NHS Lincolnshire

Prescribing and Clinical Effectiveness Bulletin

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What's new this month:

- **Nicorette Quickmist oromucosal spray is a new nicotine replacement formulation recommended for second line use (see page 2).**
- **Wherever possible modified release venlafaxine should be prescribed as one of the low cost brands: Depefex XL capsules, Ranfaxine XL capsules, Venaxx XL capsules or Venlalic XL tablets. The potential saving across Lincolnshire is in excess of £454,000pa (see page 3).**
- **Generic losartan is recommended as the A2RA of first choice in the treatment of hypertension. Therapeutic switching away for long patent life A2RAs like olmesartan and telmisartan to generic losartan is advocated. The potential saving across Lincolnshire is £1.18Mpa (see page 4).**
- **Two trials have highlighted an increased risk of fatal cardiovascular events with olmesartan. The American Food and Drug Administration (FDA) have concluded that the benefits of olmesartan within licensed indications still outweigh the risks, although this adds extra impetus to the need to review patients on olmesartan and to consider therapeutic switching to generic losartan (see page 7).**
- **A recent analysis has confirmed the results of the ONTARGET study linking combined use of ACEIs and A2RAs with adverse renal outcomes. In view of the risks, PACEF recommend that dual ACEI and A2RA therapy should only be initiated on the advice of a renal specialist (see page 8).**

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This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Back issues of the *PACE Bulletin* and other PACEF publications are available through the NHS Lincolnshire website (www.lincolnshire.nhs.uk). Click on 'Commissioning' and follow the links to PACEF.

SUMMARY OF PACEF DECISIONS: APRIL 2011 UPDATE

Drug	Indication(s)	Traffic Light Status
Aripiprazole tablets and oral solution (ABilify)	Licensed for the treatment of schizophrenia	AMBER No shared care guideline is required.
Azacitidine (Vidaza) injection	Licensed for the treatment of intermediate-2 and high-risk	RED

	myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia in adults who are not eligible for haemotopoietic stem cell transplantation	
Nicorette Quickmist Oromucosal Spray	Licensed for the relief and prevention of nicotine withdrawal symptoms associated with tobacco dependence in adults and children over 12 years of age and in pregnant and lactating women.	GREEN Second line option.
Quetiapine tablets (Seroquel)	Licensed for the treatment of schizophrenia, mania (either alone or with mood stabilisers), depression in bipolar disorder and as an adjunctive treatment in major depressive disorder.	AMBER First line quetiapine formulation of choice.
Quetiapine modified release tablets (Seroquel XL)	Licensed for the treatment of schizophrenia, mania (either alone or with mood stabilisers), depression in bipolar disorder and as an adjunctive treatment in major depressive disorder.	AMBER Standard release quetiapine should be used preferentially in new patients.

RED-RED: This signifies that a product is **not recommended** for prescribing in **either** primary or secondary care. All new products are classified as RED-RED pending assessment by PACEF.
RED: This signifies that a product has been approved for use within secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary care.
AMBER: This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; PACEF are working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care.**

REPORTING INCIDENTS TO THE NATIONAL PATIENT SAFETY AGENCY (NPSA)
The NPSA are keen to encourage the anonymous reporting of patient safety errors and systems failures both from healthcare professionals and patients. The National Reporting and Learning System (NRLS) has been set up to facilitate this process. Healthcare professionals can either report patient safety incidents through their local risk management scheme or directly into the NRLS using the eForm on the NPSA website. Please access www.npsa.nhs.uk for more information. **All healthcare professionals are encouraged to report incidents, errors and systems failures; the aim is to help the NHS to learn from things that go wrong.**

RAPID DRUG ASSESSMENT: *NICORETTE QUICKMIST OROMUCOSAL SPRAY*

Nicorette Quickmist oromucosal spray is the first nicotine replacement therapy (NRT) oral spray formulation. It is licensed for the relief and prevention of nicotine withdrawal symptoms associated with tobacco dependence in adults and children over 12 years of age and in pregnant and lactating women. The licensed dose is one to two sprays every 30 to 60 minutes up to 4 sprays per hour and a maximum of 64 sprays in any 24 hour period. At maximum dose, a dual pack of Nicorette Quickmist costs £4.02 per day and lasts for 4.6 days; the nasal spray at maximum daily dose costs £4.47 per day. The oromucosal spray is comparable in terms of speed of action to the nasal spray and is likely to be better tolerated. Both the oromucosal and nasal spray formulations are more costly than either the chewing gum or lozenge formulations.

