Coping with complexity

A resource to support pre-registration and early career pharmacists in clinical decision-making

Chartered Institute of Ergonomics & Human Factors

NHS Health Education England

NHS Education for Scotland

Contents

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Scope

This guidance is aimed at early career pharmacists, especially those in foundation pharmacist positions managing the transition from education to the workplace environment. It was prepared in response to a request from David Gibson, Associate Dean Foundation Pharmacists, School of Pharmacy and Medicines Optimisation (North), National Curriculum Lead, Interim Foundation Pharmacist Programme (HEE) and Lead Clinical Pharmacist at County Durham and Darlington Foundation Trust.

Support in clinical decision-making is recognised as an educational development need for early career pharmacists, making the transition from a university education where there is very little exposure to the clinical environment into the work environment. This situation is compounded by a policy landscape which puts the pharmacist in a central role for clinical management of long-term complex morbidities, making clinical decision making and taking responsibility for patient outcomes increasingly important. The guidance will also be of use to those involved in the education and mentorship of early career pharmacists.

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Foreword

This educational resource has been designed to support the development of newly qualified pharmacists undertaking the Foundation Pharmacist Programme. The aim of foundation training is to promote and embed 'the right behaviours', helping inexperienced practitioners acquire the skills, competencies and values necessary for working in extended clinical roles and improving therapeutic outcomes.

First and foremost, the Foundation Pharmacist Programme is work based. Skills and competencies must therefore be developed in what might best be described as naturalistic settings. This presents a significant challenge for newly qualified professionals in any sector, but it is compounded for pharmacists by the comparative lack of practice exposure during undergraduate training. Naturalistic settings are characterised by their dynamic nature, where conditions are constantly changing, information is incomplete and the goals of work are often ill-defined and competing. In healthcare, work is often 'high stakes' and carried out under time pressure by multi-disciplinary teams. In short, even the most routine situations can be summed up as 'complex.'

Decision-making is key to care delivery. The RPS Foundation Pharmacist Framework recognises the need for decision-making to be driven by high-quality information and to be supported by appropriate strategies for managing risk and uncertainty. It also makes it clear that while decision-making should be person-centred, ensure safety and optimise care outcomes, this cannot be done in isolation from other goals, such as cost-effectiveness of treatment. Effective decision-making is often seen as one of the hallmarks of the expert professional, and it is recognised that such expertise develops as a function of experience. Considerable research has gone into unpacking this developmental process, much of it in the area of clinical practice. While there are a number of models which describe the maturation of decision-making, it is recognised that these have limits in practice. Klein and colleagues (1993) suggest that this is because models are often based on the study of subjects in artificial environments that fail to mirror the complexities of normal work. Decision-making is highly dependent on the context in which it takes place. This led to the concept of naturalistic decision-making which seeks to understand how decisions are taken within complex work settings.

In clinical settings, having a good understanding of the complexity of the work system is sometimes described as 'situational awareness'. This term often attracts criticism in the safety science world, primarily because it is difficult to define or objectively measure. However, as a real-world principle it can be a useful starting point for developing understanding of complexity. The key elements of situational awareness are 'what is going on right now?' and 'what will happen next?'. Understanding both of these requires the practitioner to hold some sort of mental model of their work system.

The aim of this resource is to introduce basic theory regarding clinical decision-making in complex situations and to explain how a systems approach can support competency development. The underpinning principles are drawn from the concept of Threat and Error Management (TEM) which is seen as the overarching safety management approach embedded in commercial pilot training and flight operations. There is considerable evidence to indicate a positive impact on all operational outcomes, not just safety, and it specifically addresses decision-making as a critical element of normal practice. Its success is derived from its embedding within routine work

activities (UK Civil Aviation Authority, 2014). Consequently, this resource also provides a practical framework that will support the newly qualified pharmacist in adopting these principles in their own work.

It is worth reiterating that effective decision-making is an advanced skill and can only be fully developed through experience. This resource is not a 'decision aid'; rather, it is intended to enhance decision-making skill development by opening up a discussion about complexity and uncertainty and how these may be managed on a practical level. It can used prospectively by individuals to support decision-making, but it is also intended that it is used retrospectively as part of reflective practice. It is considered that output of the suggested systems tool could be a useful discussion focus for Foundation Pharmacists and their Educational Supervisors. Much of expert decision-making is implicit; such discussions can help make this 'unconscious competence' explicit, not only supporting individual practitioner development, but also potentially enhancing the development of future resources. In aviation, TEM is not seen as a 'tool', but rather as an operational philosophy, designed to raise individuals' awareness of their vulnerability. Daily practice of the principles provokes a mindset where practitioners become used to spotting 'error potential' and are better able to guard against it.

This resource is comprised of three sections:
• **Part 1: Theoretical concepts**
• **Part 2: Practical approaches**
• **Part 3: Applying the principles.**

The materials should be used by both Foundation Pharmacists and their Educational Supervisors as a focus for reflective discussion.

Introduction

The heart of pharmacy professionalism is considered to be the delivery of safe and effective care, and clinical decision-making is fundamental to achieving this. The development of the Standards for Pharmacy Professionals (GPhC, 2017) reflects healthcare reform initiatives which have seen expanded practice roles for pharmacists, based on a pharmaceutical care model. The ultimate vision is to support the clear direction of the NHS Five Year Forward View (FYFV; NHS England, 2019a) and the NHS Long Term Plan (LTP; NHS England, 2019b).

The FYFV and LTP strategies place great emphasis on service integration, including new models of care combining primary and secondary care and health and social care. The LTP creates significant demands for clinical pharmacists, including Primary Care Networks (PCNs), clinical pharmacists, pharmacists providing the NHS Community Pharmacy Consultation Service (CPCS) and pharmacists providing care in the LTP major disease areas (particularly cancer, mental health, cardiovascular and respiratory), alongside the increase in acuity and service improvements such as seven-day services in hospital.

This new direction also places a greater emphasis on pharmacist independent prescribing. This is a different and much more complex environment in which to function. 'Person-centred' healthcare involves supporting and empowering people as active contributors to their own health, safety and wellbeing, and requires holistic understanding of an individual's total healthcare experience. The direction of change is captured within *We are the NHS: People Plan for 2020/21* which describes a "sustainable supply of prescribing pharmacists with enhanced clinical and consultation skills". Similar initiatives exist across the home nations (Scottish Government, 2013; Welsh Pharmaceutical Committee, 2019). This change in role will require enhanced decision-making capability.

Decision-making has perhaps traditionally centred around a relatively simple triage process to decide whether referral to a physician is necessary, with the decision being arrived at largely as a result of protocol-driven questioning. The pharmacist may then make a product recommendation from the limited range of medicines available without a prescription. In contrast, the enhanced pharmacist role frequently takes the pharmacist into that space where difficult therapeutic decisions are commonplace, and in the face of uncertainty, sole responsibility must be taken for patient outcomes. Furthermore, there is increasing recognition of the importance of involving the patient – as the expert in their own lived experience of health and illness – in any decision-making process.

Evidence-informed decision-making is thus an essential competence for advanced practice, and like any such competence, it must be developed through education and professional development programmes. Such programmes must accurately define what is meant by evidence-based decision-making and provide opportunities to acquire skills and demonstrate competency to a level commensurate with experience.

There is a paucity of literature exploring understanding of how experienced pharmacists make decisions, and even less about how decision-making skills are developed through education and training. Furthermore, the few studies that do exist suggest that understanding expert pharmacist decision-making is hampered by the fact that even in situations where complex therapeutic decisions are commonplace, practitioners lack the language to articulate their internal decision-

making processes to support the learning of those less experienced (Anakin et al., 2020). A study by Magola and colleagues (2018) noted that inexperienced pharmacists themselves recognise that decision-making is challenging, and cite the main difficulty being applying their knowledge, especially in unfamiliar scenarios. This is exacerbated by the perceived loss of individual support compared to that provided when under training and they also feel the weight of professional liability quite keenly. The Foundation Pharmacist Programme seeks to address this by matching pharmacists with an Educational Supervisor, a relationship that should support the development of clinical competencies, including decision-making.

Pharmacists are not alone among the healthcare and allied professions. Even for medicine, where considerably more work has been done, relatively little is known and it is still accepted that there are significant weaknesses in educational curricula when it comes to development of decision-making competencies (Anakin et al., 2020).

KEY LEARNING DEVELOPMENT POINT 1:
### The importance of effective mentorship

Supporting new and early career pharmacists requires provision of 'safe space' for decision-making. At a practical level, being overloaded with work tasks removes the space necessary for this reflection, but there are also other considerations. The internal 'illness scripts' described in Section 1.1 are not possessed by novices but can be to some extent shared, through educational supervision and also through externalising them by building banks of case studies for novices to use. Educational supervision should support the learner in 'deliberate and effortful practice' of engaging with such scenarios. There should be high-quality learner-specific feedback provided, with space and time for the learner to reflect and assimilate the experience into their own 'schemas'.

This educational supervision needs to extend to support for the development of adaptive capacity. A degree of autonomy is required: clinicians need to be able to make decisions, observe the outcome of that decision, reflect and apply this learning. They need freedom to be able to behave differently in future if they perceive this to be necessary. This can be challenging for pharmacists generally, who are recognised as risk averse (Rosenthal et al., 2016) with a strong tendency towards rule-based behaviour. High-risk industries spend a lot of time on training that considers 'going off' standard operating procedures. Opportunity to adapt in high-risk environments is recognised to enhance adaptive capacity in future events (Dekker and Lundstrom, 2007) – it is important to allow clinicians the opportunity to deal with this, while managing the risks involved.

This is recognised within the GPhC Standards where it is noted that there will be times when professionals are faced with conflicting legal and professional responsibilities. Open discussion has no doubt been hampered by a punitive legislative framework, but effective 'real time' mentorship, combined with peer support, should aid reflection and allow open discussion that supports novice pharmacists in coming to a decision, but also provides a 'sense check' that ensures that these decisions do not have unduly serious negative outcomes.

