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Background

- The Indian pharmaceutical industry is expected to be worth US\$ 130 billion by 2030. In terms of both volume and value, India is the 3rd largest producer of pharmaceuticals in the world. Pharmacoeconomic (PE) analyses are crucial for allocating healthcare resources because many patients do not have easy access to or the means to pay for them.¹
- PE can aid in decision-making, evaluate how affordable medicines are for patients, ensure that they have access to them when needed, and compare various product for treatment of diseases. It will provide evidence opposing the promotion of certain high-priced medicines and services.²
- Decision-makers can be misled by poorly designed PE studies. High quality and well-designed PE studies are required to improve the decision-making process.
- Although health economic studies are useful in decision-making for the efficient use of healthcare resources to maximize health benefits, there are hardly few reports about their qualities.

Objective

We assessed the quality of PE studies conducted in India to report key areas of focus on the findings from the reviewed studies.

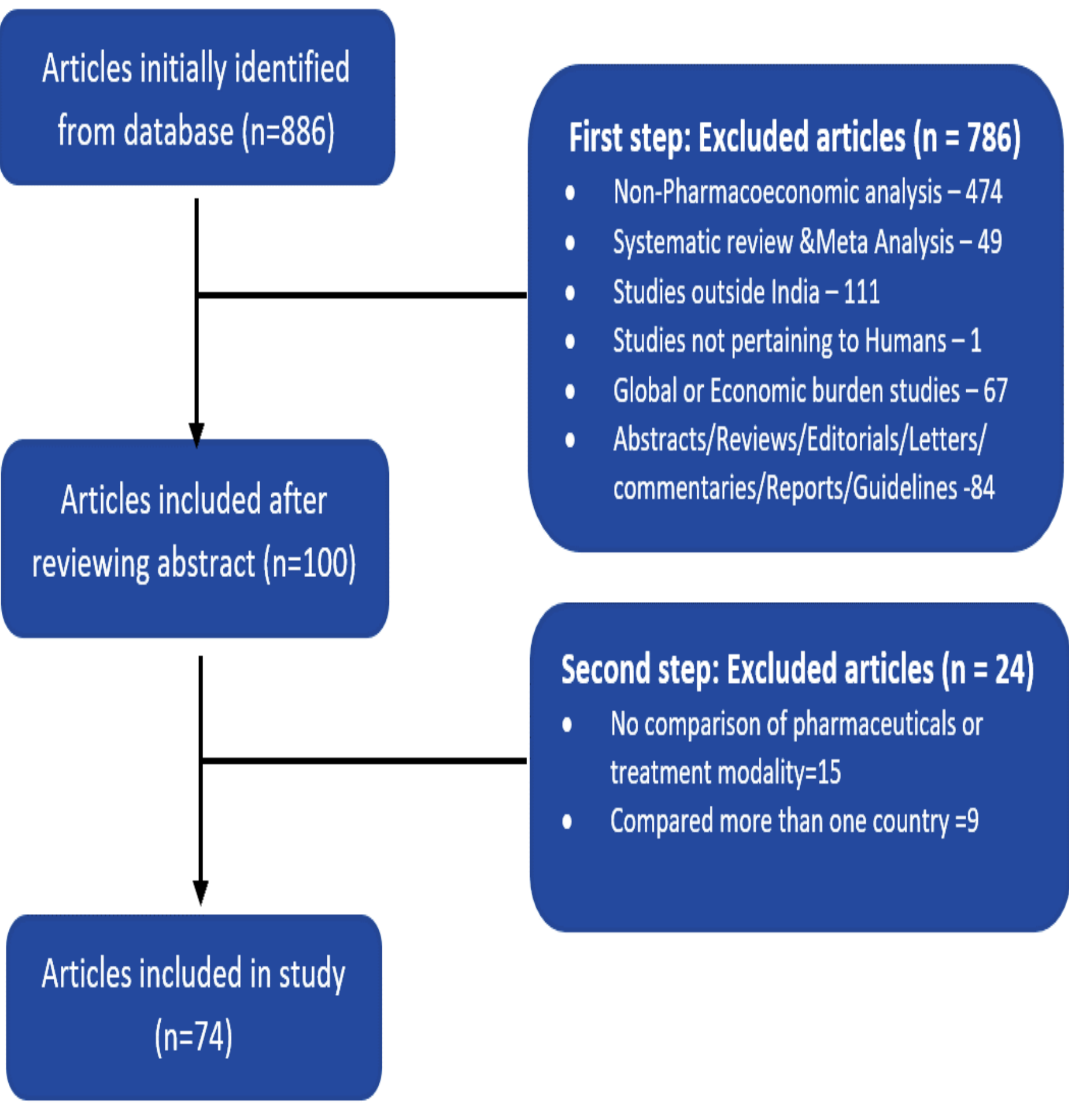
Methodology

- A targeted literature review was conducted using well-defined search strategy in PubMed to identify PE studies conducted in India from May 2017-April 2022.
- Only PE evaluation studies were included, whereas trial-based cost analyses were excluded.
- The quality of included studies was assessed using Quality of Health Economic Studies (QHEs) tool, which comprised of 16 evaluation criteria related to objectives, source, funding, perspective, sub-group analysis, scales, and economic modelling related parameters.³
- Based on scores (100-points), studies were rated as good (>75), fair (50-74) and poor (<49) quality.⁴

Results

Search strategy provided 888 studies; 95 of these were PE studies, and 74 were included in analysis (Figure 1).

Figure 1. Study selection flow chart



Results- continuation

- Included studies cost-effectiveness analysis (CEA; n=55), Cost-Benefit analysis (CBA; n=5), Budget-impact analysis (BIA; n=4), cost-consequences analysis (CCA), cost-utility analysis (CUA) (each n=1), and burden of illness (BOI; n=8).
- The average quality score was 64, with 15 studies rated as ‘good’, 51 ‘fair’, and 8 ‘poor’. We observed that primary outcome measures, stating negative outcomes, reporting bias, along with implementing statistical and sensitivity analysis significantly affected the quality score (Figure 2).
- Most studies were CEA (74%), had QALY (59%) as outcome measure, and assessed cost parameters with respect to health program (43%), followed by drug (25%), vaccine (13%), and health screening (11%). Maximum of the included studies were published in 2021 (n=20) (Figure 3).

