Pharmacy Services

Dear Lewis

Thank you for your questions relating to the discussion at the Health and Sport Committee on 4th February 2020 and for giving me the opportunity to provide clarification.
You ask some important questions concerning the reasons behind the policy of not returning medicines into the supply chain once they have been dispensed but the use of patients own drugs within a hospital setting. I shall try to lay out the issues that result in this approach. I addition to the professional and legislative aspects I will describe below it is important to acknowledge the patient perspective. Work done previously with patients suggests around 60% of those asked would be prepared to accept medicines which had been reused provided they could be guaranteed as safe. It is this challenge to guarantee safety that is also reflected in the description below.

Use of returned medicines.
Pharmacists are regulated by the General Pharmaceutical Council and are required to abide by their standards. Whilst there is no specific guidance on the reuse of medicines it does have standards that relate to registered pharmacies that state:
Medicines and medical devices are obtained from a reputable source, safe and fit for purpose, stored securely, safeguarded from unauthorised access, supplied to the patient safely and disposed of safely and securely.
When medicines that have been dispensed for a patient and then returned to the pharmacy a pharmacist would find it difficult to satisfy themselves that those standards could be met if returning the medicines to stock. While this may seem overly cautious it is not possible to guarantee the integrity of the product and this could introduce risks to patients. It could mean that the product has been tampered with or that it will no longer have the same use by date/shelf life. There could even be scenarios where medicines could be returned and reintroduced into stock several times with additional risk each time.
In addition to this both the UK medicines regulator (MHRA) and the professional pharmacists body (Royal Pharmaceutical Society) say that medicines should not be reused because of concerns over quality. The safety of the patient should be the focus.

Another important factor in the reuse of returned medicines relates to legislation. The Falsified Medicines legislation came into force in February 2019. This legislation requires medicines to have an anti-tampering device and when used require to be electronically removed from a centrally held database (decommissioned). This is to reduce the risk of counterfeit medicines entering the supply chain.

Storage Requirements
In order to maintain stability of pharmaceuticals within their defined shelf life certain storage requirements are required to be maintained. As part of the licensing agreement the pharmaceutical industry must undertake studies to provide evidence of stability of each product under different conditions. Temperature, relative humidity and exposure to air are all factors in the stability of medicinal products. Where storage conditions fall outwith those stated by the manufacturer then the shelf life cannot be guaranteed. This is particularly important if a medicine was to be reintroduced into the supply chain after being dispensed to a patient where it could have been stored out with those temperatures for a period of time e.g. next to a radiator.

The majority of medicines maintain their shelf life when stored at room temperature i.e. 20-25C. Homes in the UK may generally be maintained at those temperatures but there is no way of knowing if they have been stored in a warmer area of the household for an extended period of time. Some types of medicines require to be stored in the fridge between 2-8C e.g. vaccines, insulin, some biotech products. For many products avoiding freezing may be even more important than maintaining a temperature below 8C. In general the impact of poor storage conditions is a reduction in efficacy. That could impact directly on a patient's health.
Your query relating to compliance aids relates also to the impact of storage on medicines stability (hence unstable). To be included in a multi compartments compliance aid (MCA), medicines must be removed from their original packaging. Manufacturers of medicines have robust data on the stability of their products when stored in their original packaging. There is very little reliable data available on the stability of medicines after they are removed from their original packaging and stored under different conditions. Not all medicines are suitable for inclusion in MCA as the medicine may be particularly affected by moisture in the atmosphere or by light.
Following on from the stability aspect of medicines in MCAs, although these may be of value to help some patients with problems managing their medicines and maintaining independent healthy living, they are not the best intervention for all patients and there is little quality evidence that indicates improved adherence.
Patients with long term conditions will have regular reviews of the management of their condition but the frequency of such a review will vary in response to the needs of the patient. There is national guidance on polypharmacy reviews which has been developed by the Scottish Government Therapeutics Branch http://www.polypharmacy.scot.nhs.uk/home/
Primary Care Pharmacists do undertake polypharmacy reviews for patients in primary care and this has been part of the role for many years. This is an area recognised in the GMS Contract Pharmacotherapy specification as a level 3 specialist service for pharmacists. Directors of Pharmacy are working to implement the Pharmacotherapy service of the GMS Contract and are committed to using the skills and experience of pharmacists in these specialist areas to improve pharmaceutical care. There are discussions at each Health and Social Care Partnership level on how best to use the available pharmacy resource for maximum effect. Board areas will be considering the best use of their existing primary care teams in order to meet the needs around polypharmacy. In NHS Greater Glasgow and Clyde we are developing a plan for pharmacists to deliver polypharmacy clinics to each GP practice during 2020-21

Use of Patient's Own Medicines in hospital.
When a medicine is dispensed for a patient in community pharmacy it becomes the property of that patient. It is therefore acceptable for patients to bring in their own medicine and to use them as they would at home. The medicines will be checked in hospital to ensure there has been no confusion e.g. a relatives' medication brought in, and also an examination will take place to assess the integrity of the medication e.g. is the medicine still in date.
Using a medicine brought in by one patient for another is however a different matter. The medicine does not belong to the new patient and therefore effectively would have to be returned into stock or supplied by the pharmacy for use by another patient. In those circumstances the same standards apply as described under reuse of returned medicines. The professional and regulatory responsibility of the pharmacist and pharmacy means that this would count as a new supply but the quality and integrity of the product could not be guaranteed.

