Patient Safety Collaborative Manual

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APHCRI CENTRE OF RESEARCH EXCELLENCE

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FOREWORD

Australian general practice has a key role in how the health system ensures safe and high quality care, particularly for individuals living with complex illnesses. On average, general practice provides 345,000 patient encounters and writes over 287,000 prescriptions per day. There will be a small level of adverse events associated with these consultations and prescriptions; analysis of such adverse events shows that at least half are thought to be preventable.

Understanding, recording and analysing these adverse events has not proven to be easy in general practice, which is why this Manual is so valuable. Unlike the hospital setting, the structure of general practice is such that finding dedicated resources to devote solely to safety and quality initiatives is impractical. This Manual is practical, instructive and helpful. It is not a weighty tome, which makes it attractive, but it is rich in ideas, tips and suggestions.

Reference is made to the Australian Safety and Quality Framework for Health Care, which was endorsed by Health Ministers in 2010. The vision is for safe and high quality care for all Australians, supported by three core principles. These principles are that care is consumer centred, driven by information and organised for safety.

This Manual is particularly focused on two of three core principles, through its 'Key Concepts' approach. The first concept, engaging the team, is the key to being organised for safety. The approach to deriving information from patient encounters can only be achieved by a practice that is organised for safety.

The information that can be gained by adopting the approaches outlined in this Manual will be invaluable. The focus on accurate patient health summaries, on clinical audit, on automated trigger tools, event logs, significant event analysis and medication reviews when considered by experienced GPs must enhance patient safety and the quality of care.

It is most heartening to read this Manual and to contemplate the benefits that will accrue to consumers of health care, wherever it is applied.

Professor Chris Baggoley

Australian Government

Chief Medical Officer

Patient Safety Collaborative Manual

AIM

The main aim of this manual is to support those general practices engaged in the patient safety collaborative to provide safer care.

INTRODUCTION

Patient safety is a much broader concept than just clinical care. It hinges on access to care, confidentiality, medical equipment, information exchange, medication use, complaints handling, consultation duration, scope of practice, and responsiveness of the organisation to adverse events, among other things. Even the most dedicated and highly qualified GP will find there are aspects of their practice set-up that can be improved. In this collaborative practices will engage in elements of this broad scope to improve patient safety. This will include a simple survey tool to assess the practice's patient safety culture, to develop priorities for improvement, and focus on some specific areas.

The Royal Australian College of General Practitioners has developed a set of Standards to improve safety and quality in general practices [1]. One of the RACGP Standards [1, 2] is for clinical risk management of near misses, slips, lapses or mistakes. These Standards are utilised by Australian General Practice Accreditation Limited and GPA Accreditation Plus for accreditation of Australian general practices.

The Australian Safety and Quality Framework for Health Care [3] which has been endorsed by the Health Minsters in 2010 highlighted the need for safe and high quality care which has also been recognised by the Australian Commission on Safety and Quality in Health Care. It has been said that there is urgent need for "development of a nationally coordinated, systematic and effective means of reporting errors and near misses within primary health care" [4].

LESSONS IN PATIENT SAFETY

I saw a 68 year old gentleman who presented to see me to discuss his piles. He is a patient who had been attending to see me for a couple of years. He was overweight, had hypertension and had booked his appointment online and when doing so had put in a reason "piles". We discussed this and at the end of the consultation he mentioned that in the last day or so he felt upper abdominal discomfort and his usual antacid was not helping. I promptly diagnosed GORD and prescribed him a PPI. He rang back the next day late evening and spoke to a colleague (as I was not there). The discomfort was still there and he was advised to attend the following day. He saw my registrar the next day, who reviewed the history, did an ECG, which showed ST elevation in lateral leads and he was admitted to a coronary unit.

We all I am sure have similar stories of misdiagnosis and delayed diagnosis. What do we do about them, how do we react, what do we say to our patients, what do we do to stop it occurring again?

The theories and concepts of patient safety having some unique features and these are highlighted by Berwick [5] in his personal reflections and learning about patient safety. Lesson 1, is to focus on the harm rather than errors, *"How can we keep patients from being hurt in our hands?"* . Lesson 2, rules and breaking rules together are required to generate safety, *Rules should be more like instructions for driving a car, allowing the driver to adapt to current circumstances, than a point-by-point recipe for baking a cake*. Lesson 3, is to focus on the stories rather than reporting numbers alone, *Reporting that loses the story is mostly a waste*. Lesson 4, is that technology and conversation together are important to generate safety, *Technology without collective mindfulness makes things worse, not better. Safety requires the continual exploration of meaning*. Lesson 5, utilising other industries' safety plans in health care is not sufficient to generate safety, *the simple-minded adoption of safety practices from other industries is problematic because the range of risk levels in health care is extremely wide*. Lesson 6, healing is a part of safety; *Part of our safety culture must focus on the healing side. We have to heal people who are hurt, the injured person and the person who caused the injury*.

I thought	I learned
The problem is errors	*The problem is harm*
Rules create safety	*Rules and breaking the rules create safety*
Reporting is necessary to track problems and progress	*Stories are necessary to gain knowledge*
Technology is the mainstay of safety	*Conversation is the mainstay of safety*
Health care is mostly the same as other high hazard industries	*Health care differs a lot from other high hazard industries*
What's important happens before the injury	*What happens after the injury is equally important*

ERRORS, 'VIOLATIONS' AND HARMS IN GENERAL PRACTICES

Errors and violations will occur in general practice because it is a complex system that involves humans making multiple decisions in a highly complex environment in the face of competing priorities. The contributing factors for medical errors or violations are related to clinical issues, system issues, human factors or combinations of them [6, 7]

'Violations' are defined as deliberate deviations from standard procedure. On first sight the usual reaction is that violations are not a good thing and should be eliminated. However, they are common and frequent in healthcare e.g. much of paediatric prescribing can be considered to be a violation. The situation is therefore complex as violations can have positive and negative aspects. On the one hand they might actually create patient safety and increase productivity but on the other hand they may pose a threat to patient safety, particularly when it is an extreme violation [8]. As with many things in patient safety, culture is all important. A 'just' culture is a culture that recognises that a priority is improving patient care and the learning from an error or violation is very important; such a culture can even improve the reporting of patient safety threats because it is seen as fair. A just culture also recognises that occasionally situations may require holding an individual to account. There are processes that support a 'just' culture. For example, an incident decision tree tool (http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900) may provide transparency of how a practice manages patient safety incidents, errors and violations [9].

