

**PROTOCOL FOR**  
**OUT- PATIENT MANAGEMENT**  
**FOLLOWING**  
**LIVER TRANSPLANTATION**

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## 1. AIM OF POST TRANSPLANT FOLLOW-UP

The aim of liver transplant is to restore good health, well-being and independence to recipients. However, lifelong follow-up is necessary to maximise these aims and monitor the liver graft by:

### 1.1 Monitoring graft function:

Liver function tests, other investigations as indicated, eg. Doppler ultrasound, CT/MR, liver biopsy.

Observe for disease recurrence.

### 1.2 Monitoring immunosuppression:

Blood Ciclosporin, Tacrolimus or Sirolimus concentrations.

### 1.3 Detection/treatment of complications:

including rejection, infection, vascular and biliary complications, tumour and drug-induced complications, including hypertension, diabetes, renal impairment and hyperlipidaemia.

### 1.4 Health promotion advice and support for patients and relatives from a multi-disciplinary team.

## 2. SCHEDULE

The usual schedule of clinic visits, which will vary according to patients' health and location, is as follows:

### TIME POST TRANSPLANT

### FREQUENCY OF VISITS

**discharge to 6 weeks**

weekly - 2/52

**6 weeks to 3 months**

fortnightly

**3 months to 6 months**

monthly - 6/52

**6 months to 1 year**

2-3 monthly

**after 1 year**

3 to 6 monthly

These visits will alternate between referring hospital and the transplant unit once the patient's condition is stable. The transplant unit clinic may be an outreach clinic located at the referring hospital.

Patients on the waiting list for liver transplantation will be seen at regular intervals (usually 4-6 weekly) although the frequency of review can be much less in those patients with Childs A cirrhosis who are stable

### 3. SHARED CARE

After 6 months post-transplant, clinic visits may alternate between RIE and the recipient's referring hospital, following agreement with the referring physician. The arrangements are as follows:-

- 3.1 Secure agreement with referring physician in writing.
- 3.2 Send referring physician link to relevant protocol on the SLTU website
- 3.3 Outreach clinics, where patients are seen in their local hospital at a clinic run jointly by the referring physician and transplant unit staff ie consultant hepatologist and transplant co-ordinator take place in Aberdeen, Dundee, North and South Glasgow, Inverness and Wishaw.

### 4. RESULTS AND CORRESPONDENCE FROM REFERRING PHYSICIANS AND GPs

- 4.1 The Transplant Co-ordinators are responsible for requesting and obtaining results on behalf of SLTU Medical Staff from Referring Physicians and GPs.
- 4.2 Results should be returned to SLTU either in writing or by fax to the Transplant Co-ordinators on 0131 242 1722.
- 4.3 All abnormal results will be reviewed by SLTU consultant staff at the weekly follow-up meeting.

### 5. ROLE OF GENERAL PRACTITIONER

- 5.1 The GP's assistance in post transplant follow-up care is encouraged to facilitate on-going monitoring between hospital clinic visits and will be requested on an individual basis.
- 5.2 The GP remains the patient's first line of medical contact for all general non-transplant related health enquiries.
- 5.3 GPs can access the shared-care protocols on the Lothian Joint Formulary site at the following address

<https://www.ljf.scot.nhs.uk/SharedCareofMedicines/Shared%20Care%20Agreements/Pages/default.aspx>

### 6. ROUTINE CLINIC DUTIES

- 6.1 Weight
- 6.2 Blood pressure
- 6.3 Blood sampling

#### 6.3.1 **Routine for all visits**

##### 6.3.1.1 Clinical Chemistry:

Na, K, CO<sub>2</sub>, urea, creatinine, bilirubin, ALT, GGT, alkaline phosphatase  
albumin

-10 ml in plain (brown) monovette tube.

blood levels ciclosporin, tacrolimus or sirolimus

- 2.5 ml in EDTA (red) monovette tube.

#### 6.3.1.2 Haematology

Full blood count

-2.5 mls in EDTA (red) monovette tube.

