BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049872
Article Type:	Original research
Date Submitted by the Author:	04-Feb-2021
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Keywords:	GENERAL MEDICINE (see Internal Medicine), Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, QUALITATIVE RESEARCH

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Implementation of a complex intervention to improve hospital discharge: Process evaluation of a cluster randomized controlled trial

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Word count: 5086

Number of Tables: 1

Number of Figures: 4

Number of supplementary files: 3

Abstract

Objectives: In this article, we report on the implementation of a cluster randomized controlled effectiveness-implementation hybrid trial testing the effectiveness of a medication review at hospital discharge combined with a communication stimulus between hospital physicians (HPs) and general practitioners (GPs) on rehospitalisation of multimorbid older patients.

Design: For this mixed method process evaluation, we developed a framework on the basis of Grant et al., paying special attention to the multilevel nature of the intervention.

Setting: General internal medicine wards in Swiss hospitals.

Participants: In the 21 participating hospitals, process evaluation data was collected from 15 chief physicians, 60 senior HPs, 65 junior HPs and 187 GPs.

Process evaluation components: We collected data on recruitment, delivery, and response from chief physicians (semi-structured interviews), senior HPs, junior HPs, GPs (surveys), and patients (via HPs). Quantitative data was summarised using descriptive statistics, and interviews were analysed using thematic analysis.

Results: Implementation was successful in recruitment of hospitals and HPs and in response of HPs, patients, and GPs. Implementation success was mixed regarding intervention delivery to patients and GPs. Implementation was deficient in recruitment and retention of patients. We identified a multitude of implementation facilitators and barriers as well as strategies to overcome the latter.

Conclusions: The results from this evaluation will support interpretation of the findings of the effectiveness study and – positive results given – dissemination of our approach to further hospitals. In addition, the implementation strategies presented may help researchers to plan future studies in the hospital setting.

Trial registration: ISRCTN18427377

Keywords

Process evaluation; effectiveness-implementation hybrid study; cluster randomized controlled trial; framework; mixed method; hospital discharge; medication review

Article summary

Strengths and limitations of this study

- We used both quantitative and qualitative approaches to achieve an adequate insight into the implementation of the intervention.
- Our process evaluation was performed before instead of alongside or after the analysis and publication of the effectiveness findings, which is an innovative approach for process evaluations and ensures that the evaluation is blind to trial outcomes.
- Our application and extension of the framework described by Grant et al. could serve as example and template for future implementation studies of complex multilevel interventions.
- The results from this evaluation will support interpretation of the findings of the effectiveness study and – positive results given – dissemination of our approach to further hospitals.
- The number of junior hospital physicians' responding to the survey was limited by frequent rotations between and within hospitals.

Background

Polypharmacy – often defined as the concomitant use of five or more medications – is associated with increased risk of adverse events, prescription errors, low patient adherence, morbidity, hospitalisation rates, and mortality.[1-4] During hospitalisation, patients are usually prescribed additional drugs while few drugs are deprescribed, so that the extent of polypharmacy is higher at discharge than at admission.[5] Poor communication between healthcare providers after discharge additionally contributes to suboptimal prescribing.[6]

Previous systematic reviews provide some evidence that reducing polypharmacy improves health-related outcomes in older people, and that a variety of discharge planning interventions can reduce adverse events and healthcare utilization in the post-discharge period.[7 8] To our knowledge, no study has so far analysed the effects of a discharge strategy which incorporates *both* key aspects of deprescribing and collaborative communication between hospital physicians (HP) and general practitioners (GP) at hospital discharge. We therefore performed a two-armed cluster randomized controlled trial (RCT) investigating an intervention aimed at improving inappropriate medication and information transfer at hospital discharge for patients of advanced age with polypharmacy.[9] The complex intervention involved multiple sites, different levels of healthcare providers, and different time points during the patients' hospital stay. A pragmatic approach allowed adapting the intervention to local conditions in the participating hospitals.

For complex RCTs, process evaluations are recommended to contextualize results.[10 11] It is often crucial to not only know whether but also when, why, and how interventions 'work', particularly in the case of flexible and multisite interventions which may be implemented and received in different ways at the different sites.[10 12] Various theoretical frameworks exist to guide the design and conduct of process evaluations.[10 13-15] For cluster RCTs specifically, Grant et al. [16] developed a framework which considers the multilevel design with clusters and targeted individuals. We extended Grant's framework to evaluate the implementation of our trial with regard to recruitment of participants, intervention delivery, response of all parties involved, and maintenance of the intervention.

Methods

Design and setting

This was a pre-planned mixed method process evaluation of a cluster RCT involving 21 hospitals in the German-speaking part of Switzerland. The process evaluation, part of an effectiveness-implementation hybrid trial,[17] was conducted in parallel to the main cluster RCT; effectiveness outcomes will be published separately. The study protocol for the full trial has been published elsewhere.[9] The intervention was a teaching session for senior HPs in internal medicine wards and rehabilitation hospitals, who instructed junior HPs on a patient-centred discharge procedure including critical medication review. This procedure was facilitated by a checklist (online supplementary appendix 1). Depending on the hospital, junior and/or senior HPs carried out the discharge procedure on the patient. Additionally, two adaptations to the discharge letter were introduced: a reorganisation of the medication lists so that medication changes could easily be identified by the aftercare GP, and an invitation to the GP to discuss (potential changes of) the medication plan. In the control arm, usual discharge procedures were followed. Patients were followed up for 6 months beyond discharge for outcomes such as re-hospitalisation, other physician contacts, current medication and quality of life, collected by questionnaires at 1, 3, and 6 months. Of repeatedly unreachable patients, relatives or GPs could be contacted. Ethical approval was obtained from the Ethics committee of the Canton of Zurich (BASEC-No. 2018-00215).

The process evaluation was based on a framework of Grant et al.[16] and was tailored to the specific multilevel nature of our intervention. Our adapted framework distinguishes process elements (recruitment of the hospitals as well as recruitment, delivery, and response, on the level of senior HPs, junior HPs, and patients) from impact elements (Figure 1). We reported results in accordance with the Standards for Reporting Implementation Studies (StaRI) checklist.[18]

Figure 1

Participants

The recruitment procedure is described in the study protocol.[9] We questioned chief physicians who decided about participation in the study, senior and junior HPs who were directly involved in the delivery of the intervention to patients, and GPs as downstream receivers of the intervention. Patients were not

directly questioned. An overview of the flow of hospitals, senior HPs, junior HPs, GPs, and patients through the study is shown in Figure 2.

Figure 2

Objectives

For the framework elements specified in Figure 1, we aimed to explore and describe implementation along the following dimensions:

- Implementation fidelity, i.e. the *quality* of the implemented intervention compared with what was intended
- Intervention dose, i.e. the *quantity* of the implemented intervention
- Feasibility and acceptability, based on views and experiences of participants
- Facilitators and barriers to implementation
- Implementation support strategies to target facilitators, overcome barriers, and ultimately improve implementation

Data collection

We collected both qualitative and quantitative data (see online supplementary appendix 2 for the data collection tools). We conducted semi-structured interviews with chief physicians at the beginning of the study, short paper-based surveys with senior HPs after instruction, and an online-survey at the end of the study with senior HPs and junior HPs. Both surveys had open-end questions and quantitative parts. In addition to questions about feasibility and awareness, the online survey contained two case vignettes with the intent of assessing knowledge transfer and increased awareness induced by our intervention to HPs. The case vignettes described two model patients, and HPs were asked about their recommendations regarding the patients' medication. The case vignettes were pretested with three GPs at our institute and revised according to their responses. The fourth dedicated data collection tool was a short postal survey of GPs at the end of the study capturing their opinions regarding hospital discharge, with focus on the discharge letter, medication, and contact. An overview of the data collection tools with response numbers and rates is incorporated into Figure 2.

In addition to these dedicated data collection tools, we used data from study instruments such as the patient-specific checklists (online supplementary appendix 1) where the intervening HPs had ticked off

which parts of the intervention had actually been delivered. Finally, we recorded how chief physicians had initially planned to implement the intervention, and used our emails and protocols of phone calls with participants and patients.

Data analysis

Quantitative data was analysed with the R statistical software version 3.5.1 [19] and Microsoft Excel (2016). We reported medians, interquartile ranges (IQR), maxima (max) and minima (min), or proportions (% of non-missings) and numbers (*n*), and compared groups using Wilcoxon and chi-square tests as appropriate. Significance was assumed for p values < 0.05. Likert scale items were dichotomized for most summaries.

The semi-structured interviews were analysed by deductive thematic analysis,[20] with a predefined focus on 'facilitators' and 'barriers' (to study participation). Two researchers (TG, SNJ) independently coded the 15 interviews until saturation (i.e. no further emergence of new codes) was reached, and subsequently grouped the codes into themes. The codes and themes were harmonized by consensus among all authors. Qualitative answers from the paper-based survey with senior HPs were also summarised according to the resulting themes.

Patient and public involvement

Patients were not involved in the planning of the study, but patient involvement is a core component of the medication review part of our intervention (see online supplementary appendix 1).

Results

The results are presented along the elements specified in the framework (Figure 1) and structured into a) quantitative results, b) qualitative results, and c) implementation strategies. The response rates for each data collection tool are given in Figure 2.

Hospitals

Recruitment

We approached 162 chief physicians of hospitals with a general internal medicine ward or of rehabilitation hospitals in German-speaking Switzerland: 16% (*n* = 26) by personal inquiry and 84% (*n* = 136) by postal dispatch. Of all chief physicians, 83% showed no interest (no response: *n* = 116, active declining: *n* = 19). We presented the study to the remaining 27 chief physicians and staff (typically volunteering senior HPs) out of which six chose not to participate. All hospitals that declined participation were asked for reasons for non-participation, and 16 hospitals replied: Lacking resources were mentioned most frequently, followed by temporal overlap with other ongoing projects (scientific studies, or adoption of a new hospital information technology system), unsuitability of the hospital (organization or patient population), or low expected benefit for the hospital (e.g. when the established discharge procedure was perceived as similar to the study intervention).

Ultimately, 21 hospitals agreed to participate. Of these, 16 were acute and 5 rehabilitation hospitals, 2 were academic and 19 non-academic hospitals, and ward sizes ranged from 15 to 180 beds.

From the interviews with the chief physicians, we identified 13 themes; 8 corresponding to facilitators and 5 to barriers to study participation and implementation. Themes with constituent codes and example quotes are presented in Table 1. As an immediate reaction to barriers identified, we summarised potential solutions and presented them to subsequently approached hospitals. For instance, to mitigate concerns of undue effort, we recommended to involve non-medical personnel for administrative tasks and provided time estimates required for the different study steps. We also tried to target facilitators, e.g. by emphasizing the potential benefits for the clinics and by preparing a study announcement for the hospitals to use for information and marketing purposes.

Table 1

Senior HPs

Recruitment

Recruitment of senior HPs was organized by the chief physicians. In total, 74 (40% female) senior HPs participated (median 3 per hospital, IQR 2-5, min 1, max 9). The median work experience was 15 years (IQR 10-24), not significantly different between study arms (p = 0.971). Of the 60 senior HPs responding to the initial paper-based survey, 23% (*n* = 14) had experience with scientific studies, and 35% (*n* = 21)

had been involved in a project or study regarding related topics (polypharmacy/appropriate medication, frailty, discharge management, or communication with GPs). All but three of the responding senior HPs found the topic of the study very relevant or relevant to them. Motivation for participation in the study were most frequently quality improvement (45%, *n* = 27) and relevance of the topic (28%, *n* = 17), but 23% (*n* = 14) of senior HPs stated that they had no motivation or that it was the chief physician's decision. The most frequently mentioned concerns were methodological limitations regarding recruitment, follow-up or risk of bias (22%, *n* = 13) and missing resources/high workload (8%, *n* = 5), but the majority of senior HPs (62%, *n* = 37) mentioned no concerns.

Delivery

The intervention was delivered to senior HPs in terms of an instruction by the study team. This instruction covered theory with deprescribing examples (1 hour, intervention group only) and data handling/study conduct (1 hour, both study arms). The theory part provided current evidence on medication review and (lack of) benefits of example drugs for patients of advanced age. The instruction was performed uniformly by the principal investigator using presentation slides.

Response

All but one of the senior HPs stated that the instruction had met their expectations. The study aim, the study flow in the hospital, and their role in the study were very clear or clear to all but three senior HPs. The senior HPs' attitudes and response to the checklist and adaptation of the discharge letter as declared in the online survey at the end of the study are shown in Figure 3. The majority of senior HPs appreciated the relevance of the topic and perceived the intervention as feasible and helpful. For example, respondents stated that the checklist reminded them to review drugs more critically (46%, *n* = 11), to consistently motivate patients to visit their GPs within 7 days (38%, *n* = 9), or to discuss treatment goals with the patients (17%, *n* = 4). Fewer (42%) senior HPs declared that they would continue using the checklist after the study (Figure 3Bg). Two senior HPs suggested that the checklist could be improved by choosing the time period from hospital discharge to GP visit individually for each patient (instead of 7 days as required by the checklist).

To the five questions regarding (de)prescribing decisions (case vignettes, see online supplementary appendix 2), 69% (*n* = 69) of responses in the intervention group were pro-deprescribing

(reducing/stopping or switching to phytotherapeutics, vs. continuing/increasing), while in the control group, the corresponding proportion was 71 % (n = 71, p = 0.877).

Figure 3

Junior HPs

Recruitment

Frequent rotations of junior HPs within and between hospitals necessitated their recruitment and instruction by senior HPs rather than the study team. Their exact recruitment number is therefore unknown, but 164 junior HPs were ultimately involved in intervention delivery (54% female), with a median of 6 (IQR 4-10, min 1, max 28) per hospital. Their median work experience was 2 years (IQR 1-4, min 1, max 10), with no significant difference between study arms (p = 0.590).

Delivery

The junior HPs' instruction was either incorporated into their mandatory continuing education, performed in a dedicated meeting for groups of junior HPs, or by means of a one-to-one instruction. In most hospitals, a mix of formats was applied. In total, senior HPs spent a median of 45 minutes (IQR 18-60) to deliver the theory part of the instruction (intervention group); individual junior HPs were instructed for a median of 15 minutes (IQR 10-30). To improve delivery to junior HPs, we provided the senior HPs with presentation slides covering both theory and data handling, and distributed practice material, summaries with key information, and extensive information leaflets for junior HPs.

Response

The junior HPs' attitudes and response to the intervention are shown in Figure 3. The checklist and the adaptations to the discharge letter were rated feasible and helpful by the majority of junior HPs (Figure 3B and Figure 3C). Fifty percent (n = 19) stated that they were reminded to question each drug in the patients' medication regimes more rigorously, 45% (n = 17) felt stimulated to motivate the patients to visit their GP after discharge, and 21% (n = 8) to discuss treatment goals with their patients. Only a minority (31%, n = 10) intended to continue using the checklist after the study (Figure 3Bg),

For the five medication review questions in the case vignettes, in the intervention group, deprescribing was suggested in 70% (n = 111) of responses, vs. 59% (n = 68) in the control group (p = 0.103).

Patients

Recruitment and reach

Patients were recruited at admission to the ward by the participating HPs on duty. The total number of recruited patients was 614 (50% in the intervention group), with a median of 21 patients (IQR 15-38, min 8, max 91) per hospital. To facilitate recruitment, we provided the hospitals with a disposable information sheet for patients, and a condensed version to be used for verbal clarification when recruiting patients. In the digital survey at the end of the study, most HPs stated that the short statement was used always (65%, *n* = 66) or sometimes (25%, *n* = 25) when recruiting patients.

