



Standard di cura e linee guida

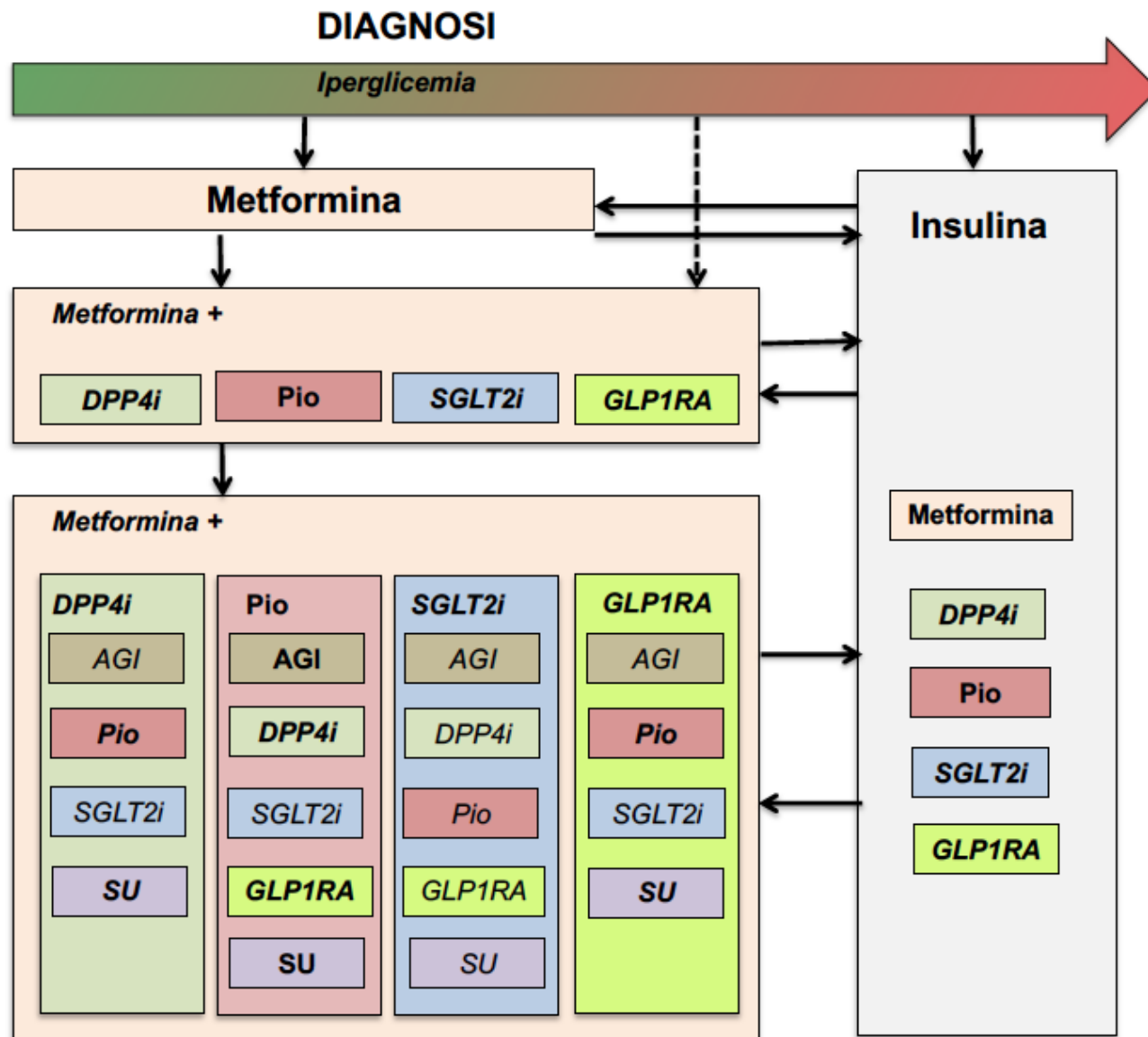
Opportunità e problemi alla luce della Legge Gelli