An international pilot study [10] that included Australia created a nomenclature for describing errors in general practices. Findings were similar across different health care systems and errors were classified as:

Errors are by-products of useful cognitive functions [Leape]

Process errors (79%)	Knowledge and skills errors (21%)
Errors in office administration (20%)	Errors in the execution of a clinical task (5%)
Investigation errors (13%)	Errors in diagnosis (14%)
Treatment errors (29%)	Wrong treatment decision with right diagnosis (2%)
Communication errors (15%)	
Payment errors (1%)	
Errors in healthcare workforce management (2%)	

32% of these errors resulted in patient harm and 9% of these harms were very serious or extremely serious [10].

Avery et al. [11] examined medical records for 1,777 patients and found that the prevalence of prescribing or monitoring errors is 12% among them, it was higher in older patients (≥75 years, 38%) and patients on more drugs (30% five or more drugs, 47% ten or more drugs). Also, common errors were identified as *incomplete information on the prescription* (31%), *dose/strength errors* (17%) *and timing errors* (10%) for prescribing errors. *Failure to request monitoring* (69%) was commonest among monitoring errors [11].

These studies provide a window into the errors occurring in General Practice. Berwick said, more important than errors is the harm patients come to. The reason for this is that it is 'harm' that matters to patients. We know that not all errors lead to harm and not all harm occurs from errors. We also know from other industries that the safest organisations are not the ones that have eliminated errors, but found ways of capturing the errors before they cause harm. Indeed, the definition of patient safety encapsulates this focus on harm or adverse outcome.

You can't change the human condition, but you can change the conditions under which humans work [Reason]

"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare"[12].

Unfortunately, the risks and harm rates in General Practice are under-estimated due to poor data and difficulties in measuring safety incidents [13, 14]. Internationally there have been some studies estimating the level of harm in primary care. England has recorded 8% [15], the US 24% [16] and 2% in Scotland 2% [17] of consultations. In the United Kingdom, one study identified 337 significant event analyses in general practices and found that 26.7% were categorised as patient safety incidents, with 6.5% of these classified as serious or life

threatening and 19.9% potentially serious [18]. Overall, 28.5% of all significant event analyses were related to medicine management.

Methods to capture harm occurring in practice include event reporting e.g. when a harm is identified, and regular case note review. Approaches have been designed to do this in a pragmatic way in General Practice and they form two of the change concepts in this collaborative.

AUSTRALIAN GENERAL PRACTICES

Once the level of harm occurring and the reasons for it are understood we can try and make care safer by improving our systems. This collaborative will use a multifaceted approach to systems improvement. We will need to be unflinchingly open about how errors can occur and then innovative about how to minimise the harm that can result. By sharing, implementing and monitoring solutions we can learn how to make our practices safer for patients and improve our culture of patient safety.

DEVELOPING A PATIENT SAFETY COLLABORATIVE MANUAL

We used Knowledge Translation and Exchange (KTE) as framework through four approaches to develop this manual:

Literature review

We reviewed the literature to identify errors and harms in primary care, common errors, trigger tool and patient safety guideline.[19]

Consultations with national and international experts on patient safety

We approached national and international experts on patient safety to obtain feedback on the gaps that have been identified through the interviews with general practice staff and accreditation surveyors, and by our partners: Improvement foundation (Australia) which runs the Australian Primary Care Collaboratives (APCC) Program, Australian General Practice Accreditation Limited (AGPAL), Australian Commission on safety and Quality (ACSQHC), Royal Australian College of General Practitioners (RACGP) and the Chronic Illness Alliance (CIA). We collected the feedback for experts through two rounds.[20] (Acknowledgment of consultations, Appendix 1)

Interviews with highly experienced AGPAL surveyors who are involved in accreditation of Australian general practices

Tin order to explore accreditation surveyors' perceptions of the impact of accreditation on patient safety and how to improve patient safety in Australian general practices, a qualitative study was undertaken with a purposive national sample of Australian General Practice Accreditation Limited (AGPAL) surveyors. Semi-structured telephone interviews were undertaken. All interviews were audio recorded and summarised.

All surveyors agreed that to some extent accreditation has improved general practice performance in quality and safety. High performance in patient safety was categorised as general practices having a significant incidents register, providing documentation of near misses, slips, lapses, or mistakes, and engaging in regular clinical meetings to discuss incidents and how to avoid them in the future. Surveyors suggested that this occurred in only 5-10% of general practices. They provided recommendations on how to improve the safety culture in general practice.

There is 'softness' around patient safety in accreditation of Australian general practices due to the lack of verifiable information. We recommend some changes in the accreditation process to meet the Australian Safety and Quality Framework for Health Care which has been endorsed by Health Ministers.[21]

Interviews to identify their characteristics and activities of a national sample of Australian general practices performing highly in safety and quality

We identified a national sample of high performing Australian general practices based on: a) performance in Australian General Practice Accreditation Limited (AGPAL) and Australian Primary Care Collaborative (APCC) Program databases, b) national award winners, c) nomination by experts. Semi-structured face to face interviews were undertaken to investigate patient safety in general practice through these questions:

   I.   What happens in your practice when someone makes an error? --for example, abnormal lab results are not seen, or the wrong dose of medication is given "slips, lapses, mistakes and near misses"
   II. Have you instituted any procedures to improve patient safety? (e.g. significant incidents register, documentation of slips, lapses, mistakes and near misses, regular clinical meetings to discuss / and how to avoid in the future)

   III. What do you believe are the major sources of error or harm?

   IV. Do you have any information about rates of error or harm?

   V.   What is the relationship between accreditation and patient safety?

We conducted interviews in 22 practices representing all Australian states and territories. Fifty three participants took part in interviews: 19 general practitioners, 18 practice managers, 15 practices nurses and 1 community pharmacist. All interviews were audio recorded, transcribed and analysed. The main findings explained the effective risk management in high performing general practices and how to improve it. Most of these views reflected in concepts, changes ideas and measures in this manual. Also, most of the staff confirmed the feasibility to generalise these measures among Australian general practices.[22]

DEFINITIONS OF KEY CONCEPTS

Safety Culture

The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

                                        Health and Safety Commission of Great Britain [23]

> **Patient safety**: the reduction of risk of unnecessary harm associated with health care to an acceptable minimum.
>
> **Patient safety incident**: an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.
>
> **Incident reporting**: collecting and analysing information about an event that could have harmed or did harm a patient in a health-care setting.
>
> **Harmful incident or adverse event**: an incident that resulted in harm to a patient.
>
> **Error**: failure to carry out a planned action as intended or application of an incorrect plan.
>
> **Near miss**: an incident that did not reach the patient.
>
> **Violation**: deliberate deviation from an operating procedure, standard or rules.
>
>
> WHO Patient Safety Curriculum Guide 2011 [24]

CHANGE CONCEPTS

> 1. Engaging the team
> 2. Data quality
> 3. Finding harm
> 4. Prevent

CHANGE CONCEPT 1 ENGAGING THE TEAM

Aims: To generate a culture of patient safety in participating practices

Patient safety is a much broader concept than just clinical care. It hinges on all aspects of the health service including: access to care; confidentiality; medical equipment; information exchange; medication use; complaints handling; consultation duration; scope of practice; and responsiveness of the organisation to adverse events. Even the most dedicated and highly qualified GP will find there are aspects of their practice set-up that can be improved. In this collaborative we will ask practices to use a simple survey tool to assess the culture of patient safety in their practice and to suggest areas for change [25, 26].

