Cabinet Secretary for Health and Sport
Jeane Freeman MSP

Scottish Government
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Lewis McDonald
Convener
Health and Sport Committee

06 November 2020

Dear Lewis,

I am writing in response to the Health and Sport Committee's letter of 23 March to set out more detailed answers to the questions posed by the Committee after my attendance at the Committee's inquiry into the Supply and Demand for Medicines at the beginning of March. I would also like to thank you for providing an extension. There will be some overlap with my letter of 11 September.

Data and information technology

Use of information technology

In 2019, the Pharmacy and Medicines and Primary Care Division commissioned NHS National Services Scotland (NSS) to bring together a broad range of users, including patient representatives, to explore the potential transformation of prescribing and dispensing pathways across Primary Care in the context of extended multi-disciplinary team (MDT) working. Three multi-disciplinary workshops were held between September and November 2019. The workshops brought together clinical staff from across primary care as well as representatives of national organisations, territorial health boards and independent contractors, including GP practices and community pharmacy. The work identified a number of key focus areas and critical dependencies required to deliver an end to end digital solution that will support paper-light and eventually paper-free approaches across the prescribing and dispensing pathway.

In order to build upon this, the Pharmacy and Medicines Division, the Primary Care Division and the Digital and Digital Health & Care Directorate are now co-sponsoring a work programme to be delivered by NSS and the NHS Education for Scotland (NES) National Digital Service (NDS). It is anticipated that the programme will continue for at least a two-year period during which prioritised and funded outputs will be developed and delivered with a view to digitalising the prescribing and dispensing pathway to support full electronic prescribing and dispensing across primary care and also between primary and secondary care.

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Digital platform

The National Digital Platform is intended to provide the technical architecture which ensures that key things are only done in one way across Scotland, such as how people are identified and where clinical data is stored, thus avoiding having to have a different log-in for every system and the duplication of information. It is envisaged that the NSS/NDS work programme described earlier will be a key enabler in supporting a person-centred electronic health record ensuring relevant data are accessible to health and social care teams where and when needed, as will the implementation of HEPMA, which I will refer to later.

Access to information

As part of our response to COVID-19, health boards rapidly deployed the Emergency Care Summary (ECS) across the network of community pharmacies, providing access to information about the acute and repeat prescriptions prescribed as well as information such as allergies. This has been warmly welcomed by the profession.

Patient Outcome data

As outlined previously, there is little provision in existing NHS IT systems to collect information about the purposes for which medicines are prescribed and the outcomes achieved by particular medicines. While this gap is a common feature of health systems in the UK and internationally, it is a significant constraint on the development of medicines policy and is a particular focus for the pharmaceutical industry, for whom data about outcomes achieved is of obvious scientific and commercial interest.

Dr Brian Montgomery's Review of Access to New Medicines recognised Scotland's reputation for high quality data. It also identified some of the gaps in existing IT capabilities and highlighted the need to develop a more sophisticated approach to the measurement of outcomes achieved by medicines. As the Committee will know, the Review made six recommendations specifically on data, including data capabilities, data requirements, data sets and a recommendation to "establish a multi-agency taskforce or equivalent to report on data requirements to support the assessment and introduction of new medicines going forwards." In my letter, dated 13 January 2020, I described the work we are undertaking to address the data challenges, including the establishment of a Data Scoping Taskforce to determine the digital capabilities required to utilise real world health data to support the assessment and introduction of new medicines, together with ensuring on-going safe, effective use of established medicines.

The Taskforce Report was published on 18th September 2018, and proposed five actions which are being considered as part of a range of ongoing policy initiatives including the Digital Health and Care Strategy, the Chief Medical Officer's Realistic Medicine approach and the ongoing development and implementation of a Hospital Electronic Prescribing and Medicines Administration (HEPMA) system. I will come back to this later in my letter. This work is now informing our current plans.

Changes will take time to develop and implement so this work is being progressed in phases, with the development of data and datasets and the initial focus on cancer and ultra-orphan medicines.

More recently the Interim Chief Pharmaceutical Officer has commissioned a specific piece of work to use cancer as an exemplar on how this can be progressed. As I have stated previously we are evolving our approach to medicines data with a view to enhancing Scotland's international reputation in health data research.

Cancer Medicines Outcomes Programme (CMOP)

As a group, cancer medicines account for the highest proportion of new medicines introduced within NHS Scotland each year. Currently most of the information about the efficacy and side effects of cancer medicines is obtained through the results of clinical trials. However the outcome of these medicines in the local populations may be different to those reported in trials. The Cancer Medicines Outcome programme (CMOP) is a collaborative programme between NHS Greater Glasgow and Clyde and the University of Strathclyde, funded by the Scottish Government. The aim of CMOP is to explore how to maximise the use of existing and new evolving electronic datasets to gather information on clinical outcomes such as survival rates, duration of therapy and treatment side effects. A recommendation in Dr Montgomery's Review of Access to New Medicines was to develop, agree and implement a national cancer dataset – this programme is a vital first step towards achieving that.

