ALBUMINURIA – GUIDELINES FOR ALBUMINURIA TESTING IN PEOPLE WITH DIABETES MELLITUS OR AT RISK OF CHRONIC KIDNEY DISEASE

Version:	2.0
Ratified by:	Clinical Biochemistry Senior Staff Group
Date ratified:	18th May 2016
Name of originator/author:	Dr Edmund Lamb
Director responsible for implementation:	Prof F Muhlschlegel
Date issued:	1st June 2016
Review date:	31st May 2019
Target audience:	Clinical staff (medical, nursing and scientific), Trust wide and primary care

Version Control Schedule

Version	Date	Author	Status	Comment
1.0	1st October 2014	Dr Edmund Lamb	Final	Earlier guidance put in Q-Pulse format
2.0	1st June 2016	Dr Edmund Lamb	Final	Guidance updated to include non-diabetic kidney disease and a single cut-off of 3.0 mg/mmol as per NICE CG182. Also changed into Sharepoint format

Contents

1 Policy Summary

This policy gives guidance on when and how to screen for albuminuria in patients with diabetes or with other conditions that increase risk of chronic kidney disease.

2 Introduction

Albuminuria is an increase in the urinary loss of albumin. Establishing the diagnosis has both prognostic and management implications in the care of patients with diabetes mellitus and chronic kidney disease. The following local guidelines are based on guidance from the National Institute for Health and Care Excellence (NICE).

When and who to screen for albuminuria

Testing for albuminuria should be offered to people with chronic kidney disease or with conditions which place them at increased risk of chronic kidney disease (NICE CG182):

- Diabetes (NICE NG17, NG18, 28). In people with diabetes, the best possible metabolic control should be achieved before investigating for albuminuria. Patients should not be screened during intercurrent illness. Screening is not indicated in patients with established proteinuria. In the case of type 1 diabetes, screening should be offered annually from age 12 years.
- Hypertension (NICE CG127)
- Cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral vascular disease or cerebral vascular disease)
- Structural renal tract disease
- Recurrent renal calculi or prostatic hypertrophy
- Multisystem diseases with potential kidney involvement – for example, systemic lupus erythematosus
- Family history of end-stage kidney disease (glomerular filtration rate <15 mL/min/1.73 m^2) or hereditary kidney disease
- Opportunistic detection of haematuria
- Following an episode of acute kidney injury if the glomerular filtration rate remains below 90 mL/min/1.73m^2

How to assess albuminuria

An early morning (first sample of the day) mid-stream urine sample should be collected into a plain sterilin pot and sent to the laboratory. If the first urine sample of the day is not available, use a random sample, but be aware that this is associated with an increased risk of false positive results.

The sample container **must** be labelled with the full name, NHS number and sample date.

Very occasionally, it may be desirable to confirm the diagnosis by measuring albumin loss in a timed overnight collection. The laboratory can supply urine collection containers.

See Appendix A for flowchart.

Further investigation

An albumin-to-creatinine ratio (ACR) <3.0 mg/mmol requires no further investigation until the patient's next annual review. Patients demonstrating ACRs ≥3.0 mg/mmol should have urine samples sent to the laboratory on two further occasions (ideally within one month) for ACR measurement. Patients demonstrating increased ACRs in one or both of these further samples have 'higher risk' urine albumin loss and should be managed accordingly (e.g. see relevant NICE guideline). If the initial ACR is >70 mg/mmol (approximately equivalent to 1 g/day proteinuria) then proteinuria is confirmed and a subsequent sample is not required. You may wish to discuss the management of such patients with the secondary care diabetes or nephrology teams.

