

■ TDM

Therapeutic drug monitoring of voriconazole

From Mr A. B. Sutherland, MRPharmS

I write in order to impart a cautionary tale to my hospital colleagues surrounding the use of voriconazole. I see this product used increasingly in day-to-day practice as fungal infections become more common and resistance to existing azole antifungals becomes an increasing problem.

My cautionary tale starts with a young patient called "A". She presented with a deep invasive aspergillus mediastinitis after complex heart surgery. She was immediately started on intravenous voriconazole 7mg/kg twice a day (in keeping with the summary of product characteristics) which she tolerated well. Over the first weekend the microbiologist requested that a plasma level be taken. This was diligently done and the level returned a week later at 0.12mg/L. This was reported by our laboratory as "subtherapeutic" with a caveat that these levels had not been ratified by Pfizer. Action was swift, with medics increasing the dose to 12mg/kg twice a day and another "trough level" was sent a few days later. This time, the level was returned as "undetectable". Again, action was swift. The dose was increased further to 18mg/kg twice a day.

Over the weekend of the second dose increase, while on call, I received a request for information. "A" had become covered in a bright red, erythematous, exfoliative rash that

was getting worse. On physical examination of the child, the rash appeared to be well demarcated to those areas of the body that were exposed to light — head, chest, upper arms, feet and face. On discussion with "A's" parents, they commented that they had noticed some change in skin pigmentation over the course of the last few days, but that it had only started getting exceptionally bad in the last 48 hours. On review of drug administration using our electronic patient record and prescribing system, it was quite clear that the changes in skin condition were temporally related to the dose increases with voriconazole. A discussion with senior medical staff resulted in the reduction of voriconazole dose to standard 7mg/kg, the initiation of sunblock therapy, and a consensus that voriconazole levels would no longer be reviewed.

The evidence for therapeutic drug monitoring of voriconazole is weak. In our hospital, the rationale is based on Smith *et al.*¹ They noted that those with low plasma levels (<2mg/L) tended to have poorer outcomes in terms of disease progression and fungal breakthrough. However, on closer inspection of this paper, there are several flaws — only 28 of the worst performing patients from a total cohort of 188 were reviewed and patients on voriconazole who were not deteriorating did not have their plasma levels monitored.

There have been no large-scale controlled studies to examine the thresholds for treatment failure or toxicity with voriconazole and there is massive interpatient variability in plasma levels due to the non-linear nature of clearance of voriconazole.² There is also likely to be a pharmacogenetic

component to voriconazole clearance, although this is yet to be proven.³ Therapeutic drug monitoring of voriconazole is expensive and slow and therefore it is a measure of efficacy that is essentially useless at the present time.

I would urge all pharmacists in all clinical areas to bear this in mind, and remind our medical colleagues that we are supposed to be treating patients and not "numbers".

Adam Sutherland

Clinical Pharmacist, Paediatric Intensive Care
Yorkhill Hospital, Glasgow

References

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2. Brown J and Freeman BB. Rethinking the use of voriconazole therapeutic drug monitoring in allogeneic haematopoietic stem cell transplant recipients. *Bone Marrow Transplantation* 2005;36:177.
3. Leveque D, Nivoix Y, Jehl F, Herbrecht R. Clinical pharmacokinetics of voriconazole. *International Journal of Antimicrobial Agents* 2006;27:274–84.

■ WORK BREAKS

Call for reasonable work breaks

From Mrs L. K. Gilpin, MRPharmS

I would like to further the debate on work breaks in pharmacy. Lorry drivers and others are, quite correctly, pilloried for not taking appropriate rest periods, but pharmacists are expected to work for ridiculously long periods without taking breaks. Considering the focus on patient safety, is this really a viable way forward for the profession?

This is an issue that can affect locum pharmacists more than others because they are generally expected to fit in with the ethos of each pharmacy at which they work. Ever since Locum Voice, the pressure group for locum pharmacists was formed, this has been one of the topics of most concern to it.

There is obviously a great deal of pressure being exerted on the individual pharmacist to work without a break in some community pharmacies.

We have the European Working Time Directive that has been used to great effect by some pharmacists but the threat of European law

should not be necessary. It should be obvious to owners and managers alike that people need reasonable breaks, not least to minimise the chance of errors being made.

I would call upon all of these owners and managers to put into place a system in their pharmacies for ensuring that reasonable breaks are available for their staff, pharmacists and locums.

I would also invite primary care organisations to check that this has been carried out and the Royal Pharmaceutical Society to put into place a framework for safe working in this regard.

