CLEAR III GUIDANCE FOR VIDEO RECORDING MODIFIED RANKIN SCALE ASSESSMENTS

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2. Introduction

Acute stroke trials require a robust measure of functional outcome. At present, the modified Rankin Scale (mRs) is the most popular outcome measure (table 1) and is an ordinal scale with 6 categories ranging from zero (no symptoms) to five (complete physical dependence). A sixth category can be added to signify death.

Table 1 – The Modified Rankin Scale	
Description	**Score**
No symptoms at all	0
No significant disability despite symptoms; able to carry out all usual duties and activities	1
Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance	2
Moderate disability; requiring some help, but able to walk without assistance	3
Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance	4
Severe disability; bedridden, incontinent and requiring constant nursing care and attention	5
Dead	6

Despite this being the most commonly used assessment, there are some concerns. Inter-observer variability is recognised meaning that observers often disagree even when assessing the same patient which in a clinical trial could compromise assessment of the endpoint, reduce statistical power and ultimately harm the trial.

Digital video recording of mRs assessments will address this concern in the CLEAR III trial. It will limit the effect of inter-observer variability by allowing central “off-line” scoring by a small number of expert investigators. It will also permit validation and re-scoring of initially misclassified patients, or in situations where disagreements occur (there will always be some disagreement but a consistent approach to these subjects is crucial). It will also help ensure quality of data (via source data verification and by ensuring adherence to interview procedures) and most importantly provide a mechanism through which we can ensure blinded endpoint assessment in the CLEAR III trial.

3. Getting Started

Before starting the study there are some simple tasks we ask you to follow (as well as completing training). We want you to;

1) Ensure you and all others at your centre have completed all relevant training.

2) Ensure you are comfortable using the equipment (you can watch a video demonstration and the notes here will help).

3) Perform a test assessment and upload (the process here is described below).

4. Observer Training

All investigators must be trained in mRs assessment using a validated web-based training programme before beginning participation in the CLEAR III trial. A link to the training web-sites can be found on the CLEAR III trial website. Each participant must register their own training account. The link for mRs training is **http://clear-3.trainingcampus.net/.** You will be unable to upload any assessments if training has not been completed. Observers will also be shown how to operate the video camera and given a practical demonstration on video upload procedures.

5. Participant Consent

The use of video recording is documented in the participant information sheet. No separate consent is required for use of the video recording. If a proxy is used, a separate consent form can be used for them (see section 10).

6. Guide to Performing the Rankin Assessment

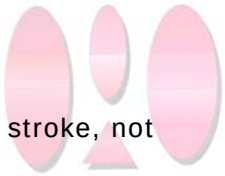
mRs assessments will be performed on survivors in standard fashion according to each centre's normal practice, although guidance is available here. All assessments should ideally be performed in a quiet and private clinic room, or if needed by a patient's bedside with the curtains drawn or at home if they are unable to attend the hospital. If home assessments are performed, it is the responsibility of the local investigator team to ensure relevant policies and procedures are in place.

Whenever possible, the assessor should remain constant across the follow-up period for a given patient. Also, we advise that those who have been heavily involved in clinical care of the participant do not perform the assessment where this can be avoided. We recognise these restrictions may sometimes be impractical and they are not mandatory.

The mRs assessment must be recorded using a digital video camera. The patients face and upper body should be visible on screen **unless the participant clearly has the most severe level of disability (for example a mRs score of 5) or where coma or intubation render assessment impractical.** In this scenario we advise, as would be the case in normal practice, that a proxy be used to provide information and thus should be interviewed on video in place of the participant. For dysphasic patients who need a proxy to answer for them, it is ideal if both the patient and proxy can be seen together in the video.

Use of a proxy - A suitable proxy is a relative, member of nursing or medical staff or other carer. In some scenarios, for example in those with dysphasia or memory impairment, interview of both the participant and a proxy may be required. In the most severe cases of disability, it may be sufficient for the video to contain a brief statement outlining level of dependency. If no proxy is available, or a proxy does not consent to be videoed (see below) the principal or other local investigator could substitute and be videoed.

Note that only symptoms arising since the stroke should be considered. Walking aids or other necessary mechanical devices are disregarded provided that the patient can use these without external assistance.



The score of 0 is awarded to patients who have no residual symptoms after their stroke, not even minor symptoms.

If patients have any symptoms resulting from the stroke, whether physical or mental, then they should be scored at least 1 on the Rankin scale. For example, if they have any new difficulty in speech, reading or writing, in physical movement, sensation, vision or swallowing, or any change in their mood that does not limit their activities, they still should score 1. Patients in this category can continue to take part in all of their previous work, social and leisure activities. For this purpose, "usual" is regarded as any activity that they used to undertake for a monthly basis or more frequently.

