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The Role of Pharmacy in Pharmacogenomics

“Providing the right medicine, at the right dose, with optimal outcome”

Pharmacogenomics is the study of how an individual’s genetic information determines how they will respond to medicines.

The development and application of pharmacogenomics (PGx) in clinical practice is an expanding area in healthcare which aligns with national and NHS priorities across Great Britain (GB).[1,2,3] Pharmacists are medicines experts with a background of scientific training and are therefore well equipped to play an integral part in the development of PGx. From system leadership to implementation of services, pharmacists can tailor and personalise the prescribing of medicines based on genetic information. There are many benefits of PGx, including reduced time to patient therapeutic response, increased patient safety, reduced adverse effects of medicines and reducing pressures on healthcare systems. It is vital that the pharmacy workforce is prepared and builds the knowledge and skills required to confidently lead and support at the forefront of PGx.

IMPROVING PATIENT CARE THROUGH PHARMACOGENOMICS

The Genome UK strategy[4] was launched in 2020, with a clear vision to enable people to lead longer healthier lives by utilising genomic technologies to provide personalised therapy to treat illnesses, identify genetic risk factors for certain diseases and to detect cancers earlier. The Genome UK implementation plan aims for collaborative working between all UK nations to develop genomics services and to realise the potential of genomics for the benefit of patient care.[4,5]

The sequencing of the human genome in 2003[6] and the launch of initiatives such as the NHS 100,000 Genomes Project[7] in the UK in 2012, have greatly contributed to our understanding of the human genome, leading to a greater appreciation for the role that PGx can play in diagnostics, treatment and disease management. PGx uses an individual’s genetic information to determine how that person responds to medicines. For example, variation in an individual’s genome can either increase the therapeutic effects of a medicine or render that medicine ineffective.[8] These genome variations can also be used to predict the likelihood of a patient experiencing adverse drug reactions to certain medicines, and therefore empower healthcare professionals to determine the most appropriate medicine and dose for each patient.

EXAMPLE OF PGx BENEFITING PRACTICE WITHIN CANCER CARE

Dihydropyridine Dehydrogenase (DPYD) testing is widely used within clinical practice across all UK nations.[5] The DPYD test determines whether a patient has a DPD enzyme deficiency resulting in an inability to breakdown fluoropyrimidine-based chemotherapy. The implementation of DPYD testing has enabled the routine screening of all cancer patients eligible for treatment with fluoropyrimidine-based chemotherapy, enabling appropriate dose modifications or complete avoidance. This significantly improves patient safety, reducing side effects and decreasing hospitalisations and even death.[5]

THE BENEFITS OF PHARMACOGENOMICS TO PATIENTS AND THE NHS

Healthcare is moving away from a 'one-size-fits-all' approach to patients' treatment, being replaced by a more tailored, personalised approach. A growing international evidence base demonstrates that pharmacogenomics enables medicines optimisation and improved patient safety from medicines.

Evidence suggests that the use and clinical application of PGx can lead to:

BENEFITS TO THE PATIENT

- Reduced medication related harm to patients by ensuring they receive the most suitable treatment from the start, with faster and improved therapeutic response and reduced adverse reactions;[9]
- Increased medicines adherence by increasing patient confidence in their tailored medicines;'[10]
- Improved survival rates in high-risk patients due to more accurate and effective use of therapies following an early diagnosis;[9]

BENEFITS TO THE NHS

- Potentially contributing to the reduction of medicines waste by using the right drug, at the right dose, the first time. International guidelines have shown that annually in the UK primary care sector, one in eleven new prescriptions dispensed of a pharmacogenomic related medicine requires the patient to receive a dose or drug change to their treatment;[11]
- More efficient use of clinicians' time for greater patient benefit due to improved patient response potentially resulting in reduced clinicians' contact requirements;[10]
- Potential reduction in overall cost of healthcare as a result of fewer patients experiencing adverse drug reactions e.g. reduced number of medicines a patient must trial to find an effective treatment, and potentially reduced hospital admissions related to adverse drug reactions.[9,11,12,13,14,15]

THE FUTURE ROLE OF PHARMACY IN PHARMACOGENOMICS

Pharmacists are key professionals working on the frontline of healthcare and are the experts in medicines. Their unique training in science and healthcare enables pharmacists to articulate complex medicines issues in a patient-friendly way. International evidence demonstrates diverse opportunities for pharmacists 'and pharmacy teams' in PGx across all sectors of pharmacy. (Table 1).[14,15,16,17,18,19]

Pharmacists and pharmacy teams increasingly lead and support the development and delivery of new services, utilising their clinical expertise to advise on when and where PGx testing could be piloted. They have the fundamental pharmacological understanding to optimise the use of PGx test results for better patient outcomes. PGx is a natural expansion of of the role of the pharmacist and the pharmacy team when it becomes part of everyday practice.