Part 1: Theoretical concepts

Decision-making: Making the implicit explicit
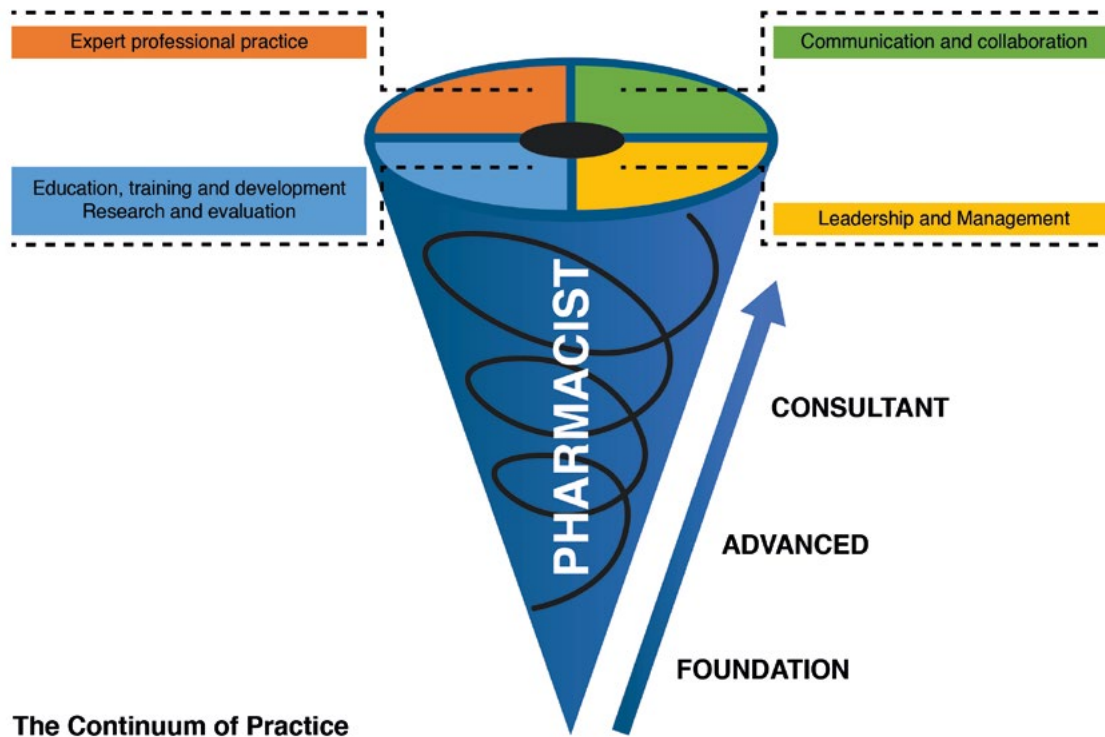
Definitions (RPS, 2019)

Clinical decision-making: Choosing a course of clinical action.

Expert: Operationally defined as those who are recognised within their profession as having the necessary skills and abilities to perform at the highest level.

Evidence-based: Evidence-based practice (EBP) requires that decisions about health care are based on the best available, current, valid and relevant evidence. This often refers to clinical guidelines such as NICE and SIGN.

Evidence-informed: 'Evidence-informed is used often these days and is the catch-phrase of choice as it appears to provide more flexibility regarding the nature of the evidence and its use, i.e., it implies that many different levels of evidence and types of evidence [...] are needed and used to support decisions in clinical practice. Therefore, clinicians use guidelines to inform, rather than dictate, their decision. Many people believe that "Evidence-informed practice extends beyond the early definitions of evidenced-based practice."'

1.1 How do experts make decisions?

Decisions need to be made quickly, acknowledging uncertainty and within a potentially rapidly evolving clinical situation. As complexity increases, the more expertise is needed, and the greater the development need for the Foundation Pharmacist. Unpacking this is key to devising strategies for training and development (and measuring their impact). Much of what has been done in this has been in medicine, but the principles are unlikely to be different.

What is known so far?

- Fundamentally, decision-making is about practical reasoning. Practitioners have to interpret the clinical context and create a coherent narrative that allows them to rationalise incomplete evidence 'with a practical interpretive lens'.
- This practical reasoning has three elements:
  - 'sense-making' – how practitioners interpret the situation,
  - the course of action they select, and
  - 'adaptation' – how events are understood retrospectively. Reflection on decision-making events is then applied to enhance future performance. This may occur rapidly within the same decision-making event (known as 'reflection-in-action') or may happen over a longer time frame ('reflection-on-action') shaping performance in future decision-making events (Schon, 1983).
- While there are various models which try to describe decision-making (and other aspects of professional behaviour), most recognise a developmental aspect, moving from competency, through proficiency to expertise. 'Competency' is seen as rule-guided behaviour, characterised by recognising and discriminating between situations, allowing individuals to carry out routine tasks. 'Proficiency' is associated with a more holistic approach, drawing on more than just 'the rules'. In routine situations, behaviour becomes more automatic, although in more complex scenarios, an analytical approach is still used. The hallmark of 'expert practice' is that situational understanding becomes intuitive rather than analytical.
- In intuitive decision-making, experts make effective use of what would be considered 'organised knowledge.' Rather than seeing information as discrete facts, as novices do, it is arranged (internally and often unconsciously) into 'high-level concepts.' In healthcare terms, this tends to manifest as a large set of representative cases (or 'illness scripts') that can then be compared with a new clinical situation (Schmidt and Rikers, 2007). A more familiar example that illustrates this point is the expert chess player. Simon and Gobert (1996) asked players of different skill levels to recall the position of chess pieces on a board. In some scenarios, the pieces were arranged randomly, while in others they were located logically according to chess rules. For the 'random' boards, there was no difference between expert and novice recall. However, when the pieces were located logically, expert recall was significantly better. Experts 'see' the board differently – not in terms of the physical relationship between pieces, but the functional 'chess' relationship between them.

Game
Experts recalled correctly a significant higher number of pieces than novices.

Random
The number of pieces correctly recalled does not differ between experts and novices.

- Effective decision-making comes with inherent risks. Things will not always go according to plan. Expert decision-makers accept this and factor it into their practice. In weighing up possible courses of action, hazards and risks (and their outcomes) are considered, as are mitigation strategies. This is the underpinning philosophy of threat and error management (TEM).

1.2 Decision-making is complex cognitive work

At the heart of decision-making is the cognitive ability to reduce uncertainty. This is achieved through a combination of technical skills and knowledge, personal qualities and clinical experience.

Technical skill competency and knowledge are important, but it is the appropriate selection and application of these that denotes the expert. The latter point indicates decision-making skills are to some extent a function of time and experience, although it is recognised that support strategies can be developed, and these can be used for training and development.

The first step is understanding the cognitive constructs used by clinicians. Important aspects to consider include:

- Expert decision-makers are often described as 'being able to maintain the bigger picture' or 'having good situational awareness' or 'being able to reduce a problem to a state that is manageable.' Building this bigger picture requires effective information gathering but also the ability to recognise relevant information.
- In doing this, they demonstrate a capacity for 'macro-construction' – they are able to accurately capture and hold a working model of the system in which they are working. At some level, they recognise this can't be complete or even necessarily correct, so they are aware (unconsciously) of the dangers of decision-making bias (see Key Learning Development Point 2), and always reconsider evidence that the 'model' is wrong.
- It follows therefore that decision-making is an iterative process.
- Experts also recognise that clinical decision-making goes beyond just the clinical; decisions which consider allocation of resources, cost administration and priority setting will impact on the clinical aspects.
- Complex cognitive work includes recognising that successful decision-making depends on:
  - the knowledge, strategies and skills held by individual expert practitioners (as described above), and
  - work and domain driven factors that shape, support and constrain performance.
- While expert decision-makers generally rely on pattern selection, there is still an analytical element (albeit unconscious) that 'checks' for pattern fit. If no good fit is found, then a switch is made to a more conscious analytical model before selecting a course of action. If the situation is not resolved, the cycle starts again, with more information being gathered.

1.3 How do novices make decisions?

Research into decision-making is extensive, and numerous strategies and models have been described, many of which are applicable to clinical practice. A full consideration of these is beyond the scope of this document, but there are some theories that may provide useful insight to the developing practitioner.

Rational decision making

Many clinical decision-making models (including the limited resources available for pharmacy) have similarities with the 'rational decision-making model' shown below.

On the surface, this seems very straightforward, and for simple decisions it probably is. If an old car keeps breaking down, the problem (unreliability) is obvious and a new car is needed. An individual will have sufficient insight into their own life to establish decision criteria – the maximum they can afford to pay, the type of journeys they take and how many other people may need to use the car. They probably already have some idea of 'alternatives' and have been building a shortlist of next cars over the last few months, and can also access plenty of information about running costs, performance and the optional extras available to help them identify the best option. They also feel reasonably confident about implementing the decision because even if it's not perfect, it's not a matter of life and death. Things may be very different in a clinical context. Both time and information may be very limited. Even identifying the problem may be very difficult in a patient with long-standing multimorbidities. Despite the drawbacks of this model, it is of value because it represents the 'starting point' on the journey to developing decision-making expertise. It could also be argued that rational decision-making is 'best' because it is rigorous. However, this is simplistic – it is slow, and relies on gathering objective data in a sequential fashion. It is much harder when cues are less obvious and present simultaneously, which is often the case in clinical scenarios.
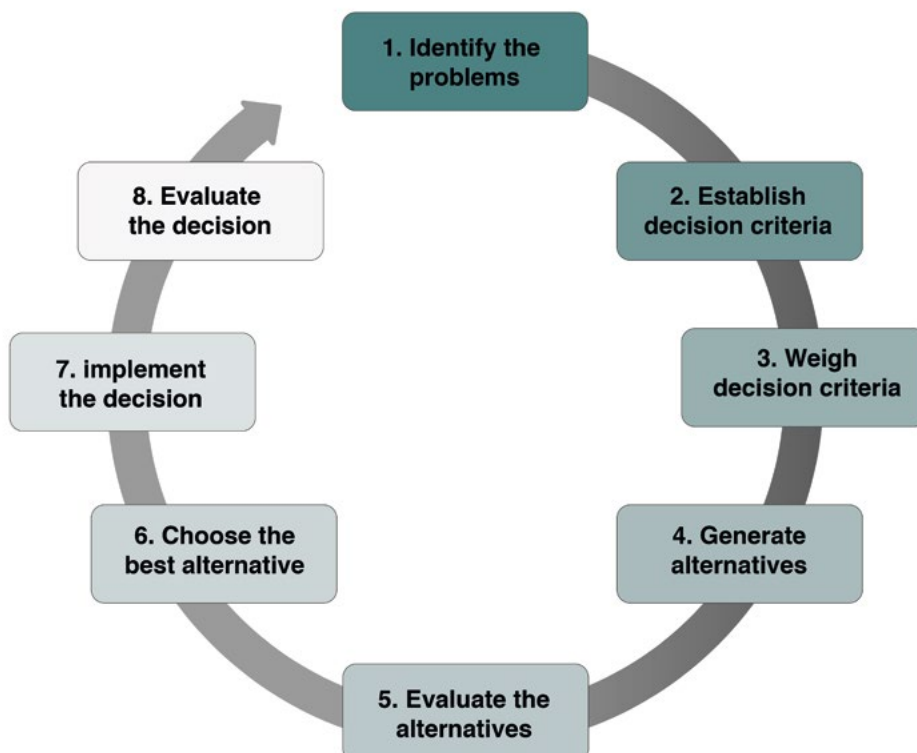
Dual Process Theory (DPT)

Kahneman (2011) describes decision making as the product of two interacting systems. System 1 is intuitive, using decision-making shortcuts (heuristics), relying on tacit knowledge generated from previous experience. System 2 is an analytical (rational) approach, requiring critical evaluation of evidence. This is much slower and requires more conscious effort. Experts are thought to use both – even when a clinician has a lot of experience to draw on, System 2 provides a useful balance to monitor the accuracy of a System 1 decision. While this theory is widely accepted, it suggests a dichotomous approach. While Kahneman suggests that it is not 'all or nothing' and decision-makers may switch from System 1 to System 2, other models that appear in the healthcare literature (such as cognitive continuum theory) build on DPT by attempting to identify characteristics of the decision-making task that predispose it to either System 1 or 2 processing. Intuitive (System 1) decision-making is more likely when the number of cues is large (and they present simultaneously), and the 'measurement' of these cues is subjective. System 2 (analytical) is more likely when the decision is associated with the presentation of a small number of objective cues. As a scenario develops, the availability and type of cues may evolve as more information is gathered, and the decision maker may switch modes.

