Labelling
A Pre-requisite for Biological Quality Assurance

Labelling
What is labelling?

I remember my early lectures for my degree, when we discussed this matter. In a sense it was taken in the spirit of Cogito Ergo Sum. Not "I think, therefore I am" but the ontological "I am labelled therefore I exist." Labelling is a human way of giving existence to something - even if it does not exist (2).

With my degree course of psychology, the question was what are we studying, and the clear and simple answer "The mind" comes to mind (yes the pun was intended). But is the mind a label that we have created for something that does not exist; and by labelling it do we give it existence?

I will leave this esoteric question (and all of its consequences) for another time. But it does show that words have lots more power that we initially think. It is why scientists choose their words (labels) very carefully. We know what we mean by alloquot, and we know why we use that label rather than any other "sloppy?" label. It is to be sure that we know exactly what we are talking about.

And that is what labelling is about, it is about trying to make sure that we are picking up, looking at, using and whatever else - exactly what we expect to be dealing with. The label gives the item it is attached to a validity and a security that would not be there without the label.

In our own world we use techniques to make the words work and label our materials very accurately. It is crucially important that we do the same with the biological material that we work with. After all this is the main objective of the work.

How To Label
The Pocket Oxford Dictionary describes a label as "piece of paper etc. attached to an object to give information about it."

There have been many documents that have looked at how to label material in the IVF area (1, 4, 5). Some of these are linked to other more general medical approaches (4) which are concerned about patient labelling to ensure that "the wrong limb is not taken away from the wrong patient in the wrong operating suite." The title of the article is very apt here - Patient Identification Correct Patient, Correct Site, Correct Procedure. It would appear that labelling is fraught with errors everywhere, and that it is clear that we all need to ensure that we label in the best way, and that those labels are checked.

But what are the rules for labelling?

Some of these include ensuring that there is at least a human readable label attached to

whatever is being labelled. That label should contain at least two different identifying features, for example patient name and date of birth. But even these have the potential for confusion. If Mrs Zed born on 1st April 1990 is compared with Mrs Zed born on 4th January 1990 these two ladies can easily be confused, despite the data being different. If a hospital number were added, this would increase the resilience of the labelling system and reduce the likelihood of errors.

It is not in the remit of this paper to look at the considerable details of how to ensure that a human readable label is best set up - but it can be seen that this is not a small topic in its own right. The book by the Mortimers (5) is worth reading as a good starting point. But it is very important to look at the whole in a risk assessment context to ensure that a good protocol is set up (another issue that the Mortimers (5) raise).

However, labels are not just about ensuring that two patients or tissue from two patients are kept distinct, but should include other aspects that ensure that correct media is used, and that appropriate methodologies are employed for the whole process.

As an example, if a Cell Banking organisation is using media for a particular cell line, then a bottle for that media is normally allocated to that cell line. This will ensure that refilling a "dirty" pipette with media only contaminates the media with the cell line currently worked on and no other cell line (by use of the potentially contaminated media).

It can be seen that the contamination is a failure in the procedure. The "dirty" pipette (in that it probably contains cells from this cell line and media now) should not have been used twice - even in the same line. But the risk assessment has shown that by allocating the bottle to this cell line, then if this error occurs, the contamination is a "minor" error that does not affect this or other cell lines.

Coming back to the question of how to label, we have a number of issues to deal with. The rules that seem to work best include:

- Ensure that there is at least one human readable label with at least two unique (and easily distinguishable) items of information on the label that will identify the target. The more information that is checked, the less likely there are to be errors. But humans are prone to information fatigue, so this has to be tempered with reason.
- If possible apply further label(s) (either human readable or machine readable) to increase resilience of labelling.
- Use machine readable labelling for verification and quality control at all stages if possible. The machine readability should not just verify the label, but should verify its relation to other labels and the process itself.
- If a disposable item has both a body and a cap, ensure that both body and cap are labelled. Check at usage time that both of these match. Do not label the cap alone. If a cap is switched, then the base is incorrectly labelled.

