



Health Economics Research Centre

**A RANDOMISED CONTROLLED TRIAL OF
ALTERNATIVE TREATMENTS TO INHIBIT VEGF
IN AGE-RELATED CHORIODAL
NEOVASCULARISATION (IVAN)**

Operating Cost Questionnaire

Date on which questionnaire was completed:

Main respondent's contact details

Contact Name:

Job Title:

Centre:

Telephone Number:

Email Address:

Additional staff providing information:

Contact Name:

Job Title:

Email Address:

Question(s) completed:

Contact Name:

Job Title:

Email Address:

Question(s) completed:

Contact Name:

Job Title:

Email Address:

Question(s) completed:

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OPERATING COST QUESTIONNAIRE

Thank you for taking time to complete this questionnaire. Your answers will be kept confidential and will only be used for the IVAN study.

The aim of this research is to collect information on the costs and resources required to (a) administer intra-vitreous injections of ranibizumab or bevacizumab for the treatment of neovascular age-related macular degeneration (nAMD) and (b) monitor outcomes in patients who have received ranibizumab or bevacizumab at any point in the past 2 years.

The information that you provide on this questionnaire is essential for us to assess the cost-effectiveness of ranibizumab or bevacizumab and the cost-effectiveness of the continuous and discontinuous therapy regimens evaluated in IVAN.

Notes on filling in the questionnaire:

- We are interested in the cost of treatment/monitoring in **routine clinical practice**, *not* the cost of IVAN clinics.
- This questionnaire should be completed by someone (e.g. a clinic manager) who is involved in running NHS clinic sessions in which ranibizumab/bevacizumab are given or in which patients are monitored following ranibizumab/bevacizumab treatment.
- If you don't know the answer to any given question, please complete all questions that you can answer and pass the questionnaire on to others at your centre so that they can complete additional sections. If nobody at your centre has the information required to answer a particular question, please give your best guess wherever possible and otherwise leave it blank and complete and return the remainder of the questionnaire.
- Please write "0" in response to any questions to which the answer is zero.
- All costs should **include VAT**. If you prefer to give costs excluding VAT, please state clearly which costs exclude VAT.

1a. Which of the following 5 options best describes the clinics you run for patients receiving ranibizumab/bevacizumab **on the NHS** (*outside* of clinical trials)?

(please tick (✓) or underline the appropriate option)

- A one-stop service in which monitoring and investigations for patients who have received ranibizumab/bevacizumab are conducted in the same clinic as ranibizumab/bevacizumab is administered.
- Separate monitoring and treatment clinics run on *different* days, whereby patients attend the clinic for monitoring/investigations on a separate occasion from their intra-vitreous ranibizumab/bevacizumab injections.
- Separate monitoring and treatment clinics run on the *same* day: e.g. a monitoring clinic run in the morning, followed by a treatment clinic in the afternoon of the same day.
- A mixture of the first three options.

(If you ticked this option, please answer the questions below)

a) What proportion of patients receiving intra-vitreous ranibizumab/bevacizumab injections attend one-stop clinics?
.....%

What determines whether a patient attends a one-stop clinic?
.....
.....

- None of these options (*If you ticked this option, please provide details*)
.....
.....
.....
.....
.....