Recognition primed decision-making (RPD)

RPD considers decision-making in naturalistic settings, reflecting the fact that decision-making is context-specific (Klein et al., 1993).

Recognition primed decision-making model
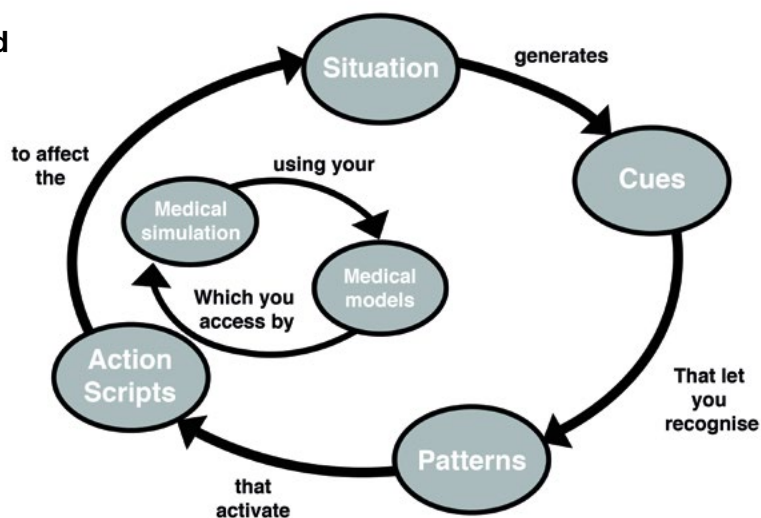
The decision-maker gathers information about the problem within its setting. These cues fall into patterns which are recognised. This recognition suggests a particular course of action (the 'action script') which is then tested against the decision-maker's mental models. Actions generate further cues which are evaluated and the process is repeated until resolution is achieved. This model sits well with the concept of situational awareness described previously and is the model which underpins threat and error management.

While novice decision-makers are likely to rely more on analytical approaches, elements of other models are likely to be used. Even recently qualified pharmacists will have some experience (as well as a significant amount of knowledge) that can be accessed. Furthermore, expertise can often be drawn upon. In situations which are commonly encountered, expert decision-making is codified into a set of rules which can be used by less experienced practitioners.

Clinical decision-making is often complex, and resists the application of a single model, but by considering multiple models, it is possible to identify some key points that are useful for the developing decision-maker:

- All decision models recognise the importance of information gathering – high-quality, relevant information is likely to produce a better decision.
- Such information is context specific.
- Information may be objective or subjective.
- Not all information may be apparent or easily available.
- Effective decision-making relies on being able to build mental models, not just of the current situation, but also how this situation may change in response to the decision-maker's actions.
- Decisions often involve pattern recognition, and this improves with experience. Pattern recognition underpins the development of decision-making shortcuts or heuristics. Heuristics are personal constructs which often remain unspoken and are therefore subject to bias.

KEY LEARNING DEVELOPMENT POINT 2:
Decision-making is subject to bias

There are many different types of bias, but the types most likely to affect clinical decision-making include:

- **Affective bias** – the emotion triggered by a decision has a particularly high weight. The 'old' model of pharmacist decision-making used protocol-driven questioning to decide if referral was necessary, followed by recommendation of an over-the-counter product. Research suggests that while pharmacists recognised they should be using an evidence-based approach, their product recommendation actually has two key drivers: safety and patient desire for a particular product. So long as it was safe, the pharmacist would supply the desired product even if it was not likely to be the most effective (Hanna and Hughes, 2010).

- **Anchoring bias** – particularly high weight is given to the first piece of information received. Information uncovered later in the process is viewed as less important.

- **Availability bias** – judgements about probability of an event/diagnosis are based on the ease of recall for previous examples. Another type of availability bias is reliance on information that can easily be obtained. The concept of 'unknown unknowns' is related to this as it is highly likely that information important to decision-making exists but that the decision maker is unaware of.

- **Recency bias** – a recent particular event which will be very clear in recent memory, and likely to influence later decisions.

- **Escalation of commitment bias** – this is similar to the 'sunk costs fallacy' where the more time and effort invested into a decision, the more likely a person is to continue down that route, even when new evidence comes to light to suggest a better alternative.

- **Confirmation bias** – selective harvesting of information that supports the decision, ignoring data that does not fit.

What all these biases have in common is that they are unconscious. The important thing is to accept that they influence decision-making and actively consider the level of significance. Effective mentorship should create time and space to allow for, and support, this reflection.

Acknowledging the use of heuristics recognises the activity of 'modelling' the problem. One way of minimising the risk of bias is to make this modelling more conscious – and to challenge that model.

KEY LEARNING DEVELOPMENT POINT 3:
Explicitly building working mental models supports better decision-making

Think about a person living with diabetes, who after many years of good control, now suddenly appears to have trouble with managing their blood glucose levels. The 'problem' here is not the blood glucose levels per se, but whatever it is that is causing the change (and the impact it will have on health), and this can be very difficult to unpack.

When establishing 'decision criteria', while there will be some insight into options available (from guidelines and local protocols etc.), the decision-maker will not be the person living with the outcomes of the decision, so decision criteria need to be established in partnership with the other stakeholders. This may extend beyond the patient – many clinical decisions have impact on carers and family members. Similarly, when deciding between options, you will need to have some idea of the risks and benefits of each option and be able to view those risks through the eyes of other stakeholders.

Even implementing and evaluating a decision can be very difficult – the patient leaves with some sort of treatment plan, but when will they be seen again and how much insight can be achieved into the impact of decision during a short consultation? Modelling decision-making can be useful, but what models like this fail to capture is the complexity behind each of the steps. So, rather than modelling decision-making, the aim should be to 'model the problem', recognising that even if the patient's condition is common, the patient experience is highly context specific and this needs to be built into the model.

In short, decision-making is easiest when:

- The right information is available to
  - identify the problem;
  - define decision criteria; and
  - come up with alternative options.
- Risks between these alternative options can be accurately assessed.
- The system is resilient. Resilient systems are systems which design in risk mitigation steps. This is important at all levels and, at the individual practitioner level, it is important to recognise the risks associated with the decisions and consider steps to mitigate these risks. Good modelling supports all these steps.

KEY LEARNING DEVELOPMENT POINT 4:
Building useful working models is best supported by a systems (Human Factors) approach

System: "A set of inter-related or coupled activities or entities (hardware, software, buildings, spaces, communities and people) with a joint purpose" (Dul et al., 2012). It is the interactions between these entities that give rise to outcomes. Systems can be huge, but they can also be very small – a pharmacist interacting with a person to optimise their medicines use is still a system, and might be more complex than it might first appear. Small systems are likely to have interactions with other systems, or they may be 'nested' entirely within another system.

Complexity: Complex systems are those in which the entities are numerous (and hard to describe) and interact with each other in multiple and often unpredictable ways.

Emergence: Given that complex systems are characterised by these unpredictable interactions, this means that the outcomes are often similarly unpredictable. Such outcomes are described as 'emergent.' Many of the important outcomes, including safety, fall into this category.

Human Factors/Ergonomics (HFE): The practice that (i) takes a systems approach to understanding work, (ii) is design-driven (not relying on behavioural change for improvement) and (iii) focuses on dual outcomes of optimising system performance and improving human wellbeing (Dul et al., 2012).

A lack of support for development of decision-making capacity is not unique to pharmacy – healthcare curricula, reflecting professional behaviours, are articulated in terms of course outcomes. Assessment is designed to capture these, with teaching and learning activities to support assessment success. While the words 'systems', 'safety' and 'evidence-informed decision making' are frequently cited in documentation, there is very little guidance for healthcare educators as to how they might support students in developing competencies in these areas. Methodology and methods to support safety and decision making are largely absent from educational programmes. Human Factors/Ergonomics as a discipline has much to offer here, not least a range of methods and tools that can be used by non-experts to gather information about their system and support decision-making.

1.4 A framework for coping with risk: Threat and error management (TEM)

TEM is based on a number of key assumptions (Dekker and Lundstrom, 2007; UK CAA 2014):

- It's (potentially) dangerous out there! Risky situations (threats) will be encountered.
- People will make mistakes (errors). This can be particularly hard for newly qualified pharmacists to deal with, especially as undergraduate training tends to focus on error reduction or elimination. In recent years, Education Standards have indicated that "any evidence of an assessment demonstrating unsafe practice must result in failure" (GPhC, 2011). While this is a high-level statement, and institutions have shown creativity in the way this Standard is met, there is the risk that 'error' is viewed as a negative endpoint, rather than a normal outcome of everyday work. This can lead to a reduced focus on error recovery strategies (Vosper and Hignett, 2018).
- It is not possible to avoid all the threats and errors. The aim is to manage these by detecting them as early as possible and responding to them in a timely and appropriate way. The aim is to prevent threats and errors from developing into adverse outcomes.
- Day-to-day work is complex and context specific. A consideration of potential threats and errors needs to be carried out in each specific context. The complete context needs to be considered – that is to say, systems thinking is required.
- The systems thinking approach that underlies TEM informs decision-making. It increases both the amount and quality of information that can be gathered to inform the decision, but also improves sensitivity in relation to evaluating the outcomes of decision-making. When a practitioner has a good understanding of their system, it is easier to predict not only what might go wrong, but how this might be recognised and responded to in a timely fashion.
- 'Threats' are not just threats to safety, but to any desirable outcome, including organisational outcomes such as financial performance, user satisfaction and reputational standing.

Threats

In the aviation model, threats are considered to be hazards beyond the influence of the flight crew that have to be 'managed'. These are generally divided into anticipated (an example here would be forecast weather, as a detailed consideration of weather is an inherent part of flight planning, and forecast weather is generally reasonably accurate); unanticipated (which would include things like aircraft malfunction, or weather that was different from that forecast); and latent (unlikely to be obvious to flight crew and often only uncovered as a result of the ongoing analysis that is part of the safety management system). These latent issues may include, for example, organisational culture, or rostering patterns that make fatigue more likely. Latent threats may also include poorly designed equipment and sub-optimal standard operating procedures.

Errors

In TEM, errors are defined according to Reason's taxonomy (1990). An error is any "occasion in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency". Systems are discussed in more detail later in this document, but in very simple terms, systems can be defined as a set of elements that are united in a common purpose. Such elements might include people (and their human vulnerabilities), equipment (and its design), procedures, working practices etc. These are all closely interconnected and together all contribute to the outcomes of the system, good or bad. Errors should therefore be viewed as belonging to the system, rather

than to individual people. When reflecting on adverse events, rather than blaming individuals for errors, the question that should be asked is, 'why did the system allow this error to occur?'.

