3. Jahresversammlung der Medizininformatik-Initiative

Dortmund, 11.September 2019

Digitales Wissensmanagement: Aktivitäten der AWMF – Aspekte mit Bedeutung für die klinische Forschung

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AWMF und AWMF-Institut für Medizinisches Wissensmanagement

Die Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften

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Leitlinien im AWMF-Register 2010-2018

…liegen bis dato „verkapselt“ vor

AWMF-IT Projekt: Gesamtkonzept

Vorbereitung
Bestands- und Bedarfsanalyse

Planung
Erstellung des Lastenhefts

Pilotprojekt DissoLVe

Gefördert durch:

Bundesministerium für Gesundheit

aufgrund eines Beschlusses des Deutschen Bundestages

Qualitätsicherung
Erstellung des Pflichtenhefts

Umsetzung & Proof of Concept

Datenmodell, Terminologie, Schnittstellen, Infrastruktur

Implementierung in den „Lebenszyklus“ von Leitlinienwissen:
Iterativer Prozess

- Evaluierung
- Implementierung
- Entwicklung
- Verwaltung

2016-2017 | **2018** | **2019** | **2020-2021** | **2022-2024**

Beratung, Supervision:
AWMF-Task Force IT

Siehe auch Vorstellung im Rahmen der Delegiertenkonferenz Nov. 2018
https://www.awmf.org/fileadmin/user_upload/Die_AWMF/Delegiertenkonferenz/DK-2018-11/TOP_12_20181110_AWMF-Delkonf_Kopp.pdf

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AWMF- TASK FORCE IT

Sitzungen:

29.01.2019 - Lastenheft
05.09.2019 - Pflichtenheft

Koordination	
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Prof. Dr. med. Andreas **Dietz** (DGHNO)	PD Dr. med. Thomas **Köhnlein** (DGP)
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Prof. Dr. med. Dirk **Müller-Wieland** (Vertr. Dr. Rebecca Epsch)	Prof. Dr. med. Markus **Wallwiener**, MHBA (DGS)

Externe Beratung / Erweiterte Task Force	
Dr. Ursula **Arning** (ZB Med) (Vertr. Constanze Beringer)	Regina **Hanke** (DGP)
Birger **Haarbrandt** (DGfW)	Falk **Huneke** (DGfW)
Thorsten **Karge** (usergroup clinical guideline services)	Erik **Wohlfahrt** (usergroup clinical guideline services)
Rüdiger **Henrici** (j:karef, DGZMK)	Kenan **Hasan** (Amboss)
Emrah **Hircin** (Amboss)	Christian **Senger** (intermedix Deutschland GmbH/CompuGroup)
Ralph Roman **Moser** (intermedix Deutschland GmbH/CompuGroup)	Prof. Dr. Per Olav **Vandvik** (Magic) (Vertr. Linn Brandt MD)
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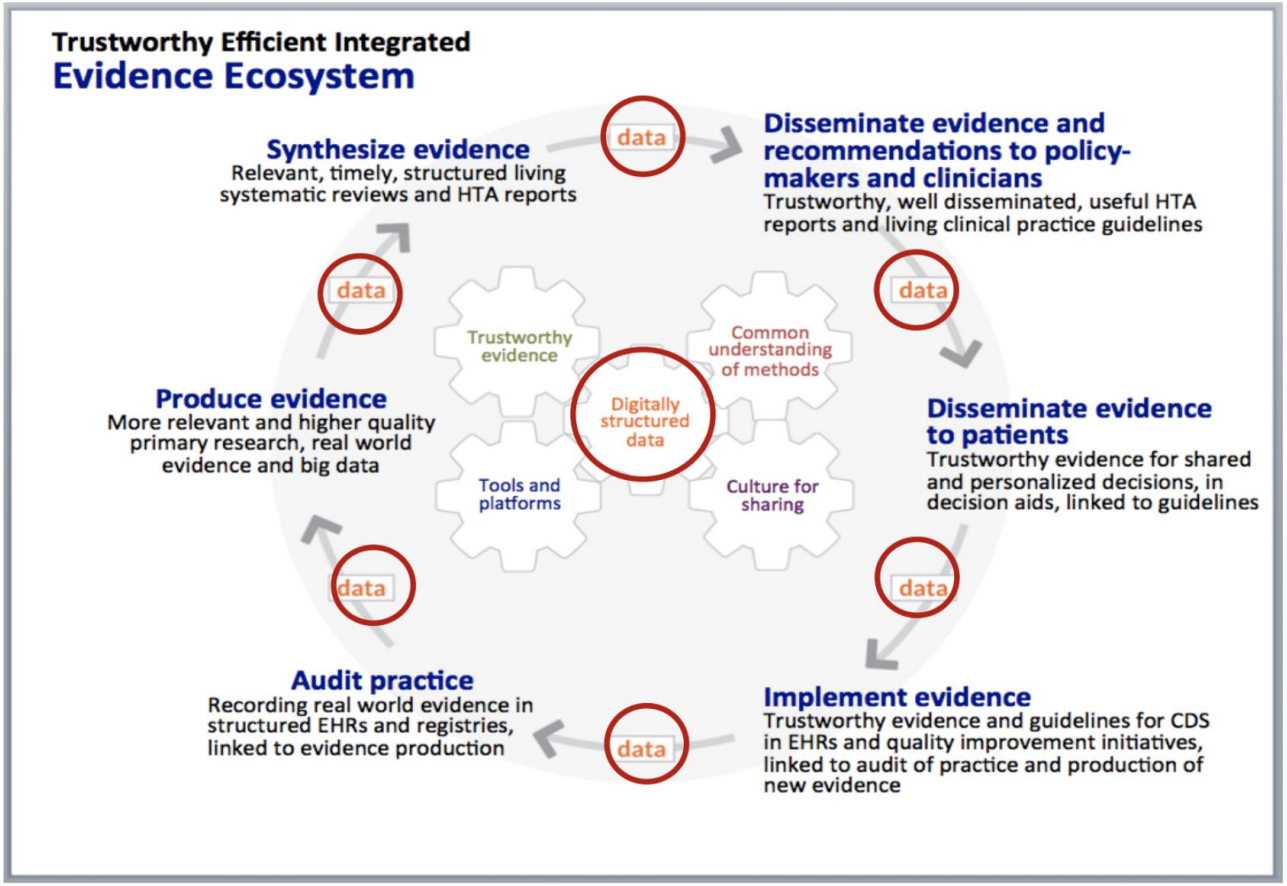
Vision für einen vertrauenswürdigen und effizienten Umgang mit“Evidenz“ in Forschung, Implementierung und Evaluierung



