Second International Consensus on Periprosthetic Joint Infection
July 25-27, 2018

Thomas Jefferson University, Philadelphia

ICM 2018

Mission

- Bring together expert doctors and scientists from around the world to determine the state of art related to orthopedic infections

ICM 2018

Mission

- Improve musculoskeletal care of **patients** by preventing or better treating orthopedic infections

International Consensus Group Discovery

Why bother?

International Consensus Group Discovery

Literature is not definitive on many issues

CDC Guidelines for SSI Prevention

Much of what we have is based on thin science, if any at all

Challenges of Generating Evidence

- To do studies on infection large sample sizes are needed
- n=5,000, n= 22,000, n= 36,000

Challenges of Generating Evidence

- Not everything we do needs "randomized, prospective studies"

Scholar Innovators

Glove during surgery

Hand washing- sterile techniques

Antibiotics

Ran Equipose

SPECIAL ARTICLE

EQUIPOISE AND THE ETHICS OF CLINICAL RESEARCH

BENJAMIN FREEDMAN, PH.D.

Abstract The ethics of clinical research requires equipoise — a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial. Should the investigator discover that one treatment is of superior therapeutic merit, he or she is ethically obliged to offer that treatment. The current understanding of this requirement, which entails that the investigator have no "treatment preference" throughout the course of the trial, presents nearly insuperable obstacles to the ethical commencement or completion of a controlled trial and may also contribute to the termination of trials because of the failure to enroll enough patients.

I suggest an alternative concept of equipoise, which would be based on present or imminent controversy in the clinical community over the preferred treatment. According to this concept of "clinical equipoise," the requirement is satisfied if there is genuine uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment. (N Engl J Med 1987; 317: 141-5.)

THERE is widespread agreement that ethics requires that each clinical trial begin with an honest null hypothesis.[1,2] In the simplest model, testing a new treatment B on a defined patient population P for which the current accepted treatment is A, it is necessary that the clinical investigator be in a state of genuine uncertainty regarding the comparative merits of treatments A and B for population P. If a physician knows that these treatments are not equivalent, ethics requires that the superior treatment be recommended. Following Fried, I call this state of uncertainty about the relative merits of A and B "equipoise."[3]

Equipoise is an ethically necessary condition in all cases of clinical research. In trials with several arms, equipoise must exist between all arms of the trial; otherwise the trial design should be modified to exclude the inferior treatment. If equipoise is disturbed during the course of a trial, the trial may need to be terminated and all subjects previously enrolled (as well as other patients within the relevant population) may have to be offered the superior treatment. It has been rigorously argued that a trial with a placebo is ethical only in investigating conditions for which there is no known treatment[2]; this argument reflects a special application of the requirement for equipoise. Although equipoise has commonly been discussed in the special context of the ethics of randomized clinical trials,[4,5] it is important to recognize it as an ethical condition of all controlled clinical trials, whether or not they are randomized, placebo-controlled, or blinded.

The recent increase in attention to the ethics of research with human subjects has highlighted problems associated with equipoise. Yet, as I shall attempt to show, contemporary literature, if anything, minimizes those difficulties. Moreover, there is evidence that concern on the part of investigators about failure to satisfy the requirements for equipoise can doom a trial as a result of the consequent failure to enroll a sufficient number of subjects.

The solutions that have been offered to date fail to resolve these problems in a way that would permit clinical trials to proceed. This paper argues that these problems are predicated on a faulty concept of equipoise itself. An alternative understanding of equipoise as an ethical requirement of clinical trials is proposed, and its implications are explored.

Many of the problems raised by the requirement for equipoise are familiar. Shaw and Chalmers have written that a clinician who "knows, or has good reason to believe," that one arm of the trial is superior may not ethically participate.[6] But the reasoning or preliminary results that prompt the trial (and that may themselves be ethically mandatory)[7] may jolt the investigator (if not his or her colleagues) out of equipoise before the trial begins. Even if the investigator is undecided between A and B in terms of gross measures such as mortality and morbidity, equipoise may be disturbed because evident differences in the quality of life (as in the case of two surgical approaches) tip the balance.[3-5,8] In either case, in saying "we do not know" whether A or B is better, the investigator may create a false impression in prospective subjects, who hear him or her as saying "no evidence leans either way," when the investigator means "no controlled study has yet had results that reach statistical significance."

Late in the study — when P values are between 0.05 and 0.06 — the moral issue of equipoise is most readily apparent,[9,10] but the same problem arises when the earliest comparative results are analyzed.[11] Within the closed statistical universe of the clinical trial, each result that demonstrates a difference between the arms of the trial contributes exactly as much to the statistical conclusion that a difference exists as does any other. The contribution of the last pair of cases in the trial is no greater than that of the first. If, therefore, equipoise is a condition that reflects equivalent evidence for alternative hypotheses, it is jeopardized by the first pair of cases as much as by the last. The investigator who is concerned about the ethics of recruitment after

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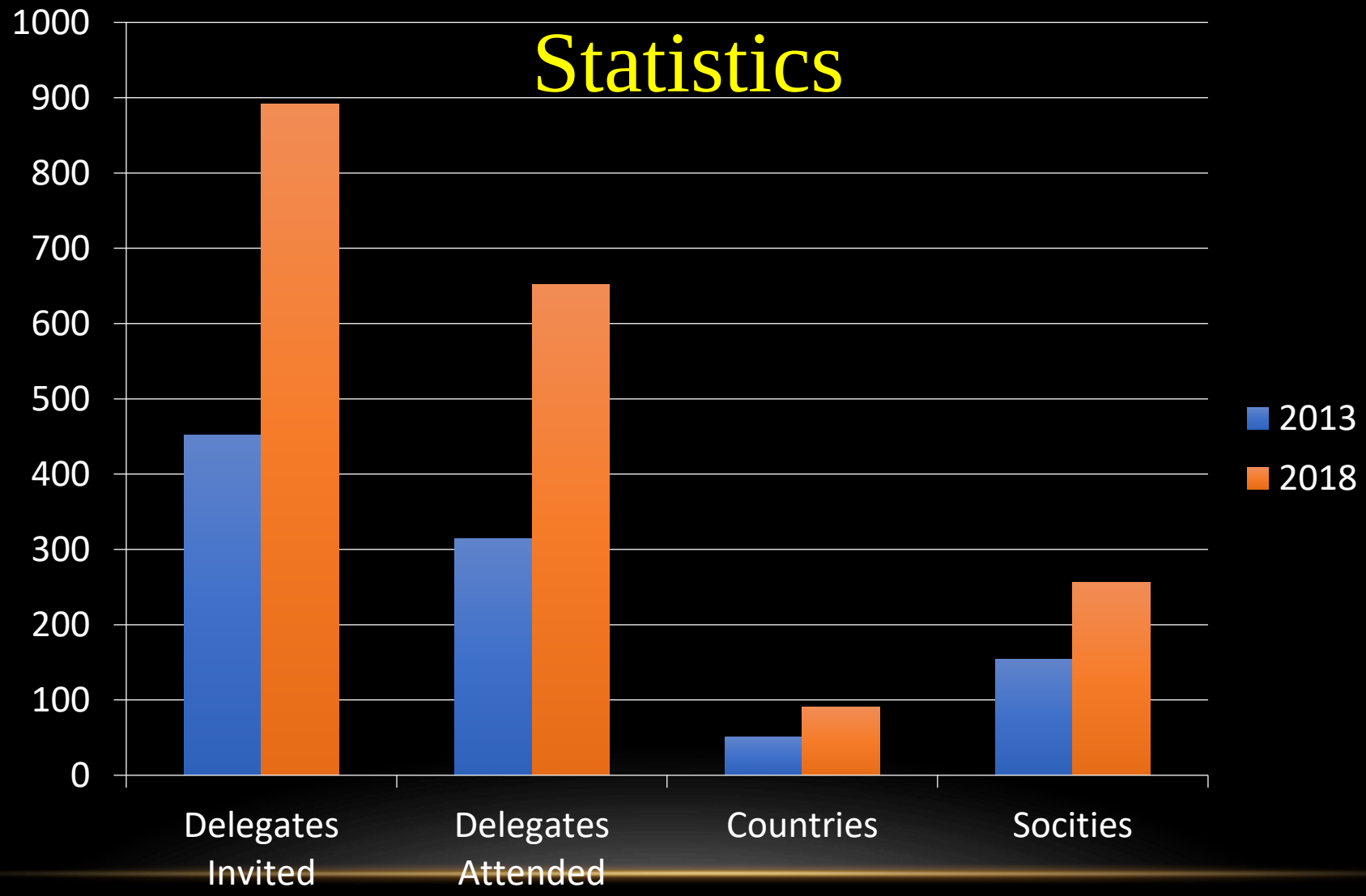
First International Consensus on Periprosthetic Joint Infection
August 1-3, 2013

Javad Parvizi MD, FRCS

Thomas Jefferson University, Philadelphia

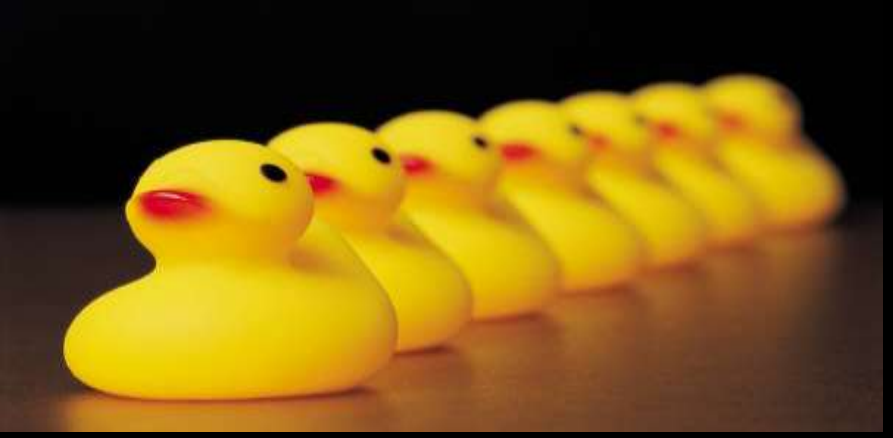
ICM 2013

Statistics



Delegates

- 890 Delegates
- 98 Countries
- Over 200 societies
- 98 Presidents



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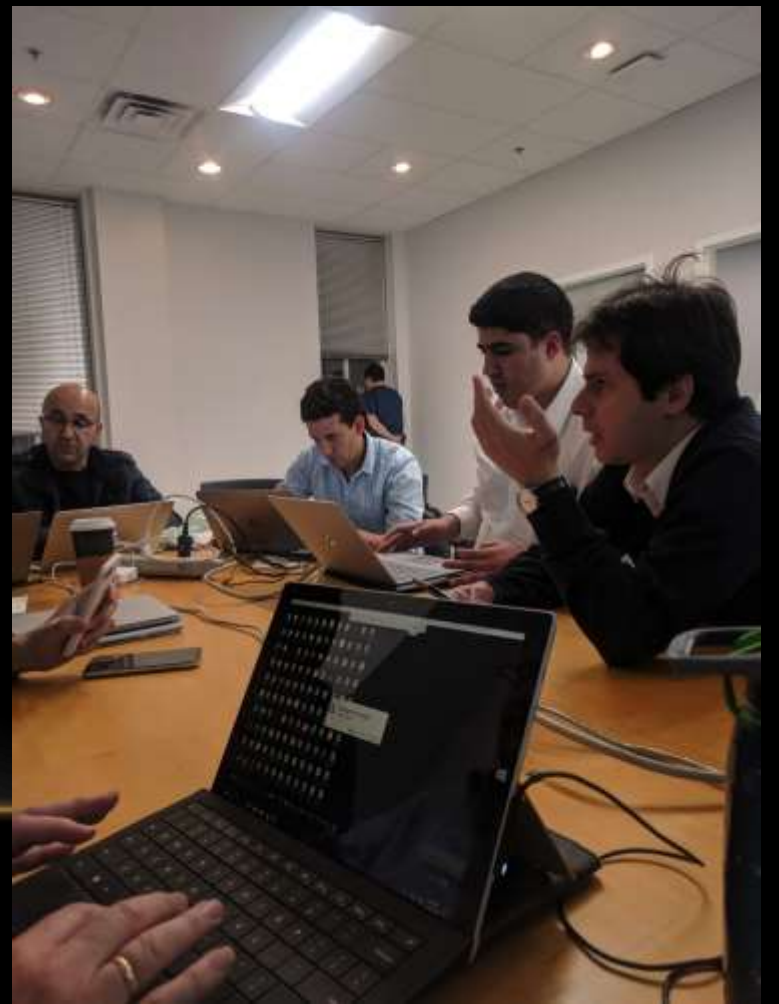
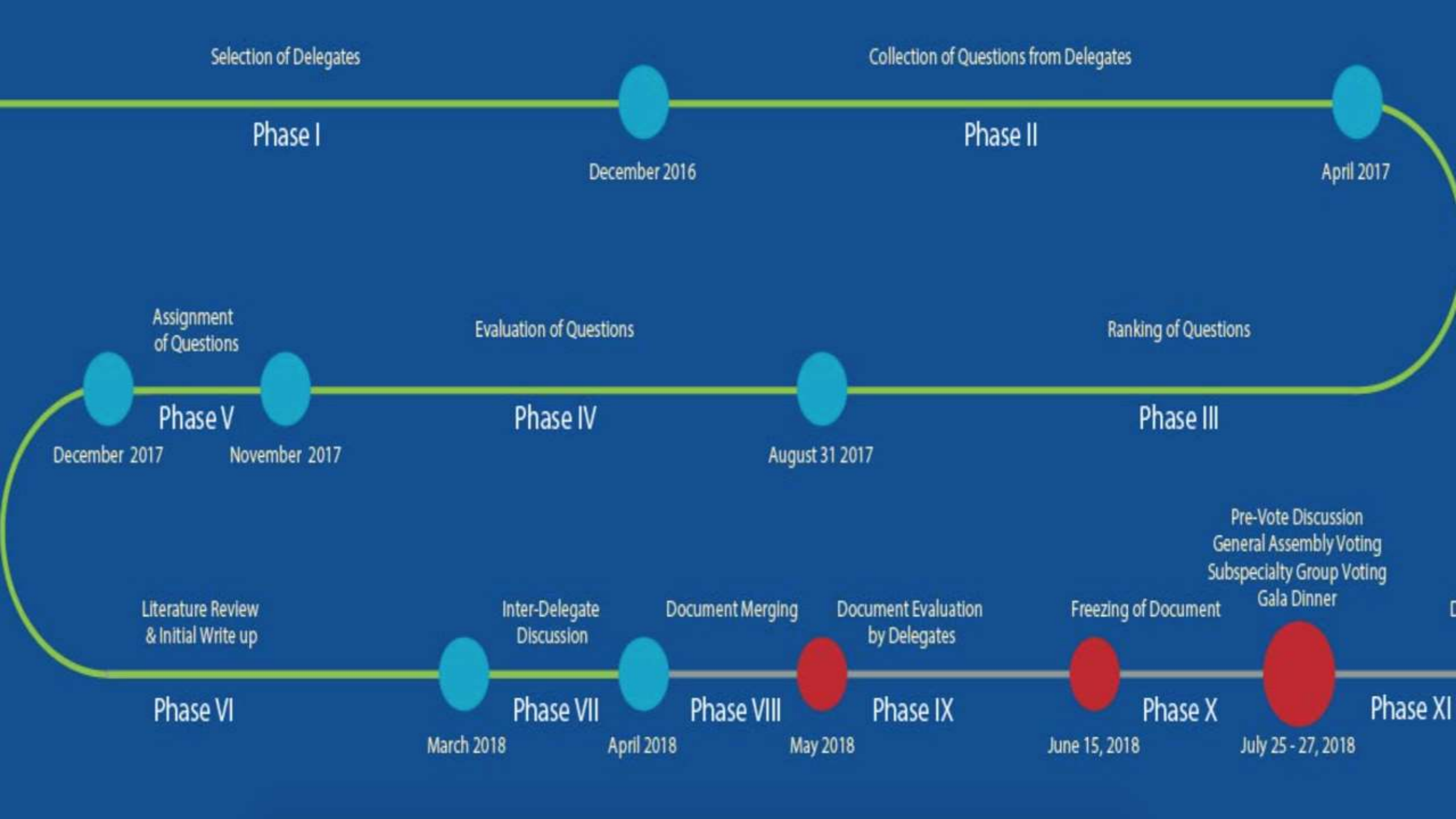
Delphi Steps

Thorsten On Skype




Selection of Delegates
Phase I
December 2016
Collection of Questions from Delegates
Phase II
April 2017
Assignment of Questions
December 2017
Phase V
November 2017
Evaluation of Questions
Phase IV
August 31 2017
Ranking of Questions
Phase III
Literature Review & Initial Write up
Phase VI
March 2018
Inter-Delegate Discussion
Phase VII
April 2018
Document Merging
Phase VIII
May 2018
Document Evaluation by Delegates
Phase IX
Freezing of Document
Phase X
June 15, 2018
Pre-Vote Discussion
General Assembly Voting
Subspecialty Group Voting
Gala Dinner
July 25 - 27, 2018
Phase XI

Step VI: Systematic Review

- Over 200,000 publications reviewed

Step XII

Voting

July 26-27,2018

ICM 2018

- Subspecialties:
  - General (171)
  - Hip and knee (157)
  - Shoulder (77)
  - Spine (65)
  - Trauma (52)
  - Foot and ankle (42)
  - Oncology (34)
  - Sports (20)
  - Biofilm (20)
  - Elbow (16)

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- Class 1: Clinically important, high evidence
- Class 2: Clinically important, low evidence
- Class 3: Clinically less important, high evidence
- Class 4: Clinically less important, low evidence

G-1 (Former G-158) What modifiable and non-modifiable host related factors contribute to an increased risk of SSI/PJI?

RESEARCHED BY:

Setor Kunutsor

Literature:

- In pooled analysis of 14 studies, Kerkhoffs and colleagues reported an increased risk of infection following total knee arthroplasty (TKA) when obese were compared to non-obese patients

- In pooled analysis of eight studies, age (as a continuous exposure) was not associated with the risk of PJI. However, findings from two studies suggested that patients aged 75 years and above had an increased risk of SSI following primary THA

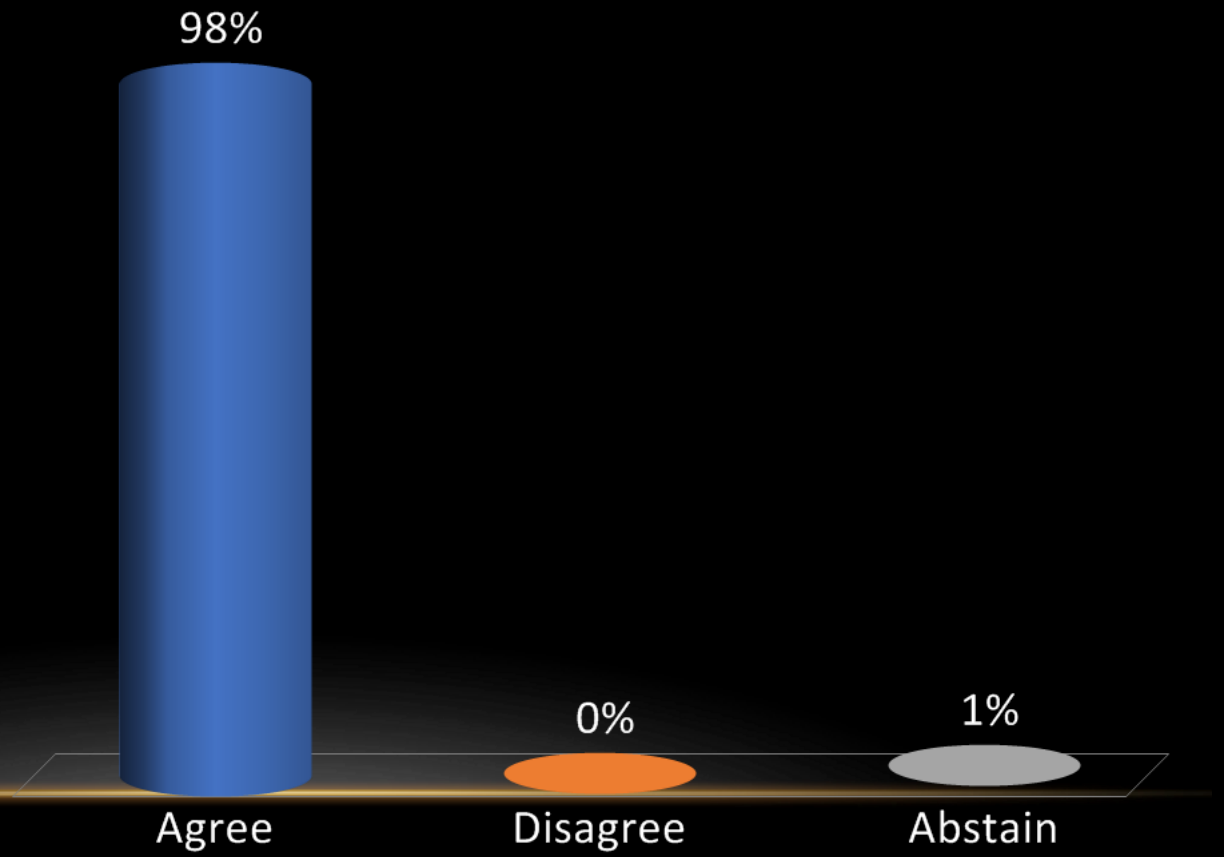
- In pooled analysis of eight studies, Chen and colleagues demonstrated that males had a higher risk of infection after TKA than females. Recent pooled multivariate analysis of 28 studies confirms the emerging evidence

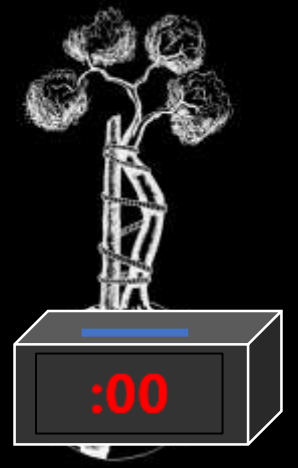
- Pooled analysis shows that black populations (compared with the white race) have an increased risk of PJI/SSI

Recommendation: Modifiable host related factors such as BMI, smoking, alcohol consumption, diabetes, malnutrition and other and certain medical co-morbidities have been shown to increase the risk of SSI/PJI. Non-modifiable factors such as increasing age, male gender, and low-socioeconomic status have also been shown to increase the risk if SSI/PJI.

