

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

In this article, Stephen Goundrey-Smith describes how “smart” pack technology is developing and what it means for medication adherence monitoring. The impact on pharmacy practitioners and others is also discussed

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 regimens¹ 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,² 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,³ 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.⁴

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 data 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.

KEY POINTS

- Medication adherence is a major issue for patients in the UK and elsewhere
- Technologies are being developed to monitor adherence and now a worldwide data standard exists to support them, so their use is likely to increase
- New devices can provide data on individuals' medicine-taking behaviour and will have a major impact on the personalisation of healthcare and on pharmacy practice
- The pharmacy profession should take the lead

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 author

Stephen Goundrey-Smith MSc, MRPharmS, is a pharmaceutical informatics specialist with his own consultancy, SGS PharmaSolutions (e-mail sgspharma@hotmail.com)

implementation have not been fully considered by clinicians, health provider organisations or healthcare managers. The business model for adopting these technologies in future will vary around the world, depending on the locality and the healthcare system. It may be that, in some countries, smart packs will be used at source for packaging by the pharmaceutical industry. However in others, the technology might be deployed in the pharmacy, with community pharmacy staff packaging medicines into smart packs, just as they now dispense into compliance aids.

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.

The chief barrier to adoption of these devices is cost. Intelligent blister packs generally cost \$7.50 per unit for prototype use, and less than \$1 per unit in production. Cost savings are possible for bulk production of these devices, but the cost per unit is still a major limiting factor given the potentially high volume of use of these devices in any health economy. As well as the unit costs of 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.

The configuration of the software itself should not be a barrier to deployment of this technology. With the data standard, it will be possible to pre-program the smart pack based on the medicine packaged in it, or pharmacies could program the smart pack locally according to specific monitoring requirements or agreements with health commissioners.

Areas that will need special consideration should these technologies become more widespread are the issue of child safety and also the question of accessibility by patients with arthritis in their hands or similar disabilities.

Pharmacists leading the way

Given these technologies' potential to revolutionise pharmacy practice, it is vital that pharmacists are aware of them and are involved with commissioning and piloting services that use them. The health service and commercial pharmacy operators in both the primary care and secondary care sectors will undoubtedly be looking at how these devices could be used to improve the quality of patient care at the institutional level, and device manufacturers will be working with them to pilot these technologies. However, ultimately these technologies will have an impact on the working lives of pharmacists, and it is vital that pharmacists consider the implications.

Pharmacists have a key role in medicine adherence: they see patients more often than doctors about medication-related issues, and the use of "smart" packs would provide them with more data than have been available previously on which to base their decisions and advice to patients. Pharmacies are the ideal places for adherence to be assessed, because pharmacists are able to see the patient at the point of medicine supply. Pharmacists are also primarily involved in the issue of medicines waste, and will be the people most likely to see the medicines that a patient has not taken when they are returned to the pharmacy and thus will alerted to a potential adherence issue. Thirdly, pharmacies are a

place where monitoring technologies can be supplied (eg, blood pressure and blood glucose monitoring devices), and these have a place in measuring and supporting adherence to treatment.

However, there are issues associated with smart pack technology that will determine how these technologies may be used at the point of patient care, and which pharmacists will be closely involved with. The first is the ethical issue concerning consent

for the use of the technology. Since the device obtains data from patients, as they use their medicines, and makes it potentially available to a third party, from an ethical perspective patients will need to give their consent for the smart pack to be used and the data to be gathered. They may also need to give specific consent for the data to be made available to a particular healthcare professional. Depending on the healthcare economy, payers may insist on consent being obtained in a particular way.

Another issue is that of acceptability and usability. Patients will prefer using a pack that does not look like a medicines pack and that will enable medicines use data to be collected in a way that is as least disruptive as possible to the patient's usual routine. For this reason, the precise physical design of these adherence monitoring packs will be critical to their widespread adoption.

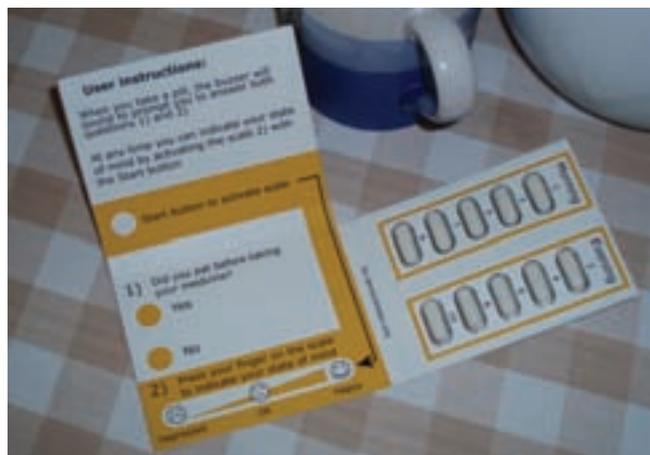
Pharmacists having more data on patients' medicine-taking behaviours could put them in a position to address behavioural issues in a way that they have not been able to previously. Preliminary evidence of this potential change in practice has been shown in a study of the MEMS device in patients with 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

- 1 Kripalani S, Yao X, Haynes RB. Interventions to enhance medication adherence in chronic medical conditions: a systematic review. *Archives of Internal Medicine* 2007;167:540–50.
- 2 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care—mapping the problem, working to a solution: a systematic review of the literature. *BMC Medicine* 2009;7:50.
- 3 Saini SD, Schoenfeld P, Kaulback K, Dubinsky MC. Effect of medication dosing frequency on adherence in chronic diseases. *American Journal of Managed Care* 2009;15:22–33.
- 4 Goundrey-Smith SJ. *Principles of electronic prescribing*. Springer; 2008, p142.
- 5 Matsuyama JR, Mason BJ, Jue SG. Pharmacists' interventions using an electronic medication monitoring device's adherence data versus pill counts. *Annals of Pharmacotherapy* 1993;27:851–5.



The Cypak electronic blister pack