Quality in Practice Committee

Repeat Prescribing

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This guidance represents the view of the ICGP which was arrived at after careful consideration of the evidence available.

The guide does not however override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of individual patients in consultation with the patient and/or guardian or carer.

Evidence-Based Medicine

Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

In this document you will see that evidence and recommendations are graded according to levels of evidence (Level 1 – 5) and grades of recommendations (Grades A-C) respectively. This grading system is an adaptation of the revised Oxford Centre 2011 Levels of Evidence.

Levels of evidence

Level 1: Evidence obtained from systematic review of randomised trials

Level 2: Evidence obtained from at least one randomised trial

Level 3: Evidence obtained from at least one non-randomised controlled cohort/follow-up study

Level 4: Evidence obtained from at least one case-series, case-control or historically controlled study

Level 5: Evidence obtained from mechanism-based reasoning

Grades of recommendations

A Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels 1, 2)

B Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels 3, 4).

C Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level 5).

Due to the paucity of research on repeat prescribing, many of the recommendations in this guide are based on general reasoning rather than definitive research i.e. equivalent to Evidence level 5 and they are, therefore, Grade C recommendations

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Section 1 Introduction

1.1 Background

General practitioners in many countries have developed systems whereby patients can obtain prescriptions for medicines without the need for a face-to-face consultation (indirect prescriptions).

The proportion of indirect prescriptions varies from practice to practice and from doctor to doctor. Various studies have estimated the proportion as being in the range 29-75% of all items prescribed.[1] Although there is no very recent data, it is likely that this proportion is rising over time and the proportion in older patients (e.g. over 75 years) is generally higher than it is in younger patients – up to 90% in patients over 75yr. in one study.[2]

While the issuing of prescriptions without a consultation represents a major convenience for the patient and can save time for the doctor, it does carry significant additional risks of medication error over and above that which might occur when a prescription is issued during a face-to-face encounter. It is important, therefore, that doctors have repeat prescribing systems in place which minimise this potential for harm to patients.

1.2 Aims of the Document

The aims of this document are to:

- highlight the risks to patient safety associated with indirect and/or repeat prescribing
- make recommendations regarding how repeat prescribing systems should be established, operated and maintained to reduce the risk of harm to patients while ensuring maximum efficiency in the administration of the practice

1.3 Key Points/ Recommendations

- Practices should develop clear repeat prescribing policies and procedures that are written and available to staff, patients and carers
- The repeat prescribing policy needs to deal with issues of
    - how repeat prescriptions are authorised and reauthorised
    - how the current lists of medicines allowed on repeat prescription are communicated to staff, patients, carers and pharmacists
    - how repeat prescription requests are handled
    - how prescriptions are generated
    - how prescriptions are checked and signed by doctors (authorised)
    - how, when and by whom medication reviews are conducted
    - how the repeat prescribing system is audited and quality assured

- A regular (at least annual) medication review needs to be carried out to ensure that
    - The medicines prescribed are still tolerated, effective and required
    - Any monitoring required has occurred and the results of same are satisfactory
    - The prescription remains correct with regard to dosage, duration, absence of contra-indications and interactions etc.
    - The patient's condition remains stable such that continued repeat prescribing is deemed safe and justified
    - The patient understands all aspects of their medications and has their concerns explored and dealt with

- The repeat prescribing system should include a method for incident reporting and recording and be subject to regular audit and quality review

Section 2: Risks of Indirect Repeat Prescribing

Prescribing medicines is fraught with an inherent potential for error and consequent harm to patients (**see Figure 1**). When medicines are prescribed without direct observation or contact with the patient, the potential for error may go undetected and lead to more substantial or sustained harm to the patient.

Figure 1: Risks of medicines

- Side effects (ADRs – adverse drug reactions)
  - Known/ anticipated
  - Unknown/ unanticipated
- Contra-indications – current or past illnesses
- Interactions
  - Drug- drug interactions (including interactions with non-prescribed drugs)
  - Drug- food interactions
- Prescription errors
  - Wrong dose
  - Incomplete/ insufficient dose
  - Excessive dose

.

Although few studies of repeat prescribing have focused on patient harms, one such study in Finland found that such problems were fairly common among patients in receipt of repeat prescriptions.[3] **[Level 3]**

Studies of the operational aspects of repeat prescribing systems consistently reveal:

- Lack of regular or sufficient review by doctors of patients on repeat prescriptions
- Lack of adherence to the expected intervals between issuing of repeat prescriptions with evidence of both underuse (excessively long intervals between issuing of prescriptions leading to undersupply) and overuse (excessively short intervals between issuing of prescriptions leading to oversupply)
- Unauthorised supply of medicines on repeat prescriptions
  - Including the issuing of medicines from hospital prescriptions without GP authorisation and
  - Issuing of medicines on patient request without doctor's sanction
- Prescribing errors such as
  - inclusion of unintended items
  - omission of items that should have been included
  - errors of dose, formulation or amount
- Issuing of repeat prescriptions to the wrong patient.[2] **[Level 3]**

How to improve repeat prescribing systems

Twenty two studies, of which fourteen were randomised controlled trials, aimed at improving the care of patients on repeat medicines were systematically reviewed by De Smet and Dautzenberg.[2] Findings revealed that the most effective interventions involved the review of medicines by a pharmacist supplemented by either access to the patient record or an interview with the patient. **[Level 1]**

More recent detailed qualitative research has highlighted the issue of 'exceptions' not formally covered by the practice's repeat prescribing policy and the complex and important role fulfilled by reception staff.[4] To improve repeat prescribing systems a detailed and sophisticated assessment and understanding of how they are actually operating on the ground is required. **[Level 5]**

Section 3: Features of a Repeat Prescribing System

A seminal document entitled 'Saving time, helping patients: a good practice guide to repeat prescribing', published by the UK National Prescribing Centre in 2004, deals comprehensively with the key issues in designing a safe and effective repeat prescribing system.[5]

The key areas identified for consideration are:

1. Authorisation/ Re-authorisation of Repeat Prescriptions
   – how the repeat prescription gets authorised

2. Handling of repeat prescription requests
   – how the patient may request and the repeat prescription
   - turnaround time for completion of signed prescription ready for collection
   - procedures for collection of repeat prescription

3. Authorisation and other checks
- – how the administrative staff can know whether or not the repeat prescription is authorised and what the procedures are if it is not