Level of Evidence: Strong

A. Agree
B. Disagree
C. Abstain





G-9 (Former G-108) Should routine dental clearance be obtained prior to total joint arthroplasty (hip/knee/shoulder/ankle)?

RESEARCHED BY:

William V Arnold

Emad Mustapha Al-Bushra

Juan Ottolenghi

Literature:

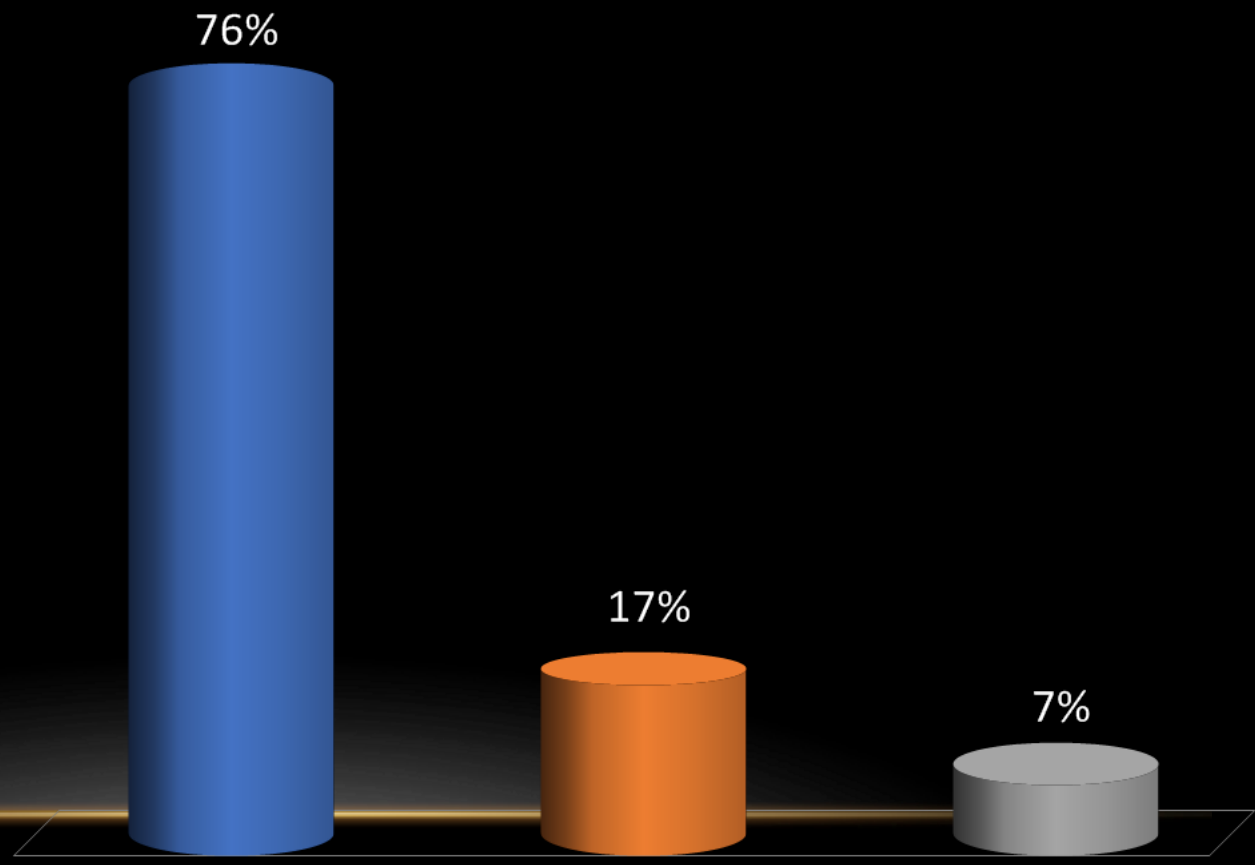
- Only one retrospective study has compared the incidence of PJI in a population of patients who underwent dental clearance prior to arthroplasty with a population of arthroplasty patients who had no such clearance.

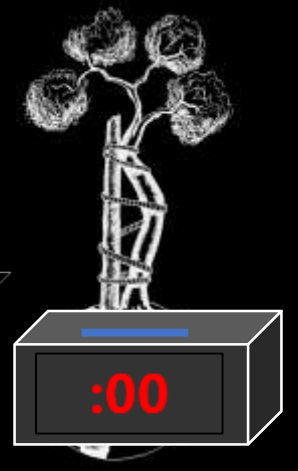
- This latter group of patients was not a prospective matched control cohort, but rather was composed of hip fracture patients treated with non-elective arthroplasty. The conclusion of this study was that dental clearance prior to arthroplasty did not provide a significant decrease in PJI.

Recommendation: No. While dental pathology has been reported in a subset of patients undergoing joint arthroplasty, there are no prospective controlled studies supporting the role of pre-surgical dental clearance in reducing the rate of subsequent PJI.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





G-17 (Former G-66) Does the type of venous thromboembolic (VTE) prophylaxis influence the risk of SSI/PJI in patients undergoing orthopedic procedures?

RESEARCHED BY:

Ronald Huang James J Purtill I. Remzi Tozun

Literature:

- Meta-analysis 2, Prospective/Randomized 2, Retrospective 30

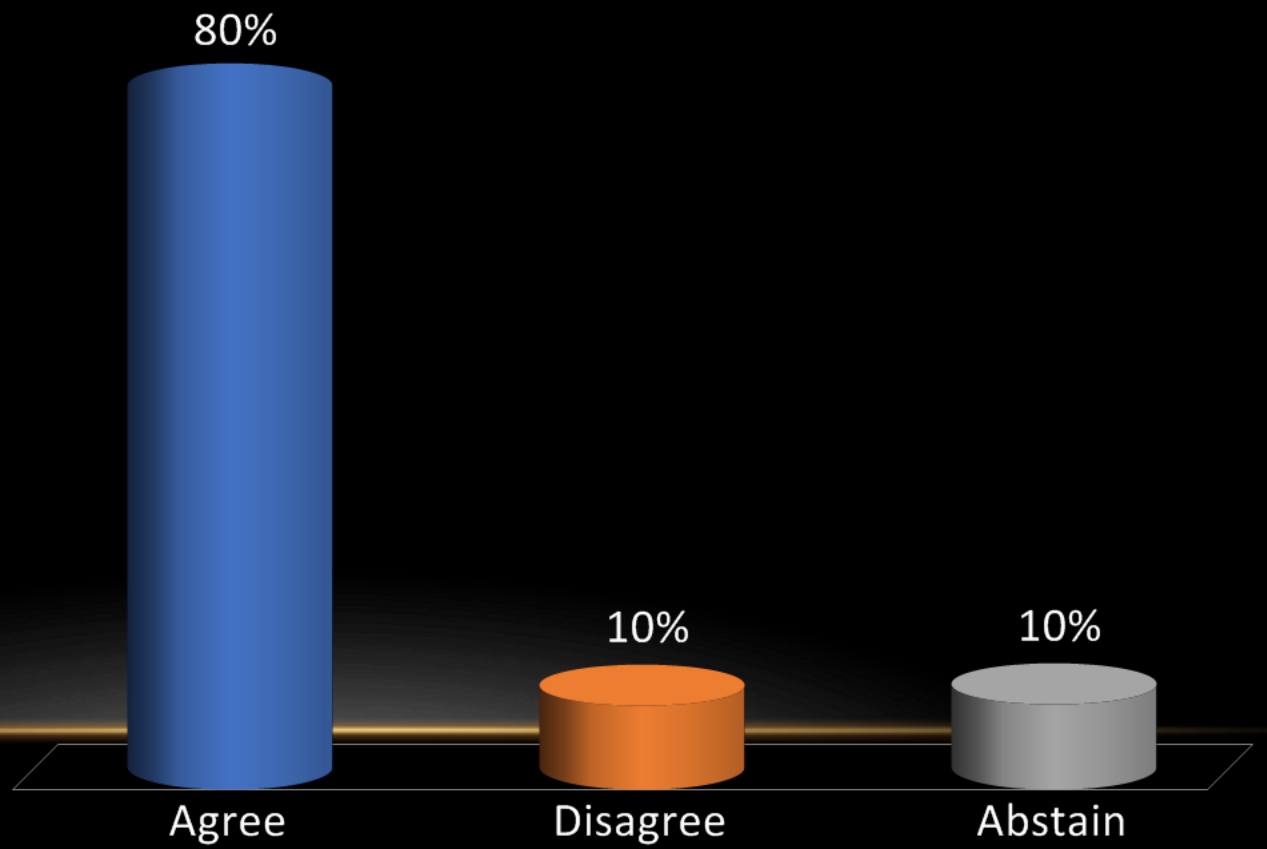
- A prospective cohort study showed a significantly higher rate of surgical site infections in patients receiving LMWH prophylaxis dosing compared with patients receiving therapeutic warfarin with or without bridging therapy .

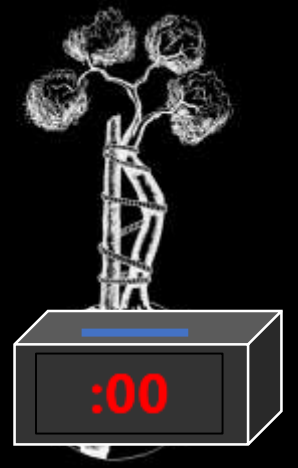
- Two recent meta-analyses of RCTs found no difference in SSI/PJI rates in TJA patients receiving rivaroxaban versus enoxaparin
-
- Randomized trial demonstrated that n patients receiving enoxaparin, there was nearly eight times the number of wound complications compared to other modalities

Recommendation: Yes. In a majority of studies evaluating venous thromboembolic (VTE) prophylaxis in patients undergoing total joint arthroplasty (TJA), aspirin appears to result in a lower risk of SSI/PJI than anticoagulants (vitamin K antagonists, heparin-based products, factor Xa inhibitors, and direct thrombin inhibitors).

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





G-75 (Former G-22) Does allogeneic blood transfusion increase the risk of SSI/PJI?

RESEARCHED BY:

Trisha Peel Luis Pulido Kalin Mihov

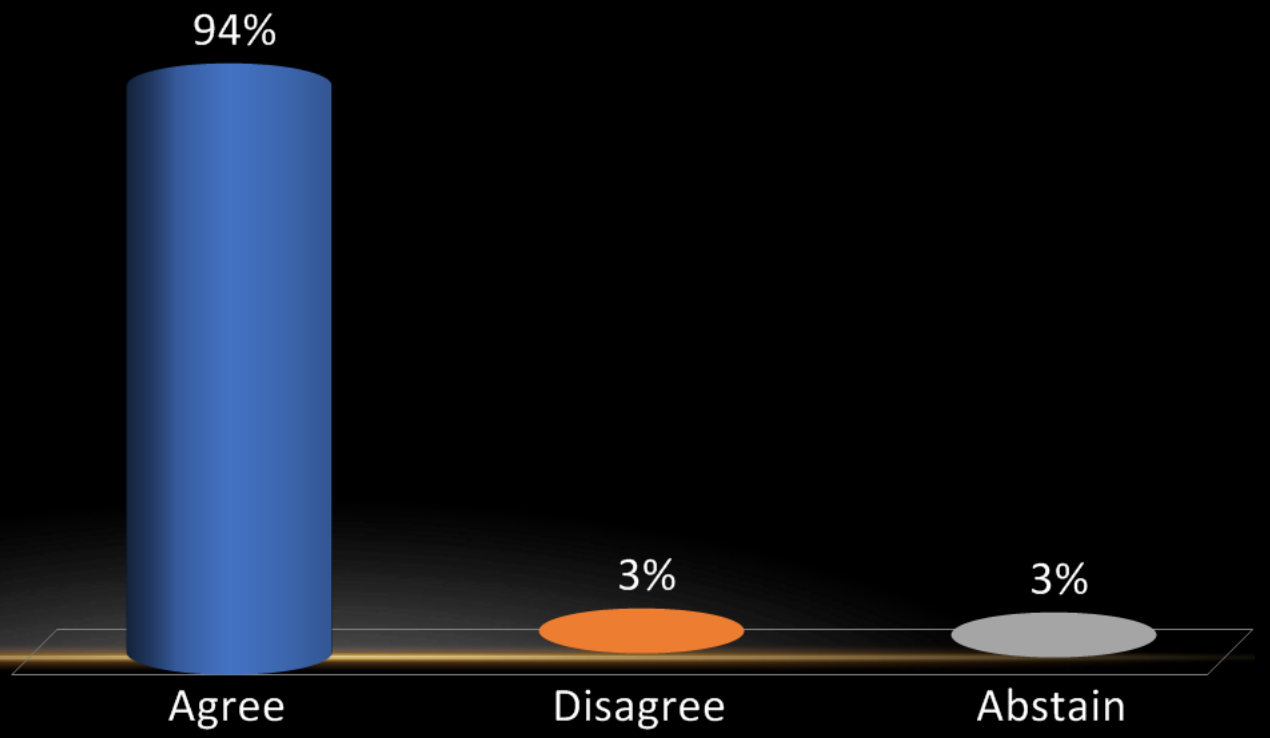
Literature:

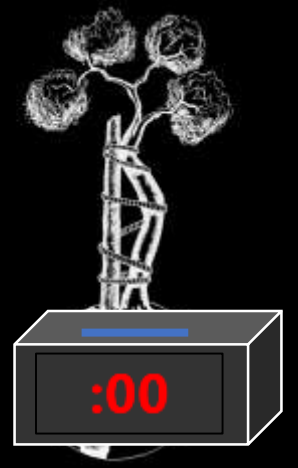
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 22
- Many studies consistently demonstrate that allogenic blood transfusion is a risk factor for PJI.
- Five studies demonstrate that allogenic transfusion increases infection rate compared to autologous transfusion

Recommendation: Yes. Allogenic blood transfusion is associated with an increased risk of SSI / PJI.

Level of Evidence: Strong

A. Agree
B. Disagree
C. Abstain





G-79 (Former G-110) Should extended (beyond 24 hours) antibiotic prophylaxis be administered to patients with surgical drain in place?

RESEARCHED BY:

Werner Zimmerli

Ed McPherson

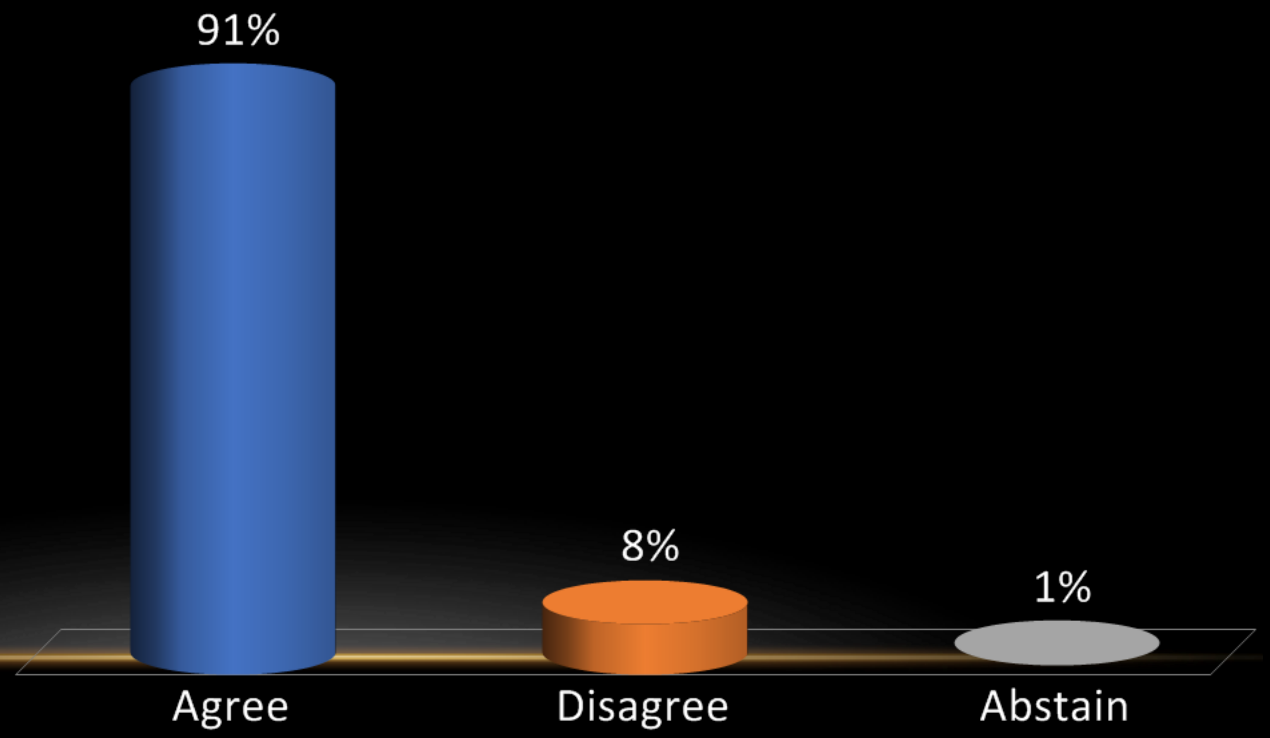
Literature:

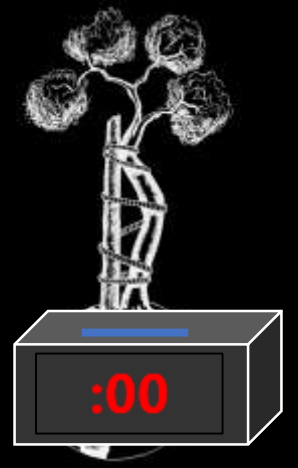
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 6
- There is minimal evidence that extended antibiotics demonstrates a reduced rate of infection
- There is minimal literature that antibiotics should be administered in patients with drains

Recommendation: No. There is no indication for prolonged antibiotic prophylaxis regardless of the presence of surgical drains. Prolonged prophylaxis is potentially dangerous, because it increases the fraction of resistant microorganism on the skin microbiome.

Level of Evidence: Strong

A. Agree
B. Disagree
C. Abstain





G-105 (Former G-143) What is the optimal irrigation solution (type, volume, frequency) to be used during clean elective orthopedic procedures?