#### 6.3.2 Specific to certain categories

6.3.2.1 Glucose - all clinic visits in first 3/12

6.3.2.2 Lipids - annually

6.3.2.3 Serum anti-HBs - sample to virology

all clinic visits in patients transplanted for hepatitis B-for first 12 months only

6.3.2.4 Alcohol - (yellow tube to clinical chemistry)

- at all clinic visits in patients transplanted for Alcoholic Liver  
Disease.

#### 6.4 History:

enquire specifically about:

- symptoms on last visit
- new symptoms
- jaundice, stool/urine colour, fever, abdo pain
- dyspepsia, vomiting, diarrhoea
- cough, dyspnoea
- headaches, paraesthesia, tremor
- fluid retention, arthralgia, fatigue

#### 6.5 Record drugs:

6.5.1 immunosuppression

Ciclosporin (Neoral), tacrolimus (specify Adoport, Prograf or  
Advagraf), sirolimus, azathioprine or mycophenolate, prednisolone.

6.5.2 other drugs

6.5.3 check patient's medication record book "Greenbook"

#### 6.6 Arrangements:

6.6.1 Contact for alterations in therapy

6.6.2 Next appointment

#### 6.7 Documentation

The clinic findings will be recorded on a standard outpatient form (Appendix I).

## 7. CLINIC REVIEW

The out patients seen in the preceding week will be discussed at a weekly clinic review attended by consultant hepatologist, consultant surgeon, medical registrar and transplant co-ordinator(s). Changes in therapy and other action will then be communicated via the transplant co-ordinators on behalf of the SLTU medical staff by telephone and documented in the case notes. Alteration in therapy or other action will also be included in the clinic letter sent to the GP and referring physician.

## 8. IMMUNOSUPPRESSION

### 8.1 CALCINEURIN BLOCKER (TACROLIMUS/CICLOSPORIN)

#### 8.1.1 Introduction

The primary immunosuppressive drug will be one of the calcineurin blockers **tacrolimus** or **ciclosporin**. There are now a number of generic tacrolimus or ciclosporin formulations available. It is important to prescribe the tacrolimus brand **Neoral** by name to ensure that the correct formulation is given

- Tacrolimus - Prograf , Advagraf or Adoport
- Ciclosporin - Neoral

#### 8.1.2 Dosing

The dosage of tacrolimus or ciclosporin must take account of not only the blood concentration, but also the time since transplant, the history of rejection and the side effects, particularly the presence of renal impairment. Toxicity within the recommended blood concentrations can occur.

The dose of immunosuppressive drugs should take account of the relative risks of rejection - the high risk patients are those with a previous history of rejection, younger patients, females and those transplanted for auto immune diseases. (eg. autoimmune hepatitis and primary biliary cirrhosis). Severely malnourished patients and those with renal failure have a lower risk of rejection.

#### 8.1.3 Recommended trough blood levels

##### 8.1.3.1 Tacrolimus

0 - 3 months post transplant	5 - 12 ug/l
after 3 months post transplant	4 - 10 ug/l

##### 8.1.3.2 Ciclosporin

0 to 6 months	100 - 150µg/l
6 months onwards	70 - 100µg/l

#### 8.1.4 Dosage Adjustment

If patient has tacrolimus/ciclosporin concentration too high or too low, consider the reason prior to adjusting the dose, eg:

- tacrolimus/ciclosporin too high:

Did the patient take ciclosporin/tacrolimus on the day of the assay?  
Has the patient taken any new drugs?

- tacrolimus/ciclosporin too low:

Is the patient compliant?  
Is there impaired absorption? Vomiting or diarrhoea?

Has the patient taken any new drugs?

**If adjusting dose, increase or decrease by approximately 20%**

#### 8.1.5 Tacrolimus/ciclosporin toxicity

Warning evidence of tacrolimus/ciclosporin toxicity:  
headaches, paraesthesia, tremor, fits, nausea, vomiting, diarrhoea,  
hypertension, hyperkalaemia, renal impairment, arthralgia, diabetes mellitus

#### 8.1.6 Drug Interactions

Assume any drug may interact with tacrolimus/ciclosporin until you know it does not.