Edoardo Mannucci

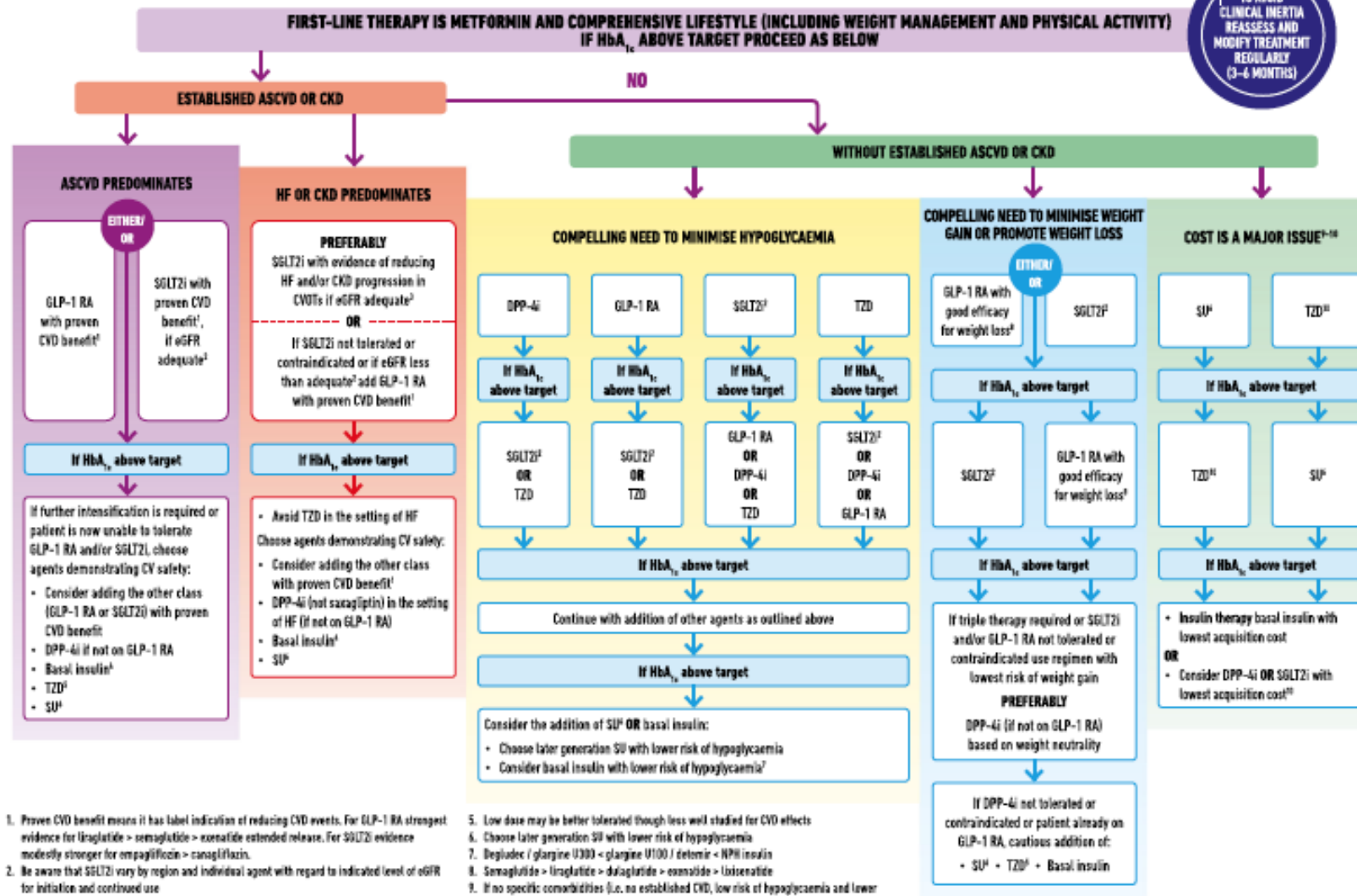
Conflitti di interessi

Negli ultimi due anni, E. Mannucci ha ricevuto:
compensi per consulenze da ***AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck e Novo Nordisk***
compensi per relazioni a corsi/convegni da ***Abbott e Eli Lilly***
compensi da agenzie in simposi sponsorizzati da ***Abbott, Allergan, AstraZeneca, Boehringer Ingelheim, Bruno, Eli Lilly, Menarini, Merck, Novo Nordisk, Sanofi e Takeda***

La struttura diretta da E. Mannucci ha ricevuto:
finanziamenti per attività di ricerca e/o educative da ***AstraZeneca, Bayer, Boehringer Ingelheim, Molteni e Novo Nordisk***
compensi per trial clinici da:
AstraZeneca, Eli Lilly, Genentech, Janssen, Novartis e Novo Nordisk.