Quelle:
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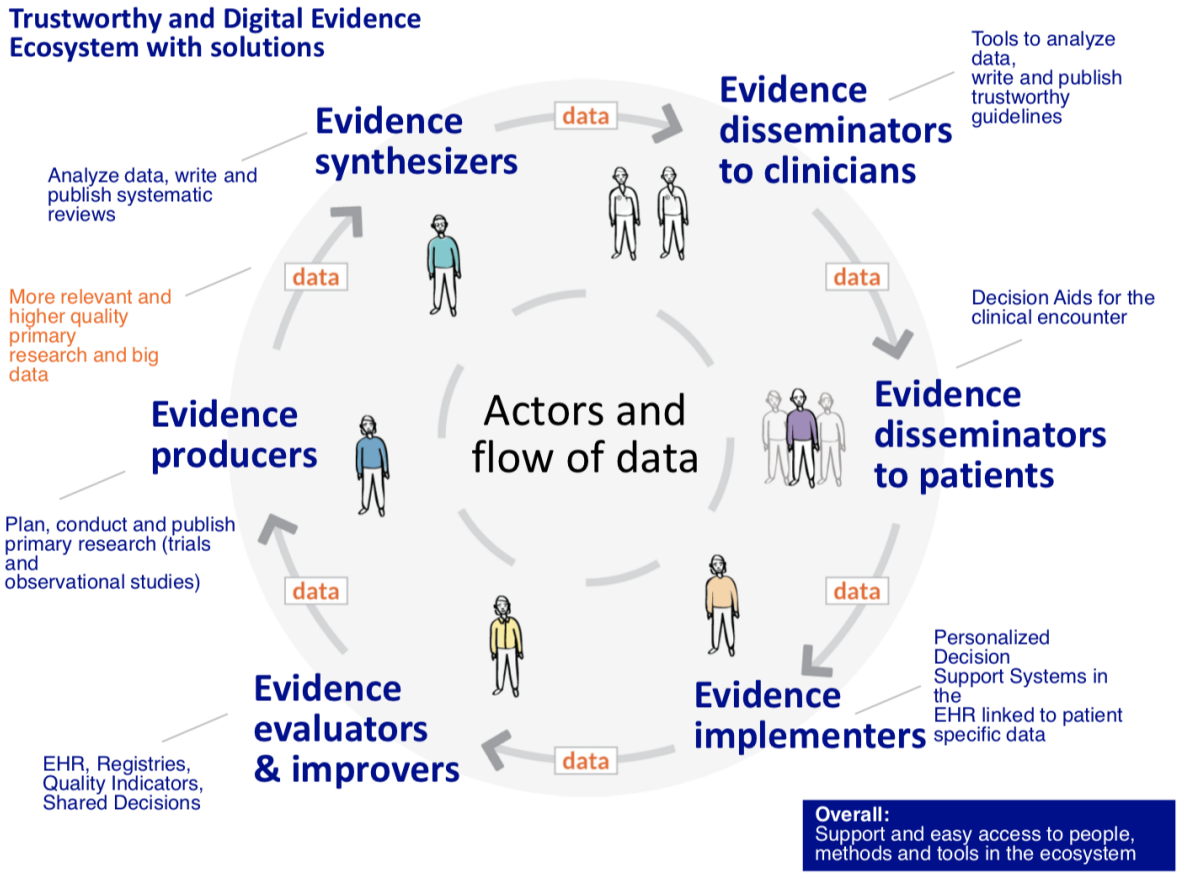
Praktische Umsetzung: Beispiel Cochrane



