A Pharmacogenomic Competency Resource for All Prescribers

Introduction

Pharmacogenomics (PGx) is the study of how genetic variation influences drug response, to enable safer and more effective prescribing.(1) A pharmacogenomic test is a genetic test which focusses on genes that affect drug metabolism, efficacy, or risk of adverse reactions and therefore informs treatment decisions rather than predicting disease susceptibility.(1)

Across the UK and internationally, PGx is a developing strategic priority, central to major policy frameworks such as the Genome UK strategy(2) and Life Sciences Sector plan.(3) Within these plans, workforce upskilling is identified as a critical challenge to pharmacogenomic implementation across all four UK nations.(4–8) National genomic workforce strategies have been developed within England (1) for individual professions and in Wales for the whole healthcare workforce, to initiate progress towards embedding PGx into routine care.(9)

The routine use of PGx testing is evolving from the current use of single-gene testing (e.g., *DPYD* for fluoropyrimidines) to the use of multi-gene panel testing within research programmes across the UK,(10–12) and further developments are predicted to include broader panels for pre-emptive use.(13)

Purpose

This resource has been developed to support prescribers in building and expanding their pharmacogenomic competence. Its aim is to enable healthcare professionals across all disciplines to prescribe safely and effectively using pharmacogenomic testing, ultimately improving patient outcomes through medicines optimisation.

This resource can be used by various groups:

- Trainee prescribers not currently using pharmacogenomic testing
- Registered prescribers in settings where pharmacogenomic testing is not currently implemented
- Registered prescribers currently practising in settings where pharmacogenomic testing is in use
- Groups of educators, higher education institutions, and organisations providing training to prescribers

Instances when this resource may be used:

- *Self-assessment* - for expanding or changing scope of practice or even returning to practice
- *Evidence for trainees* - that they demonstrate competence
- *Guidance for regulators, educators, and professional bodies* - to inform standards and curriculum development
- *Organisational structure development* - to inform prescribing practice and governance systems
- *Portfolio development* - to continue education and prescriber revalidation relating to pharmacogenomics

It can be used by any prescriber at any point in their career to underpin professional responsibility for prescribing when using pharmacogenomic testing.

Benefits of using this resource include:

- To standardise pharmacogenomic education and competence across prescribing professions
- Supports design and validation of educational prescribing programmes

Other applications for this resource

- Provide professional organisations or specialist groups with a basis for the development of levels of prescribing competency within pharmacogenomics, from 'recently qualified prescriber' through to 'experienced prescriber'
- Stimulate discussions around pharmacogenomic prescribing competencies and multidisciplinary skill mix at an organisational level.
- Inform the development of organisational systems and processes that support safe and effective prescribing, including the use of pharmacogenomic testing. For example, local clinical governance frameworks.
- Inform the development of education curricula relating to pharmacogenomic education.
- Inform and assure patients/carers about the competencies of a safe and effective prescriber in relation to pharmacogenomic testing.

Scope

This resource is designed to complement the competency framework for all prescribers to:

- Support any prescriber regardless of their professional background or setting and does not contain statements that relate to certain professions or clinical settings.
- Contextualise and reflect on different areas of practice, levels of expertise and settings
- Reflect the key competence and skills needed by all prescribers to utilise pharmacogenomic testing within day-to-day practice. It should not be viewed as a curriculum but as the basis upon which a prescribing curriculum could be developed.
- Apply equally to independent prescribers, community practitioner nurse prescribers and supplementary prescribers, but the latter should contextualise the resource to reflect the structures imposed when entering a supplementary prescribing relationship.

Scope Limitation

This resource is designed as an enabling tool and is not intended to disadvantage any prescribing profession. Prescribers are not expected to hold knowledge of pharmacogenomic tests that fall outside of their specific scope of practice. It is also acknowledged that pharmacogenomic testing pathways may not yet be available or commissioned in all areas of practice at any given time.

Development of this resource

In 2025, the RPS were commissioned by NHS England (led by the NHSE Network of Excellence in Pharmacogenomics and Medicines Optimisation) to develop this resource as a reflection of the need to raise the awareness of the increasing number of pharmacogenomic tests available within mainstream clinical practice across the UK. The expertise and experience from a UK-wide multidisciplinary task and finish group and a further validation group were utilised to support and refine the development of this resource. This resource has been developed to provide the pharmacogenomic context to existing prescribing competencies within the current RPS competency framework for all prescribers, regardless of professional background.(14) Therefore, the pharmacogenomic resource sits beside the current competency framework for prescribers, as an additional resource to support the development of competence around the use of pharmacogenomic testing.

