AVOIDING HARM: Tackling Problematic Polypharmacy through strengthening Expert Generalist Practice

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Abstract

Problematic polypharmacy is a growing challenge. Medication that is intended to improve patients' health and wellbeing is instead becoming part of the problem. The way we practice medicine has become one of the drivers for the problems. Dealing with the challenge will need us to think differently about how we do clinical care.

A 2013 Kings Fund report stated that tackling problematic polypharmacy requires us to actively build a principle of 'compromise' in to the way we use medicines. There are implications for how we consult and make decisions with patients, in how we design health practice and systems to support that decision making, and in our understanding of the process of research – how we generate the knowledge that informs practice.

This review considers the current state of play in all three areas and identifies some of the work still need to do in order to generate the practice-based evidence needed to tackle this most challenging problem.

Finding a way to redesign practice to address problematic polypharmacy could offer a template for tackling other related complex issues facing medical practice such as multimorbidity, chronic pain and complex mental health.

The Challenge of Problematic Polypharmacy

Polypharmacy is now a routine medical intervention. Defined as the concomitant use of multiple medicines on a long-term basis, it represents an approach to medical care that has expanded significantly in scale and scope over the last twenty years [1]. Around one third of people aged 75 and over take 6 medicines or more a day [2]. The last two decades has seen the number of people prescribed 5+ medicines a day increase four-fold [2].

Appropriate Polypharmacy offers significant potential benefit to both individual and population health [1]. However, the 2013 Kings Fund report also recognises a new challenge – that of Problematic Polypharmacy [1]. A person on ten or more medicines a day is over three times more likely to be admitted to hospital than someone on 1-3 medicines per day [3]. The risk of adverse reactions and medication errors increases with higher prescribing [1]. 40% of people taking 5 or more medicines a day report feeling burdened by their use [4]. Many factors contribute to problematic polypharmacy, including patient, professional and health system issues. The Kings Fund therefore defines problematic polypharmacy with reference to what is experienced by the patient: being when the "intended benefit of the medication is not realised" [1]. This definition requires us to consider explicitly what we mean by 'intended benefit'.

Work to date to address the challenges associated with polypharmacy has centred on the principles of medicines optimisation: "ensuring people get the right choice of medicines, at the right time, and are engaged in the process by the clinical team" [5]. In practice, this focuses on the safe and effective use of medicines to enable the best outcomes [5], involving whole practice teams in safely delivering medicines to patients. The intended benefit is optimal medical impact from medication with minimal side effects or risk.

Medicines optimisation programmes have been criticised for a lack of person-centred focus in defining 'best' practice and outcomes with relation to decisions about medication use [6]. Indeed, the 2013 Kings Fund report described that addressing problematic polypharmacy would require *compromise* between medical and patient perspectives on the use of medicines [1]. Intended benefit may still be biomedical outcomes. For some patients, priorities for care may reflect different benefits.

Achieving compromise in order to meet whole-person needs is the expertise of the medical generalist. Generalist practice describes the skills needed to integrate biomedical and biographical perspectives of individual illness to generate an individually *tailored* interpretation of what is wrong and what needs doing [7]. The goal of generalist practice is to support health as a resource for daily

living – a means to an end rather than the end itself [7]. Generalist skills offer a mechanism to deliver robust, safe compromise.

However, the 2019 NHS Long Term Plan recognises a shortage of capacity of generalist skills in the hospital setting [8]. In the community/primary care setting, research highlights four barriers to use of generalist skills in practice [9] and in particular with reference to decision making around prescribing practice [10]. A 2017 survey of prescribers including GPs, pharmacists and nurse prescribers described that tailoring of medicines was inhibited by the 4Ps of Permission, Prioritisation, Professional training and Performance management [10]. Professionals described a perceived lack of *permission* to work beyond guidelines – an approach needed to achieve tailoring and compromise. They highlighted a failure to *prioritise* this complex task in a multitude of other competing priorities in their daily work, meaning they lacked the 'head space' to tailor medication use. People described both a lack of *professional training* in the complex decision making required for tailoring, exacerbated by a lack of confidence in using the skills they did have. Finally, they challenged *performance management* processes which at best ignored , and at worse criticised, this area of practice.

As yet, and for a variety of reasons that I shall return to, we have no evidence-based description of an expert-generalist-prescribing intervention. However, we do have a growing body of research evidence and professional scholarship that offers us insights in how we could overcome the described barriers. This review aims to provide an evidence-informed overview of the state of play and proposes next actions for avoiding harm from problematic polypharmacy through strengthening expert generalist practice.

