Welsh population by continuing to invest in our core NHS services for the long term. We are also continuing and increasing our investment in sustainable social services. Ensuring the long term stability of our health and care services is our priority for preventative investment in this budget.

The NHS Planning Framework, which is also the Minister's Direction to the NHS, always seeks to align with the Wellbeing of Future Generations Act and to continue to strengthen how organisations work to deliver their plans using the five ways of working. Since the beginning of the pandemic there has also been a strong focus on the **four harms** that have been the key quality context within which services and care must be provided.

All four harms are relevant to the well-being of future generations but the need to prevent harm "from wider societal actions/lockdown" also provides a broader and longer term context to planning and investment in health and social care.



The NHS Planning Framework sets an expectation of a broad approach to prevention to be applied in all aspects of planning. This is supported by Welsh Government policy that is set out from a perspective of prevention, whether that is a more traditional public health perspective or in unscheduled care or planned care. Health Board Integrated Medium Term Plans, for example, also considered prevention in terms of models of care and decarbonisation including active travel schemes.

Preventative approaches to all physical and mental health and wellbeing will ultimately avoid escalation of conditions and illness. Opportunities for investment must be considered that will support future generations and inform future service provision. We have sadly learned throughout this public health crisis that those with underlying conditions have suffered

disproportionately. Learning from COVID should provide foundations for the implementation of preventative initiatives that can make an impact on reducing all four harms.

Our aim is to take significant steps to shift our approach from treatment to prevention. The vision we have established in *A Healthier Wales* is to place a greater focus on prevention and early intervention.

Support sustainable, longer term funding of Social Care Services

The Inter Ministerial Group on Paying for Care has been looking at long term options. Our officials have recently provided technical briefing to the Finance, Health and Communities committees

Clearly the financial environment has changed significantly over the last number of months. We are also keen to understand the UK government's developing position on social care funding. Welsh Ministers have always favoured a UK solution of these matters, but we have been working in the Inter Ministerial Group in the knowledge we may need to forge our own path.

The capital limit used in charging for residential care was raised to £50,000. As a result residents can retain up to this level of their capital without having to spend this on their care. A maximum charge of £100 a week for domiciliary care was introduced on 6 April 2020 so as to complete this commitment

Promote integration of Health and Social Care Services

A Healthier Wales is the long-term plan for health and social care in Wales. Two years on from the launch of the strategy, and in the context of COVID, we are reviewing the 40 priority actions.

The Integrated Care Fund (ICF) and Transformation Fund (TF) have continued to deliver integrated health and social care services across Wales and have been used as a mechanism for additional resources to support the COVID response

Transitional funding for the ICF and TF will continue in 2021-22.

£89m ICF revenue and £40m ICF capital, together with £50m revenue for TF and £10m for Transformation Programme (TP). The focus of the next phase of the TF and ICF projects will be on moving successful integrated approaches from projects towards core business and core health and social care funding. Communities of Practice have been established to share best practice and experiences and to consider successful models of care as envisaged by AHW. These started with Hospital 2 Home services and will now continue on the themes of Place-based care; Emotional and Mental Health Services; and Technology Enabled Care.

Up to the COVID emergency, partnerships were making progress on joining up services, scaling up models of care and investing in specialist accommodation, innovating whilst building on

lessons past. During the COVID emergency, Regional Partnership Boards (RPBs) and the services they have developed have shown that partnerships have the strength and agility needed to respond to health emergencies in a cohesive manner.

Most notable has been the hospital to home projects (rapid discharge) and admission avoidance models developed through the ICF and TF that have provided an essential service during the COVID 19 response. The ICF Capital programme has pivoted resources to support intermediate care and reablement, and facilitate hospital discharges. These projects were and are fundamental for hospitals in terms of the capacity and the resources required for the COVID 19 response and have been accelerated significantly. The majority of ICF projects and services continued or were modified during the crisis.

RPBs have refreshed their ICF revenue investment plans for 2020-21 to ensure the care and support needs of their populations are met through the development of integrated services.

RPBs are taking forward integrated projects/services funded from the additional £10 million to support hospital discharge services for COVID patients.

Another essential element of the response has been the use of digital technology to support new ways of working and caring for people. Nearly 100,000 video consultations have taken place across the Attend Anywhere platform. 3,000 NHS clinicians and 207 care home teams have been trained to use the programme, and over 90% of users rated the programme good or excellent. We are running pilot schemes to determine if the service could be rolled out further to pharmacy, dentistry and optometry.

To complement Attend Anywhere, Digital Communities Wales has procured electronic tablets to support care home residents across Wales. This has helped people to maintain a family connection and access vital health services during the pandemic. In the first phase, 1,051 electronic tablets are being provided to 584 care homes. Over 380 front line staff have been trained to support residents in using the digital technology.

Ensure a sustainable health and social care workforce

As part of *A Healthier Wales,* Health Education and Improvement Wales (HEIW) and Social Care Wales (SCW) jointly led the development of a workforce strategy for health and social care in partnership with key stakeholders across Wales. The strategy was launched in October 2020. Among the aims of the strategy is to develop a sustainable and healthy workforce in health and social care. HEIW and SCW have set out the priorities over the winter period in a delivery plan designed to support the Winter Protection Plan and wider health and social care system. Further details on funding for Social Care Wales are later in the paper.

In December 2020, we agreed the NHS Wales education commissioning and training plan for 2021-22, supported by a total investment of £227.901m, an increase of £17.5m from 2020-21.

This is a record level of funding and will increase workforce supply to ensure a sustainable health and social care system, as set out in *A Healthier Wales*.

Reduce and Control Spend on Agency Staff

The Welsh Government worked collaboratively with health boards and trusts to design of a control framework for expenditure on agency and locum staff including increasing board level scrutiny, minimising their deployment and improving value for money through capping rates and more effective procurement. The control framework was issued in health circular WHC/2017/042 addressing the impact of NHS Wales Medical Agency and Locum deployment in Wales, which came into effect in November 2017 and was designed to work alongside the All Wales Framework Contact for Agency Nurses which was introduced in April 2017 and designed to deliver better value for money through economies of scale.

Despite some 6% increase in workforce numbers between June 2019 and June 2020, COVID has had a significant impact on the need for workforce and experienced staff working additional hours via agencies has provided a valuable contribution to the Wales wide effort. Earlier ground work to improve the value for money of agency deployment through framework contracts will have delivered better value for money for this investment. Nonetheless, agency expenditure has increased as part of our investment in additional staff throughout this year.

Forecast spend on locum and agency staff in 2020-21 is £195m, compared to an outturn of £177m in 2019-20, and increase of 10% in year. However, it should be noted that this expenditure remains highly volatile, and the outturn for 2020-21 may be significantly different from current forecasts.

Reduce health inequalities, and ensure fair access to health and care services in rural areas.

Reducing health inequalities across Wales, including rural areas, remains a Ministerial priority and the COVID pandemic has brought reducing health inequalities into even sharper focus.

Rural areas often depend on wider collaborative arrangements for delivery of care and services for its patients and to create equity of access. For example Hywel Dda and Powys health boards have developed strong relationships with partner health boards to ensure patients have access to the services they need.

Technology enabled care and digital innovation, including video consultations and remote working, have become an integral part of primary, secondary and community care, supporting people in receiving care and advice safely in their own homes. For those patients and their families, who live in rural parts of Wales, this has been especially welcome, reducing time and travel costs.

8. The impact of COVID on allocations

Details of how the pandemic has influenced allocations to budget lines within the Health and Social Services MEG, including examples of any changes made to allocations within the Draft Budget from previous years as a result of COVID.

The Health and Social Services MEG has had gross additional funding totalling £1,442m in the first and second supplementary budgets for 2020-21 to support the NHS and social care responses to COVID. Further funding for the mass vaccination programme is due to be allocated in the third supplementary budget. This additional funding is partially offset by the non-recurrent contribution of £114m the MEG made to the central COVID reserve in the first supplementary budget.

Welsh Government has received £766m in total in the Spending Review for 2021-22 as a result of COVID related spending in England. In order to ensure that any decisions on the allocation of this funding best meet the evolving challenges presented by the pandemic, it is prudent to retain as much flexibility as possible now and allocate funding at final Budget as we better understand the impact of the winter months on the spread of the disease. Confirmation of funding for the ongoing health and social care response will be confirmed before the beginning of the new financial year, ensuring that ongoing interventions are able to continue.

In order to ensure that we are able to continue effectively dealing with the current and projected cases of COVID, and maintain an operation that can maximise its ability to help reduce transmission rates, £10m will be allocated initially to sustain the contact tracing workforce. It is important that the contact tracing workforce is maintained through 2021 to have the capacity to investigate and trace new positive cases and close contacts, and to cope with any future peaks in cases. This investment will significantly help with regional recruitment and workforce planning for what is a central part of the Government's strategy to restart the economy while containing the spread of the virus.

9. Transformation

How the Welsh Government intends to support service transformation in the longer term (i.e. beyond the life of the current Transformation Fund), to ensure progress on the transformation agenda can be sustained, and that there is a focus on rolling out the learning from successful pilots;

• How this budget will support the development of a 'whole system approach', with greater integration of health and social care, as described in A Healthier Wales;

• Any other specific areas of funding targeted at support for service change or development;

• How the Welsh Government, in setting its budget, will balance the need to meet existing service pressures with the need to transform services and develop new models of care.

The Transformation Fund (TF) is one of the key funding mechanisms to support the implementation of *A Healthier Wales* launched in summer 2018. The fund's key objective is to enable the scaling of new models of seamless local health and care to regional and in some cases national footprints, and thereby change the way health and social care are delivered in Wales.

The COVID emergency has had a significant impact on transformation projects. Officials have been working closely with regional teams to enable flexibility so that projects were able to contribute to the response. This resulted in reprioritisation and projects in the categories of hospital-to-home, stay-well-at-home, and digital categories were accelerated, whilst other efforts that were less directly relevant to the response but important to system transformation were postponed or slowed down.