RESEARCHED BY:

Ashley Blom

Setor Kunutsor

Andrew Fleischman

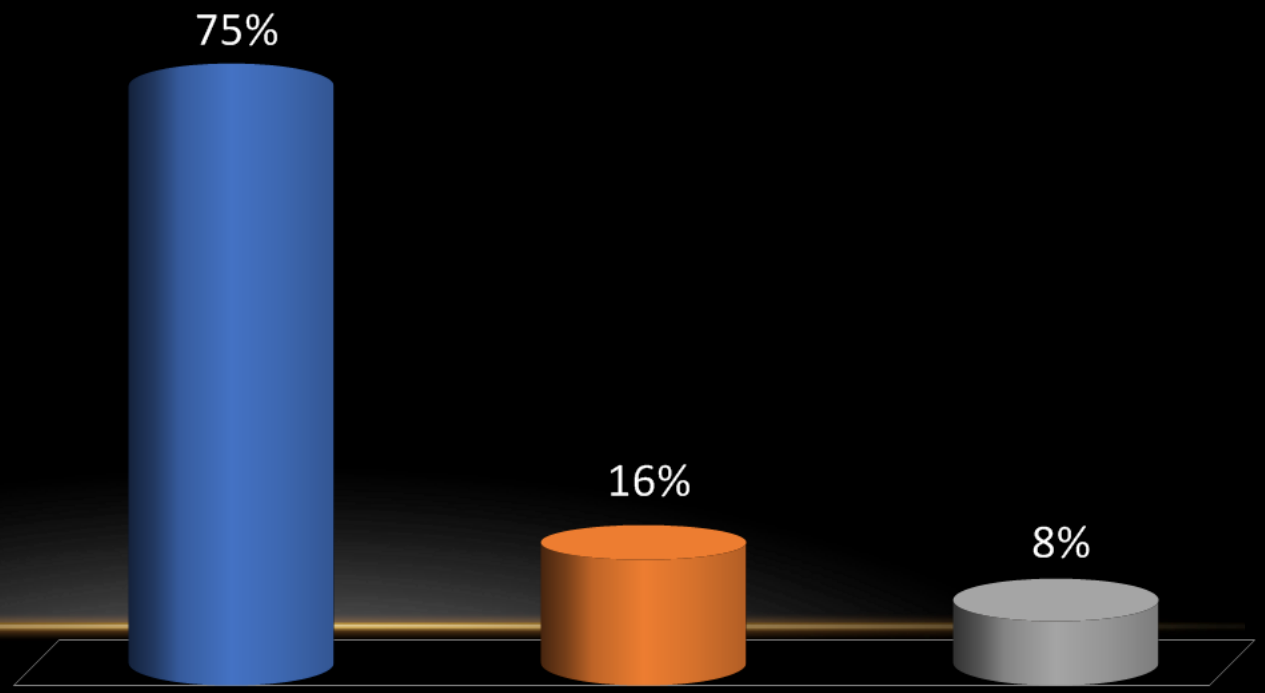
Literature:

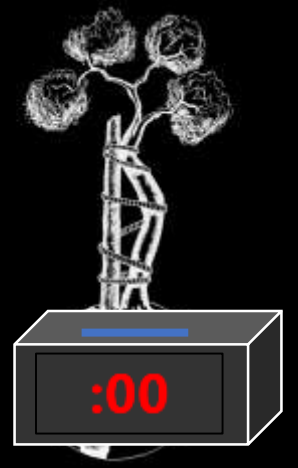
- Meta-analysis 0, Prospective/Randomized 5, Retrospective 14
- Many studies, including prospective RCTs, demonstrate that dilute betadine decreases the rate of infection
- There are minimal studies regarding the optimal volume of irrigation needed

Recommendation: There is ample evidence to support use of sterile dilute povodine- iodine for the irrigation of wounds during surgical procedures. The optimal volume of irrigation solution is not known.

Level of Evidence: Strong

A. Agree
B. Disagree
C. Abstain





G-127 (Former G-148) What is the recommended time interval that would divide acute and chronic PJI (four weeks, 90 days, etc)?

RESEARCHED BY:

Marjan Wouthuyzen-Bakker, MD

Jeppe Lange, MD

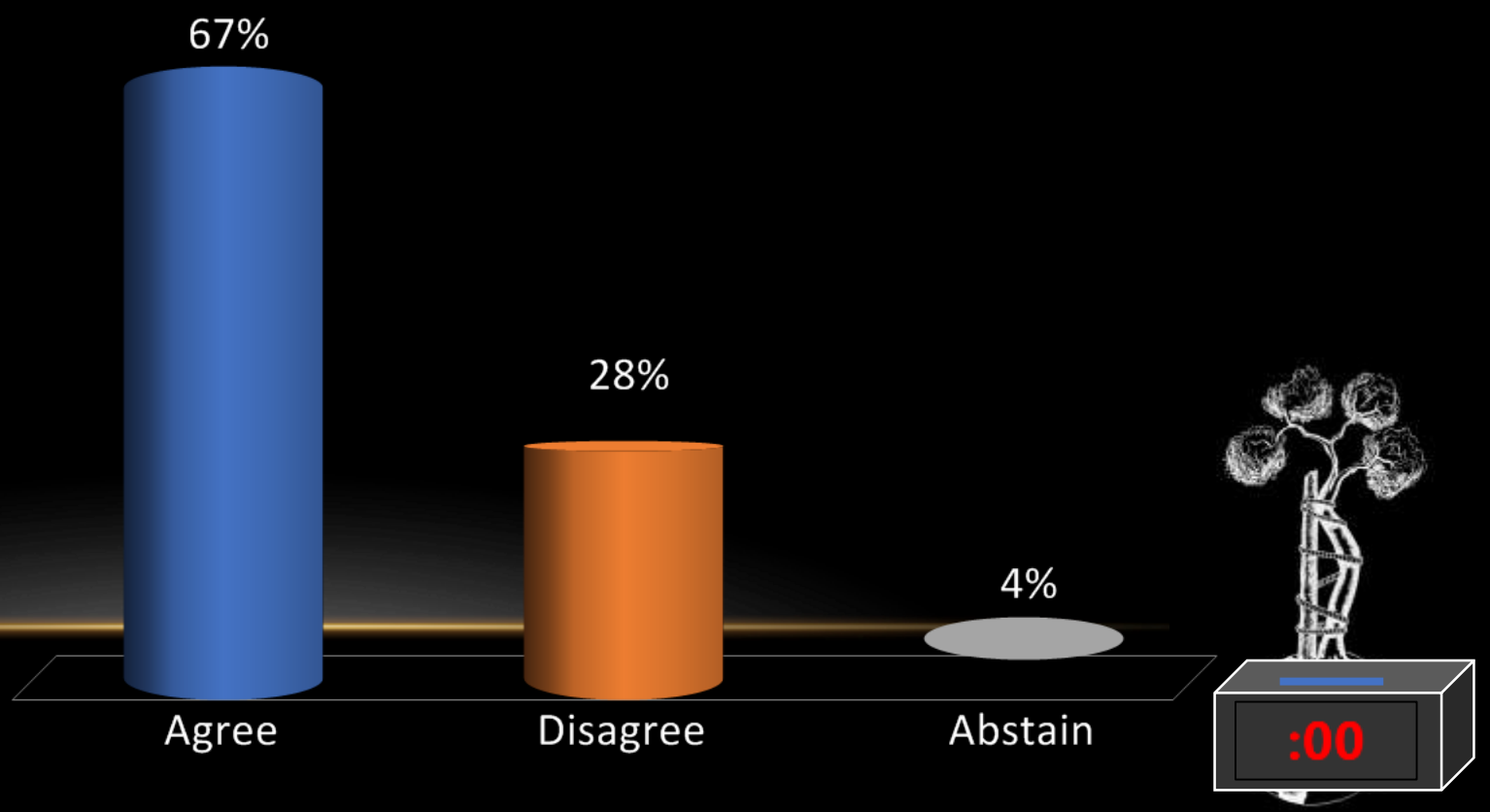
Literature:

- Meta-analysis 0, Prospective/Randomized 1, Retrospective 35
- Carli et al. observed in a mouse model with a proximal tibial implant infection, using a high initial bacterial inoculum (3x10 5 CFU), that a biofilm is evident after 2 weeks of injection, but extends and is covered by fibrinous tissue and multiple host cells after 6 weeks.
- The majority of the proposed PJI classification schemes in literature use a wide variety in time intervals (3 weeks - 3 months), but all are based on expert opinions.
- Some clinical reports have supported the usefulness of a 3-week time interval, but others have not.

Recommendation: There is no evidence-based time interval that divides acute from chronic PJI. It is recommended that a time interval of 3 weeks after the onset of symptoms should be used as cut-off between acute and chronic. It is recommended, that a time interval of 3 weeks after the index arthroplasty should be applied in early post-surgical) PJI when the onset of symptoms is not clear.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain



G-139 (Former G-113) Should perioperative antibiotics be withheld prior to obtaining an intra-operative aspirate and/or tissue samples for culture in suspected infected revision total joint arthroplasty cases?

RESEARCHED BY:

Natividad Benito Robert Barrack Giuseppe Sessa

Literature:

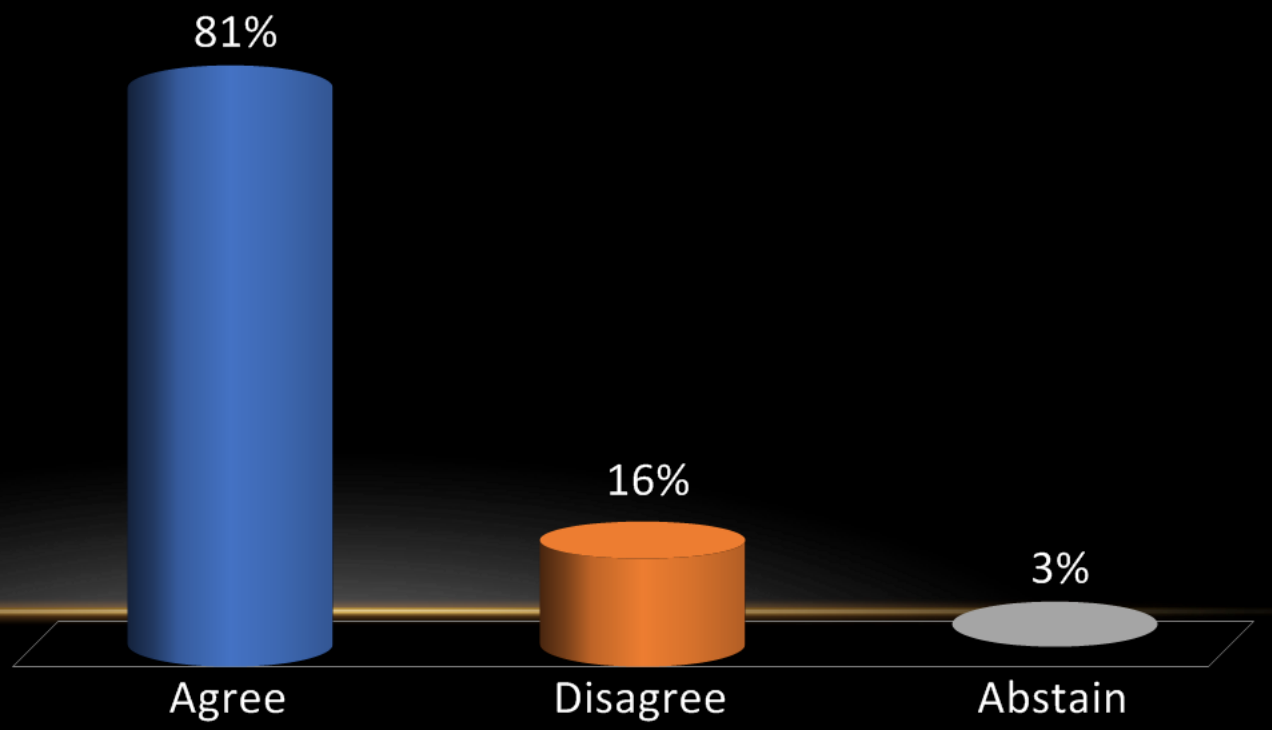
- Two randomized clinical trials, two prospective cohort studies, one systematic review of the literature, three retrospective studies.

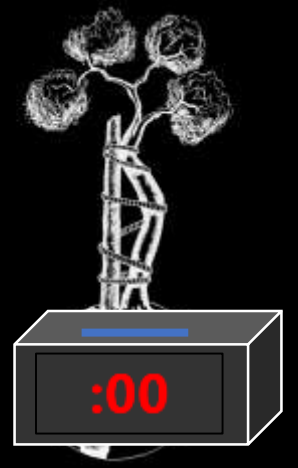
- The literature overwhelmingly supports giving prophylactic antibiotics at the onset of the case, rather than holding them for cultures to be obtained.

Recommendation: Prophylactic antibiotics antibiotics should not be witheld in patients undergoing revision joint arthroplasty

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





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- Class 1: Clinically important, high evidence
- Class 2: Clinically important, low evidence
- Class 3: Clinically less important, high evidence
- Class 4: Clinically less important, low evidence

HK-7 (former HK-65) - Is one dose of preoperative antibiotic adequate for patients undergoing total joint arthroplasty?

RESEARCHED BY:

Timothy Tan MD, USA

Wei Huang MD, China

Thorsten Seyler MD, USA

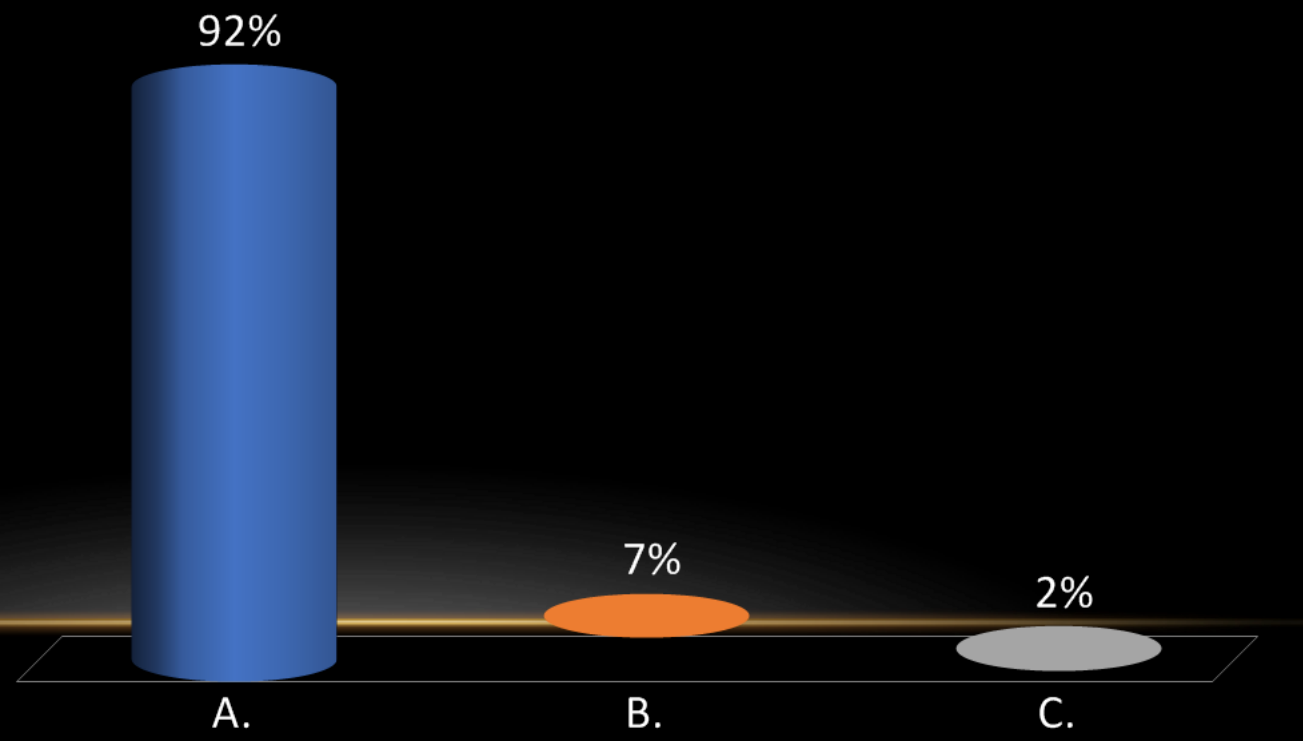
Literature:

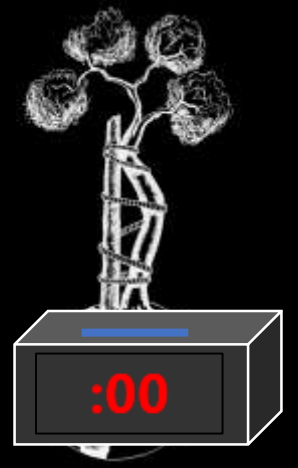
- **Meta-analysis 1, Prospective/Randomized 1, Retrospective 23**
- WHO and CDC recommend for single preoperative antibiotic dosing
  - There is insufficient arthroplasty literature to support this recommendation
- A meta-analysis concluded that postoperative antibiotics did not reduce the rate of infection, however, they reported that the quality of evidence was very low

Recommendation: Despite the current guidelines from CDC advocating for a single dose of perioperative antibiotics, these studies are underpowered and primarily in specialties outside orthopaedics. From the limited evidence available, it does appear that a single preoperative dose of antibiotics, compared to multiple doses, does not increase the rate of subsequent SSI/PJI. A randomized prospective study in patients undergoing elective arthroplasty in underway that should answer this question definitively.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-65 (Former G-61) Does the type of anesthesia (general vs. neuraxial) influence the risk of subsequent SSI/PJI?

RESEARCHED BY:

Andrew Fleischman

Stavros G Memtsoudis

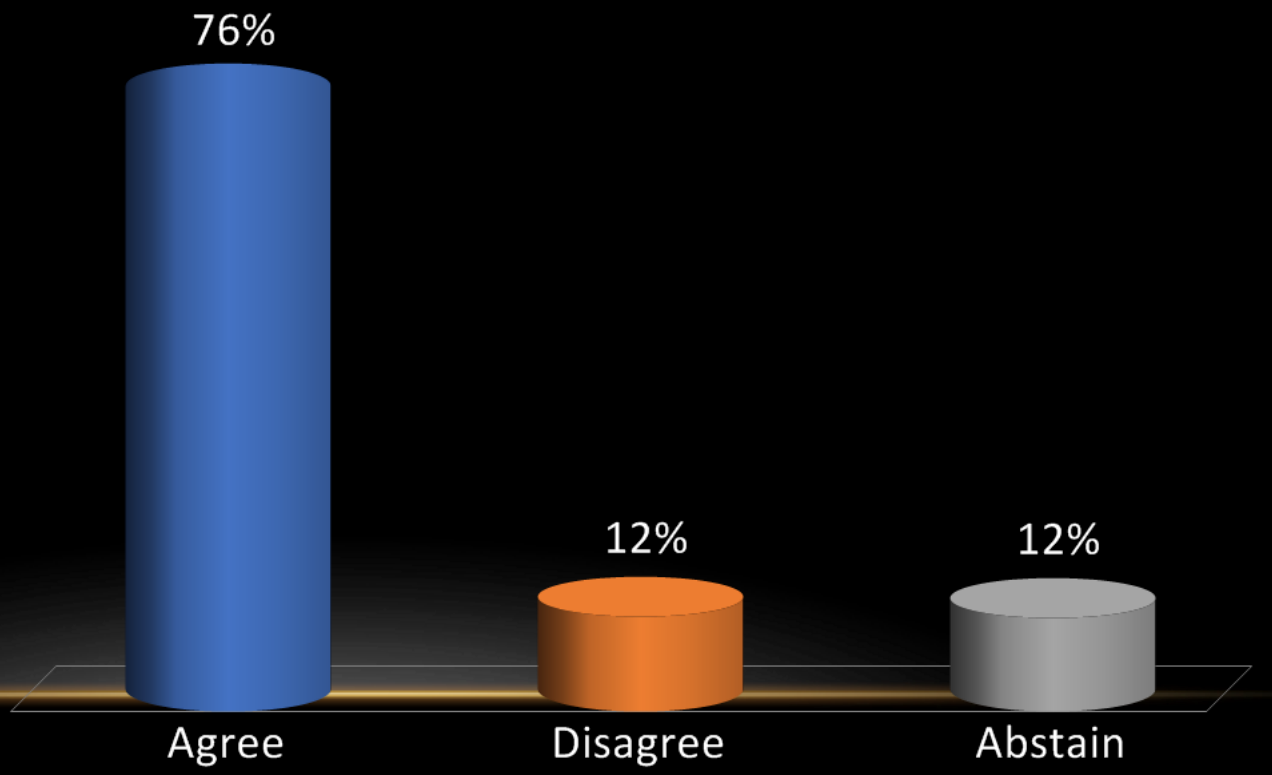
Literature:

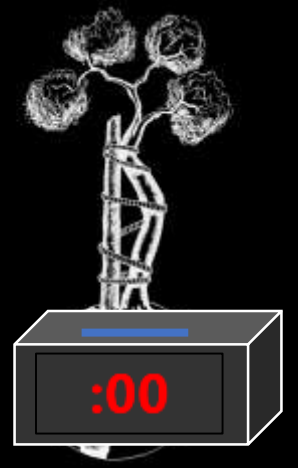
- Meta-analysis 2, Prospective/Randomized 0, Retrospective 16
- Several retrospective, and meta-analysis have demonstrated that general anesthesia has a higher rate of infection and wound complications than neuraxial anesthesia.
- Large database and registry studies also demonstrate increased infection with general anesthesia
- There are no high quality randomized studies available

Recommendation: Compared to general anesthesia (GA), neuraxial anesthesia (NA) appears to be associated with reduced risk of SSI/PJI after total hip arthroplasty (THA) and total knee arthroplasty (TKA).

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-13 (Former G-85) How should a patient with a pre-operative urinary tract infection (UTI) be managed prior to undergoing elective joint arthroplasty?

