



THE SHAPING A
TECHMED HEALTHY
EVENT FUTURE

11:00 – 12:15 | From novelty to application: translating medical technologies | Dr. R.G. Pleijhuis

Evidencio: a standardized platform enabling clinical use of (AI) algorithms as certified medical devices

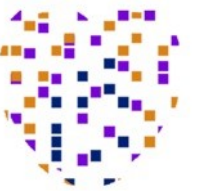
Dr. R.G. Pleijhuis – Internist-allergologist/immunologist / CMO Evidencio

DISCLOSURE SLIDE

Potential conflicts of interest



Co-founder and CMO of medical prediction platform 'Evidencio'



How it all started...

In daily clinical practice, a tangle of decision support tools was/is used, sometimes even with conflicting results.





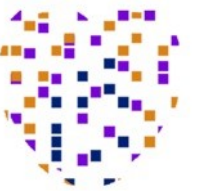
Steep increase in prediction algorithms

The current focus is on developing new clinical prediction algorithms rather than implementing those already existing.

Lack of:

- Validation
- Standardization
- Scalability
- Integration
- **MDR compliance**

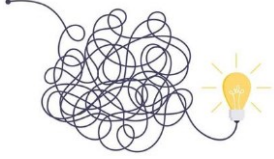







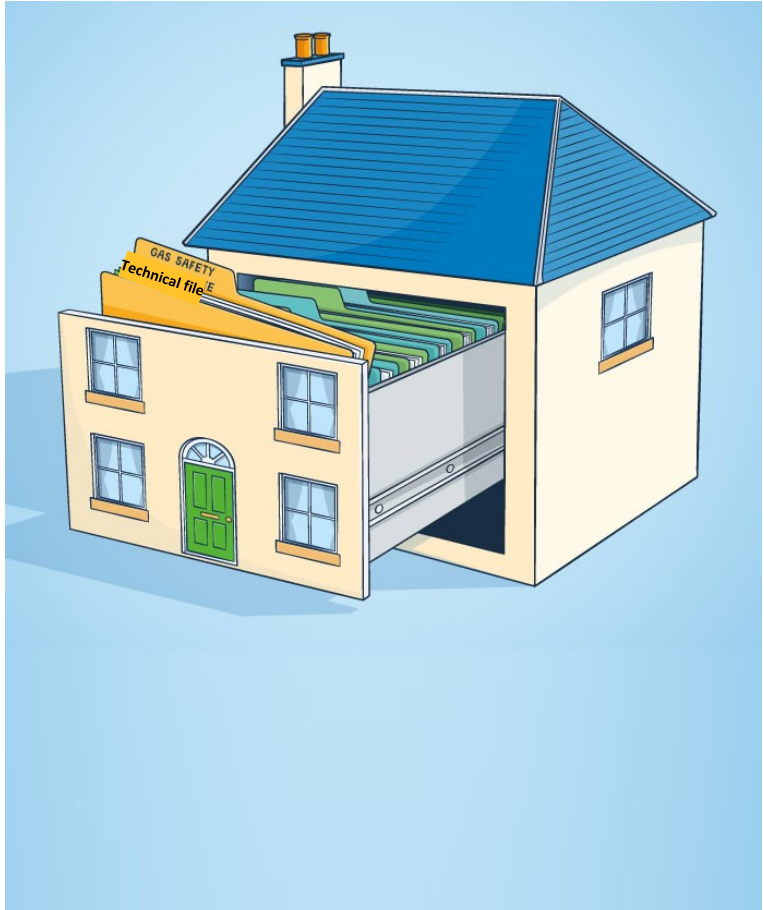
Medical device regulation (MDR)

Clinical algorithms *must* be **CE-certified** prior to *general* use

CE-certification is often considered challenging:

 Complex regulation	 Long waitinglists
 Labour-intensive	 Expensive

Alternative for CE-certification for local application

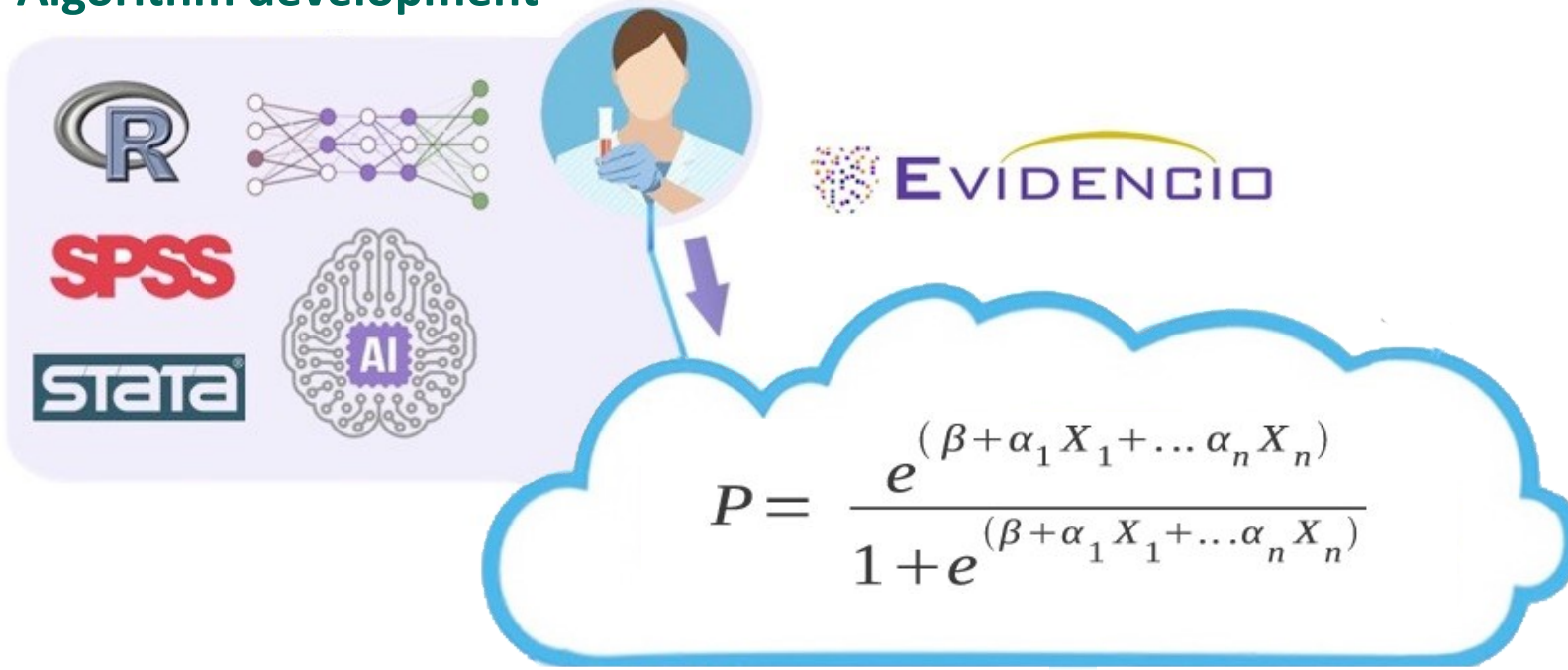


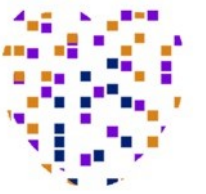
‘In-house development’

- Only use within own institution is permitted
- No CE-certified alternative available on the market
- Extensive evaluation/technical file still required!

Algorithm development

1





1 Standardized algorithm creation

Evidencio offers tools for researchers to create functional prediction algorithms in a standardized manner.

Settings Variables Formula segments RScript

Calculation method

- Linear model
- Logistic regression
- Cox regression
- Custom model
- RScript**
- External API
- Custom Language

Model variable type

- Standard model**
- UMLS model

Automatic calculations

- Automatic**
- Manual

Default style for categorical variables

- Buttons**
- List

Measurement type

- SI**
- Imperial

→

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Reset Continue

EVIDENCIO

Models

Search results for 'Abc'

The ABC Bleeding risk score

The ABC (Age, Biomarkers, Clinical history) risk score has been developed to predict the risk of bleeding in patients with atrial fibrillation. The ABC bleeding risk score is internally and externally validated using two clinical trial databases.

Research authors: Ziad Hijazi, Jonas Oldgren, Johan Lindbäck, John H Alexander, Stuart J Connolly, John W Eikelboom, Michael D Ezekowitz, Claes Held, Elaine M Hylek, Renato D Lopes, Agneta Siegbahn, Salim Yusuf, Christopher B Granger, Lars Wallentin, ARISTOTLE and RE-LY investigators

Model author: T. A. Huetting
Last modified: 2021-06-28

Private

Details

LOT V-2.1-2326.21.06.28 CE

CKD-EPI

estimated glomerular filtration rate was determined using the Chronic Kidney Diseases... ml/min

20 65 130

Predict result for

1-year 2-year 3-year

The calculated bleeding risk is: 0.4 %

Conditional information
A one-year bleeding risk below 1% can be categorised as Low risk.