Change Ideas:
Use Medical Office Survey of patient safety culture [26] annually to measure the culture and use to create a practice wide discussion.

Measures:

I.   Survey scores in each component

Features of practices that have a focus on patient safety
➢ Practice manager, staff, employed doctors, partners have a shared understanding and commitment to quality and safety

> ➢ Significant events are recorded. Examples include: errors; near misses; confidentiality breaches; communication breakdowns; and complaints.
>
> ➢ Significant events are managed in a way that encourages openness and identification of the root causes rather than disciplinary action
>
> ➢ Actions to be taken are recorded, reviewed and checked to confirm implementation
>
> ➢ Each person in the organisation can contribute to discussions
>
> ➢ Training, workload, IT infrastructure, working environment and equipment are optimised to support all activities within the practice

CHANGE CONCEPT 2 DATA QUALITY: MAINTAINING ACCURATE PATIENT HEALTH SUMMARIES

Aims: To create systems for improving medical records continuously in general practices through:

Developing systems for creating and maintaining accurate patient health summaries

Checking progress by monthly audit using a data-checking tool

Uploading verified health summaries to the internet electronic health record (e-Health).

With the launching of patient controlled electronic medical record, it is more important than ever to have accurate patient summaries. Much of the iatrogenic harm to patients may be prevented by involving them and by effective information exchange between primary and secondary care. Letters generated to specialists, GP Management Plans and transfer of care summaries all require an up-to-date current medication list and diagnosis list [27].

Pen Computing Systems works with the Improvement Foundation to provide IT systems for Collaboratives. In this Safety Collaborative practice clinical software such as Best Practice, Zedmed, Genie and Medical Director can be searched at the touch of a button to provide audit information. We have developed a measure of the quality and accuracy of clinical notes by searching the entire patient database for completeness of data. By crossmatching medications to diagnoses we can establish a measure of accuracy and a way to show improvements over time. Clearly less common uses of particular medications will mean this measure will never reach 100%. The notes audit will also measure recordings of allergies, smoking, alcohol, ATSI status and other measures of completeness.

Change Ideas:

I.   Develop system for continuous updating of past medical history as diagnoses evolve, currently taken medication and new diagnoses are made.

II. Involve patients in the process of keeping records up to date by printing health summary ideally in the form of Medicare rebatable GPMP [or GPMP review]

III.   Make verified records available on the e-Health

I.   Monthly report of PCS CAT 'clinical data self-assessment tool'

II.   Monthly data extraction tool to assess concordance of medication list and diagnosis list as an extension to PCS CAT

III.   Record the number of e-Health uploads.

Suggestions to improve records – Hills Medical Service, Aldgate

1. For paper letters from hospital and specialists, use highlighter pen over new diagnoses. Appropriate staff member then adds the new medical history
2. For ARGUS electronic letters click 'add diagnosis to medical history' at the time the letter is electronically moved from the inbox to patient correspondence
3. For investigations which indicate a new diagnosis click 'add diagnosis to medical history'
4. Appropriate staff member to tidy medical history file according to instructions:
    a. Remove admin procedures such as 'results given in person'
    b. Remove duplicate diagnoses
    c. Remove minor or expected conditions such as 'URTI'
    d. Sort operations and one-off events into inactive problem list
    e. Confirm past history items flagged to 'appear in summaries and letters'
5. Doctor or nurse to confirm current medication and correct medical history list at the time of producing GP Management Plan or specialist referral letter
6. Whole of practice to use pick list for medical history entries to allow future electronic audit
7. Nurse/receptionist team with doctor back up to be "summary team" who are trained to turn paper notes for new patients into electronic medical records
8. Patients are asked to check their GPMP or Patient Health Summary for completeness. In addition they are asked to identify the following:
    a. Allergies to medicines
    b. Aspirin or other regular over-the-counter medications
    c. Medications prescribed by specialists including eye drops and injections/implants
    d. Operations
    e. Medical conditions that have required hospital trip/referrals or long term treatment
    f. Family history in parents or siblings of: cancers, heart disease or diabetes
9.   Add 'reason for prescription' to long term medications if missing from active diagnosis list then correct the list
10. Use community pharmacist - 'Medscheck' or HMR/RMMR to cross-match with medication list

Examples of the way PCS Clinical Audit Tool can measure accuracy and completeness of a practice electronic medical record
1.   Cross-check that there is a relevant diagnosis with specific medications

i.	Cytotoxic	>	cancer/Autoimmune condition
ii.	Puffers	>	respiratory
iii.	Spiriva	>	COPD
iv.	Lithium	>	Bipolar affective disorder
v.	SSRI and SNRI	>	Psychiatric disorder
vi.	Nitrates	>	ischaemic heart disease
vii.	NSAID/COX2	>	inflammatory/rheumatological
viii.	Hypoglycaemic	>	diabetes
ix.	Frusemide	>	heart failure
x.	Amiodarone	>	arrhythmia
xi.	Digoxin	>	atrial fibrillation
xii.	Warfarin	>	thromboembolic disease or atrial fibrillation
xiii.	PPI	>	upper gastroenterological
xiv.	Bisphosphonate	>	Osteoporosis
xv.	Raloxifene	>	Osteoporosis

2. Allergy status recorded

3. Smoking status recorded in adults

4. Proportion of summary history items that come from searchable pick list

5. Existence of duplicate patient files

6. Mismatch between HbA1c testing and diagnosis of diabetes

7. Number of patients with apparent ongoing treatment with antibiotics

8. Proportion of medicines listed as "current" not prescribed in the last 12 months

CHANGE CONCEPT 3 FINDING HARM

A) USING AN AUTOMATED TRIGGER TOOL

Aims: To use an automated trigger tool to identify patients who might have experienced harm in general practice.