If in doubt, contact SLTU pharmacist (Bleep 5132) and monitor U/Es, creatinine and blood tacrolimus/ciclosporin concentrations at least 2 x weekly. The following drugs are known to interact:

- 8.1.6.1 increase tacrolimus/ciclosporin concentration (anticipate toxicity and reduce dose or be guided by blood ciclosporin/tacrolimus concentrations measured  $< 1/52$  after starting medication).

amiodarone	clarithromycin
danazol	diltiazem
erythromycin	fluconazole (> 200 mg/day)
itraconazole	ketoconazole
nicardipine	progestogens
antiretroviral therapy	protease inhibitors

- 8.1.6.2 reduce tacrolimus/ciclosporin concentration (anticipate increase requirements but be guided by blood tacrolimus/ciclosporin concentrations measured  $> 1/52$  after starting medication).

carbamazepine	griseofulvin
phenobarbitone	phenytoin
primidone	rifampicin

- 8.1.6.3 increase risk of hyperkalaemia

potassium-sparing diuretics  
ACE inhibitors -  
Angiotensin II receptor antagonists

8.1.6.4 increase risk of nephrotoxicity (monitor urea + creatinine 2 x week initially).

aciclovir  
co-trimoxazole  
gentamicin  
neomycin

amphotericin  
ganciclovir  
NSAIDs  
any nephrotoxic drugs.

8.1.7 Tacrolimus in Patients with Anaemia/Hypoalbuminaemia

Because the drug is highly red blood cell and protein bound, increased efficacy/toxicity for a given whole blood concentration will occur if there is anaemia or hypoalbuminaemia.

8.1.8 Tacrolimus/Ciclosporin in Patients with Hepatic Dysfunction

Tacrolimus concentration is increased if hepatic function is decreased. Ciclosporin (Neoral) concentration may be reduced in severe cholestasis or steatorrhoea.

8.1.9 Shared care protocols are available at

<https://www.ljf.scot.nhs.uk/SharedCareofMedicines/Shared%20Care%20Agreements/Pages/default.aspx>



## 8.2 PREDNISOLONE

Prednisolone is used initially as an immunosuppressant but will normally be discontinued after 3/12.

Reduce prednisolone dose as follows:

<u>TIME POST TRANSPLANT</u>			<u>DAILY DOSE</u>
0	-	3 weeks	20mg
3	-	6 weeks	15mg
6	-	9 weeks	10mg
9	-	12 weeks	5mg
after 3 months			0*

\*The only exception to discontinuation is:

- patients transplanted for autoimmune hepatitis who may remain on 5mg/day to reduce risk of disease recurrence.

If the patient receives high dose steroid therapy for cellular (acute) rejection, restart prednisolone at 20 mg per day and reduce according to the above schedule, taking the episode of rejection as time zero.

## 8.3 AZATHIOPRINE

Continue at 1 mg per kg once daily, unless bone marrow suppression as follows:

WBC	2 - 3	$\times 10^9/l$	:	0.5mg per kg per day
	< 2	$\times 10^9/l$	:	stop
Platelets	40 - 60	$\times 10^9/l$	:	0.5mg per kg per day
	< 40	$\times 10^9/l$	:	stop

## 8.4 MYCOPHENOLATE MOFETIL

Also known simply as Mycophenolate or MMF, this drug which is a similar but more potent immunosuppressant to azathioprine, may be used in 3 situations:

8.4.1 in patients with early chronic rejection, in combination with tacrolimus.

8.4.2 in patients with renal impairment to allow either

8.4.2.1 Replacement of CNI with MMF and Prednisolone

8.4.2.1 Dose reduction of CNI in combination with MMF.

The dosage is 1 - 2g/day. It is less prone to causing marrow suppression than azathioprine but has significant risk of GI intolerance, both nausea and diarrhoea, which can be reduced by introducing the drug in a step wise manner and dividing the daily dose.

### **Generic MMF may be used in all patients**

8.4.3 The sequence of steps in patients with mild-moderate renal impairment more than 6 months after transplant and with normal graft function is as follows:

- i) Urinary PCR
- ii) Consider renal ultrasound scan if not done recently

If creatinine clearance in range 20 - 70ml/min and investigations do not suggest renal impairment for reasons other than CNI toxicity and therefore changing from CNI to MMF and prednisolone.

