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/ INTRODUCTION

The Agency for Health Quality and Assessment of Catalonia (AQuAS) has been commissioned by Ministry of Health of Spain to develop a methodological framework for the assessment of digital health technologies (dHTA). We present the results of a survey performed as a starting point for the development of this theoretical framework.



/ OBJECTIVE

To gain knowledge on the way that HTA of digital health technologies is performed at HTA agencies around the globe, what methodological frameworks are currently being used for this purpose, what domains are considered within these frameworks and what domains are missing.



/ METHODS

A survey was elaborated based on a prospective analysis of the literature and using the Microsoft Forms tool.

Briefly, the questions were oriented to:

- Identify which HTA agencies carried or had carried out dHTA.
- Detect what frameworks they were using for this purpose.
- Know the experiences related to the use of the reported frameworks.
- Know the opinions on some specific issues of the dHTA. For example, if AI should be assessed differently than other digital health technologies or in which stage of digital health technology life-cycle it should be carried out the assessment.

The number of questions to be answered in the survey ranged between 6 and 38 depending on the previous given answers. The survey was sent to the 7 agencies that form the Spanish HTA agencies network (RedETS) and to INAHTA, i-HTS, HTAsiaLink and REDETSa, which spread it among their member agencies.

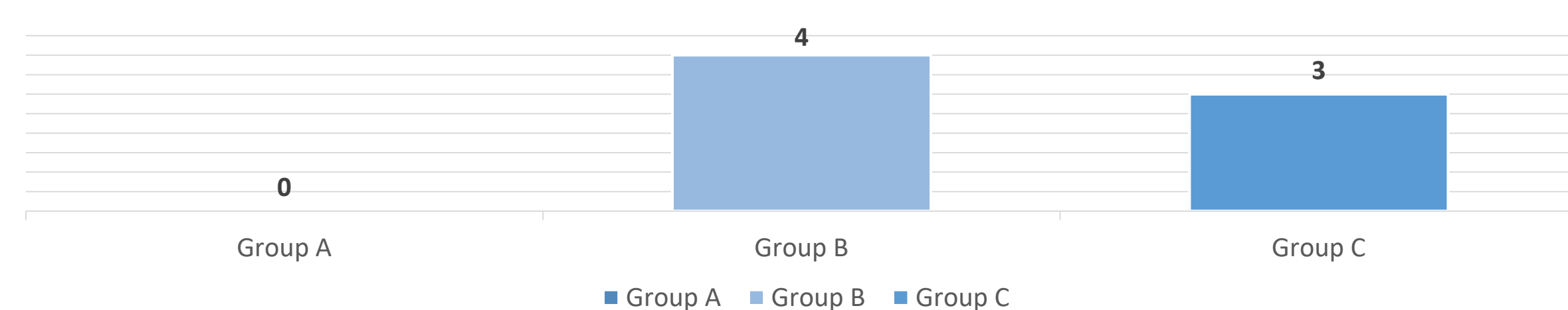


/ RESULTS

To facilitate the analysis and interpretation of the results, respondents were classified into 3 categories: Group A (HTA agencies that perform dHTA using a specific framework for this purpose), Group B (HTA agencies that perform dHTA without using a specific framework for this purpose) and Group C (HTA agencies that do not perform dHTA).

