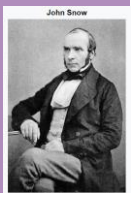
根拠に基づいた医療
Evidence based medicine

概要および
根拠がない場合はどうするか？
An introduction &
What if there is no evidence?

ジョンスノー：1854年にロンドンのソーホーで流行したコレラの原因を追跡した業績のため、現代疫学の父の一人とされている。

John Snow: one of the fathers of modern epidemiology, because of his work in tracing the source of a cholera outbreak in Soho, London, in 1854.



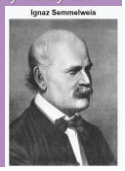
Ignaz Semmelweis：産科クリニックで手を消毒することで、「産褥熱」の発生を大幅に削減することができる。
この考えは医療界に拒否された

https://en.wikipedia.org/wiki/Ignaz_Semmelweis

Ignaz Semmelweis: "childbed fever" could be drastically cut by the use of hand disinfection in obstetrical clinics

Ideas rejected by medical community

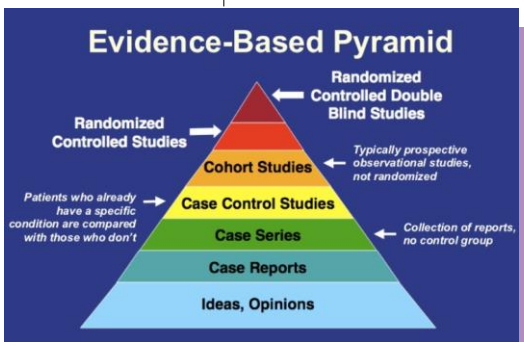
https://en.wikipedia.org/wiki/Ignaz_Semmelweis

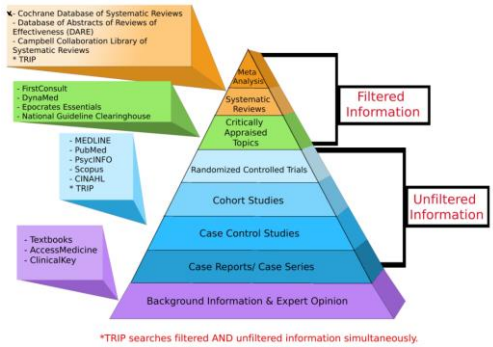


David Sackett：エビデンスベースドメディスンの父：理論から現場へ。最適な根拠を臨床の場で用いる概念を提示。公衆衛生に重点が置かれていた疫学統計を臨床診療と融合させた。

David Sackett: Father of evidence-based medicine: the concept of basing clinical care on best evidence, from theory to practice.
Merge of statistics of epidemiology, which was focused on public health, with clinical practice

https://www.medscape.com/viewarticle/844845





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根拠がない場合はどうするか？
There is no evidence – then what?

"Common praxis" – what is correct?
The answer varies given time and geography.
Are there myths in surgery?

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Learning goals:

Understand the pyramid of evidence
How to reason when there is no evidence
"It has not been proven method A is better then method B" – understand this is not evidence the methods are equally good.

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Absence of evidence is not evidence of absence

治療をする利点に対するエビデンス（根拠）がないからと言って、治療に効果がないという根拠にはならない。
If there is no evidence for benefit of a treatment, this is not evidence the treatment is without effect.

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Absence of evidence is not evidence of absence

手術前に動物を空腹にした方が良いという根拠はない
これは手術の直前に食べ物を与えて良いという根拠にはならない
No evidence of benefit of starving the animal before surgery
This is not evidence you can give food immediately before surgery

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You should:

Have a critical mind-set
Base your decisions on evidence
But if there is no evidence – can you use common sense?
批判的な考え方を持つ
根拠に基づいた判断をする
しかし証拠がない場合は、常識を使用できるか？

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Two treatments are compared
No difference: P>0.05

Are they "equally" good?

Most statistical tests are designed to find a difference
Test of equivalence is a special test

Routines

ルーチンワークは保証を与える
しかし、変更する-新しい方法を取り入れる-ことが難しい
Routines give security
But may be difficult to change – implement new methods

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Examples from surgery Wound healing and lasers…

Evidens for better wound healing by use of lasers? Review article: "Treatment of pressure ulcers: a systematic review."
http://jama.jamanetwork.com/article.aspx?articleid=183029

"No clear benefit was identified in 21 RCTs evaluating adjunctive therapies including electric current, ultrasound, light therapy, and vacuum therapy."

Wound healing…

The worlds first professor of wound healing, Professor Finn Gottrup, Denmark: usually rats are used in studies. Very good wound healing = bad model for wound healing in geriatric people (and probably our patients too).

Example: canine mammary tumor

Remove lymph node under 5th mammary gland?

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More examples: Hand hygiene

Wash hands, then alcohol, then gloves…?...

