

CSM2020 - Agile Software Development Project

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1 Health System Monitoring

You are approached by a multi-disciplinary research team from Aberystwyth University, whose research efforts focus on the application of wearable technologies in health. After a series of discussions the research team, i.e., your customers, provided a set of descriptions of the main aspects of the desired software and its functionalities. The product, the end-users, and their roles are discussed in this section. A first interview/meeting with your customers to acquire further information, details and clarifications will soon be organised.

1.1 Medical Background

Diabetes mellitus is a group of metabolic diseases characterised by an elevated blood glucose concentration (i.e., hyperglycemia) as a result of defects in insulin secretion and/or an inability to use insulin. Sustained elevated blood glucose levels place patients at risk for microvascular and macrovascular diseases as well as neuropathies (peripheral and autonomic). Diabetes affects approximately 382 million adults worldwide, and is predicted to increase to 439 million adults by 2030. A sedentary lifestyle is considered as one of the major risk factors for diabetes and its complications.

The fundamental goal for the management of diabetes is glycemic control using diet, exercise, and, in many cases, medications such as insulin or oral hypoglycemic agents. Physical activity in particular is a key management tool for any type of diabetes and may assist in preventing difficult complications. Evidence show that regular exercise undertaken by individuals with Type 2 diabetes results in improved glucose tolerance, increased insulin sensitivity, and decreased HbA1C [7]. Regular exercise participation may also prevent or delay the transition to Type 2 diabetes for individuals with pre-diabetes at high risk for developing the disease [8]. Thus, all individuals with diabetes or pre-diabetes should be encouraged to be physically active to improve their health and life longevity.

When a patient is first diagnosed, normally, the general practitioner (GP) runs the initial tests in order to make a diagnosis. In most of the cases, medication is prescribed, and, as part of the treatment, the patient is asked to revisit for regular reviews. The National Institute for Health and Clinical Excellence (NICE) recommends that all people with diabetes should receive nine key test as described in [9]. These tests allow the GP to evaluate the progress of treatment and to make appropriate adjustments to the prescribed medication.

As stated previously, maintaining an appropriate level of physical activity is an effective strategy for diabetes management, therefore the GP may refer the patient to a rehabilitation centre. There, trained personnel evaluate the patient's physiological condition and advice on whether a training program is appropriate. The latter is a personalised exercise protocol, designed to improve quality of life and to speed up the patient's treatment. It is an iterative, longitudinal process where a rehabilitation doctor monitors and assesses the patient's health and progress, in order to design the next iteration's (or trial's) physical activities.

1.2 Software Product Requirements

Your customers ask for a software product that facilitates longitudinal interventions to and the continuous assessment for diabetic patients. The software is expected to ease the monitoring and treatment of patients by providing reliable mechanisms i) to collect and visualise data, ii) to allow doctors make accurate assessments, iii) to present end-users with results and summaries in a secure and efficient way, and finally iv) to coordinate the rehabilitation process.

The software will be used by participating GPs, rehabilitation doctors (RDs), patients and registered sports centres (referred to as SC from here onwards).

1.2.1 Users Roles and Required Features

Here is a description of the roles of end-users, and a list of features that the software product must offer to them:

GP role: A GP is responsible for registering patients with the system. This involves the generation but also the maintenance of confidential records¹. A record consists of a unique identification number, the personal information of the patient, medical history and diagnoses, as well as a record of any historical data related to past and current prescriptions. The GP must be able to add, change and delete these details from a user-friendly interface.

A GP must will conduct regular NICE tests for his/her patients, and submit the results in the system's database. All stored information must be easily accessible and clearly presented to the GP. Remember that monitoring a diabetic patient is a longitudinal process therefore the GP must be able to compare results of different trials. In addition, historical data should be utilised in order to observe the progress of a treatment over time. Printable versions of all reports, charts, figures and summaries must become available, when needed.

GP requirements: Every GP must have appropriate access to create and make changes to patient records, run NICE tests and collect their results (details on NICE tests and further requirements are found in section 1.4). They must not be allowed to make changes to data related to the rehabilitation training programs. However, summaries must be visible to them, as part of the patient continuous evaluation.

Finally, the GP must be able to refer a patient to an RD within the system. By doing this, the corresponding RD is expected to receive a notification message and be granted access to view the patient record.