Delivery

In median, each senior HP completed 2 checklists (IQR 0-10, min 0, max 20), while junior HPs filled out a median of 5 checklists (IQR 4-8, min 1, max 25). The HPs declared that checklist activities were begun during the patients' hospital stays – as opposed to shortly before discharge – for the majority of patients (median over HPs 61%, IQR 33-86%, min 0%, max 100%).

Intervention delivery to patients (in intervention hospitals) was high: The proposed activities were reportedly carried out in 95% (*n* = 3780 ticks on the 14-item-checklists). All but three checklist items had been ticked in over 90%, and the lowest execution rate (83%) was reported for 'motivating patients to consult their GP within 7 days'.

Response

According to half of the HPs in the intervention group responding to the specific question in the digital survey (*n* = 51), patients appreciated being involved in decisions regarding their medication plan, and only 7% of the patients (median over senior and junior HPs; IQR 0-25%, min 0%, max 60%) rejected proposed changes to their medication plans. Common reasons for patients' resistance to medication changes were habits/being used to a specific drug, believing in its positive effect, loyalty to the GP who prescribed the drug, or a general resistance to change. Some HPs additionally mentioned that the patients' addiction to the medication (e.g., to benzodiazepines or opioids) or communication barriers (language) impeded changing the medication plan.

During follow-up, the majority of patients did not return the required documents in time and had to be reminded by phone call. The overall dropout rate within the first month after discharge was 32% (*n* =

198 patients, see Figure 2). Most frequent reasons for dropping out were inability or unwillingness to return the requested documents. Patients mentioned being too sick or old to fill out the questionnaire, lack of motivation/perceived benefit, or previous unawareness of the questionnaire. Dropout rates varied between hospitals (median 31%, IQR 26%-38%, min 13%, max 55%).

GPs

Delivery

The intervention was delivered to GPs indirectly via adaptations to the discharge letter, i.e. the reorganised presentation of the patients' medications, and the communication offer to discuss medication changes with the HPs. The communication offer, as a fixed component of the intervention, was quantitatively well implemented (in rare cases only added after an early reminder) but often inserted very inconspicuously at the end of the discharge letter. For 22% of patients in the intervention hospitals and 18% in control hospitals, the GPs were contacted by HPs during the hospital stay already. Regarding the presentation of the patients' medication in the discharge letter, a flexible implementation approach was required, mainly due to the rigidity of the hospitals' clinical information systems. Three modes of implementations were accepted, with decreasing preference (number of hospitals who chose the option is indicated in brackets): a) Dedicated table of medication changes, with reasons (n = 1), b) Separate tables of admission and discharge medication, adjacent or in immediate sequence, again with explanations of medication changes (n = 8), c) Table of discharge medication only, with changes explained in the text body (n = 3). Inspection of the discharge letters revealed that medication changes were often insufficiently explained, irrespective of the presentation mode.

Response

Of the GPs responding to the postal survey (n = 187), the vast majority considered a comparison of admission and discharge medication in the discharge letter helpful (91%, Figure 4). Most also agreed that HPs should review the long-term medication of patients (74%) and appreciated being contacted in case of medication alterations (76%). Only few GPs (10%) would contact the HPs themselves when noticing a change. In the absence of contact, most GPs (74%) declared to usually – but depending on the individual case – adopt changes to the long-term medication made by HPs. Many GPs stated that an explanation for modifying/altering the medication was very important. Another issue raised by many GPs was that switching between original and generic drugs could confuse patients and entail the risk of

double intake. They proposed that the medication should be reset to preparations used at admission or at least that patients should be informed.

Documenting GP-initiated contacts with HPs following patient discharge was in the responsibility of HPs who reported 14 contacts in total.

Figure 4

Maintenance

The median patient inclusion period per hospital was 205 days (IQR 168-271 days, min 23, max 325), corresponding to approximately 7 months per hospital. Inclusion intensity varied over time and among hospitals and was not noticeably influenced by roughly monthly newsletters (online supplementary appendix 3). The designated contact persons in the hospitals (study nurse, clinical trials unit, senior HP, or chief physician) were reminded by email and phone if patient recruitment was still low. Not only recruitment yield but also immediate dropout rates changed over time in some hospitals. Regarding qualitative aspects of study delivery, when asked in the online survey whether their discharge management had changed over the course of the study, 15% (*n* = 14) of the responding HPs agreed, declaring for instance that they had reviewed drugs more carefully or earlier, had explained them more carefully to the patients, and that their contact with GPs had intensified.

Context

Swiss health care setting

Switzerland is organized as a federalist system of 26 cantons enjoying a high degree of autonomy vis-à-vis the federal government.[21] The federalist organization of health care results in regulated competition between hospitals and high variability e.g. in clinic information systems used by hospitals.[22] While hospitals mandatorily use digital patient records, this is not the case for ambulatory physicians including GPs. In fact, digitalization in the ambulatory health care sector in Switzerland is rather low: In 2018, only 43% of GPs documented their patient records fully electronically.[23] The fragmented digitalization of ambulatory health care likely hinders effective communication between hospitals and GPs.

COVID-19

The coronavirus disease 19 (COVID-19) pandemic had serious implications for this hybrid trial. The novel virus hit Switzerland in early March 2020, whereupon hospitals were ordered to stop all elective surgeries and ongoing trials. At that time point, the study was still ongoing in 13 (of the 21) hospitals, of which 10 had to stop and 3 to postpone recruitment, thus limiting the study sample and delaying completion of the study.

Discussion

This process evaluation provides insights into the implementation of a cluster RCT set at the interface between hospital care and general practice. Using a tailored version of the well-established framework by Grant et al. for process evaluations of complex multilevel interventions, increased knowledge about the trial's implementation on different levels was gained.

The implementation was successful in recruitment of hospitals and HPs, and in response of HPs, patients, and GPs. However, implementation results were mixed regarding intervention delivery to patients and GPs in terms of quantity and/or quality, and deficient in recruitment and retention of patients. Details are discussed in the following sections.

Hospital level

As expected, it was challenging to recruit hospitals that face market competition to participate in an external study without providing financial incentives. In addition to barriers related to resources, chief physicians mentioned concerns regarding methodological or organizational limitations (Table 1) and motivation of HPs. The majority of these issues have been reported before in a systematic review exploring barriers towards the implementation of hospital-based interventions.[24] As for facilitators, we found that a perceived benefit to the clinic or chief physician was crucial.

HP level

Most senior HPs showed motivation to participate in the study, e.g. because of expected quality improvements or in recognition of the topic's relevance. Almost one out of four, however, stated that they only participated following the hospital/chief physician's decision. This is problematic, as lack of

motivation is a well-known barrier towards implementation.[24] To increase motivation, Geerligs et al. suggest to share informal intervention 'success stories'.[24] In our case, these could be examples of patients with successfully improved medication lists, or a positive communication experience with a GP. Involving senior HPs earlier in the study design might further benefit the study by stimulating an essential sense of ownership.[24]

To capture the change in knowledge and attitudes of HPs towards deprescribing (a proxy for the expected training effect in our intervention model), we relied on case vignettes. Readiness to deprescribe in defined patient conditions was not significantly different between intervention and control group (which might partly be attributable to methodical limitations, see section 'Strengths and Limitations' below). However, to capture the positive impact of an intervention, it is also important to take views and experiences of staff into account.[12] The HPs' feedback to the intervention was positive: The adaptations of the discharge letter, especially the comparison of discharge with admission medication, were welcomed not only by senior and junior HPs but also by GPs (see section 'GP level' below). This is particularly interesting as it could be implemented in clinical information systems without increasing the HPs' workload. Regarding the checklist, the majority of HP stated that the proposed activities were feasible, and that the checklist was useful. Nonetheless, only a minority (one out of three) of junior and senior HPs intended to use the checklist after the study. The reasons for this are unclear. We can only speculate that additional time need or costs must have exceeded the expected benefits.[25] Further exploration of potential reasons for this reluctance is needed before scaling up the dissemination of our checklist.

Patient level

This intervention was targeted at multimorbid patients over 60 years of age. It is well known that recruiting and retaining old, multimorbid, frail and cognitively impaired patients is challenging.[12] Hence, old and frail patients are often excluded from trials,[26] even though they might profit most from interventions regarding medication review or communication. Recruiting frail or cognitively impaired patients was encouraged within this study and accordingly brought along some difficulties. For instance, the detailed information forms overwhelmed most of these patients. The short statement we provided to HPs was partially useful to overcome this barrier. However, the reluctance of vulnerable and multimorbid patients to take on another task (the one of study participation) besides their high burden of disease remained a major challenge. This is mirrored by the fact that the final number of recruited patients was

substantially lower than expected, even taking the COVID-19 pandemic barriers towards recruitment into account.

Judging by the checklist ticks, the intervention was well delivered to the patients in terms of quantity, but we were unable to evaluate delivery quality, i.e., to what extent HPs involved the patients and what effort they made in reviewing the patients' medication.

We assessed the patients' acceptance of our approach only indirectly via HPs. HPs declared that approximately half the patients appreciated being involved in decisions regarding their medication plans, and only very few rejected the proposed changes with reasons similar to those identified in a recent qualitative studies with older adults and their carers.[27 28] Interestingly, a recent systematic review detected a lack of family involvement in managing medications of older patients across transitions of care,[29] an aspect which might merit further investigation.

The variability of dropout rates and reasons for dropout between and even within hospitals suggested that quality of patient information (particularly regarding the patients' post-discharge responsibilities) and the type of recruited patient population (i.e., proportion of patients with cognitive impairment or with a high number of diseases) varied among hospitals and HPs. Many patients were unable or unwilling to fill out the required questionnaires during follow-up. Lyles et al. [30] suggested that remuneration of participants in recognition of their time commitment and a consistent, clear and persistent communication with participants were important factors in enrolling and retaining subjects.

GP level

Similar to other researchers of routine care,[31] we faced the dilemma inherent to any flexible implementation approach: Allowing high flexibility to suit the local circumstances may increase recruitment chances while decreasing implementation fidelity. We gave the hospitals much freedom in the intervention delivery to GPs, in particular regarding the adaptations of the discharge letter, which resulted in suboptimal implementation. The contact offer was presented very inconspicuously in several hospitals, and the medication changes were often not properly explained.

The high response rate of GPs contacted by postal dispatch and their feedback on the relevance of the topic indicated the need for better discharge protocols, thus justifying our trial. Accordingly, much literature is available on this topic. For instance, several studies from different countries reported that GPs appreciated receiving information on medication changes and reasons in the discharge letter.[32-35] Our findings show that GPs perceived this as more convenient than having to actively call the – often

unavailable or difficult to contact – HPs. Therefore, and not too surprisingly so, the number of GPs contacting HPs after their patients' discharge was low. However, the number was so exceptionally low that we must also assume incomplete documentation by HPs. The finding that most GPs reportedly adopted changes introduced by HPs is in accordance with a Danish qualitative study which concluded that the poor continuity of medication changes at sector transition was not due to the GPs' deliberate actions of removing the patients' medications but presumably to procedural errors in the follow-up on the patient after discharge instead.[36]

Strengths and limitations

We used both quantitative and qualitative approaches to achieve an adequate insight into the implementation of the intervention as proposed by the United Kingdom Medical Research Council guidelines.[11 37] Moreover, we performed the evaluation before instead of alongside or after the analysis and publication of the main findings, which, to our knowledge, is an exception and an innovative approach for process evaluations and ensures that the evaluation is blind to (and thus not biased by) trial outcomes.

The practical and well-structured framework by Grant et al. proved very useful in conducting this multilevel process evaluation. It has already been applied in numerous process evaluations of cluster RCTs [31 38-42] but was often reduced to specific elements.[31 37-39 42] While Roberts et al. claimed to be the first to use the framework in its entirety for a process evaluation of a cluster RCT,[41] we used an even more extensive version adapted to our intervention: The framework was extended with additional levels for the intermediary providers (junior HP) and the overarching institutions (hospitals). This comprehensive approach allowed us to study every level of the intervention delivery and response. Future strategies of hospital discharge optimisation may benefit from this knowledge about barriers to be tackled and facilitators to be taken into account on every level of the intervention. This may ultimately contribute to narrow the gap between the evidence of such strategies and their application in routine care.

Limitations of the study were the small sample of HPs, and that non-responders potentially introduced a selection bias (volunteer bias) to the digital survey. The low response rate of junior HPs was partially due to the frequent rotations; many junior HPs were no longer working at the hospital at the time of the process evaluation (which we anticipated). Furthermore, there might have been some desirability bias in the answers of HPs and chief physicians. We also faced potential bias due to unblind chief physicians

and senior HPs, which was inevitable during the hospital recruitment process. Lastly, it is conceivable that some selection bias was introduced by HPs recruiting fitter patients, even though we tried to mitigate this.

Conclusion

The process evaluation framework by Grant et al. proved helpful for investigating the implementation of a complex and multifaceted intervention at different levels in a hospital setting. Our approach can be tailored and adapted to similar interventions. The findings of our process evaluation will inform the interpretation of the effectiveness study's results and may be helpful for other researchers of routine hospital care, as well as for developing future dissemination strategies of an optimized hospital discharge procedure.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics committee of the Canton of Zurich (as part of the full effectiveness-implementation trial, BASEC-No. 2018-00215).

Availability of data

The datasets used and/or analysed during the current study are available from the last author (SNJ) on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This work was funded as part of the National Research Programme "Smarter Health Care" (NRP 74) by the Swiss National Science Foundation (grant no. 407440_167193, 7 December 2016). Additional funding was provided by the University of Zurich and the University Hospital of Zurich.

Author contributions

YR, TG, and SNJ contributed to conceptualization, investigation, methodology. YR performed the formal analysis and visualization and wrote the original draft. SNJ was responsible for funding acquisition and supervision. TG was responsible for project administration. YR, TG, and SNJ reviewed, edited and approved the final version of the manuscript.

Acknowledgements

We thank Susan Groth (our study nurse) and Petra Hug-Gresens for their invaluable contributions to the study.

