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Routine Pre-cesarean *Staphylococcus aureus* Screening and Decolonization: A Cost-Effectiveness Analysis

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Abstract

Objectives—To estimate the economic value of screening pregnant women for *Staphylococcus aureus* carriage before cesarean delivery.

Study Design—Computer simulation model.

Methods—We used computer simulation to assess the cost-effectiveness, from the third-party payer perspective, of routine screening for *S aureus* (and subsequent decolonization of carriers) before planned cesarean delivery. Sensitivity analyses explored the effects of varying *S aureus* colonization prevalence, decolonization treatment success rate (for the extent of the puerperal period), and the laboratory technique (agar culture vs polymerase chain reaction [PCR]) utilized for screening and pathogen identification from wound isolates.

Results—Pre-cesarean screening and decolonization were only cost-effective when agar was used for both screening and wound cultures when the probability of decolonization success was ≥50% and colonization prevalence was ≥40%, or decolonization was ≥75% successful and colonization prevalence was ≥20%. The intervention was never cost-effective using PCR-based laboratory methods. The cost of agar versus PCR and their respective sensitivities and specificities, as well as the probability of successful decolonization, were important drivers of the economic and health impacts of preoperative screening and decolonization of pregnant women. The number needed to screen ranged from 21 to 2294, depending on colonization prevalence, laboratory techniques used, and the probability of successful decolonization.

Conclusions—Despite high rates of cesarean delivery, presurgical screening of pregnant women for *S aureus* and decolonization of carriers is unlikely to be cost-effective under prevailing epidemiologic circumstances.

Staphylococcus aureus surgical site infections (SSIs) are associated with substantial morbidity among women who undergo cesarean delivery, resulting in increased postoperative length of stay, increased risk of readmission, and high medical costs.[1] The increasing incidence of postsurgical wound infections has paralleled a rise in the cesarean

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delivery rate. As many as 20% of women who deliver by cesarean are affected by an SSI, and *S aureus* is the causative agent implicated in 25% to 50% of puerperal infections.[1–8]

Up to 35% of Americans are chronic or intermittent carriers of *S aureus*, with higher rates observed among individuals with risk factors for colonization such as healthcare exposure, recent antibiotic use, immune system compromise, and chronic health conditions such as diabetes and hepatitis.[5,9–12] Previous studies have shown that preoperative *S aureus* screening and subsequent decolonization of carriers may lessen rates of SSIs among other surgical populations.[13–17] These measures may be of benefit in the setting of planned cesarean delivery, but formal studies to determine the safety and efficacy of this practice have not yet concluded.[18] The economic value of implementing this strategy among pregnant women, who tend to be younger and healthier than many patients with healthcare-associated *S aureus* infections, has also not been studied.

To address this issue, we developed a computer simulation model to estimate the cost-effectiveness and health impact of routine preoperative *S aureus* screening and decolonization for women undergoing planned cesarean delivery.

MATERIALS AND METHODS

This study was exempted by the University of Pittsburgh Institutional Review Board. Our stochastic decision analytic model, developed using TreeAge Pro 2009 (TreeAge Software, Williamstown, Massachusetts), addressed the decision of whether to screen women for *S aureus* colonization and decolonize carriers before planned cesarean delivery. Analyses assumed a third-party payer perspective (accounting for only the direct costs of illness) and time horizon for outcomes equal to the duration of the puerperal period, or approximately 1 month postdelivery. The 1-month timeline was utilized as a reasonable average based on clinical experience. Because wound infections vary in severity (some are minor, requiring fewer than 28 days of home health treatment, and some are major, requiring 1–2 months of treatment), we used 1 month as an average. The model assumed that the large majority of the impact on the woman's quality of life and costs would take place within this time period.