GLUCOSE-LOWERING MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH

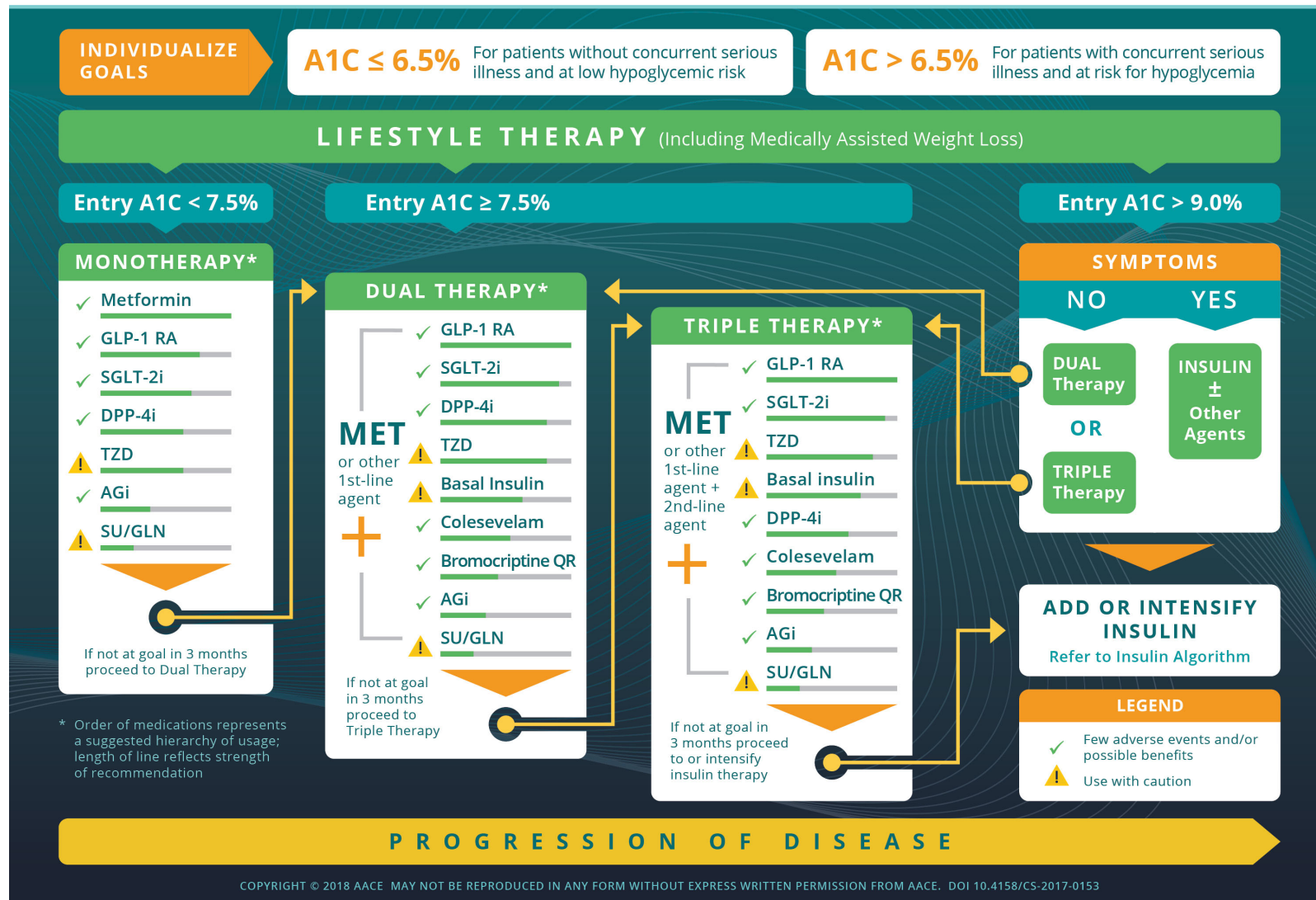


ADA-EASD Consensus Statement, 2018

Fig. 2 Glucose-lowering medication in type 2 diabetes: overall approach

Treatment of T2DM: AACE/ACE, 2017

Glycemic Control Algorithm



Legge n. 24/2017

Le linee guida e gli aggiornamenti delle stesse elaborati dai soggetti di cui al comma 1 sono integrati nel Sistema nazionale per le linee guida (SNLG), il quale è disciplinato nei compiti e nelle funzioni con decreto del Ministro della salute, da emanare, previa intesa in sede di Conferenza permanente per i rapporti tra lo Stato, le regioni e le province autonome di Trento e di Bolzano, con la procedura di cui all'articolo 1, comma 28, secondo periodo, della legge 23 dicembre 1996, n. 662, e successive modificazioni, entro centoventi giorni dalla data di entrata in vigore della presente legge. L'Istituto superiore di sanità pubblica nel proprio sito internet le linee guida e gli aggiornamenti delle stesse indicati dal SNLG, previa verifica della conformità della metodologia adottata a standard definiti e resi pubblici dallo stesso Istituto, nonché' della rilevanza delle evidenze scientifiche dichiarate a supporto delle raccomandazioni.

Decreto Ministero della Salute 27 febbraio 2018

Per le modalità relative all'inserimento, allo sviluppo, al completamento e alla valutazione delle linee guida si rimanda ad apposito manuale operativo, predisposto dall'Istituto superiore di sanità e pubblicato sul relativo sito istituzionale.

Manuale operativo SNLG (ISS)

- Qualità (metodo GRADE)
- Condivisione
- Controllo e verifica



AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 1: SCOPE AND PURPOSE

DOMAIN 2: STAKEHOLDER INVOLVEMENT

DOMAIN 3: RIGOUR OF DEVELOPMENT

DOMAIN 4: CLARITY OF PRESENTATION

DOMAIN 5: APPLICABILITY

DOMAIN 6: EDITORIAL INDEPENDENCE

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

Scores of guidelines on pharmacological treatment of type 2 diabetes

	SCOPE & PURPOSE			STAKEHOLDER INVOLVEMENT			RIGOUR OF DEVELOPMENT								CLARITY			APPLICABILITY				INDEP.	
	Objectives described	Health question described	Population described	All professional groups involved	Target population involved	Target users defined	Systematic search of evidence	Selection criteria defined	Strength and limitations described	Methods for recommendations	Benefits and risks considered	Clear link with evidence	External review	Update procedure	Recommendations unambiguous	Different options presented	Key recommendations identifiable	Barriers and facilitators	Tools for implementation	Resource implications	Monitoring/auditing criteria	Content not influenced by sponsor	Conflict of interest considered
AMD SID (standard)	7	7	7	1	1	2	4	3	5	4	6	5	5	1	6	7	7	1	1	1	1	5	5
ADA (standard)	7	7	7	1	1	2	1	1	4	4	5	2	1	1	6	7	7	1	1	6	1	4	1
ACE AACE (guideline)	7	7	7	1	1	2	3	1	3	4	5	2	1	1	5	5	6	1	1	1	3	5	7