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Tables

Table 1. Facilitators and Barriers to study participation from the chief physicians' perspective

Facilitators		
Themes	**Codes**	**Quotes**
Quality improvement	Standardization of processes (discharge, medication review)	"That we get a certain standardization of the processes with these intervention tools; also when there are rotations – we have junior HP that stay for two years, then the next ones arrive – that we can integrate that in our process flows, certain tools, to standardize that." [D-01]
	Communication with GPs	"It's always a little ambivalent: on the one hand [the GPs] want to be informed, on the other hand they don't like to be called. Because they feel that they are being interrupted, and you don't really know what the best strategy is to communicate with your GP." [D-02]
	Patient outcomes (medication, hospital readmission, safety, satisfaction)	"For me it's actually about patient safety" [D-03]
Quality control	Benchmarking	"That it will reveal where we actually stand with our hospital, that there is also some possibility of benchmarking." [D-03]
	Validation of the hospital's strategy	"It is also just for us to check 'is our philosophy somehow also the right one; what can we improve?" [D-04]
Teaching	Teaching junior HPs	"We work with many very young junior HPs, so we thought that nothing better could have happened to us than receiving such a support as your checklist." [D-05]
	Sensitization/awareness of HPs	"My personal expectation, which I have also communicated to my senior HPs, is that we raise awareness for the discharge management, and in particular for the medication." [D-06]
Scientific interest	intrinsic interest	"As I said, we want to do science, this is part of our job here, so that is certainly one of the key factors." [D-07]

Relevance	Important topics	"So in the end it is the topic that tipped the scales, it is an important topic, it is an everyday topic, it is a topic that has been studied little else, with big consequences ... that is the main point." [D-08]
	Challenging topics	"The transition of medication in the hospital to GPs is a problem that we are aware of. It is somehow a difficult interface, which we have of course already identified ourselves." [D-09]
Credibility	Evidence based approach	"Many of these quality measures that are in place in hospitals today give a lot of work, and we are not sure how much they are worth... For me, it is crucial that it is studied scientifically rather than some authority coming along and saying 'now you have to do that.'" [D-10]
	Ownership	"The fact that [the study] is run by the University Hospital Zurich also played a role for me personally." [D-11]
Publicity	Individual	"It's also a bit of a flagship for me, that I brought the University of Zurich to [this hospital], along with myself, I might say. So this is my personal interest in the whole story." [D-06]
	Hospital	"We were published in the newspaper with too high readmission rates, and this is a tool to look at this." [D-12]
Fitting conditions	Right time, right place	"And now that a study has just been completed, this actually fits into our sequence quite well." [D-07]
	Target population	"We treat many patients who are older than 60 years (...). Many of them have many drugs. [The study] inclusion criteria are more than five; we sometimes have patients with 20 or more drugs, with proper polypharmacy." [D-11]
	Complementary to ongoing projects	"And when we received the offer to participate in this study, we saw it as the perfect complement to the other projects currently underway." [D-06]
Barriers		
Themes	**Codes**	**Quotes**
Resources	Limited time and workforce	"[It's] always the effort." [D-10]
	Lack of financing	"I mean, there is no provision for research to be carried out in clinical practice, and we are not compensated for it." [D-10]
Methodological limitations	Challenging patient population (oldest old, cognitive limitations, health literacy)	"99.9% of our patients do not know what 'quality of life' is. This questionnaire is complete hokum in the countryside, you can just forget about it. Because the standard answer will be: 'You tell me'." [D-06]

	Insufficient data quality	"Not necessarily the amount of time, but the accuracy of the work [by the junior HPs], or, in other words, whether they still achieve the same quality in intense periods, under more strain." [D-12]
	Staff fluctuation	"I'm retiring, there's a successor who doesn't know that I've agreed to this... But I'll tell him. And I have now also obliged [name of a senior HP]; I told him that he has to take over, and as you have heard, there are also changes among the senior HPs." [D-08]
	Intervention parts already established (usual care)	"Regarding the 'communication with the GPs' it is possible that the hurdle you are trying to overcome is not there at all in our hospital. (...) This will be difficult to evaluate." [D-12]
Organizational limitations	Technical limitations/information technology	"At first glance, it all sounds simple, but we saw for ourselves, you were there too, there were already a few hurdles where we simply had to think about a few things, how to do that, the hospital information system is of course not the same everywhere, but these are more the technical and organizational things." [D-08]
	Integration in clinical routine/ Paper-based data collection	"'Whether it can be sensibly implemented in everyday clinical practice; that was certainly a topic of discussion."[D-10]
Motivation of staff	Missing motivation/scepticism	"I think the only hurdle we have to face now is, of course, that the junior HPs, who already have a large workload, must now be motivated and convinced that this is a good thing that it's worth investing time for now."[D-05]
Relationship with GPs	Concern of bypassing GPs	"I think it is important – because we are in very close contact with the GPs – that [the GPs] will not get the feeling that we are participating in a study with their patients and [the GPs] might not have wanted that."[D-05]

Themes identified from the interviews, with corresponding codes and example quotes from chief physicians (anonymized). Abbreviations: HP, hospital physician; GP, general practitioner

Figure legends

Figure 1. Framework model for process (dark grey) and impact evaluation (light grey). Abbreviations: HP, hospital physician; GP, general practitioner; cRCT, cluster randomised controlled trial

Figure 2. Flow of hospitals, senior HPs, junior HPs, GPs, and patients through the study, by study arm. Blue boxes illustrate data collection tools with number of responses [response rates]. Abbreviations: HP, hospital physician; GP, general practitioner

Figure 3. Attitudes and perception of feasibility and usefulness of tools and procedures by junior and senior HPs. Questions about general attitudes (A) were answered by HPs in both study arms (senior HPs: *n* = 44, junior HPs: *n* = 65); questions regarding checklist (B) and discharge summary (C) were only directed at the intervention group (senior HPs: *n* = 24, junior HPs: *n* = 38).

Figure 4. GPs' views on medication review and communication at hospital discharge. (*n* = 187)

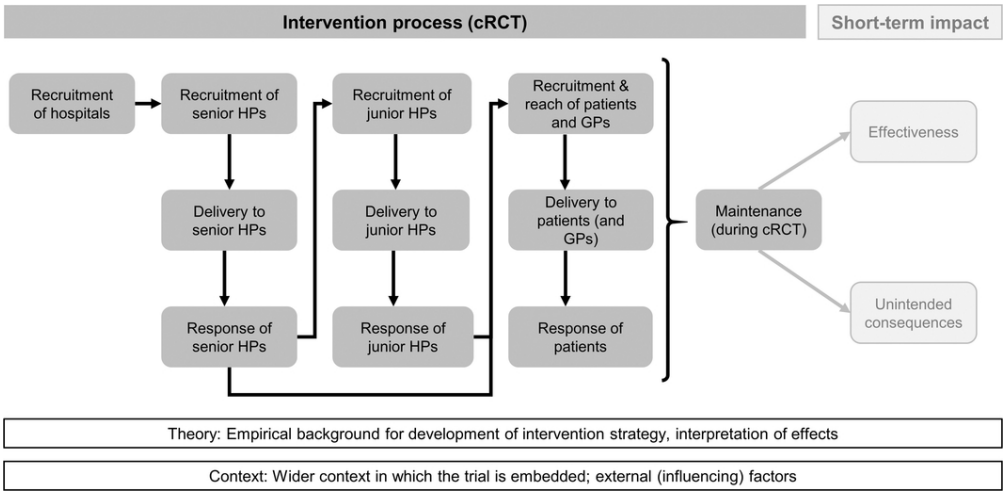

Figure 1. Framework model for process (dark grey) and impact evaluation (light grey).
Abbreviations: HP, hospital physician; GP, general practitioner; cRCT, cluster randomised controlled trial

90x43mm (300 x 300 DPI)

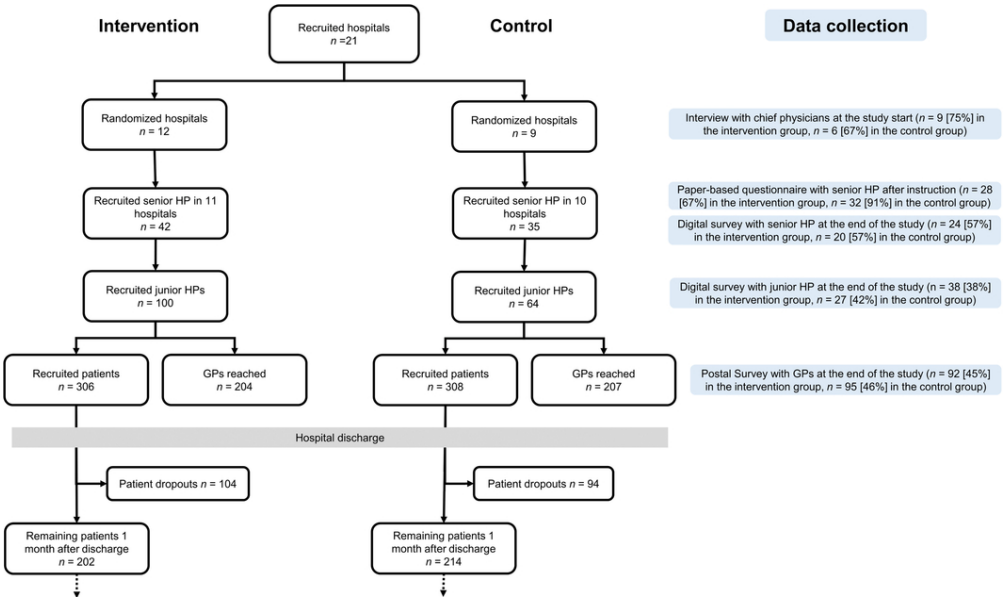

Figure 2. Flow of hospitals, senior HPs, junior HPs, GPs, and patients through the study, by study arm. Blue boxes illustrate data collection tools with number of responses [response rates]. Abbreviations: HP, hospital physician; GP, general practitioner

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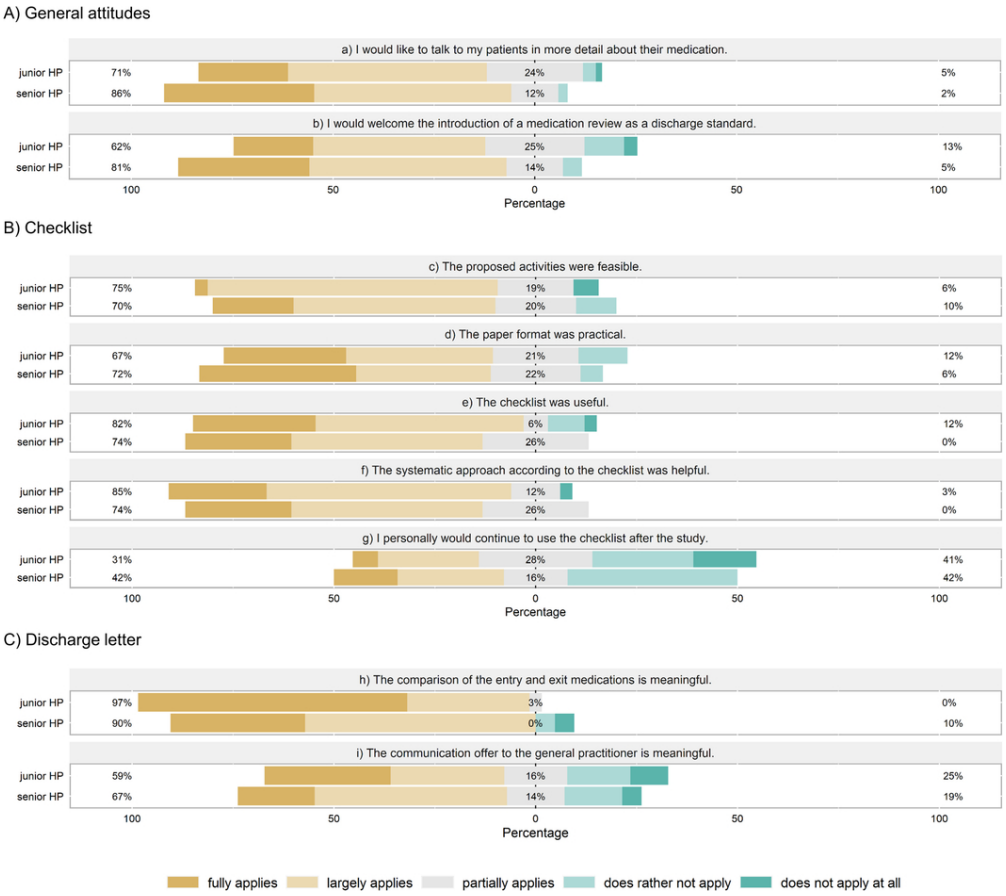

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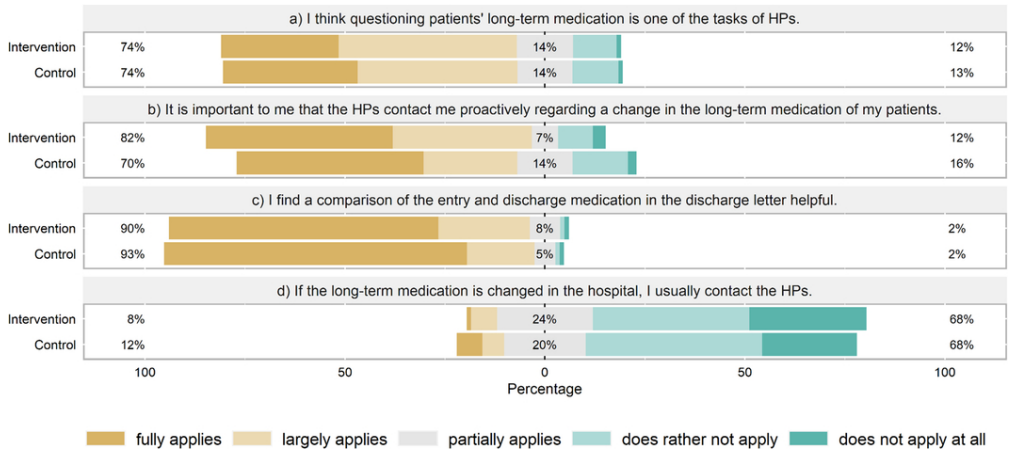


Figure 4. GPs' views on medication review and communication at hospital discharge. (*n* = 187)

89x40mm (300 x 300 DPI)

Online supplementary appendix 1

Discharge-Checklist

Patient-ID: ……

Date: ……

	Yes	No
1: Have you collected the **main complaint** of the patient?	❑	❑
2: Have you and your patient discussed the **treatment goals from his own point of view** ?	❑	❑
3: Have you compiled a full list of all the patient's **drugs at admission**?	❑	❑
4: Have you decided for every single drug whether		
▪ the patient will indeed **take it as prescribed**?	❑	❑
▪ the **indication** of the drug is correct for this patient?	❑	❑
▪ the **risk of side effects** (present or expected) is less than the benefit incurred?	❑	❑
▪ the **dose** is correct for this individual patient (age, comorbidities)?	❑	❑
▪ there is no **alternative drug** with a better benefit-to-risk ratio?	❑	❑
5: Have you decided whether a **new drug** is indicated?	❑	❑
6: Did you **involve the patient** in the changes you are proposing?	❑	❑
7: Have you provided the patient with a **discharge medication list** together with an invitation to use it?	❑	❑
8: Have you motivated the patient to consult the family doctor/general practitioner **within 7 days**?	❑	❑
9: Did you send the **list of modified or newly introduced** medications to the family doctor/general practitioner?	❑	❑
10: Have you offered the family doctor/general practitioner **to discuss** medication changes?	❑	❑

11: Was there any **contact with the general practitioner during the hospital stay** in view of the imminent discharge of the patient? ❑ Yes / ❑ No

Discharging Physician:

Name: …… Junior HP ❑ / Senior HP ❑ Signature: ……

Thank you very much!

Online supplementary appendix 2

Data collection tools (translated from German)

- Semi-structured interview with the chief physicians at the study start
- Paper-based survey with senior hospital physicians after the instruction
- Digital survey with senior and junior hospital physicians at the end of the study: Intervention group
- Digital survey with senior and junior hospital physicians at the end of the study: Control group
- Postal survey with general practitioners at the end of the study

Online supplementary appendix 2

Semi-structured interview with the chief physicians at the study start (Interview guide)

Themes	Questions	Probes
Motivation for participation	1. What tipped the scales for participation? 2. Were there additional reasons?	■ Did the following aspects (also) play a role? - discharge management - medication review - Education/ training junior HP - contact to GPs
	What are your expectations of the study for your clinic?	■ if improved medication review: owing to… - increased awareness? - Improved organisation/structure? ■ If improved communication with GP: for… - Quality improvement? - improving relations? ■ Are you hoping for a reduction in the rate of rehospitalization? ■ What role does «marketing/prestige» play?
	1. Does the fact that the intervention is conducted as a scientific study (instead of a quality support programme) make a difference for you? 2. Why?	■ If study is a plus point: Did the following aspect (also) play a role? - general scientific interest - credibility
Concerns regarding the study	1. Were there also hurdles/barriers/obstacles? What did you have to weigh up against? 2. Why were these not decisive?	■ Hospitals that could not participate gave us the following reasons: • - Time expenditure (especially for senior HP) • - lack of financing of the study • - no direct benefit for the hospital Why did these points play a lesser role for you?
Special circumstances (internal/external)	Are there any internal or external particularities/circumstances in your hospital that could be important for us?	■ for the (short or longterm) implementation ■ How is the relation/contact to GPs (and acute hospitals, for rehabilitation centres) ■ For rehabiltiation centres: How is the quality of admissions? (from acute hospitals)
Miscellaneous	Spontaneous input	

Online supplementary appendix 2

Paper-based survey with senior hospital physicians after the instruction

1. On which ward(s) do you work? *(open end)*

2. Have you ever been involved in a project or study on the following topics?

- Polypharmacy/appropriate medication:	□ scientific study	□ project
- Older, frail people:	□ scientific study	□ project
- Discharge management:	□ scientific study	□ project
- Communication/contact with general practitioner:	□ scientific study	□ project
- Others: ……..	□ scientific study	□ project

3. What was your motivation to participate in the study? *(open end)*

4. Do you have concerns about the study? If so, which ones? *(open end)*

5. Please rate the following statements *(5-point likert scale)*
   - The study objective is clear.
   - The course of the study in the hospital is clear.
   - My tasks in the study are clear to me.
   - The instruction has met my expectations.
   - The subject of the study is relevant for me.