The vision of CMOP is to create a national clinical effectiveness oncology resource to measure the clinical and patient reported outcomes of cancer medicines used in the real world and provide rapid feedback of findings to inform clinical practice. The work programme, to date, has two primary aims:

- Co-ordinate an incremental programme of planned studies to test the connectivity and linkage of current and evolving local and national datasets to determine clinical outcome data for cancer medicines; and
- Test the feasibility of collecting and analysing quality of life data from clinical practice, aligned to the early exemplar studies, to inform a potential enhanced data strategy for collection and analysis of patient reported outcome measures (PROMS).

Year one of the programme focussed on patients receiving medicines for prostate cancer and malignant melanoma; year two looked at gynaecological cancers and colorectal cancer; and year three focused on multiple myeloma, renal and head and neck cancers and non-small cell lung cancer.

Building on the foundations of the initial 3-year programme of CMOP, further funding has been secured to grow a scalable and sustainable capability of expertise in cancer medicines intelligence to drive continued improvement in the safe and effective use of these medicines across Scotland. This also includes driving quality improvement in patient care and dataset capability, using real world evidence to inform health technology assessment and reimbursement systems and providing strategic leadership and oversight in the development of patient reported outcomes for medicines (PROMs) for use in clinical practice in relation to cancer medicines. I believe this will position Scotland as a centre of excellence in the area of cancer medicines surveillance through establishing a national, and international network to support global cancer medicine outcomes.

Hospital Electronic Prescribing and Medicines Administration (HEPMA)

Hospital Electronic Prescribing and Medicines Administration (HEPMA) systems link the medicines prescribed, dispensed and administered in hospital to an individual patient. This makes HEPMA an important enabler for a single electronic patient record, which can link between primary and secondary care. In terms of confirming that HEPMA will be in place across all Health Boards by March 2021, I would like to clarify that the date refers to the initial onboarding of HEPMA systems so that all Health Boards have HEPMA implementation processes underway, but not necessarily completed. As you will appreciate, implementation is less about the technology itself and more about the clinical teams using HEPMA and the associated change management. Hence why the shared learning aspect is an important cornerstone of our approach.

By March 2021, there will be a mix of Health Boards having completed their roll-out and supporting benefits realisation developments, others will be working towards full HEPMA implementation and considering regional convergence. Whilst COVID-19 has undoubtedly set timescales back a little, there is evidence of the added benefits of HEPMA in this unprecedented time, and existing examples of how the service can scale up to deliver technology solutions as we have seen, for example, with the roll out of digital consultations. In addition there are opportunities to learn from and use resources from Boards where HEPMA has already been implemented to increase the pace of roll out.

In terms of progress to date, four Health Boards (NHS Ayrshire & Arran, NHS Dumfries & Galloway, NHS Forth Valley and NHS Lanarkshire) have either implemented or are close to completing implementation of HEPMA. These Boards are now focusing on benefits realisation by developing local reporting tools to maximise the use of available data to support service improvement, audit and monitoring.

One Health Board (NHS Fife) is in the process of finalising their preferred HEPMA system and two others (NHS Borders and the Golden Jubilee) are finalising business case. All other Health Boards have commenced HEPMA implementation, with six Boards working together as a North of Scotland collaboration (NHS Grampian, NHS Highland, NHS Tayside, NHS Shetland, NHS Orkney and NHS Western Isles). My officials continue to work with Health Boards to ensure a local and regional approach to delivery across all the remaining Boards and to support this we have established a national HEPMA Implementation Oversight Board.

<u>HEPMA Oversight Board</u>

The role of the HEPMA Implementation Oversight Board is to provide national leadership to and effective oversight of the implementation of HEPMA systems by advising, monitoring and challenging implementations and convergence across the three regions. The Oversight Board will also inform and direct the alignment of implementations with wider national policy, digital developments, the Digital Health and Care Strategy and the National Digital Platform.

In order to further support the implementation phase at a local level Health Boards are being asked to develop a high level road map with milestones to support the implementation of HEPMA, including the opportunities for regional convergence and alignment of clinical processes. At a national level the Oversight Board will work with Health Boards who have HEPMA implementation experience to drive forward the roll-out of HEPMA.

The local and national approaches will assist with monitoring and information sharing as well as supporting regional working and convergence. The plan is for the Oversight Board to continue to provide oversight until the convergence work is completed.

HEPMA procurement process

The Committee has asked a number of questions about the procurement process and achieving a uniform standard. A national multi-supplier framework for HEPMA was developed alongside a national Full Business Case in 2016. HEPMA suppliers were required to meet a set of national standards that described NHS Scotland's operational requirements for HEPMA. There was a rigorous assessment process and a robust clinically-led decision making process underpinning the framework, driven by ensuring any HEPMA system under consideration met the required standards and provided appropriate interoperability with existing systems.

When the multi-supplier framework was in place, Health Boards were then able to undertake a local mini-competition to determine which HEPMA system on the national framework offered best value and was the best fit to meet their local requirements. In undertaking the mini-competition Health Boards were driving down costs as well as increasing the functionality being offered. In advance of the national multi-supplier framework a number of Health Boards had progressed with local business cases and implementations based on the patient safety benefits of HEPMA.

