

## Clinical Check Guidance

Issue No. 1

### Who is this guidance for?

The Pharmacy Forum NI has produced this guidance for all pharmacists who undertake clinical checks as part of their pharmacy practice.

### What this guidance will tell you

This guidance highlights the key areas to be considered when undertaking a clinical check:

- Patient characteristics
- Medication regimen
- Administration and monitoring

### The regulatory standard

The Northern Ireland Regulator's *Professional Standards for Sale and Supply of Medicines*<sup>1</sup> set out our professional responsibilities for clinical checking and dispensing medicines. It states pharmacists must ensure that:

- A clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient
- The patient receives sufficient information and advice to enable the safe and effective use of the prescribed medicine
- Appropriate records of clinical interventions are maintained

Providing a safe and quality service is a key principle of the Pharmaceutical Society of NI Code of Conduct, Ethics and Performance for Pharmacists in NI<sup>2</sup>. Patient safety is essential and lies at the heart of quality patient care. Ensuring that a comprehensive clinical check is carried out is a key step in ensuring the safety of the dispensing process.

## What is a clinical check?

Clinical checks involve the identification of pharmacotherapeutic problems through evaluation of all relevant information including patient characteristics, disease states, medication regimen, and where possible laboratory results. The purpose of a clinical check by a pharmacist is to ensure that the medicine supplied is both safe and effective for use by a particular patient in relation to the risk and benefit to the patient<sup>3</sup>.

## Why are clinical checks important?

Pharmacists have a key role in patient safety by ensuring that medicines are prescribed and administered safely. The clinical check of prescribed medicines prior to dispensing is a crucial 'safety net' in preventing patient harm<sup>4</sup>. By using a structured, logical approach to the clinical check, pharmacists can balance the risks and benefits of a prescribed medicine and, in doing so; improve the medicines safety and effectiveness.

### Key Points

- The clinical check is more than a simple accuracy check or check for interactions. It is to ensure that each medicine supplied is both **safe** and **effective** for the intended patient's use:
- Every prescription should be clinically assessed by a pharmacist, based on the information available, to determine for each patient:
  - suitability of the medication
  - unlicensed or off-label use
  - appropriateness of the quantity
  - dose frequency
  - notable omission of intended medication
- safety and therapeutic effectiveness can be effected by:
  - inherent patient factors
  - the type of the medicines involved
  - administration and monitoring of medicines
- Consider clinical appropriateness of generic versus branded medicines<sup>5</sup>
- Information should be obtained from other relevant sources
- Appropriate records of clinical interventions should be maintained

## What records of clinical checks need to be kept?

The Regulatory Standard<sup>1</sup> states that 'appropriate records of clinical interventions are maintained'. The Pharmaceutical Society of NI Code<sup>2</sup> also states that these records should be made 'promptly or as soon as practicable'. Ideally records should be made at the time of the check or intervention.

Record keeping is important for continuity of care, evidence of the benefit of pharmacy input and improving patient care. As best practice pharmacists should keep a record of significant clinical checks and interventions made, including communication or discussions with the prescriber and decisions agreed with the prescriber and other healthcare professionals. Records should also be kept of significant communication between the pharmacist and the patient. Pharmacists should consider recording:

- Patient details
- Pharmacist name
- Prescriber/healthcare professional who was contacted
- Summary of the query and the outcome
- Date and time of communication
- Advice given to the patient if appropriate

### Where should these records be kept?

Records of significant interventions should be kept in the patient's medication record (PMR). This is the most likely place that any pharmacist, for example a locum pharmacist, would find information about specific patients. Depending on the circumstances it may also be appropriate to make this record in an interventions record book, hand-over record book or the prescription register. Pharmacists have a professional duty to keep records of error logs, near miss logs and significant interventions made. Such evidence is required by pharmacy inspectors.

### Clinical checking medication

Here are a few key points to consider for an effective clinical check on a prescribed medicine, however this list is by no means exhaustive, or in order of importance and the pharmacist's experience and clinical judgement are invaluable tools. Examples are included in the boxes.

#### Patient characteristics

##### Age

Doses for specific age ranges are common for elderly and paediatric patients.

- A 4 year old child was prescribed midazolam 10 mg/mL oromucosal solution 2.5 mL when required for seizure. The correct dose should have been 2.5 mg (0.25 mL) i.e. a ten-fold overdose
- An elderly patient was prescribed escitalopram at a dose higher than 10 mg daily
- An elderly patient was prescribed digoxin 250 micrograms daily.

##### Weight (and in some cases body surface area)

Be aware that patients who are at extremes of weight may require lower or higher doses of medicines. Consider where it is appropriate to use adjusted body weight.

- A 6 year old child was prescribed 10 mL twice daily of atenolol syrup 25 mg/5 mL i.e. 50 mg twice daily. The correct dose should have been 10 mg (2 mL) twice daily. Paediatric dose is based on body weight.
- When dosing aminoglycosides in patients at extremes of body weight

## Gender

Physiological differences in genders can impact on the use of medicines and medical devices.