The Transformation Fund has been extended by twelve months and £50m to allow regions to recover their transformation activity and project delivery, which has been paused due to the COVID emergency. Funding profiles have been confirmed to delivery partnerships to support delivery and sustainability planning, as well as a managed approach to ending time-limited contracts for some project staff. The total allocated is less than the full TF budget for 2021-22, to allow for targeted support to scaling existing regional projects to multi-region and national coverage, particularly approaches which contribute to COVID recovery. This will also include consideration of outputs from Communities of Practice which have been developed as a part of the TF approach.

Welsh Government is working with regional partners to shape options for a future programme for RPBs, beyond April 2022. This reflects a commitment in *A Healthier Wales* to align funding streams and activity to maximise impact and to provide more co-ordination and coherence to strategic transformation funding across health and social care.

Transformation funding is time limited and all Regional Partnership Boards (RPBs) have been required to develop business cases to support the priorities for on-going investment and how these services will be sustained going forward. All RPBs have submitted their plans to Welsh Government and received feedback on sustainability and impact on outcomes, which will be reinforced through conditions in 2021-22 funding letters.

Evaluation is a central part of Transformation Funding with a framework and measures agreed at the start of delivery and tested through an independent mid-point evaluation. Evaluation requirements have been reviewed to reflect the impact of COVID on timetables, and to capture the impact of COVID response on delivery and outcomes. All RPBs will be required to submit an updated independent evaluation report by end of April 2021, followed by a final report in April 2022. These reports will also inform the publication of two further national evaluation reports.

In order to share experiences and best practice across RPBs a number of thematic Communities of Practice (CoP) are being established. These themes include Hospital 2 Home services; Place-based care; Emotional and Mental Health Services; and Technology Enabled Care.

The CoPs involve practitioners and project delivery managers and aim to:

- bring together teams working on similar models across Wales;
- share progress and learn from each other through joint activities and discussion;
- support the scaling of new models of care across regions;
- provide examples of best practice approaches from the UK;
- contribute towards the future priorities in delivering A Healthier Wales.

The first CoP was established in July 2020 to focus on Hospital 2 Home Services and has been jointly hosted with the Social Care Institute for Excellence (SCIE) and the NHS Wales Delivery Unit. Learning from this first CoP will be used to shape further CoPs in other thematic areas, during 2021.

As we move into the final year of the fund, the Transformation Fund team will continue to work closely with regions to support their delivery and ensure that expenditure and delivery remain on track. Funding will be kept under close review.

By providing additional funding in this structured and nationally managed way we are able to support regions to design and test new services and models of care over a relatively short period of time, then to embed successful projects into business as usual, replacing historic approaches.

Transformation Fund Opportunity

The Transformation Fund's structured approach to supporting "new models of seamless local health and care" through transformation funding has been developed and refined over the past two years. This approach has previously been limited to RPBs, but we will consider how this can be used to support rapid introduction and scaling of new ways of working required in health as part of our stabilisation and reconstruction following COVID. The transformation fund process, governance and evaluation (including Communities of Practice) would be replicated

with a tighter focus on health and hospital challenges and through targeted funding to LHBs specifically. This work would also draw on reviews of COVID response and opportunities such as the NHS Innovation Study which is due to be published in January 2021.

Innovation

We continue to invest strategically in areas that will support and improve services through applied research and innovation, supporting initiatives that seek to systemically spread and adopt new ways of working and models of care.

The Bevan Commission **Innovation Exemplars** and the complementary **Health Technology Exemplars** programme delivered in partnership with WG support NHS Wales' staff to work collaboratively with industry to implement innovative health technology. These programmes aim to improve NHS Wales ways of working, solving health problems and improving health outcomes; and to provide a mechanism to develop, accelerate the scale up and widespread adoption of innovative health technology products and services.

An all-Wales network of **Research, Innovation & Improvement Co-ordination Hubs (RIICHs)** was established in 2019 , tasked with bringing together all research, innovation and improvement activity within their areas, undertaking a coherent analysis of this activity with a focus on identifying good practice, lessons learnt from successful pilots, and new ways of working / new models of care that are affordable and sustainable.

To help maintain progress and ensure learning is systemically spread and adopted, Welsh Government has supported focussed **Intensive Learning Academies**, a key commitment within *A Healthier Wales*. High quality, professional leadership will be a critical part of the success and resilience of health and social care integration in the future. These academies will play a key role in the development of competent leaders that understand the importance of joint leadership and the strategic and professional development needed to support it. Three academies will be live from April 2021: Applied Learning for Preventative Health Academy; Value Based Health & Care (VBHC) Academy; All-Wales Academy for Innovation in Health and Social Care.

10. Primary care and care closer to home

The budget allocated for primary care services, and how this compares to amounts allocated in the last three years.

We continue to invest in primary care through the delivery of the Primary Care Model for Wales, and in 2021-22 will build on the agreed investment provided in 2020-21 for the primary care contracts.

Planning and implementing the rebalancing of the health and wellbeing system is complex and cannot simply be tracked in terms of budgets and recording of expenditure, but through demonstrating the shift of services being delivered in both primary and community settings. We will continue to support health boards to strengthen their whole system planning through the IMTP process.

Our definition of primary care is broad as set out in the Primary Care Model for Wales. As well as those services contracted from GPs, dentists, community pharmacists and optometrists, our definition also includes the wide range of services, care and support for people's health and wellbeing in the wider community.

The NHS Health Board accounts for primary care report spend for the last 3 years of:
2019-20 £947.338 million
2018-19 £911.739 million
2017-18 £876.346 million
These figures exclude GP prescribing and are net of dental patient changes recovered

To what extent is this achieving the policy aim of shifting care from hospitals to primary care/community settings?

The Welsh Government allocates significant funding to health boards. The majority of this funding is unhypothecated and therefore is not a robust measure for tracking the rebalancing of the system in line with the vision in *A Healthier Wales* of more preventative care closer to home.

New service delivery models such as 111, phone/contact first and the Urgent Primary Care Centres emphasise the urgent primary care agenda which works at the interface of primary and secondary care, breaking down service boundaries on the path to delivering *A Healthier Wales*. This year:

- We have supplemented the 'top sliced' investment in WAST/111 in 2020/21 for the development of the transformative 'contact first' model. This model seeks to signpost patients who want or need urgent advice or an assessment to the right place, first time to optimise experience and outcome. The model will enable booking of patients into emergency department slots over the course of the day to reduce crowding, and navigate people to GP and community services, reducing unnecessary demand on busy emergency care services. An evaluation is underway. Agreement on recurrent funding for 2021/22 and 2022/23 is required at an early stage to enable extension of workforce contracts and recruitment of call handlers and clinical staff to furnish the model.

- Health Boards have been allocated funding to support development and delivery of 24/7 urgent primary care centres in 2020/21. This model will be staffed by a combination of

physiotherapists, GPs, ANPs, APPs and other clinicians able to safely assess and treat patients with urgent care needs in their community, without needing to access the emergency department. This aligns closely to a Healthier Wales and the desire to shift resources to the community, enabling people to be assessed and treated close to home and only present at hospital if essential.

- An evaluation will be undertaken to understand how successful the centres have been over the winter period in terms of managing patients with urgent care needs, value for money, staff experience and other key success factors. This evaluation will contribute to the design of a national 24/7 urgent primary care model. Agreement on funding for 2021/22 at an early stage is required to roll over staff contracts into the new financial year and to enable proper evaluation of the model over a longer period.

The Contract Reform Programme, underway in Primary Care, has a focus on enabling appropriate services to be moved away from secondary care delivery to a community based approach. Taking learning from approaches in Optometry in Aneurin Bevan is key to that progress and it is clear that where services shift, resources will need to follow. This does not come without difficulty and we continue to manage that interface. However, the flexibility within HB funding means they have a degree of discretion in terms of directing funds – particularly evidenced during the COVID response. Through reforming and strengthening contract arrangements, we aim to facilitate the shift towards more community based care. Our approach to delivery of the COVID vaccine will see us contracting this service to all four providers for the first time, which will not only strengthen skills and resilience in vaccine delivery as a whole but also offers a significant learning point on contracting on a Primary Care wide basis which in turn will inform future funding arrangements for the service as a whole.

There are a range new models of care being rolled out across Wales enabling care at or close to home. Examples include:

- the Attend Anywhere digital platform which enables people to have phone and video consultations with health professionals
- Consultant Connect which enables primary care professionals to seek phone advice from hospital specialists to support people to stay well or access care at home
- Virtual group consultations to provide advice to people on how to manage their long term health conditions
- Urgent primary care centres in local communities to provide same day access
- Increased capacity of community rehabilitation support (the 4 discharge to recover and assess pathways)

11. Social care

The planned allocation for social care:

Social Care Workforce grant

As part of the funding to support *A Healthier Wales* we increased the Social Care Workforce grant by £10m to £40m in 2020-21. Given the significant pressures facing the sector as a consequence of the pandemic and in line with previous uplifts, this has been increased to £50m in the draft budget for 2021-22. In 2019-20, and 2020-21, local authorities used this funding to support the delivery of sustainable services and the sustainability of the workforce. For example some local authorities have previously used part of this funding to support providers in the independent sector to meet uplifts to the statutory living wage.

Social Care Wales

Social Care Wales will continue to have a critical role in 2021-22 by supporting the improvement and well-being of the social care sector; continuing the expansion of the social care workforce register; and supporting the sector and workforce to stabilise and recover following the COVID 19 pandemic and EU Exit.

In 2021-22 the Grant in Aid Core Funding to Social Care Wales will increase by £2m to £22.383m. This will enable Social Care Wales to deliver its statutory functions as set out in the Regulation and Inspection of Social Care (Wales) Act 2016 and to fulfil its remit for leading improvement across the social care sector in Wales.