Structure of the pharmacogenomic resource in relation to the original framework

The competencies within the framework are presented as two domains reflective of the original competency framework for all prescribers. Each competency and supportive statement are presented within a table format within this document, with the corresponding pharmacogenomic interpretation described within the corresponding box. Therefore, within:

- Domain One (The consultation) - the pharmacogenomic competence a prescriber needs relating to the consultation competencies are described within this domain.
- Domain Two (Prescribing governance) - the pharmacogenomic competence a prescriber needs relating to prescribing governance competencies are described within this domain.
- Case studies demonstrate the competencies required by all prescribers related to pharmacogenomic testing (see Appendix One).

Domain One – The consultation

Pharmacogenomic testing is used to predict the risk of adverse drug reactions or response to medicines. A sound understanding of pharmacogenomics enables healthcare professionals to better anticipate that risk leading to improved medicines optimisation within a consultation.

Within domain one, there are common themes summarised below:

- *Genetic variability* - Pharmacogenomics focuses on how individual genetic differences determine how patients metabolise and respond to medicines. Variations in genes which encode drug-metabolising enzymes, transporters, or receptors can influence whether a medication is effective or causes adverse effects. These genetic differences can also contribute to hypersensitivity reactions.
- *Consent aspects* - Any form of consent for pharmacogenomic testing (often verbal is sufficient) should ensure patients understand the implications for treatment, privacy, and potential future use of their genetic data and how this differs to obtaining genetic information to diagnose genetic conditions.
- *Risk-benefit aspects* - Pharmacogenomic testing can introduce some extra considerations to treatment decisions, balancing the benefits of personalised therapy against challenges such as access to testing and potential for incidental findings. Transparent discussion of the benefit, limitations and risks with patients and other members of the multidisciplinary team supports shared decision-making.
- *Relevance of family history* - Family history can indicate inherited genetic traits that affect drug response. Obtaining this information complements pharmacogenomic test results and contributes towards the prediction of adverse reactions or therapeutic failure.
- *Cultural competence and impact of understanding on patients with learning disabilities*- It is essential to explain pharmacogenomic concepts using a culturally sensitive and accessible approach. For example, when dealing with patients who have learning disabilities, clear language and tailored communication should be used to ensure understanding and informed decision-making.
- *Variant frequency and ethnicity* - Due to the inherited nature of genetic variation, pharmacogenomic variants often occur at different frequencies across different ancestral and ethnic groups, which can influence drug response and safety. Recognising these patterns helps prescribers avoid assumptions and ensures equitable but personalised care to all patients.

Competency One: Assessing the patient

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
1.1 Undertakes the consultation in an appropriate setting.	*No exceptional pharmacogenomic interpretation required*
1.2 Considers patient dignity, capacity, consent and confidentiality.	Prescribers should support patients by ensuring they understand the purpose, benefits and risks of pharmacogenomic testing and safeguarding of genetic data regardless of their current level of understanding.
1.3 Introduces self and prescribing role to the patient/carer and confirms patient/carer identity.	*No exceptional pharmacogenomic interpretation required*
1.4 Assesses the communication needs of the patient/carer and adapts consultation appropriately.	
1.5 Demonstrates good consultation skills and builds rapport with the patient/carer.	
1.6 Takes and documents an appropriate medical, psychosocial and medication history including allergies and intolerances.	Prescribers should take a patient history that includes ethnicity or ancestry, relevant family history, known genetic information, and any family history of adverse drug reactions or variable responses potentially linked to genetics. Document any prior pharmacogenomic test results, including those from the independent sector, and note their impact on past prescribing.
1.7 Undertakes and documents an appropriate clinical assessment.	*No exceptional pharmacogenomic interpretation required*
1.8 Identifies and addresses potential vulnerabilities that may be causing the patient/carer to seek treatment.	Prescribers should be aware that certain health conditions, symptoms, or adverse drug reactions may be linked to specific pharmacogenomic variants in the patient. During the consultation, it's equally important to explore and respect the patient's own views, concerns, and expectations about the use of genetic information in their care.
1.9 Accesses and interprets all available and relevant patient records to ensure knowledge of the patient's management to date.	Prescribers should review all available PGx test results (NHS and non-NHS (with care of test quality assurance)), including relevant family data. Assess the quality and clinical validity of results in context of the patient's history, considering test timing and relevance of variants or star alleles tested.
1.10 Requests and interprets relevant investigations necessary to inform treatment options.	Prescribers should assess patients' eligibility for PGx testing, ensuring patients understand its purpose, interpretation, and limitations. Use validated sources to support clinical interpretation and ensure evidence-based testing contributes to holistic care within local and national pathways.
1.11 Makes, confirms or understands, and documents the working or final diagnosis by systematically considering the various possibilities (differential diagnosis).	Prescribers should have an awareness of how genetic information may contribute to and affect the patient's diagnosis relating to treatment.
1.12 Understands the condition(s) being treated, their natural progression, and how to assess their severity, deterioration and anticipated response to treatment.	*No exceptional pharmacogenomic interpretation required*
1.13 Reviews adherence (and non-adherence) to, and effectiveness of, current medicines.	*No exceptional pharmacogenomic interpretation required*

