STOPPFrail (Screening Tool of Older Persons Prescriptions in Frail adults with limited life expectancy): consensus validation

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Abstract

Objective: to validate STOPPFrail, a list of explicit criteria for potentially inappropriate medication (PIM) use in frail older adults with limited life expectancy.

Design: a Delphi consensus survey of an expert panel comprising academic geriatricians, clinical pharmacologists, palliative care physicians, old age psychiatrists, general practitioners and clinical pharmacists.

Setting: Ireland.

Subjects: seventeen panellists.

Methods: STOPPFrail criteria were initially created by the authors based on clinical experience and literature appraisal. Criteria were organised according to the physiological system; each criterion accompanied by an explanation. Using Delphi consensus methodology, panellists ranked their agreement with each criterion on a 5-point Likert scale and provided written feedback. Criteria with a median Likert response of 4/5 (agree/strongly agree) and a 25th centile of ≥4 were included in the final list.

Results: all panellists completed three Delphi rounds. Thirty criteria were proposed, 27 were accepted. The first two criteria suggest deprescribing medications without indication or where compliance is poor. The remaining 25 criteria include lipid-lowering therapies, alpha-blockers for hypertension, anti-platelets, neuroleptics, memantine, proton-pump inhibitors, H2-receptor antagonists, anti-spasmodic agents, theophylline, leukotriene antagonists, calcium supplements, bone anti-resorptive therapy, selective oestrogen receptor modulators, non-steroidal anti-inflammatory, corticosteroids, 5-alpha-reductase inhibitors, alpha-1-selective blockers, muscarinic antagonists, oral diabetic agents, ACE-inhibitors, angiotensin receptor blockers, systemic oestrogens, multivitamins, nutritional supplements and prophylactic antibiotics. Consensus could not be reached on the inclusion of acetylcholinesterase inhibitors. Full consensus was reached on the exclusion of anticoagulants and antidepressants from the list.

Conclusion: STOPPFrail comprises 27 criteria relating to medications that are potentially inappropriate in frail older patients with limited life expectancy. STOPPFrail may assist physicians in deprescribing medications in these patients.

Keywords: frail, life expectancy, deprescribing, polypharmacy, explicit criteria older people

Introduction

Population demographics are changing globally, with the greatest proportional increases seen in those aged ≥70 years [1]. Many older people are surviving longer with complex comorbid illnesses including dementia, chronic kidney disease, cardiovascular disease, chronic lung disease and cancer, many of which contribute to frailty and poor survival prognosis [2, 3]. Chronic illnesses coupled with normal physiological ageing can have a negative impact on cognition and functional ability. In such patients, the final months of life are often characterised by frailty and increased dependency thus requiring re-evaluation of treatment goals, particularly medications intended to have long-term preventative effects.
such as lipid-lowering drugs, anti-diabetic agents and cognitive enhancing drugs.

Nursing home residents are usually frail, with high levels of functional dependency, multiple co-morbid illnesses and high levels of medication use [4, 5]. In Ireland, 6% of adults aged ≥65 years live in nursing homes, increasing to 12% in those 80–84 years and 25% in those over 85 years [6]. In the United States, similar figures are seen with ~5% of adults’ ≥67 years living in institutional care [7]. These proportions are likely to increase with current demographic trends. Currently, the median length of time from nursing home admission to death in the United States is 5 months and within 1 year of admission, 65% of residents have died [8]. Clearly, the majority of older patients requiring admission to nursing homes have a limited life expectancy compared with those residing in the community. However, this frail group represents some of the highest consumers of prescription medications, despite a clearly reduced likelihood of long-term clinical benefit. The SHELTER study reports the rate of polypharmacy (5–9 drugs) and excessive polypharmacy (≥210 drugs) in nursing home residents to be 48.7 and 24.3%, respectively [9].

Inappropriate prescribing (IP) is also prevalent in older adults. IP pertains to the mis-prescribing, over-prescribing and under-prescribing of medications in the context of a person’s co-morbidities, full medication regimen, functional and cognitive status as well as treatment goals and life expectancy [10]. In one US study of nursing home residents with dementia, more than half received at least one daily drug of questionable benefit [11]. Polypharmacy and IP in older adults are linked to adverse drug events (ADEs), which can have a negative impact particularly on frail, multi-morbid nursing home residents [12].