In 2021-22 there will be three key areas that this funding will support:

1. Increased costs due to the expansion of statutory regulatory regime – including the planned expansion of the registration of the social care workforce.
2. Supporting the stabilisation and recovery of the social care sector through delivery of the Workforce Strategy
3. Implementation of research and data strategies, and ongoing work to support service transformation, including the delivery of the Social Care National Data Strategy

The increased work programme is critical to ensure that Social Care Wales is able to continue to meet the needs of the social care sector and workforce post COVID 19, and continue to deliver its functions to support well-being and improvement.

Third Sector Support

We will continue to support Third Sector organisations operating in Social Care by allocating an additional £1.5m in 2021-22. In 2021-22 we will be moving into the second year of the three

year Sustainable Social Services Third Sector Grant. £0.89m is being added to the grant for 21-22 to meet the increased project costs as the projects develop into year two. Over the three years, we will be increasing the total commitment on this grant by £4.9m, bringing the total investment up to £25.9m. Projects have been refocussed in response to the pandemic projects to deliver in the current situation and to respond to needs of people needing care and support or carers needing support arising from the pandemic.

A key requirement of the funded schemes is that they deliver early intervention and preventative actions that address care and support needs in line with the priorities of Taking Wales Forward, Prosperity for All and *A Healthier Wales*. The funded projects will support the well-being goals and principles that underpin the Well-being of Future Generations (Wales) Act 2015. The funded schemes will support carers, children and young people, physical or sensory disabilities, learning disabilities and older people.

In addition to the third sector organisations funded through the Sustainable Social Services Third Sector grant funding is being provided to Third Sector organisations whose activities are essential within the Social Care sector and for organisations that support specific social care policy priorities. In total funding of over £11m will be awarded to Third Sector organisations operating in the Social Care sector.

Any additional funding identified for 2021-22, and details of the targeting – where appropriate - for such funding;

We are investing £0.576m in Foster Wales. Recruitment of foster carers is key to the success and development of local authority fostering. It was identified that a requirement to achieve this goal would be the development of an “all Wales brand for Local Authority fostering”, a consistent national brand for Local Authority fostering that reflects the strengths and personalities of the 22 Local Authorities - ‘Foster Wales’ is this brand. Foster Wales presents an opportunity to rebalance service provision, address demands, and improve quality of placement choice for children. Foster Wales will

- increase local placement accessibility, sufficiency, and choice. Giving control back to the local authorities to make best use of those placements when *they* need them, reducing the reliance on third parties and removing placement blockage.
- enable services to meet the evolving needs of children and families. Recruitment campaigns will be targeted to meet service needs.
- facilitate the recruitment of a new pool of foster carers. Recruitment and training can be focused to develop skills in reunification work, complex needs and parent and child fostering.
- enable children who need a foster carer to have access to the right foster carer, at the right time and in the right location

An investment of £0.319m was provided during 2020-2021 to 'kick-start' the campaign by providing the infrastructure for the campaign. During 2021-2022 £0.576m will be invested to further support the roll-out and implementation of the Foster Wales brand.

Support for ensuring the ongoing viability and stability of social care services, including residential and domiciliary care;

The Inter Ministerial Group on Paying for Care has been looking at long term options. Our officials have recently provided technical briefing to the Finance, Health and Communities committees

Clearly the financial environment has changed significantly over the last number of months. We are also keen to understand the UK government's developing position on social care funding. Welsh Ministers have always favoured a UK solution of these matters, but we have been working in the Inter Ministerial Group in the knowledge we may need to forge our own path.

• ***Support for carers.***

In 2021-22 we will continue funding to support activity that takes forward our three national priorities for carers, allocating £1.245m. This includes £1 million to local health boards and their carer partnerships, for a range of activity to support carers of all ages and covers any new activity which they felt necessary to help carers in their areas manage the impact of the pandemic. We will also allocate £0.236m to the ongoing work of the National Young Carer's ID card project, which is co-produced with Carers Trust Wales and local authorities. In addition to this there are projects within the Sustainable Social Services Third Sector grant that will help improve carers' awareness of their rights, but also support broader cultural and structural changes for the future, in terms of service design, delivery and training of health and social care professionals.

12. ICT

An up to date assessment of the costs of delivering the Welsh Government's vision for digital and data, as described in A Healthier Wales, and including increased support for digital and virtual care.

As part of A Healthier Wales the Welsh Government committed to supporting health and social care transformation by making the best use of digital, data and technology. Significant additional investment of £50 million per year was made available across 5 priority areas, linked to stronger delivery and leadership arrangements. The five areas were:

- Services for the public and patients
- Services for professionals
- Cyber security and resilience
- Modernising devices and cloud-ready services
- Investing in data and intelligent information

Independent reviews of Digital Governance and Digital Architecture were completed in 2019, assessing capability against the vision for digital and data set out in A Healthier Wales. Recommendations from these reviews informed decisions on the future configuration of digital health and care, which was confirmed by Welsh Government in September 2019. This work includes establishing a Chief Digital Officer for Health and Care, transitioning NWIS to a new Special Health Authority, a new governance framework for digital health and care, a strategic infrastructure investment plan over several years, and four further strategic reviews.

Assessment of the costs of Digital Transformation

At the strategic level, our assessment of the costs of delivering digital transformation draws on work by the Public Accounts Committee and Wales Audit Office, on comparability with the level of investment in other parts of the NHS (set out in recent reviews of digital transformation in NHS England by the National Audit Office and House of Commons Public Audit Committee), and a realistic assessment of the speed at which investment can be increased in Wales.

The digital response to COVID has demonstrated how targeted transformation can be delivered very quickly, but has also highlighted that there are capacity limits in our digital delivery infrastructure. Ministerial commitments from 2019 on new structures and additional investment reflect the need to develop capacity and capability alongside increases investment, in parallel with each other.

At the operational level, our assessment of costs draw on forecast costs of individual strategic transformation programmes, and estimates of infrastructure investment. This assessment is continually reviewed and available resources are prioritised to essential transformation and infrastructure investment, for example to address network capacity and to replace ‘legacy’ equipment and systems which are still in use beyond their intended life.

Based on our current assessment, we are increasing our support for digital and virtual care in two ways.

- We will allocate an additional £10m to support the set-up of the new NHS Wales Special Health Authority for Digital, which will support the expanded delivery of national digital services, including several systems which are essential to COVID response and reconstruction, and also significantly enhance capacity for national digital infrastructure.

This is needed to support increased remote working and virtual consultation, and to maintain the resilience and cyber security of our networks.

- Transformation funding through the Digital Priorities Investment Fund will increase from £50m to £75m, to maintain the pace and scale of the digital changes we have seen as part of COVID response, to transition COVID response services to business as usual where they offer lasting value, and in particular as part of COVID recovery and reconstruction.

This additional investment will also develop the capacity and capability of the digital workforce and our digital delivery structures, including the establishment of a new digital Special Health Authority, a Chief Digital officer for health and Care and supporting office, and transition to new governance and decision making arrangements for digital health and care.

Digital and technology enabled working will be an essential part of new ways of working required urgently to address backlogs and waiting lists and to support continued shift from hospital as seen through Transformation Fund projects delivered by RPBs.

Digital Transformation Funding

Since 2019-20 the Digital Priorities Investment Fund (DPIF) has initially prioritised investment towards replacing infrastructure and devices which were beyond end of life, and to essential strategic programmes including the Welsh Community Care Information Services (WCCIS) Programme, and a new National Data Resource (NDR) Programme, and enhancements to digital cancer informatics services. Most DPIF funded programmes are strategic multi-year investment programmes.

The DPIF has been rapidly deployed to support key elements of COVID digital response, including mobile devices, remote working, video consultation, and increased network bandwidth. This has inevitably had an impact on the amount of funding available for digital transformation investment which was planned before COVID, including strategic infrastructure investment. Even so, DPIF has continued to support active programmes and essential investment, and has also supported some new programmes which are linked to COVID response or recovery, such as new digital systems for Intensive Care, which are a key part of COVID response.

Funding for NWIS / Digital Health & Care Wales

NHS Wales Informatics Service (NWIS) is the national digital delivery service for NHS Wales, currently hosted within Velindre NHS Trust. From April 2021, NWIS functions are planned to transfer to a new NHS Wales Special Health Authority (SHA), to be known as Digital Health and Care Wales (DHCW). The DHCW establishment programme has reviewed the additional costs of operating as a Special Health Authority, including for example a chair and board members,

executive directors, and additional corporate governance overheads. These additional SHA costs are approximately £2.0m. Welsh Government are working with NWIS to confirm the future core funding requirement for the delivery of national digital services, including a transfer from capital investment in equipment and infrastructure to revenue costs of cloud hosted services and subscription licence models.

We expect digital transformation to be a major element of COVID recovery through 2021 and 2022, as part of rapidly shifting to new ways of working which use technology, data and digital. These new ways of working must drive efficiency and scale to address backlogs and waiting lists, should aim to reduce face-to-face contact and hospital pressures, and will need to do that without increasing demand for healthcare staff. It is important that the new digital Special Health Authority is adequately resourced to lead the delivery of these new services. We will invest the funding necessary to ensure the new organisation is established with a stable recurrent baseline allocation.

COVID19 Digital Response

The digital response to COVID has been delivered at an accelerated pace, with several all-Wales programmes deployed nationally in 6-8 week cycles. These include:

- An all-Wales video consultation service, led by the Technology Enabled care Programme and supported by NWIS. Since March over 86,000 virtual consultations have taken place and more than 12,000 professionals have been given access to the service which is now available across over 100 specialties in Primary, Secondary and Community care and is being extended to Dental, Community Pharmacy & Optometry. User feedback from clinicians and patients is overwhelmingly positive.

- Significant investment in mobile and remote working has involved support for devices, increased network bandwidth, capacity and resilience, and specific remote working services. This has included an all-Wales deployment of Microsoft Teams and Office 365 in April and May, and remote desktop access for all GPs in Wales. Remote working capability for all staff has enabled clinicians to work from home when self-isolating and has underpinned all of the close partnership working between Welsh Government, NHS Wales and other partners.

