Finding the right Medical Device information in Scientific Literature

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Agenda

In this presentation, we will discuss:

- **New Medical Device Regulations (MDR 2017/745) and Medical Device Guidelines (MEDDEV 2.7/1 rev 4) and their implications**
- **How Embase addresses these requirements**
- **(Case study) How to design effective literature searches for Clinical Evaluation Reports to identify:**
  - **Device performance**
  - **Comparison of device with existing device(s)**
  - **Adverse device effects**
- **How to set a scheduled search for Post-Market Surveillance (PMS)**

European Medical Device Regulations (MDR 2017/745) and a revised CER guidance (MEDDEV 2.7/1 rev 4) reflect more stringent requirements for clinical data

New European **Medical Device Regulations (MDR 2017/745)** and a **revised CER guidance (MEDDEV 2.7/1 rev 4) have been released**. Both documents reflect more stringent requirements for clinical data.

MEDDEV 2.7/1 rev 4	MDR 2017/745
June 2016	May 2017

The relevant guidelines should be applied to all medical devices sold in European Union, including those manufactured elsewhere. If a company plans to sell a medical devices in Europe, it must produce and maintain a **Clinical Evaluation Report (CER).**

Post-market surveillance (PMS) is an integral part of the European Medical Device Regulation (MDR), nicely aligned with the requirement to evaluate medical device thorough the life-cycle of the product.

EU Medical Devices Regulation timelines: three-year transition period ending in 2020

On April 5, 2017 the EU adopted the new Medical Device Regulations (**MDR 2017/745**), replacing the two existing directives, the Medical Devices Directive (MDD) and the Active Implantable Medical Devices (AIMD) Directive.

The new regulation will enter into force after a **three-year transition period ending in spring 2020**. This means that the market access framework for all member countries of the European single market (EU member states including the UK, the members of the EEA – Iceland, Lichtenstein and Norway, and through bilateral treaties Switzerland) will change significantly.

Timelines

- April 5, 2017: The EU Medical Device Regulation was adopted.
- May 5, 2017: The Regulation was published in the Official Journal of the European Union.
- **May 26, 2017: The Regulation entered into force and will apply in parallel with the current medical devices directive MDD 93/42/EEC for a transition period of three years.**
- December, 2017: The process of re-designating Europe's Notified Bodies under the new regulation begins. The first designations are expected to be finalized 12 to 18 months from the date of publication of the legislation.
- **May 25, 2020: The transition period ends and Medical Devices Regulation becomes mandatory.**

MDR will address inherent weaknesses in old directives and rapid evolution of science and technology in the field of medical devices

Compared to the MDD, MDR 2017/745 introduces:

- **Life-cycle approach to ongoing CE Marking compliance**. Conformity assessment procedures are more complex, and equivalence will be more rigorously interpreted
- Clinical data and **Clinical Evaluation Report** (CER) will face heavy scrutiny and require recurring updates
- Reinforcement of the criteria for designation and processes for **oversight of Notified Bodies**
- Improved transparency through the establishment of a comprehensive **EU database on medical devices** and of a **device traceability system** based on Unique Device Identification
- Inclusion of certain **aesthetic devices** which present the same characteristics and risk profile as analogous medical devices
- Introduction of an "**implant card**" containing information about implanted medical devices for a patient
- Manufacturers must fulfill **increased post-market surveillance requirements**, perform more **Post-Market Clinical Follow-up** (PMCF) studies, and deliver **Periodic Safety Update Reports** (PSUR) for class IIa devices and above

Post-market surveillance (PMS) shall be proportionate to the risk class

For each medical device, whether it is a high risk active implant or a low risk walking aid, **post-marketing data shall be collected**.

MDR outlines that the **PMS system shall be proportionate to the risk class** of the device. Previously, a reactive approach for lower risk devices, e.g. in the form of vigilance registries, would be acceptable, as long as strong clinical evidence for safety and performance was expected based on pre-market data.

Currently, it is more likely that your Notified Body requires you to **proactively collect data** on the clinical safety and clinical performance of your device, **regardless of its classification**.

'*for any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system.' MDR*

Clinical Evaluation Reports lifecycle

Clinical evaluation involves the assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device.

Companies are required to prepare and submit a **clinical evaluation report** with the technical file as part of the **CE Marking**. The initial report is just the beginning of the CER's lifecycle.

When to update CER?

CER has to be regularly updated based on **ongoing clinical evaluations**, or as part of the **post-market surveillance and vigilance operations**. Updates to the CER are required:

- Every year (class IIb and implantable devices)
- When **new information from post-market surveillance** are received that could change the current evaluation
- Every 2-5 years if the device is not expected to carry significant risks and is well established (IIa)

CER must be based on clinical data

The **CER must be based on clinical data**, which may include clinical data from:

- **literature**
- **clinical experience**
- **clinical trials**

or any combination of the three.

Search strategies, **full search results**, **appraisal strategy and results**, **analysis of the data** and a **clear and functional list of references** must be included in the CER.

MEDDEV 2.7.1 rev 4 includes detailed information on:

- **Where to search for literature**
- **How to search for literature**
- **How to record the process** of collecting, appraising and analyzing the items found.

MEDDEV 2.7.1 rev 4 Guidelines - Where to Search for Literature

Appendix A4 of **MEDDEV 2.7/1 rev 4**, highlights the **important literature databases to be used as sources**, specifically stating:

- "**MEDLINE**® or **PubMed**® can provide a good starting point for a search. However, with potentially **incomplete coverage of European journals and reduced search features**, comprehensiveness is not necessarily guaranteed."

- "databases may need to be used to **ensure adequate coverage of devices and therapies in use in Europe**, to identify **relevant clinical trials** and publications of user experience, and **to facilitate searches by device name and manufacturer.** Listed additional databases include **Embase**® and the Cochrane Central Trials Register."

MEDDEV 2.7.1 rev 4 Guidelines – How to Search for Literature

Types of search (MEDDEV 2.7/1 rev 4)
"Objective, non-biased, systematic search and review methods should be used:

- **PICO** (patient characteristics, type of intervention, control and outcome queries)
- **Cochrane Handbook for Systematic Reviews of Interventions.."**

The **Cochrane Handbook** outlines eight general steps for preparing a systematic review:

1. Defining the review question(s) and developing criteria for including studies
2. **Searching for studies (Embase,..)**
3. Selecting studies and collecting data
4. Assessing risk of bias in included studies
5. Analyzing data and undertaking meta-analyses
6. Addressing reporting biases
7. Presenting results and "summary of findings" tables
8. Interpreting results and drawing conclusions

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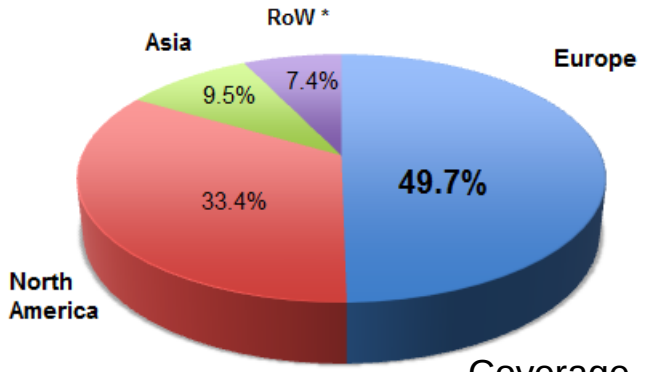
HOW EMBASE ADDRESSES MEDDEV 2.7.1_4 REQUIREMENTS

How Embase addresses MEDDEV 2.7/1_4 requirements

Embase is the most comprehensive biomedical literature database (over 8,300 journals and 32 million records). It contains over **2,900 journals that are not in MEDLINE**.



