

The “NO TEARS” diabetes medication review

Jane Diggle

A medication review offers an ideal opportunity to critically examine a person’s medicines with the individual, with the goal of ensuring that the treatment regimen is effective, safe and acceptable to the person. It can give individuals the opportunity to express any concerns they have about their treatment and should help to: improve medication concordance and patient satisfaction; reduce unnecessary medicine wastage; and, hopefully, optimise health outcomes. A medication review should be a key element of every diabetes consultation and, in this article, the author describes various strategies to support more effective diabetes medication reviews, with a focus on the “NO TEARS” tool.

Publisher’s note

This article was originally published in the UK in *Diabetes & Primary Care* 17: 125–30. It has been reproduced with kind permission from the author.

The Australian context

Cik Yin Lee, Pharmacist at Frost’s Pharmacy, Rosanna, Vic, and Research Fellow at Royal District Nursing Service, St Kilda, Vic; Rajna Ogrin, Senior Research Fellow at Royal District Nursing Service, St Kilda, Vic.

With the progression of diabetes, its effective management will require the addition of pharmacotherapy to achieve optimal outcomes, with intensification of therapy over time likely in many cases. Furthermore, people with diabetes may develop complications of the disease, as well as comorbidities common with ageing, necessitating the administration of a number of medications. There are a number of medication management system supports in Australia, called Medication Management Review (MMR) programs (Department of Health, 2014a; 2014b), similar to the UK Medicines Use Review services outlined in this article. The MMRs are provided by pharmacists, and they are funded by the Australian Government to support GPs to ensure their patients are taking the right medications for them, thereby increasing the likelihood of patient concordance with therapy, optimising the impact of the medicines and minimising the number of medication-related problems. The MMR programs currently available in Australia are as follows:

Home Medicines Review (HMR)

Developed for people living in the community, the HMR is a comprehensive clinical assessment involving a consumer living at home in the community, an accredited pharmacist, their GP and their regular community pharmacy. The aim of this program is to identify, resolve and prevent drug-related problems.

Residential Medication Management Review (RMMR)

A comprehensive clinical assessment provided to a permanent resident of an Australian Government-funded residential care facility by an accredited pharmacist. Like the HMR, the aim of the RMMR program is to identify, resolve and prevent drug-related problems.

Medication Use Review (MedsCheck) and Diabetes Medication Management (Diabetes MedsCheck)

These services are structured pharmacy services,

Citation: Diggle J (2016) The “NO TEARS” diabetes medication review. *Diabetes & Primary Care Australia* 1: 65–72

Article points

1. There are many issues relating to medication, including the need for optimisation of therapy over time and the role of medicines in risk reduction, that need to be discussed in helping people with diabetes to set personalised goals and agree realistic expectations.
2. Medication reviews provide an opportunity to assess the efficacy, acceptability, safety and tolerability of drugs, which should improve medication concordance, enhance patient satisfaction, reduce unnecessary wastage of medicines and maximise the benefit of the interventions.
3. Using tools such as “NO TEARS” should help to structure the review process and support healthcare professionals in making the most efficient use of limited time.

Key words

- Medication review
- NO TEARS
- Patient involvement

Author

Jane Diggle is a Practice Nurse with a particular interest in diabetes. Jane works in the Wakefield District, West Yorkshire, UK.

“Having a tool that is similar to the UK’s ‘NO TEARS’ medicines review strategy may help to improve the provision of medication review services within primary care.”

involving face-to-face consultations between the pharmacist and consumer in the community. These services are designed to sit between *ad hoc* medication reviews that occur at the time of dispensing and HMRs. They are conducted by a registered pharmacist in the pharmacy’s designated consultation area (Department of Health, 2014b).

These services are not comprehensive clinical reviews in the manner of the HMR and are limited by the information available at the time of the consultation. They aim to facilitate discussion with the consumer focusing on improving medicine use through education, self-management and medication adherence strategies, with the goal of improved health outcomes.