- An all-Wales digital contact tracing platform was commissioned developed and deployed by NWIS in less than 40 days in April and May and has enabled local teams to work together as part of a national system. This has delivered notably better performance outcomes than the contact tracing service in England.

- An all-Wales digital vaccine platform has been developed in house as an enhancement of the existing Wales Immunisation System (WIS) and went live in early December. On day one

Wales delivered a total of 1500 vaccines, all digitally recorded, compared to England's delivery of 5000.

• Extensive work has been undertaken to integrate all-Wales digital testing services, building on the existing national Welsh Laboratory Information Management Service (WLIMS). This has ensured that all tests undertaken in NHS Wales labs are immediately reported into contact tracing services and could be reported into the NHS COVID App from launch, unlike England, which had a delay of several weeks before NHS test results were available to App users. WLIMS also ensures that all COVID test results are made available to GPs in Wales as part of the primary care health record. WLIMS was upgraded nationally in early December to provide enhanced functionality and capacity, enabling it to handle increased COVID testing volumes.

Digital response to COVID has been achieved at a relatively modest cost (compared to total COVID expenditure) of less than £30m, with around £10m of that invested in devices and equipment which will have at least a 2-3 year life. We will build on these examples of rapid and effective all-Wales deployment of digital services as part of COVID response to drive further digital transformation into non-COVID areas, and as part of post COVID recovery and reconstruction.

13. Withdrawal from the European Union

Information about budget allocations within your portfolio as a result of the UK's exit from the EU.

The UK Government's negotiations with the EU on the future relationship have continued throughout the year. We still do not have full clarity about whether an agreement can be reached by the end of the Transition Period, or if so, what the nature of that agreement might be. This context of uncertainty regarding the nature and impact of the future relationship has continued to make budgetary planning very challenging.

EU Transition cuts across a broad range of policy areas within health and social care, meaning that relevant activity is mainstreamed across different budgets. It is therefore not always possible to disaggregate specific 'EU Transition' funding from overall policy budgets.

Nevertheless, there are some specific parts of the budget which make a particular contribution. During the process of withdrawal from the EU, a specific budget allocation (£0.260m in 2020-21) has been included to support the activities of some of our key partners in ensuring as smooth a transition as possible for the health and social care system. This allocation has most recently

been used to fund activities in the Welsh NHS Confederation, Public Health Wales in relation to health security and FSA Wales in relation to new functions. Whilst some of these current activities end in 2020-21, we anticipate that we will need to keep this ability to fund projects where a particular need is identified.

The Committee has been briefed on EU Transition in health and social care at various stages of the UK's departure from the EU. An important part of these preparations has been to ensure robust arrangements for ensuring continued supply of critical goods (including medicines and Medical Devices and Clinical Consumables - MDCCs) throughout any potential periods of disruption. We have continued to participate in UK-wide continuity of supply programmes where these are appropriate for Wales, and anticipate that we will contribute £0.237m towards the implementation of these arrangements in 2021/22.

In addition to the required short term support in managing the transition to a new relationship with the EU, the 2021/22 year is an important one in maximising our ability to influence future policies and programmes in ways which benefit health and well-being in Wales. After leaving the EU we will need to maintain resilient supply chains, protect devolved powers, and pursue new opportunities arising from changing relationships with the UKG and EU. This will include NHS supply chain development opportunities which should support SME cluster, foundation economy and circular economy priorities. It will also include NHS engagement with universities and industry in securing opportunities from new trade relationships, UK Common Frameworks (Internal Market Bill); and securing our share of UK research funding and successor EU structural funding.

Separate to any costs of future development, the budget has needed to take account of direct costs of additional functions coming to FSA Wales as a result of leaving the EU. Additional funding will be allocated to FSA Wales in the Mental Health, Wellbeing and Welsh Language MEG in 2021-22.

Annex A

Health, Social Care and Sport Committee - Date: 13th January 2021

Commentary on each of the Actions within the Health and Social Services MEG, including an analysis and explanation of changes between the Draft Budget 2021-22 and the Second Supplementary Budget (October 2020).

Action: Delivery of Core NHS Services		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
9267.236	8347.301	(919.935)

This Action supports the main funding to the NHS in Wales as well funding to Public Health Wales and the NHS body Health Education & Improvement Wales.

Explanation of Changes to Delivery of Core NHS Services Action

Remove 20-21 in-year Covid Allocations & Adjustments

- **£(842.400)m** in year COVID allocations (2nd Supp)
- **£(497.104)m** in year COVID allocations (1st Supp**)**
- **£75.910m** in year COVID re-directed funding (1st Supp)

MEG to MEG changes for new MEG on MHW&WL

- **£(16.803)m** Budgets moved to MHW&WL MEG

New allocations for 21-22

- **£10.000m 21-22** COVID allocation in respect of Contact Tracing
- **£230.000** NHS Growth (approx)
- **£20m** Mental Health
- **£81.986m** Other NHS allocations inc, Genomics, ATMPs and Primary Care
- **£16.372m –** HEIW as part of £17.5m for Workforce
- **£10.000 -** Public Health Wales, new Health Protection Service

MEG to MEG transfers for 21-22

- **£(3.863)m** MEG to MEG

Allocations within MEG for 21-22

- **£(4.033) –** technical adjustments

Action: Delivery of Targeted NHS Services		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
130.818	136.424	5.606

This action supports other various health budgets including NHS Workforce, *A Healthier Wales* and other health budgets.

Explanation of Changes to Delivery of Targeted NHS Services Action

Remove 20-21 one off in-year Adjustments

- **£(0.5)m** in year COVID allocation adjustments (1st Supp)
- **£(20.9)m** in year allocation of immigration surcharge income
- **£(2.296)m** baseline adjustments for Invest to Save and EU exit funding

MEG to MEG changes for new MEG on MHW&WL

- **£(10.000)m** Budgets moved to MHW&WL MEG

New allocations for 21-22

- **£37.700m** – additional allocation to A Healthier Wales BEL

Allocations within MEG for 21-22

- **£1.554m –** technical adjustments

Action: Support Education & Training of the NHS Workforce		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
23.542	27.905	4.363

Education and training is fundamental to securing sustainable NHS services in the future. This action supports a range of activities undertaken in support of ensuring a sustainable workforce with the skills to address the demands on the service both now and in the future. The majority of the funding within this action covers the additional costs incurred by NHS UHB and Trusts in Wales for teaching (hosting) medical and dental students as part of their undergraduate studies. In addition it supports the training of a number of postgraduate training places across Wales, including clinical academic posts. Funding within this action also support Consultants clinical excellence awards which are given for quality, excellence, and exceptional personal contributions.

Explanation of Changes to Support Education & Training of the NHS Workforce Action

Remove 20-21 in-year Covid Allocations & Adjustments

- **£3.300m** in year COVID re-directed funding (1st Supp)
- **£(1.047)m** in year COVID allocations (1st Supp**)**

New allocations for 21-22

- **£1.142m** additional allocation as part of £17.5m for Workforce

Allocations within MEG for 21-22

- **£0.968m** Technical adjustment

Action: Public Health Programmes		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
22.669	14.941	(7.728)

This action funds a variety of public health programmes such as Organ & Tissue Transplantation, Immunisation, Payments to Public Health England who provides a number of specialist health protection services and some reference laboratory services to Wales, Healthy Start and NICE

Explanation of Changes to Public Health Programmes

20-21 in-year Covid Adjustment

- **£0.665m –** re-directed Covid funding (1st Supp)

MEG to MEG changes for new MEG on MHW&WL

- **£(7.189)m** Budgets moved to MHW&WL MEG

Allocations within MEG for 21-22

- **£(1.204)m – Technical adjustments**

Action: Effective Health Emergency Preparedness Arrangements		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
6.025	6.025	-

This action enables Welsh Government to ensure that NHS Wales is fully prepared and resilient to deal with the full range of hazards and threats identified in National Risk Assessments. This includes the highest risk of influenza pandemic and managing the health consequences of a terrorist incident involving hazardous materials.

Funding remains at the same level as in the October Supplementary Budget.

Action: Social Care & Support		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
5.615	4.562	1.053

This Action provides funding for both Safeguarding and Advocacy and Older People Carers and People with Disabilities.

The programme of work for Safeguarding and Adult Advocacy primarily supports the continued implementation of the Social Services and Well-being (Wales) Act 2014 (The 2014 Act) and promotes a preventative agenda to improve outcomes for children and adults at risk. In 2019-20 the implementation of the NPP (now Wales Safeguarding Procedures) will be a priority, supporting Regional Safeguarding Boards to take this forward, along with continued support to NISB. The role of Safeguarding Boards encompasses both prevention and protection for children and adults at risk of abuse, neglect or other forms of harm.

It also funds programmes of work to support carers in carrying out their roles as carers whilst maintaining their own health and well-being. This is central to ensuring that the rights for carers in the Social Services and Well-being (Wales) Act 2014 make a real difference in supporting carers and involves a strong element of investing to save since informal, unpaid carers are estimated to provide 96% of the care in Wales, care that would otherwise have to be provided from social care budgets.

Funding to support taking forward programmes to improve the life chances of disabled people and in particular the Improving Lives Programme for People with a Learning Disability, launched in June 2018. Funding is also used to take forward actions within the Framework of Action for People with Integrated Framework for Action of Care and Support for People Who are Deaf or Living with Hearing Loss.

Explanation of Changes to the Social Care and Support Action

Remove 20-21 in-year Covid Allocations & Adjustment

- **£(1.053) -** in year COVID allocation (2nd Supp)

Action: Partnership & Integration		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
0.526	0.526	-

This Action provides funding to assist with the integration of health and social services and the implementation of the Social Services and Well-being (Wales) Act 2014. In addition it also funds improvements to advice and guidance on continuing healthcare which should help people to access the support they need to meet their health needs. It also supports the consideration of a social care levy contributing to the wellbeing goals of a prosperous and resident Wales by considering options to provide the anticipated funding required in future to meet the increasing demands for social care resulting from an ageing population.