¹GDPR and Data Protection Act 2018 should be considered and several aspects of it must be reminded to the users where appropriate.

RD role: An RD is responsible for designing the personalised training programs. For each patient referred to the RD, an initial physiological evaluation must be performed ². The physiological evaluation and its phases are discussed in section 1.5.

Should the results of the initial physiological evaluation are positive, the RD will design a personalised training program. He/she decides on the duration of the program (usually 6 months), and the frequency by which the exercise trials should take place (usually 3 times per week, but that depends on the patient).

Subsequently, the exercise trial must have the following properties, decided and set by the RD:

- Type – to begin with, the system must support only aerobic exercise (i.e., running on a treadmill), but the system should be flexible to accommodate more exercise types in the future,
- Duration – this is how long an exercise should last in minutes,
- Intensity – level of difficulty of the exercise in speed (km/h) and slope (degrees).

A complete design of the training program must be summarised and explained to the patient.

Furthermore, at the end of each trial the second phase of the physiological evaluation (i.e., the exercise phase) is used to assess the patient's health and condition, apart from the ECG. These results along with the actual treadmill parameters that the patient used during the trial (notice that the patient might not be able to complete the whole duration, or have changed the slope), are sent to the RD. Next, the RD must be able to compare all acquired data sets and visualise the findings, so that accurate assessments are possible. Again, summaries of the information must be generated so that the process and the findings are communicated to the patient.

RD requirements: The RD must have appropriate access to view a patient record, as long as the latter is referred to him/her by a GP. The RD must be able to conduct initial physiological evaluations for patients, the requirements of which are found in section 1.5. In doing so, the RD must be given access to only view the NICE tests associated with the patient. The RD must not be able to change any of the NICE test results as they can only be run by the GPs.

A patient should never be offered a training program without having his/her physical condition assessed. That is, the system must not allow any RD to proceed to any exercise designing, unless a physiological evaluation is complete.

The RD must be able to decide the configuration of the exercise trails (mainly configuration of the treadmill exercises), thus to design a personalised training program, a summary of which must be clearly shown in the end. A printable version must become available, if needed. In addition, the exercise configuration has to be communicated to the selected SC. For further information on this, please refer to the role and requirements of an SC.

Finally, the RD must receive notifications if a patient has missed an exercise trial. The RD must also be given the option to ask for a new appointment with the patient and vice versa. For further information on these, please refer to the role and requirements of a patient.

²Note that patients who perform poorly in the physical tests may be advised not to participate in the rehabilitation program.

SC role: The registered sport centres must connect to the system as SC users and announce their availability and potential changes to their opening hours. Once a patient is submitted to a training program, he/she must select a convenient sports centre to visit. The SPs therefore might be selected based on proximity, but this is a lesser feature at the moment. Once selected, the SC must automatically receive a copy of the patient's identification number and the corresponding training program (i.e., the treadmill configuration; type, duration, intensity). The latter is assumed to be installed automatically on the treadmill, and does not have to be shown in the first release of the software. Nevertheless, a simulation of this feature and appropriate documentation are desired.

SC requirements: The SC must be given the functionality to update service status, availability and opening hours. For instance, if the facilities are busy or closed for any reason, the corresponding sports centre must be depicted as *unavailable* in the patient's user interface.

The SC must be able to receive limited information about patients. It could be simulated in the first release, but it must happen the beginning of an exercise trial. Also, the SP must be able to provide short feedback related to the completion of every trial. This information must be added into the patient's record and become available to both GPs and RDs for their consideration.

Patient role: The patient's role is to primarily receive information about appointments, training program designs and exercise configurations (exercise trials left, etc.). No changes can be made to the system by patients, although they must be able to generate summaries of their progress and historical information.

Patient requirements: The patient must be able to notify the RD in case an exercise trial is missed and to ask for an appointment, if necessary. Most importantly, the patient must be able to get an up-to-date list of available SCs and select the most convenient for the completion of the next exercise trial.

1.3 Configurable and Secure System

It is a necessary requirement that all means of inserting data into the system are highly configurable. That is, end-users must be able to edit questionnaires, tests, and forms with respect to their roles. Nothing should be hard-coded, although the system must start with a default setup and configuration. For example, the GP must be given appropriate tools to edit all questionnaires before attempting to complete them with the patient's input.