- iii) Commence MMF 500mg bd, increasing to 1g bd if no side effects.
- iv) Once established on full dose MMF, commence prednisolone 10mg/day and half dose of CNI.
- v) Continue to half dose of CNI at monthly intervals until discontinued all together, providing LFTs remain normal.
- vi) Reduce Prednisolone to 7.5mg. Further reduction should be discussed with consultant hepatologist.

## 8.5 SIROLIMUS

Sirolimus is usually used as renal-sparing immunosuppressant in a similar way to mycophenolate.

Side effects of Sirolimus include delayed wound healing, dyslipidaemia, marrow suppression, haemolysis and proteinuria.

If changing from CNI to Sirolimus

Prior to commencing sirolimus

- (i) send urine specimen for PCR
  - If PCR >50mg/mmol (protein >0.5g), the consultant will decide if the benefit of starting sirolimus outweighs the risk of increasing proteinuria
  - If PCR >100mg/mmol (protein >1g) sirolimus is not recommended and should only be started under careful consideration
- (iii) Commence Sirolimus at 2mg once a day.  
If there are concerns about the patients white cell count consider starting on 1mg Sirolimus and leaving half-dose CNI until trough level available.
- (iv) Half-dose of CNI for three days then stop. (If on Ciclosporin dose should also be halved but needs to be taken at least 4 hours before or after Sirolimus)
- (v) Azathioprine or MMF should not be discontinued until 1 month post change over.
- (vi) FBC, LFTs and Sirolimus level should be checked after 7-10 days
- (vii) Trough levels should be taken as with CNIs
- (viii) Levels 4-6ng/ml ( be guided by the LFTs)
- (ix) If proteinuria present on commencement of sirolimus, urinary PCR at each clinic visit is required
- (x) If no proteinuria then an annual urinary PCR should be carried out

As Sirolimus is not licensed in liver transplantation GPs may not be willing to prescribe - in this case contact Janice Davidson, Senior Research Nurse, to organise supplies.

## 8.6 OTHER DRUGS

At 3 months post-transplant, the following drugs can be discontinued:

ranitidine  
fluconazole  
co-trimoxazole

Valganciclovir (unless patient is on MMF, when valganciclovir should be continued for 6 months post transplant)

## 9. MANAGEMENT OF SPECIFIC PROBLEMS

### 9.1 ABNORMAL LIVER FUNCTION TESTS     *see inpatient protocol and appendices.*

If symptomatic or severe, admit to SLTU.

If asymptomatic and mild, may monitor and perform non-invasive investigations (eg. blood tests and ultrasound/Doppler) as outpatient. The history and pattern of abnormality may guide investigation, but in general, consider the following, whilst remembering that imaging is fallible (eg. normal Doppler does not exclude hepatic vein obstruction, and normal USS does not exclude biliary obstruction).

#### 9.1.1 Biliary problem? (predominant increase in alk phos)

Ultrasound: - if biliary dilatation → MRCP.

#### 9.1.2 Hepatic problem? (predominant increase in transaminases)

##### 9.1.2.1 ?Vascular problem

Doppler: if abnormal or inconclusive → CT angiogram

##### 9.1.2.2 ?Rejection - Liver biopsy

##### 9.1.2.3 ?Viral hepatitis

Blood - Virology (CMV, EBV, HBV, HCV, HEV).

May require liver biopsy

##### 9.1.2.4 Recurrence of original disease?

Serology, biopsy, and/or appropriate imaging

### 9.2 FEVER

If the patient or his/her GP contacts SLTU because of a fever, consider admission to SLTU or referring hospital. Consider bacterial, viral, fungal or other infection, and remember rejection and ischaemia can cause fever. See in-patient protocol. Common causes of fever after discharge from hospital are CMV infection and cholangitis due to biliary strictures

**Remember clarithromycin causes increased tacrolimus/ciclosporin concentration.**

### 9.3 CMV

If patient is suspected of having CMV diseases send 10ml red (EDTA) tube to virology for CMV-DNA PCR. If appropriate can also send tissue (gastric, colonic, liver biopsy material) for CMV culture - discuss cultures beforehand with virology (Duty Virologist, RIE bleep 5981).