Praktische Umsetzung: MAGIC APP

MAGIC Evidence Ecosystem Foundation

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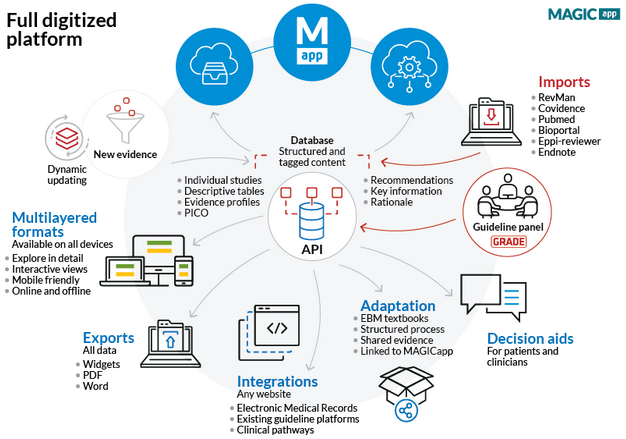
A new approach to producing and disseminating guidelines

MAGICapp is a tool that helps users and organizations to author and publish digitally structured Clinical Practice Guidelines based on high-quality evidence, enabling clinicians and patients to make well-informed healthcare decisions at the point of care.

Learn more



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Vision für einen vertrauenswürdigen und effizienten Umgang mit“Evidenz“ in Forschung, Implementierung und Evaluierung

Quelle:
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PICO – Annotation und endpunktbezogene Ergebnisdarstellung

Population	Intervention	Comparator
Patients with sepsis	Corticosteroids	No corticosteroids

Evidence profile Graphical view Summary

Outcome Timeframe	Study results and measurements	Absolute effect estimates No corticosteroids	Corticosteroids	Certainty of the Evidence (Quality of evidence)	Plain text summary
Mortality Longer term (60 days to 1 year)	Relative risk 0.94 (CI 95% 0.89 - 1.00) Based on data from 6438 patients in 9 studies Follow up: 60 days-1 year.	371 per 1000	349 per 1000 Difference: **22 fewer per 1000** (CI 95% 41 fewer - 0)	**Low** Due to serious imprecision and indirectness	Corticosteroids possibly achieve a small reduction in long-term mortality.
Mortality Short term (28-31 days)	Relative risk 0.93 (CI 95% 0.84 - 1.03) Based on data from 9433 patients in 36 studies Follow up: 14-30 days.	254 per 1000	236 per 1000 Difference: **18 fewer per 1000** (CI 95% 41 fewer - 8 more)	**Low** Due to serious imprecision; borderline inconsistency and publication bias.	Corticosteroids may achieve a small or no reduction in short-term mortality.
Shock reversal 1 week	Relative risk 1.26 (CI 95% 1.12 - 1.42) Based on data from 2802 patients in 13 studies Follow up: 7 days.	464 per 1000	585 per 1000 Difference: **121 more per 1000** (CI 95% 56 more - 195 more)	**High**	Corticosteroids increase the chance of shock reversal in the first week.
Neuromuscular weakness	Relative risk 1.21 (CI 95% 1.01 - 1.45) Based on data from 6178 patients in 7 studies	250 per 1000	303 per 1000 Difference: **53 more per 1000** (CI 95% 3 more - 113 more)	**Low** Due to serious imprecision and indirectness and borderline inconsistency.	Corticosteroids may increase the risk of neuromuscular weakness.
Gastrointestinal bleeding	Relative risk 1.09 (CI 95% 0.86 - 1.38) Based on data from 4243 patients in 17 studies	35 per 1000	38 per 1000 Difference: **3 more per 1000**	**Low** Due to serious indirectness and imprecision.	Corticosteroids may have little or no difference on gastrointestinal bleeding

