



## On the Radar

Issue 398

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### On the Radar

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### The Implant Files: Deadly devices

<https://medicaldevices.icij.org/>

This past week has seen the release of the work of the International Consortium of Investigative Journalists (ICIJ) and its network of journalists and partner organisations looking into the issue of medical devices, including the regulation and safety of the many devices. Devices range from minor objects such as pins and screws through to life-saving (and high risk when they fail) devices such as pacemakers, defibrillators, heart valves, joint prostheses and implantable infusion pumps.

The project site is at <https://www.icij.org/investigations/implant-files/> with the database available at <https://medicaldevices.icij.org/>

These issues have now been widely reported. A selection of the coverage includes:

#### ICIJ

*Medical Devices Harm Patients Worldwide As Governments Fail On Safety*

<https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/>

*Patients Fight For Answers As Broken Implants Cause Unseen Agony*

Woodman S

<https://www.icij.org/investigations/implant-files/patients-fight-for-answers-as-broken-implants-cause-unseen-agony/>

## **BMJ**

*Medical device industry: international investigation exposes lax regulation*

Lenzer J

BMJ. 2018;363:k4997.

<https://doi.org/10.1136/bmj.k4997>

*Surgeons call for compulsory registers of all new medical devices*

Coombes R

BMJ. 2018;363:k5010.

<https://doi.org/10.1136/bmj.k5010>

*FDA recommends “modernizing” review of devices in wake of global investigation*

Lenzer J

BMJ. 2018;363:k5026.

<https://doi.org/10.1136/bmj.k5026>

*How lobbying blocked European safety checks for dangerous medical implants*

Bowers S, Cohen D

BMJ. 2018;363(k4999).

<https://doi.org/10.1136/bmj.k4999>

*What happens when the world’s biggest medical device maker becomes a “health services provider”?*

Lenzer J

BMJ. 2018;363:k4917.

<https://doi.org/10.1136/bmj.k4917>

## **ABC**

*The Implant Files: Deadly devices*

<https://www.abc.net.au/news/2018-11-26/implant-files-shine-light-on-medical-device-industry/10521480>

Radio National, Health Report, *How can we improve medical device safety in Australia?*

<https://www.abc.net.au/radionational/programs/healthreport/mandatory-reporting-key-to-improving-medical-device-safety/10556022>

Radio National, Background Briefing

*The Implant Files (Part 1)*

<https://www.abc.net.au/radionational/programs/backgroundbriefing/global-investigation-reveals-extent-of-harm-by-medical-devices/10552726>

*The Implant Files (Part 2)*

<https://www.abc.net.au/radionational/programs/backgroundbriefing/medical-device-manufacturers-exploit-regulatory-loopholes/10567418>

ABC TV, 730 Report, *Some medical implants putting patients at risk*

<https://www.abc.net.au/news/2018-11-26/some-medical-implants-putting-patients-at-risk/10556478>

*The Implant Files reveal how breast implants linked to rare cancer set off alarm bells*

<https://www.abc.net.au/news/2018-11-27/implant-files-breast-implants-probe-exposes-tga-flaws/10496080>

*Fay Sherret died after being infected with deadly bacteria and global authorities knew the risks*  
<https://www.abc.net.au/news/2018-11-27/fay-sherret-died-after-being-infected-with-deadly-bacteria/10558770>

**The Guardian**

*Revealed: faulty medical implants harm patients around world*  
<https://www.theguardian.com/society/2018/nov/25/revealed-faulty-medical-implants-harm-patients-around-world>

*The Guardian view on medical implants: patients need protecting (editorial)*  
<https://www.theguardian.com/commentisfree/2018/nov/26/the-guardian-view-on-medical-implants-patients-need-protecting>

**Reports**

*Reducing opioid-related harm: a hospital pharmacy landscape paper*  
 The Society of Hospital Pharmacists of Australia  
 Collingwood: SHPA; 2018. p. 52.

URL	<a href="https://www.shpa.org.au/news/landmark-report-reveals-urgent-collaboration-needed-stem-looming-opioid-epidemic">https://www.shpa.org.au/news/landmark-report-reveals-urgent-collaboration-needed-stem-looming-opioid-epidemic</a>
Notes	The Society of Hospital Pharmacists of Australia has produced this report examining current hospital pharmacy practices in Australia around opioids. The report looks at the link between the prescribing and supply of opioids to patients after surgery in public and private hospitals nationally and the heightened risk of long-term misuse and dependence. This analysis suggests an urgent need for a coordinated, multidisciplinary response. The report suggests that the inconsistencies in provision of pharmacy services that could reduce risk of opioid misuse, extremely high use of sustained release opioids and poor handover of discharge information for use by General Practitioners. The data used in the analysis has been collected from 135 metropolitan, regional and rural Australian facilities. The report includes 33 recommendations to scale up proven local strategies to improve patient care nationwide, as relevant to pharmacy, medical and nursing, consumer and government stakeholder groups.

