WORKING WITH PROTOCOLS

What is a protocol?

An agreed standardised way of performing a task. A process that is repeatable and reproducible.

Why use a protocol?

Under Council Directive 97/43/Euratom of June 1997 individual National legislations of EU members will all include a section with wording similar to this:

Duties of Employer

The employer shall ensure that written procedures for medical exposures … are in place and -

shall take steps to ensure that they are complied with by the practitioner and operator; ….

The employer shall ensure that written protocols are in place for every type of standard radiological practice for each piece of equipment

(Taken from UK legislation IR (ME) R 2000)

There are more details on exactly what must be set out by the employers and followed by all categories of staff.

There is still room for slightly different interpretations on exactly what must be laid out unequivocally and what left to the discretion of the worker to modify with respect to individual circumstances. So we can still think profitably about how these laws are best followed in our own departments

EANM Technologist Workshops

At the EANM Congress in Barcelona in 1999 the Technologist Committee ran a workshop on Protocols and addressed issues including

- Why do we need protocols – legally and practically?
- Are they altogether a good thing?
- Do they change the need for staff training and experience?
- Do staff like working by them?
- Who writes and who approves the protocols?
- What should be included in them?
- Why should it be there?
- How prescriptive do they need to be?
- Should they describe everything or leave room for common sense
- How much room is there for modification to individual patient?
- Is there room for individual parameter choice?

The following is largely taken from notes produced by the group leaders at that session

What are the advantages of working to set Protocols?

- It enables all procedures to be undertaken in a standard manner.
- It should lead to inter-operator independence, any member of staff should produce same/similar results
- It enables new staff to familiarise themselves with studies quickly
- It enables all staff to perform less frequently performed studies safely without relying on memory.
- It provides a consistent presentation of data
- It encourages confidence in results
- Providing written instructions enables minor disciplinary/corrective action to be taken for deviations from the accepted department procedure.
- It enables audit procedure
- ? It prevents all/some errors

There are some consequences that some people may think are useful but are they altogether a good thing?

- It allows procedures to be performed without background knowledge.
- ? It lets the staff work without having to think too much
- ? It allows employment of less well qualified or experienced staff with consequent saving to department budget.

There are some possible disadvantages as well

- It may lead to mindless working - Leading to lack of interest in the work.
- It can mean a lack of “ownership” of technologists’ work - leading to demotivation.
- Misunderstandings may lead to misuse - is this dependent on how well written protocols are; is it possible to be foolproof?
- Useful individual adaptations may not be made, leading to sub-optimal images or QC tests in a few cases.
- Employment of less well-qualified or experienced staff may lead to issues of diminished patient care and image quality.

Protocols have a tendency not only to minimise failures, but in the process also to eliminate genius…….

W van Hoorn, EANM Presentation, Sept 1999

It is a challenge to write the best protocols to make the most of the advantages and minimise the disadvantages.

Guidelines

National and even international guidelines for NM procedures are increasingly available or under construction. This is linked to a drive for nationally agreed targets and the application of Evidence Based Practice.

As stated on the British Nuclear Medicine Society (BNMS) website http://www.bnms.org.uk/bnms.htm, they have mainly been put together by consensus opinions of acknowledged experts, drawing on published evidence, and, by looking at the key points in a procedure where quality can be affected, aim to set standards for its performance. They are all intended to be "dynamic documents" flexible enough to change with changing evidence and technology. Some guidelines for the UK are available on this site.

> *Guidelines in Nuclear Medicine have been, and continue to be, developed by a number of organisations throughout the world. National regulations on the administration of radioactive substances and differences in clinical practice and service delivery mean that guidelines do not readily apply across regional and national boundaries.*

In the United States the Society of Nuclear Medicine Guidelines for most procedures are available to download from http://www.snm.org/policy/new_guidelines_1.html and have formed a **basis** for most others

European Association of Nuclear Medicine Guidelines for a few procedures are available to download from http://www.eanm.org/. Each is prefaced by the statement that the purpose of the guideline is to offer to the nuclear medicine team a framework, which could prove helpful in daily practice.

These frameworks, therefore, can form the backbone of a local protocol but clearly cannot supply the detail required in each individual department

RADIATION PROTECTION 118 - Referral guidelines for imaging of the EU can be found on www.europa.eu.int/comm/environment/radpr...8/rp-118-en.pdf

Who should write protocols?

Excluding radiopharmacy procedures, there are generally three disciplines with potential input into protocols. Although there is a good deal of knowledge held in common between the three groups, clearly there are different major areas of expertise. Medical staff know what structures and distributions they must see and at what stages in a study in order to make a diagnosis. They also have legal responsibility, when Heads of Department, for what happens there. This must dictate the main shape of a protocol. Physicists know what the equipment should be capable of and the inner workings of the processing algorithms. Technologists know the practical side of the local equipment, what is feasible in patient management and what is time efficient. They will also have an experience in what problems can most commonly occur. Ideally aall three can contribute, with their relevant inputs, to provide a protocol that produces the best quality and most useful images in a way that is workable and easily followed. In the UK the ARSAC holder should be involved in drawing them up and they should be approved in some way. i.e. a local radiation safety committee

Who feels some control of the protocols?