#### Valganciclovir dosing for prevention of CMV

CrCL (ml/min) (Cockcroft Gault)	Valganciclovir tablets
≥ 60	900mg once daily
40-59	450mg once daily
25-39	450mg every 2 days
10-24	450mg twice weekly
< 10	Use oral solution

#### Valganciclovir (oral) dosing for treatment of CMV

CrCL (ml/min) (Cockcroft Gault)	Valganciclovir tablets
≥ 60	900mg twice daily
40-59	450mg twice daily
25-39	450mg once daily
10-24	450mg every 2 days
< 10	not recommended- discuss with pharmacist

Alternatively IV ganciclovir may be used in certain cases e.g.(severe disease, unresponsive disease. Usually for a 2 week initial course)

CrCL (ml/min) (Cockcroft Gault)	Ganciclovir (IV) dose
>70	5mg/kg 12 hourly
50-69	2.5mg/kg 12 hourly
25-49	2.5mg/kg 24 hourly
10-24	1.25mg/kg 24 hourly
<10	1.25mg/kg 24 hourly (given after HD on dialysis days)

If patient is well and lives sufficiently close to the transplant unit or their referring hospital to visit twice daily, it may be possible to administer this IV course as an out patient.

## 9.4 HYPERTENSION

### Definition of Hypertension

Systolic BP  $\geq$ 140mmHg and/or  
Diastolic BP  $\geq$ 90mmHg

### Targets for treatment are:

Diabetes or renal disease absent	BP<140/90 mmHg
Diabetes or renal disease present	BP < 130/80 mmHg

### Treat as follows:-

- |            |  |
|------------|--|
| Step one   | lifestyle modification<br>Consider reducing ciclosporin/tacrolimus   |
| Step two   | <b>No proteinuria:</b> Amlodipine (5-10mg od)<br><b>Proteinuria:</b> Ramipril (1.25-5mg od) or<br>Losartan (50mg-100mg od) |
| Step three | Ramipril or Losartan AND amlodipine  |
| Step four  | Addition of doxazosin 1mg daily (maximum of 16mg daily)<br>-monitor for hyperkalaemia                                      |

## 9.5 HEADACHES

9.5.1 Exclusion of serious pathology (eg. intracranial space occupying lesion or infection).

9.5.2 Consider tacrolimus/ciclosporin toxicity.

9.5.3 Simple analgesia

9.5.4 Anti-migraine regime

Treatment: paracetamol and metoclopramide  
sumatriptan

Prophylaxis: pizotifen  
propranolol  
amitriptyline

## 9.6 OBESITY

A common problem post-transplant. Document BMI. Management includes:

9.6.1 Stop prednisolone (if possible).

9.6.2 Keep tacrolimus/ciclosporin at lower end recommended range.

9.6.3 Refer to SLTU dietician (Bleep 2907).

9.6.4 Screen for diabetes mellitus/hyperlipidaemia.

## 9.7 HYPERLIPIDAEMIA

Monitor annually.

If cholesterol > 5.0mmol/l or established CVD, or hypertension + CVD risk > 20% at 10 yr (see BHS chart) introduce a statin: drug of choice is simvastatin or atorvastatin

Monitor LFTs fortnightly for first three months of therapy and check CK if patient complains of myalgia. (if cholestatic → cholestyramine)

## 9.8 DIABETES MELLITUS

Criteria for diagnosis of new onset diabetes mellitus after liver transplantation:

Symptomatic of hyperglycaemia (eg. Polyuria)                      Random plasma glucose  $\geq$  11.1mmol/l

Asymptomatic    Random plasma glucose  $\geq$  11.1mmol/l  
on two separate occasions.

Or

Fasting plasma glucose  $\geq$  7.0 mmol/l

Or

Two hour oral glucose tolerance  
test  $\geq$  11.1mmol/l

### Stepwise treatment Diabetes after Transplant

Step one    Therapeutic lifestyle change; patient education

Step two    Monotherapy with oral hypoglycaemic agent

Step three    Oral combination therapies to maximum  
effective dose of agents in each class

Step four    Insulin +/- oral agent

Step five    Insulin monotherapy adjusted to achieve target  
glucose levels

## 9.9 OSTEOPOROSIS

9.9.1 Suspected osteoporosis should be confirmed by DEXA scanning (either at referring hospital or at WGH -refer on TRAK)

9.9.2 Treatment should be provided with bisphosphonates- Alendronate 70mg weekly or Risedronate 35mg weekly.

9.9.3 Patients on long-term steroids should have DEXA scans every 3 years.

## 9.10 CARDIOVASCULAR DISEASE RISK

Patients on long term immunosuppression following liver transplant are at increased risk of cardiovascular disease (coronary artery disease and stroke) due to hypertension, hyperlipidaemia, obesity, diabetes and renal dysfunction. Their risk should be calculated annually using BHS charts (see appendix 2).