Figure 1 depicts the general structure of the model. At baseline, women were 27.1 years old (the median age at pregnancy in the United States) and preparing to undergo a planned cesarean delivery with standard antibiotic prophylaxis.[19] Screening was assumed to occur alongside testing for Group B streptococcus at routine 35- to 37-week prenatal visits. This assumption was based on the rationale for Group B streptococcus screening at the same gestational age; colonization with *S aureus* can be transient, so screening should be conducted as close to delivery as possible to serve as a reliable proxy of colonization status at that time.[2,9]

The probability of a woman screening positive was influenced by the *S aureus* colonization prevalence and the sensitivity and specificity of the laboratory technique used, either agar culture or polymerase chain reaction (PCR). All women with a positive test result, regardless of true colonization status (eg, true and false positive), received a preoperative decolonization regimen of twice-daily intranasal mupirocin ointment and daily chlorhexidine gluconate washes for 5 days.[15] This regimen is generally considered safe—reported side effects are minor (eg, nasal itching and discomfort, skin irritation)—and assumed not to result in a quality-adjusted life-year (QALY) decrement.[15,16,20]

When successful, decolonization was assumed to mitigate the risk of post-cesarean infection for the duration of the puerperal period. Women colonized with *S aureus* were assumed to be 3 to 5 times more likely to experience staphylococcal post-operative wound infection than their noncolonized counterparts, consistent with studies among other surgical

populations (likeliest value for colonized women: 9%, range: 4%–20%; likeliest value for noncolonized women: 2.25%, range: 0.80%–6.67%).[2,15,21–24]

Women who experienced a post-cesarean wound infection received empiric antibiotic treatment for methicillin-susceptible *S aureus* (MSSA) until laboratory results were available. Identification of methicillin-resistant *S aureus* (MRSA) resulted in a transition to MRSA-appropriate antibiotic coverage for 7 to 14 days, while MSSA infection was treated with a 7-day course of antibiotics.[25] Cesarean wound infection carried a risk of hospitalization and wound-opening procedure in both the inpatient and outpatient settings, and 50% of women who underwent a wound-opening procedure were assumed to receive subsequent home healthcare.

Data inputs were derived from a variety of sources of various design and quality, including large-scale national databases, prior studies, and literature review (where available); the remainder were assumptions based on experience at Magee-Womens Hospital, a large, university-based academic women's hospital in Pittsburgh, Pennsylvania, that performs approximately 10,000 deliveries per year (Table 1). Inpatient stay cost and duration data came from the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample, a longitudinal database of inpatient hospital stay data maintained by the Agency for Healthcare Research and Quality.[26,27] Pharmaceutical costs were set equivalent to the national wholesale price listed in the Red Book.[28] Procedure and laboratory cost data were based on the Centers for Medicare & Medicaid Services reimbursement algorithm National Limitation Amount.[29,30] A 3% discount rate was applied to all costs and utility values, as recommended by the Panel on Cost-Effectiveness in Health and Medicine.[37].

Healthy pregnant women accrued an age-adjusted 0.92 QALY per year of life and a projected life expectancy QALY estimate of 43.96.[38] Women who developed a wound infection were ascribed a QALY weight of 0.6 for the duration of an inpatient stay, if any, and 0.7 for treatment as an outpatient. Given the paucity of data available from studies of pregnant women, these QALY values were drawn from a cost-effectiveness analysis of appendectomy wounds and were likely conservative estimates of the detriment attributable to a cesarean wound infection.[31] QALY decrements were attributed for the duration of antibiotic treatment, or 7 to 14 days for an MRSA infection and 7 days for an MSSA infection. Infected wounds that required opening accrued an additional 7 days, and patients who required home health treatment were ascribed 7 extra days of QALY decrements.

