



DODICESIMO CONVEGNO DI TRAUMATOLOGIA CLINICA E FORENSE

19° Corso di Ortopedia, Traumatologia e Medicina Legale

**LE CAUSE DI INSUCCESSO IN ORTOPEDIA
E IN MEDICINA RIABILITATIVA:
DAL PLANNING AL CONTENZIOSO**

PROBLEMATICHE GIURIDICHE E MEDICO LEGALI
LA DIFFICOLTA' APPLICATIVA DELLA LEGGE GELLI-BIANCO



Presidenti

F.M. Donelli, M. Gabrielli, G. Varacca

4 - 5 Novembre 2022

Palazzo dei Congressi - Salsomaggiore Terme (PR)

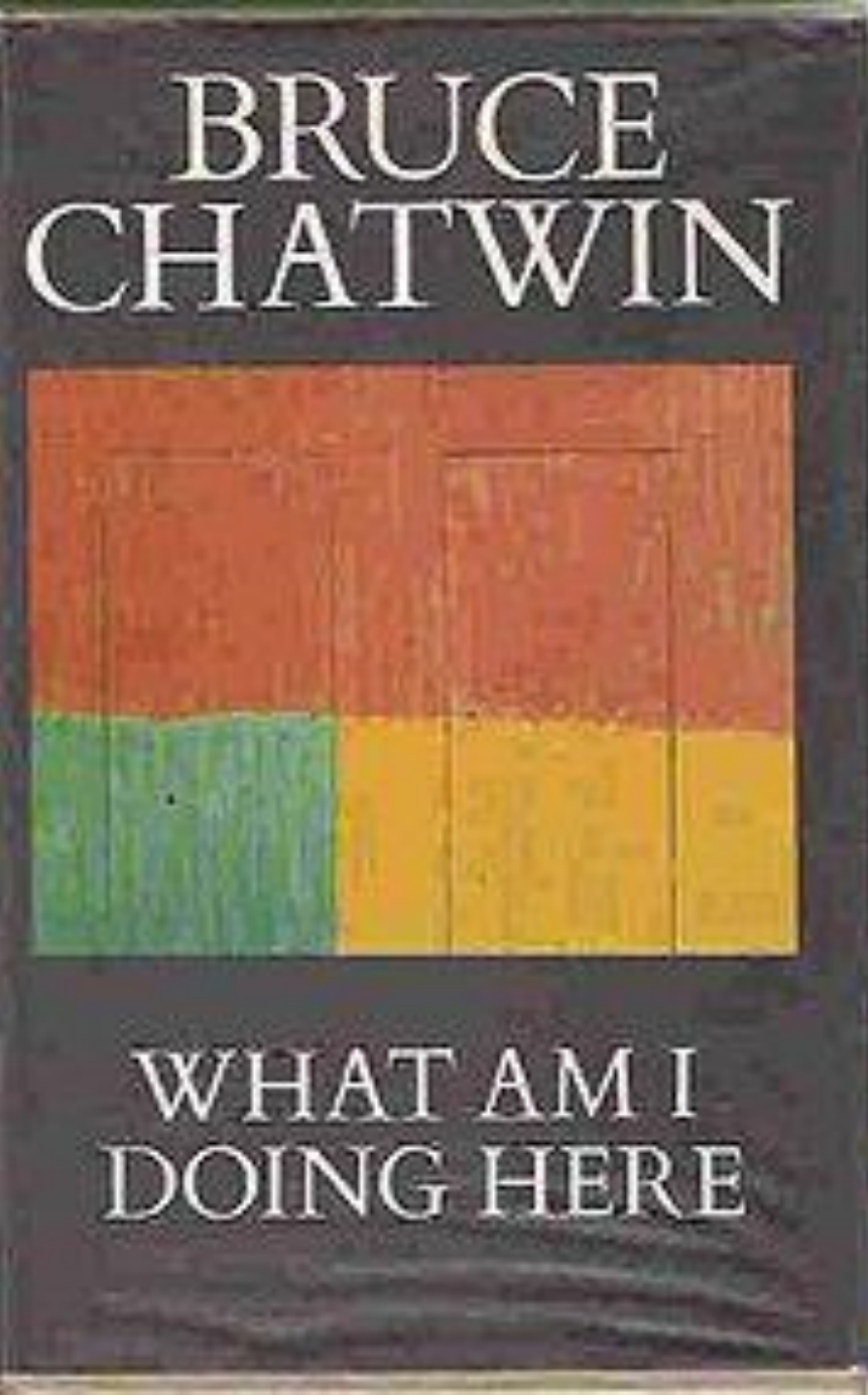


**Evidence-Based Medicine
e identificazione dell'**ERRORE**
in Ortopedia e Traumatologia**



Gustavo Zanolì,
Roberto Biscione,
Alessandro Gildone,
Massimiliano Manfredini

Luca Liverani
Giuseppe De Rito



Gustavo Zanoli: Disclosure



Private general orthopaedic surgeon

- Patients approx. 40%
- NHS approx.40%
- Insurances approx.20%

Teaching (0,5%)

Voluntary research activity

- (Cochrane work is actually at my own costs...)

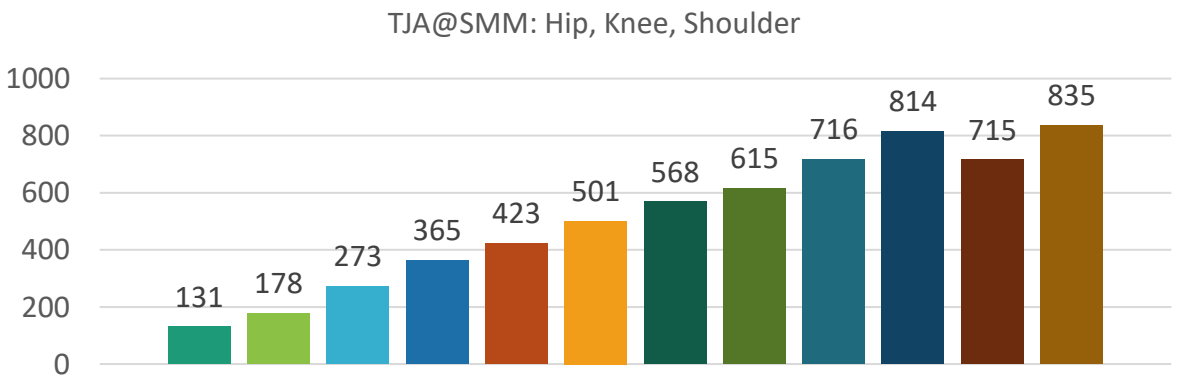
(many invitations, travel expenses)

- Depuy, Stryker, Zimmerr-Biomet, Thornier etc.
- ...

No funding for this presentation



Dr. G. De Rito, MD



G.L.O.B.E.

Dal 2003: surgical editor



Cochrane
Musculoskeletal

Trusted evidence.
Informed decisions.
Better health.



G.L.O.B.E.

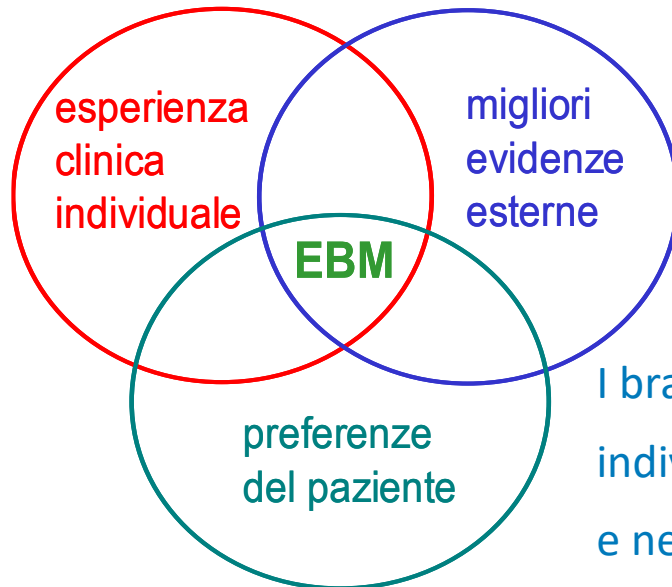
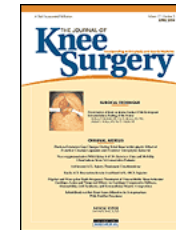


EBM: definizione semplificata (per Ortopedici!)



L'EBM è un approccio logico e razionale che aiuta i clinici a prendere decisioni imparando a gestire la grande quantità di nuove informazioni disponibili.

Kuhn J Knee Surg 2005

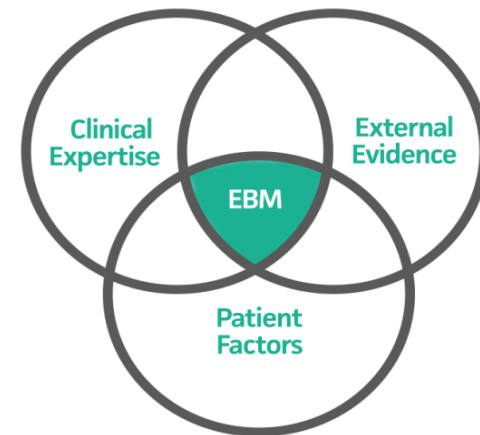


I bravi medici usano sia l'esperienza clinica individuale sia le migliori evidenze esterne, e nessuna delle due da sola è sufficiente.

Sackett BMJ 1996

Nell'EDEN dell'EBM...

- ...non ci sarebbero errori!





SAPER ESSERE
competenze
relazionali



SAPER FARE
Competenze
tecniche



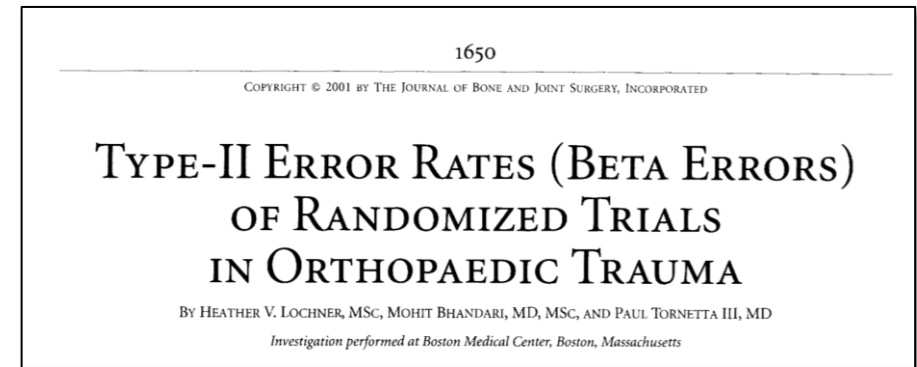
SAPERE
competenze
metodologiche

Errori metodologici in letteratura

COME AGISCE L'ERRORE DI CAMPIONAMENTO

Si possono commettere due tipi di errore utilizzando un test di ipotesi:

Stato di Natura		
Azioni	H_0 è vera	H_0 è falsa
Si accetta H_0	DECISIONE CORRETTA	Si commette Errore di II tipo
Si rifiuta H_0	Si commette Errore di I tipo	DECISIONE CORRETTA



Measurement Error and Misclassification in Orthopedics: When Study Subjects are Categorized in the Wrong Exposure or Outcome Groups

5000 pts

100 PJIs (outcome)

		Outcome		
		PJI	Non-PJI	Total
Exposure	Depression	21	979	1000
	No depression	49	3951	4000
Total		70	4930	5000

← 30 →

1000 pts with depression (exposure)

		Outcome		
		PJI	Non-PJI	Total
Exposure	Depression	30	970	1000
	No depression	70	3930	4000
Total		100	4900	5000

← 1470 →

30/100 PJI misclassified as non-PJI
30% decrease in sensitivity
Relative Risk = 1.7

No Misclassification of PJI
100% Sensitivity and Specificity
Relative Risk = 1.7

1470/4900 non-PJI misclassified as PJI
30% decrease in specificity
Relative Risk = 1.0

Visual Abstract: Chad A Krueger, MD

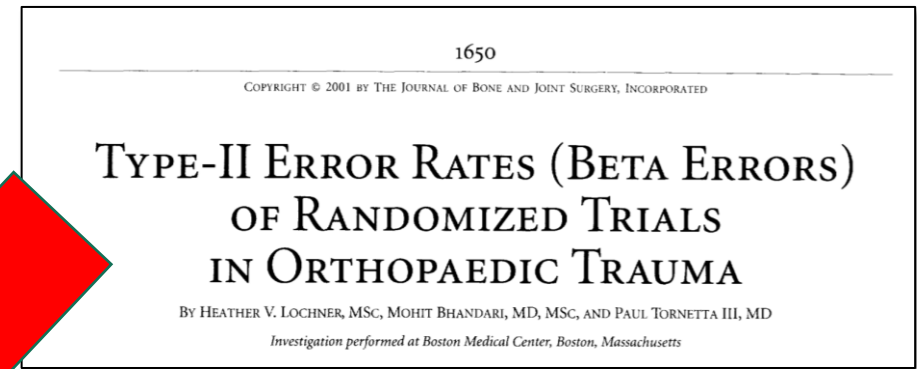


Errori metodologici in letteratura

COME AGISCE L'ERRORE DI CAMPIONAMENTO

Si possono commettere due tipi di errore utilizzando un test di ipotesi:

Stato di Natura	H_0 è vera	H_0 è falsa
Azioni		
Si accetta H_0	DECISIONE CORRETTA	Si commette Errore di II tipo
Si rifiuta H_0	Si commette Errore di I tipo	DECISIONE CORRETTA



Percent Error and Misclassification in Orthopedics: When Study Groups are Categorized in the Wrong Exposure or Outcome Groups

1000 pts

100 PJIs (outcome)

Exposure	Outcome		
	PJI	Non-PJI	Total
Depression	21	979	1000
No depression	49	3951	4000
Total	70	4930	5000

30/100 PJI misclassified as non-PJI
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Exposure	Outcome		
	PJI	Non-PJI	Total
Depression	30	970	1000
No depression	70	3930	4000
Total	100	4900	5000

No Misclassification of PJI
100% Sensitivity and Specificity
Relative Risk = 1.7

Exposure	Outcome		
	PJI	Non-PJI	Total
Depression	321	679	1000
No depression	1249	2751	4000
Total	1570	3430	5000

1470/4900 non-PJI misclassified as PJI
30% decrease in specificity
Relative Risk = 1.0

← 1470 →

Visual Abstract: Chad A Krueger, MD

THE JOURNAL OF ARTHROPLASTY

G.L.O.B.E.