If all groups have been involved, then hopefully all groups will feel their points of view have been heard. If they are too long winded or complicated they may not be followed or the short cut will seem too tempting. This is particularly true when something is, for whatever reason, no longer working very well and needs to be changed.

Who suggests modifications and how are they introduced?

Again hopefully anyone will be allowed to express an opinion that a change is necessary and, in any case, that regular reviews, involving all disciplines, are undertaken.

Adaptations – realisation that we are dealing with individual cases.

Can protocols be written to fit all possible occasions? If they are too prescriptive, what can the individual technologist to when it comes to special circumstances and "difficult" patients? It should be possible to write in alternatives or ranges of values giving some room for modification “if required”, thus leaving some judgement up to the technologist. Examples might be in areas such as;

- Position e.g., where individual views or a prone WB bone scan might be performed rather than supine for a patient unable to maintain this position.
- Counts per view might be reduced to shorten time (patient in pain or not cooperative), with a minimum value set.
- Numbers of views e.g. limited for a bed-bound lung scan, or extra views needed of a kyphotic spine in a bone study, again with priority views made clear.

Instructions should be clear as to how and where to record any adaptions made so that clinician reporting knows what has happened and why.

How much room for modification there is in computer processing protocols, e.g. drawing irregular ROIs around unusual kidneys or trying different filters, is often more a factor of the computer system than one of local choice. Some are inflexible so that, for example, it is necessary to draw a ROI over a non-existent kidney in order for the software to produce the curves that are wanted, or drawing extra ROIs over regions of a horseshoe or grossly enlarged kidney cannot easily be accomplished within the set protocols. Sometimes it is not easy to try a different filter in a reconstructed myocardium when there has been a poor uptake and atypically few counts obtained. It should be possible to include instructions for dealing with these situations and ranges of values, where they may be used added. The challenge is to do this whilst still producing a document that is small enough to use easily.

How should a protocol be written?

There was a consensus that protocols should be divided into general areas with specific procedures detailed separately.

What should be included in a protocol?

The groups came up with a list from which the outline is constructed.

If protocols are carefully written there should still be room for using the training and skills of a technologist to produce the optimum images in each case but it by no means a simple task.

Of course protocols are of no use whatsoever if they are not followed. It can be a good idea to make regular checks that this is happening.

Good luck

OUTLINE PROTOCOL

Reasons for the study

- Common clinical indications for the study; included as an extra check that only appropriate studies are undertaken.
- Who to ask if there seems to be a discrepancy.

Preparing Radiopharmaceuticals

Procedures for the production of radiopharmaceuticals are not in the scope of this article. However the technologist should be assured that;

- the appropriate quality control has been performed on the radiopharmaceuticals
- they are approved for use before administration

Identification of patients and consent

- Location/availability of information leaflets for each of the examinations?
- Identity checking procedure
- Checking procedure on pregnancy and breastfeeding
- Checking procedure for previous studies
- Checking procedure for any contraindications
- How to obtain informed consent by questionnaires/written forms/ asking patient to sign declaration according to department policy.

Patient preparation

- Procedure for checking that any dietary restrictions have been followed. e.g. fasting for six hours before a Meckel's study.
- Procedure for checking that the patient has not been taking any drugs that might interfere with the study e.g. Thyroxin or contrast media in thyroid imaging.

Dose

- Nuclide and compound used, e.g. ^{99m}Tc - Methylene diphosphonate
- Routine range of administered activity with justifications for special cases e.g. increases/decreases for weight, reduction of scan time.
- Method of dose adjustment for children, e.g. formula, graph or table
- Method of administration e.g. i.v. oral and any special instructions.

Time before imaging starts

- Minimum time before the study may commence to allow for the desired biodistribution

Equipment Preparation

- Procedure for determining that the appropriate daily quality control has been satisfactorily performed.
- Technical details – for each machine/camera
    - Collimator used
    - Energies used, window width and whether centred or offset.
    - Computer programs/macros used
    - Matrix used
    - Zoom factor, (remember the effect on apparent matrix size).
    - Image orientation

Study details

- Patient positions.
- Views required.
- Number and sequence of images.
- Counts/time per view.
- Any surface markings needed.
- Any findings requiring further views.
- Image identification, anatomical and time markers.

Processing instructions

- Computer programs/macros used
- Brief explanation of programs with subroutines
- Values of any factors to be input
- How to define ROIs, manual/auto/circular/rectangular with any special instructions e.g. at least one pixel outside the kidney if using the “Goris” algorithm for background subtraction.
- Curve labelling and legends
- Image display colour scale, format and sequence

Patient care after examination

- Any special further instructions e.g. warning regarding the ongoing effects of a diuretic.
- Radiation protection instructions e.g. avoiding children and pregnant people for 24 hours, according to agreed departmental procedures.

Example Pictures.

A set of images with good positioning, resolution, contrast, properly arranged and labelled would serve as a standard to aim for. Images with common problems or artefacts could be useful but these might be kept in a general file for training purposes.