Coverage

Recommended by (regulatory) authorities:

- **EMA** for Pharmacovigilance
- **European Commission** for Clinical Evaluation Reporting of medical devices
- **NICE** and **Cochrane** for Evidence Based Medicine

- **Embase has unmatched coverage of devices and therapies in use in Europe**
- **Powerful search capabilities** to find results based on Booleans, proximity, wildcards and dozens of filters, limits
- **PICO search** framework
- Ability to **create, save, share and schedule** complex search strategies
- **Facilitate searches by device name and manufacturer based on in-depth indexing**
- **Unique** coverage of over **2.7m conference abstracts** from >8,100 conferences
- **Much more** coverage of **non-English** content and **randomized controlled trials**
- **2.3 Million records about medical devices** are indexed in Embase

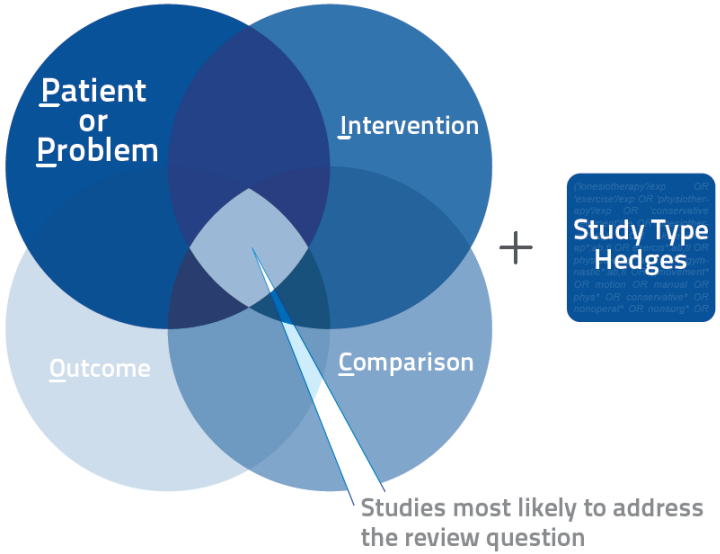
Using the PICO Framework to Structure a Question and Search for Evidence

P = Patient

I = Intervention

C = Comparison/control

O = Outcome



PICO is a method to structure the elements (concepts) of the review question into a search strategy.

On the next few slides, we'll look at PICO to answer a diagnostic question:
What is the value of chest radiography in diagnosis of asthma?

P (Patient, Problem or Population)

A generic formula for this search strategy is:

1. **Disease Emtree preferred term**
   ‘name of the disease’/exp
2. **Disease term as free text search (in title, abstracts, keywords)**
   ‘name of the disease’ OR ‘synonyms for the disease’
3. #1 OR #2

e.g.

'**asthma**'/exp OR ('asthma' OR 'asthma bronchiale' OR 'asthma pulmonale' OR 'asthmatic' OR 'asthmatic subject' OR 'bronchial asthma' OR 'bronchus asthma' OR 'childhood asthma' OR 'chronic asthma' OR 'lung allergy‘):ab,ti,kw

Sampson M, McGowan J, Cogo E, et al. An evidence-based practice guideline for the peer review of electronic search strategies. Journal of Clinical Epidemiology 2009 (Sep); 62(9): 944–952

I (Intervention)

A generic formula for this search strategy is:

1. **Emtree preferred term**
   ‘name of the intervention’/exp
2. **Intervention (e.g. drug) as free text search**
   ‘name of intervention’ OR ‘synonyms for the intervention’
3. #1 OR #2

e.g.

'**thorax radiography**'/exp OR ('x chest' OR 'chest radiogram' OR 'chest radiograph' OR 'chest radiography' OR 'chest radiology' OR 'chest roentgenogram' OR 'chest roentgenography' OR 'chest roentgenology' OR 'chest x ray' OR 'chest xray' OR 'mass chest x-ray' OR 'thoracic radiography' OR 'thoracic roentgenology' OR 'thoracic x ray' OR 'thorax radiogram' OR 'thorax radiograph' OR 'thorax radiography' OR 'thorax radiology' OR 'thorax roentgenogram' OR 'thorax roentgenography' OR 'thorax roentgenology' OR 'thorax x ray' OR 'thoraxradiography‘):ab,ti,kw

Sampson M, McGowan J, Cogo E, et al. An evidence-based practice guideline for the peer review of electronic search strategies. Journal of Clinical Epidemiology 2009 (Sep); 62(9): 944–952

Logical Operators

The Boolean **OR operator** is used to search the terms **within** each individual concept.

PICO is using **AND** Boolean logical operators to search **between** the concepts:

P-elements

AND

I-elements

AND

C-elements

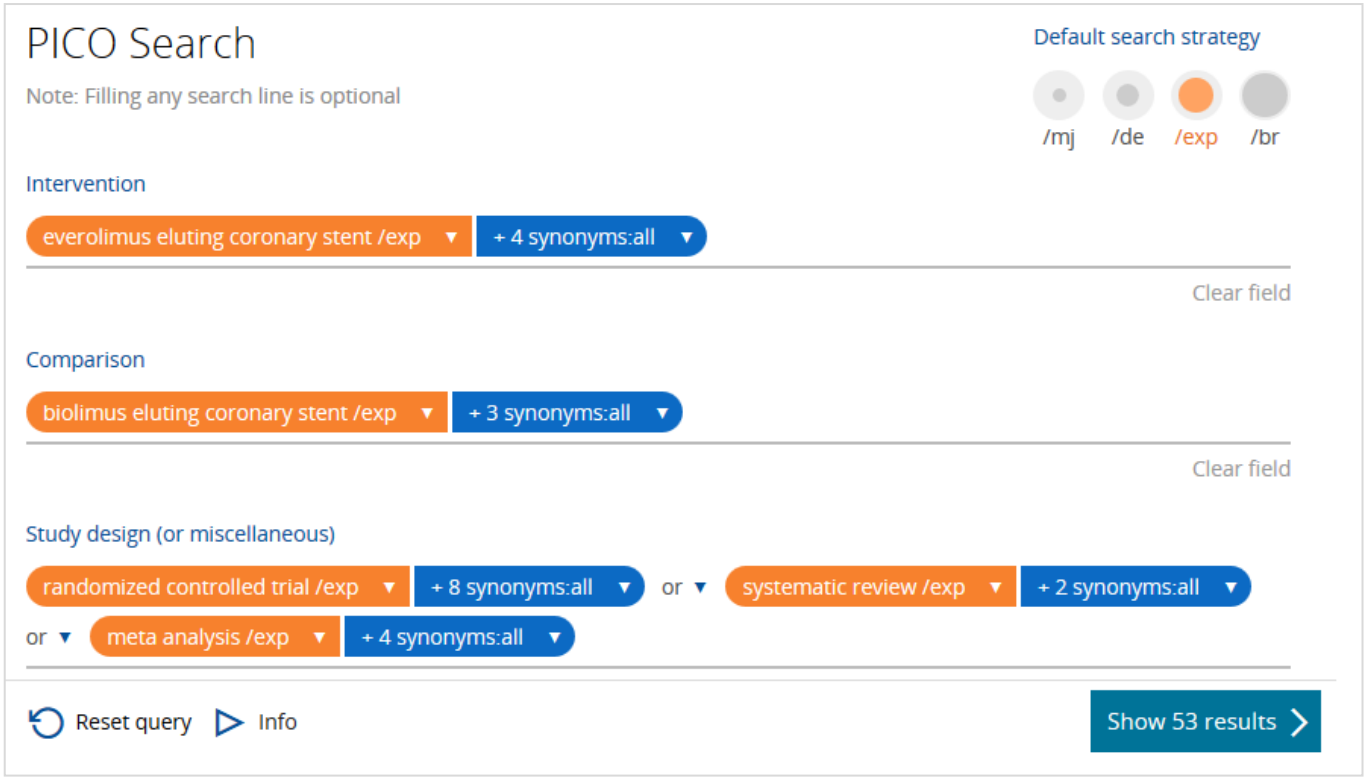
AND

O-elements

Sampson M, McGowan J, Cogo E, et al. An evidence-based practice guideline for the peer review of electronic search strategies. Journal of Clinical Epidemiology 2009 (Sep); 62(9): 944–952