Each simulation run consisted of 1000 hypothetical pregnant women who proceeded through the model 1000 times, for a total of 1 million outcomes per simulated scenario. The incremental cost-effectiveness ratio (ICER) of each scenario was calculated using the equation below, and results were interpreted in the context of 2 cost-effectiveness thresholds: $50,000 per QALY and $100,000 per QALY.[39]

$$\mathrm{ICER}=\frac{\mathrm{Cost}_{\mathrm{intervention}}-\mathrm{Cost}_{\mathrm{no\ \ intervention}}}{\mathrm{Effectiveness}_{\mathrm{intervention}}-\mathrm{Effectiveness}_{\mathrm{no\ \ intervention}}}$$

The number needed to screen (NNS), or the number of women who would need to be screened to prevent 1 post-cesarean wound infection, regardless of true colonization status or decolonization treatment rendered, was calculated as follows:

$$\mathrm{NNS}=\frac{\mathrm{Total\ \ number\ \ of\ \ women}}{\mathrm{Infections}_{\mathrm{no\ \ intervention\ \ group}}-\mathrm{Infections}_{\mathrm{intervention\ \ group}}}$$

Probabilistic sensitivity analyses simultaneously varied all parameters throughout the ranges listed in Table 1. Additional sensitivity analyses explored key variables and those with the greatest uncertainty/variability. We systematically explored the effect of varying *S aureus* colonization prevalence from 1% to 50%, in order to capture the variation that may occur based on geographic location, individual risk factors such as healthcare exposure or recent antibiotic use, and body site swabbed (eg, anterior nares vs groin). The probability of successful decolonization was varied across the range of 0% to 90% to account for factors such as differing anatomical colonization site(s), decolonization regimen efficacy, local antimicrobial resistance patterns, and patient compliance. The laboratory techniques used for screening and wound isolate identification were also explored in the following combinations (screening-wound isolate): agar-agar, PCR-agar, and PCR-PCR to account for variation in the cost, availability, and turnaround time of these diagnostics. Finally, we varied the costs associated with hospitalization (± $1000).

RESULTS

Table 2 presents ICER values (dollars per QALY) for a variety of colonization prevalence and decolonization success rate scenarios. The combination of agar-based screening and wound culture yielded the lowest ICER values across all decolonization success and colonization prevalence scenarios. ICER values were driven by low incremental effectiveness values; even when the incremental costs were low ($3), the gain in QALYs due to screening were minute (range: 0.000001 to 0.00307) for all scenarios. When ICER values below $50,000 to $100,000 per QALY were considered cost-effective, the intervention was favorable when the probability of decolonization success was ≥50% and the colonization prevalence was ≥40%, decolonization was ≥75% successful and colonization prevalence was ≥20%, or the decolonization success rate was ≥90% and the colonization prevalence was ≥20%. Exploratory analyses of colonization prevalence >50% revealed that the testing scenario with a pairing of agar-agar became an economically dominant intervention (less costly and more effective than no testing or decolonization) when the probability of decolonization success was ≥75% and the colonization prevalence was ≥95%, or the probability of successful decolonization was ≥90% and the colonization prevalence was ≥75%. Varying the cost of hospitalization did not significantly change our results. For the agar-agar pairing, ICER values were $5897 per QALY (hospitalization cost + $1000) and $13,220 (hospitalization cost – $1000) at a 90% decolonization success rate and 50% colonization rate.

The use of PCR for screening and agar for wound cultures led to higher ICER values than the agar-agar screening and culture combination. The intervention was never found to be cost-effective (ICER values ≤$50,000 to $100,000 per QALY) when the probability of decolonization success was ≤90% and the probability of colonization with *S aureus* was ≤50%. Exploratory analyses of colonization prevalence >50% revealed that the intervention was cost-effective when the probability of decolonization success was ≥75% and colonization prevalence was ≥80%, or decolonization was ≥90% effective and colonization prevalence was ≥95%. The pairing of PCR and agar was never economically dominant. The combination of PCR-PCR for screening and wound isolates yielded the highest ICER values across all scenarios; this combination was never found to be cost-effective if the probability of decolonization success was ≤90% and the *S aureus* colonization prevalence was ≤50%, and was never economically dominant in any scenario, even if colonization prevalence was 100%.

