

Safe handling of genetic materials

How can hospital pharmacists ensure that their departments are ready to handle genetic materials? This was a subject discussed at the 12th EAHP congress. Hannah Pike reports

There is an increasing need for awareness of the importance of genomics in the development of new vaccines and tests, Philippa Brice, science policy and dissemination manager at the Public Health Genetics Unit, Cambridge, told the congress. Increasing knowledge of genetics and genomics will aid faster and more rational drug discovery processes and will help guide treatment choice, she said.

Although some treatments based on genetic tests are already being used, true personalised medicine, where a patient's drug, dose, and risk prediction can all be determined from a genetic test, is still a long way off. Further research into the interactions between genetic and environmental factors and their influence on drug response is needed, as are new technologies that will minimise the cost and maximise the utility of pharmacogenetic testing. However, the "advance guard" of genomic applications is arriving, she said, and pharmacists will need more genomic literacy in the future, which may involve communication with the wider genetics community.

Dr Brice emphasised that pharmacogenetics is only a tool, and cannot replace the need for proper clinical management. She also posed the question of who will perform pharmacogenetic tests in the future. "Will it be the molecular geneticists, or is that something that pharmacists will want to retain ownership of?" she asked.

Handling genetic materials

Despite some setbacks in the testing of gene therapy, this technology is certain to be developed, V'Iain Fenton-May, quality control pharmacist for Welsh Hospitals, based at St Mary's Pharmaceutical Unit, Cardiff, told the congress. "There is far too much to gain not to progress with it," he said. It is also a fact that we are going to transfer some of this material using vial vectors. Since these are materials that we do not want to contaminate the environment, hospital pharmacies need to have facilities where genetic and viral material can be safely handled and manipulated, he said.

The 12th congress of the European Association of Hospital Pharmacists, entitled "New therapies in the 21st century: challenges for hospital pharmacy", was held in Bordeaux, France on 21–23 March. **Hannah Pike** is editor of *Hospital Pharmacist*

Despite there being little information available about how these products should be handled, pharmacy must plan for the future when it comes to the design of aseptic units, Mr Fenton-May said. Pharmacists already handle cytotoxic materials, and a very low level of cytotoxic contamination in the environment is considered to be acceptable in the UK. However, we do not know if there is an "acceptable" level for viral contamination. Until proved otherwise, we can only assume that there is no safe level. Mr Fenton-May suggested that this means using separate facilities to handle these products.

Contamination is likely to occur on the outside of the syringe being used to introduce the gene to the desired site, and a decontamination process is needed to ensure that this surface is clean before it leaves the manipulation area. "We need to make sure that we have no rogue viruses inserting genes into the wrong areas," he warned.

Mr Fenton-May said that in the early 1980s he was one of the advocates of using negative pressure cabinets for handling cytotoxics and, although this may not have been necessary, it was a safe decision. "Now I suggest separate facilities which can be decontaminated until we know better," he said.

Mr Fenton-May said that those who are currently designing an aseptic unit should install an extra room on the side in which viral transfer can be handled. "It is a small price to pay at the design stage but an impossible wall to climb when you have already got a new unit," he said.



Rebecca Brice: genomic literacy is important



V'Iain Fenton-May: plan now for the future

Knowledge gaps

Mr Fenton-May said that he could not find any published information specifically relevant to how hospital pharmacists should manipulate viral and genetic products. He recommended that hospital pharmacists be aware of and understand the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), even though they are written for the pharmaceutical industry.

"If we want to look at any sort of gene removal or viral removal from products we must look at what the industry has been told to do. Only then do we know the baseline of what we are receiving", he added.

Another gap in our knowledge is which decontamination regimens should be used for viral products. Researchers in Cardiff and London are currently undertaking work in this field. Mr Fenton-May explained that the first challenge is to create a reproducible, recoverable standard in order to be able to understand deactivation curves in the way that we do for microbes. He explained that since most virologists deem their viruses to be too fragile to survive in the environment, there is not really an equivalent of bacterial environmental monitoring standards for viruses.

Coverage of the congress will continue in the next issue of *Hospital Pharmacist*