How Embase addresses MEDDEV 2.7/1_4 requirements

Ability to build searches in Embase.com using a structured **PICO framework**, which also allows **easy incorporation of Emtree terms and synonyms**, supports the **creation of comprehensive CERs.**



CASE STUDY

Case study

Scenario: **Manufacturer needs to create a CER for coronary stent (everolimus eluting coronary stent)**

Goal: Find critical information needed for successful regulatory submissions that includes:

- **Device clinical performance**
- **Comparison of device with an existing device**
- **Device safety – finding adverse device effects**

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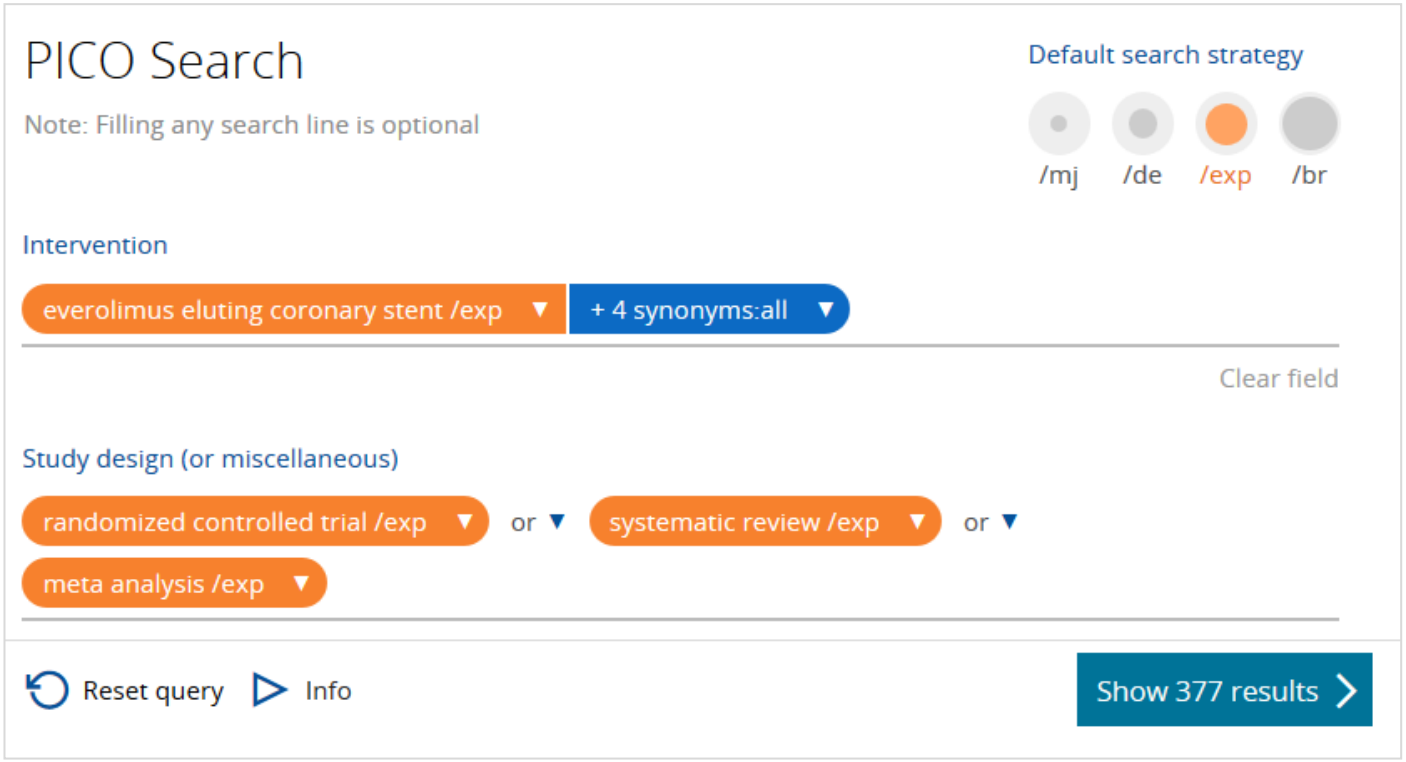
DEVICE CLINICAL PERFORMANCE

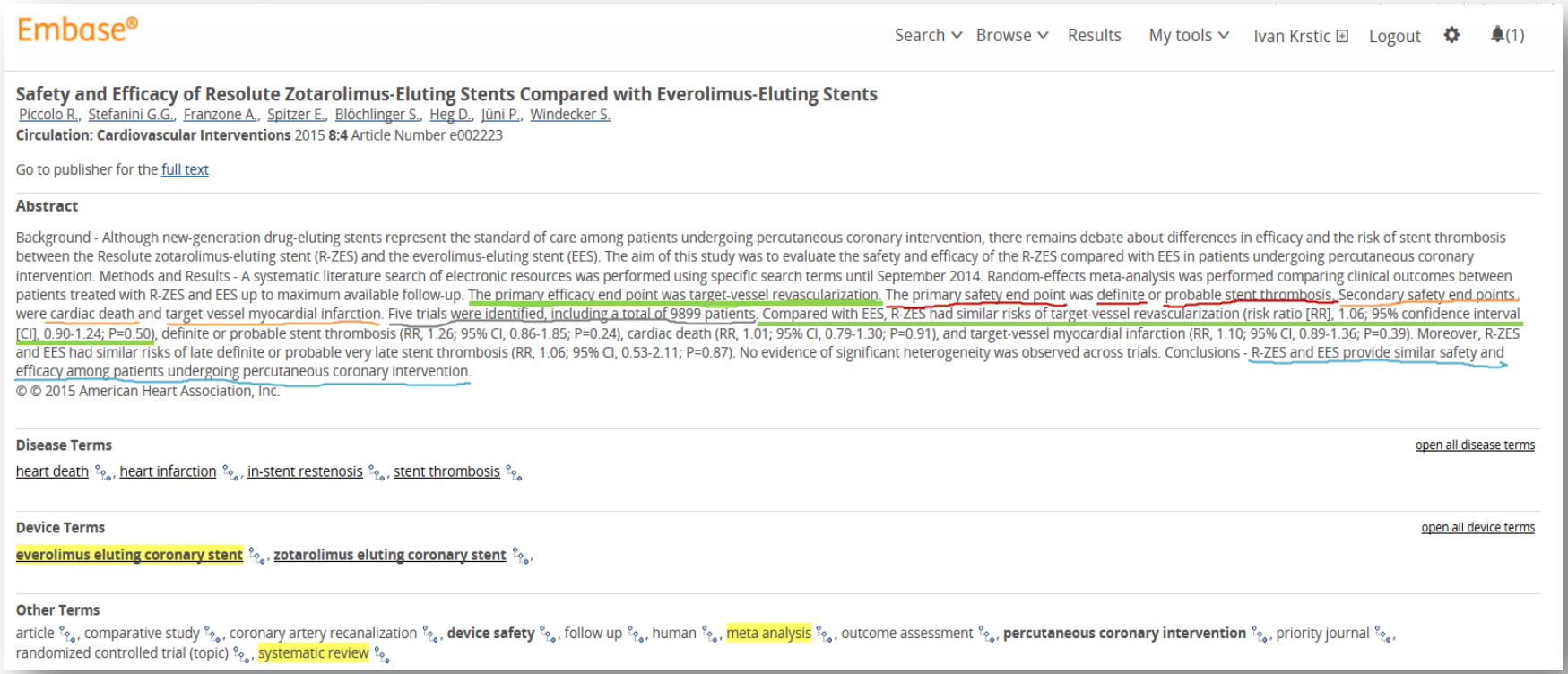
Clinical performance information

Sensitive search created using PICO search form

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent') **AND**
('randomized controlled trial'/exp OR 'systematic review'/exp OR 'meta analysis'/exp)



Example of a result



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Search Browse Results My tools Ivan Krstic Logout (1)

Safety and Efficacy of Resolute Zotarolimus-Eluting Stents Compared with Everolimus-Eluting Stents

Piccolo R., Stefanini G.G., Franzone A., Spitzer E., Blöchlinger S., Heg D., Jüni P., Windecker S.