6. Would you like further assistance/tools? If so, which ones? *(open end)*

7. We try to make the participation in the study as convenient as possible for you. We are pleased to receive suggestions for improvement or other comments. *(open end)*

Online supplementary appendix 2

Digital survey with senior and junior hospital physicians at the end of the study: Intervention group

Personal details

- In which hospital did you participate in the Hospital Discharge study? *(open end)*
- What was your position during the Hospital Discharge Study?
  □ Senior hospital physicians / □ Junior hospital physicians
- How many years have you been working as a physician? *(integer)*
- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I would like to talk to my patients in more detail about their medication.
  - I would welcome the introduction of a medication review as a discharge standard.

Instruction of junior hospital physicians (only for senior hospital physicians)

- How much time (in minutes) did you spend for the content part of the instruction of all involved junior hospital physicians (only for the theoretical part, without explanation of the course of studies and handling of the study material)? *(integer)*
- How was the instruction of the junior hospital physicians delivered?
  □ Incorporated into mandatory continuing education (e.g. assistant training, journal club)
  □ At a specially convened meeting
  □ Single instruction
  □ I don't know
  □ Other (please specify)

Instruction by the senior hospital physicians (only for junior hospital physicians)

- How long (in minutes) did the content part of the training by the senior hospital physicians take (only theoretical part, without explanation of the course of studies and handling of the study material)? *(integer)*
- How was the instruction by the senior hospital physicians delivered?
  □ Incorporated into mandatory continuing education (e.g. assistant training, journal club)
  □ At a specially convened meeting
  □ Single instruction
  □ I don't know
  □ Other (please specify)

Patient recruitment

Online supplementary appendix 2

- Did you use the prepared patient information (on the laminated document) for the recruitment of patients?
  □ Yes
  □ Sometimes
  □ No
  □ I don't know

Checklist

- Approximately how many checklists have you filled out? (*integer*)
- For which percentage of patients did you already start filling out the checklist before the discharge consultation? *(in percent, on a slider)*
- Please indicate how well the following statements apply *(5-point likert scale)*
  - The proposed activities were feasible.
  - The paper format was practical.
  - The checklist was useful.
  - The systematic approach according to the checklist was helpful.
  - I personally would continue to use the checklist after the study.
- What activity did the checklist remind you of that you would otherwise not consistently perform? *(multiple answers possible)*
  □ discuss treatment goals with the patient
  □ question every single drug
  □ motivate patients to contact their general practitioner within 7 days
  □ none
  □ other (please specify)
- How could the checklist be improved? *(open end)*

Discharge letter

- Please indicate how well the following statements apply *(5-point likert scale)*
  - The comparison of the entry and exit medications is meaningful.
  - The communication offer to the general practitioner is meaningful.

Patient reaction

- Please indicate how well the following statement applies *(5-point likert scale)*
  - My patients appreciated being involved in decisions regarding their medication plan.
- What percentage of patients rejected your drug change proposals? *(in percent, on a slider)*
- What reasons were given for the opposition? *(open end)*

Case vignettes

Online supplementary appendix 2

The following two case studies refer to the following situation: You have already gathered the patient's preferences and needs. Assuming that the patient is open to your suggestions, what would you prescribe from a medical point of view?

Example 1:

An 82-year-old female patient has had type 2 diabetes for 15 years. She also suffers from arterial hypertension, dyslipidemia, gonarthrosis on both sides and sleep disorders. So far, no cardiovascular events. She is physically severely restricted by her joint pain and lives in seclusion. Her HbA1c is 6.9%. She takes two antidiabetics, three antihypertensives, a statin, an aspirin, a PPI, two analgesics and a hypnotic.

- What would you recommend regarding diabetes treatment?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the statin?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the aspirin?
  □ expand / □ continue / □ reduce/deprescribe
- Explanations *(optional, open end)*

Example 2:

A 75-year-old male patient with mild cognitive impairment has arterial hypertension, COPD after nicotine abuse, moderate overweight and lumbo-tebral arthrosis. He's spry for his age. The passionate alpinist reports occasional dyspepsia after fondue eating in the alpine hut and suffers under sleep disturbance. Gastroscopy 10 years ago showed mild antral gastitis. He takes three antihypertensives, a long-acting bronchodilator, two analgesics, a ginko preparation, a hypnotic and a PPI every other day.

- What would you recommend regarding the PPI?
  □ continue / □ replace with phytotherapeutics / □ in rare reserve/deprescribe
- What would you recommend regarding the hypnotic?
  □ continue / □ replace with herbal medicine/ □ in rare reserve/deprescribe
- Explanations *(optional, open end)*

Final questions

- Has your discharge management changed during the course of the study? If so, how? *(open end)*
- Would you have liked additional support from us? If yes, which? *(open end)*
- Would you have liked additional support from your senior hospital physicians? If yes, which? *(open end, only for junior hospital physicians)*
- Finally, we would like to ask you: What do you think the focus should be at hospital discharge? *(open end)*
- Comments *(open end)*

Online supplementary appendix 2

Digital survey with senior and junior hospital physicians at the end of the study: Control group

Personal details

- In which hospital did you participate in the Hospital Discharge study? *(open end)*
- What was your position during the Hospital Discharge Study?
  □ Senior hospital physicians / □ Junior hospital physicians
- How many years have you been working as a physician? *(integer)*
- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I would like to talk to my patients in more detail about their medication.
  - I would welcome the introduction of a medication review as a discharge standard.

Patient recruitment

- Did you use the prepared patient information (on the laminated document) for the recruitment of patients?
  □ Yes
  □ Sometimes
  □ No
  □ I don't know

Case vignettes

The following two case studies refer to the following situation: You have already gathered the patient's preferences and needs. Assuming that the patient is open to your suggestions, what would you prescribe from a medical point of view?

Example 1:

An 82-year-old female patient has had type 2 diabetes for 15 years. She also suffers from arterial hypertension, dyslipidemia, gonarthrosis on both sides and sleep disorders. So far, no cardiovascular events. She is physically severely restricted by her joint pain and lives in seclusion. Her HbA1c is 6.9%. She takes two antidiabetics, three antihypertensives, a statin, an aspirin, a PPI, two analgesics and a hypnotic.

- What would you recommend regarding diabetes treatment?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the statin?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the aspirin?
  □ expand / □ continue / □ reduce/deprescribe
- Explanations *(optional, open end)*

Online supplementary appendix 2

Example 2:

A 75-year-old male patient with mild cognitive impairment has arterial hypertension, COPD after nicotine abuse, moderate overweight and lumbo-tebral arthrosis. He's spry for his age. The passionate alpinist reports occasional dyspepsia after fondue eating in the alpine hut and suffers under sleep disturbance. Gastroscopy 10 years ago showed mild antral gastitis. He takes three antihypertensives, a long-acting bronchodilator, two analgesics, a ginko preparation, a hypnotic and a PPI every other day.

- What would you recommend regarding the PPI?

  □ continue / □ replace with herbal medicine/ □ in rare reserve/deprescribe

- What would you recommend regarding the hypnotic?

  □ continue / □ replace with phytotherapeutics / □ in rare reserve/deprescribe

- Explanations *(optional, open end)*

Final questions

- Has your discharge management changed during the course of the study? If so, how? *(open end)*
- Would you have liked additional support from us? If yes, which? *(open end)*
- Would you have liked additional support from your senior hospital physicians? If yes, which? *(open end, only for junior hospital physicians)*
- Finally, we would like to ask you: What do you think the focus should be at hospital discharge? *(open end)*
- Comments *(open end)*

Online supplementary appendix 2

Postal survey with general practitioners at the end of the study

- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I think questioning patients' long-term medication is one of the tasks of hospital physicians.
  - It is important to me that the hospital physicians contact me proactively regarding a change in the long-term medication of my patients.
  - I find a comparison of the entry and discharge medication in the discharge letter helpful.
  - If the long-term medication is changed in the hospital, I usually contact the hospital physicians.

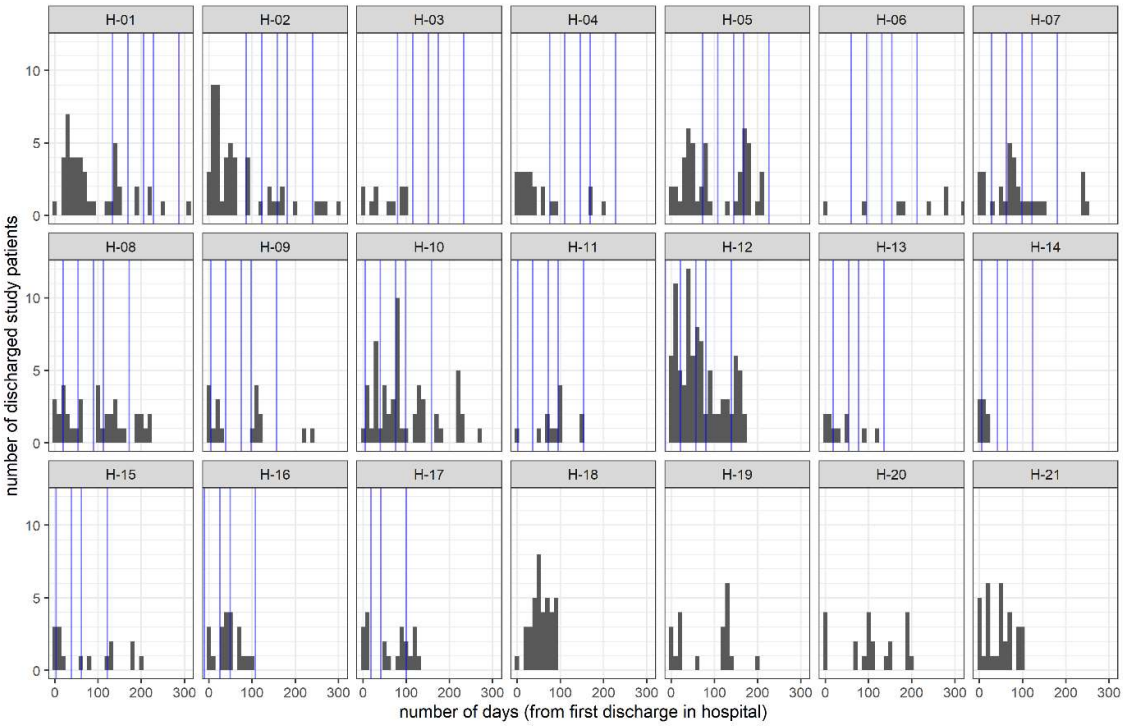
    → Follow up: If you do not normally make contact: What do you do if the long-term medication of your patient is changed in the hospital?

    □ I usually reset the medication to the previous medication.

    □ I usually accept the change of medication.

- (Optional) Further comments on hospital discharge *(open end)*

Online supplementary appendix 3



Numbers of discharged study participants (patients) over time, per hospital. Time was adjusted to the date of the hospital's first study patient discharge. Blue vertical lines indicate dates of newsletter dispatch. Hospitals that started study activities later due to COVID-19 no longer received newsletters.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	4-5	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	4-5	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	4, 6	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	4-5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	5-6	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	5	The population targeted by the intervention and any eligibility criteria.
Description	**9**	5-6	A description of the implementation strategy	4-5	A description of the intervention
Sub-groups	**10**	-	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	6	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	5	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	6	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	-	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	(separately)	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	Study protocol	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	7	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	(planned, (separately)	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	7-12	Proportion recruited and characteristics of the recipient population for the implementation strategy	7-12	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	7-12	Primary and other outcome(s) of the implementation strategy	(separately)	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	9-14	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	-	Resource use, costs, economic outcomes and analysis for the implementation strategy	(separately)	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	(planned, (separately)	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	7-12	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	7-12	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	13-14	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	-	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	14-18	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	18	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	-	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	18-19	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Implementation of a complex intervention to improve hospital discharge: Process evaluation of a cluster randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049872.R1
Article Type:	Original research
Date Submitted by the Author:	31-Mar-2021
Complete List of Authors:	Rachamin, Yael; University of Zurich; University Hospital Zurich Grischott, Thomas ; University of Zurich; University Hospital Zurich Neuner-Jehle, Stefan; University of Zurich; University Hospital Zurich
Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	General practice / Family practice, Patient-centred medicine, Pharmacology and therapeutics, Qualitative research, Research methods
Keywords:	GENERAL MEDICINE (see Internal Medicine), Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, QUALITATIVE RESEARCH

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Implementation of a complex intervention to improve hospital discharge: Process evaluation of a cluster randomized controlled trial

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Word count: 5395

Number of Tables: 1

Number of Figures: 4

Number of supplementary files: 3

Abstract

Objectives: To study the implementation of a cluster randomized controlled effectiveness-implementation hybrid trial testing the effectiveness of a medication review at hospital discharge combined with a communication stimulus between hospital physicians (HPs) and general practitioners (GPs) on rehospitalisation of multimorbid older patients.

Design: Extension of Grant's mixed method process evaluation framework to trials with multilevel clustering.

Setting: General internal medicine wards in Swiss hospitals.

Participants: Convenience samples of 15 chief physicians (of 21 hospitals participating in the effectiveness trial), 60 (74) senior HPs, 65 (164) junior HPs and 187 (411) GPs.

Implementation strategy: Two-hour teaching sessions for senior HPs on a patient-centred, checklist-guided discharge routine.

Process evaluation components: Data collection on recruitment, delivery, and response from chief physicians (semi-structured interviews), senior HPs, junior HPs, GPs (surveys), and patients (via HPs). Quantitative data were summarised using descriptive statistics, and interviews analysed using thematic analysis.

Outcome measures: Intervention dose (quantitative), implementation fidelity (qualitative), feasibility and acceptability, facilitators and barriers, implementation support strategies.

Results: Recruitment of hospitals was laborious but successful, with 21 hospitals recruited. Minimal workload and a perceived benefit for the clinic were crucial factors for participation. Intervention dose was high (95% of checklist activities carried out), but intervention fidelity was limited (discharge letters) or unknown (medication review). Recruitment and retention of patients was challenging, partly due to patient characteristics (old, frail) and the COVID-19 pandemic: Only 612 of the anticipated 2100 patients were recruited, and 31% were lost to follow up within the first month after discharge. The intervention was deemed feasible and helpful by HPs, and the relevance of the topic appreciated by both HPs and GPs.

Conclusions: The results from this evaluation will support interpretation of the findings of the effectiveness study and may inform researchers and policy makers who aim at improving hospital discharge.