For information about the Commission’s work on medication safety, see  
<https://www.safetyandquality.gov.au/our-work/medication-safety/>

*Stemming the Superbug Tide: Just A Few Dollars More*  
 Organisation for Economic Cooperation and Development  
 Paris: OECD Publishing; 2018. p. 224.

URL DOI	<a href="http://www.oecd.org/health/stepping-the-superbug-tide-9789264307599-en.htm">http://www.oecd.org/health/stepping-the-superbug-tide-9789264307599-en.htm</a> <a href="https://doi.org/10.1787/9789264307599-en">https://doi.org/10.1787/9789264307599-en</a>
Notes	This report from the OECD suggests that ‘superbug’ infections could cost the lives of around 2.4 million people in Europe, North America and Australia over the next 30 years unless more is done to stem antibiotic resistance. However, it also contends, three out of four deaths could be averted by spending just USD 2 per person a year on measures as simple as handwashing and more prudent prescription of antibiotics. The argument put forward is that short-term investment to stem the superbug tide would save lives and money in the long run. The authors call for a five-pronged assault on antimicrobial resistance -- by promoting <b>better hygiene</b> , ending the <b>over-prescription of antibiotics</b> , <b>rapid testing</b> for patients to determine whether they have viral or bacterial infections, <b>delays in prescribing antibiotics</b> and mass <b>media campaigns</b> .

	<p>Along with the report, a Policy Brief, Executive Summary, Key findings for selected countries, including Australia, Press release, and an interactive maps are available at <a href="http://www.oecd.org/health/stemming-the-superbug-tide-9789264307599-en.htm">http://www.oecd.org/health/stemming-the-superbug-tide-9789264307599-en.htm</a></p> <p>The key findings sheet for Australia notes that:</p> <ul style="list-style-type: none"> <li>• It is estimated that an average of 290 persons die each year in Australia due to infections from eight resistant bacteria. By 2050, an estimated total of 10 430 persons will die due to AMR (antimicrobial resistance).</li> <li>• By 2050, health care costs in Australia could reach \$370 million.</li> <li>• Australia has a national AMR plan that reflects Global Action Plan objectives, with an operational plan and monitoring arrangements, in line with what most OECD countries are doing in this area.</li> <li>• An antimicrobial stewardship programme is implemented in most health care facilities nationwide, in line with what most OECD countries are doing in this area.</li> <li>• Australia has nationwide awareness-raising campaigns targeting the majority of stakeholders with no monitoring mechanisms, lagging behind what most OECD countries are doing in this area.</li> <li>• AMR is incorporated in curricula and continuing medical education for all relevant health cadres in Australia, in line with what most OECD countries are doing in this area.</li> <li>• A broad policy package combining stewardship programmes, enhanced environmental hygiene, mass media campaigns, and rapid diagnostic testing could avert 180 deaths and save 15 million dollars per year in Australia.</li> </ul>
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For information about the Commission’s work on antimicrobial use and resistance in Australia, see <https://www.safetyandquality.gov.au/antimicrobial-use-and-resistance-in-australia/>

For information about the Commission’s work on healthcare associated infection, see <https://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/>

## Journal articles

*Overdiagnosis of Penicillin Allergy Leads to Costly, Inappropriate Treatment*

Rubin R

Journal of the American Medical Association. 2018;320(18):1846-8.

DOI	<a href="https://doi.org/10.1001/jama.2018.14358">https://doi.org/10.1001/jama.2018.14358</a>
Notes	<p>This commentary looks at an issue that has been attracting some interest in this era when antimicrobial resistance and scarcity of antimicrobial development have generated some concern about a reduced repertoire of antimicrobials. Penicillin allergy is apparently quite widespread; but the question is to how much of this is known, presumed and even challenged. The author notes that “penicillin is ...the most commonly implicated medication when patients report a drug allergy. Approximately 10% of US residents have been labeled as allergic to penicillin, often since childhood.” But the issue is that “a growing body of evidence suggests that as few as 10% of people who report they’re allergic to the antibiotic really are.” But once someone is labelled as such, “it’s rarely questioned, and the label sticks, increasing the patient’s risk of receiving suboptimal antibiotic therapy.” The piece looks at how these beliefs can be safely challenged and more appropriate antimicrobials used.</p>