Circulation: Cardiovascular Interventions 2015 **8:4** Article Number e002223

Go to publisher for the full text

Abstract

Background - Although new-generation drug-eluting stents represent the standard of care among patients undergoing percutaneous coronary intervention, there remains debate about differences in efficacy and the risk of stent thrombosis between the Resolute zotarolimus-eluting stent (R-ZES) and the everolimus-eluting stent (EES). The aim of this study was to evaluate the safety and efficacy of the R-ZES compared with EES in patients undergoing percutaneous coronary intervention. Methods and Results - A systematic literature search of electronic resources was performed using specific search terms until September 2014. Random-effects meta-analysis was performed comparing clinical outcomes between patients treated with R-ZES and EES up to maximum available follow-up. The primary efficacy end point was target-vessel revascularization. The primary safety end point was definite or probable stent thrombosis. Secondary safety end points were cardiac death and target-vessel myocardial infarction. Five trials were identified, including a total of 9899 patients. Compared with EES, R-ZES had similar risks of target-vessel revascularization (risk ratio [RR], 1.06; 95% confidence interval [CI], 0.90-1.24; P=0.50), definite or probable stent thrombosis (RR, 1.26; 95% CI, 0.86-1.85; P=0.24), cardiac death (RR, 1.01; 95% CI, 0.79-1.30; P=0.91), and target-vessel myocardial infarction (RR, 1.10; 95% CI, 0.89-1.36; P=0.39). Moreover, R-ZES and EES had similar risks of late definite or probable very late stent thrombosis (RR, 1.06; 95% CI, 0.53-2.11; P=0.87). No evidence of significant heterogeneity was observed across trials. Conclusions - R-ZES and EES provide similar safety and efficacy among patients undergoing percutaneous coronary intervention.

Disease Terms open all disease terms

heart death, heart infarction, in-stent restenosis, stent thrombosis

Device Terms open all device terms

everolimus eluting coronary stent, **zotarolimus eluting coronary stent**

Other Terms

article, comparative study, coronary artery recanalization, **device safety**, follow up, human, meta analysis, outcome assessment, **percutaneous coronary intervention**, priority journal, randomized controlled trial (topic), systematic review

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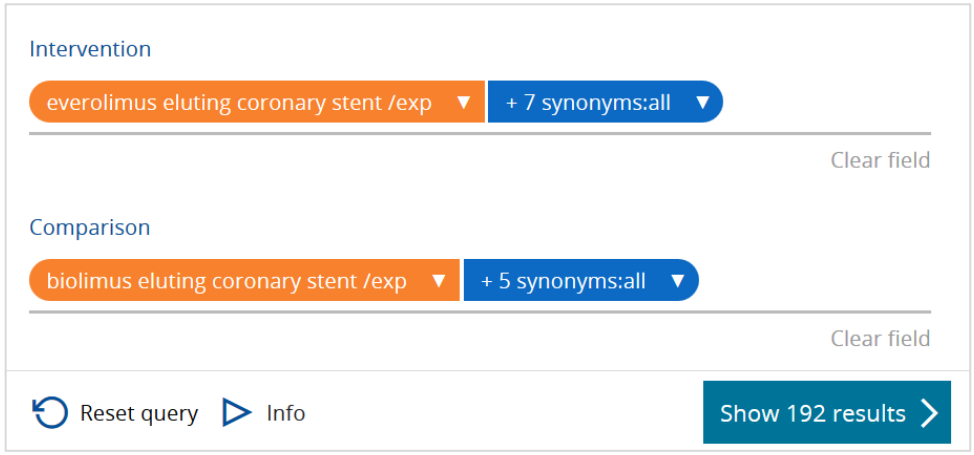
DEVICE COMPARISON

1. Sensitive (broad), specific search using PICO search form
2. Focused, non-specific search
3. More focused, specific search

Device Comparison (with a specific device)

1. Sensitive (broad), specific search using PICO search form



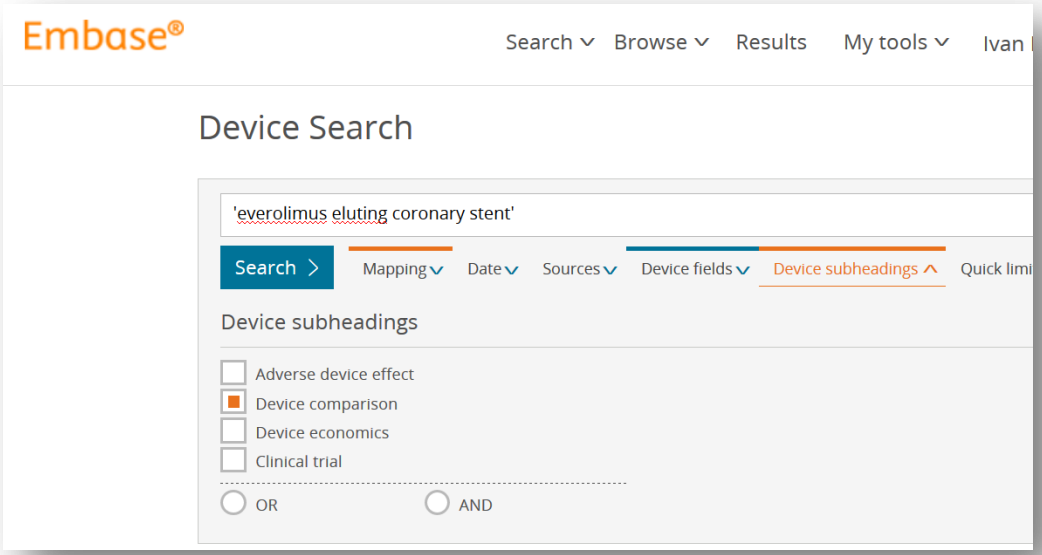
Search based on co-location of terms in records:

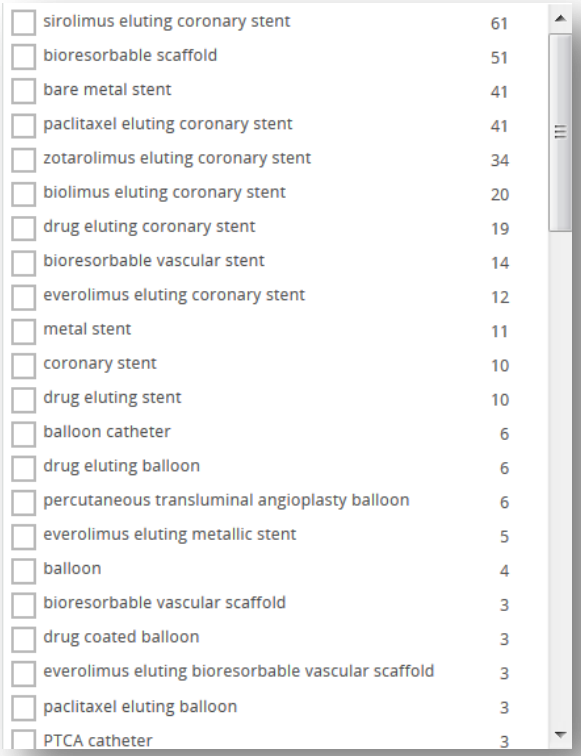
('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent‘)
AND
('biolimus eluting coronary stent'/exp OR 'biolimus a9 (device)' OR 'biolimus eluting coronary stent' OR 'umirolimus eluting coronary stent')