Multiple Vergleiche möglich

Multiple Comparison Decision Aid for squamous non-small cell lung cancer

Among a 1000 patients like you

Survival at 1 year						
Supportive care	Erlotinib	Gefitinib	Docetaxel	Paclitaxel	Permetrexed	Gemcitabine
5 months	7 months	8 months	7 months	6 months	9 months	8 months
difference →	2 more	3 more	2 more	1 more	4 more	3 more
	Certainty ⊘⊘⊘○	Certainty ⊘⊘○○	Certainty ⊘⊘○○	Certainty ⊘⊘⊘○	Certainty ⊘○○○	Certainty ⊘⊘⊘○

Liver toxicity at 1 year						
Supportive care	Erlotinib	Gefitinib	Docetaxel	Paclitaxel	Permetrexed	Gemcitabine
9 per 1000	40 per 1000	40 per 1000	14 per 1000	13 per 1000	17 per 1000	21 per 1000
difference →	31 more	31 more	5 more	4 more	8 more	12 more
	Certainty ⊘⊘⊘○	Certainty ⊘⊘⊘⊘	Certainty ⊘⊘⊘○	Certainty ⊘○○○	Certainty ⊘⊘○○	Certainty ⊘⊘⊘○

Death | Severe rash | Severe breathlessness | Severe diarrhea

Severe asthenia | Fluid retention | Severe neuropathy | Severe neutropenia

Practical issues

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Vision für einen vertrauenswürdigen und effizienten Umgang mit“Evidenz“ in Forschung, Implementierung und Evaluierung

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Patient overview - Latest

Labs
HbA1c: 8.1 (11.08.13)
Hb: 12.6 (12.08.13)
CRP: 43 (12.08.13)

Observations & Measurements
BP: 102/82 (12.08.13)
Pulse: 106 (12.08.13)
Temp: 36.2 (12.08.13)

Medication
Ticagrelor 90mg x2 (11.08.13)
Haloperidol 0.5mg x2 (11.08.13)
Pregabalin 75mg x2 (01.05.13)

Radiology
Chest xRay (11.08.13)

Conditions
Renal failure
Trigeminal neuralgia

Choice of oral anticoagulation

Weak recommendation

We suggest treatment with dabigatran, rivaroxaban or apixaban (NOAC) rather than warfarin.

Dosing and relative contraindications of NOAC

Strong recommendation

Dabigatran 150 mg x 2, rivaroxaban 20 mg x 1 and apixaban 5 mg x 2 is recommended for most patients.
A reduced dose of dabigatran 110 mg x 2, rivaroxaban 15 mg x 1 and apixaban 2,5 mg x 2 is recommended if:

- Age > 80 years old
- Concomitant use of interacting medication (e.g. verapamil)
- High bleeding risk (HAS-BLED score 3 or higher)
- Moderate kidney failure (CrCl 30-49 ml/min)

Remark: Dabigatran is eliminated primarily by the kidney, rivaroxaban and apixaban partly, and renal function should be monitored before treatment and regularly during treatment.

Quelle:
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Technische Umsetzung : Beispiel EBMonFIHR

Creating a global standard for sharing structured evidence and recommendations

How are we solving the problem? #2

EBM

We are extending the methods and infrastructure of FHIR to provide an interoperability standard for electronic exchange of knowledge from and about clinical research and recommendations. The "FHIR Resources for EBM Knowledge Assets" project (nicknamed EBMonFHIR) is approved as an HL7 development.