As pointed out by Berwick the 'problem is harm'. To reduce harm requires us to learn from harm but the challenge in General Practice is to identify the harms that may be occurring. One method of identifying harms is to regularly review the medical records. This is a very time consuming exercise. A trigger tool is an approach to quickly identify those medical records that have a higher likelihood of uncovering cases of harm. Triggers are unambiguous items that are present and are commonly recorded. They therefore may be searched for electronically and together with Pen Computing Systems we have developed electronic searches of the entire practice database to identify a list of patients who have a trigger present. Notes that contain a trigger do not necessarily mean that that patient has come to harm, only that there is a greater likelihood of harm compared with a set of records with no trigger. The next stage therefore is for a clinician to review the record to see if the patient has come to harm. The clinician randomly selects a manageable number of patients (we suggest at least 25 every three months) to search for evidence of harm relating to the trigger. Experience has shown that this process takes between 2 and 4 minutes per record. Those with a harm present are recorded in a spreadsheet and given a priority number. In the change concept 4, we described a system for acting on those patients identified by the trigger tool and found to have been exposed to harm.

Change Ideas:

   I.   Run trigger tool quarterly

   II.   Randomly select at least 25 triggered patients for notes review to identify harms

  III. Record harms in Prioritisation Grid (see change concept 3)

Measures:

   I.   Trigger rate across collaborative.

   II.   Harm rate across collaborative.

  III. Recurring themes across collaborative

Examples of triggers included in the tool
➢ Sodium <130
➢ Haemoglobin <100
➢ INR <1.6 or >5.0
➢ eGFR <60 and reduced by 10 in the last 12 months
➢ Death

> - Acute vascular event [CVA/TIA/Acute MI and related terms]

> - New cancer diagnosis

> - More than 3 different GP in the same clinic in last 3 months

> - Fractures in over 70 year olds

> - Falls in over 70 year olds

> - Urinary catheter

> - Patients on triple whammy of NSAID, ACEi or ARB, diuretic

> - Potassium >6.0

B) USING AN EVENT LOG

Aims: To use an event log to identify patients who might have been exposed to harm from general practices.

In this collaborative we will ask practices to develop an event log which will enable practices to 'capture' significant patient safety incidents, near misses, communication breakdowns, complaints and system faults. It is important that all members of the practice team can contribute to the log. Not all events that appear in the log will have led to actual harms. A process of assessing whether harm occurred and then prioritising events for further action will be needed in a similar way to those patients identified through the trigger tool.

Change Ideas:
  I. Install event log template and train all staff to be able to record events
 II. Review notes to record harms in prioritisation grid

Measures:

  I. Spread of staff (GPs, PNs, PMs, receptionists and others) who record event
 II. Classification of types of recorded events
III. Recurring themes across the collaborative

Examples of event log entries
> - Patient complaint – both formal and informal
> - Non-clinical event such as confidentiality breach
> - Patient request for transfer of care to a nearby clinic
> - Delay or missing histopathology result
> - Equipment failure – eg vaccine fridge, computers, medical supplies depleted.
> - Clinical error – eg wrong vaccination given, allergy warning ignored, pharmacy call

about wrong dose

Screen shot of event log and trigger tool template

Each column is a dropdown menu

Patient ID	Date	how identified	Event category	Event description	Severity, 1=low and 5=high	likelihood, 1=low and 5=high	Priorty score	Event location
		Trigger tool	Sodium <130		3	4	12	Here
		GP principal	Haemoglobin <100					Patient residence
		GP other	INR <1.6 or >5.0					Hospital
		Practice Manager	eGFR <60 and reduced by 10 in the last 12 months					Other
		Practice nurse	Death					
		Receptionist	Acute vascular event [CVA/TIA/Acute MI and related terms]					
		Patient	New cancer diagnosis					
		Other	More than 3 different GP in the same clinic in last 3 months					
			Fractures in over 70 year olds					
			Falls in over 70 year olds					
			Urinary catheter					
			Patients on triple whammy of NSAID, ACEi or ARB, diuretic					
			Potassium >6.0					
			Confidentiality breach					
			Billing complaint					
			Physical environment					
			Patient transfers to nearby clinic					
			Results handling					
			Equipment problem					
			Patient complaint					
			Clinical error					
			Other					

Selected for SEA	What happened?	Why did it happen? Why? Why again?	What has been learned?	What has been changed?
Yes				
No				

CHANGE CONCEPT 4 PREVENT

A) SIGNIFICANT EVENT ANALYSIS

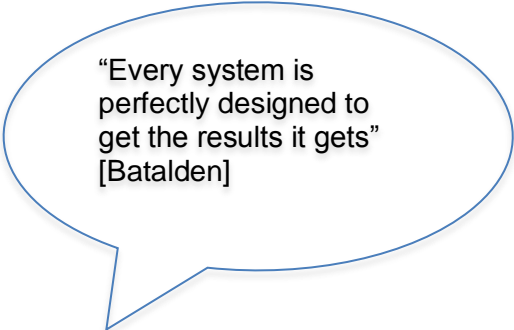**Aims**: To make systems changes within the general practice for improved patient safety through:

I. Identifying which events from the trigger tool and event log patients had experienced harm or risk of harm.
II. Prioritising which events to conduct significant event analysis.
III. Recording, sharing and undertaking actions to reduce harms

Change Ideas:

I. Analyse priortised events in the practice meeting (suggest 5 events monthly) to identify underlying causes.

II. Perform record and upload summary of significant event analysis and actions taken in Plan-Do-Study-Act format where suitable.

Measures:

I. De-identified narratives describing harms and actions taken to be accessible on APCC website
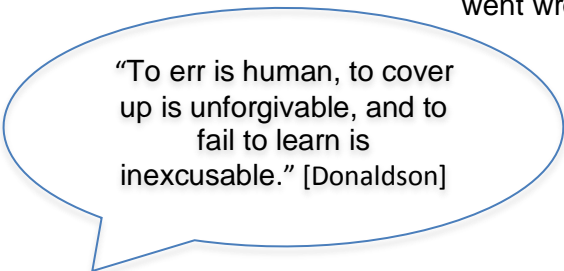
"Every system is perfectly designed to get the results it gets" [Batalden]

Significant event analysis (SEA)

"In significant event analysis, individual cases in which there has been a significant occurrence (not necessarily involving an undesirable outcome for the patient) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care and to indicate changes that might lead to future improvements" [28]

As part of the significant event analysis the team goes through a process to find out what went wrong (or right). This must be handled sensitively, it is not a process to see who messed up, as Berwick says those involved in a patient safety incident often are the second victim, after the patient. He also said that patient safety is about stories and by this he means that the qualitative understanding of what happened is

"To err is human, to cover up is unforgivable, and to fail to learn is inexcusable." [Donaldson]

really important. There is the potential for SEA to strengthen teams, support practice members after a stressful event, to be a part of professional development and to improve the quality of patient care.