PACEF Recommendation:
Nicorette Quickmist Oromucosal Spray is designated GREEN. In view of the high cost in comparison to chewing gum and lozenge formulations, it should only be considered as a second line option in patients with higher levels of nicotine addiction due to heavier smoking.

REVIEW: *QUETIAPINE TABLETS (SEROQUEL) AND QUETIAPINE PROLONGED RELEASE TABLETS (SEROQUEL XL)*

Quetiapine (Seroquel) is an atypical antipsychotic drug licensed for the treatment of schizophrenia, mania (either alone or with mood stabilisers), depression in bipolar disorder and as an adjunctive treatment in major depression. Immediate release quetiapine requires a twice daily dosage and a prolonged titration period, whereas quetiapine prolonged release tablets (Seroquel XL) are administered as a single daily dose and have a simplified dose titration regimen. At present, prescribing of standard release quetiapine remains stable in county, while prescribing of prolonged release quetiapine continues to grow. PACEF reviewed the prolonged release formulation of quetiapine in 2009. At that time, quetiapine prolonged release tablets were marginally lower in price than their immediate release equivalent in primary care. As there was no obvious cost advantage in favouring one formulation over the other, both quetiapine standard release and modified release tablets were designated as AMBER, for initiation by or on the advice of a specialist without the need for a shared care guideline. Lincolnshire Partnership Foundation Trust has recently reviewed this decision and, in view of the approaching patent expiry of standard release quetiapine in 2012, agreed to use standard release quetiapine preferentially in new patients requiring quetiapine.

PACEF Recommendation:
When the use of quetiapine (Seroquel) is clinically indicated, the standard release preparation should be used first line. Patients already receiving the modified release formulation (Seroquel XL) may continue on this if the responsible clinician decides that this is clinically appropriate. Both products are designated AMBER. Following the anticipated introduction of a generic standard release formulation during 2012, PACEF and the LPFT will review this advice.

REVIEW: *VENLAFAXINE MODIFIED RELEASE FORMULATIONS*

Approximately, 82% of all venlafaxine prescribing in Lincolnshire primary care is for Modified Release (MR) formulations. The cost comparison table below summarizes the NHS reimbursement price for all of the main brands as well as the generic price. As with many MR preparations, the *Drug Tariff* generic price is based on the price of a leading originator brand, in this case Efexor XL. As a result of this, even generic prescribing of MR venlafaxine can be extremely expensive in comparison to lower cost brands:

Cost for 28 days supply where available	**75mg**	**150mg**
Efexor XL caps / venlafaxine MR capsules *Drug Tariff*	£22.08	£36.81
Alventa XL caps	£22.50	£37.51
Depefex XL caps	**£10.40**	**£17.40**
Foraven XL caps	£22.50	£37.51
Mentaven XL caps	-	£25.92
Ranfaxine XL caps	**£10.40**	**£17.40**
Rodomel XL caps	£16.48	-
Tardcaps XL caps	£29.41	£58.86
Vaxalin XL caps	£19.90	£33.18
Venaxx XL caps	**£10.40**	**£17.40**
Venlablue XL caps	-	£36.17
Venlalic XL tabs	**£11.20**	**£18.70**

Venlaneo XL caps	-	£34.53
Vensir XL caps	£22.34	£37.51
ViePax XL tabs	£13.98	£19.98
Winfex XL caps	£29.41	£39.03

The cost comparison reveals Depefex XL capsules, Ranfaxine XL capsules, Venaxx XL capsules and Venlalic XL tablets as the lowest cost options. If all generic prescriptions for venlafaxine MR and branded prescriptions for Efexor XL were written as a low cost brand the potential saving across Lincolnshire would be in excess of £454,000pa.