Health Boards were also asked to look towards regional convergence which was not an insignificant task. A workshop was held in 2016 (a summary of the outputs is attached at Annex A) which aimed to ensure a greater understanding of the national HEPMA work, and the opportunity to explore the collaborative development of regional HEPMA roadmaps. Due to the complexities involved, the regions (with the exception of the North) have moved towards a board by board roll-out with regional convergence as the longer term view. The work from the North Region will be drawn upon to assist with the overall regional convergence plans. In addition, the framework approach taken, has resulted in all the Health Boards to date opting for the same HEPMA system, which will make the regional convergence easier to deliver in the longer term. Therefore there is not a patchwork of systems, although Health Boards may be operating different instances (versions).

HEPMA funding

In terms of funding, this is shared between Scottish Government and Health Boards. Scottish Government invested over £10m in 2019/20 to support the implementations of NHS Greater Glasgow and Clyde (£5.093m), NHS Lothian (£3.261m), the State Hospital (£335K) and the six Health Boards involved in the North of Scotland, collaboration (£1.637m). This year we have invested a further £5.963m in the North of Scotland implementation.

HEPMA implementation

You asked about who is responsible for ensuring HEPMA is implemented to a uniform standard. We, in the Scottish Government have taken a stronger focus on supporting the implementation and the wider benefits of HEPMA and are working to re-energise the roll-out as part of developing the digital strategy. I have already advised that to support this we have established a HEPMA Implementation Oversight Board, that is clinically led, and which reports into the ePharmacy Programme Board, chaired by the Interim Chief Pharmaceutical

Officer, who is overall programme sponsor, responsible for ensuring the delivery of HEPMA, in partnership with Health Boards themselves. The ePharmacy Programme Board reports into the Health & Social Care Management Board and Digital Digital Health and Care Strategic Portfolio Board which ensures that it aligns with the overall digital programme.

HEPMA shared learning

Healthcare Improvement Scotland (HIS) has been commissioned to implement a shared learning system and will be dependent on the full participation from all Health Boards. To date, Health Boards have been enthusiastic to contribute. The shared learning outputs feed into the HEPMA Implementation Oversight Board.

I believe that good progress is being made in implementing HEPMA and we are beginning to see real traction and pace. Factors contributing to this include the availability of appropriate financial resourcing, clear lines of responsibility through the Chief Pharmaceutical Officer, the introduction of a HEPMA Implementation Oversight Board, and plans for a programme of shared learning and benefits realisation, supported by HIS.

Licensing

Off-label/repurposed cancer medicines

The Scottish Government strategy *Beating Cancer: Ambition and Action* made a commitment to assess what improvements could be made to maximise the opportunities for access to off-patent medicines, including cancer medicines. In response to this commitment, HIS established an Off-label Cancer Medicines Programme, funded by the Scottish Government. Its purpose is to provide advice to Health Board Area Drug and Therapeutics Committees (ADTCs) on the managed entry of off-label uses of cancer medicines.

The two year programme is testing and evaluating the principles and methodology to support the production of advice that will maximise both use of off-label cancer medicines (where a medicines is within its patent life) and off-patent cancer medicines, where 'repurposing' a medicine presents opportunities for improving patient outcomes.

Through a 'Once for Scotland Approach', from initiation until March 2020 the programme team and group has developed and agreed guiding principles to deliver national advice for off-label and off-patent use of cancer medicines that is consistent and meets specific criteria and standards. They have also developed an operational framework and started to test the framework with the assessment of a cancer medicine. This work has subsequently been adapted to support our COVID-19 response and I have addressed the detail of this below.

Governance and guidance of off-label prescribing

There is scope for using the learning from the revised off-label cancer outcome programme that I have described above and applying it to other medicines where there is demand for off-label use. We adapted the Off-label Cancer Medicines Programme in March in response to COVID-19. The programme team was redirected to support the work of the National Cancer Medicines Advisory Group (NCMAG) convened by the SGHD COVID-19 Cancer Treatment Response Group (link). This resource along with the guiding principles and operational framework developed by the programme has enabled a rapid response to facilitate assessment and access to alternative cancer treatment during COVID-19.

The group has reviewed at least seventeen proposals and issued advice to Health Boards. Critical to the success of this work has been the multi-professional clinical leadership, participation from all three cancer networks and access to additional critical appraisal and clinical capacity to meet demand during COVID-9. My officials will give this further consideration early in 2021 as part of a wider review of our access to medicines policy which will include the governance and guidance of off-label prescribing.

Streamlining the licensing of medicines

The regulation for the licensing of medicines, the Human Medicines Regulations 2012, is currently reserved to the UK Government. Currently, manufacturers can apply to either the European Medicines Agency (EMA) or the Medicines and Healthcare products Regulatory Agency (MHRA) for a marketing authorisation or licence. The MHRA is developing new regulatory pathways and an overarching licensing framework in response to the end of the EU End of Transition Period. The MHRA has confirmed that they will continue to accept EMA decisions for a period up to 24 months from 1 January 2021.