To expect people to work without reasonable breaks is dangerous, immoral and ultimately detrimental to the profession.

Lindsey Gilpin

English National Board Election Candidate
New Malden, Surrey

■ PFIZER PRODUCTS

Small independents will lose out

From Mr P. R. Rodwell, MRPharmS

Until now I have not been concerned about the new distribution arrangement. However, I am now. How many independent pharmacies are going to lose out by Pfizer's discount structure? I believe that all small independent owners will.

In my case, I have two pharmacies — one large and one of average size — and my annual turnover for both is less than £250,000. If I take this turnover as being at the top end of my company purchases, which earn a 10.5 per cent discount from the wholesaler, then I am losing. For one of the shops, this amount is over £2,000.

Since I use UniChem, where its own shops will be well into the top discount level, can I expect some help from them? Or will Pfizer offer me individually a better level of discount? I doubt either. Looks like I may have to try out the other wholesalers.

Paul Rodwell

Wallingford, Oxfordshire

Telephone number

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■ ENHANCED SERVICES

The sooner we stop moaning the better

From Mr S. Bajaría
MRPharmS

Before the new pharmacy contract was introduced the resistance to providing new services by community pharmacists often centred on the argument that we were not being paid any extra and therefore we were not going to provide them.

After the new contract, many primary care trusts built up extensive enhanced-service portfolios to which many pharmacists signed up, but only a minority have been able to deliver. The result has been large underspends in enhanced-service budgets, money being taken away and lost opportunities.

The arguments against new services now range from not being profitable, not having the time and a lack of manpower, to too much paper work, delayed payments and a lack of support from PCTs. And let us not forget objections and non co-operation from GPs: "too much hassle" and "can't be bothered".

One could be forgiven for thinking that even if all these obstacles are overcome, it is likely that others are sure to creep in. The sooner we stop moaning, take a step out of our comfort zones and start working towards securing a future for the profession, the better.

Sunil Bajaría
Bromley, Kent

■ CONCORDANCE

Patients should have control over their treatment

From Mr J. S. Khela,
MRPharmS

How many times have we, as community pharmacists, recommended an over-the-counter product for a patient, only to find that they have ignored our advice and purchased something different, or even not purchased anything at all? I will certainly be the first to put my hand up.

Perhaps a more common personal experience is where a patient or consumer insists on purchasing a branded medicine and may refuse to purchase the clearly more cost effective, generic equivalent.

These particular scenarios may be considered as undermining to our role and we, as professionals, may be kicking ourselves every time this happens. However, pharmacy's secret weapon is that the patient should have absolute control (or perceived control) over their treatment. This should exist at the pharmacy counter and dispensary and not just during medicines use reviews and other consultations. It should exist without affecting our professional obligations and discretion.

Principal Four of the revised Code of Ethics emphasises the need for patient involvement in decision making about their care. My recent work with a GP has demonstrated how patient participation has encouraged greater concordance and compliance with therapy. Engaging patients in the solutions to the issues involved with their condition has been paramount. Simply asking them for their suggestions has given the patients a greater perception of control. By doing this I have found patients are more willing to comply and listen to my suggestions. I have also got a lot more respect from my patients (simply through their positive feedback).

Although I cannot quantify how my service has improved, I can anecdotally state that patients are more willing to buy the products I suggest and have become more confident and aware from the questions that they ask me. I would be interested to hear from anyone who may have done studies or research in this field.

Jagjiwan Singh Khela
English National Board Election
Candidate
Eastleigh, Hampshire

Pharmacy care programme is a success

From Mr P. Williams,
MRPharmS

I read, with interest, your article about the results of the recent *Journal of the American Medical Association* study into the effectiveness of pharmacy care programmes (*PJ*, 18 November, p597). We have been calling for a study into the true effectiveness of pharmacy-based concordance support for a number of years, based on the extensive and compelling anecdotal evidence we hear from pharmacists every day. There is no doubt in our minds —

and in the minds of all the pharmacists that we speak to — that such services have an immense impact on patient care, particularly for the more vulnerable patients.

The study of 200 patients over the age of 65, which included a monitored dosage system provided by MTS Medication Technologies, found such support did lead to better adherence to treatment and resulted in improvements in blood pressure and cholesterol measures.

I know, as was mentioned in the article, that comments have been made about there being some bias in the validity of the study due to different levels of observation, but I believe the results are compelling.

At long last — an extensive, well-funded and executed study into concordance support. For once and for all, this supports what pharmacists, including myself, have been saying for years; that, when properly executed, these solutions really work and the impact of rolling out properly funded programmes within the pharmacy chain will have a major impact on the health of society's vulnerable.