The table below summarizes the current availability of the four identified low cost products:

Product Name	Manufacturer	Wholesalers	Direct Supply	Notes
Depefex XL caps	Chiesi	Alliance, Phoenix Unichem		
Ranfaxine XL caps	Ranbaxy	All Wholesalers (including Maltby's)		150mg strength currently unavailable
Venaxx XL caps	Goldshield	AAH, Phoenix	Yes	
Venlalic XL tabs	Ashbourne	All Wholesalers (including Maltby's)		

PACEF Recommendation:
All practices should review their prescribing of venlafaxine MR with a view to changing all patients to a preferred low cost brand wherever possible (i.e. Depefex XL capsules, Ranfaxine XL capsules, Venaxx XL capsules or Venlalic XL tablets).

REVIEW: *ANGIOTENSIN 2 RECEPTOR BLOCKER CHOICE FOR HYPERTENSION*

What is the role of A2RAs in hypertension?

A systematic review of studies comparing ACE inhibitors with A2RAs in essential hypertension found that both classes of therapy provide similar levels of BP control and seem to have an equivalent effect on death and CV events. Any differences between ACE inhibitors and A2RAs in major events or changes in risk factors are likely to be small.

NICE Clinical Guideline 34 *Hypertension* recommends that A2RAs should be considered if patients are ACEI intolerant. In the full text guideline it states that the Guideline Development Group 'felt that the benefits from ACE inhibitors and A2RAs were closely correlated and that they should be treated as equal in terms of efficacy (although because of cost differences, ACE inhibitors should be initiated first).' An updated NICE CG is imminent, but no changes are expected to the ACEI/A2RA hierarchy.

PACEF Recommendation:
In essential hypertension there seems to be no justification for using an A2RA first line. Nonetheless, there is a role for A2RAs in patient for whom a Renin Angiotensin System (RAS) drug is indicated, but where an ACEI is precluded due to intolerance (e.g. ACEI related cough).

How common is ACEI related cough?

A2RAs are associated with a lower incidence of cough than ACEIs. A systematic review of studies directly comparing ACEI and A2RAs in hypertension suggested that in randomised controlled trials the rate of cough for ACE inhibitors was 9.9% compared to 3.2% for A2RAs. The rates observed in cohort studies were lower; 1.7% and 0.6% respectively.

The ONTARGET study included more than 25,000 patients at high cardiovascular risk but without heart failure. Patients were randomised to either telmisartan or ramipril or both treatments; 4.2% of ramipril patients stopped treatment due to cough compared with 1.1% in the telmisartan group. This is an absolute difference of 3.1% and suggests a Number Needed to Harm with ramipril of 32 over 56 months (i.e. 32 people need to be treated with telmisartan rather than ramipril for 4½ years to prevent one person having to stop treatment because of a cough).

PACEF Recommendation:
Evidence suggests that ACEI related cough is not as common as often perceived. Concern that the patient may develop an ACEI related cough is not sufficient to justify first line A2RA use. A2RAs should only be used as an alternative where there is continuing intolerance to an ACEI.

Which A2RA?

The following tables summarize the licensed indications, licensed doses for hypertension, patent life and cost of all available A2RAs:

Licensed indications for all A2RAs

Drug name	BP	HF	Post MI with LV failure	Diabetic nephropathy Type 1	Diabetic nephropathy Type 2	CV risk reduction
Candesartan	√	√				
Eprosartan	√					
Irbesartan	√				√	
Losartan	√	√			√	√
Olmesartan	√					
Telmisartan	√					√
Valsartan	√	√	√			