Device Comparison (with any device)

2. Focused (narrow), search using subheadings

'everolimus eluting coronary stent'/'device comparison' (276 hits)

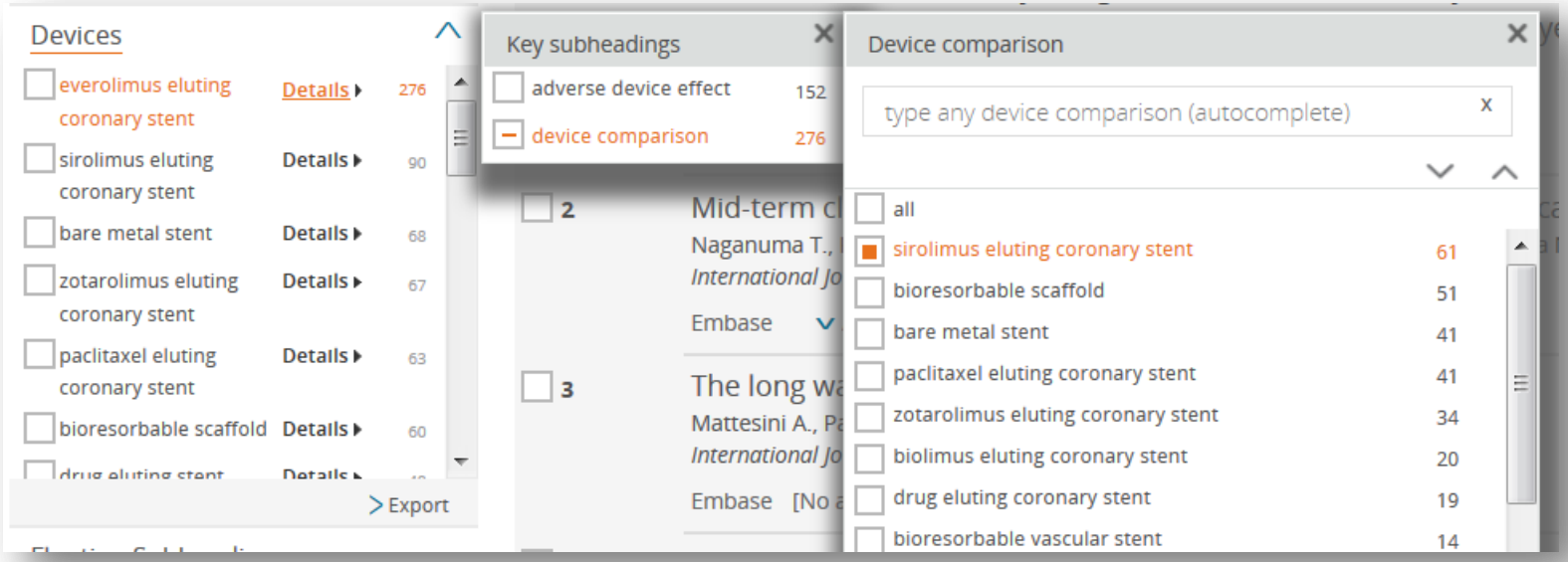




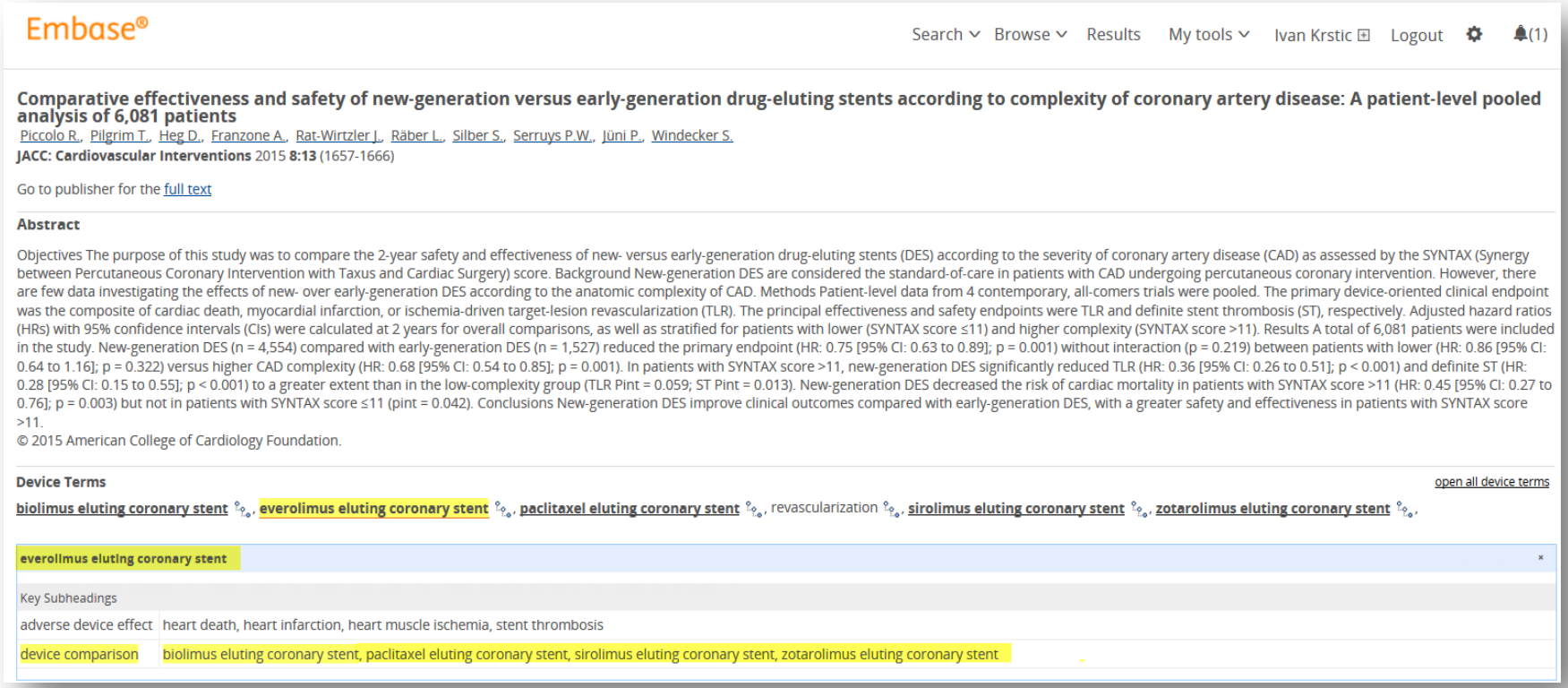
Device Comparison (with a specific device)

3. More focused (narrower), specific search based on triple-linking (indexed semantic relationships between the two devices):

'everolimus eluting coronary stent'/'device comparison'/'sirolimus eluting coronary stent'



Example of a result



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Search Browse Results My tools Ivan Krstic Logout (1)

Comparative effectiveness and safety of new-generation versus early-generation drug-eluting stents according to complexity of coronary artery disease: A patient-level pooled analysis of 6,081 patients

Piccolo R., Pilgrim T., Heg D., Franzone A., Rat-Wirtzler J., Räber L., Silber S., Serruys P.W., Jüni P., Windecker S.