Errors are considered to fall into two categories: skill-based and knowledge-based. Much of everyday work relies on skills that have been learnt to the point they have become autonomous. By this point it can usually be robustly repeated. However, a skill learnt in one context, may not be appropriate for a different situation. Carrying out the skill correctly, but in the wrong situation, is described as a **slip**. Sometimes errors may result from a task step being missed, for example, an item off a checklist or a step in a standard operating procedure is inadvertently missed. This type of error is called a **lapse**. **Mistakes** are knowledge-based errors – this is where a person has considered the situation, decided on a course of action and carries this out correctly, but the desired outcome is not achieved.

In addition to errors, it is also important to consider **violations**. Violations are deliberate actions 'against the rules'. Routine violations occur commonly, are usually well-intentioned and can have positive, neutral or negative outcomes. Often, violations are 'workarounds' – behaviours that are necessary in order to achieve the necessary outcomes in a complex situation. The concept of violations is not something that necessarily sits well with pharmacists – this is probably due in part to risk aversion, but also a historically punitive legislative framework (Langley, 2014). However, standard operating procedures, etc, cannot account for every scenario that might unfold in clinical practice. Practitioners may have to make decisions in scenarios that the designers of the procedure could not have foreseen. The ability of an individual to respond in such circumstances is known as adaptive capacity, and it is an important element of resilience. The TEM strategy makes room for these discussions, thus supporting the development of adaptive capacity.

Management – An example from aviation

A specific work-based scenario is considered (usually the flight ahead) and a plan is made by the flight crew (which will involve some initial decisions). Threats and errors considered likely to affect this specific plan are then considered. For example, information from the destination airport might indicate that there are large numbers of birds in the vicinity. The 'threat' therefore is the possibility of a bird strike. However, the crew don't leave it at this – they predict likely scenarios involving bird strikes. Some are likely to be inconsequential – if a bird hits the airframe, it may not cause any problems. However, if it gets drawn into the engines, the worst case scenario would be that the engines are disabled. This is what happened to US Airways Flight 1549 which ditched in the Hudson with no loss of life. Flight crews would know that such a scenario is very unlikely (from data shared across the sector) but they would recognise that loss of one engine was a more likely outcome. The crew would also discuss multiple potential impacts of engine loss: the loss of one engine is not an emergency (it is considered an 'abnormal situation') but it can be appreciated that if it happens at a time of high workload, such as final approach, the risks are higher than when it happens in the cruise. Again, as a result of experience, crews will be aware of errors that might arise in such situations (there have been a number of incidents where the wrong engine has been shut down with catastrophic consequences, such as British Midland Flight 92, which crashed on an M1 embankment, resulting in 47 fatalities). As well as considering generic data, the crew would consider information specific to their own context – their own experience, the particular aircraft being flown, their currency etc. In this way, the most likely scenarios can be considered and recovery strategies planned in advance. These strategies will – where possible – attempt to answer the problem by converging on standard operating procedures. For example, in the case of engine loss, the crew will take time to assess the situation (to avoid shutting down the wrong engine) before beginning, perhaps, the SOPs for an engine shutdown and a one engine-inoperative landing. As part of this, crews will have discussed cues – 'how will we know we have had a bird strike?' 'How will we recognise we have lost an engine?' 'How will we know which engine?' This discussion makes it early recognition more likely. Having considered recovery strategies in advance, it is also more likely that a timely intervention is made.

Key principles of TEM are therefore:

- 'Things will go wrong.' The aims are to:
  - minimise what will go wrong and
  - ensure that when inevitably things do go wrong, it is detected as early as possible, and
  - have pre-considered recovery strategies to hand to support timely intervention.
- TEM is essentially asking 'can *this* crew, with *this* level of training and experience, safely fly *this* route, in *this* aircraft, in *these* weather conditions?

The success of TEM in aviation stems from its embedding in all aspects of training and practice. Core competencies for all flying instructors include the ability to deliver TEM training at appropriate points in all training courses, including initial and ongoing training. However, this is reinforced through daily practice – TEM is actively discussed as part of pre-flight briefing, and reflected on as part of debriefing. It is this verbalisation of risk awareness that is so valuable. When flight crew TEM is assessed, the examiner is much more interested in the process than the outcome, as it uncovers valuable information about a crew's attitude to risk.

Risk itself is a construction – situations that appear daunting to a newly qualified pharmacist may appear much less so to a professional who has 30 years' experience of similar situations. However, it is also worth noting that this can work in both ways – inexperience may lead to an underestimation of complexity, especially where information is limited. TEM discussions make attitudes to safety (and strategies for improving it) explicit, allowing weaknesses to be identified and addressed.

How does this help with decision-making?
Firstly, being more comfortable with managing the risks associated with decision-making is likely to improve confidence. Secondly, it is an excellent mechanism for externalising decision-making processes, which supports the development of expertise.

How can this be built into the daily work of a newly-qualified pharmacist?
Even when a pharmacist is working alone, TEM principles can still be applied. One of the strengths of airline TEM is that discussing it with team members undoubtedly makes for a richer consideration of threat and error because of the different experience levels. Conversations around risk management would be an excellent topic for reflective discussions with Educational Supervisors. Depending on the circumstances, it might be possible to do this prospectively, for example, before a consultation with a patient already known to the team. However, this framework could also be used retrospectively as a tool for critical reflection on performance.

A final point to consider is that TEM demands the building of mental models about how the flight may turn out. By considering options, pilots are, in fact, identifying some likely patterns that can be drawn upon later as 'recognition primes.' The fact that crews are able to do this relatively easily is because they have a very structured flight planning framework that supports model building.
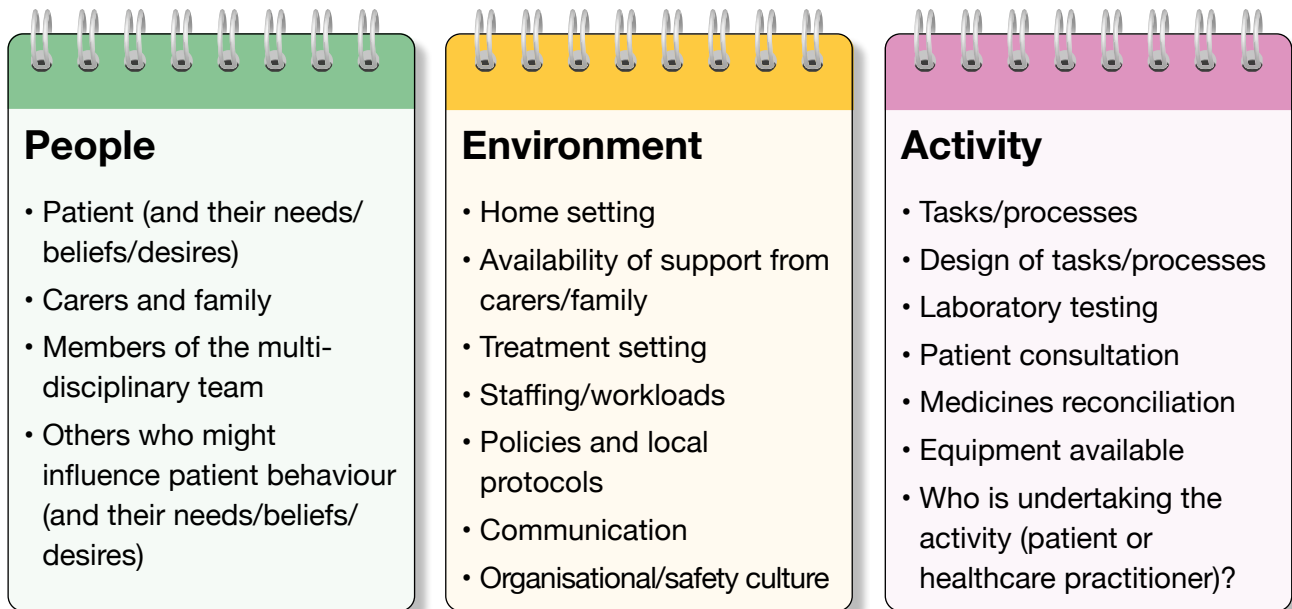
Part 2: Practical approaches

2.1 How to build a system model

From what has been discussed above, systems are a set of entities, linked in a 'common purpose' and outcomes 'emerge' as a result of interactions between these entities. While there are lots of modelling frameworks described in the Human Factors literature (and many of these are usable by non-specialists), it is probably best to start with something simple while getting used to the approach. The model below shows a modification of a Human Factors framework that is used to support an enhanced version of Significant Event Analysis used within NHS Scotland.
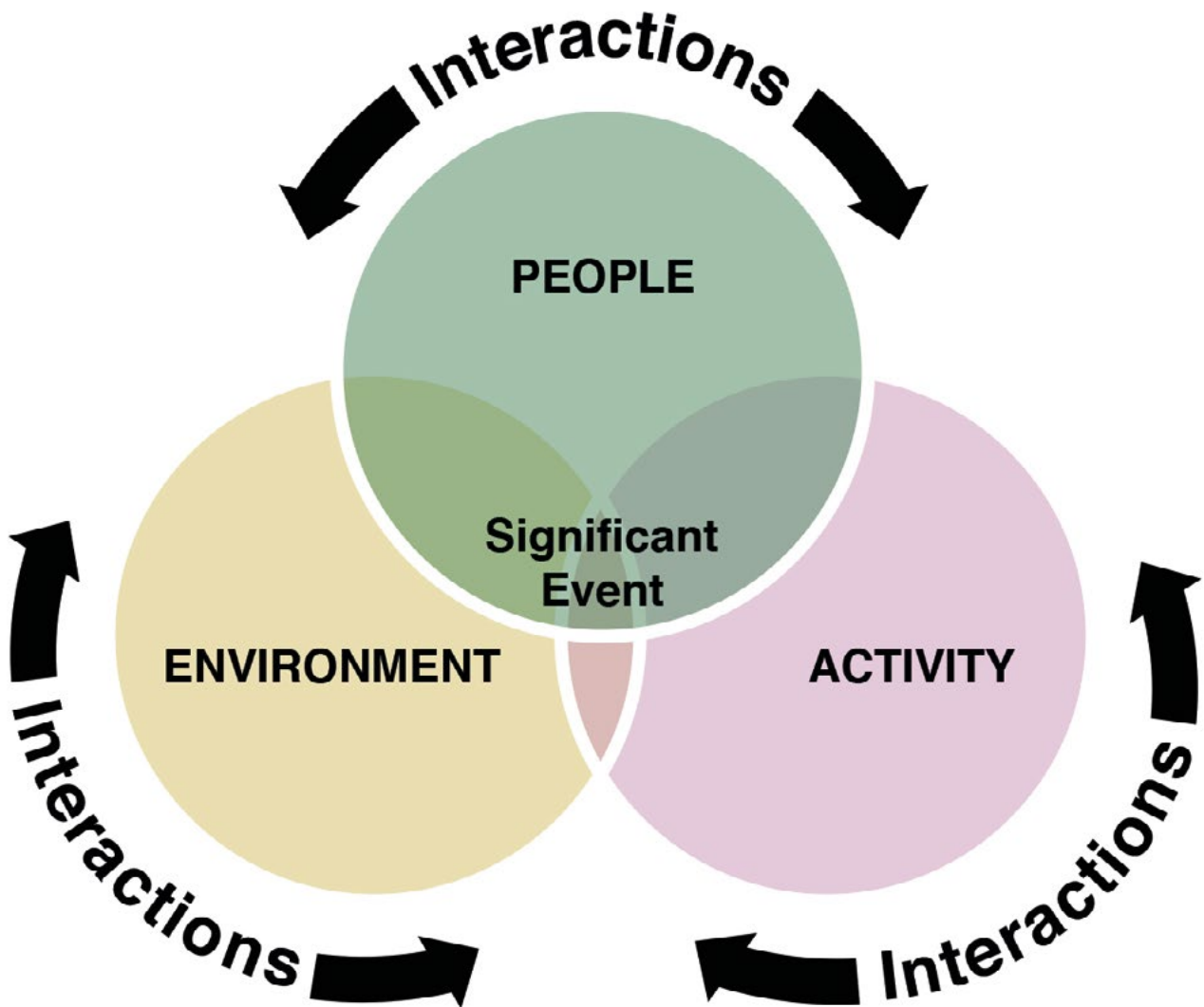
www.nes.scot.nhs.uk/shine/

We will consider the interactions later, but for now you need to think about what goes in each of the circles. To help with this, you can imagine your system as three notepads and consider what information should go on to each one.