Table 1: *The evidence-based role of pharmacy in implementing and delivering pharmacogenomics services across the world.*

ROLES	REFERENCE
Raising awareness and promoting the use of PGx in the healthcare setting	21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33
Members of multidisciplinary teams for better integration of PGx use	8, 10, 22, 23, 26, 28, 29, 35, 36, 37, 38
Identifying patients who would benefit from PGx testing e.g. during medication reviews	8, 10, 22, 23, 25, 35, 36, 37, 38, 39
Providing information and advice to patients and the public on PGx due to their accessible position at the patient interface	8, 10, 22, 30, 36, 37
Establishing, choosing, recommending, and ordering PGx tests	10, 11, 35, 36, 37, 36
Performing PGx sampling and testing	8, 10, 33, 34, 36, 37, 40
PGx data collection, analysis and management	8. 10, 11, 36, 37, 38, 40
Making recommendations on pharmacotherapy based on PGx results	8, 10, 11, 15, 23, 30, 35, 36, 37, 38, 40
Medicines optimisation, therapeutic drug monitoring and dose adjustment based on PGx results	8, 10, 31, 35, 36, 37, 38, 40, 41
Providing advice to patients on how their genetic material will be used and how test results may affect current or future treatment	8, 23, 30, 36, 37
Educating other healthcare professionals on PGx	8, 40
Developing and interpreting PGx processes, guidelines and other publications	8, 10, 37
Supporting, contributing and leading PGx research	8, 43, 45
Contributing to PGx networks and committees	8
Helping the development of infrastructure and creating PGx technologies for implementation in the healthcare sector	42

Recommendations to support pharmacy and PGx implementation across healthcare systems

1

WORKFORCE AND EDUCATION

- To ensure that pharmacy teams are integrated into the PGx multi-disciplinary teams and provide clinical and professional leadership within clinical PGx delivery across England, Scotland and Wales
- A comprehensive workforce strategy and fully resourced genomics education and training should be provided at all stages of pharmacy education. This must be related to clinical PGx competency requirements in line with all multi-disciplinary professionals involved in delivery of PGx. This should involve:
  - Integrating comprehensive PGx training (including aspects of PGx implementation) into undergraduate curriculum for pharmacy students
  - Addressing the various levels of postgraduate genomics knowledge and understanding needed by pharmacy professionals dependent on their role in PGx delivery
- Further development of the GB-wide genomic champion networks for pharmacists and other members of the pharmacy team, to signpost and raise awareness of genomics to all members of the wider multi-disciplinary team.

2

SUPPORT AND INFRASTRUCTURE

- Integration of genomics information into electronic health records accessible to all healthcare professionals involved in patient care
- Development of tools and guidance including integration into digital systems to support clinical decision making with access across different healthcare sectors by all members of the wider multi-disciplinary team
- Ensuring a streamlined and well-resourced approach to how PGx testing is implemented into clinical practice with appropriate multi-disciplinary referral pathways available and multi-disciplinary roles defined within updated clinical pathways.

3

MANAGEMENT AND ESTABLISHMENT OF GOVERNANCE PROCESSES

- Pharmacists to ensure appropriate governance (i.e. risk assessments) are in place within PGx implementation including aspects such as the obtaining and storing of relevant data, the interpretation of PGx test results and inclusion of the test process within established clinical pathways
- Regulators such as MHRA must develop robust approval processes and quality assurance frameworks to ensure safety, validity, and appropriate clinical utility of any forms of direct-to-consumer genomic and PGx testing.

4

PATIENT AND PUBLIC ENGAGEMENT

Working with governments, NHS, the public, patient representative groups and other organisations, there must be:

- A nationwide public health campaign to raise patient and public awareness and confidence in PGx and eliminate misconceptions
- Shared decision making takes place between patients, families, carers and healthcare professionals to make informed decisions around their treatment whilst translating complex information into 'patient-friendly' language. Patients and the public must be involved in service design for the NHS
- Ensuring good communication links with patients' representation, the public and the media and patient care remains the main focus in all PGx developments.

5

RESEARCH

Opportunities and funding must be available for pharmacists and pharmacy teams to lead and participate in PGx research. Research will allow continual improvement in service delivery to maximise patient benefit. Examples of research areas we would like pharmacy to have further involvement in include:

- Pharmacy's leadership role and involvement in PGx delivery across England, Scotland and Wales
- Refining existing drug-gene relationships and identifying new gene-drug pairs
- The impact, benefits and efficacy of PGx implementation on patient care related to factors such as medication safety and medicines optimisation
- Exploration of the similarities and differences of PGx within diverse patient populations e.g. sex, ethnicity, age and socio-economic groups
- Patient and public focussed research on understanding uptake, acceptance, equity of access, ethical, legal and social issues around the use of PGx.

Next steps

There is a clear role for pharmacy as a leader in the implementation of PGx across all healthcare sectors. Collaboration is needed across stakeholders to support the delivery and implementation of these recommendations. This will ensure a high level of patient safety and care is achieved throughout the implementation of pharmacogenomic services.

RPS is committed to:

- Raising awareness of PGx and de-mystifying pharmacy's involvement in PGx by development and delivery of appropriate educational resources
- Supporting the understanding of how PGx can and will increasingly influence treatment decisions to all stakeholders
- Working with other multi-professionals and national organisations to ensure patients are at the centre of our approach to the implementation of PGx
- Ensuring strong pharmacy leadership to establish pharmacy's role at the forefront of the PGx implementation by working with stakeholders across GB
- Developing a PGx professional network across GB to enable the sharing of best practice, create collaboration within areas such as research and education and support links with other genomics/ pharmacogenomics forums.

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