Original Scientific Paper

Pharmacy prescription additions

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ABSTRACT

Aims

To assess the nature of pharmacy prescription additions in a primary care setting.

Methods

Registered patients in a Whangarei general practice consulted in a three month prescribing period between 1 October 1997 and 31 December 1997 were asked to nominate their regular pharmacy. Nominated pharmacies then provided an identical set of prescription labels which were compared to the initial computerised prescribing instructions.

Results

A significant number of prescription item labels (15%) contained pharmacy additions to the original prescribing instructions. All of these were meal associations.

Conclusions

Prescriptions are a means of precise communication between a prescriber and a pharmacy. Better communication between prescriber and patient via the pharmacist would be facilitated by standardisation of auxiliary labelling, regular updates of labelling instructions, and more prescriber awareness of auxiliary labelling processes.

Key Words

Auxiliary, prescription, labels

(NZFP 2001; 28:411–414)

Introduction

Prescriptions can be viewed as a means of precise communication between a prescriber and a pharmacy. Often a clinician expects what they have written on the prescription to appear verbatim on the label. It is this author's clinical impression, when presented with medication enquiries, that a number of additions have occurred, not all of which are useful and some directly against the prescriber's intent. This paper examines pharmacy additions over a three month period in a Whangarei general practice.

Methods

Advice for this study was received in 1997 from the local branch chairman of the NZMA, and the manuscript processes reviewed (May 2001) as suitable by Dr Tim Dare, a current member of the Auckland Ethics Committee.

A list was created of all general practice patients registered with Dr Shane Reti, general practitioner, Whangarei, who received a consultation in a three month prescribing period between 1 October 1997 and 31 December 1997. The general practice is an urban general practice, with the study excluding special interest dermatology and marae clinic patients accounting for 30% of the workload. Prior consent was obtained from the patient to computer enter their regular nominated pharmacy if one existed. Each nominated pharmacy then received a list of the patients consulted with a request made to supply an identical set of medication labels to that which the patient received in the consulting period. For purposes of the trial, the pharmacist was not aware of the study, and the doctor did not alter his prescribing habits in any way. Patients with no nominated pharmacy were excluded from the study. The basic instruction set on each label was defined as having three components, 'Name and Strength', 'Frequency', and 'Other' items. The other items included prescriber instructions on timings e.g. mane, associations e.g. with food, and purposes e.g. for diabetes. Storage instructions were not assessed as part of the basic instruction set. Each label was then compared to the original computer generated prescribing instructions, and divided into three groups:

- Group 1 – basic instruction set matches exactly
- Group 2 – basic instruction set matches but with further pharmacy additions
- Group 3 – basic instruction set does not match.

Medications from group 2 and the associated variations from the basic instruction set were recorded. A phone survey of all pharmacies involved showed 'after food' and 'with food' were considered the same. All but one considered the instruction 'before food' to represent at least 30–60 minutes before food, and so 'before food' and 'with food' were assessed as disparate.

Each pharmaceutical company then provided written data and evidence relating to food associations and their product.

Results

A total of 17 pharmacies were accessed which were all of the pharmacies in the Whangarei urban area. A total of 577 individual people were consulted over the three month period generating 738 invoiced interactions. Of the 294 people who had previously nominated a pharmacy and received a prescription, 222/294 (76%) presented their prescription to their nominated pharmacy. These interactions generated 857 prescription items over the 3/12 period, with 655/857 (76%) prescription labels falling within the study criterion.

Of the 655 assessed individual script items, there were 548/655 (OR 83%, 95% CI 81%–96%) correct group 1 items, a further 95/655 (OR 15%, 95% CI 12%–17%) group 2 pharmacy additions, and 12/655 (OR 2%, 95% CI 1%–3%) were group 3 incorrect basic instruction sets. All of the group 2 additions to the basic instruction set were making an association with food with two script items 2/95 (2%) before food, 3/95 (3%) without food, 82/95 (86%) with food, and 8/95 (9%) after food.