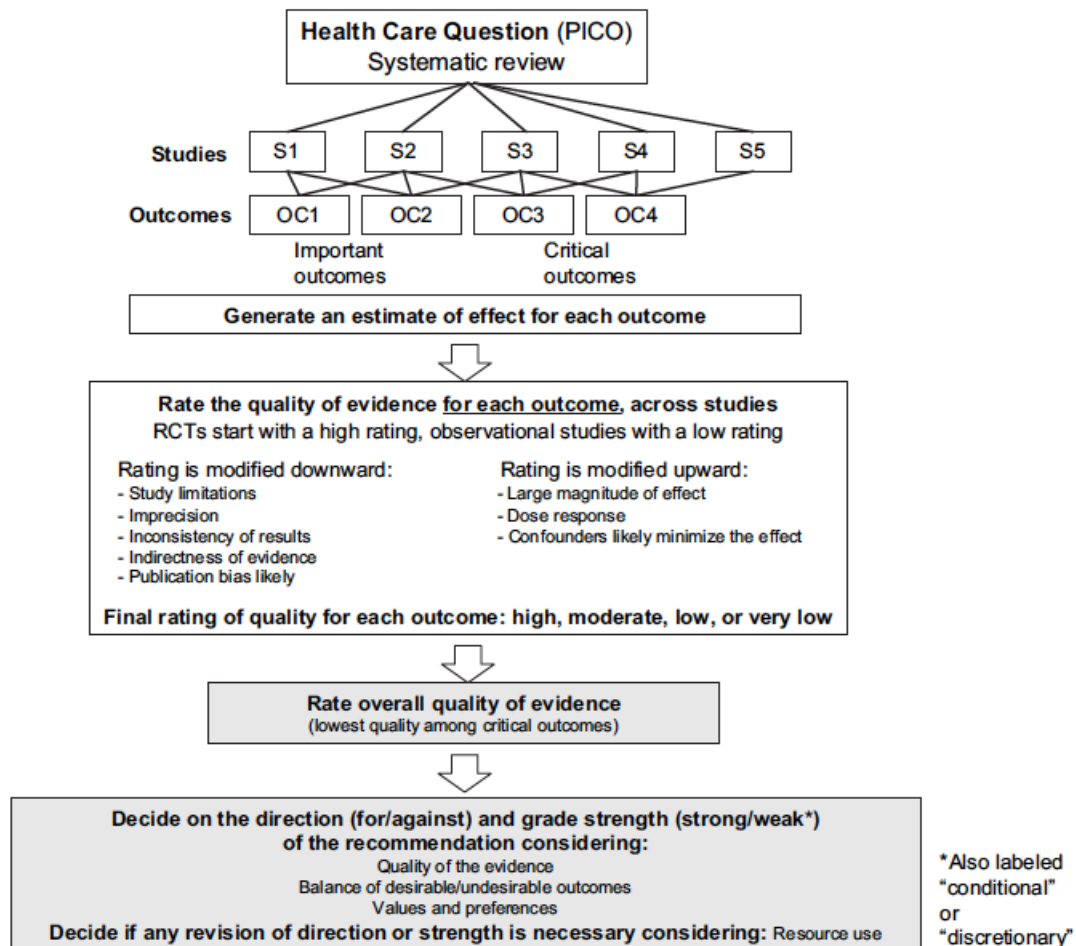
AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 3: RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

GRADE

(Grading of Recommendations Assessment, Development and Evaluation)

