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Impact of a Universal Medication Schedule on rationalising and understanding of medication; a randomised controlled trial

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ABSTRACT

Background: Patients frequently encounter difficulty understanding their prescription drug labels. This problem is more common in patients with limited health literacy (HL). Patients are not always counselled on their medicines by their doctor or pharmacist, therefore this label can be an important source of information.
Objective: To assess the impact of a Universal Medication Schedule (UMS) on the knowledge and consolidation of a prescription drug regimen compared to standard pharmacy labelling.
Methods: Seventy-six in-patients at a specialised rehabilitation hospital in Dublin, Ireland, were randomised into control (usual care) or intervention (UMS) groups. Adult in-patients, receiving oral medicines, who spoke English fluently were included. Patients with dexterity issues documented, or those unable to provide written informed consent were excluded. The Newest Vital Sign (NVS) and validated HL screening questions measured HL. A five medication regimen was presented to each participant, and they were asked questions to assess their understanding of the medication regimen and were asked to dose out the medications into a 24 h dosette box. Data analysis was conducted using SPSS® (IBM Corp.), V23.
Results: The majority of participants (n = 76) were Irish (89.5%), male (63.2%) and the median age of participants was 49 years. 46% of participants had a third level qualification, however 14.4% of participants had not completed any formal school examinations. Those in the UMS group displayed better understanding of the prescription regimen than those in the usual care group, but this was not statistically significant. (Mean score 9.28 vs 8.81, p = 0.135). Subgroup analysis did not find any additional benefit of UMS in those with limited health literacy (Mean score 8.56 vs 9.06, p = 0.514) but rather in those who said that they found instructions on tablets hard to understand (Mean score 10.00 vs 8.43, p = 0.019).
Conclusion: A UMS approach may improve patients understanding and use of their medicines.

1. Introduction

Many patients do not understand their prescription drug labels[1–4] and therefore may not take their medicines as prescribed. This problem is more common in patients with limited health literacy.[5–7] Health literacy was defined in 2012 by the European Health Literacy Consortium as entailing "people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course.[8] The European Health Literacy Survey (HLS-EU) in 2012 found that 10.3% of Irish participants had inadequate health literacy and a further 29.7% had problematic health literacy.[9]

Misunderstanding of medication regimens may lead to decreased medication adherence and suboptimal clinical outcomes. Irish research found that 1 in 10 people have taken the wrong dose of medicine because they did not understand the instructions.[10] Studies have shown that patients are not always counselled on their medicines by the prescribing doctor or dispensing pharmacist.[11–14] Therefore, the prescription drug label can be an important source of information for patients. In a study which asked patients to interpret the instructions given on the label of a prescription drug container, Wolf et al. showed that patients with low literacy had higher rates of misunderstanding compared to those with marginal or adequate literacy.[1] Two similar studies have shown that patients with poor literacy skills have difficulty correctly

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interpreting warning labels on prescription medications.[2,3] Low literacy and marginal literacy levels were shown to be statistically significant predictors of misinterpreting drug labels in a study by Davis et al.[4].

In Ireland, legislation outlines the minimum content required for prescription drug labels.[15] However, no such guidance exists in relation to dosing instructions. The Pharmaceutical Society of Ireland (PSI), the Pharmacy Regulator, offers minimal guidance, suggesting that: "labelling of dispensed medicinal products should be clear, legible and computer generated". The label must also contain the relevant information required for the safe and effective use of the product.[16]

Research from the United States of America (USA) has focused on creating an evidence base for prescription drug labels. Shrank et al. (2007)[17] summarised best practices in a systematic review. This includes: increasing font size, using clear and simple language and emphasising patient-centred information. "Sans serif" fonts such as Arial or Calibri should be used along with numbers instead of their text equivalent.[17,18] In 2008, The American College of Physicians Foundation published a "Description of Standards for an Enhanced Rx Container Label" in their White Paper: Standardizing Medication Labels: Confusing Patients Less.[19] This includes use of a "Universal Medication Schedule" or UMS to convey and simplify dosage instructions. The UMS established four standard time intervals (morning, noon, evening, bedtime) for the prescribing and dispensing of medicines.

The UMS has demonstrated its efficacy in improving patients' understanding of medication regimens.[20–22] It has been endorsed by the Institute of Medicine,[23] the United States Pharmacopoeia,[24] and the American College of Physicians.[19] The State of California[25] has passed legislation recognising the UMS as a best practice for drug labelling.