Usare EBM per studiare/ridurre l'insuccesso

- ~~Definizione/identificazione~~ degli errori
 - Diagnostici
 - Anamnesi, Esame obiettivo, Laboratorio, Imaging ecc.
 - Terapeutici
 - Classificazione in base al momento:
 - Identificazione (Lato, paziente, ecc.)
 - Indicazione
 - Esecuzione
 - Comunicazione
 - Classificazione in base al danno:
 - Nessuno, Minore, Moderato, Grave, Morte
 - Classificazione per Responsabilità:
 - Chirurgo
 - Équipe
 - Produttori
 - ...
- Misurazione/~~identificazione~~: epidemiologia degli errori
- Strategie di Prevenzione: valutazione dei risultati

**THERMAE**
DI SALSOMAGGIORE

DODICESIMO CONVEGNO DI TRAUMATOLOGIA CLINICA E FORENSE
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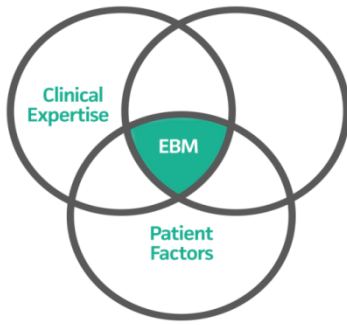
LE CAUSE DI INSUCCESSO IN ORTOPEDIA

E.B.M. identificazione dell'errore - *G. Zanoli*

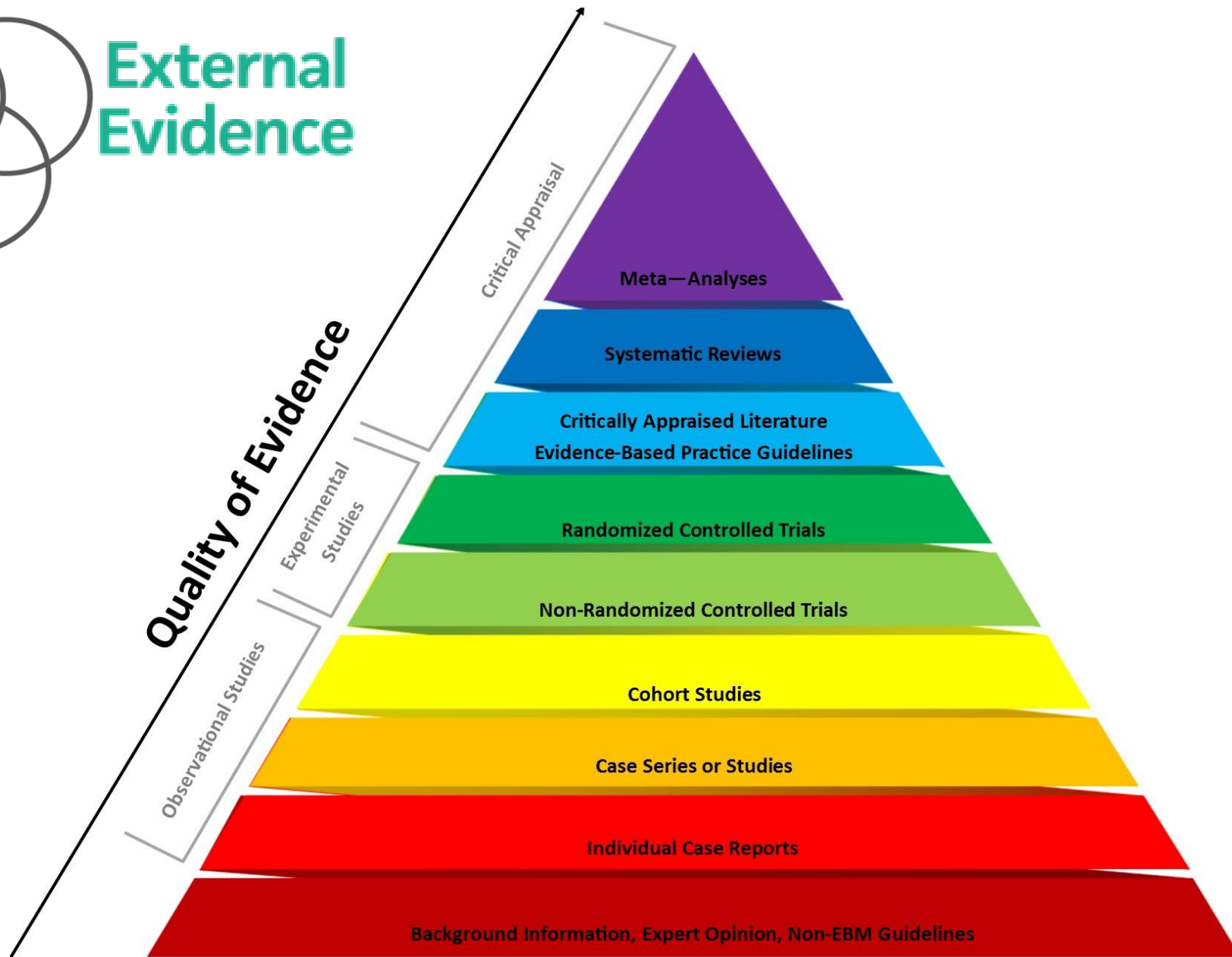


3 (4) parts clinical question

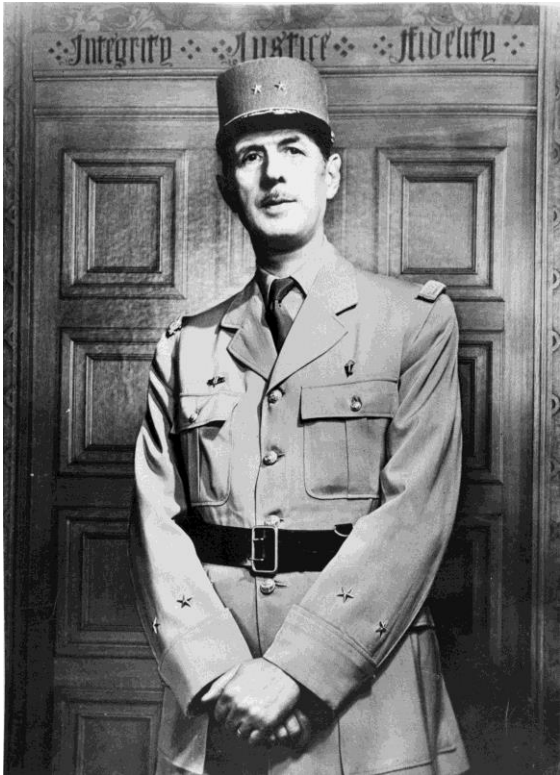
P	I	C	O	S
Problem	Intervention	Comparison	Outcome	Study design
Patient, Population, Pathology. Identify the clinical problem, as specifically as possible (ie age, sex, subgrouping etc.)	Define the clinical action to undertake Not necessarily therapy. It could be also a diagnostic manoeuvre or history taking	Choose an alternative / control. If not specified, could be any existing comparison (including no action)	Decide which is the desired outcome and how to measure it. (Establish the rules of the “game”, where the “target” is, how to “win”).	Select the appropriate study design. Often more than one design possibility, with advantages and disadvantages



External Evidence



Vasto programma...



(come disse il generale De Gaulle a chi gli proponeva di lanciare una campagna per eliminare i cretini)

...in 10 minuti!

Errori diagnostici

evation

Case Series or Studies

- Fattori da considerare:
 - Tempo, esperienza, complessità, multidisciplinarietà, incertezza, comunicazione
- Esempio (non solo fratture o tumori misconosciuti)

Diagnostic Errors in Orthopedic Surgery: Evaluation of Resident Documentation of Neurovascular Examinations for Orthopedic Trauma Patients

Eric W. Tan, Beverlie L. Ting, Xiaofeng Jia, Richard L. Skolasky and Edward G. McFarland
American Journal of Medical Quality published online 13 July 2012
DOI: 10.1177/1062860612447856

The online version of this article can be found at:
<http://ajm.sagepub.com/content/early/2012/07/13/1062860612447856>

- Metodo: valutazione retrospettiva di database interno

There was no complete (all elements) or perfect (complete bilateral) documentation. The element most often documented completely was the sensory examination. Increased examiner experience was significantly associated with decreased sensory and vascular documentation.

Errori di identificazione paziente, lato, sito ecc.

- 106 lavori
 - 39 prevalenza, 44 cause, 40 interventi
- Lavori su Prevalenza:
 - Registrazione
 - Braccialetto
 - Cartella errata e ordini medicinali
 - Amministrazione
 - Chirurgia
 - Radiologia
 - Laboratorio
 - Trasfusioni

Systematic Reviews

Patient Safety is No Accident: Orthopaedic Surgery Error Data May Be Misleading; Citing National Figures

NEWS PROVIDED BY
[American Academy of Orthopaedic Surgeons](#) →
Oct 26, 2010, 07:00 ET

SHARE THIS ARTICLE



HEALTH TECHNOLOGY ASSESSMENT
INFORMATION SERVICE™

SPECIAL REPORT

Patient Identification Errors

ECRIInstitute
The Discipline of Science. The Integrity of Independence.

G.L.O.B.E.



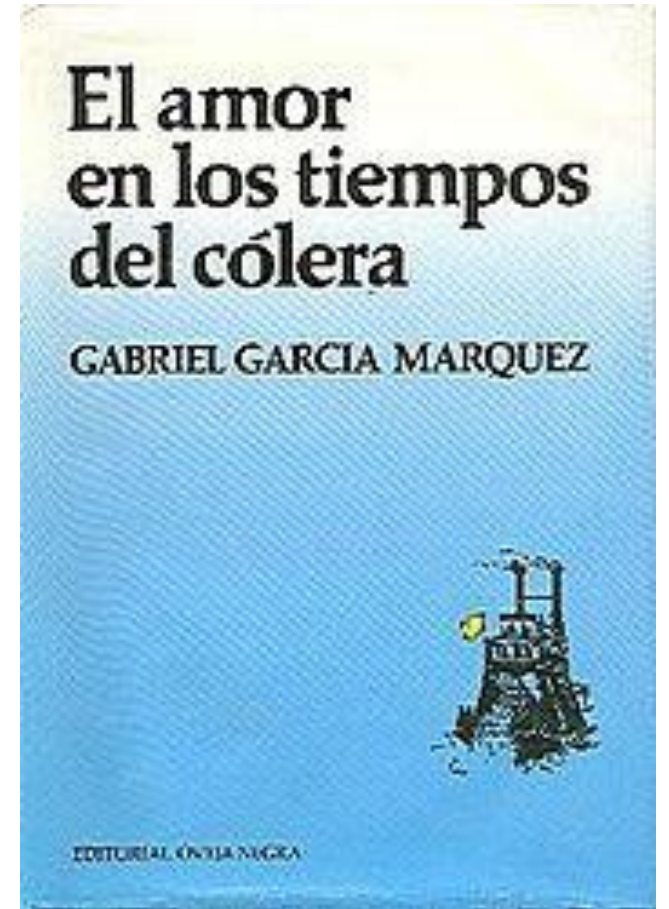
Errori di indicazione

- Subdoli
- Buonafede o malafede?
- Chi può valutarli? In quale contesto?
- Ruolo dei produttori



La Medicina ai tempi del DRG

- Personaggi:
 - Pazienti
 - Medici
 - “Aziende”
 - Università
 - Ospedali
 - Privati
 - Istituzioni di controllo
 - Agenzie
 - ISS
 - Governo
 - Locale
 - Nazionale
 - Aziende
 - Farmaci
 - Impianti
 - Congressi



Regole del gioco

- Ufficiale: Appropriatezza
 - Fare bene le cose giuste alle persone giuste nel momento giusto nel luogo giusto
- Non scritta: DRG = prodotto
 - Produrre più DRG possibile, operare il più possibile

Stepwise innovation or Failed innovation?

Lack of evidence—the anti-stepwise introduction of metal-on-metal hip replacements

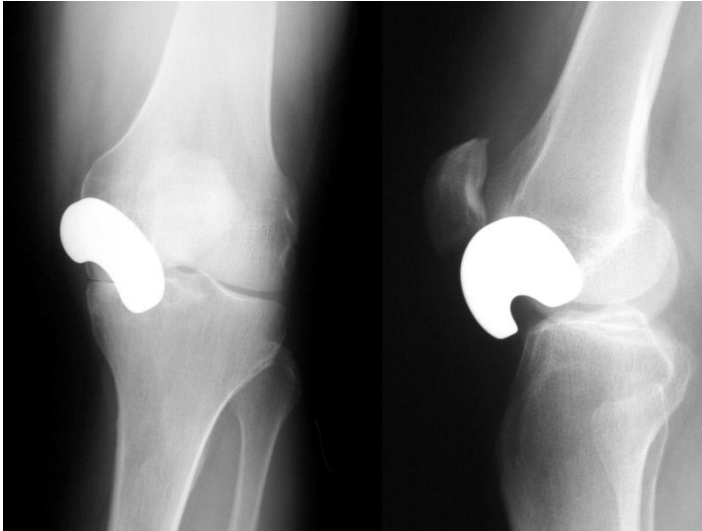
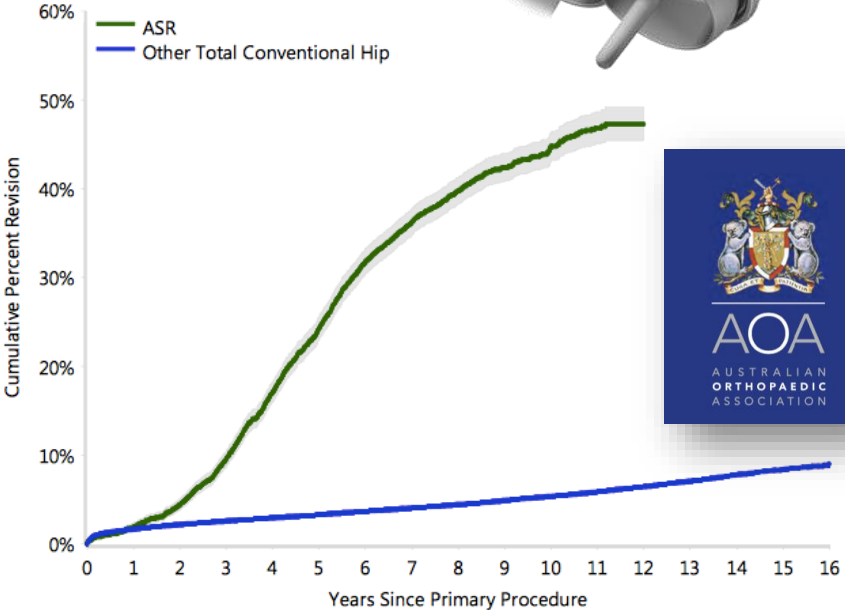
A systematic review and a comparative assessment of the literature and registry data

Aleksi REITO¹, Lari LEHTOVRTA^{1,2}, Olli LAINIALA¹, Keijo MÄKELÄ³, and Antti ESKELINEN¹



2003

2013



Errori di esecuzione:

13% degli errori in chirurgia ortopedica (Wong 2009)

- Negligenza, imperizia, imprudenza...
- Curva di apprendimento
- Stanchezza/stress

Possibili risposte:

- Insegnamento, esercitazione, addestramento
- Adeguamento turni e personale
- Navigazione, CAOS, Robotica...