2

External validation of algorithms

Evidencio's web-based validation module allows for high-throughput assessment of prediction algorithm performance.

Show validation data as:

Validation Values

Model Labels



Clear data

	Preoperative M...	Microcalcifica...	Preoperative N...	Preoperative T...	Density	Palpability	Suspicion of m...	Estrogen recep...	Presence Of DC...	Histological t...	Histological B...	Outcome	Probability
1	No	Absent	Negati...	T1	25-50%	Non-P...	Yes	Positive	Present	Ductal	Elston II	Negati...	0.5319...
2	No	Present	Positive	T1	0-25%	Non-P...	Yes	Negati...	Present	Ductal	Elston II	Positiv...	0.5302...
3	No	Absent	Negati...	T1	25-50%	Palpa...	Yes	Positive	Present	Ductal	Elston ...	Positiv...	0.5194...
4	No	Absent	Negati...	T2	50-75%	Non-P...	Yes	Negati...	Present	Ductal	Elston II	Negati...	0.5054...
5	No	Present	Negati...	T2	0-25%	Palpa...	Yes	Negati...	Present	Ductal	Elston ...	Negati...	0.4518...
6	No	Present	Negati...	T2	50-75%	Palpa...	No	Positive	Present	Ductal	Elston ...	Positiv...	0.4397...
7	Yes	Present	Negati...	T2	75-10...	Palpa...	Yes	Negati...	Absent	Lobular	Elston ...	Negati...	0.4363...
8	No	Present	Negati...	T1	25-50%	Non-P...	No	Positive	Present	Ductal	Elston I	Positiv...	0.3376...
9	No	Absent	Negati...	T1	50-75%	Palpa...	Yes	Negati...	Present	Ductal	Elston ...	Negati...	0.4226...
10	No	Absent	Negati...	T1	50-75%	Palpa...	Yes	Negati...	Present	Ductal	Elston ...	Negati...	0.4226...
11	Yes	Present	Negati...	T2	50-75%	Non-P...	Yes	Negati...	Present	Ductal	Elston I	Positiv...	0.4172...
12	No	Absent	Negati...	T2	50-75%	Palna	Yes	Negati...	Present	Ductal	Elston II	Positiv	0.4037



3

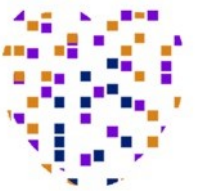
Compliance with European law



Evidencio enables cost-effective and time-efficient CE-certification of (pooled) prediction algorithms through:

- Standardization
- Established QMS
- Reuse of platform components





CE-certification of clinical algorithms

ABC RISK SCORE: 1-YEAR STROKE RISK

The ABC (Age, Biomarkers, Clinical history) risk score has been developed to predict the risk of stroke or systemic embolism in patients with atrial fibrillation. The ABC stroke risk score is internally and externally validated using two clinical trial databases.



Troponin biomarker

Indicate which Troponin biomarker is available to you

Troponin I

Troponin T

Prior stroke

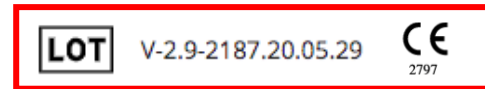
Indicate whether the patient previously suffered from a stroke or transient ischemic attack (TIA)

No

Stroke or TIA

Age

Age of the patient in years



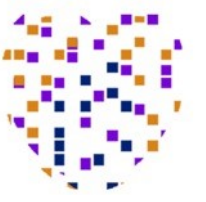
The risk of stroke or systemic embolism is: **1.7 %**

See details below.

