It sticks in our throats too

PERSONAL VIEW Sean Ainsworth, Wendy Jones

The change in recommended use of miconazole oral gel at a time when we should be encouraging evidence based prescribing in children leaves a bad taste in our mouths

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) claims to “enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe” (www.mhra.gov.uk/Aboutus/Whoweare/Ourmissionandvalues/index.htm). Why is it then that instead of changing advice in the summary of product characteristics for the most effective treatment for oral thrush (Pediatr Infect Dis J 1997;16:288-93) to minimise the potential for harm they instead make it an “off licence” product for the very group most in need of it? Miconazole oral gel was launched in 1978 and has been used to treat countless infants with symptoms of oral thrush. After more than 30 years of unchanged use the manufacturer, Janssen-Cilag, with the support of the MHRA, chose to change its licensed use in May 2008 such that it is no longer recommended in infants aged under 4 months (http://emc.medicines.org.uk/emc/assets/c/html/displayDocPrinterFriendly.asp?documentid=7301). You might assume that this action was taken in the light of serious adverse events, possibly even a fatality. But no, the reason for the change is the potential risk of choking in infants with an immature swallowing reflex. Why all of a sudden should a product with a profile that is sufficiently safe for it to be available to buy over the counter, and with no change in the product itself, suddenly have its licence changed in this manner?

The answer seems to lie in a paper published in 2004 (Ned Tijdschr Geneeskd 2004;148:1598-600). The mother of a 17 day old infant (born at 36 weeks’ gestation) was told by a pharmacist to apply the gel to her nipple before breast feeding to treat her infant’s oral candidiasis. Within minutes of beginning application by finger in small amounts twice a day. More specifically the Neonatal Formulary recommends: “Smear 1 ml of miconazole oral gel round the mouth and gums with a finger after feeds four times a day.”

It seems to us that the recent changes in the information leaflet for miconazole oral gel would probably have been sufficient, but instead the manufacturer, supported by the MHRA, has shortsightedly chosen to alter its licensing application by age, rather than take the commonsense approach to reduce the volume and to give clear guidance on the method by which the parents or carers should apply the product.

Altering licensing in this way effectively places the responsibility squarely on the shoulders of prescribers should they choose to use this otherwise effective drug for probably its commonest indication. Many will therefore be reluctant to prescribe it off licence for fear of litigation; and as a result the use of an effective drug is to be limited because one pharmacist rashly advised a mother to treat her infant’s oral candidiasis by applying the gel to her nipple rather than directly to the infant’s mouth—a method never supported by any data or even the manufacturer.

The change in recommended use of miconazole oral gel at a time when we should be encouraging evidence based prescribing in children, together with the unprecedented move to allow off-licence prescribing of the less effective alternative nystatin by community practitioner nurse prescribers, leaves a bad taste in our mouths. We hope it’s not candidiasis; the treatment might just stick in our throats.
All in the mind?

There is no pleasure greater than to denounce the wickedness of the times, and since the times are always wicked the pleasure is inexhaustible.

The Reverend Jeremy Collier MA (1650-1726) was a great denouncer of the wickedness of his times. He was famous for it; in fact, it was his métier. He did not think the Glorious Revolution was glorious and refused to swear allegiance to the new monarchs, William and Mary, and he was particularly against the degeneracy and vulgarity of Restoration comedy, which he denounced in his Short View of the Immorality and Profaneness of the English Stage, published in 1698. He was answered in kind by Vanbrugh and Congreve, whom he especially attacked, and he wrote a riposte to their riposte. It was all good clean fun.

He also wrote a series of moral essays, many in the form of a dialogue, some of medical interest. For example, his “A Moral Essay of Pain” takes up the question of the nature and utility of pain in a world ruled by divine providence. He defines pain as “an unacceptable Notice arising from some Disorder in the Body.” He goes on: “When the Continuity of the Organ is disjoin’d, the Nerves discomforth; the Stoppage of the Nerves discomposes the Muscles and produces pain.”

Collier is not so fanatic as to fail to recognise that pain is sometimes undeserved, that it afflicts the righteous as well as the unrighteous; but he is particularly exercised by the fact that a person’s psychological state affects the degree of pain that they feel, from which he concludes that pain, notwithstanding his initial definition of it, is not really physical at all. He refers to the fact that the barbarian Gauls, fighting the Romans, hardly felt their wounds but were abject cowards in the face of disease; whereas with “the Grecians” it was the other way round. He gives many other examples.

So pain for Collier is both physical and psychological. In a surprising way, therefore, he is a forerunner of Melzack and Wall’s “gate” theory of pain: that nerves that don’t transmit pain can interfere with signals from pain nerves and inhibit the perception of pain.

His dialogue “Of Drunkenness, between the toper Oenophilus and the sober Eucratius” is also of contemporary relevance. When Oenophilus says that people often drown their sorrows in drink, Eucratius replies: “To throw one World after another, is a Dismal Relief against Poverty.” Inscribes it in Whitehall, say I.

Theodore Dalrymple is a writer and retired doctor.