Despite the high prevalence rates of polypharmacy and IP in the nursing home population, there is a paucity of evidence regarding the deprescribing of medications in older frail people with poor survival prognosis. Deprescribing refers to the process of tapering or stopping medications, aimed at reducing polypharmacy and improving patient outcomes. Although healthcare professionals, patients and their relatives all acknowledge the burden of polypharmacy for older people including administration time, adverse effects and cost, all groups display passivity towards deprescribing [13]. General practitioners (GPs) cite many challenges to deprescribing including organisational factors, suboptimal medical and pharmacy records, limited time and limited training of nursing staff. Consequently, less than half use a consistent approach to deprescribing [14]. The National Institute for Health and Care Excellence recommend annual medication reviews in care home residents, during which appropriateness of medications should be optimised including deprescribing where necessary [15]. For community dwelling older adults with chronic diseases, no time frame is suggested [16, 17].

Although frailty is sometimes difficult to define, it is common in later life and increases with age [18]. Over 50% of nursing home residents [4] and 17% of community dwelling older adults are considered frail [19]. In the United Kingdom, 14% of hospital admissions have at least one frailty syndrome [20]. Not all patients who are frail have a limited life expectancy, however, numerous studies link frailty to worsening disability, hospitalisation and death [21]. In patients with frailty and limited life expectancy, medication review should primarily focus on deprescribing and symptom management, rather than aggressive preventative strategies.

Numerous explicit prescribing tools aim to guide clinicians on cessation of PIMs including Beers [22], STOPP/START [23] and FORTA criteria [24]. STOPP/START criteria have been shown to improve medication appropriateness [25, 26] and reduce the incidence of adverse drug reactions in hospitalised older adults [27]. However, these comprehensive tools are designed to detect common and preventable PIMs in the general older population and not specifically in frailer people with limited life expectancy. Indeed, STOPP/START criteria have limited applicability in this cohort. For instance, patients with limited life expectancy would be unlikely to survive long enough to derive benefit from most medications listed in the START criteria. Furthermore, STOPP criteria do not suggest discontinuing major drugs classes that are least likely to have benefits in the last year of life, e.g. statins. Therefore, with the accepted need for deprescribing in the frail older population, there is a clear associated need for specific explicit criteria to guide the prescriber. To date, no explicit guidelines exist for deprescribing in frailer older people with limited life expectancy, other than NORRGP-NH criteria, which are specific to the nursing home population [28].

We aimed to develop an explicit tool, called STOPPFrail, to assist clinicians with deprescribing medications in frailer older adults with limited life expectancy in all healthcare settings.

**Methods**

**Draft STOPPFrail criteria**

The authors, all of whom have recognised expertise in geriatric pharmacotherapy, compiled the initial draft of STOPPFrail indicators and arranged them according to physiological systems, similar to STOPP/START criteria. We then identified the target population for whom these criteria would be applicable, i.e. persons with (i) end-stage irreversible pathology, (ii) poor one year survival prognosis, (iii) severe physical functional impairment or cognitive impairment of both and those patients where (iv) symptom control is the priority rather than prevention of disease. Since the most consistent predictors of mortality are co-morbidities and functional impairment [29], our definition of patients who are appropriate for deprescribing according to STOPPFrail criteria was based on these essential indicators, rather than the presence of specific diseases, such as dementia or cancer. Also incorporated in the tool are challenges associated with medication use in this population, such as administration time and physical discomfort, as these have been reported by healthcare professionals, patients and their families to be of concern [13].
Following this, the evidence base for each drug or drug class was checked using the British National Formulary and an extensive literature review, limited to the last 20 years. Literature searches of PubMed, Cinahl and Google Scholar were undertaken. Searches included the drug in question with key words such as ‘life expectancy’, ‘frailty’, ‘older adults’, ‘poor prognosis’, ‘deprescribing’, ‘IP’ and ‘ADEs’. The draft criteria were agreed on a consensus basis by the authors and subsequently distributed to a panel of experts for validation by the Delphi technique [30], an established method for achieving consensus. The Delphi method was used for this research because of the lack of rigorous randomised controlled evidence supporting the long-term benefits of preventive drugs in frail older adults with complex comorbidities and limited life expectancy; such patients are commonly excluded from clinical trials of drug therapies [31].

