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Importance of needle size for effective intramuscular delivery of vaccines

For a significant number of vaccines, administration via the intramuscular route is recommended to provide optimal immunogenicity and to minimise adverse reactions. Subcutaneous injection has been suspected as a cause of vaccine failure[1] when administering hepatitis B, rabies, and influenza vaccines[2] owing to poor vascularity and subsequent inadequate processing of antigen. Serious complications of intramuscular injections are rare but abscesses and granulomas are seen with subcutaneous injection.[1,3]

Achieving true intramuscular injection is determined by both the injection technique and the needle size. These should be selected from a choice of non-fixed needles appropriate to the individual patient. Although standard – fixed needles are perceived as being more convenient to use – they may fail to deliver intramuscular vaccines reliably in all cases, since the body mass index of patients varies considerably.

In a recent US study,[1] the thickness of the fat pad above the deltoid muscle was measured in 220 healthcare workers presenting for hepatitis B immunisation using ultrasonagraphy. Women were found to have significantly more subcutaneous fat than men. A standard 5¼8-inch needle would have not achieved sufficient penetration for true deltoid intramuscular injection in 17% of men and nearly 50% of women.[1]

Healthcare professionals may hesitate to use longer needles on the grounds that they are likely to cause the patient more discomfort. This is in fact not the case as skeletal muscle has a poor supply of pain fibres compared with skin and subcutaneous tissue, which are richly innervated. Although pain is often attributed to the length and gauge of the needle, there is a stronger causal association between local reactions and the presence of a vaccine adjuvant.

In addition to appropriate needle length, consideration should be given to needle gauge. *Immunisation Against Infectious Diseases* recommends a 23G needle for intramuscular injection in adults and a 23G or 25G for infants.[4] It has been proposed that a wider bore 23G needle ensures that the vaccine is dissipated over a wider area, thus reducing the risk of localised redness and swelling.[5]

In summary, a standard needle size will not guarantee successful intramuscular injection in all individuals. When intramuscular vaccine administration is needed to ensure optimal immunogenicity and minimise local reactions, a selection of non-fixed needles should be available to make a choice best suited to the individual patient.

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Outpatient appointments

I welcome the recent introduction of a maximum two-week wait for an outpatient appointment for patients with suspected cancer and the accompanying referral guidelines.[1] However, I was surprised that the guidelines are expected to cover 90% of patients with cancer.

I have undertaken an audit of the electronic and paper notes of all patients with a diagnosis of colorectal cancer (CRC) registered with my practice from 1990 up to 1 April 2000. Thirty-six patients had this diagnosis. Nineteen were dead or had moved away and could not be included. Of the remaining 17 patients, nine (53%) fulfilled the current guidelines for urgent referral; in one case, the notes were unclear. All 17 patients were referred immediately on presentation.

There were seven patients who did not fulfil urgent referral criteria at the time of presentation. Two subsequently fulfilled the criteria at the time of referral but one was three months and the other 12 months after the initial presentation. Two of these seven patients were referred immediately and two within three months of presentation. Two of the seven patients not fulfilling current guidelines presented with rectal bleeding and one with altered bowel habit but as these patients were less than 60 years old they fell outside current guidelines.

It is difficult to draw conclusions from a small and retrospective audit such as this. The patients who died from CRC are more likely to have a more advanced stage of tumour[2] and therefore more likely to fulfil referral criteria. However, even if all the patients with incomplete data fulfilled the current criteria, this would only comprise 81% (29/36) of the total. These guidelines present a paradox: early-stage CRC tumours have the best prognosis,[2] yet to maintain reasonable sensitivity and specificity, these guidelines are less likely to include early tumours. I hope that careful data collection is currently being undertaken of all patients referred to hospital with suspected CRC, both within and outside the two-week referral system. This will enable the refinement of these guidelines to ensure that more early stage tumours are treated, leading to reductions in mortality.

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Counsellors in general practice

Friedli *et al* report (April *Journal*)[1] a study that found that counselling in general practice was no more clinically- or cost-effective than routine care.

I believe there is a major flaw in this study that invalidates its finding. The authors chose to measure the comparative efficacy of counsellors using a Rogerian approach in brief therapy with depressed patients. But Rogerian therapy, although a well-respected form of longer-term counselling, is not designed for brief interventions, particularly with depression. Its success depends in a large measure on a high level of client input. Depressed patients typically lack energy and motivation and can often be better helped by therapeutic strategies that allow energetic counsellor involvement.