These services include an additional focus to assist consumers with the management of type 2 diabetes. For example:

- They provide access to the necessary information and skills to self-manage their disease.
- They improve consumers’ use of blood glucose monitoring devices through training and education.
- They achieve greater blood glucose control through encouraging medication adherence and adopting lifestyle choices that achieve the goals of optimum diabetic management (e.g. smoking cessation, increasing exercise and minimising alcohol consumption).

To be eligible to receive Diabetes MedsCheck, consumer criteria are as follows:

- Diagnosed with type 2 diabetes within the past 12 months or their type 2 diabetes is less than ideally controlled, **and**
- Is unable to gain timely access to existing diabetes education/health services in their community.

Unfortunately, the uptake of MMR programs in the Australian community is low, despite there being many individuals at risk of medication-related problems who would benefit from the services. For example, the uptake of HMR within the at-risk community is less than 10% (Lee et al, 2010). The main reasons identified for the low

uptake of HMR was low referral by GPs and the poor awareness of the availability of HMR services among patients (Lee et al, 2012).

Similarly, there is a low uptake of Diabetes MedsCheck services in the community. For example in 2012, the population eligible for Diabetes MedsCheck was estimated to be 580 000. However, less than a third of the 286 pharmacies registered for delivering the service claimed for the service, and only 149 Diabetes MedsCheck service were provided (Deloitte Access Economics, 2012). Low uptake was due to the inability to integrate service delivery into the pharmacists’ daily workflow and inadequate staffing resources (Deloitte Access Economics, 2012).

Having a tool that is similar to the UK’s “NO TEARS” medicines review strategy may help to improve the provision of medication review services within primary care, particularly if undertaken collaboratively by GPs, pharmacists and others involved in providing diabetes care. Although there are similar guidelines for Australian pharmacists to provide the MMR services (e.g. Pharmaceutical Society of Australia, 2011; 2012), the “NO TEARS” strategy is a simpler tool that provides a comprehensive checklist of items that prompts health professionals to consider several key elements when providing the medication review service.

Deloitte Access Economics (2012) *Evaluation of the MedsCheck and Diabetes MedsCheck Pilot Program*. DH, Canberra, ACT. Available at: <http://bit.ly/1Tct0jZ> (accessed 29.01.16)

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Lifestyle factors and non-medicinal interventions are a key aspect of effective diabetes management; nevertheless, most people with diabetes will progress to require medication to maintain or improve control of their condition. With there now being seven classes of oral blood-glucose-lowering drugs to choose from, along with several glucagon-like peptide-1 receptor agonists and many different types of insulin, the pharmacological management of type 2 diabetes has become complex. Furthermore, diabetes prescribing now accounts for nearly 10% of all prescription costs. In England, during the financial year 2013–14, there were just over 45 million items prescribed to treat diabetes at a cost of £803 million (Health and Social Care Information Centre, 2014).

The progressive nature of the type 2 diabetes means that blood-glucose-lowering therapies often need to be intensified over time. In addition to antihyperglycaemic agents, medication is often indicated to reduce cardiovascular risk, with many people being prescribed drugs for hypertension and dyslipidaemia. Some individuals also develop diabetes-related complications, including peripheral neuropathy and erectile dysfunction, which may necessitate drug therapy. Common comorbidities such as depression may also need to be managed pharmacologically. In short, the potential pill burden for many people with diabetes is considerable.

Treatment challenges

Despite strong evidence to support the benefits of good diabetes management, especially early in the condition (Holman et al, 2008), and an abundance of evidence-based guidance to which clinicians are encouraged to refer (e.g. SIGN, 2010; Inzucchi et al, 2015; NICE, 2015), in practice we are guilty of “clinical inertia” – favouring an approach which fails to intensify therapies in a timely fashion (Heine et al, 2006). People with type 2 diabetes may, therefore, have sub-optimal blood glucose control for prolonged periods and be placed at an increased risk of developing complications.