It is important for the system to be secure, forms to be password protected and all input to be validated in order to avoid mistakes. The patient should be prompted with a consent form before participating in the program. The system must be documented appropriately and the user interfaces must utilise short and long descriptions when applicable. The system must raise warning flags and alert the end-users when necessary.

1.4 NICE Tests

The details of the NICE test are described in [9] and are also found in the appendix of this document. These tests are periodic measurements that a GP performs in order

to continuously monitor the health of diabetics patient and ultimately evaluate the effectiveness of running treatments. Although a NICE test is usually suggested every 6 months, the GP must be able to set the next appointment.

Notice that although well established, a NICE test should not be hard-coded. The GP must be able to generate new versions of the NICE test by adding new measurements, range of values, descriptions, etc.

1.5 Initial Physiological Evaluation

An initial physiological evaluation is performed by a RD and consists of two phases, namely the diet and the exercise phase.

Diet phase: The RD discusses eating habits and uses a questionnaire to collect data and assess the nutritional value of the patient's diet. A sample questionnaire is given at the appendix of this document.

Exercise Phase: The patient is asked to undertake some physical activity, while several measurements are taken. They are listed below:

- Heart rate at rest, during and after physical activity (beats per minute),
- Blood pressure at rest, during and after physical activity (NN/nn mmHg),
- Electrocardiogram (ECG) at rest and on during physical activity (arrays of numbers to plot graphs).

Note that the measurements (exercise phase) are used to assess the health condition of a patient at the end of an intervention trial throughout a personalised training program.

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Appendix

HOW HEALTHY IS YOUR DIET? QUESTIONNAIRE

This questionnaire will help you assess the nutritional value of your diet.
Answer **Yes** or **No** to the questions below and then read the supplementary information that will help you to consider making changes to your diet.

Fruit and vegetables

1. Do you eat at least 5 portions of fruit and/or vegetables every day? ☐ Yes ☐ No
*Remember that fruit juice only counts as 1 portion a day, regardless of how much you drink.
The same applies to dried fruit. Potatoes count as starchy foods and not as vegetables.
As a guide, a portion is about a handful.*
-
2. Do you eat more than four different varieties of fruit each week? ☐ Yes ☐ No
-
3. Do you eat more than four different varieties of vegetables each week? ☐ Yes ☐ No

If you have answered **No** to most of these questions, you may want to consider making some changes to your diet:

Aim to eat at least 5 portions of fruit and vegetables every day:

- Fresh, frozen, canned and dried fruit or vegetables and fruit or vegetable juices, all count.
- A portion is about 80g.
- Enjoy fruit and vegetables with meals and/or as snacks.
- Watch out for sugar or syrup in some canned fruits and vegetables, and for salt in some canned vegetables.
- Fruit juice counts as only 1 portion a day, however much you drink.
- Beans and pulses count as only 1 portion a day, however much you eat.
- Try to include lots of different varieties of fruit and vegetables.
- Try to avoid adding fat or rich sauces to vegetables.

Eating at least 5 portions of fruit and vegetables a day will contribute towards reducing the risk of coronary heart disease. They provide a variety of different vitamins and minerals, as well as being a good source of fibre.

ROUGH GUIDE TO PORTION SIZES

- Vegetables – 3 heaped tablespoons
- Salad – 1 dessert bowlful
- Grapefruit or avocado – ½ fruit
- Apples, bananas, pears, oranges and other similar size fruits – 1 fruit
- Plums and similar size fruit – 2 fruits
- Grapes, cherries and berries – 1 handful
- Fresh fruit salad – 3 heaped tablespoons
- Dried fruit – 1 heaped tablespoon
- Fruit juice – 1 glass (150ml)

Fat

- | | | |
|--|------------------------------|-----------------------------|
| 4. Do you choose low-fat products when available? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Do you choose baked, steamed or grilled options when available, rather than fried foods (such as crisps and snacks, or fish and chips)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Do you opt for lean cuts of meat or remove visible fat – for example, removing the skin on chicken or the rind on bacon? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Did you eat any oily fish last week?
<i>Examples of oily fish include mackerel, herring, sardines, trout, and fresh tuna.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If you answered No to most of these questions, you may want to consider making some changes to your diet:

Most people would benefit from eating less saturated fat. This is the type of fat found in many common foods including meat and dairy products and in many processed foods. Eating too much fat in general may contribute to weight gain, and too much saturated fat can contribute towards coronary heart disease.