If there is any activity that they used to undertake that they can no longer do since the stroke, whether because of a physical limitation or because they have chosen to give up the activity as a result of the stroke, then they should be scored 2 on the Rankin. In this category the patient has slight disability and is unable to carry out all his previous activities, but he is still able to look after all of his own affairs without any external assistance. For example, a patient would be scored in this category if he used to play golf and is no longer able to do so, or if he used to have a job whereas he now no longer works. The patient should still be able to look after himself without any daily help. In other words he will be able to dress, move around, eat, go to the toilet, prepare simple meals, undertake shopping and make short journeys by himself. He will not require any supervision from other people and could safely be left at home for periods of a week or more without any concern. **The inability to drive because of legal impediment where the participant is otherwise physically unable would not warrant a score or 2.**

Rankin category 3 is for patients who have moderate disability. These patients require some external help for daily activities but are able to walk without assistance. They may use a stick or a frame for walking but the assistance of another person is not required for this. They will be able to manage daily activities such as dressing, toileting, feeding etc, but will need help for more complex tasks such as shopping, cooking or cleaning or will need to be visited more often than weekly for some other purpose. The external help may simply be advisory, for example supervision for their financial affairs.

Patients with moderately severe disability who are unable to walk without assistant and unable to attend to their own bodily needs by themselves are given a score of 4. These patients are not independently mobile and will need help with daily tasks such as dressing, toileting or eating. They will need to be visited at least daily or will need to live in close proximity to a carer. To discriminate patients in category 4 from those in the most severe category, consider whether the patient can regularly be left along for moderate periods of a few hours during the day.

Patients who cannot be left alone even for a few hours should be given the score of 5. Patients in category 5 have severe disability and are usually bedridden, incontinent and require constant nursing care and attention. Someone else will always need to be available during the day and at time during the night, although this will not necessarily be a trained nurse.

Thus, in summary, to distinguish between patients in category 0 or 1 consider whether the patient has any remaining symptoms. To distinguish between categories 1 and 2 consider whether the patient can undertake all of his previous activities. If the patient is independent of others in activities of daily living, then he should be scored 2 rather than 3. To distinguish between category 3 and category 4 the crucial question is whether the

patient can walk without the assistance of other people. Finally, a patient who can be left by himself for a few hours during the day would be given a score of 4 rather than 5.

It is important to note that patients do not always fall neatly into one category and some judgement is usually required when scoring them. When in doubt between 2 categories, always stick to the key discriminators of the scale. Thus if the patient has remaining symptoms he scores at least 1. If the patient is unable to undertake previous activities he scores at least 2. If he is dependent upon others in activities of daily living he must score at least 3. If the patient is unable to walk without assistance he must score at least 4 and if the patient is bedridden and requires constant nursing care he will score 5. **Finally, if there is still some doubt between two alternatives on the scale, and both options appear equally valid, then the worse option should be chosen.**

As an example we have included some key discriminating questions that should be considered when using the modified Rankin scale. These are shown in more detail below (the official definitions of each category are shown below in bold and the italicized text provides guidance that may reduce inter-observer variability, without requiring a structured interview).

0. **No symptoms at all**

The patient should be unaware of any new limitation of symptom caused by the stroke, however minor.

1. **No significant disability despite symptoms; able to carry out all usual duties and activities**

The patient has some symptoms as a result of the stroke, whether physical or cognitive – for example affecting speech, reading or writing; or physical movement; or sensation; or vision; or swallowing; or mood – but can continue to take part in all previous work, social and leisure activities. The crucial question to distinguish grade 1 from grade 2 (below) may be, 'is there anything that you can no longer do that you used to do until you had the stroke?' As a guide, an activity that was undertaken more frequently than monthly could be regarded as a 'usual activity'.

2. **Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance**

The patient will be unable to undertake some activity that was possible before the stroke (e.g. driving a car, dancing, reading or working) but is still able to look after him/herself without help from others on a day to day basis. Thus, the patient can manage dressing, moving around, feeding, toileting, preparing simple meals, shopping, and travelling locally without needing assistance from anyone else. Supervision is not necessary. This grade assumes that the patient could be left alone at home for periods of a week or more without concern.

3. **Moderate disability; requiring some help, but able to walk without assistance**

At this grade the patient is independently mobile (using a walking aid of frame if necessary) and can manage dressing, toileting, feeding, etc but needs help from someone else for more complex tasks. For example, someone else may need to undertake shopping, cooking or cleaning and will need to visit the patient more often that weekly to ensure that these

activities are completed. The assistance can be advisory rather than physical: for example, a patient who needs supervision or encouragement to cope with financial affairs would be in this grade.