*Factors influencing early and late readmissions in Australian hospitalised patients and investigating role of admission nutrition status as a predictor of hospital readmissions: a cohort study*

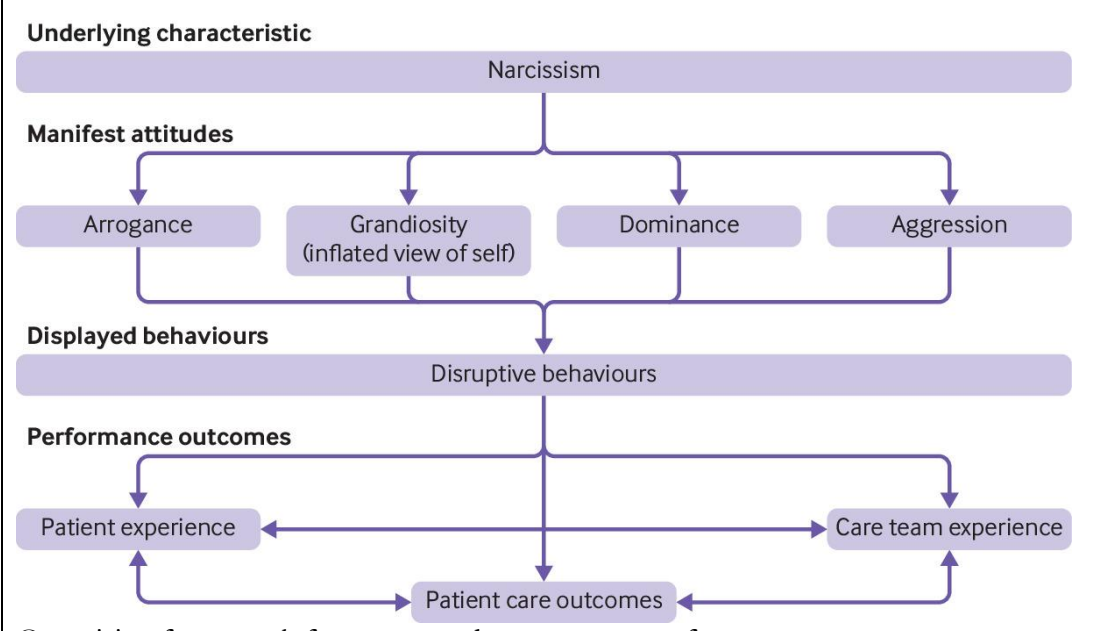
Sharma Y, Miller M, Kaambwa B, Shahi R, Hakendorf P, Horwood C, et al  
 BMJ Open. 2018;8(6).

DOI	<a href="https://doi.org/10.1136/bmjopen-2018-022246">https://doi.org/10.1136/bmjopen-2018-022246</a>
Notes	<p>This Australian study sought to identify possible predictors of early and late readmissions to hospital, particularly whether nutrition status during the initial (or index) hospitalisation can be used as a “modifiable predictor of unplanned hospital readmissions”. Using data from two tertiary-level hospitals on all medical admissions of adult over the course of 1 year, the researchers found:</p> <ul style="list-style-type: none"> <li>• <b>Malnourished</b> patients had a <b>higher risk</b> of both early and late <b>readmissions</b></li> <li>• <b>Weekend discharges</b> were <b>less likely</b> to be associated with both early and late <b>readmissions</b></li> <li>• <b>Indigenous Australians</b> had a <b>higher risk</b> of <b>early readmissions</b></li> <li>• Patients <b>living alone</b> had a <b>higher risk</b> of <b>late readmissions</b></li> <li>• Patients <b>≥80 years</b> had a <b>lower risk</b> of <b>early readmissions</b></li> <li>• Admission to <b>intensive care unit</b> was associated with a <b>lower risk</b> of <b>late readmissions</b>.</li> </ul> <p>The authors suggest that “<b>Targeted nutrition</b> intervention may <b>prevent unplanned hospital readmissions</b>.”</p>

*Excising the “surgeon ego” to accelerate progress in the culture of surgery*

Myers CG, Lu-Myers Y, Ghaferi AA

BMJ. 2018;363:k4537.