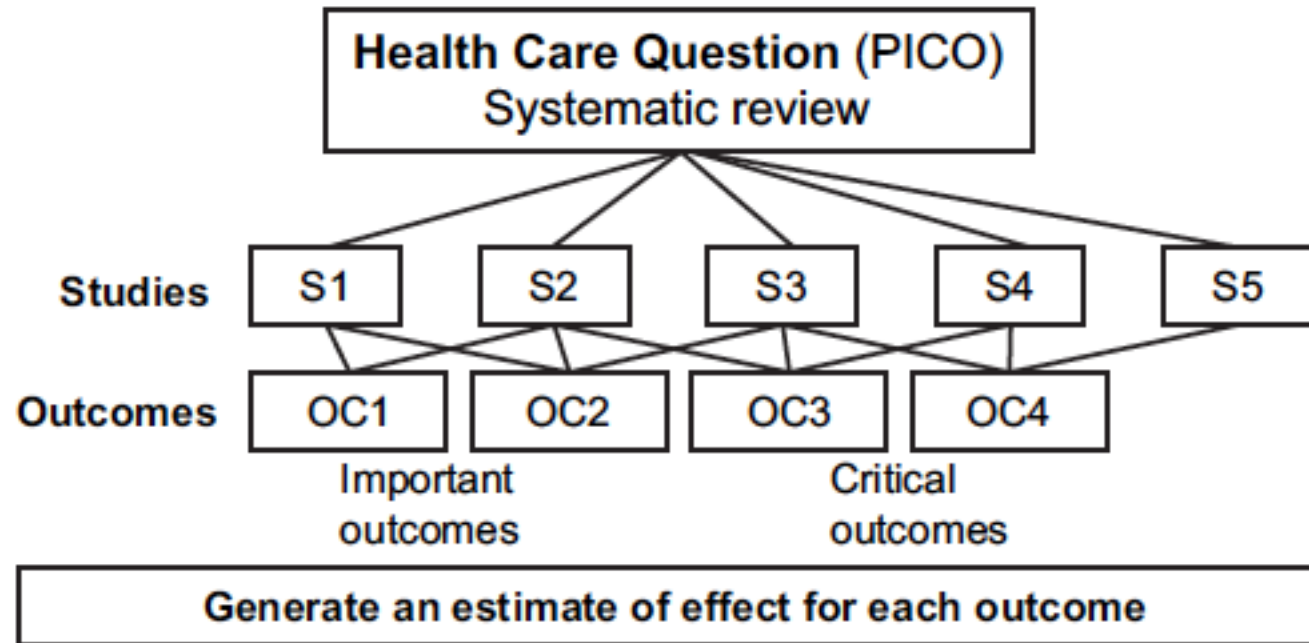


PICO framework

- Patient
- Intervention
- Comparison
- Outcome

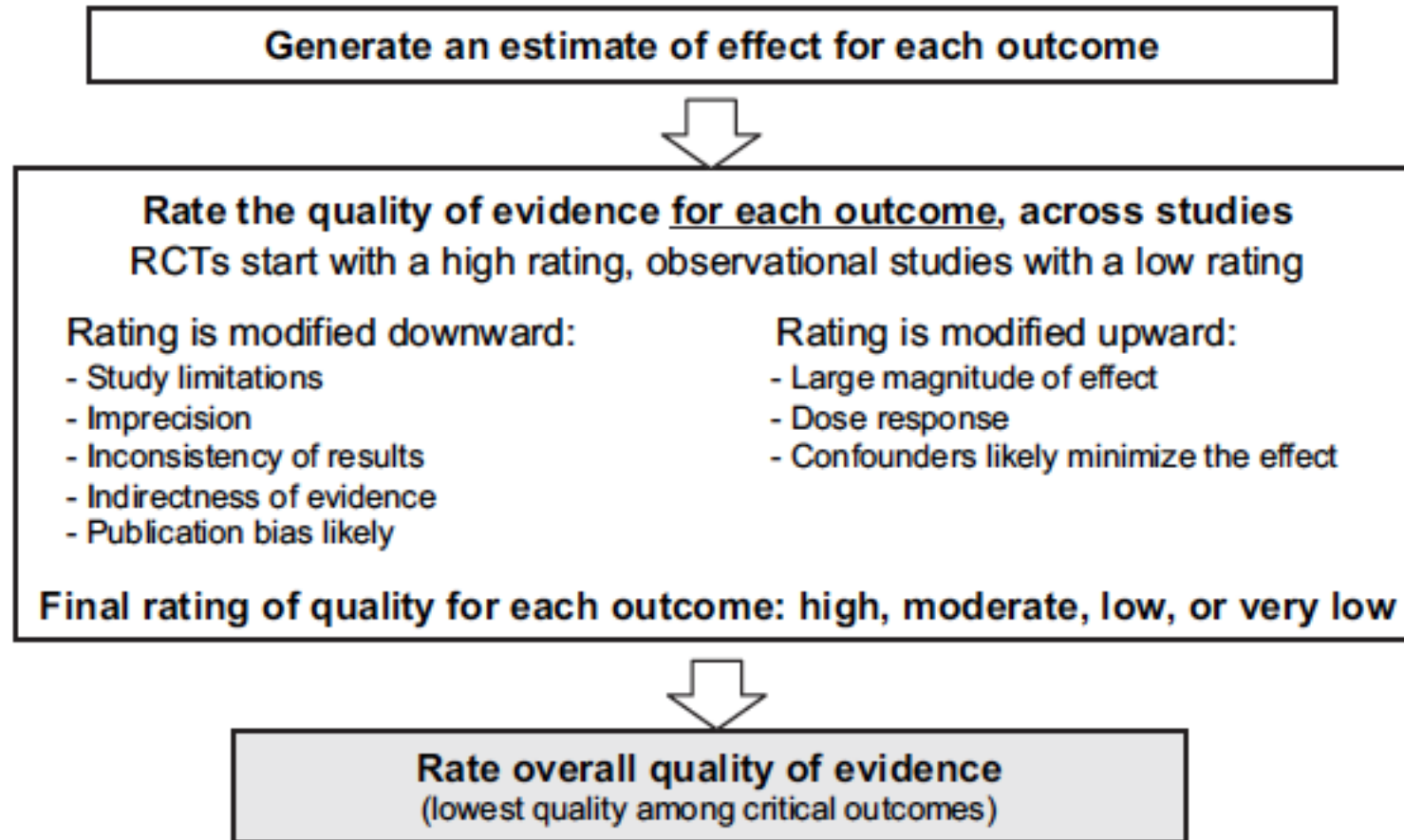
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