Peter Williams
Managing Director,
MTS Medication Technologies

■ SMALL PHARMACIES

New ESPLPS scheme has crucial flaw

From Mr S. J. Mitchell,
MRPharmS

The old Essential Small Pharmacies Scheme (ESPS) has now been transferred to primary care trusts and renamed Essential Small Pharmacy Local Pharmaceutical Services (ESPLPS), having been described as "the same in many respects". Unfortunately, there is one crucial difference that will weaken the whole scheme; that the qualifying prescription number threshold (currently 2,200 items per month) has not increased this year and I am not aware of any definite plans for an increase in future years.

The consequences of this will be obvious. Yearly prescription inflation will mean qualifying pharmacies will go over the item threshold and automatically come out of ESPLPS, never being allowed to rejoin the scheme. With the threshold for establishment payments going up every year (2,060 this year), it will not be long before the thresholds are the same

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and we will face being thrown out of the ESPLPS. If this happens we will have to struggle to stay above the establishment threshold to avoid serious financial loss, with no way back into the scheme if we fail to do so. I suggest this is not the picture of long-term security for essential pharmacies that the scheme was originally set up to protect.

I have two suggestions. One would be to increase the item threshold limit annually, as in the old ESPLPS scheme, to avoid being thrown out of the scheme through prescription inflation.

The other is to allow a pharmacy to rejoin the scheme if it drops back below the threshold, thus creating a safety net for the essential pharmacies.

I am sure that the Pharmaceutical Services Negotiating Committee would be glad to hear the views of any ESPLPS pharmacy which may be affected so that a solution can be found during continued negotiations with the Department of Health.

S. Mitchell

Watford, Hertfordshire

■ HUNTINGTON'S DISEASE

Gene therapy offers a promising prospect

From Dr I. I. Al-Janabi, MRPharmS

The article by Elizabeth Bevan and Carol Paton entitled "What evidence there is for the drug treatment of Huntington's disease" (*PJ*, 25 November, pp641–2) highlights the problems associated with the use of conventional pharmacological agents, particularly for neurological disorders. The use of these agents in Huntington's disease (HD) gives rise to adverse reactions and is limited to symptomatic intervention. The adverse reactions often result from these agents reaching tissues not intended to be acted on — analogous to putting out a fire in a house by flooding the whole town.

Gene therapy offers a promising prospect for the treatment of genetic diseases like HD which, within successive generations of one affected family, can appear at a younger age or a more severe form. The latter phenomenon, known as anticipation, is thought to be caused by the expansion of the CAG trinucleotide repeats of the mutant allele. Because most of the sufferers are heterozygotes for the

mutant allele, one gene therapy strategy for HD is to counteract the harmful effect of the mutant protein through the degradation of its progenitor, mRNA, by the use of RNA interference (RNAi). Targeted delivery of RNAi specific for the mutant mRNA should leave the normal allele expressing the required normal protein, albeit at a reduced level.¹ This approach is currently being tested in the hope of translating the results to clinical trials.

Ismail I. Al-Janabi

Epsom, Surrey

Reference

1. Denovan-Wright EM, Davidson BL. RNAi: a potential therapy for the dominantly inherited nucleotide repeat diseases. *Gene Therapy* 2006;13:525–31.

■ SECTION 60 ORDER

Allow the Society to stand or fall

From Mr D. Lee,
MRPharmS

I read, with interest, David Temple's comments on the New Zealand system in relation to the potential split in the UK (*PJ*, 18 November, p608). One important point needs to be raised.

The Pharmacy Council of New Zealand requires that pharmacists are undertaking continuing professional development with a recognised provider. The only provider recognised by the council is the Pharmaceutical Society of New Zealand. In a monopoly I would consider 90 per cent a relatively low figure. This means to me that 10 per cent of pharmacists believe that the CPD programmes are not beneficial and believe strongly enough to be willing to flout requirements of their annual practising certificate.

Dr Temple poses the question as to the percentage of pharmacists who would voluntarily retain membership of the Royal Pharmaceutical Society should it decide to split along the same lines as the PSNZ. The answer, in my view, is that the percentage would be low, and few would remain. I personally would see no benefit in remaining, given the track record of the Society.

The Society should split. Let the Society prove its worth to the members and allow it to stand or fall on its performance.