Building a generalist response

This review will therefore consider, how can strengthening expert generalist practice support the compromise needed to tackle problematic polypharmacy? Underpinning generalist medical practice and the delivery of compromise is the principle of person-centred care: that care is guided by the needs and preferences of the individual [11], recognising health as a resource for living and not an end in itself[12]. Healthcare decisions require an interpretation of illness and need based on understanding of the individual in their context, not just their disease status. Delivering person-centred care is a complex intellectual task, and certainly not a 'soft skill' [13].

To explore this further, I will examine three areas of practice: the consultation (the clinical intervention), the practice setting (the context), and scaling and sustaining practice (implications for research and scholarship).

Rethinking the consultation

Compromise needs an approach to clinical practice that supports robust and safe construction of "contextualised meaning" driving clinical decision making [14,p11]. Generalist practice constructs whole-person-centred meaning in context through the integration of knowledge/evidence on both the biomedical and biographical aspects of individual illness experience. Decisions are informed by, rather than based on, guidelines/evidence, with a clinician exercising the skills and clinical judgement of the expert generalist to robustly work beyond guidelines to deliver whole-person tailored care [15,16]. Clinicians (health care professionals from across multiple disciplines) using generalist skills create new, tailored knowledge [15] through everyday practice [16].

A (still limited) body of scholarship describes how these clinicians work beyond guidelines in practice. Gabbay's account of generating practice-based evidence, and the construction of mindlines, describes how GPs actively construct knowledge-in-practice-in-context through the use of clinical scholarship [16]. Similarly, Donner-Banzhoff used ethnographic methods to observe GPs in practice, and described the "inductive foraging" used by the GPs to construct tailored understanding of patients' illness and needs [13]. Both bodies of research describe the knowledge work [17]undertaken (in these cases) by GPs to robustly construct tailored interpretations in context. Through professional discussion, we have described these actions as the clinical scholarship [18] of professional practice.

The importance of this interpretive practice – the exercise of clinical judgement – is recognised within key systems that currently govern clinical practice. The National Institute for Health and Care Excellence (NICE) produces most UK guidelines describing best practice. The Chair of NICE, Professor Haslam, has repeatedly described that NICE produces "guidelines not tramlines" [20], with all NICE documents calling for professional judgement. Guidelines are constructed from a review of best evidence (see Box 1). The Evidence Based Medicine (EBM) movement also supports the use of clinical judgement in deciding if and when to apply evidence to an individual patient [21]. Both NICE and EBM emphasise the importance of clinical judgement. However, neither provides a robust account describing how we can recognise 'good' clinical judgement and in particular, how this

'judgement' can be distinguished from the 'clinical opinion' that appears at the bottom of the EBM hierarchy of evidence [22].

INSERT BOX 1 ABOUT HERE

As highlighted in my own research [9,10], and within informal discussions with colleagues, clinicians feel that they lack the skills and confidence to robustly defend clinical judgement and beyond protocol decisions. Professional training (and assessment) focuses on demonstrating what you know, rather than how you make use of what you know (for example, to deliver tailored decisions) [23]. Professionals feel unable to defend complex decisions, and so they do not make them. This undermines the capacity for compromise, and so contributes to problematic polypharmacy.

Responding to the challenge: Tools for generalist prescribing?

A number of tools have been developed to help clinicians "approach the challenge of inappropriate polypharmacy" [24]. In the UK, these include the 'Seven Steps to appropriate polypharmacy' in the Scottish Polypharmacy Guidance [25]; Barnett's Seven Steps to a patient-centred approach to managing polypharmacy in England [26]; and the All Wales Medicines Strategy Group Polypharmacy: guidance for prescribing [27]. All describe the need to undertake a person-centred assessment of medicines use in an individual, which considers the goals of care, reasons for taking individual medicines, and an understanding of medication adherence or resistance.

Mangin and colleagues reviewed approaches for reducing inappropriate medication use from across the world and generated a set of ten recommendations for reducing inappropriate medication use [28]. These include encouraging clinicians to always consider opportunities for deprescribing when undertaking medication reviews; correcting the lack of research evidence of outcomes on person, rather than disease, focused, medicines use; and highlighting the need for tailored prescribing decisions.

What is missing to date from the described models of prescribing practice is explicit recognition of a key barrier to tailored prescribing, namely clinicians' perception of a lack of permission, skills and confidence in 'beyond protocol' decision making [9,10]. This gap was recognised by Mangin et al [28] in their review which called for a "return to the original concept of EBM", restoring the role of a thoughtful professional "rather than a disease or algorithm technician". Addressing this gap requires attention to the process of knowledge generation (robust interpretation) in practice [15]. Drawing

on the scientific principles of epistemology (the theory of knowledge including how we judge between different types of knowledge), I have described a framework (consultation model) that can be used to both support and establish the trustworthiness of that aspect of clinical practice [15,20].

