

**Results of Recently Published Study on MSSA Screening Directly Contradicted by
Previously Published Data by McGovern et al**

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Summary

In a recent study pre-published online by Jeans et al, the authors conclude that screening for methicillin sensitive staphylococcus aureus (MSSA) and treating those that test positive before surgery significantly reduces periprosthetic joint infection (PJI) rates (Jeans E, et al. Methicillin sensitive staphylococcus aureus screening and decolonization in elective hip and knee arthroplasty. *Journal of Infection*. 2018).¹ The authors reported the combined data from all three hospitals in the Northumbria Healthcare NHS Foundation Trust.

However, McGovern and Reed previously reported published² and unpublished³ data from one of the three hospitals in the Northumbria Trust that directly contradicts the Jeans' conclusions. Jeans did not account for the confounding effect caused by the switch from Bair Hugger® forced-air warming (FAW) to HotDog® air-free warming at Wansbeck Hospital, one of the three Northumbria hospitals studied. Coincidentally, the switch to air-free warming at Wansbeck occurred at nearly the exact same time as the initiation of MSSA screening throughout the Trust.

Overlaying the previously reported data from Wansbeck Hospital on the recent data from all three hospitals, shows that the *entire* reduction in PJI rates reported by Jeans is accounted for by the massive reduction in PJIs observed at Wansbeck alone.

In fact, recalculating the results of the combined data shows that the PJI rate *increased* by nearly a full percentage point (0.68% to 1.6%) after initiating the MSSA screening protocol at the two hospitals that did not stop using Bair Hugger and switch to HotDog air-free warming. This conclusion is diametrically opposite to the author's conclusions.

What does it mean: The MSSA screening did nothing; the reduction in PJIs came 100% from discontinuing FAW.

**3M Attempts to Mislead Federal Judge With Erroneous Study Conclusions:
Previously published data contradict conclusions of the Jeans study**

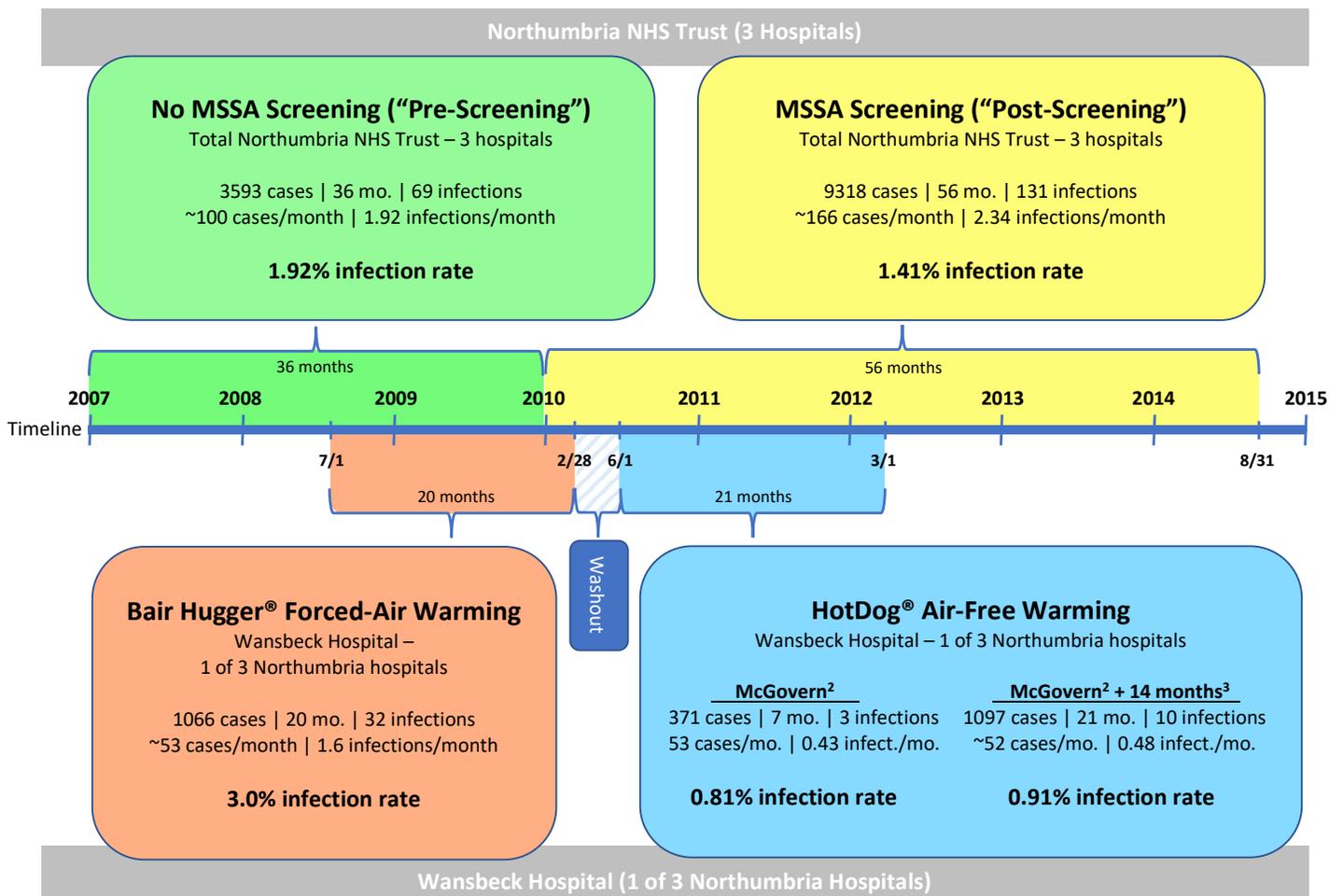
3M and their attorneys are well aware of the previously reported published and unpublished data, and their experts certainly should have recognized the inconsistency of these data. Nonetheless, they submitted these erroneous conclusions to the Federal Judge presiding over their Multidistrict Litigation (MDL) case, asking that based on this new evidence, the entire MDL be dismissed. They falsely argued that the Jeans data show that the massive reduction in PJI rates at Wansbeck Hospital were actually the result of MSSA screening, not due to the discontinuation of forced-air warming and the switch to air-free warming.