4. **Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance**

The patient requires someone else to help with some daily tasks, whether walking, dressing, toileting or eating. This patient will be visited at least once and usually twice or more times daily, or must live in proximity to a carer. To distinguish grade 4 from grade 5 (below), consider whether the patient can regularly be left alone for moderate periods during the day.

5. **Severe disability: bedridden, incontinent, and requiring constant nursing care and attention**

Someone else will always need to be available during the day and at times during the night, though not necessarily a trained nurse.

7. Recording the Rankin Assessment

There are 4 important points to remember.

1. **YOU SHOULD ENDEAVOUR TO RECORD THE ASSESSMENT IN A SINGLE FILE.**
2. **REMEMBER NOT TO GIVE ANY INFORMATION WHICH MAY REFLECT TREATMENT ALLOCATION DURING THE RECORDING.**
3. **REMEMBER NOT TO STATE ANY IDENTIFYING INFORMATION SUCH AS PARTICIPANT NAME DURING THE RECORDING.**
4. **REMEMBER NOT TO STATE YOUR RANKIN SCORE DURING THE RECORDING (EVEN IF IT IS OBVIOUSLY FIVE FOR EXAMPLE).**

A FLIP Mino video camera will be used. The camera records direct to an internal hard drive. An easily portable desktop tripod will be used to mount the video camera.

It is crucial to that the camera has sufficient battery power for the recording. When fully charged, it will record for up to 4 hours between charges. It takes approximately 3 hours to fully charge via the inbuilt USB connection (it can be charged via mains electricity also as outlined in the video). It is also recommended that, prior to any recording, that a do not disturb sign is placed on the outside of the door and that ward or clinic staff are informed recording is taking place to minimise external noise.

It is recommended that the assessment is performed with the assessor, participant and equipment positioned as shown below (figure 1).

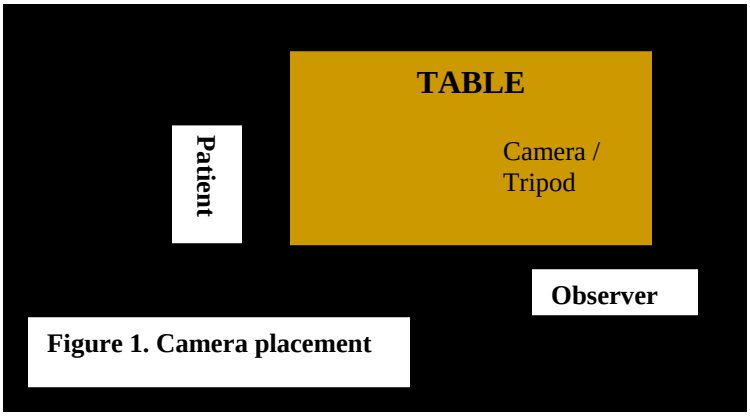
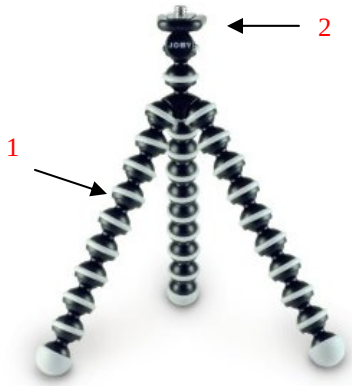


Figure 1. Camera placement

The camera should be mounted on the desktop tripod.



The desktop tripod has flexible legs (1) which may not be required, although can be used to optimise the height of camera and views of patients obtained. The camera is attached by aligning the in built screw on the tripod (2) with the corresponding area on the lower surface of the camera.
Figure 2. The Tripod

Once the camera is mounted, it should be turned on.

This is the FLIP Mino camera. .The record switch can be seen (1). The in built USB socket is located at the top of the camera (2) and is opened using the switch at the side of the camera (3). The on switch is located at the opposite side to this.
The camera lens is also shown (4).