JACC: Cardiovascular Interventions 2015 **8:13** (1657-1666)

Go to publisher for the full text

Abstract

Objectives The purpose of this study was to compare the 2-year safety and effectiveness of new- versus early-generation drug-eluting stents (DES) according to the severity of coronary artery disease (CAD) as assessed by the SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) score. Background New-generation DES are considered the standard-of-care in patients with CAD undergoing percutaneous coronary intervention. However, there are few data investigating the effects of new- over early-generation DES according to the anatomic complexity of CAD. Methods Patient-level data from 4 contemporary, all-comers trials were pooled. The primary device-oriented clinical endpoint was the composite of cardiac death, myocardial infarction, or ischemia-driven target-lesion revascularization (TLR). The principal effectiveness and safety endpoints were TLR and definite stent thrombosis (ST), respectively. Adjusted hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated at 2 years for overall comparisons, as well as stratified for patients with lower (SYNTAX score ≤11) and higher complexity (SYNTAX score >11). Results A total of 6,081 patients were included in the study. New-generation DES (n = 4,554) compared with early-generation DES (n = 1,527) reduced the primary endpoint (HR: 0.75 [95% CI: 0.63 to 0.89]; p = 0.001) without interaction (p = 0.219) between patients with lower (HR: 0.86 [95% CI: 0.64 to 1.16]; p = 0.322) versus higher CAD complexity (HR: 0.68 [95% CI: 0.54 to 0.85]; p = 0.001). In patients with SYNTAX score >11, new-generation DES significantly reduced TLR (HR: 0.36 [95% CI: 0.26 to 0.51]; p < 0.001) and definite ST (HR: 0.28 [95% CI: 0.15 to 0.55]; p < 0.001) to a greater extent than in the low-complexity group (TLR Pint = 0.059; ST Pint = 0.013). New-generation DES decreased the risk of cardiac mortality in patients with SYNTAX score >11 (HR: 0.45 [95% CI: 0.27 to 0.76]; p = 0.003) but not in patients with SYNTAX score ≤11 (pint = 0.042). Conclusions New-generation DES improve clinical outcomes compared with early-generation DES, with a greater safety and effectiveness in patients with SYNTAX score >11.

Device Terms open all device terms

biolimus eluting coronary stent, everolimus eluting coronary stent, paclitaxel eluting coronary stent, revascularization, sirolimus eluting coronary stent, zotarolimus eluting coronary stent,

everolimus eluting coronary stent

Key Subheadings	
adverse device effect	heart death, heart infarction, heart muscle ischemia, stent thrombosis
device comparison	biolimus eluting coronary stent, paclitaxel eluting coronary stent, sirolimus eluting coronary stent, zotarolimus eluting coronary stent

Outcome: increased precision i.e. only truly relevant records are retrieved significantly improving your efficiency

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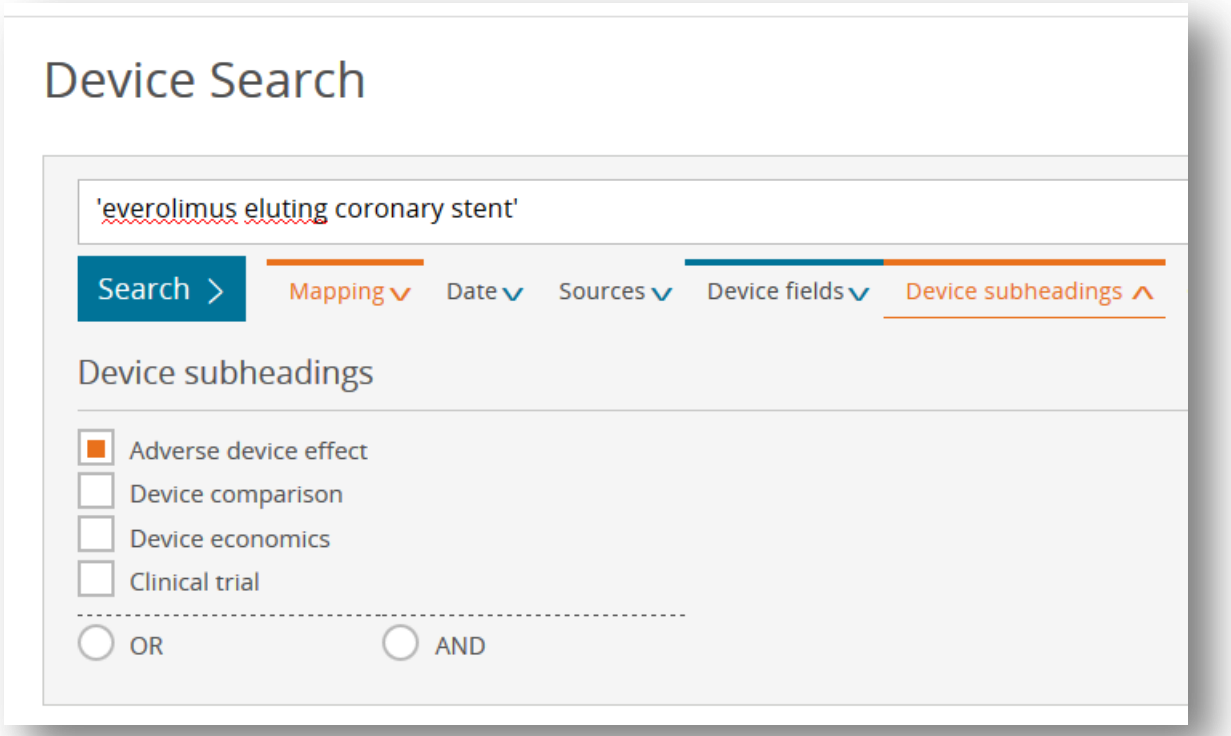
DEVICE SAFETY