The mean NNS to prevent 1 post-cesarean wound infection (regardless of true colonization status or decolonization treatment rendered) for each of the 3 pairings of laboratory methods is shown in Figure 2. A 25% probability of decolonization success was associated with the

highest NNS values across all levels of *S aureus* colonization prevalence. The NNS was 2294 for the agar-agar pairing given 1% colonization prevalence and 25% probability of successful decolonization, and an NNS of 72 was observed for the agar-agar pairing given 50% colonization prevalence and a 25% probability of decolonization success. NNS values demonstrated similar decline for 50%, 75%, and 90% probabilities of successful decolonization. When colonization prevalence was ≥25% and the probability of successful decolonization was fixed at 25%, 50%, 75%, or 90%, the NNS was approximately equal for all 3 pairings.

DISCUSSION

These results suggest that routine preoperative *S aureus* screening and decolonization of carriers for women undergoing planned cesarean is rarely a cost-effective intervention, and only for the pairing of agar-based testing and agar-based wound culture. In addition, the intervention is unlikely to be cost saving given the current epidemiologic circumstances of *S aureus* colonization in the United States. The prevalence of *S aureus* carriage among pregnant women has been reported to range from 5% to 29%, well below the 75% (or greater) value needed to yield cost savings in this study.[5,9,40–42] The cost of implementing routine surveillance and decolonization of *S aureus* carriers outweighs the potential cost savings from preventing morbidity, mortality, and increased hospital lengths of stay associated with post-cesarean *S aureus* wound infections.

There is some discordance in the rank order of the optimal pairing strategy when comparing ICER with NNS under the same circumstances (eg, probability of successful decolonization and colonization prevalence). This is likely a result of the cost difference between agar culture and PCR laboratory techniques, and the respective predictive values of agar culture and PCR for the detection of *S aureus*. Given the moderate *S aureus* colonization prevalence and relatively low incidence of post-cesarean infection in this population, cost of the intervention is a primary driver of the results. The impact of the higher sensitivity and specificity of PCR versus agar is best seen in the NNS values. Because correct ascertainment of colonization status is more likely with PCR-based screening, colonized women are more likely to get potentially beneficial presurgical decolonization treatment and there is a low probability that a presurgical decolonization regimen will be prescribed to a non-colonized woman. As a result, PCR-based screening reduces the cost and risk of unnecessary treatment, side effects, and the development of antimicrobial resistance.

Data on the short-term effectiveness of various decolonization regimens, especially for pregnant women, are equivocal.[15–17] There is a need for future studies, particularly well-designed randomized controlled trials, to better establish the efficacy of various decolonization regimens among this population. The assumption that pregnant women colonized with *S aureus* are at an increased risk of infection is based on the increased risk of *S aureus* infections seen among other surgical patients. The validity of this extension is unknown given the paucity of relevant data in the literature; additional studies of the risk of *S aureus* colonization (in the nares and other sites such as the perineum and vagina) on postpartum and post-cesarean infection would be a valuable addition to the body of knowledge.

Delivery by cesarean has become the most common major surgery among women in the United States each year. The US cesarean delivery rate (both primary and repeat procedures) has increased more than 50% since 1996 and reached an all-time high of 32.3% in 2008.[43] Historically, cesarean rates have increased with increasing age, but in recent years the rate has increased substantially across all maternal age and risk groups, race/ethnic groups, gestational ages, and geographic locations.[44] The rapidly increasing rate of cesarean

delivery, coupled with the fact that it is major abdominal surgery, has spurred questions about the clinical and nonmedical factors contributing to the upward trend.[45] An operative procedure of this magnitude is not without risk to mother and baby; cesarean deliveries have been associated with increased rates of operative complications, maternal rehospitalization, and neonatal intensive-care unit admission for neonates.[45]

Our analyses outlined the potential economic impact of implementing a routine pre-cesarean screening and decolonization program under a variety of circumstances. This study may be of interest to clinicians, infection control specialists, hospital administrators, and insurers who make complex decisions regarding the finance and practice of clinical care. As with any cost-effectiveness analysis, our findings are only intended to serve as informative evidence for the decision-making process. A sound decision is based on multiple factors such as clinical experience; budgetary constraints; competition for physical, personnel, and monetary resources; and disease epidemiology.