Analysis

The Northumbria Healthcare NHS Foundation Trust consists of three hospitals, one of which is Wansbeck Hospital. On January 1, 2010, all three of the hospitals in the Trust instituted a protocol for screening all total hip and knee replacements (THR, TKR) prior to surgery. Those patients that tested positive for MSSA were then prescribed Octenisan body wash and nasal Bactroban for five days prior to the surgery. As shown in Figure 1, the authors compared the combined retrospective PJI rates from three hospitals over the previous 36 months (“pre” screening) to the infection rates noted during the following 56 months (“post” screening).

The authors reported that the combined PJI rate for THA and TKA in the three hospitals dropped 27%, from 1.92% pre-screening to 1.41% post-screening.

Figure 1: Total PJI Rates from Three Hospitals Pre- and Post-MSSA Screening Overlapping PJI Rates from One of the Three Hospitals During the Switch from Forced-Air Warming to Air-Free Warming



THA and TKA data from Wansbeck Hospital for the period of July 2008 through January 2011 were previously published by McGovern and Reed.² The McGovern study reported the PJI rates resulting from discontinuing Bair Hugger FAW and switching to HotDog air-free warming. Coincidentally the switch in warming technologies occurred on March 1, 2010, essentially the exact same time that the MSSA prescreening protocol was initiated. Drs. Reed and McGovern later provided additional infection data for the period of January 2011 through February 2012 for a Letter to the Editor. These data are also shown in Figure 1.

As shown in Figure 1, when Wansbeck discontinued FAW and switched to air-free warming, their PJI rate dropped from 3.0% to 0.9%, a 70% reduction.

Assuming that the infection rates during each of these periods were relatively consistent, we can determine the average monthly infection rate under each condition. Determining the average monthly infection rate in the whole Northumbria Trust (three hospitals) and at Wansbeck (one hospital) allows us to separate the overlapping and mutually confounding therapies for infection reduction.

