Title Page

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Title: What's your PLAN? A pilot study of a brief intervention to improve patient self-reported understanding of their health condition and medication in an inpatient hospital setting.

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ABSTRACT

Objective

Health literacy is poor in many health service users. Although interventions exist, none have been implemented during an inpatient setting. This pilot study investigated the effect of a brief intervention, delivered by hospital pharmacists during an inpatient admission, on patient self-reported understanding of their health condition and medication – one aspect of health literacy.

Methods

Patients admitted to a tertiary hospital in New Zealand on one or more high-risk medication were included. Patients received a brief intervention discussing four steps (PLAN) to help patients: Prepare for their next health visit, Listen and share concerns, Ask questions and Note what to do next. Primary outcome was patient self-reported understanding of their health condition and medication. Secondary outcomes were number and types of pharmacist interventions, patient satisfaction, and pharmacist intervention acceptability.

Results

Thirty-eight patients received the intervention. Scores improved for how well patients felt they understood their health conditions (increase from 3.65 ± 1.16 to 4.28 ± 0.74, $p=0.027$), their medication (3.50 ± 1.11 to 4.44 ± 0.77, $p=0.001$), and how to take their medication (4.12 ± 0.95 to 4.60 ± 0.76, $p=0.051$). Additional pharmacy interventions were made for 47% of patients. Mean patient satisfaction scores were high (4.64 ± 0.57); however, pharmacist acceptability was only moderately positive with many finding the intervention only somewhat rewarding.

Conclusion

This pilot study shows that a pharmacist-delivered intervention can have an effect on an aspect of health literacy in an inpatient setting. It suggests the potential for further inpatient interventions, which target health literacy issues.

INTRODUCTION

Health literacy refers to an individual's "capacity to obtain, process and understand basic health information and services in order to make informed and appropriate health decisions".[1] Poor health literacy is associated with poorer health outcomes – in particular higher hospitalisation rates, higher health care costs and a worsening of health status – compared to those with high health literacy. This is independent of socioeconomic and educational factors, age and ethnicity.[2, 3] Low health literacy has also been associated with negative psychological effects as many people may feel ashamed to disclose their difficulties with literacy.[4] This can affect a patient's ability to use health services effectively and self-manage their health conditions and medication.[3, 5, 6] Despite its importance in optimising health outcomes, health literacy remains poor in many health service users, with low health literacy having a reported average prevalence of 20%[1, 7]; with some studies reporting rates as high as 68%.[7] In the European health literacy survey, 1 in 10 respondents had insufficient health literacy with almost 1 in 2 with limited health literacy.[8] Rates are similar within the New Zealand population, where over half (56.2%) of all adults score below the minimum health literacy required to meet daily demands of life and work. As in the European context, a social gradient appears to exist with health literacy in New Zealand. Poor health literacy rates appear to be higher in the New Zealand indigenous population (Māori), with 3 out of 4 Māori females, and 4 out of 5 Māori males reported to have poor health literacy.[9] There is a need for strategies to improve health literacy, in conjunction with initiatives to reduce demands and address complexities in the healthcare system, if we are to optimise the therapeutic benefits of any healthcare interventions and reduce ethnic disparities.[1]

Limited evidence exists in the literature on the delivery of interventions in a hospital setting which aim to improve health literacy.[10] Previous interventions have been delivered in an outpatient or primary

care setting[10], or only at hospital discharge.[11, 12] Paasche-Orlow et al. investigated the effect of

one-on-one asthma education at the point of hospital discharge, and reported that low health literacy

was not a barrier to learning or retaining asthma self-management skills.[11] Similarly, Kornburger et al.

implemented a nurse-delivered intervention at discharge, where nurses used 'teach-back' strategies to

check patient and carer understanding of discharge instructions.[12] The authors reported that the

intervention helped patients and families better understand instructions, however these findings were

reported by the nurses rather than from patients / carers themselves. The studies suggest there may be

potential for delivering interventions within a hospital setting which aim to improve health literacy.

Many significant changes to a patient's health regimen occur during an inpatient hospital admission.[13,

14] Patients who have poor health literacy may have difficulty understanding these changes and

processing the information given during the hospital stay, which can lead to re-admissions, poor health

outcomes and increased mortality.[14-16] The risk of hospital re-admission has been reported to be

almost 1.5 times higher for those with low health literacy compared to those with adequate health

literacy.[15] The inpatient hospital stay thus represents an important opportunity where interventions

targeting health literacy can be delivered. Early intervention during the inpatient stay may help patients

plan for upcoming health visits after discharge from hospital by encouraging better communication

between the patient and the healthcare team, such as between tertiary, secondary and primary care

services. For example, patients who received a health literacy intervention in the Emergency

Department reported that the intervention was useful to confirm learning and improve doctor-patient

communication.[17] Whilst it is important to deliver health literacy initiatives for patients in the

ambulatory setting on a long-term basis, it is important to begin addressing some of the health literacy

barriers early in the patient journey before discharge.