As a primary care counsellor, I frequently integrate a number of approaches when doing brief work with depression. This is normal practice. So in addition to using the core conditions of Rogerian therapy to establish a therapeutic alliance, I may use cognitive behaviour therapy to help patients to define and modify maladaptive patterns of thought and behaviour; I might draw on transactional analysis to help them to understand their patterns of interacting; I might use systems theory to help them to unravel and change the dynamics of their family relationships; I might use behavioural remodelling to help them to overcome the effects of early trauma; or I might use Gestalt techniques to help them to release painful emotions.

In short, to restrict me to the use of one therapy would make me about as effective as a GP who is restricted to prescribing just one pill for every ill!

Counselling is a very young profession that has only recently begun the task of validating itself empirically. However, GPs who employ appropriately trained counsellors know that we are clinically effective, that we dramatically reduce referrals to secondary services, and that we provide a user-friendly service that is highly valued by patients and doctors alike.

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1. Friedli K, King M, Lloyd M. The economics of employing a counsellor in general practice: analysis of data from a randomised controlled trial. *Br J Gen Pract* 2000; **50**: 276-283.

Psychological status and menstrual disturbance

The paper by Shapley *et al* (June *Journal*)[1] is a welcome addition to the literature on psychological status and menstrual disturbance. They report a prospective study on the association between Hospital Anxiety and Depression Scale scores and consultation for increased vaginal bleeding. However, despite finding no association, the authors suggest that GPs should consider the impact of psychological status on the presenting symptom of increased vaginal bleeding when referring to a specialist.

The authors appear influenced by the perceived weight of research evidence showing an association between menstrual disturbance and psychiatric morbidity. They quote Gath *et al*[2] and Ballinger[3] as consistent evidence of an association between complaints of heavy menstruation and symptoms of psychological disturbance. However, mental state was not strongly related to indices of excessive menstruation and consultation in the study by Gath *et al*; moreover, the cross-sectional nature of these studies means the direction of any association is unclear, a fact commented on by Ballinger *et al* in other works.[4]

The emphasis on seeking psychological attributions for gynaecological complaints has a long history.[5] Goudsmit and Gadd[6] suggest that a psychological label is often used to explain the inexplicable and it may be that the difficulty with patients who report increased vaginal bleeding is that doctors do not fully understand their complaint. Improving our understanding of the meaning of the problem to individual women may be a more appropriate way to understand the complaint of menstrual disturbance and consultation. A qualitative study of women presenting to GPs with heavy bleeding found that women related in different ways to 'heavy' periods. Many women complained of a relative change in 'heaviness' and the perception that their cycle had changed was important in the definition of their complaint.[7] Those who believed their periods were always heavy had different attitudes.

The prospective study by Shapley *et al* will hopefully result in a change in emphasis in research in this area.

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Does excessive antibiotic use increase minor health complaints?

Patient demand for antibiotics is one factor contributing to antibiotic over-prescription.[1] Paradoxically, some patients are reluctant to use medicines because they believe that conventional (but not alternative) medicines have a harmful effect on health. In reality, antibiotic use is not risk-free and is known to be associated with specific short-term side-effects.[2] The possibility of antibiotics contributing to longer-term minor health problems is seldom considered. As part of our questionnaire research into minor health complaints – defined as problems not requiring medical intervention – we collected data from 943 members of the general population who completed an anonymous postal questionnaire (450 males, 493 females, mean age = 53.96 years, return rate from one mailing sent to addresses from a telephone book = 37.7%). Antibiotic use was assessed by asking people to record the number of courses over the previous year, analgesic use was assessed using a six-point frequency scale, and minor health complaints were

assessed using three- to five-point scales depending on the complaint.

Significant correlations between antibiotics and minor health complaints could arise either because the minor health complaint elicits more requests for antibiotics, due to clinical need or because patients with dysphoric mood visit the GP more frequently, *or* because antibiotics have a small, negative effect on minor health complaints through some unknown mechanism, *or* because both antibiotic use and minor health complaints are correlated with a third factor (e.g. age). Spearman correlations between minor health complaints and antibiotics are shown in Table 1. We also show correlations between analgesics and minor health complaints for comparison with another type of treatment. There are the same three possible reasons for association between minor health complaints and analgesics.