Your name for this clinic	What is provided in this clinic (e.g. monitoring of nAMD pts, administration of ranibizumab/bevacizumab)	Length of clinic (hours)	Frequency with which it is run (e.g. weekly)	Total no. pts attending this clinic			Proportion of clinic attendees who receive ranibizumab/bevacizumab in this clinic			Proportion of clinic attendees who have previously received ranibizumab/bevacizumab but are <u>NOT</u> treated on this visit			% of clinic attendees enrolled in clinical trials	Other clinics run at the same time that share facilities (e.g. OCT/FFA rooms)	
				Mean (average)	Min	Max	Mean (average)	Min	Max	Mean (average)	Min	Max		No. clinics	Total no. pts
A2: Review/monitoring clinics attended by ≥1 patients who have received ranibizumab and/or bevacizumab in the last 2 years but in which <u>no</u> pts receive ranibizumab or bevacizumab today															
							0%	0%	0%	%	%	%	%		
							0%	0%	0%	%	%	%	%		
							0%	0%	0%	%	%	%	%		
B: One stop clinics during which most patients receive both monitoring AND an intra-vitreous injection of ranibizumab or bevacizumab															
							%	%	%	%	%	%	%		
							%	%	%	%	%	%	%		
							%	%	%	%	%	%	%		
C: Other clinics that do not fit into the above categories but which are attended by (a) ≥1 patients who have received ranibizumab and/or bevacizumab in the last 2 years and/or (b) ≥1 patients who will be given ranibizumab or bevacizumab in this clinic															

Your name for this clinic	What is provided in this clinic (e.g. monitoring of nAMD pts, administration of ranibizumab/bevacizumab)	Length of clinic (hours)	Frequency with which it is run (e.g. weekly)	Total no. pts attending this clinic			Proportion of clinic attendees who receive ranibizumab/bevacizumab in this clinic			Proportion of clinic attendees who have previously received ranibizumab/bevacizumab but are <u>NOT</u> treated on this visit			% of clinic attendees enrolled in clinical trials	Other clinics run at the same time that share facilities (e.g. OCT/FFA rooms)	
				Mean (average)	Min	Max	Mean (average)	Min	Max	Mean (average)	Min	Max		No. clinics	Total no. pts
							%	%	%	%	%	%			
							%	%	%	%	%	%			
							%	%	%	%	%	%			

Abbreviations: FFA, fundus fluorescein angiography; OCT, optical coherence tomography.

If there was insufficient space in the table, please give further details of your clinics or the way in which they are run here.

.....

.....

.....

.....

.....

.....

2. Rooms and staff required to run each type of clinic

Question 3 should be answered for each of the 4 types of clinic defined in Question 3 that apply to your centre.

- If you run separate injection/monitoring clinics, please give details of your injection clinics in Q3A1 (pages 7-8) and your monitoring clinics in Q3A2 (pages 9-10)
- If you run one-stop clinics, please give details of these in Q3B (pages 11-12)
- If you run any other types of clinic for ranibizumab/bevacizumab patients, please give details of these in Q3C (pages 13-14).

Please note that we are primarily interested in usual care clinics, rather than those run specifically for clinical trials.

- If you run separate clinics *exclusively* for patients participating in clinical trials you do **not** need to describe the trial clinics here.
- However, please do give details of clinics in which some but not all patients are enrolled in clinical trial(s).

If any of these 4 categories include clinics that require very different numbers of staff or rooms, please complete the questionnaire separately for each type of clinic that uses a different amount of resource use or requires a different number of staff, by printing out extra copies of these pages or by copying and pasting the relevant questions later in this Word document. For example, if you run 2 one-stop clinics each week, with 5-15 patients being seen at the smaller clinic and 20-40 being seen at the larger clinic, please fill in Question 2B separately for each clinic, recording your answers for your small one-stop clinic on pages 7-8 and answers for the large one-stop clinic on a different sheet.

If you have used any continuation sheets for this question, how many continuation sheets have you used?

If you have used continuation sheets, please record below which clinics are described in each section (using the clinic names that you specified in Q3):

A1 (Injection clinics):

A2 (Review clinics):

B (One stop clinics):

C (Other clinics):

Continuation sheet 1:

Continuation sheet 2:

A1) Injection clinic(s) in which most patients receive an intra-vitreous injection of ranibizumab or bevacizumab without also undergoing OCT, FFA or a detailed optometric assessment

i) How long does the average patient spend in the clinic at each visit?hours

ii) Please provide details of the rooms that are used in each clinic session for your **injection clinic(s)**.

If necessary, please give a range of values or complete this question separately for different types/sizes of injection clinic.