Foods containing fat should be eaten in moderate amounts:

- Choose lower-fat and/or leaner versions whenever you can. 'Lower-fat versions' means things like meat with the fat cut off, poultry without the skin, and fish without batter.
- Avoid frying foods and instead opt for grilled, baked, boiled, steamed, dry-fried or microwaved choices.
- Replacing some saturated fats with monounsaturated fats and polyunsaturated fats will help to improve the ratio of 'protective' cholesterol to 'harmful' cholesterol in your blood.
- Eating oily fish regularly can help reduce the risk of coronary heart disease.
- Beans and pulses are good alternatives to meat as they are naturally very low in fat.

Starchy foods

- | | | |
|---|------------------------------|-----------------------------|
| 8. Do you base your main meals around starchy foods?
<i>For example, potatoes, pasta, rice or bread.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 9. Do you regularly choose wholemeal bread or rolls rather than white? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 10. Do you regularly eat wholegrain cereals, with no added sugar? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 11. Do you regularly include pulses in your diet?
<i>For example, beans and lentils.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If you answered No to most of these questions, you may want to consider making some changes to your diet:

Aim to base all meals on a good-sized serving from this group, choosing wholegrain types when you can.

- Starchy foods contain carbohydrate mainly in the form of starch, which provides energy. They also contain some protein, minerals, vitamins and fibre.
- Fibre helps the digestive system function properly, preventing bowel disorders such as constipation.
- Try to avoid frying foods in this food group (eg, chips), or adding too much fat (eg, spreading butter on bread), or adding rich sauces or dressings (eg, cheese sauce on pasta).

Sugar

- | | | |
|---|------------------------------|-----------------------------|
| 12. Do you regularly eat sugar-coated breakfast cereals or add sugar to your breakfast cereals? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 13. Do you add sugar to your drinks? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 14. Do you regularly drink sweet fizzy drinks? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 15. Do you regularly eat cakes, sweets, chocolate or biscuits at work? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If you have answered Yes to most of these questions, you may want to consider making some changes to your diet:

- Foods high in added sugar include soft drinks, sweets, jams, cake, puddings, biscuits, pastries and ice-cream. If you eat foods and drinks containing sugar, eat them mainly at mealtimes rather than in between meals, to reduce the risk of tooth decay.
- Sugar can count for a lot of additional calories during the day, especially if you add sugar to every drink.

Salt

- | | | |
|---|------------------------------|-----------------------------|
| 16. Do you regularly add salt to food during cooking? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 17. Do you regularly add salt to meals at the table? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 18. Do you regularly eat savoury snacks at work?
<i>For example, crisps or salted nuts.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 19. Do you regularly eat pre-prepared meals?
<i>For example, pre-prepared sandwiches, ready meals or canned soups.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 20. Do you regularly eat processed meats such as ham or bacon, or smoked fish? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 21. Has your GP advised you that you have high blood pressure? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If you have answered Yes to most of these questions, you may want to consider making some changes to your diet:

Reducing the amount of salt in your diet can help keep your blood pressure down, especially if this is part of a healthy diet that includes plenty of fruit and vegetables. Reducing your blood pressure reduces the risk of developing heart disease and stroke, even if your blood pressure is already within the normal range.

Drinks and alcohol

- | | | |
|--|------------------------------|-----------------------------|
| 22. Do you drink plenty of fluids at regular intervals during the working day? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 23. Do you opt for a variety of different drinks, including water, at work? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 24. Do you avoid sugary fizzy drinks? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 25. Do you drink less than 2-3 units of alcohol a day if you're a woman, or less than 3-4 units of alcohol a day if you're a man?
1 unit of alcohol is equivalent to 100ml of 10% ABV (alcohol by volume) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

For example 1 unit is:

- ½ pint (300ml) of bitter, lager or cider (3% to 5% ABV), or
- 1 small glass of white or red wine, 100ml (4fl oz), 10% ABV, or
- 1 pub measure of spirits, 25ml (1fl oz), or
- 1 small glass of sherry, 50ml (2fl oz)

If you have answered **No** to most of these questions, you may want to consider making some changes to your diet:

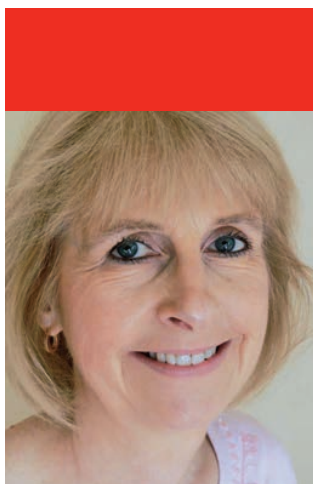
- In climates such as in the UK, we should drink about 1.2 litres (6 to 8 glasses) of fluid every day to stop us getting dehydrated.
- Too much alcohol can damage the heart muscle, increase blood pressure and lead to weight gain. However, moderate drinking – between 1 and 2 units a day – may help protect the heart in men aged over 40 and women who have gone through the menopause.

Eating habits

- | | | |
|---|------------------------------|-----------------------------|
| 26. Do you skip breakfast more than once a week? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 27. Do you skip lunch more than once a week? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 28. Do you skip evening meals more than once a week? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 29. Do you skip meals and snack instead on most days? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If you have answered **Yes** to most of these questions, you may want to consider making some changes to your diet:

- It's not necessarily bad for you to skip meals and replace them with snacks, as long as the snacks you eat provide sufficient nutrients to replace those of a complete meal. Many people, particularly those who do lots of physical activity, snack throughout the day to maintain their energy levels.
- Skipping meals on a regular basis, particularly breakfast, disturbs the body's metabolism and can affect the way that you feel in a variety of different ways. It can also make it more difficult for you if you are trying to lose weight. Try to establish a regular eating pattern with no longer than 3 or 4 hours between meals and snacks.



Sandra Waddingham
Diabetes Education Facilitator
North Lancashire PCT

Diabetes Matters



NINE PROCESSES OF CARE FOR DIABETES

The National Institute for Health and Clinical Excellence (NICE) recommends that all people with diabetes should receive nine key tests at their annual diabetes review. These important markers ensure diabetes is well controlled and are designed to prevent long-term complications. The nine key tests are: weight, blood pressure, smoking status, HbA_{1c}, urinary albumin, serum creatinine, cholesterol, eye examinations and foot examinations. This review discusses the importance of each marker of improved long-term care of patients.



Key points:

- NICE recommends that all people with diabetes receive nine key tests at their annual review
- Currently only 53% of people with type 2 diabetes receive all nine tests
- Informed decision-making and agreeing management plans with patients is much more likely to lead to better outcomes

Practice nurses are very familiar with the nine key tests for people with diabetes and yet the National Diabetes Audit results for 2009/10 showed that only half of people with type 2 diabetes (53%) receive all nine of the tests. The National Diabetes Audit has been conducted for seven years and shows steady progress over the years; however, there is obviously still room for improvement.

Type 2 diabetes is a complex long-term condition characterised by hyperglycaemia which significantly increases risk of macro- and microvascular disease. Macrovascular disease damages large blood vessels, and causes strokes, heart attacks and peripheral artery disease

(affecting blood flow in the legs and feet causing intermittent claudication and gangrene). Damage to the smaller blood vessels, microvascular disease, is responsible for retinopathy, renal disease and neuropathy.

Diabetes care is complex and requires regular monitoring in addition to lifestyle changes and medical management, all of which involves the participation of the patient to make it work. For this reason it is essential to involve patients in their care, helping and supporting them to make informed decisions. Agreeing a management plan with a patient generally means they are much more likely to carry it out.

“Only half of people with type 2 diabetes receive all nine of the tests”



Table 1: Targets for the nine processes of care for diabetes

- **Weight**
Aim for a healthy weight between a BMI of 18.5 and 24.9 kg/m²
- **Blood pressure**
<140/80 mmHg with no kidney, eye or cerebrovascular damage; <130/80 mmHg with evidence of kidney, eye or CV damage
- **Smoking status**
Check smoking status at annual review
- **HbA_{1c}**
Optimum level 6.5%
- **Urinary albumin**
<2.5 mg/mmol for men;
<3.5 mg/mmol for women
- **Serum creatinine**
>150 micromol/L - discontinue metformin
- **Cholesterol**
TC <4.0 mmol/L; LDL-C <2.0 mmol/L
- **Eye examinations**
Screening at least annually
- **Foot examinations**
Screening at least annually

WEIGHT MANAGEMENT AND DIABETES

A high percentage of people with type 2 diabetes are overweight at diagnosis. Insulin resistance means that the body produces insulin but fails to recognise and use it. The pancreas works harder to produce more insulin, but eventually fails. Over-production of insulin stimulates the appetite, making people feel hungry and eat more, resulting in gradual weight gain before and after diabetes is diagnosed. As a result, patients find it difficult to lose weight.