4. Generation and signing of repeat prescription

5. Medication review
   – when and how the doctor reviews the patient's medications

   – what is the expected use of the medicine by the patient and how this communicated to him or her

6. Quality assurance of the repeat prescribing system
   - audit and review

7. The community pharmacist's role

Zermansky identified that a practice repeat prescribing system needs to define and clarify the respective responsibilities and tasks of the practice staff; administrative staff and clinical staff (i.e. doctors / nurses).[6] Acceptance of patient requests and the physical generation of a prescription are tasks usually delegated to reception/ secretarial staff. Checking on whether the prescription is authorised, that the prescription is being sought at the appropriate interval (compliance check), the checking of the review date and flagging patients for review and ensuring reviews are undertaken as scheduled are seen as managerial tasks although elements of these may also be delegated (with appropriate training and safeguards) to reception/ secretarial staff. The clinical control is the preserve of the doctor and involves decisions about initial authorisation, medication review, reauthorisation and prescription signing.

3.1 Authorisation/ Re-authorisation of Repeat Prescriptions

It should be clear who may authorise or re-authorise repeat prescriptions and how a record of this is added to the patient's medical record and repeat medicines list. Authorising or re-authorising a repeat prescription should, ideally, be undertaken face-to-face by a doctor who is familiar with the patient. Agreement on the need for the medicine and its review should be discussed and agreed with the patient as part of a medication review process (see below). ***Blank prescriptions should never be signed for later completion by either the doctor or a delegate.*** To do so is breach of terms of service. The ultimate responsibility for a prescription being issued to a patient lies with the doctor who signs the prescription.

Patients and their carers should also be involved in decisions about their medicines. Any change of medication on the repeat prescription should, ideally, lead to a medication review at a face-to-face consultation to ensure that the patient is clear about their new medication regimen. This is especially important after a hospital visit or admission where additions and deletions of repeat medications are particularly common.

The documentation of a repeat prescription in the medical record should include the indication and information on any monitoring or special precautions required. Duration should also be recorded. Use of 'prn' or 'as required' is best avoided but, if deemed appropriate, a maximum daily dose must be stated along with monitoring of consumption at each reauthorisation to avoid oversupply.

Issues to be covered with a patient before initiating a repeat prescription include:

- Indication or rationale for the medicine
- Confirmation of the absence of any allergy or sensitivity to the drug
- Formulation, dosage and quantity of the medicine
- Duration of the drug therapy
- Adverse reactions, interactions, contra-indications and special precautions
- Any laboratory monitoring that will be required and how and when it will be provided
- Number of repeats/ length of time between reviews
- Exploration of any patient concerns
- Explanation of the repeat prescribing system and provision of an information leaflet
- Date for clinical review with the proviso that the patient may return at any time if he/she has a concern

Information also needs to be given to patients to be retained by them e.g. the provision of a patient held medication record. This should include information on which drugs the patient is on; what they are for; the dosing regimen; and what the patient should do in the event of experiencing adverse events. Cards with this sort of information already exist for certain drugs such as warfarin, corticosteroids and methotrexate.

It is particularly important to keep track of amendments, additions and deletions. Medical records should always accurately reflect the currently authorised repeat medicines and practice staff, the patient, carers and community pharmacists also need to be kept up to date with the current authorised repeat prescription.

Externally generated prescriptions, such as hospital prescriptions, require special attention to all of the above issues. Hospital prescriptions often get transferred into the repeat prescribing system without a face to face consultation. While this is not ideal, the risks of transcriptions errors leading to incorrect medication administration can be reduced by attaching the actual hospital prescription to the newly issued GMS prescription. Where information from the hospital is supplied highlighting additions, deletions and changes to the

patient's previous prescription this information should be added to the medical record and also supplied to the pharmacy.

3.2 Handling of repeat prescription requests

Practices need to develop policies around how repeat prescription requests are handled.

- Who should be allowed to request a repeat prescription?
  – the patient, patient's representative, others?
- How are they allowed to make requests?
  – written, phone, text, e-mail; on a standardised request form? (need to consider confidentiality)
- What patient details are required: e.g.
  - Name, address, date of birth
  - Medicines requested including dose and frequency
  - Number of months prescription required (– see Medication Review below)
- When are they allowed to make requests?
  - mornings only, afternoons only or at a dedicated time in the day (possibly via a dedicated telephone line)?
- What will be the turnaround time for requests? - insufficient time may not allow for proper clinical review but excess time may lead to more pressure to override the system on an urgency basis
- How will the patient be informed about the repeat request system?
  – word of mouth; practice leaflet; repeat prescribing leaflet; practice website?

3.3 Authorisation and other Checks

When medications are requested there needs to be a process whereby it is checked that the medication has been authorised by a doctor. Where the medicine has never been authorised before the patient should be seen by a doctor. Where the authorisation has expired, the patient should also be seen by a doctor but provision may need to be made to continue the supply of medicine until the patient can be seen. Where the medicine is authorised, a prescription form may be generated and given to the doctor for assesment and signature.

Compliance checks also need to be in place to identify if patients are requesting medicines before they are due (oversupply) or if they are requesting medicine when they are overdue (undersupply). Compliance issues need to be flagged to prescribing doctors and a process put in place to oblige the patient to attend a face-to-face consultation. Information about why a review is needed in these circumstances could be provided to patients in the form of a leaflet. If the doctor is satisfied that an immediate review is not needed (e.g. because the patient has been seen recently) the review period should be reset.

Other Checks Required:

When generating repeat prescriptions the following information needs to be checked:

- Identity of patient matches that of the person named on the prescription
- The repeat medicines requested are those currently authorised and are not based on an out of date list of repeat medicines
- Drug name, dose, dosing frequency, quantity and duration are within expected and specified limits
- Indication is a licensed indication (or some rationale specified for any unlicensed use)

- There are no contra-indications that have emerged since initial authorisation e.g. no new relevant illnesses

3.4 Generation and Signing of Repeat Prescriptions

When a request for an authorised repeat prescription is made a prescription will usually be generated (most commonly computer generated) and left for a doctor to assess and sign. This process should be streamlined so that prescriptions are not mislaid or fail to be signed. Both the administrative staff and the doctor signing the prescription should look out for prescribing errors – such as wrong medicine, wrong dosage etc. The doctor signing the prescription should, ideally, be familiar with the patient and should, in all instances, have access to the patient's record at the time of signing. Doctors should undertake this task in a quiet area and have protected time to do it. Where patients are on multiple medicines, it is desirable that quantities of medicines should be prescribed in such a way as to synchronise supplies of medicines. While this can be difficult to achieve in ill patients whose medicines may change frequently, once patients' conditions stabilise it will usually be possible to bring supplies of medicines into alignment.