Name of room	Number of rooms of this type used per clinic session by pts who have had ranibizumab/ bevacizumab	Number of patients who have had/are having ranibizumab/ bevacizumab who use this type of room in the average clinic session	Number of other patients who use this type of room in the average session when your injection clinic is run (including pts attending other clinics running at the same time)
Sterile room(s) where injection is administered			
OCT room(s) or machine(s)			
FFA room(s) or machine(s)			
Visual testing lanes			
Consulting room(s)			
Optometric assessment room(s)			
Waiting area(s)			
Recovery room(s)			
Other (please specify)			

Abbreviations: FFA, fundus fluorescein angiography; OCT, optical coherence tomography.

iii) List in the table below all the staff who are involved in your injection clinic(s) each time they are run.

If necessary, please give a range of values or complete this question separately for different types/sizes of injection clinic.

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	Number of staff (e.g. no. clinicians) involved in injection clinic	Proportion of their time during this clinic session that is spent on the injection clinic (rather than other clinics running at the same time)
Example of how to complete the table for Grade 5 nurses if three Grade 5 nurses will be involved in your injection clinic during any given clinic session, two of whom are also involved in other clinics run at the same time and spend around half of the clinic session on the injection clinic.						
<i>EXAMPLE - NURSES</i>	<i>Staff nurse</i>	<i>5</i>	<i>Treatment room</i>	<i>Helping with intravitreal injections</i>	<i>1</i>	<i>100%</i>
	<i>Staff nurse</i>	<i>5</i>	<i>Various</i>	<i>Running clinic, visual testing, fluorescein injections</i>	<i>2</i>	<i>50%</i>
Staff required for your clinic						
Nurses						
Healthcare assistants						
Clinicians						

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	Number of staff (e.g. no. clinicians) involved in injection clinic	Proportion of their time during this clinic session that is spent on the injection clinic (rather than other clinics running at the same time)
Optometrists						
Ophthalmic photo-graphers/ technicians						
Administrative coordinators						
Data collection & management support staff						
Other administrative staff						
Eye clinic liaison officers						
Other (please specify)						

A2) Monitoring clinic(s) attended by one or more patients who have received ranibizumab and/or bevacizumab in the last 2 years but in which no pts receive ranibizumab or bevacizumab injections

i) How long does the average patient spend in the clinic at each visit?hours

ii) Please provide details of the rooms that are used in each clinic session for your **monitoring clinic(s)**.

If necessary, please give a range of values or complete this question separately for different types/sizes of monitoring clinic.

Name of room	No. rooms of this type used per clinic session by pts who have had ranibizumab/bevacizumab	No. patients who have had/are having ranibizumab/bevacizumab who use this type of room in the average clinic session	No. other patients who use this type of room in the average session when your monitoring clinic is run (including pts attending other clinics running at the same time)
Sterile room(s) where injection is administered			
OCT room(s) or machine(s)			
FFA room(s) or machine(s)			
Visual testing lanes			
Consulting room(s)			
Optometric assessment room(s)			
Waiting area(s)			
Recovery room(s)			
Other (please			

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	No. staff (e.g. no. clinicians) involved in monitoring clinic	Proportion of their time during this clinic session that is spent on the monitoring clinic (rather than other clinics running at the same time)
Optometrists						
Ophthalmic photo-graphers/ technicians						
Administrative coordinators						
Data collection & management support staff						
Other administrative staff						
Eye clinic liaison officers						
Other (please specify)						

B) One stop clinic(s) during which most patients receive both monitoring (e.g. OCT, FFA and/or a detailed optometric assessment) AND an intra-vitreous injection of ranibizumab or bevacizumab

i) How long does the average patient spend in the clinic at each visit?hours

ii) Please provide details of the rooms that are used in each clinic session for your **one stop clinic(s)**.

If necessary, please give a range of values or complete this question separately for different types/sizes of one-stop clinic.