My officials have strengthened their working relationships at official level with the MHRA and continue to work together to ensure appropriate licensing arrangements will be in place. Establishing a strong strategic partnership with the MHRA is critical to ensuring that we understand and influence work undertaken by the agency including but not limited to their remit in the development of new regulatory pathways for medicines. The MHRA is currently leading work that will focus on health technology assessment (HTA) functions. The Scottish Medicines Consortium (SMC) are actively supporting this work (which is in the developmental stages) and are a member of the core strategic group taking this forward. Within this core strategic group the SMC are considered equal partners alongside the National Institute for Care and Excellence (NICE), enabling the Scottish policy perspective to be included early in developmental changes. Having the SMC represented as an equal partner in the core strategic group alongside MHRA and NICE signals the way in which we want to work with the MHRA across the regulatory portfolio.

Clinical trials

The Scottish Government, through the Chief Scientist Office (CSO), funds research within NHS Scotland in two ways. First, CSO provides support funding to non-commercial research projects to enable Health Boards and clinicians to engage, as well as resourcing research infrastructure, for example to enable studies to recruit patients. Second, through two response mode committees, the CSO funds proposals from the clinical community in Scotland for new research. This provides patients with the opportunity to access the latest medicines as well as trials involving re-purposed medicines.

Pricing

The regulation for the pricing of medicines is a matter reserved to the UK Government. However, it is a Scottish Government policy objective to achieve, within devolved competence, the best possible prices for medicines. Whilst medicine pricing is reserved and regulated through the UK Voluntary Pricing and Access Scheme (VPAS), a key objective that was achieved during the VPAS negotiations was to establish binding commitments on Governments across the UK and the pharmaceutical industry to greater transparency and parity in medicine pricing.

VPAS was introduced in January 2019 and includes provisions that allow the UK Health Administrations to share the details of previously confidential pricing arrangements as well as imposing new responsibilities on pharmaceutical companies to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK. Scottish Government officials are currently working with the other UK administrations to ensure that these provisions are fully implemented.

Dr Brian Montgomery's Review of Access to New Medicines (2016) noted that the "general approach of NHS Scotland to the negotiation of prices has tended to be reactive". One of his recommendations was to make greater use of National Procurement to lead negotiations on behalf of NHS Scotland on the reimbursement cost of new medicines. My policy officials have been considering how to implement the recommendations from Dr Montgomery's Review in a way that accords with the Scottish Government's undertakings under the joint UK VPAS. Work is ongoing with key stakeholders on possible new steps to make the fullest use of devolved powers to achieve the best prices for new medicines in the NHS in Scotland.

There is clearly a growing interest from the pharmaceutical industry to explore outcome-based reimbursement and commercial payment agreements. Scottish Government officials are actively considering new opportunities in relation to innovative and flexible approaches to pricing, including dealing with some of the associated uncertainty about a medicine's clinical and/or cost effectiveness.

As I have explained in previous correspondence, progress since the end of 2018 has been slower than first intended, as it has been necessary for officials and NHS partners to devote substantial time to the preparation of medicine supply contingency plans for the eventuality of a no deal EU Exit and, more recently, COVID-19 priorities. Critical to the delivery of any novel pricing approaches is the NHS capability to collect outcome data, which is why a strategic approach to data collection and the interdependency with the Digital Health and Care Strategy is important. This year's Programme for Government outlines our commitment to refresh the Digital Health & Care Strategy and create a dedicated data strategy for health & social care for the first time. This is a key enabler in delivering the necessary functionality to support data collection in a way that does not place a burden on clinicians.

In the meantime, there is already an established route for pharmaceutical companies to propose outcome-based pricing schemes via a Patient Access Schemes (PAS) and there are a number of such schemes already in operation across the NHS in Scotland. One of the main challenges is the lack of a national system to underpin routine data collection on medicine outcomes, meaning they are resource intensive and rely on individuals, usually pharmacists, manually collating and analysing the data. CMOP is an example of using real world outcome data to consider the impact of cancer medicines in patients. The CMOP programme is growing a scalable and sustainable capability of expertise in cancer medicines intelligence to drive continued improvement in the safe and effective use of these medicines across Scotland. The lessons learnt in cancer can then be applied across other clinical priority areas.

Inequality of scrutiny

I am certainly supportive of the principle of the same level of scrutiny that is undertaken for medicines, being applied to other interventions. However, I am also mindful to the challenges associated with achieving this. In the main this is due to the less mature evidence base available on the clinical and cost effectiveness of these interventions.

As you are aware, the national body for the assessment of non-medicine health technologies, the Scottish Health Technologies Group (link), is keen to accept assessments for high profile technologies and has strong links with national planning. We have recently put in place a new policy team in the Scottish Government's Planning and Quality Directorate to manage this work with joint interests in the Chief Scientist Office and the Economy Directorate. Supportive developments have been discussed with the Health and Social Care Management Board and are being actively followed up. We are also engaging with the MHRA reform agenda to improve parity of scrutiny, in part of our response to the Independent Review of Medicines and Medical Devices *First Do No Harm* report.