1.14 Refers to or seeks guidance from another member of the team, a specialist or appropriate information source when necessary.	

Competency Two: Identify evidence-based treatment options available for clinical decision making

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
2.1 Considers both non-pharmacological and pharmacological treatment approaches.	Prescribers should understand how to prioritise one pharmacological and/or non-pharmacological approach over another based on the patient's genetic information available, supporting more individualised and effective care planning.
2.2 Considers all pharmacological treatment options including optimising doses as well as stopping treatment (appropriate polypharmacy and deprescribing).	*No exceptional pharmacogenomic interpretation required*
2.3. Assesses the risks and benefits to the patient of taking or not taking a medicine or treatment.	Prescribers should understand that pharmacogenomic testing enhances the risk-benefit assessment by providing patient-specific genetic insights, thereby supporting more informed clinical decisions regarding the initiation, continuation, or discontinuation of therapy.
2.4. Applies understanding of the pharmacokinetics and pharmacodynamics of medicines, and how these may be altered by individual patient factors	Prescribers should be aware that a patients' genetic differences (variation) affect drug response, making PGx key to optimising efficacy and reducing ADRs to ensure the safe use of prescribed medicines. As PGx evolves, not all findings are immediately actionable, and results may need revisiting as evidence grows.
2.5. Assesses how co-morbidities, existing medicines, allergies, intolerances, contraindications and quality of life impact on management options	
2.6. Considers any relevant patient factors and their potential impact on the choice and formulation of medicines, and the route of administration	
2.7. Accesses, critically evaluates, and uses reliable and validated sources of information.	*No exceptional pharmacogenomic interpretation required*
2.8. Stays up to date in own area of practice and applies the principles of evidence-based practice.	
2.9. Considers the wider perspective including the public health issues related to medicines and their use and promoting health.	
2.10. Understands antimicrobial resistance and the roles of infection prevention, control and antimicrobial stewardship measures.	Prescribers should understand how pharmacogenomic data can guide antibiotic selection by predicting a patient's likelihood of experiencing adverse drug reactions or their potential response to treatment. Additionally, other aspects of genomic medicine may provide insights into possible antimicrobial resistance.

Competency Three: Present options and reach a shared decision

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
3.1. Actively involves and works with the patient/carer to make informed choices and agree a plan that respects the patient's/carer's preferences	Prescribers should involve patients in decision making about the potential implications of testing, including how results may influence therapeutic options and prescribers should have an awareness of the need for the patient to share information with family members if potentially relevant for them.
3.2. Considers and respects patient diversity, background, personal values and beliefs about their health, treatment and medicines, supporting the values of equality and inclusivity, and developing cultural competence	*No exceptional pharmacogenomic interpretation required*
3.3. Explains the material risks and benefits, and rationale behind management options in a way the patient/carer understands, so that they can make an informed choice.	Pharmacogenomics can inform benefit-risk discussions by offering insight into likely treatment responses. However, prescribers should be aware that results are not always definitive. Clinical judgment remains essential, as genetic data should be interpreted alongside other patient factors. Its permanence also underscores the need for careful, long-term consideration.
3.4. Assesses adherence in a non-judgemental way; understands the reasons for non-adherence and how best to support the patient/carer	*No exceptional pharmacogenomic interpretation required*
3.5. Builds a relationship which encourages appropriate prescribing and not the expectation that a prescription will be supplied	
3.6. Explores the patient's/carer's understanding of a consultation and aims for a satisfactory outcome for the patient/carer and prescriber.	