Our study may have underestimated the potential benefit of implementing a screening and decolonization strategy. Precesarean screening and decolonization could mitigate the risk of developing *S aureus* mastitis, which affects 2% to 33% of breast-feeding women.[7] It could also limit transmission of *S aureus* from mothers to their newborns, thereby minimizing infections in a vulnerable population with immature immune systems. Additionally, some women may require a repeat surgical procedure and thus may benefit from the decolonization intervention. Also, we limited our outcomes to the puerperal period; however, some women may have impacts lasting longer than 1 month. We did not attempt to quantify the impact of decreased *S aureus* colonization in the population or the subsequent epidemiologic impact. Finally, routine surveillance could provide important data on the epidemiology of *S aureus* among the population of pregnant women.

Overall, our study findings indicate that screening pregnant women for *S aureus* with decolonization before cesarean delivery is not a cost-effective intervention under prevailing epide-miologic circumstances, despite the increasing rate of delivery by cesarean. Future studies are needed to ascertain the safety and efficacy of various decolonization regimens for this population, as is delineation of the risk of postpartum and post-cesarean infection attributable to *S aureus* colonization at different anatomical sites such as the nares, vagina, and perineum.

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Take-Away Points

Screening pregnant women for *Staphylococcus aureus* before cesarean delivery is unlikely to be cost-effective under currently prevailing epidemiologic circumstances in the United States.

- The results were similar for analyses with cost-effectiveness thresholds of $50,000 per quality-adjusted life-year (QALY) and $100,000 per QALY
- Additional studies are needed to ascertain the safety and efficacy of decolonizing pregnant women, as well as the risk of post-cesarean infection attributable to *S aureus*.