Figure 3. The FLIP Mino Device

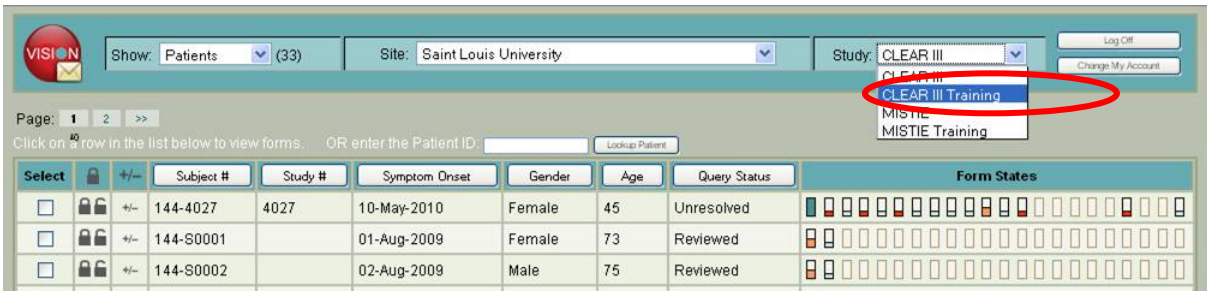
Once the equipment is set up, simply press the record switch to begin recording and you can verify that camera position is appropriate from the LCD screen. **Always ensure the red light on the LCD screen is present (which means the camera is recording) before starting your assessment.**

After the assessment is complete, remember to stop recording.

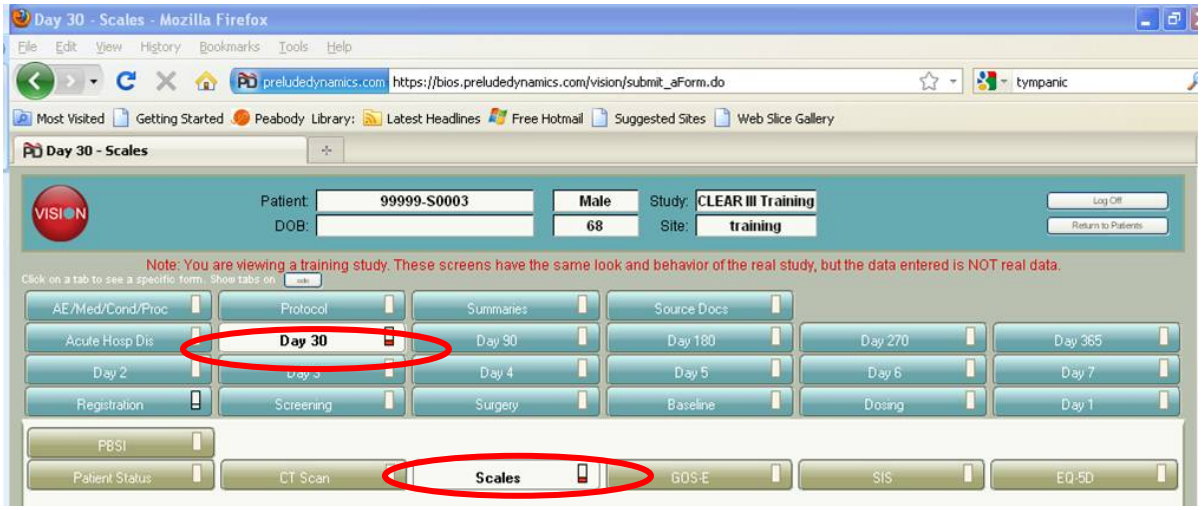
8. Saving the Assessment and Upload to the Endpoints Centre

First, the camera needs to be connected to a USB port on your computer. The computer should automatically recognise the camera. Sometimes a window of files located on the camera will automatically open. This can be closed but does allow you to view the clip. The recorded clips will be approximately 20 to 70 megabytes.

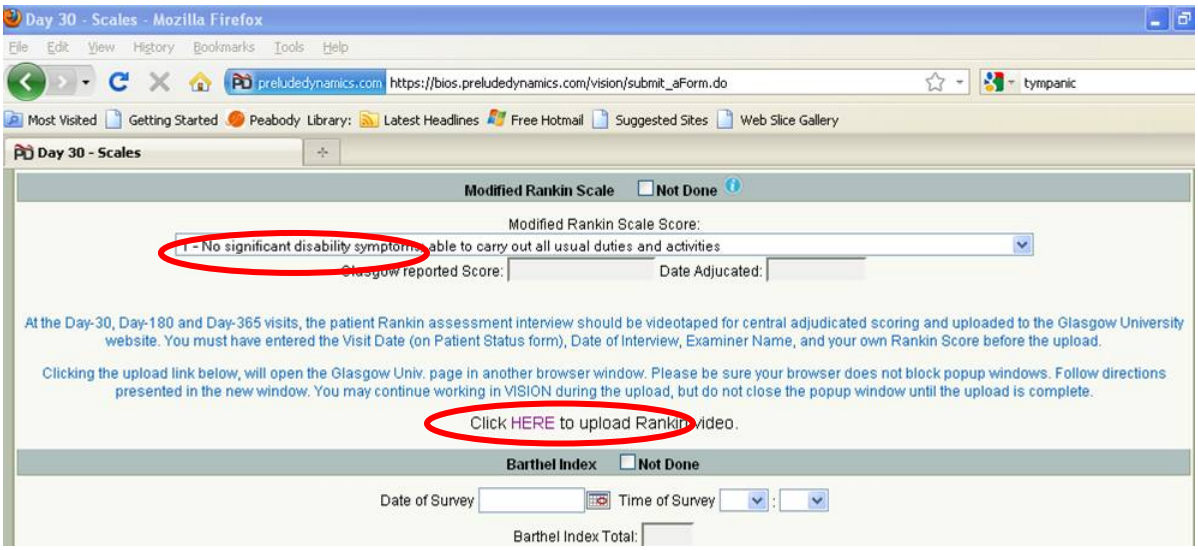
8.1 - In EDC , go to CLEAR III Training for practice, or to your patient's page for real data (the training example is shown below):