The first area of focus is the pre-screening period of the Jeans study, which temporally corresponds to the Bair Hugger FAW warming period. By subtracting Wansbeck from the Total, we can determine the average number of cases and PJIs per month and then calculate the PJI rates at the two “non-Wansbeck” hospitals:

<u>Hospital(s)</u>	<u>Cases/month</u>	<u>PJI/month</u>	<u>PJI rate</u>
Total 3 hospitals	100	1.92	1.92%
<u>Wansbeck Hosp.</u>	<u>53</u>	<u>1.6</u>	<u>3.0%</u>
Non-Wansbeck (2)	47	0.32	0.68%

Next, we can similarly analyze the post-screening period of the Jeans study, which temporally corresponds to the HotDog air-free warming period. Once again, by subtracting Wansbeck from the Total, we can determine the average number of cases and PJIs per month and then calculate the PJI rates at the two “non-Wansbeck” hospitals. First using the published McGovern data for the HotDog air-free warming period (7 months):

<u>Hospital(s)</u>	<u>Cases/month</u>	<u>PJI/month</u>	<u>PJI rate</u>
Total 3 hospitals	166	2.34	1.41%
<u>Wansbeck Hosp.</u>	<u>53</u>	<u>0.43</u>	<u>0.81%</u>
Non-Wansbeck (2)	113	1.91	1.69%

Alternatively using the published McGovern data² (7 months) plus an additional 14 months of non-published results reported by McGovern and Reed³ (21 months total) for the HotDog air-free warming period:

<u>Hospital(s)</u>	<u>Cases/month</u>	<u>PJI/month</u>	<u>PJI rate</u>
Total 3 hospitals	166	2.34	1.41%
<u>Wansbeck Hosp.</u>	<u>52</u>	<u>0.48</u>	<u>0.91%</u>
Non-Wansbeck (2)	114	1.86	1.63%

Discussion

Curiously, the Jeans study made no mention of the previously published, massive 81% reduction in PJI rates attributed to the discontinuation of Bair Hugger FAW and the switch to HotDog air-free warming at Wansbeck, reported by McGovern et al. The authors were most certainly aware of the published McGovern data. Apparently, the only difference in the total joint replacement protocols between Wansbeck Hospital and the other two hospitals in the Northumbria Trust was the simultaneous switch from forced-air warming to air-free warming at Wansbeck. The screening protocol for MSSA was used at all three hospitals.

These data show that temporally corresponding with the switch in warming therapies at Wansbeck, the PJI rate dropped 73%, from 3.0% to 0.81% in the published McGovern study and 70% from 3.0% to 0.91% in the combined data. When the very favorable Wansbeck PJI improvements are subtracted from the Total Northumbria Trust results, it is apparent that the two hospitals that did not switch to HotDog warming had dramatically *higher* PJI infection rates after screening and treatment were initiated. These data show that temporally corresponding with the initiation of MSSA screening and treatment at the two non-Wansbeck Hospitals, the PJI rate *increased* 140% from 0.68% to 1.63%. Considering the apparently adverse effect of MSSA screening shown by the Jeans study, it is interesting to speculate as to whether the decrease in PJI rates correlating with the switch to HotDog warming would have been even greater without the apparent negative influence of the MSSA screening protocol.

Jeans et al concluded, “The MSSA screening and eradication protocol used in our institution was effective at reducing rates of MSSA PJI.” However, this reexamination of the Jeans data in light of the Wansbeck influence on those data leads to a diametrically opposite conclusion: the *entire* PJI rate improvement reported by Jeans for the Total three hospital Trust is accounted for by the dramatic improvement at one hospital—Wansbeck. Further, the Wansbeck PJI rate decrease is temporally correlated with the discontinuation of Bair Hugger FAW and the switch to HotDog air-free warming. Finally, when the Wansbeck influence is subtracted from the Total three hospital Trust, the PJI rates at the non-Wansbeck hospitals *increased* by 140% with the initiation of the MSSA screening protocol, a conclusion opposite to the authors’.

References

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2. McGovern P, Reed M, et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br*. 2011;93(11):1537-1544.
3. McGovern P, Reed M. Personal communication.