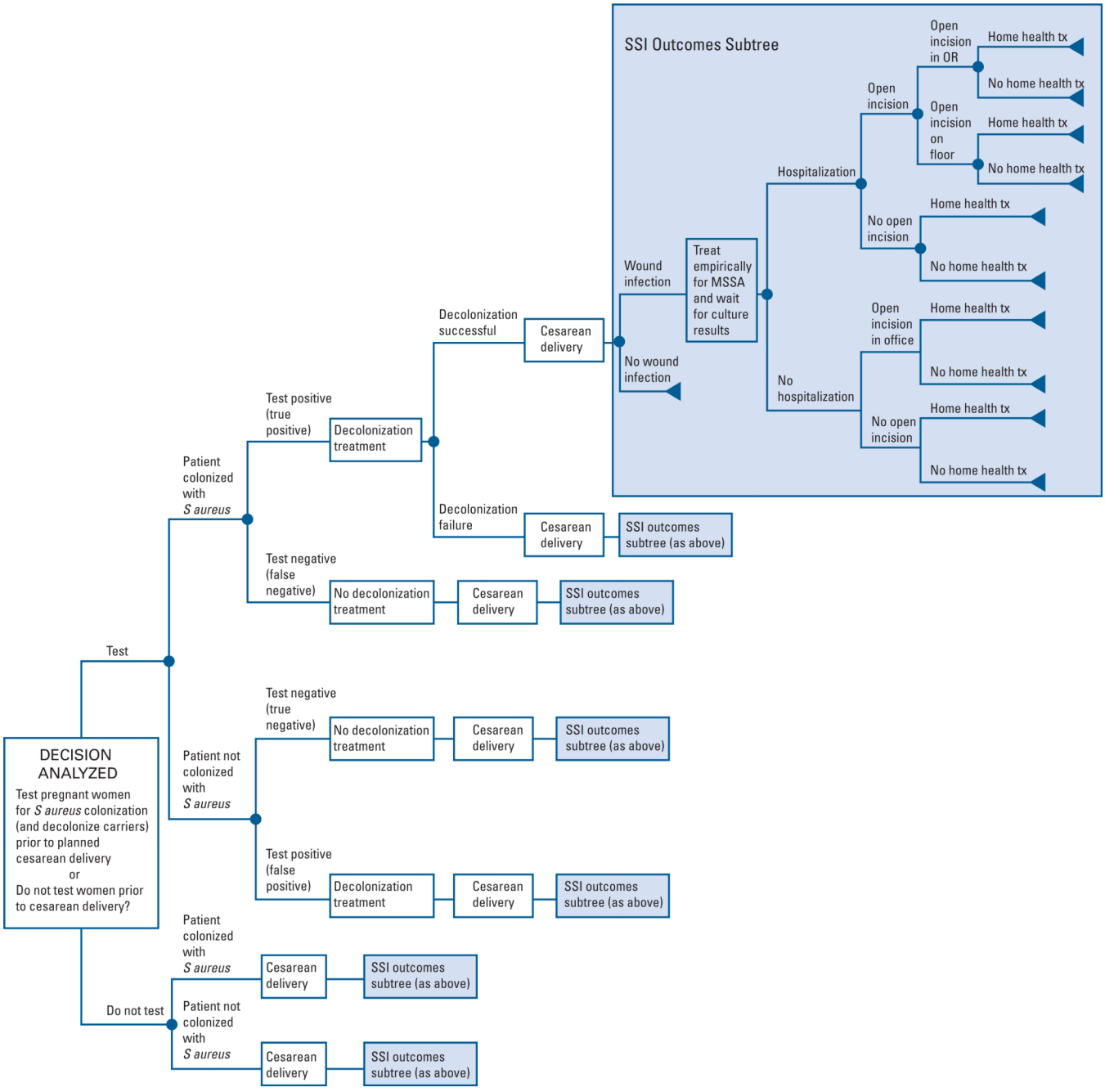

Figure 1. General Model Structure

MSSA indicates methicillin-susceptible *Staphylococcus aureus*; OR, operating room; SSI, surgical site infection; tx, treatment.