Dan Lee

Queenstown, New Zealand

 THE SOCIETY

Fees should be a personal choice

From Mr D. G. Miller,
MRPharmS

I read, with interest, the **Broad spectrum** by two members of the Royal Pharmaceutical Society's Council (*PJ*, 25 November, p634) and the letter by another Council member (*PJ*, 25 November, p635), proposing the separation of the regulatory function of the Society from its professional and leadership function. While I can totally support this view from a philosophical perspective, I am still to be fully convinced in practice and would join the authors in welcoming a debate.

In particular, I am concerned that there is the danger that the control of standards for students, preregistration trainees and pharmacists (along with continuing professional development and revalidation) would have to be under the control of the regulator. With the drive in the Foster Report to reduce the number of regulators, any proposed General Pharmaceutical Council could be merged into an existing regulator like the Health Professions Council. If this were to happen there is a major danger that pharmacy would no longer be in control of its own direction.

I do accept, however, that there is ample evidence that the current system is not working, despite the current Council being configured with a majority of pharmacists. There are, indeed, recent examples from a regulatory perspective: as a pharmacist, I am unsure what extra services I obtain from the Society for the £283 I am required to pay compared with the fee of £93 for a pharmacy technician. Perhaps there is an assumption of a major salary differential, but this is

certainly not the case for a newly qualified hospital pharmacist. In addition, the extra £35 to maintain the "SP" on the Register for supplementary prescribers, unique to the Society, is nothing but a kick in the teeth for those who have endeavoured to take the profession forward by additional study and practice. Perhaps the current structure of the Council assumes all members have their fees paid by their employer?

There is a vacuum in the professional leadership of pharmacy evidenced by the plethora of new and existing representative bodies that promote and support certain factions of the profession. That is, in my view, an indictment of the current overemphasis on regulation with a professional and regulatory body that due to the dead hand of regulation emphasises what cannot, rather than what can, be done by pharmacists and technicians.

I totally agree that there is a need, if the profession is to thrive and prosper into the 21st century, for it to be allowed the freedom to think, push forward the boundaries of practice and modernise ways of working. It will be the role of the three national boards to undertake this role. In England, developments such as the new community pharmacy contract, the White Paper "Our health, our care, our say" and the creation of foundation hospitals present external opportunities and threats to the profession. As a profession we have an opportunity to look outwards and to move forward and address these national issues and to demonstrate our value to the public. These boards can become, supported by the individual members delivering pharmaceutical care, the public face of pharmacy demonstrating the value of the profession to the public we serve, to the press who inform that public and to the

national politicians they elect to legislate and govern on their behalf.

I may be more convinced if the proposed professional body was brave enough to allow voluntary membership so that fees were a personal choice, providing a true market and financial accountability.

David Miller

*English National Board Candidate
(elected unopposed)
Sunderland*

 TECHNICIANS

Accredited checking technician status lost when leaving Boots

From Ms V. Standing,
RegPharmTech

I am a former employee of Alliance Boots who achieved accredited checking technician status within the company and I have been qualified for 16 months. One of the criteria with this course requires one to re-register every two years to maintain the qualification. As this date approached I began to make enquiries concerning the matter. On contacting Boots The Chemists, I was told that it would not be possible to re-register with it having left the company. I spoke to other pharmacy technicians who have worked for other companies and found that this was not the case for them even though the individuals had not funded the course themselves. I then made more enquiries with other training organisations which offer this course and was extremely disappointed to find out that they could not help me either.

I now find myself in a situation where I will have to restart the course again if I want to maintain my current status. Considering this is a nationally recognised

qualification, I think it is unprofessional of them not to inform potential candidates of this situation when we have put so much time and effort into qualifying. I thought it necessary to alert both current and future accredited checking technicians working for Alliance Boots that their hard work may be in vain if they wish to progress outside the company.

Victoria Standing

*Catterick Garrison,
North Yorkshire*

PRADIP PATEL, pharmacy superintendent at Boots The Chemists, responds: In order to respond to this question, it may be helpful to separate registration as a pharmacy technician and accuracy checking training. Once an individual registers as a pharmacy technician, their registration remains valid as long as they adhere to the Code of Ethics and undertake continuing professional development.

In relation to accuracy checking training, the Royal Pharmaceutical Society has endorsed a framework for the training and reaccreditation that outlines a model of good practice. Alliance Boots follows the recommendations of this framework and has processes in place to support good practice and ensure patient safety.

When an individual who undertakes the task of accuracy checking moves to another employer, the new supervising pharmacist has a responsibility under the Pharmacists Code of Ethics (Part 2 A1 (f)) to ensure that any delegated tasks are delegated to persons competent to perform them.

Therefore, the responsibility does lie with the new employer to put in place a process to meet the requirements of the Code of Ethics.

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