It is important to always consider causes of increased albumin loss not attributable to intrinsic renal disease. These can include menstrual contamination, vaginal discharge, uncontrolled hypertension, symptomatic urinary tract infection, uncontrolled diabetes, heart failure, intercurrent illness and strenuous exercise. In patients with type 1 diabetes and albuminuria, suspect other causes of renal disease:

- in the absence of progressive retinopathy
- if blood pressure is particularly high
- if proteinuria develops suddenly
- if significant haematuria is present
- in the presence of systemic ill health

Do not assess proteinuria using:

- reagent strips unless they are capable of specifically measuring albumin at low concentrations and expressing the result as an ACR.
- the protein:creatinine ratio (PCR). ACR has greater sensitivity than PCR for low levels of proteinuria. For quantification and monitoring of levels of proteinuria of ACR 70 mg/mmol or more, PCR can be used as an alternative. ACR is the recommended method for people with diabetes.

3 Purpose and Scope

This policy gives guidance that is consistent with guidance developed by NICE and is intended for use by primary and secondary care in East Kent.

4 Definitions

To allow for variation in urinary concentration, albuminuria is reported as a ratio of urine albumin to urine creatinine concentrations as mg of albumin/mmol of creatinine.

Albuminuria (previously called 'microalbuminuria') is an increase in the urinary loss of albumin above or equal to the clinically significant threshold of 3.0 mg/mmol. Note that 3.0 mg/mmol is not a reference range, which would be a much lower value, but a risk threshold. The diagnosis of albuminuria requires the demonstration of increased albumin loss in at least two out of three urine samples collected in the absence of infection or an acute metabolic crisis.

Higher levels of albuminuria, for example that detectable by crude clinical tests such as protein 'dipsticks', is often referred to as proteinuria (or 'macroalbuminuria') and relates to concentrations >30 mg/mmol.

In the international classification of kidney disease, ACR <3.0 mg/mmol is regarded as normal or slightly increased (category A1), 3-30 mg/mmol as moderately increased (category A2), and >30 mg/mmol as severely increased (category A3).

Increased albumin loss in an overnight collection is defined as an overnight albumin rate of loss >20 μg/min.

5 Duties

All staff involved in requesting, measuring or interpreting urinary albumin loss must adhere to this policy.

6 Policy specific information

Not applicable.

7 Key Stakeholders, Consultation, Approval and Ratification Process

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy. This document was prepared in consultation with Dr I John, Consultant Nephrologist and CKD lead, and Dr M Flynn, Trust Consultant and lead for diabetes and endocrinology, EKHUFT.

Copies of correspondence relating to this guidance may be found on the shared drive.

8 Review and Revision Arrangements

Three years from implementation date, by author.

9 Dissemination and Implementation

SharePoint, by proactive implementation through the Divisions by appropriate clinical leads and by proactive dissemination to primary care partners.

10 Document Control including Archiving Arrangements

Archive of this document will be through SharePoint.

11 Monitoring Compliance

Within the Trust, compliance with this policy must rest with the requesting Divisions. Compliance may be assessed by occasional pre-analytical request vetting within the laboratory and by retrospective clinical audit.

12 References

National Institute for Health and Care Excellence. Chronic kidney disease in adults: assessment and management. CG182, July 2014.

National Institute for Health and Care Excellence. Diabetes (type 1 and type 2) in children and young people: diagnosis and management.NG18, August 2015.

National Institute for Health and Care Excellence. Hypertension in adults: diagnosis and management. CG127, August 2011.