Processes involved with supply for a patient at discharge (why does it take 3 hours to dispense)
Unlike medicines supplied on prescription via a community pharmacy, the prescription written for a patient who is ready for discharge from hospital is part of a broader 'immediate discharge letter' (IDL) which provides summarised information for the GP about the patient's admission to hospital. For this reason the IDL takes longer for the doctor to prepare than a

standard GP prescription. The pharmacy team does not usually start to process the medicines aspect of the IDL until this is completed by the doctor. Once written, the pharmacist must review the IDL for accuracy and clinical appropriateness before sending it to the pharmacy for dispensing. It is likely that the pharmacist will be covering a number of clinical areas and the volume of discharges means that there is likely to be a short delay before the pharmacist can screen the prescription. If there are queries or changes required the pharmacist may have to contact the prescriber to discuss these and the pharmacist may also speak to the patient to discuss medication. In areas where hospital geography facilitates near patient dispensing, the pharmacy team will usually be able to dispense the medicines within an hour. However, in more traditional hospital buildings, the pharmacy may be some way away from the ward and the time taken to dispense will be longer due to higher volumes of prescriptions going through a single dispensary and time required for transportation back to the ward. Hospital pharmacy teams are trialling a number of different methods to reduce the time taken for patients waiting for their prescriptions:

- Use of patients' own medicines to reduce the number of medicines that require to be dispensed
- Dispensing only new and changed medicines
- Supply of original packs early in the patient's stay ready to take home
- Increase role of pharmacy teams (where resources allow) earlier in the patient's stay to reduce the risk of issues with the patient's prescription being identified at the point of discharge
- Consideration of different models of supply e.g. community pharmacy supply to allow patients to be discharge earlier and pick up their medicines at a time that is convenient for them.
- Better discharge planning and use of anticipated discharge dates to facilitate earlier dispensing of medicines.

In NHS GGC the IDL is sent electronically to both the GP and the community pharmacy to support continuity of pharmaceutical care.

Access to Records

Appropriate access to a patient's healthcare record is vital to support the ability of healthcare professionals to perform their duties however it is important to provide only the information that is required. Information governance considerations are important to ensure that patient information is utilised appropriately but this means that as roles develop greater access may be required. Boards have a Caldicott Guardian appointed to ensure we use patient data appropriately. Role based Access Control is put in place for access to electronically held patient data to ensure that as much as is possible access is tailored to need. A clear example of this would be for access to a prescribing system – you would only wish prescribers to be able to prescribe but others may require to be able to read that information. The ability to add or remove different roles makes this system more agile to changes based on the needs of the individual. Some of the technical issues relating to roll out of community pharmacy access to clinical portal are due to the different organisations involved and their different software and hardware abilities. These may not be insurmountable but can take time to work through. In NHS GGC we have learned from other Boards who have tested with early access to clinical portal and we have shared learning with three other Boards involved in the SPSP Pharmacy in Primary Care collaborative. This learning enabled us to build our access, test the concept in a safe manner and then expand and extend as the service develops. We are proactively sharing our experience with other Boards via contact made on social media, through the specialist interest groups, Director of Pharmacy group and eHealth groups.

HEPMA
In NHS GGC the HEPMA Full Business Case (FBC) has been approved. The programme team is being recruited and preparations being made for beginning the “design & build” phase. The “design and build” phase will take 9 months followed by a two month pilot phase. There will then be an 18-month roll out across 330 wards. The current programme plan predicts that the roll out will be complete during 2022/23.

The national strategy to reduce the requirements for handwritten prescriptions in our hospitals is through the national HEPMA programme. Directors of Pharmacy are fully supporting this programme through leading local implementations and business case development.

Implementing HEPMA will provide patient-level hospital prescribing information at a level of depth and detail previously unavailable. This creates opportunities to join this data with other information about outcomes, to explore links between medicines and the broader patient experience. Existing analysis and data warehouse tools, in addition to innovative initiatives such as iCAIRD, can enable NHS organisations to analyse practice and implement improvements. Adopting standard approaches to clinical coding (e.g. dm+d, SNOMED CT) and integration (e.g. FHIR) will facilitate the joining up of data such as prescribing and outcomes.

As Co-Chair of the HEPMA Implementation Oversight Board, I will provide you a copy of the update on HEPMA implementation when it is available.

I hope my responses provides further clarity for the Committee on the range of issues discussed during my evidence on 4TH February 2020.

Yours sincerely

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