Antibiotic use correlates with the majority of minor health complaints, whereas this is not the case between minor health complaints and analgesics: this is not a statistical artefact caused by greater variability in antibiotic versus analgesic use. Age is negatively correlated with analgesic use ($P<0.001$) but unrelated to antibiotic use. Although some of the correlations between minor health complaints and antibiotics may be due to the former causing the latter (e.g. people prone to sore throats requesting more antibiotics or anxious patients visiting the GP more often), the correlations between atopic symptoms and antibiotics are difficult to explain in this way. In addition, some correlations are consistent with known short-term effects of antibiotics (diarrhoea, candidiasis). When compared with the low association between analgesics and minor health complaints, these data raise the possibility that high levels of antibiotic use have a small but long-term deleterious effect on a range of different minor health complaints.

Perhaps patient beliefs about the effects of medicines on health are not entirely wrong. More importantly, making patients aware of the possibility that overuse of antibiotics may have negative consequences may dampen patient enthusiasm for antibiotic treatment when it is not clinically indicated.

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Reference

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Table 1. Correlations between minor health complaints and antibiotic and analgesic use.

	Antibiotics	Analgesics
Colds	0.21[c]	0.02
Sore throat	0.23[c]	0.02
Wheeze	0.19[c]	0.01
Eczema	0.14[c]	0.08[a]
Blocked nose	0.15[c]	0.02
Itchy eyes	0.05	0.05
Constipation	0.09[b]	0.01
Diarrhoea	0.07[a]	0.02
Heartburn	0.12[c]	0.09[b]
Thrush	0.17[c]	0.02
Cystitis	0.09[b]	0.00
Tired	0.20[c]	0.01
Anxious	0.08[b]	0.02
Depressed	0.11[b]	0.02

[a]$P<0.05$; [b]$P<0.01$; [c]$P<0.001$.

Randomised trials in primary care

I was intrigued to read the paper by van der Windt *et al* (May *Journal*)1 regarding the practical aspects of conducting pragmatic randomised trials in primary care, as we are undertaking a related trial and have encountered similar problems.

In this study, 11 GPs of the 61 recruited contributed 50% of the participants in the trial, which may reflect a selection and recruitment bias at a number of stages. Patients may attend a particular doctor with a particular illness for many reasons, including the level of their perceived interest in musculoskeletal medicine. Recruitment bias may also be due to the nature or demography of a practice or because doctors themselves have a particular interest or, indeed, lack of interest in musculoskeletal medicine or research. A GP's knowledge of his own patients as people will influence recruitment. This pattern raises two questions. First, are patients entered in the trial by high referrers different to those entered by practitioners referring few? And secondly, are the results of studies with this potential bias applicable to all patients?

That there was an increased success rate in those who were allocated to injection and indicated a preference for that intervention raises important methodological questions about the use of placebo. It also raises fascinating questions about the efficacy of what we do in practice and the reasons for its effectiveness.

I congratulate the authors on highlighting many areas of difficulty in performing clinical research in primary care and providing practical suggestions for increasing the quality of such research. In short, patients seem to disappear when you start a trial and the patients that appear may not be representative. As researchers we are frustrated by recruitment difficulties and possible selection bias but as GPs dealing with individuals we can see why and how.

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Reference

1. van der Windt DAWM, Koes BW, van Aarst M, *et al*. Practical aspects of conducting a pragmatic randomised trial in primary care: patient recruitment and outcome assessment. *Br J Gen Pract* 2000; **50**: 371-374.

Correction

In the letter to the Editor entitled 'General practitioners' prescribing data for multiple sclerosis patients indicates a link with asthma' from J Evans, C Rogers, and C M Wiles (*Br J Gen Pract* 2000; **50**: 323) there was an error in the following sentence:

Some 216 MS patients were identified, giving a prevalence of 91.9 per 105 (within the 24 GP practices' population in 1996).

The sentence should have read as the following:

Some 216 MS patients were identified, giving a prevalence of 91.9 per 10^5 (within the 24 GP practices' population in 1996).

We apologise to the authors for any confusion this may have caused.