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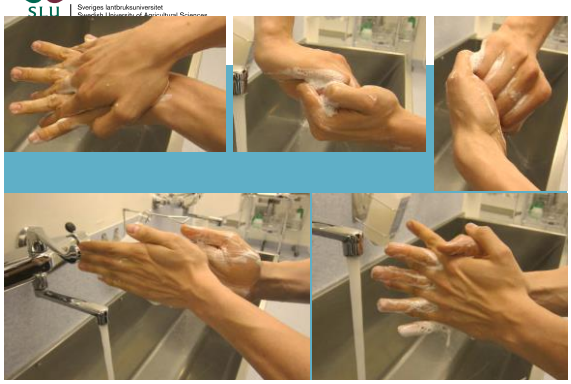

Hand hygien…

And then alcohol – is this necessary?

No proof this will lower the surgical site infection, SSI.

Can I then skip the alcohol?

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SSIのリスク要因 - 手術期間
Risk factors for SSI – duration of surgery

Veterinary Surgery
33:542–550, 2004

A Prospective Study of Postoperative Surgical Site Infections in Dogs and Cats

SIMONE EUGSTER, DrMedVet, PETER SCHAWALDER Prof DrMedVet, FRÉDÉRIC GASCHEN, PD, DrMedVet, Diplomate ECVIM-CA & ACVIM, and PATRICK BOERLIN, Prof DrMedVet

Animals— Dogs and cats that had surgery (1010 interventions) during 58 weeks from April 1999 to June 2000.

Results— Wounds with "infection/inflammation" occurred in 5.8% and "infected" wounds in 3% of patients. The outcome "infection" was associated with 3 major risk factors (duration of surgery, increasing number of persons in the operating room, dirty surgical site) and 1 protective factor (antimicrobial prophylaxis). The outcome "infection/inflammation" was associated with 6 significant factors (duration of anesthesia, duration of postoperative intensive care unit stay, wound drainage, increasing patient weight, dirty surgical site, and antimicrobial prophylaxis).

Conclusions— SSI frequency in companion animals is comparable with the frequency observed in human surgical patients. Several significant predictive factors for SSI in small animals surgery were identified.

Less bacteria on clean shoes… but SSI is not reduced

Can I then skip the clean shoes?

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Ned Tijdschr Geneeskd. 2011;155(18):A2954.

[Sterile gloves are not necessary in minor surgery].

[Article in Dutch]

Bruens ML, van den Berg PJ, Giard RW.

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Abstract

According to the practice guideline of the Dutch Workingparty on Infection Prevention (WIP) sterile gloves have to be worn during minor surgery by the general practitioner. This is based on the microbiological principles of Spaulding and is not supported by other evidence. Current literature suggests that using clean, nonsterile gloves, instead of sterile gloves, does not result in a greater risk of wound infection in primary closed wounds after minor surgery. Also, in daily practice, only 24% of general practitioners actually wear sterile gloves. We therefore propose to modify the guideline: using clean, nonsterile gloves during minor surgery is sufficient.

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Absence of evidence….

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Ned Tijdschr Geneeskd. 2011;155(18):A3341.

[Sterile gloves are necessary in minor surgery].

[Article in Dutch]

van den Broek PJ.

Leids Universitair Medisch Centrum, afd. Infectieziekten, Leiden, the Netherlands. p.j.van_den_broek@lumc.nl

Abstract

The use of sterile gloves as part of asepsis during surgery goes back to the end of the nineteenth century, but now the preventive value of this measure during minor surgery is questioned. One randomized study showed no difference in wound infection rates whether sterile or nonsterile gloves were used for repair of uncomplicated lacerations of the skin. An observational and a retrospective study in minor dermatological surgery confirm that the use of sterile or nonsterile gloves makes no difference for excisions of tumours as long as no reconstructions of the skin are performed. However, in more complicated minor dermatological surgery, 80% less wound infections were observed when sterile gloves were used. In conclusion, the available evidence is too limited to change the recommendation to use sterile gloves for minor surgery.

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Sterile Versus Nonsterile Gloves for Repair of Uncomplicated Lacerations in the Emergency Department: A Randomized Controlled Trial

Wound repair by the physician wearing gloves that were non-sterile (n=408) or sterile (n=408). SSI 4,4 vs 6,1 %

Perelman, Ann Emerg Med. 2004 Mar;43(3):362-70.

Comment: Evid Based Med 2004;9:182 doi:10.1136/ebm.9.6.182 , Therapeutics http://ebm.bmj.com/content/9/6/182.full

No equivalence….

- …comparable... – ”no clinically important difference”…

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Gloves in surgery

Common with holes in the gloves

- INDICATOR GLOVES = double, different color

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Cochrane Database Syst Rev. 2006 Jul 19;(3):CD003087.

Double gloving to reduce surgical cross-infection.

Tanner J, Parkinson H.

AUTHORS' CONCLUSIONS: There is no direct evidence that additional glove protection worn by the surgical team reduces surgical site infections in patients, however the review has insufficient power for this outcome.