1. Focused, non-specific search
2. Sensitive (broad) search using Emtree and free text (Search Strategy for PMS)

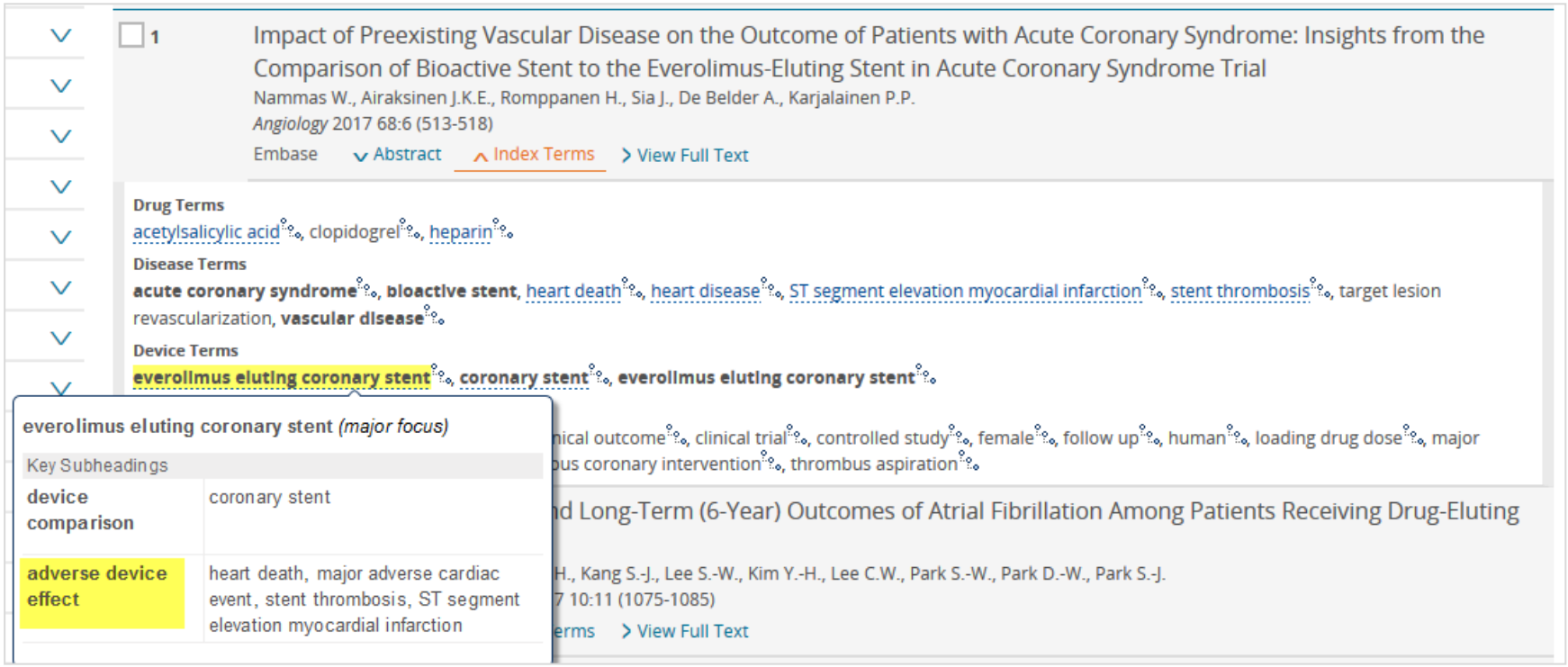
Device Safety

1. Focused search using subheadings:

'everolimus eluting coronary stent'/'adverse device effect'



Example of a result



Search Strategy for Post-Market Surveillance (PMS)

2. Sensitive search using Emtree and free text:

('**everolimus eluting coronary stent**'/exp OR '**promus element**' OR '**xience xpedition**' OR '**xience-v**' OR '**everolimus eluting coronary stent**')
AND
('**adverse device effect**'/exp OR '**adverse device effect**'/lnk OR '**device safety**'/exp OR '**device failure**'/exp OR '**equipment safety**' OR **device-induced** OR '**device infection**'/exp OR **misplacement*** OR '**complication**'/exp OR **complicat*** OR '**risk**'/exp OR **risk*** OR '**side effect**'/exp OR **complaint*** OR '**injury**'/exp OR **injur*** OR '**death**'/exp OR **death*** OR **died** OR **mortality** OR **fatalit*** OR **obstruction*** OR **failure*** OR **perforat*** OR **rupture*** OR **breakag*** OR **malfunction*** OR **impair*** OR **hazardous** OR **irritant*** OR **irritat*** OR (**patient*** NEAR/2 **discomfort***):de,ab,ti,kw OR ((**device** OR **equipment** OR **mechanical** or **technical**) NEAR/2 (**safety** OR **failure*** OR **malfunction*** OR **withdrawal** OR **ineff*** OR **problem***)):de,ab,ti,kw OR ((**adverse** OR **side** OR **undesirable** OR **unwanted** OR **lack** OR **allergic** OR **fatal** OR **unexplained** OR **loss** OR **unexpected**) NEXT/2 (**effect*** OR **reaction*** OR **event*** OR **outcome***)):de,ab,ti,kw)

2,357 **hits**

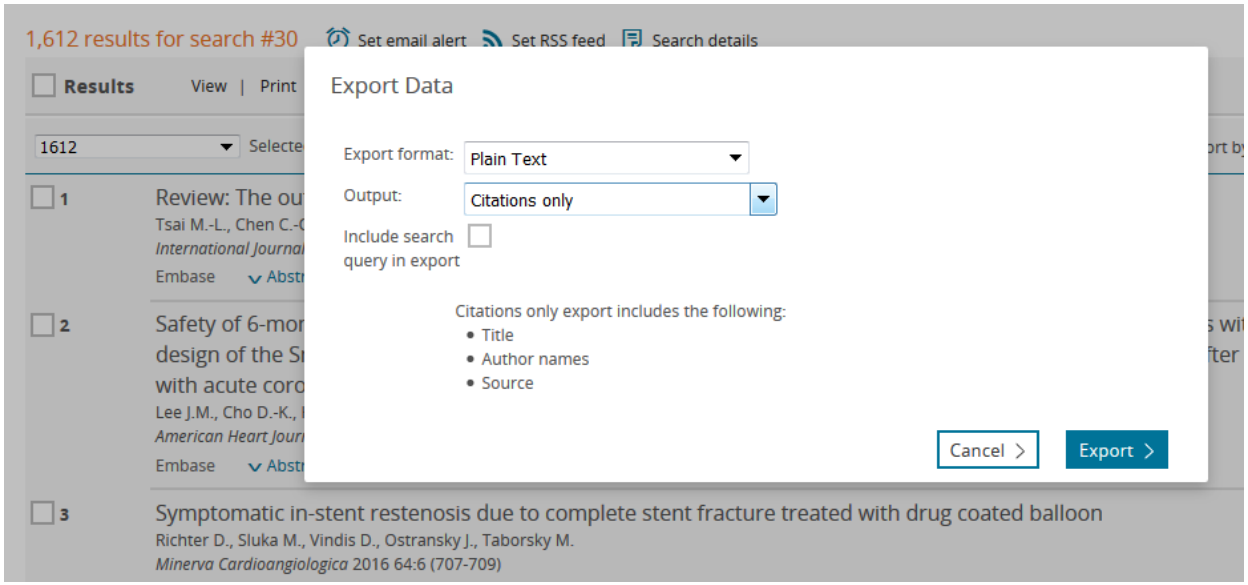
MEDDEV 2.7.1 REV 4 GUIDELINES

HOW TO RECORD THE PROCESS OF COLLECTING RECORDS

Search strategies, full search results and a clear and functional list of references must be included in the CER

Embase Session Results (15 Nov 2016)

No.	Query	Results
#30	'everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent' AND ('adverse device effect'/exp OR 'complication'/exp OR 'postoperative complication'/exp OR postoperative NEXT/2 complication* OR complicat* OR 'risk'/exp OR risk* OR 'side effect'/exp OR (adverse OR side OR undesirable OR unwanted OR lack) NEXT/2 (effect* OR reaction* OR event* OR outcome*))	1612