The SAGE 5 Steps consultation model [20] describes the epistemological principles (5 steps) needed to support robust generation of knowledge in practice in context [15] – see Box 2. Clinicians should pay attention to, and document their thinking/decision making, with reference to: a clear statement of GOALS of care with the default being to support health for daily living; a considered EXPLORATION of a full data set; the construction of a TAILORED EXPLANATION; a clear process of professional SAFETY NETTING; and follow up of the patient for IMPACT ASSESSMENT. This fifth step recognises that a tailored explanation is always an interpretation constructed to support a goal. The quality of the interpretation lies in the process of its construction (the first 4 stages) but also its utility – whether it offers value to an outcome [15].

INSERT BOX 2 ABOUT HERE

The SAGE 5 Steps model provides a framework that addresses each of the 4P barriers to tailored decision making previously described: in recognising the legitimacy of professional interpretive practice, and the complexity of the task (and so prioritisation). It provides a framework to support the application of skills, and an epistemologically robust framework for critically reviewing and defending decision making; as well as performance management/assessment.

Both the clinical tools described [25-27] and the SAGE 5 Steps model [20] can be understood as complex interventions supporting professional practice. As such, they can – and should – be subjected to critical evaluation through research in order to understand the impacts on professional practice and patient outcomes. The principles behind the SAGE model have been assessed within Quality Improvement activity [29]. Both models describe principles of practice that will be recognised by and familiar to many professionals:

> "The good physician treats the disease. The great physician treats the person who has the disease" (Osler) [cited in 30]

However formal research evaluation of either consultation approach has yet to be done.

Addressing barriers: rethinking the organisation of practice

The polypharmacy models described offer evidence-informed guidance to inform the interaction between clinician and patient and so support and change professional practice. But consultations

happen in an organisational context. Contextual factors can both support and undermine practice [9,10, 31]. Successful implementation of new ways of working requires us to pay attention to the context as well as the intervention itself [32]. For generalist expertise to improve the 'compromise' needed to address problematic polypharmacy, we need to look not just at what clinicians and patients are doing, but also to think about the organisation of practice.

Repeat prescribing supporting long term medication use occurs mainly in the primary care (general practice) context. In the UK in 2018, 1.1 billion prescription items were dispensed in the community, at a cost of £8.8billion [33]. Improvements to the organisation of prescribing practice has come through the development of Medicines Optimisation systems [5]. The principle behind NHS England Medicines Optimisation programme is simple: to "improve outcomes and value" [5]. Measures to achieve these goals include the introduction of practice systems that improve outcomes for patients by helping them take their medicines correctly, avoid unnecessary medicines and reduce wastage, and improve safety [5]. Medicines Optimisation has contributed to significant improvements in practice areas such as antibiotic prescribing and reducing the use of medicines that are not clinically or cost effective. Utilising the clinical skills of pharmacy teams within primary care settings has been a crucial part of this success [5].

But Medicines Optimisation approaches, to date, have not fully embraced the challenge of implementing 'compromise' and in particular the 4P's to generalist practice that my work has described [10].

The principles of Medicines Optimisation recognise the importance of a patient-centred approach (see Box 3) and so potentially addresses 'Permission' as a barrier to person-centred care. However, as described practice models do not offer specific guidance on how to ensure that principle #1 (understanding the patient's experience) should be used to guide or moderate choices raised by principle #2 (evidence based use of medicines). The approaches to strengthen generalist expertise within the SAGE 5 Steps model [20] may help address this challenge.

INSERT BOX 3 HERE

However further work is also needed to tackle the wider organisational barriers to achieving compromise in practice. As discussed, these include how to appropriately prioritise the work needed within the wider context of a primary care service, how to build the teams and resources needed to support professional practice, and how to appropriately performance manage this complex area of work [10]. Again, the research literature offers us insights in to how we might address these wider organisational gaps and challenges, including the use of burden measurement tools to identify

patients most at risk; building continuity of approach across communities of practice; and the revision of performance management tools (see Table 1).