Conditional information

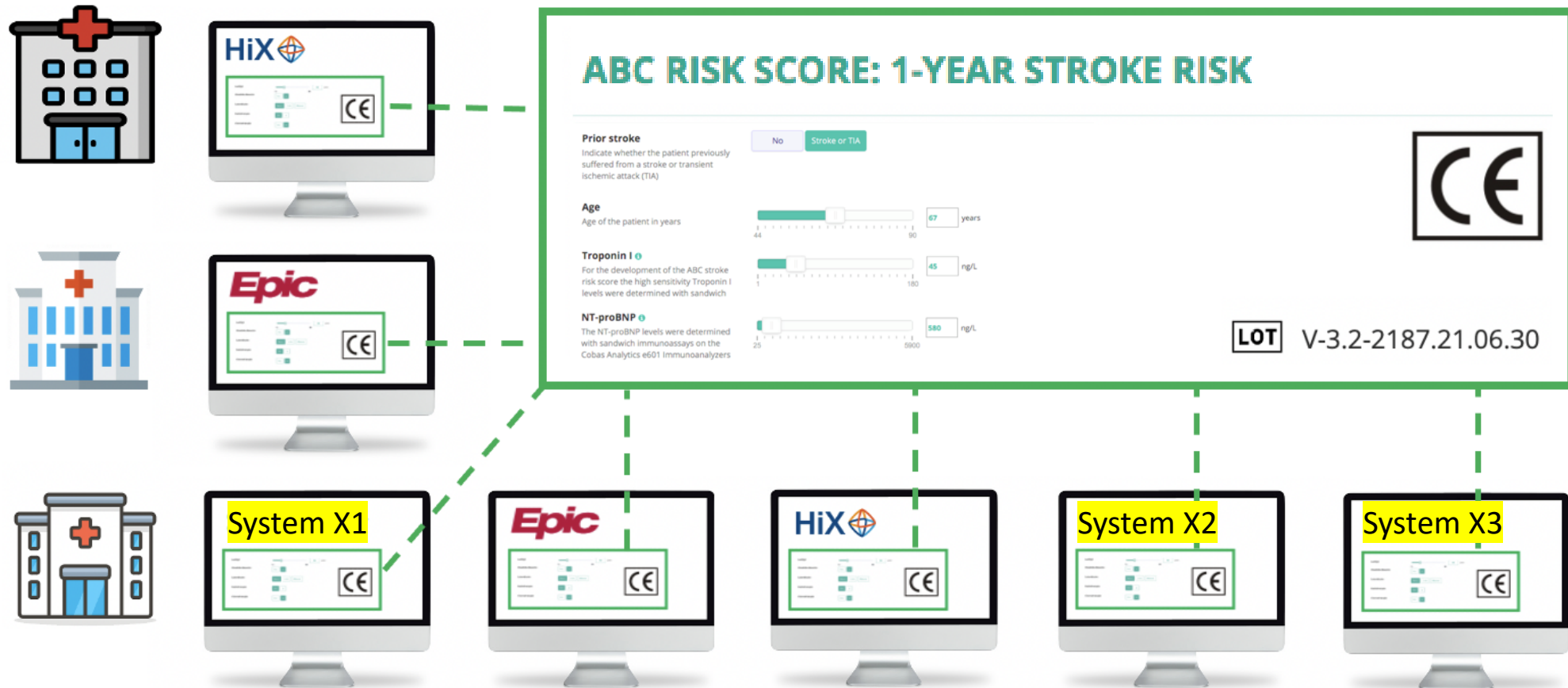
The patient can be classified as **medium risk** for stroke or systemic embolism.

The ABC stroke risk score has been developed and validated on data from patients who have all undergone anticoagulation treatment. It is uncertain whether, and by how much the risk of stroke could increase if the patient did not receive anticoagulant treatment.

































4 Algorithm integration in EHR systems

API-based integration of CE-marked algorithms in multiple hospitals.

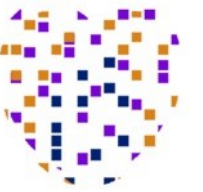


Efficiency & cost reduction through standardization

	ISO-13485 certified QMS	NEN-7510 & ISO-27001	Setting up technical file	Assessment by Notified Body	Algorithm integration	Post-market surveillance	Periodic audits	Algorithm maintenance
DIY								
Evidencio	-	-						

	ISO-13485 certified QMS	NEN-7510 & ISO-27001	Setting up technical file	Assessment by Notified Body	Algorithm integration	Post-market surveillance	Periodic audits	Algorithm maintenance
DIY								
Evidencio	-	-						

DIY = Do it yourself



Take home messages: what to consider?