People

- Patient (and their needs/beliefs/desires)
- Carers and family
- Members of the multi-disciplinary team
- Others who might influence patient behaviour (and their needs/beliefs/desires)

Environment

- Home setting
- Availability of support from carers/family
- Treatment setting
- Staffing/workloads
- Policies and local protocols
- Communication
- Organisational/safety culture

Activity

- Tasks/processes
- Design of tasks/processes
- Laboratory testing
- Patient consultation
- Medicines reconciliation
- Equipment available
- Who is undertaking the activity (patient or healthcare practitioner)?

Once the notepads are filled in, it soon becomes clear that even with a very specific example, they can get full very quickly.

There are a number of things to consider here.

How much should be included? This is about defining the system boundary; what is (and isn't) part of the system? A physical boundary (transition) could be the handover (physical movement) of patients from the pharmacy back to general practice, whereas a service boundary could be the transfer of information between a screening database and a disease register. Service boundaries are much softer than the physical boundaries, and not signposted with clear warnings.

On a practical note, an individual healthcare practitioner will mostly be focusing on parts of the system within their control, but by identifying where boundaries are drawn, the scope of activity can be articulated. As part of this, it is also important to define the overall system purpose. What are the desirable outcomes? The undesirable? In the case of a patient with diabetes, the desirable outcome might be getting HbA1c levels into the appropriate range, whereas an undesirable outcome might be the development or progression of complications such as retinopathy.

What if, even after defining the system, the notepads all get very full, very quickly and everything in there seems really important? This is probably a sign that the system is very complex, and it may be that when it comes to decision-making in such a system you need help.

What if two of the notepads are packed full, but the third is almost empty? This will alert the healthcare practitioner to 'information gaps' which will need to be addressed. A similar situation might arise where there is plenty on a notepad, but gaps are still obvious – it might be that there is plenty of information on the 'people pad', but very little about the patient.

Practical tip: Users may get different results from the systems analysis depending on which perspective is highlighted. For example, in the methotrexate example (**see Section 3.2**), the system could be reviewed primarily from the healthcare professional's perspective of 'my safe methotrexate prescribing system' or, alternatively, it could be turned round, describing it from the patient's perspective of 'my personal medication management system'. Flipping the system in this way often makes information gaps more apparent.

2.2: Explore system interactions

How is this done?
This requires understanding of the activity happening within the system. Often staff believe this is already well understood, especially in healthcare where much of day-to-day work is directed by evidence-based guidelines, standard operating procedures and local protocols. However, effective procedures writing is challenging and such documents are not always optimal.

This inevitably leads to workarounds – short cuts that allow the job to get done, despite the constantly changing pressures under which work happens. It is also important to remember that patients (and other people such as carers) undertake activity too – so healthcare professionals should consider if they have any insight into patient activity in the system. Often, this is a real blind spot, and can be made worse by a healthcare practitioner's unchallenged assumptions that a patient will be compliant with their treatment. **'Flipping the system' will raise awareness of these gaps, but they still need to be closed.**

It is through information gathering that interactions between system entities can be identified. It is these interactions that generate the outcomes. The aim is to identify the important interactions. These could be 'good' and support positive outcomes or 'bad' and make undesirable outcomes more likely. By understanding this, it is possible to re-design the work to keep the good and get rid of the bad interactions. For example, when trying to measure blood pressure, the design of the equipment has a big impact on how easy the task is. The manual sphygmomanometer is quite challenging to use. Design is one factor – it then interacts with other factors (perhaps recent experience, or the environment is too noisy to hear the Korotkoff sounds). The introduction of the electronic sphygmomanometer was a design-based solution to getting rid of some of these potentially poor interactions.

> **Practical tip: How can a better understanding of the work system be achieved, i.e. how can the notepads be filled out effectively?** This will require observation of activity as it happens. This needs to be 'active observation' – with the opportunity to enter into dialogue with others about the way they do things and the reason behind their behaviours. It also requires individuals to actively reflect on the things they do. What governs behaviour in the workplace? It might be quite uncomfortable at times – for example, having to reflect on occasions they might 'go off SOP'. But if there is time and space to reflect on the reasons behind this behaviour, it sheds light on the constraints and limitations of the work environment, and opens up the opportunity for better understanding of the system.

Other sources of data about the system may include things like incident reports, audits and learning activities such as sessions for sharing good practice. It is also worth remembering that patient activity can be the hardest to capture. This is not routinely built into practice, and any patient consultation, especially if it is carried out remotely and therefore may lead to the missing of important cues, needs to be carried out with the intention of capturing system interactions that might impact on outcomes. Any decisions made need to consider this. 'Flipping the system' is especially important when patients are living with long-term conditions and should always be considered.

2.3: A note about the limitations of models

In reality, the underpinning principle is that accurately modelling a system is not possible. Firstly, there is the issue of complexity – in complex systems, it is impossible to fully capture their entirety. Secondly, such systems are by their nature constantly changing and the best that can be hoped for is a snapshot. Finally, there is an argument that there is no one true system – 'systems' can be considered to be social constructs and therefore each person within the system experiences that system differently.

It is clear from incident reporting and investigation that there are often seemingly incongruent versions of the same incident from the different people involved. What we are trying to do with a systems approach is just come up with a working model that gives enough insight to allow practice to be optimised. In order to do this, it is imperative that we gain multiple perspectives from system stakeholders.

2.4: Turning the notepad results into a decision

One way of thinking about the work done in analysing the system is that it is something like a risk assessment. The resultant model allows the application of TEM principles to the specific system. Risky aspects have been identified, but also, in identifying interactions that support good outcomes, existing control measures have also been recognised. By taking this a stage further and putting the findings into some sort of risk hierarchy, there is some 'evidence' to guide the selection of a forward course of action. Not only this, but some of the evidence gained supports the suggestion of interventions that maximise the likelihood of your decision being successful.

Ability   Demand   Ability   Demand   Ability   Demand

2.5 Making good decisions requires you to understand the capabilities of system stakeholders

'Flipping the system' can provide a better perspective from the patient's point of view and taking a Human Factors approach to this means the following questions are being asked:

- Can this person (worker, team, patient etc)...
- With this training (or information)...
- Do these tasks...
- With this equipment (or service)...
- To these standards (performance)...
- Under these conditions... repeatedly and reliably, without injury.

Success in carrying out a task (such as taking medication) depends on two factors: the demands exerted by the task (how hard is the task?) and the capabilities of the person carrying out the task (how well equipped is the user to carry out the task?).

In the **picture above**, it can be appreciated that if the capabilities of the user far exceed the demands exerted by the task, then there will be no problem – the task can be completed easily. If the imbalance is the other way round and the demands of the task far exceed the capabilities of the user, then it will be impossible to do the task. A third (and common) possibility is the situation where the user's capabilities just about meet the demands of the task. In this situation, it is possible that the task will be completed satisfactorily, but it can be appreciated that under certain circumstances where either the demands of the task increase or the capabilities of the user are reduced, the task may become impossible.

Task demands may increase for a number of reasons. A common one is the fact that tasks tend to be designed as though they will be the only task carried out by the user. In reality, workers are likely to have to cope with multiple tasks at the same time. Breakdown of equipment, increased pressures from management, etc may all increase demands. Individual capabilities vary on a daily basis – a worker may be fatigued, or perhaps their eyesight isn't great, and it's fine when they're completing the task in a brightly lit area, but as the light dims, they are unable to adapt. Intelligent task design minimises the task demands and maximises user capability. It is imperative for those involved in system and work design to know their users and their capabilities.

Practical tip: It is worth reflecting on how to get the best out of any patient consultation time, and think about a suitable questioning strategy. What sort of questions might elicit information about patient capabilities? Questions like 'tell me about a typical day...' or 'tell me about how you make sure you take the right tablets...' can reveal a lot. Asking this latter question might, for example, reveal that patients respond to cues which, from a professional perspective, would be recognised as inherently problematic, such as: "Well, I know I have to take three small round white ones, two big pink tablets and a little brown one."

2.6: Work guide

1. Define system (consider 'flipping')

2. Use framework to gather information (fill out notepads)

3. Identify and gather missing information (consider careful use of patient consultation to fill in gaps in patient perspective)
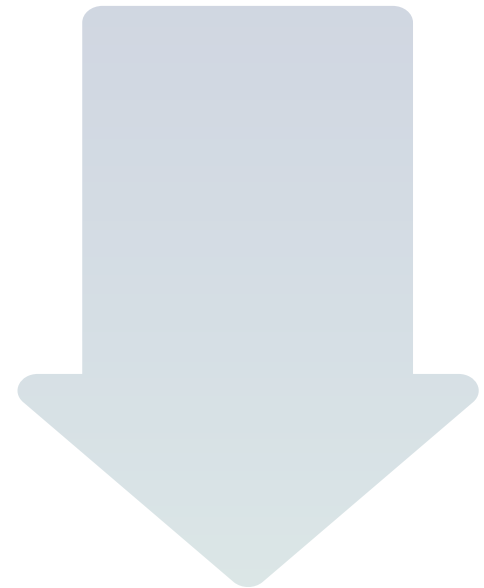
4. Identify interactions

5. Identify problem

If you think it's beyond you to make the decision, get help

6. Define decision criteria ('goals of treatment')

7. Decide alternative options

8. Use knowledge of interactions to risk assess options

9. Implement 'reasonable' option

Reflect on and evaluate decision. If necessary, repeat cycle.