3.5 Medication Review

Patients receiving long term medicines through the repeat prescribing system need to be reviewed at regular intervals. The precise interval will vary according to the patient's disease(s) but generally speaking it is believed that the interval between reviews should not be more than one year. The number of repeats allowed can usefully be tied to the review interval. Thus patients needing only one annual review (e.g. patients stabilised on Thyroxine) could be put on a 12 months repeat prescription. Patients needing six monthly review (e.g. patients on the oral contraceptive) could be put on a 6 month repeat. Most patients, though, seem to require somewhat more frequent review and the commonest default interval is three months which is then ensured by issuing a 3 monthly repeat. Prescriptions should be repeated at whatever interval is required by the need for review which, in turn, needs to be judged on a case-by-case basis.

Three levels of review have been described. These are:-

- **Level 1:** prescription review – a review of the patient's list of current medications whereby medicines are reviewed for dosing errors, possible interactions etc.
  Level 2: treatment review – a review of the patient's current medications with respect to the conditions for which they were prescribed – this requires access to the patient record.
- **Level 3**: Full medication review – a review of the patient's current medications during a face to face consultation with the patient which allows for review of the medications' effectiveness, detection of adverse reactions, interactions etc.

For all of these types of medication reviews it is helpful to know what medicines or combinations of medicines, or combinations of medicines and conditions are most likely to be the source of clinical problems for the patient. A number of tools to aid in this process have been developed over the years although most of these were developed originally as research tools. STOPP [7] (Screening Tool of Older Persons potentially inappropriate Prescribing) is the latest and possibly most effective tool for the detection of potentially inappropriate prescribing in older people. Other tools include the RCGP Prescribing Safety Indicators that were developed by Professor Tony Avery and colleagues at the Universities of Nottingham and Manchester. See Appendix 1 for a full

list of medication review tools and a detailed explanation of how to apply the STOPP tool and the RCGP Prescribing Safety Indicators.

The medication review process should also address the following:

- Has the condition for which the medicine been prescribed improved or, at least, remained stable?
- Is the medicine still required and if so, at the same dosage/ frequency?
- Is the medicine still tolerated?
- Has any necessary monitoring (e.g. blood tests) been carried out and are the results of any monitoring tests satisfactory?
- Are there undesirable combinations of medicines on the repeat prescriptions e.g. drugs that interact?
- Are doses and intervals for taking the medicine correct?
- Is the patient's condition stable enough to indicate that issuing of further prescriptions without face-to-face contact is warranted?
- Does the patient understand what the medicine is for, how to take it, what adverse effects to look out for, and what to do if the medicine is not effective or is causing adverse effects?
- Has the patient any other concerns?
- Agree date for next review

3.6 Quality Assurance of the Repeat Prescribing System

In order to be quality assured any repeat prescribing system needs to be managed by an identified clinical lead,have formal staff training, incident reporting and audit review processes in place.

All staff involved in the repeat prescribing system should be informed of the design of the overall system and trained in detail on the aspects of the system with which they are directly involved. They should be capable of describing to patients how the system operates. An incident reporting mechanism should be in place for the recording of critical incidents and near misses in relation to repeat prescribing. Staff need to be informed of the incident reporting mechanism, including how and where incidents should be recorded. All staff involved within the system need to be encouraged to feedback to the clinical lead on their experience of the operation of the system and should feel free to make suggestions for its improvement.

The critical incident records should include a patient identifier (e.g. initials or practice number) and details of the patients' medicines regimen and other relevant information about the incident. Incidents should be recorded on the day they occur or as soon as possible thereafter. Serious incidents, where there is a risk of immediate patient harm or a patient complaint, must be notified ***immediately*** to the clinical lead who should initiate any appropriate action. Less serious incidents can be discussed at the next available staff meeting. Review of incidents should be focused on resolving the immediate issue but also on steps to prevent similar future events.

In addition, the functioning of the entire repeat prescribing system should be reviewed at regular (perhaps annual) intervals by means of an audit. While each General Practice surgery will have it's own individual repeat prescribing system in place, there are many commonalities among systems. The ICGP Repeat Prescribing Sample Audit provides examples of many of the administrative and clinical criteria that might form the basis for an audit of a practice's repeat prescribing system.

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APPENDIX 1

Tools to aid medication review

One of the requirements of a safe and effective repeat prescribing system is that patients on long term medication received via the repeat prescribing system have their medicines reviewed at regular intervals. As noted in the Quick Reference Guide there are three levels at which such a review can be conducted.

- Level 1 – Prescription Review – a review of the patient's list of current medications
- Level 2 – Treatment Review – a review of the patient's current medications in the light of their clinical record (i.e. with information from the record on the diagnoses for which the medicines have been prescribed)
- Level 3 – Full Medication Review – a review of the patient's current medications during a face to face consultation with the patient which allows for review of the medications' effectiveness, detection of adverse reactions, interactions etc.

For all of these types of medication reviews it is helpful to know what medicines or combinations of medicines, or combinations of medicines and conditions are most likely to be the source of clinical problems for the patient. A number of tools to aid in this process have been developed over the years although most of these were developed originally as research tools. Several of the better known of these tools that have gone on to be applied in the clinical (as opposed to purely research) setting have been developed specifically for the elderly population. This is not surprising as the elderly are known to be particularly vulnerable to what have been dubbed preventable drug related morbidity (PDRM). Table 1 below lists a selection of such tools that may be used to judge the safety and/or appropriateness of prescribing. Some of these tools are easier than others to use in the context of a medication review such as might be undertaken as part of the operation of a repeat prescribing. Most require information on the patient's clinical conditions in addition to the medication(s) prescribed in order to arrive at a judgement and, hence, are most suited to a Level 2 or Level 3 review. For some, though, there is a version which can be applied solely the list of medicines and, hence, can be used for Level 1 (i.e. prescription only) review.