8.2 - Select your patient, then the appropriate visit and then scales.

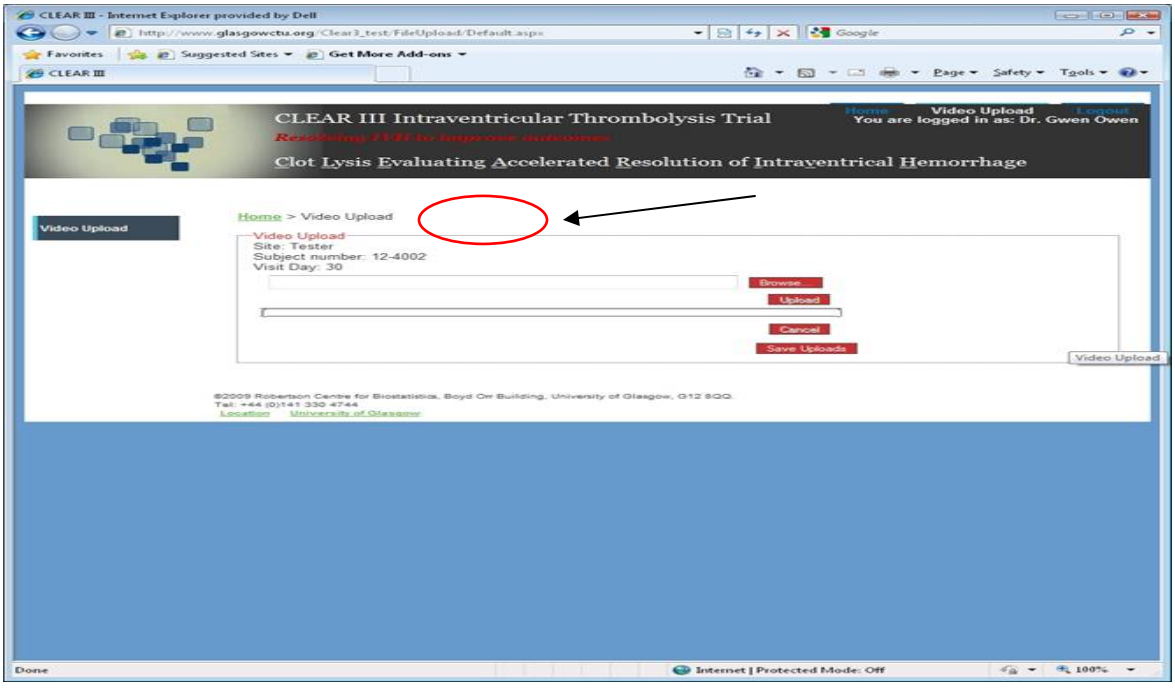


8.3 - Using the dropdown to select the modified Rankin scale. Enter your score then click on 'Click the HERE to upload the image'.