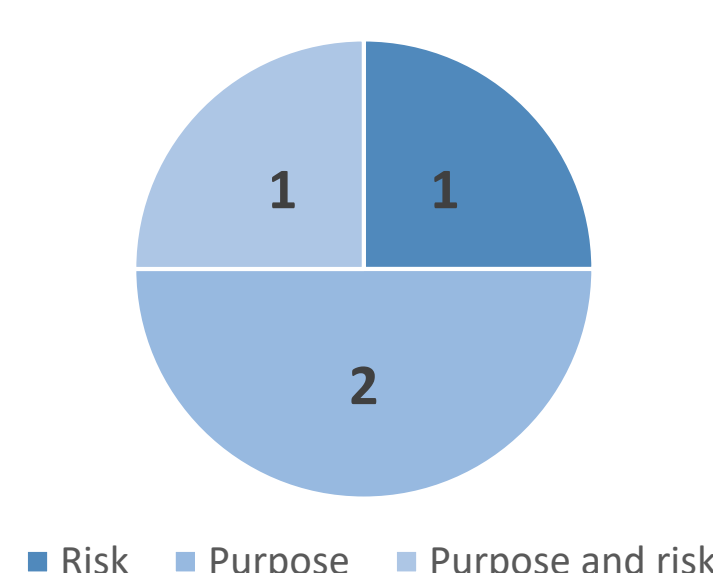
National HTA agencies

A total of 10 responses were received from 7 HTA agencies (0 in group A, 4 in group B and 3 in group C).

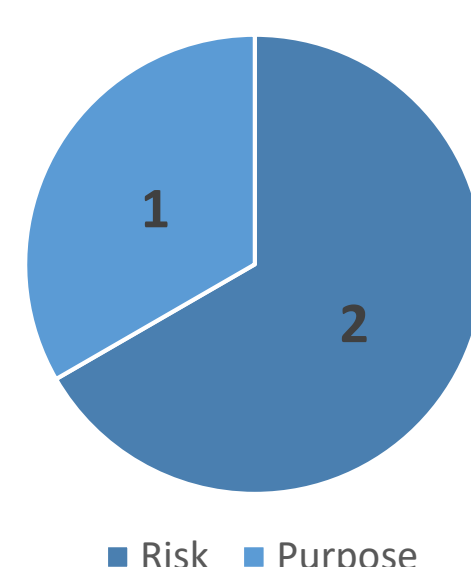


1 agency classified in group B stated that the methodological framework used for dHTA needs to incorporate some additional domains (environmental impact, suitability for disease and data quality).

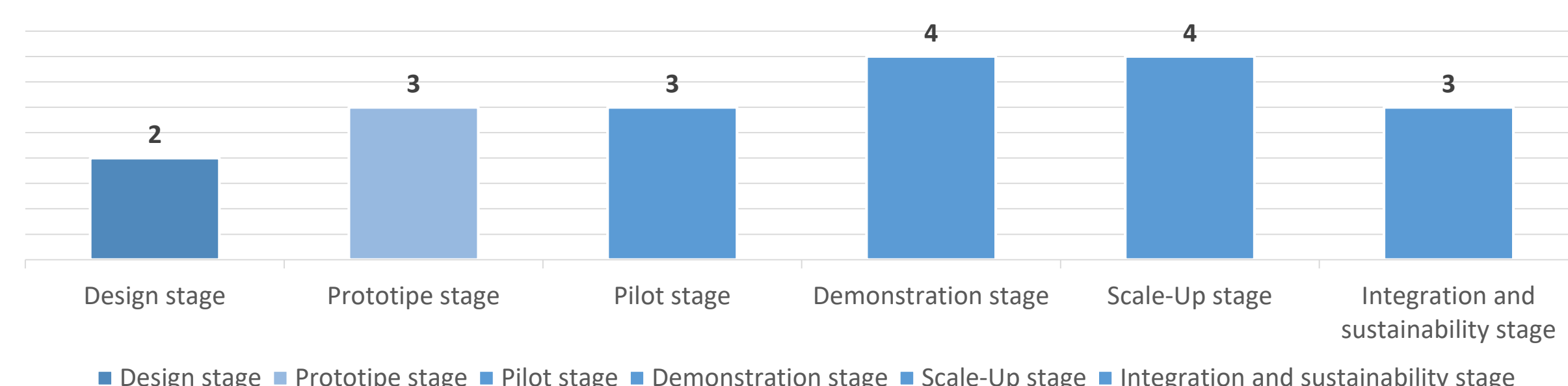
About the assessment of AI, 4 agencies from group B declared that AI algorithms should be assessed with different domains according to their purpose (n=2), their risk (n=1) or both purpose and risk (n=1).



About the assessment of AI, 3 agencies from group B declared that AI algorithms should be assessed with different levels of evidence according to their purpose (n=1) or their risk (n=2).