Tables 2 and 3 list all the criteria used in two of these tools. Table 2 is the STOPP (Screening Tool of Older Persons potentially inappropriate Prescribing) which was developed by a team of physicians and pharmacists in University College Cork.[7] It is the latest and possibly most effective tool for the detection of potentially inappropriate prescribing in older people. Table 3 lists what have become known as the RCGP Prescribing Safety Indicators that were developed by Professor Tony Avery and colleagues at the Universities of Nottingham and Manchester.[8] These were derived, in part, by review of all existing measures (as listed in Table 1) and honing them down to those applicable to UK general practice and which pertain specifically to known safety risks.

There are also tools to highlight medicines which ought to be prescribed for patients and which they may not be receiving (potential prescribing omissions, PPOs). One such tool is the START tool – Screening Tool to Alert doctors to Right Treatment – which was

developed by the same team who developed the STOPP criteria. However, the use of these tools is beyond the scope of this guide.

Table 1 – Potential Sources of Prescribing Indicators

Sources of Potential Prescribing Indicators	Comments
Beers criteria	The granddaddy of prescribing indicators. Developed in the US in the 1990s specifically to detect potential prescribing problems in older people. Contains many indicators relating to drugs not prescribed here or no longer prescribed.
British National Formulary	Highly regarded source of reasonably independent prescribing information. Does not provide prescribing indicators as such but is a good (succinct, reliable, objective) reference source for deciding on whether a particular drug is a good/ best choice for a particular condition
Medication Appropriateness Index	Developed in the US. Applicable to all prescribing (not just elderly). A mixture of a schema for picking up prescribing errors (correct dose, route etc.) and a schema requiring a lot of clinical judgement on whether a medicine is indicated or not. Requires diagnostic information so not suited to Level 1 review.
Prescribing Appropriateness Index	Developed in the UK (Manchester) mainly by pharmacists. Quite similar to Medication Appropriate Index but developed using a consensus building approach with UK GPs.
National Patient Safety Agency (UK) documents (various)	The National Patient Safety Agency has produced a number of reports highlighting specific medication problems that have led to identified cases of prescribing related harm. NPSA did not produce indicators as such but their work has been fed into the RCGP Indicators – see below.
National Service Framework for Older People – Medicines Related Aspects (UK)	This framework highlighted the risks of prescribing related harm in the elderly and has suggested procedures to reduce same. It does not specify prescribing indicators as such but they can be inferred from the framework.
PINCER Trial indicators	The PINCER trial was a large RCT conducted in the UK of a pharmacist-led intervention to identify and correct prescribing problems in general practice. The trialists used a range of indicators of hazardous prescribing, inadequate monitoring and potentially hazardous dosing instructions. These indicators and the PINCER trial have fed very substantially into what became the RCGP indicators (see below).
Preventable drug-related morbidity indicators	Derived from a large epidemiological study using GP data to identify instances where potentially hazardous prescribing could be shown fairly definitively to have caused actual morbidity (preventable drug related morbidity). This led to identification of the most frequently problematic combinations of drugs and conditions.
Quality and Outcomes Framework (UK)	The Quality and Outcomes Framework (QOF) had a number of prescribing indicators mostly relating to drugs that ought to be prescribed if a patient was identified as having a particular risk factor (e.g. statins in hyperlipidaemia) i.e. PPOs. Also has some general indicators about conduct of medication reviews but does not specify their content.
STOPP	Invented in Cork ☺ Relates to elderly (>65yrs) specifically. Some of the indicators require diagnosis for application but some can be applied to prescription only (and, hence, can be used for Level 1 review). Most are fairly GP relevant (even though developed in hospital setting) but some can be time consuming to apply.
RCGP Prescribing Safety Indicators	Derived using insights and indicators from sources cited above (in this table) Selected using a consensus building approach but also evaluated for GP relevance, ease of application (using UK GP computer systems particularly), focus on safety and feasibility of use in GP revalidation

Table 2 - STOPP (Screening Tool of Older People's potentially inappropriate Prescriptions.

The following have been identified as potentially inappropriate in persons aged ≥ 65 years of age

A. Cardiovascular System

1. Digoxin at a long-term dose > 125µg/day with impaired renal function∗ (increased risk of toxicity).

2. Loop diuretic for dependent ankle oedema only i.e. no clinical signs of heart failure *(no evidence of efficacy,compression hosiery usually more appropriate).*

3. Loop diuretic as first-line monotherapy for hypertension *(safer, more effective alternatives available).*

4. Thiazide diuretic with a history of gout *(may exacerbate gout).*

5. Non-cardioselective beta-blocker with Chronic Obstructive Pulmonary Disease (COPD) *(risk of bronchospasm)*.

6. Beta-blocker in combination with verapamil *(risk of symptomatic heart block).*

7. Use of diltiazem or verapamil with NYHA Class III or IV heart failure *(may worsen heart failure).*

8. Calcium channel blockers with chronic constipation *(may exacerbate constipation).*

9. Use of aspirin and warfarin in combination without histamine H2 receptor antagonist (except cimetidine because of interaction with warfarin) or proton pump inhibitor *(high risk of gastrointestinal bleeding).*

10. Dipyridamole as monotherapy for cardiovascular secondary prevention *(no evidence for efficacy).*

11. Aspirin with a past history of peptic ulcer disease without histamine H2 receptor antagonist or Proton Pump Inhibitor *(risk of bleeding).*

12.Aspirin at dose > 150mg day *(increased bleeding risk, no evidence for increased efficacy).*

13. Aspirin with no history of coronary, cerebral or peripheral arterial symptoms or occlusive arterial event *(not indicated).*

14. Aspirin to treat dizziness not clearly attributable to cerebrovascular disease *(not indicated).*

15. Warfarin for first, uncomplicated deep venous thrombosis for longer than 6 months duration *(no proven added benefit).*

16. Warfarin for first uncomplicated pulmonary embolus for longer than 12 months duration *(no proven benefit).*

17. Aspirin, clopidogrel, dipyridamole or warfarin with concurrent bleeding disorder *(high risk of bleeding).*

∗ GFR <50ml/min.