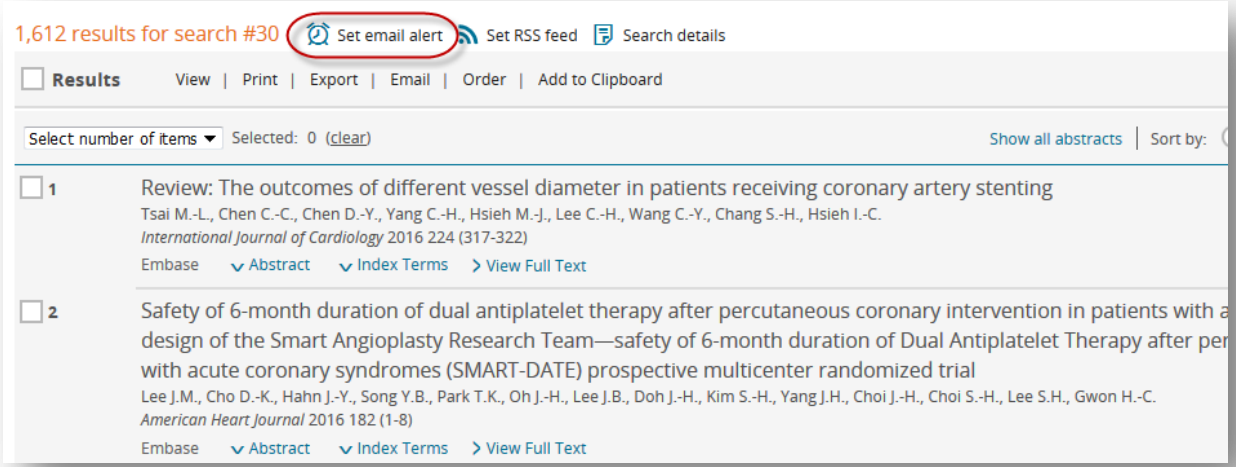


AUTOMATIZE SEARCHING FOR POST-MARKET SURVEILLANCE

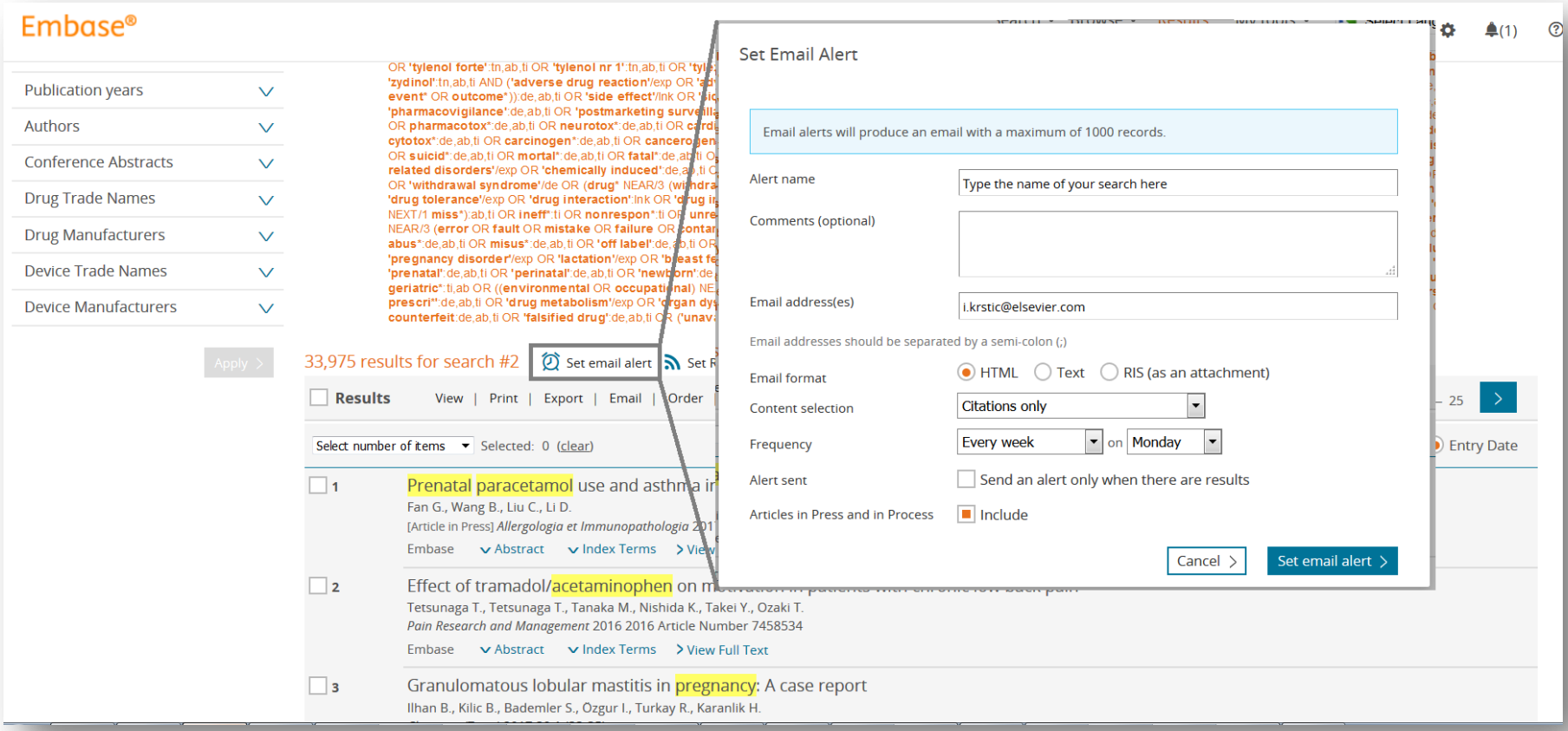
Automatize Searching for Post-Market Surveillance

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent')
AND
('**adverse device effect**'/exp OR '**adverse device effect**'/lnk OR '**device safety**'/exp OR '**device failure**'/exp OR '**equipment safety**' OR **device-induced** OR '**device infection**'/exp OR **misplacement*** OR **'complication**'/exp OR **complicat*** OR **'risk**'/exp OR **risk*** OR '**side effect**'/exp OR **complaint*** OR '**injury**'/exp OR **injur*** OR '**death**'/exp OR **death*** OR **died** OR **mortality** OR **fatalit*** OR **obstruction*** OR **failure*** OR **perforat*** OR **rupture*** OR **breakag*** OR **malfunction*** OR **impair*** OR **hazardous** OR **irritant*** OR **irritat*** OR (**patient*** NEAR/2 **discomfort***):de,ab,ti,kw OR ((**device** OR **equipment** OR **mechanical** or **technical**) NEAR/2 (**safety** OR **failure*** OR **malfunction*** OR **withdrawal** OR **ineff*** OR **problem***)):de,ab,ti,kw OR ((**adverse** OR **side** OR **undesirable** OR **unwanted** OR **lack** OR **allergic** OR **fatal** OR **unexplained** OR **loss** OR **unexpected**) NEXT/2 (**effect*** OR **reaction*** OR **event*** OR **outcome***)):de,ab,ti,kw)

Set up an email alert



Email Alert - Automatized Search for PMS



Email Alert history is auditable

This is the history of alert "PV alert" as exported on 01 May 2016 19:38 GMT. This alert was originally set up on 22 Dec 2015 10:11 GMT.

Alert name	Event	Search que	Date & time (GMT)	Records in	Frequency	Recipients	Status
PV alert	Automatic run	'adverse d	25.04.2016 03:10	2353	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	18.04.2016 03:10	3446	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	11.04.2016 03:10	1913	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	04.04.2016 03:10	2178	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	28 Mar 2016 03:10	2923	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	21 Mar 2016 03:10	2192	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	14 Mar 2016 03:10	2131	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Send now alert	'adverse d	08 Mar 2016 15:25	315	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (content sele	'adverse d	08 Mar 2016 15:25	n/a	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	07 Mar 2016 03:10	3215	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	29.02.2016 03:10	1716	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (enabled)	'adverse d	22.02.2016 18:46	n/a	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (disabled)	'adverse d	22.02.2016 18:46	n/a	Every week on Monday	i.krstic@elsevier.com	Off
PV alert	Send now alert	'adverse d	22.02.2016 18:43	0	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	22.02.2016 03:10	2383	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	15.02.2016 03:10	3209	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	08.02.2016 03:10	1906	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	01.02.2016 03:10	2871	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	25.01.2016 03:10	1820	Every week on Monday	i.krstic@elsevier.com	On

Summary

Embase®

In this presentation, we've discuss:

- **New Medical Device Regulations (MDR 2017/745) and Medical Device Guidelines (MEDDEV 2.7/1 rev 4) and their implications**
- **How Embase addresses these requirements**
- **(Case study) How to design effective literature searches to identify:**
  - **Device performance**
  - **Comparison of device with existing device(s)**
  - **Device safety – finding adverse device effects**
- **How to set an automatized search for PMS**

Thank you!

Any questions?

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