Licensed hypertension doses and cost of A2RAs

	Recommended doses for hypertension	**Cost for 28 days (DT March 2011)**
Candesartan (Amias) tablets	4mg once daily	£9.78
	8mg once daily	£9.89
	16mg once daily	£12.72
	32mg once daily	£16.13
Eprosartan (Teveten) tablets	300mg once daily	£7.31
	400mg once daily	£7.89
	600mg once daily	£14.31
Irbesartan (Aprovel) tablets	75mg once daily	£9.69
	150mg once daily	£11.84
	300mg once daily	£15.93
Losartan (generic) tablets	**25mg once daily**	**£1.64**
	50mg once daily	**£1.54**
	100mg once daily	**£1.74**
Losartan (Cozaar) tablets	12.5mg once daily	£8.09
	25mg once daily	£16.18
	50mg once daily	£16.18
Olmesartan (Olmetec) tablets	10mg once daily	£10.95
	20mg once daily	£12.95

	40mg once daily	£17.50
Telmisartan (Micardis) tablets	20mg once daily	£12.50
	40mg once daily	£12.50
	80mg once daily	£17.00
Valsartan (Diovan) capsules	40mg once daily	£13.97
	80mg once daily	£13.97
	160mg once daily	£18.41

Source: *MIMS* March 2011 and *Drug Tariff* March 2011

Patent Life of A2RAs

	Patent Expiry	**Notes**
Candesartan	April 2012	Imminent patent expiry renders product switching away from this medicine unnecessary
Eprosartan	April 2012	Imminent patent expiry renders product switching away from this medicine unnecessary
Irbesartan	August 2012	Imminent patent expiry renders product switching away from this medicine unnecessary
Losartan	Already available as a generic	Should at least be preferred first line A2RA in new patients. Product switching is recommended.
Olmesartan	**February 2017**	**Long patent life makes product switching away from this medicine a priority.**
Telmisartan	**January 2017**	**Long patent life makes product switching away from this medicine a priority.**
Valsartan	May 2011	Imminent patent expiry renders product switching away from this medicine unnecessary

PACEF Recommendation:
All A2RAs are licensed for hypertension. Losartan has a wider license portfolio than most including heart failure, diabetic nephropathy (type 2) and CV risk reduction. Longer patent-life A2RAs (telmisartan and olmesartan) have limited licensed indications, largely focussed on hypertension. Generic losartan is substantially lower in cost than any other currently available A2RA and should be used as the A2RA of first choice in hypertension. Olmesartan and telmisartan are expensive and have long patent lives. As a result of this it is recommended that all patients currently prescribed either olmesartan or telmisartan for hypertension should be considered for a therapeutic switch to losartan. The estimated annual saving if all telmisartan and olmesartan was switched to generic losartan (assuming telmisartan 20/40/80mg and olmesartan 10/20/40mg are equivalent to losartan 25/50/100mg) would be £1.18Mpa.

NICE TECHNOLOGY APPRAISAL TA 213: *ARIPIPRAZOLE FOR THE TREATMENT OF SCHIZOPHRENIA IN PEOPLE AGED 15 TO 17 YEARS*. (JANUARY 2011)

Aripiprazole is recommended as an option for the treatment of schizophrenia in people aged 15 to 17 years who are intolerant of risperidone or for whom risperidone is contraindicated or whose schizophrenia has not been adequately controlled by risperidone.

Aripiprazole should be initiated at a dose of 2mg (using aripiprazole oral solution) for two days, titrated to 5mg for 2 additional days to reach the recommended daily dose of 10mg. When appropriate, subsequent doses should be administered in 5mg increments without exceeding the maximum daily dose of 30mg daily.

PACEF Recommendation:
Aripiprazole (Abilify) is designated AMBER for the treatment of schizophrenia in people aged 15 and above. It should only be initiated following specialist advice as a second line option after risperidone. No shared care guideline is required.

NICE TECHNOLOGY APPRAISAL 218: *AZACITIDINE FOR THE TREATMENT OF MYELODYSPLASTIC SYNDROMES, CHRONIC MYELOMONOCYTIC LEUKAEMIA AND ACUTE MYELOID LEUKAEMIA* (MARCH 2011)

Azacitidine is recommended as a treatment option for adults who are not eligible for haematopoietic stem cell transplantation and have:

intermediate-2 and high-risk myelodysplastic syndromes according to the International Prognostic Scoring System (IPSS) **or**

chronic myelomonocytic leukaemia with 10–29% marrow blasts without myeloproliferative disorder **or**

acute myeloid leukaemia with 20–30% blasts and multilineage dysplasia, according to the World Health Organization classification **and**

if the manufacturer provides azacitidine with the discount agreed as part of the patient access scheme.

