28.4.2022

Dear Kirsty and Lisa

Participant safety during the evaluation of Paxlovid in a community setting in the PANORAMIC trial is of paramount importance, but it also vital that the evaluation also reflects how the drug may be used in clinical practice. The PANORAMIC team fully recognises the need for rigour in the assessment of potential participants at screening but consider that the requirement for this to be based on the full care record to be unduly onerous and not reflective of how the drug is being used in clinical practice.

Within **England**, delivery of Paxlovid for COVID-19 is through ~100 Covid Medicines Delivery Units (CMDUs). To date, 7,940 Paxlovid prescriptions have been issued. The information we have is that 80-90% of the triage and treatment / dispensing decisions are medically-led (most secondary care clinicians, some GPs working for CMDUs on a sessional basis), the rest are pharmacist-led. For both workforce models, CMDU clinical leads predominantly use the summary care record (SCR) along with hospital notes.

A pilots scheme has been undertaken using a Pharmacy led service at the Royal Cornwall Hospital NHS Trust. Prescribing Pharmacists and Nurse Prescribers issue antiviral medicines based on telephone consultations during which they take a drug history from patients, and then make reference to the Summary Care Record, and if necessary, the hospital notes (an electronic resource in their case called MAXIMs) which contains all hospital letters and prescriptions. To date, 226 prescriptions have been issued by this service (out of a total of 712 prescriptions for nMABs, molnupiravir, and Paxlovid). There have been no reported adverse events or DATIX records. While this is not definitive it provides considerable confidence the model and other services are now seeking to adopt it.

In **Northern Ireland**, 634 of the 3058 participants treated by the direct access deployment service that is organised along similar lines have received paxlovid.

In **Scotland**, Paxlovid is prescribed by secondary care teams; the proposal is that the same processes they used in routine NHS care be used for assessing eligibility for Paxlovid in PANORAMIC. Clinicians have two main sources of information with regard to concomitant medications and drug interactions both accessible through the Clinical Portal:

- The **Emergency Care Summary** (ECS) contains a list of recent acute prescriptions, current repeat prescriptions, recorded drug allergies/adverse reactions and patient details from the GP record. ECS does include recently discontinued repeats, but not ones from a long time ago (more than ~1 year). It does not include items prescribed out-with general practice, e.g. hospital only prescriptions or OOH prescription. A record of Hospital only and OOH prescriptions is available from within the main Care Portal screen.
- The **GP summary** contains all of the above plus a copy of the higher priority conditions or procedures listed in the summary of the GP record. It also includes some biometric information e.g. BP readings.

Both the GP summary and the ECS are updated/extracted at least daily. Information about the ECS is available at:https://www.cps.scot/news/emergency-care-summary andhttps://static1.squarespace.com/static/601d44b7e8475c7d8be2ea36/t/616ff7032df1493e5488f40a/1634727684605/ecs-faq.pdf

Between late December and 17th April, over 2455 prescriptions were issued for Paxlovid in Scotland; 2158 linked to the non-hospitalised cohort ('limited deployment') and 297 to hospitalised patients (excluding patients within scope of the RECOVERY Trial). All Boards are using the ECS, supplemented by patient provided information with the option to reach out to the patients GP or specialist if necessary); no Health Boards in Scotland are routinely prescribing Paxlovid with access to the full GP record.

Based on replies from all but two Health Boards, over 50% of Paxlovid prescriptions issued in Scotland have been via pharmacist prescribers with the largest Boards (GG&C and Lothian) using pharmacist prescribers exclusively for prescribing to the non-hospitalised cohort. None of the Health Board leads (who are senior doctors and pharmacists within Health Boards) were aware of individuals coming to harm using the processes outlined in the table below.

Health Board	No. of Paxlovid prescriptions issued	Proportion of prescriptions issued by medically qualified professionals	Any individuals known to have come to harm?*(full Datix review has not been carried out)*
A&A	77	No response	
Borders	61	Mostly medically qualified	No
D&G	81	25: 75 medical: pharmacist	No
Fife	100	80:20 medical: pharmacist (trend is towards pharmacist prescribing)	No
F.Valley	26	Majority pharmacists	No
Grampian	258	20: 80 medical: pharmacist	No
GG&C	947	All outpatient prescribing has been by pharmacists. A small volume of in-patient prescribing that has been medically qualified	No
Highland	157	No response	
Lanarkshire	238	90:10 medical: pharmacist (trend is towards pharmacist prescribing)	No
Lothian	249	All outpatient prescribing has been by pharmacists.	No
Orkney	9	Medically qualified	No
Shetland	12	Medically qualified	No
Tayside	205 (excludes w/c 4th and 11th April)	80:20 medical: pharmacist	No
W.Isles	35	50:50 medical: nursing	No

In **Wales**, since December 2021, 1,300 people have been treated in the service, with 841 receiving paxlovid through the national deployment process for highly vulnerable. Health Care professionals Issue the medicine under a patient group directive (PGD). The Welsh Clincial Portal (WCP) is used and not the full care record to check eligibility. They consider that the WCP has the information required to prescribe in many cases, but it does not always contain the full drug history. Tests such as renal and liver function are available in the WCP. The full care record can be accessed for patients

who live in Cardiff, and as the service is based there, this may inform eligibility checks of referrals from time to time, but is not considered essential in many cases. However, paxlovid eligibility and prescribing is initially based on patient-reported drug history. If the clinician assesses a patient to be unable to provide a reliable drug history or lacks capacity, HCPs do not prescribe paxlovid and instead refers the patient for consideration for an nMAB. The Welsh Central Service is not aware of any safety concerns that have arisen from their processes and practice.

On the basis of the available information we consider that there is sufficient evidence that paxlovid may be prescribed safely based on the summary care record (or equivalent in other Devolved Administrations) and information provided by the patient. Furthermore, there is good preliminary evidence that that the eligibility assessment can be safely conducted by appropriately qualified healthcare professionals including pharmacists and nurse prescribers. Participants in PANORAMIC will have regular safety follow up (more extensive than that in routine care). We recognise that the information from routine practice is not definitive but consider it is sufficiently encouraging to allow non-medical prescribers to undertake eligibility assessment and to make the assessment of eligibility based on the summary care record and information provided by the patient, with escalation to other sources of information when clinically indicated.

With best wishes

Chris Butler and Paul Little
CIs, PANORAMIC