DOI	<a href="https://doi.org/10.1136/bmj.k4537">https://doi.org/10.1136/bmj.k4537</a>
Notes	<p>Concerns about culture, including bullying, have emerged in many settings in many countries. This piece in the <i>BMJ</i> looks at the ‘surgeon ego’ and how the need for ‘healthy self-confidence’ should not be allowed to develop into a disruptive and destructive force. The authors argue that the “the field at large must reiterate its commitment—in both word and deed—to selecting, training, and maintaining a population of surgeons prepared to act and interact in ways that deliver the best outcomes to patients in the modern healthcare environment.”</p>  <p>The flowchart illustrates the relationship between underlying characteristics, manifest attitudes, displayed behaviours, and performance outcomes. It starts with 'Narcissism' as the underlying characteristic, which leads to four manifest attitudes: 'Arrogance', 'Grandiosity (inflated view of self)', 'Dominance', and 'Aggression'. These attitudes lead to 'Disruptive behaviours', which then impact 'Performance outcomes' in terms of 'Patient experience', 'Care team experience', and 'Patient care outcomes'. There are feedback loops between patient and care team experience, and between care team experience and patient care outcomes.</p> <p>Organising framework for causes and consequences of surgeon ego</p>

*Looking beyond Mortality in Transplantation Outcomes*

Lamas DJ, Lakin JR, Trindade AJ, Courtwright A, Goldberg H  
 New England Journal of Medicine. 2018;379(20):1889-91.

DOI	<a href="https://doi.org/10.1056/NEJMp1806950">https://doi.org/10.1056/NEJMp1806950</a>
Notes	The latter part of the 20 <sup>th</sup> century and the first decades of the 21 <sup>st</sup> have seen transplantation surgery move from pioneering with often heartbreaking failure to almost routine with survival expected. In light of this is this Perspective piece that suggests that there is a need to look beyond survival and look at other aspects of outcomes, such as quality of life.

*Not all organ dysfunctions are created equal – Prevalence and mortality in sepsis*

Capan M, Hoover S, Ivy JS, Miller KE, Arnold R  
 Journal of Critical Care. 2018;48:257-62.

DOI	<a href="https://doi.org/10.1016/j.jcrc.2018.08.021">https://doi.org/10.1016/j.jcrc.2018.08.021</a>
Notes	Sepsis is a common and potentially dangerous occurrence. This US study sought to identify specific symptoms (of particular organ dysfunction) that put patients at the greatest risk of dying from sepsis. Early recognition and response to sepsis can be vital to reducing sepsis morbidity and mortality. The authors report finding that “Highest odds ratio (OR) associated with increased mortality risk was identified as <b>fraction of inspired oxygen</b> (FiO <sub>2</sub> ) > 21% (OR = 5.8 and 95% Confidence Interval (CI) 1.8–35.6), and <b>elevated lactate</b> >2.0 mmol/L (OR = 2.45 (95% CI = 2.1–2.8)).” The most commonly observed measures of “organ dysfunction within mortality visits included elevated lactate (> 2.0 mmol/L), mechanical ventilation, and oxygen saturation (SpO <sub>2</sub> )/FiO <sub>2</sub> ratio (< 421) at least once within 48 h prior to or 24 h after anti-infective administration.” The study found that patients with worsening <b>kidney function</b> had the highest mortality rate, followed by those requiring <b>mechanical ventilation</b> , while <b>hypotension</b> was linked with lower mortality rates. The researchers also found that treating patients for an infection within 24 hours of being admitted to the hospital significantly lowered their risk of dying.

*American Journal of Medical Quality*

Volume: 33, Number: 6 (November/December)

URL	<a href="http://journals.sagepub.com/toc/ajmb/33/6">http://journals.sagepub.com/toc/ajmb/33/6</a>
Notes	A new issue of the <i>American Journal of Medical Quality</i> has been published. Articles in this issue of <i>American Journal of Medical Quality</i> include: <ul style="list-style-type: none"> <li>• Interprofessional Rounds Improve Timing of Appropriate <b>Palliative Care Consultation</b> on a Hospitalist Service (Rafina Khateeb, Margaret R Puelle, Janice Firn, D’Anna Saul, Robert Chang, and Lillian Min)</li> <li>• Improved Outcomes With <b>Integrated Intensivist Consultation for Cardiac Surgery Patients</b> (Omer W Sultan, Lori L Boland, Tyler G Kinzy, Roman R Melamed, Susan C Seatter, Robert S Farivar, Lisa L Kirkland, and M Mulder)</li> <li>• Effect of <b>Ambulatory Transitional Care Management on 30-Day Readmission Rates</b> (Jonathan Ballard, Wade Rankin, Karen L Roper, Sarah Weatherford, and Roberto Cardarelli)</li> <li>• Evaluation of a <b>Distance Learning Curriculum for Interprofessional Quality Improvement Leaders</b> (Megan E Gregory, Jennifer L Bryan, Sylvia J Hysong, Isabelle S Kusters, Rebecca S Miltner, Diana E Stewart, Natalie Polacek, LeChauncy D Woodard, J Anderson, A D Naik, and K M Godwin)</li> <li>• Assessing the Impact of an <b>Order Panel Utilizing Weight-Based Insulin and Standardized Monitoring of Blood Glucose for Patients With Hyperkalemia</b> (Kelby Brown, Jr, Tracy L Setji, Sarah L Hale, April Cooper, Beatrice Hong, R</li> </ul>