Health literacy is a complex concept, consisting of different components including cognitive abilities, academic skills such as numeracy, and health knowledge and understanding.[18] In a model proposed by Ownby et al., the areas of health literacy which are most amenable to intervention are academic skills, and health knowledge. The primary objective of this study was to determine the effect of a pilot brief intervention, delivered in an inpatient setting, on one aspect of health literacy – patient self-reported understanding of their health condition and medication. As this was a pilot, we chose to focus on the knowledge and understanding aspect of health literacy, as we felt health knowledge was an area that pharmacists were best equipped to educate and improve on, rather than academic skills.[18] The intervention builds on previous research[10], by focusing holistically on the patient and encouraging skill-building, rather than single aspects such as numeracy or comprehension. As this was an initial pilot with limited resourcing, the intervention was evaluated in a pre-defined high-risk population, where patients taking at least one high-risk medication (as defined by the national quality and safety commission),[19] were targeted for intervention. This was based on previous research suggesting that interventions which aim to address health literacy issues can have particular impact on reducing medication errors,[12] as well as guidance from the local medication safety team. The intervention was delivered by several clinical pharmacists, in line with research which shows that interventions delivered by health professionals are most effective for improving health literacy.[10] Secondary objectives were to capture the number and type of clinical pharmacist interventions made as alongside the intervention, patient satisfaction, and pharmacist acceptability of the intervention.

METHODS

Study design and participants

This was a two-week prospective study conducted at a large regional teaching hospital in Auckland, New Zealand with approximately 1000 beds. Patients admitted to inpatient hospital care who were either

taking or initiated on one or more high-risk medication during their hospital stay were eligible for inclusion. A 'high risk medicine' was defined based on information provided by the Health Quality and Safety Commission (HQSC) New Zealand as either insulin, warfarin or low-dose methotrexate.[19] Patients admitted to intensive care or off-site hospital wards, or were living in residential care prior to hospital admission were excluded. Each working day, eligible patients were identified by clinical pharmacists using in-house dispensing reports and via referral from the Emergency Department pharmacist and other health professionals including nursing, medical and other pharmacy staff. To help with identification of eligible patients, clinical pharmacists raised awareness of the intervention to nursing and medical staff through presentations and education at the ward level. Marketing materials (stickers and pamphlets) were also developed and distributed to staff and patients. Two weeks prior to the start of the intervention, clinical pharmacists were educated on health literacy and how to deliver the interventions to improve health literacy. Pharmacist education included didactic teaching with verbal presentation and a visual slide deck, and role plays of patient-pharmacist consultations.

During the two-week study period, clinical pharmacists delivered the brief intervention (described below) to eligible patients and provided patients with information leaflets about their high-risk medicine, and a personalised card listing information about the patient's medicine regimen. Caregivers were invited to be present during pharmacist interactions with patients, where patients who did not manage their own medication. A PLAN 'champion' was assigned to each clinical pharmacy team during this period, who provided support and feedback on the intervention, to help ensure consistency in intervention delivery. Ethics approval was sought from the New Zealand Health and Disability Ethics Committees, however this was deemed not required as the study was considered a low-risk audit of usual service delivery.

The intervention

The intervention delivered was adapted from previous health literacy initiatives: the National Patient Safety Foundation "Ask Me 3™" program from the US, and from the national HQSC "PLAN" programme. "Ask Me 3™"is a program designed to improve patient and provider communication, and empower patients and families to be active members of the healthcare team.[20] The Ask Me 3™ program has been associated with improved patient communication with health practitioners and higher patient satisfaction when delivered in outpatient ambulatory care settings.[21-24] "PLAN" uses principles from Ask Me 3™ but adapted for the New Zealand setting by the HQSC, and piloted in a primary care setting with local consumers of Māori, Pacific and European ethnicity.[19] PLAN consists of four steps which encourages patients to build skills around Preparing for their next health visit, Listening and sharing concerns, Asking questions and Noting what to do next.