Competency Four: Prescribe

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
4.1. Prescribes a medicine or device with up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions and ADRs.	Prescribers should understand PGx variability as part of their knowledge of medicines. Genetic differences can affect treatment response, and SmPCs increasingly include genomic guidance to support personalised prescribing, especially considering factors like ethnicity and comorbidities.
4.2. Understands the potential for adverse effects and takes steps to recognise, and manage them, whilst minimising risk	Prescribers should understand how pharmacogenomic testing can help predict the risk of ADRs whilst recognising that ancestry and family history may influence susceptibility and support safer, personalised prescribing.
4.3. Understands and uses relevant national, regional and local frameworks for the use of medicines	*No exceptional pharmacogenomic interpretation required*
4.4. Prescribes generic medicines where practical and safe for the patient and knows when medicines should be prescribed by branded product.	No exceptional pharmacogenomic interpretation required
4.5. Accurately completes and routinely checks calculations relevant to prescribing and practical dosing.	Prescribers should apply pharmacogenomic result-informed guidance to support safe and effective decision-making. This requires not only familiarity with relevant pharmacogenomic resources but also the use of clinical judgement to interpret results within the holistic context of the patient case.
4.6. Prescribes appropriate quantities and at appropriate intervals necessary to reduce the risk of unnecessary waste	*No exceptional pharmacogenomic interpretation required*
4.7. Recognises potential misuse of medicines; minimises risk and manages using appropriate processes	*No exceptional pharmacogenomic interpretation required*
4.8. Uses up-to-date information about the availability, pack sizes, storage conditions, excipients and costs of prescribed medicines.	*No exceptional pharmacogenomic interpretation required*
4.9. Electronically generates and/or writes legible, unambiguous and complete prescriptions which meet legal requirements.	*No exceptional pharmacogenomic interpretation required*
4.10. Effectively uses the systems necessary to prescribe medicines	*No exceptional pharmacogenomic interpretation required*
4.11. Prescribes unlicensed and off-label medicines where legally permitted, and unlicensed medicines only if satisfied that an alternative licensed medicine would not meet the patient's clinical needs.	*No exceptional pharmacogenomic interpretation required*
4.12. Follows appropriate safeguards if prescribing medicines that are unlicensed, off-label, or outside standard practice.	Prescribers should understand that in certain cases, PGx testing may support off-label or non-standard treatments where guidelines are limited. Prescribers must document decisions clearly, assess risks and

	benefits, and prioritise safety using the best available evidence.
4.13. Documents accurate, legible and contemporaneous clinical records	*No exceptional pharmacogenomic interpretation required*
4.14. Effectively and securely communicates information to other healthcare professionals involved in the patient's care, when sharing or transferring care and prescribing responsibilities, within and across all care settings	Prescribers should understand that genetic results remain constant (although interpretation may evolve) and could have relevance to other healthcare professionals involved in the patient's current or future care.

Competency Five: Provide information

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
5.1. Assesses health literacy of the patient/carer and adapts appropriately to provide clear, understandable and accessible information	*No exceptional pharmacogenomic interpretation required*
5.2. Checks the patient's/carer's understanding of the discussions had, actions needed and their commitment to the management plan	Prescribers should recognise that PGx results can impact treatment plans. In some cases, delaying or adjusting treatment choices. Unlike other clinical tests, genetic results remain constant. Interpretation of genetic results may evolve, and may need revisiting over time.
5.3. Guides the patient/carer on how to identify reliable sources of information about their condition, medicines and treatment.	*No exceptional pharmacogenomic interpretation required*
5.4. Ensures the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific timeframe	*No exceptional pharmacogenomic interpretation required*
5.5. Encourages and supports the patient/carer to take responsibility for their medicines and self-manage their condition	*No exceptional pharmacogenomic interpretation required*

