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ORIGINAL RESEARCH ARTICLE

Theoretical Underpinnings of a Model to Reduce Polypharmacy and Its Negative Health Effects: Introducing the Team Approach to Polypharmacy Evaluation and Reduction (TAPER)

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Abstract

Background Polypharmacy, particularly among older adults, is gaining recognition as an important risk to health. The harmful effects on health arise from disease–drug and drug–drug interactions, the cumulative burden of side effects from multiple medications and the burden to the patient. Single-disease clinical guidelines fail to consider the complex reality of optimising treatments for patients with multiple morbidities and medications. Efforts have been made to develop and implement interventions to reduce the risk of harmful effects, with some promising results. However, the theoretical basis (or pre-clinical work) that informed the development of these efforts, although likely undertaken, is unclear, difficult to find or inadequately described in publications. It is critical in interpreting effects and achieving effectiveness to understand the theoretical basis for such interventions.

Objective Our objective is to outline the theoretical underpinnings of the development of a new polypharmacy intervention: the Team Approach to Polypharmacy Evaluation and Reduction (TAPER).

Methods We examined deprescribing barriers at patient, provider, and system levels and mapped them to the chronic care model to understand the behavioural change requirements for a model to address polypharmacy.

Results Using the chronic care model framework for understanding the barriers, we developed a model for addressing polypharmacy.

Conclusions We discuss how TAPER maps to address the specific patient-level, provider-level, and system-level barriers to deprescribing and aligns with three commonly used models and frameworks in medicine (the chronic care model, minimally disruptive medicine, the cumulative complexity model). We also describe how TAPER maps onto primary care principles, ultimately providing a description of the development of TAPER and a conceptualisation of the potential mechanisms by which TAPER reduces polypharmacy and its associated harms.

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Key Points

Interventions designed to reduce polypharmacy have been difficult to interpret owing in part to a lack of understanding of their underlying mechanisms by which there are purported to exert their effects.

We describe the development process of an operationalised clinical pathway to reduce polypharmacy by linking it to the underpinning care models, mapping the known barriers, and depicting the facilitators that were built into the intervention.

1 Introduction

The life expectancy of the population and, consequently, the number of people living with multimorbidity have increased [1]. Multimorbidity is naturally linked to increasing levels of disease burden. Disease burden is distinct from multimorbidity and may include diagnoses that carry little or no morbidity in of themselves, even though they represent risk factors of multimorbidity, such as abnormal physiological measures (e.g. hypertension or osteoporosis) [2]. Multimorbidity is also linked to increased treatment burden, where treatment regimes become increasingly complex and require substantial resources from the patient [3–5]. Treatment burden is associated with reductions in quality of life and treatment adherence. Optimising the management of multiple chronic conditions is an important challenge for today's healthcare system, specifically maximising the benefits and minimising the harms and treatment burden for the individual patient [6–8].

One key aspect of treatment burden is the burden of medications and polypharmacy. The most common definition of polypharmacy is the use of five or more long-term medications [9]. Polypharmacy is associated with negative health outcomes in older adults including falls, impaired cognition and poorer nutrition [10–13]. Other potential negative consequences include drug–drug interactions, drug–disease interactions and difficulties patients face in managing complicated medication regimes, resulting in sub-optimal adherence, negative outcomes, wasted resources and excessive treatment workloads [11, 14–19]. Excessive polypharmacy, defined as ten of more medications, carries an even greater risk of negative consequences [20]. These potential harms become even more salient as vulnerability to medication side effects in general increases with age [11]. Multiple medications can be expected with multimorbidity and may serve to reduce the burden of the multiple chronic diseases. However, as the number of medications climbs, the risk of unintended harmful or unwanted effects of medications and potentially unnecessary or unwanted medications (i.e. inappropriate prescribing) also increases. Interventions focused on medication burden aim to reduce the number of unnecessary or unwanted medications as well as those carrying a high risk of adverse effects or contributing to unwanted side effects either on their own or in combination with other medications to either achieve improved or unchanged health outcomes. Termed deprescribing, [9, 21] these interventions aim to reduce these harms associated with polypharmacy by identifying and ceasing medications that are no longer benefitting the patient such as by reducing the dose, or by stopping or switching to a safer medication [8]. Notable efforts have been undertaken by several national and trans-national organisations to increase awareness of the potential harms of polypharmacy, promote research in the field, and provide support to patients and practitioners [11, 22–24].