Regular monitoring of weight should take place to help patients reach and maintain a healthy body weight. Helping patients understand why they find it so challenging to lose weight and empathising with them can motivate and empower them to be more proactive in at least maintaining a stable weight. When developing a management plan it is advisable to agree on small sustainable changes, which are more likely to be achieved and maintained.

A structured education programme should be considered and/or a referral to the local dietitian as local protocols dictate. In my experience patients gain a tremendous amount from the education programmes which are now available to them.

NICE recommends: Weight and diet

- Patients should have access to individualised and ongoing nutritional advice from dietitian
- Dietary advice should be sensitive to needs of patient, including culture and beliefs, willingness to change and effects on quality of life
- Advice based on healthy balanced eating, *ie* high-fibre, low glycaemic index carbohydrates, low-fat dairy products, limited intake of saturated and trans fats and including oily fish
- Overweight people should aim to lose 5-10% of body weight, although smaller amounts will still be beneficial in long term
- Limits for carbohydrate and alcohol intake, as well as meal patterns, should be decided with patient
- People using insulin and/or insulin secretagogues need advice on avoiding, recognising and treating hypoglycaemia
- All people with diabetes should avoid excess energy intake and should be discouraged from using foods marketed specifically for people with diabetes

BLOOD PRESSURE

Blood pressure (BP) has long been recognised as a significant marker in the development of the long-term complications of diabetes and so there should be great emphasis on controlling hypertension. There are rarely any symptoms when BP is raised or uncontrolled, and because people feel well, high BP can be present for many years before being diagnosed.

Once diabetes has been confirmed, BP should consistently be kept <140/80 mmHg: if the patient has kidney, eye or cerebrovascular damage, the target should be <130/80 mmHg.

BP should be reviewed in people with newly diagnosed diabetes and treatment should be altered only if and/or where existing therapy is no longer appropriate. For example, it may be appropriate to include an ACE inhibitor if further therapy is needed. Many people with long-standing hypertension may no longer be taking treatment which follows newer regimens and recommendations. People with newly diagnosed diabetes without hypertension or evidence of renal impairment should have their BP checked at least annually. However, in my experience, BP

measurements are taken at most visits to the surgery once a patient has been diagnosed with diabetes and so BP is generally well monitored.

NICE recommendations for follow-up of blood pressure measurements

- 1 month – >150/90 mmHg
- ≤ 2 months – >140/80 mmHg
- ≤ 2 months – >130/80 mmHg with kidney, eye or cerebrovascular damage
- Lifestyle advice should be offered at the same time, including the benefits of diet and exercise

SMOKING STATUS

People with diabetes are at even greater risk if they smoke. Diabetes increases the risk of macrovascular disease and smoking further increases this risk.

Smoking decreases the amount of available oxygen in the body and also has a significant effect on lipid levels. By increasing low-density lipoproteins (LDL) and decreasing beneficial high-density lipoproteins (HDL), atherosclerosis is speeded up and the likelihood of strokes, heart attacks and peripheral vascular disease is increased. BP is also affected by smoking because it increases adrenaline, causing constriction of blood vessels which increases BP. Smoking is also thought to impact on blood glucose levels by increasing insulin resistance which means the available insulin is less able to metabolise and convert glucose into energy.

Encouraging patients to appreciate the relationship between smoking and diabetes and the significant increase in their risks should go some way to helping them to decide whether to give it up. There are a wide range of education materials, support groups and pharmacotherapy options that can help people to quit smoking.

NICE recommends: Smoking

People with diabetes are at high risk of cardiovascular disease and therefore should:

- Be referred to local stop smoking services
- Receive behavioural support from the local stop smoking service
- Use nicotine replacement therapy (NRT)/varenicline or bupropion if clinically indicated

Diabetes Matters



GLYCOSYLATED HAEMOGLOBIN

Glycosylated haemoglobin (HbA_{1c}) is a key marker of the effectiveness of diabetes care. This simple blood test measures the average blood glucose levels over the previous three months. Glucose attaches itself to red blood cells and as these cells live for approximately 120 days the average glucose level during that time can be measured.