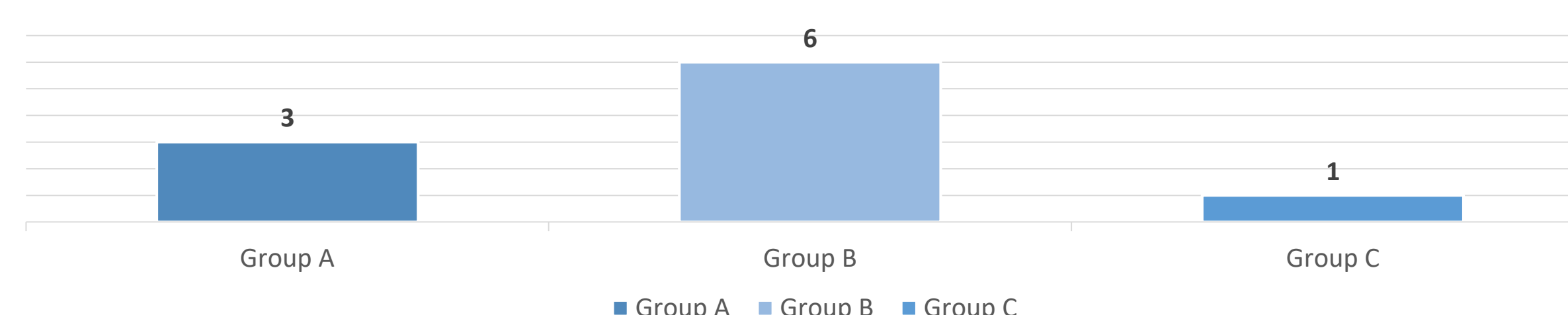


Concerning the technology's life-cycle stage at which the assessment of digital health technologies should be carried out, the agencies answered:



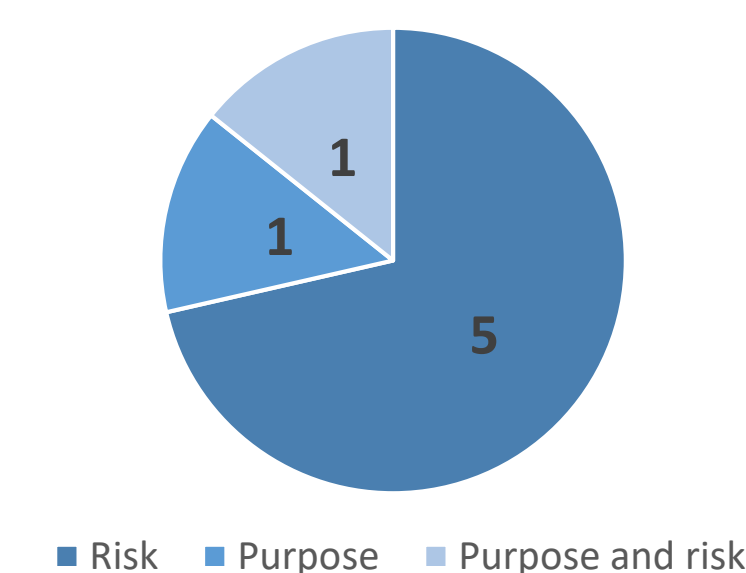
International HTA agencies:

A total of 10 responses were received from 10 HTA agencies (3 in group A, 6 in group B, and 1 in group C). The agencies were from Belgium (n=1), Canada (n=1), Finland (n=1), France (n=1), Germany (n=2), Italy (n=1), Scotland (n=1), Taiwan (n=1) and United Kingdom (n=1).