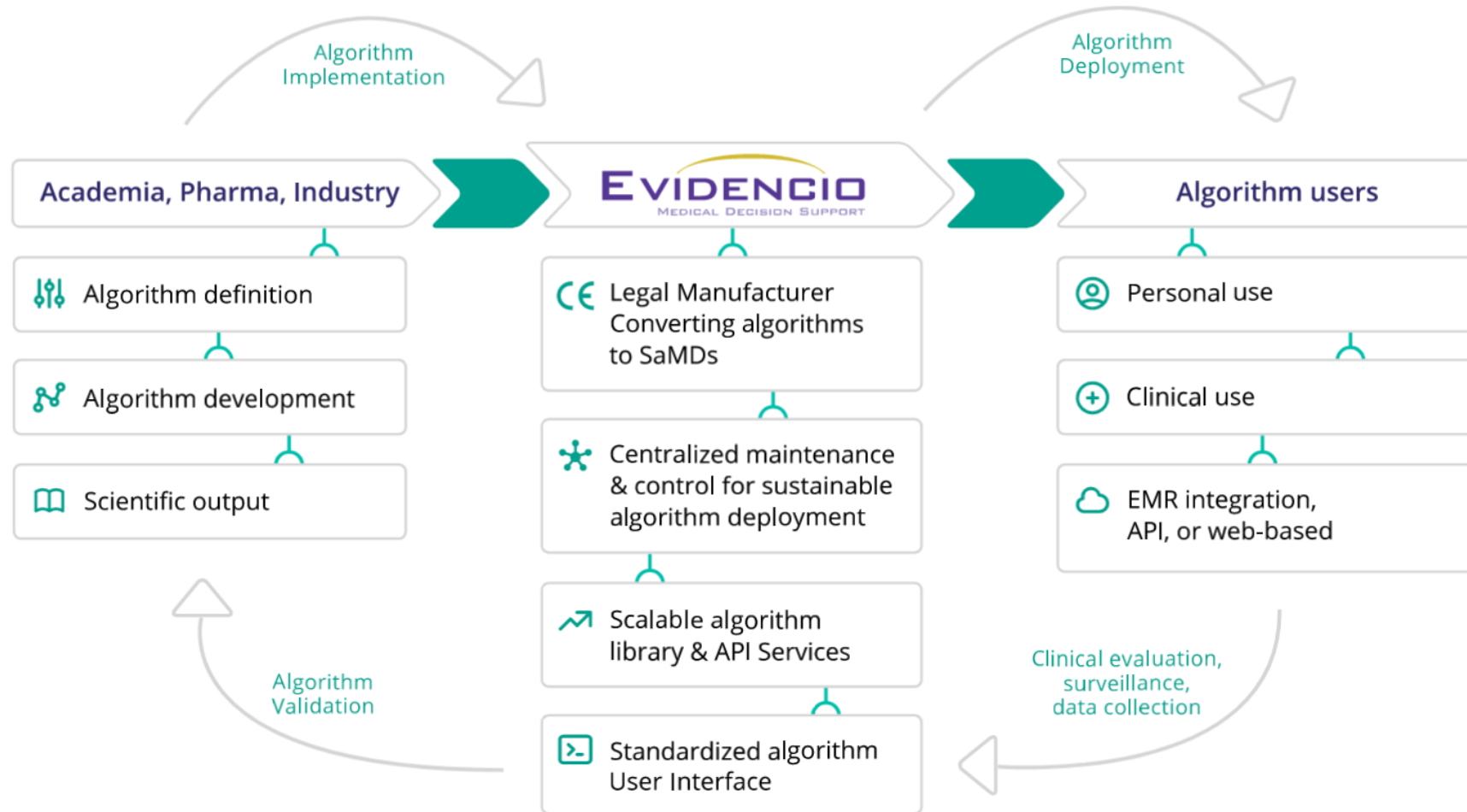
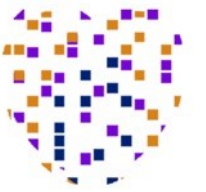
Ask yourself the question if:

- ... your algorithm qualifies as a medical device (MDR)
- ... your algorithm will be applied outside your institution (CE needed?)
- ... additional studies are needed to back up your medical claims
- ... you are comfortable with being legally liable in case of unexpected outcomes

Other considerations:

- Choose your intended use/medical claims wisely
- Think about ways how to distribute and implement your algorithm
- Save time and money by using a standardized approach

Creating a standardized algorithm ecosystem



More info? Please send an e-mail to rgp@evidencio.com or visit www.evidencio.com



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Examples: when to comply to the MDR?

HHS Public Access
 Author manuscript
Lancet. Author manuscript; available in PMC 2019 June 13.

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Antibiotic allergy

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Federatie Medisch Specialisten

RICHTLIJNEN Zoek NIEUWS INSTRUCTIES WERKWIJZE

Zoek richtlijn

Zoek op richtlijn of trefwoord



Penicillin Allergy Decision Rule (PEN-)

Identifies low-risk penicillin allergies.

INSTRUCTIONS
 Apply this calculator to patients who have reported a penicillin allergy.

When to Use

Five years or less since reaction	<input checked="" type="checkbox"/> No 0	Yes +2
Anaphylaxis or angioedema OR Severe cutaneous adverse reaction	<input checked="" type="checkbox"/> No 0	Yes +2
Treatment required for reaction	<input checked="" type="checkbox"/> No 0	Yes +1