HbA_{1c} is expressed as a percentage and indicates how well diabetes is controlled. Generally, 6.5% is the optimum level to aim for; however, many patients will control their glucose levels at a slightly higher percentage for a number of reasons. The HbA_{1c} test result will often inform treatment changes and dictate whether a patient requires a change in treatment such as an increase in drug dose, additional drug or different treatment regimen.

A significantly raised HbA_{1c} that is left uncontrolled will cause serious damage to blood vessels, leading to organ damage and life-threatening disease. As well as the long-term risks to health, a persistently high blood glucose level also makes patients feel lethargic and prone to minor infections such as urinary tract infections, skin lesions, and infected cuts and scratches.

NICE recommends: HbA_{1c} targets

- General target for people with type 2 diabetes is 6.5%
- However, HbA_{1c} target levels should be individualised and agreed with the patient
- Quality of life including hypoglycaemia should be considered when discussing HbA_{1c} targets with patients
- Avoid intensive management of less than 6.5%
- Measure HbA_{1c} levels 2-6 monthly depending on the level of control and/or treatment changes *etc.*
- Remember HbA_{1c} monitoring is invalid in erythrocyte abnormalities

URINARY ALBUMIN

Traces of protein in the urine are an early warning that all is not well with a patient's kidneys. An early morning urine sample should be collected for albumin:creatinine ratio (ACR) to be measured in the laboratory. The test should be delayed if a patient

has diagnosed or suspected urinary tract infection, or if a woman is menstruating.

If a patient has an abnormal result, a repeat test should be done at their next two clinic visits within a maximum of 3-4 months. Urinary albumin:creatinine ratio levels are considered to be within normal limits if they are <2.5 mg/mmol for men and <3.5 mg/mmol for women. If two or more raised ACR results are received other causes of renal disease should be considered before confirming diabetic nephropathy.

The National Diabetes Audit warned that measuring urinary albumin:creatinine ratio was the test least likely to be carried out in patients with diabetes.

NICE recommends: Renal disease

Renal disease (not caused by diabetes) is suspected if the ACR is raised, plus one of the following:

- Absence of retinopathy
- Persistently high blood pressure resistant to treatment
- Previously normal ACR with development of proteinuria >100 mg/mmol
- Haematuria
- Rapidly worsening GFR
- The patient is obviously unwell

NICE recommends: Urinary albumin

In cases of raised ACR NICE guidance recommends:

- Start ACE inhibitor and titrate to full dose
- Advise women regarding pregnancy and ACE inhibitors
- If ACE inhibitors are not tolerated change to an angiotensin 2-receptor antagonist
- Maintain blood pressure <130/80 mmHg

SERUM CREATININE

A simple non-fasting blood test for serum creatinine and estimated glomerular filtration rate (eGFR) should be included in the annual review. If serum creatinine levels are >130 micromol/L or the estimated glomerular filtration rate is below 45 ml/min/1.73 m² then the patient's dose of metformin should be reviewed if appropriate. Once the creatinine level reaches 150 micromol/L or the eGFR is <30 ml/min/1.73 m² metformin should be stopped.

A rising serum creatinine and a decreasing eGFR are indicative of renal disease.

NICE recommends: Serum creatinine

- Measure serum creatinine and eGFR annually
- Discontinue metformin when serum creatinine is 150 micromol/L or higher, or the eGFR is less than 30 ml/min/1.73 m²
- Refer to specialist renal services in line with agreed local protocols

UKPDS Risk Engine: www.dtu.ox.ac.uk/riskengine

Input

Age Input : 62 years

Duration of Diabetes : 11 years

Sex : ☒ Male ☐ Female

Atrial Fibrillation : ☒ No ☐ Yes

Ethnicity : White

Smoking : Non-Smoker

HbA_{1c} : 8.3

Systolic BP : 145 mmHg

Total Cholesterol : 5.8

HDL Cholesterol : 1.1 mmol/l

Output

10 year risk 0 15 30 100

CHD : 33.3%

Fatal CHD : 24.4%

Stroke : 11.6%

Fatal Stroke : 1.8%

Adjusted for regression dilution

Details

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Diabetes Matters



CHOLESTEROL

As the relationship between cardiovascular risk and diabetes is well documented, people with diabetes should be managed according to recommendations for secondary prevention of CV events. The UK Prospective Diabetes Study (UKPDS) risk engine should be used to assess cardiovascular risk in patients with type 2 diabetes.

