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Sterile vs Non-Sterile Gloves for Traumatic Wounds in the Emergency Department

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In this issue of the *EMJ*, Zwaans *et al* present a randomised controlled trial that asked whether the use of non-sterile gloves and dressings affects risk of infection when suturing traumatic wounds in the Emergency Department[1].

Most randomised trials compare two treatments so they can determine which is better. However, such a "superiority" design would not make sense when comparing the effect of sterile and non-sterile gloves as there is no reason to think that non-sterile gloves should be *superior* in terms of reducing wound infections. There may nevertheless be other reasons to prefer non-sterile gloves if they are "not much worse" – perhaps because they are cheaper, more accessible, or generate less packaging waste. Zwaans *et al* therefore chose a non-inferiority trial design. Instead of asking whether sterile or non-sterile gloves are "better", their trial asked whether non-sterile gloves are "much worse" than sterile equivalents.

To answer such a question, Zwaans *et al* first had to specify "how much worse" they would be willing to accept. This "non-inferiority margin" is a matter of judgement and depends on factors such as the downsides of sterile gloves (e.g. cost, accessibility, and environmental burden) and the magnitude of the risk they seek to avoid (e.g. wound infection). The trial team chose a non-inferiority margin of 2%, which would have allowed them to conclude that non-sterile gloves are "non-inferior" if the upper bound of the 95% confidence interval for the difference in infections between the groups was less than 2%.

As wound infection is a relatively rare outcome, Zwaans *et al* estimated they would need 2,140 participants to detect a statistically significant difference between the groups. Unfortunately, the trial was stopped early and so only 1,480 of the planned 2,140 participants (69%) were recruited. So what can readers take away from this trial given that it stopped prematurely and did not recruit to target?

First, it is worth highlighting that this is the largest trial to have addressed the question. As wound infection is such a rare outcome – and these trials are clearly difficult to deliver – this may be the best evidence we can expect to see for some time. Second, although this study is the largest available, it is not the first[2-5]. Pooling these data with that from earlier trials in a

meta-analysis may be sufficient to determine whether sterile gloves confer an advantage over non-sterile gloves.

Third, the study was formally underpowered but only according to the assumptions pre-specified by the authors, which include the estimated prevalence of wound infection and the choice of non-inferiority margin. Zwaans *et al* based their power calculation on an estimated infection prevalence of 3.5% amongst the patients treated with sterile gloves. However, the actual infection rate was 6.8% and so the trial may have required fewer participants to detect a difference than initially anticipated. This might explain how – despite stopping early – the study was still able to demonstrate non-inferiority as the upper bound of the 95% confidence interval (1.5%) was lower than the pre-specified non-inferiority margin (2%).

However, the choice of non-inferiority margin is also up for discussion. Zwaans *et al* may have had good reasons for choosing 2% and this value might be a reasonable choice for major hospitals in The Netherlands. However, there is nothing fixed about this non-inferiority margin and clinicians in other settings may be willing to accept a larger degree of risk.

The mean difference between the groups in this trial was -1.1% (infections lower in the *non-sterile* group) with a 95% confidence interval of -3.7% to 1.5%. Although the trial did not recruit to target, the true difference between the groups is likely to fall somewhere between the range -3.7% and 1.5%. As the 95% confidence interval overlaps zero, the trial did not demonstrate the superiority of either approach and cannot exclude the possibility that sterile gloves and gowns make no difference at all to the number of infections. This is consistent with earlier trials that reported no difference between the groups[2-5]. However, even the upper bound of the confidence interval (i.e. 1.5%) is low given that most superficial wound infections can be treated effectively with oral antibiotics. It is possible that this small degree of excess "harm" may be acceptable for some wounds, although clinicians may choose to take additional precautions in those at higher risk of infection (e.g. large size) or in an area that may tolerate infection poorly (e.g. face, overlying metalwork).

However, the main risk of stopping a trial prematurely is not under-recruitment but because early closure may expose the data to bias. For example, researchers that are unblinded to

treatment allocation could observe the emerging outcome data and stop recruitment at a point at which these confirm their pre-existing belief in the efficacy (or otherwise) of the intervention. A well-designed trial should include defences against this bias, such as blinding of the trial team to outcome data and pre-determined stopping criteria. It should therefore be possible to publish trials that do not recruit to target when they include both (1) a convincing reason as to why the study stopped short of the agreed recruitment target and (2) a clear description of the trial processes so that readers can be confident that the decision was not influenced by emerging treatment effects unless these caused safety concerns that forced the study to stop. In this case, a service re-configuration that integrated primary care services within the ED led to a significant fall in recruitment from 50 to fewer than 10 participants per month. This fall could not be reversed despite multiple initiatives to stimulate recruitment. Perhaps most importantly, the study team was blinded to treatment allocation and outcome data, and the authors have provided assurance that no interim analysis was undertaken before the team decided to stop the trial.

In light of this evidence, emergency physicians may be reassured that – if non-sterile gloves increase the risk of wound infection at all – this risk is very small. This information may be particularly useful for those working in low-resource settings (e.g. wilderness, expedition, conflict zones, or some low- and middle-income countries) and likely justifies the Wilderness Medical Society position that "wounds should be treated using a clean field, including gloves and instruments; sterility is not necessary"[6]. Even in well-resourced settings, the *possibility* of a very small increased risk of a treatable complication should be balanced against the excess cost and environmental waste of using individually packaged sterile gloves and gowns. Other elements of wound care (e.g. debridement of devitalised tissue and copious irrigation) may be higher priority than sterile gloves and gowns in the management of traumatic wounds in the Emergency Department.

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