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MANAGING UNCERTAINTY IN ANDROLOGY

With andrology gaining more prominence as a discipline, **David Sanders** talks through the pre-examination process.

With andrology, like all other disciplines, having the appropriate sample is key to being able to provide an accurate report. This is further complicated as the patient collects their own sample, often at home, rather than being collected by trained staff.

These samples are normally diagnostic semen samples for fertility assessment, post-vasectomy analysis or urine for the investigation of retrograde ejaculation. Additionally, samples may be provided for cryopreservation or treatment. It is this stage in the investigation that many of the uncertainties within the analysis can occur. By identifying these steps and implementing controls, the laboratory can work towards reducing uncertainty.

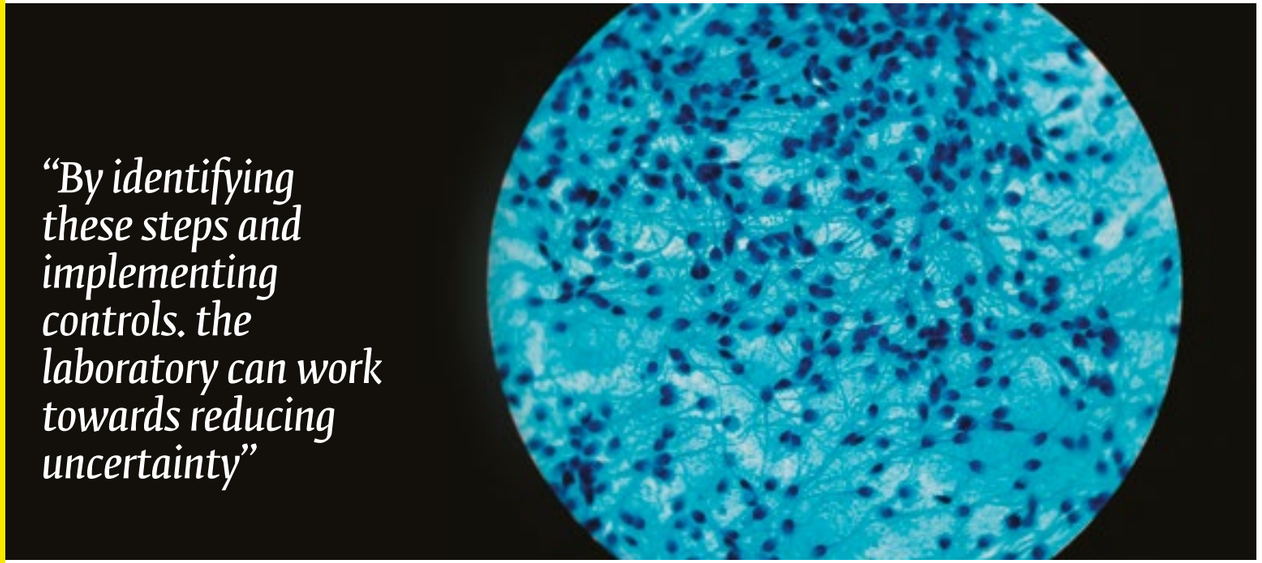
Information is key

The pre-examination processes can be divided into: information, specimen collection, transportation, reception, rejection, handling, preparation and storage.

Information is key to ensuring that the samples received are suitable for analysis. This information should be provided to both the clinicians referring into the service and the patients. It should be considered that the clinicians referring to the service will have a wide range of expertise. Some will have specialist knowledge, fertility doctors, urologists, whilst others' knowledge-base will be more generalised. All information provided must take this into consideration.

Clinicians will need to know the scope of the service the laboratory provides and how the patient is referred into the service. The referral process may be different depending in the element of the service they are accessing. They will require names and contact details of key staff within the laboratory and how advice is provided. It is important that the clinicians are aware of the process for patients, they should be able to explain how to book the appointment with the laboratory and any information they require prior to collecting and delivering the sample.

For patients, some elements of the information need to be more detailed. Where possible information should be provided in clear easy to understand



language, avoiding the use of medical terminology or jargon. The information should clearly state the location and opening hours of the laboratory, also the times at which samples are accepted. There needs to be instructions to enable the patient to book their appointment, if that is a requirement of the laboratory.

Producing the sample

Once they have booked their appointment, there must be specific instructions to enable the patient to correctly produce their sample. Patients need to abstain from sexual activity for a minimum of 48 hours and a maximum of seven days. When producing the sample, it needs to be clear that the sample should be produced by masturbation and the whole ejaculate collected. The laboratory need to have considered alternative options if the patient is unable to produce the sample by masturbation for religious or cultural reasons. Non-toxic condoms are available for this purpose. When obtaining samples for treatment or cryopreservation, there may be other reasons why the sample cannot be obtained by masturbation. Patients may have suffered spinal injury, there can be a blockage or absence of the vas deferens, erectile disfunction or they may be affected by retrograde ejaculation. Laboratories may then need to consider alternative methods for obtaining sperm. These can include vibro-electric stimulation, surgical sperm recovery or retrieval of sperm from post-coital urine samples.