RESEARCHED BY:

Young-Kyun Lee

Bülent Atilla

Andrew Battenberg

Literature:

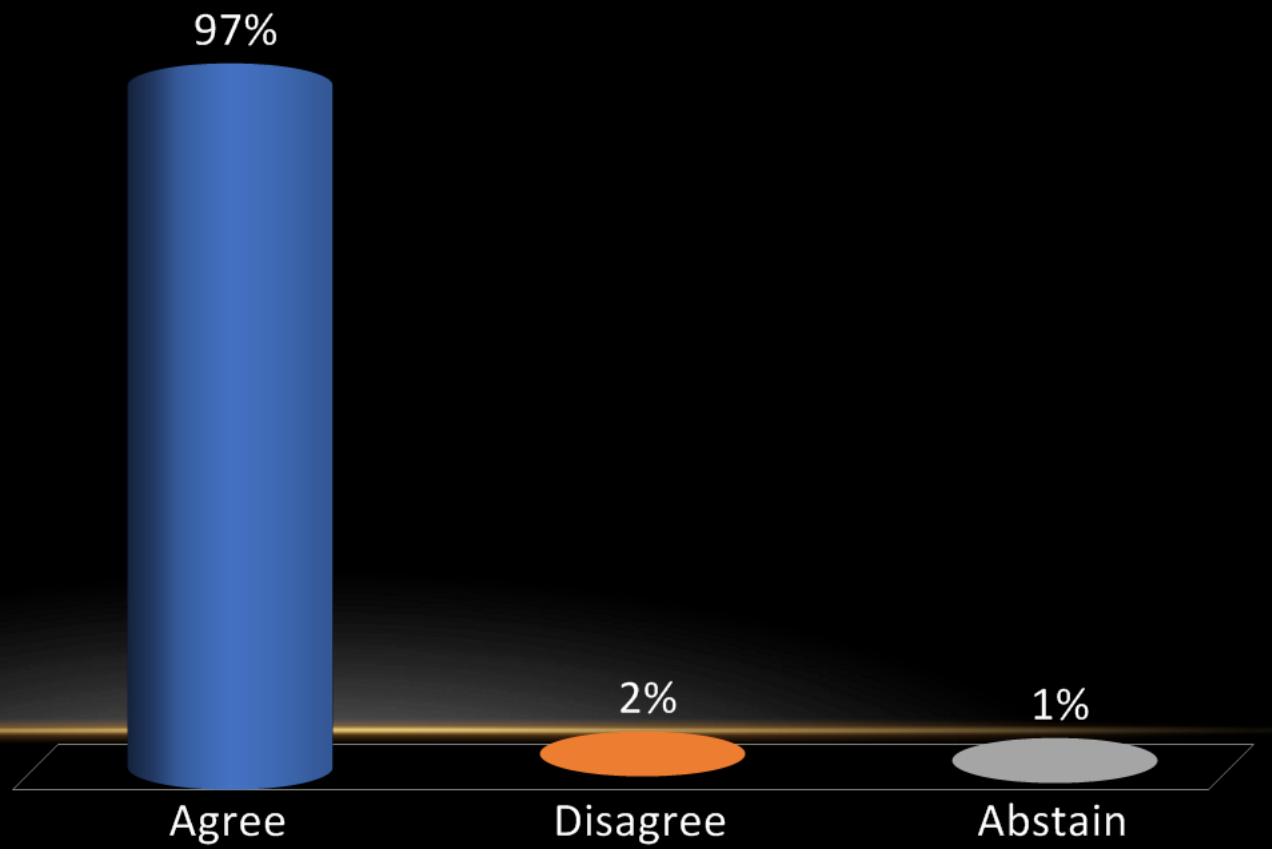
- To date, there are no studies reporting on symptomatic pre-operative UTI that goes untreated prior to elective TJA, making comparison difficult

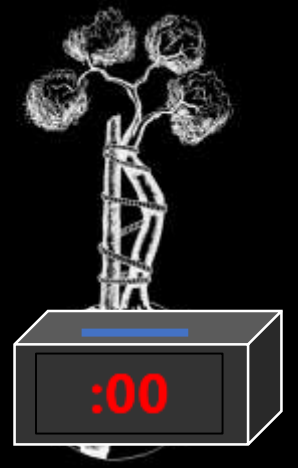
- Current data is limited to large institutional and publicly available databases; 3 demonstrated preoperative UTI as a risk while smaller retrospective studies fail to find a difference (3).

Recommendation: Pre-operative UTI should be treated with appropriate antibiotics prior to elective total joint arthroplasty (TJA).

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-3 (Former G-54) Does the presence of skin lesions (i.e. boils, grazes, folliculitis, etc) in the proximity of the surgical site or distant from the surgical site predispose patients to SSI/PJI? If so, is it necessary for patients with these skin lesions to undergo treatment prior to elective total joint arthroplasty?

RESEARCHED BY:

Hao Shen Peter Thomas Qiojie Wang

Literature:

- In a retrospective study on 2349 patients with clean surgical wounds (of different surgical specialties), the wound infection rate in the 53 patients with remote skin infections was 20.7% compared with 6.9% in the 2141 patients without remote infections ($p < 0.001$).

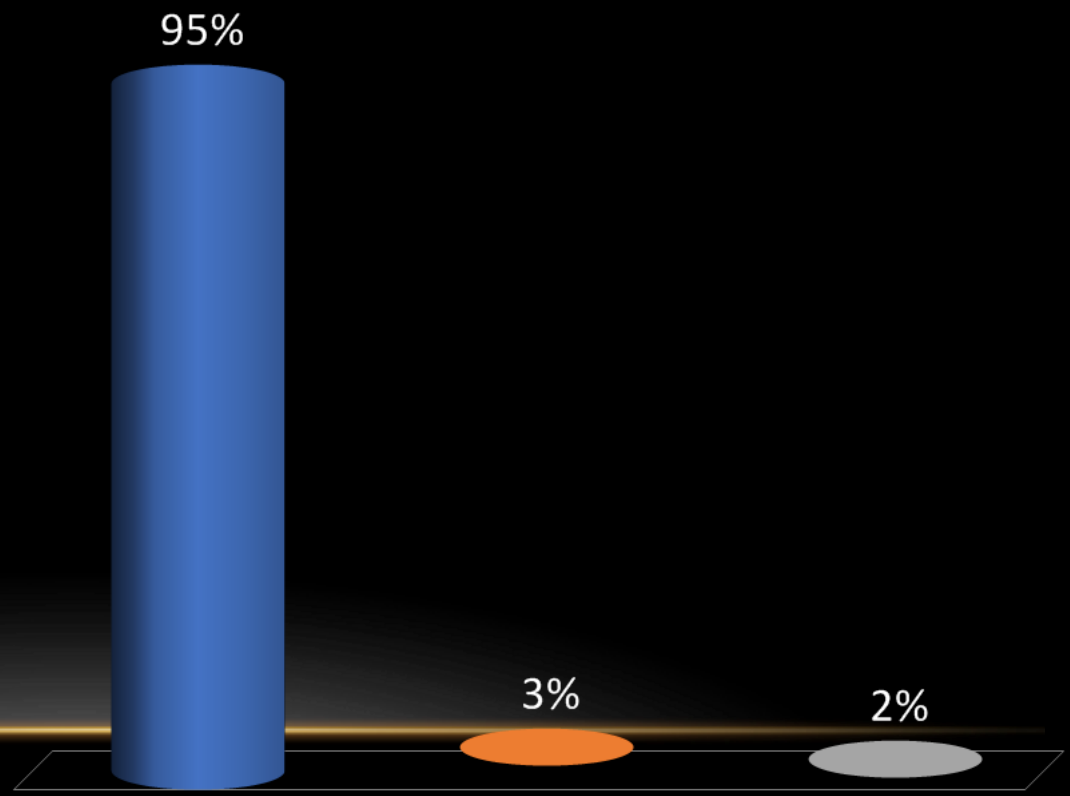
- There are no existing studies evaluating the risk of SSI when incisions are placed through eczematous or psoriatic lesions.

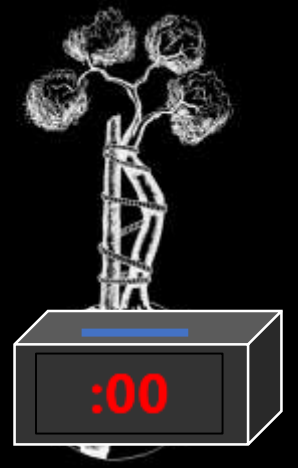
- Ulceration of the skin (including neoplasm) is a significant risk factor for surgical site infection.

Recommendation: The presence of active skin infection, either in the proximity or distant to the surgical site, can potentially increase the risk of SSI/PJI in patients undergoing elective TJA. Surgery should be delayed until these lesions are treated and/or resolved. Placing surgical incisions through eczematous or psoriatic lesions should be avoided, whenever possible.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





screening for diabetes and glycemic control reduce the risk of SSI/PJI?

RESEARCHED BY:

Noam Shoat

Javad Parvizi

Literature:

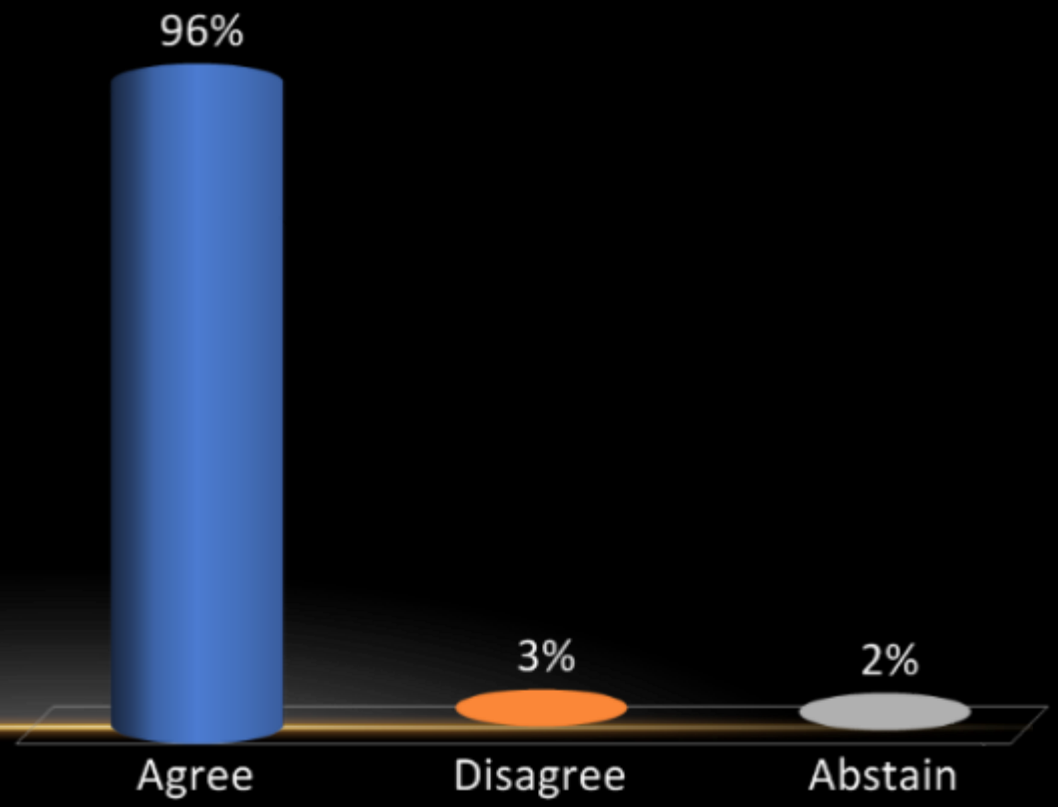
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 19

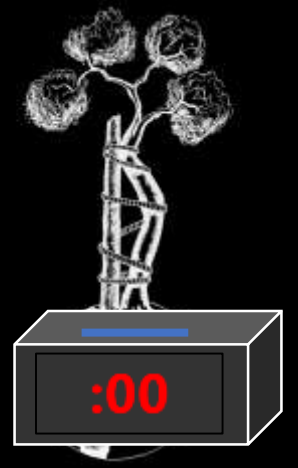
- The prevalence of diabetes in patients undergoing TJA has been shown to be 20.7% (40.9% of these were undiagnosed)
-
- Inadequately controlled diabetes is associated with greater risk of PJI, though no studies exist that show tight control reduces this risk

Recommendation: The routine screening for diabetes and glycemic control has the potential to reduce the incidence of surgical site infection (SSI) and/or periprosthetic joint infection (PJI) following total joint arthroplasty (TJA).

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





G-34 (Former G-153) What is the threshold for HbA1C that is predictive of subsequent SSI/PJI in patients undergoing orthopedic procedures?

RESEARCHED BY:




Hasan Nahouli William Jiranek Brian A Klatt Majd Tarabichi

Literature:

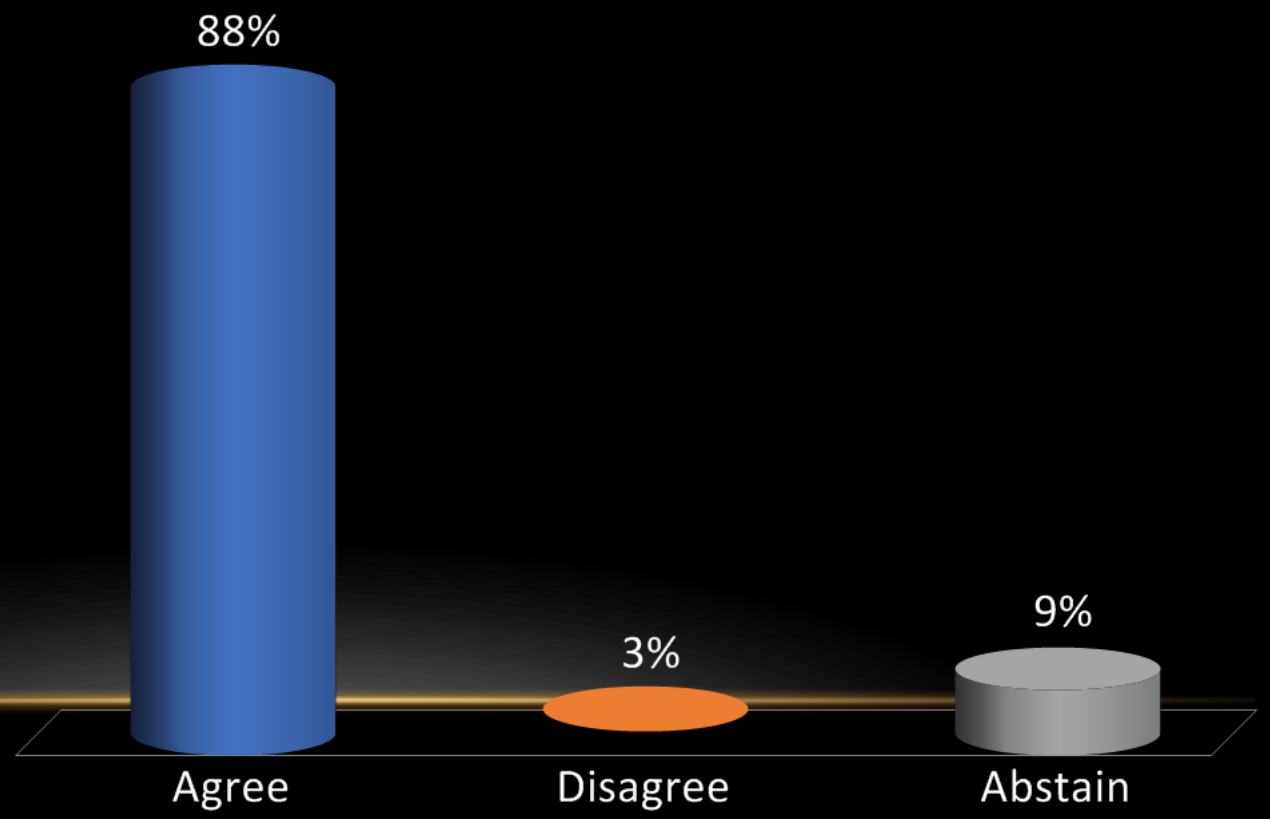
- Meta-analysis 2, Prospective/Randomized 2, Retrospective 18

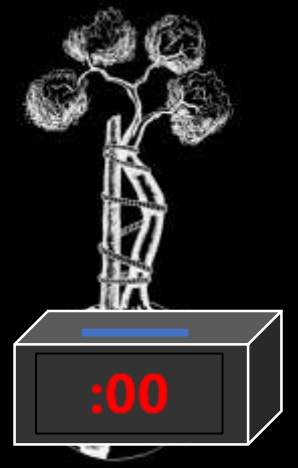
- Multiple studies have found that a HbA1c greater than either 7.5% or 8% to be significantly associated with wound complications and SSI, though its poor specificity limits it clinical applicability.

Recommendation: The upper threshold for HbA1c that may be predictive of subsequent SSI/PJI is most likely to be within the range of 7.5-8%.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





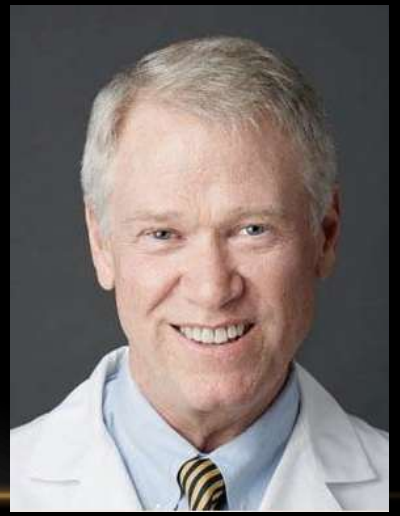
G-49 (Former G-74) Does the use of laminar flow in the operating room reduce the risk of subsequent SSI/PJI in patients undergoing orthopedic procedures?

RESEARCHED BY:


Arash Aalireazaie


Everth Merida


Kelly Vince


Greg Stocks

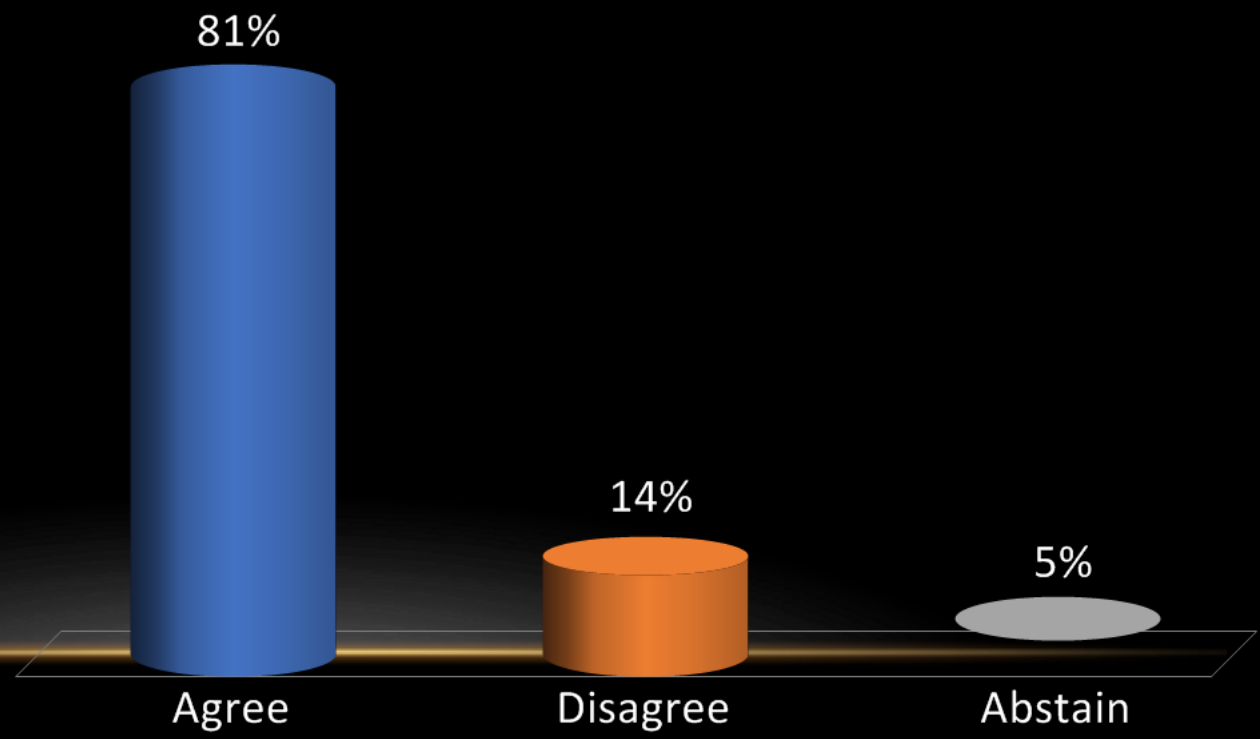
Literature:

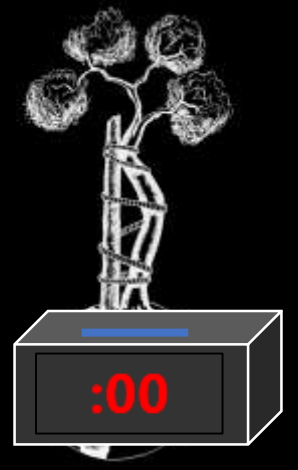
- Meta-analysis 0, Prospective/Randomized 1, Retrospective 20
- Early studies suggested LAF was effective in reducing SSI/PJI
- 6 retrospective studies found no difference in rate of SSI/PJI with use of LAF
- 3 recent studies linked use of LAF to increase in rate of SSI/PJI

Recommendation: Recent orthopedic literature has not demonstrated that the use of laminar flow systems (LAF) reduces surgical site infection (SSI) or periprosthetic joint infection (PJI) in orthopedic surgery. At this time, is not necessary to perform a clean orthopedic surgery procedure, including elective joint replacement surgery, in an operating theatre equipped with LAF systems.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





G-117 (Former G-77) Does the use of surgical drains increase the risk of subsequent SSI/PJI?