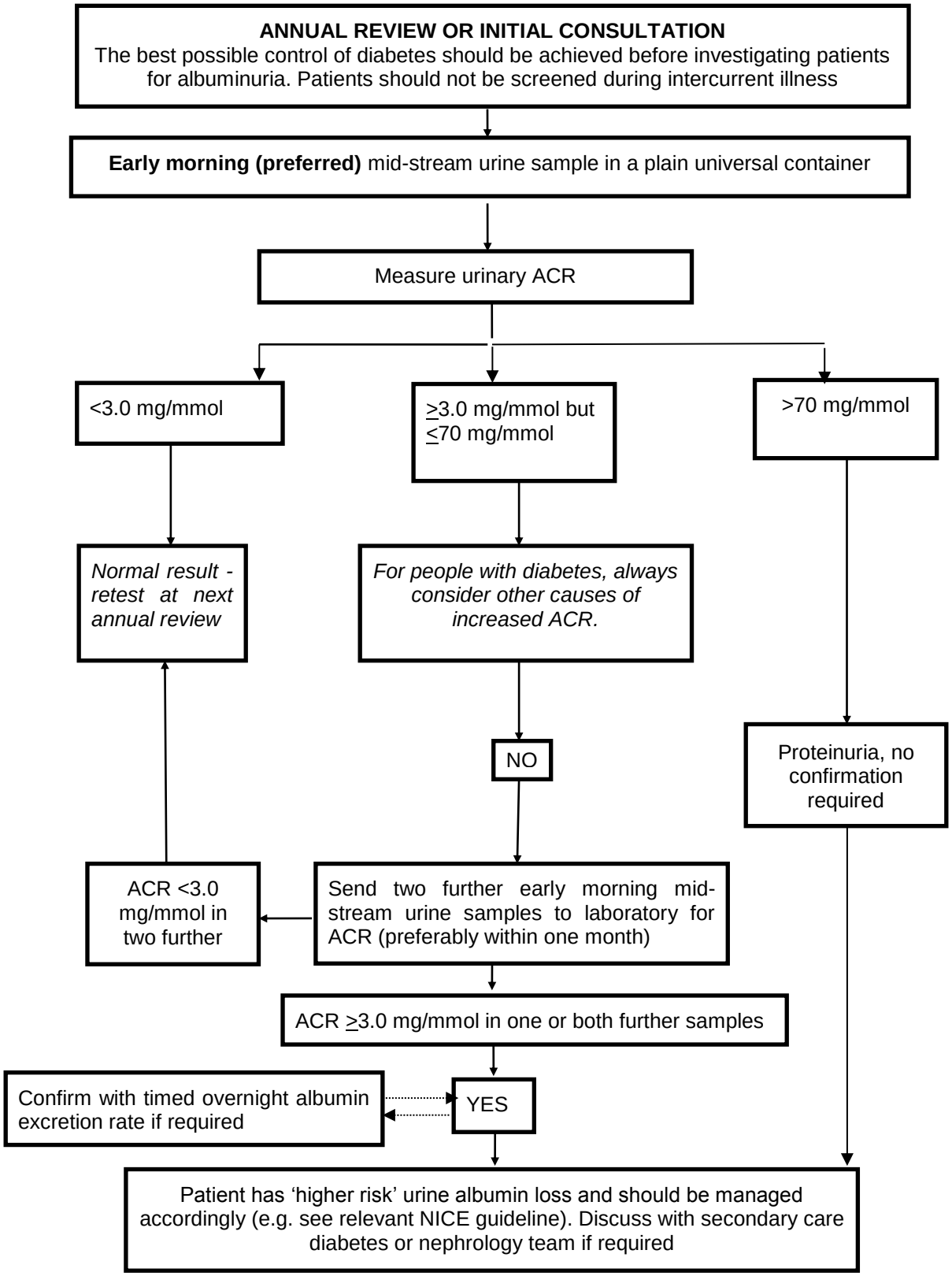
National Institute for Health and Care Excellence. Type 1 diabetes in adults: diagnosis and management NG17, August 2015.

National Institute for Health and Care Excellence. Type 2 diabetes in adults: management NG28, December 2015.

13 Associated Documentation

Not applicable

Appendix A: Flow chart: screening for albuminuria



Appendix B - Equality Impact Assessment

Equality and Human Rights Impact Analysis (EHRIA)

Part One – Screening Tool

Name of the policy, strategy, function or methodology:	ALBUMINURIA – GUIDELINES FOR TESTING

Details of person completing the EHRIA	
Name	Dr Edmund Lamb
Job Title	Consultant Clinical Scientist
Directorate/Department	Laboratory Medicine
Telephone Number	722-4112

1. Identify the policy, strategy, function or methodology aims

What are the main aims, purpose and outcomes of the policy, strategy, function or methodology?
To ensure a consistent and rational approach to the investigation of albuminuria across the health service in East Kent ensuring best use of health service resources.
Does it relate to our role as a service provider and/or an employer?
Service provider.