The patient should use a wide-mouth sample container to collect the sample. This should be batch toxicity tested prior to use, guidance is available on the most appropriate methods for testing.

Where the sample containers are used for cryopreservation or treatment samples, they must be CE marked as an IVD device. There should be a process of batch traceability for these containers so that each one can be traced to its original batch and their toxicity test report. Ideally each container should also be pre-weighed prior to issue so that the volume of the sample can be determined from its weight. Not only are the sample containers toxicity tested, there should be a process for acceptance testing of all reagents and consumables linked to the analysis of the samples. It is the responsibility of the laboratory to risk assess the requirement and depth of the acceptance testing required. This process should be documented by the laboratory and records of the testing and risk assessments retained.

Making the delivery

Samples need to be delivered to the laboratory in a timely manner and should ideally be assessed within 60 minutes of ejaculation. After this length of time, pH starts to decrease due to a build-up of carbon dioxide and motility may decrease. Because of the timings involved the use of couriers for transporting from remote drop-off location is not practical. It is normally the patient who will deliver the sample to the laboratory themselves, it is however acceptable for a representative of the patient to deliver the sample if all the information required regarding sample collection is complete. With patient who are providing samples for HFEA licenced processes, cryopreservation or treatment, it needs to be delivered in person by the patient. It is important that during the transport process, the samples are protected from extremes of temperature. An effective method for transporting samples is to place them in an inside pocket of a jacket or other item of clothing. Both extremes of heat and cold can affect the motility and viability of the sperm within the samples.

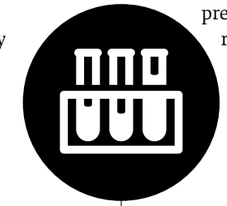
Providing a room

For samples for HFEA licenced procedures, to maintain chain of custody, and where patients are unable to deliver samples to the laboratory for examination to be started within 60 minutes of production the laboratory may wish to consider providing a room for patients to use to produce their sample on site. It is not acceptable for patient to be directed to use the nearest toilet, by producing their sample in the public toilet they are performing a lewd act and may be liable to legal action if caught. Any toilet, even one within the laboratory is not the ideal place for a patient to use to produce a sample. The room provided should be private and ideally situated away from the main flow of people walking past. It should be equipped with a washbasin and be situated close to a toilet, this is especially important if investigating patients for retrograde ejaculation as they will be required to provide a urine sample as well. The furnishings within the room should be comfortable but also easy to clean and decontaminate. The laboratory will also need to consider if they are going to provide material to stimulate the patient. This can be provided in different formats, magazines, DVD's, electronic storage or even requesting that patients provide their own. Any provision of this type of material need to be managed carefully and take into consideration the age of the patients attending. By making these types of images available to a minor, the laboratory should take into consideration any legal and ethical concerns, or other alternative offences. However, by providing stimulation for patients it may improve the chances of them providing a sample for analysis.

Acceptance criteria

When the patient delivers the sample to the laboratory, it is preferable that they are met by a member of staff and do not just drop their sample in a box or tray. It is at this point that the laboratory has a chance to ensure that they gather all the necessary information regarding sample collection. The request form should have provision to record the date and time of collection of the sample, number of days of abstinence prior to collection, completeness of ejaculate, the identity of the person delivering the samples. Where the laboratory uses patient samples for training or quality control purposes, the patient should positively agree to its use and should sign the request form confirming consent. The laboratory should have defined the acceptance criteria for the samples and have a process for rejecting samples that do not meet these criteria. Samples may potentially be rejected for many reasons, collected in an inappropriate container, the sample or form not labelled, incorrect abstinence period or incomplete ejaculate. Whilst a laboratory may choose to still accept and process these samples, this should be documented and the report should state the potential limitations of the analysis.

Where a sample is rejected, ideally it should be done whilst the patient is still present and the reasons for rejection explained to them. If appropriate the patients should be offered the opportunity to rebook their appointment and the referring clinician informed. Once the sample has been received, it should be passed to the staff responsible for analysis without delay. Once in the laboratory, the samples should be allowed to liquefy and warm prior to analysis, an incubator set to keep the sample at 37°C is helpful for this. All samples must start the critical parts of the analysis within 60 minutes of sample production, it is not acceptable to retain the samples to be assessed at a later stage.



On receipt the sample should be checked to ensure it complies with lab acceptance criteria

A controlled process

In summary, by controlling and assuring the pre-examination phase, the laboratory can ensure that the sample they are receiving analysis is appropriate to the tests being performed and, therefore, that the results reported by the laboratory are representative of the patients' true fertility. Clinicians and patients must have sufficient information to ensure that they fully understand the processes involved. Samples must be collected in containers which the laboratory has confirmed, using appropriate methodology, are non-toxic to sperm. Samples should be transported to the laboratory in a manner that protects them from extremes of temperature, where appropriate the laboratory may consider providing facilities for the patient to use on site. On receipt the sample should be checked to ensure it complies with the laboratories acceptance criteria and all necessary information regarding collection should be recorded on the form. After receipt the sample should be transported directly to the laboratory and then examined promptly. BMS

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