Trial registration: ISRCTN18427377

Keywords

Process evaluation; effectiveness-implementation hybrid study; cluster randomized controlled trial; framework; mixed method; hospital discharge; polypharmacy; medication review

Article summary

Strengths and limitations of this study

- We used both quantitative and qualitative approaches to achieve an adequate insight into the implementation of the intervention.
- Our process evaluation was performed before instead of alongside or after the analysis and publication of the effectiveness findings, which is an innovative approach for process evaluations and ensures that the evaluation is blind to trial outcomes.
- Our application and extension of the framework described by Grant et al. could serve as example and template for future implementation studies of complex multilevel interventions.
- The results from this evaluation will support interpretation of the findings of the effectiveness study and – positive results given – dissemination of our approach to further hospitals.
- The number of junior hospital physicians' responding to the survey was limited by frequent rotations between and within hospitals.

Background

Polypharmacy – often defined as the concomitant use of five or more medications – is associated with increased risk of adverse events, prescription errors, low patient adherence, morbidity, hospitalisation rates, and mortality.[1-4] During hospitalisation, patients are usually prescribed additional drugs while few drugs are deprescribed, so that the extent of polypharmacy is higher at discharge than at admission.[5] Poor communication between healthcare providers after discharge additionally contributes to suboptimal prescribing.[6]

Previous systematic reviews provide some evidence that reducing polypharmacy improves health-related outcomes in older people, and that a variety of discharge planning interventions can reduce adverse events and healthcare utilization in the post-discharge period.[7 8] To our knowledge, no study has so far analysed the effects of a discharge strategy which incorporates *both* key aspects of deprescribing and collaborative communication between hospital physicians (HP) and general practitioners (GP) at hospital discharge. We therefore performed a two-armed cluster randomized controlled trial (RCT) investigating the effect of a medication review and improved information transfer at hospital discharge for patients aged 60 years or older with polypharmacy on rehospitalisation rates.[9] The intervention was implemented via a teaching session and patient-centred checklists for HPs, and adaptations to the discharge letters. The complex intervention involved multiple sites, different levels of healthcare providers, and different time points during the patients' hospital stay. A pragmatic approach allowed adapting the intervention to local conditions in the participating hospitals.

For complex RCTs, process evaluations are recommended to contextualize results.[10 11] It is often crucial to not only know whether but also when, why, and how interventions 'work', particularly in the case of flexible and multisite interventions which may be implemented and received in different ways at the different sites.[10 12] Various theoretical frameworks exist to guide the design and conduct of process evaluations.[10 13-15] For cluster RCTs specifically, Grant et al. [16] developed a framework which considers the multilevel design with clusters and targeted individuals. We extended Grant's framework to evaluate the implementation of our trial with regard to recruitment of participants, intervention delivery, response of all parties involved, and maintenance of the intervention.

The aim of our study was to provide information about process evaluation outcomes on different levels of the complex intervention, in order to inform the interpretation of the effectiveness outcomes. The effectiveness outcomes will be published separately.

Methods

Design and setting

This was a pre-planned mixed method process evaluation of a cluster RCT involving patients (aged 60 years or older with five or more drugs prescribed) from 21 hospitals in the German-speaking part of Switzerland. The process evaluation, part of an effectiveness-implementation hybrid trial,[17] was conducted in parallel to the main cluster RCT; effectiveness outcomes are still being collected and will be published separately. The study protocol for the full trial has been published elsewhere.[9] The intervention was a patient-centred discharge procedure including critical medication review combined with a communication stimulus between HPs and GPs. The implementation strategy included a) a two-hour teaching session for senior HPs in internal medicine wards and rehabilitation hospitals who instructed junior HPs, b) a checklist facilitating the medication review (online supplementary appendix 1), and c) two adaptations to the discharge letter (reorganisation of the medication lists so that medication changes could easily be identified by the aftercare GP, and invitation to the GP to discuss potential changes of the medication plan). In the teaching session, senior HPs were presented some background evidence on the significance of multimorbidity and polypharmacy, and on age-dependent target values, and were then instructed on how to apply a simple medication review tool to the patients' medication lists [18 19] (see also checklist, online supplementary appendix 1). This was demonstrated on an example patient with multimorbidity and polypharmacy. Senior HPs were encouraged to engage in a discussion. In the second hour of the teaching session, data collection procedures were explained. In the control arm, senior HPs were given a "sham" instruction (covering the significance of multimorbidity and polypharmacy, and explaining data collection procedures) and patients were discharged according to the usual discharge procedures as established in the individual hospitals.

Patients were followed up for 6 months beyond discharge for outcomes such as re-hospitalisation, other physician contacts, current medication and quality of life, collected by questionnaires at 1, 3, and 6 months. After repeated requests for pending answers, we contacted the patients' relatives and/or GPs for complete follow up data. Ethical approval was obtained from the Ethics committee of the Canton of Zurich (BASEC-No. 2018-00215).

The process evaluation was based on a framework of Grant et al.[16] which we then tailored to the specific multilevel nature of our intervention (Figure 1). The original framework of Grant et al. distinguishes process elements (recruitment, delivery, and response), of clusters and individuals from impact

elements (effectiveness and unintended consequences). We added the levels “hospitals” (the entities being recruited by the study team) and “junior HPs” (who delivered the intervention to patients). We reported results in accordance with the Standards for Reporting Implementation Studies (StaRI) checklist.[20]

Figure 1

Participants

The recruitment procedure is described in the study protocol.[9] We questioned chief physicians who decided about participation in the study, senior and junior HPs who were directly involved in the delivery of the intervention to patients, and GPs as downstream receivers of the intervention. Patients were not directly questioned. An overview of the flow of hospitals, senior HPs, junior HPs, GPs, and patients through the study is shown in Figure 2.

Figure 2

Outcomes

For the framework elements specified in Figure 1, we aimed to explore and describe implementation along the following dimensions (where applicable):

- Intervention dose, i.e. the *quantity* of the implemented intervention (e.g. adherence rates)
- Implementation fidelity, i.e. the *quality* of the implemented intervention compared with what was intended
- Feasibility and acceptability, based on views and experiences of participants
- Facilitators and barriers to implementation
- Implementation support strategies to target facilitators, overcome barriers, and ultimately improve implementation

Data collection

We collected both qualitative and quantitative data (see online supplementary appendix 2 for the data collection tools). We conducted semi-structured interviews with chief physicians at the beginning of the

study, short paper-based surveys with senior HPs after instruction, and an online-survey at the end of the study with senior HPs and junior HPs. Both surveys had open-end questions and quantitative parts. In addition to questions about feasibility and awareness, the online survey contained two case vignettes with the intent of assessing knowledge transfer and increased awareness induced by the teaching session. The case vignettes described two model patients, and HPs were asked about their recommendations regarding the patients' medication. The case vignettes were pretested with three GPs at our institute and revised according to their responses. The fourth dedicated data collection tool was a short postal survey of GPs at the end of the study capturing their opinions regarding hospital discharge, with focus on the discharge letter, medication, and contact. An overview of the data collection tools with response numbers and rates is incorporated into Figure 2.

In addition to these dedicated data collection tools, we used data from study instruments such as the patient-specific checklists (online supplementary appendix 1) where the intervening HPs had ticked off which parts of the intervention had actually been delivered (intervention dose). Finally, we recorded how chief physicians had initially planned to implement the intervention, and used our emails and protocols of phone calls with participants and patients.

Data analysis

Quantitative data was analysed with the R statistical software version 3.5.1 [21] and Microsoft Excel (2016). We reported medians, interquartile ranges (IQR), maxima (max) and minima (min), or proportions (% of non-missings) and numbers (*n*), and compared groups using Wilcoxon and chi-square tests as appropriate. Significance was assumed for p values < 0.05. Likert scale items were dichotomized for text summaries.

The semi-structured interviews were analysed by deductive thematic analysis,[22] with a predefined focus on 'facilitators' and 'barriers' (to study participation). Two researchers (TG, SNJ) independently coded the 15 interviews until saturation (i.e. no further emergence of new codes) was reached, and subsequently grouped the codes into themes. A theme was accepted if listed by both of the two researchers, and similar themes of the researchers' list were merged by consensus. If there was disagreement between the two researchers, the third researcher (YR) operated as referee. Qualitative answers from the paper-based survey with senior HPs were also summarised according to the resulting themes.

Patient and public involvement

Patients were not involved in the planning of the study, but patient involvement is a core component of the medication review tool (see online supplementary appendix 1).

Results

The results are presented along the elements specified in the framework (Figure 1) and within each element further structured into a) quantitative results, b) qualitative results, and c) implementation strategies. The response rates for each data collection tool are given in Figure 2.

Hospitals

Recruitment

We approached 162 chief physicians of hospitals with a general internal medicine ward or of rehabilitation hospitals in German-speaking Switzerland: 16% (*n* = 26) by personal inquiry and 84% (*n* = 136) by postal dispatch. Of all chief physicians, 83% showed no interest (no response: *n* = 116, active declining: *n* = 19). We presented the study to the remaining 27 chief physicians and staff (typically volunteering senior HPs) out of which six chose not to participate. All hospitals that declined participation were asked for reasons for non-participation, and 16 hospitals replied: Lacking resources were mentioned most frequently, followed by temporal overlap with other ongoing projects (scientific studies, or adoption of a new hospital information technology system), unsuitability of the hospital (organization or patient population), or low expected benefit for the hospital (e.g. when the established discharge procedure was perceived as similar to the study intervention).

Ultimately, 21 hospitals agreed to participate. Of these, 16 were acute and 5 rehabilitation hospitals, 2 were academic and 19 non-academic hospitals, and ward sizes ranged from 15 to 180 beds.

From the interviews with the chief physicians, we identified 13 themes; 8 corresponding to facilitators and 5 to barriers to study participation and implementation. Themes with constituent codes and example quotes are presented in Table 1. As an immediate reaction to barriers identified, we summarised potential solutions and presented them to subsequently approached hospitals. For instance, to mitigate concerns of undue effort, we recommended to involve non-medical personnel for administrative tasks and provided time estimates required for the different study steps. We also tried to target facilitators,

e.g. by emphasizing the potential benefits for the clinics and by preparing a study announcement for the hospitals to use for information and marketing purposes.

Table 1

Senior HPs

Recruitment

Recruitment of senior HPs was organized by the chief physicians. In total, 74 (40% female) senior HPs participated (median 3 per hospital, IQR 2-5, min 1, max 9). The median work experience was 15 years (IQR 10-24), not significantly different between study arms (p = 0.971). Of the 60 senior HPs responding to the initial paper-based survey, 23% (n = 14) had experience with scientific studies, and 35% (n = 21) had been involved in a project or study regarding related topics (polypharmacy/appropriate medication, frailty, discharge management, or communication with GPs). All but three of the responding senior HPs found the topic of the study very relevant or relevant to them. Motivation for participation in the study were most frequently quality improvement (45%, n = 27) and relevance of the topic (28%, n = 17), but 23% (n = 14) of senior HPs stated that they had no motivation or that it was the chief physician's decision. The most frequently mentioned concerns were methodological limitations regarding recruitment, follow up or risk of bias (22%, n = 13) and missing resources/high workload (8%, n = 5), but the majority of senior HPs (62%, n = 37) mentioned no concerns.

Delivery

The intervention was delivered to senior HPs in terms of an instruction by the study team (see Methods, section 'Design and Setting'). The instruction was performed uniformly by the principal investigator using presentation slides.

Response

All but one of the senior HPs stated that the instruction had met their expectations. The study aim, the study flow in the hospital, and their role in the study were very clear or clear to all but three senior HPs. The senior HPs' attitudes and response to the checklist and adaptation of the discharge letter as declared in the online survey at the end of the study are shown in Figure 3A, 3B and 3C, respectively. The majority of senior HPs appreciated the relevance of the topic and perceived the intervention as

feasible and helpful. For example, respondents stated that the checklist reminded them to review drugs more critically (46%, *n* = 11), to consistently motivate patients to visit their GPs within 7 days (38%, *n* = 9), or to discuss treatment goals with the patients (17%, *n* = 4). Fewer (42%) senior HPs declared that they would continue using the checklist after the study (Figure 3B). Two senior HPs suggested that the checklist could be improved by choosing the time period from hospital discharge to GP visit individually for each patient (instead of 7 days as required by the checklist).

To the five questions regarding (de)prescribing decisions (case vignettes, see online supplementary appendix 2), 69% (*n* = 69) of responses in the intervention group were pro-deprescribing (reducing/stopping or switching to phytotherapeutics, vs. continuing/increasing), while in the control group, the corresponding proportion was 71 % (*n* = 71, *p* = 0.877).

Figure 3

Junior HPs

Recruitment

Frequent rotations of junior HPs within and between hospitals necessitated their recruitment and instruction by senior HPs rather than the study team. Their exact recruitment number is therefore unknown, but 164 junior HPs were ultimately involved in intervention delivery (54% female), with a median of 6 (IQR 4-10, min 1, max 28) per hospital. Their median work experience was 2 years (IQR 1-4, min 1, max 10), with no significant difference between study arms (*p* = 0.590).

Delivery

The junior HPs' instruction was either incorporated into their mandatory continuing education, performed in a dedicated meeting for groups of junior HPs, or by means of a one-to-one instruction. In most hospitals, a mix of formats was applied. In total, senior HPs spent a median of 45 minutes (IQR 18-60) to deliver the theory part of the instruction (intervention group); individual junior HPs were instructed for a median of 15 minutes (IQR 10-30). To improve delivery to junior HPs, we provided the senior HPs with presentation slides covering both theory and data handling, and distributed practice material, summaries with key information, and extensive information leaflets for junior HPs.

Response

The junior HPs' attitudes and response to the intervention are shown in Figure 3A, Figure 3B and Figure 3C. The checklist and the adaptations to the discharge letter were rated feasible and helpful by the majority of junior HPs (Figure 3B and Figure 3C). Fifty percent (*n* = 19) stated that they were reminded to question each drug in the patients' medication regimes more rigorously, 45% (*n* = 17) felt stimulated to motivate the patients to visit their GP after discharge, and 21% (*n* = 8) to discuss treatment goals with their patients. Only a minority (31%, *n* = 10) intended to continue using the checklist after the study (Figure 3B),

For the five medication review questions in the case vignettes, in the intervention group, deprescribing was suggested in 70% (n = 111) of responses, vs. 59% (*n* = 68) in the control group (*p* = 0.103).

Patients

Recruitment and reach

Patients were recruited at admission to the ward by the participating HPs on duty. The total number of recruited patients was 612 (50% in the intervention group), with a median of 21 patients (IQR 15-37, min 8, max 91) per hospital. To facilitate recruitment, we provided the hospitals with a disposable information sheet for patients, and a condensed version to be used for verbal clarification when recruiting patients. In the digital survey at the end of the study, most HPs stated that the short statement was used always (65%, *n* = 66) or sometimes (25%, *n* = 25) when recruiting patients.

Delivery

Depending on the hospital, junior and/or senior HPs carried out the discharge procedure on the patient. In median, each senior HP completed 2 checklists (IQR 0-10, min 0, max 20), while junior HPs filled out a median of 5 checklists (IQR 4-8, min 1, max 25). The HPs declared that checklist activities were begun during the patients' hospital stays – as opposed to shortly before discharge – for the majority of patients (median over HPs 61%, IQR 33-86%, min 0%, max 100%).

Intervention delivery to patients (in intervention hospitals) was high: The proposed activities were reportedly carried out in 95% (*n* = 3766 ticks on the 14-item-checklists). All but three checklist items had been ticked in over 90%, and the lowest execution rate (83%) was reported for 'motivating patients to consult their GP within 7 days'.