Background Information, Expert Opinion, Non-EBM Guidelines

JB & JS
REVIEWS

ARTHROSCOPIC SIMULATION: THE FUTURE OF SURGICAL TRAINING

A Systematic Review

Systematic Reviews

Saad Lakhani, MBChB,
MSc(Distinction)
Omar A. Selim, MBBCh
Muhammad Zahid Saeed,
MBBS, FRCS(Tr&Orth),
FEBOT(Tr&Orth)

*Investigation performed at the Royal
Free Hospital in affiliation with
University College London Medical
School, London, United Kingdom*

Abstract

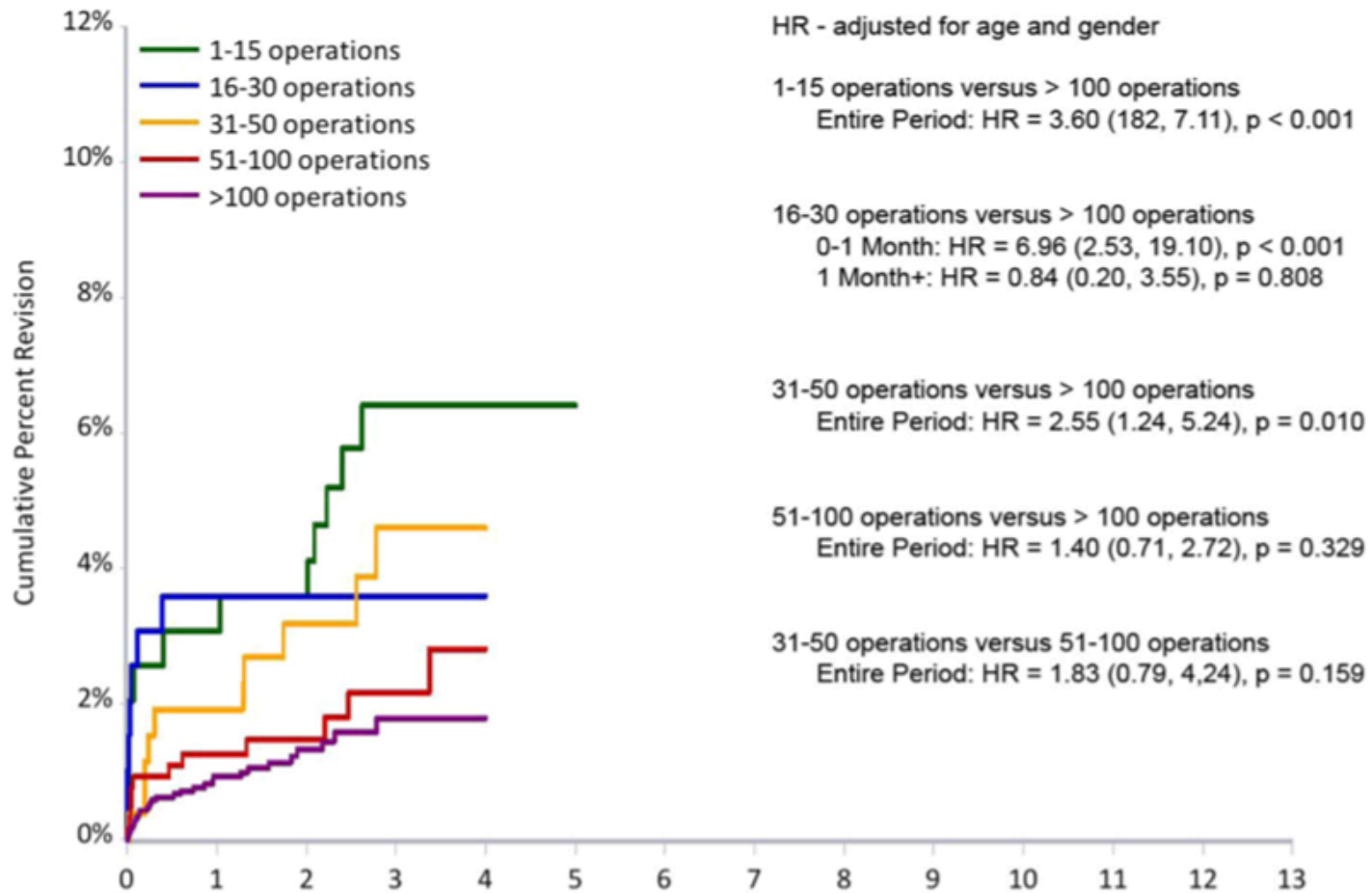
Background: Arthroscopic simulation has rapidly evolved recently with the introduction of higher-fidelity simulation models, such as virtual reality simulators, which provide trainees an environment to practice skills without causing undue harm to patients. Simulation training also offers a uniform approach to learn surgical skills with immediate feedback. The aim of this article is to review the recent research investigating the use of arthroscopy simulators in training and the teaching of surgical skills.

Methods: A systematic review of the Embase, MEDLINE, and Cochrane Library databases for English-language articles published before December 2019 was conducted. The search terms included arthroscopy or arthroscopic in combination with simulation or simulator.

Results: We identified a total of 44 relevant studies involving benchtop or virtually simulated ankle, knee, shoulder, and hip arthroscopy environments. The majority of these studies demonstrated construct and transfer validity; considerably fewer studies demonstrated content and face validity.

Conclusions: Our review indicates that there is a considerable evidence base regarding the use of arthroscopy simulators for training purposes. Further work should focus on the development of a more uniform simulator training course that can be compared with current intraoperative training in large-scale trials with long-term follow-up at tertiary centers.

Learning curve 1



For surgeons who have performed >100 procedures, revision rate reduced from 6% for the first 15 procedures to 2% after first 100.

Learning curve 2

Acta Orthopaedica 2013; 84 (1): 25–31

25

Hip prosthesis introduction and early revision risk

A nationwide population-based study covering 39,125 operations

Mikko Peltola¹, Antti Malmivaara¹, and Mika Paavola^{1,2}

The **first 15 operations** with a new stem or cup model had an increased risk of early revision surgery.

The **risk of early revision** at the implementation phase should be considered when a new type of THA is brought into use.

Peltola Acta Orthop 2013



Operative Treatment in 120 Displaced Intraarticular Calcaneal Fractures

Results Using a Prognostic Computed Tomography Scan Classification

ROY SANDERS, M.D., PAUL FORTIN, M.D., THOMAS DiPASQUALE, D.O.,
AND ARTHUR WALLING, M.D.

When results were compared by year, a distinct learning curve appeared (Tables 3 and 4). The worst results occurred at the start of the series, whereas the number of excellent-good results improved each successive year (1987, 24%; 1988, 54%; 1989, 73%; 1990, 84%). When these data were further analyzed with respect to fracture type and year, it appeared that Type II articular fractures were easier to fix than Type III articular fractures. With time, even Type III results improved. Despite a better outcome for Type II and III articular fractures over time, however, the results of operative intervention in Type IV articular fractures were not improved on even after four years.

Errori di comunicazione

- Mancata comunicazione fra professionisti:
 - 24,7% degli errori in ortopedia (Wong 2009)
 - 48,6% degli errori di lato (Stahel 2010)
 - 100% degli errori di persona (Stahel 2010)
- Mancata comunicazione con pazienti:
 - Errori di comunicazione medico-paziente
 - Errori causati da comunicazione medico-paziente



Ortopedici...incerti?

Clin Orthop Relat Res (2015) 473:3564–3572
DOI 10.1007/s11999-015-4304-z

Clinical Orthopaedics
and Related Research®
A Publication of The Association of Bone and Joint Surgeons®



SYMPOSIUM: PSYCHOSOCIAL ASPECTS OF MUSCULOSKELETAL ILLNESS

Do Surgeons Treat Their Patients Like They Would Treat Themselves?

Clin Orthop Relat Res (2016) 474:1360–1369
DOI 10.1007/s11999-015-4623-0

Clinical Orthopaedics
and Related Research®
A Publication of The Association of Bone and Joint Surgeons®



CLINICAL RESEARCH

Do Orthopaedic Surgeons Acknowledge Uncertainty?

Teun Teunis MD, Stein Janssen MD, Thierry G. Guitton MD, PhD,
David Ring MD, PhD, Robert Parisien MD



Incertezza

Dobbiamo abituarci a convivere con l'incertezza, l'imprevisto, il mistero non perché non abbiamo scoperto le regole di funzionamento della natura ma perché abbiamo scoperto che l'incertezza è insita nelle sue regole.

Antonio Bonaldi



Available online at www.sciencedirect.com

ScienceDirect

Health Professions Education 4 (2018) 67–69



www.elsevier.com/locate/hpe

The Art of Acknowledging that We Know Nearly Nothing

Jimmie Leppink



G.L.O.B.E.

Comunicare (l'incertezza)



Available online at www.sciencedirect.com

ScienceDirect

Health Professions Education 4 (2018) 97–106



www.elsevier.com/locate/hpe

Communication Skills in Patient-Doctor Interactions: Learning from Patient Complaints

Janine W.Y. Kee^{a,*}, Hwee Sing Khoo^b, Issac Lim^b, Mervyn Y.H. Koh^c

Four main themes of communication errors were identified, namely: non-verbal (eye contact, facial expression and paralanguage), verbal (active listening and inappropriate choice of words), and content (poor quantity and quality of information provided); and poor attitudes (lack of respect and empathy)

The only effective and ultimately the only correct recommendation is to openly address the complication of PJI. The patient should be informed of the possibility of an infection as soon as possible and undergo appropriate diagnostic tests. This can only be done through an open and honest dialogue with the patient. Complaints are unnecessary and irrelevant, due to hygiene standards observed in most operating rooms around the world. As a rule, PJIs should be considered a random event. Responsibilities can be attributed to the surgeon or to the attending physician only in the case of delays or a wait-and-see approach to diagnostic outcomes and subsequent treatment. In a nutshell, the best thing is to be honest.

Parvizi and Gehrke cit in Basile 2021



Esempio di Classificazione in base al danno

- **Nessuno**, no harm (near miss)
- **Minore**, low harm (minimal harm—patient(s) required extra observation or minor treatment)
- **Moderato**, moderate harm (short-term harm—patient(s) required further treatment, or procedure)
- **Grave**, severe harm (permanent or long-term harm)
- **Morte**, death

A total of 257 incident reports were analysed. Four main thematic categories emerged. These were: (1) stages of the surgical journey – 118/191 (62%) of deaths occurred in the post-operative phase; (2) causes of patient deaths – 32% were related to severe infections; (3) reported quality of medical interventions – 65% of patients experienced minimal or delayed treatment; (4) skills of healthcare professionals – 44% of deaths had a failure in non-technical skills

Panesar et al. *BMC Musculoskeletal Disorders* 2012, **13**:93
<http://www.biomedcentral.com/1471-2474/13/93>



RESEARCH ARTICLE

Open Access

Mortality as an indicator of patient safety in orthopaedics: lessons from qualitative analysis of a database of medical errors

Sukhmeet S Panesar^{1,2,3*}, Andrew Carson-Stevens⁴, Bhupinder S Mann⁵, Mohit Bhandari⁶ and Rajan Madhok⁷







Original Article

The impact of system and diagnostic errors for medical litigation outcomes in orthopedic surgery

Norio Yamamoto ^{a, b}, Takashi Watari ^{c, d} , Ayako Shibata ^e, Tomoyuki Noda ^f, Toshifumi Ozaki ^g

All of the claims in which the orthopedic surgeon lost were associated with a diagnostic or system error, with the most common one being system error.

Archives of Orthopaedic and Trauma Surgery (2022) 142:3659–3665

<https://doi.org/10.1007/s00402-021-03958-1>

ORTHOPAEDIC SURGERY

Litigations in orthopedics and trauma surgery: reasons, dynamics, and profiles

Martin Gathen ¹ · M. Jaenisch ¹ · F. Fuchs ¹ · L. Weinhold ² · M. Schmid ² · S. Koob ¹ · D. C. Wirtz ¹ · M. D. Wimmer ¹

Our results could not confirm the often-stated trend of having more litigations against orthopedic and trauma surgeons. Although the absolute numbers increased, the number of litigations per 1000 patients treated declined. Patients who underwent elective surgery were more likely to file complaints than emergency patients.



Impatto sui Chirurghi Ortopedici (infezioni: 0.5-3% primo impianto 20% revisioni)



RESEARCH ARTICLE

Surgeons are deeply affected when patients are diagnosed with prosthetic joint infection

Charlotte Mallon¹, Rachael Gooberman-Hill^{1,2}, Ashley Blom^{1,2}, Michael Whitehouse^{1,2}, Andrew Moore^{1*}

The impact is shown to be greater when the complication is unexpected, results from elective surgery and leads to severe disability [14]. Such events can lead to intense emotional responses, impaired decision making, difficulty concentrating, a negative impact on clinical judgement and deleterious changes to practice [9,10]. The cumulative effect of these reactions may potentially impact upon surgeons' personal and professional identities [10], and lead to a greater risk of error and suboptimal patient care [34]. Evidence suggests that surgeons may become increasingly conservative and risk-averse in response to these events [14], potentially reducing access to care for high-risk patients.

Basile et al. *J Orthop Traumatol* (2021) 22:44
<https://doi.org/10.1186/s10195-021-00607-6>

Journal of Orthopaedics
and Traumatology

ORIGINAL ARTICLE

Open Access

Prosthetic joint infections and legal disputes: a threat to the future of prosthetic orthopedics

Giuseppe Basile^{1*}, Mario Gallina¹, Alberto Passeri², Rosa Maria Gaudio³, Nicolò Castelnuovo⁴, Pasquale Ferrante⁵ and Giorgio Maria Calori⁶



If this evidence is provided, liability should be excluded, because one must accept that portion of risk intrinsically related to the medical-surgical activity, that is, of minimum risk or tolerable risk



Responsabilità dei produttori

Cureus

Open Access Original
Article

DOI: 10.7759/cureus.29861



The Impact of Sterile Instrument Set Wrapping Defects on Trauma and Orthopaedic Surgery Theatre Lists

Fitzgerald Anazor¹, Vusumuzi Sibanda¹, Kalsoom Altaf¹, Lisa Downer², Jai Relwani¹

1. Trauma and Orthopaedics, William Harvey Hospital, Ashford, GBR 2. Decontamination Contract Support Officer, Kent and Canterbury Hospital, Canterbury, GBR

Corresponding author: Fitzgerald Anazor, fitzgerald.anazor@nhs.net

Patient Safety in Surgery

BioMed Central

Editorial

Open Access

Errors in handling and manufacturing of orthopaedic implants: the tip of the iceberg of an unrecognized system problem?