Expert panel selection

In June 2015, 25 experts were invited to participate in the Delphi process. Panellists were selected on the basis of their recognised academic credentials, clinical practice, experience and geographical diversity. After the study design and aims were explained to each participant, 17 agreed to participate. The panel consisted of consultant geriatricians (n = 6), clinical pharmacologists (n = 3), old age psychiatrists (n = 1), palliative care physicians (n = 3), as well as senior academic primary care physicians (n = 2) and clinical pharmacists with an interest in geriatric pharmacotherapy (n = 2). All of the panellists were affiliated with Irish university teaching hospitals (two in Northern Ireland). The panel was provided with an electronic repository containing supporting references for the proposed STOPPfrail criteria. Panellists’ completed the Delphi process between July 2015 and February 2016.

Data collection and analysis

Each round was sent to the panellists using an online survey (SurveyMonkey®). The first Delphi round consisted of 30 criteria. Each criterion was presented in the same format, i.e. a drug or drug class deemed potentially inappropriate followed by an explanatory sentence. Panellists rated their agreement with each statement on a 5-point Likert scale, where 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree, 0 = unable to offer an opinion [32]. In Round 1, panellists were also asked to offer suggestions or comments (including new drugs) as appropriate.

Statistical analysis

For each statement, consensus was based on the median Likert response and interquartile range. A median value of 4 or 5 with a 25th centile of ≥4 was accepted for inclusion in the tool, i.e. only statements with at least 75% of respondents agreeing or strongly agreeing were included. Proposed criteria with a median value of ≤3 were rejected: those with a median value of 4 or 5 and a 25th centile of <4 were rephrased in accordance with panellists’ suggestions and included in the next Delphi round. Statistical analysis was performed using IBM SPSS® Statistics version 22.

Results

All panelists completed the Delphi validation process in three rounds (Figure 1); 27 criteria comprise the final STOPPfrail tool (Table 1). Full statistical analysis (i.e. the phrasing of criteria and the distribution of the responses for each round) is available in the Supplementary data, available in Age and Ageing online.

In Round 1, 20 criteria were accepted. The first proposed criterion included in STOPPfrail was a general statement that any drug prescribed without a clinical indication should be discontinued. The remaining 19 criteria accepted included lipid-lowering agents, alpha-blockers for hypertension, neuroleptics, proton-pump inhibitors, theophyllines, leukotriene receptor antagonists, selective oestrogen receptor modulators (SEORMs), non-steroidal anti-inflammatories, steroids, 5-alpha reductase inhibitors and alpha-blockers in catheterised patients, muscarinic antagonists, diabetic oral agents, angiotension-converting-enzyme inhibitors, angiotensin receptor antagonists, multivitamins and nutritional supplements.

Two criteria were rejected in Round 1. The first was the prescription of anticoagulants as a preventative measure. Our research group proposed discontinuation of anticoagulants as we considered that the bleeding risk and cost of treating outweighed the potential benefits to patients in whom cognition and function were poor. Panellists agreed that in the majority of people meeting the criteria for STOPPfrail, anticoagulants should be stopped; however, this criterion was rejected due to their concern over the minority of patients in whom stopping anticoagulants would be potentially inappropriate. Specifically, the majority considered that, regardless of frailty and life expectancy, stroke was an unfavourable outcome. Both panellists and the authors agreed that individual clinical judgement should be applied based on individual preferences and priorities with regard to anti-coagulation. In recent years, anti-coagulation has become easier, safer and more efficient
STOPPFrail is a list of potentially inappropriate prescribing indicators designed to assist physicians with stopping such medications in older patients (≥65 years) who meet ALL of the criteria listed below:

1. End-stage irreversible pathology
2. Poor one year survival prognosis
3. Severe functional impairment or severe cognitive impairment or both
4. Symptom control is the priority rather than prevention of disease progression

Section A: General
A1. Any drug that the patient persistently fails to take or tolerate despite adequate education and consideration of all appropriate formulations.
A2. Any drug without clear clinical indication.

Section B: Cardiovascular system
B1. Lipid lowering therapies (statins, ezetimibe, bile acid sequestrants, fibrates, nicotinic acid and acipimox)
These medications need to be prescribed for a long duration to be of benefit. For short-term use, the risk of ADEs outweighs the potential benefits [43–45].
B2. Alpha-blockers for hypertension
Stringent blood pressure control is not required in very frail older people. Alpha blockers in particular can cause marked vasodilatation, which can result in marked postural hypertension, falls and injuries [46].

Section C: Coagulation system
C1. Anti-platelets
Avoid anti-platelet agents for primary (as distinct from secondary) cardiovascular prevention (no evidence of benefit) [47].

Section D: Central Nervous System
D1. Neuroleptic antipsychotics
Aim to reduce dose and gradually discontinue these drugs in patients taking them for longer than 12 weeks if there are no current clinical features of behavioural and psychiatric symptoms of dementia (BPSD) [48–52].

D2. Memantine
Discontinue and monitor in patients with moderate to severe dementia, unless memantine has clearly improved BPSD (specifically in frail patients who meet the criteria above) [53–56].

Section E: Gastrointestinal system
E1. Proton Pump Inhibitors
Proton Pump Inhibitors at full therapeutic dose ≥8/52, unless persistent dyspeptic symptoms at lower maintenance dose [57].

E2. H2 receptor antagonist
H2 receptor antagonist at full therapeutic dose for ≥8/52, unless persistent dyspeptic symptoms at lower maintenance dose [57].

E3. Gastrointestinal antisapsmodics
Regular daily prescription of gastrointestinal antisapsmodics agents unless the patient has frequent relapse of colic symptoms because of high risk of anticholinergic side effects [57].

Section F: Respiratory system
F1. Theophylline
This drug has a narrow therapeutic index, requires monitoring of serum levels and interacts with other commonly prescribed drugs putting patients at an increased risk of ADEs [58–60].

F2. Leukotriene antagonists (Montelukast, Zafirlukast)
These drugs have no proven role in COPD, they are indicated only in asthma [61].

Disclaimer (STOPPFrail)
Whilst every effort has been made to ensure that the potentially inappropriate prescribing criteria listed in STOPPFrail are accurate and evidence-based, it is emphasised that the final decision to avoid or initiate any drug referred to in these criteria rests entirely with the prescriber. It is also to be noted that the evidence base underlying certain criteria in STOPPFrail may change after the time of publication of these criteria. Therefore, it is advisable that prescribing decisions should take account of current published evidence in support of or against the use of drugs or drug classes described in STOPPFrail.

The second criterion rejected in Round 1 was the use of antidepressants in patients with advanced dementia. Reasons for rejection included possible benefits outside

due to novel anticoagulant drugs. Therefore, panelists felt that in patients receiving anticoagulants with minimal side effects, continuation was warranted.
antidepressant effects such as analgesic effects, appetite stimulation and anxiolytic properties. Feedback suggested that cessation in patients with severe dementia was a reasonable approach, but not in all patients with limited life expectancy. Panellists feared that antidepressant therapy could be stopped in patients who derived benefit from treatment and that the risk of relapse outweighed the potential benefit of discontinuation.

Eight criteria were deemed inconclusive after Round 1. The first was a general criterion of deprescribing any drug with which patients fail to comply. Feedback suggested that the explanatory sentence should remind users to try all appropriate measures to improve compliance before deprescribing; this criterion was rephrased accordingly for Round 2. Other drugs for which there was uncertainty among the panel were anti-platelets, memantine, acetylcholinesterase inhibitors, H2-receptor antagonists, calcium and vitamin D supplements, bone anti-resorptive/anabolic agents and prophylactic antibiotics. Feedback was incorporated into rephrasing the criteria for Round 2.