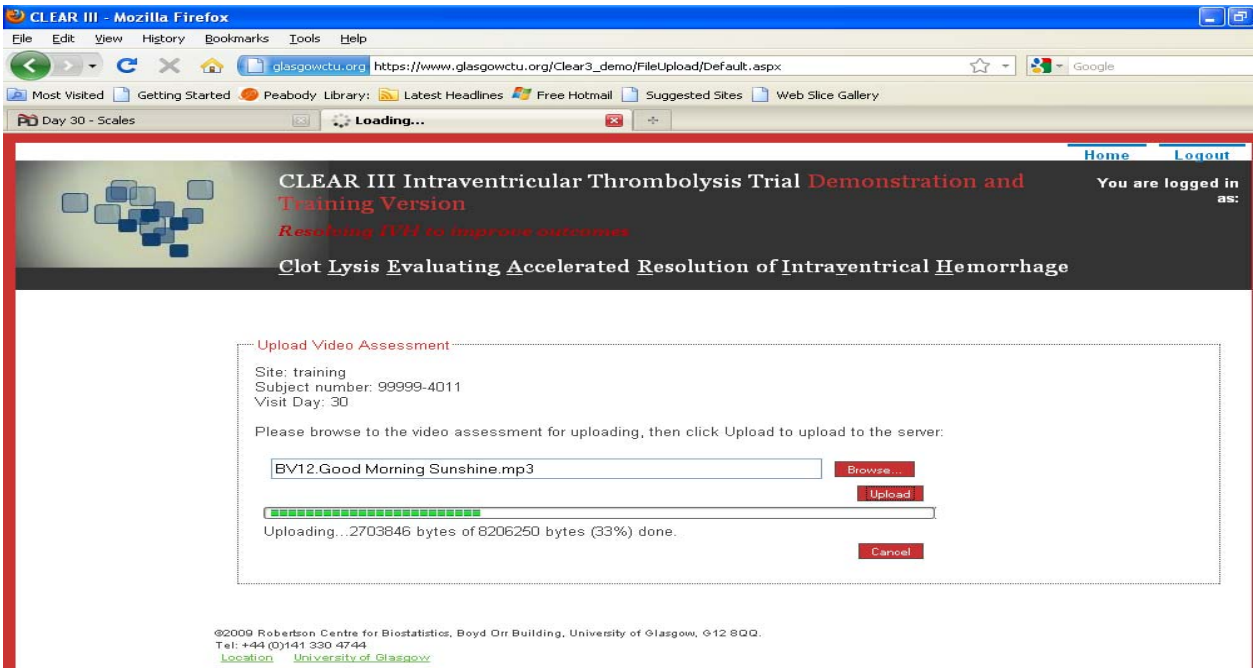


8.4 - You will then be directed to the Glasgow Rankin upload page:

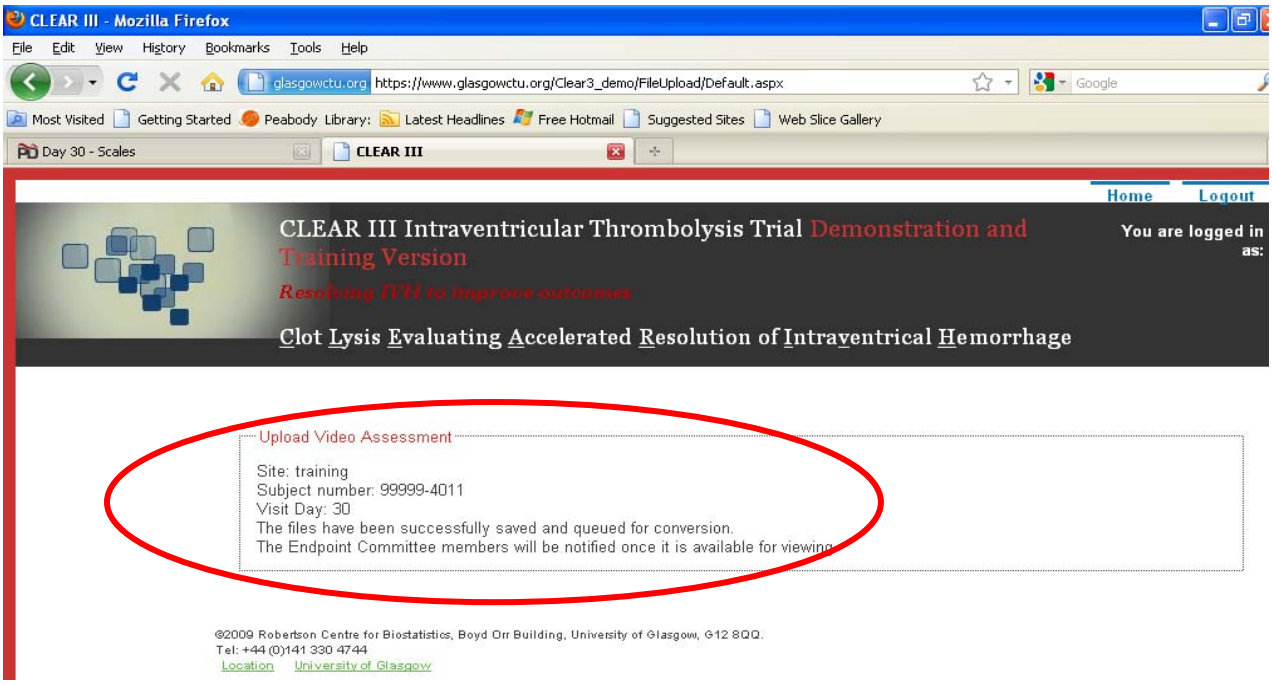
First you will need to locate the video recording. The recorded files are located by opening the My Computer folder, then the Flip Camera, then the DCIM folder, then the 100 video folder. This will open a list of clips on the camera numbered chronologically in order of date filmed (from the first to most recent).
Once the correct file has been identified, click on it and it will be added to the upload box and then click on upload.