After diabetes has been diagnosed, a full fasting lipid profile should be conducted and repeated annually. If treatment is initiated or increased, a further lipid profile should be done 1-3 months later. NICE guidance recommends a total cholesterol (TC) level <4.0 mmol/L and a low-density lipoprotein (LDL) level <2.0 mmol/L. To achieve these cholesterol levels most patients will need drug therapy. NICE recommends starting with simvastatin 40 mg and increasing to a dose of 80 mg daily if required or a statin of equal cost and clinical effectiveness.

NICE recommends: Cholesterol

- Statins not to be used in pregnancy
- Aim for total cholesterol below 4.0 mmol/L and low-density lipoproteins below 2.0 mmol/L
- Consider a more effective statin or ezetimibe if there is evidence of cardiovascular disease or raised ACR, to achieve target lipid levels as above

EYE EXAMINATIONS

Patients' eyes should be screened at diagnosis and then annually, assuming all is well. Practice nurses are often responsible for preparing patients for their eye screening, explaining what to expect and why

NICE recommends: Eye examinations

- Routine annual eye examinations or earlier if indicated
- Use a quality-assured digital screening programme with appropriately trained staff
- Emergency referral to the ophthalmologist in the following circumstances: sudden loss of vision, pre-retinal or vitreous haemorrhage, retinal detachment, rubeosis iridis which is when new abnormal blood vessels develop on the surface of the iris

Table 2: Classification of foot problems in patients with diabetes

Classification	What it means	Recommended follow-up
Low risk	Normal sensation Palpable foot pulses	Annually
Increased risk	Neuropathy or Absent foot pulses	3-6 monthly by specialist team
High risk	Neuropathy or Absent foot pulses AND Deformity/skin changes or Previous ulcer	1-3 monthly by specialist team
Ulcerated foot	New ulceration/swelling or Discolouration	Refer urgently to multidisciplinary foot care team within 24 hours

the examination is important. It is important to explain that persistently high blood glucose levels can adversely affect the retina and lead to deterioration in vision. Patients should be encouraged to report any changes in their vision and referred urgently to ophthalmology, as appropriate. It is helpful to explain that patients will be given eye drops before their eye examination to dilate their pupils ready for retinal photography, and point out that this means they will be unable to drive home.

FOOT EXAMINATIONS

Foot examinations by appropriately trained staff should take place annually. The examination should include testing of foot sensation using a 10 g monofilament; palpation of foot pulses; inspection of any foot deformity and inspection of the patient's footwear. Patients need to learn how to take care of their feet and to report any concerns as a matter of urgency.

CONCLUSION

The most recent National Diabetes Audit clearly shows that not all people with type 2 diabetes are receiving the nine processes of care as recommended by NICE. The document shows the percentage of patients in each PCT achieving all nine, the average being 53%. Not all the care received by patients achieved the recommended targets.

General practice staff are in the main responsible for the management of type 2 diabetes and more specifically practice nurses deliver most of this care. The importance of involving and empowering patients so that informed decisions can be made before agreeing management plans with patients was highlighted by NICE. There are two elements to achieving the nine processes of care: the first is to ensure that all patients with diabetes in the practice receive all the expected care and the second is that a greater percentage of those patients should achieve targets in line with NICE guidance. Patients will then be more likely to achieve better outcomes, leading to a better and healthier quality of life.

more information

- www.diabetes.org.uk
- www.dtu.ox.ac.uk/riskengine for the UKPDS risk engine.
- NICE. The management of type 2 diabetes. Clinical guideline 66. May 2008.
- NICE. Type 2 diabetes: prevention and management of foot problems. Clinical guideline 10. Jan 2004
- NICE. Smoking cessation services in Primary Care, Pharmacies, Local Authorities & workplaces, particularly for manual working groups, pregnant women and hard to reach communities. Public Health guideline 10. Feb 2008.
- National Diabetes Audit 2009-2010. The National Information Centre. <http://www.ic.nhs.uk>