B. Central Nervous System and Psychotropic Drugs.

1. Tricyclic antidepressants (TCA's) with dementia *(risk of worsening cognitive impairment).*

2. TCA's with glaucoma *(likely to exacerbate glaucoma).*

3. TCA's with cardiac conductive abnormalities *(pro-arrhythmic effects).*

4. TCA's with constipation *(likely to worsen constipation).*

5. TCA's with an opiate or calcium channel blocker *(risk of severe constipation).*

6. TCA's with prostatism or prior history of urinary retention *(risk of urinary retention).*

7. Long-term (i.e. > 1 month), long-acting benzodiazepines e.g. chlordiazepoxide, fluazepam, nitrazepam, chlorazepate and benzodiazepines with long-acting metabolites e.g. diazepam *(risk of prolonged sedation, confusion, impaired balance, falls).*

8. Long-term (i.e. > 1 month) neuroleptics as long-term hypnotics *(risk of confusion, hypotension, extra-pyramidal side effects, falls).*

9. Long-term neuroleptics (> 1 month) in those with parkinsonism *(likely to worsen extra-pyramidal symptoms)*

10. Phenothiazines in patients with epilepsy *(may lower seizure threshold).*

11. Anticholinergics to treat extra-pyramidal side-effects of neuroleptic medications *(risk of anticholinergic toxicity).*

12. Selective serotonin re-uptake inhibitors (SSRI's) with a history of clinically significant hyponatraemia *(noniatrogenic hyponatraemia <130mmol/l within the previous 2 months).*

13. Prolonged use (> 1 week) of first generation antihistamines i.e. diphenydramine, chlorpheniramine, cyclizine, promethazine *(risk of sedation and anti-cholinergic side effects).*

C. Gastrointestinal System

1. Diphenoxylate, loperamide or codeine phosphate for treatment of diarrhoea of unknown cause *(risk of delayed diagnosis, may exacerbate constipation with overflow diarrhoea, may precipitate toxic megacolon in inflammatory bowel disease, may delay recovery in unrecognised gastroenteritis).*

2. Diphenoxylate, loperamide or codeine phosphate for treatment of severe infective gastroenteritis i.e. bloody diarrhoea, high fever or severe systemic toxicity *(risk of exacerbation or protraction of infection)*

3. Prochlorperazine (Stemetil) or metoclopramide with Parkinsonism *(risk of exacerbating Parkinsonism).*

4. PPI for peptic ulcer disease at full therapeutic dosage for > 8 weeks *(earlier discontinuation or dose reduction for maintenance/prophylactic treatment of peptic ulcer disease, oesophagitis or GORD indicated).*

5. Anticholinergic antispasmodic drugs with chronic constipation *(risk of exacerbation of constipation).*

D. Respiratory System.

1. Theophylline as monotherapy for COPD. *(safer, more effective alternative; risk of adverse effects due to narrow therapeutic index)*

2. Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate-severe COPD *(unnecessary exposure to long-term side-effects of systemic steroids).*

3. Nebulised ipratropium with glaucoma *(may exacerbate glaucoma).*

E. Musculoskeletal System

1. Non-steroidal anti-inflammatory drug (NSAID) with history of peptic ulcer disease or gastrointestinal bleeding,unless with concurrent histamine H2 receptor antagonist, PPI or misoprostol *(risk of peptic ulcer relapse).*

2. NSAID with moderate-severe hypertension (moderate: 160/100mmHg – 179/109mmHg; severe: ≥180/110mmHg) *(risk of exacerbation of hypertension).*

3. NSAID with heart failure *(risk of exacerbation of heart failure).*

4. Long-term use of NSAID (>3 months) for relief of mild joint pain in osteoarthtitis *(simple analgesics preferable and usually as effective for pain relief)*

5. Warfarin and NSAID together *(risk of gastrointestinal bleeding).*

6. NSAID with chronic renal failure∗ (risk of deterioration in renal function). ∗ estimated GFR 20-50ml/min.

7. Long-term corticosteroids (>3 months) as monotherapy for rheumatoid arthrtitis or osterarthritis *(risk of major systemic corticosteroid side-effects).*

8. Long-term NSAID or colchicine for chronic treatment of gout where there is no contraindication to allopurinol *(allopurinol first choice prophylactic drug in gout)*

F. Urogenital System

1. Bladder antimuscarinic drugs with dementia *(risk of increased confusion, agitation).*

2. Bladder antimuscarinic drugs with chronic glaucoma *(risk of acute exacerbation of glaucoma).*

3. Bladder antimuscarinic drugs with chronic constipation *(risk of exacerbation of constipation).*

4. Bladder antimuscarinic drugs with chronic prostatism *(risk of urinary retention).*

5. Alpha-blockers in males with frequent incontinence i.e. one or more episodes of incontinence daily *(risk of urinary frequency and worsening of incontinence).*

6. Alpha-blockers with long-term urinary catheter *in situ* i.e. more than 2 months *(drug not indicated).*

G. Endocrine System

1. Glibenclamide or chlorpropamide with type 2 diabetes mellitus *(risk of prolonged hypoglycaemia).*

2. Beta-blockers in those with diabetes mellitus and frequent hypoglycaemic episodes i.e. ≥ 1 episode per month *(risk of masking hypoglycaemic symptoms).*

3. Oestrogens with a history of breast cancer or venous thromboembolism *(increased risk of recurrence)*

4. Oestrogens without progestogen in patients with intact uterus *(risk of endometrial cancer).*

H. Drugs that adversely affect those prone to falls (≥ 1 fall in past three months)

1. Benzodiazepines *(sedative, may cause reduced sensorium, impair balance).*

2. Neuroleptic drugs *(may cause gait dyspraxia, Parkinsonism).*

3. First generation antihistamines *(sedative, may impair sensorium).*

4. Vasodilator drugs known to cause hypotension in those with persistent postural hypotension i.e. recurrent > 20mmHg drop in systolic blood pressure *(risk of syncope, falls).*

5. Long-term opiates in those with recurrent falls *(risk of drowsiness, postural hypotension, vertigo).*

I. Analgesic Drugs

1. Use of long-term powerful opiates e.g. morphine or fentanyl as first line therapy for mild-moderate pain *(WHO analgesic ladder not observed).*

2. Regular opiates for more than 2 weeks in those with chronic constipation without concurrent use of laxatives *(risk of severe constipation).*

3. Long-term opiates in those with dementia unless indicted for palliative care or management of moderate/severe chronic pain syndrome *(risk of exacerbation of cognitive impairment).*

J. Duplicate Drug Classes

Any regular duplicate drug class prescription e.g. two concurrent opiates, NSAID's, SSRI's, loop diuretics, ACE inhibitors *(optimisation of monotherapy within a single drug class should be observed prior to considering a new class of drug).* This excludes duplicate prescribing of drugs that may be required on a prn basis e.g. inhaled beta2 agonists (long and short acting) for asthma or COPD, and opiates for management of breakthrough pain.