Poor medication concordance is another major obstacle to achieving maximum benefit with drug treatments. It has been estimated that only

around half of the medicines prescribed for long-term conditions are actually taken (Department of Health, 2001). Furthermore, over a decade ago, DARTS (the Diabetes Audit and Research Tayside Study; Donnan et al, 2002) demonstrated very poor concordance with oral hypoglycaemic drug therapy. Of the 2920 people included in the study, “adequate adherence” (defined as $\geq 90\%$) was found in only around one-third of those prescribed either sulphonylurea or metformin alone. The association between poor adherence and daily number of tablets was linear and statistically significant.

Also pertinent here, from a health system perspective, is the issue of wastage. The gross annual cost to the NHS of medicines wastage in England has been estimated to be around £300 million (York Health Economics Consortium and School of Pharmacy – University of London, 2009).

The reasons for poor medication concordance are highly complex, with many potential influencing factors, including denial over the diagnosis, forgetfulness, absence of symptoms and concerns about side effects.

The stories about medications that people encounter in newspapers, on television or on the Internet can, alongside advice and opinion from family and friends, have a considerable impact on attitudes regarding medication; but, as we all know, such information may be unreliable and inaccurate. The medication review is an ideal opportunity to dispel any myths that proliferate in this way.

Patient involvement in treatment decisions

Current health policy advocates greater patient involvement in decisions about treatment, hence the slogan “No decision about me, without me” (Department of Health, 2010). It has been suggested that increasing the involvement of patients in prescribing decisions and supporting them in taking their medicines will lead to improvements in patient safety, health outcomes and satisfaction with care (Shaw, 2002).

The extent to which an individual wishes to engage in this process will vary, but it is something we should offer to every patient. People can only make informed decisions if they have a good understanding of their condition and the

Page points

1. Despite strong evidence to support the benefits of good diabetes management, in practice we can be guilty of “clinical inertia” – favouring an approach that fails to intensify therapies in a timely fashion.
2. Current health policy advocates greater patient involvement in decisions about treatment, and it is believed that this will lead to improvements in patient safety, health outcomes and satisfaction with care.

Box 1. Some of the key factors for healthcare professionals to take into account during a medication review.

- The medication prescribed being appropriate for the individual’s needs
- The medication being effective for the individual
- The cost-effectiveness of the choice
- Any monitoring that is required having been carried out
- Drug interactions
- Side effects
- Adherence – are they taking it?
- Concordance – do they want to take it?
- Concomitant use of over-the-counter or complementary medicines
- Lifestyle and non-medical interventions
- The current evidence base (benefit versus risk)
- Changes to the person’s condition and the development of any comorbidities that may impact current treatment

therapies that are being prescribed to manage it. The fascinating *Diabetes Information Jigsaw Report* investigated what people with diabetes understood about their condition and how it was treated and revealed that one in three people did not know what their medication was for or how

Box 2. Examples of questions that the “Ask about Medicines” campaign suggested patients might like to ask their healthcare professional.

- Why do I need to start taking medicines?
- When and how should I take them?
- What will happen if I don’t take these medicines?
- Why is it important to take these tablets?
- Will these cure my diabetes?
- Do I have to pay for my prescriptions?
- What different tablets are available?
- What are the side effects I should look out for?
- What should I do if I get any of the side effects?
- Are there any alternatives to these tablets?
- Is it alright to take these tablets with the other tablets I am already taking?
- What happens if the tablets don’t work for me?
- Will I need to take other tablets as well?
- Do I have to have any tests to see if the tablets are working?

to take it (Browne et al, 2000). One of the most eye-opening findings was that just 10% of those taking a sulphonylurea were aware that it could cause hypoglycaemia. According to Diabetes UK, not all people with diabetes wish to undertake formal education courses; nevertheless, it is hugely disappointing that only 12% of people newly diagnosed with type 2 diabetes were offered structured education in 2011–12 (Diabetes UK, 2014).