Competency Six: Monitor and review

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
6.1. Establishes and maintains a plan for reviewing the patient's treatment	Prescribers should review treatment plans when new medicines (which could be a potentially interacting drug such as enzyme inhibitors or inducers) are added, as these may affect PGx findings. Drug–drug–gene interactions and adjusted review periods may be needed to maintain safe, effective therapy to retain appropriate clinical context over time.
6.2. Establishes and maintains a plan to monitor the effectiveness of treatment and potential unwanted effects	*No exceptional pharmacogenomic interpretation required*
6.3. Adapts the management plan in response to on-going monitoring and review of the patient's condition and preferences.	
6.4. Recognises and reports suspected adverse events to medicines and medical devices using appropriate reporting systems	Prescribers should be aware of pharmacovigilance initiatives e.g. The Yellow Card Biobank, which supports reporting ADRs with genetic links and are helping to build evidence for safer, personalised prescribing.

Domain Two - Prescribing governance

Pharmacogenomics is an evolving field and this resource has been developed in the context of contemporaneous practice, although this position may change in the future as the development of a UK regulatory framework to support pharmacogenomic testing is underway.(15) To reflect this, traditional reference resources used for prescribing practices such as the BNF or SmPCs are continually being updated with pharmacogenomic content to support prescribers.

Common themes within domain two

Within Domain two, there are common themes as summarised below:

Commissioning of pharmacogenomic testing – Each UK nation has a different approach to the commissioning and regulation of pharmacogenomic testing, but all approaches include evaluating the clinical utility and cost-effectiveness of a testing approach to ensure equity of access to testing within a nation.(16,17) The availability of testing may change depending on commissioning.

Digital capability to utilise pharmacogenomic data – Each UK nation is at a different stage of implementing the digital infrastructure required to integrate pharmacogenomic data into routine clinical care.

Consent and data re-use – Verbal consent is often considered acceptable for pharmacogenomic testing. Within research settings, consent would be subject to research and ethics governance.

Direct-to-consumer (DTC) testing - Involves pharmacogenomic tests sold directly to individuals without clinician involvement. In 2025, the British Society for Genetic Medicine (BSGM) and partners issued a statement advising that DTC testing could be referred to in practice but should complement, not replace clinical services and highlighted its limitations and risks.(18)

Competency Seven – Prescribe safely

Supporting statement from competency framework for all prescribers	**PGx reflection on existing supporting statement**
7.1. Prescribes within own scope of practice and recognises the limits of own knowledge and skill.	*No exceptional pharmacogenomic interpretation required*
7.2. Knows about common types and causes of medication and prescribing errors and knows how to minimise their risk.	
7.3. Identifies and minimises potential risks associated with prescribing via remote methods	
7.4. Recognises when safe prescribing processes are not in place and acts to minimise risks	
7.5. Keeps up to date with emerging safety concerns related to prescribing	
7.6. Reports near misses and critical incidents, as well as medication and prescribing errors using appropriate reporting systems, whilst regularly reviewing practice to prevent recurrence.	

Competency Eight – Prescribe professionally

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
8.1. Ensures confidence and competence to prescribe are maintained	*No exceptional pharmacogenomic interpretation required*
8.2 Accepts personal responsibility and accountability for prescribing and clinical decisions, and understands the legal and ethical implications	Prescribers must understand the legal and ethical duties around PGx testing, especially regarding consent and data reuse. Reusing results without renewed consent risks undermining accountability, governance, and patient autonomy. Transparent decision-making and alignment with evolving ethical standards are essential when applying genomic data in new clinical contexts.
8.3 Knows and works within legal and regulatory frameworks affecting prescribing practice.	Prescribers should be aware that the regulatory framework supporting pharmacogenomic testing is currently under development. While integration into clinical practice is progressing, it is important to recognise that comprehensive regulatory structures are still being established.
8.4 Makes prescribing decisions based on the needs of patients and not the prescriber's personal views.	*No exceptional pharmacogenomic interpretation required*
8.5 Recognises and responds to factors that might influence prescribing	Prescribers should consider factors influencing prescribing, including non-NHS and direct-to-consumer testing. Patients may seek treatment changes based on such results, requiring careful clinical judgement. Prescribers must assess test reliability, support access to validated pathways, and stay informed on evolving regulations.
8.6 Works within the NHS, organisational, regulatory and other codes of conduct when interacting with the pharmaceutical industry	*No exceptional pharmacogenomic interpretation required*