Outcomes

The primary outcome of the study was to determine the effect of the brief intervention on patient self-reported health understanding of their health condition and medication. Secondary outcomes were to measure the clinical pharmacy interventions made by the pharmacists during the study period, evaluate patient satisfaction, and assess pharmacist acceptability of the intervention. Effect of the intervention was measured via a self-report questionnaire which assessed how patients perceived their understanding about their health condition, their medication, and how to take the medication. Responses were scored using a scale ranging from 1 (not at all [poor understanding]) to 5 (very well [excellent understanding]). The questionnaire was delivered via a mobile application or, for pharmacists without access to a smartphone, via a paper-based questionnaire. The questionnaire was administered to patients before and after the intervention – usually at two different time points during the patient's hospital stay, such as on admission and prior to discharge – though in some cases, the pre- and post-

intervention questionnaire had to be administered in the same session due to the risk of loss to follow-up for patients transitioning within the hospital. Information on the patient's age, ethnicity, gender, medicine regimen and sources of medicines information were also collected. Prior to the intervention, patients were asked "do you think you should know more about your medication?" to gauge patient's self-perceived need for knowledge about their medication before the intervention. Responses to this were scored on a semantic scale ranging from 1 (definitely not) to 5 (definitely yes). Data collected via the mobile application were uploaded onto a secure server whilst data collected via the paper-based questionnaire were transcribed onto a central electronic spreadsheet.

For each patient seen, pharmacists also recorded details of any pharmacy interventions made, such as addressing medicines management or adherence issues. This intervention tracking served to evaluate how the PLAN initiative influenced other pharmacist interventions. Each intervention was then graded by the pharmacist based on their potential to cause harm to the patient – with 1 being minimal harm to 5 being severe harm. Incidents requiring further escalation such as risk incident reporting for local risk issues or national pharmacovigilance reporting for serious adverse events were followed up according to in-house standard operating procedures.

Patient satisfaction with the intervention was evaluated by asking patients to rate how useful they found the intervention on a semantic scale from 1 (not useful) to 5 (very useful). Patients had the opportunity to provide further written or verbal feedback on the intervention. The acceptability of the intervention to pharmacists and their perceptions of PLAN were assessed by asking pharmacists 5 questions: whether they completed the intervention for their patients, what the main barrier(s) were to deliver the intervention, how rewarding they found the experience, how useful they thought the intervention was for their patient(s), and what they thought about the use of the mobile application for

data collection. These questions were emailed to pharmacists via an online survey link after the study period was over.

Statistical analysis

Descriptive statistics were conducted to characterise the study population. The primary outcome of health knowledge scores before and after the intervention were compared using a two-tailed t-test. Secondary outcomes were characterised using descriptive statistics.

RESULTS

A total of 38 patients received the intervention over the two-week study period. Outcome data were available from 26 patients due to missing data resulting from errors in data upload to the hospital server. Patients were distributed across several hospital services – general medicine (55%), surgery (29%), mental health (11%) and paediatrics (5%). Most patients were on insulin (47%) or warfarin (42%) alone. One patient was on two high risk medication (methotrexate and warfarin), whilst another was on all three. Characteristics of the study population are summarised in Table 1. When asked whether they should know more about their medication, the majority (81%) scored this 3 or more, indicating that most felt they should know more.

Understanding of health condition and medication

All three parameters measured in terms of patient self-reported understanding of their health condition and medication improved after the intervention, however only two of the three parameters reached statistical significance: how well patients understood their health condition, and their medication(Table 2). When asked whether they thought they should know more about their medication, the mean (±SD)

score was 3.48 **±** 1.25, suggesting mixed responses with some patients feeling they should know more about their medication, whilst others did not.

Clinical pharmacist interventions

Of the 38 patients seen by pharmacists, 18 (47%) received an additional clinical pharmacy intervention. Of these, 7 patients received 2 interventions, and 3 patients received 3 interventions. Most of these concerned medicines management (29%), knowledge about the condition (25%), and adherence (14%). Other interventions included advice on adverse effects (7%), formulation (3%), interactions (4%), administration (11%), and referrals to other health professionals (7%). In terms of risk of harm, most were deemed to not have no or minimal risk of harm, with only one intervention graded as a 4, where the patient revealed during the consultation that they were intentionally non-adherent with their warfarin.

Patient satisfaction

Most patients (96%) found the intervention useful (rating it 4 or more) with a mean (±SD) score of 4.64 ± 0.57.

Pharmacist intervention acceptability

Of the 38 clinical pharmacists eligible to respond to the pharmacist acceptability questionnaire, 21 responded (55%). Of the 21 that responded, 11 (52%) stated that they had delivered the intervention to one or more patients. The main barrier identified to delivering the intervention was lack of time. Pharmacist feedback on how rewarding it was to deliver the intervention, and how useful they perceived the intervention was for patients, was only moderately positive. Most (64%) pharmacists

reported the intervention was only 'somewhat rewarding', and just under half (45%) thought the

intervention was only 'somewhat useful' for their patient (Table 3).