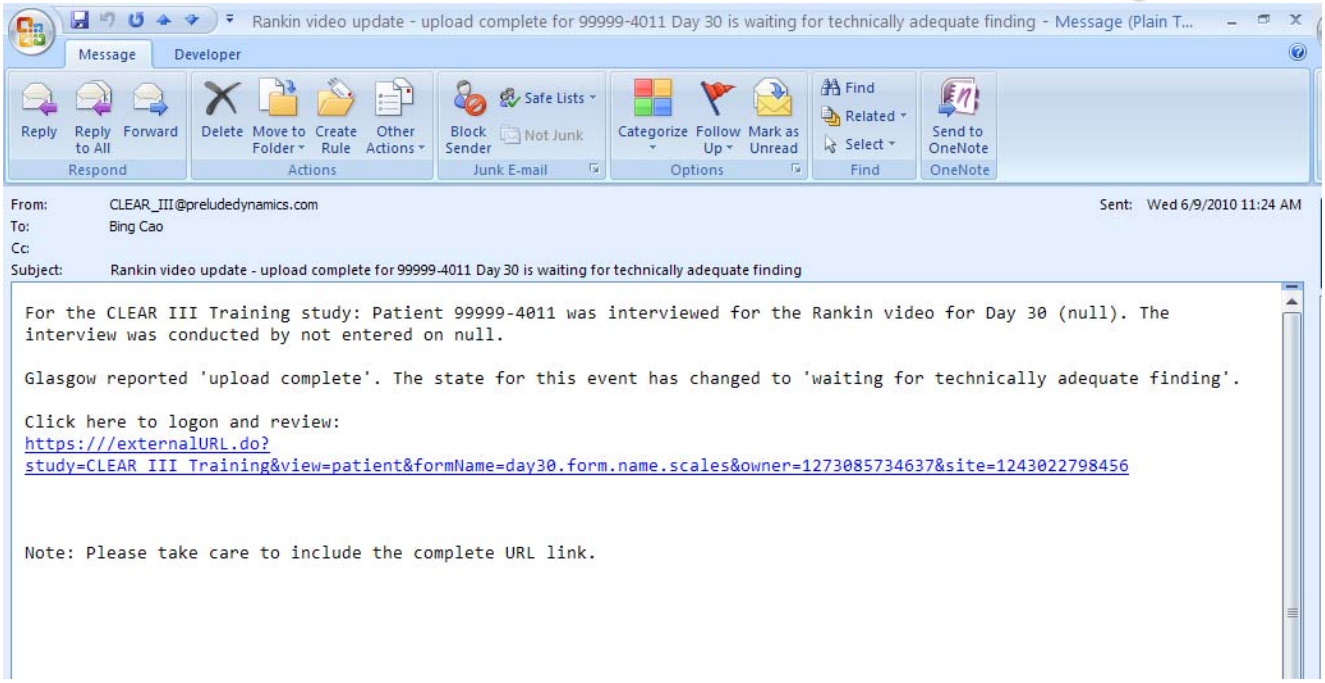
Progress will be shown by the green bar. Upload of the video may take 30 – 40 minutes for a very large file.



8.5 - A notice will appear on the screening if the video is loaded successfully



8.6 - You will also receive an email confirmation from EDC for video uploading



Thereafter, you will be notified when the video is deemed technically adequate (or not) and when a score is assigned.

The outcomes manager from Glasgow may contact you by email for further information if required.

9. Further Practical Guidance / Example Questions

Please use your judgment over how to start the interview and what topics to cover: an obviously disabled patient will be interviewed very differently from an apparently well individual.

We would like you to ask **open questions** to illustrate:

Previous activity levels

How the stroke has affected your patient and how is he or she now. In particular,

- What symptoms your patient still has
- What activities have been lost (and why)
- For daily activities, what is the level of dependence or what does he or she need help for
- How does he or she describe mobility and capability to handle essential functions such as eating, toileting and washing

IF SUBJECT IS IN A COMA: Interview a surrogate or care-taker on camera. Make statements, such as:

"The subject is in the ICU on ventilation, alert and oriented (x___) requiring full nursing care."

Do not state the subject's score on camera.