Panellists agreed with the inclusion of anti-platelet agents, but raised concerns over their cessation when their indication was secondary prevention. Similar to the feedback for anti-coagulation, panellists were concerned about the minority of patients where deprescribing may be inappropriate. It was felt that secondary prevention should incorporate specialist judgement, and that a generalised statement would not be appropriate. Hence, it was decided that primary prevention should be the focus of this criterion. Panellists welcomed the inclusion of calcium supplementation and anti-resorptive therapy in STOPPFrail, but asked for clarity around the explanatory sentence, i.e. cessation where the indication was osteoporosis and not malignancy. Evidence is lacking on whether long-term use of calcium is beneficial due to methodological flaws in studies and high dropout rates [33]. Patient compliance with calcium supplements is poor; those most likely to be non-compliant have a history of smoking, poor mobility and previous fractures [34]. Anti-resorptive medications are challenging to administer, have a less favourable side effect profile and in some cases have been shown to continue to have clinical benefits after cessation, e.g. bisphosphonates. For these reasons, the panellists agreed to cessation in those with limited life expectancy.

Consensus could not be reached on two criteria after Round 2. i.e. cessation of (i) memantine and (ii) acetylcholinesterase inhibitors in advanced dementia. A third Delphi round was therefore prepared for circulation. In this round, consensus was obtained for memantine and it was included in the STOPPFrail tool. Consensus was not achieved for acetylcholinesterase inhibitors with no trend towards acceptance (Table 2). Panellists reported that the evidence base for acetylcholinesterase inhibitors in advanced dementia was still developing, and the possibility that unrecognised benefits existed could not be dismissed. The DOMINO-AD trial was cited to support their exclusion [35, 36]. This trial suggests that in patients where acetylcholinesterase inhibitors are stopped, the admission rate to nursing homes in the following year is increased compared with those who continue acetylcholinesterase inhibitors. However, this difference is only seen in the first year following cessation. After three rounds, no additional concerns were raised by the panel thus it was decided by the authors that a fourth Delphi round was unnecessary.

The final consensus STOPPFrail criteria are presented in Table 1. An explanatory sentence to aid the decision to deprescribe the medication in question is present for clarification purposes, particularly to guide deprescribing drugs which cannot be stopped abruptly, i.e. neuroleptics and long-term steroids.

### Discussion

STOPPFrail is an explicit list of 27 PIMs in frail older adults with limited life expectancy. The criteria are not designed to replace clinical judgement, but rather to assist clinicians with medication reviews and assessment of treatment goals in this specific patient cohort. Recognition of those patients to whom STOPPFrail is applicable may be challenging for less experienced physicians; in these circumstances, the use of simple mortality predictive tools may be helpful to guide life expectancy, e.g. the Walter Index [37] or the CIRS-geriatric scale [38]. However, we anticipate that the majority of clinicians who will use this tool will be experienced in recognising patients who are appropriate for its application, i.e. GPs or senior hospital specialists with prognostic knowledge of the diseases they manage. In the interest of simplicity and for the tool to be user friendly, we did not want STOPPFrail to be contingent on the use of another tool to determine eligibility.

Polypharmacy is a well-described problem in this cohort. This research aims to put a framework on the guiding principle of deprescribing in late life, i.e. that the benefits of many preventive medications are negligible in those with a limited life expectancy. Although many IP explicit tools exist, there has been an unmet need for a concise explicit tool to assist deprescribing in this specific patient cohort. STOPPFrail is a short tool, focusing on 27 key indicators, suggesting that it will be easy to use, time efficient and therefore more likely to be implemented. Like STOPP/START criteria [23], STOPPFrail criteria are listed according to physiological system, thereby allowing users to structure their approach to deprescribing. We aimed for a concise set of criteria that can be easily deployed in paper and electronic format. Electronic application of medication assessment criteria are challenging and the discussion of their potential benefits and implementation is beyond the scope of this paper. However, electronic implementation of

### Table 2. Acetylcholinesterase inhibitors Delphi results

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<th>Acetylcholinesterase inhibitor</th>
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the STOPP/START criteria is the focus of the SENATOR clinical trial [39], currently recruiting patients, and similarly there is the potential for the electronic implementation of STOPPFrail criteria.

Developing this tool required discussing many controversial treatments, e.g., those used in the treatment of hypertension. The authors and panellists agreed that a generalised statement about discontinuing all anti-hypertensives would be contentious. Therefore, it was decided to focus on the drug class least likely to be prescribed as a first-line agent and most likely to cause orthostatic hypotension and falls in an older cohort, i.e., alpha-blockers.