Name of room	No. rooms of this type used per clinic session by pts who have had ranibizumab/bevacizumab	No. patients who have had/are having ranibizumab/bevacizumab who use this type of room in the average clinic session	No. other patients who use this type of room in the average session when your one stop clinic is run (including pts attending other clinics running at the same time)
Sterile room(s) where injection is administered			
OCT room(s) or machine(s)			
FFA room(s) or machine(s)			
Visual testing lanes			
Consulting room(s)			
Optometric assessment room(s)			
Waiting area(s)			
Recovery room(s)			
Other (please specify)			

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Abbreviations: FFA, fundus fluorescein angiography; OCT, optical coherence tomography.

iii) List in the table below all the staff who are involved in your one stop clinic(s) each time they are run.

If necessary, please give a range of values or complete this question separately for different types/sizes of one stop clinic.

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	No. staff (e.g. no. clinicians) involved in 1-stop clinic	Proportion of their time during this clinic session that is spent on the 1-stop clinic (rather than other clinics running at the same time)
Example of how to complete the table for Grade 5 nurses if three Grade 5 nurses will be involved in your one stop clinic during any given clinic session, two of whom are also involved in other clinics run at the same time and spend around half of the clinic session on the injection clinic.						
<i>EXAMPLE - NURSES</i>	<i>Staff nurse</i>	<i>5</i>	<i>Treatment room</i>	<i>Helping with intra-vitreous injections</i>	<i>1</i>	<i>100%</i>
	<i>Staff nurse</i>	<i>5</i>	<i>Various</i>	<i>Running clinic, visual testing, fluorescein injections</i>	<i>2</i>	<i>50%</i>
Staff required for your clinic						
Nurses						
Healthcare assistants						

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	No. staff (e.g. no. clinicians) involved in 1-stop clinic	Proportion of their time during this clinic session that is spent on the 1-stop clinic (rather than other clinics running at the same time)
Clinicians						
Optometrists						
Ophthalmic photo-graphers/ technicians						
Administrative coordinators						
Data collection & management support staff						
Other administrative staff						
Eye clinic liaison officers						
Other (please specify)						

C) Other clinic(s) that don't fit into the above categories but which are attended by (a) one or more patients who have received ranibizumab and/or bevacizumab in the last 2 years AND/OR (b) one or more patients who will be given ranibizumab or bevacizumab in this clinic

If necessary, please use continuation sheets to give details of different types of clinic falling into this category.

i) How long does the average patient spend in the clinic at each visit?hours

ii) Please provide details of the rooms that are used in each clinic session for your **other clinic(s)**.

If necessary, please give a range of values or use the continuation sheets to complete this question separately for different types/sizes of clinic.

Name of room	No. rooms of this type used per clinic session by pts who have had ranibizumab/bevacizumab	No. patients who have had/are having ranibizumab/bevacizumab who use this type of room in the average clinic session	No. other patients who use this type of room in the average session when your other clinic is run (including pts attending other clinics running at the same time)
Sterile room(s) where injection is administered			
OCT room(s) or machine(s)			
FFA room(s) or machine(s)			
Visual testing lanes			
Consulting room(s)			
Optometric assessment room(s)			
Waiting area(s)			
Recovery			

room(s)			
Other (please specify)			

Abbreviations: FFA, fundus fluorescein angiography; OCT, optical coherence tomography.

iii) List in the table below all the staff who are involved in your other clinic(s) each time they are run.

If necessary, please give a range of values or use the continuation sheets to complete this question separately for different types/sizes of clinic.

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	No. staff (e.g. no. clinicians) involved in other VEGF clinic	Proportion of their time during this clinic session that is spent on the other VEGF clinic (rather than other clinics running at the same time)
Example of how to complete the table for Grade 5 nurses if three Grade 5 nurses will be involved in your other clinic during any given clinic session, two of whom are also involved in other clinics run at the same time and spend around half of the clinic session on the injection clinic.						
<i>EXAMPLE - NURSES</i>	<i>Staff nurse</i>	<i>5</i>	<i>Treatment room</i>	<i>Helping with intra-vitreous injections</i>	<i>1</i>	<i>100%</i>
	<i>Staff nurse</i>	<i>5</i>	<i>Various</i>	<i>Running clinic, visual testing, fluorescein injections</i>	<i>2</i>	<i>50%</i>
Staff required for your clinic						
Nurses						
Healthcare assistants						