INSERT TABLE 1 HERE

As yet, there are no research studies that pull all of these factors together to evaluate a new generalist complex intervention to address problematic polypharmacy. We do have a Cochrane review evaluating the impact of introducing evidence-based medicines optimisation tools (eg STOPP-START, Beers criteria, Medication Appropriateness Index) to address polypharmacy [39]. Results demonstrate improved quality and safety governance outcomes (for example, a reduction in biomedically defined inappropriate prescribing) but with uncertain evidence of benefit for 'clinically significant outcomes' and patient-centred care. Newer studies now seek to evaluate multi-faceted (complex) interventions that recognise the range of clinician, patient and context components needed to address problematic polypharmacy [40-45]. Each study has a slightly different focus for its intervention. It is likely that we will need innovative research methods, for example realist synthesis [46], to help us integrate the findings and so draw wider conclusions on redesigning prescribing practice.

Implications for research and scholarship

This current body of research will provide us with 'proof of concept' statements: evidence of what could work to address problems associated with polypharmacy. What comes next is the implementation stage – assessing whether the principle works when we seek to deliver it at scale in the primary care setting. Implementing complex interventions into everyday practice and at scale requires yet another set of knowledge and skills [32,47].

Yet there is a common theme running through each stage discussed here: the theme of knowledge work and the robust generation and application of knowledge in, and for, practice [17,18.48,49]. At a consultation level, the generalist clinician works to integrate biomedical and biographical understanding of illness to generate new knowledge-in-practice of compromise. At a practice level, the generalist team works to integrate the multiple elements needed to enable and support this complex knowledge work. Now, at the systems level clinicians and academics must work together to

integrate the knowledge and insights from their different contexts to co-produce solutions to shared problems.

Evans & Scarborough recognised this process as a new understanding of how research works [49]. Their observations of health services research in action revealed two types of practice: bridging and blurring. Bridging refers to the (perhaps) more traditional review of scholarship and research: where objective knowledge is generated in a controlled setting, with the use of new 'knowledge translation' tools and workers to deliver this new understanding to the context in which it is to be used. They also observed examples of blurring: where academics and applied workers came together to co-produce new knowledge-in-context. The clinical practice of tailored prescribing involves the generation of knowledge-in-practice-in-context [16]. Arguably therefore, the generation of robust research-evidence describing the mechanisms and impact of such practice requires methodological approaches able to deal with this 'blurring'.

Evans & Scarborough didn't seek to judge between the approaches they observed [49]. However, they did note that both produce different types of knowledge and so raise questions for us on how we judge 'best' evidence. Our understanding of best evidence is currently largely driven by the epistemological assumptions of the Evidence Based Medicine movement (EBM) [21]. EBM shapes both our understanding of 'best knowledge' for practice (as discussed), but also best methods for producing knowledge (through research). The EBM hierarchy of evidence judges between different types of knowledge based on the methodology used to generate it. Yet EBM was originally developed within a specialist, biomedical setting and the epistemological assumptions (and so hierarchy) reflect the ontological beliefs and knowledge work of that context. However these biomedical assumptions about 'best evidence' have now been applied more broadly across health care setting including into areas which require attention to 'beyond biomedical' thinking One unintended consequence has been a negative impact on achieving the clinical compromises discussed here [15,28].

Glasziou and Chalmers have challenged the current methodology-based definition of best evidence on the grounds that it is contributing to research waste: the generation of research that doesn't deliver any impact [50,51]. They propose that research should instead be judged by three components: the relevance or appropriateness of the research question, the appropriateness of the methodology *for the question*, and the impact of the research. Their broader vision of research quality may offer a framework by which to judge the generation of knowledge from a blurred model of research that reverses the current direction of flow of knowledge translation [52]. Instead of focusing on the implementation of biomedical research in practice (evidence-based practice), we may also use, for example, Living Lab models [54] to capture the 'daily scholarship' of clinicians [18]

and patients [6] alike in order to generate the practice-based evidence [52] needed to develop tailored healthcare .

In conclusion

Building compromise in to the way we practice medicine, and use medication, will need changes to the way we make, use and evaluate clinical decisions – the knowledge work of clinical practice. The expertise of generalist practice: built on the robust generation of tailored interpretations of illness need; informed, but not driven by, disease-focused evidence offers a way forward. In the UK, the need, and urgency, for this shift in direction has been recognised recently in the publication of the Future Doctor Programme [53], and by the work of the WISE GP programme (www.wisegp.co.uk) [48].

Building capacity for clinical compromise will require changes in the way we design and deliver healthcare. This review has highlighted the need for a sustained shift in goals of healthcare, recognising quality defined by whole-person outcomes (capacity to live daily life); in the training, ongoing professional support and performance management of healthcare professionals; and in the design of systems supporting learning from practice, including research. Tackling problematic polypharmacy will need whole system changes to address barriers to the generation, use and assessment of knowledge for practice in real-time and in context.

We have an opportunity to address a key clinical challenge: how to tailor medical care to the needs of the individual patient. Finding a way to redesign practice to address problematic polypharmacy could also offer a template for tackling other related complex issues facing medical practice such as multimorbidity, chronic pain and complex mental health. In tackling problematic polypharmacy, we may also describe a new model for evidence-informed innovation of practice for the holy grail of whole-person-centred healthcare.

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Box 1: Statement of use within NICE guidelines [24]

"The recommendations in this guideline represent the views of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guidance fully in to account, alongside the needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guidance does not override the responsibility to make

decisions appropriate to the circumstances of the individual , in consultation with them, their families or carer or guardian.”

Box 2: the FIVE STEPS of the SAGE consultation model [19]

The generalist consultation seeks to describe, identify and support health as a resource for daily living. This is achieved through focusing on the goals of health care to support daily living. Even where medicines are the primary interest of the clinician the consultation focuses on the Goals of care, the Gaps in care (outstanding needs) and individuals Grasp (expectations) from the health care – including mediation – that they are using.

The specific five steps address:

GOALS of care: the clinician explores a biographical account of living with illness along with the goals for, gaps in, and grasp of care.

EXPLORATION: the clinician works the illness experience with reference to the patient's story, the clinician's contextual knowledge, and biomedical knowledge (including guidelines)

TAILORED EXPANATION: the clinician takes responsibility for (co-)constructing and sharing with the patient an explanation of what is happening and why

SAFETY NET: the clinician's responsibility to identify and address risk

IMPACT: the ultimate test of the interpretation (knowledge constructed) lies in following up with the patient and assessing the impact of the decision.

Box 3: Medicines Optimisation: four principles of a patient-centred approach [5]

1. Aim to understand the patients experience
2. Evidence based choice of medicines
3. Ensure medicines use is as safe as possible
4. Make medicines optimisation part of routine practice

Table 1: Potential practice level changes driving improvement in compromise/expert generalist prescribing

BARRIER	POTENTIAL SOLUTION
Prioritisation	**Identifying patients experiencing problematic polypharmacy** 40% of patients taking 5+ medicines a day feel burdened by their medication [4]. This group may benefit from a generalist review and discussion of compromise. But 60% of people don't feel burdened – polypharmacy is potentially appropriate, and they may not benefit from additional review. Using burden tools such as the Living with Medicines Questionnaire [4] offers one way to identify and prioritise patients who may need a different approach. Patients have different expectations of medicines [34] which affects the way they use, and/or resist, medicines [35]. Prioritising goal setting with patients is important. Frailty is commonly viewed as one marker of vulnerability to burden and problematic polypharmacy – and is a risk factor commonly recorded in primary care practice in the UK. However Reeve & Bancroft's quality improvement work suggested that factors predicting need for generalist review are not captured solely by biomedical parameters, but relate to issues such as mental health and social support [29]. These observations are supported by empirical research looking at experiences of living with long term conditions [36]. Prioritisation of patients may need to focus on non-biomedical parameters
	Prioritising and Protecting Professional time: In 2013, practitioner told us they didn't have time to tailor clinical decisions in trying to fit busy consultations in to short time periods [9]. In 2017, a repeat survey now revealed that clinicians didn't have the *head space* [10]. Practitioners are now regularly engaged in a volume and array of decision making. What has been described as the "cognitive load" [37] upon clinicians is ever growing. Even with more time, longer consultations, clinicians don't have the capacity to manage the volume of knowledge work expected of them: in dealing with complex medical conditions, in contributing to major new configuration of services, in managing growing levels of uncertainty. A solution focused on longer consultation time with patients, that doesn't recognise the wider calls on professional load is unlikely to be successful.
Professional practice: communities of practice	Gabbay recognised the importance of teams to support beyond protocol decision making and the generation of contextually relevant, collective practice-based-evidence (mindlines) from the evidence-based-guidelines-for-practice that come from outside of the practice context [16]. With General Practice teams evolving, and GP roles change, implications for supporting compromise and complex decision making need to be thought through. Sharing the data needed for exploration of problems, and

	the interpretive practice of decision making (see Box 1) requires continuity of approach across a team of clinicians, and across a primary and secondary care interface.
Performance Management	Performance management drives clinical actions [10http://www.sspc.ac.uk/media/media_486342_en.pdf]. For example, a review of the Scottish Quality & Outcomes framework concluded that performance management led to more bureaucratic, less individualised care with an increasing biomedical focus [38]. Revitalising generalist (whole-person-centred) care will need a review and revision of performance management tools.