PACEF Recommendation:
Azacitidine (Vidaza) injection is designated RED for the treatment of intermediate-2 and high-risk myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia in adults who are not eligible for haemotopoietic stem cell transplantation.

NEW TRIALS IN BRIEF

Olmesartan and the ROADMAP study: increased risk of fatal cardiovascular events

In this randomised controlled trial (RCT), 4,447 people with type 2 diabetes, normoalbuminuria and at least one other cardiovascular (CV) risk factor were randomised to olmesartan 40mg daily or placebo for a median of 3.2 years. Microalbuminuria developed in fewer people receiving olmesartan than placebo (8.2% vs. 9.8%, Absolute Risk Reduction (ARR) 1.6%, Number Needed to Treat 63 over 3.2 years). However, death from CV causes (a secondary outcome) was higher in the olmesartan group than the placebo group (15 deaths (0.7%) vs. 3 (0.1%); Absolute Risk Increase 0.6%, Number Needed to Harm 167 over 3.2 years.

PACEF Comment:
This study found that olmesartan delayed the onset of microalbuminuria in patients with type 2 diabetes and normoalbuminuria. ACE inhibitors have also been shown to delay the onset of microalbuminuria in type 2 diabetics with normoalbuminuria. It is of concern that more patients taking olmesartan compared with placebo had fatal cardiovascular events. This may be a chance finding or it may demonstrate a direct effect of olmesartan. A smaller trial of olmesartan in type 2 diabetics (ORIENT) also found a higher rate of CV death in those receiving olmesartan compared with placebo. In response to this, the

American Food and Drug Administration (FDA) has conducted a safety review of olmesartan in relation to these two trials. They have concluded that when olmesartan is used to treat hypertension within license, its benefits continue to outweigh the risks. They do not recommend olmesartan as a treatment to delay or prevent microalbuminuria in diabetic patients. In addition, the FDA is also conducting a wider safety review of a possible link between cancer and A2RAs. Safety concerns around olmesartan reinforce PACEF advice issued earlier in this *Bulletin* that emphasize first line ACEI use and endorse product switching away from olmesartan to losartan in patients requiring an A2RA due to ACEI intolerance.

Reference
Haller H et al., Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. *NEJM* 2011;364:907-917

Angiotensin Converting Enzyme Inhibitor (ACEI) and Angiotensin 2 Receptor Antagonist (A2RA) combination therapy

Using a Canadian database, this retrospective analysis compared combined use of ACEIs and A2RAs with monotherapy with either agent in 32,312 people over 65 years. The primary outcome was doubling of serum creatinine or development of end-stage renal disease requiring dialysis or all cause death. This was more common in people receiving combination therapy (5.2 events vs. 2.4 events per 1000 patients per month). Hyperkalaemia was also more common with combination therapy. The majority of people receiving combination therapy (86.4%) did not have indications established in clinical trials (e.g. heart failure, proteinuria).

PACEF Comment:
This analysis suggests that the combined use of ACEIs and A2RAs is associated with adverse renal outcomes. These results are similar to the results found in the ONTARGET study which compared telmisartan 80mg, ramipril 10mg and the combination of both drugs in patients at high cardiovascular risk but without heart failure. This study also found an increased risk of renal impairment associated with combination treatment and found no difference in the primary outcome of CV death, MI, stroke and heart failure. Local practice audits suggests that use of combined ACEI and A2RA therapy is not uncommon. The evidence for the use of combination treatment is limited and conflicting. Local ULHT nephrologists advocate combination use in patients with renal disease to achieve a reduction in proteinuria. This is based on small trials of short duration that suggest dual blockade may be beneficial. The CHARM-added study provides some evidence supporting combination therapy in heart failure. In this study, adding candesartan to an ACEI improved outcomes, but beta blocker use was low and the doses of ACEI were lower than recommended. In contrast the VALIANT study of valsartan in heart failure suggested that adding valsartan to an ACEI is not likely to be beneficial. In view of the risks, PACEF recommend that dual ACEI and A2RA therapy should only be initiated on the advice of a renal specialist.