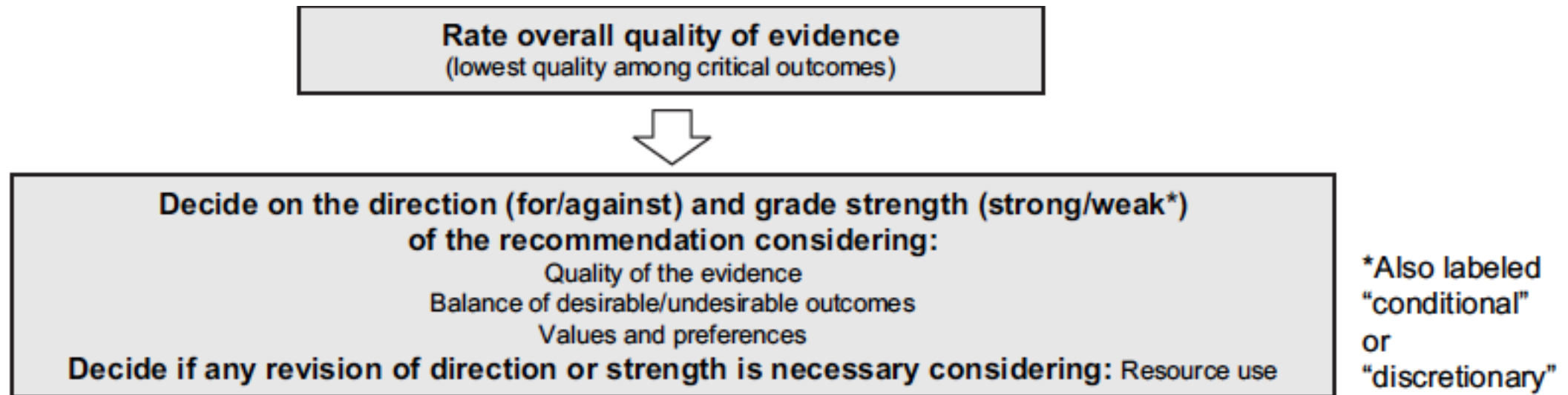
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AGREE (Appraisal of Guidelines for Research and Evaluation) - II