Staff type	Post	Grade /band	Room in which he/she is based	Role(s) in clinic	No. staff (e.g. no. clinicians) involved in other VEGF clinic	Proportion of their time during this clinic session that is spent on the other VEGF clinic (rather than other clinics running at the same time)
Clinicians						
Optometrists						
Ophthalmic photo-graphers/ technicians						
Administrative coordinators						
Data collection & management support staff						
Other administrative staff						
Eye clinic liaison officers						
Other (please specify)						

3. Are there any afternoons or mornings in which your clinic facilities are not used at all? (e.g. weekends or Friday afternoons)

YES/NO (please circle or underline the appropriate response to this and all subsequent yes/no questions)

a) If **YES**, please state when your clinic facilities are not used at all:

.....

a) Please provide details of average number of people using these facilities during clinic sessions in which **no** patients who have received ranibizumab or bevacizumab in the last 2 years are seen. Please note that we do not require a detailed breakdown for these clinics: simply an indication of how much these rooms are used at times when they are not being used by patients who have had ranibizumab/bevacizumab.

Name of room	Approximate number of rooms of this type used per clinic session	Approximate number of patients who use <u>each</u> room of this type in the average clinic session
Sterile room(s) where injection is administered		
OCT room(s) or machine(s)		
FFA room(s) or machine(s)		
Visual testing lanes		
Consulting room(s)		
Optometric assessment room(s)		
Waiting area(s)		
Recovery room(s)		
Other (please specify)		
.....		
.....		
.....		
.....		

4. Please indicate how often the assessments or procedures listed below are done and what facilities, staff and time is required each time.

For any tests that no patients will receive, please give the proportion as 0%.

If more than 50% of injections at your centre are done at one-stop clinics, please complete the third column (indicated by *) based on patients attending your one-stop clinic; otherwise, please complete this column based on patients attending your injection-only clinics.

Please record the tests and investigations that are done in routine clinical practice, NOT those required under the IVAN trial protocol.

Assessment	Approx proportion of clinic visits in which this test is performed in routine NHS clinical practice			Room in which test is done	Staff conducting assessment (post and grade)	Approx time required for each test – inc preparation & updating notes (minutes)	
	Clinic visit immediately before ranibizumab/bevacizumab is <u>initiated</u>	Clinic visits in which ranibizumab/bevacizumab is administered*	Clinic visits by pts who have had ranibizumab/bevacizumab in the last 2 yrs but who are <u>not</u> treated in this visit			If 1 eye tested	If both eyes tested
<p><i>Example: All patients undergo Test A before they start treatment.</i></p> <p><i>If 100 patients receive ranibizumab/bevacizumab this month, around 50 of these patients will have Test A before (or after) their injection.</i></p> <p><i>If 100 patients who have previously had ranibizumab/bevacizumab attend monitoring-only visits this month, around a third of them will have Test A.</i></p>							
<i>Example: Test A</i>	100%	50%	33%	Consulting room	Consultant	10	15
Assessment/consultation with clinician	%	%	%				

Assessment	Approx proportion of clinic visits in which this test is performed <i>in routine NHS clinical practice</i>			Room in which test is done	Staff conducting assessment (post and grade)	Approx time required for each test – inc preparation & updating notes (minutes)	
	Clinic visit immediately before ranibizumab/bevacizumab is <u>initiated</u>	Clinic visits in which ranibizumab/bevacizumab is administered*	Clinic visits by pts who have had ranibizumab/bevacizumab in the last 2 yrs but who are <u>not</u> treated in this visit			If 1 eye tested	If both eyes tested
Intra-ocular pressure (IOP)	%	Before injection: _____% After injection: _____%	%				
Evaluating refraction	%	%	%				
Evaluating cylindrical and spherical correction	%	%	%				
Distance visual acuity using Snellen chart	%	%	%				
Distance visual acuity using LogMAR chart	%	%	%				
Near visual acuity (e.g. using Bailey Lovie)	%	%	%				