Approaches to improve the appropriateness of prescribing fall into two broad categories. There are explicit medication-based approaches that involve lists of potentially inappropriate medications that are generally chosen as they have a higher risk for adverse effects in older adults. Examples include the Beers List and STOPP Criteria [25, 26]. There are also broader implicit approaches, which require more time, knowledge and judgement as they are less algorithmic and more principle based [11, 27]. There is also some evidence that a team approach that includes pharmacists and prescribers is effective in different settings, including primary care. Explicit medication-based potentially inappropriate medication approaches only account for a proportion of adverse medication reactions and it is possible to be taking multiple "appropriate" medications and still experience harm from their combined effects [28–32]. The single most important predictor of harm is the absolute number of medications [24]. In this scenario, all medications, including those not on potentially inappropriate medication lists, must be considered in order to reduce risk. Implicit approaches such as a comprehensive geriatric assessment or the geriatric palliative approach [33] encourage a broader view of the patient; however, across both explicit and implicit approaches, very few directly consider patient preferences or priorities in an operationalised manner [11, 34].

Despite the evidence of some effectiveness for, and pharmacoeconomic benefit of, these deprescribing efforts as interventions, there is a high degree of heterogeneity in intervention type and of reporting developmental processes [27, 35–38] and often no clear effect on medication-related problems of importance to patients. One possible reason for the large number of studies with no clear intervention effect on medication problems could be the heterogeneity of intervention components, and the lack of clarity regarding the

mechanisms of effect that are being tested during the development of the intervention model [37]. We conducted a systematic review of the deprescribing literature and found that, while pilot or feasibility studies were sometimes reported, the rationale describing the hypothesised mechanisms underpinning the intervention were generally absent, thus limiting interpretation of the observed data in order to refine future interventions [38, 39]. This is described as Phase 0 [40] or the 'development' element [41] of the Medical Research Council framework for intervention development. This information gap has been noted by others developing interventions in this area [42]. While development work may have occurred, it was either not reported or poorly described for interventions that have published findings. Consequently, broad benefits to research in the field in terms of understanding successful designs and key components remain unknown when the details surrounding intervention development are not reported or published [43]. Without this information, it is unclear what potential mechanisms were tested in each intervention, which is of particular importance within polypharmacy research given the heterogeneity of results reported for different interventions, and the evidence around the limited effect of general strategies aimed at changing clinical practice (e.g. guidelines, audit and feedback) [44].

To address this specific gap shown in the research literature, we aim to describe the development process of the Team Approach to Polypharmacy Evaluation and Reduction (TAPER), a deprescribing intervention. We used an evidence-based and theory-based approach to the development of TAPER, which follows elements of the updated MRC guidance on developing and evaluating complex interventions [45] and the reporting here follows the GUIDED reporting guidance for intervention development [46]. The development of TAPER involved consideration of known barriers and facilitators to deprescribing and used the chronic care model (CCM) to map them to generate the intervention components. Once the intervention was created on this basis, we examined it against broader models of polypharmacy and primary care. The intervention was developed for reducing the harms of polypharmacy and is aligned with the quaternary prevention paradigm. Quaternary prevention, a term, defined in the *WONCA International Dictionary for General/Family Practice*, is a unifying framework that organises a family physician's scope of practice in addressing demedicalisation as a preventive strategy. The aim is to reduce excessive medical interventions, including overtreatment, by a process that encompasses identifying the risk of overmedicalisation, actions to support active patient protection from overmedicalisation and the suggestion of ethical alternatives [47–49]. This paper will provide the basis for understanding the results of subsequent intervention and implementation trials of TAPER specifically, as well as providing a theoretical basis for describing and understanding other interventions in the polypharmacy field.

2 Methods

There were two methods used in the development process of TAPER: literature review and stakeholder perspectives [27]. First, we performed a narrative review to enable an evidence-based and theory-based approach to inform the development of the deprescribing intervention (i.e. TAPER), and involved summarising the literature in the prioritised areas of medical care, the target populations (patients, providers, health system, organisation), the area of care of interest (polypharmacy) and the setting (primary care) [50, 51]. Specifically, the review consisted of four steps. Step 1, review the peer-reviewed literature on commonly used models and frameworks in medicine: in particular, the concept of minimally disruptive medicine (MDM), the cumulative complexity model and the six key elements of the chronic care model. Step 2, review and synthesise the peer-reviewed literature on patient-level, provider-level, and system-level barriers and facilitators of deprescribing. As the latter part of Step 2, the identified barriers were mapped onto the facilitator elements of the CCM, which in turn were used to guide design choices for TAPER. Step 3, in order to confirm the intervention design, we reviewed the peer-reviewed literature on the functions and outcomes of primary care and mapped the key domains (i.e. person-focused care, care over time, comprehensiveness, coordination) underpinning its effectiveness to TAPER. Step 4, we reviewed and mapped the Kaufmann key requirements (i.e. evidence supported, clinically robust, person centred) for effective polypharmacy interventions to TAPER. We further describe the literature from Steps 1 and 2 below (See 'Theoretical Underpinnings Overview'). This process explicitly considering the elements described in Steps 1–3 occurred during the TAPER intervention development, and continued in reviewing the pilot and feasibility study randomised controlled trial. We have formalised the description of this in this paper, as well as added the framework mapping, which we undertook after development. Our results section comprises the latter part of Step 2, and Steps 3–4.

Second, findings from focus groups involving key stakeholders representing a diversity of perspectives (e.g. community-dwelling older adults, caregivers of patients with dementia) as well as consumer safety groups and specific advice from a consumer advocate for patient safety focused on medications (JT) were incorporated into the core design of TAPER. The process used is consistent with MRC guidance on developing complex interventions, including: patient-provider shared decision making in medication-related decisions; embedding the value of person centredness in patient–provider interactions; creating a conversational space to solicit patient/family

member expertise, experiences, preferences and priorities; and, using these information sources effectively alongside evidence-based medication for polypharmacy-related decisions [39, 45].

2.1 Theoretical Underpinnings Overview

2.1.1 MDM Model and Cumulative Complexity Model

The MDM care model is defined as "a patient-centred approach to care that focuses on achieving patient goals for life and health while imposing the smallest possible treatment burden on patient's lives" [52, 53]. This theory-based model was selected to guide our intervention design because it facilitates healthcare professionals working with patients with multiple chronic diseases (i.e. multimorbidity, those most likely to have a significant polypharmacy burden), to design care that is person centred and aims to minimise overtreatment in any setting. While applicable to any setting, this is relevant to primary care and to quaternary prevention, respectively.

The MDM care model involves two strategies: (1) identifying the right care and (2) ensuring this care is implemented [29, 30]. To identify the right care, there must be an acknowledgement of the work required of patients, the workload capacity of patients and the biopsychosocial complexity in which the patient operates. Identifying the right care also involves 'integrating the inputs' (workload-capacity balance). Embedded and described within the MDM model is the cumulative complexity model. The cumulative complexity model is defined as a "conceptual framework that defines the workload-capacity balance and practically-orients MDM-care" and provides a rationale for adverse outcomes in patients related to multimorbidity and polypharmacy [5, 52].

The second strategy of the MDM care model seeks to effect change to make the right care happen for that patient. This is done by prioritising feasibility, making sense of it all by coordinating care activities around a patient goal, using available resources, and monitoring and responding (remaining flexible and dynamic to mirror natural trajectories of chronic disease and life) [29, 30]. We allowed the MDM care model (and CCM) to guide intervention development in all aspects (e.g. person-centred approach, doctor-pharmacist teamwork, structured clinical pathway).

2.1.2 CCM

The CCM was designed to support practice change at the provider and organisational level, to change from a reactive model of care focused on acute episodes to one that focused on the continuity of care for patients with chronic diseases. We selected this model to guide our intervention design as it is well accepted, is more clearly aligned to multimorbidity and polypharmacy through its six elements than general behavioural change models, was shown in a recent systematic review to be associated with improved outcomes in chronic care management [1, 54] and is synergistic with the key dimensions of primary care (discussed below) through which better population health outcomes are achieved [55].

The CCM argues that better chronic disease management is a result of productive interactions of six elements: (1) health system, organisation of healthcare, (2) self-management support, (3) delivery system design, (4) decision support, (5) clinical information systems and (6) community resources and policies [54, 56]. Interventions that target multiple elements have been shown to be more effective at improving patient care [57]. Specifically, the health system refers to the entity that would be implementing the model and includes programme planning, which consists of measurable goals for better chronic disease management. Self-management support highlights the critical role of the patient in managing their own care, and includes providing educational resources, skills training or psychosocial supports to help patients manage their own care. Delivery system design refers to how care and follow-up is planned and coordinated and emphasises team-based care. Decision support involves the integration of evidence into daily clinical practice. Clinical information systems involve the development of information systems that support care in a proactive and relevant manner. For example, information systems that serve as a population surveillance tool that identify sub-groups of patients who may need proactive care. Finally, community resources and policies involve fostering partnerships with community organisations that support patients. When these elements interact productively with one another, better functional and clinical outcomes will ensue [58]. We used the six CCM elements to map the identified patient-level, provider-level and system-level barriers of deprescribing.

2.2 Patient-Level, Provider-Level, and System-Level Barriers and Facilitators of Deprescribing

Moving from broad consideration of medical models and frameworks to a more detailed focus on polypharmacy, the literature identifies multiple specific barriers and facilitators to reducing the harms of polypharmacy in routine clinical practice at the patient, provider and system levels [59–62]. We synthesised the barriers into themes and mapped them to one or more level (patient, provider and system) at which they may apply.

3 Results

The development of TAPER involved the consideration of known barriers and facilitators to deprescribing and mapping the barriers to the relevant elements of the CCM. The intervention components were then designed to align and further enhance or facilitate the CCM elements by addressing these barriers. We then examined the intervention against broader models of polypharmacy and primary care.

Based on our review of the literature on patient-level, provider-level, and system-level barriers of deprescribing, we consolidated the reported barriers to reducing the harms of polypharmacy into 20 themes (Table 1). Of these, five barriers applied uniquely to patients including no opportunity to discuss cessation, belief that their healthcare provider (HCP) is not up to date on recent evidence, belief that the HCP will not support cessation, fear of abandonment from their HCP if they discontinue their medications and fear of not being able to restart medications. There were three barriers that applied uniquely to HCPs including knowledge/skill deficit, fear of increased workload and concern that patients will not understand the deprescribing process. There were two barriers that applied uniquely to the system: fragmented care and a lack of financial incentive. The remaining barriers were cross-cutting themes across two or more levels including patients and providers (four barriers), providers and the system (two barriers), and patients, providers and the system (four barriers).

After categorising the barrier levels, we mapped them to the six key elements of the CCM: self-management support, health system, delivery system design, decision support and clinical information systems. The element of community resources and policies was considered out of scope for our model. We then designed intervention components to further enhance or facilitate the relevant CCM elements (Fig. 1). We provide a summary of the intervention components (italicised text) and a brief description below.

Regarding self-management support, we focused on a *person-centred approach*; our model asks patients to reflect and record their experience prior to staged consultations as part of a *doctor-pharmacist teamwork* with an explicit patient-focused agenda that operationalises goals, priorities and experience of medications, including the financial burden, laying the basis for the conversation and shared decision making. Additionally, a staged longitudinal model allows the patient time to reflect at each step. Any concepts that are part of the model, such as "pause and monitor™" are explained to the patient and the monitoring plan of what/who/how often is explicitly recorded.

Health system aspects were the most challenging to account for in the design of TAPER. *Doctor-pharmacist teamwork* reduces duplication of efforts, distributes the workload and leverages the expertise of both providers [32]. The three-step process, verified medication list and automatic machine screen in the TAPER model minimises time spent on administrative tasks such as medication reconciliation, looking up evidence sources to identify potentially inappropriate or risky medicines/combinations and avoids the duplication of efforts by team members. This therefore maximises the available consult time for the cognitive work of the medication review and discussion with the patient. However, the barriers arising from fragmented care across the wider health system and the lack of financial incentive are currently beyond the scope of the TAPER.

Delivery system design was partially operationalised and communicated as *preventative care*. Reducing medication burden within TAPER is framed as a routine part of preventative care with specific appointments focussed on discussing medication cessation as a *structured clinical pathway* (Fig. 2). We operationalised TAPER by development of a web-based platform (TaperMD™) for the clinical pathway that allows all in the circle of care to access as a common record. This facilitates the integration of the steps of TAPER and fosters the necessary teamwork in planning and coordination among providers as well as having been designed and feasibility tested for inclusion in routine primary care workflow, with explicit use of key stakeholders in the codesign as well as feasibility testing [63]. Initial work with patients in understanding their perspectives on the key elements for successful deprescribing informed integration of these (patients priority preferences and experiences of their medications) in combining with the other necessary delivery system elements to consider for deprescribing: evidence support presented in a unique way that visually maps onto polypharmacy and continuity of care. TAPER's "pause and monitor™" framework includes structured recommendation recording, prompts for monitoring and recording of side effects and criteria for restarting, evidence support on the rate of discontinuation and expected discontinuation effects. Criteria for monitoring and restarting medications is agreed upon, and similarly systematically recorded within TaperMD™.