	<p>Herbst, R C Musser, S Freeman, T Shaikewitz, J Greenlee, and N P Setji)</p> <ul style="list-style-type: none"> <li>• Measuring Value in Internal Medicine Residency Training Hospitals Using Publicly Reported Measures (Adam Schickedanz, Reshma Gupta, Vineet M Arora, and Clarence H Braddock, III)</li> <li>• Using HFACS-Healthcare to Identify <b>Systemic Vulnerabilities During Surgery</b> (Tara N Cohen, Sarah E Francis, Douglas A Wiegmann, Scott A Shappell, and Bruce L Gewertz)</li> <li>• Descriptive Analysis of Associated Factors for Urgent Versus Nonurgent <b>Inpatient Spine Transfers</b> to a Tertiary Care Hospital (Gregory D Schroeder, James C McKenzie, David S Casper, Seth Stake, Joseph Buchholz, Chris Kepler, Jeffery A Rihn, Barret I Woods, K E Radcliff, I D Kaye, K Nicholson, D G Anderson, A S Hilibrand, A R Vaccaro, S Khan, and M F Kurd)</li> <li>• <b>Handoff Tool Enabling Standardized Transitions</b> Between the Emergency Department and the Hospitalist Inpatient Service at a Major Cancer Center (Carmen E Gonzalez, Norman Brito-Dellan, Srinivas R Banala, David Rubio, Mohamed Ait Aiss, T W Rice, K Chen, D C Bodurka, and C P Escalante)</li> <li>• Patterns of <b>Narcotic Prescribing by Orthopedic Surgeons</b> for Medicare Patients (Matthew R Boylan, Kelly I Suchman, J D Slover, and J A Bosco)</li> <li>• Delivery of <b>Standardized Patient Instructions</b> in the After-Visit Summary Reduces Telephone Calls Between Clinic Visits (Stefanie Deeds, Stephanie Carr, Michelle Garrison, and Tyra Fainstad)</li> <li>• Patient Adoption and Utilization of a Web-Based and Mobile-Based <b>Portal for Collecting Outcomes</b> After Elective Orthopedic Surgery (Kerri Bell, Eugene Warnick, K Nicholson, S Ulcoq, S J Kim, G D Schroeder, and A Vaccaro)</li> <li>• A Health Plan's Journey to <b>Identifying Meaningful Quality Measures</b> (Misty Roberts, Faith Green, and Worthe Holt)</li> <li>• Are We Confident of <b>Across-Hospital Mortality Comparisons?</b> (Richard L Fuller, John S Hughes, Norbert I Goldfield, and Graham Atkinson)</li> <li>• A <b>Patient-Centered Measure Reduction Strategy</b>: Three Lenses of Value (Umbereen S Nehal, Jack Maypole, and Matthew Sadof)</li> <li>• Effect of a Resident-Led ICD-10 Code-Focused Review of <b>Inpatient Documentation on Length of Stay</b> (Rachel E Elam, Monique Bethel, P C Brown, G Collins, R L Perry, L Merchen, D J Fallaw, and N S Nahman, Jr)</li> </ul>
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*BMJ Quality and Safety* online first articles

URL	<a href="https://qualitysafety.bmj.com/content/early/recent">https://qualitysafety.bmj.com/content/early/recent</a>
Notes	<p><i>BMJ Quality and Safety</i> has published a number of 'online first' articles, including:</p> <ul style="list-style-type: none"> <li>• <b>Reducing hospital admissions for adverse drug events</b> through coordinated pharmacist care: learning from Hawai'i without a field trip (Michael A Steinman)</li> <li>• <b>Physician characteristics</b> associated with <b>patient experience scores</b>: implications for adjusting public reporting of individual physician scores (Kathryn Elizabeth Engelhardt, Richard S Matulewicz, John O DeLancey, Ryan P Merkow, Christopher M Quinn, Lindsey Kreutzer, Karl Y Bilimoria)</li> </ul>