2. Assess the likely impact on human rights and equality

Use this table to check if the policy, strategy, function or methodology:

- could have a negative impact on human rights or on any of the equality groups, or
- could have a positive impact on human rights, contribute to promoting equality, equal opportunities or improve relations.

It is not necessary to complete each box, nor to mark whether it is positive or negative, although you can do this if you find it helpful.

	Protected Characteristic								
	Race	**Sex**	**Disability**	**Sexual Orientation**	**Religion or belief**	**Age**	**Gender reassignment**	**Marriage & Civil Partnership**	**Pregnancy & Maternity**
Could this policy, procedure, project or service affect this group differently from others? **YES/NO**									
Could this policy, procedure, project or service promote equal opportunities for this group? **YES/NO**									
Right to life *e.g. decisions about life-saving treatment, deaths through negligence in hospital*									
Right not to be tortured or treated in an inhuman or degrading way									
Right to respect for private and family life e.g. *respecting lgb relationships, confidentiality*									
Right to freedom of thought, conscience and religion *e.g. respect for cultural and religious requirements*									
Right to freedom of expression *e.g. access to appropriate communication aids*									
Right to freedom of assembly and association *e.g., right to representation, to socialise in care settings*									
Right to education *e.g. access to basic knowledge of hygiene and sanitation*									
Right to liberty e.g. informal detention of patients who do not have capacity									

3. How does it impact on people's human rights and equality?

Using the table above, explain anticipated impacts. If a full EHRIA is recommended, you can summarise the impacts - it is not necessary to set these out in detail,

Could people's human rights be impacted negatively? Could the policy, strategy, function or methodology result in inequality or discrimination?
No
Could this policy, strategy, function or methodology result in positive impacts on people's human rights or equality? Could it present opportunities to promote equality?
No

4. Recommendations

Is a full EHRIA recommended? If not, give reasons
No. The policy has equal impact.

5. Publication of EHRIA

Give details of where Screening Tool or the full EHRIA will be published and when this will take place
n/a.

Details of person completing the EHRIA	
Name	Dr Edmund Lamb

Signed

Date: 1st June 2016

Approval and sign-off	Name
Head of Department/Director	Prof F Muhlschlegel

Signed …… Date: ……

Appendix C – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	As described
4.	**Ratification process**	Yes	By senior clinical biochemistry staff group 19th May 2016
5.	**Review arrangements**	Yes	Through Q-Pulse
6.	**Control of documents, including archiving arrangements**	Yes	Through Q-Pulse
7.	**Associated documents**	n/a	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	n/a	
10.	**Any other requirements of external bodies**	n/a	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	n/a	

Appendix D – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Title of document:	ALBUMINURIA – GUIDELINES FOR TESTING		
Version Number:	2.0		
Approval Date:		**Dissemination lead:**	
Previous document already being used?	Yes		
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	Electronic on Q-Pulse and SharePoint		
Proposed instructions regarding previous document:	Remove and replace with version 2.0		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (i.e. paper or electronic)**	**Comments:**
Trust clinical staff	SharePoint	electronic	
Trust clinical staff	Newsletters	electronic	
CCG leads	Via C Waters, CCG commissioner	electronic	Sent 16th March 2016. No feedback received

Author's Dissemination Record - to be Used Once Document is Approved – to be kept with the master document

Date document forwarded to be put on the Trust's central register / in SharePoint:		**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**
Ivy Court Surgery Tenterden	Edmund Lamb	Informal teaching session	13th April 2016
Ashford learning set at Wye Surgery	Edmund Lamb	Informal teaching session	4th May 2016