Appendix 1. Sources of information for patients and clinicians

For Patients

For drug information leaflets which patients can print out:
http://emc.medicines.org.uk, http://patient.co.uk and http://cks.library.nhs.uk

For useful information and links to other websites: http://www.askaboutmedicines.org

For professionals

Useful sites for health professionals to get information on prescribing issues include:

- https://www.medicines.org.uk/emc/ which provides the UK approved information sheets for prescription medicines.
- Clinical Knowledge Summaries provide really useful information on prescribing as well as other aspects of managing conditions commonly seen in primary care http://cks.nice.org.uk/#?char=A
- All current UK Medicines Information Q&As can be found through the NICE Evidence Search searching in www.evidence.nhs.uk and filtering by type of information 'Evidence Summaries' and Source 'UKMi'. This site also has a link to the BNF another useful and reliable source of information, though you have to log into the website if using the online version (hence no links to BNF in this module).
- The Medicines and Healthcare Products Regulatory Agency's (MHRA) Drug Safety Update and the NHS Central Alert System provide information and advice to support the safer use of medicines relevant to your practice and alert you to safety information about medicines you prescribe.
- The National electronic Library for Medicines has extensive information on the safe, effective and efficient use of medicines.
- The National Prescribing Centre (now part of NICE) publishes a range of materials to help you improve the safety and clinical and cost effectiveness of your prescribing.
- The Electronic Medicines Compendium lists Summaries of Product Characteristics and Patient Information Leaflets[8].

Decision aids

The following websites contain patient decision aids for a range of topics:

- NHS Shared Decision Making (http://sdm.rightcare.nhs.uk/pda/)
- NHS England Patient Decision Aids
  http://www.england.nhs.uk/ourwork/pe/sdm/tools-sdm/pda/
  Patient UK Decision Aids (http://www.patient.co.uk/decision-aids)
  Ottawa Hospital Research Institute Decision Aids by Health Topic (http://decisionaid.ohri.ca/AZlist.html)

Other

Background reading on topics and conditions:

- GP Notebook (www.gpnotebook.co.uk)
- MedlinePlus (http://medlineplus.gov/)
- Lab Tests Online UK (www.labtestsonline.org.uk/)
- Links to www.bnf.org were not added to this module, as a password is required for access, making navigation difficult for some readers. However the website is useful.

Appendix 2. Key points for safe repeat prescribing[47]

Authorising repeat prescriptions:

- Only appropriately qualified prescribers should be allowed to put medications on repeat prescription
- An appropriate review date needs to be set taking account of the need for monitoring of therapeutic benefits and potential adverse effects.

Dealing with requests for repeat prescriptions:

- Patients need to know how the practice repeat prescription works, and what the rules are. Requests for repeat prescriptions in many practices are now made on-line
- Requests must be dealt with accurately, securely and within an agreed timeframe, e.g. 48 hours
- With paper-based systems, patients should be encouraged to use the repeat prescription request slip rather than giving oral requests.

Deciding if the repeat prescription should be generated:

- An administrative check needs to be done to determine:
  - is the drug on the repeat prescriptions list?
  - is the drug within its review date?
  - is the request earlier (or later) than expected?
- If in doubt, the responsible prescriber should be asked to make the decision about whether a further prescription should be generated.

Prescription production, signing and return to patient:

- Most repeat prescriptions are generated electronically and there are significant safety benefits to this
- A qualified prescriber needs to check that the prescription is safe (with reference to the patient's records where appropriate) before signing
- If a review is required the patient should be advised of this, and an appointment should be made.

Appendix 3. Calculating whether a statin is needed

QRisk and ASSIGN

QRISK2, which is validated for people up to age 84, is the only validated tool that has been identified which assesses CVD risk in people over 80.

ASSIGN is used in Scotland, however it uses pre-treatment BP levels and takes no account of co-existing CKD or AF. ASSIGN 2 is being developed (2015) but until then it is advised that, for patients on anti-hypertensives, one adds 20 mm Hg to the person's current BP.

Older patients

For people 85 years or older consider atorvastatin 20 mg, as statins may be of benefit in reducing the risk of non-fatal myocardial infarction, taking account of factors that may make treatment inappropriate[26].

NICE guidance acknowledges that few trials assessing cardiovascular outcomes have recruited many people older than 80 years, but states that the important effect of age on CVD risk suggests that all people in this group should be offered statin therapy.

However, there is no evidence to validate the CVD benefits and side-effects of statin therapy such as effect on muscle and renal function in this age group. Controversy also exists about the efficacy of statins in preventing or promoting other chronic diseases of ageing such as Parkinson's disease, or age-related macular degeneration[26]. Two recent systematic reviews found no evidence that statin therapy reduced cognitive decline in people with Alzheimer's or vascular dementia, nor do they have any effect on prevention of dementia[34],[35].

It has also been suggested that in the elderly, high cholesterol is not only normal but helpful, and that lowering it could cause a whole host of problems, from muscle wasting to neurological decline, accelerating the aging process, especially in Asians[44,45,46].

The Australian National Pharmacy Service recommends that statin prescribing in people aged over 75 years should be guided by the benefits and risks of treatment, lipid measures, clinical judgement about co-morbidities, patient preferences and life expectancy [27].

Decision-making aids

There are various aids that can be used to help people make their decision.

- NICE has one on-line, which is long and detailed:

www.nice.org.uk/guidance/cg181/resources/cg181-lipid-modification-update-patient-decision-aid2

- www.qintervention.org uses QRISK
- http://statindecisionaid.mayoclinic.org/ is very easy to use, doesn't use QRISK, but produces very easy-to-see smiley face charts[33].

It should be borne in mind that many of the same factors put people at risk of CVD and diabetes, so lifestyle changes are very important.

Risk of Diabetes

Statins may increase the risk of developing diabetes: see Box 6

Box 6. Do statins cause diabetes?

The recent Joint British Society consensus statement on CVD[28] states that for people on statins: "*there is a small increase in risk of developing diabetes, but the benefits of cholesterol-lowering greatly exceed any risk associated with diabetes*."

A recent systematic review of 14 primary prevention trials found that statin therapy increased diabetes by an absolute risk of 0.5% while reducing death by a similar amount[29]. 1 in 5 new cases of diabetes were actually caused by statins[29].

An analysis of the evidence surrounding statin prescribing found statins increased the relative risk of developing diabetes by 10% [30].

Two systematic reviews considered the effect of moderate versus intensive statin therapy on risk of developing diabetes[31.32].

- Both reviews reported that ***intensive*** statin therapy resulted in a greater increased risk of new onset diabetes compared to ***moderate*** dose statin therapy.
- One review reported that compared '*with **moderate**-dose statin therapy, the number needed to harm per year for **intensive**-dose statin therapy was 498 for new-onset diabetes*'[31].

The figures in Box 6 are hard for health professionals to understand and explain to patients, let alone for patients to grasp, especially in the context of a 10-minute consultation which may have to deal with several issues.

Controversies

The issue of mass prescribing of statins has generated a huge amount of controversy, especially in the BMJ. An editorial by Ben Goldacre stated that 'in broad terms, statins are cheap and more likely to do good than harm', but also mentions shortcomings of the data. On a population level, political and social change is

needed to facilitate the lifestyle changes which are likely to deliver large health benefits, well beyond lipid lowering[36].

Arguments about the medicalisation of thousands of people are fascinating, but ultimately it is the patient's decision. We can help them by using our clinical judgement and giving them the information they need, though in some cases (such as statins) where the experts disagree, it is impossible to give a black-and-white answer.