- Antibiotic was not prescribed for a long enough period for UTI in male patients
- Finasteride: crushed, broken or dissolved finasteride tablets should not be handled by women as the drug is film coated to protect from the active ingredient, and this is lost when the coat is compromised
- Not prescribing/dispensing the correct length of catheter

## Pregnant and breastfeeding women

Inappropriate use of medicines in this patient group can lead to severe consequences.

- ACE inhibitors were not stopped during pregnancy
- Inadequate review of valproic acid in women intending to become pregnant
- Codeine in breastfeeding mothers increases risk of opioid toxicity in infants.

## Allergies and intolerances

It is good practice to confirm with a patient that they do not have any allergies to any medicines or ingredients of medicines, particularly if they are newly prescribed. The most obvious example is penicillin.

- A patient with peanut allergy prescribed Toviaz® (fesoterodine fumarate) had an anaphylactic reaction

## Renal and hepatic function

If there is a degree of liver or renal impairment, metabolism and clearance of a medicine could be reduced resulting in the need to adjust the dose.

- Exercise caution with opioid use in patients with reduced hepatic function. Opioids undergo significant first pass metabolism, and as a result lower doses should be used initially with slow up-titration
- Elderly patients are likely to have reduced renal function to some extent. As a result, it is unusual to see digoxin at doses above 125 micrograms daily in this patient group, as digoxin is almost exclusively excreted renally

## Ethnicity

A patient's ethnic origin can affect the choice or dose of a medicine.

- NICE hypertension guidelines recommend first line treatment with a calcium channel blocker for black people with African or Caribbean family origin even if they are under 55

## Co-morbidities

Co-morbid states are perhaps one of the largest determinants of the suitability of a medication and dose. Access to specific information (e.g. hepatic and renal function) may not be readily available to community pharmacists. Consider any relevant information regarding concurrent disease. Additionally, consider specific disease states which preclude the use of medications. Clues to co-morbid states can sometimes be derived from other drugs e.g. if a patient is on a phosphate binder, they are likely to have some renal impairment. Further questioning can elucidate this information.

- A patient with rheumatoid arthritis on methotrexate was prescribed folic acid 400 micrograms weekly instead of folic acid 5 mg weekly
- An elderly patient who was taking an ACE inhibitor was also prescribed trimethoprim and Effercitrate® for a UTI, the combination caused acute renal failure and high potassium
- A patient with asthma was prescribed propranolol
- Patients with Parkinson's disease should not be prescribed anti-emetics such as cyclizine, prochlorperazine or metoclopramide as they can worsen motor function

## Patient preferences

This includes how patients understand their medicines and what they are for and also dietary issues and religious beliefs.

- Vegans may not want to use animal based products such as porcine insulin
- Jehovah's Witness may choose to avoid blood derived products
- Jewish law forbids any oral use of medication containing glycerol, stearates, lactose, and porcine products
- Hindus and Sikhs may choose to avoid medication containing animal products, particularly bovine derived products (for example, gelatin containing capsules)
- Muslims may choose to avoid medication containing porcine products or alcohol

## Medication Regimen

### Indication

There is a need to understand what the medicine has been prescribed for.

- An 11 year old child with ADHD prescribed dexamethasone 2 mg daily instead of dexamfetamine
- A 5 year old child prescribed Oxynorm® liquid 5 mg/ 5 mL instead of oxybutynin 5 mg/5 mL
- A patient prescribed methotrexate for psoriasis without folic acid 5 mg weekly

### Dose and frequency

The dose and frequency need to be checked to ensure they are suitable for the indication and the individual patient.

- A patient prescribed pregabalin 300 mg three times daily over a 5 year period. Maximum dose is 600 mg daily
- A patient with an organ transplant was prescribed Advagraf® 500 micrograms instead of 5 mg resulting in organ failure
- A 39 year old patient with restless legs syndrome was prescribed ropinirole 5 mg five tablets daily i.e. 25 mg. Maximum daily dose for restless legs syndrome is 4 mg daily
- An elderly patient was prescribed Ebixa® Oral Solution (10 mg/mL) 5 ml nocte for 1 week, 10 mL nocte for 1 week then 20 mL nocte thereafter. The dose was stated in millilitres instead of milligrams resulting in 10 times overdose
- Rivaroxaban 15 mg twice daily was prescribed for longer than 21 days in the initial treatment of DVT or PE
- A patient receiving oral morphine 20 mg daily was switched to subcutaneous diamorphine, 90 mg was prescribed instead of the 30 mg dose intended
- A patient was prescribed MXL® 60 mg bd, instead of MST Continus®, MXL® is only licenced as a once daily dose

When a change of dose in a regular medication is noted, it is good practice to confirm either with the patient or the prescriber that the dose change was intentional, and not accidental.