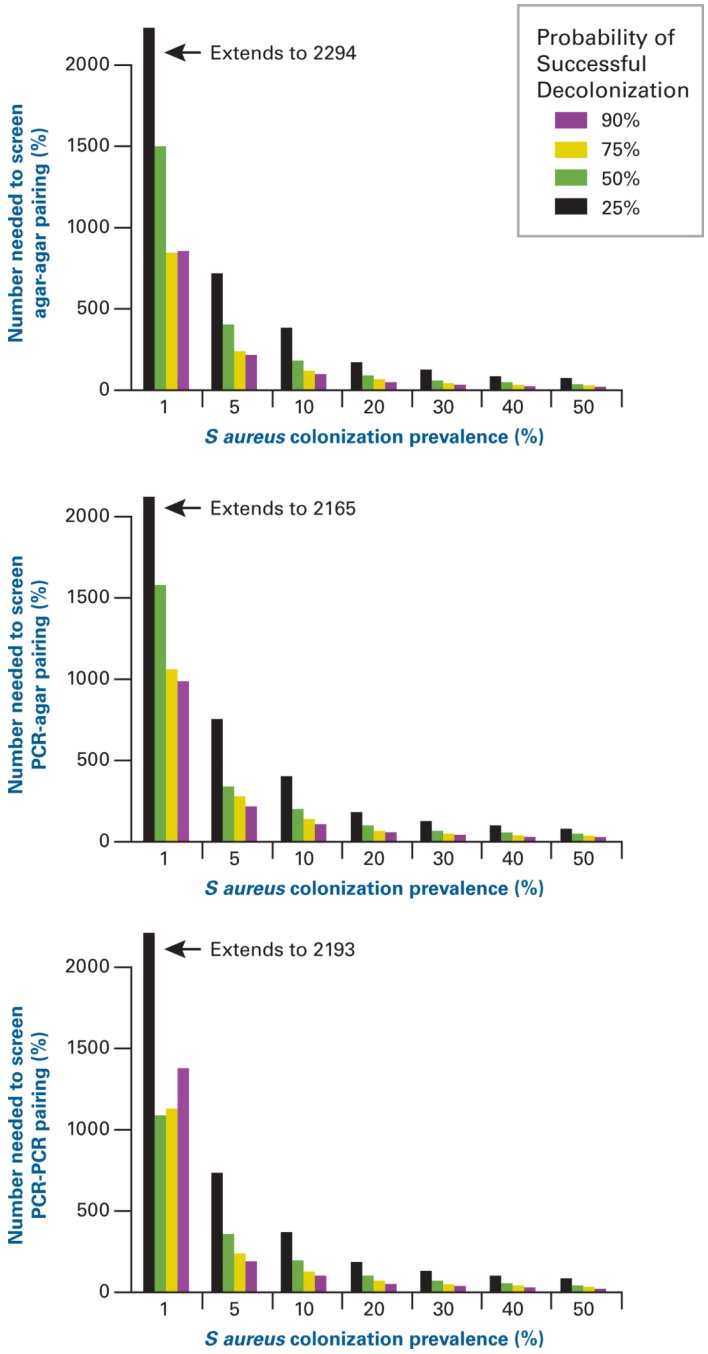

Figure 2. Number Needed to Screen to Prevent 1 Post-cesarean Wound Infection
PCR indicates polymerase chain reaction.

Table 1

Model Data Inputs

Variable	Distribution Type	Mean,[a] Median,[b] or Mode[c]	Standard Deviation or Range	Reference
Patient characteristics				
Age of pregnant women, y	—	27.1[b]	—	[19]
QALY value: inpatient treatment of wound infection	—	0.60	—	[31]
QALY value: outpatient treatment of wound infection	—	0.70	—	[31]
Costs, $				
Laboratory				
Agar screening/wound culture	—	12.34[a]	0.95	[29]
PCR screening/wound culture	—	50.27[a]	5.53	[29]
Pharmaceuticals				
Cephalexin (per day)	γ	7.47[a]	5.71	[28]
Chlorhexidine (full course)	γ	6.44[a]	2.88	[28]
Mupirocin (full course)	γ	8.07[a]	1.38	[28]
Sulfamethoxazole-trimethoprim (per day)	γ	3.29[a]	1.27	[28]
Unasyn (per day)	γ	65.25[a]	14.80	[28]
Vancomycin (per day)	γ	31.49[a]	16.84	[28]
Hospitalization				
Maternal hospitalization for wound infection	γ	6110.53[a]	394.47	[26,27]
Procedures and supplies				
Home health supplies (per week)	γ	34.78[a]	6.96	Assumption[d]
Home health visitation (per week)	γ	469.75[a]	93.91	Assumption[d]
Open wound incision in outpatient setting	γ	50.41[a]	4.55	[30]
Open wound incision in OR	γ	735.18[a]	45.54	[30]
Open wound incision on ward	γ	74.89[a]	7.20	[30]
Duration, days				
Antibiotic treatment for MRSA	—	7–14	—	[25]
Antibiotic treatment for MSSA	—	7	—	[25]
Empiric antibiotic treatment	Δ	1.5 [c]	1.0–2.0	Assumption[d]
Home health treatment	Δ	28[c]	14–42	Assumption[d]
Maternal hospitalization for wound infection	γ	3.8[a]	0.1	[26,27]
Probability, %				
Conditions and procedures				
Wound infection if *S aureus* colonized	Δ	9	4–20	[2,15,21–24]
Wound infection if not *S aureus* colonized	Δ	2.25	0.8–6.67	[2,15,21–24]