Response

According to half of the HPs in the intervention group responding to the specific question in the digital survey (*n* = 51), patients appreciated being involved in decisions regarding their medication plan, and only 7% of the patients (median over senior and junior HPs; IQR 0-25%, min 0%, max 60%) rejected proposed changes to their medication plans. Common reasons for patients' resistance to medication changes were habits/being used to a specific drug, believing in its positive effect, loyalty to the GP who prescribed the drug, or a general resistance to change. Some HPs additionally mentioned that the patients' addiction to the medication (e.g., to benzodiazepines or opioids) or communication barriers (language) impeded changing the medication plan.

During follow-up, the majority of patients did not return the required documents in time and had to be reminded by phone call. The overall loss to follow up rate within the first month after discharge was 31% (*n* = 194 patients, see Figure 2). Most frequent reasons for loss to follow up were inability or unwillingness to return the requested documents. Patients mentioned being too sick or old to fill out the questionnaire, lack of motivation/perceived benefit, or previous unawareness of the questionnaire. Loss to follow up rates varied between hospitals (median 31%, IQR 26%-38%, min 9%, max 55%).

GPs

Delivery

The intervention was delivered to GPs indirectly via adaptations to the discharge letter, i.e. the reorganised presentation of the patients' medications, and the communication offer to discuss medication changes with the HPs. The communication offer, as a fixed component of the intervention, was quantitatively well implemented (in rare cases only added after an early reminder) but often inserted very inconspicuously at the end of the discharge letter. For 22% of patients in the intervention hospitals and 18% in control hospitals, the GPs were contacted by HPs during the hospital stay already. Regarding the presentation of the patients' medication in the discharge letter, a flexible implementation approach was required, mainly due to the rigidity of the hospitals' clinical information systems. Three modes of implementations were accepted, with decreasing preference (number of hospitals who chose the option is indicated in brackets): a) Dedicated table of medication changes, with reasons (*n* = 1), b) Separate tables of admission and discharge medication, adjacent or in immediate sequence, again with explanations of medication changes (*n* = 8), c) Table of discharge medication only, with changes

explained in the text body (*n* = 3). Inspection of the discharge letters revealed that medication changes were often insufficiently explained, irrespective of the presentation mode.

Response

Of the GPs responding to the postal survey (*n* = 187), the vast majority considered a comparison of admission and discharge medication in the discharge letter helpful (91%, Figure 4). Most also agreed that HPs should review the long-term medication of patients (74%) and appreciated being contacted in case of medication alterations (76%). Only few GPs (10%) would contact the HPs themselves when noticing a change. In the absence of contact, most GPs (74%) declared to usually – but depending on the individual case – adopt changes to the long-term medication made by HPs. Many GPs stated that an explanation for modifying/altering the medication was very important. Another issue raised by many GPs was that switching between original and generic drugs could confuse patients and entail the risk of double intake. They proposed that the medication should be reset to preparations used at admission or at least that patients should be informed.

Documenting GP-initiated contacts with HPs following patient discharge was in the responsibility of HPs who reported 14 contacts in total.

Figure 4

Maintenance

The median patient inclusion period per hospital was 205 days (IQR 168-271 days, min 23, max 325), corresponding to approximately 7 months per hospital. Inclusion intensity varied over time and among hospitals and was not noticeably influenced by roughly monthly newsletters (online supplementary appendix 3). The designated contact persons in the hospitals (study nurse, clinical trials unit, senior HP, or chief physician) were reminded by email and phone if patient recruitment was still low. Not only recruitment yield but also immediate loss to follow up rates changed over time in some hospitals. Regarding qualitative aspects of study delivery, when asked in the online survey whether their discharge management had changed over the course of the study, 15% (*n* = 14) of the responding HPs agreed, declaring for instance that they had reviewed drugs more carefully or earlier, had explained them more carefully to the patients, and that their contact with GPs had intensified.

Context

Swiss health care setting

Switzerland is organized as a federalist system of 26 cantons enjoying a high degree of autonomy vis-à-vis the federal government.[23] The federalist organization of health care results in regulated competition between hospitals and high variability e.g. in clinic information systems used by hospitals.[24] While hospitals mandatorily use digital patient records, this is not the case for ambulatory physicians including GPs. In fact, digitalization in the ambulatory health care sector in Switzerland is rather low: In 2018, only 43% of GPs documented their patient records fully electronically.[25] The fragmented digitalization of ambulatory health care likely hinders effective communication between hospitals and GPs.

COVID-19

The coronavirus disease 19 (COVID-19) pandemic had serious implications for this hybrid trial. The novel virus hit Switzerland in early March 2020, whereupon hospitals were ordered to stop all elective surgeries and ongoing trials. At that time point, the study was still ongoing in 13 (of the 21) hospitals, of which 10 had to stop and 3 to postpone recruitment, thus limiting the study sample and delaying completion of the study.

Discussion

This process evaluation provides insights into the implementation of a cluster RCT set at the interface between hospital care and general practice. Using a tailored version of the well-established framework by Grant et al. for process evaluations of complex multilevel interventions, increased knowledge about the trial's implementation on different levels was gained.

Recruitment of hospitals was laborious but successful. Minimal workload and a perceived benefit for the clinic proved to be crucial for participation. Intervention dose was high, but intervention fidelity was limited (adaptations to discharge letter) or unknown (medication review). Recruitment and retention of patients was challenging, partly due to patient characteristics (old, frail) and the COVID-19 pandemic. The intervention was deemed feasible and helpful by HPs, and the relevance of the topic appreciated by both HPs and GPs.

Hospital level

As expected, it was challenging to recruit hospitals that face market competition to participate in an external study without providing financial incentives. In addition to barriers related to resources, chief physicians mentioned concerns regarding methodological or organizational limitations (Table 1) and motivation of HPs. The majority of these issues have been reported before in a systematic review exploring barriers towards the implementation of hospital-based interventions.[26] As for facilitators, we found that a perceived benefit to the clinic or chief physician was crucial.

HP level

Most senior HPs showed motivation to participate in the study, e.g. because of expected quality improvements or in recognition of the topic's relevance. Almost one out of four, however, stated that they only participated following the hospital/chief physician's decision. This is problematic, as lack of motivation is a well-known barrier towards implementation.[26] To increase motivation, Geerligs et al. suggest to share informal intervention 'success stories'.[26] In our case, these could be examples of patients with successfully improved medication lists, or a positive communication experience with a GP. Involving senior HPs earlier in the study design might further benefit the study by stimulating an essential sense of ownership.[26]

To capture the change in knowledge and attitudes of HPs towards deprescribing (a proxy for the expected training effect in our intervention model), we relied on case vignettes. Readiness to deprescribe in defined patient conditions was not significantly different between intervention and control group (which might partly be attributable to methodical limitations, see section 'Strengths and Limitations' below). However, to capture the positive impact of an intervention, it is also important to take views and experiences of staff into account.[12] The HPs' feedback to the intervention was positive: The adaptations of the discharge letter, especially the comparison of discharge with admission medication, were welcomed not only by senior and junior HPs but also by GPs (see section 'GP level' below). This is particularly interesting as it could be implemented in clinical information systems without increasing the HPs' workload. Regarding the checklist, the majority of HPs stated that the proposed activities were feasible, and that the checklist was useful. Nonetheless, only a minority (one out of three) of junior and senior HPs intended to use the checklist after the study. The reasons for this are unclear. We can only speculate that additional time need or costs must have exceeded the expected benefits.[27]

Further exploration of potential reasons for this reluctance would be needed before scaling up the dissemination of our checklist.

Patient level

This intervention was targeted at multimorbid patients over 60 years of age. It is well known that recruiting and retaining old, multimorbid, frail and cognitively impaired patients is challenging.[12] Hence, old and frail patients are often excluded from trials,[28] even though they might profit most from interventions regarding medication review or communication. Recruiting frail or cognitively impaired patients was encouraged within this study and accordingly brought along some difficulties. For instance, the detailed information forms overwhelmed most patients. The short statement we provided to HPs was partially useful to overcome this barrier. However, the reluctance of vulnerable and multimorbid patients to take on another task (the one of study participation) besides their high burden of disease remained a major challenge. This is mirrored by the fact that the final number of recruited patients was substantially lower than expected, even taking the COVID-19 pandemic related barriers towards recruitment into account.

Judging by the checklist ticks, the intervention was well delivered to the patients in terms of quantity (dose), but we were unable to evaluate delivery quality (fidelity), i.e., to what extent HPs involved the patients and what effort they made in reviewing the patients' medication.

We assessed the patients' acceptance of our approach only indirectly via HPs. HPs declared that approximately half the patients appreciated being involved in decisions regarding their medication plans, and only very few rejected the proposed changes with reasons similar to those identified in a recent qualitative studies with older adults and their carers.[19 29] Interestingly, a recent systematic review detected a lack of family involvement in managing medications of older patients across transitions of care,[30] an aspect which might merit further investigation.

The variability of loss to follow up rates and reasons for loss to follow up between and even within hospitals suggested that quality of patient information (particularly regarding the patients' post-discharge responsibilities) and the type of recruited patient population (i.e., proportion of patients with cognitive impairment or with a high number of diseases) varied among hospitals and HPs. Many patients were unable or unwilling to fill out the required questionnaires during follow up. Lyles et al. [31] suggested that remuneration of participants in recognition of their time commitment and a consistent, clear and persistent communication with participants were important factors in enrolling and retaining subjects.

GP level

Similar to other researchers of routine care,[32] we faced the dilemma inherent to any flexible implementation approach: Allowing high flexibility to suit the local circumstances may increase recruitment chances while decreasing implementation fidelity. We gave the hospitals much freedom in the intervention delivery to GPs, in particular regarding the adaptations of the discharge letter, which resulted in suboptimal implementation fidelity. The contact offer was presented very inconspicuously in several hospitals, and the medication changes were often not properly explained.

The high response rate of GPs contacted by postal dispatch and their feedback on the relevance of the topic indicated the need for better discharge protocols, thus justifying our trial. Accordingly, much literature is available on this topic. For instance, several studies from different countries reported that GPs appreciated receiving information on medication changes and reasons in the discharge letter.[33-36] Our findings show that GPs perceived this as more convenient than having to actively call the – often unavailable or difficult to contact – HPs. Therefore, and not too surprisingly so, the number of GPs contacting HPs after their patients' discharge was low. However, the number was so exceptionally low that we must also assume incomplete documentation by HPs. The finding that most GPs reportedly adopted changes introduced by HPs is in accordance with a Danish qualitative study which concluded that the poor continuity of medication changes at sector transition was not due to the GPs' deliberate actions of removing the patients' medications, but presumably due to procedural errors in the follow up on the patient after discharge instead.[37]

Strengths and limitations

We used both quantitative and qualitative approaches to achieve an adequate insight into the implementation of the intervention as proposed by the United Kingdom Medical Research Council guidelines.[11 38] Moreover, we performed the evaluation before instead of alongside or after the analysis and publication of the main findings, which, to our knowledge, is an exception and an innovative approach for process evaluations and ensures that the evaluation is blind to (and thus not biased by) trial outcomes.

The practical and well-structured framework by Grant et al. proved very useful in conducting this multilevel process evaluation. It has already been applied in numerous process evaluations of cluster RCTs [32 39-43] but was often reduced to specific elements.[32 38-40 43] While Roberts et al. claimed to be the

first to use the framework in its entirety for a process evaluation of a cluster RCT,[42] we used an even more extensive version adapted to our intervention: The framework was extended with additional levels for the intermediary providers (junior HP) and the overarching institutions (hospitals). This comprehensive approach allowed us to study every level of the intervention delivery and response. Following our example, the framework could be further extended to handle any number of clustering levels.

We described many implementation support strategies. future trials on hospital discharge optimisation may benefit from information on barriers to be tackled and facilitators to be taken into account on every level of the intervention. This may ultimately contribute to narrow the gap between the evidence of such strategies and their application in routine care.

Limitations of the study were the small sample of HPs, and that non-responders potentially introduced a selection bias (volunteer bias) to the digital survey. The low response rate of junior HPs was partially due to the frequent rotations; many junior HPs were no longer working at the hospital at the time of the process evaluation (which we anticipated). Furthermore, there might have been some desirability bias in the answers of HPs and chief physicians. We also faced potential bias due to unblind chief physicians and senior HPs, which was inevitable during the hospital recruitment process. Lastly, it is conceivable that some selection bias was introduced by HPs recruiting fitter patients, even though we tried to mitigate this.

Conclusion

The process evaluation framework by Grant et al. proved helpful for investigating the implementation of a complex and multifaceted intervention at different levels in a hospital setting. Our approach can be tailored and adapted to similar interventions. The results from this evaluation will support interpretation of the findings of the effectiveness study and – positive results given – dissemination of our approach to further hospitals. In addition, the barriers and facilitators, as well as targeted implementation strategies presented may help researchers and policy makers to plan and implement future studies and quality improvement programmes in the hospital setting.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics committee of the Canton of Zurich (as part of the full effectiveness-implementation trial, BASEC-No. 2018-00215). Informed consent was obtained from all individual participants included in the study.

Data availability statement

The datasets used and/or analysed during the current study are available from the last author (SNJ) on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This work was funded as part of the National Research Programme “Smarter Health Care” (NRP 74) by the Swiss National Science Foundation (grant no. 407440_167193, 7 December 2016). Additional funding was provided by the University of Zurich and the University Hospital of Zurich.

Author contributions

YR, TG, and SNJ contributed to conceptualization, investigation, methodology. YR performed the formal analysis and visualization and wrote the original draft. SNJ was responsible for funding acquisition and supervision. TG was responsible for project administration. YR, TG, and SNJ reviewed, edited and approved the final version of the manuscript.

Acknowledgements

We thank Susan Groth (our study nurse), Petra Hug-Gresens, and all physicians and patients who directly or indirectly provided data for this study, for their invaluable contributions to the study.