The UK Government has introduced a Medicines and Medical Devices Bill to ensure that the UK can maintain an up to date, dynamic system for regulating medicines, clinical trials, veterinary medicines and medical devices as well as enacting changes to medical devices enforcement and information sharing powers after the end of the EU Transition Period. The Bill will create targeted delegated powers that enable updates to the regulatory systems for medicines and medical devices. This will not involve any changes to the current law at this time but will enable changes to be made in the future. The Bill will also consolidate the enforcement framework relating to medical devices, introduce a new system of civil sanctions (monetary penalties) for breaches of the Medical Devices Regulations 2002 and provide an information gateway to enable the sharing of information held by the UK Secretary of State about medical devices, for example to warn members of the public about safety concerns.

Supporting prescribing decisions

There are a range of tools to support General Practitioners (GPs), and other prescribers, in assessing and making decisions about medicines and other technologies. These tools include SIGN guidelines, local formularies and therapeutic handbooks and advice from the SMC and other organisations. More specifically, as part of the General Medical Services (GMS) contract we have introduced a national pharmacotherapy service and pharmacists, pharmacy technicians and pharmacy assistants are becoming embedded in GP practices as members of the wider multidisciplinary team. At least two thirds of the GP practices across Scotland are receiving a level of pharmacy team support based on local need, further strengthening and supporting prescribing decisions made by GPs and others. The range of activities include dealing with medications on hospital discharge, medicine requests and queries, and polypharmacy reviews.

Polypharmacy

NHS Scotland has led the way on addressing the burden of polypharmacy. Polypharmacy reviews focus on patients with multiple morbidities. A holistic polypharmacy review should result in a medication regime that is tailored to the patient, and will often result in de-prescribing, although this is not the primary driver. The 2018 NHS Scotland Polypharmacy Guidance states that 11% of unplanned hospital admissions are attributable to harm from medicines, and polypharmacy reviews aim to reduce this while also providing financial benefit. Until 2012/13 there was an annual volume increase in medication of 3%; since the introduction of the first Polypharmacy Guidance in 2012 the rate of volume increase has fallen each year. For the first time there has been a fall in the volume (items) of medicines prescribed in primary care in 2018/19.

Social Prescribing

As I advised in February when I responded to the Committee's report on social prescribing there is a growing interest in the contribution which social prescribing by healthcare practitioners can make to helping people into physical activity and sport, as well as to experience the physical and mental health benefits of a wide range of other activities available within their local communities. As I detailed in my previous response, we are making progress in this area but there is always more that can be done to build on this, including increasing the pace and scale. I therefore committed to establishing a short life working group to examine social prescribing of physical activity - identify and communicate examples of best practice and co-produce resources for practitioners in the many roles which make up the overall system**.** This commitment was reiterated in the Programme for Government. The establishment of the Working Group has been delayed by the COVID-19 pandemic but will recommence shortly. We continue to work with partners who are delivering social prescribing initiatives.

Realistic Medicine

As you know Realistic Medicine is primarily about changing the culture of the way healthcare is practised in Scotland – to persuade professionals that they are the stewards of healthcare resources and they must help to redirect resource from low value to higher value care and reduce the waste and harm. The online Scottish Atlas of Healthcare Variation will be an important tool in supporting clinicians do just that.

Scottish Atlas of Healthcare Variation

The Scottish Atlas of Healthcare Variation is a key component of our work to support healthcare professionals to practise Realistic Medicine, by seeking out and tackling unwarranted variation in health, treatment and outcomes. Atlas maps can help ensure the prevention of harm and waste caused by overuse and overtreatment. By doing so, resources currently used with little or no clinical benefit can be freed up and redirected to address the under-provision of clinically appropriate care elsewhere.

The Atlas includes maps on prescribing data, which aim to support clinicians in identifying optimal approaches and outcomes in care. For example, as part of the suite of cardiovascular maps we published a map showing variation in 'triple whammy' prescribing, which refers to patients who take three types of medication together: an ACE inhibitor or ARB (a drug for treating high blood pressure), a diuretic, and an non-steroidal anti-inflammatory (NSAID: a type of painkiller, including aspirin and ibuprofen). ACE inhibitors/ARBs and diuretics are often prescribed together, but if taken with an NSAID the patient can suffer kidney damage.

General Medical Council guidance on 'decision making and consent'

On 30 September, the General Medical Council (GMC) launched updated guidance on *decision making and consent*. The guidance focuses on person centred care and aligns with the Realistic Medicine agenda in Scotland. It promotes shared decision making as the key to ensuring people receive the treatment and care that they need, based on what matters to them, and ensuring they have all the information they need to give informed consent.

Decision making and consent (link) provides a framework to help doctors practise shared decision making. The focus is on the importance of ongoing and meaningful dialogue and empowering people to take an active role in in their care and treatment. This updated guidance provides an opportunity to bring person centred care to the forefront and allow clinicians to reflect on any areas for improvement when helping patients to make healthcare decisions. It also addresses some of the issues raised by the Paterson inquiry and Independent Medicines and Medical Devices Safety (*First Do No Harm*) review. Practising in line with the guidance can help to mitigate the likelihood of similar circumstances arising in the future.