Competency Nine – Improving prescribing practice

Supporting statement from competency framework for all prescribers	PGx reflection on existing supporting statement
9.1 Improves by reflecting on own and others' prescribing practice, and by acting upon feedback and discussion	*No exceptional pharmacogenomic interpretation required*
9.2 Acts upon inappropriate or unsafe prescribing practice using appropriate processes	
9.3 Understands and uses available tools to improve prescribing practice	
9.4 Takes responsibility for own learning and continuing professional development relevant to the prescribing role	
9.5 Makes use of networks for support and learning.	

9.6 Encourages and supports others with their prescribing practice and continuing professional development.	
9.7 Considers the impact of prescribing on sustainability, as well as methods of reducing the carbon footprint and environmental impact of any medicine	

Competency Ten – Prescribe as part of a team

Supporting statement from competency framework for all prescribers	**PGx reflection on existing supporting statement**
10.1 Works collaboratively as part of a multidisciplinary team to ensure that the transfer and continuity of care (within and across all care settings) is developed and not compromised.	*No exceptional pharmacogenomic interpretation required*
10.2 Establishes relationships with other professionals based on understanding, trust and respect for each other's roles in relation to the patient's care.	
10.3 Agrees the appropriate level of support and supervision for their role as a prescriber.	
10.4 Provides support and advice to other prescribers or those involved in administration of medicines where appropriate.	

Glossary

(* To be added before publication)

Acknowledgements

(* To be added before publication)

- Task & Finish Group membership for this project
- Validation group membership for this project
- RPS staff membership

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Appendix One – Pharmacogenomic testing case studies

**Case study examples are provided for illustrative purposes to aid understanding and may not represent the current availability of specific tests. **

Case study 1. Clopidogrel and *CYP2C19* pharmacogenomic testing

A 65-year-old man experiences sudden left-sided weakness after an afternoon nap. He is admitted to the local A&E and is diagnosed with a suspected acute stroke and transferred to the acute stroke unit. Following examination, the prescriber intends to start treatment with clopidogrel in14 days' time as per national stroke guidelines. The prescriber identifies the need for a *CYP2C19* pharmacogenomic testing before clopidogrel initiation, to determine if the patient can metabolise clopidogrel effectively.

The prescriber:

- Assesses the patients' eligibility for PGx testing, ensuring patients understand its purpose, interpretation, and limitations using validated resources to support clinical interpretation
- Establishes if there has been any prior pharmacogenomic testing found in the patients' medical record of either the patient or within their family history
- Engages with the patient and their relatives to explain the purpose, benefits, and risks of the test before requesting pharmacogenomic testing
- Refers to relevant resources when receiving the test result to inform the treatment decision
- Explains the genetic result and its implications for clopidogrel when making a shared decision about antiplatelet prescribing.
- Explains the relevance of the genetic result for any other medications and explains that unlike other clinical tests, genetic results remain constant, although the interpretation of results may evolve, and may need revisiting over time.
- Prescribes an appropriate antiplatelet for the patient
- Documents the event and treatment decisions within medical records and shares the results within the GP discharge letter
- Describes within the patient record that other drugs metabolised by the same enzyme (e.g., citalopram) may be affected if prescribed, informing current and future treatment choices
- Reviews treatment plans when new medicines (which could be a potentially interacting drug such as enzyme inhibitors or inducers) are added, as these may affect PGx findings. Drug–drug–gene interactions and adjusted review periods may be needed to maintain safe, effective therapy and retain appropriate clinical context over time.

Competencies shown: 1.2, 1.6, 1.9, 1.10, 1.11, 2.4, 2.7, 2.8, 3.1, 3.3, 4.1, 4.12, 4.14, 4.15, 5.2, 6.1, 8.2, 10.1, 10.2

***Case study 2. Gentamicin and MT-RNR1* pharmacogenomic testing**

A baby is born by C-section at the local hospital maternity ward at 32 weeks' gestation. After 48 hours the baby starts to show clinical signs of poor feeding, lethargy and a spiking temperature. The baby has a suspected diagnosis of early-onset neonatal sepsis and is transferred to the neonatal intensive care unit. After a thorough examination, the prescriber decides to start empirical treatment with gentamicin in combination with another antibiotic aligned with trust guidance.