Variable	Distribution Type	Mean,[a] Median,[b] or Mode[c]	Standard Deviation or Range	Reference
Hospitalization (given wound infection)	Δ	2.0[c]	1.5–2.5	[32], Assumption[d]
Inpatient wound-opening procedure (given hospitalization)	Δ	95[c]	91–99	Assumption[d]
Wound opening in OR	Δ	15[c]	0–36	Assumption[d]
Wound opening on ward	Δ	85[c]	64–1	Assumption[d]
Outpatient wound-opening procedure	Δ	20	5–40	Assumption[d]
Home health after wound opening	—	75	—	Assumption[d]
Home health after outpatient wound opening	—	25	—	Assumption[d]
Laboratory				
Agar culture sensitivity	Δ	90	95.5–100	[33–36]
Agar culture specificity	Δ	95	97.5–100	[33–36]
PCR sensitivity	Δ	97	98.125–100	[33–36]
PCR specificity	Δ	95.5	98.34–100	[33–36]
Sensitivity analyses	**Values**		**Source**	
Probability of colonization	1%–50% (by increments of 5%)		Assumption	
Probability of successful decolonization	25%, 50%, 75%, 90%		Assumption	
Laboratory technique (screening/wound isolate)	Agar-agar, PCR-agar, PCR-PCR		Assumption	

MRSA indicates methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *Staphylococcus aureus*; OR, operating room; PCR, polymerase chain reaction; QALY, quality-adjusted life-year.

[a] Mean value.

[b] Median value.

[c] Mode value.

[d] Assumption based on experience at Magee-Womens Hospital.

Table 2

Incremental Cost-Effectiveness Ratios for Maternal *Staphylococcus aureus* Screening and Decolonization Before Cesarean Delivery[a]

	ICER by Probability of *Staphylococcus aureus* Colonization, $/QALY						
Screening/Wound Culture Method	**1%**	**5%**	**10%**	**20%**	**30%**	**40%**	**50%**
25% Probability of decolonization success							
Agar/agar	10,631,077	1,313,767	922,940	402,799	283,477	203,473	179,303
PCR/agar	18,244,123	5,085,743	3,410,549	1,360,614	951,692	758,448	607,422
PCR/PCR	23,128,146	5,259,576	2,705,445	1,443,178	995,366	805,703	649,926
50% Probability of decolonization success							
Agar/agar	3,942,569	869,499	344,783	184,171	110,492	**79,069 (C–E)**	**54,554 (C–E)**
PCR/agar	12,506,785	2,611,239	1,510,744	706,479	494,562	358,580	279,146
PCR/PCR	8,643,593	2,501,542	1,501,343	761,849	481,436	341,625	281,063
75% Probability of decolonization success							
Agar/agar	1,739,106	486,301	195,540	**91,616 (C–E)**	**55,068 (C–E)**	**38,768 (C–E)**	**25,121 (C–E)**
PCR/agar	7,751,050	2,134,213	960,480	478,422	309,852	217,078	170,734
PCR/PCR	8,488,401	1,791,167	963,867	468,356	299,476	212,607	162,942
90% Probability of decolonization success							
Agar/agar	1,512,341	434,147	174,660	**69,714 (C–E)**	**37,634 (C–E)**	**19,491 (C–E)**	**9993 (C–E)**
PCR/agar	9,726,700	1,700,280	804,716	367,620	245,711	172,807	133,869
PCR/PCR	14,427,708	1,482,124	776,970	377,815	230,870	165,887	128,213

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ICER indicates incremental cost-effectiveness ratio; PCR, polymerase chain reaction; QALY, quality-adjusted life-year.

[a]Cells with boldface values and delineated by (C–E) indicate scenarios in which the intervention was cost-effective when values below $50,000 to $100,000 per QALY were considered cost-effective.