Johannes K Fakler*, Yohan Robinson, Christoph E Heyde and Thilo John

47 pazienti consecutivi, protesi da cementare impiantata come non cementata

THE JOURNAL OF
ARTHOPLASTY
The Journal of Arthroplasty

AAHKS
AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

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MISCELLANEOUS | VOLUME 35, ISSUE 8, P2259-2266, AUGUST 01, 2020

Medical Device Recalls in Orthopedics: Recent Trends and Areas for Improvement

Sravya P. Vajapey, MD, MBA • Mengnai Li, MD, PhD

Published: March 21, 2020 • DOI: <https://doi.org/10.1016/j.arth.2020.03.025> • [Check for updates](#)

Orthopedic device recalls remain a significant concern and constitute, on average, 16.6% of all class II medical device recalls from 2015 to 2019. Packaging errors were the most common reasons for orthopedic device recalls, followed by design flaws and manufacturing issues



G.L.O.B.E.

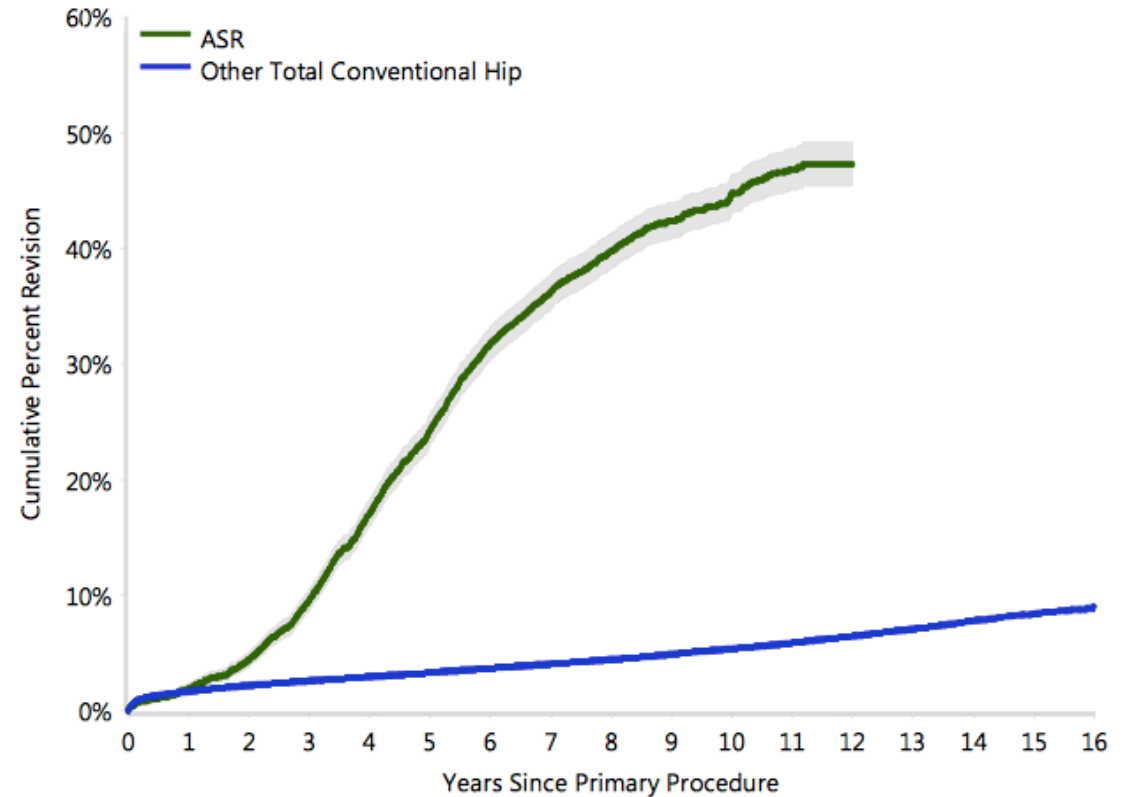
Identified and no longer used



2003 Introduzione sul mercato (FDA 2005)
 2005 prime segnalazioni di fallimenti precoci

2007 AJRR: RR a 2 anni 5.2% vs 2%

2008 FDA: 400 segnalazioni
 2010 NJR: RR a 7 anni 12% vs 3%
 2010 *Richiamo volontario (93.000 pz, sic)*
 2011 Segnalazione del Ministero alle ASL
 2012 *Striscia la notizia*



Misurazione/~~identificazione~~: epidemiologia degli errori. Numeri attendibili?

- Surveys di chirurghi
- Analisi retrospettiva di database locali/nazionali
- Studi osservazionali

> [J Bone Joint Surg Am.](#) 2009 Mar 1;91(3):547-57. doi: 10.2106/JBJS.G.01439.

Medical errors in orthopaedics. Results of an AAOS member survey

David A Wong ¹, James H Herndon, S Terry Canale, Robert L Brooks, Thomas R Hunt, Howard R Epps, Steven S Fountain, Stephen A Albanese, Norman A Johanson

Affiliations + expand

> [J Formos Med Assoc.](#) 2007 Mar;106(3):212-6. doi: 10.1016/S0929-6646(09)60242-4.

Patient safety in Taiwan: a survey on orthopedic surgeons

Cheng-Ta Yang ¹, Hsin-Hsin Chen, Sheng-Mou Hou

Affiliations + expand

PMID: 17389165 DOI: [10.1016/S0929-6646\(09\)60242-4](#)

Free article

Review > [J Bone Joint Surg Br.](#) 2009 Oct;91(10):1274-80.

doi: [10.1302/0301-620X.91B10.22644.](#)

Wrong-site surgery in orthopaedics

P M Robinson ¹, L T Muir

Affiliations + expand

PMID: 19794159 DOI: [10.1302/0301-620X.91B10.22644](#)

Observational Study > [Int J Risk Saf Med.](#) 2022;33(3):319-332. doi: 10.3233/JRS-210051.

Never events in orthopaedics: A nationwide data analysis and guidance on preventative measures

Ahmed T Hafez ¹, Islam Omar ², Balaji Purushothaman ³, Yusuf Michla ³, Kamal Mahawar ⁴ ⁵

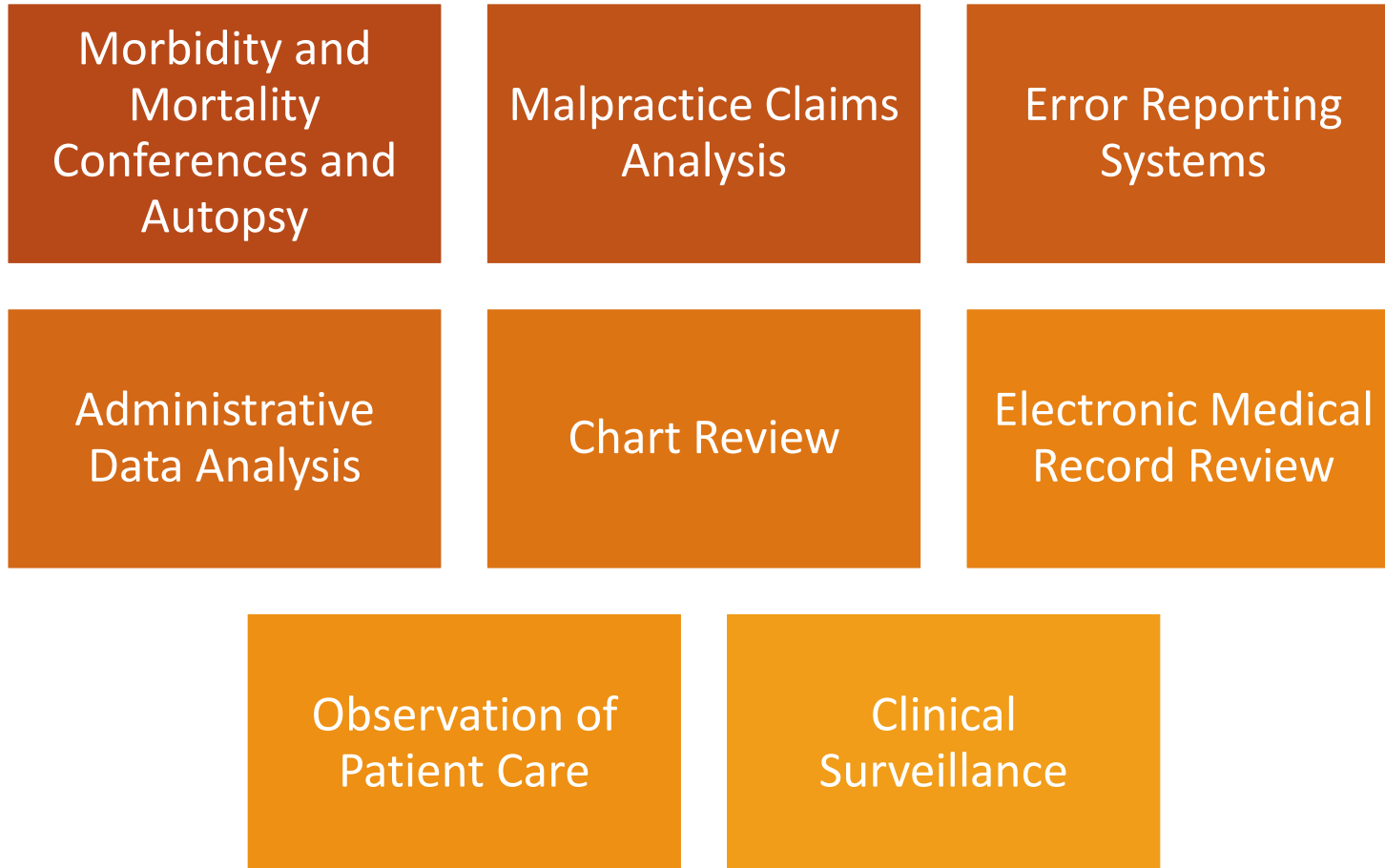
Affiliations + expand

PMID: 34486990 DOI: [10.3233/JRS-210051](#)



Misure di errore e complicanze

J Gen Intern Med. 2003



Ann Surg. 2009 Aug;250(2):187-96. doi: 10.1097/SLA.0b013e3181b13ca2.

The Clavien-Dindo classification of surgical complications: five-year experience.

Clavien PA¹, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, de Santibañes E, Pekolj J, Slankamenac K, Bassi C, Graf R, Vonlanthen R, Padbury R, Cameron JL, Makuuchi M.

Clin Orthop Relat Res (2012) 470:2220–2226
DOI 10.1007/s11999-012-2343-2

Clinical Orthopaedics
and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CLINICAL RESEARCH

Reliability of a Complication Classification System for Orthopaedic Surgery

Ernest L. Sink MD, Michael Leunig MD, Ira Zaltz MD,
Jennifer Claire Gilbert MS, John Clohisy MD,
Academic Network for Conservational Hip Outcomes Research Group

Clin Orthop Relat Res (2015) 473:1574–1581
DOI 10.1007/s11999-014-3597-7

Clinical Orthopaedics
and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

SYMPOSIUM: PATIENT SAFETY: COLLABORATION, COMMUNICATION, AND PHYSICIAN LEADERSHIP

Use of the National Surgical Quality Improvement Program in Orthopaedic Surgery

Cesar S. Molina MD, Rachel V. Thakore BS,
Alexandra Blumer BS, William T. Obrebsky MD, MPH, MMHC,
Manish K. Sethi MD



G.L.O.B.E.



Misurare l'errore in ortopedia

Open Access

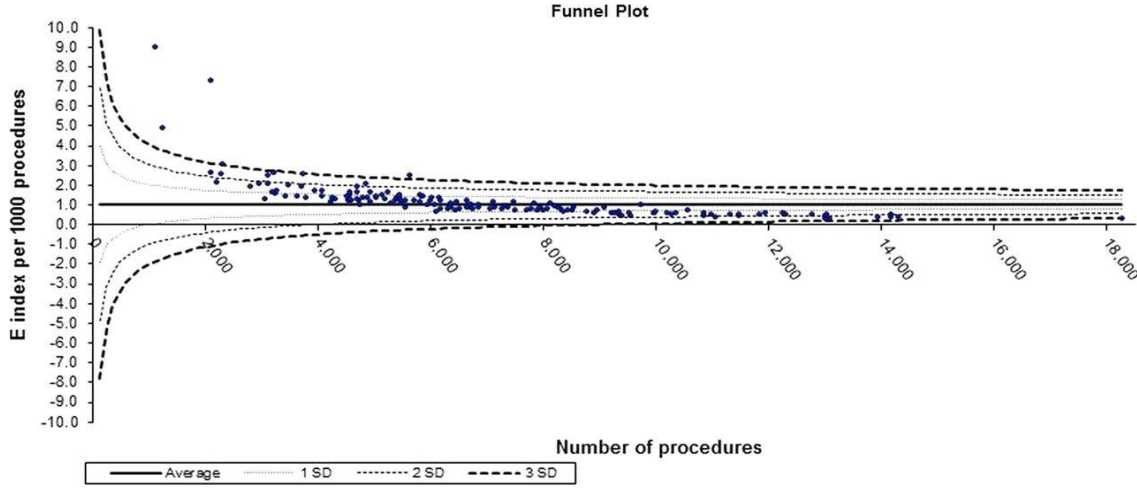
Research

BMJ Open The orthopaedic error index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach

Sukhmeet S Panesar,^{1,2} Gopalakrishnan Netuveli,³ Andrew Carson-Stevens,⁴ Sundas Javad,⁵ Bhavesh Patel,⁶ Gareth Parry,^{7,8} Liam J Donaldson,⁹ Aziz Sheikh²

- Orthopaedic error index:
 - $E = 0.5P + 0.5S$
 - Frequenza percentuale (P = propensity)
 - Danno provocato (S = Severity)
 - Da 0 a 100

Orthopaedic Error Index for all hospitals in England.



Among the 155 hospitals, 5 lay outside the prespecified control limits. These were hospitals that had relatively small numbers of procedures, but high OEI values. Of note, there is an almost linear association with larger hospitals having fewer errors.



Strategie di Prevenzione



The NEW ENGLAND
JOURNAL of MEDICINE

Perspective
NOTES OF A SURGEON


FREE PREVIEW

On Washing Hands

Atul Gawande, M.D., M.P.H.