*International Journal for Quality in Health Care* online first articles

URL	<a href="https://academic.oup.com/intqhc/advance-access">https://academic.oup.com/intqhc/advance-access</a>
Notes	<i>International Journal for Quality in Health Care</i> has published a number of 'online first' articles, including:

- Coping with more people with more illness. Part 2: new generation of **standards for enabling healthcare system transformation and sustainability** (Jeffrey Braithwaite; Charles Vincent; W Nicklin; R Amalberti)

## Online resources

[UK] National Institute for Health Research

<https://discover.dc.nihr.ac.uk/portal/search/signals>

The UK's National Institute for Health Research (NIHR) Dissemination Centre has released the latest 'Signals' research summaries. This latest release includes:

- Partial **knee replacements** may save costs compared with total knee replacements
- Intravenous oxytocin reduces severe bleeding after **vaginal delivery**
- Steroids rapidly reduce children's **croup** symptoms and shorten hospital stays
- Routine use of a mechanical compression device is no better than manual chest compression in **cardiac arrest**
- **Insulin pumps** offer little value over multiple injections for children at the onset of diabetes
- **Telemedicine** programme can prolong life for **heart failure patients**
- **Delirium** is common among adults receiving palliative care and could be better recognised
- Cognitive behavioural therapy may not work for people with **schizophrenia** who haven't completely responded to drug treatment
- **Joint infection** after **hip replacement** is linked to some risk factors that could be modified
- **Abdominal aortic aneurysm screening** for women is unlikely to be a fair use of resources.

[WHO] Handle antibiotics with care in surgery

[https://www.who.int/infection-prevention/tools/surgical/infographic\\_SSI.pdf?ua=1](https://www.who.int/infection-prevention/tools/surgical/infographic_SSI.pdf?ua=1)

The World Health Organization has produced this infographic on the use of antibiotics in surgery.

**HANDLE ANTIBIOTICS WITH CARE**

**HANDLE ANTIBIOTICS WITH CARE IN SURGERY**  
Misuse of antibiotics puts all surgical patients at risk

World Health Organization

Up to **33%** of surgical patients get a postoperative infection, of which **51%** can be antibiotic resistant

Up to **15%** of women around the world get an infection after a caesarean section

**43%** of patients have surgical antibiotic prophylaxis (SAP) inappropriately continued after the operation

**REDUCE** the risk of surgical site infection (SSI) by improving SAP and infection prevention and control practices

**IMPROVE** quality of care and patient safety and reduce antimicrobial resistance (AMR) through SSI reduction

**WHAT SHOULD HEALTH WORKERS DO TO PREVENT AMR IN SURGERY?**

Give intravenous SAP  
- when recommended, depending on the type of operation  
- within 120 minutes preceding surgical incision

For effective SAP, adequate antibiotic tissue concentrations should be present at the time of surgical incision and throughout the procedure. Thus, antibiotics with a short half-life should be administered closer to incision time.

Improvement of antibiotic use in surgical services should be part of the antimicrobial stewardship programme

**WHO SHOULD BE INVOLVED IN ENSURING APPROPRIATE ANTIBIOTIC USE IN SURGERY**

SURGEONS, ANAESTHETISTS, OPERATING ROOM NURSES, INFECTIOUS DISEASES DOCTORS, INFECTION PREVENTION & CONTROL TEAM, SURGICAL WARD STAFF, PHARMACISTS, SENIOR MANAGERS AND PROCUREMENT STAFF, PATIENTS AND THEIR FAMILIES (CIVIL SOCIETY)

**WHAT SHOULD YOU NOT DO?**

Avoid prolonging SAP postoperatively

Avoid antibiotic wound irrigation

Avoid continuing antibiotic prophylaxis because there is a drain (evaluate each case)

Avoid giving antibiotic treatment unless there is a proven or suspected SSI or other infection

These recommendations are based on evidence from studies in adult patients, but they are considered valid also for paediatric patients

**HEALTH CARE WITHOUT AVOIDABLE INFECTIONS**

[www.who.int/infection-prevention/publications/ssi-guidelines/en](http://www.who.int/infection-prevention/publications/ssi-guidelines/en)



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