Funding remains at the same level as in the October Supplementary Budget.

Action: Sustainable Social Services		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
51.215	12.715	38.500

The majority of this Action funds the Sustainable Social Services Third Sector grant. Funding in this Action is also used to support delivery of the Social Services and Well-being (Wales) Act 2014, implementation of the Regulation and Inspection of Social Care Act 2016 (RISCA) and improvement of Social Care Services which deliver the changes required to achieve our vision for a social care in Wales that improves well-being and puts people and their needs at the centre of all care and support. Our principles include cultivating practice that promotes voice and control, independence, coproduction, person-centred care and prevention and early intervention approaches.

Explanation of Changes to the Sustainable Social Services Action

Remove 20-21 in-year Covid Allocations & Adjustments

- **£(40.195)m** in year COVID allocations (1st Supp**)**
- **£0.195m** in year COVID re-directed funding (1st Supp)

New allocations for 21-22

- **£1.500m –** Allocation for 3rd Sector support

Action: Social Care Wales		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
19.398	22.613	3.215

This Action provides grant in aid funding to Social Care Wales a Welsh Government Sponsored body.
Social Care Wales (SCW) is funded to regulate the social care workforce, build confidence in the workforce, and lead and support improvement in social care.

Key priorities include:

- set standards for the care and support workforce, making them accountable for their work
- develop the workforce so they have the knowledge and skills to protect, empower and support those who need help
- work with others to improve services for areas agreed as a national priority
- set priorities for research to collect evidence of what works well
- share good practice with the workforce so they can provide the best response
- provide information on care and support for the public, the workforce and other organisations.

Explanation of Changes to the Social Care Wales Action

New Allocation for 21-22

- **£2.000m –** New allocation for SCW

Allocations within MEG for 21-22

- **£1.215m –** 20-21 Technical adjustments

Action: Older People Commissioner		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
1.589	1.589	-

This action funds the Older People's Commissioner for Wales, an independent statutory commissioner. The Commissioner's role and statutory powers are defined by the Commissioner for Older People (Wales) Act 2006 and accompanying Regulations. The Act outlines the action that the Commissioner is able to take to ensure that the interests of older people are safeguarded and promoted when public bodies discharge their functions and the assistance the Commissioner may provide directly to older people in certain situations.

The Commissioner for Older People (Wales) Act 2006 and the Commissioner for Older People in Wales (Amendment) Regulations 2008 require the Commissioner to produce and submit an estimate of the income and expenditure of their office, to be examined by Welsh Ministers and laid before the assembly before the start of the financial year.

Funding remains at the same level as in the October Supplementary Budget.

Action: Supporting Children		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2021-22 £m**	**Change £m**
96.359	93.691	(2.668)

The bulk of funding in this action supports the childcare offer (which is subject to scrutiny by the CYP&E Committee). This action also contains his action funding for the Looked after Children Transition Grant (LACTG) which provides funding for a number of initiatives which improve outcomes for looked after children so that all children in care have the same life chances as other children. It also contains the Vulnerable Children budget which supports children who have been adopted to ensure they and their family have the necessary access to support services to begin their family life.

Explanation of Changes to the Supporting Children Action

Remove 20-21 in-year Covid Allocations & Adjustments

- **£(24.500)m** in year COVID allocations (2nd Supp)
- **£(30.000)m** in year COVID allocations (1st Supp**)**
- **£30.956m** in year COVID re-directed funding (1st Supp)

New allocations for 21-22

- **£19.876m –** new allocations as part of Draft Budget

MEG to MEG transfers for 21-22

- **£1.000m** MEG to MEG, budget correction from EPS.

Action: CAFCASS Cymru		
2020-21 Supplementary Budget October 2020 £m	**Draft Budget 2020-21 £m**	**Change £m**
12.152	13.652	1.500

Cafcass Cymru is a demand-led operational service delivers a statutory service to the Family Court in Wales on behalf of Welsh Ministers. Cafcass Cymru practitioners work with nearly 9,000 of the most vulnerable children and young people in the family justice system, ensuring our interventions promote the voice of the child, is centred on their rights, welfare and best interests to achieve better outcomes for the child involved in the Family Justice System in Wales.

The organisation seeks to influence the family justice system and services for children in Wales, providing high quality advice to Ministers and ensuring the needs of Welsh families and children are reflected in process and policy developments. Of the £10.267m budget, 92% is attributed to staffing costs and 8% to commissioned services and infrastructure costs. Aside from staffing and running costs for the organisation, the budget provides grant funding to support separated parents, when directed by the Family Court, to have contact with their children. The budget also funds the provision of the Working Together for Children programme which supports parents who have separated, or are separating, to better manage their own behaviour to ensure the emotional, practical and physical needs and best interest of their children are paramount.

Explanation of Changes to the CAFCASS Cymru Action

Allocations within MEG for 21-22

- **£1.500m** in respect of additional core funding agreed in 20-21.

Archwilio Cymru
Audit Wales

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To: Nick Ramsay MS
Chair
Public Accounts Committee
The Senedd
Via email:
nick.ramsay@senedd.wales

Dai Lloyd MS
Chair
Health, Social Care and
Sport Committee
The Senedd
Via email:
dai.lloyd@senedd.wales

Reference: AC/237/caf
Date issued: 15 December 2020

Dear Nick and Dai

Procurement and supply of PPE during the COVID-19 pandemic

I am writing to update you on work Audit Wales is carrying out looking at the procurement and supply of Personal Protective Equipment (PPE) during the COVID-19 pandemic.

There has been a good deal of interest in the issue of PPE since the outset of the pandemic. The Health, Social Care and Sport (HSCS) Committee commented on the supply of PPE in its July 2020 report on the impact and management of COVID-19 in health and social care. The Public Accounts Committee received evidence about PPE procurement, including domestic supply chains, in September 2020 as part of its inquiry into public procurement.

More recently, interest has been heightened by the publication of two reports by our colleagues in the National Audit Office. The first of these looked at UK Government procurement during the COVID-19 pandemic, which included a significant focus on procurement of PPE for health and social care in England. There was extensive media coverage of the NAO's findings in relation to a twin-track approach to identifying suppliers, a high-priority lane to assess and process potential PPE leads from government officials, ministers' offices, MPs and members of the House of Lords, senior NHS staff and other health professionals.

The second report looked more broadly at the supply of PPE in England, with extensive coverage of the large increase in the cost of PPE during the pandemic.

About our work

I thought it may be helpful to explain more about our work, which covers the same areas as the NAO: procurement and supply of PPE. We intend to build on the work of the HSCS Committee and to probe in more depth in some specific areas, notably procurement. We expect our work to have a forward-looking focus but based on a robust understanding of the lessons from the early phases of the pandemic.

Our scope takes in the procurement and supply of PPE for all public services. However, in practice, the primary focus will be the NHS and social care. Also, while recognising that there has been local procurement of PPE, this will not be a significant focus of our work. We will focus primarily on the national procurement, led by the Welsh Government and NHS Wales Shared Services Partnership (Shared Services).

We are currently in the fieldwork phase of the study. We have already interviewed several Welsh Government and Shared Services staff. We still have more interviews to carry out over the coming weeks. We have also gathered detailed documentary evidence.

In seeking evidence, we have also written to organisations that supplied evidence related to PPE as part of the HSCS Committee inquiry earlier this year. We have specifically asked for any new evidence or issues that they may wish to share with us.

Our fieldwork so far has focussed on the procurement of PPE. We still have a significant amount of work to do to complete our emerging picture on both procurement and supply. Our intention is to complete our fieldwork and issue our full findings in the spring.

Facts, figures and some emerging findings

In advance of our full report, I thought it would be helpful to share some facts and figures as well as some early emerging findings. I would emphasise that these are early findings and not set in stone. Nonetheless, given the high level of public interest and importance of these issues, I consider that there is merit in setting out the facts around some aspects of what we have found to inform any ongoing scrutiny.

At the start of the pandemic, the Welsh Government had a ‘pandemic stockpile’ of PPE, developed as part of UK wide arrangements, which it intended to distribute to health and social care bodies. The Welsh Government told us this equipment was crucial during the first wave. However, the stockpile was prepared for an influenza pandemic. Updated guidance on protecting NHS staff from coronavirus required some additional PPE, which was either not in the stockpile at all, or was not held in sufficient quantities to meet the extra demands posed by the

coronavirus. The Welsh Government, like other governments around the world, therefore needed to very quickly procure items such as fluid resistant gowns and respirators. Further, we understand that that some expected deliveries from existing suppliers did not materialise, exacerbating the pressure to quickly acquire more PPE.

The Welsh Government told us that it originally anticipated that there would be a UK-wide approach to PPE procurement. However, it agreed with the UK Government that, given the challenges, the Welsh Government would instead get funding via the Barnett formula and take on responsibility for procuring its own PPE. The Welsh Government told us it had continued to work with the UK Government and other devolved nations on procuring PPE, where opportunities have arisen.

The work to rapidly procure PPE for NHS Wales was led by the NHS Wales Shared Services Partnership and Welsh Government officials. Shared Services has taken on responsibility for providing PPE to services beyond the NHS, notably to social care and independent contractors in primary care.

Spend and distribution of PPE

As set out in our recent NHS Wales Finances Data Tool, at the end of September 2020 the NHS had spent £130 million on PPE for Wales. This includes £17 million in local procurement by health boards and trusts on top of £113 million spent by Shared Services on PPE. The Shared Services total includes £37 million for supply of PPE to social care and primary care services, such as GPs, pharmacists and opticians.

Shared Services expects to spend £239 million on PPE for Wales by the end of March 2021, with social care and primary care accounting for 43% (£104 million) of this expenditure.