"Better is a masterpiece, a series of stories set inside the four walls of a hospital that end up telling us something unforgettable about the world outside."
—MALCOLM GLADWELL, author of *BLINK*

Atul Gawande
AUTHOR OF *COMPLICATIONS*




BETTER

A SURGEON'S NOTES ON PERFORMANCE

PICADOR

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THE CHECKLIST MANIFESTO • HOW TO GET THINGS RIGHT

ATUL GAWANDE
BESTSELLING AUTHOR OF
BETTER AND COMPLICATIONS

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ATUL GAWANDE
CHECKLIST
COME FARE ANDARE MEGLIO LE COSE



EINAUDI



Strategie di Prevenzione: valutazione dei risultati

- Osservazionali
- Valutazioni a posteriori
- Before and after
- Confronto di coorti
- RCT?

Journal of Orthopaedics 16 (2019) 86–90



ELSEVIER

Contents lists available at [ScienceDirect](#)

Journal of Orthopaedics

journal homepage: www.elsevier.com/locate/jor



Review article: Current literature on surgical checklists and handoff tools and application for orthopaedic surgery

Bilal Sleiman^a, Zain Sayeed^{d,e}, Muhammad T. Padela^{a,c,d,e,*}, Abdurrahman F. Padela^a, Vamsy Bobba^e, Walid Yassir^{a,e,f}, Todd Frush^e, Khaled J. Saleh^{a,b,c,**}

> [J Orthop Surg Res](#). 2011 Apr 18;6:18. doi: 10.1186/1749-799X-6-18.

Can the surgical checklist reduce the risk of wrong site surgery in orthopaedics?--Can the checklist help? Supporting evidence from analysis of a national patient incident reporting system

Sukhmeet S Panesar¹, Douglas J Noble, Saqeb B Mirza, Bhavesh Patel, Bhupinder Mann, Mark Emerton, Kevin Cleary, Aziz Sheikh, Mohit Bhandari

Observational Study > [Int J Risk Saf Med](#). 2022;33(3):319-332. doi: 10.3233/JRS-210051.

Never events in orthopaedics: A nationwide data analysis and guidance on preventative measures

Ahmed T Hafez¹, Islam Omar², Balaji Purushothaman³, Yusuf Michla³, Kamal Mahawar^{4,5}

Affiliations + expand

PMID: 34486990 DOI: [10.3233/JRS-210051](#)

> [Healthc \(Amst\)](#). 2016 Dec;4(4):307-311. doi: 10.1016/j.hjdsi.2016.01.005. Epub 2016 Mar 8.

Efficacy of surgical safety checklist: Assessing orthopaedic surgical implant readiness

Benjamin G Thomasson¹, David Fuller², John Mansour³, Robert Marburger⁴, Erin Pukenas⁵

Affiliations + expand

PMID: 28007224 DOI: [10.1016/j.hjdsi.2016.01.005](#)

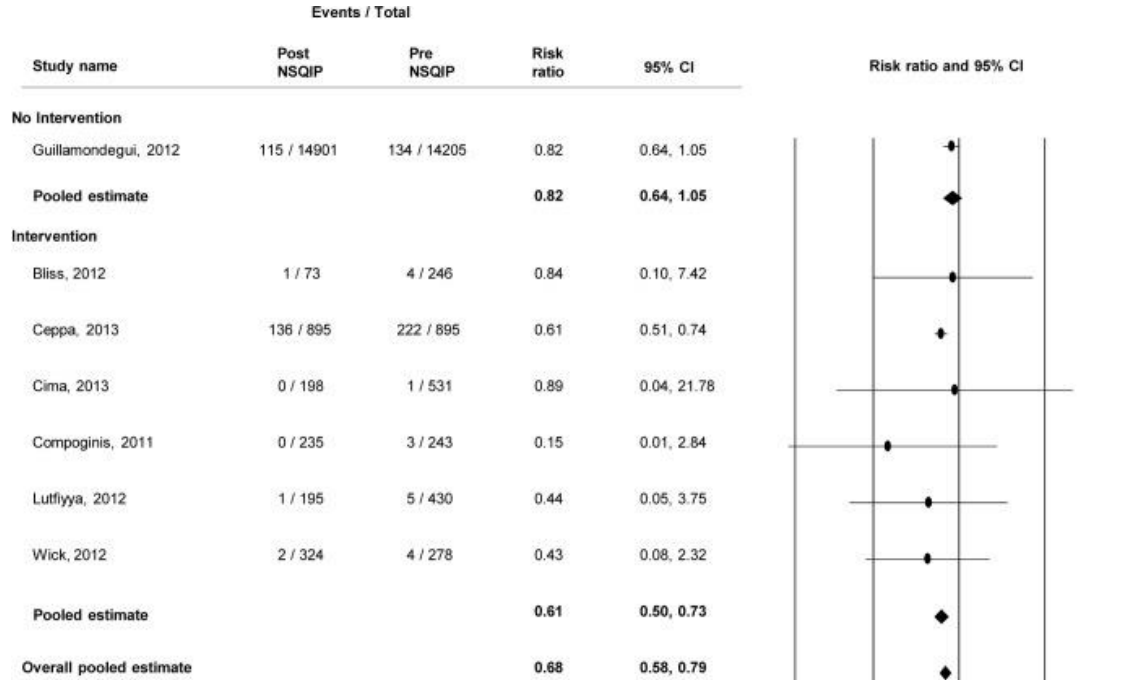
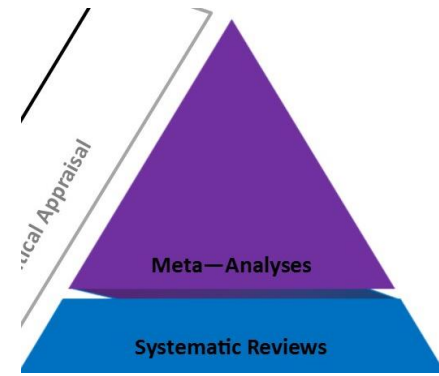


Effetto Hawthorne (Effetto dello sperimentatore)

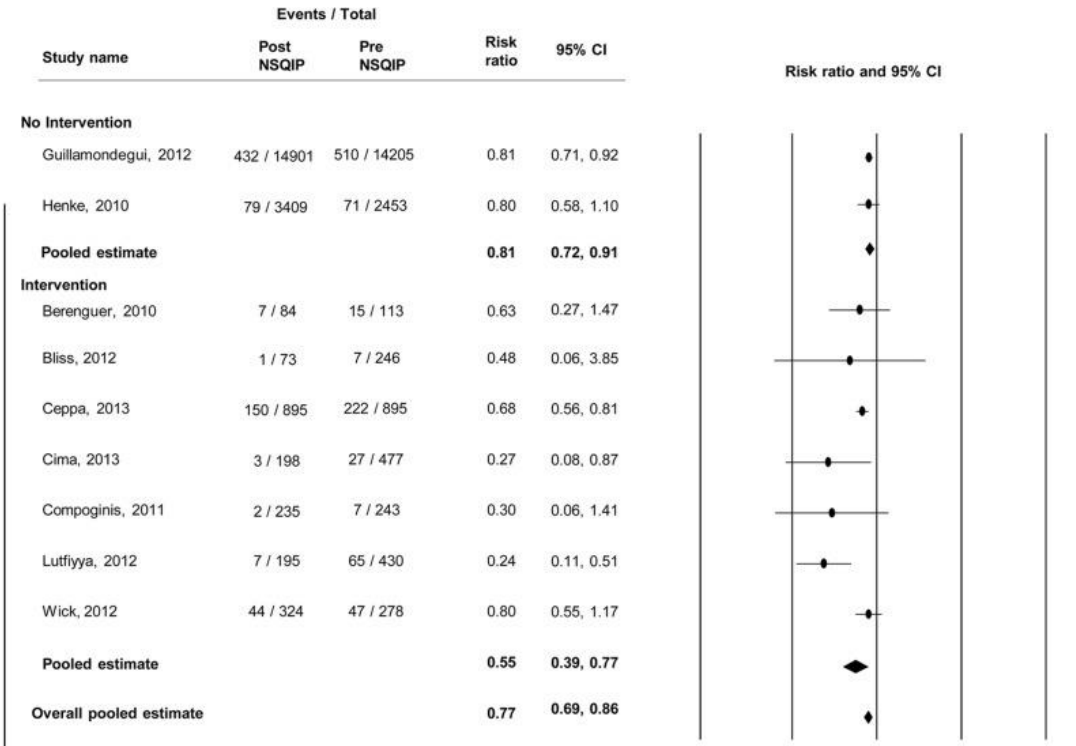
- Anni ' 20-30. Sperimentazioni negli stabilimenti di Hawthorne (Chicago) della Western Electric.
- 1^a fase: verificare cali di produttività dovuti al peggioramento delle condizioni ambientali.
- Risultati opposti alle aspettative.
- **Definizione**: L' atto di osservazione/supervisione può influenzare il comportamento dei soggetti della ricerca e confondere gli effetti di altre variabili indipendenti.

Change in Adverse Events After Enrollment in the National Surgical Quality Improvement Program: A Systematic Review and Meta-Analysis

Joshua Montroy¹, Rodney H. Breau^{1,3,4*}, Sonya Crossen¹, Kelsey Witiuk¹, Andrew Binette², Taylor Ferrier², Luke T. Lavallée⁴, Dean A. Fergusson^{1,3}, David Schramm^{1,3,5}



Heterogeneity:
 No intervention: $I^2=0.0\%$, $p\text{-value}=1.0$
 Intervention: $I^2=0.0\%$, $p\text{-value}=0.94$
 Overall: $I^2=0.0\%$, $p\text{-value}=0.57$

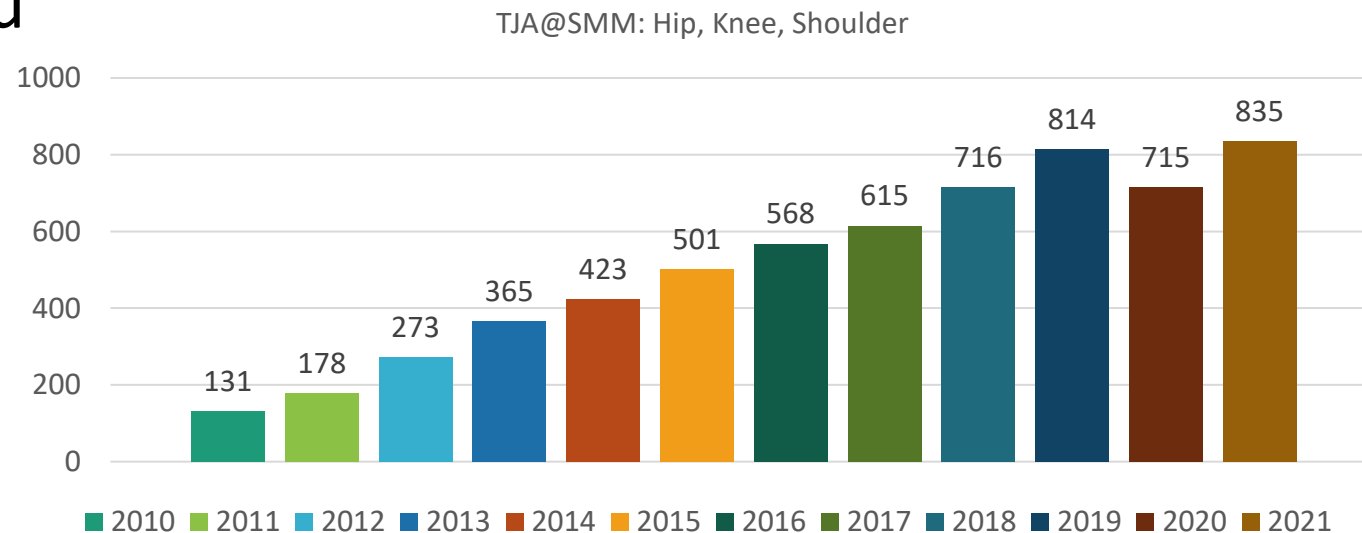
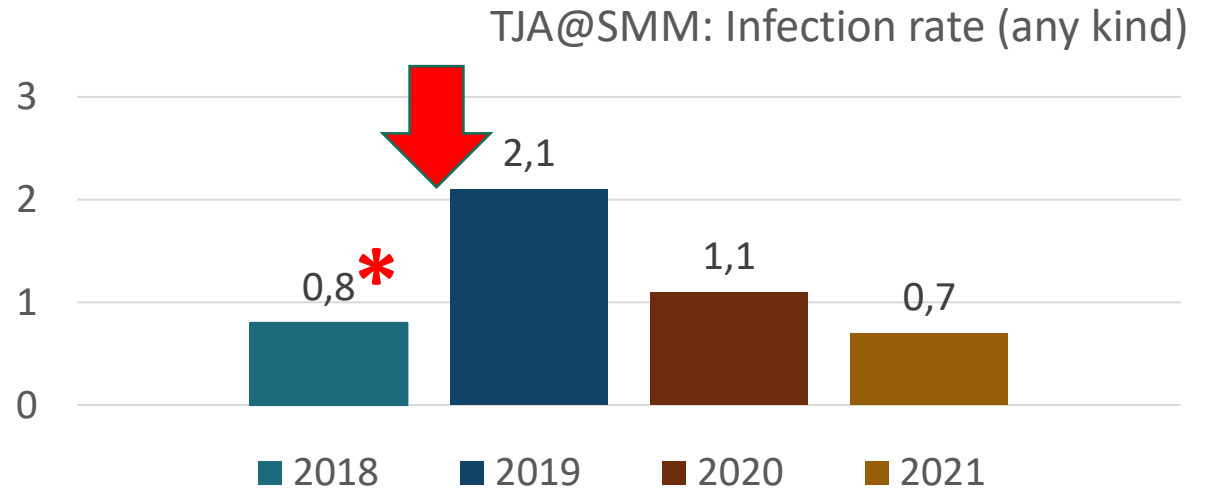


Heterogeneity:
 No intervention: $I^2=0.0\%$, $p\text{-value}=0.96$
 Intervention: $I^2=47.0\%$, $p\text{-value}=0.08$
 Overall: $I^2=50.7\%$, $p\text{-value}=0.04$



Esempio personale: (ortopedia SM Maddalena, dati dott. De Rito – dott.ssa Maritati)

- Sorveglianza attiva e prospettiva delle infezioni protesiche dal 2019
- * 2018: stima approssimativa solo su casi emergenti





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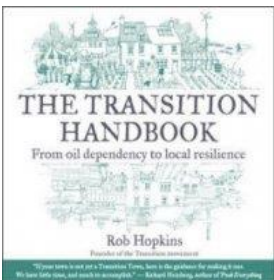
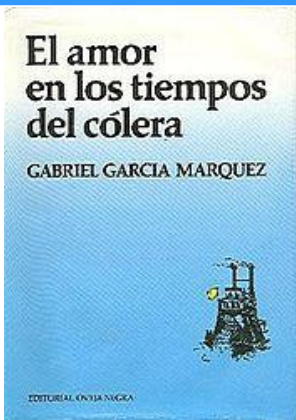
Between good and best, maybe we can settle for *better*...