There is a range of techniques that can be used as part of the SEA. One of the most effective methods of understanding a significant event is a combination of the 'five whys' method together with using the Ishikawa/fishbone diagram. By repeatedly asking the question 'why?' (five is a rule of thumb only – more or less questions may be needed) it is possible to dig through the layers to find the root causes of a problem and understand the story. First ask why did the event occur? Why did that situation arise? Keep asking why until there is agreement about the root causes. A good way of visually capturing the information from the 5 Whys method is to record it in a fishbone diagram. From here ideas and tests of change can be modified using the PDSA methodology to create sustainable improvements that prevent recurrences.

Example of significant event analysis
INR 6.2, Haematoma Why? Patient took wrong dose warfarin Why? Patient misheard or misunderstood telephone advice from receptionist to take a reduced dose Why? There was no written confirmation of instructions Why? Not all patients attend for point-of-care INR checks Why? Patients have continued previous pattern of care Action: Appropriate staff member to identify all patients who rely on telephone INR results, GP to ask patient to attend for point-of-care INR checks.

Using a framework developed in Scotland [29] practices document what happened? Why did it happen (using the 5 whys)? What has been learned? What has been changed? A brief narrative of this kind is one of the most powerful ways to share experiences as part of a GP collaborative.

Significant Event Analysis record (adapted from Scottish NHS)
Date of significant event: Date of significant event meeting: What happened? "Describe what actually happened in detail. Consider, for instance, how it happened, where it happened, who was involved and what the impact or potential impact was on the patient, the team, organisation and/or others". Why did it happen? Why? Why again? "Describe the main and underlying reasons – positive and negative – contributing to why the event happened. Consider, for instance, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event". What has been learned?

> "Have relevant team members have been involved in the analysis of the event? Consider, for instance: a lack of education & training; the need to follow systems or procedures; the vital importance of team working or effective communication".
>
> What has been changed?
>
> "Outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. E.g. PDSA cycles"

B) IMPROVING MEDICATION SAFETY IN PATIENTS WITH MULTI-MORBIDITY

Aims: To improve medication safety in patients with multi-morbidity by conducting an annual medication review in conjunction with community pharmacist.

Change Ideas:

I. Develop a registry of patients 75 years or over on 10 or more regular medicines per day.

II. Arrange with community pharmacist for MedsCheck [30] or Home Medication Review [31], for residential aged care patients Residential Medication Management Review (RMMR)[32].

III. Identifying opportunities for safely deprescribing.

IV. Add annual recall.

Measures:

I. Proportion of eligible patients who have had a medication review in the last 12 months

II. The number and percentage of those 75 and over who are on high risk medications:

      a. benzodiazepines

      b. tricyclic antidepressant

      c. aspirin AND warfarin

      d. non-steroidal anti-inflammatory drugs AND ACE inhibitors AND diuretics.

One of the biggest challenges facing all developed world health systems is multi-morbidity [33]. If GPs follow all the recommended guidelines for each disease or continue all the medications commenced by specialists and hospital, then our patients end up on many medicines [33-35] . The consequences of polypharmacy are worse in the elderly who might have decreased clearance rates for medicines, increased frailty leading to falls and a reduced tolerance for the cognitive effects of medicines leading to confusion [figure 1]. Part of the skill of general practice is to sort out patient priorities, stop inappropriate medicines and to be alert for interactions. In a study of over 70 years olds living in the community 58% of drugs were able to be stopped which led to 88% of patients improving in health while only 2% of the drugs needed to be recommended [36]. In an Australian survey of harm from

medicines in general practice 10.4% experienced adverse drug reaction in the previous 6 months with many causing hospital admission [37].

This part of the Patient Safety Collaborative will focus on identifying patients who could benefit from annual medication reviews ideally conducted first by the community pharmacist and then by the GP. The aim is to review each medicine using a structured approach that takes into account the patients' goals, evidence for possible benefit [numbers needed to treat] and evidence for risk [number needed to harm] and the potential for interaction[38]. For most patients the GP is the only doctor with the skills and experience to prevent single disease guidelines being followed at the expense of patient safety. In this collaborative we will focus on patients taking 10 or more regular medications which is predicted to be about 15% of the over 75 year olds.
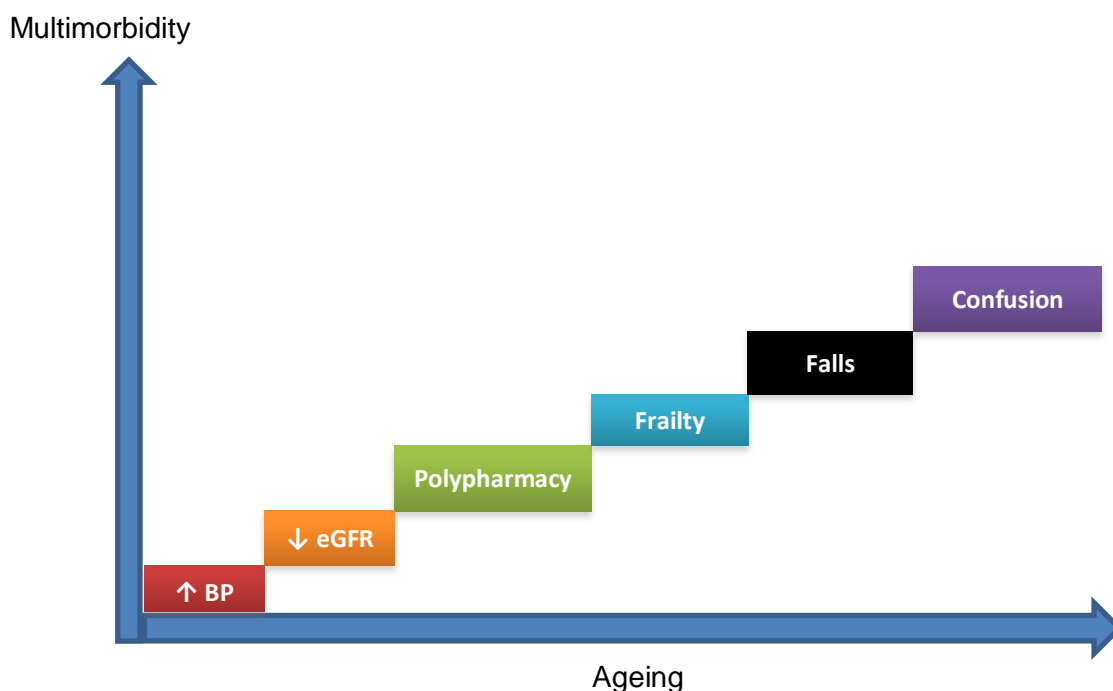
Guide to deprescribing by Le-Coutier [39]