Reference
McAlister FA et al. The safety of combining angiotensin-converting-enzyme inhibitors with angiotensin receptor blockers in elderly patients: a population-based longitudinal analysis *CMAJ* 2011. DOI:10.1503/cmaj.101333

The POET-COPD Study: tiotropium versus salmeterol in Chronic Obstructive Pulmonary Disease (COPD)

An RCT in 7376 patients with moderate to very severe COPD and at least one exacerbation in the previous 12 months compared tiotropium 18mcg daily

(Handihaler) with salmeterol 50mcg twice daily (metered dose inhaler) for 1 year. People were allowed to continue on all other COPD medications except antimuscarinics and long acting beta agonists (LABAs); 53.5% of people were taking inhaled corticosteroids (ICS). The time to first exacerbation (primary outcome) was increased by 42 days with tiotropium as compared with salmeterol (187 days vs 145 days, 17% relative risk reduction). Also tiotropium significantly reduced the risk of moderate exacerbations by 14% and of severe exacerbations by 28% A total of 1,277 patients (34.4%) in the tiotropium group and 1,414 (38.5%) in the salmeterol group had at least one exacerbation over the year (ARR 4.1%, NNT 25).

PACEF Comment:
This study suggests that tiotropium, as compared with salmeterol, significantly increased the time to the first moderate or severe exacerbation in moderate to very severe COPD and significantly decreases the annual rate of exacerbations. The benefit was seen in all the major sub-groups considered in this trial (including COPD severity) and was independent of the concomitant use of ICS. The results are particularly applicable to COPD patients whose FEV1 is less than 50% and who are having frequent exacerbations; such a patient could be appropriately managed with tiotropium alone (plus salbutamol) as an *alternative* to long-acting beta agonist plus inhaled corticosteroid combination inhaler. For a COPD patient for whom initiation of long-acting bronchodilator is being considered, formoterol Easyhaler remains first choice on grounds of cost; where control of symptoms is considered inadequate (after a suitable trial period) it is appropriate to discontinue formoterol (or other long-acting beta-agonist) and initiate a trial of tiotropium.

Reference
Vogelmeier C et al. Tiotropium versus salmeterol for the prevention of exacerbations of COPD *N Engl J Med* 2011;364:1093 1103

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY: *DRUG SAFETY UPDATE* (April 2011)

Atypical (second-generation) antipsychotics: reminder to monitor and manage weight, glucose and lipid levels

- People with schizophrenia are three times more likely to die from natural causes (mainly cardiovascular disease) compared with people without mental health disorders.
- Schizophrenia is also associated with modifiable and non-modifiable risk factors for CV morbidity and mortality (e.g. smoking, poor diet, sedentary lifestyle, family history of CVD).
- Some atypical (second-generation) antipsychotics are associated with significant weight gain, dyslipidaemia and hyperglycaemia; clozapine, olanzapine and quetiapine are especially implicated.
- The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study confirms under-treatment of schizophrenic patients for metabolic disorders.

Advice for healthcare professionals:

- GPs and primary healthcare professionals should monitor the physical health of people with schizophrenia at least once a year (focus on CVD risk assessment).
- People with schizophrenia at increased risk of CVD and/or diabetes (e.g. raised BP, raised lipids, smokers, increased waist measurement) should be identified at the earliest opportunity and treated according to NICE guidance.

- Encourage and educate patients to maintain a healthy diet and regular exercise.

PACEF Comment:
New QOF indicators are designed to pick up on this agenda:
MH11 The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of alcohol consumption in the preceding 15 months.
MH12 The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of BMI in the preceding 15 months.
MH13 The percentage of patients aged 40 years and over with schizophrenia, bipolar affective disorder and other psychoses who have a record of total cholesterol:HDL ratio in the preceding 15 months.
MH14 The percentage of patients aged 40 years and over with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood glucose level in the preceding 15 months.

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