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AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 2: STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.

Condivisione

- ***Con tutti i professionisti coinvolti***

Non possono esistere linee guida diverse (e potenzialmente non concordi) per una stessa condizione clinica, formulate da società scientifiche di settori diversi

- ***Con i pazienti***

Ogni intervento medico produce effetti favorevoli su alcuni ambiti e sfavorevoli su altri. Solo i pazienti possono fornire un peso adeguato ai singoli ambiti

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

Scores of guidelines on pharmacological treatment of type 2 diabetes

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AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 5: APPLICABILITY

- 18. The guideline describes facilitators and barriers to its application.
- 19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
- 20. The potential resource implications of applying the recommendations have been considered.
- 21. The guideline presents monitoring and/or auditing criteria.

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

Scores of guidelines on pharmacological treatment of type 2 diabetes

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AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 6: EDITORIAL INDEPENDENCE

- 22. The views of the funding body have not influenced the content of the guideline.
- 23. Competing interests of guideline development group members have been recorded and addressed.

Il futuro degli standard di cura

- ***Sintesi***

Documenti snelli (raccomandazioni, non manuali)



Il futuro degli standard di cura

- ***Sintesi***

Documenti snelli (raccomandazioni, non manuali)

- ***Focalizzazione***

Formulazione di linee guida sugli argomenti più importanti e per i quali esiste sufficiente evidenza; il resto verrà affidato a documenti di consenso o position statements (non inseriti nel SNLG)



Il futuro degli standard di cura



- ***Sintesi***

Documenti snelli (raccomandazioni, non manuali)

- ***Focalizzazione***

Formulazione di linee guida sugli argomenti più importanti e per i quali esiste sufficiente evidenza; il resto verrà affidato a documenti di consenso o position statements (non inseriti nel SNLG)

- ***Frazionamento***

Non più un'edizione generale degli standard, ma linee guida specifiche su singoli argomenti, formulate con il coinvolgimento di professionisti (Società Scientifiche, istituzioni, ecc.) diversi

Conclusioni: la legge 24/2017 e le linee guida

- ***Rischi***

Complessità (la realizzabilità del sistema resta dubbia)

- ***Opportunità***

Spinta verso il rigore metodologico

Impulso alla condivisione

Attenzione all'applicabilità e all'implementazione