The addition of a second pair of surgical gloves significantly reduces perforations to innermost gloves.

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Benefit of mask?

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ANZ J Surg. 2010 Mar;80(3):169-73.

Use of face masks by non-scrubbed operating room staff: a randomized controlled trial.

Webster J, Croger S, Lister C, Doidge M, Terry MJ, Jones J.

BACKGROUND: Ambiguity remains about the effectiveness of wearing surgical face masks. The purpose of this study was to assess the impact on surgical site infections (SSIs) when non-scrubbed operating room staff did not wear surgical face masks.

METHODS: Eight hundred twenty-seven participants undergoing elective or emergency obstetric, gynecological, general, orthopaedic, breast or urological surgery in an Australian tertiary hospital were enrolled. Complete follow-up data were available for 811 patients (98.1%). Operating room lists were randomly allocated to a 'Mask group' (all non-scrubbed staff wore a mask) or 'No Mask

RESULTS: Overall, 83 (10.2%) surgical site infections were recorded:

CONCLUSION: Surgical site infection rates did not increase when non-scrubbed operating room personnel did not wear a face mask.

Assume there is evidence
Do we follow recommendations?

Example: hand hygiene, doctors versus nurses

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Br J Anaesth. 2011 Oct;107(4):553-8. Epub 2011 Jun 10.

Hand-hygiene practices in the operating theatre: an observational study.

BACKGROUND: The current prevalence of healthcare-associated infections (HCAIs) is a major public health concern. Patient contact in the operating theatre (OT) can contribute to HCAI via microbial contamination. The application of hand hygiene is effective in reducing infection rates. Limited data are available on adherence to hand-hygiene guidelines by OT staff.

METHODS: Covert direct observations of OT staff at an academic medical centre were performed by a single, trained observer. The primary outcome was the frequency of hand-hygiene application by OT staff, including anaesthesiologists, anaesthesia nurses, surgeons, surgical nurses, and medical students. 'Sterile' scrubbed staff members were excluded. The following hand-hygiene opportunities were monitored: (i) entering or leaving the OT;

RESULTS: A total of 28 operations were observed (60 h of observations). On average, 0.14 hand-hygiene applications per hour per staff member were witnessed. Upon entering or leaving the OT, hand hygiene was performed in 2% (7/363) and 8% (28/333) of opportunities.

CONCLUSIONS: Frequent interactions between patient, staff, and OT environment were observed. Adherence to hand-hygiene guidelines by OT staff was extremely low. This potentially exposes patients to microbial transmission, HCAIs, and patient harm.

Think about ”habit” – this is how I usually do…
Difficulty in following new recommendations?

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BMC Vet Res. 2014 May 7;10:106. doi: 10.1186/1746-6148-10-106.

Video observation of hand hygiene practices during routine companion animal appointments and the effect of a poster intervention on hand hygiene compliance.

Anderson ME[1], Sargeant JM, Weese JS.

RESULTS: Observation of hand hygiene practices was performed in 51 clinics for approximately 3 weeks each using 2 small wireless surveillance cameras: one in an exam room, and one in the most likely location for hand hygiene to be performed outside the exam room following an appointment. Data from 38 clinics were included in the final analysis, including 449 individuals, 1139 appointments before and after the poster intervention, and 10804 hand hygiene opportunities. Overall hand hygiene compliance was 14% (1473/10894), while before and after patient contact compliance was 3% (123/4377) and 26% (1145/4377), respectively. Soap and water was used for 87% (1182/1353) of observed hand hygiene attempts with a mean contact time of 4 s (median 2 s, range 1-49 s), while alcohol-based hand rub (ABHR) was used for 7% (98/1353) of attempts with a mean contact time of 8 s (median 7 s, range 1-30 s). The presence of the posters had no significant effect on compliance, although some staff reported that they felt the posters did increase their personal awareness of the need to perform hand hygiene, and the posters had some effect on product contact times.

Doors into surgery room
Why?

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Infect Control Hosp Epidemiol. 2006 Aug;27(8):835-40. Epub 2006 Jul 20.

Surgical site infection surveillance: analysis of adherence to recommendations for routine infection control practices.

A total of 856 patients were observed;
Doors were opened an average of 12 times during an operation

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If there is no evidence – what do we do?

Can we use ”common sense”?

The ”Parachute study”

BMJ 2003

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Observational data = weak

Advocates of evidence based medicine have criticized the adoption of interventions evaluated by using only observational data.

> The basis for parachute use is purely observational,
>
> Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump

Everyday routines in surgery…

Routines will lower the risk of errors.

Is this partly a rite? Cap (hat), mask, special shoes, alcohol….

Perhaps important to help us to focus on the patient and the surgical procedure. ”A surgeon’s mind”

Careful with…

One case… I have heard…

アルコールの使用をやめるべき、と言っているわけではない

To be clear: we are not telling you to stop using alcohol

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Keep a critical attitude

… and use common sense…

THANK YOU

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