RESEARCHED BY:

Gregory Deirmengian, MD

Snir Heller, MD

Kier Blevins, MD

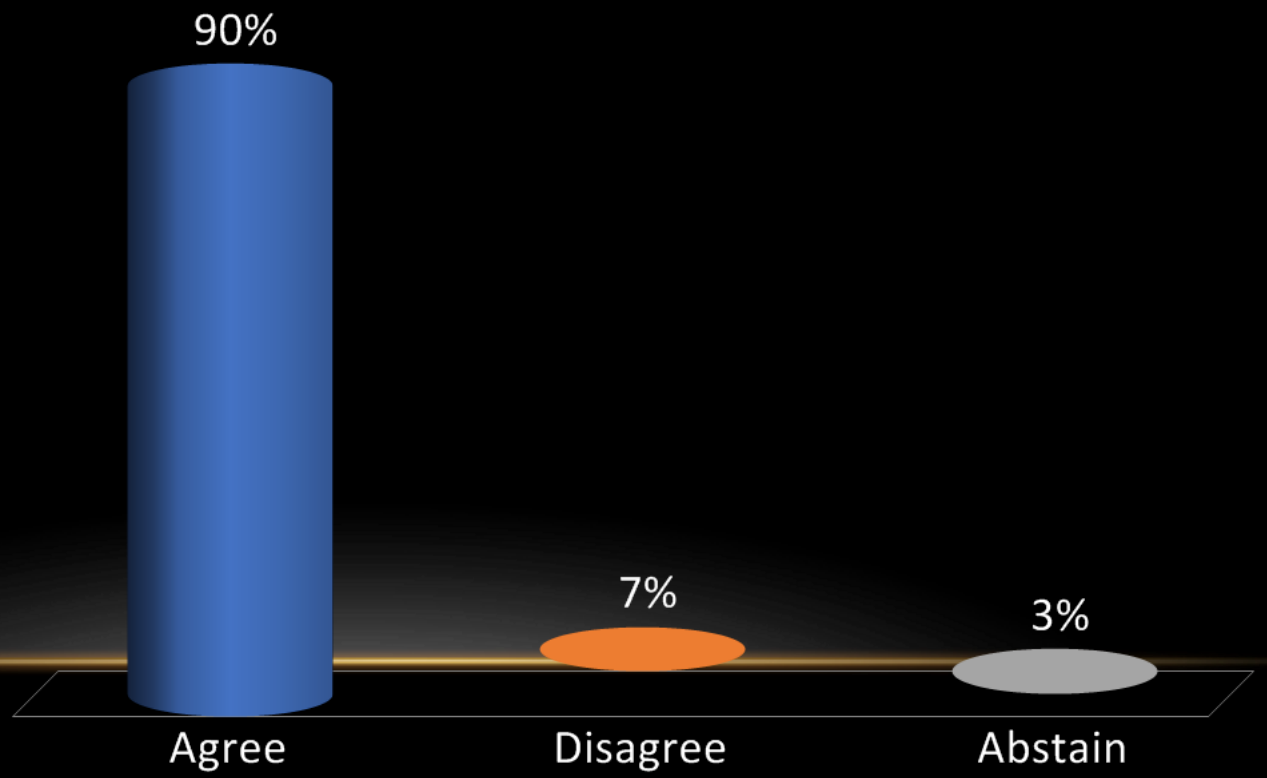
Literature:

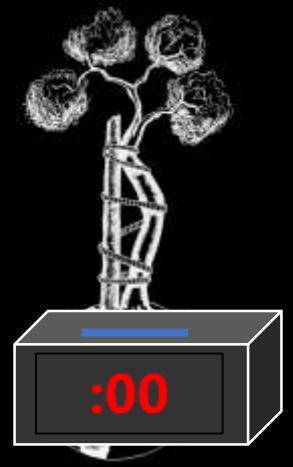
- **Meta-analysis 0, Prospective/Randomized 0, Retrospective 14**
- **Several studies demonstrate no difference in the infection rate with the use of drains.**
- **Several studies reveal in increased rate of blood transfusions in patients with drains**

Recommendation: There is no direct evidence to suggest that the use of surgical drains (for < 48 hours) leads to an increase in the rate of subsequent SSI/PJI. The use of surgical drains lead to a higher volume of blood loss and an increased need for allogeneic blood transfusion, which may indirectly increase the rate of SSI/PJI.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





HK-12 (former HK-83): Is there sufficient evidence to support the use of antibiotic-loaded cement in primary TKA or THA to reduce the risk of SSI/PJI?

RESEARCHED BY:

Yale Fillingham, MD

Sergei Oshkukov, MD

Ali Parsa, MD

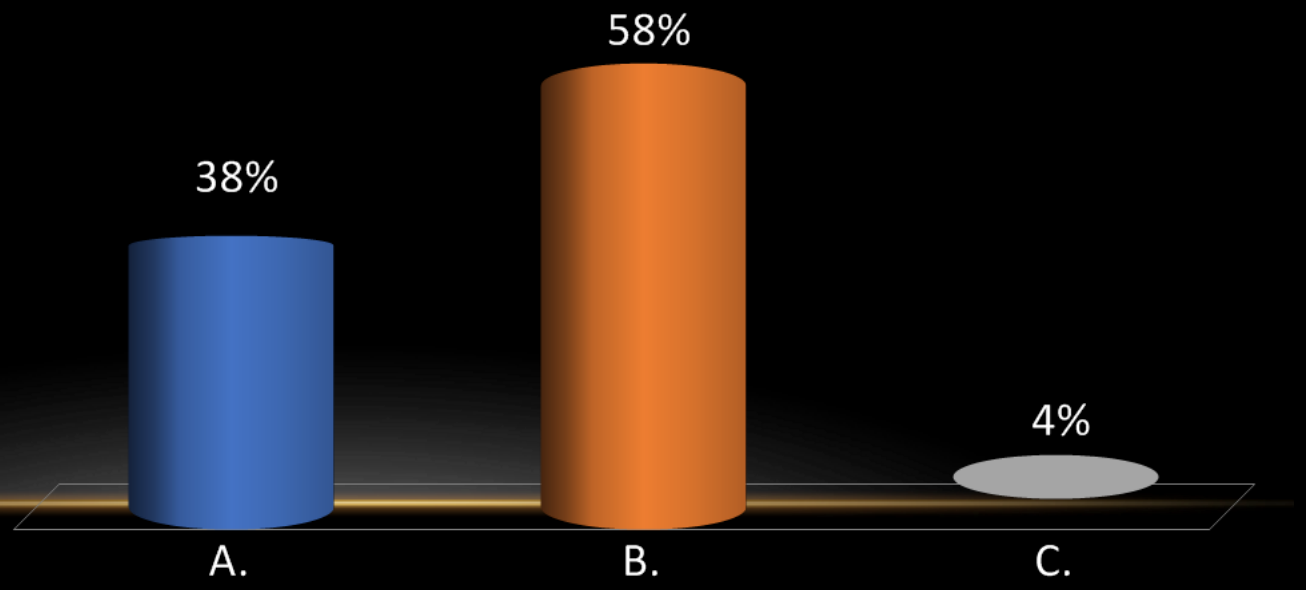
Literature:

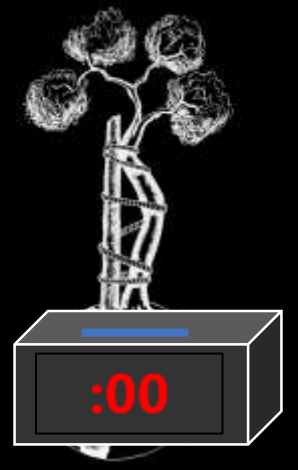
- Meta-analysis 1, Prospective/Randomized 0, Retrospective 26
- A number of retrospective studies have correlated use of antibiotic-loaded cement with lower rates of wound infection and failure in THA and TKA, whereas others show no difference
- No evidence exists demonstrating that use of antibiotic-loaded cement reduces incident of SSI/PJI in primary hip or knee arthroplasty

Recommendation: There is no conclusive evidence to demonstrate that routine use of antibiotic-loaded cement in primary TKA or THA reduces the risk of subsequent SSI/PJI. Recent high level evidence and registry data has not demonstrated a reduction in SSI/PJI. Furthermore, the added cost, the potential for emergence of resistant organisms, and the potential adverse effect of antibiotics on the host provide adequate reasons to refrain from routine use of antibiotic loaded cement during primary total joint arthroplasty.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





ICM 2018

- Class 1: Clinically important, high evidence
- Class 2: Clinically important, low evidence
- Class 3: Clinically less important, high evidence
- Class 4: Clinically less important, low evidence

HK-29 (former HK-22) Does changing the drapes during debridement, antibiotics, and implant retention affect the rate of success?

RESEARCHED BY:

Plamen Kinov MD,
Bulgaria

Akos Zahar MD,
Germany

Thorsten Gehrke MD,
Germany

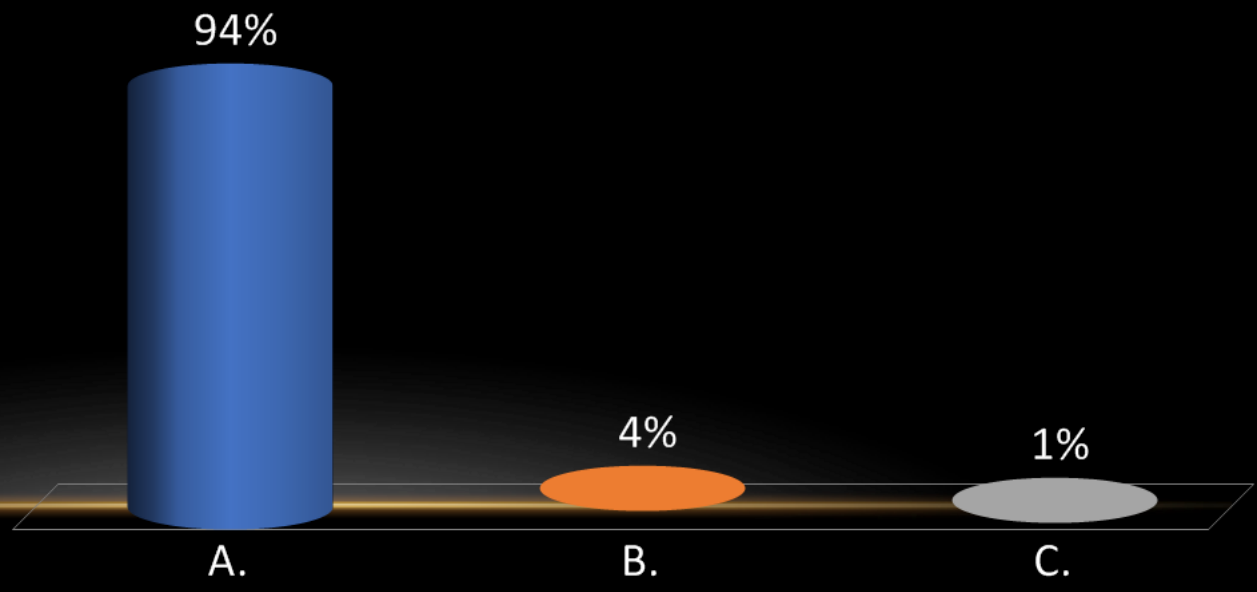
Literature:

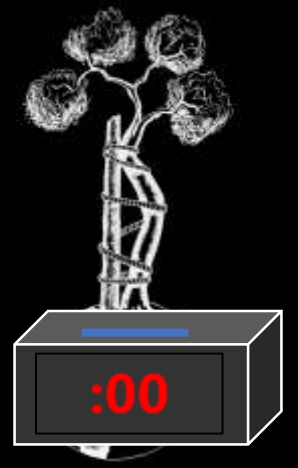
- There are no studies that assess the impact of changing the drapes during DAIR.
- After a literature review of 51 papers, only one study was identified that indirectly mentioned the use of clean draping during the surgical procedure.
- Changing the drapes during DAIR can be performed at the surgeon’s discretion.

Recommendation: The impact and effectiveness of changing the drapes during debridement, antibiotics, and implant retention (DAIR) has not been investigated and therefore it can be performed at the surgeon's discretion.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





G-35 (Former G-48) Does the number of individuals in the operating room affect the rate of SSI/PJI? If so, what strategies should be implemented to reduce traffic in the operating room?

RESEARCHED BY:

Eleftherios Tsiridis

Daniel Del Gaizo

Literature:

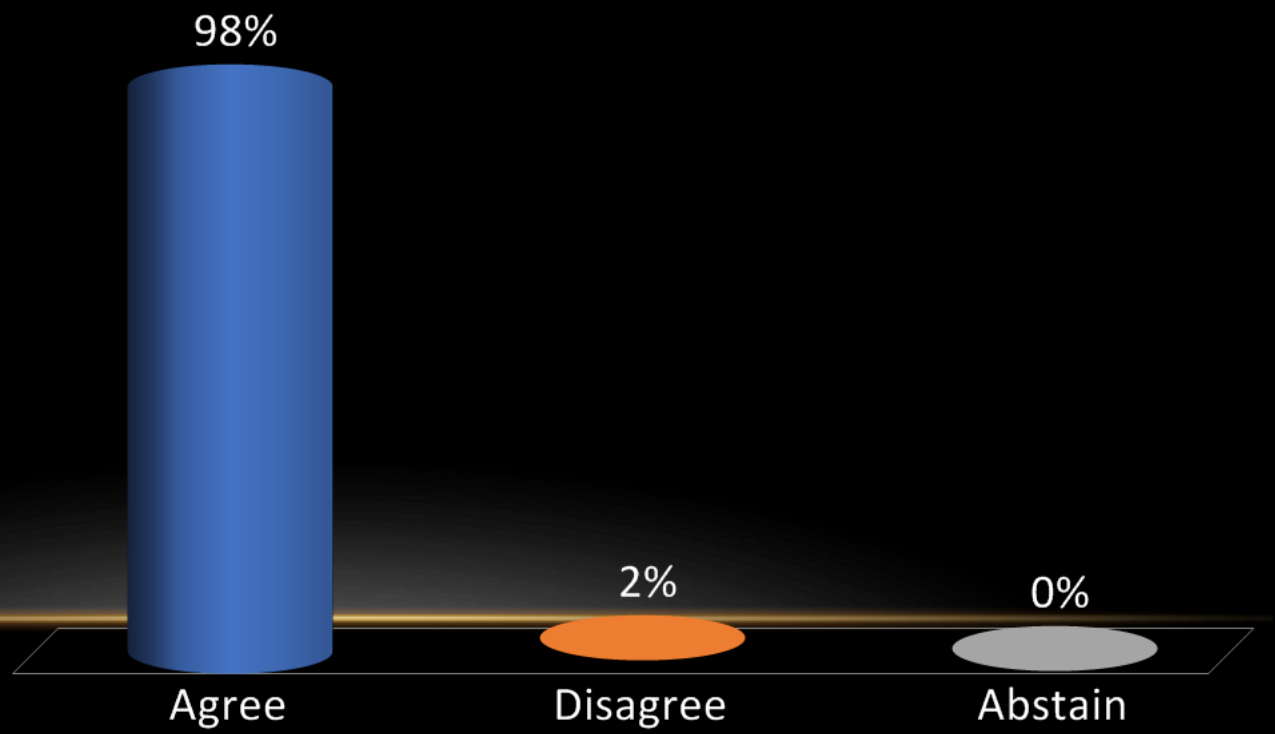
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 29

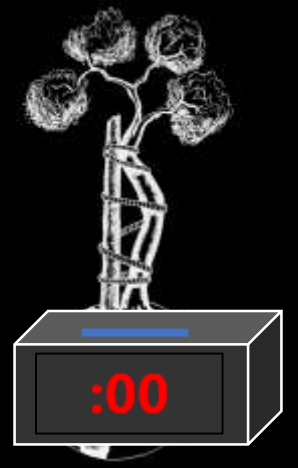
- Multiple studies show an increased trend in PJI associated with high OR traffic and increased rate of door opening.
-
- Systemic and behavioural measures in the OR have been shown to significantly reduce the incidence of superficial PJI and a non-significant decrease in the deep PJI.

Recommendation: Yes. The number of individuals in the operating room (OR) and door openings (DO) during total joint arthroplasty (TJA) are correlated to the number of airborne particles in the OR. Elevated airborne particles in the OR can predispose to subsequent periprosthetic joint infection (PJI). Therefore, operating room traffic should be kept to a minimum. Multiple strategies, outlined below, should be implemented to reduce traffic in the OR during orthopaedic procedures.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





G-53 (Former G-2) Are light handles a source of contamination during orthopedic procedures?

RESEARCHED BY:

Daniel Schweitzer Peteris Studers Darko Talevski Elie Ghanem

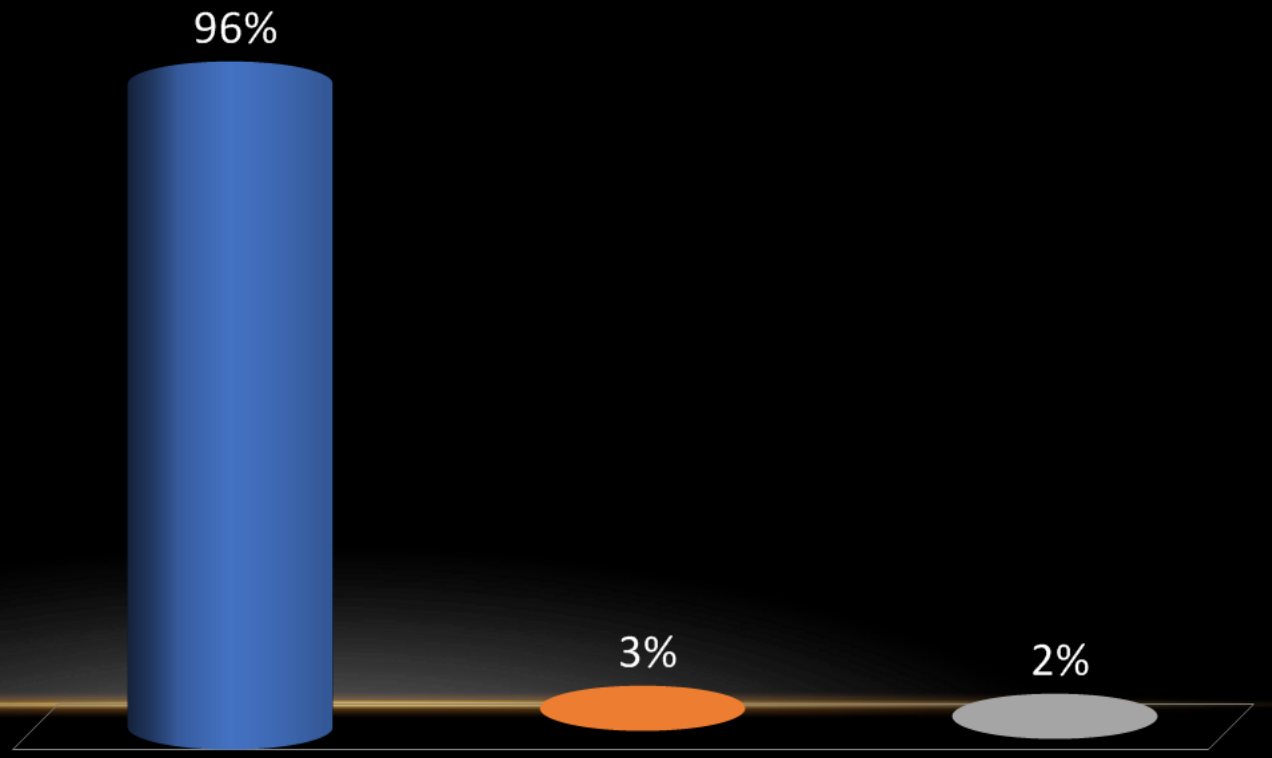
Literature:

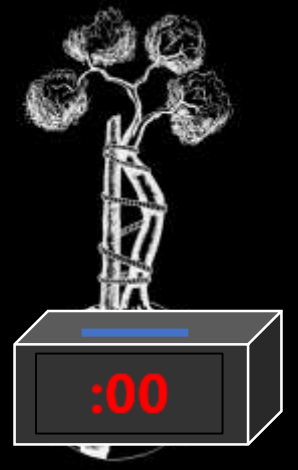
- Meta-analysis 1, Prospective/Randomized 7, Retrospective 0
- Strong evidence demonstrating that light handles are source of contamination
- No evidence linking contamination of light handles to increased incidence of PJI

Recommendation: Yes. Light handles are a possible source of contamination during orthopaedic procedures.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





HK-18 (former HK-47) - Does the use of personal protection suits (space suits) influence the rate of SSI/PJI in patients undergoing joint arthroplasty?