DISCUSSION

This pilot study demonstrates that a brief intervention, delivered by clinical pharmacists during the

inpatient hospital stay, leads to improvements in patient's self-reported understanding of their health

condition and medication. Although only one aspect of health literacy was evaluated in this pilot, it

suggests there may be potential for interventions which target health literacy to begin during hospital

admission. Whilst there are many studies that report the effectiveness of health literacy interventions,

these have primarily been conducted in ambulatory care settings.[10] This study represents an

important contribution to the health literacy and pharmacy literature as there is widespread evidence

that patients are at high-risk of medicine errors during, and when transferring from, their hospital stay

into primary care[13, 14], which may be compounded by poor health literacy.[15, 16] The hospital

admission therefore has the potential to be an excellent opportunity for health literacy interventions to

be initiated, with ongoing follow-up after discharge to the community. However, it is important to

consider a patient's readiness for receiving information prior to intervention, as the stress, potential

anxiety and acute illness associated with an inpatient stay may affect the effectiveness of the

intervention.

The findings from our study support previous literature that demonstrate the effectiveness of

interventions that aim to improve health literacy are delivered by health professionals, have undergone

pilot-testing and focus on self-management and skill-building for patients.[10] The intervention used in

our study was built on these principles, by using clinical pharmacists to deliver the intervention,

adapting the intervention from previously piloted health literacy programmes[19, 20], and focusing on

building skills to empower patients to make the most of their healthcare interactions. These factors may have contributed to the effectiveness of the intervention and should be considered by others involved in designing interventions to improve some or all aspects of health literacy. We found that self-reported measures of understanding of health and medication improved across all parameters assessed – their understanding of their health condition, their medication, and how to take their medication. However, this was measured by self-report which has certain limitations.

Firstly, self-report measures were used which only determines what the patient thought about their own understanding regarding their conditions and medication, and therefore could only provide a subjective measure. The outcome measure also only focused on one aspect of health literacy – knowledge and understanding – and has not been validated. It is therefore unknown how these self-report measures of *perceived* change in knowledge and understanding relate to *actual* health literacy. Whilst there are objective validated health literacy tools available which assess multiple aspects of health literacy, it was not practical to use these in our pilot study in an inpatient setting as they are time-consuming to administer, and may therefore be better suited to a research or ambulatory setting, rather than in hospital practice. As the study was a pilot study within a real practice setting, we chose to focus on improving just aspect of health literacy that was considered to be the most relevant to the patient, in terms of the health and medication issues they may face after hospital discharge. Further research is needed to understand whether this intervention had any impact on other aspects of health literacy.

Second, the sample size consisted only of 38 patients. Due to technological issues, further data from 12 patients were lost, leaving only 26 patients for analysis. This small sample size, data loss, and the short study period, limits the generalisability of the results. The study period was too short to evaluate changes in outcomes such as healthcare utilisation, provider-patient relationships, medicine adherence

and adverse effects, and we cannot know whether improved health literacy persisted beyond the hospital stay. Our study findings therefore represent only initial investigations, as a proof-of-concept; further research into inpatient health literacy interventions, and its effect on other aspects of health literacy beyond understanding and knowledge, is needed. Larger follow-up studies of longer duration that include a control group would be useful to confirm the results from this study.

Third, pharmacist performance in delivering the intervention was not assessed. Whilst a PLAN 'champion' was assigned to each clinical team to support and feedback on the intervention throughout the study period, individual assessments were not undertaken. As such, there may have been variability between pharmacists in the way the intervention was delivered, which could have impacted on intervention effectiveness. There may also have been variability in the follow-up time between the pre- and post-intervention questions administered by pharmacists. This may have affected the questionnaire responses due to short-term memory effects. Unfortunately, the follow-up times were not recorded, and could be another factor that may have influenced intervention effectiveness. The evaluation questions were also administered by pharmacists, which may have introduced an element of social desirability bias.[25, 26] Interestingly, pharmacist satisfaction with delivering the intervention was only moderately positive. Compared to patient reports where the majority found the intervention useful, many pharmacists thought the intervention was only 'somewhat' useful for patients. This difference in perception could represent a barrier to implementation in routine clinical practice. Possible reasons for this could be a lack of familiarity with the intervention, despite training, and competing priorities for pharmacists in terms of which pharmacy interventions to deliver for patients. Indeed, pharmacists reported time as one of the key barriers to delivering the intervention. Unfortunately, time spent per patient to deliver the intervention was not measured so it cannot be ascertained whether this 'lack of time' is due to an actual or perceived barrier. Future studies should include individual assessments of

pharmacist intervention delivery, and focus on streamlining the intervention with pharmacists' routine workflow to increase efficiency and uptake.