The prescriber:

- The prescriber identifies the need for a *MT-RNR1* point-of-care test prior to prescribing the gentamicin as per reference sources (MHRA alert) as the presence of a *MT-RNR1* gene variant can increase the risk of aminoglycoside (gentamicin) induced hearing loss.
- Uses the result to inform the selection of antibiotic for the baby, within the window for effective antibiotic prescribing
- Documents the result of pharmacogenetic testing within the patient record.
- Explains the purpose, benefits and limitations of the test and implications of the result to the baby's parents. Ensures they have appropriate understanding of the need for the test and familial implications, whilst keeping communication appropriate and patient centred.
- Engages the baby's parents in a discussion about the potential family history of hearing loss and how it could affect the future prescribing of aminoglycosides
- Discusses the need for the patients' parents to share information with family members if potentially relevant for them guided by clinical judgement.
- Documents the event details thoroughly within medical records and ensures the pharmacogenomic test result is included in the discharge letter to the GP, with a recommendation to record it in the primary care system ensuring continuity of care across settings and multidisciplinary working.

Competencies shown: 1.2, 1.6, 1.10, 1.11, 2.3, 2.4, 2.5, 2.6, 2.10, 3.1, 4.1, 4.2, 4.13, 4.14, 10.1.

Case study 3. Codeine and pharmacogenomic testing

A 29-year-old 34-week pregnant patient visits the GP practice with severe lower back pain. Despite taking paracetamol regularly, she is still suffering pain which is affecting her daily life. The local prescribing guidelines recommend codeine in this scenario. The prescriber is aware that *CYP2D6* metaboliser status can impact codeine treatment response and checks to see if they can access testing. The prescriber takes a comprehensive medical history from the patient, including allergies and personal and family history of adverse drug reactions before proceeding with the prescription.

After 24 hours after starting codeine treatment, the patient develops excessive sedation, nausea, and respiratory depression. She is admitted to the maternity unit at her local hospital and receives foetal monitoring which shows reduced movements potentially due to increased exposure of codeine. The codeine treatment is stopped immediately, and she is closely monitored for any changes in her or the babies' signs or symptoms. The patient makes a full recovery and returns to the GP practice following the birth of her baby for further back pain control. She also asks the prescriber's opinion of direct-to-consumer testing (as she has read about this online) and believes her DNA may have caused this reaction to occur.

The prescriber:

- Refers to guidance/ resources around pharmacogenomic testing and the prescribing of codeine treatment
- Is aware that certain health conditions, symptoms, or adverse drug reactions may be linked to specific pharmacogenomic variants in the patient.
- Reviews the patient including hospital discharge letters to ensure knowledge of the patient's management to date including information about her possible ADR to codeine and any testing done in hospital.
- Discusses an alternative option to manage the pain with the patient, including both pharmacological and non-pharmacological options in the absence of pharmacogenetic testing.
- Advises the patient to avoid the use of codeine in the future and to inform other prescribers
- Submits a Yellow Card report to the MHRA for further exploration of this adverse drug reaction.
- Discusses considerations of direct-to-consumer testing with the patient, including benefits and limitations of testing and access to treatment pathways.

Competencies shown: 1.6, 1.8, 1.9, 1.10, 2.1, 2.4, 2.5, 2.6, 3.3, 4.1, 4.2,4.3, 4.10, 6.4, 8.5

Case study 4. Capecitabine and *DPYD* pharmacogenomic testing

A 62-year-old woman has been referred to the cancer centre for adjuvant chemotherapy following surgery for stage III colorectal cancer. After assessment, the prescriber plans to start capecitabine chemotherapy as a first-line treatment. The prescriber is aware of the MHRA safety alert, recommending the use of *DPYD* gene tests to predict the likelihood of the patient experiencing adverse drug reactions from fluoropyrimidine drugs (e.g., capecitabine, 5-FU).