In addition to the spend on PPE for Wales, as of the end of September, the Welsh Government had spent £37 million on PPE on behalf of other parts of the UK. It expects to recoup this expenditure. We have not yet examined the financial arrangements in place with the other nations.

The NAO's report on the supply of PPE highlights the significant increases in the cost of PPE at the outset of the pandemic. Shared Services told us that for many items it was a 'seller's market' with governments globally competing for scarce supply. We will be looking in more depth at the relative costs of items before the pandemic and during the pandemic. Where appropriate to do so, we will try to make comparisons with the prices paid by other parts of the UK.

As at 29 November 2020, Shared Services has distributed just under 480 million items of PPE since 9 March 2020[1] with around 240 million of these being issued to the social care sector. The 480 million items include 90.5 million aprons, 120 million masks[2], 4 million face visors, 255 million gloves and 2 million gowns[3].

The Welsh Government and Shared Services intended to build up a 24-week buffer stock of PPE by the end of November 2020. Shared Services told us that at the end of November the PPE buffer stock was largely in place. They were awaiting delivery of FFP3 Respirators made by a particular brand, which have been particularly difficult to source globally, and the receipt of orders that had been placed for gloves. We have visited the warehouse, where a proportion of the buffer stock is held. This visit reinforced to us the scale of the logistical operation. But we have not yet reviewed the modelling used to assess whether the buffer stock is sufficient for 24 weeks and we will do so as part of our fieldwork in the coming weeks.

Contracting approach

Under the Public Contract Regulations 2015 and related guidance[4] public bodies can enter contracts without competition or advertising so long as there are genuine reasons for extreme urgency. The Welsh Government, via Shared Services, has used these emergency exemptions for its procurement of PPE. Some details of contracts have been placed retrospectively on the Sell2Wales website. As part of our work we will be confirming that the correct contract notification procedures are being followed.

Shared Services has agreed contracts with around 100 different providers. However, many of these are for relatively low values. Around three-quarters of the suppliers have contracts valued at less than £1 million and around half are less than £150,000. Some 94% of the expenditure to the end of September 2020, including the expenditure on behalf of other parts of the UK, was with five suppliers.

While most of the PPE contracts are direct with suppliers, some of the larger contracts involve agents acting as intermediaries with overseas manufacturers. As

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[1] Data source – Stats Wales: Weekly number of PPE items issued by date. The reporting of PPE items issued is based on individual units, except for: gloves where a unit is reported based on the unit size of a pack and hand sanitiser where the unit is a bottle regardless of size.

[2] This figure includes: Type I and Type II mask, Type IIR masks, FFP2 masks, FFP3 masks.

[3] This figure includes: Gowns (fluid resistant) and Gowns (other).

[4] Regulation 32 and Procurement Policy Note 01/20: Responding to COVID-19 – March 2020

part of our fieldwork we are exploring further the use of agents and associated costs.

Although the bulk of PPE came from international suppliers, the Welsh Government and NHS worked with Welsh manufacturers to develop local supply chains. Welsh Government officials told us that this involved collaborative working within the Welsh Government, NHS and Industry Wales through the critical equipment requirements engineering team (CERET). We intend to explore this aspect of the procurement in more detail in the coming weeks.

Checks and approval arrangements

Shared Services and the Welsh Government told us that they have never had an equivalent to the twin-track 'high priority lane' approach to identifying potential suppliers described by the NAO in its report on COVID-19 procurement in England. In Wales, the Life Sciences Hub played a key role as a first point of contact for potential suppliers and manufacturers which, where appropriate, were referred to Shared Services. Shared Services told us that they also identified new suppliers through their existing networks, through suppliers getting in touch themselves and through other referrals. While there were referrals from politicians, Shared Services told us that these were subject to the same process, scrutiny and prioritisation as any other contacts. We are carrying out work to more fully understand how suppliers were identified and how referrals were managed.

The Welsh Government and Shared Services put in place revised governance arrangements around the letting of PPE contracts. All orders over £1 million in value already required the prior approval of the Welsh Government. In addition, a system of due diligence checks, scrutiny arrangements and a hierarchy of approvals were introduced involving the board of Velindre NHS Trust, which hosts Shared Services, and depending on the value and nature of the contract. Shared Services set up a new Finance Governance Group to support rapid decision making. This Group comprised senior managers from the NHS including specialists in areas like audit, fraud prevention, procurement, accountancy, and law.

The Welsh Government and Shared Services told us that the nature of the market during the pandemic meant that in some cases suppliers required an advance payment. To manage the risks, in a small number of instances, Shared Services made these payments though an independent escrow account. Shared Services and Welsh Government told us that this approach meant that the suppliers could see that the funding was in place but could not draw down the money until Shared Services had received the goods and checked that they met the required quality standards. All advance payments had to be approved by the Finance and Governance Group, with the Group referring advance payments more than 25% of a contract's value to Welsh Government for prior approval. We will be exploring in more detail how this system worked in practice as well as the work to check quality, which involved the Surgical Materials Testing Laboratory (SMTL) based in Bridgend.

The NHS Internal Audit service carried out a review of Financial Governance Arrangements during the COVID-19 Pandemic, with a focus on PPE, between March and August 2020. It found that the procedures around background checks, approvals and recording of decisions that the Welsh Government and NHS had put in place were complied with in all cases. It also noted that there were some improvements made to the financial governance arrangements and quality of documentation over the period. As part of our work we plan to test a sample of contracts. In doing so, we intend to place reliance on the work of Internal Audit in verifying compliance, while asking broader questions on value for money.

Next steps

Over the coming weeks, we intend to complete our work on procurement and then start to look in more depth at the issues around maintaining supply to the frontline staff. We will then start to form our conclusions, draft our report and go through our usual process of clearing it for factual accuracy with the Welsh Government and the other named parties.

In the meantime, if there is anything else we can do to help you and your committees on this matter please let me know.

Yours sincerely

ADRIAN CROMPTON
Auditor General for Wales

Vaughan Gething AS/MS
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Llywodraeth Cymru
Welsh Government

Dai Lloyd MS
Chair, Health Social Care and Sport Committee
Welsh Parliament
Cardiff
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21 December 2020

Dear Dai,

I'm writing in response to your letter of 10 December 2020 regarding the successor arrangements for the major health condition delivery plans.

The Deputy Minister for Health and Social Services announced in February that the cancer, heart conditions and stroke delivery plans would be replaced by December with successor arrangements. The Deputy Minister also confirmed that the other delivery plans (liver and respiratory disease, diabetes and neurological conditions, end of life care and critical care) would be extended by one-year in order to provide additional time to put in place successor arrangements. Unfortunately, the pandemic has drawn the relevant officials involved in these policy areas into supporting the pandemic response and also mitigating the impact of the pandemic on services covered by these delivery plans. It has also stopped related work on evaluating the impact of each of these plans.

I confirmed to the Senedd on 25 November that the successor arrangement for the cancer plan has been delayed but that I hoped to be in a position to publish a new approach in March 2021. I am considering if we can also publish the heart disease and stroke documents alongside this. Until that time, the current delivery plan approaches remain in place to guide NHS planning and national programmes of work. The successor arrangements to delivery plans are intended to set the medium-term direction for the development of specific clinical services and are not intended to set out how the NHS in Wales will recover from the pandemic.

The Deputy Minister signalled in February, and I confirmed in November, that the new approach to major conditions would need to fit in with and take advantage of the opportunities set out in A Healthier Wales. These include the development of the National Clinical Framework, an NHS Executive function and the potential for Quality Statements.

We have given significant thought and attention over the past two years to the strengths and weaknesses of the delivery plan approach. It is the consideration of these that has led our thinking in terms of developing a new format for the years ahead. I am keen that we

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build on everything we have put in place in recent years but learn how the approach to date can be improved upon. My officials have been developing throughout the past year the concept of Quality Statements that will be underpinned by NHS implementation plans at clinical network level as part of the intended NHS Executive function. We have undertaken some preliminary engagement with stakeholders on the Quality Statement for Cancer and heart conditions but I look forward to setting out more detail in the coming months.

The successor approaches for those plans not replaced by March 2021 will be a matter for the new government to consider following the elections in May 2021.

Thank you for writing to me on this matter.

Yours sincerely,

Vaughan Gething AS/MS
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

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Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Llywodraeth Cymru
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Ein cyf/Our ref MA/VG/0003/21

Dr Dai Lloyd MS
Chair, Health, Social Care and Sports Committee

5 January 2021

Dear Dai,

I wrote to you in August and in October replying to your requests for information about the rationale for laying a Legislative Consent Memorandum before the Senedd for the Medicines and Medical Devices Bill and the on-going discussions between the Welsh Government and Department of Health and Social Care (DHSC) on the proposal for a medical device information system (MDIS). On 2 December, I laid a Supplementary Legislative Consent Memorandum on the Bill concerning a Government amendment passed by the House of Lords that the Devolved Administrations (DAs) should be consulted before any regulations under Clause 16 (new Clause 18) are made, irrespective of whether the proposed regulations are seen as relating primarily to supporting specific device safety elements or supporting the wider healthcare system.

As you know a debate on the legislative consent motion on the Bill has been scheduled for 12 January. I am writing to update you on recent developments and my intentions in relation to the motion.

Since the summer there has been much discussion between officials of the Welsh Government, the other DAs and DHSC about the design, functions and governance of the medical device information system. I also corresponded with and met Lord Bethell to progress matters. This has resulted in a draft memorandum of understanding (MOU) that includes a number of assurances relating to the operation of the information system. For example it emphasises the importance of four nation consultation and reporting on the operation of the MDIS, the establishment of joint officials' working groups to discuss and draft the regulations, escalation arrangements in the event of disagreement and technical operational matters. There are also safeguards on issues such as the use and sale of data. A copy of Lord Bethell's recent letter and draft MOU, which has to be agreed by Devolved Administrations, is attached.