BETWEEN THE LINES

Theodore Dalrymple

Where indeed would our casualty departments be . . . were it not for those who are “thys prodigal of their Person”?

Head broke, and it may be his limbs raked, into the Bargain; now when a Wound is thus impertinently made, ought it not to put the patient to some Trouble? He that’s thus prodigal of his Person, and makes his Limbs serve in an ill Cause, ought to meet with a Mutilification; The Punishment is but a just return for the Pride, and the Smart, it may be, the best Cure for the Folly.

Where indeed would our casualty departments be, what work would they have to do, were it not for those who are “thys prodigal of their Person”? Collier is not so fanatic as to fail to recognise that pain is sometimes undeserved, that it afflicts the righteous as well as the unrighteous; but he is particularly exercised by the fact that a person’s psychological state affects the degree of pain that they feel, from which he concludes that pain, notwithstanding his initial definition of it, is not really physical at all. He refers to the fact that the barbarian Gauls, fighting the Romans, hardly felt their wounds but were abject cowards in the face of disease; whereas with “the Grecians” it was the other way round. He gives many other examples.

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FROM THE FRONTLINE
Des Spence

Falling through the ICE

I don’t like unsolicited advice, and I don’t much believe in the value of lessons or tutors. Advice is mere opinion, and life is about forming our own opinions. Medicine is full of advice, much out of date and the rest impossibly complicated, concealing the fact that it is just plain wrong. But humanity is sustained by being told what to do, so don’t ask intelligent people to actually think—this they are not trained to do. Learning concepts by rote is seen as the concrete foundation of any “good” education.

In many a modern medical text the phrase “patient agenda” appears. This very good idea seems so obvious that it is hardly worthy of explanation: that all patients have a reason for seeing a doctor. (Though I suppose there may be some doctors who would scratch their heads in consternation at such a radical suggestion.) So in GP training (and indeed in enlightened undergraduate courses) we teach how to crack open this patient agenda by using that jackhammer of a good education, the acronym—in this case ICE (ideas, concerns, and expectations). This is expressed in three magic questions asked of the patient: “Do you have any idea what is causing the problem?” “Do you have any particular concerns?” and “What do you expect us to do about the problem?” In theory it’s smiles all round, back slapping, and vigorous shaking hands as the patient’s anxieties are revealed. If only it were really that simple.

My toes curl in embarrassment when neighbours briefly stop complaining about my fat cat pay and pension to tell me, laughing, that their doctor “didn’t seem to know what was wrong and even asked me what I thought was causing it and what treatment I expected!” I try to explain that this is not a result of dumbing down of medical degrees but is a modern idea about patients (“clients”) being “involved” and of “engaging” them as “stakeholders” in their care by addressing their layperson’s medical “agenda.” But they eye me with suspicion and jeeringly mumble, “But they’re the doctor. You lot should know.”

So we need to be wary of applying ICE, for it may lead to trouble in many a consultation (see Filler, BMJ 2008;337:a3135) and even to official complaints. There are many ways to find out why your patients have come to see you, and usually professional judgment and experience are enough. It is time to rethink (at least to rephrase) ICE or even to have a good new think, because concrete is a very hard landing indeed.

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“i’ll bet you a fiver it’s not”

STARTING OUT
Kinesh Patel

Post-take ward rounds are not usually an opportunity to earn some much needed cash, so you can imagine my surprise when the consultant playfully offered me a cash reward to make a diagnosis on a patient with a rare condition.

Why did the consultant bet money against my diagnosis? Because the condition in question was vanishingly rare, and with odds of nearly a million to one he believed (not unreasonably) that his money would be safe. Why did I admit the patient? Because the case struck a chord among my somewhat hazy recollections of the information I learnt for my postgraduate examinations.

Which is why it is so surprising to me that the medical establishment has become complicit in allowing medicine to be dumbed down. The entry criteria to be a medical registrar—according to the ubiquitous person specifications—no longer include a requirement to have passed the Member of the Royal College of Physicians (MRCP) examination in its entirety. Instead that’s just listed as “desirable.”

In the place of an examination that is based on acquiring facts and the objective assessment of clinical skills are the new work based assessments, including, among others, the multi-source feedback evaluations and the “mini-CEX” (some of the junior doctors were rather disappointed to learn that this didn’t involve a pretty nurse).

So we’ve gone from a written test for everyone in which cheating was almost impossible and that had unknown examiners to a mode of assessment in which, most trainees will admit, it is easy to be fraudulent. Why? So that those who are incapable of passing their exams within four years of qualifying are still eligible to enter higher specialist training without any real validated proof that they have accumulated medical knowledge, including the minutiae.

This change may serve to accelerate the progress of weaker candidates up the career ladder, but it surely can’t be in the best interests of patients. At best this is the beginning of a slippery slope—and who knows where it may end.

One thing is certain, though: if any right thinking person were designing a healthcare system they would make absolutely sure that the most senior medical person in the hospital for over half the week would have as much knowledge and as many examinations under their belt as possible.

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