Markers of poor concordance

Failure to order sufficient quantity of medication or failure to collect prescriptions on time, or indeed at all, provides evidence of poor medication concordance and is worth checking as part of the review process. However, it is important to recognise that collection of a prescription does not guarantee its use.

Medication reviews

NICE (2011) recommends that “people with diabetes agree with their healthcare professional to start, review and stop medications to lower blood glucose, blood pressure and blood lipids,” as part of its quality standard for diabetes in adults. One aspect of this process is the measurement of the proportion of people with diabetes who have received a medication review in the previous 12 month period.

The medication review has been defined as “a structured, critical examination of a patient’s medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste” (Shaw, 2002). Up until 2012, there was a “medication review” indicator within the Quality and Outcomes Framework (QOF), with a requirement to undertake a medication review every 15 months for all patients being prescribed repeat medicines. Despite being “retired” as a QOF indicator, most GP clinical systems continue to provide prompts to carry out medicine reviews.

The underlying principles of such a review include the following (Shaw, 2002).

- All individuals should have a chance to raise questions and highlight problems about their medicines.

- Medication review seeks to optimise the impact of treatment for the individual.
- The review should be undertaken in a systematic way, by a competent person.
- Any changes resulting from the review should be agreed with the individual.
- The review should be documented in the individual’s notes.
- The impact of any change should be monitored.

During the review, the healthcare professional will be checking, among other things, the factors presented in *Box 1*. The quantity and breadth of items presented in *Box 1* illustrates the fact that a great deal needs to be covered in the relatively short time-frame of a typical diabetes consultation, and any strategies to make the most efficient use of the time would thus be useful. As part of this, I believe that we could do a lot more to help individuals prepare for their medication review.

The “Ask about Medicines” campaign ran from 2003 to 2009 and its mission was to encourage better communication between patients and their health professionals (Shaw, 2009). Central to the campaign were some suggested questions that patients might like to ask their healthcare professional (examples appear in *Box 2*). Following on from this campaign, a guide specific to diabetes medicines was produced and may still be downloaded from <http://bit.ly/1HfjW75> (accessed 14.05.15).

If such a resource were given to individuals prior to their review, they could formulate pertinent questions about their medication and be better prepared. The healthcare professional could then concentrate effort on what really matters to the individual.

Another useful resource is the “NO TEARS” tool, which was designed to provide a framework upon which to structure a medication review (Lewis, 2004). As the focus of this paper, this tool is described in detail below.

The “NO TEARS” tool

The “NO TEARS” tool can be used as a mental prompt, but it also has sufficient flexibility that it can be tailored to suit the individual practitioner’s

particular consulting style. Its purpose is to maximise the value of a medication review within the confines of a 10-minute consultation. Given the increasing complexities of diabetes management, this time constraint presents a real challenge; nevertheless, this is a useful tool providing a structure for diabetes medication reviews. The name “NO TEARS” is a mnemonic (see *Box 3*), and the seven components are described below in the context of diabetes, based on my own clinical experience.

Box 3. The “NO TEARS” medicines review strategy (adapted from Lewis, 2004).

Need and indication

- Does the person know why each drug is being taken?
- Is each drug still needed?
- Is the diagnosis refuted?
- Is the dose appropriate?
- Was long-term therapy intended?
- Would non-pharmacological treatment be better?

Open questions

- Allows patients to express views
- Helps to reveal any problems they may have

Tests and monitoring

- Assess disease control
- Are any conditions undertreated?
- Use an appropriate reference for monitoring advice (e.g. the British National Formulary)

Evidence and guidelines

- Has the evidence base changed since initiating drug?
- Are any drugs now deemed “less suitable”?
- Is dose appropriate (e.g. frail and elderly)?
- Are other investigations now advised (e.g. echocardiography)?