Supporting people to make an informed choice

We know that the COVID-19 pandemic has created new and ongoing challenges for many doctors and that the profession continues to adapt to enable flexible delivery of services. Increased use of remote consultations, more frequent multidisciplinary team working and greater need for delegation are just a few examples of this. The way clinicians have adapted and embraced new ways of contact is testament to the commitment and dedication of our medical workforce. It has transformed models of care whilst maintaining the high quality experience for people accessing healthcare services. Many Health Boards now include questions for patients to ask that will help them make an informed choice about the treatment and care that is right for them on the back of appointment letters and we are looking to include similar questions within virtual consultations. The Scottish Government has provided NHS 24 with funding to develop and promote a campaign to raise awareness that it is alright for people to ask questions of their professionals. This campaign will be developed and run over the next two years.

Supporting staff to practise shared decision making

In addition, local Health Board Realistic Medicine Leads will be able to support staff to improve their communication and shared decision making skills by signposting to local development opportunities. NHS Education for Scotland has also produced an online introductory module on shared decision making and the CMO has encouraged staff to complete it.

GP awareness raising and engagement

As part of the GMS arrangements, GP practice participation in GP clusters is a mandatory feature of practice contracts. GP clusters are professional groupings of general practices that meet regularly, with each practice represented by their Practice Quality Lead (PQL). GP practices must appoint a PQL and provide agreed local and national data extractions to enable intelligence led quality planning, quality improvement and quality assurance, as well as adoption of Realistic Medicine initiatives. This is supported by measures such as contractual provision for protected time.

GP practices and clusters are supplied with information on prescribing, outpatient referrals and admissions to hospital to support quality activity in these areas. Practices are also supplied with risk predictive information based on the High Health Gain Potential predictive tool to support them to identify individuals with more complex needs and to consistently deliver anticipatory care planning.

GP practices engage in quality improvement activities as agreed through GP cluster quality improvement planning. Practices supply information to Health and Social Care Partnerships (HSCPs) and Health Boards on their workforce and demand for their services to improve sustainability and facilitate service redesign. GP clusters work with the wider system, in particular HSCPs, to achieve whole system quality improvement. Quality Improvement is a continuous process. Individual doctors have a professional responsibility to maintain their skills and knowledge, and contribute and comply with systems to protect patients. GPs continue to be registered with the GMC, undergo annual appraisal, learn from Significant Adverse Events, contribute to confidential enquiries and comply with NHS Complaints procedures and Duty of Candour legislation.

GP practices participate in a cluster quality peer review process, whereby their quality improvement activity and quality data are reviewed by their cluster. Healthcare Improvement Scotland's Quality of Care Approach involves an increased emphasis on local systems of assurance. Service providers evaluate the quality of care they provide and identify areas for local improvement work. As GP clusters mature, Scottish Government will expect practices and clusters to take part in the peer-led values driven assurance process. The methodology for this will be negotiated by the Scottish Government and the Scottish General Practitioners Committee of the BMA (SGPC).

Community Pharmacy Contract

This year the Scottish Government agreed a three year financial settlement that provides predictability and stability for both community pharmacy owners and NHS Boards up to the end of 2022/23. The purpose being to provide financial stability in order to focus on the development of pharmaceutical care services.

As the Committee will be aware our plans to launch the NHS Pharmacy First Scotland service in April were delayed due to COVID-19 until July 2020, although we took the opportunity to extend the existing Minor Ailment Service to the whole population. NHS Pharmacy First Scotland ensures that community pharmacies are the first port of call for minor illnesses and common clinical conditions. It provides all users with a consultation, providing advice which includes self-care; treatment, if appropriate, from a nationally approved list of medicines ensuring consistency for patients and cost effectiveness for Health Boards; or referral to another healthcare professional such as an optometrist. An evaluation of the NHS Pharmacy First Scotland service will be undertaken at key stages of implementation.

Further to this, we are re-branding the Medicines: Care and Review service which provides greater opportunities to support people with long-term conditions by identifying and prioritising risk from medicines with a view to minimising adverse drug reactions, address existing and preventing potential problems with medicines and providing structured follow-up and interventions where necessary.

<u>Promotion and communications</u>

Officials have been working to develop a Primary Care Communications Toolkit. It has been created to provide the four independent contractor groups, Health Boards, HSCPs and professional bodies with information and materials to support them in communicating on how Dental, GP Practice, Optometry and Community Pharmacy services are being delivered differently as a result of COVID-19. In addition further communication is planned relating to winter planning and the Redesign of Urgent Care.