## Duration

Duration of therapy is a critical part of maximizing the benefit of a medication for a patient.

- Loading doses for longer than recommended e.g. amiodarone twice daily
- Combination antiplatelet therapy for longer than intended
- Continuation of oral bisphosphonates for longer than 5 years (increased risk of atypical femoral fracture)
- Antibiotic therapy continued for too long, increasing the risk of complications like *Clostridium difficile*
- Oral iron therapy continued long after their stores have been repleted
- Long-term use of benzodiazepines

## Quantity

The quantity and dose of repeat medicines should be considered together with the prescribing interval to identify potential over or under use of medicines.

- Paracetamol containing medicines were dispensed in quantities over a specific time period that resulted in greater than the maximum dose e.g. more than eight tablets per day

## Adverse drug reactions and interactions

Therapies should be evaluated for any clinically significant drug interactions, duplication of therapy and antagonistic activity. Consider pharmacodynamic and pharmacokinetic interactions, not forgetting to include herbal remedies and over the counter medication.

- A patient taking methotrexate was prescribed trimethoprim
- A patient taking simvastatin 40 mg was prescribed amlodipine 10 mg – dose of simvastatin should have been reduced to 20 mg

## Drug compatibility

Check medicines for physical and pharmacological incompatibility.

- Parecoxib should not be administered in a syringe driver with other medicinal products or water for injection, as this may cause precipitation

## Administration and Monitoring

### Route of administration

Check if the prescribed route is suitable for the patient and if the preparation is available for the route prescribed.

Check for compatibility issues that may arise from administration via a certain route or co-administration with food or other medicines.

- Insulin needles that are incompatible with the insulin pen
- Insulin needles that are the incorrect length
- Parents not supplied with a 1 mL oral syringe for measuring a small volume for a baby
- Phenytoin should not be administered via an enteral feeding tube where possible, owing to its unpredictable absorption profile when given via this route
- Lorazepam tablets can be administered sublingually (off label), but this will only work with certain brands. Additionally, the patient's mouth must be moist enough to allow absorption
- Consider the interaction of enteral feeds with medicines for patients who get their medication via this route

### Medicine administration aids

Check if adherence aids are required and are available e.g. spacer device, eye drop device, braille, large type font on labels, additional information sheets, MCA (Medicines Compliance Aid).

- Dabigatran which should not be removed from the manufacturer's original packaging, was dispensed in medicine administration aids
- Children under 5 years with chronic asthma: corticosteroid and bronchodilator therapy should be delivered by pressurised metered-dose inhaler and spacer device, with a facemask if necessary

### Drugs which require careful monitoring

For medications which require careful monitoring the pharmacist should check the latest results and ascertain if any dosage adjustments are required. Community pharmacists may not have access to latest results. Monitoring of bloods is also required after dose alterations. Reinforcing this information with the patient can help prevent adverse reactions to new medicines.

- For example, digoxin, phenytoin, methotrexate, lithium
- Check with a patient who has just been started on an ACE inhibitor that they are due to have blood tests checked within two weeks of initiation

## Sources of relevant information and useful Medicines information websites.

The actual resources that will be available will depend on the pharmacy setting and it may not be possible to obtain all the information needed. Options include:

### Patient level information

- Prescription and Patient Medication Record
- The Patient and/or their carer
- GP and other healthcare professionals – such as nurse, dietician, microbiologist, physiotherapist
- Methotrexate/oral anticoagulant (warfarin) booklets; insulin passport
- Electronic Care Record
- Medical and nursing care notes/additional ward charts
- Laboratory tests

### Drug information

- BNF and MIMS
- Regional Medicines and Poisons Information Centre - 028 9504 0558

### Useful Websites

- Northern Ireland Medicines Formulary <http://niformulary.hscni.net>
- Medicines Information National Website <http://www.ukmi.nhs.uk>
- Electronic Medicines Compendia (SPC/PIL) <http://www.medicines.org.uk/emc/>
- NICE <http://www.nice.org.uk>
- BNF <http://www.bnf.org>
- MIMS <http://www.mims.co.uk/>

## References

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## Working Group

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## Clinical Check Checklist

### Patient characteristics

Age, particularly children and the elderly  
Pregnant and breastfeeding women  
Weight (and in some cases body surface area)  
Gender  
Allergies and intolerances  
Renal and hepatic function  
Ethnicity  
Co-morbidities  
Patient preferences

### Medication Regimen

Indication  
Dose and frequency  
Duration  
Quantity  
Adverse drug reactions and interactions  
Drug compatibility

### Administration and Monitoring

Route of administration  
Medicine administration aids  
Drugs which require careful monitoring

### Clinical intervention required?

Action as appropriate

### Clinical intervention recorded?

- Patient details
- Pharmacist name
- Prescriber/healthcare professional who was contacted
- Summary of the query and the outcome
- Date and time of communication
- Advice given to the patient if appropriate