The prescriber:

- Accesses the patient record to review whether *DPYD* genetic testing has already been requested and interpret any relevant history and results.
- Decides that the patient will need a *DPYD* genetic test before they commence the capecitabine prescription.
- Explains the purpose, benefits and limitations of the test to the patient in the context of their chemotherapy treatment, including possible impact on treatment plan and start date, considering their level of genomics understanding.
- Requests the *DPYD* test along with other relevant investigations to inform treatment options.
- Explains to a new staff member why the patient needs to come back to clinic next week and is not being started on the capecitabine treatment today.
- Interprets the *DPYD* result and discusses this with other members of the multidisciplinary team who have more experience in using pharmacogenomic reports, before making a decision about prescribing.
- Educate the patient on adverse effects that they may experience regardless of the outcome of the test result and establish a plan for monitoring and patient reporting of their condition and potential unwanted effects. The prescriber should be aware that the results are not always definitive and clinical judgement is essential, as genetic data should be interpreted alongside other patient factors.

Competencies shown: 1.9, 1.10, 1.11, 2.3, 2.4, 2.5, 2.6, 3.1, 3.3, 5.2, 6.1, 7.1, 8.2, 8.3, 9.1, 9.2, 9.3, 9.4, 9.5, 10.3, 10.4

Case study 5. Carbamazepine and pharmacogenomic testing

A 42-year-old man, originally from China, now living in the UK, visits the dentist experiencing sudden, electric shock-like pain in the right side of his face consistent with trigeminal neuralgia. After initial assessment, the prescriber considers carbamazepine as an effective first-line treatment but whilst referring to reference sources e.g. the BNF and drug SmPC, the prescriber notices there is a caution listed regarding the increased risk of Steven-Johnson Syndrome (SJS) in patients of Han Chinese or Thai descent, due to the increased likelihood of carrying the *HLA-B*15:02* allele. Patients who carry the *HLA-B*31:01* allele are also at increased risk of experiencing hypersensitivity reactions with carbamazepine.

The prescriber:

- Takes and documents the patient history including ethnicity, ancestry and relevant family history. Explains the relevance of this to the use of the medicine, and possibility of accessing pharmacogenetic testing, in a culturally competent way, while considering the patient's level of genomics understanding.
- Reviews all available PGx test results (NHS and non-NHS (with care of test quality assurance)), including relevant family history of testing.
- Explores availability of testing within local services, prior to prescribing carbamazepine and the patient's eligibility within resources (e.g. NHSE NTD)
- Discusses treatment options with the patient including pharmacological and/or non-pharmacological approaches, based on the patient's genetic information available
- Discusses with the patient, the risk of starting the medicine without PGx testing due to the patient's ethnicity and potential ancestry and the severity of the adverse effects that could be experienced as a result.
- Prescribes an appropriate analgesic following shared decision making with the patient.
- Documents aspects of the decision making within the patients' health record

Competencies shown: 1.6, 1.9, 1.10, 2.1, 2.3, 2.4, 2.5, 2.6, 3.1, 3.3, 4.1, 4.2, 4.13, 4.15, 8.2,

Appendix Two *(Resources to be refined/amended and added to host webpage)

Medicines safety

- MHRA Guidance on Pharmacogenomics **-** https://www.gov.uk/mhra

Clinical Guidance

- CPIC (Clinical Pharmacogenetics Implementation Consortium) **-** https://cpicpgx.org - Provides peer-reviewed, evidence-based guidelines for implementing pharmacogenomic testing in clinical practice.
- DPWG (Dutch Pharmacogenetics Working Group) **-** https://www.knmp.nl - Offers recommendations for drug dosing based on genetic profiles.
- ClinPGx

Pharmacovigilance

- *MHRA yellow card biobank* - https://yellowcard.mhra.gov.uk/biobank

Education

- NHSE Genomic Education Programme - https://www.genomicseducation.hee.nhs.uk - Guidance and education on genomic medicine aspects including GeNotes
- Pharmacogenomics: resources to support answering questions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- NHS Wales Health Education and Improvement Wales - https://heiw.nhs.wales/our-work/genomics/ Genomics Education such as an introduction course for genomics
- Scottish education webpages?

Position statements

RPS position statements

- PGx Position Statement
- Genomic Medicine Position Statement

BPS/RCP

- Personalised-prescribing-full-report.pdf.aspx

Regulation and commissioning of testing

- NHS England » National genomic test directory
- Home - electronic medicines compendium (emc)
- New pharmacogenomics centre to help UK move towards personalised prescribing - News - University of Liverpool