Although the arrangements have not gone as far as I would have wished towards joint Ministerial governance of the MDIS an MOU is a positive compromise approach to the information system. This is now envisaged as a partnership involving other agencies,

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manufacturers, clinicians, individuals and the four governments. The proposed frequent Ministerial meetings on the MDIS as the preparation of the regulations progresses provides a real level of Ministerial oversight.

In terms of the regulations and the principles proposed by the DAs Lord Bethell has given an assurance that “we are committed to ensuring that any MDIS regulations will implement an operational model which will serve the best interests of patients across the UK and take account of the particular considerations of the DAs”.

Scotland and Northern Ireland had already given legislative consent to the proposals before agreement was reached with the Welsh Government to progress to an MOU. In the light of the assurances, the cross over with a significant reserved matters, the likely significant benefits of the information system to patient safety and medical device improvement and innovation, which I have previously outlined, I intend to recommend that the Senedd approves the legislative consent motion to the Medicines and Medical Devices Bill. This will ensure that Wales fully participates in the MDIS.

I have written in similar terms to the Chair of the Legislation, Justice and Constitution Committee, Mick Antoniw MS and I am also copying this letter to all Members of the Senedd.

Yours sincerely,

Vaughan Gething AS/MS
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Department of Health & Social Care

From the Lord Bethell
Parliamentary Under Secretary of State for Innovation (Lords)

39 Victoria Street
London
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Tel: 020 7210 4850

11 December 2020

Dear Vaughan,

MEDICAL DEVICES INFORMATION SYSTEM (MDIS)

Thank you for the extremely helpful meeting yesterday. I hugely welcomed your agreement on the opportunities that the MDIS can offer and am delighted that you believe that Wales should be part of a UK-wide medical devices information system. As I indicated, this is something which I am committed that all four nations work closely together on as work progresses, and I am confident that in doing so we can make a significant difference for the safety of patients using medical devices.

I explained yesterday that in light of the critical need to make swift progress on the MMD Bill after the end of the Transition Period, and the risk that amending the Bill at Third Reading would introduce delays in securing Royal Assent, that I would be unable to amend the Bill after Lords Report stage, should the Senedd not agree legislative consent for clause 18.

You explained that, in order to provide the necessary assurances to the Senedd, you would welcome a Memorandum of Understanding (MOU) summarising the key commitments and outlined in my previous correspondence of 4th December. In light of our discussion, this now includes a further commitment to ongoing Ministerial engagement on MDIS, as well as outlining my intention to amend the Bill to extend the reporting requirement at clause 44 of the Bill to apply to regulations made under clause 18. Given the interest that legislatures in the Devolved Administrations will have in the operation of the MDIS, I have made clear that reports prepared on clause 18 regulations will be shared with Ministers in all four nations. The MOU is attached at Annex A. I will also ask that Ministers from Scotland and Northern Ireland endorse the enclosed MOU.

As discussed yesterday I would therefore be grateful for your confirmation by Monday 14th December that you do not wish me to table an amendment to the Bill to remove Wales from the territorial scope of clause 18, and that in light of the assurances I have given, that you intend to recommend that the Senedd give legislative consent. I recognise, of course, that no guarantee can be given on consent until the Senedd debate has taken place on 12th January.

Yours,

Bethell

LORD BETHELL

ANNEX A – MEMORANDUM OF UNDERSTANDING

Memorandum of Understanding

Between:

Department of Health and Social Care
And
The Welsh Government, The Scottish Government and The Northern Ireland Assembly

Concerning:

Participation in United Kingdom
Medical Device Information System (MDIS) established under clause 18 of the Medicines and Medical Devices Bill

11th December 2020

Introduction

1. The Medical Device Information System (MDIS), or more than one such system, can be established by regulations made under clause 18 of the Medicines and Medical Devices (MMD) Bill following consultation with Welsh Government Ministers, Scottish Government Ministers and the Northern Ireland Department of Health and public consultation.

2. Establishing MDIS will facilitate the tracking of medical devices by their unique identifiers to individual patient records, ensuring that safety concerns can be identified and followed up promptly. Equally, information collected under the MDIS has the potential to inform future regulation of medical devices, by building our understanding of how particular devices interact with different cohorts of patients. It will support improved post-market surveillance of medical devices on the market, as well as minimising harm to patients in the future by informing when, how and for what purpose products are authorised for use.

3. The primary function of MDIS made under the power will concern the safety and performance of medical devices, and therefore relates to reserved matters. It also has significant potential to support devolved responsibilities to improve patient safety and clinical outcomes. Assessment of the data collected in the MDIS could also improve understanding of patient outcomes for different devices, informing clinical practice and procedures in the future.

4. MDIS work is in its early stages. Close-working between the nations from the outset will support effective dialogue on the MDIS proposals, plans for public consultation across the UK, and the development of operational details and arrangements to deliver the system. It is right that we take this early opportunity to build effective cross-UK working from the start, whilst allowing for the natural evolution of that close-working between the four nations as we progress from early policy development towards implementation and operation of the system.

5. This memorandum of understanding (MOU) sets out principles that will underpin engagement between the UK Government and Ministers in the Devolved Administrations on the development of the UK-wide MDIS, the proposed information system to be established by clause 18 of the MMD Bill. It covers consultation requirements, reporting requirements, official-level working arrangements, how Ministers from all four nations will work together, and other related issues. The points set out in this MOU will be kept under review as development and implementation of the regulations for the MDIS progresses. This MOU is not legally binding and the arrangements it sets out do not extend the statutory duties to consult and report in the MMD Bill.

A. Consultation Requirements

6. Clause 43 of the MMD Bill introduces a legal requirement for the Secretary of State of Health and Social Care, to carry out a public consultation before making regulations under clause 18 of the MMD Bill. In addition, the Secretary of State must specifically consult Welsh Ministers, Scottish Ministers and the Department of Health in Northern Ireland before regulations under clause 18 are made.

7. Further details on how all parties to this MOU will participate in the development of these consultation and engagement exercises are set out in Section C below.

B. Reporting Requirements

8. An amendment to the MMD Bill at Lords Report Stage will require that the Secretary of State provides the UK Parliament with a report every two years on how regulations made under clause 18 have operated during that time. The report must contain a summary of any concerns and proposals raised during consultation in preparing a report, and the Secretary of State's response to those concerns or proposals. This includes providing advance notice of further regulatory change that the Secretary of State is proposing to make.

9. The Secretary of State would be required to consult such persons as the Secretary of State considers appropriate before developing this report. Given the duty to consult the Devolved Administrations before making regulations under clause 18 of the MMD Bill, it would of course be appropriate to consult the Devolved Administrations when preparing the report under clause 44. This would mean that any issues or proposals raised by the Devolved Administrations during consultation on preparation of the report will need to be summarised and responded to within the report.

10. It is recognised that Ministers in the Devolved Administrations may also wish to provide similar reports to their respective legislatures. Copies of the report prepared by the Secretary of State will be shared with Ministerial counterparts in the Devolved Administrations.

C. Official Working Level Arrangements

<u>Four UK Nations Working Group for the MDIS Regulations</u>

11. All four UK nations will participate in an officials' working group, which will meet regularly and provide a forum to discuss all aspects of the proposed framework to establish regulations that work for the four nations. It is proposed that this group will:

    - Work together to develop plans for early and meaningful engagement with patients and the public, clinicians, providers, and industry in all four nations on the proposed operation of any MDIS recognising that the experts in identifying and talking to the appropriate organisations in each of the nations are those who work in the individual nations.
    - Discuss the provision and development of briefing, communication and consultation materials to support wider engagement.
    - Discuss emerging timescales and plans for public consultation on the MDIS, seeking feedback on plans to help in the development of public consultation and regulations in the longer term.
    - Consider emerging policy options that will inform areas of the regulations such as the establishment of the MDIS, information collection, use and sharing, and enforcement.
    - Discuss issues that may fall outside of regulations but where it may be appropriate to develop agreed standard operating procedures, ensuring there is flexibility in the operating system that is backed by agreed processes.

- Contribute to, and ensure, robust underpinning policy development and analysis reflecting available evidence and data.

12. Should any decisions agreed by this forum need further sign off or, in the event the working group cannot agree, it is proposed that discussions will be escalated through official channels to a more senior level.

Technical Working Groups for the MDIS

13. NHS Digital, (working with the Department of Health and Social Care and NHSX) as the organisation responsible for establishing and operating a future MDIS, will hold detailed, technical discussions under three working groups that will be coordinated by a project group, reporting into the Medical Device Safety Programme (MDSP) Steering Group. Officials from the devolved administrations can join all working groups and project meetings relating to the operational development of the MDIS. It is proposed that these groups will:

    - Support the design and implementation of any proposed UK-wide MDIS;
    - Support the information governance and legal processes required to develop and implement the MDIS; and
    - Work with the Medicines and Healthcare Products Regulatory Agency (MHRA), device manufacturers and relevant system partners across the four nations to implement a Product Information Master (PIM) database for all relevant products in the UK supply chain.

Medical Device Safety Programme (MDSP) Steering Group

14. Officials are establishing a cross system-programme of work for England under a Medical Device Safety Programme (MDSP) that builds upon previous initiatives and will work alongside the UK-wide MDIS and focus on improved clinical specialty level outcome registries, device tracking and patient/clinician decision support.

15. We consider it important that all four nations are given the opportunity to see how the wider MDSP elements operate together, even where they are for England only, to give space to share ideas and experiences.

16. The MDSP will have an over-arching Steering Group, with senior officials from the Devolved Administrations having representatives in attendance. The operation of this group will:

    - recognise the benefits of the MDIS being considered alongside the other (England-only) elements of the MDSP under the Steering Group,
    - consider with Devolved Administration colleagues the terms of reference, frequency and appropriate attendance for their engagement with this group; and
    - provide a senior official level governance and escalation mechanism for the operational aspects of MDIS whilst ensuring that this reflects the unique position of MDIS as a UK-wide endeavour relative to the wider MDSP.