Inevitably, explicit STOPPFrail criteria will be compared with implicit deprescribing criteria designed for use in older populations, such as the Garfinkel algorithm [40] and the CEASE criteria [41, 42], which have small-scale clinical trial evidence to support their efficacy. Despite this evidence, implicit criteria for prescribing and deprescribing have not come into routine clinical practice. It remains to be seen whether STOPPFrail, as the first systematic set of explicit deprescribing criteria designed specifically for older people with advanced frailty and poor survival prognosis, holds a greater likelihood of being applied in the routine clinical situation than implicit criteria sets.

Finally, appropriate use of STOPPFrail criteria may have pharmaco-economic benefits. Older frail adults with a poor survival prognosis account for a growing proportion of the population and a disproportionately high level of medication consumption. Implementation of safe, evidence-based deprescribing in this population, may improve patients’ quality of life through reduced ADEs, related hospitalisations and mortality. The true value of STOPPFrail will need to be tested by means of randomised controlled trials examining its impact as an intervention on patient quality of life, healthcare utilisation, medication costs and mortality.

### Key points
- STOPPFrail comprises 27 criteria for potentially inappropriate medications in frail older adults with limited life expectancy.
- STOPPFrail may serve to assist physicians in deprescribing medications in a structured fashion in this group.
- STOPPFrail can be applied in frail older adults with limited life expectancy in any healthcare setting.

### Supplementary data
Supplementary data are available at *Age and Ageing* online.

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### Disclaimer and intellectual property of STOPPFrail
STOPPFrail recommendations are based partly on evidence base and partly on expert consensus and are intended to guide prescribers and others who routinely...
review the medication of older people with advanced frailty (physical and/or cognitive) and poor survival prognosis. As such, the STOPPFrail criteria are offered as a clinical tool to assist the process of considered deprescribing in this particular patient population. STOPPFrail criteria are not meant to over-ride the clinical judgement of the prescriber/medication reviewer in individual cases and do not replace the responsibility of the prescriber/medication reviewer in the matter of medication selection or deselection for individual patients.

STOPPFrail criteria, now published and in the public domain, may be used by any appropriately trained person as an assistive tool in the process of medication review of this particular cohort of older people. STOPPFrail criteria are not constrained by copyright and in themselves are not patentable as intellectual property. The term ‘STOPPFrail’ is, however, protected by copyright and cannot be used for commercial purposes except by University College Cork, Ireland or with the expressed written consent of University College Cork, Ireland.

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Potentially inappropriate medication prescribing is associated with socioeconomic factors: a spatial analysis in the French Nord-Pas-de-Calais Region

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Abstract

Background: potentially inappropriate medication (PIM) prescribing is common in older people and leads to adverse events and hospital admissions.

Objective: to determine whether prevalence of PIM prescribing varies according to healthcare supply and socioeconomic status.

Methods: all prescriptions dispensed at community pharmacies for patients aged 75 and older between 1 January and 31 March 2012 were retrieved from French Health Insurance Information System of the Nord-Pas-de-Calais Region for patients affiliated to the Social Security scheme. PIM was defined according to the French list of Laroche. The geographic distribution of PIM prescribing in this area was analysed using spatial scan statistics.

Results: overall, 65.6% (n = 207,979) of people aged 75 years and over living in the Nord-Pas-de-Calais Region were included. Among them, 32.6% (n = 67,863) received at least one PIM. The spatial analysis identified 16 and 10 clusters of municipalities with a high and a low prevalence of PIM prescribing, respectively. Municipalities with a low prevalence of PIM were characterised by a high socioeconomic status whereas those with a high prevalence of PIM were mainly characterised by a low socioeconomic status, such as a high unemployment rate and low household incomes. Markers of healthcare supply were weakly associated with high or low prevalence clusters.

Conclusion: significant geographic variation in PIM prescribing was observed in the study territory and was mainly associated with socioeconomic factors.

Keywords: inappropriate prescribing, older people, scan statistics, pharmacoepidemiology