Anticoagulant Dosage Monitoring and Adjustment:

Guidance for Biomedical Scientists

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Introduction

This guidance is intended for biomedical scientists with roles in anticoagulation services, as well as laboratory managers, service leads, educators and governance teams. It provides clarity on when and how biomedical scientists can safely adjust the dose of a prescribed anticoagulant, and under what legal and professional conditions.

The document outlines the key distinctions between Prescribing, Patient Specific Directions (PSDs), and local protocols. It explains why Patient Group Directions (PGDs) are not appropriate for dose adjustments, and sets out the governance, training and documentation requirements needed to support safe practice.

Developed in response to member enquiries and recent guidance updates, this document brings together relevant standards from the HCPC, Specialist Pharmacy Service and national training frameworks. It aims to support services in developing clear, lawful and safe models for biomedical scientist-led anticoagulation care — with warfarin dosage monitoring and adjustment providing the most established example.

Clinical context for anticoagulant dosage monitoring

Anticoagulant therapy is a well-established pharmaceutical intervention in the treatment of venous thromboembolism or as a prophylactic treatment in clinical conditions with a high risk of thrombosis, such as atrial fibrillation. For many years oral anticoagulants have been coumarin derivations, mainly warfarin, which inhibits production of functioning vitamin K dependent clotting factors and requires careful monitoring and dosage adjustments as required to ensure clinically effective therapy and patient safety. More recently pharmaceutical advances have seen the introduction of new treatment options in the form of Direct Oral Anticoagulants which do not require regular monitoring. However, warfarin therapy is still the clinical treatment of choice for some patients, requiring anticoagulant monitoring and dosage adjustment services. Biomedical scientists have been and are increasingly involved in delivering these services across NHS settings, often utilising computerised dosing management eHealth tools to support dosing decisions and adjustments for warfarin patients.

Warfarin must be carefully and safely monitored based on the result of the Prothrombin Time blood test used to calculate the standardised International Normalised Ratio (INR). Patients are assigned a target INR range based on their clinical condition which should both reduce the risk of a blood clot and serious bleeding. As everybody reacts differently to warfarin medication regular monitoring with dose adjustment as required is necessary to ensure an individual's INR is kept within their target range and prevent a patient being underdosed (risk of blood clot) or overdosed (risk of serious bleeding). For this reason, regular INR monitoring and timely, accurate dose adjustment are essential with anticoagulant services being delivered by healthcare professionals who are trained, competent and operating within a defined framework of clinical responsibility.

Prescribing vs Patient Group Directions vs Patient Specific Directions

It is important to understand the distinctions between regulations in law for Prescribing, Patient Group Directions (PGDs), Patient Specific Directions (PSDs) and a local dosing protocol:

- **Prescribing**: This refers to a medical prescriber (a medically qualified doctor or dentist) or a non-medical prescriber (such as a nurse or pharmacist) who has completed appropriate prescribing qualifications and is legally authorised to practice as an independent prescriber. Prescribers have the legal authority to issue prescriptions, are responsible for assessing patients (whether newly diagnosed or with existing conditions), and are accountable for decisions about clinical management, including prescribing. A prescription authorises the supply of a medicine and provides instructions for its use.
- **Patient Group Direction (PGD)**: This is a specific legal framework that allows certain registered health professionals to supply and/or administer medicines to a defined group of patients without a prescriber's individual instruction for each patient (this is not prescribing)**.** However, PGDs do not provide a legal basis for adjusting the dose of a medicine that a patient already possesses, and they must not be used for this purpose. This is particularly relevant for anticoagulants like warfarin, where the medicine is prescribed and the dose is adjusted over time based on INR results. NICE guidance reinforces this by stating that dose adjustments must not be made to a medicine supplied under a PGD once it is in the patient's possession
- **Patient Specific Direction (PSD)**: A PSD is not defined in legislation but is usually a written instruction signed by a prescriber, allowing another healthcare professional to supply and/or administer medicines to a named individual. The

prescriber must have assessed that individual on a one-to-one basis and provided directions for treatment. In practice, the prescription itself or a notation in the patients' medical record can serve as a PSD.

Local mechanisms for adjusting medication dosages

Some medicines, including anticoagulants, may require the dose to be titrated or adjusted according to the individual's response. Where this is the case, the prescription must make this requirement explicit.

Dosage adjustments for prescribed anticoagulant medications may be managed by appropriately trained and competent healthcare professionals, using locally produced and approved written protocols. The relevant protocol should be used to advise the individual to adjust the dosage of their medication, if required to maintain optimum treatment. Written protocols have no legal standing in respect of medicines legislation and are subject to local agreements between healthcare professionals and their organisations.

Template protocols should be produced for each medicine by the anticoagulant specialist team, including prescribers and clinicians with a specialist knowledge of the medicine. Written protocols covering advice on dosage adjustment should reflect many of the principles governing other medicines frameworks, such as PGD's, in terms of development, organisational approval and review.