Adverse events

- Are there any side effects?
- Are any over-the-counter or complementary medicines being taken?
- Check for interactions, duplicates or contraindications
- Don’t misinterpret an adverse reaction as a new medical condition

Risk reduction or prevention

- Opportunistic screening
- Risk reduction (e.g. falls) – are drugs optimised to reduce the risks?

Simplification and switches

- Can treatment be simplified?
- Does the person know which treatments are most important?
- Explain any switches related to cost-effectiveness

Page points

1. One of the most important considerations in medication reviews is why each drug is being prescribed and whether the patient benefits from taking it.
2. Encouraging patients to be more actively involved in prescribing decisions by asking open questions may improve concordance.
3. It is useful to use several methods to assess the effectiveness of diabetes medications, these include biochemical testing, as well as asking about symptom relief.

N – Need and indication

One of the most important considerations in medicines reviews is why each drug is being prescribed and whether the patient benefits from taking it. This might involve confirmation that the correct diagnosis was made in the first place (e.g. was hypertension diagnosed based on a blood pressure reflecting the evidence base?).

The rationale for prescribing each drug should be questioned (e.g. is it for symptom control or is it to reduce long-term complications?) so that efficacy may be measured against expected outcome. It is important to reassess ongoing need and determine whether circumstances have changed (e.g. weight loss may alter treatment requirements and drug doses). It is an opportunity to consider lifestyle, changes to which can make a significant difference to long-term outcomes. Sometimes people will try to improve lifestyle in order to reduce medication, and seeing a positive outcome can be a powerful motivator.

Some drugs are meant to be used for a fixed period (e.g. dual antiplatelet therapy post-myocardial infarction) but may not have been stopped. Conversely, certain medications are stopped prior to procedures. For example, it is recommended that metformin be suspended before intravascular administration of iodinated contrast agents and not recommenced earlier than 48 hours after the test (electronic Medicines Compendium, 2015). Similarly, metformin tends to be stopped during the acute phase of an illness – owing, for instance, to the risk of lactic acidosis in people taking this drug who experience an acute worsening of renal function (electronic Medicines Compendium, 2015) – but it is worth checking that it has subsequently been re-instated.

People with diabetes can develop other conditions, or there may have been a deterioration of pre-existing conditions, which can affect management or the ongoing safety of the drugs being prescribed. Recent hospital admissions and outpatient appointments may have resulted in changes to medication or the addition of new drugs that may not be compatible with current medications.

O – Open questions

Individuals’ understanding of their treatment, as well as their health beliefs and attitudes, will influence whether or not they take prescribed medications, and so this is an important area to explore.

Open questions like those listed below are useful because they encourage a person to express their views.

- What do you think about your medications?
- What are you taking regularly?
- What other over-the-counter medications do you take?
- How and when do you take your medications?
- Do you know why you are taking *X*?
- Have you any concerns or worries about taking your medication?

Encouraging patients to be more actively involved in prescribing decisions may improve concordance. Asking, as non-judgementally as possible, whether they miss any medications, or have difficulties accessing their prescription, opening the packaging or swallowing tablets, is also useful (this may require some closed questions). Other areas that may be useful to explore with individuals include: who collects their prescriptions; and whether a dosette box might be beneficial.

T – Tests and monitoring

There are several ways of assessing the effectiveness of diabetes medications. It may be appropriate to ask about symptom relief for those who were experiencing symptoms. However, for many, the primary goal of therapy is to reduce the risk of developing complications rather than symptom control. HbA_{1c} is often regarded as the definitive measure of good glycaemic control and it may be used to assess a person’s response to a new therapy and for gauging ongoing efficacy. The HbA_{1c} is, however, a composite measure reflecting both fasting and postprandial hyperglycaemia, and so, in certain circumstances and for certain blood-glucose-lowering therapies (including insulin), it may be more appropriate to check the individual’s own blood glucose monitoring record.