Part 3: Applying the principles

3.1 Introduction

The aim of this resource is to introduce some of the underpinning theory of decision-making theory in complex clinical scenarios. By understanding performance-influencing factors, novice practitioners can gain deeper insight into how expert staff approach complex scenarios. Making the implicit explicit in this way supports the Foundation Pharmacist in actively developing these skills. This section considers three scenarios which should be recognisable by most Foundation Pharmacists. The notepad tool is used to capture the way in which pharmacists of differing levels of experience might decide on a course of action. There are a number of points to consider:

- The content of the notepads is far from exhaustive – the selection of elements is based on clinical realism combined with effectiveness in highlighting specific learning points. In real-life, the notepads may be much busier. This is not something to be frightened of – it should be considered as a first step to embracing complexity. Poor outcomes often result from attempts to over-simplify a scenario; by considering the messy reality, users are at least primed to recognise where threat might arise, and timely action can be taken.
- A number of different pharmacist 'personas' are described in each scenario. These were selected to reflect a realistic progression of the case. As a Foundation Pharmacist, this is worthy of reflection. In approaching complex decision-making, peers are one of the best sources of support and guidance. In any clinical setting, it is useful to think about who might be worth approaching to become part of a peer network.
- While these scenarios were being constructed, it became apparent that the move from less experienced pharmacist to advanced practitioner was accompanied by a change in focus, moving from 'drugs', through 'patient' to 'person living with a condition'. That is an interesting learning point, but also underlines the importance of less experienced practitioners 'flipping the system' to ensure they don't miss this perspective.
- Similarly, recognition of 'threats' is not as common for less experienced staff – this lack of awareness of complexity is a recognised issue at this stage, and so it is worth Educational Supervisors encouraging discussion and reflection specifically around this point.

The scenarios were built with input from expert practitioners who used the headings in the notepads as a framework for discussing the entirety of their experience in these scenarios. The final pages of this section contain reflections from an expert on Type 2 diabetes. This illustrates just what is meant by clinical complexity!

3.2 Worked example 1: Methotrexate

Andrea is 72 years old with longstanding rheumatoid arthritis. She always collects her medicines from the same pharmacy and is very reliable in terms of bringing her blood monitoring and dosage record booklet with her. She is visiting the pharmacy to collect her latest prescription. The Foundation Pharmacist has seen the prescription and will be dealing with this the next day.

Current medication
- 15mg methotrexate (MTX), once weekly (always dispensed as 6 x 2.5mg tablets), supplied in blister packs because of known problems with strength and dexterity
- Folic acid 1mg, od (except for day of methotrexate dose)
- Atorvastatin (due to high risk of CVD); 20mg od (on)

Foundation Pharmacist
Maryam is a 24-year-old Foundation Pharmacist, working in a community pharmacy. During her pre-registration year she attended a seminar on safer methotrexate prescribing (where the issues of labelling and packaging as well as tablet strengths were discussed) so she decides to approach this as CPD opportunity and uses the tool.

Educational Supervisor
Ayodele is an experienced community pharmacist. He has worked in his current role for 15 years and knows the community well.

Senior rheumatology pharmacist
Mark is the senior rheumatology pharmacist in the local hospital rheumatology service. He has responsibility for managing all patients on disease modifying anti-rheumatic drugs and regularly follows up patients every six months to monitor disease progression.

The Foundation Pharmacist's perspective:

People

Patient:

All evidence (frequency of dispensing, regular attendance at pharmacy with blood monitoring and dosage record booklet) suggests highly compliant.

Identified as high risk for CVD.

Maryam is completely comfortable because it's a straightforward dispensing scenario and she feels she is aware of the major safety issues. She also notes that Andrea's medicines are dispensed in blister packs, so she is content that the patient will keep the medicines in their original packaging.

Environment

Patient is only coming in to collect prescription, so time is limited.

NICE guideline on management of rheumatoid arthritis in adults.

Local protocols; Patient Medication Record.

Activity

Check blood monitoring and dosage booklet to ensure that dispensed items match exactly the form that the patient is used to.

Need to make sure labelling is correct (so that folic acid and MTX can't get mixed up and that it is clear that the MTX is for weekly dosing).

Needs to ask the patient some questions to spot any signs of toxicity.

Threat
Risk of MTX toxicity.

Error
Recognises possible danger of labelling and packaging errors (because this was covered at the seminar).

Andrea comes into the pharmacy, and Maryam checks the blood monitoring and dosage record booklet. She notes that the white blood cell count is 4×10^9/L. As part of the preparation, she had noted that 3.5 was the cut-off level for referral to prescriber, so she is not unduly concerned. Similarly, the creatinine level is in the range that requires continuous monitoring, but is at the very low end of it (160 mmol/L). She asks rather closed questions like 'are you feeling OK?' which Andrea confirms. However, Maryam notices a few things that cause her some concern, like a dry and continuous cough. Her first thought is Covid. Ayodele, her Educational Supervisor, is available to discuss the plan.

Educational Supervisor's perspective:

People

Patient:
WBC count is lower than the bottom end of the normal range. Although creatinine level isn't severely impaired, there has actually been a >30% increase since previous measurement.

Ayodele understands the targeted questions to ask.

Environment

Busy environment, so doesn't have time to explore any further how the toxicity might have arisen. Consequently 'accepts' possibility that it might be to do with age-related kidney changes.

Activity

Checks blood monitoring and dosage booklet.

Asks appropriate questions, revealing ulceration of oral mucosa.

Threat
Risk of MTX toxicity.

Error
Recognises potential error of 'misdiagnosing' toxicity.

Ayodele suggests that Andrea contacts the hospital rheumatology support telephone line, which she does, and leaves a message on the answer phone. Mark, as the senior rheumatology pharmacist, picks up the message and contacts Andrea, arranging for a video consultation. He organises for Andrea to have a blood test to check for toxicity, but his experience allows him to recognise the sort of issues that might be occurring, and he knows what questions to ask.

Senior rheumatology pharmacist's perspective:

People

Patient:
While there might be some signs of kidney impairment, Mark thinks there are likely to be other explanations, as he was involved in the original decision to ensure that Andrea's medicines were not dispensed in child-proof containers.

Senior rheumatology pharmacist: Experienced, regularly manages patients like this.

Andrea's daughter: She was in the house at the time of the consultation. She normally comes in three times a week to see her mum and help with housework. Andrea was happy for her to join the consultation as she "doesn't do phones and computers".

Environment

Switch to remote consultations due to Covid. Challenge of monitoring patients remotely but getting used to it.

Busy environment – Mark has a high case load (but he recognises the need to take time to get Andrea to 'talk through' the medicines use).

Activity

Further tests reveal situation is worsening.

Ask Andrea to 'tell me how you manage your medicines' (flipped system). This reveals patient is (a) struggling even with the blister packs, so is getting daughter to decant the tablets (b) showing signs of mild cognitive impairment.

Patient has also been taking maximum possible doses of NSAIDs.

Mark establishes that Andrea's daughter comes in three times a week to see her.

Threat
Without getting to the bottom of where the toxicity has come from, this will just be a recurring problem.

Takes a lot of time out of Mark's schedule, may impact on other patients.

Error
Recognises Andrea may be taking the drugs incorrectly. Also recognises the 'full remit' of ways that this might be done (eg confusing folic acid with MTX, taking MTX daily etc).

Recognised potential labelling and packaging errors, so asks to see medication.

It seems likely that the problems have arisen from the decanting of medicines. Mark suggests that the folic acid is changed to a single 5mg dose to be taken the day after the methotrexate dose. This means that Andrea's daughter is able to be there to remove the tablets from the blister packs and ensure that the correct medicines are taken. Monitoring frequency is increased, with a view to reviewing pain management medication if kidney function continues to worsen.

3.3 Worked example 2: Complexity in community pharmacy

Marjorie is 73 years old, and rings the community pharmacy asking for advice. She has advanced non-small cell lung cancer and has recently been seen by the palliative care nurses to manage her pain. Marjorie is worried because she doesn't want to leave her house due to Covid-19. The palliative care team recently started her on regular modified release morphine twice daily for pain. The palliative care team advised that if Marjorie became constipated she should seek advice from her community pharmacy. Marjorie has not opened her bowels for four days.

Past medical history
- Iron deficiency anemia
- Heart failure
- Advanced non-small cell lung cancer

Current medication
- Paracetamol 1g qds
- Morphine sulphate MR 15mg bd
- Morphine sulphate liquid 10mg/5ml when required
- Ferrous sulphate 200mg bd
- Furosemide 40mg od
- Ramipril 5mg od
- No known drug allergies (NKDA)

Foundation Pharmacist
Mohammed is a 26-year-old Foundation Pharmacist who is working as a relief pharmacist. He regularly works in this store and he is comfortable and familiar with the processes, procedures and staff.

Community pharmacist manager
Simon is a 58-year-old experienced community pharmacist manager who has worked in the same shop for more than 20 years. He knows Marjorie well and has good ties with the palliative care team and the local GP surgery.

Palliative care pharmacist
Abi is a 43-year-old palliative care pharmacist working in the community. She has never met the patient before but has access to her palliative care and GP notes.

Supporting patients with palliative care is an important role for community pharmacy, especially due to the pressures that Covid is putting on to palliative care services. Mohammed is comfortable with the working environment and he is used to working in this pharmacy. He has never met Marjorie before but he is able to access the Patient Medication Record and Supplementary Care Record if necessary to confirm any specific details. He undertakes a thorough history over the phone, and identifies that that the constipation is most likely to be due to the opioid analgesic medication. Mohammed also recognises that diet and fluid status can contribute to constipation and provides advice about this.

The Foundation Pharmacist's perspective:

People

Patient: Marjorie is on regular analgesia for pain with opiates likely to cause constipation.

Also taking other drugs that may cause constipation.

Foundation Pharmacist: Mohammed is familiar with this clinical situation.

Environment

Challenge of trying to assess patient over the phone and ensure appropriate advice.

Mohammed feels comfortable and supported.

Activity

Need to consider other potential causes of constipation (eg medication) and for any red flags.

Advice about diet and fluid intake to reduce risk of constipation.

Organise supply of laxatives for patient or relative to collect.

Marjorie rings the community pharmacy but Simon is here this time and answers the phone. He undertakes a similarly comprehensive consultation over the phone and again suspects that Marjorie has opiate induced constipation. However, he also questions her about how much morphine sulphate liquid she is taking for breakthrough pain. Marjorie confirms that she has a lot of pain and is taking regular swigs from the bottle every two hours and has used a 100ml bottle in the last two days. She agrees to the plan to try a laxative and Simon arranges to get a palliative care team member to contact her for her ongoing pain management.

The experienced community pharmacist's perspective:

People

Simon's experience leads to more in-depth questioning which reveals severe pain and an increased need for analgesia.

Environment

Familiarity with local systems and pathways means able to contact palliative care team for support.

Activity

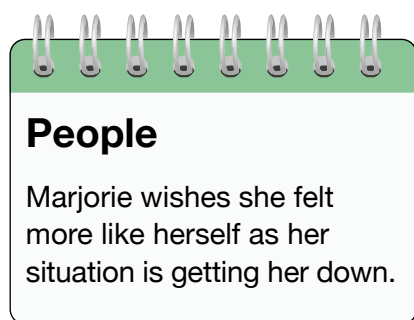Consideration of the patient concordance with the medication regimen.