Prepare   discuss deprescribing at start of therapy

Recognise   poly-pharmacy, adverse drug reactions (including falls in older people), lack of efficacy, and change in treatment goals, often due to the onset of terminal illness, dementia and/or frailty

Prioritise   one medicine at a time starting with the medicine suspected of causing the adverse drug reaction or consider using risk assessment tools

Wean always wean central nervous system-active medicines (especially benzodiazepines, opioids by perhaps 25% a month), beta blockers, corticosteroids, levodopa typically over weeks and months

Monitor   withdrawal syndromes, discontinuation syndromes, rebound, recurrence of illness, cognition, falls and quality of life

SUMMARY OF PATIENT SAFETY COLLABORATIVE

	Aims	Change ideas	Measures
1	To generate a culture of patient safety in participating practices	Use Medical Office Survey of patient safety culture [26] annually to measure the culture.	• Survey scores in each component
2	To create systems for improving medical records continuously in general practices through: I. Developing systems for creating and maintaining accurate patient health summaries II. Checking progress by monthly audit using a data-checking tool III. Uploading verified health summaries to the internet patient controlled electronic health record (e-Health).	• Develop system for continuous updating of past medical history as diagnoses evolve, currently taken medication and new diagnoses are made. • Involve patients in the process of keeping records up to date by printing health summary ideally in the form of Medicare rebtable GPMP [or GPMP review] • Make verified records available on the e-Health	• Monthly report of PCS CAT 'clinical data self-assessment tool' • Monthly data extraction tool to assess concordance of medication list and diagnosis list as an extension to PCS CAT • Record the number of e-Health uploads.
3	To use an automated trigger tool to identify patients who might have been exposed to harm in general practice.	• Run trigger tool quarterly • Randomly select at least 25 triggered patients for notes review to identify harms • Record harms in prioritisation grid	• Trigger rate across collaborative • Harm rate across collaborative • Recurring themes across collaborative
4	To use an event log to identify patients who might have been exposed to harm from general practices.	• Install event log template and train all staff to be able to record events • Review notes to record harms	• Spread of staff (GPs, PNs, PMs, receptionists and others) who record event • Classification of types of recorded events • Recurring themes across the collaborative

		in prioritisation grid	
5	To make systems changes within the general practice for improved patient safety through: I. Identifying which events from the trigger tool and event log exposed patients to harm . II. Prioritising which events to conduct significant event analysis. III. Recording, sharing and undertaking actions to reduce harms	• Analyse priortised events in the practice meeting (suggest 5 events monthly) to identify underlying causes • Perform , record and upload summary of significant event analysis and actions taken in Plan-Do-Study-Act format where suitable	• De-identified narratives describing harms and actions taken to be accessible on APCC website

6	To improve medication safety in patients with multi-morbidity by conducting an annual medication review in conjunction with community pharmacist.	• Develop a registry of patients 75 years or over on 10 or more regular medicines per day
		
		• Arrange with community pharmacist for MedsCheck [30] or Home Medication Review [31], for residential aged care patients Residential Medication Management Review (RMMR)[32].
		
		• Identifying opportunities for safely deprescribing.
		
		• Add annual recall.
			• Proportion of eligible patients who have had a medication review in the last 12 months
			
			• The number and percentage of those 75 and over who are on high risk medications:
			
			    o benzodiazepines
			
			    o tricyclic antidepressant
			
			    o aspirin AND warfarin
			
			    o non-steroidal anti-inflammatory drugs AND ACE inhibitors AND diuretics.

APPENDIX 1

APPENDIX 2

Introduction to Patient Safety

  ➢ What we know about the epidemiology of patient harm from their medical care

  ➢ Inevitability of human error so purpose of safety is to reduce harms. Errors can lead to harm, not all errors cause harm and not all harms is from errors. What we know about the ways to measure patient harms –from NHS trigger tool learning video in which first two columns allow understanding of the nature of errors whereas the third column allows measurement of both errors and harms.

Staff	Patient	Metrics
Surveys	Comments	Adverse event rate
Event reporting [log]	Ideas	Sentinel event rate
Executive walk-around	Surveys	Audit data
Sentinel events	Complaints	Record quality tool
Staff observations		

  ➢ What works to reduce harms

Results of de-identified Medical Office Survey on Patient safety

What was learnt about our team functioning, what would we like to change, what steps are necessary to achieve this.

Patient Safety collaborative aims – introduction

First Action Period

  ➢ Set up clinical software to run PCS Trigger Tool

  ➢ Use PCS Trigger Tool to identify 25 records for a clinician with diagnostic skills (may be a nurse or a GP) to identify if harm occurred or important near miss

  ➢ Hold a 'Significant Event Analysis' meeting [SEA] to review causes and identify actions for at least 3 events

  ➢ Conduct PDSA to improve records. Ask "what will make the biggest immediate improvements to our records"

➢ Use PCS PenCat tool to develop a registry of patients who might benefit from a medication review process. Starting with "community living over 75 year olds on 10 or more doses of medication per day"

APPENDIX 3

TRIGGER TOOL

Tool is run over entire database. Random sample of at least 25 'triggered' patients records are reviewed by practice nurse or GP to identify harms. Harms are then prioritised to identify opportunities for improved safety systems within the clinic.

1. Sodium <130

2. Haemoglobin <100

3. eGFR <60 and reduced by 10 in the last 12 months

4. Death

5. Acute vascular event [CVA/TIA/Acute MI and related terms]

6. New cancer diagnosis

7. More than 3 different GP in the same clinic in last 3 months

8. Fractures in over 70 year olds

9. Falls in over 70 year olds

10. Urinary catheter

11. Patients on triple whammy of NSAID, ACEi or ARB, diuretic

12. Potassium >6.0

APPENDIX 4

1. Convert or purchase Medical Officer Survey on Patient Safety as a web based survey or computer readable paper survey – eg Survey Monkey. Anticipate 100 practices, each with average 5 GP, 2 Nurses, 1 Practice manager, 4 Receptionists ie. 1200 responses.