RESEARCHED BY:

Mark Spangehl MD,
USA

Xianlong Zhang MD,
China

Literature:

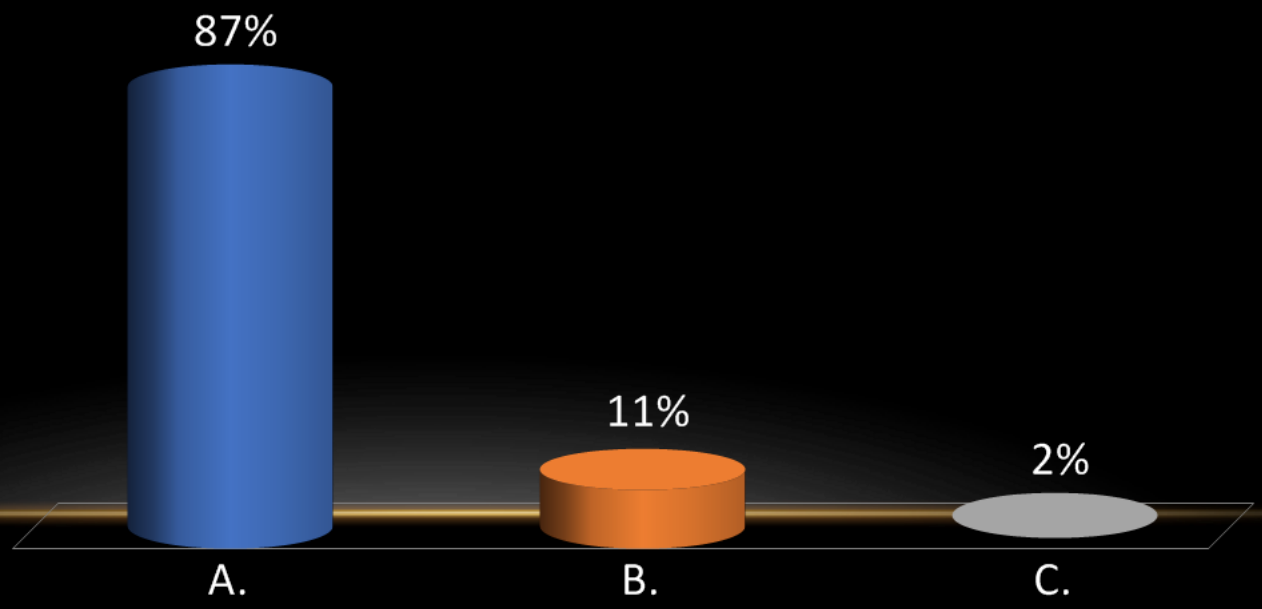
- Meta-analysis 1, Prospective/Randomized 3, Retrospective 17

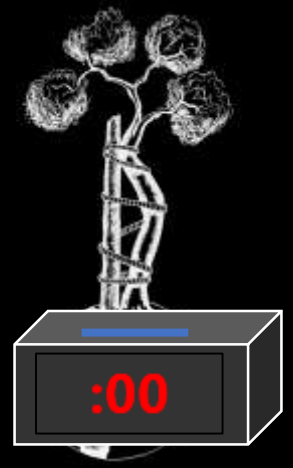
- Meta-analysis of body exhaust suits (Blomgren et al.)
  - Body exhaust suits were associated with a significant reduction in deep infection rates (RR 0.11, 95% CI 0.09-0.46)

Recommendation: In the absence of strong evidence, we believe the use of personal protection suits (space suits) does not reduce the rate of subsequent SSI / PJI in patients undergoing joint arthroplasty.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





HK-23 (former HK-36) Does the surgical approach of primary THA affect the incidence of subsequent SSI/PJI?

RESEARCHED BY:

Eleftherios Tsiridis MD, Greece

Stefano Bini MD, USA

Majd Tarabichi MD, USA

Literature:

- **Meta-analysis 8, Randomised/Prospective 3, Retrospective 13**

- One RCT: No SSI/PJI in standard PL approach, 1 SSI and 1 PJI in MIS group
  - All studies underpowered to associate relationship between approach and SSI/PJI

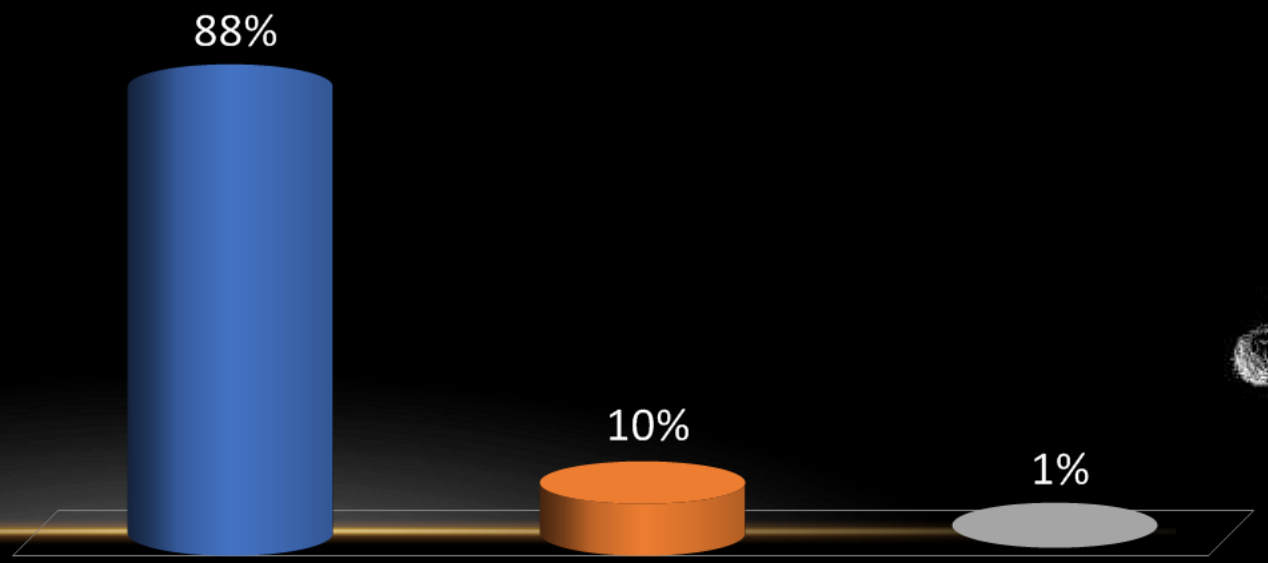
- 2 of the 8 meta-analyses specifically examined THA approach and infection:
  - PL has lowest risk for overall complications, incl. infection
  - PJI rate of 0.2/100-person-years for DA and 0.4/100-person-years for PL (RR=0.55, p=0.002)

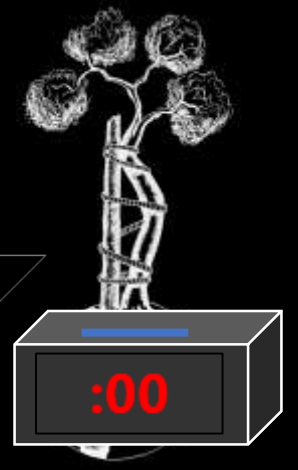
- Registry data: contradictory findings or no association found

Recommendation: The surgical approach in primary THA does not affect the incidence of subsequent SSI/PJI.

Level of Evidence: Strong

A. Agree
B. Disagree
C. Abstain





HK-100 (former HK-76) Is there a role for intraoperative autoclaving and re-use of an infected prosthesis as a spacer during resection arthroplasty?

RESEARCHED BY:

Samuel Wellman MD, USA

Biagio Moretti MD, Italy

Lluís Font-Vizcarra MD, Spain

Andrew Battenberg MD, USA

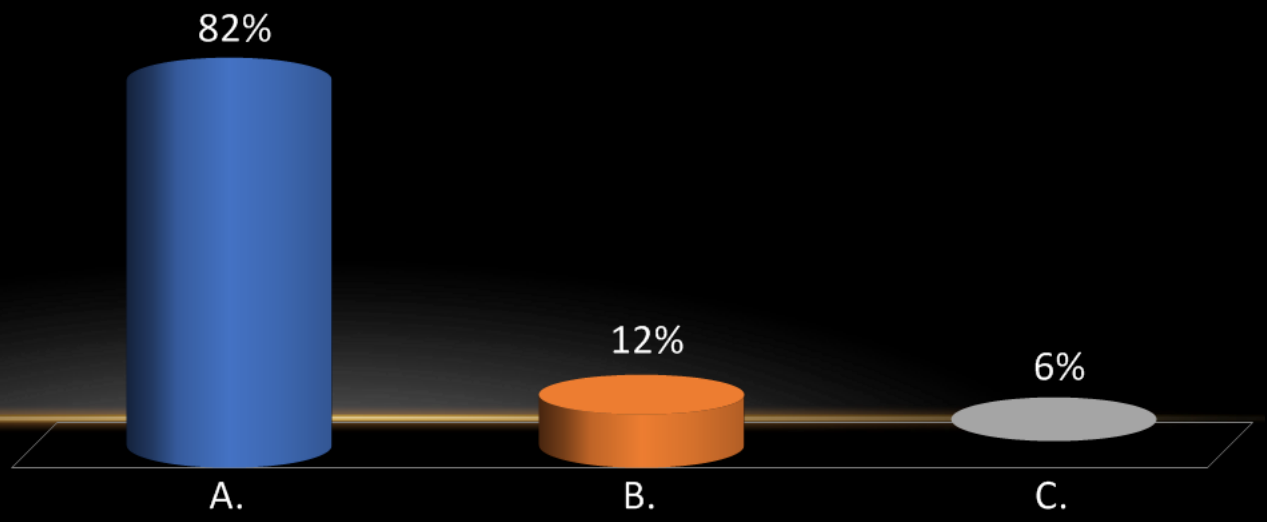
Literature:

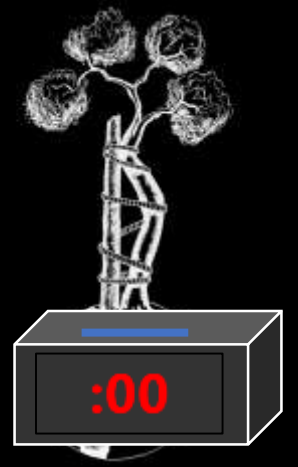
- **Meta-analysis 0, Prospective/Randomized 0, Retrospective 16**
- Hofmann et al. reported 44/50 patients (88%) with an autoclaved femoral component as a spacer had successful reimplantation and were infection free at latest follow-up
  - Lee et al reported 19/20 patients successfully treated in a similar study
- Only one study discussed the use of autoclaved hip components, and while they reported excellent results in 31/32 patients, information on autoclave protocol and other details were lacking

Recommendation: Multiple studies have demonstrated that the re-use of autoclaved prosthetic components, during knee resection arthroplasty, did not compromise the eradication of an established infection. Though a viable option, there are potential legal implications associated with the re-use of autoclaved components and a proper standard for autoclaving of these components is also not known. Re-use of autoclaved components in resection arthroplasty, particularly for the knee, may be suitable in scenarios when proper dynamic spacer components are not available or for economic considerations.

Level of Evidence: Moderate

A. Agree
B. Disagree
C. Abstain





ICM 2018

- Class 1: Clinically important, high evidence
- Class 2: Clinically important, low evidence
- Class 3: Clinically less important, high evidence
- Class 4: Clinically less important, low evidence

G-26 (Former G-16) Does a patient with a colostomy have an increased risk for SSI/PJI?

RESEARCHED BY:

Marcelo Lizarraga Ferrand

Georgios Komnos

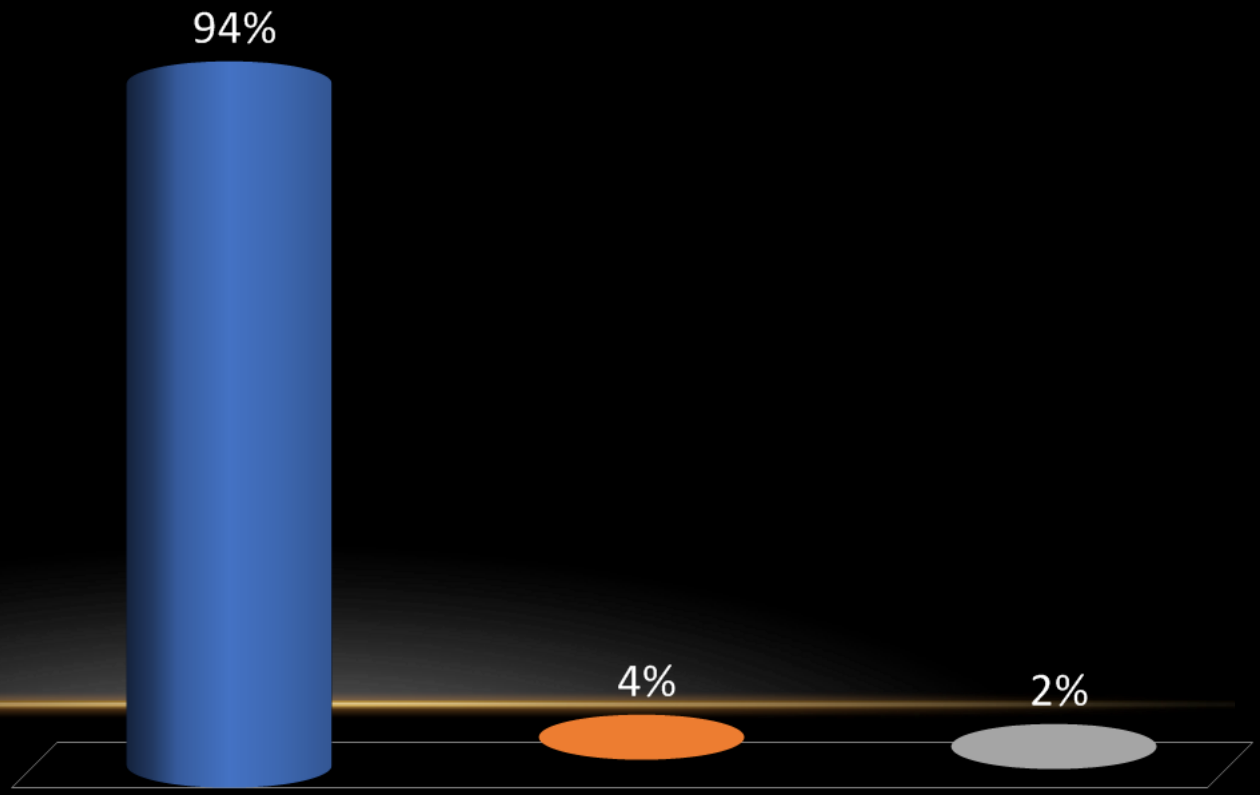
Literature:

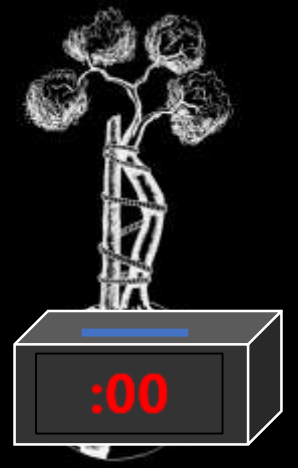
- Meta-analysis 2, Prospective/Randomized 0, Retrospective 12
- There is minimal evidence to suggest that a prior arthroscopy of the hip increases the risk of subsequent surgical site/prosthetic joint infection.
- Majority of studies underpowered

Recommendation: There is currently no evidence in the literature to determine if a patient with colostomy is at an increased risk for SSI/PJI following an arthroplasty procedure. It is however our recommendation to ensure that the patient has a leak free and clean colostomy in place to prevent soiling.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-37 (Former G-119) Should surgeons and personnel in the OR wear a mask and a cap in the operating room?

RESEARCHED BY:

Kevin Tetsworth

Rajendra Shetty

Literature:

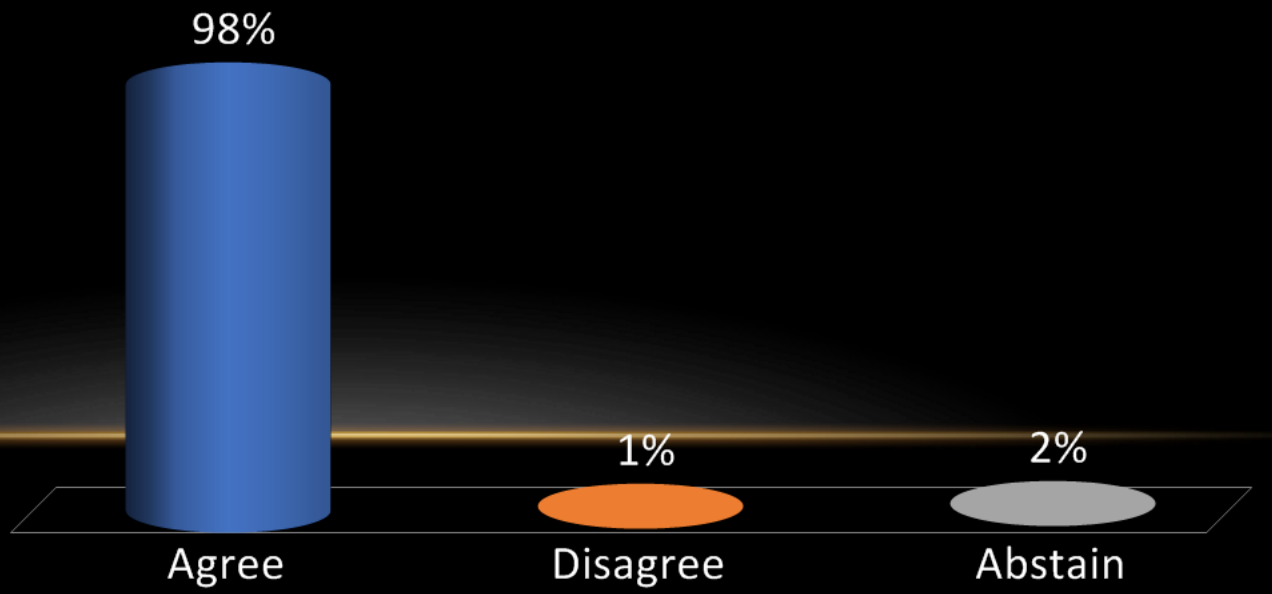
- Meta-analysis/Systematic review 2, Prospective/Randomized 0, Retrospective 12

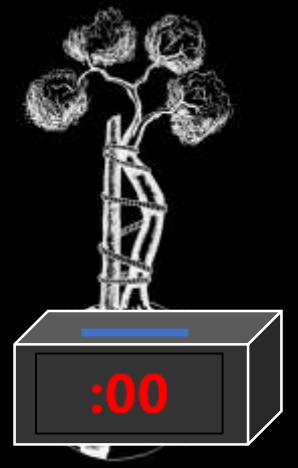
- Multiple systematic reviews found that the evidence regarding the efficacy of surgical facemasks in preventing postoperative wound infection is inconclusive

Recommendation: Yes. The use of surgical facemasks and caps by staff in the operating room is presumed to reduce the frequency of surgical site infections. There is a paucity of data with few studies addressing this topic. The long-standing established standard of surgical facemasks and caps in the operating room should continue despite the lack of strong evidence demonstrating clinical efficacy and a lack of persuasive evidence for altering current clinical practice. Evidence for the potential role for surgical facemasks in protecting staff from infectious material encountered in the operating room is also controversial. In the absence of convincing clinical evidence either for or against wearing masks and caps in the OR, it is advisable at this time to continue to follow local or national health and safety regulations.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-38 (Former G-62) Does the type of cap worn by the OR personnel matter?

RESEARCHED BY:

Rajeev Sharma

Naasha Talati

Paul Manner

Kier Blevins

Literature:

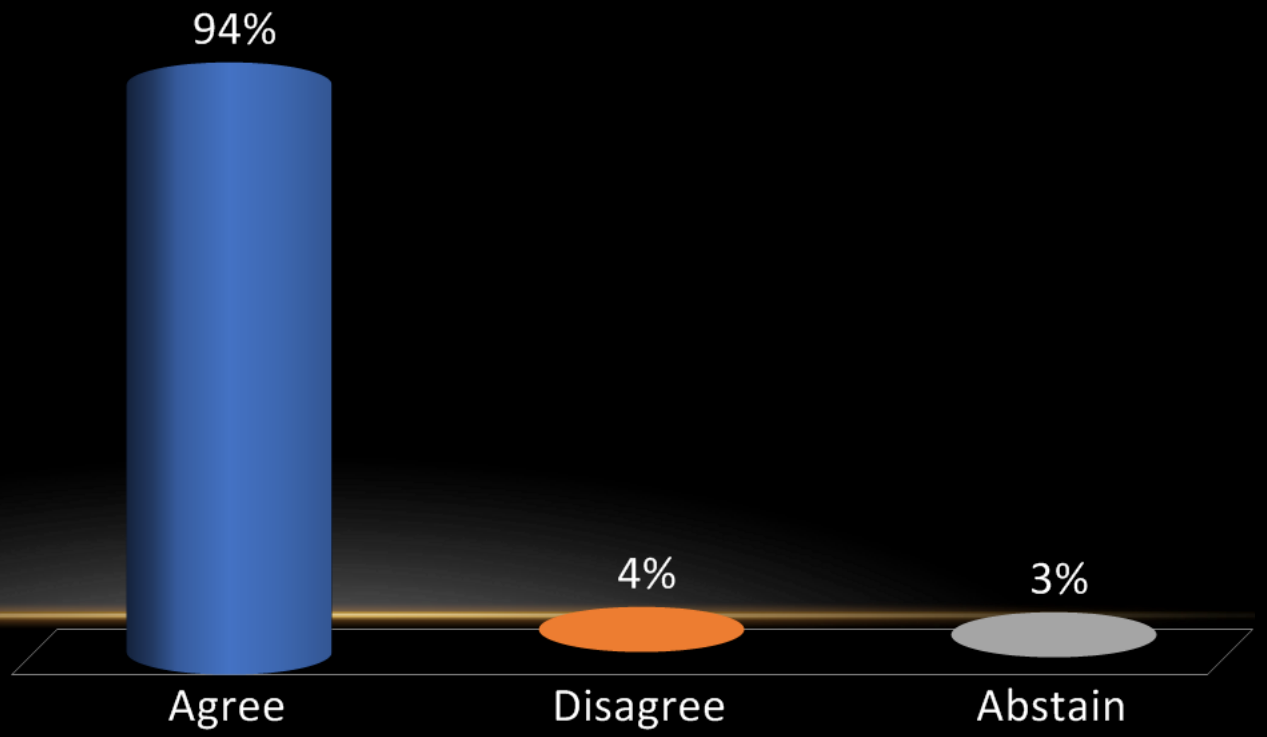
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 9
-
- Significantly higher number of airborne particulates are seen when disposable bouffant hats were used compared to cloth surgical caps ($p<0.05$) and a greater amount of microbial shedding at the sterile field compared to disposable skull caps ($p<0.05$).

