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Collaborative Position statement for Pharmacy professionals and Genomic Medicine

APRIL 2023

In collaboration with:



ALL WALES
CHIEF PHARMACIST GROUP

Pharmacy professionals and Genomic Medicine

Pharmacy professionals are experts in medicines with a background of scientific training and can significantly contribute to the impact of genomics on healthcare delivery. The term pharmacy professionals includes both pharmacists and pharmacy technicians, but the authority for certain roles may be delegated to members of the wider pharmacy team. It is important that pharmacy professionals are acknowledged as key stakeholders in the implementation, delivery and evaluation of genomic services. Pharmacy professionals are skilled at interpreting complex scientific data and use evidence-based medicine to support shared decision making in their established patient-facing roles within the multidisciplinary team (MDT). As a result, they are well placed to perform key roles related to genomic medicine by supporting patient understanding, maximising the benefits of precision medicine across the integrated care system, and to play a key role in genomics implementation in healthcare.

Wider enablers

Genomics is the study of an organism's complete set of genetic information and how this knowledge can be applied.^{1,2} Genomic medicine involves performing genomic tests (sometimes referred to as genetic tests) to identify changes in an individual's DNA, RNA, genes, chromosomes or proteins which can be used to tailor their clinical care.³ Genomic testing can be used in disease screening, diagnosis or to make treatment decisions.³ When used to inform treatment decisions, genomic medicine is an example of precision medicine. Genomics is currently influencing the management of certain medical conditions and is set to expand to many other clinical areas in future healthcare.⁴ Pharmacogenomics (PGx) is just one aspect of genomics. Pharmacogenomics involves performing a genomic test to determine how an individual is predicted to respond to a medicine.⁵ Whilst pharmacy professionals have leading roles in the implementation and delivery of pharmacogenomics within medicines optimisation services, their roles in genomic medicine should not be limited to pharmacogenomics.

1. World Health Organisation. Questions and Answers: The main difference between genomics and development of the organism. <https://www.who.int/news-room/questions-and-answers/item/genomics> [Last accessed 20-3-2023]
2. Genomics Education Programme. Core concepts: What is genomics? <https://www.genomicseducation.hee.nhs.uk/education/core-concepts/what-is-genomics/> [Last accessed 20-3-2023]
3. Medline (online). Genetic testing. <https://medlineplus.gov/genetics/understanding/testing/genetic-testing/> [Last accessed 20-3-2023]
4. National Human Genome Research Institute. Genomics and Medicine. <https://www.genome.gov/health/Genomics-and-Medicine> [Last accessed 20-3-2023]
5. Royal Pharmaceutical Society. Position Statement: The role of pharmacy in pharmacogenomics. <https://www.rpharms.com/development/pharmacogenomics/pgx-position-statement> [Last accessed 20-3-2023]

Established pharmacy roles in genomics and future potential for pharmacy professionals

Pharmacy professionals in the UK have already established roles in the application of genomic medicine in some areas of clinical practice, such as antimicrobial stewardship and infectious disease, cancer care and the management of certain genetic conditions such as monogenic diabetes and cystic fibrosis (CF).

The pharmacy professions believe that the future role of pharmacy in genomics should be expanded to both lead and support relevant aspects of genomic implementation across all healthcare sectors, as outlined in the Genome UK strategy produced by the UK Government and the implementation plans published by the devolved nations.^{6,7,8} Furthermore, the Royal College of Physicians in partnership with the British Pharmacology Society recognise that pharmacists are a key part of MDTs in the implementation and delivery of pharmacogenomics in their Personalised Prescribing document.⁹

Pharmacy professionals have the skills and expertise to apply the practice of genomic medicine across all sectors. The following roles are examples of how pharmacy professionals are currently fulfilling or could fulfil genomic responsibilities in the current UK healthcare system design. **These illustrative examples do not limit the future potential impact that pharmacy professionals could have on all aspects of genomic service delivery as key members and leaders within the wider multidisciplinary team.**

6. UK government. Genome UK Strategy – The future of healthcare. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/920378/Genome_UK_-_the_future_of_healthcare.pdf [Last accessed 20-3-2023]
7. Welsh Government. Genomics Delivery Plan for Wales 2022-2025. https://www.gov.wales/sites/default/files/publications/2022-11/genomics-delivery-plan-for-wales_0.pdf [Last accessed 17-02-2023]
8. English Government. Genome UK 2022-25: Implementation plan for England. <https://www.gov.uk/government/publications/genome-uk-2022-to-2025-implementation-plan-for-england/genome-uk-2022-to-2025-implementation-plan-for-england#:~:text=Actions%20our%20genomics%20delivery%20partners,will%20have%20%20main%20components.> [Last accessed 13-3-2023]
9. Royal College of physicians. Personalised Prescribing. <https://www.rcp.ac.uk/projects/outputs/personalised-prescribing-using-pharmacogenomics-improve-patient-outcomes> [Last accessed 13-3-2023]