Note that the above rules start with a human readable label. This is the ultimate fall back label. If all else fails the human must be able to retrieve the situation - hence the comment to put at least two labels and at least two different identifying pieces of information on the target.

What to Label

Up to this point, what has been labelled has been called the target. But what should this target be? This is a question that has to be addressed by each organisation as part of its risk strategy. For complete and absolute risk reduction, the answer has to be Everything. But this can become impractical. Do you really want to label the waste bin?

But before we throw away the embryo with the media, let us review the situation and consider the risks. After all, risk assessment is one of the starting points that makes us consider labelling.

Let us take a simple example - do we label pipettes or not? They are used just once and they are throw away tools of the trade.

The risk reduction stance says that pipettes are labelled and checked at time of use. We have the HFEA[1] example where a pipette was used to pick up sperm and then left in a hood. The next user of the hood believed that the pipette was clean and used it to pick up some media for washing embryos. The end result was to bathe embryos in sperm.

As the press were told, this is not a major problem; sperm cannot inseminate embryos. But that is not the issue. The embryos may have been eggs; or the sperm may have come from the HIV bank and so on. Just because in this case the error was "minor" does not reduce the real magnitude of the potential error. An error was made because the label on the pipette was not checked before use. This error, although potentially minor in this example, could have had more damaging effects in different circumstances.

So the question comes around - what should be labelled? To reduce or mitigate risk to its lowest level then everything should be labelled. It is for each organisation to review its own risk management approaches and to decide what should be labelled, what can reliably be left unlabelled, and what the residual risks are and what mitigating actions are in place. Having documented these risks, then the organisation can make its own decisions about what should be labelled and what can be left unlabelled.

Going back to the "How to label" question, HFEA Alert 9[2] shows why body and cap should both be labelled and checked. A switched cap had labelled the wrong body. The consequent behaviour was unavoidable.

---

[1]The HFEA is the UK Regulatory Authority - The Human Fertilisation and Embryology Authority. It was set up by Parliamentary Statute in 1991 in order to license, regulate and generally control the workings of the UK clinics that provided assisted reproductive techniques. It looks to improve quality by regulating how clinics should work. For example, it has guidance that suggests that clinics should "double witness" all laboratory work where gametes or embryos are moved from one location to another.

[2]The HFEA has introduced an "Alert System" whereby any adverse event in a UK clinic is notified to the HFEA, and the HFEA logs this and reports this potential risk to all other clinics.

Alert 9 describes the situation where media in a petri dish was used to wash embryos in a second dish. By some unusual handling, the cap of the media was placed on the embryo dish. The result was that the embryos were disposed of, and the media was incubated. This could have been the last embryos of an oncology patient. So, again, this may not be the "trivial" issue that it appears.

What Type of Label

Having decided that we need to label, what sort of label is to be used on what?

What sort of labels are there?

At the crudest, embryologists resort to scratching information into the glass. There are significant advantages of this. The labelling is permanent and will not get removed. But a number of other embryologists will ask about the chemicals released by this process.[3]

We can put on sticky labels with hand written or printed details. These are fine on glass and plastic, but we have to resort to other types of labels for the patients themselves. In this case wrist bands are often used. These are fine whilst in wards, or in procedures; but I don't want to walk the streets with a wrist band on (or an ankle tag). Alternatives for this could be the use of credit card type identification methods (at the risk of raising the ID cards issue), which may be replaced by wrist tags only on admission.

Labelling large glass/plastic items is relatively easy with these examples, but what about straws, or small ampoules and the like. With the need for a human readable label, we have to say that sticky labels are going to be around for a long time. We know that equipment like the Brady Printers can print labels that are in about 4 point type and can just about be read when the labels are on straws.

But machine readable labels are also worthy of consideration. Here we have the concept of the barcode as an alternative printable label. For items that are used transiently, these are an ideal method of identification. However, for items that have to be frozen, and/or looked at in bulk, then this has its own limitations, and at this point RFIDs[4] come into their own. These small labels can be applied to all sorts of containers and, in many cases, are small enough not

---

[3]In fact, different embryologists are correctly concerned about the hazardous nature of most labels. Questions that have been raised by embryologists include:

- Does scratching glass and/or plastic release toxins that affect development?
- Do inks used on glass and/or plastic release toxins that affect development?
- Do inks used on printed paper release toxins that affect development?
- Do glues used for attaching labels to glass and/or plastic release toxins that affect development?
- If bar codes are used, does the laser light damage or affect the biological material?
- If RFIDs are used, do the radio or magnetic waves affect development?