Skills and training for Pharmacists

Achieving Excellence in Pharmaceutical Care aims to transform pharmacy across all areas of practice, develop the workforce and provide the best, person-centred care. One of the commitments was to undertake a review of post qualification pharmacist programmes, to help align them with evolving service needs with a view to developing a Career Framework for pharmacists in Scotland. In response to this, NES Pharmacy established an Advisory Group to provide expert advice on the future options for this Framework focusing on early careers, advanced practice level careers, consultant level careers as well as develop clinical and professional leaders. The Advisory Group's recommendations for the implementation of a Pharmacist Career Framework were published in a report (link) at the end of September. In addition to this, the General Pharmaceutical Council (the pharmacy regulatory body) recently proposed reforms to the current initial education and training of pharmacists which will address the undergraduate and pre-registration pharmacist elements. I am pleased to say that we are in a strong position in Scotland to support this as we have undertaken a significant amount of work over the last two years to consider options to recruit and select people with the right values and attributes to pharmacy undergraduate programmes, refreshing the undergraduate and pre-registration programme content and identify the quality management processes to ensure effective governance of any new arrangements for courses.

In addition, within Scotland we have had our own NES post-registration foundation training programme for many years, which has mainly been used to support the newly qualified pharmacists in a work-based training programme within the managed service (hospital and more recently within GP practice pharmacy). There are plans to expand this to all newly qualified pharmacists taking up posts within community pharmacies in Scotland, from September 2021, which would be linked to and include independent prescribing training. The programme is linked to financial and contractual arrangements between the Scottish Government and Community Pharmacy Scotland.

Single National Formulary

The new national formulary platform uses the NHS Business Services Authority 'Dictionary of Medicines and Devices' (dm+d) as its underlying data source, providing a robust recognised NHS standard for uniquely identifying medicines. All medicines contained within the dm+d have unique identifiers that are compliant with SNOMED clinical terminology standards. In practice this means that the medicines recommended on the formulary, including the specific formulations of each medicine, can be extracted from the formulary platform in a format that is recognised by clinical systems such as HEPMA which will support integration with HEPMA and other systems.

In terms of maintaining a flexible approach and ensuring adherence by prescribers, during the course of this programme of work we have listened carefully to feedback from across the NHS and wider stakeholder groups. This has informed a revised approach to developing a national formulary which seeks to transition from the 11 local formularies in a measured way that ensures local clinical ownership and decision making.

This revised approach involves existing local formulary teams working collaboratively to initially develop regional formularies that will be made available to prescribers via the new national platform.

This approach ensures that the function of developing a formulary continues to be delivered by Health Boards underpinned by local clinical ownership and existing governance arrangements.

By utilising existing local formulary teams to evolve formulary recommendations regionally, we believe that the end-product will continue to reflect local needs and retain the buy-in of local prescribers.

The new national platform has been developed and is ready to host the formulary recommendations. The first region to utilise the new platform will be the East of Scotland, where NHS Lothian are currently transitioning their formulary to the new platform. This will be completed this year, with discussions between local formulary teams in the East region then continuing with a view to reaching a consensus on the preferred regional medicine choices. Once consensus is reached the formulary will be updated and made available for the other Health Boards in the region to adopt. Progress and learnings will be shared throughout with the other Health Boards, with a view to informing an approach to replicating this model in the West and North regions during 2021.

As described above, the approach being taken is driven by local formulary teams with regional recommendations built from the existing formularies. The regional formularies will therefore be created using existing local processes and governance arrangements. The approach being taken actively encourages the sharing of best practice between Health Boards within each region. In addition, we will work closely with the Area Drug and Therapeutics Committee Collaborative (ADTCC) to ensure the development of appropriate forums to support national discussions on best practice between each region.

Information about medicine spend

Medicines spend across all Health Boards has been recorded and published (link) in a number of monthly and annual publications by Public Health Scotland, and previously Information Services Division, for some time. Monthly open access data is available on Prescribing Activity, categorised by British National Formulary chapter down to individual general practices across Scotland; Dispensing open data along with annual publications such as the Dispenser Payments and Prescription cost analysis and the National Therapeutic Indicators. These tools ensure that Boards and those working in Primary Care can ensure that services are being delivered to meet the needs of the local population, but also improve prescribing practice and drive better value and efficiencies through the system.

Waste

A significant reduction in waste and costs can be generated by better medicines use. At a patient level, caring for patients with multi-morbidities and polypharmacy is an increasing global challenge. A number of prescribing strategies have been published which lead to structured reviews of appropriateness, efficacy and tolerability of treatment. Through consideration of more appropriate treatment or non-pharmaceutical management of a condition, there is the potential to reduce medication burden on patients.

A substantial component of waste is where medication is not taken as prescribed (often referred to as non-adherence) and we are working to develop tools to identify patients with medication adherence issues to allow them to be prioritised for clinical review.

Medicines management continues to develop as an expert field in NHS Scotland, consistently delivering improvements to patient safety, effective care and efficient spending.

NHS Discovery provides comparative healthcare information for quality improvement, benchmarking and performance management across NHS Scotland. This information is used to produce quality prescribing information. Since 2012, the Scottish Government has published National Therapeutic Indicators, providing data on the variation in prescribing across Scotland, allowing outlier prescribing to be identified. Some initiatives that boards have been working on include:

- increasing the use of generic medicines in secondary care
- reducing the amount of drugs dispensed in primary care by more regularly reviewing the medicines that are being prescribed
- switching from high-cost drugs to cheaper alternatives (biosimilars) to achieve the same results.