Threat

That Marjorie is taking too much morphine.
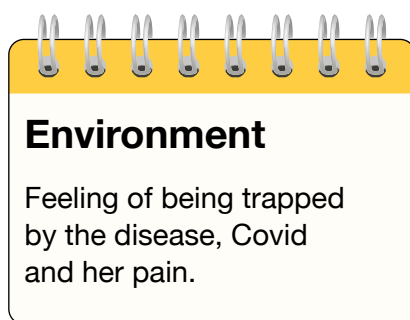
That Marjorie's pain may not be adequately controlled.

Marjory is worried about Covid-19 and the risk of getting the virus with her cancer. This is affecting her mental state and ability to manage. She feels the pain is also affecting her mental state and ability to cope. She wishes that the pain would go away so that she can get on with the things she knows will help her cope (e.g. gardening).
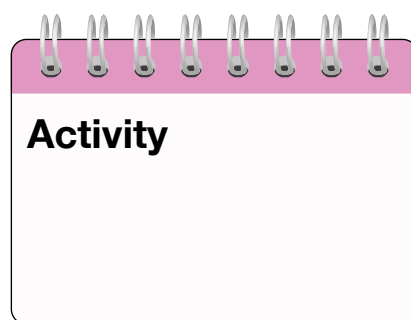
The patient's perspective:

People

Marjorie wishes she felt more like herself as her situation is getting her down.

Environment

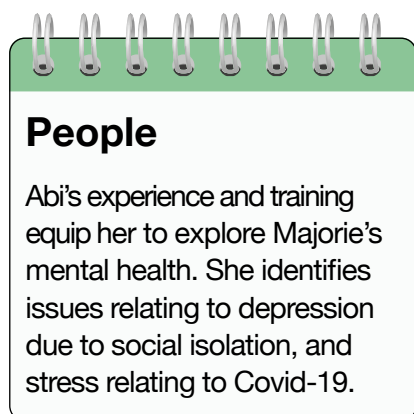Feeling of being trapped by the disease, Covid and her pain.

Activity

Following the community pharmacy referral, Abi phones Marjorie. Together they explore the problems of the constipation and pain management. Abi investigates other important potential symptoms such as nausea and shortness of breath, and explores Marjorie's food and fluid intake. She also considers the other medication. Abi discovers that Marjorie no longer needs the iron as this was started a year ago because she was receiving chemotherapy, and her hemoglobin is now normal. Abi also discovers that Marjorie has been told to restrict her fluid intake due to her heart failure and needs to keep this below 1.5 litres a day. Abi also identifies that the furosemide could contribute to the constipation but knows it is required for managing Marjorie's heart failure.

One threat that Abi is very aware of is that the constipation may be due to bowel obstruction caused by the progression of Marjorie's cancer, but her detailed patient history allows her to rule this out. Abi is satisfied that the constipation was probably due to opioid side effects due to high use of breakthrough doses. She agrees with community pharmacy plan of supply of laxatives, but also puts a plan in place to ensure escalation if there has been no change within 48 hours.
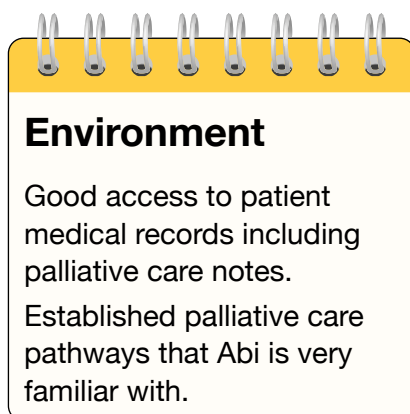
Abi also explores current pain relief and advises Marjorie on best use of breakthrough pain doses. She increases the dose of regular medication and advises Marjorie how to seek help for on-going pain issues. Having identified a psychological element to the pain management, Abi also provides Marjorie with access to psychological support to manage anxiety and depression.

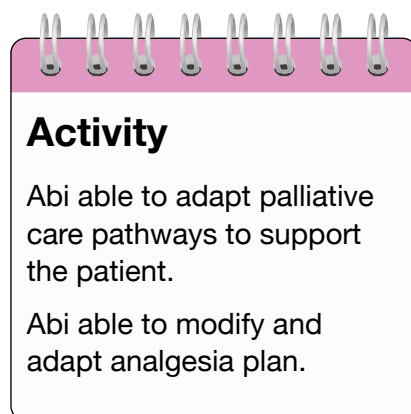## The palliative care pharmacist's perspective:

People

Abi's experience and training equip her to explore Majorie's mental health. She identifies issues relating to depression due to social isolation, and stress relating to Covid-19.

Environment

Good access to patient medical records including palliative care notes.

Established palliative care pathways that Abi is very familiar with.

Activity

Abi able to adapt palliative care pathways to support the patient.

Abi able to modify and adapt analgesia plan.

Threat

Recognition that mental health issues are common in elderly/palliative care scenarios, and if these are not addressed, outcomes are likely to be poor.
That there is a more sinister cause of the constipation such as bowel obstruction.

3.4 Worked example 3: Type 2 diabetes decision

John, aged 70, was admitted to an acute hospital trust overnight following a fall. He has been reviewed by the medical team who are currently investigating the reason for the fall. They have withheld the blood pressure medication as the patient is hypotensive. Plans to investigate the cause of the fall include postural blood pressure monitoring, diabetes specialist review and full falls risk assessment, including a pharmacy review of the medication.

Co-morbidities
- Chronic kidney disease (CKD)
- Heart failure (HF)
- Previous myocardial infarction (MI)
- Hypercholesterolaemia
- Type 2 diabetes

Current medication
- Metformin 1g bd
- Gliclazide 80mg bd (om and teatime)
- Atorvastatin 20mg od (on)
- Ramipril 1.25mg od
- Bisoprolol 1.25mg od
- No known drug allergies (NKDA)

Due to Covid-19, the ward environment is challenging. Personal protective equipment such as face masks and Covid workplace requirements make it challenging to talk to patients. Communication through face masks and minimised patient contact can lead to a reliance on use of either written sources of information or phone calls with relatives. This can often mean missing the whole patient perspective.

Foundation Pharmacist
Ayisha is a 29-year-old Foundation Pharmacist. She is on her second clinical rotation working in an acute hospital. Her previous rotation was in gastroenterology wards. Today there are 30 new patients who require medicines reconciliation and appropriate clinical review. There is a clinical pharmacy technician to support but Ayisha has a dispensary commitment in the afternoon.

Educational Supervisor
Helen is a 54-year-old elderly care pharmacist. She has been supervising pharmacists for 20 years and has extensive clinical experience of covering multiple clinical areas.

General practice pharmacist
Paul is a 38-year-old practice pharmacist. Previously he has undertaken jobs in both hospital and community pharmacy. He has undertaken the Centre for Pharmcy Postgraduate Education training pathway and has been a GP practice pharmacist for two years.

Diabetes expert clinical pharmacist
Rayhul is a 43-year-old senior diabetes pharmacist who is practicing at an advanced level. His role involves him working as a core member of the diabetes multi-disciplinary team delivering both in-patient and out-patient clinical care. He also works with the Primary Care Network to develop and deliver diabetes pathways.

The Foundation Pharmacist's perspective:

Ayisha feels comfortable tackling the situation – she aware it's a complex condition, but it formed a major component of her practice education at university. She is also confident of the guidance contained within the NICE Guidelines for Management of Type 2 Diabetes. Ayisha's first thought is that John should be on an antiplatelet for his MI. Ayisha also recognises that John is on a number of medications that could have contributed to his fall. She recommends a monitoring plan to gain some insight into the impact of these drugs on John. From his clinical details, Ayisha can see that he is at high risk of another cardiovascular event, so she consults the NICE Guidelines for lipid management. When the threats are considered, a CV event is first and foremost in her mind and this triggers the consideration of a series of activities including plans to measure HbA1c, full lipid profile, blood pressure, etc. However, Ayisha also considers that with diabetes and a previous MI, John's risk is likely to be high, and so she suggests increasing the statin dose to 80mg. She also makes a note to speak to John about exercise and diet. In reflecting on 'flipping the system', Ayisha can see that she doesn't know much about John, and so adds some questions under the 'activities' reminding her to explore current diet and also what limitations there might be in respect of exercise. She also notes that talking to John may be difficult due to the need to wear PPE.

People

Patient:

Cardiovascular risk

-Missing antiplatelet

-Statin. Dose is low, plan to increase to 80mg daily.

Fall review identified ramipril and bisoprolol can reduce blood pressure plus gliclazide can cause hypoglycaemic episodes.

Foundation Pharmacist: Complex situation but comfortable tackling it as the patient is on commonly used drugs.

Environment

NICE guideline on lipid management and management of type 2 diabetes.

Busy ward environment.

PPE being worn by all healthcare staff.

Challenging to discuss care with patient.

Activity

Counsel patient on diet and exercise, including exploring current diet.

Monitor HbA1c and BMs for diabetes to ensure fall not related to hypos.

Monitor blood pressure to ensure fall not related to low BP.

Check lipid profile to determine need to increase statin.

Check U&E to ensure ramipril not effecting kidney function.

Threat

Cardiovascular risk.

Falls risk is complicated and needs a multifaceted approach to formulating a plan.

Pressures of time and workload to see multiple patients on the ward.

Error

Focus on the NICE Guidelines for managing cardiovascular risk means that the importance of focusing on the acute issues is missed

The Educational Supervisor's perspective:

John is transferred to the ward where the Helen works. Ayisha approaches her for feedback on the interventions that they have made on the admissions unit to enable them to reflect upon the case. Helen spoke to John's wife when she rang to talk to the nurses and was able to get more detail on the statin and antiplatelet situation – the MI occurred five years ago, and the statin dose was lowered at the time due to muscle pain. From this conversation, it seemed the statin adherence was poor because of John's ongoing concerns about the statin side effects. Helen tells Ayisha that this is a common problem (from the literature and also from her own experience) and suggests some questions that might allow this to be explored. These would perhaps be along the lines of exploring intolerance – is it, for example, that John has muscle pain that he believes to be caused by statins, or is it because he is concerned about the side effects of taking statins long term? Careful questioning and support might allow Ayisha to begin exploring whether there is genuine intolerance, calling for a change of medication, or not. Helen raises the importance of discussing this issue during the acute hospital admission and the need to communicate back out into primary care.

Helen also discovered from the relative that John takes enteric coated (EC) aspirin which he buys from the community pharmacy. This is because he prefers EC to the dispersible formulation, but the local formulary will only accept dispersible aspirin. Helen recognises that not picking up on the fact that John was taking aspirin is an error that needs to be addressed – if John had sustained a head injury during his fall, there is a risk of an intracranial bleed.

Helen also recognises that issues of age, potential CKD and the sulphonylurea all increase the risk of hypoglycaemia. She understands that this needs specialist input and ensures that advice is sought from the diabetes team.

People

John's wife confirmed the statin dose but revealed adherence issues. Also confirmed patient usually takes aspirin bought OTC.

Environment

Ability to focus more on John's pharmaceutical issues as the ward environment is less hectic.

Desire to minimise length of stay due to Covid.

Activity

Identified issue with potential CKD and Gliclazide likely to increase hypoglycaemia risk. Review current and previous U&E.

Check for evidence of head injury.

Discuss statin issues with John.