2. Develop PCS PenCat to be able to generate registries, trigger tool and outcome measures

3. The numerical data for each trigger in the trigger tool available for understanding how the trigger tool is working.

4. Generate Safety Collaborative web portal for uploading significant event log, significant event analysis outcomes, PDSA relating to each of the aims.

5. Concordance of medication list with medical history list

6. List of at risk patients with poly-pharmacy who should have medication review [>75 years,10 or more regular medicines per day]

7. The number and percentage of those 75 and over who are on high risk medications:

   a. benzodiazepines

   b. tricyclic antidepressant

   c. aspirin AND warfarin

   d. non-steroidal anti-inflammatory drugs AND ACE inhibitors AND diuretics.

Section 2: Clinical Guidance

2.1 Drug review process

This review should be undertaken in the context of holistic care considering each medication and its impact on the individual clinical circumstances of each patient. As part of this it is important to consider the cumulative effects of medications.

Number	CRITERIA / CONSIDERATIONS	PROCESS/GUIDANCE		References / Further reading or Examples
1	Is there a valid and current indication? Is the dose appropriate?	Identify medicine and check that it does have a valid and current indication in this patient with reference to local formulary. Check the dose is appropriate (over/under dosing?)		e.g. PPIs- use minimum dose to control GI symptoms - risk of *c.diffcle* and fracture e.g quinine use- see MHRA advice re safety e.g. long term antibiotics
2	Is the medicine preventing rapid symptomatic deterioration?	Is the medicine important/essential in preventing rapid symptomatic deterioration? If so, it should usually be continued or only be discontinued following specialist advice.		e.g. Medications for Heart failure, medications for Parkinson's Disease are of high day to day benefit and require specialist input if being altered. review of doses may be appropriate e.g. digoxin
3	Is the medicine fulfilling an essential replacement function?	If the medicine is serving a vital replacement function, it should continue.		e.g. thyroxine and other hormones
4	Consider medication safety Is the medicine causing: -Any actual or potential ADRs? -Any actual or potentially serious drug interactions?	Contraindicated drug or high risk drugs group?	Strongly consider stopping	See High Risk Drug section e.g is the patient on a high risk combination " triple Whammy" Ref. "STOPP" List BNF Sections to Target
		Poorly tolerated in frail patients? For guidance on frailty see Gold National Framework	Consider stopping	
		Particular side effects?	May need to consider stopping	
5	Consider drug effectiveness in this group/person?	For medicines not covered by steps 1 to 4 above, compare the medicine to the 'Drug Effectiveness Summary' which aims to estimate effectiveness.		Ref. Drug Effectiveness Summary Ref NNT/NNH Medication used for dementia patients- see Gold SF
6	Are the form of medicine and the dosing schedule appropriate? Is there a more cost effective alternative with no detriment to patient care?	Is the medicine in a form that the patient can take supplied in the most appropriate way and the least burdensome dosing strategy? Is the patient prepared to take the medication? UKMI Guidance on choosing medicines for patients unable to swallow solid oral dosage forms should be followed.		Consideration should be given to the stability of medications. Ensure changes are communicated to the patients' Pharmacist: *Would this patient benefit form Chronic medication Service*?
7	Do you have the informed agreement of the patient/carer/welfare proxy?	Once all the medicines have been through steps 1 to 6, decide **with the patient/carer/or welfare proxies** what medicines have an effect of sufficient magnitude to consider continuation/discontinuation.		

2.4 High Risk Medication: Medication most associated with admission due to adverse drug reaction

In a 2004 UK study the most common drug groups associated with admission due to adverse drug reaction ('ADR') were:

NSAIDs	29.6%	Beta blockers	6.8%
Diuretics	27.3%	Opiates	6.0%
Warfarin	10.5%	Digoxin	2.9%
ACE	7.7%	Prednisolone	2.5%
Antidepressants	7.1%	Clopidogrel	2.4%

Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients M Pirmohamed et al, BMJ 2004;329:15-19

2.5   Numbers needed to treat drug effectiveness summary (see references for additional information)

ACE INHIBITORS

Indication	NNT per annum	To do what	Notes
Elevated Vascular Risk [Normal LV]	280	Prevent one death [all causes]	Trial ran for 5 years
Impaired LV Function-mild/moderate	30	Prevent one death [all causes]	Likely symptomatic benefit
Combination Therapy including ACE			
ACE + Indapamide	55	Prevent one stroke	Trial ran for 5 years
Secondary Prevention post MI > 80 yrs [ACE+ BB +ASP+ STAT]	33	Prevent one Death	
ACE + Beta blocker for impaired LV	14	Prevent one death	Likely symptomatic benefit
Impaired LV Mild /moderate ACE + BB	15	Prevent one Death	Likely symptomatic benefit
Impaired LV Severe ACE + BB + Spiro	7	Prevent one Death	Likely symptomatic benefit
ASPIRIN Primary Prevention	Enormous	No longer recommended	
ASPIRIN Post Stroke/ TIA	100	Prevent one stroke or MI or Vascular Death	
DYPYRIDAMOLE In addition to ASPIRIN post stroke/TIA	100	Prevent one vascular event	BNF caution in cardiac disease
	Equivalent to		
CLOPIDOGREL post stroke or TIA	Dypridamole + Aspirin	Prevent one vascular event	
ATRIAL FIBRILLATION			
AF + another risk factor WARFARIN v ASPIRIN	40	Prevent one Stroke- no difference in mortality	
AF (Secondary Prevention after Stroke) WARFARIN v ASPIRIN	16	Prevent one stroke	
ASPIRIN	No effect		
			BP > 140/90 trial predominantly systolic hypertension
HYPERTENSION			
Cardiovascular morbidity and mortality >80 yrs			
Low Risk	80	Avoid one cardiovascular event	2 years for effect
High Risk [Diabetes, vascular disease]	32	Avoid one cardiovascular event	2 years for effect
Cerebrovascular morbidity and mortality > 80 yrs	122	Avoid one cerebrovascular event	2 years for effect
Cardiovascular morbidity and mortality > 60yrs			
Low Risk	107	Avoid one cardiovascular event	4.5 years for effect
High Risk [Diabetes, vascular disease]	40	Avoid one cardiovascular event	4.5 years for effect
HYPERTENSION *(Tayside Day Hospital cohort)*	36	Prevent one death	NNT 30 if also Cardiovascular Disease