Figure 2. Summary statistics of QHEs scores

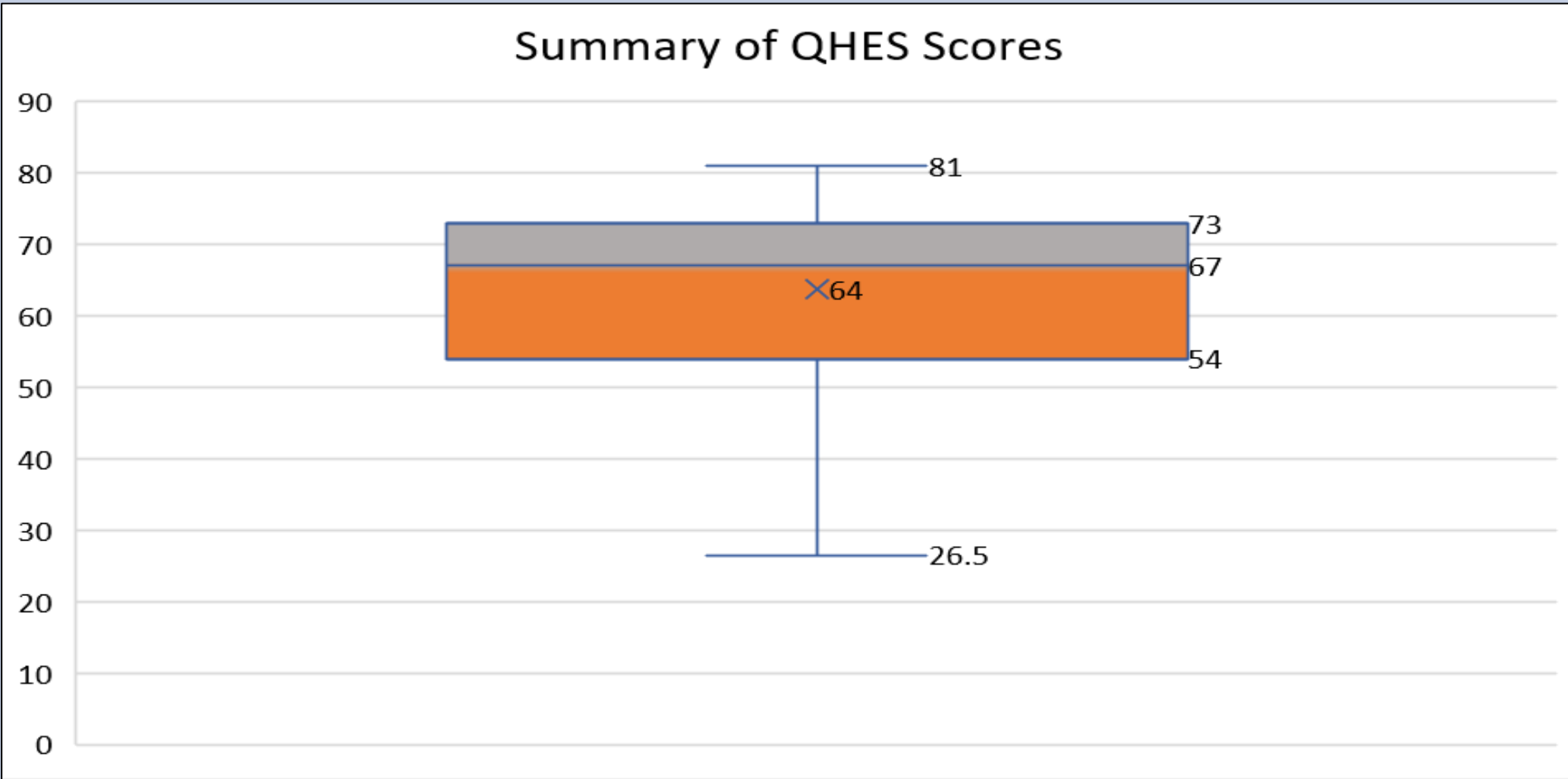
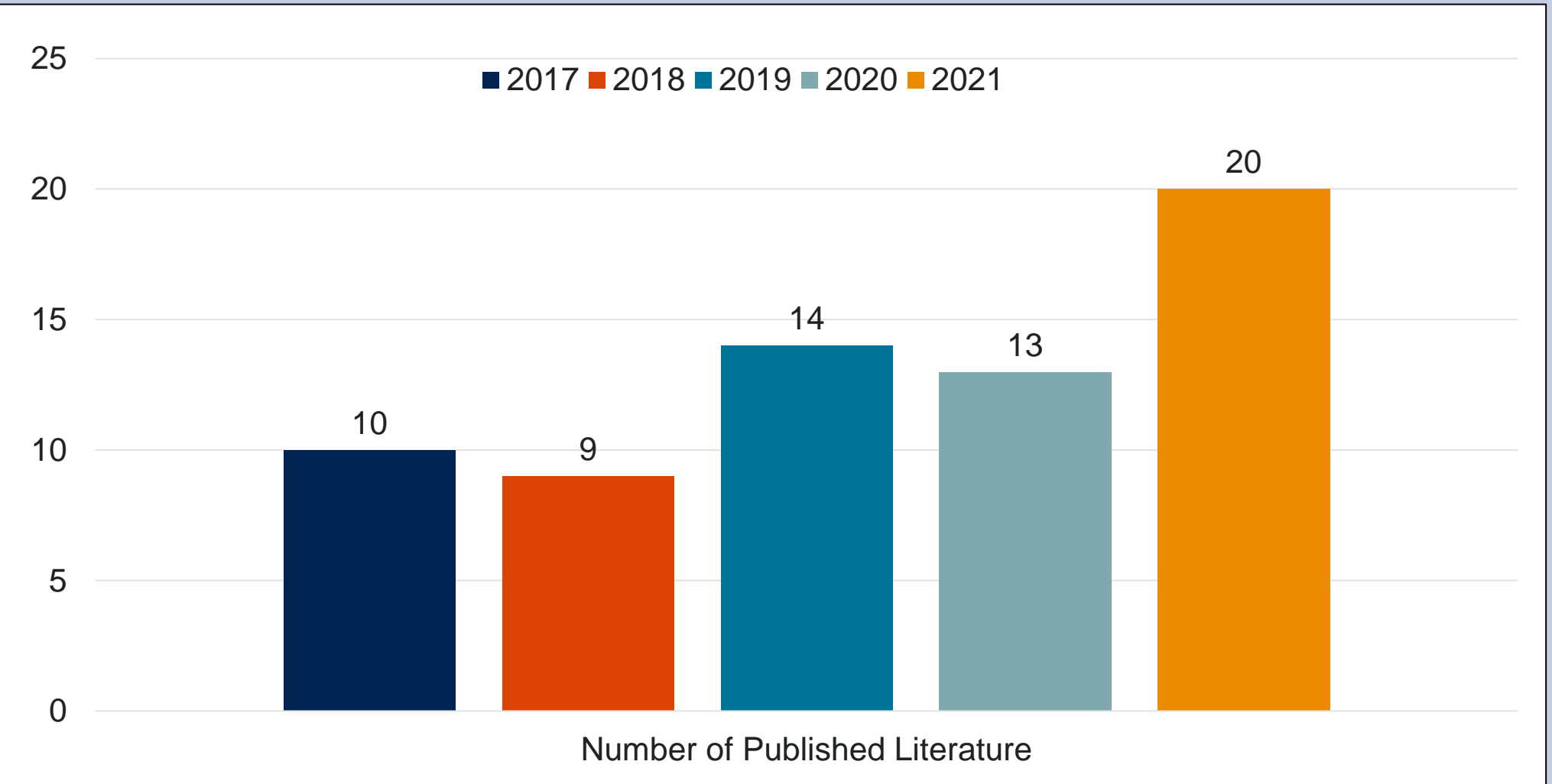