Decision support and clinical information systems are combined in the pathway, operationalised in TaperMD™. We structured the pathway to provide feedback on potential medication concerns or opportunities to reduce burden to clinicians as an *automated machine medication screen,* which is dynamic and immediately adaptable for integration of any new evidence, evidence-based guidelines, guidance or polypharmacy tools that become available. We developed this machine screen as a unique dashboard with easy visual cues and integrating all current evidence sources simultaneously, checking back to source literature [64, 65]. The

Table 1 Mapping patient-level, provider-level, and system-level barriers to deprescribing to CCM

Theme	Barriers			CCM elements
	Patient level	Provider level	System level	
No opportunity to discuss cessation	☒	☐	☐	Delivery system design
Believe HCP not up to date on recent evidence	☒	☐	☐	Delivery system design
Believes that the HCP will not support cessation	☒	☐	☐	Delivery system design
Fear of lack of support following cessation	☒	☒	☒	Self-management support
Fear of abandonment from HCP if they discontinue their medications	☒	☐	☐	Delivery system design/self-management support
Fear of not being able to restart medications	☒	☐	☐	Delivery system design/self-management support
Fear of side effects and unknown consequences	☒	☒	☐	Decision support
Knowledge/skill deficit	☐	☒	☐	Self-management support/clinical information systems
Fear of increased workload	☐	☒	☐	Delivery system design/health system
Concern patients may not understand the deprescribing process	☐	☒	☐	Delivery system design/self-management support
Scepticism of deprescribing	☒	☒	☐	Delivery system design/self-management support
Belief that medications are all beneficial	☒	☒	☐	Decision support
The pressure to prescribe from recommendations contained within the medical model	☐	☒	☒	Health system
Focus on disease-specific guidelines	☐	☒	☒	Health system
Increasing cost of prescriptions is a concern for patients, prescribers and payers	☒	☒	☒	Health system
Medication nonadherence	☒	☒	☒	Delivery system design/self-management support
Lack of other treatment options	☒	☒	☒	Delivery system design
Lack of perceived adverse events	☒	☒	☐	Decision support
Fragmented care	☐	☐	☒	Health system
Lack of financial incentive	☐	☐	☒	Health system

CCM chronic care model, *HCP* healthcare provider

evidence support screen flags both simple, specific, interactions and potentially inappropriate medication flags (and reasons) for single medicines in the traditional way as well as cumulative burdens, some of which were developed specifically for the pathway. Also included are some disease-specific screens that are turned on and off according to the patient's diagnosis list. These are presented in a visually intuitive manner, with explanatory reminder notes to guide conversation and provide links to the evidence for deprescribing. Furthermore, patient considerations are a central component of the process. By being patient focussed, rather than disease focussed, conflicting aspects of clinical guidelines can be appropriately considered with regard to the patient's priorities. The pathway structure tailors to patient goals and priorities for treatment, symptom control and function with operationalisation of these elements, utilising evidence to guide, rather than drive, decision making.

The concept of the MDM care model is embedded in TAPER in two distinct ways. First, there is an explicit process of soliciting, recording, integrating and following up on patient priorities and preferences in TAPER. In TAPER, patients are asked about their most important functional goals, symptom priorities for treatment and the relative importance of outcome priorities (current symptoms and prevention of disease deterioration; longevity and prevention of future disease). These responses focus the medication plan and are operationally carried into the pharmacist and physician conversations in the follow-up with the patient.

Second, patients are explicitly asked about other sources of their treatment burden: if they find taking their medications burdensome overall or, more specifically, if they find their medications a financial challenge and would like to explore less expensive alternatives. Patients are also asked which medications they would like to stop and why as well as about their experience of the effects of their medications, particularly any side effects of their medications individually or overall. Answers to these questions are reviewed by the pharmacist and family physician when developing a plan.