STATINS	NNT per annum	To do what	
MI or Angina	80 to 170	Major Coronary Event.	No difference in Mort to 5 years
Post Stroke [Atrova 80 v Placebo]	165	One Cardiovascular Event	No difference in Mort to 5 years
Tight HbA1c Control Strategies			
Microvascular Risk			
ADVANCE [HbA1c7.3% v 6.5%]	333	One microvascular event [predominantly retinal]	Trial ran 5 years
UKPDS [HbA1C 7.9% v 7%]	200	One microvascular event [predominantly retinal]	Trial ran 10 years
Macrovascular Risk	No difference at 10 years		
Metformin			
Overweight /obese Diabetic	50	One MI or Diabetes event or Death	10 year follow up
Standard < 140 BP control in diabetes any means	57	One Stroke or major diabetes event or death	8 year follow up
Tight BP control in diabetes			
BP 120 v BP 134	500	Prevent one stroke	4 years minimum for effect
Number needed to harm for this strategy	50		

Osteoporosis [Alendronate + Calcium/VitD]	2y Prevention Vertebral #	2y Prevention Hip #	Notes for Osteoporosis
70 -74 years	65	430	NNT per annum to prevent further #
75 - 79 years	45	180	Potential symptomatic benefit re Vertebral #
80 - 84 years	60	105	**Normally 2 years needed to see effect.**
85 - 89 years	55	45	
90+years	40	40	

High Risk Combinations	**Warfarin**	**Drugs that are tolerated poorly in frail patients**	**STOP if dehydrated**
These combinations are noted to be particularly high risk and should be looked for and stopped at every drug review. **NSAID** +ACE or ARB + Diuretic ['Triple Whammy' combo] +eGFR <60 +diagnosis heart failure +Warfarin +age >75 without PPI **Heart Failure** +Glitazone +NSAID +Tricyclic antidepressant	+ another antiplatelet. +NSAID +Macrolide +Quinolone +Metronidazole +azole antifungal **Drugs for which specialist advice is strongly advised before altering include:** • anticonvulsants for epilepsy • antidepressant, antipsychotic and mood stabilising drugs (eg lithium) • drugs for the management of Parkinson's Disease • amiodarone • disease-modifying antirheumatic drugs.	It is particularly important to clarify if patients on the following have a **Valid and Current Indication** and are still felt to be effective. • Digoxin in higher doses 250 microgram + • Antipsychotics • Tricyclic antidepressants • Benzodiazipines particularly long term • Anticholinergics • Phenothiazines [eg prochlorperazine] • Combinations painkillers [eg cocodamol v paracetamol]	• ACE inhibitors • Angiotensin 2 Receptor Blockers • NSAIDs • Diuretics • Spironolactone , Eplerenone • Metformin **In Dehydrated Adults** For example those suffering from more than minor vomiting/diarrhoea. Restart when well (eg 24 to 48 hrs eating and drinking normally). Adults with advanced heart failure can decompensate rapidly off drugs and adults with more than minor dehydration in this group need urgent specialist advice.

DELETED SCENES

C) Reduction in the harm from diagnosed and undiagnosed impaired renal function.

Aims: To reduce the harm from diagnosed and undiagnosed impaired renal function through:
   I.   Improving recording of chronic kidney disease.
   II.   Organising eGFR check for patients who are taking medications that can adversely affect renal function who have not had eGFR checked within the last 12 months
   III.   Performing an annual 'kidney check' for patients with chronic kidney disease.

Change Ideas:
   I.   Develop a system to record the diagnosis of chronic kidney diseases for patients with reduced eGFR twice, at least 3 months apart

   II.   Generate list of patient on nephrotoxic medication and recall for eGFR and ACR if not done in <12 months

   III.   Recall CKD patients identified as not having the ingredients of annual kidney check recorded.

Measures:

   I.   Proportion of patients with eGFR<60 on two consecutive occasions at least 3 months a part who have *renal impairment* recorded as an active diagnosis

   II.   Proportion of target patients who have had renal function monitoring in the last 12months

   III.   Proportion of patients who have had an annual kidney check

We know that 10% of Australian general practice patients have CKD using the definition of eGFR less than 60 on two consecutive occasions at least 3 months a part [40]. Why is this important? Many of the medicines commonly prescribed become dangerous as renal function declines or can critically impair renal function. Once identified in past history lists most GP software systems will have a prescribing alert when prescribing one of these medicines. Likewise letters to specialists and patient-held GPMP and e-Health will carry the information. In this part of the collaborative practices will be encouraged to develop a registry of patients with CKD using an automated search of eGFR results using adapted PenCat tool.

'Kidney check' involves checking morning urine for albumin-creatinine ratio AND eGFR AND blood pressure. Patients identified by computer search to be taking renal-critical medicines will be invited for an annual blood test to monitor eGFR.

Commonly prescribed drugs that may need to be reduced in dose or ceased in CKD:
➢ Antivirals
➢ Benzodiazepines
➢ Colchicine
➢ Digoxin
➢ Fenofibrate
➢ Gabapentin
➢ Glibenclamide
➢ Insulin
➢ Lithium
➢ Metformin
➢ Opioid analgesics
➢ Sotalol
➢ Spironolactone

Commonly prescribed drugs that can adversely affect kidney function in CKD:
➢ NSAIDs and COX-2 inhibitors
➢ ACE inhibitors/angiotensin receptor blockers (ARBs)
➢ Diuretics
➢ Combinations of NSAIDs/COX-2 inhibitor, ACEI/ARBs and diuretics
➢ Aminoglycosides
➢ Lithium

Legal Repercussions regarding Event Logs – Medico-Legal Advised from RACGP[1]

"Practices may find it beneficial to keep a record of de-identified near misses and mistakes to facilitate quality improvement initiatives. In April 2005 the RACGP obtained legal advice from Milstein and Associates which is pertinent to the use of event registers/records. The advice is still relevant and is available at
www.racgp.org.au/content/navigationmenu/practicesupport/standardsforgeneralpractices/changes_to_college_standards_advice_re_medical_legal_repercussions.pdf

Notifying your medical defence organisation is vital.

The RACGP recommends that GPs notify their medical defence organisation of all events or circumstances that they perceive might give rise to a claim and certainly before any action is taken to resolve a complaint or apologise for a mistake involving clinical care."

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