Figure 3. Year-wise trend of PE evaluation studies



- The most common therapeutic area in which the included studies were conducted was infectious disease (44%), cardiology (14%), and oncology (12%).
- Out of the 74 studies, 15 were of high quality, 49 were of fair quality, and 10 were of poor quality. None of the studies had extremely poor quality (Figure 4).
- Studies published in endocrinology and hematology therapeutic areas had the highest mean QHEs score (74, n=3 studies), whereas studies published in gynecology therapeutic area had the lowest mean QHEs score (52, n=3 studies) (Figure 5).

Figure 4. Distribution of studies in QHEs quality quartiles



Figure 5. Mean QHEs score by different therapeutic areas

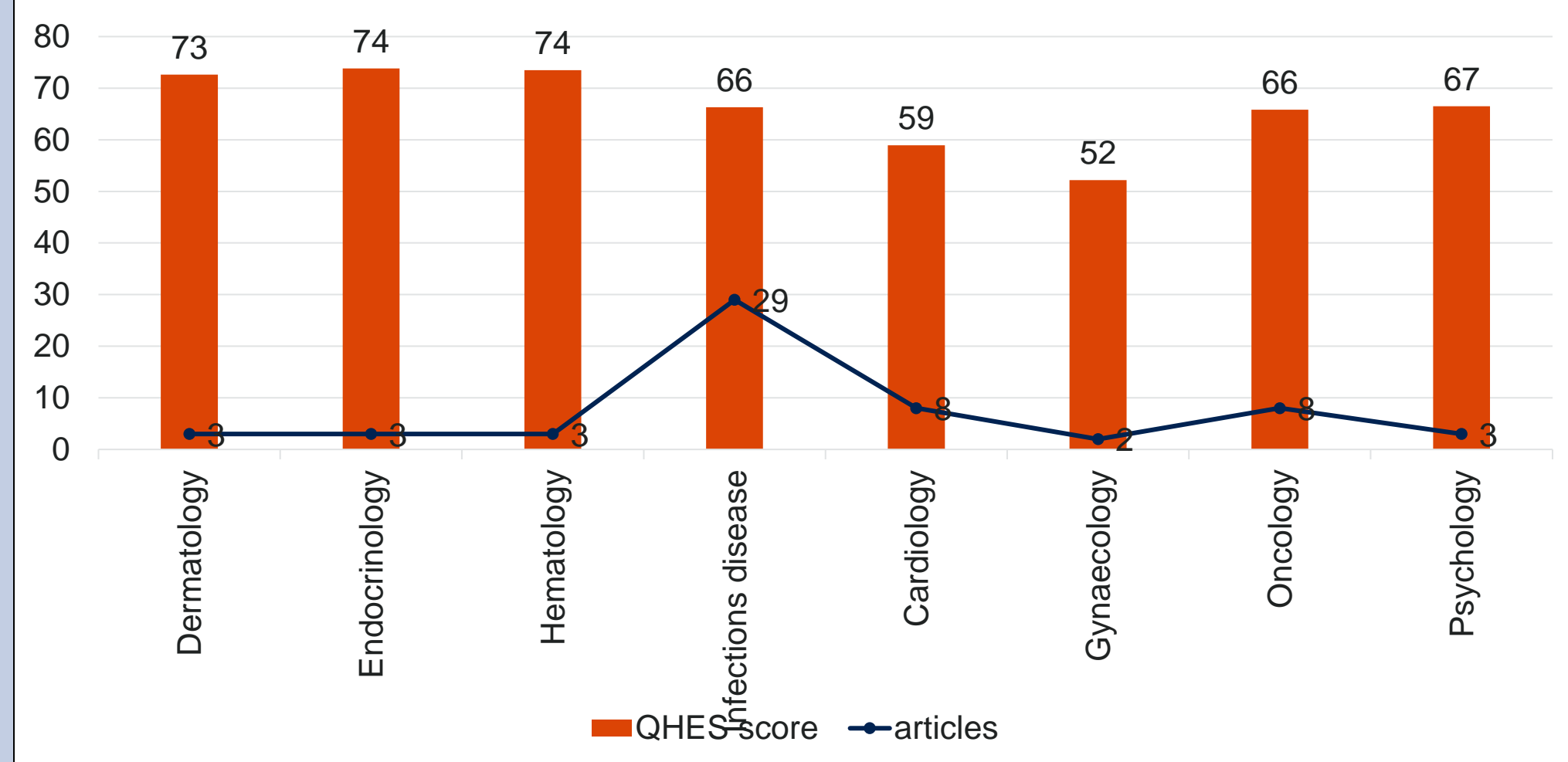
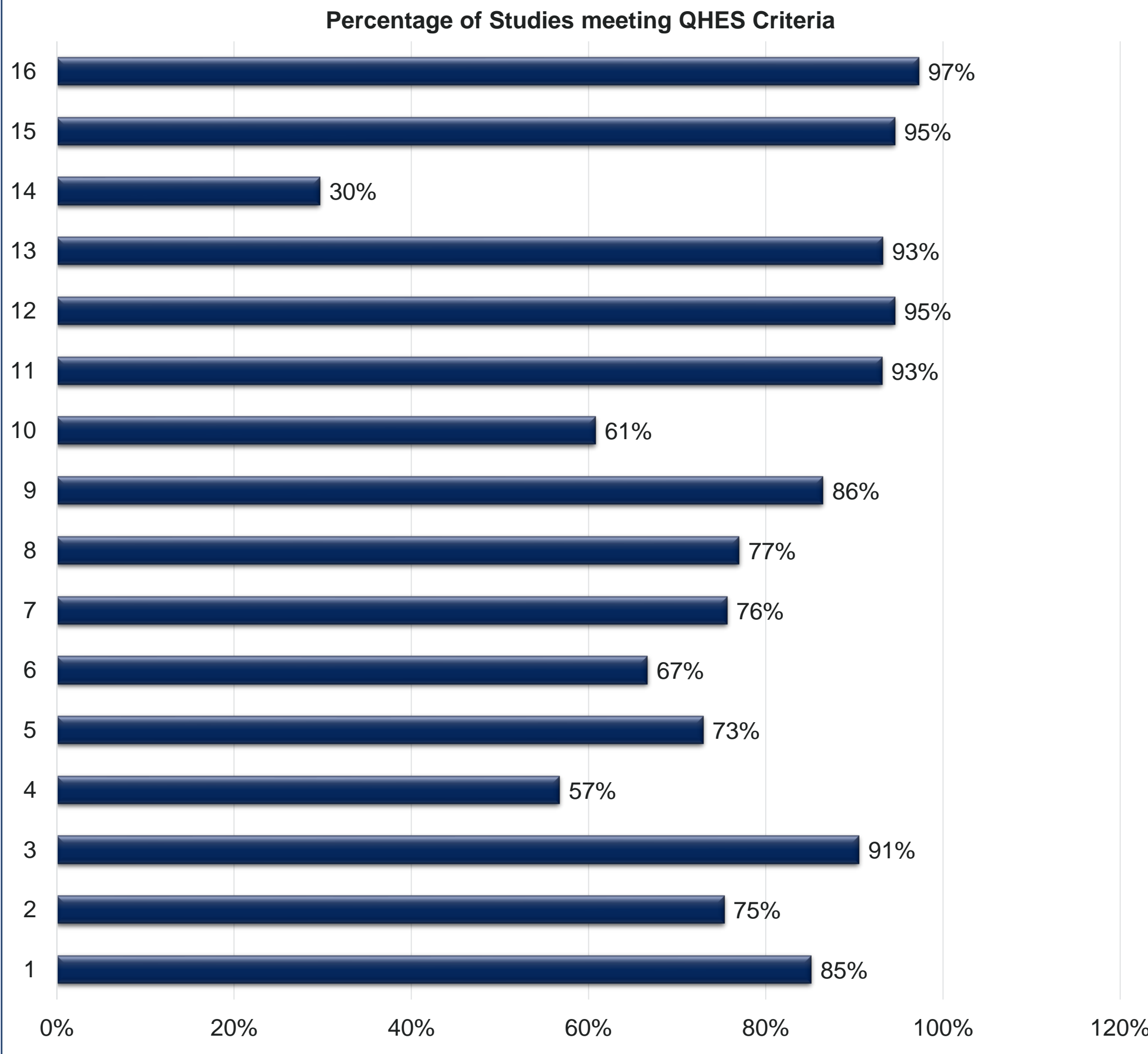