Deprescribing/disinvestment

Importantly, rather than focusing on deprescribing and disinvestment, it is perhaps more helpful to consider the options to invest in better performing medicines, medical devices and other products. A key component of any formulary governance process, prescribing protocol or prescribing guidance is to encourage the prescribing of the most clinical and cost effective medicine taking into consideration the latest available evidence in addition to any SMC recommendation. The Realistic Medicine approach I have described earlier, seeking to reduce unnecessary variation, directing resources to higher value care, reducing waste and harm and focusing on shared decision making, is also an important aspect to our approach. It is, of course, also important to recognise the benefits and value of innovation.

Peer Approved Clinical System

The Peer Approved Clinical System (PACS) Tier One and Two processes, which replaces the previous Individual Patient Treatment Request process, underpins Health Board decision making. Both processes provide an opportunity for doctors on a ‘case by case’ basis for individual patients, to request the use of a licensed medicine under particular sets of circumstances. In the case of PACS Tier Two, we have introduced refreshed decision making criteria, clear accompanying guidance and a National Review Panel. The guidance for PACS Tier Two makes it clear that the cost of the medicine must not be part of the decision making process.

As part of the review of the PACS Tier Two system, a number of responses also offered comments about the budget impact and opportunity cost of greater access to new medicines, in the context of PACS Tier Two and in general. We are considering these issues as part of any further enhancements to the PACS process in response to a six and twelve month review. This work has been delayed as a result of COVID-19 and I will be writing to the Committee on this matter in due course.

I hope this is helpful.

Kind regards

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Healthcare Improvement Scotland

NHS SCOTLAND

Summary Report
December 2016

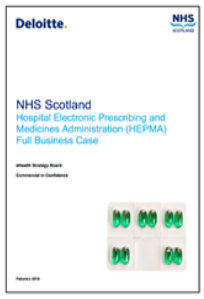
Hospital Electronic Prescribing and Medicines Administration (HEPMA): Learning and Benefits Workshop, 15th November 2016

Introduction

72 delegates attended with 15 NHS boards represented.

The objective of the day was to **support NHS Boards to have a greater understanding of the national HEPMA work, and the opportunity to explore the collaborative development of regional HEPMA roadmaps.**

Going Forward: Commitment to e-Health



Scottish Government has committed funding to support safe implementation of HEPMA across Scotland. Successful implementation means that Scottish health boards will have taken another step towards comprehensive electronic patient record systems.

Through HEPMA patient safety and prescribing practice will improve. In addition, we will have a level of detailed information that we have never had before be able to make informed decisions around medicines use in our hospitals.

Event Feedback (19% of attendees responded)

79% Agreed that the event supported NHS Boards to have a greater understanding of the national HEPMA work

93% Agreed that the event supported collaborative development of regional HEPMA roadmaps

71% Agreed that the workshop would help their board in planning and implementing HEPMA

Priority Considerations

- Leadership enabling cultural change
- Patient safety
- Regional governance and links to regional planning
- Regional configuration
- Phasing of funding
- Provision of dedicated programme support
- System choice and evaluations
- Alignment with PMS
- Alignment of clinical and technical workflow
- Alignment with multi-professional training and development
- Convergence of drug dictionaries / formularies

Healthcare Improvement Scotland

NHS SCOTLAND

Summary Report December 2016

Regional Workshops: Creating regional road maps – reflecting and building on what we have heard.

Delegates were given an opportunity to explore regional approaches and ask key questions of HEPMA teams from boards that have progressed implementation. There was some similarity between the groups so these have been presented to give the scope of the points covered across the three groups and avoid duplication

West Region

NHS Ayrshire & Arran, NHS Dumfries and Galloway, NHS Forth Valley, Golden Jubilee, NHS Greater Glasgow and Clyde, and NHS Lanarkshire

- Appropriate governance needs to be put in place first
- ADTC chairs to establish clinical forum
- Use programme management support to help shape the way forward
- Close ties between clinical / technical workflow
- Alignment of drug dictionaries
- Harmonise security policies

East Region

NHS Borders, NHS Fife, NHS Lothian, NHS Tayside

- Develop potential alliances (Lothian and Borders) and (Tayside and Fife)
- Details of basis of alliances by end of 3 months
- Don't duplicate, "pinch with pride", learn from early adopters
- Leadership in engagement critical
- Organisation buy in/ownership in Boards
- Identify Champions (nurse engagement crucial)
- Understand timelines in each Board for phasing of funding
- Set up local steering board

North Region

NHS Grampian, NHS Highland, NHS Western Isles, NHS Shetland and NHS Orkney.

- Clinical benefits must be the priority – patient safety and pathways
- Collaboration –who's in & who's not?
- Early December meeting to agree approach, phasing and governance.
- Clarify whether, in defining the collaborative model, how much is systems dependant.