Introduction to EBMonFHIR:
https://docs.google.com/viewer?a=v&pid=forums&srcid=MDc2OTg0NTE1NDQ3MjM4MDU2OTIBMTE2NDc0NzAwNDIxMDExOTUzNzkBR09jX1BhTk1Bd0FKATAuMQEBdjI&authuser=0

Quelle: Brian Alper

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Aktivitäten im Guidelines International Network (G-I-N)

GIN Tech - Sharing of data within the Evidence Ecosystem

G-I-N 2018 MANCHESTER
11 – 14 SEPTEMBER 2018

G-I-N Tech

EBSCO Health

NICE National Institute for Health and Care Excellence

Evidence Prime
The solutions for health care decisions

MAGIC making GRADE the irresistible choice

DUODECIM

EBMonFHIR

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Vision für einen vertrauenswürdigen und effizienten Umgang mit“Evidenz“ in Forschung, Implementierung und Evaluierung

HL7 International

Page | Discussion

PicoElementDefinition FHIR Resource Proposal

MoM Hot Topic

This page documents a Pending FHIR Resource Proposal

Main Page
Categories

groups
Work Groups
User Groups

meetings
WGM Information

general

Contents [hide]

1 PicoElementDefinition
- 1.1 Owning work group name
- 1.2 Committee Approval Date:
- 1.3 Contributing or Reviewing Work Groups
- 1.4 FHIR Resource Development Project Insight ID
- 1.5 Scope of coverage

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Quelle:https://wiki.hl7.org/index.php?title=PicoElementDefinition_FHIR_Resource_Proposal

Workshop der G-I-N Tech Working Group 2018

Präsentationen:
Linn Brandt (Magic), Ilkka Kunnamo (Duodecim), Brian Alper (EBSCO)

What has been accomplished so far

- Data flow from Cochrane Revman/Archie to guideline development tools (MAGICApp, GRADEpro) where it is available in structured format
- Export of data from guideline development tools to publication platforms and tools
- Linked data
- PICO ontology by Cochrane
- Code mapping between EHR codes and concepts used by clinical decision support tools

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Von der Evidenz zur Empfehlung - strukturierte Entscheidung

Purpose of EtD frameworks

The purpose of EtD frameworks is to help groups of people (panels) making healthcare recommendations or decisions move from evidence to decisions.

EtD frameworks:

- Inform panel members' judgements about the pros and cons of each intervention that is considered
- Ensure that important factors that determine a decision (criteria) are considered

Andrews et al, GRADE 14., J Clin Epidemiol. 2013 Jul ;66(7):719-25.

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GRADE Evidence to Decision Framework (EtD)

1. **Problem**
   Is the problem a priority?
2. **Desirable Effects**
   How substantial are the desirable anticipated effects?
3. **Undesirable Effects**
   How substantial are the undesirable anticipated effects?
4. **Certainty of evidence**
   What is the overall certainty of the evidence of effects?
5. **Values**
   Is there important uncertainty about or variability in how much people value the main outcomes?
6. **Balance of effects**
   Does the balance between desirable and undesirable effects favor the intervention or the comparison?
7. **Resources required**
   How large are the resource requirements (costs)?
8. **Certainty of evidence of required resources**
   What is the certainty of the evidence of resource requirements (costs)?
9. **Cost effectiveness**
   Does the cost-effectiveness of the intervention favor the intervention or the comparison?

https://gradepro.org/

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GRADE Evidence to Decision Framework (EtD)

„Summary of judgement“

KRITERIEN					SUMMARY OF JUDGEMENTS
PROBLEM	No	Probably no	Probably yes		**Yes**
DESIRABLE EFFECTS	Trivial	Small	Moderate		**Large**
UNDESIRABLE EFFECTS	Large	**Moderate**	Small		Trivial
CERTAINTY OF EVIDENCE	Very low	Low	**Moderate**		High
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**		No important uncertainty or variability
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	**Favors the intervention**
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	Moderate savings	Large savings
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	**Moderate**		High
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	**Favors the intervention**
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased
ACCEPTABILITY	No	Probably no	Probably yes		Yes
FEASIBILITY	No	Probably no	**Probably yes**		Yes

https://gradepro.org/

Von der Leitlinie zur Studie

10. Forschungsbedarf

Die Expertengruppe hat im Rahmen der Konsensuskonferenz verschiedene relevante Fragestellungen, die derzeit unzureichend beantwortet werden können, erarbeitet. Darunter fallen die Relevanz des ASL-Titers zu Therapieentscheidungen bzw. im Verlauf sowie die Relevanz der Tonsillektomie bei Kindern mit Psoriasis. Ebenso ist in diesem Zusammenhang die Relevanz der Bestimmung von HLA-Cw602 und die Bedeutung bakterieller Abstriche für das therapeutische Prozedere nicht vollständig geklärt. Es besteht die Frage, welche die adäquate Bildgebung bei Kindern darstellt. Darüber hinaus wurde der vorzeitige Epiphysenschluss durch verschiedene Systemtherapeutika z. B. Acitretin aber auch Biologika als unzureichend erforscht dargestellt. Auch besteht weiterhin die Frage nach Triggerung eines Psoriasisschubes durch Impfungen.