Table 3 – RCGP Prescribing Safety Indicators - indicators rated as valid for assessing the prescribing safety of GPs

A: Cardiovascular and respiratory disease

1. Beta-blocker to a patient with asthma (excluding patients who also have a cardiac condition, where the benefits of beta-blockers may outweigh the risks

2. Short-acting nifedipine (excluding patients with Raynaud's disease)

3. Digoxin at a dose >125 µg daily in a patient with renal impairment (for example, CKD3 or worse)

4. Digoxin at a dose of >125 µg daily for a patient with heart failure who is in sinus rhythm

5. Diltiazem or verapamil in a patient with heart failure

6. Aspirin at a dose >75 mg daily for ≥1 month in a patient aged >65 years

7. Long-acting beta-2 agonist inhaler to a patient with asthma who is not also prescribed an inhaled corticosteroid

B: Central nervous system (including analgesics)

8. Aspirin to a child aged ≤16 years

9. Metoclopramide or prochlorperazine in a patient with Parkinson's disease

10. Benzodiazepine or Z-drug for ≥21 days in a patient aged >65 years who is not receiving benzodiazepines or Z-drugs on a long-term basis

11. Initiation of benzodiazepine or Z-drugs basis for ≥21 days in a patient >65 years with depression

C: Anti-infective agents

12. Mefloquine to a patient with a history of convulsions

D: Women's health and urinary disorders

13. Combined hormonal contraceptive to a woman with a history of venous or arterial thromboembolism

14. Oral ortransdermal oestrogens to a woman with a history of breast cancer

15. Oral ortransdermal oestrogen without progesterone in a woman with an intact uterus

16. Combined hormonal contraceptive to a woman aged ≥35 years who is a current smoker

17. Combined hormonal contraceptive to a woman with body mass index ≥40

E: Musculoskeletal

18. NSAID, without co-prescription of an ulcer healing drug, to a patient with a history of peptic ulceration

19. NSAID in a patient with heart failure

20. NSAID in a patient with chronic renal failure (for example, CKD3 orworse)

21. Long-term (>28 days) NSAID (except for ibuprofen ≤1200 mg daily) in a patient aged >65 years

F: Hazardous co-prescriptions, interactions, and allergy

22. Warfarin in combination with an oral NSAID

23. Phosphodiesterase type-5 inhibitor (for example, sildenafil) to a patient who is also receiving a nitrate or nicorandil

24. Clarithromycin or erythromycin to a patient who is also receiving simvastatin, with no evidence that the patient has been advised to stop the simvastatin while taking the antibiotic

25. Potassium salt or potassium sparing diuretic (excluding aldosterone antagonists) to a patient who is also receiving an ACE inhibitor or angiotensin II receptor antagonist

26. Verapamil to a patient who is also receiving a beta-blocker drug

27. Penicillin-containing preparation to a patient with a history of allergy to penicillin

G: Laboratory test monitoring

28. Warfarin to a patient without a record of international normalised ratio having been measured within the previous 12 weeks (excluding patients who self monitor)

29. Amiodarone without a record of liver function being measured in the previous 9 months

30. Amiodarone without a record of thyroid function being measured within the previous 9 months

31. ACE inhibitor or angiotensin II receptor antagonist without a record of renal function and electrolytes being measured prior to starting therapy

32. Lithium without a record of a lithium level being measured within the previous 6 months

33. Methotrexate without a record of a full blood count within the previous 3 months

34. Methotrexate without a record of liver function having been measured within the previous 3 months

Operationalising STOPP

The STOPP tool highlights issues with the following drugs/ classes of drugs:-

- Digoxin
- Loop diuretics
- Thiazide diuretics
- Beta-blockers
- Calcium channel blocker and specifically diltiazem and verapamil
- Vasodilators
- Asprin
- Warfarin
- Clopidrogel
- Dipyridamole
- Tricyclic anti-depressants
- Benzodiazepines
- Neuroleptics
- Phenothiazines
- Anti-cholinergics
- SSRIs
- First generation antihisamines (e.g. diphenydramine, cyclizine, chlorpheniramine, promethazine)
- Diphenoxylate
- Loperamide
- Codeine
- Prochlorperazine (Stemetil)
- Metoclopramide
- PPIs (protein pump inhibitors)
- Anticholinergic antispasmodics
- Theophylline
- Systemic corticosteroids
- Nebulised itrapropium
- Non-steroidal anti-inflammatories
- Long term corticosteroids for RA or OA
- Colchicine
- Bladder anti-muscarinics
- Alpha-blockers
- Glibenclamide
- Chlorpropamide
- Oestrogens
- Opiates

Thus, in conducting a medication review of your repeat prescribing one should first look out for the occurrence of any of these drugs or drug classes in your patients aged over 65 years. If the patient is on any of the drugs listed one should then look at the STOPP criteria to see if they have a relevant condition which may make use of the drug problematic or if they are on any other drug with which the index drug should not be co-prescribed.