[4]RFIDs or Radio Frequency Identifiers are used in stores to stop theft. But as time has moved on, they have become smaller and cheaper and are finding their way into many other applications. Their advantage is that they do not need batteries to work.

to impact current processes.

But there is even the possibility of using chemical labels on containers. These are microscopic chemical markers that can be uniquely associated with containers. These are probably not suitable for biological work at the moment, as the readers are currently enormously expensive.

It is fair to say that no single solution will apply to all situations. From experience it would seem that secure numerical coding on human read labels, standard patient names and other identifying data need to be on all medium storage vessels. For other vessels, it is important to have a mixture, including barcodes, RFIDs and any other new technology that comes along.

Just to create another discussion point, at the moment biological labelling is not considered as a possibility for the Assisted Reproductive World. It is being used world wide in other spheres. So with further progress in that field, it may be that we will see the biological labelling of individual cells in the future - so do not consider that we have reached the limit yet.

Does Labelling Create Quality Assurance?

No.

The real answer is that labelling is often seen as the panacea to risk reduction, where it is in fact only a tool to be used as part of a well thought through process. Labelling is the easy solution that allows us to see that Mr Smith is not Mrs Ghandi. Or less obviously, but the idea promoted by the labelling gurus, that Mr Smith's sperm is not the correct sperm to use to fertilise Mrs Ghandi's eggs.

But, as we have already discussed above, the mixing of the incorrect sperm and egg is the simplest of issues. The real issues arise in much simpler tasks. The issues are not just about the Telegraph (3) headline "Labelling blamed for IVF baby mixup." The implication is that labelling went wrong. So no technical method would then stop the mixup - no RFID readers; no barcode readers; no double witnessing. All of this is immaterial if the original label was incorrectly placed. The article is stating that the labels were incorrectly applied to the sperm. "The labels were switched."

So we come to the need to ensure that process is handled correctly and individually. A simple solution is only print the labels for one patient at a time, and apply these before moving on. Too simple too trite. But the emotion is correct. This is all about handling process, and labels are part of the tool set to deliver - not the solution on their own.

If the whole process is controlled, then the most risky point of the process has to be the initial labelling of the patient, and potentially the initial labelling of the material. If that is handled in a tightly controlled environment, and the continuing labelling is controlled, then we are as close as we can be to quality assurance. The message of this document is that labelling is important - but it alone is not the solution to quality assurance.

How Do I Move Forward to QA?

The subject of labelling is complex and needs careful consideration before jumping in with any particular solution. It is more appropriate to look at the particular situation and use the most suitable label for the application. Come and talk to EPCoT Systems Ltd for a considered approach to using labels within a totally controlled process environment.

Peter A. Parker
June 2007

EPCoT Systems Limited
PO Box 114
Pinner
Middlesex
HA5 1TQ

Tel: +44 20-8537 0395
Fax: +44 20-8931 5218

email:peterparker@onetel.com

Selected Bibliography

1. Brison DR, Hooper M, Crtichlow JD, Hunter HR, Arnesen R, Lloyd A, Horne G *Reducing risk in the IVF laboratory; implementation of a double witnessing system* (Clinical Risk Vol 10 No 5 Sept 2004 pp176-180)
2. Dawking R *The God Delusion* (Bantam Press London, 2006)
3. Derbyshire D *Labelling Blamed for IVF Baby Mixup* Daily Telegraph 23rd June 2004
4. Edozien E *Patient Identification Correct Patient, Correct Site, Correct Procedure* (Safer Health Care July 2007)
5. Mortimer D & Mortimer S, *Quality and Risk Management in the IVF Laboratory* (Cambridge University Press, 2005)