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S2k Leitlinie Therapie der Psoriasis bei Kinder und Jugendlichen
https://www.awmf.org/leitlinien/detail/ll/013-094.html

Von der Leitlinie zur Studie

P I C O – Frage

↓

Systematische Suche

↓

Keine/unsichere Evidenz

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Keine/Schwache Empfehlung

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Forschungsfrage

↓

Abgleich mit Versorgungsdaten

↓

Studie

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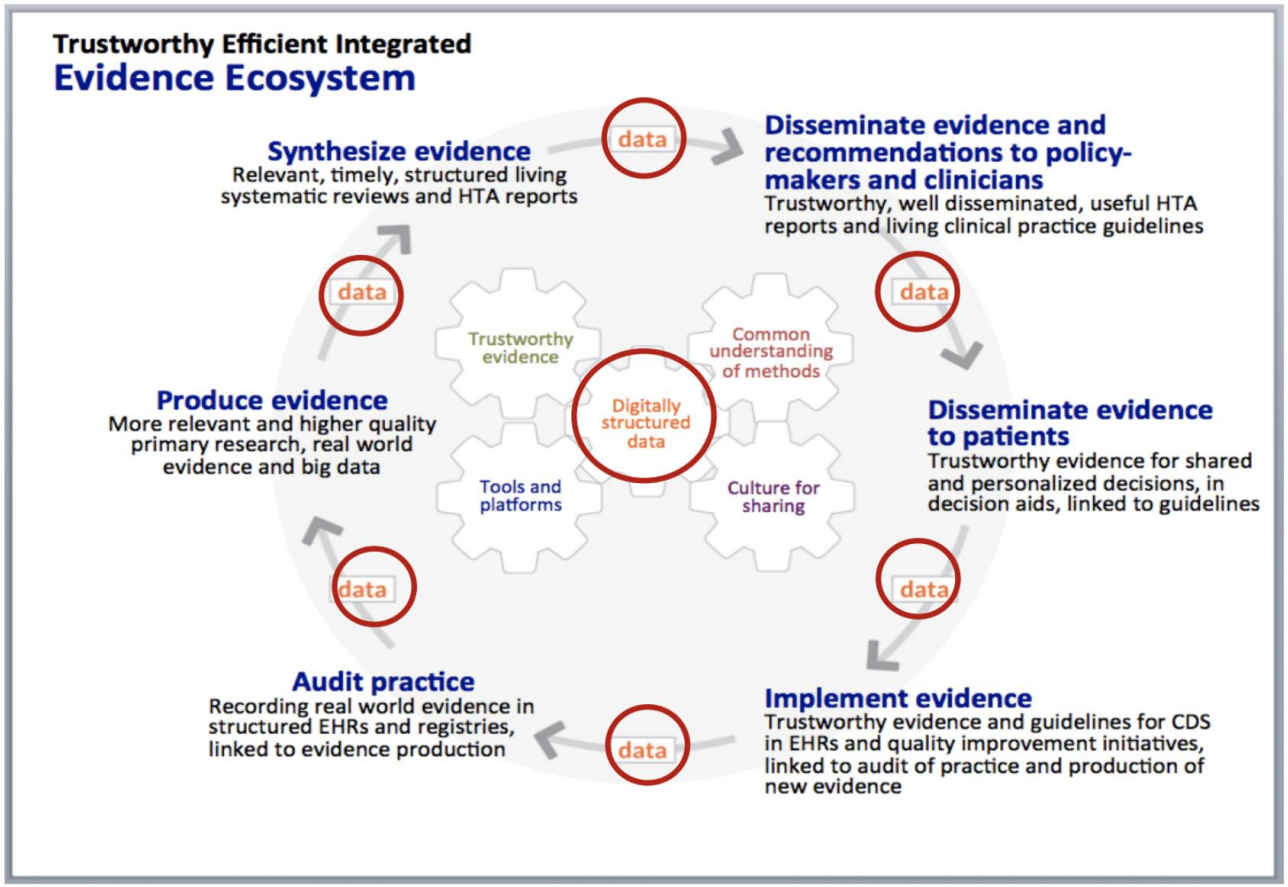

Quelle:
MAGIC

Herzlichen Dank für Ihre Aufmerksamkeit!