The relevance of these findings to other patients and the sustainability of these benefits in the long-term is currently not known and further investigation into this will be needed. If this intervention proves to be effective in larger studies and on a longer-term basis, there is potential for the information collected during the health literacy intervention to be passed on to primary care to allow a seamless transition of care into the community and regular review and follow-up.

CONCLUSION

This study is the first to provide proof-of-concept that interventions delivered within an inpatient hospital setting by clinical pharmacists were perceived by patients as helpful for improving understanding of their health condition and medication. Significant improvements in patient self-reported understanding of their medication and health condition were supported by positive feedback from patients about the intervention. It suggests that the inpatient hospital stay can be a valuable opportunity for discussions about medication to take place before discharge into the community. Pharmacist feedback was however less positive with time perceived as a barrier to implementation. However, the significant benefits reported by patients support the potential of inpatient health literacy interventions. Staff training, refinement of the intervention and change management techniques may be needed prior to incorporation as part of usual care. It provides scope for future research to explore the potential inclusion of health literacy interventions into routine clinical pharmacy practice.

KEY MESSAGES

What is already known on this subject

- Health literacy is poor in many health service users

- The inpatient hospital setting represents an important opportunity to intervene as many healthcare changes occur during this time

- Few health literacy interventions have been investigated within inpatient hospital settings

What this study adds

- A pharmacist-delivered intervention in an inpatient setting can lead to significant improvements in patient self-reported understanding of medication and their health condition

- Patient satisfaction was high and feedback positive suggesting potential for future interventions which focus on health literacy to be delivered in an inpatient care setting

CONTRIBUTORS

ZL, KA and AC were involved in the original literature search, study conception and design, study data collection, data analysis, interpretation and the writing of the report. All authors have approved the final article.

DECLARATION OF INTERESTS

TABLES

Table 1 – characteristics of the study population (n=38 unless otherwise specified – number less than 38 for certain parameters due to missing data)

Characteristic	Mean ± SD or n (%)
Age (n=33)	**61 ± 18 years**
Gender (n=33)	**13 (39%) male**
Clinical service - General medicine - Surgery - Mental health - Paediatrics	 21 (55%) 11 (29%) 4 (11%) 2 (5%)
High risk medicine involved (n=36) - Insulin - Warfarin - Methotrexate - 2 medicines - 3 medicines	 17 (47%) 15 (42%) 2 (5%) 1 (3%) 1 (3%)
Usual source of medicines information (n = 28) - Doctor - Pharmacist - Internet - Nurse - Family - Other - Multiple	 9 (32%) 4 (14%) 3 (11%) 2 (7%) 2 (7%) 1 (4%) 7 (25%)

Table 2 – patient self-reported understanding of their health condition and medication before and after PLAN intervention (n=26)

Question	Pre-intervention* (mean ± SD)	Post-intervention* (mean ± SD)	p-value
How well do you understand your health condition?	3.65 ± 1.16	4.28 ± 0.74	0.027
How well do you understand what your medication are for?	3.50 ± 1.11	4.44 ± 0.77	0.001
How well do you understand how to take your medication?	4.12 ± 0.95	4.60 ± 0.76	0.051

Responses scored using a semantic scale ranging from 1 (not at all) to 5 (very well).

Table 3 – Pharmacist feedback on PLAN intervention (N = 21 unless otherwise specified – number less than 21 for some questions due to incomplete responses)

Parameter	n (%)
Did you PLAN any patients during the study period?	
- Yes	11 (52%)
- No	10 (48%)
What was the main barrier to completing a PLAN for your patients? (n=17)	
- Didn't have enough time	9 (53%)
- No patients fitted criteria	6 (35%)
- Didn't understand PLAN process	1 (6%)
- None – I completed PLAN for all eligible patients	1 (6%)
If you did PLAN one or more patients, how rewarding was the experience? (n=11)	
- Somewhat rewarding	7 (64%)
- Quite rewarding	3 (27%)
- Very rewarding	1 (9%)
How useful did you think PLAN was for your patient? (n=11)	
- Somewhat useful	5 (45%)
- Quite useful	5 (45%)
- Very useful	1 (9%)
Do you think the app was a useful way to collect data (n=10)	
- No prefer paper	4 (40%)
- Yes, but needs better functionality	3 (30%)
- Yes – prefer app	3 (30%)
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