Although the UMS has the potential to enhance patient understanding of prescription regimens worldwide, to date most research has been carried out in a US population. An exploratory study in Ireland supported the use of UMS in Irish patients recruited from an outpatient clinic.[20] Our study investigated whether similar results would be obtained from an in-patient setting at a specialist rehabilitation hospital in Ireland. We felt that it was useful to undertake this research in a rehabilitation setting as most in-patients have recently had a life-changing illness or injury and may not have had much prior experience in dealing with health materials. In addition, they are a vulnerable cohort of patients and knowing more about their understanding of prescription medicines would inform future care provisions, as well as increase the evidence base for UMS which would allow for future development of standards for prescription drug labelling in Ireland.

The aim of this research is to investigate the impact of a Universal Medication Schedule (UMS) on participants' ability to understand and consolidate a medication regimen compared to usual care.

2. Methods

2.1. Hypothesis

It was hypothesised that patients receiving the UMS would display better understanding and better consolidation of the medication regimen compared to usual care.

2.2. Ethics approval

Approval was sought and granted for the research study by the Ethics Committee of the National Rehabilitation Hospital (NRH), Dun Laoghaire, Ireland.

2.3. Research setting and participants

This study was conducted at the NRH in Dun Laoghaire in Ireland. The NRH is a 110 bed facility in South County Dublin which provides specialist rehabilitation services to patients who, as a result of an accident, illness, or injury, have acquired a physical or cognitive disability and require specialist medical rehabilitation. Specialist rehabilitation is provided across four programmes: the Brain Injury Programme (BIP); Spinal Cord System of Care (SCSC); Prosthetic, Orthotic and Limb Absence Rehabilitation (POLAR); and the Paediatric Programme. The hospital operates under the CARF (Commission for Accreditation of Rehabilitation Facilities) framework, which adopts an interdisciplinary goal-orientated approach to treatment.[26]

The research population comprised of in-patients at the NRH who were taking regular medicines. Inclusion criteria were; the ability to speak English fluently; being 18 years of age or older; and being willing to provide written informed consent. Exclusion criteria were; patients who had impaired dexterity which would lead to difficulty filling a dosette box; and patients receiving their medicines via a Percutaneous Endoscopic Gastrostomy tube.

A sample size calculation was conducted based on results from a previous study.[20] The calculation was based on the minimum sample size formula for a prospective, single-centre, randomised, two-parallel arm, controlled trial with blinded outcome ascertainment. A total of 100 patients (50 per arm) were required to show a difference between two arms with an alpha level of 0.05 and 90% power.

2.4. Patient identification and recruitment

The Clinical Nurse Manager (CNM) on each of the eight hospital wards was consulted and identified suitable patients who met the inclusion criteria of the study. The patient was then approached and an introduction letter and patient information leaflet about the study was provided. Patients were followed up after 7 days and were given the option to participate in the study. If the patient agreed, an appointment was scheduled. Written informed consent was obtained from each patient. Details such as participant age, gender, nationality and education level were recorded.

2.5. Study design

This study was designed as a pilot randomised controlled trial. LS, a research pharmacist unconnected with the study participants, conducted the randomisation based on study number using a dedicated website.[27] Participants were allocated to one of two groups (intervention or control). The allocation sequence was concealed through use of individual sequentially numbered opaque sealed envelopes prepared by LS. The number on the envelope corresponded to the participants' study number. The primary researcher EMM, who recruited participants, was not involved in this step of the process. Once participants had consented to participate in the trial, they were assigned to the control or intervention group. This was revealed by opening the envelope corresponding to their study number. Neither participants nor EMM were blinded to the intervention.

2.6. Intervention groups

Patients in the intervention group were shown a set of five medicines in amber prescription vials. These prescription vials were labelled using a patient-centred label (PCL). Participants in the intervention group also received a Universal Medication Schedule (UMS) which detailed the number of tablets to be taken and when to take them, as well as printed warning instructions. Administration instructions are standardized to provide explicit timing with these standard intervals. UMS instructions also use simplified text, numeric characters instead of words to detail the dose, and "carriage returns" to place each dose on a separate line to clearly identify every time period a medicine is taken.

Patients in the control group were shown the same set of five medicines in identical amber prescription vials. However, the prescription labels used in this group were designed using standard pharmacy labels. These patients did not receive a UMS. Discontinued drug names were chosen for this research study, as it was thought that