Table 1. Group 2 Individual Medication Additions

Most formulations were in tablet form. Where there were several formulations, the documentation provided demonstrated no difference in advice from one formulation to another except for Flagyl which was only in tablet form. Medications appearing several times were represented by more than one pharmacy, except Triamizde which was represented twice by the same pharmacy. Four medications, Glucophage, Flucloxacillin, Diamicron and Adalat received variations in advice from several pharmacies.

From the pharmaceutical companies, the main documented reason for food associated advice, related to absorption of the product either being maximised or hindered. This in turn has the potential to cause side effects specific to the primary mechanism of action. The other less frequent reason given, related to the non specific, directly irritant gastrointestinal side effects which could be potentially diminished with or without food.

Discussion

This study showed that a significant number 95/655 (15%) of basic prescribing instructions were added to by pharmacies. A medline search of the literature suggests that there is no New Zealand data examining pharmacy mediated prescription instruction additions.

The addition of prescribing instructions comes into the category of auxiliary labelling.

The auxiliary label is intended to provide a small amount of important supplementary information about the prescription.[1] In New Zealand, the Pharmacy Practice Handbook[2] addresses the issue of prescribing additions under the heading of *Cautionary and Advisory Labels*. The reasons for using these labels are given as follows: '1. to prevent or reduce adverse reactions from medicines and to warn of important side effects, 2. to ensure that the medicine is taken in the most effective manner'.

Cautionary and advisory labels should be regularly updated, and standardised into a single acceptable format

All of the additions in this study were auxiliary labelling associated with meals. *The Dispensing Guide*, published by the Pharmaceutical Society of New Zealand,[3] clarifies some of the meal associations by stating 'There is no perceived difference between 'immediately before', 'during', 'immediately after' or 'with food'.'

The guide also serves as the definitive source for Cautionary and Advisory Labelling detailing 13 preferred labelling styles in short annotated and full formats. Validation of the meal associated auxiliary labels arises such that where bioavailability is reduced by >20%, the advice is 'Label 3 – Take each dose on an empty stomach (short format) – one hour before OR two hours after food (long format)'. Those medicines causing GI upset in >5% are labelled 'Reference B – with food'.

This author believes that the practice of pharmacy additions to prescriptions in its current form has several drawbacks:

1. Patient confusion due to varying meal associations

In this study, variations existed between seven pharmacies for three separate medications resulting in the same medication being labelled either 'with food', 'before food' or 'after food' by different pharmacies. In all cases the computer shortened version was used which is unacceptably vague. Padron[4] similarly comments on automation and 'stilted language' on auxiliary labels. *The Dispensing Guide* is the recognised source of label advice in New Zealand.[5] However it is unclear on what evidence some of the meal associations are derived viz: the 5% threshold before Reference B ('with food'), and the potential for confusion when using the short or long instructions. Review of

Key points

- 15% of basic prescribing instructions were added to by pharmacies.
- All of the additions in this study were auxiliary labelling associated with meals.
- The practice of pharmacy additions to prescriptions may lead to patient confusion due to varying meal associations.
- Uncontrolled additions to medication labelling could increase the ad hoc use of the medication label as a general marketing or inappropriate health marketing tool.

Table 1. Group 2 Individual Medication Additions

Medication	Label frequency	No of pharmacies	Added pharmacy advice
Adalat (Bayer)	6	4	5 with and 1 after food
Allopurinol (Glaxo)	7	5	with food
Augmentin (Douglas)	22	9	with food
Bactrim (Roche)	1	1	after food
Betnesol (Glaxo)	1	1	after food
Bezalip (Roche)	1	1	with food
Buscopan (Boehringer)	1	1	before food
Capoten (Bristol Myers)	1	1	without food
Daonil (Aventis)	1	1	with food
Diamicron (Servier)	3	3	2 after food and 1 with food
Digoxin (Glaxo)	5	3	with food
Doxycycline (Douglas)	11	6	with food
Dynacirc (Novartis)	1	1	with food
Erythromycin (Pacific)	1	1	with food
Ferrograd (Abbott)	2	2	with food
Flagyl (Aventis)	1	1	after food
Flucloxacillin (Douglas)	2	2	1 without and 1 before food
Glucophage (Pacific)	7	6	5 with and 2 after food
Isoptin (Knoll)	3	3	with food
Lamisil (Novartis)	1	1	with food
Minocycline (Wyeth)	1	1	with food
Nystatin (Bristol Myers)	1	1	after food
Ponstan (Parke Davis)	2	2	with food
Prednisone (Apotex)	5	4	with food
Semi Daonil (Aventis)	1	1	with food
Slow K (Novartis)	2	2	with food
Surgam (Aventis)	1	1	after food
Tamoxifen (Douglas)	2	2	with food
Triamizide (Pacific)	2	1	with food