BMJ 2002;324:859-860 (13 April)

Editorials

Too much medicine?

Almost certainly



- Less Rituals, transparent and judicious use of shortcuts
- Simplify «digestion» of large data
- Fight fake-news and anti-scientific thinking
- Be aware of financial interests and defensive medicine
- Avoid Harms
- Engage in registration, quality monitoring ecc.
- **Errors** aren't our sole problems
 - End of the low-cost fossil fuel Era
 - Climate Changes
 - Economic (& moral) Crises
 - Wars for resources
- We need to De-grow and start the Transition...

Cosa ci serve davvero?

“Politics rather than promising paradise should avoid hell”
(Mario Giro)



AFS – Intercultura centennial meeting
Trento e Rovereto May 1-3 2015

Evitare l'inferno

There are certainly cases of gross misconduct and malpractice, and we must always protect our patients. We should neither apologize for nor excuse inappropriately performed surgeries. It is our professional, ethical, and moral duty to regulate surgeons who may routinely cause harm due to negligence or poor skill. However, poor patient outcomes occur at the hands of excellent surgeons as well, and we should always remember that the vast majority of orthopedic surgeons carry with them the same desire to do well by their patients and provide excellent care. We challenge you to take into account all these considerations when speaking to patients about their previous orthopedic care.



Orthopedics in Glass Houses

John Y. Kwon, MD¹, and Christopher P. Miller, MD¹

When you judge others, you do not define them, you define yourself.

Wayne Dyer

“We got another disaster from the outside hospital,” my resident reported (Figure 1). “Does this guy know anything about ankle fractures?” Upon examining the radiograph I paused to consider the situation that the surgeon may have found himself in. But what do I tell my patient? What lessons can my resident learn?

Much has been written regarding the disclosure of medical errors to patients, and there is increasing literature regarding disclosure of errors made by one’s colleagues. Gallagher et al recently convened a panel of experts from various fields including patient safety, malpractice law, bioethics, and health policy and published various recommendations for disclosure of a fellow clinician’s harmful errors.¹ The authors recommended improved colleague-to-colleague communication and transparent disclosure of errors as a shared professional responsibility with a collective approach to accountability.

Although the same ethical, moral, and legal issues apply regardless of medical subspecialty, the field of orthopedic surgery has unique considerations. Although the detection of substandard care in other specialties may require exhaustive examination of the medical record, often a single radiograph is all that is required in our field.

The assessment we make of a *radiograph* for healing, alignment, positioning of implants, etc is a by-product of our orthopedic training. It doesn’t take much time to determine what was done, how well (or poorly) it was performed, and prognosticate on outcomes. However, the assessment we make of the *surgeon* who performed the surgery is a far more complex process and often subconscious in nature. During our weekly trauma rounds, I occasionally hear a trainee denounce a surgeon when examining a poor radiographic outcome, especially when performed at the well-known “outside” hospital. “Bad” surgeon (or usually a more descriptive term) is often what is said. However, although “bad” surgery may be closer to the truth of things at times, usually there is more to the story. In this context, for the sake of collegiality, consider the following when examining a colleague’s work.

Resources

Great operative outcomes require a cohesive operative team doing a lot of complex tasks properly, all at the same time.



Figure 1. Ankle Radiograph.

Whether it be staff or equipment, other surgeons may simply not have access to resources that you have readily available and may take for granted.

When we fix ankle fractures at our institution, we can choose from 5 different ankle fracture plating systems. We operate with a senior Harvard orthopedic resident or fellow in combination with a dedicated orthopedic OR team. Additionally, we’ve had the opportunity to train with some of the greatest surgeons in the world. We better get it right, and most of the time we do. However, even with all of these available resources, sometimes

¹Beth Israel Deaconess Medical Center, Harvard School of Medicine, Department of Orthopaedics, Boston, MA, USA

Corresponding Author:

John Y. Kwon, MD, Harvard Medical School, Chief, Division of Foot and Ankle Surgery, Department of Orthopaedics, Beth Israel Deaconess Medical Center, 330 Brookline Ave, Stoneman 10, Boston, MA 02215, USA.
Email: jkwn@bidmc.harvard.edu

Piccola proposta personale

- Disaccoppiare indennizzo del danno dalla valutazione dell'errore
- Giusto indennizzo per tutti, invalidità civile ecc. a prescindere dalle responsabilità
- Valutazione dell'errore (e prevenzione della reiterazione) affidata ad organi competenti (direzioni sanitarie, ordine dei medici, società scientifiche...)
 - Azioni correttive
 - Sanzioni extrema ratio





DODICESIMO CONVEGNO DI TRAUMATOLOGIA CLINICA E FORENSE

19° Corso di Ortopedia, Traumatologia e Medicina Legale

19° Corso di Ortopedia, Traumatologia e Medicina Legale

DODICESIMO CONVEGNO DI TRAUMATOLOGIA CLINICA E FORENSE

GRAZIE



EVIDENCE

Evidence-Based Medicine e identificazione dell'ERRORE in Ortopedia e Traumatologia



Gustavo Zanolì,
Roberto Biscione,
Alessandro Gildone,
Massimiliano Manfredini
Luca Liverani
Giuseppe De Rito



G.L.O.B.E.

Studi osservazionali

THE JOURNAL OF BONE & JOINT SURGERY • JBJS.ORG | MAY 2009 • VOLUME 91-A • SUPPLEMENT 3

DESIGN, CONDUCT, AND INTERPRETATION OF NONRANDOMIZED ORTHOPAEDIC STUDIES—A PRACTICAL APPROACH

THE JOURNAL OF BONE & JOINT SURGERY • SUPPLEMENT 3 • AMERICAN VOLUME

Registri Nazionali Artroprotesi



Rompere il femore?

Increased risk of intraoperative and early postoperative periprosthetic femoral fracture with uncemented stems

7,169 total hip arthroplasties from 8 Danish centers

Martin LINDBERG-LARSEN^{1,2}, Christoffer C JØRGENSEN^{3,2}, Søren SOLGAARD^{4,2}, Anne G KJERSGAARD^{4,2}, and Henrik KEHLET^{3,2}. On behalf of the Lundbeck Foundation Centre for Fast-Track Hip and Knee Replacement Collaborative Group⁵

Results — Of 7,169 primary consecutive THAs, 5,482 (77%) were performed using uncemented femoral components. The total incidence of periprosthetic femoral fractures \leq 90 days postoperatively was 2.1% (n = 150). 70 fractures were detected intraoperatively (46 required osteosynthesis). 51 postoperatively detected fractures occurred without trauma (42 of which were reoperated) and 29 were postoperative fall-related fractures (27 of which were reoperated). 134 fractures (2.4%) were found in uncemented femoral components and 16 (0.9%) were found in cemented femoral components (p < 0.001). Uncemented femoral stem (relative risk (RR) = 4.1, 95% CI: 2.3–7.2), medically treated osteoporosis (RR = 2.8, CI: 1.6–4.8), female sex (RR = 1.6, CI: 1.1–2.2), and age (RR = 1.4 per 10 years, CI: 1.2–1.6) were associated with increased risk of periprosthetic femoral fracture when analyzed using multivariable regression analysis.

Ask not what a Registry can do for you
Ask what you can do for a Registry



*Future orthopaedic surgeons
will not thank us
for establishing a Registry,
they will rather wonder
why it took us so long*



G.L.O.B.E.



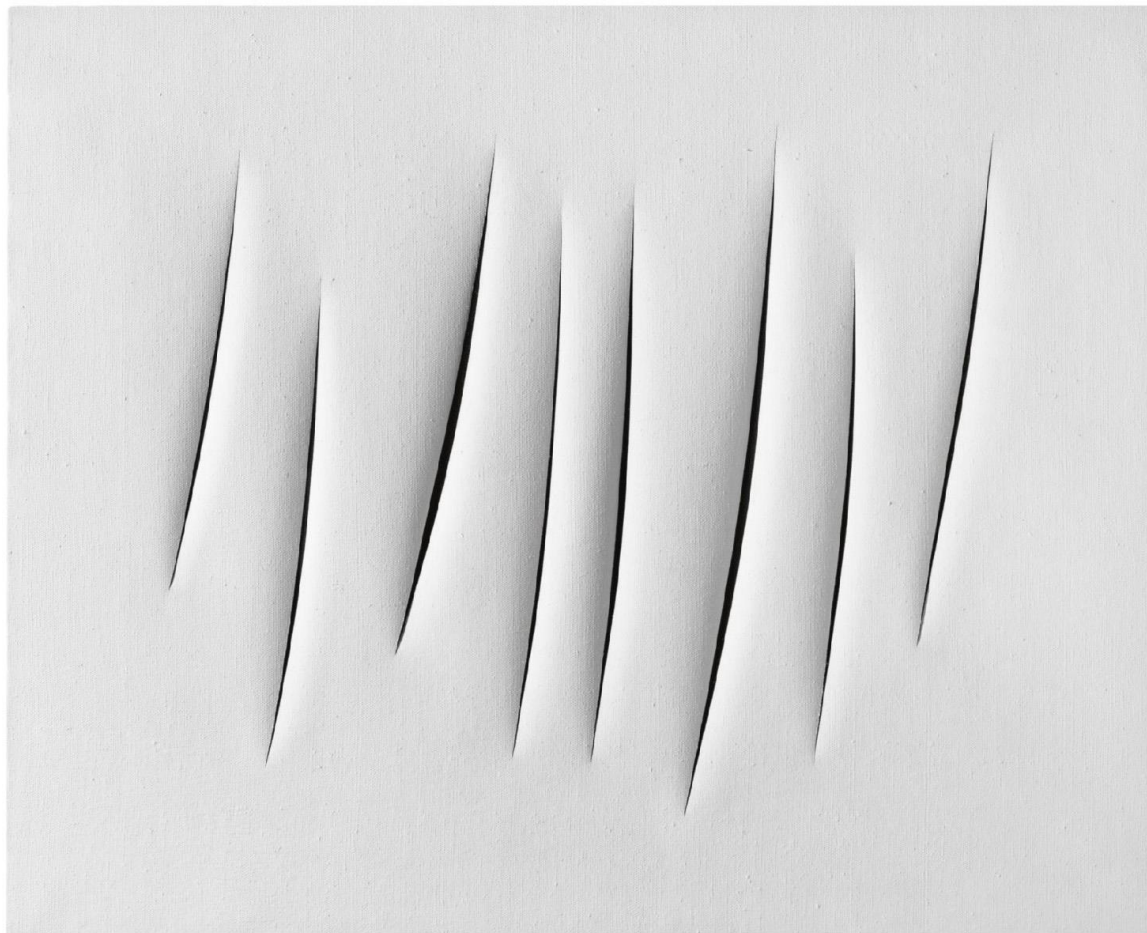
Registro Italiano ArtroProtesi

Report
Annuale 2020

Report RIAP 2020

- <https://riap.iss.it/riap/it/attivita/report/2021/10/29/registro-italiano-artroprotesi-report-annuale-2020/>

Vorreste essere un suo paziente?



Bad Science

Missing Data

Comparators

Sub-groups

A posteriori

“ideal patients”

Outsourcing

Per-protocol

Bad Pharma™

Ben Goldacre

Bestselling author of Bad Science

How drug companies
mislead doctors and
harm patients

364 pages



2017

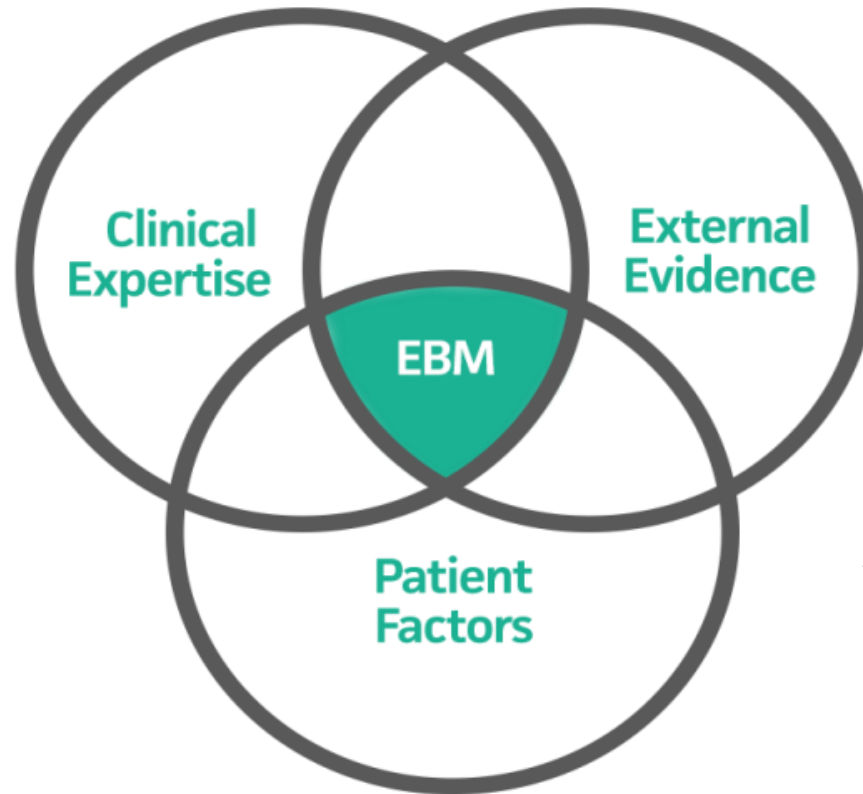


2021

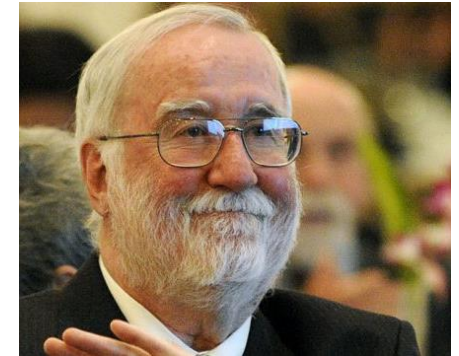


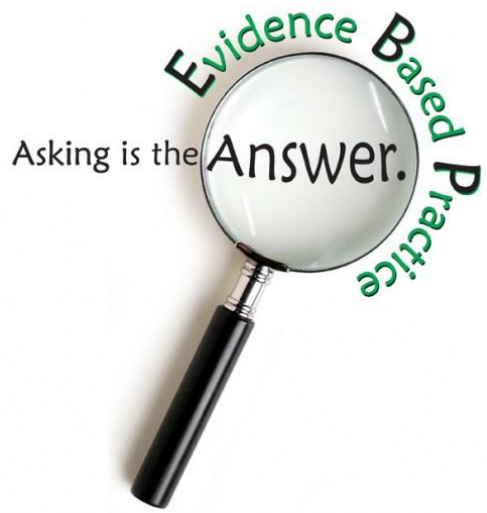
G.L.O.B.E.