Person-centered care and collaboration

CURRENT DEFINED ROLES

- **Advising on the use of targeted precision medicines** e.g., contributing to genomic MDT discussions, using patients' somatic (acquired) and germline (inherited) genomic results to individualise treatment plans in cancer care
- **Discussing genetic test results with patients** within and outside of their prescribing role to explain the impact of genomics on treatment decisions e.g., discussing DPYD test results with patients and their carers
- **Ensuring relevant test results are available to clinical teams to inform appropriate treatment choices** e.g., ensuring CYP2C19 test results are obtained and acted upon prior to patients commencing clopidogrel for the treatment of ischaemic stroke (within a service improvement pilot phase of implementation at the time of publishing)
- **Identifying patients who may have a genetic condition for appropriate testing and management** e.g., identifying patients with signs and symptoms of Familial Hypercholesterolaemia (FH) for appropriate diagnosis and management

DEVELOPING ROLES

- **Identifying the need for genomic referral** within pre-agreed referral criteria, pharmacy professionals could refer directly to clinical genetic services
- **Making recommendations based on genomic test results** with the aim to optimise patients' medicines and engage with the wider MDT (e.g., genetic counsellors, specialist teams, care home staff)
- **Shared decision making** to support patients to understand genomic test results and their impact on treatment choices as part of a medicines optimisation strategy

Professional practice

CURRENT DEFINED ROLES

- **Checking genetic test results when required as part of prescription verification**, e.g., checking DPYD gene status when clinically verifying prescriptions for fluoropyrimidine chemotherapy
- **Obtaining consent, requesting, and interpreting genomic test results** to inform patients' treatment choices e.g., interpreting HLA-B*57:01 test results to inform abacavir prescribing
- **Management of practical aspects of the medicine supply pathway**, e.g., in gene therapy and Advanced Therapy Medicinal Products (ATMPs), pharmacy professionals may manage medicine storage and supply (sometimes including aseptic reconstitution and preparation)
- **Supporting and monitoring the management of patients with certain genetic related conditions** e.g., manage patients care within monogenic diabetes specialist clinics

DEVELOPING ROLES

- **Consenting and performing a genomic test** by supporting appropriate consent and testing pathways (where appropriate) in all areas of practice, including care homes, GP practices and pharmacy premises
- **Interpreting test results and counselling patients** across all healthcare sectors (with the appropriate level of training) and then supporting patients and their carers with their genetic test results and the implications of the results on the patients current and future care with consideration for cultural competence and awareness
- **Prescribing using genomic test results and advising other healthcare professionals** on the use of genomic results when making prescribing decisions including knowledge of gene-drug interactions, professional judgement on complex drug-gene-drug interactions and medicine-related treatment choices based on available genetic information
- **Establishing patient safety** by interpreting and using genomic test results (where available) to ensure the safety of medicine interventions across all sectors of healthcare and diverse populations as genomic test results become available to all key healthcare professionals involved in the patients' care pathway

Leadership and management

CURRENT DEFINED ROLES

- **Co-leading on the implementation of pathways for new genetic tests in clinical practice to ensure robust clinical governance is in place**, such as clinical guidelines and risk assessments and providing pharmacy related input that could impact on the testing pathway design, e.g., pharmacy professionals co-led on the implementation of TPMT/NUDT15 testing for patients with acute lymphoblastic leukaemia (ALL)
- **Quality assurance of targeted medicines for use in clinical practice**, e.g., ensuring that innovative ATMPs are of adequate quality for intended use¹⁰
- **Advocating for the use of pharmacogenomics in healthcare systems** e.g., a regional NHSE antimicrobial stewardship pharmacist and consultant pharmacists for genomics have taken leading roles in advocating for the implementation of pharmacogenomics

DEVELOPING ROLES

- **Wider advocating for the use of pharmacogenomics in healthcare systems across and in all devolved nations including representation of population diversity** (see RPS position statement for the role of pharmacy in pharmacogenomics)⁵
- **Collaboration with health informatics** to support the accurate, appropriate and retrievable integration of genomic results into electronic healthcare records and electronic prescribing and medicines administration (ePMA) records. Safe, secure and effective use of results into decision support tools will also result in safe and effective medicines use for all patients
- **Ensuring governance** is established by adopting and developing national and regional guidance and policy for the introduction and ongoing use of genomic testing while ensuring equity of access to genomic tests and subsequent related treatments
- **Development of appropriate PGx gene panels** alongside expert genomic professionals to produce panels with appropriate clinical utility in practice