Drug or Drug Class	**Issue to be checked before repeat prescribing in patients over 65 years**
Digoxin	Do not prescribe in dose >125mcgm daily in patients with impaired renal function (GFR <50ml/min)
Loop diuretics	Do not prescribe for dependent ankle oedema only (i.e. without other signs of heart failure) Do not prescribe as first line monotherapy for hypertension
Thiazide diuretics	Do not prescribe in pateints with a history of gout
Beta-blockers	Do not prescribe non-cardioselective betablocker with COPD Avoid combination with verapamil Do not prescribe in patients with diabetes and frequent hypoglycaemic episodes
Calcium channel blockers	Avoid with chronic constipation
Diltiazem and verapamil	Do not use in NYHA Class III or IV heart failure
Vasodilators	Avoid in patients with persistent postural hypotension Do not prescribe in patients prone to falls
Asprin	Avoid combination with warfarin without H2 antagonist (not cimetidine) or PPI Avoid in patients with past history of peptic ulcer without H2 antagonist or PPI Avoid at dose >150mg/day Do not prescribe without a history of coronary, cerebral or peripheral arterial symptoms or occlusive event Do not prescribe to treat dizziness not clearly attributable to cerebrovascular disease Do not prescribe with concurrent bleeding disorder
Warfarin	Do not prescribe for first uncomplicated DVT for longer than 6months Do not prescribe for first uncomplicated pulmonary embolus for longer than 12 months Do not prescribe with concurrent bleeding disorder
Clopidrogel	Do not prescribe with concurrent bleeding disorder
Dipyridamole	Do not prescribe with concurrent bleeding disorder
Tricyclic anti-depressants	Do not prescribe in patients with dementia Do not prescribe in patients with glaucoma Do not prescribe in patients with conductive abnormalities Do not prescribe in patients with constipation Do not co-prescribe with an opiate Do not co-prescribe with a calcium channel blocker Avoid in patients with prostatism or history of urinary retention
Benzodiazepines	Do not prescribe long acting benzodiazepines long term (>1month) Do not prescribe in patients prone to falls
Neuroleptics	Do not prescribe neuroleptics as long term hypnotics long term (> 1month) Do not prescribe long term (>1month) neuroleptics in patients with parkinsonism Do not prescribe in patients prone to falls
Phenothiazines	Do not prescribe in patients with epilepsy

Anti-cholinergics	Do not use to treat extra-pyramidal side effects of neuroleptic medications
SSRIs	Do not prescribe in patients with a history of clinically significant hyponatremia
First generation antihisamines (e.g. diphenydramine, cyclizine, chlorpheniramine, promethazine)	Avoid prolonged (>1 week) use Do not prescribe in patients prone to falls
Diphenoxylate	Do not use to treat diarrhoea of unknown cause Do not use to treat severe infective gastroenteritis
Loperamide	Do not use to treat diarrhoea of unknown cause Do not use to treat severe infective gastroenteritis
Codeine	Do not use to treat diarrhoea of unknown cause Do not use to treat severe infective gastroenteritis
Prochlorperazine (Stemetil)	Do not prescribe to patients with parkinsonism
Metoclopramide	Do not prescribe to patients with parkinsonism
PPIs (protein pump inhibitors)	Do not prescribe at full therapeutic dose for > 8 weeks
Anticholinergic antispasmodics	Do not prescribe in patients with constipation
Theophylline	Do not use as monotherapy for COPD
Systemic corticosteroids	Do not use as maintenance therapy instead of inhaled corticosteroids in moderate-severe COPD
Nebulised itrapropium	Do not prescribe in patients with glaucoma
Non-steroidal anti-inflammatories	Do not prescribe in patients with history of peptic ulcer disease or gi bleeding unless with concurrent H2 receptor antagonist or PPI or misoprostol Do not prescribe in patients with moderate-severe hypertension Do not prescribe in patients with heart failure Do not prescribe long term (>3 months) for relief of mild joint pain in osteoarthritis Do not co-prescribe with warfarin Do not prescribe in patients with chronic renal failure (GFR < 50ml/min) Do not prescribe long term for treatment of gout where there is no contraindication for allopurinol
Long term corticosteroids	Do not prescribe corticosteroids long term (>3 months) as monotherapy for RA or OA
Colchicine	Do not prescribe long term for treatment of gout where there is no contraindication for allopurinol
Bladder anti-muscarinics	Do not prescribe in pateints with dementia Do not prescribe in patients with chronic glaucoma Do not prescribe in patients with chronic constipation Do not prescribe in patients with chronic prostatism
Alpha-blockers	Do not prescribe in men with frequent incontinence Do not prescribe in patients with a long term urinary catheter
Glibenclamide	Do not prescribe in patients with type 2 diabetes
Chlorpropamide	Do not prescribe in patients with type 2 diabetes
Oestrogens	Do not prescribe in patients with a history of breast cancer Do not prescribe in patients with a history of venous thromboembolism Do not prescribe without progesterone in patients with an intact uterus

Opiates	Do not prescribe long term opiates in patients prone to falls Do not prescribe long term powerful opitates (morphine, fentanyl) first line for mild to moderate pain Do not prescribe regular opiates (for >2 weeks) in patients with constipation without concurrent laxatives Do not prescribe long term opiates in patients with dementia unless indicated for palliative care or management of moderate/severe chronic pain syndrome

Here is a worked example of the application of the STOPP criteria:-

Applying the STOPP Criteria – A worked example

A 72 year old woman with:-

- 12yr history of type II diabetes,
- 6 yr history of hypertension
- 5 yr history Depression
- 3 yr history Osteoporosis detected on DEXA scanning
- history of ankle oedema (of uncertain cause and duration).

On the following repeat medications

- Daonil (glibenclamide) 5mg daily x 30
- Frusemide 20mg daily x 30
- Tritace (ramipril)10mg daily x 30
- Dalmane (flurazepam)30mg nocte x 30
- Amitriptyline 75mg nocte x30
- Fosamax (alendronate) 70mg once weekly x 4
- Ixprim (paracetamol/ tramadol) two as required x 100
- Nexium (esomprazole) 40mg od x 30

Each of the medicines she is on are checked against the STOPP criteria to identify any potential issues. All of the drugs she is on, except ramipril and alendronate, are flagged on the STOPP criteria as causing potential problems in this age group (i.e. over 65 years).

- Thus, the *glibenclamide* may cause hypoglycaemia and metformin would be a more appropriate hypoglycaemic agent
- The loop diuretic, *frusemide* should not be used for dependent ankle odema and, in the absence of any indicators of heart failure, should be stopped.
- The Dalmane *(flurazepam)* is a long-acting benzodiazepine which, in this age group, is associated with risks of prolonged sedation, confusion, impaired balance and falls and ought to be stopped.
- The *amitriptyline* is a tricyclic antidepressant (TCA) which, particularly with the opiate (tramadol), is likely to cause constipation. Also if she has dementia (which can present as 'depression') this may be worsened by the TCA. A non-sedating SSRI would be a preferred choice for management of depression.
- The Ixprim contains the moderatedly potent opiate *tramadol*. Long term use without a coprescribed laxative risks constipation. Long term opiates may also increase the risk of falls and are also contraindicated in dementia. Paracetamol alone in full doses should be tried first.
- The proton pump inhibitor Nexium (*esomeprazole*) should not be used at full therapeutic doses for more than 8 weeks. Her gi symptoms may relate to the alendronate which should be taken 30 minutes before breakfast and the paient remain standing up for this time. If still required it should be used at a maintenance dose or on an as required basis.