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Tables

Table 1. Facilitators and Barriers to study participation from the chief physicians' perspective

Facilitators		
Themes	**Codes**	**Quotes**
Quality improvement	Standardization of processes (discharge, medication review)	"That we get a certain standardization of the processes with these intervention tools; also when there are rotations – we have junior HP that stay for two years, then the next ones arrive – that we can integrate that in our process flows, certain tools, to standardize that." [D-01]
	Communication with GPs	"It's always a little ambivalent: on the one hand [the GPs] want to be informed, on the other hand they don't like to be called. Because they feel that they are being interrupted, and you don't really know what the best strategy is to communicate with your GP." [D-02]
	Patient outcomes (medication, hospital rehospitalisation, safety, satisfaction)	"For me it's actually about patient safety" [D-03]
Quality control	Benchmarking	"That it will reveal where we actually stand with our hospital, that there is also some possibility of benchmarking." [D-03]
	Validation of the hospital's strategy	"It is also just for us to check 'is our philosophy somehow also the right one; what can we improve?" [D-04]
Teaching	Teaching junior HPs	"We work with many very young junior HPs, so we thought that nothing better could have happened to us than receiving such a support as your checklist." [D-05]
	Sensitization/awareness of HPs	"My personal expectation, which I have also communicated to my senior HPs, is that we raise awareness for the discharge management, and in particular for the medication." [D-06]
Scientific interest	intrinsic interest	"As I said, we want to do science, this is part of our job here, so that is certainly one of the key factors." [D-07]

Relevance	Important topics	"So in the end it is the topic that tipped the scales, it is an important topic, it is an everyday topic, it is a topic that has been studied little else, with big consequences ... that is the main point." [D-08]
	Challenging topics	"The transition of medication in the hospital to GPs is a problem that we are aware of. It is somehow a difficult interface, which we have of course already identified ourselves." [D-09]
Credibility	Evidence based approach	"Many of these quality measures that are in place in hospitals today give a lot of work, and we are not sure how much they are worth... For me, it is crucial that it is studied scientifically rather than some authority coming along and saying 'now you have to do that.'" [D-10]
	Ownership	"The fact that [the study] is run by the University Hospital Zurich also played a role for me personally." [D-11]
Publicity	Individual	"It's also a bit of a flagship for me, that I brought the University of Zurich to [this hospital], along with myself, I might say. So this is my personal interest in the whole story." [D-06]
	Hospital	"We were published in the newspaper with too high rehospitalisation rates, and this is a tool to look at this." [D-12]
Fitting conditions	Right time, right place	"And now that a study has just been completed, this actually fits into our sequence quite well." [D-07]
	Target population	"We treat many patients who are older than 60 years (...). Many of them have many drugs. [The study] inclusion criteria are more than five; we sometimes have patients with 20 or more drugs, with proper polypharmacy." [D-11]
	Complementary to ongoing projects	"And when we received the offer to participate in this study, we saw it as the perfect complement to the other projects currently underway." [D-06]
Barriers		
Themes	**Codes**	**Quotes**
Resources	Limited time and workforce	"[It's] always the effort." [D-10]
	Lack of financing	"I mean, there is no provision for research to be carried out in clinical practice, and we are not compensated for it." [D-10]
Methodological limitations	Challenging patient population (oldest old, cognitive limitations, health literacy)	"99.9% of our patients do not know what 'quality of life' is. This questionnaire is complete hokum in the countryside, you can just forget about it. Because the standard answer will be: 'You tell me'." [D-06]

	Insufficient data quality	"Not necessarily the amount of time, but the accuracy of the work [by the junior HPs], or, in other words, whether they still achieve the same quality in intense periods, under more strain." [D-12]
	Staff fluctuation	"I'm retiring, there's a successor who doesn't know that I've agreed to this... But I'll tell him. And I have now also obliged [name of a senior HP]; I told him that he has to take over, and as you have heard, there are also changes among the senior HPs." [D-08]
	Intervention parts already established (usual care)	"Regarding the 'communication with the GPs' it is possible that the hurdle you are trying to overcome is not there at all in our hospital. (...) This will be difficult to evaluate." [D-12]
Organizational limitations	Technical limitations/information technology	"At first glance, it all sounds simple, but we saw for ourselves, you were there too, there were already a few hurdles where we simply had to think about a few things, how to do that, the hospital information system is of course not the same everywhere, but these are more the technical and organizational things." [D-08]
	Integration in clinical routine/ Paper-based data collection	"'Whether it can be sensibly implemented in everyday clinical practice; that was certainly a topic of discussion."[D-10]
Motivation of staff	Missing motivation/scepticism	"I think the only hurdle we have to face now is, of course, that the junior HPs, who already have a large workload, must now be motivated and convinced that this is a good thing that it's worth investing time for now."[D-05]
Relationship with GPs	Concern of bypassing GPs	"I think it is important – because we are in very close contact with the GPs – that [the GPs] will not get the feeling that we are participating in a study with their patients and [the GPs] might not have wanted that."[D-05]

Themes identified from the interviews (*n* = 15), with corresponding codes and example quotes from chief physicians (anonymized). Abbreviations: HP, hospital physician; GP, general practitioner

Figure legends

Figure 1. Framework model for process (dark grey) and impact evaluation (light grey). Abbreviations: HP, hospital physician; GP, general practitioner; cRCT, cluster randomised controlled trial

Figure 2. Flow of hospitals, senior HPs, junior HPs, GPs, and patients through the study, by study arm. Blue boxes illustrate data collection tools with number of responses [response rates]. Abbreviations: HP, hospital physician; GP, general practitioner

Figure 3. Attitudes and perception of feasibility and usefulness of tools and procedures by junior and senior HPs. Questions about general attitudes (A) were answered by HPs in both study arms (senior HPs: *n* = 44, junior HPs: *n* = 65); questions regarding checklist (B) and discharge summary (C) were only directed at the intervention group (senior HPs: *n* = 24, junior HPs: *n* = 38). The percentages given indicate 1) largely applies or applies, 2) partially applies, 3) does rather not or not apply.

Figure 4. GPs' views on medication review and communication at hospital discharge. The percentages given indicate 1) largely applies or applies, 2) partially applies, 3) does rather not or not apply (GPs: *n* = 187).

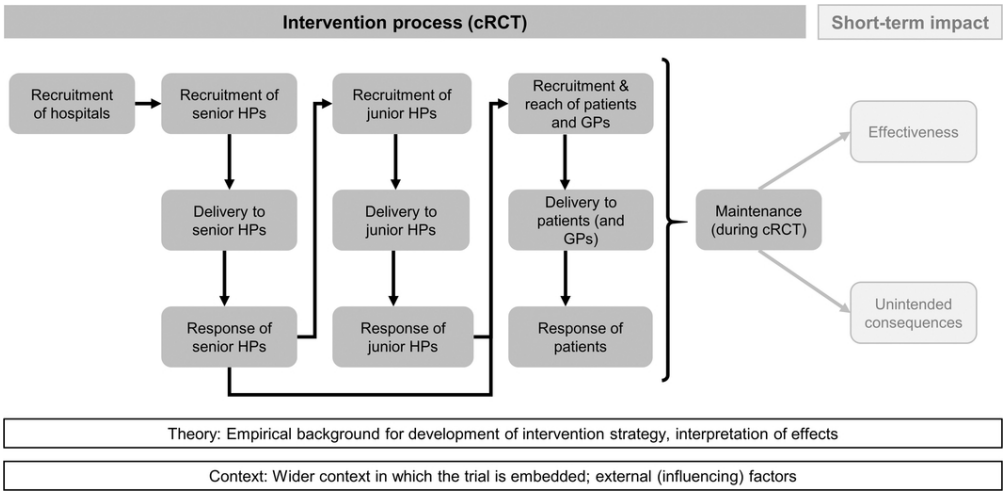

Figure 1. Framework model for process (dark grey) and impact evaluation (light grey).
Abbreviations: HP, hospital physician; GP, general practitioner; cRCT, cluster randomised controlled trial

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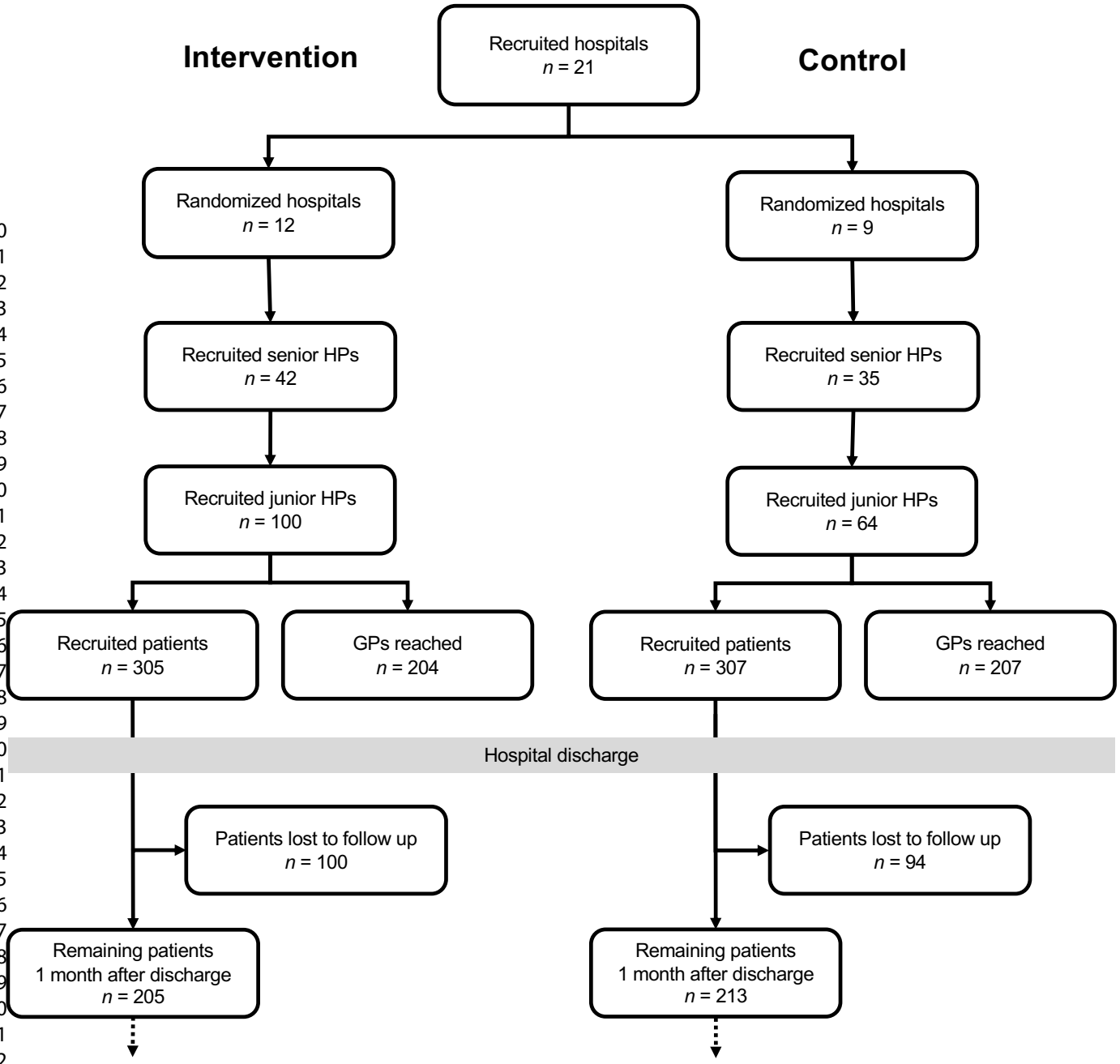

Data collection

Interview with chief physicians at the study start (*n* = 9 [75%] in the intervention group, *n* = 6 [67%] in the control group)

Paper-based questionnaire with senior HPs after instruction (*n* = 28 [67%] in the intervention group, *n* = 32 [91%] in the control group)

Digital survey with senior HPs at the end of the study (*n* = 24 [57%] in the intervention group, *n* = 20 [57%] in the control group)

Digital survey with junior HPs at the end of the study (*n* = 38 [38%] in the intervention group, *n* = 27 [42%] in the control group)

Postal survey with GPs at the end of the study (*n* = 92 [45%] in the intervention group, *n* = 95 [46%] in the control group)

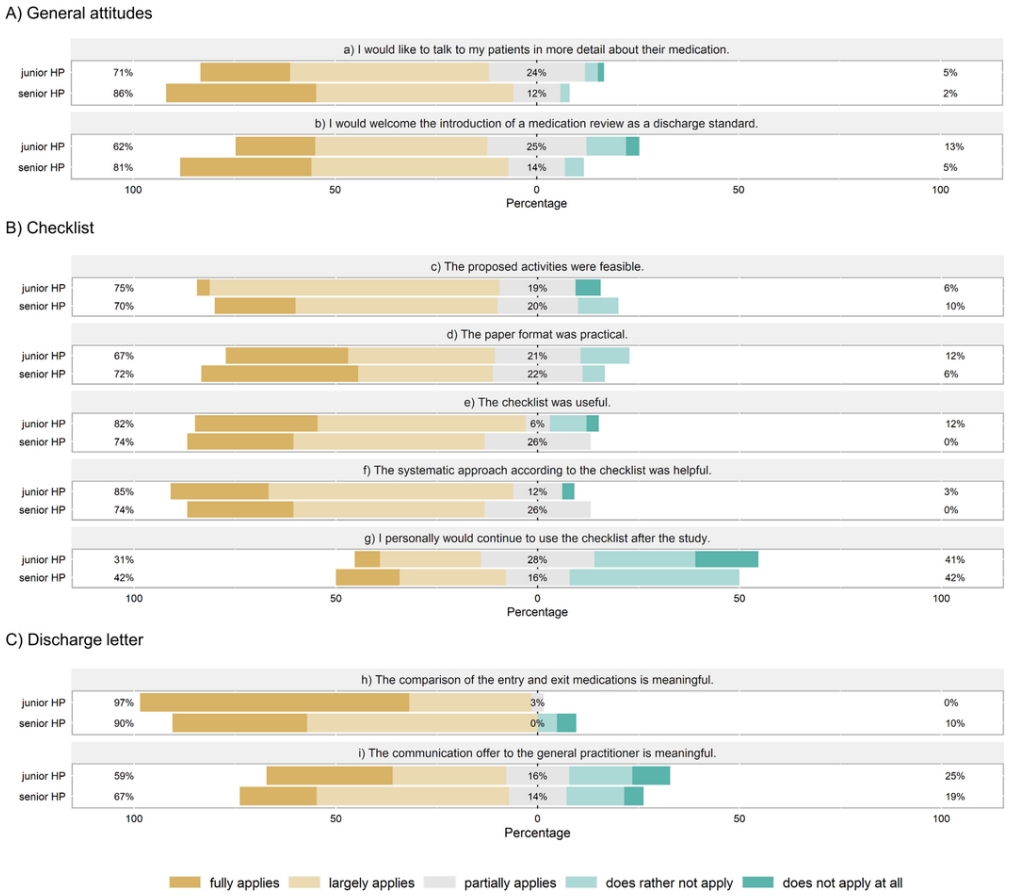

Figure 3. Attitudes and perception of feasibility and usefulness of tools and procedures by junior and senior HPs. Questions about general attitudes (A) were answered by HPs in both study arms (senior HPs: n = 44, junior HPs: n = 65); questions regarding checklist (B) and discharge summary (C) were only directed at the intervention group (senior HPs: n = 24, junior HPs: n = 38). The percentages given indicate 1) largely applies or applies, 2) partially applies, 3) does rather not or not apply.

89x79mm (300 x 300 DPI)

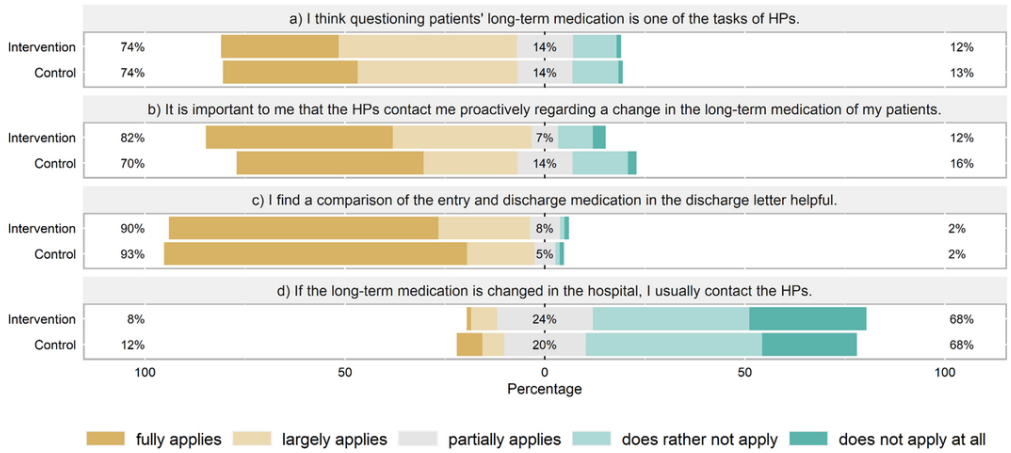

Figure 4. GPs' views on medication review and communication at hospital discharge. The percentages given indicate 1) largely applies or applies, 2) partially applies, 3) does rather not or not apply (GPs: n = 187).

