IT in practice: how “smart” packaging can help with medication adherence

Medication adherence, or compliance, is a problem. It has been estimated that between 20 and 50 per cent of patients are not adherent to their medication regimens and therefore do not receive the medicines they have been prescribed. Furthermore, a recent systematic review of medicines management suggests that only 4 to 21 per cent of patients are receiving the optimum benefit from their medicines, and adherence is an important factor in this.

The many reasons for non-adherence include: patients forgetting to take their medicines, off-putting side effects, a lack of tangible efficacy of the medication, greater than once daily frequency of administration, inability to understand complex dosing instructions, and patients exercising their prerogative of choice for a variety of personal or social reasons.

However, regardless of the reason, pharmacists are all too familiar with the end results — patients who suffer because they are not taking a prescribed medicine and excessive amounts of wasted medicines. The cost of non-adherence, however, is much more than the cost of not taking the medicine. It encompasses the cost of the disease not being treated, in terms of working days lost and reduction in quality of life, with associated costs of acute treatment and hospital admission. Non-adherence is a major and far-reaching problem.

Smart pack technologies

Technologies are now available that enable adherence monitoring. Were these to be implemented, not only would they improve adherence, but they would also have far-reaching implications for pharmacy practice. One such technology is the “smart” pack, where a medicine blister pack has a microchip incorporated into it, to enable the capture of medicines use-related data. Such a device can record when a medicine is taken or administered; give a reminder when the next dose is due (pack beeps at the required time); provide other features, such as expiry date warning, storage conditions monitoring and tamper alerts. The device can also record responses to simple monitoring questions following each dose, for example, “is your blood sugar normal?” (yes/no), “how do you feel?” (Lickert scale responses).

Data from these devices could be downloaded to a mobile telephone or other reading software to build up a record of individual patient adherence data, which could be used as a prompt for patient counselling by healthcare professionals.

Given the widespread use of blister packaging for solid dose forms, this type of technology has the potential to become commonplace once device manufacturing costs decrease and technical standards are available to support them.

Adherence monitoring devices

A number of electronic adherence monitoring devices have been developed. Pharmacists may have come across the Aardex MEMS device, which has been trialled extensively in the UK. This device records when the cap is removed by the patient. However, this does not necessarily mean the patient has taken a dose, therefore limiting its usefulness.

“Smart” packs, where a blister pack has a microchip to record information about the use of the medicine and gather adherence data, are being developed by organisations such as Cypak, and Stora Enso.

However, there is a need for a data standard to enable the storage and communication of data generated by “smart” devices. Lack of standard datasets has in the past been identified as a major factor for the lack of widespread interface between medical devices and electronic prescribing systems.

Worldwide data standard

The Continua Alliance, a consortium of device and packaging manufacturers, pharmaceutical companies, software vendors and hardware/IT services providers operating in 189 countries, has developed a worldwide standard data model for electronic medication adherence devices, with an IEEE (Institute of Electrical and Electronics Engineers) accreditation. This world dat a standard (IEEE Std 11073-10472-2010) was published in March 2010. It is an open standard, which allows any device manufacturer to join and adopt the standard. This means that the dataset can be adopted to enable electronic adherence data collection in a variety of treatment presentations, for example, injectables and inhalers as well as blister packs.

It also means that the adoption of the standard is not adversely affected by major changes in the technology market place.

The world data standard for these technologies is significant because it will allow smart pack manufacturers to compete with each other on features, rather than on technical standards. This has two major implications:

• The technical interoperability of these devices is assured, so health providers can concentrate on selecting the best device to meet the required patient care objectives
• The data can be shared between different healthcare record systems and, therefore, different health professional groups

Several features are enabled by Std 11073-10472-2010. The core feature is recording a medicine administration event. Optional features include: confirming correct usage of a medicine, subjective patient impressions at the time of administration (how does the patient feel?); storage conditions monitoring; anti-tamper mechanisms; expiry date warnings; and medicine administration reminders.

Other areas being considered are interface links with monitoring devices (blood pressure or blood glucose monitoring). At present, there is no plan to include a drug nomenclature in the devices, since development and implementation of an appropriate drug nomenclature standard for these devices would slow the development and adoption of an overall standard.

Impact on healthcare systems

Although the technologies exist and a data standard is available, the implications of their...
The Cypak electronic blister pack

The Cypak electronic blister pack was developed for the pharmaceutical industry, as regulatory adoption happens at source in the production described above, there are costs associated with the implementation of back-end systems and change in workflow processes. There are also costs associated with the regulatory burden of using these devices. This is certainly an issue where device adoption happens at source in the pharmaceutical industry, as regulatory approval will be needed for each new pack.

However, there are likely to be some regulatory and professional issues if these devices are introduced further down the supply chain at the individual pharmacy operator level.

For example, Apotheker in Germany has industrialised the compliance packaging process, by packing medicines in such smart packs for distribution to local pharmacies. A similar model is used by health provider Kaiser Permanente in the US.

Pharmacists having more data on patients’ medicine-taking behaviours could put them in a position to address behaviour issues in a way that they have not been able to previously. Preliminary evidence of this potential change in practice has been shown in a study of the MEMS device in patients with diabetes.5 Feedback from the MEMS device gave more information on medicine-taking behaviour than manual pill-counting adherence monitoring, and enabled more patient education interventions, before resorting to pharmacological interventions. Pharmacists will, therefore, need good patient communication skills and may need to develop different approaches to communication about medicine-taking behaviour. This could be based on a coaching and mentoring approach.

Conclusion

These technologies are centred on the use of medicines, so it is essential that the pharmacy profession takes the lead on their implementation. It is to be hoped that pharmacists will be able to debate the issues concerning these technologies and form a consensus about their use before they are introduced by major healthcare providers.

References