It is also notable that she is not being prescribed calcium and vitamin D supplements which she should be on with her alendronate. This is a PPO addressed by the START tool – see above. She is also on several drugs prone to causing sedation (flurazepam, amitriptyline, and tramaodol) which collectively greatly increase her risk of falls which it would be particularly important to avoid in this patient because of her osteoporosis. The risk of renal function problems or hyperkalaemia with the ACE inhibitor are not flagged by the STOPP criteria (which is a flaw in these indicators) but should be checked for.

Operationalising RCGP Safety Indicators

The RCGP Indicators highlight the following drugs/ groups of drugs:-

- Beta-blockers
- Short acting nifedipine
- Digoxin
- Diltiazem
- Verapamil
- Aspirin
- Long acting beta-agonists
- Metoclopramide
- Prochlorperazine
- Benzodiazpines
- 'Z' drugs (zopiclone, zolpidem etc.)
- Mefloquine
- Combined oral contraceptives
- Oral or transdermal oestrogen
- NSAIDs
- Warfarin
- Phosphodiesterase type-5 inhibitor (e.g. sildenafil)
- Clarithromycin
- Erythromicin
- Potassium salts
- Potassium sparing diuretic (excluding aldosterone antagonists)
- Penicillin containing antibiotic
- Amiodarone
- ACE inhibitor
- Angiotensin II receptor antagonist
- Lithium
- Methotrexate

If one of this list of drugs is on the patient's repeat prescription then the table below identifies the issue(s) to be checked before issuing the repeat prescription. As with the STOPP criteria these indicators can be used to identify drugs on the patient's repeat prescription which might cause problems.

Drug or Drug Class	Issue to be check on repeat prescription
Beta-blockers	Not suitable if patient has asthma (unless cardiac condition where benefit may outweigh risks)
Short acting nifedipine	Avoid except for Raynaud's disease
Digoxin	Do not exceed 125mcgm daily if renal impairment i.e. CKD 3 or worse) Do not exceed 125mcgm daily in patients with heart failure if in sinus rythmn
Diltiazem	Avoid in heart failure
Verapamil	Avoid in heart failure
Aspirin	Do not exceed dose of 75mg daily for >1 month in patients over 65 years Do not prescribe to child under 16 years
Long acting beta-agonists	Do not prescribe to asthma patient who are not simultaneously on an inhaled corticosteroid
Metoclopramide	Avoid in Parkinson's disease
Prochlorperazine	Avoid in Parkinson's disease
Benzodiazpines	Do not initiate for >21 days in patients over 65 year not already on one
'Z' drugs (zopiclone, zolpidem etc.)	Do not initiate for >21 days in patients over 65 year not already on one
Mefloquine	Avoid in patients with a history of convulsions
Combined oral contraceptives	Avoid in women with a history of thromboembolism
Oral or transdermal oestrogen	Avoid in women with a history of breast cancer; without progesterone in women with intact uteri; women over 35 yrs who are current somkers; women with body mass index >40
NSAIDs	Do not prescribe to patients with history of peptic ulcer unless with a PPI; Avoid in patients with heart failure Avoid in patients with renal failure (CKD 3 or worse)
Warfarin	Do not co-prescribe with NSAID Do not prescribe without a record of INR within previous 12 weeks
Phosphodiesterase type-5 inhibitor (e.g. sildenafil)	Do not co-prescribe to patient on nitrate or nicorandil
Clarithromycin	Do not prescribe to patient on simvastatin unless advised to stop simvastatin during antibiotic course
Erythromicin	Do not prescribe to patient on simvastatin unless advised to stop simvastatin during antibiotic course
Potassium salts	Do not prescribe to patient on ACE inhibitor or ARB
Potassium sparing diuretic (excluding aldosterone antagonists)	Do not prescribe to patient on ACE inhibitor or ARB
Penicillin containing antibiotic	Do not prescribe to patient with a history of penicillin allergy
Amiodarone	Do not prescribe without a record of liver function being measured within previous 9 months Do not prescribe without a record of thyroid function being measured within previous 9 months
ACE inhibitor	Do not prescribe without a record of renal function and electrolytes having been measured before starting
Angiotensin II receptor antagonist	Do not prescribe without a record of renal function and electrolytes having been measured before starting
Lithium	Do not prescribe without a record of lithium having been checked within the previous 6 months
Methotrexate	Do not prescribe without a record of a full blood count having been measured within the previous 3 months Do not prescribe without a record of liver function having been measured within the previous 3 months

Applying the RCGP Prescribing Safety Indicators – A worked example

A 54 year old man with:-

- 5 year history of hypertension and angina
- Acute myocardial infarction 1 year ago with coronary artery stents in situ
- 6 month history of erectile dysfunction

On the following repeat medications:-

- Atenolol 50mg daily x30
- Aspirin 75mg daily x30
- Plavix (clopidrogel) 75mg daily x30
- Tritace (ramipril) 10mg daily x30
- Imdur (isosorbide mononitrate) 120mg daily x30
- Sildenafil 50mg prn x4

If these medicines are checked against the RCGP prescribing safety indicators the following issues are raised:-

- In relation to the beta-blocker, *atenolol*, one needs to check the patient does not have asthma. Even if he does there may be a judgement required as to benefit to risk ratio as the atenolol is for a cardiac condition
- In relation to the *aspirin* there is no issue yet as the patient is under 65 years
- In relation to the ACE inhibitor, *ramipril*, there should be record of renal function and electrolytes having been measured before this was started.
- The phosphodiesterase inhibitor, *sildenafil*, should not be co-prescribed with a nitrate (Imdur, *isosorbide mononitrate*). It may be that the nitrate was started before he had his stent inserted and, if his angina is now resolved it may be stopped. If he continues to need the nitrate it is not safe to continue the sildenafil.

There are issues relating to the type of stent (bare metal or drug eluting) and the duration of aspirin and clopidrogel but these issues are not addressed by these indicators. Likewise, there may be a case for his being on statin therapy which is not addressed – this is a potential prescribing omission (PPO).