A periodic review of other parameters is vital, including renal and liver function, as these affect

the metabolism of oral agents and thus have a potential impact on safety (e.g. Scheen, 2014).

Agreeing realistic targets and sharing results with individuals can help them see the benefits of taking certain medications and can help to reinforce ongoing medication concordance.

E – Evidence and guidelines

The evidence base in medicine is constantly evolving. As new evidence emerges, treatment recommendations may change, and so it is essential to consider whether the approach is still in line with current guidelines or whether any of the prescribed drugs are now considered to be less suitable and if the most appropriate doses are being used.

A – Adverse events

Most drugs are associated with potential side effects (adverse reactions to medicines are implicated in 5–17% of hospital admissions [Zhang et al, 2009]), and where these are troublesome, people may decide to stop taking them or to take them less often than recommended. Individuals should be asked about side effects and given strategies to deal with them, such as adjusting doses, switching to another medicine with a different side-effect profile, or even changing the timing of taking medicines. Other drugs may be prescribed to mitigate side effects, although it may be more appropriate to consider alternatives that are better tolerated or better suited to an individual. Preparing people for likely side effects is also a useful strategy.

Some diabetes medications are associated with well-recognised risks, such as that of hypoglycaemia with sulphonylureas and insulin. With regard to hypos, it is essential that individuals know how to minimise the risk, how to recognise signs and symptoms, and how to manage episodes appropriately. The implications for driving and for certain occupations need to be discussed and documented.

R – Risk reduction or prevention

A key objective of diabetes treatment is to reduce the risk of developing complications. In the absence of troublesome symptoms, it can be difficult to convey the value of taking

medications now to prevent potential problems in the future (Ortendahl and Fries, 2006). Healthcare professionals need to translate raw data from clinical trials or risk calculators into information that individuals can understand and use to make an informed choice. This involves helping them to decide if the benefits of a therapy outweigh all the possible known side effects or risks associated with the drug itself.

S – Simplification and switches

Keeping drug regimens simple helps to improve adherence and some regimens are unnecessarily complicated. Findings from the aforementioned DARTS (Donnan et al, 2002) suggested the following potential ways to improve medication concordance: simplifying drug regimens; minimising tablet counts; and using once-daily, modified-release or fixed-combination preparations. That is not to say that simplifying and switching is without issues, but it is worth considering, and in some cases there are substantial potential benefits.

Conclusion

There are many issues relating to medication that we need to convey to people with diabetes, including the need for optimisation of therapy over time and the role of medicines in risk reduction. We have to identify barriers related to medication-taking and help people to set personalised goals and agree realistic expectations.

The NHS spends a huge amount on medication, and diabetes is a condition which tends to require multiple medicines. The evidence suggests that medication concordance is a particular problem for those with long-term conditions, and, given the current economic constraints, it is imperative that we make the most efficient use of scarce resource. Medication reviews provide an opportunity to assess the efficacy, acceptability, safety and tolerability of drugs, which should improve medication concordance, enhance patient satisfaction, reduce unnecessary wastage of medicines and maximise the benefit of the interventions.

Improving how we help patients prepare for their medication review and using tools like

Page points

1. Healthcare professionals need to translate raw data from clinical trials or risk calculators into information that individuals can understand and use to make informed choices.
2. Keeping drug regimens simple helps to improve adherence and some regimens are unnecessarily complicated.
3. It is important to identify barriers related to medication-taking and help people to set personalised goals and agree realistic expectations.

Further information from the UK

A Guide to Medicines Review
(National Prescribing Centre)

<http://bit.ly/1MHyYE6>

A Single Competency Framework for all Prescribers
(National Prescribing Centre)

<http://bit.ly/1GJWGPO>

“NO TEARS” should help to structure the process and support healthcare professionals in making the most efficient use of limited time. ■

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