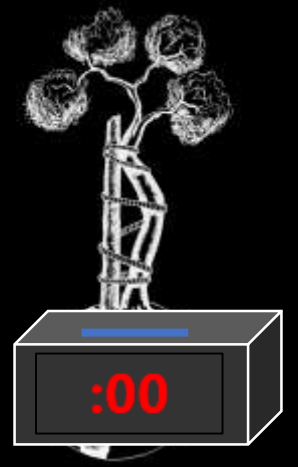
- A more recent study revealed that surgical site infection (SSI) rates were not significantly different ($p=0.016$) in surgical cases where attending surgeon's wore bouffant hats (8%) versus those who wore surgical skull caps (5%).

Recommendation: Unknown. The evidence would suggest that, since normal hygiene such as daily shampooing and showering does not result in bacterial decontamination of operating room (OR) personnel, some form of disposable head covering is prudent. Whether this takes the form of a bonnet, bouffant, or helmet is unknown. We recommend that the cap should cover the entire scalp, ears, and facial hair.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-42 (Former G-43) Does strict adherence to not wearing OR attire outside the hospital or outside the restricted OR area reduce the risk of SSI/PJI?

RESEARCHED BY:

Kier Blevins

Annette W-Dahl

Parag Sancheti

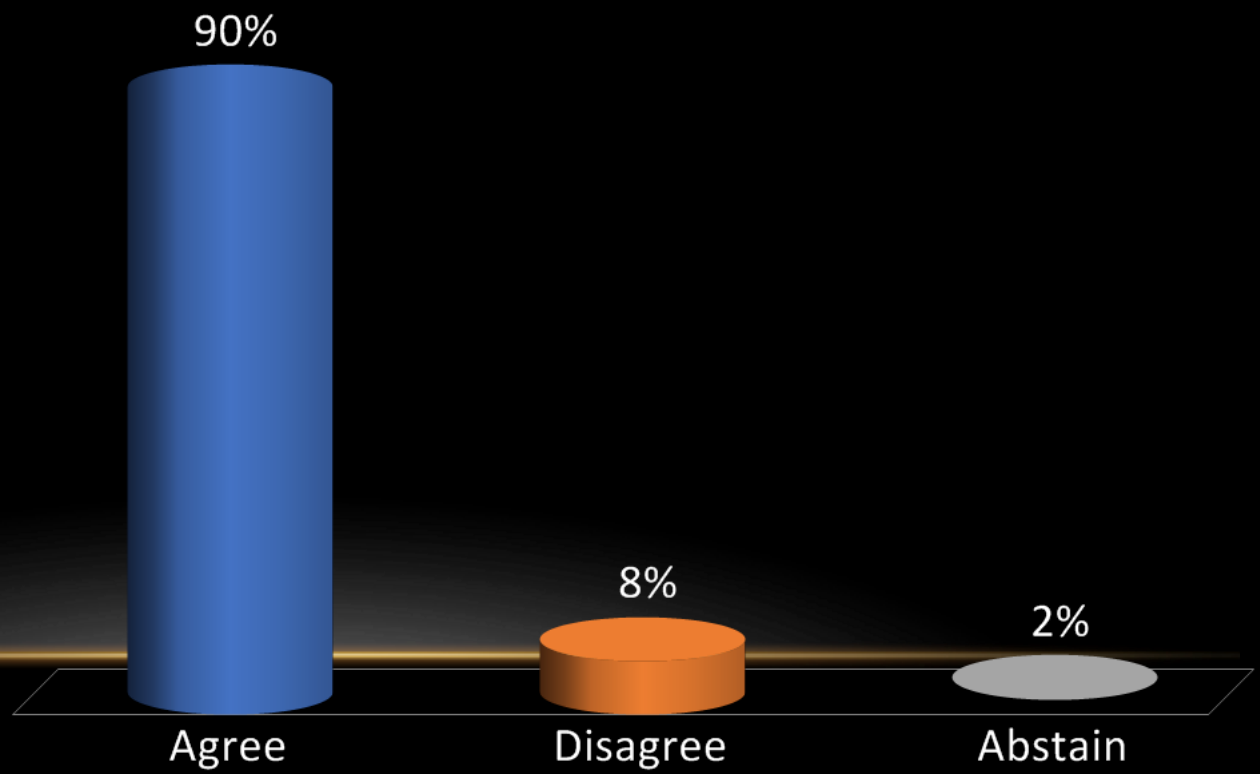
Literature:

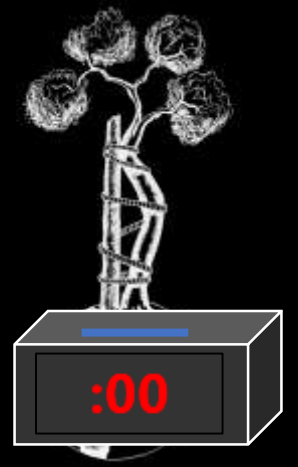
- Meta-analysis 1, Prospective/Randomized 5, Retrospective 0
- Limited evidence to suggest that wearing of OR attire outside of hospital increases clothing contamination
- No studies evaluating if OR attire worn outside of OR or hospital has an impact of SSI/PJI

Recommendation: We recommend that OR personnel wearing attire that has come into contact with outside the restricted OR environment, do not wear the same attire during elective arthroplasty or complex orthopedic procedures.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





G-59 (Former G-28) Does changing the electrocautery tip during surgery reduce the rate of subsequent SSI/PJI?

RESEARCHED BY:

Michael J Petrie Rob Nelissen Anil Gambhir

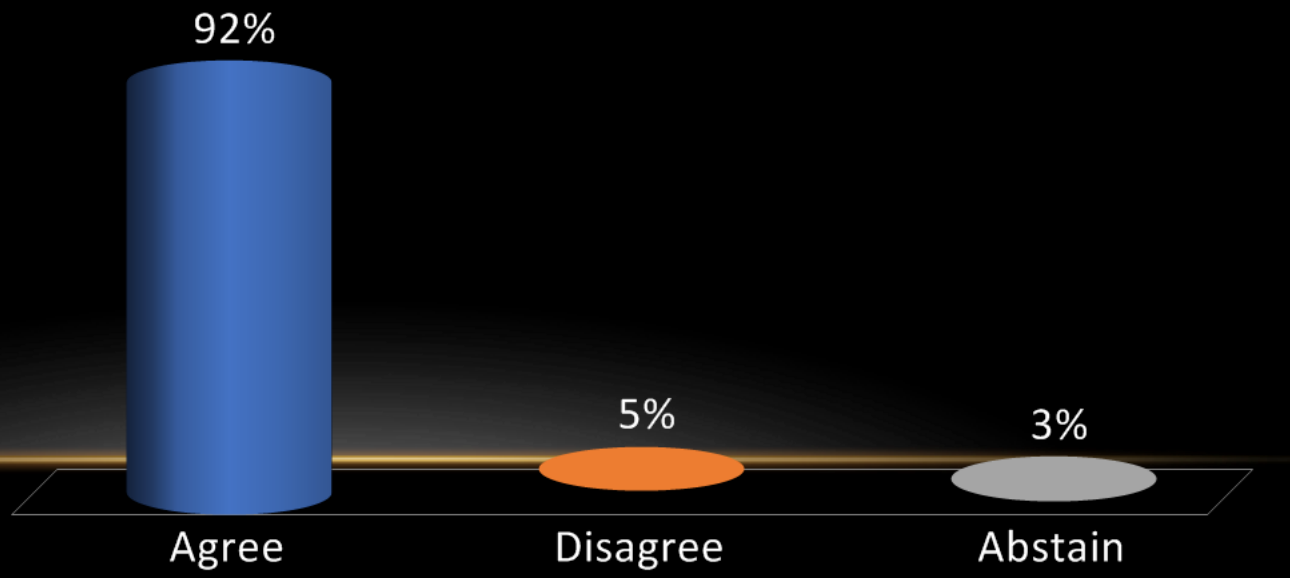
Literature:

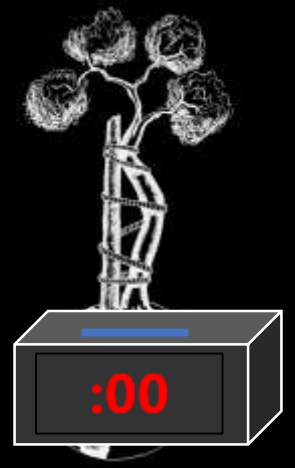
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 10
- No current evidence exists directly linking time of use of electrocautery tip to increased contamination levels or incidence of SSI/PJI
- Higher incidence of electrocautery tip contamination noted in setting of known infection

Recommendation: While it is clear that electrocautery tips may become contaminated during surgery, no study has been able to prove a relationship between the amount of time that an electrocautery tip is exposed and its contamination. However, in cases where there is known infection, such as a 1-stage or 2-stage exchange arthroplasty for PJI, we do recommend changing the electrocautery tip at the end of the "dirty" portion of the procedure and prior to reimplantation of components.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain



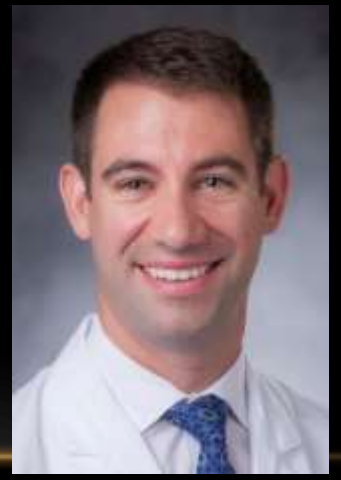


G-80 (Former G-52) Does the presence of other implants from prior surgery in the affected joint alter the perioperative antibiotic prophylaxis?

RESEARCHED BY:

Jose Cordero-Ampuero

Stephen Kates



Mitchell Klement

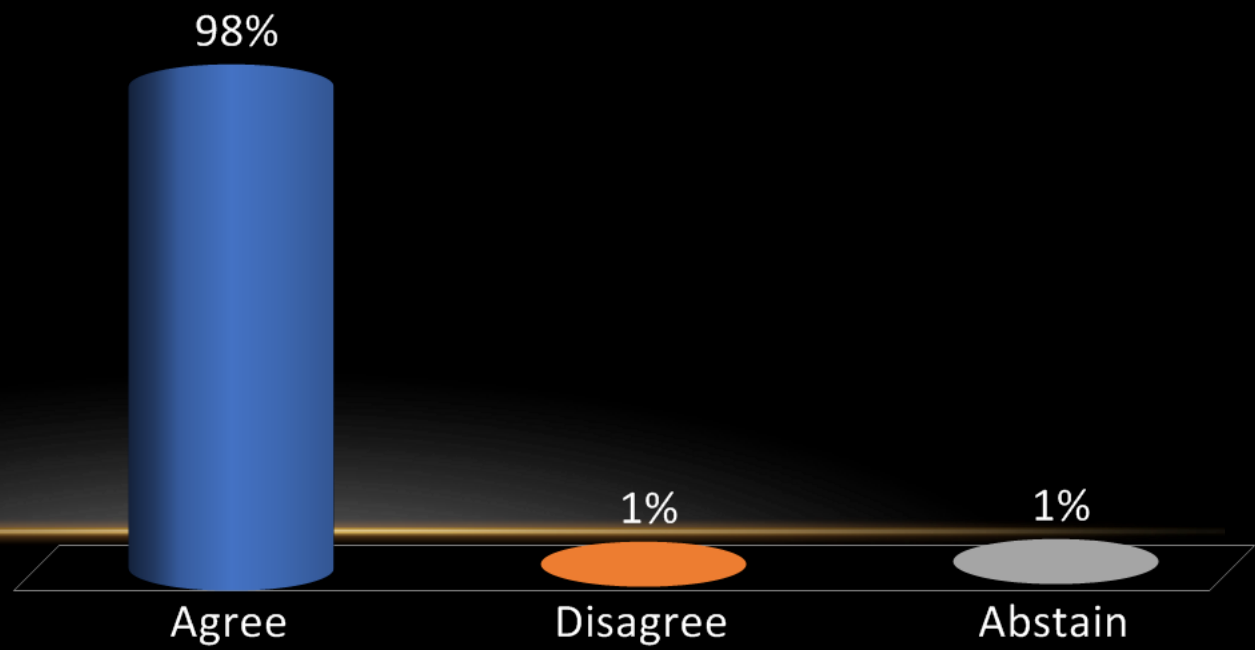
Literature:

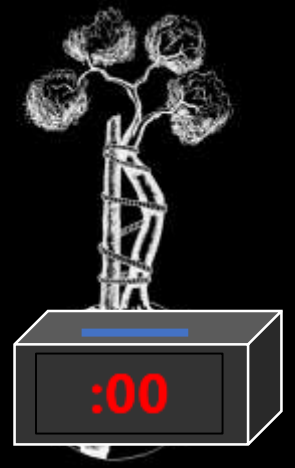
- Meta-analysis 1, Prospective/Randomized 0, Retrospective 15
- Conversion THA and TKA have complication rates closer to revision TJA than primary TJA, including increased SSI and PJI
- It is unclear whether prior hardware, host factors or extended operative duration required for conversion are responsible for increased complications rate

Recommendation: There is currently no evidence to suggest the use of alternate or additional perioperative antibiotics in joint surgery when prior implants exist from previous surgery. There is an increasing body of literature to suggest that conversion hip and knee arthroplasty carries a risk of SSI/PJI similar to revision surgery rather than primary surgery and altering antibiotics may be one method to mitigate this risk. However, studies will need to be conducted to either confirm or refute this statement given the lack of evidence.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





G-106 (Former G-123) What antiseptics can be used to prevent biofilm formation?

RESEARCHED BY:

Silvestre Ortega-Pena

Mark Smeltzer

Kenneth Urish

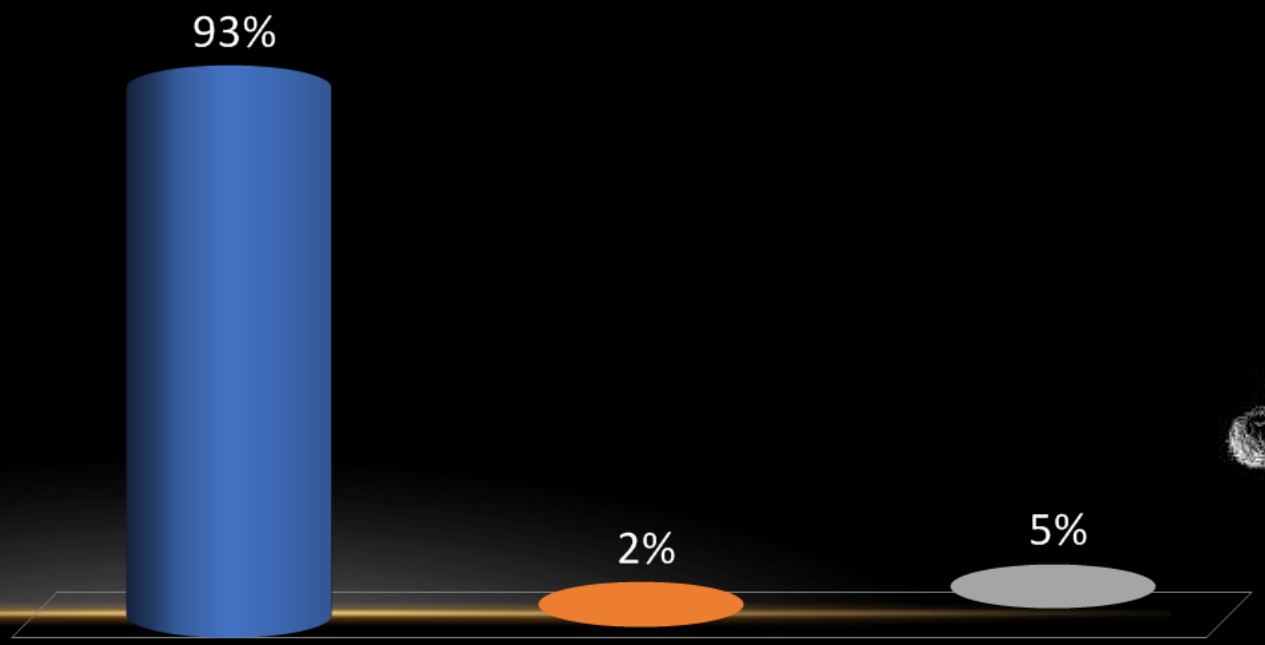
Literature:

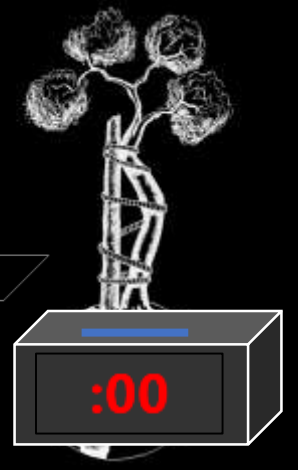
- Meta-analysis 0, Prospective/Randomized 1, Retrospective 5,
- There are minimal studies in orthopaedics and in-vivo regarding the use of antiseptic agents for biofilm formation.
- One randomized study for gingival biofilm formation
- Majortity of studies are in-vitro

Recommendation: Although several studies have demonstrated the ability of certain antiseptic agents to prevent biofilm formation in vitro, the ability of antiseptics to provide prevention of biofilm formation in vivo is uncertain. They may have utility in the context of revision surgery due to existing infection but this issue has not been adequately studied.

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





C 113 (Former C 13) Do patients need to refrain from getting the surgical incision wet or submerged in water to prevent SSI/PJI? If so, for how long postoperatively?

RESEARCHED BY:

Emmanuel Thienpont

Georgios Komnos

Jessica Jennings

Elvira Montañez

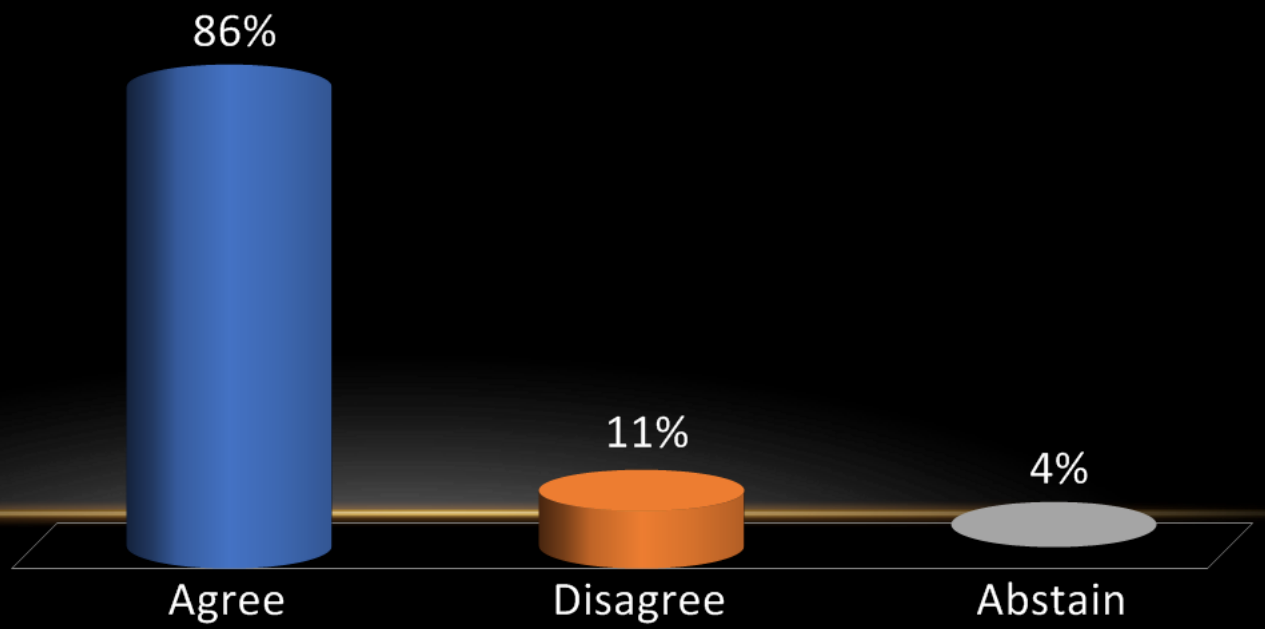
Literature:

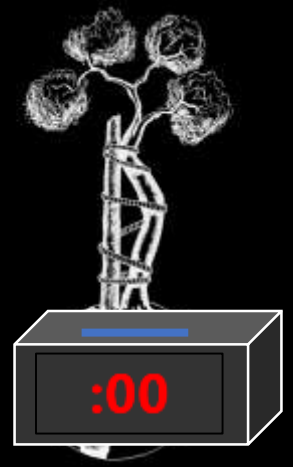
- Meta-analysis 1, Prospective/Randomized 4, Retrospective 17
- There are several studies in arthroplasty and outside orthopaedics that demonstrate no difference with early showering regarding infection rates.