Aspirin 75mg/day for patients with pre-existing CVS complications or for primary prevention if any of above risk factors and a calculated CVD risk > 20% at 10 yrs.

## 10. MALIGNANCY SCREENING

### 10.1 CERVICAL CANCER

There is no indication for increased surveillance in women taking post transplant immunosuppressive therapy after the first year, in patients with no history of cervical intraepithelial neoplasia

For women aged 25-65 years who require liver transplantation:-  
Offer cervical screening at the time they are put on the transplant list if they have not been screened within 3 years if aged 25-49 years or 5 years if aged 50-64 years  
Offer cervical screening within the year after transplantation as persistent infection with HPV would put them at increased risk of developing CIN  
Treat any abnormality on cervical screening as high grade abnormality and refer promptly for colposcopy

### 10.2 DERMATOLOGY

- All patients post transplant should receive a copy of the British Association for Dermatology patient information leaflet: Patients with an Organ Transplant <http://www.bad.org.uk/shared/get-file.ashx?id=133&itemtype=document>
- Patients should be made aware of the increased risk of developing skin cancer after transplant
- We should ensure that there is a rapid referral to specialist dermatological care in any case of suspected malignancy
- Advice on skin care should be reinforced as part of the transplant annual review and in addition a skin check should be undertaken by an appropriately trained member of staff.
- As patients treated by SLTU are referred from health boards around Scotland establishing a fast track referral system to appropriate specialists in each of these health boards is potentially difficult Therefore in that circumstance a transplant patient with a suspicious skin lesion this should either be fast tracked to an appropriate dermatologist in NHS Lothian or if the patient were an outpatient this responsibility would be clearly transferred by urgent letter to the responsible clinician in the patient's own health board.

### 10.3 COLON CANCER

Patients with ulcerative colitis transplanted for primary sclerosing cholangitis are at particularly high risk of colon cancer. They require annual screening colonoscopy.

Patients who do not have ulcerative colitis should participate in the National Bowel Screening Programme.



## 10.4 BREAST SCREENING

Female patients should undergo standard mammography screening

## 11. HEPATITIS B

11.1 The standard treatment for patients with hepatitis B infection is tenofovir or entecavir

11.2 Patients with hepatitis B who have Delta virus infection should have their anti-HBs titre checked at each clinic visit. If anti-HBs titre < 100 units, give 10,000 units of hepatitis B immunoglobulin (HBIG) (obtained from Pharmacy) as an intravenous infusion over 5 hours. Initial rate of infusion at 0.1ml/kg/hour for 10 minutes, if tolerated this can be doubled every 10 minutes to maximum of 1ml/kg/hour.

## 12. HEPATITIS C

The majority of patients will now have cleared their HCV infection pre transplant.

If patients still have active HCV infection, HCV recurrence is universal; the effect on the graft is variable. If treatment is required post transplant then the following applies:-

Patients who are treatment naive should receive 12 weeks treatment with epclusa (sofosbuvir, velpatasvir) or maviret (glecaprevir and pibrenatsvir)

Actual drug choice may be decided according to local guidelines

Patients who have previously been treated and failed treatment should be treated with Vosevi (sofosbuvir, velpatasvir and voxilaprevir) for 12 weeks.

Treatment is no longer dependent on genotype

Liaison with Dr Andrew Bathgate is encouraged

## 13. ALCOHOLIC LIVER DISEASE

13.1 Patients transplanted for alcoholic liver disease will have signed a contract prior to transplant agreeing to:-

- 1) continued abstinence from alcohol
- 2) testing for alcohol in blood
- 3) alcohol counselling if required

13.2 Blood should be taken for ethanol on a regular basis.

## 14. INFLUENZA

Patients should receive annual influenza vaccine.