Discharge planning – ensure plan in place for restarting ramipril and bisoprolol appropriately dependent upon ongoing BP. Ensure statin issue dealt with and appropriately communicated to primary care.

Threat
Rushed discharge planning.

Error
Missed aspirin on admission – risk of intracranial bleed increased following fall if John had sustained a head injury.

John had a face-to-face conversation with Paul following his discharge from hospital. Careful questioning by Paul elicited more detail about the statin non-adherence. John had seen some newspaper articles that talked about the side effects. He realised he was a bit achy and worried that this might be because of the statin. This meant he doesn't always take it, depending on how bad his anxiety is at the time. Paul is able to provide sufficient information to reassure John, and also raises the problem of increased cardiovascular risks by constantly starting and stopping the medication.

Paul utilises his communication skills, recognising that it's no good just asking if the patient 'eats a good diet'. Instead, he gets John to describe a typical day's eating. Concerns about diet lead to recommendation for follow-up with a dietitian. The primary care records indicate that John's BP is always on the lower side of normal, and when Paul measures it during the consultation, it is still fine, so he decides to leave the John on his current anti-hypertensive medication due to the benefits post MI/in diabetes.

Paul follows up the discharge plan that regular blood glucose monitoring is necessary, and arranges for this. When the HbA1c result comes back, this is slightly higher than he would like, which convinces him that the plan for tight monitoring and control of blood glucose is the right one.

The general practice pharmacist's perspective:

Paul recognises the limited information available about the hospital admission and that this makes decision making challenging about the next steps with the care plan. However, he does have greater access to information about John's long-term health. John is also able to be much more involved, meaning Paul has both improved understanding of John's perspective and is also able to work with him to establish an individualised plan that meets his needs. Due to Covid, most of these ongoing consultations are virtual and Paul recognises this is likely to pose a general threat.

People

Conversation with John to understand his views and perspectives. Able to negotiate plan for both statins and diet.

Environment

More information is available relating to John's long-term BP and HbA1c enabling a longer term plan of care.

Activity

Practice pharmacist considers referral to local frailty support services to access physiotherapy/ OT.

Threat

Patient stops statin periodically due to anxiety about side effects, potentially increases cardiovascular risk.

Challenges of ensuring that communication from secondary care flows to primary care in a timely and accurate way.

Risk of missing important information due to remote consultation.

The specialist diabetes pharmacist's perspective:

The specialist diabetes pharmacist, Rayhul, came to review the patient as part of the diabetes specialist team. The focus during the consultation was on the acute admission. Rayhul is able to understand the multimorbid complexity of the situation. He also recognises that there are many possible causes of the fall, including peripheral neuropathy, retinopathy, hypoglycaemia, hypotension or a simple trip. He also recognises that John's needs can best be met through input from the wider MDT, but also that this is complicated because of the need to communicate effectively and understand how to involve others in the care.

People

Consider patient's frailty, mental health and motivation to personalise care plans.

Need to support patient to undertake diabetes self-care.

Multiple professional involved e.g. dietitian, podiatry, medics, nurses, mental health, cardiology and renal team.

Environment

National and local guidelines and pathways adapted for the individual needs.

Seen within the acute setting but able to ensure continuity of care after discharge from hospital.

Activity

Monitoring of appropriate laboratory testing.

Adjustment to meet the changing requirements.

Patient education about the medication, self-care.

Ongoing medicine optimisation including adherence.

Pharmacist ensures accurate and timely flow of information from themselves to the rest of the MDT.

Threat

That there isn't sufficient time to capture all the information necessary.

The care plan is unmanageable from John's perspective.

That communication between the members of the MDT team (and John) may not be optimal.

Error

Multiple possible errors as a result of poor communication.

This scenario involves multimorbid polypharmacy with a high disease burden. John's care pathways need to be assessed, and individual targets should be set where possible as well as developing a mutually agreed care plan. John's frailty, mental health and motivation should be considered. He will need support with self-care, including footcare, hypoglycaemia management and appropriate screening (eg retinopathy, kidney function). There is a need to involve multiple professionals in John's care and this will require clear communication pathways. The care pathway should be built around John's needs.

Reflections on complexity

The scenarios were developed based on reflections provided by experienced practitioners with expertise in the selected conditions. The notepad tool was used to guide the reflection. In the following section, the specialist diabetes pharmacist Rayhul explains the thinking underpinning the Type 2 diabetes scenario, which highlights just how complex living with and managing such a condition can be.

People

Individual

This individual has multiple morbidity and polypharmacy, so in real terms has a high burden of disease. I would want to assess this person's care pathways and where possible set them individualised targets and a mutually agreed care plan.

They are 70 years old and I would want to know if they are frail, and if they have dependences for daily activities of living. If they have had a frailty assessment, I would want to know not only which frailty score has been used, but to understand the validity of this scoring for this person. So, for example, you could use something like 'time to get up and go,' but this may not be valid in people who have Parkinson's disease. The International Diabetes Federation (IDF) Index looks at frailty in relation to co-existing chronic diseases, impairments in activities of daily living and any cognitive decline. I like this holistic view of frailty and I think this works well when considering someone with diabetes.

I would also want to consider mental health screening for this person. People living with diabetes have a massive array of daily considerations for good self-care. There is also a cost, both in terms of morbidity for the person, but also financially in treating someone with diabetes who has poor mental health (costs can increase by 50%). Up to 40% of people living with diabetes may struggle with their psychological wellbeing. There are lots of screening tools, such as Diabetes UK Information prescriptions for mental wellbeing, Problem Areas in Diabetes (PAID) screening tool, Generalised Anxiety Disorder (GAD-7), PHQ-9 Depression Test Questionnaire, the Diabetes Distress Scale (DDS-17), the Hypoglycaemia Fear Survey (HFS-IIW) and mSCOFF (questionnaire to screen for eating disorders). I would also want to be conscious of the language we are using, being reflective of the 'Language Matters' document from NHS England.

Motivation levels should be assessed. This will give you an idea of how to plan for treatment now and in the future. It may also direct your decision making around technology that might be available in the future e.g. Freestyle Libre (you would need to be motivated enough to do appropriate downloads of the data). I would also want to have a discussion around adherence with therapy. Barriers to good care should be explored and understood. It may be that there are cultural or language barriers. Tool such as local educators, translators, etc should be employed where necessary.

People with diabetes need training for good self-care. People living with diabetes should attend structured education and can attend refresher training in addition to this. This person would also need to know how to do their own daily foot checks, to be able to do their blood glucose monitoring, to be able to treat a hypoglycaemia event and also to know when to attend other screening, such as for retinopathy and urine microalbumin (UACR) to screen for kidney disease. For the UACR the person will need to be trained on how to take the sample. This training should

not be a one-off, it should be revisited at annual reviews and ideally members of the extended team e.g. community pharmacists, etc. should be recommending and advising good self-care, reinforcing the message. In terms of risk perception, I would want to know that the person understands the importance of managing a hypoglycaemic event appropriately and also that they understand the Driver and Vehicle Licensing Agency guidelines.

Team

Diabetes team: Provides holistic management of a person with diabetes.

Cardiology team: This person has a very high cardiovascular risk. Both cardiologists and diabetologist need to work together to ensure the right medications are started for this person. Particularly if newer agents such as SGLT2s are started, a clear indication and acceptance of implications for each speciality needs to be taken into account.

Renal team: There are strict criteria for referral though to renal teams. The person needs both UACR and eGFR to assess their KDIGO (Kidney Disease Improving Global Outcomes) category of renal disease. The urine also needs to be dipped to ensure there is no haematuria. A UACR can be taken at any time of day for screening and may need to be repeated if the result is positive as other lifestyle factors may influence the result.

Improving access to psychological therapies teams: May potentially be of use for people with diabetes. However, due to the nature of the mental health issues associated with diabetes, generic mental health services may not be useful. If a locality has access to a psychologist who has experience with people living with diabetes, then this is what should be used.

Podiatry/vascular teams: This person would need assessing for peripheral vascular disease and foot checks are a fundamental part of this.

Dietitians: I would consider if the person would be suitable for referral to a dietitian. The person may wish to try to put their diabetes into remission which needs huge dietetic support. Also, they may be eligible for bariatric surgery and need dietetic support.

Practice nurses: They often manage people's day-to-day care and they may be appropriate to contact if follow up is needed.

Diabetic specialist nurses: It may be a case of getting them to know the emergency helpline number or you may ask for the specialist nurses to follow up with them more appropriately.

Others who may influence: It may be that you can get others involved in education and cultural support. Some areas have involved faith leaders to help educate people with diabetes and key members within the community. Community pharmacists, in my opinion, are under-utilised and we should not forget about the New Medicines Scheme, which allows people to get help and advice about medication from their pharmacist. Of course, communication may be an issue and we may need an interpreter or someone who can sign on a call.

Environment

The environment in which someone might receive their care may have changed dramatically, and this has been exacerbated by the Covid crisis. Offering video calls, telehealth and face-to-face appointments has now become routine. We need to ensure that whatever is chosen is appropriate and safe for the person who you are caring for.

Virtual can be useful: It can give flexibility for people to attend appointments, and it can be useful in people with poor hearing as they can lip read. This is in contrast to in-person appointments in hospital where healthcare practitioners are masked. It can also be useful if family/friends want to attend to try to help support.

We need to get the right person managing each part of the pathway, so I would give consideration as to whether a referral is needed into any specialist services or if at any point I can discharge someone's care back to a GP or primary care network pharmacist for follow up. With this person I would want to be managing them following our local diabetes guidelines and I could refer through to the European Association for the Study of Diabetes (ASD)/American Diabetes Association (ADA) guidance from which they were designed for more detail.

I would want to communicate any changes I had made with the consultant and any other relevant secondary team members and the GP would need oversight on all care. Many of these people are managed within multiple organisations. So, for example if they have any renal issues that require intervention, they may be managed by a tertiary centre assigned to the Trust. Policies and protocols may need to be co-owned.

This person is on a medication that could cause a hypoglycaemic event and they need to have a documented conversation about DVLA guidance and be counselled on how to treat a hypo.

Activity

It's important with people with diabetes that you work in a logical way. We use clinic pro formas to ensure we have covered all the important information and that we have up-to-date results.

Design of tasks/processes: Laboratory testing is extensive and, depending on their medications, they will need urea and electrolyte tests, liver function test, B12, folate, lipid profile (including triglycerides), urine microalbumin, full blood count and HbA1c.

Patient consultation: There are so many things to consider – sick day rules, hypos, driving, foot checks, medications, what their readings mean. Patient education is key to getting the foundations laid here. Structured education should be encouraged and completed as soon as possible after diagnosis and then revisited if needed.

Medicines reconciliation: There are many possible side effects and/or interactions with medications for diabetes and therefore you need to regularly check on adherence and have discussions on alternative approaches. A medication not taken can be very costly both economically and in terms of morbidity and mortality.

Equipment available: We need to know if they are home monitoring blood glucose and blood pressure and if they weigh themselves, etc.

In terms of the overall model, we need to think who is undertaking the activity (patient or practitioner). Patients self-care 99% of the time and so this is why the education you give them in the time you have available is so important. Back it up with leaflets, share the screen if video calling, show them the numbers and the trends.

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