the labelling advice occurs approximately every two years. It is this author's opinion that cautionary and advisory labels should be regularly updated, and standardised into a single acceptable format.

2. Potential loss of compliance due to infrequent meal activities

The Dispensing Guide comments, 'The timing of medication, so that it is taken at the same time as, or immediately after, a meal or snack, provides an excellent aid to compliance.' Several studies have demonstrated increased compliance of medication-taking by association with regular daily activities.[6,7] This presupposes that such an activity occurs and is regular for each patient.

Where meal activities occur infrequently or not at all, due to say irregular hours e.g. shift workers, business people or poor socio-economic situations, then such advice may ultimately end up decreasing compliance. This argument may resolve to balancing issues of compliance against side effects. It is this author's view that auxiliary instructions should be discussed and negotiated in the context of each patient's particular circumstances at each point of contact.

3. Added instruction contradictory to prescriber's wider view intentions

The prescribing practitioner, having awareness of overall patient-family context, may consider a potential side effect unlikely or on balance less serious than the problem at hand. The prescriber may deliberately not associate a medication with an eating activity. Pharmacy additions may therefore actively act against the prescribers intentions. *The Dispensing Guide* appropriately comments, 'Similarly to improve compliance or reduce side effects some medicines may be dosed in a manner which accounts for a reduced oral availability when taken with food.' One response to this issue may be at a prescriber's education level with use of the little utilised annotation NCL (no cautionary label). Another would be for prescribers' computerised instructions to include auxiliary advice which could then be specifically changed at prescriber level.

> Auxiliary instructions should be discussed and negotiated in the context of each patients particular circumstances at each point of contact

4. Encourages ad hoc additions to prescription labels

There is general agreement in the literature for a label to have a basic minimum instruction set. It is the area over and above this that less agreement occurs.[8] Whilst there is a place for well-defined auxiliary instructions, the ad hoc addition of other messages requires much greater scrutiny. Uncontrolled additions to medication labelling could increase the ad hoc use of the medication label as a general marketing or inappropriate health marketing tool. One set of prescribing labels contained the message 'We advise a cervical smear test three yearly'. This sort of advice should remain with practitioners experienced in this area. The Medicines Regulations[9] state what must appear on a label, but are relatively vague and open-ended as to what should not appear. A code of ethics might encompass this issue and further clarification of acceptable and unacceptable labelling practices is warranted.

To safely and correctly maximise the advantages of auxiliary labelling may require behaviour modification at the prescriber level also. Some actions that might achieve this are:

1. Greater awareness and use of the NCL annotation.
2. Verbal confirmation of instructions that might be added.
3. Standing orders of instructions that can or cannot be added for each practitioner.
4. Computerised addition of the auxiliary labelling instructions at prescriber level which could then be amended as required.

Overall, it is the opinion of this author that medication labels should only represent what was originally written by the prescriber unless otherwise negotiated and discussed. The following items are put forward as discussion points to address this issue:

Discussion points for default pharmacy additions to prescriptions

1. Standardisation and regular updating of dispensing instructions.
2. Standardisation of cautionary and advisory label formats.
3. Greater prescriber awareness and use of the NCL annotation.
4. Addition of computerised auxiliary labelling instructions at prescriber level.
5. Regulation of the use of the prescription label as a health message delivery mechanism and general marketing tool.

Acknowledgements

Dr Ray Littler, Centre for Applied Statistics, University of Waikato, for the statistical assessment. The pharmacies, pharmaceutical companies and the Pharmaceutical Society of New Zealand who contributed information.

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