Recommendation: Patients need to refrain from getting the surgical incision wet for the first 48 hours after surgery.However, with an occlusive dressing in place protecting the incision, the patients may shower during this period

Level of Evidence: Limited

A. Agree
B. Disagree
C. Abstain





G-125 (Former G-130) What is the definition of a sinus tract?

RESEARCHED BY:

Jeffrey Lange, MD

Jesse Otero, MD

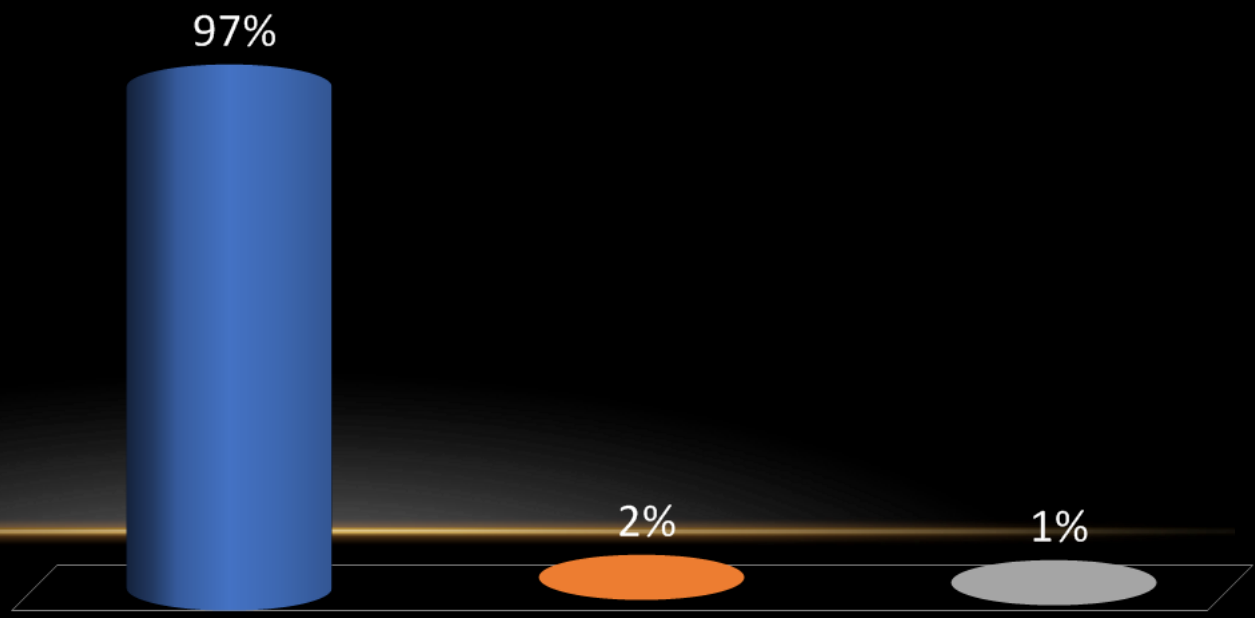
Literature:

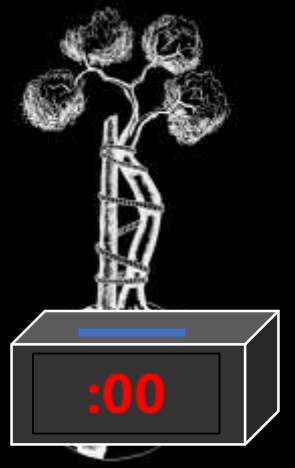
- **A sinus tract (latin: hollow, cavity) is an abnormal channel connecting a cavity lined with granulation tissue to an epithelial surface.**
- **Historically described by Edwin-Smith Papyrus, Hippocrates, Richard Wiseman**
- **Classifications made by Ger and Cierny-Mader**

Recommendation: A sinus tract has the following characteristics:
1) It is an abnormal channel through the soft tissues that allows communication between ajoint prosthesis and the outside environment, known or presumed to be colonized by bacteria.
2) Its presence may be confirmed with direct visualization of an underlying prosthesis,evidence of communication with fistulogram, ultrasound, computed tomography, or MRI.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





HK-33 (former HK-37) Does the type of bearing surface influence the incidence of SSI/PJI after total hip arthroplasty?

RESEARCHED BY:

Rihard Trebse MD,
Greece

Sumon Nandi MD,
USA

Literature:

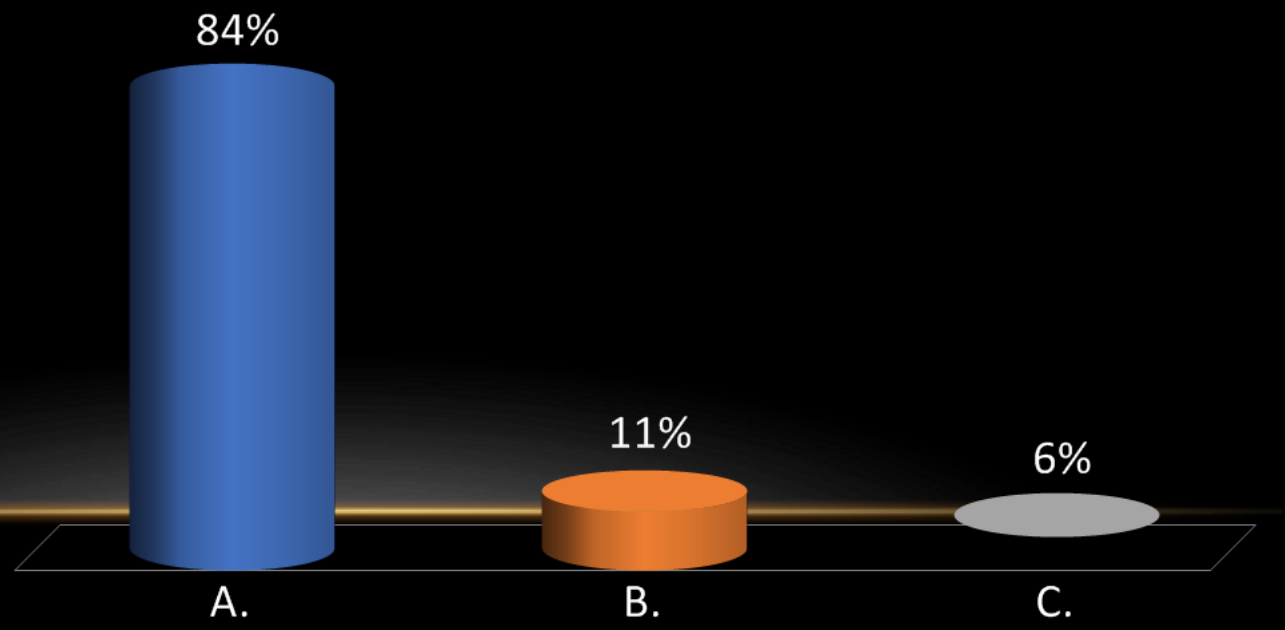
- **Meta-analysis 2, Prospective/Randomized 2, Retrospective 7**

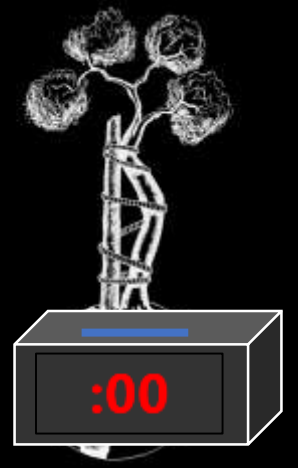
- **Moderate to strong evidence suggesting higher infection rate with metal on metal but no difference in infection rate between metal-on-polyethylene, ceramic-on-ceramic, and ceramic-on-polyethylene bearings.**

Recommendation: There is a higher incidence of periprosthetic joint infection (PJI) with metal-on-metal total hip arthroplasty; however, there is no difference in risk of PJI among other bearing surfaces.

Level of Evidence: Moderate to strong

A. Agree
B. Disagree
C. Abstain





HK-85 (former HK-132) What is the minimum necessary volume of irrigation solution to use in debridement, antibiotics, and implant retention treatment of acute PJI?

RESEARCHED BY:

Wayne G. Paprosky MD,
United States of America

Evan Schwechter MD, United States of America

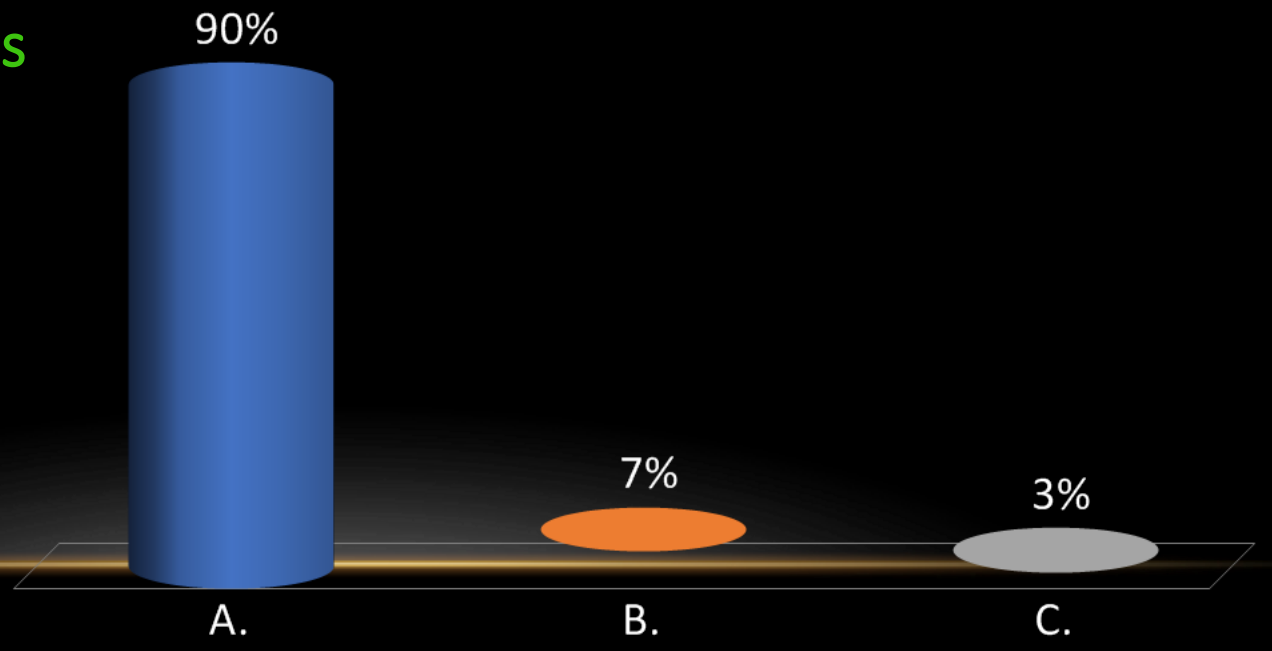
Literature:

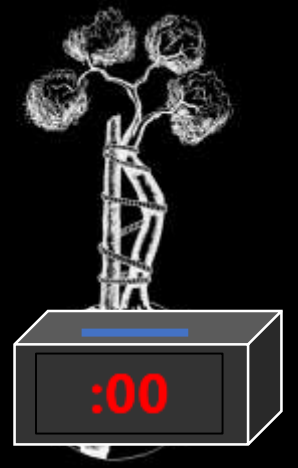
- **Meta-analysis 0, Prospective/Randomized 1, Retrospective 11**
- There are a small number of studies providing limited secondary data regarding the ideal volume of irrigation to be used during TJA
  - These studies either did not take biofilms into account or did not examine volume of irrigation solution as an endpoint
- Limited evidence available indicates the presence of staphylococcal infection, elevated ASA score, or purulence are more likely to determine failure than volume of irrigation.
- Delegates performed a comprehensive systematic review of the literature relating to open DAIR treatment of acute postoperative and hematogenous hip and/or knee PJI.
  - Typically 6 to 9L of solution were used during a single DAIR treatment, with twelve of the fourteen studies utilizing up to 9L or more of irrigation solution
- No studies currently exist directly linking the necessary volume of irrigation to use in debridement, antibiotics, and implant retention in acute PJI

Recommendation: We recommend that 6-9L of irrigation solution, including antiseptic solution such as dilute betadine, is used during debridement, antibiotics, and implant retention (DAIR) treatment of acute periprosthetic joint infection (PJI).

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





HK-120 (former HK-87):Should heterotopic ossification (HO) be removed during resection arthroplasty of an infected prosthetic joint?

RESEARCHED BY:

Konstantinos Malizos, MD Andrew Freiberg, MD Per Kjaersgaard-Anderson, MD

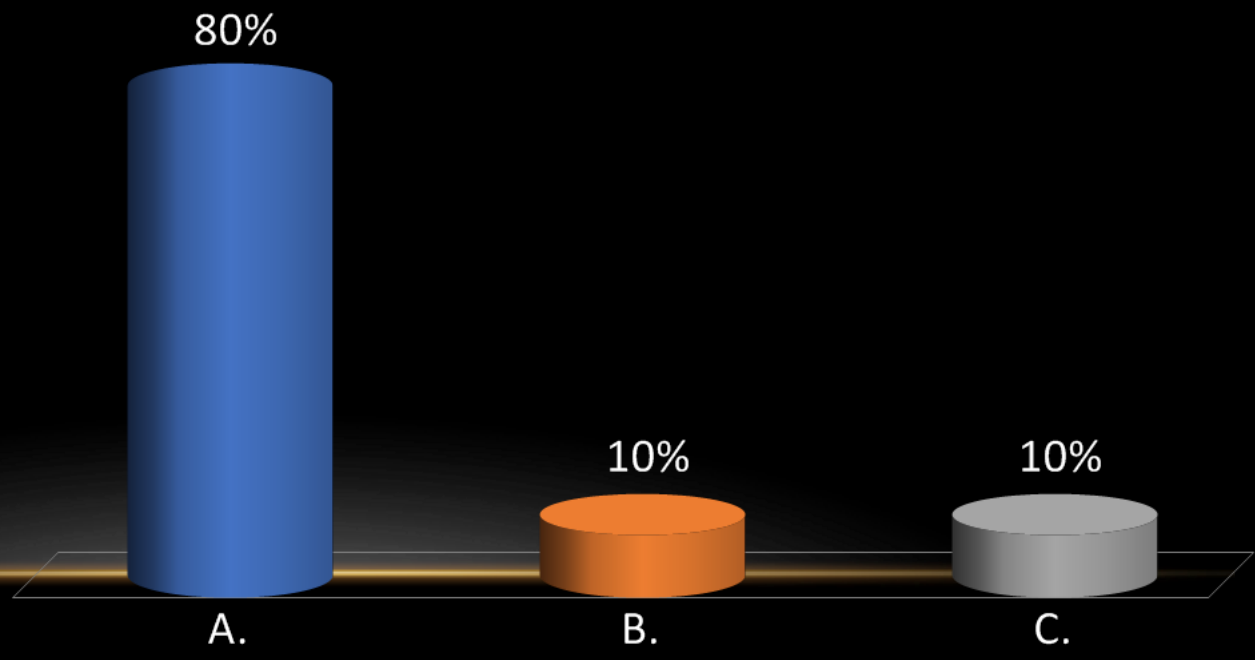
Literature:

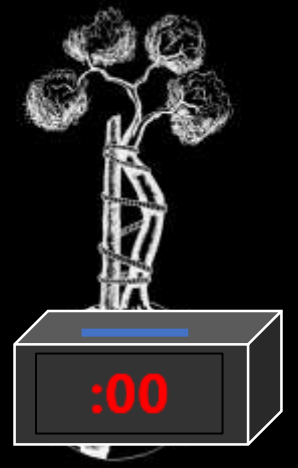
- Meta-analysis 0, Prospective/Randomized 0, Retrospective 0
- No studies evaluating HO excision during resection arthroplasty

Recommendation: We recommend that surgeons give a strong consideration to removal of accessible heterotopic ossification (HO) in an infected prosthetic joint that will not compromise future reconstruction.

Level of Evidence: Consensus

A. Agree
B. Disagree
C. Abstain





Step XIII

Dissemination of the Information

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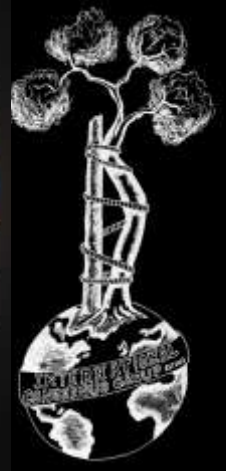


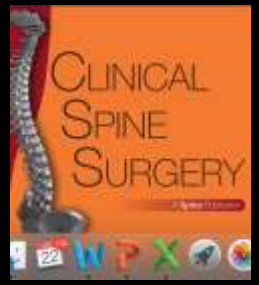
Step XIII

Dissemination of the Information

- J. of Shoulder and Elbow Surg

- Foot and Ankle Int.

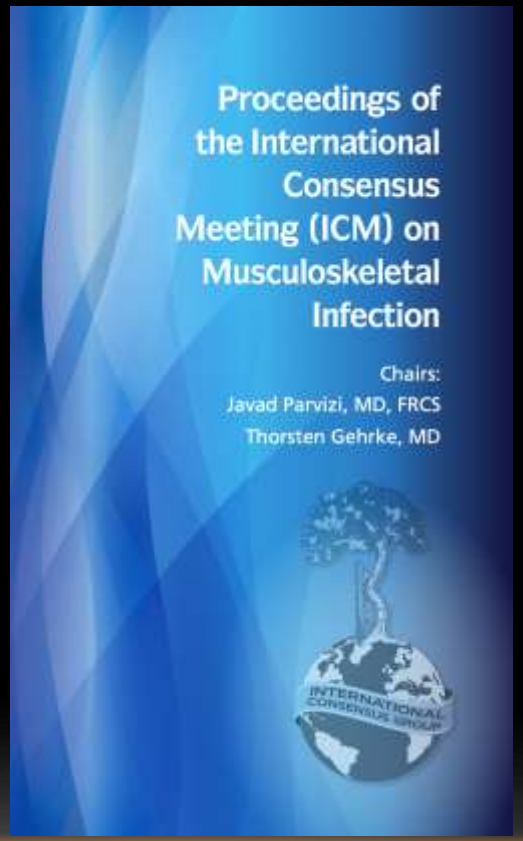
- Spine



- Trauma
- Sports

Step XIII

Dissemination of the Information

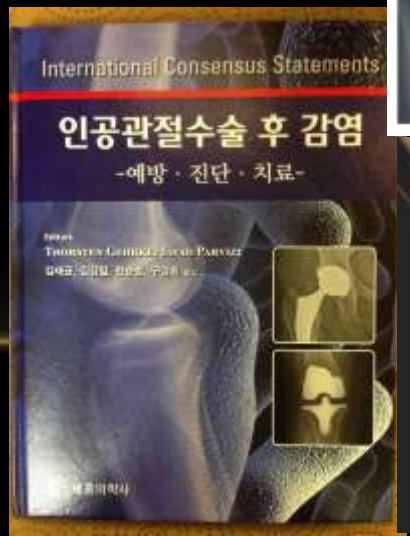


Step XIII

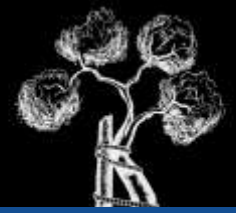
Dissemination of the Information

Translations

- Spanish
- Chinese
- Japanese
- Italian
- Korean
- Portuguese
- Russian
- Turkish
- Farsi
- Czech
- Indonesian
- German
- Polish
- Arabic
- Ukrainian
- French
- Greek
- Bulgarian
- Romanian
- Dutch/Africaans



Sreeram Penna MD



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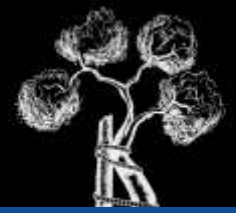

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