Local protocols, governance and professional responsibilities

Biomedical scientists can play a key role in anticoagulant management services including dosage monitoring and adjustment, under clear local protocols, provided the legal framework, governance processes and professional standards are all in place. Guidance from the Specialist Pharmacy Service (SPS) and the HCPC provides clarity on what is required at both organisational and individual levels.

Protocols and prescribing authority

For a biomedical scientist to adjust a patient's anticoagulant dose, the medicine must have been prescribed by a qualified prescriber, with the requirement for dosage adjustment explicit in the prescription. This would also be supported by the patient being referred by their prescriber to anticoagulant management services for treatment monitoring.

The SPS guidance *Managing dosage adjustments for prescribed medicines* (January 2025) confirms that, where a prescription explicitly allows for titration, trained healthcare professionals can use an agreed local protocol to make adjustments without issuing a new prescription. The protocol acts as a clinical framework, not a legal authority in itself - its validity depends on the original prescription and the prescriber's oversight.

Protocols must be developed by a multidisciplinary team (including the prescriber) and tailored to the individual where required. They should include clear parameters (e.g. INR targets, dose limits, escalation points, and monitoring intervals). Protocols must be formally approved by the organisation (e.g. via clinical governance or medicines management committees), regularly reviewed, and linked to appropriate training and competency frameworks.

Competence, training and scope of practice

Biomedical scientists must only adjust anticoagulant doses if they are trained, competent, and authorised to do so within their organisation. The HCPC Standards of Proficiency for biomedical scientists include:

- Standard 4.3: "make reasoned decisions to initiate, continue, modify or cease treatment… and record the decisions and reasoning appropriately"
- Standard 13.7: "conduct appropriate assessment or monitoring procedures,

treatment, therapy or other actions safely and effectively”

These standards support biomedical scientist involvement in treatment modification, provided it is evidence-based, patient-specific, and within scope.

All biomedical scientists involved in anticoagulant dosage management and adjustment must be able to demonstrate appropriate training, supervised experience, and assessed competence. This may include completion of in-house training, external qualifications or supervised clinical placements. Ongoing CPD and review are essential, particularly where local protocols or technologies evolve.

Communication and record-keeping

Biomedical scientists must communicate dose changes clearly to patients and/or carers using accessible language. Written dosage schedules, calendars or slips should help reinforce instructions - especially when doses vary by day.

Every adjustment must be documented in the patient’s clinical record, including the new dose, date, next test interval and the biomedical scientist making the adjustment. Where appropriate, changes should also be communicated to the patient’s GP or referrer.

SPS guidance recommends that organisations also consider labelling requirements and system design to reduce the risk of dosing errors - particularly where home dosing and telehealth models are in use.

Oversight and audit

Anticoagulant dosing activity by biomedical scientists must sit within a robust governance structure. This includes:

- Formal protocol approval and review

- Competency tracking
- Audit of dosing accuracy and INR outcomes
- Clear lines of accountability and escalation

Regular reviews of individual and service-level performance support both quality assurance and patient safety. Organisations may choose to include prescribing professionals in service oversight - but this is not essential provided that local protocols are safe, signed off and working as intended.

In summary, the SPS guidance and national professional standards support the involvement of biomedical scientists in anticoagulant dosing - under a defined legal framework, with appropriate training and clinical governance in place.

Conclusion

Biomedical scientists in the UK can play a vital role in anticoagulant dosage monitoring and adjustment under well-defined conditions. National guidance from the Specialist Pharmacy Service and professional standards from the HCPC support this role, provided it is done under clear local protocols, with proper training and governance. PGDs are not the route for this work; instead, it requires a prescriber's authority and the evidenced expertise of HCPC-regulated biomedical scientists.

Operating within these frameworks enables biomedical scientists to support timely, safe and effective anticoagulant care. SPS guidance confirms that this approach can optimise treatment and reduce risk. IBMS members involved in anticoagulation services should feel assured that, with the right competencies and local support, their involvement in dosing is appropriate and valued. By following the guidance outlined above, biomedical scientists can confidently contribute to anticoagulant therapy management as an integral part of the healthcare team - improving patient outcomes and upholding the high standards of practice expected in the UK.

REFERENCES

1. Patient Specific Directions (PSD) - SPS - Specialist Pharmacy Service https://www.sps.nhs.uk/articles/patient-specific-directions-psd/
2. Managing dosage adjustments for prescribed medicines – SPS - Specialist Pharmacy Service https://www.sps.nhs.uk/articles/managing-dosage-adjustments-for-prescribed-medicines/
3. Understanding why PGDs cannot be used for dose adjustments - SPS - Specialist Pharmacy Service https://www.sps.nhs.uk/articles/understanding-why-pgds-cannot-be-used-for-dose-adjustments/
4. MPG2 Patient group directions: Full guideline - NICE https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941
5. hcpc-uk.org https://www.hcpc-uk.org/globalassets/resources/standards/standards-of-proficiency---biomedical-scientists.pdf

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