La EBM costituisce un approccio alla pratica clinica dove le decisioni cliniche risultano dall'integrazione tra **l'esperienza del medico** e l'utilizzo coscienzioso, esplicito e giudizioso delle **migliori evidenze scientifiche disponibili**, mediate dalle **preferenze del paziente**.



David Sackett

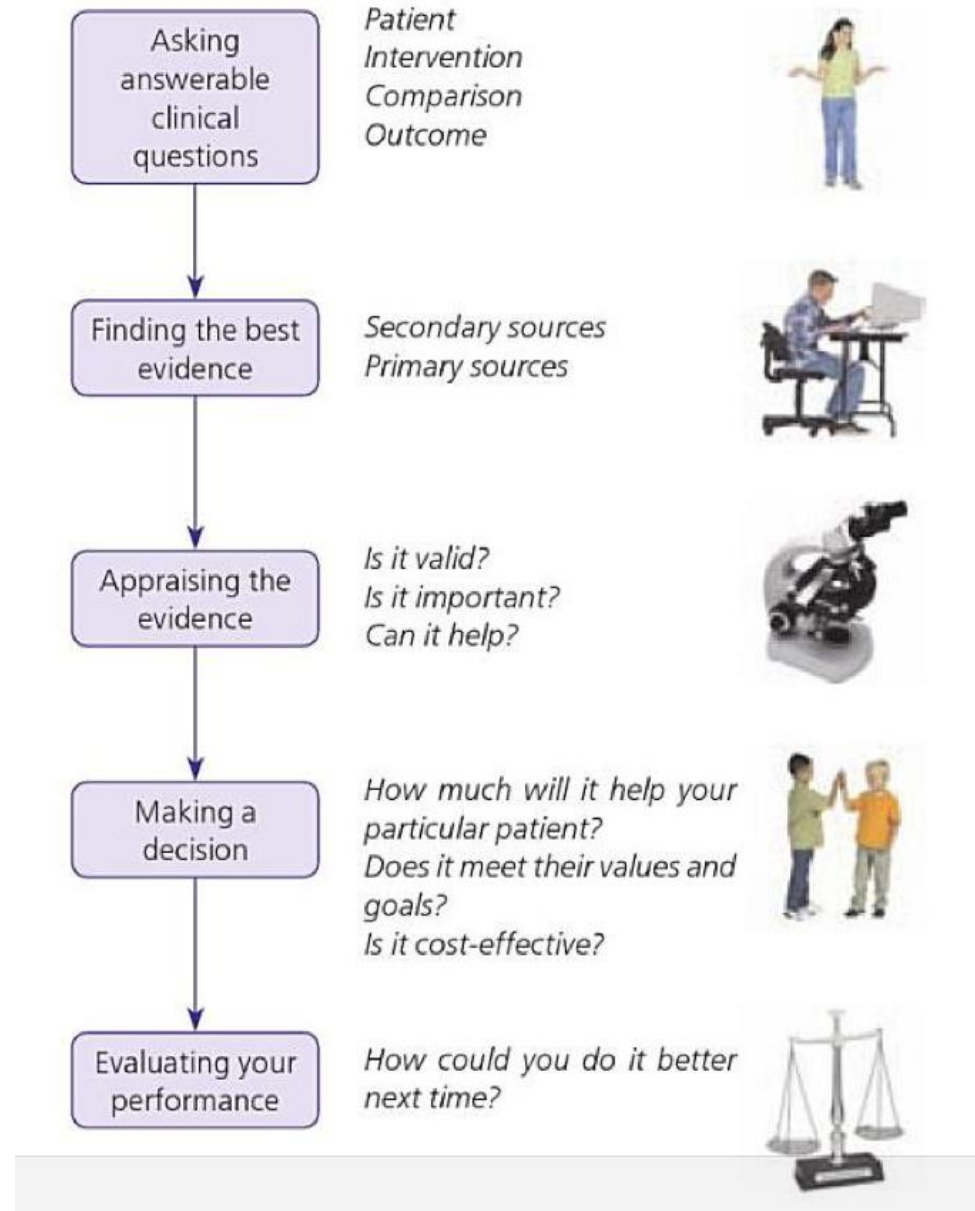




5 A's of Evidence Based Practice Process



- Ask
- Acquire
- Appraise
- Apply
- Analyze



Confronto

Serie di casi

- Utile solo a chi li ha trattati
- INUTILE AI CONGRESSI

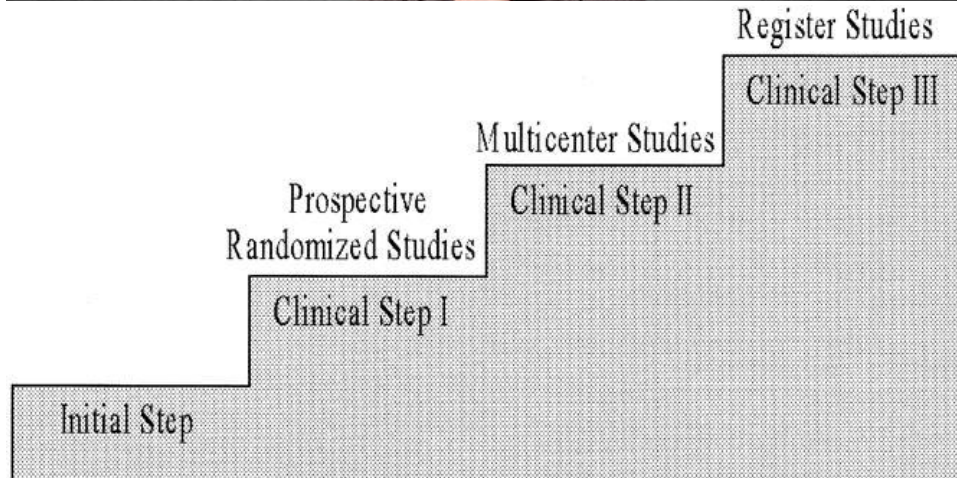
Confronti storici o quasi-random


- Prima-dopo, Uno sì e uno no
- (bias di selezione)


Randomizzazione corretta

- Pazienti assegnati a caso
- Nessuno deve essere in grado di prevedere in che gruppo finirà il prossimo paziente

Come si dovrebbe fare: Stepwise introduction



 The Journal of Arthroplasty
Volume 26, Issue 6, September 2011, Pages 825-831



The Stepwise Introduction of Innovation into Orthopedic Surgery: The Next Level of Dilemmas

Henrik Malchau MD, PhD ¹, Charles R. Bragdon PhD, Orhun K. Muratoglu PhD

AOA-COA Symposium

The Evidence-Based Approach in Bringing New Orthopaedic Devices to Market*

By Emil H. Schemitsch, MD, FRCS(C), Mohit Bhandari, MD, MSc, FRCS(C), Scott D. Boden, MD, Robert B. Bourne, MD, FRCS(C), Kevin J. Bozic, MD, MBA, Joshua J. Jacobs, MD, and Rad Zdero, PhD

RSA and Registries: The Quest for Phased Introduction of New Implants

Rob G.H.H. Nelissen, MD, PhD, Bart G. Pijls, MD, Johan Kärrholm, MD, PhD, Henrik Malchau, MD, PhD, Marc J. Nieuwenhuijse, MD, and Edward R. Valstar, MSc, PhD

Investigation performed at Leiden University Medical Center, Leiden, The Netherlands

Practical guide to the Idea, Development and Exploration stages of the IDEAL Framework and Recommendations

C. P. Pennell¹, A. D. Hirst², W. B. Campbell⁴, A. Sood², R. A. Agha⁵, J. S. T. Barkun⁶ and P. McCulloch³

¹Department of Surgery, Maimonides Medical Center, Brooklyn, New York, and ²Vattikuti Urology Institute, Henry Ford Hospital, Detroit, Michigan, USA, ³IDEAL Collaboration, Nuffield Department of Surgical Science, Oxford, and ⁴Interventional Procedures and Medical Technologies Advisory Committees, National Institute for Health and Care Excellence, and ⁵Department of Plastic Surgery, Guy's and St Thomas' NHS Foundation Trust, London, UK, and ⁶Department of Surgery, Division of Hepatobiliary and Transplant Surgery, McGill University Health Centre, Royal Victoria Hospital, Montreal, Quebec, Canada

BJR ■ **EDITORIAL**

The era of phased introduction of new implants



Come si fa di solito... (Lars Lidgren 1999)



**Between two evils,
I always pick the one I never tried before.**

“Mae West”



And Orthopaedic Surgeons ??

OR 99

Department of Orthopaedics, University Hospital Lund



G.L.O.B.E.

Luigi Pirandello

Sei personaggi
in cerca d'autore
Enrico IV



...terapie in cerca di autore...

- 1. novità
- 2. la imparo
- 3. mi chiedo a chi la posso applicare
- 4. se non c'è lo invento...

Lack of evidence—the anti-stepwise introduction of metal-on-metal hip replacements

A systematic review and a comparative assessment of the literature and registry data

Aleksi REITO¹, Lari LEHTOVIRTA^{1,2}, Olli LAINIALA¹, Keijo MÄKELÄ³, and Antti ESKELINEN¹

The very foundation of current health care management is to have a robust, evidence-based approach, characterized by the promotion of unbiased, highly reliable types of evidence.

Any innovation should work under ideal circumstances (“can it work?”) as well as the usual circumstances (“does it work in practice?”).

Unfortunately, orthopedics and especially the field of joint replacement surgery have had more than their fair share of **unsuccessful innovations that have violated these principles.**



Innovazioni di successo: sutura artroscopica di cuffia



Linee Guida SICSeG

Giornale Italiano di Ortopedia e Traumatologia
2021;47:6-25; doi: 10.32050/0390-0134-318

*Coordinamento del progetto
ed elaborazione del documento*

Roberto Padua
Gustavo Zanoli

Redazione

Marco Viganò

Linee Guida SICSeG

Il trattamento chirurgico delle rotture della cuffia dei rotatori in età adulta

BOX 2. Sulla chirurgia artroscopica nel trattamento delle lesioni della cuffia dei rotatori.

La sutura artroscopica della cuffia dei rotatori è stata proposta la prima volta nel 1980 ma ha preso piede negli anni '90, rivoluzionando il modo di approcciarsi alla chirurgia della spalla. Dopo lo scetticismo iniziale, oggi nessun chi-

ministratori, policy maker e pazienti) di sottoscrivere – separatamente dalle evidenze scientifiche – la seguente **PRESA DI POSIZIONE** (*Raccomandazione Forte, ma basata sul consenso di esperti*):

- **Si raccomanda di prendere in considerazione solamente la chirurgia artroscopica quale tecnica di prima scelta per la riparazione routinaria delle lesioni della cuffia dei rotatori, fatta eccezione per le lesioni isolate del sottoscapolare o lesioni massive che richiedano interventi comunque differenti dalla semplice sutura (trasposizioni tendinee, protesi ecc.).**
- **La tecnica a cielo aperto (nella sola accezione mini-open) deve essere considerata una tecnica di salvataggio per casi eccezionali e non può essere in nessun caso posta come indicazione elettiva di partenza. I chirurghi che intendano affrontare la patologia della cuffia dei rotatori devono necessariamente avere padronanza della tecnica artroscopica.**
- **Le strutture pubbliche e private dove si effettuano interventi di riparazione della cuffia dei rotatori devono necessariamente dotarsi di strumentazione artroscopica specifica per la spalla e assicurarsi che i chirurghi siano sufficientemente competenti nella metodica.**
- **In nessun modo la scelta di effettuare la chirurgia artroscopica deve comportare una perdita economica in termini di DRG, essendo peraltro più dispendiosa come utilizzo di materiali di consumo pur in assenza di differenze globali in termini di analisi costi-efficacia. Si invitano i sistemi sanitari regionali ad armonizzare le tariffe nel rispetto di una corretta codifica.**

Robotica



- RCT:
 - almeno 40 (pubmed)
 - 57 (Cochrane library)
- Revisioni Sistematiche:
 - Almeno 6 nel 2021!
 - 16-20 RCT inclusi



Università Commerciale Luigi Bocconi
Scuola Superiore Universitaria
Corso di Laurea Magistrale in Management

L'adozione delle innovazioni disruptive in ambito health care:

Il caso Mako

RELATORE: Prof.ssa Nicoletta Corrocher

CONTRORELATORE: Prof.ssa Paola Cillo

Tesi di laurea magistrale di **PAOLA GIUFFRIDA**

Matr. **1330935**

Anno accademico **2012/2013**

Robotica

- Conflitti di interesse

- Of the 54 studies meeting inclusion criteria, 49 (91%) had an author financial COI. Conflicted studies were more likely to report favorable results of robotics than nonconflicted studies.

- Dati da Registro Australiano

- + 34,2% nel 2020
- Restoris MCK 4,2 % di revisione a 5 anni
- Migliore UKR: 4,7%
- Migliori TKR: 2%
- Maggior rischio di revisione per infezioni

The Impact of Author Financial Conflicts on Robotic-Assisted Joint Arthroplasty Research

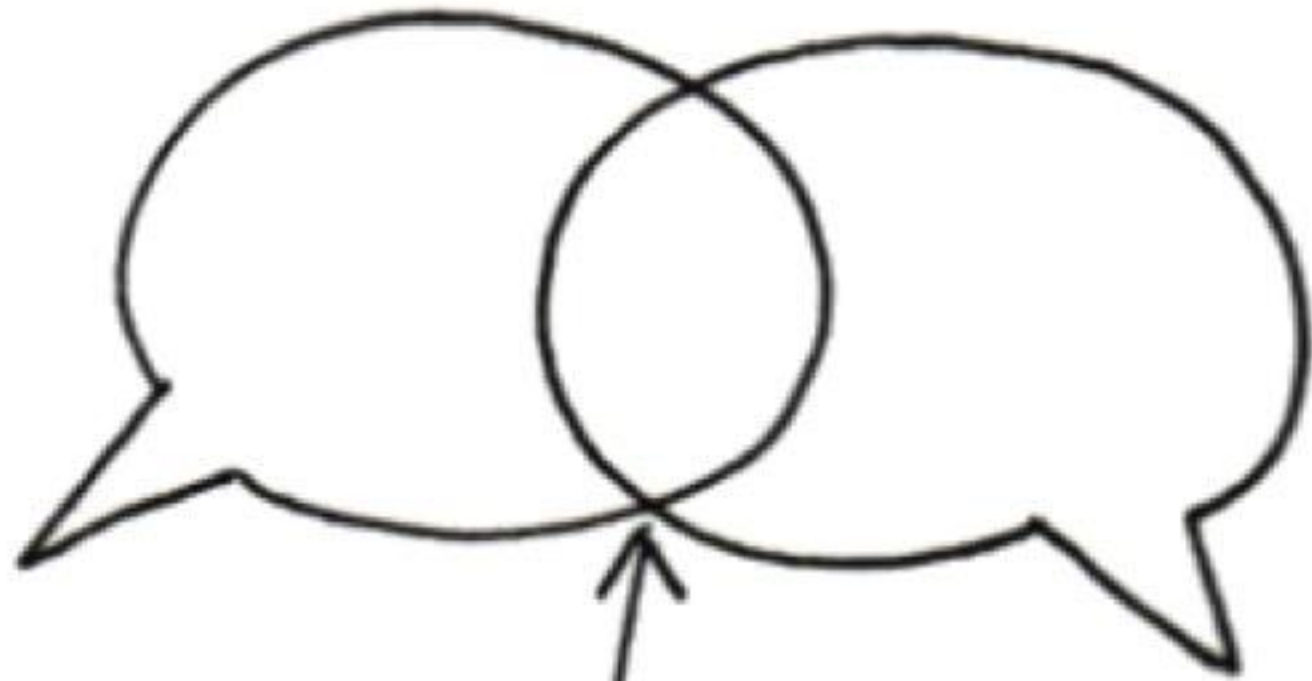
Michael J. DeFrance, DO • Michael F. Yayac, MD • P. Maxwell Courtney, MD, FRCS

Matthew W. Squire, MD

Australian Orthopaedic
Association National Joint
Replacement Registry

Hip, Knee & Shoulder Arthroplasty





Qui viene
il bello.