89x40mm (300 x 300 DPI)

Online supplementary appendix 1

Discharge-Checklist

Patient-ID: ……

Date: ……

	Yes	No
1: Have you collected the **main complaint** of the patient?	❑	❑
2: Have you and your patient discussed the **treatment goals from his own point of view** ?	❑	❑
3: Have you compiled a full list of all the patient's **drugs at admission**?	❑	❑
4: Have you decided for every single drug whether		
▪ the patient will indeed **take it as prescribed**?	❑	❑
▪ the **indication** of the drug is correct for this patient?	❑	❑
▪ the **risk of side effects** (present or expected) is less than the benefit incurred?	❑	❑
▪ the **dose** is correct for this individual patient (age, comorbidities)?	❑	❑
▪ there is no **alternative drug** with a better benefit-to-risk ratio?	❑	❑
5: Have you decided whether a **new drug** is indicated?	❑	❑
6: Did you **involve the patient** in the changes you are proposing?	❑	❑
7: Have you provided the patient with a **discharge medication list** together with an invitation to use it?	❑	❑
8: Have you motivated the patient to consult the family doctor/general practitioner **within 7 days**?	❑	❑
9: Did you send the **list of modified or newly introduced** medications to the family doctor/general practitioner?	❑	❑
10: Have you offered the family doctor/general practitioner **to discuss** medication changes?	❑	❑

11: Was there any **contact with the general practitioner during the hospital stay** in view of the imminent discharge of the patient? ❑ Yes / ❑ No

Discharging Physician:

Name: …… Junior HP ❑ / Senior HP ❑ Signature: ……

Thank you very much!

Online supplementary appendix 2

Data collection tools (translated from German)

- Semi-structured interview with the chief physicians at the study start
- Paper-based survey with senior hospital physicians after the instruction
- Digital survey with senior and junior hospital physicians at the end of the study: Intervention group
- Digital survey with senior and junior hospital physicians at the end of the study: Control group
- Postal survey with general practitioners at the end of the study

Online supplementary appendix 2

Semi-structured interview with the chief physicians at the study start (Interview guide)

Themes	Questions	Probes
Motivation for participation	1. What tipped the scales for participation? 2. Were there additional reasons?	■ Did the following aspects (also) play a role? - discharge management - medication review - Education/ training junior HP - contact to GPs
	What are your expectations of the study for your clinic?	■ if improved medication review: owing to… - increased awareness? - Improved organisation/structure? ■ If improved communication with GP: for… - Quality improvement? - improving relations? ■ Are you hoping for a reduction in the rate of rehospitalization? ■ What role does «marketing/prestige» play?
	1. Does the fact that the intervention is conducted as a scientific study (instead of a quality support programme) make a difference for you? 2. Why?	■ If study is a plus point: Did the following aspect (also) play a role? - general scientific interest - credibility
Concerns regarding the study	1. Were there also hurdles/barriers/obstacles? What did you have to weigh up against? 2. Why were these not decisive?	■ Hospitals that could not participate gave us the following reasons: • - Time expenditure (especially for senior HP) • - lack of financing of the study • - no direct benefit for the hospital Why did these points play a lesser role for you?
Special circumstances (internal/external)	Are there any internal or external particularities/circumstances in your hospital that could be important for us?	■ for the (short or longterm) implementation ■ How is the relation/contact to GPs (and acute hospitals, for rehabilitation centres) ■ For rehabiltiation centres: How is the quality of admissions? (from acute hospitals)
Miscellaneous	Spontaneous input	

Online supplementary appendix 2

Paper-based survey with senior hospital physicians after the instruction

1. On which ward(s) do you work? *(open end)*

2. Have you ever been involved in a project or study on the following topics?

- Polypharmacy/appropriate medication:	□ scientific study	□ project
- Older, frail people:	□ scientific study	□ project
- Discharge management:	□ scientific study	□ project
- Communication/contact with general practitioner:	□ scientific study	□ project
- Others: ……..	□ scientific study	□ project

3. What was your motivation to participate in the study? *(open end)*

4. Do you have concerns about the study? If so, which ones? *(open end)*

5. Please rate the following statements *(5-point likert scale)*
   - The study objective is clear.
   - The course of the study in the hospital is clear.
   - My tasks in the study are clear to me.
   - The instruction has met my expectations.
   - The subject of the study is relevant for me.

6. Would you like further assistance/tools? If so, which ones? *(open end)*

7. We try to make the participation in the study as convenient as possible for you. We are pleased to receive suggestions for improvement or other comments. *(open end)*

Online supplementary appendix 2

Digital survey with senior and junior hospital physicians at the end of the study: Intervention group

Personal details

- In which hospital did you participate in the Hospital Discharge study? *(open end)*
- What was your position during the Hospital Discharge Study?
  □ Senior hospital physicians / □ Junior hospital physicians
- How many years have you been working as a physician? *(integer)*
- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I would like to talk to my patients in more detail about their medication.
  - I would welcome the introduction of a medication review as a discharge standard.

Instruction of junior hospital physicians (only for senior hospital physicians)

- How much time (in minutes) did you spend for the content part of the instruction of all involved junior hospital physicians (only for the theoretical part, without explanation of the course of studies and handling of the study material)? *(integer)*
- How was the instruction of the junior hospital physicians delivered?
  □ Incorporated into mandatory continuing education (e.g. assistant training, journal club)
  □ At a specially convened meeting
  □ Single instruction
  □ I don't know
  □ Other (please specify)

Instruction by the senior hospital physicians (only for junior hospital physicians)

- How long (in minutes) did the content part of the training by the senior hospital physicians take (only theoretical part, without explanation of the course of studies and handling of the study material)? *(integer)*
- How was the instruction by the senior hospital physicians delivered?
  □ Incorporated into mandatory continuing education (e.g. assistant training, journal club)
  □ At a specially convened meeting
  □ Single instruction
  □ I don't know
  □ Other (please specify)

Patient recruitment

Online supplementary appendix 2

- Did you use the prepared patient information (on the laminated document) for the recruitment of patients?
  □ Yes
  □ Sometimes
  □ No
  □ I don't know

Checklist

- Approximately how many checklists have you filled out? (*integer*)
- For which percentage of patients did you already start filling out the checklist before the discharge consultation? *(in percent, on a slider)*
- Please indicate how well the following statements apply *(5-point likert scale)*
  - The proposed activities were feasible.
  - The paper format was practical.
  - The checklist was useful.
  - The systematic approach according to the checklist was helpful.
  - I personally would continue to use the checklist after the study.
- What activity did the checklist remind you of that you would otherwise not consistently perform? *(multiple answers possible)*
  □ discuss treatment goals with the patient
  □ question every single drug
  □ motivate patients to contact their general practitioner within 7 days
  □ none
  □ other (please specify)
- How could the checklist be improved? *(open end)*

Discharge letter

- Please indicate how well the following statements apply *(5-point likert scale)*
  - The comparison of the entry and exit medications is meaningful.
  - The communication offer to the general practitioner is meaningful.

Patient reaction

- Please indicate how well the following statement applies *(5-point likert scale)*
  - My patients appreciated being involved in decisions regarding their medication plan.
- What percentage of patients rejected your drug change proposals? *(in percent, on a slider)*
- What reasons were given for the opposition? *(open end)*

Case vignettes

Online supplementary appendix 2

The following two case studies refer to the following situation: You have already gathered the patient's preferences and needs. Assuming that the patient is open to your suggestions, what would you prescribe from a medical point of view?

Example 1:

An 82-year-old female patient has had type 2 diabetes for 15 years. She also suffers from arterial hypertension, dyslipidemia, gonarthrosis on both sides and sleep disorders. So far, no cardiovascular events. She is physically severely restricted by her joint pain and lives in seclusion. Her HbA1c is 6.9%. She takes two antidiabetics, three antihypertensives, a statin, an aspirin, a PPI, two analgesics and a hypnotic.

- What would you recommend regarding diabetes treatment?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the statin?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the aspirin?
  □ expand / □ continue / □ reduce/deprescribe
- Explanations *(optional, open end)*

Example 2:

A 75-year-old male patient with mild cognitive impairment has arterial hypertension, COPD after nicotine abuse, moderate overweight and lumbo-tebral arthrosis. He's spry for his age. The passionate alpinist reports occasional dyspepsia after fondue eating in the alpine hut and suffers under sleep disturbance. Gastroscopy 10 years ago showed mild antral gastitis. He takes three antihypertensives, a long-acting bronchodilator, two analgesics, a ginko preparation, a hypnotic and a PPI every other day.

- What would you recommend regarding the PPI?
  □ continue / □ replace with phytotherapeutics / □ in rare reserve/deprescribe
- What would you recommend regarding the hypnotic?
  □ continue / □ replace with herbal medicine/ □ in rare reserve/deprescribe
- Explanations *(optional, open end)*

Final questions

- Has your discharge management changed during the course of the study? If so, how? *(open end)*
- Would you have liked additional support from us? If yes, which? *(open end)*
- Would you have liked additional support from your senior hospital physicians? If yes, which? *(open end, only for junior hospital physicians)*
- Finally, we would like to ask you: What do you think the focus should be at hospital discharge? *(open end)*
- Comments *(open end)*

Online supplementary appendix 2

Digital survey with senior and junior hospital physicians at the end of the study: Control group

Personal details

- In which hospital did you participate in the Hospital Discharge study? *(open end)*
- What was your position during the Hospital Discharge Study?
  □ Senior hospital physicians / □ Junior hospital physicians
- How many years have you been working as a physician? *(integer)*
- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I would like to talk to my patients in more detail about their medication.
  - I would welcome the introduction of a medication review as a discharge standard.

Patient recruitment

- Did you use the prepared patient information (on the laminated document) for the recruitment of patients?
  □ Yes
  □ Sometimes
  □ No
  □ I don't know

Case vignettes

The following two case studies refer to the following situation: You have already gathered the patient's preferences and needs. Assuming that the patient is open to your suggestions, what would you prescribe from a medical point of view?

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- What would you recommend regarding diabetes treatment?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the statin?
  □ expand / □ continue / □ reduce/deprescribe
- What would you recommend regarding the aspirin?
  □ expand / □ continue / □ reduce/deprescribe
- Explanations *(optional, open end)*

Online supplementary appendix 2

Example 2:

A 75-year-old male patient with mild cognitive impairment has arterial hypertension, COPD after nicotine abuse, moderate overweight and lumbo-tebral arthrosis. He's spry for his age. The passionate alpinist reports occasional dyspepsia after fondue eating in the alpine hut and suffers under sleep disturbance. Gastroscopy 10 years ago showed mild antral gastitis. He takes three antihypertensives, a long-acting bronchodilator, two analgesics, a ginko preparation, a hypnotic and a PPI every other day.

- What would you recommend regarding the PPI?

  □ continue / □ replace with herbal medicine/ □ in rare reserve/deprescribe

- What would you recommend regarding the hypnotic?

  □ continue / □ replace with phytotherapeutics / □ in rare reserve/deprescribe

- Explanations *(optional, open end)*

Final questions

- Has your discharge management changed during the course of the study? If so, how? *(open end)*
- Would you have liked additional support from us? If yes, which? *(open end)*
- Would you have liked additional support from your senior hospital physicians? If yes, which? *(open end, only for junior hospital physicians)*
- Finally, we would like to ask you: What do you think the focus should be at hospital discharge? *(open end)*
- Comments *(open end)*

Online supplementary appendix 2

Postal survey with general practitioners at the end of the study

- Please indicate how well the following statements apply to you: *(5-point likert scale)*
  - I think questioning patients' long-term medication is one of the tasks of hospital physicians.
  - It is important to me that the hospital physicians contact me proactively regarding a change in the long-term medication of my patients.
  - I find a comparison of the entry and discharge medication in the discharge letter helpful.
  - If the long-term medication is changed in the hospital, I usually contact the hospital physicians.

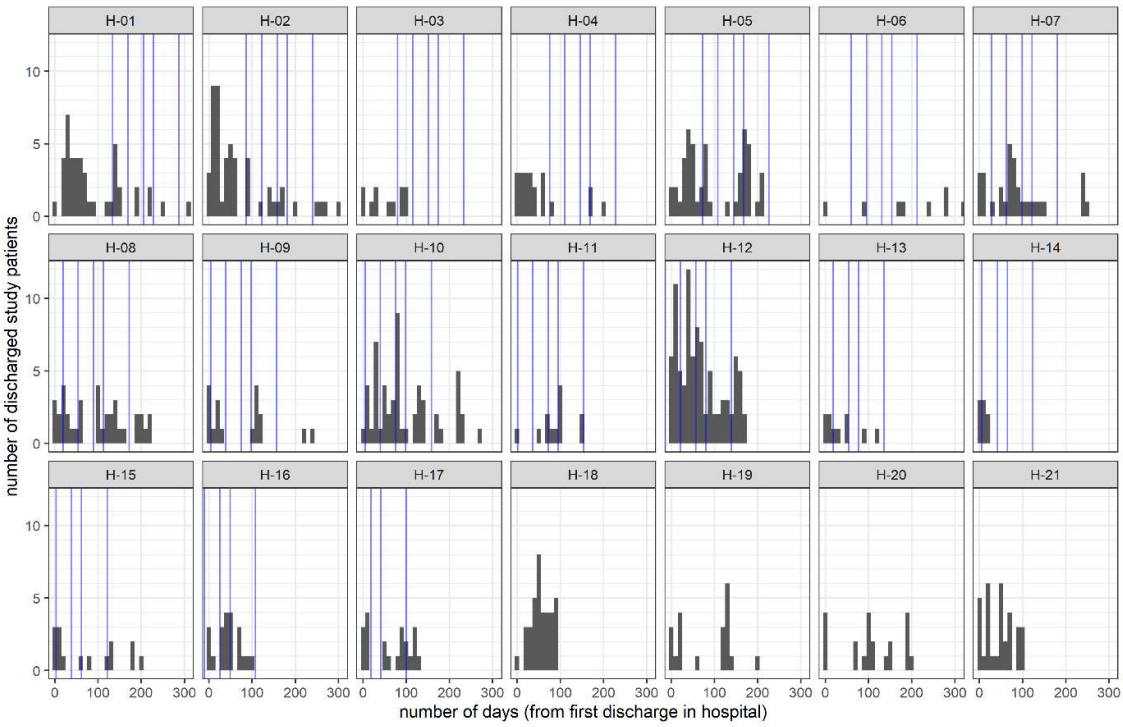
    → Follow up: If you do not normally make contact: What do you do if the long-term medication of your patient is changed in the hospital?

    □ I usually reset the medication to the previous medication.

    □ I usually accept the change of medication.

- (Optional) Further comments on hospital discharge *(open end)*

Online supplementary appendix 3



Numbers of discharged study participants (patients) over time, per hospital. Time was adjusted to the date of the hospital's first study patient discharge. Blue vertical lines indicate dates of newsletter dispatch. Hospitals that started study activities later due to COVID-19 no longer received newsletters.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	5	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	5,6,8	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	15	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	7	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	6	The population targeted by the intervention and any eligibility criteria.
Description	**9**	6	A description of the implementation strategy	6	A description of the intervention
Sub-groups	**10**	-	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	7-8	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	6-7	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	8	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	-	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	(separately)	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	Study protocol	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	9	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	(planned, (separately)	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	10-12	Proportion recruited and characteristics of the recipient population for the implementation strategy	10-12	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	10-12	Primary and other outcome(s) of the implementation strategy	(separately)	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	10-14	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	-	Resource use, costs, economic outcomes and analysis for the implementation strategy	(separately)	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	(planned, (separately)	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	10-12	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	10-12	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	15	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	-	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	16-20	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	20	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	-	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	20-22	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		