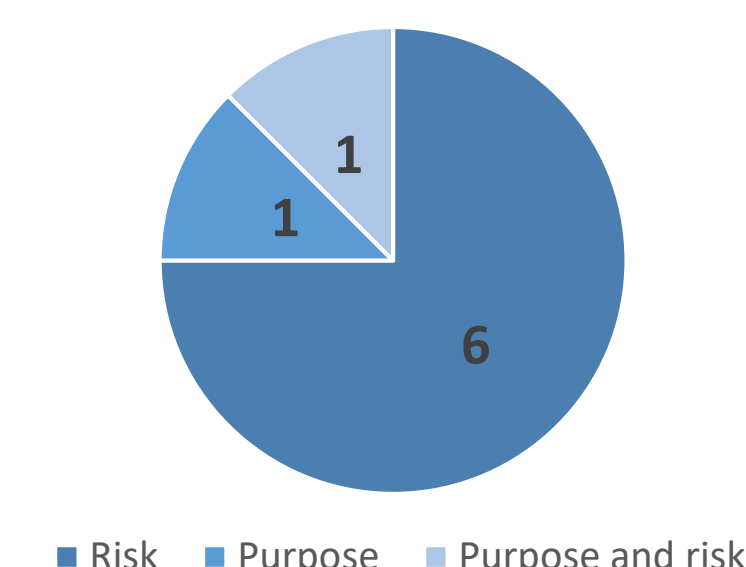


2 agencies classified in group A and 2 in group B, stated that the methodological framework used for dHTA needs to incorporate additional domains (interoperability, technical stability, data protection, regulation compliance, usability or accessibility)

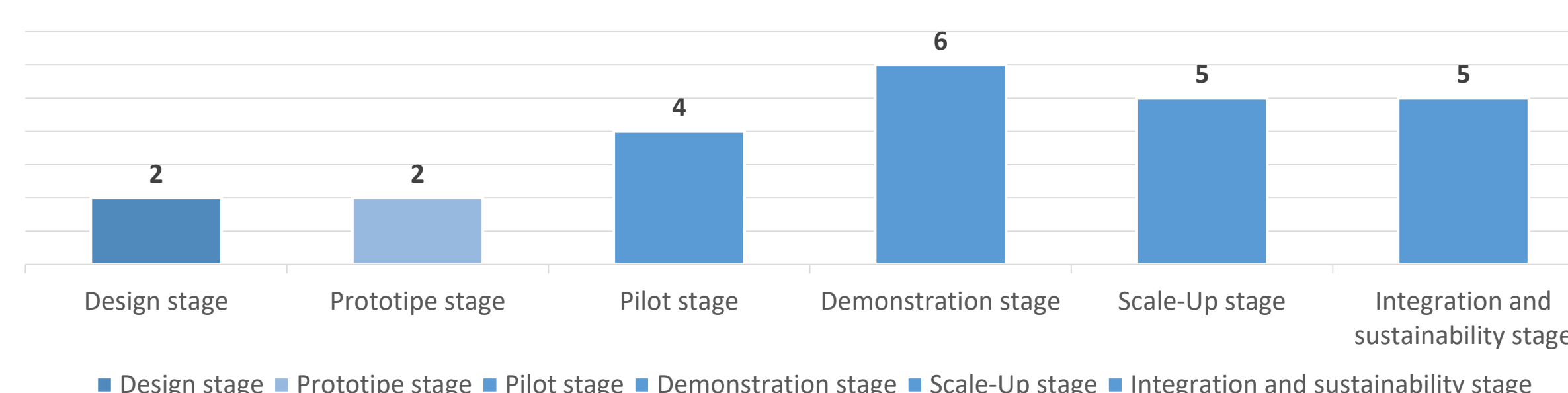
About the assessment of AI, 7 agencies from groups A and B declared that AI algorithms should be assessed with different domains according to their purpose (n=1), their risk (n=5) or both purpose and risk (n=1).



About the assessment of AI, 8 agencies from groups A and B declared that AI algorithms should be assessed with different levels of evidence according to their purpose (n=1), their risk (n=6) or both purpose and risk (n=1).



Concerning the technology's life-cycle stage at which the assessment of digital health technologies should be carried out, the agencies answered:



/ CONCLUSIONS

Although the characteristics of digital health technologies differ from those of conventional health technologies, a small number of agencies surveyed stated that they use specific methodological frameworks for their evaluation. In total, 2 published specific frameworks were identified (Digi-HTA and Methodology guide for the clinical development of medical devices by HAS). Our results suggest the need to adapt or develop new methodological frameworks that consider specific domains for the assessment of digital health technologies.

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