(This is the good stuff.)

Six proposals for EBM's Future



1. Don't skip "step 0", but foster doubt, **uncertainty** and honesty
2. Beware overdiagnosis: our definitions are as important as our tests
3. It is the patient's decision: practise and teach Shared Decision Making alongside EBM
4. **Take non-drug interventions as seriously as pharmaceuticals**
5. Build clinical practice "laboratories" to study translation and uptake
6. Invest long-term in automating evidence synthesis

Glasziou, BMJ Clinical Evidence 2015





The IDEAL Collaboration

Idea, Development, Exploration, Assessment, Long-term follow-up

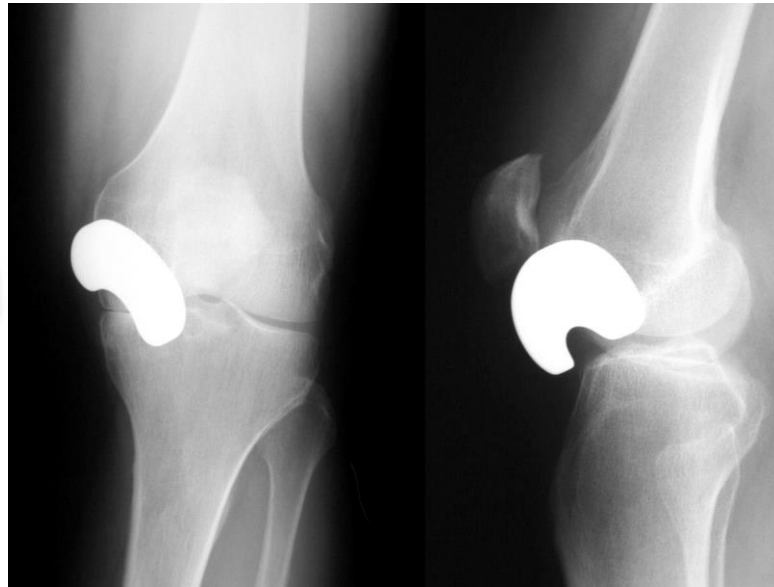
Table 1. Defining characteristics of IDEAL framework phases

Phase 1 IDEA	Phase 2a DEVELOPMENT	Phase 2b EXPLORATION	Phase 3 ASSESSMENT	Phase 4 LONG TERM MONITORING
Initial report Innovation may be planned, accidental or forced Focus on explanation and description	“Tinkering” (rapid iterative modification of technique and indications) Small experience from one centre Focus on technical details and feasibility	Technique now more stable Replication by others Focus on adverse effects and potential benefits Learning curves important Definition and quality parameters developed	Gaining wide acceptance Considered as possible replacement for current treatment Comparison against current best practice	Monitoring late and rare problems, changes in use

Table 2. Key recommendations for research design at each IDEAL phase

IDEA <i>Professional Innovation Database</i>	DEVELOPMENT <i>Prospective Development Studies</i>	EXPLORATION <i>Phase IIS Study</i>	ASSESSMENT <i>Surgical RCT</i>	LONG TERM MONITORING <i>Prospective Registries</i>
Compulsory reporting of all new innovations Confidential entry allowed to encourage reporting of failed innovations (similar to CHRP system) Hospital or institution to be informed separately as a professional duty	Detailed description of selection criteria Detailed technical description Prospective account of ALL cases consecutively, including those NOT treated with new technique/device Clear STANDARDISED definitions of outcomes reported Description of ALL modifications, and when they were made during the series Registration of PROTOCOL before study starts Use of Statistical Process Control (SPC) methods to evaluate progress	To evaluate technique prospectively and co-operatively To develop a consensus over <i>definition</i> of the procedure, <i>quality</i> standards and <i>indications</i> To gather <i>data</i> for <i>power calculations</i> To evaluate and monitor <i>learning curves</i> To achieve consensus on the <i>trial question</i> To develop a <i>multi-centre randomised trial (RCT)</i>	RCT – question agreed in Phase IIS Use power calculations from Phase IIS Use learning curve data to decide entry points for clinicians Use Phase IIS consensus to define operation, quality control AND outcome measures Use modified RCTs or recognised alternative if RCT not feasible: Feasibility RCT Expertise-based RCT Cohort multiple RCT Step-wedge design Controlled-interrupted time series	Should monitor indications as well as outcomes SPC used for quality control (Shewart charts, CUSUM, VLAD)


Innovazioni?



- 53 studi
- 74% placebo migliorati
- 51% non differenze

RESEARCH

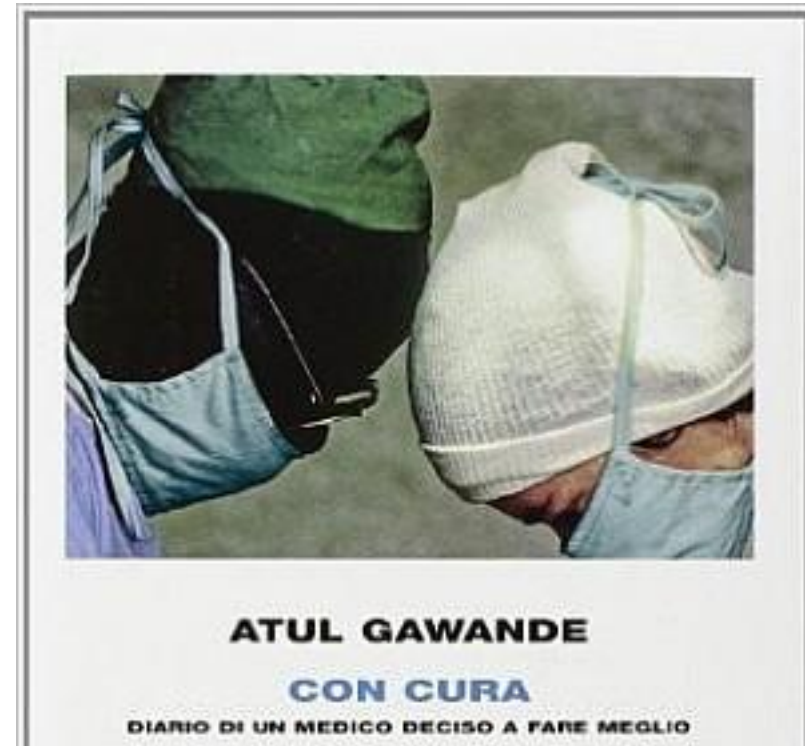
Use of placebo controls in the evaluation of surgery: systematic review

 OPEN ACCESS

Karolina Wartolowska *NDORMS research fellow*^{1 2}, Andrew Judge *university research lecturer*^{1 2 3}, Sally Hopewell *senior research fellow*^{2 4}, Gary S Collins *NDORMS senior research fellow*^{2 4}, Benjamin J F Dean *DPhil student*^{1 2}, Ines Rombach *statistician*^{1 2}, David Brindley *DPhil student*^{1 2 5 6}, Julian Savulescu *Uehiro chair in practical ethics*⁷, David J Beard *professor of musculoskeletal sciences*^{1 2 8}, Andrew J Carr *professor of orthopaedic surgery*^{1 2 8}

Atul Gawande - Better

- Diligence
 - Casualties of war
- Doing right
- Ingenuity



Ortopedici...incerti?

Clin Orthop Relat Res (2015) 473:3564–3572
DOI 10.1007/s11999-015-4304-z

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SYMPOSIUM: PSYCHOSOCIAL ASPECTS OF MUSCULOSKELETAL ILLNESS

Do Surgeons Treat Their Patients Like They Would Treat Themselves?

Clin Orthop Relat Res (2016) 474:1360–1369
DOI 10.1007/s11999-015-4623-0

Clinical Orthopaedics
and Related Research®
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CLINICAL RESEARCH

Do Orthopaedic Surgeons Acknowledge Uncertainty?

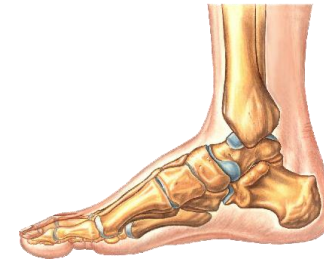
Teun Teunis MD, Stein Janssen MD, Thierry G. Guitton MD, PhD,
David Ring MD, PhD, Robert Parisien MD



Systematic Review

Low Level of Evidence and Methodologic Quality
of Clinical Outcome Studies on Cartilage Repair
of the Ankle

John M. Pinski, M.S., Lorraine A. Boakye, B.A., Christopher D. Murawski, B.S.,
Charles P. Hannon, B.S., Keir A. Ross, B.S., and John G. Kennedy, M.D., F.R.C.S.(Orth)



Most studies assessing the clinical outcomes of
cartilage repair of the ankle are of a **low level**
of evidence and of **poor methodologic quality**.





Systematic Review

Limitations and Sources of Bias in Clinical Knee Cartilage Research

Jamie Worthen, M.D., CPT Brian R. Waterman, M.D., MC, USA,
Philip A. Davidson, M.D., and James H. Lubowitz, M.D.



Table 2. Total number and overall rate of adverse events

Complications	Number of patients
Mortality and major complications	
Death	850 (0.83%)
Deep wound infection	270 (0.27%)
Organ/space infection	190 (0.19%)
Myocardial infarction	335 (0.33%)
Deep vein thrombosis	748 (0.73%)
Pulmonary embolism	405 (0.40%)
Stroke	145 (0.14%)
Coma	20 (0.02%)
Peripheral nerve injury	88 (0.09%)
Sepsis	518 (0.51%)
Septic shock	176 (0.17%)
Wound dehiscence	162 (0.15%)
Total major complications	3907
Minor complications	
Urinary tract infection	1534 (1.51%)
Pneumonia	616 (0.60%)
Superficial surgical site wound	685 (0.67%)
Wound dehiscence	162 (0.15%)
Total minor complications	2997
Total complications	6742

Table 3. Top 10 procedures with highest number of adverse events and adverse event rates

Rank	Procedure	CPT [®] code	Number of adverse events
1	Open treatment of femoral neck fracture, internal fixation or prosthetic replacement	27236	767 (27.41%)
2	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	27125	477 (26.18%)
3	ORIF intertrochanteric femur fracture with intramedullary implant	27245	695 (26.06%)
4	ORIF intertrochanteric femur fracture with plate and screw	27244	354 (24.07%)
5	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	27235	140 (15.87%)
6	Revision of THA	27134	191 (12.74%)
7	Revision of TKA, with or without allograft, 1 component	27486	103 (12.17%)
8	Lumbar arthrodesis	22612	208 (10.91%)
9	Revision of TKA, both femoral and tibial components	27487	134 (8.18%)
10	Laminectomy, single vertebral segment; lumbar	63047	155 (7.15%)
	Total		3224/6742 (47.8%)

CPT[®] = current procedure terminology; ORIF = open reduction and internal fixation.

Table 1. Top 30 orthopaedic surgery procedures in order of frequency

Rank	CPT [®] code	Procedure	Number of patients
1	27447	TKA	29,139 (28.61%)
2	27130	THA	17,645 (17.32%)
3	29881	Arthroscopy knee (chondroplasty), with meniscectomy (medial or lateral)	8791 (8.63%)
4	29827	Shoulder arthroscopy, rotator cuff repair	3516 (3.45%)
5	29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (list separately in addition to code for primary procedure)	3427 (3.36%)
6	29880	Arthroscopy, knee (chondroplasty), with meniscectomy (medial or lateral)	3215 (3.16%)
7	29888	Arthroscopically aided ACL	3077 (3.02%)
8	27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	2798 (2.75%)
9	27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture, with intramedullary implant	2667 (2.62%)
10	63030	Laminotomy (hemilaminectomy), with decompression of nerve root, lumbar	2421 (2.38%)
11	63047	Laminectomy, single vertebral segment, lumbar	2169 (2.13%)
12	23472	Total shoulder arthroplasty	1998 (1.96%)
13	22612	Arthrodesis lumbar	1906 (1.87%)
14	27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	1822 (1.79%)
15	27446	Arthroplasty, knee, condyle and plateau; medial or lateral compartment	1665 (1.63%)
16	27487	Revision of TKA, both femoral and tibial components	1639 (1.61%)
17	27134	Revision of THA	1499 (1.47%)
18	27244	ORIF of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture	1471 (1.44%)
19	29877	Arthroscopy knee, débridement/shaving of articular cartilage (chondroplasty)	1328 (1.30%)
20	27814	Open treatment of bimalleolar ankle fracture, including internal fixation	1219 (1.20%)
21	27792	ORIF of distal fibular fracture (lateral malleolus), including internal fixation	1018 (1.00%)
22	29807	Arthroscopy, shoulder, surgical; repair of slap lesion	997 (0.98%)
23	23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff), open; chronic	929 (0.91%)
24	27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	882 (0.87%)
25	63075	Discectomy, anterior, cervical, single interspace	864 (0.85%)
26	27486	Revision of TKA, with or without allograft; 1 component	846 (0.83%)
27	23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	749 (0.74%)
28	29806	Arthroscopy, shoulder, surgical; capsulorrhaphy	742 (0.73%)
29	22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace, cervical below C2	716 (0.70%)
30	22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace, single interspace; lumbar	707 (0.69%)

CPT[®] = Current Procedure Terminology; ORIF = open reduction and internal fixation.