D. Ministerial Engagement

17. Given the interest that Ministers in the Devolved Administrations have in the development and operation of the MDIS, Ministers in Wales, Scotland and Northern Ireland are assured that discussions on the MDIS will be included on the agenda for the weekly four nations Ministerial meetings, as necessary and helpful. This will provide a regular, ongoing opportunity through which Ministers from all four nations can consider progress or issues on the MDIS established under clause 18 of the MMD Bill.

E. Related Issues

Consideration of local data collection arrangements:

18. Consideration will be given to the mechanisms for collection of information from providers and how this can best work alongside existing local arrangements in the four nations. It is right that such decisions are part of a wider conversation to make sure that all aspects associated with different approaches are fully considered in the context of the objectives for the MDIS.

Use of data by other bodies for research

19. On the provision of data from the MDIS to commercial organisations, such as for research purposes, as the operators of the MDIS, NHS Digital will work solely on a cost-recovery basis, with data only being shared when it is safe, ethical, and legal to do so, and where the purpose directly benefits the health and care of patients. This can include, for instance, sharing data under appropriate safeguards with researchers, but would exclude sharing for insurance or marketing purposes for example. For the MDIS, the regulations setting out the legitimate purposes for which data could be shared will be subject to both public consultation and consultation with the Devolved Administrations and will remain subject to the data safeguards referenced above.

Workshops

20. There is a commitment to deliver bi-monthly workshops to develop options for the MDIS design and UK-wide interoperability. These workshops, which will run in parallel with the planned consultation process for the development of the MMD Bill regulations, will include the Devolved Administrations, patients, clinicians and will focus on the technical design and interoperability of the MDIS. They will recognise that the four nations will each have varying local system capabilities and priorities for optimising the approach which will be captured and explored through this planned collaboration.

Nation-specific pilots

21. There is a commitment to offer nation-specific pilots, at each stage of the phased implementation, to ensure the MDIS meets local requirements of key stakeholders.

Conclusion

22. We are committed to the UK-wide MDIS delivering the greatest possible benefit for patients in all four nations. It offers us all a significant opportunity to ensure the safe use of medical devices. This MOU reflects our collective agreement and commitment to working effectively as this work evolves.

Signatures

Date

Senedd Cymru
Y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon

—

Welsh Parliament
Health, Social Care and Sport Committee

Agenda Item 3.4

Nicola Stubbins
President, ADSS Cymru

15 December 2020

Dear Nicola

Many thanks to you and Alwyn for giving evidence last week to the Committee's inquiry into the Covid-19 outbreak. During the course of the meeting, you raised a number of issues about which the Committee has asked me to seek further clarification.

Hospital discharge guidance

You told us that there was still some variation in the way that hospital discharge guidance was being interpreted and that you were aware of examples from across Wales where discharges from hospital were being made to care homes without them having received a test result for the patient.

Can you please provide further information on the following points:

- is this happening currently, and how widespread a problem is it;
- are there any particular regions or areas of Wales where this is more of a problem than others;
- what processes are in place to record when this happens;
- what action is taken where this is found to have happened.

Weekly staff testing

You also told us that some care homes have stopped weekly testing of staff because of issues around capacity to book and undertake tests; the time taken for results to come back; and a general lack of confidence in the testing system.

Can you please tell us:

- how widespread a problem this is;
- what happens when a care home opts out of the testing programme.

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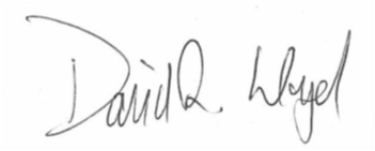
Collection and availability of data

Finally, we asked you about whether sufficient and timely data is collated centrally around key social care indicators to inform decision-making during the pandemic, including the identification of needs and the commissioning and resourcing of services. You told us that there were gaps in data collection and availability, and agreed to provide an explanatory note on where the gaps are in the data currently being collected by the Welsh Government and how this could be improved.

We are hoping to have an evidence session with the Deputy Minister for Health and Social Services in the new year, and would like to be able to discuss these matters, amongst others, with her. As such, it would be helpful if you were able to provide this information by Friday 8 January.

Yours sincerely



Dr Dai Lloyd MS
Chair, Health, Social Care and Sport Committee

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Dear Dr Lloyd

Thank you for affording us the opportunity to provide supplementary evidence in order to clarify some of the points that Members raised during the evidence session on 9 December 2020. We have addressed the questions under the themes below.

Hospital Discharge Guidance

All regions have developed robust standard operating procedures agreed between Health Boards and Local Authorities, which enables statutory agencies to follow the COVID-19 discharge guidance issued by Government. In the main, those procedures are being adhered to. However, there are still incidences in various parts of Wales where those procedures are not being adhered to, which leads to poor (and in some cases very poor) discharge practice. For example, some individuals are being discharged without having a negative test or ambulances turn up at care homes on a Sunday evening or overnight with a resident in the back and the care home manager feels pressurised into having to accept them rather than them returning to hospital.

In trying to understand why procedures are not followed, it is our perception that the interpretation of the guidance is dependent on the pressure to discharge from hospital. Care homes have been very clear about the guidance and will insist on a negative test result before considering the admission, however, that does not mean that attempts are made to discharge without the test result or asking for the discharge to happen before the result is known. There are also incidences of Health Boards trying to use 'technicalities' to bend the rules. For example, a care home resident may have spent time (often for a lengthy period of time/overnight) in a hospital assessment unit, as opposed to being admitted to a ward. The hospitals then insists that as they have not 'technically' been admitted they should be able to return to the care home from which they originated without isolation or without making use of a step-down facility.

This in our view poses very real risks. In these instances, there is a reliance on care home providers to have the confidence to challenge such discharges and refused to admit patients into care homes when the process has not been followed. However, this is not easy and is not helped when, in one region, care homes have to deal with two District General Hospitals who apply different time scales in hospital (A&E) before a negative test is required.

When a sub-optimal (unsafe) discharge has occurred that incident will be recorded by the care home or Local Authority and will be escalated with the Health Board so that the incident can be reviewed, and any learning implemented. At times, such incidents have constituted a safeguarding concern, so have been investigated in line with statutory safeguarding processes. However, there have been occasions when an incident has been escalated with health colleagues but there has been no resolution or feedback provided

back to us in local government to understand whether any appropriate action has been taken. So, there is a variability that needs to be addressed but, more importantly, health colleagues must be respectful, understanding and supportive of providers when they are reluctant to take citizens who are still COVID+ or their test status is unknown.

Weekly staff testing

Again, there is some variability in terms of testing across the regions. For example, in Powys, Public Health Wales (PHW) had recently stopped weekly testing but has now reinstated it. In Carmarthenshire, routine Weekly testing of care home staff is no longer in place, however, it will be reintroduced shortly, following the introduction of the Lateral Flow Tests for asymptomatic staff. In other areas, weekly testing is undertaken if determined necessary by PHW because there has been a COVID outbreak, otherwise it is done fortnightly. We know from providers that this is a time-consuming process and concerns have been raised around using the test portal and lighthouse labs and particularly the paperwork, time and effort this has creates for care homes. However, the timeliness of test turn around is still the most significant challenge and cause of frustration for providers. Anecdotal evidence shows that in some cases, it can take up to 4 days for test results to be received, which is not acceptable. Local Authorities, providers and care staff must have confidence in the system, otherwise we will see increase staff opt-out of the process.

Collection and availability of data

The current information being collected is very generic and not specific. As one colleague stated:

"This is supposed to be a whole system approach but all we get is figures thrown from one side of the system i.e. there are 150 people awaiting a discharge in hospital. We are not able to respond by saying we have discharged patients in the last 7 days; or are providing domiciliary care packages to so many residents on a weekly basis. In addition, we focus on those who require support from Social Services, we are never told how many patients who do not need any Social Services input are awaiting to be discharged, which is a far greater number."

Capturing this full range of data would be allow a whole picture to be painted and not just focussing on one part of the system but the whole system and what it is providing to the whole community, not the small numbers who are in hospital at any one time.

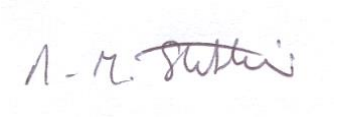
There are good practice examples of data collection and mining. The Gwent Community Care Sub-Group (CCSG), for example, has developed regional data situation reports (SitReps). In particular they have developed a sitrep for care homes which monitor the number of care home vacancies, especially in clean care homes, where there are no COVID outbreaks. They have also developed a domiciliary care sitrep to monitor care packages and staff absence. In addition, a Closed Setting group established by Aneurin Bevan University Health Board (ABUHB), regularly monitor care home incidents and infection rates as well as how many staff and residents are COVID positive. From a commissioning perspective regular data is obtained on vacancy rates, financial risk, numbers of staff isolating, incidents and out of incident data (care homes and domiciliary care). All this is reported to CCSG on a weekly basis and all commissioners. This has led a number of Gwent-wide regional initiatives to increase capacity in the health and social care work force:

- Feasibility of developing a staffing bank for emergency deployment
- Partnership with Coleg Gwent to access the student body to add capacity
- 18 students recruited to ABUHB's Resource Bank during first wave of pandemic.
- Feasibility of utilising ABUHB's resource bank workers to provide emergency cover in care homes.

- DWP's Kickstart Scheme regionally promoted as a way to increase staff capacity.
- Technical Co-ordinating COVID-19 Group – Mutual Aid Agreement for Local Authorities and partnership agencies to support ABUHB staff capacity and vaccination rollout.

I hope the Committee finds this additional information helpful. If you require any further information, please do not hesitate to contact our Policy and Research Lead, Paul Pavia, within the ADSS Cymru Business Unit [redacted]

Yours sincerely,



Nicola Stubbins
ADSCC President

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