Figure 6. Quality of studies per item of the QHEs

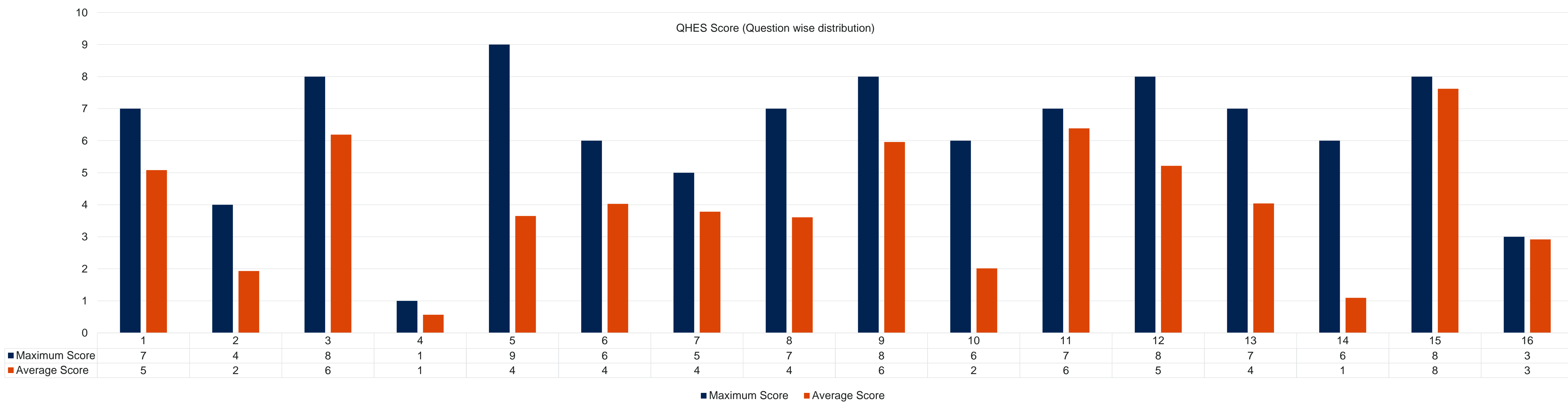


- The mean percentage of QHEs criteria met was 78%. (Figure 6).
- Source of funding element (dimension 16) was reported used in all, but two studies and justification of conclusions/recommendations (dimension 15) was well reported. The uncertainty element (dimension 5) and direction and magnitude of potential biases element (dimension 14) were reported poorly overall (Figure 7).

Conclusion

- Our study showed that most of PE studies conducted in India are of fair quality.
- It also highlighted inadequate reporting of health economic evaluation studies with respect to certain items such as direction and magnitude of potential bias, sub-group analysis, primary outcomes, incremental analysis, and uncertainty.
- This study indicates the need for adherence to standard guidelines, to ensure all elements of health economic evaluations are well reported for better understanding and interpretation of the research. This can help to improve the quality of the pharmacoeconomic research in India.

Figure 7. QHEs instrument dimension scores



References

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Conflict of Interest

Patel N, Yanamala S, Gautam R, and Rai MK are employees of EVERSANA.

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