10. Specialist Pharmacy Service. The role of pharmacy in the successful delivery of ATMPs. (ATMPs)-The Role of Pharmacy in the Successful Delivery of Advanced Therapy Medicinal Products Information for Chief Pharmacists – SPS – Specialist Pharmacy Service – The first stop for professional medicines advice [Last accessed 13-3-2023]

5. Royal Pharmaceutical Society. Position Statement: The role of pharmacy in pharmacogenomics. <https://www.rpharms.com/development/pharmacogenomics/pgx-position-statement> [Last accessed 20-3-2023]

Education

CURRENT DEFINED ROLES

- **Genomic education roles are currently incorporated into certain pharmacy leadership roles** e.g., consultant pharmacists for genomics and other pharmacy roles related to genomics
- **Pharmacy Genomics Workforce Transformation** e.g. genomics specialist pharmacists are contributing to national workforce strategy and planning, working with national NHS bodies

DEVELOPING ROLES

- **Health promotion** to raise awareness of genomic medicine and screening initiatives with the public to ensure diverse communities are targeted providing an inclusive approach
- **Developing additional educational programmes and resources** for all professionals across health and social care, as well as patients and carers aligned with a strategic vision set by educational leadership organisations
- **Ensuring pharmacy educational standards** are met from initial education and training, through to supporting the practicing workforce, in accordance with professional curricula and competency frameworks that include genomics

Research

CURRENT DEFINED ROLES

- **Limited postgraduate research opportunities are established** and undertaken by a small number of pharmacy professionals in the form of doctorate degrees/fellowships to explore certain clinical aspects related to the use of genomics in clinical practice

DEVELOPING ROLES

- **Leading on practice research** to explore aspects of genomic implementation, as well as the efficacy and cost effectiveness of delivering different genomic testing strategies via established research training opportunities e.g., HEI courses, fellowships and mentorship schemes
- **Supporting equality and diversity in research** to aid recruitment and inclusion of participants to appropriate research programmes/clinical trials due to pharmacy's contact with diverse communities of varied populations e.g., ancestry/ethnicity
- **Service evaluation/improvement** by pharmacy professionals to explore the impact, outcomes, and equity of implementation of genomic testing on patient pathways
- **Supporting research into genetic factors** which may predispose patients to development of adverse drug reactions

Conclusion

The mainstreaming of genomics into routine clinical practice is described across the UK in national genomic strategies and will have a significant impact on all healthcare professional groups including pharmacy. Pharmacy is well placed to fulfil a wide range of roles in genomic medicine and there are significant opportunities for novel approaches to patient care by pharmacy professionals with the appropriate knowledge and skills.

Collaborative working development group representatives

| NAME | ROLE | ORGANISATION |
|-----------------|---|--|
| Sophie Harding | RPS Pharmacogenomic Programme Lead (GB) and Advanced Oncology Pharmacist, Velindre University NHS Trust | Royal Pharmaceutical Society & NHS Wales |
| Jessica Keen | BOPA Genomics sub-committee representative and GMSA North-West pharmacy lead | British Oncology Pharmacy Association (BOPA) |
| Emma Groves | Pharmacy subject matter lead at GEP (also GMSA North-East & Yorkshire pharmacy lead) | Genomics Education Programme (GEP) |
| Jennifer Laskey | Lead Cancer Services Pharmacist, West of Scotland Cancer Network representative | Directors of Pharmacy Scotland group (NHS Scotland) |
| Hayley Wickens | Chair of UKCPA Genomic sub-committee (also Consultant Pharmacist in Genomics - Central & South GMSA) | United Kingdom Clinical Pharmacy Association (UKCPA) |
| Rachel Palmer | South-West GMSA Pharmacy Lead | NHS GMSA Pharmacy Leads (England) |
| Nicola Husain | Education and Training Lead, NPPG | Neonatal and Paediatric Pharmacist Group (NPPG) |

| NAME | ROLE | ORGANISATION |
|--------------------------|--|---|
| Rosalind Gittins | President of CMHP (also Director of Care Standards and Practice) | College of Mental Health Pharmacy (CMHP) |
| Roisin O'Hare | Immediate Past President of GHP (also Northern Ireland Lead Clinical Education Pharmacist) | Guild of Hospital Pharmacists (GHP) (NI Universities Network/ Health and Social Care in NI (HSC)) |
| Helga Mangion | NPA Policy Manager | National Pharmacy Association (NPA) |
| Adam Osprey | Policy and Development Pharmacist | Community Pharmacy Scotland (CPS) |
| Tina Hancock | Lead Pharmacy Technician - SACT production UHNM | Association of Pharmacy Technicians UK (APTUK) |
| Gordon Hockey | Director, Legal team | Pharmaceutical Services Negotiated Committee (PSNC) |
| Emma Barnes | Regional Manager, West Midlands, CPPE | Centre for Pharmacy Postgraduate Education (CPPE England) |
| Yvonne Dennington | RPS Business manager - Admin support | RPS |

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