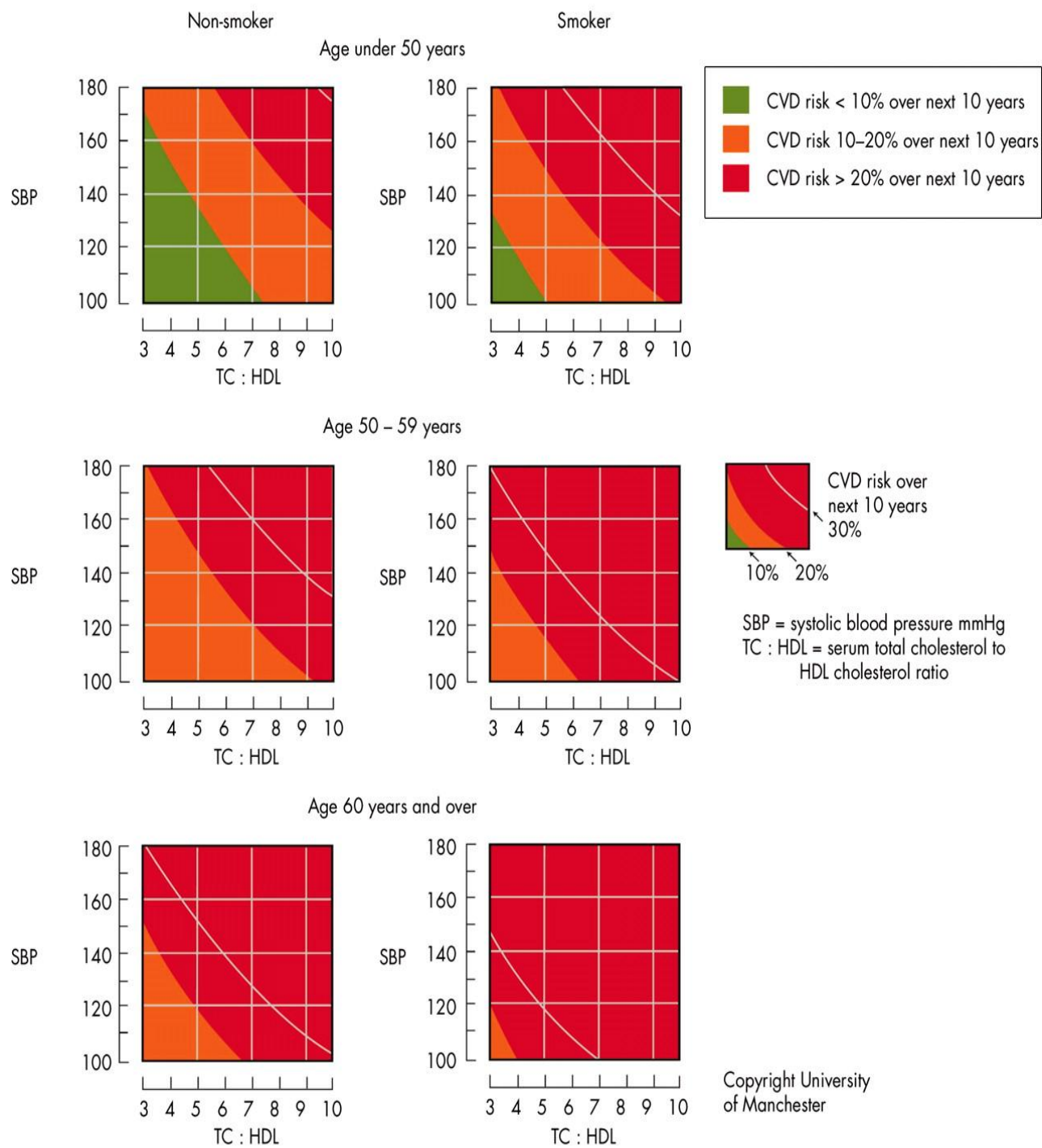
## 15. PNEUMOCOCCAL VACCINATION

Patients should receive pneumococcal conjugate vaccine (PCV23) at least once as per UK DOH handbook



APPENDIX 2: Cardiovascular Risk Charts

NON-DIABETIC MEN



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**NON-DIABETIC WOMEN**