PROBING IS CRUCIAL

NO PRINTED LIST OF QUESTIONS CAN REPLACE AN INTELLIGENT CROSS-EXAMINATION

Here is an example for a patient with moderately good recovery

At the start of the camera recording, first say:

This is patient number __ __ __ - __ __ __ for his/her __ month visit in the CLEAR-III trial.

Thank you for agreeing to let me ask you some questions. I would like to find out how you were before you had the stroke, what sorts of activities you used to do and how independent you were, then how the stroke affected you at the time, and finally to ask about what symptoms you have now: what activities you have returned to, what you are able to do for yourself or what help you need.

Can I start by asking you to tell me what you were like before you had the stroke, please? How independent were you and what sorts of things did you do?

When you first suffered the stroke, how did it affect you – do you remember enough to tell me what symptoms you had?

Now that some time has passed and you have started to recover, can you tell me what symptoms you have now?

Would you tell me what activities you are able to do now and about anything you used to do that you are no longer able to do? … Why?

Can you tell me about how you manage walking or moving about?

Can you describe how you manage with everyday activities like getting dressed, washing, eating, going to the bathroom? What help do you need for these?

10. Example Proxy Consent

At the time of the original consent, there is no way of knowing whether the patient can participate in videotaping at 30, 180 and 365 days from study entrance.

If someone other than the patient is videotaped, the study leadership would like you to complete a “consent to videotape” with the proxy (see next page).

Furthermore:

- If a proxy fails to sign consent before the recording, do not film the proxy.
- If the proxy recalls the consent after recording,
  - The recording is not used and is erased as soon as possible
- If the proxy refuses or recalls the consent after recording,
  - The coordinator will then interview the PI who will describe the subject’s condition. **We still need the data in videotape format**!

Please copy the next page and use as your Proxy Consent Form

CLEAR III Proxy Videotaping Consent

The purpose of this document is to obtain your consent to talk with you on videotape

1. In the CLEAR III study, we record each patient at three follow-up visits
2. Today, we are unable to record an interview with the patient who is enrolled in the CLEAR III study but too ill to speak
3. We would like to record you instead while you briefly describe the patient's condition
4. The purpose of the recording is to have the same central readers at the University of Glasgow evaluate every patient's condition
5. Only physicians and staff at the University of Glasgow will see the video in a professional hospital research setting
6. The recording will not be broadcast or used for any other purpose and no other copies will be made
7. The recording may be stored on a computer server for 15 years

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Videotape Consent

I, the undersigned, hereby give my permission to be videotaped for the purposes described above.

Name: _____

Signature: _____

Relationship to study patient: _____

Date: _____

Signature/role of CLEAR III interviewer: _____

Date: _____

11. Frequently Asked Questions

What counts as an activity?

An activity can range from a sport, driving, working, playing games or socialising to looking after a family member. Generally speaking a relevant activity should be something performed at least on a monthly basis, and something that was done prior to the stroke.

What is the activity is still performed but not as well or frequently?

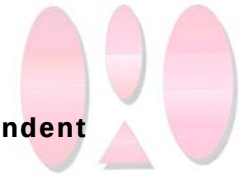
Any activity performed half as often (or less) than before the stroke should count as an activity loss if it is associated with impairment. If a patient still does the activity as frequently but is simply not as good as before (such as golf or other sports) then this in isolation need not count as an activity loss.

What if I think my patient could do the activity but chooses not to?

This can be difficult. An activity loss in association with an impairment which could realistically limit that activity should be scored as an activity loss. Where the activity loss is not due to impairment then it alone does not necessitate a score of 2. This includes examples such as driving where the patient has made a full recovery but has a legal restriction. Probing to establish the nature of the impairment associated with activity loss and whether other activities are lost is critical in this setting?

My patient needs help with carrying heavy shopping but can do everything else. Does this mean he is dependent?

Many stroke patients will become independent with their basic activities of daily living and function independently with the exception of tasks such as the 'weekly shop' and more complex financial matters. This may be because of loss of the ability to drive meaning they are taken to the shops. In this situation it should be clarified whether the patient could walk to the nearest shop and independently purchase crucial items such as bread and milk. If this is possible and the patient needs no other help then they should be classed as independent. If the patient can manage all other activities of daily living and basic financial tasks such as paying bills, personal banking and purchasing items but gets help with more complex financial tasks such as moving house or paying taxes, they should be classed as independent.



My patient can take a few steps unsupported. Does this count as independent walking?

Walking counts as independent provided it is not assisted by another person (walking aids such as a cane are allowed) and is used toward a goal at least reasonably frequently. For example, someone who can take 5 or 6 steps unaided after being helped to stand who cannot independently move around the house does not have independent mobility. Someone who can walk unaided with a zimmer frame to the toilet and back does.