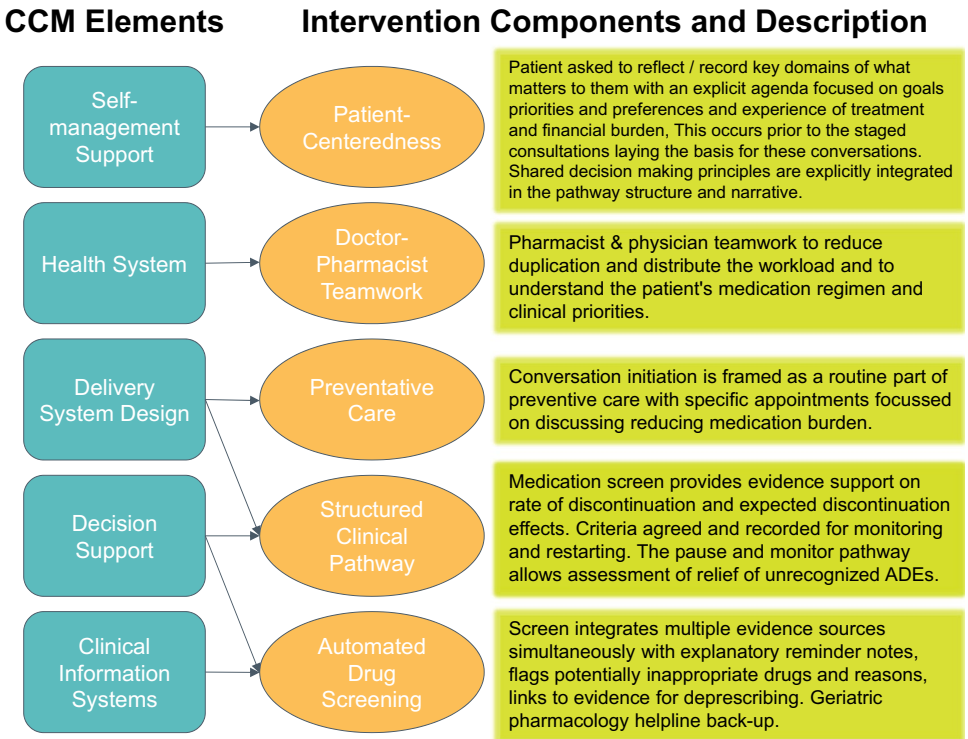

Fig. 1 Mapping of Team Approach to Polypharmacy Elimination and Reduction (TAPER) components to chronic care model (CCM) elements. *ADEs* adverse drug events

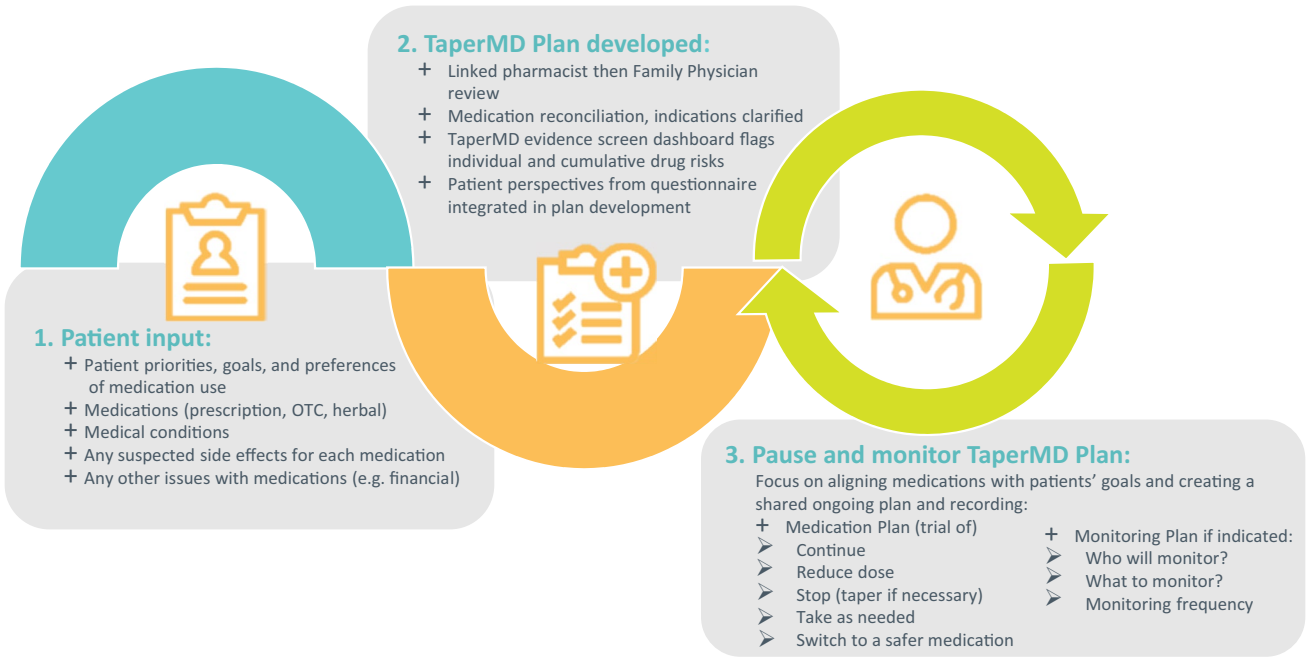

Fig. 2 Team Approach to Polypharmacy Elimination and Reduction (TAPER) structured operationalised clinical pathway. *OTC* over the counter

3.1 Alignment with Core Mechanisms Underpinning the Effectiveness of Primary Care

Primary care is the setting in the health system where most medical care is provided [66]. It is well suited to models of care delivery to address polypharmacy: it has the workforce capacity to reach the entire applicable population and provides the setting where overall co-ordination of care and pharmaceutical management for patients with multimorbidity currently occur. Primary care is also the current setting

for most clinical preventive care and where there is most evidence for effectiveness in improving health equity and population outcomes [67–69]. The mechanisms by which it achieves this have been well studied and include first contact care, person-focused care, care over time, comprehensiveness and coordination [68, 70].

After mapping TAPER to the CCM, we validated TAPER's alignment with the key dimensions of primary care that evidence demonstrates underpin its effectiveness [67]:

- Person focused: unlike other approaches that are medication criteria focused (e.g. BEERS list, STOPP criteria), TAPER explicitly seeks patient preferences and considers the patient's constellation of comorbidities rather than attempt to silo each disease state.
- Coordination: the family physician acts as the hub. The family physician is the co-ordinator and integrator of care, is aware of the specialty care and medication recommendations, and is well positioned to integrate and prioritise these. In our work in understanding how deprescribing works best, patients indicated a strong preference for their family physician to co-ordinate and prioritise their medications rather than the alternative, which is the patient being the default for communication, negotiation and prioritisation of multiple providers and their treatment recommendations [39]. A system-level barrier related to this (fragmented care) is not currently addressed in TAPER and maps onto this aspect of the primary care model, identifying a gap.
- Comprehensiveness of primary care is enhanced by supporting the primary care team as the hub in this approach polypharmacy. TAPER leverages the comprehensive potential of the working relationship among the pharmacist, physician and the patient. It facilitates how the care conversation can be enhanced by contextual information, by explicitly collecting and recording information about the whole range of their conditions, treatments and understanding of the range of management recommendations and treatments from others, social and illness context, priority preferences and goals and resources as well as available non-pharmacological alternatives in developing a rational plan.
- Care over time: TAPER is a longitudinal pathway that involves a planned follow-up ("pause and monitor™") to assess the safety and tolerability of any medication reductions and to assess the effect of changes. This ongoing conversation has agreed criteria for both monitoring and restarting, and the access to first contact care in primary care supports seamless implementation. This aligns perfectly with the existing primary care function of continuity of care over time.

3.2 Proposed Key Requirements for Effective Polypharmacy Interventions

Kaufmann et al. [27] proposed key elements for effective polypharmacy interventions: that they be evidence supported, clinically robust and person centred. TAPER aligns with these elements in the following ways. The individual patient medication list in TAPER is uniquely mapped to all available evidence for flagging the potential risks of harmful effects of medications and potentially inappropriate prescribing. The evidence support was developed specifically focused on patients with polypharmacy with screening for cumulative side effect burdens, some developed specifically for the pathway, and a visual presentation allowing simultaneous assessment across all medications. The comprehensive structured pathway for a multidisciplinary medication review and monitoring by pharmacists and physicians in partnership with patients (the "Team") is clinically robust—it has been successfully implemented in routine clinical care and the feasibility randomised controlled trial showed preliminary evidence of a reduction in prescribed medications and improved outcomes at a 6-month follow-up [63]. The pathway is explicitly person centred: integrating patient priorities and preferences, patient experience of medication effects and patient characteristics relevant to medications. We operationlised all these elements of the pathway in a web-based pathway platform, TaperMD™. Access to this resource is shared among the patient's clinical team.

4 Discussion

The development process of TAPER involved the consideration of known barriers to deprescribing and using the CCM to map them to generate intervention components. Once the intervention was created on this basis, we examined it against broader models of polypharmacy and primary care.

TAPER aligns with the concepts of MDM, is congruent with Kaufmann et al.'s [27] proposed elements of polypharmacy interventions, and addresses most barriers to deprescribing identified in the literature. However, two identified barriers are not addressed in TAPER. These gaps are at the health system level, in relation to care for patients with multiple prescribers (fragmented care) and to appropriate financial incentives.

First, having more than one prescriber at a time is a common experience for older adults [62]. This frequently results in poor communication between different prescribers and to the confusion in responsibility and ownership of prescribing and stopping medications [62]. In addition, a perceived hierarchy system between the family physician and specialist often prevents the family physician from starting a dialogue

[62]. TAPER is a team approach in which the pharmacist and the physician work together, and this interdisciplinary approach is known to be effective in reducing polypharmacy in primary care settings, but TAPER does not yet consider communication with other outside prescribers such as specialists within the Tool, though this is currently being trialled in an implementation project, where all providers in the circle of care have access to the plan [71, 72]. As an initial step, in jurisdictions where healthcare records are not integrated, a base template letter is provided in TAPER, which the family physician may send to the specialist if appropriate. The letter outlines TAPER, its aims and alignment with patient's priorities, and requests their support for the "pause and monitor™" phase.

Second, reducing polypharmacy by deprescribing involves an extra effort and initiative from clinicians and payment models may not necessarily reflect this [73]. The models we mapped TAPER against were not comprehensive, and important aspects that are identified barriers such as provider reimbursement were not considered in this evaluation against existing models. However, Conklin et al. suggest that the issue could be overcome if a potential "fee-for-service" methodology, with a specific funding mechanism for deprescribing, is implemented.

TAPER requires conditions of coordination and partnership between a pharmacist and physician, as well as with patients to realise the full potential. This may be efficient in certain settings, such as a family health team or long-term care facility but may require greater organisational logistics for small or rural practices, through virtual consultations, which are possible within the operationlised TAPER model in TaperMD™. The integrated platform is intended to foster greater coordination and partnership, and this has occurred where TAPER was implemented in regions where this was not pre-existing.

There is an observed high degree of heterogeneity in the intervention type in deprescribing research and studies have often reported no clear effect on medication-related problems of importance to patients [27, 35–38]. The lack of clarity regarding the mechanisms of effect that are being tested by a particular intervention makes it difficult for those planning or refining interventions to understand and build on what may be successful elements [37]. It would be helpful if, in designing and reviewing polypharmacy interventions, Phase 0 [40] or the 'development' element of the MRC framework for intervention development is explicit [41]. That is, the theoretical rationale describing the hypothesised mechanisms underpinning the intervention are detailed as explicit parts of both design development and published reports (and sought by journal reviewers to support this process). [38, 39]. Broad benefits to research in general, and polypharmacy in particular, in understanding successful designs and key components remain unknown when these details surrounding intervention development are not reported or published [43]. Without this information, it is unclear what potential mechanisms were tested in each intervention, which is of particular importance within polypharmacy research given the heterogeneity of results reported and the range of different intervention elements and contexts, combined with the known limited effect of general strategies aimed at changing clinical practice [44]. Reporting of these elements will aid those designing and refining future interventions as well as improving the interpretation of data and the comparison of different interventions and theoretical groupings.

4.1 Future Research

TAPER was designed to be a pathway for routine preventive care focused on reducing the harms of polypharmacy in the primary care setting; however, it is designed for adaptation to other system contexts, and to allow a patient access point with integration into other patient-facing data systems. TAPER was developed for individuals with polypharmacy. Aggregate information from the pathway on specific medication groupings and patterns of medication recommendations could be extracted as part of overall clinical information systems and used to inform quality improvement on a clinic or population level to identify sub-groups of patients needing proactive care, or the aggregate impact of intervention.

5 Conclusions

We developed TAPER as an evidence-based and theory-based structured clinical pathway for a comprehensive multidisciplinary medication review by pharmacists and physicians in partnership with patients, focused on reducing the medication burden, and, through this, the harms of polypharmacy. By explicitly outlining theoretically linked mechanisms, results from studies using TAPER should be replicable and easier to interpret. It is our hope that this detailed description of theoretical work will help us and others in developing and refining interventions and in understanding using an implementation science lens why interventions, and specific components of interventions such as TAPER, may be an effective approach to polypharmacy. Our work described here complements other work we have done in feasibility testing (clinicaltrials.gov NCT02562352) [34, 39]. TAPER has been previously described in detail using the TIDier framework [64, 74]. We are currently running a multi-site randomised controlled trial of the model (clinicaltrials.gov NCT02942927), assessing implementation domains using the RE-AIM model [75], alongside

effectiveness to explore these theoretical relationships as well as using these data to fully elucidate the model of care.

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Declarations

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Conflicts of interest/competing interests Dee Mangin, Larkin Lamarche, Jeffrey A. Templeton, Jennifer Salerno, Henry Siu, Johanna Trimble, Abbas Ali, Jobin Varughese, Amy Page and Christopher Etherton-Beer have no conflicts of interest that are directly relevant to the content of this article.

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Authors' contributions DM had the idea for the manuscript and led design of the model for the pathway, approach to goals and priorities as well as evidence assessment presentation, in consultation with coinvestigators and other stakeholders as described here and in other papers. DM, LL, JT and AA drafted the first version of the manuscript. All authors contributed to and critically revised the manuscript.

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