Assessment	Approx proportion of clinic visits in which this test is performed <i>in routine NHS clinical practice</i>			Room in which test is done	Staff conducting assessment (post and grade)	Approx time required for each test – inc preparation & updating notes (minutes)	
	Clinic visit immediately before ranibizumab/bevacizumab is <u>initiated</u>	Clinic visits in which ranibizumab/bevacizumab is administered*	Clinic visits by pts who have had ranibizumab/bevacizumab in the last 2 yrs but who are <u>not</u> treated in this visit			If 1 eye tested	If both eyes tested
Reading speed	%	%	%				
Contrast sensitivity	%	%	%				
FFA	%	%	%				
OCT	%	%	%				
Slit-lamp examination	%	%	%				
Dilated fundus examination	%	%	%				
Colour fundus photography	%	%	%				
Routine screen for changes in ocular motility	%	%	%				
Routine screen for eyelid/pupil responsiveness	%	%	%				

5. What staff are required in the treatment room while intra-vitreous injections of ranibizumab or bevacizumab are being administered?

Please state post and grade for each role

.....
.....
.....

a) How long are the treatment room and staff required for each patient receiving intra-vitreous injection in one eye?

(Please **include** any time spent preparing or cleaning the room between uses and any time spent completing paperwork or electronic records relating to the injection.)

The room is required for minutes per injection

Nurse is required for minutes per injection

Ophthalmologist is required for minutes per injection

..... is required for minutes per injection

..... is required for minutes per injection

b) Would you consider giving intravitreal injections into both eyes during the same clinic visit? YES / NO

i) If YES, please give details of how this would be done.

Please state: approximately what proportion of patients get often bilateral injections; whether the second injection would be given immediately or how long a gap would be left between injections; whether the patient would leave the treatment room between injections and (if not) how long the treatment room would be required for if both eyes were to be injected.

.....
.....
.....

6. Are pre-prepared injection packs (containing the consumables and instruments required for injection) used for the administration of ranibizumab or bevacizumab injections?

YES/NO

a) If YES, in approximately what proportion of injections are pre-prepared injection packs used%

b) What is the cost per pre-prepared injection pack (including VAT)?

.....

7. Please provide details of the staff involved in fundus fluorescein angiography (FFA), including any staff involved in preparing the patient for the test.

Staff role	Post	Grade	No. minutes spent per FFA conducted (including preparing patient for test)
Nurse(s)			
Healthcare assistants			
Ophthalmic technician/ photographer			
Clinician(s)			
Other (please specify)			

8. Approximately how many people live in the area served by your hospital?

.....

9. What facilities did you set up or modify in order to offer ranibizumab/bevacizumab injections to NHS patients?

Room	Number of rooms of this type that you <u>set up</u> or <u>modified</u> in order to offer ranibizumab/bevacizumab
Waiting rooms	
Sterile rooms suitable for intra-vitreous injections	
Visual testing lanes	
OCT rooms	
FFA rooms	
Consultation rooms	
Optometric assessment rooms	
Recovery rooms	
Other rooms (please specify)	

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Abbreviations: FFA, fundus fluorescein angiography; OCT, optical coherence tomography.

10. What percentage (%) of 'On Costs' or 'overheads' does your trust charge?

.....

c) Are overheads applied only to staff costs? YES/NO

d) If **NO**, what other resources are overheads applied to?

.....

.....

11. Are there any other costs or resources that are required to run clinics for administering ranibizumab/bevacizumab or monitoring outcomes that you have not mentioned above?

YES/NO

a) If **YES**, provide details below

.....

12. If you have any comments on the questionnaire (such as difficulties that you encountered interpreting or finding the information for any specific sections, or any suggestions you may have for improving this questionnaire), please record them here.

.....

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE