# Rapid Health Technology Assessment for Agenas

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# Competing interests declaration

The author declares that he will not receive either benefits or harms from the publication of this report.

# Introduction

The idea of a "rapid" assessment of a health technology, although not new, seems to have become dominant in contemporary practice (EUnetHTA 2012). The theoretical rationale for carrying out a "rapid" assessment is strong: resource-saving and the possibility of inputting in real time into the decision-making process seem to be incontrovertible advantages. The main drawback of rapid actions appears to be the loss of detail and perhaps lower reliability of the product, as the relatively hurried nature of the process may lead researchers to "cut corners" to meet production timelines.

Article 15 of the European Directive on the application of patients' rights in cross-border healthcare sees the use of HTA to "*support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies*" (EU 2011).

More specifically, Article 7 of European Directive on Transparency of measures regulating the prices of medicinal products directs *"Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed 30 days, provided that the reference medicinal product has already been included in the public health insurance system*"

and:

*"Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7."* (Article 8) (EU 2012)

A Ministero della Salute systematic review report commissioned to Agenas surveyed current methodological practices in HTA report development. The review concluded that there was no defined and universally accepted core HTA methodology. Although consolidated methods based on biostatistics, epidemiology, health economics and sociology for some domains currently exist, uptake and consistent use has been desultory (Corio 2011). Although the focus of the Agenas 2011 report was not specifically on rapid

assessments, during the course of report development the authors noticed a similar lack of consensus on the meaning of the term “rapid” and lack of development of its methods and acceptance.

As the potential advantages of rapid production are difficult to deny, the Italian HTA programme could benefit from clear guidance on how to conduct a rapid assessment to achieve some consensus on the practice and its practical meaning.

Agenas developed this short report to describe current practices in rapid assessment and propose an outline method for its inception and adoption.

# Methods

To describe current practices in Rapid Assessment we carried out searches for documents reporting methods and practices as at 10 October 2012. We were looking for reports of prospective studies, surveys, interviews with HTA developers and reviews of current output from HTA agencies and bodies. The objects of the enquiry were practices and methods for rapid development of health technology reports. A decision on the content of the proposed guidance was then reached on the basis of the evidence and our experience as HTA developers.

# Results

The searches identified 28 titles of possible interest. After screening, 10 titles were read in abstract form to assess content. Four referred to items to grey literature (i.e. were abstracts of studies presented at meetings but not followed up by a full publication) and three were on rapid systematic reviews. The remaining three were retrieved in full-text format and read (Chase 2009, Australian Safety & Efficacy Register of New Interventional Procedures Surgical - ASERNIP 2007, Warren 2007). An additional item identified was a presentation at a HTAi conference (Inger 2006).

The study by Warren et al compared 39 “standard” reports by the UK’s NICE with as many rapid assessments by the private provider BUPA and found 90% of concordance. As the studies are not listed in the Warren et al manuscript it is difficult to know what types of NICE documents were included in the study. This matters because NICE has been producing a number of systematic reviews with economic models incorporated. These are not the same as a full HTA report with numerous additional dimensions or domains (e.g. ethical and social). In summary it is not clear how generalizable the results are to standard HTA reports, especially those produced by Agenas which have a detailed contextual analysis (Warren 2007).

The ASERNIP report is the most comprehensive and on-topic document we identified.

The report aimed to assess

- current practice in the preparation of rapid reviews by HTA organizations (through a survey of 18 responding agencies);

- methodology of rapid reviews (by carrying out a systematic review of the evidence base underpinning methods);

- any differences in the essential conclusions of rapid compared full reviews on the same topic (using 33 rapid reviews from 8 agencies as the index and full HTA reports as comparators).

The definition of a rapid review used in the report was “health technology assessment products that took between one and six months to complete, which utilised a comprehensive, systematic or quasi-systematic search strategy” (ASERNIP 2007).

The ASERNIP team reports that the HTA producing agencies suggested restricted research questions and truncated search strategies as potential methods for limiting the time taken to complete a review. Content of the rapid reviews varied greatly and none of the included studies described guidelines for the methodology underpinning rapid reviews. There was no agreed definition of rapid review with each agency adopting a different approach. Although full reports provided far more detail than their rapid counterparts, no differing conclusions were identified and there was no evidence that rapid reports were of inferior quality or potentially mislead decision makers (ASERNIP 2007).

The study uses the terms “rapid review” and “rapid HTA assessment” as synonymous.

The report’s conclusions are that “a rapid review should be written in answer to specific questions, rather than as a quick alternative to a comprehensive systematic review. The speed of review completion should be due to a specified direction, rather than as a result of a curtailed and perhaps overly simplified methodology. In this manner, rapid reviews could be used to inform specific policy decisions in a timely manner without losing any of the important information that may be expected from a comprehensive review. It is perhaps the appropriate use, as opposed to the exact methodology, of a rapid review that requires future consideration.” The authors also recommend greater transparency in the reporting of methods, rather than development of a standardised format (ASERNIP 2007). The identified presentation appeared to be an earlier version of the ASERNIP report (Inger 2006).

The paper by Chase et al contains methodological guidance ("toolkit") for adaptation of HTA reports across different contexts and is not directly relevant to rapid HTA report crafting.

# Discussion

There is scanty work on the empirical underpinnings of methods of rapid HTA reports and no reliable definition of such a product exists, although no one seems to question its usefulness. Very few literature items discussed the definition, content and methods of a rapid HTA report. A number of papers or abstracts addressed use and structure of rapid reviews, a topic which is not quite the same as a rapid HTA report (which traditionally has a wider focus with many dimensions). Even the most detailed report available (ASERNIP 2007) equivocated on the significance of the product by using the words "rapid review" and "rapid assessment" as synonymous. The most important contribution appears to be the relationship between the structure and content of a rapid assessment and its intended use. The uses and aims of Rapid Assessments produced by Agenas will have to defined by the commissioner, the Italian Ministry of Health.

In summary current practice seems to allow for a variety of products by at least 8 HTA agencies (identified as producers of rapid products by the ASERNIP survey).

On the basis of the findings and the Agenas experience of production of HTA reports it is recommended that a rapid HTA assessment for the Italian programme be identified as *a HTA document answering very specific research and policy questions, with searches for evidence conducted in the English language (for the less context-dependant domains) and in Italian (for any context-dependent domain) and with a restricted number of domains (not more than 4). Choice of domains should be dictated by the questions being asked*.

Further changes to the definition will take place if necessary after discussion with the Ministry of Health.

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## Annex 1

Search strategy

The following databases were searched Pubmed/Medline, Cochrane Library (including DARE and HTA databases and The Cochrane Database of Methodology Reviews), Centre for Reviews and Dissemination, HTA agencies websites (see below).

The following strategies were used:

## Pubmed:

| | | |
|---|---|---|
| **Rapid: Title/Abstract** | **AND** | **HTA: (Title/Abstract)**<br><br>**OR**<br><br>**Health technology assessment: (Title/Abstract)** |

## Cochrane Library

| | | |
|---|---|---|
| **Rapid assessment method (title/abstract/keywords)**<br><br>**OR**<br><br>**Rapid (title/abstract/keywords)** | **AND** | **HTA (title/abstract/keywords)**<br><br>**OR**<br><br>**Health technology assessment: (title/abstract/keywords)** |

**NB: the search was limited to "Methods Studies" and "Technology Assessments"**

## Other HTA websites/databases searched:

**Agency for Healthcare Research and Quality (AHRQ)**
**Australian Safety and Efficacy Register of New Interventional Procedures**
**Technologies in Health (CADTH: Catalan Agency for Health Technology Assessment (CAHTA) /**
**International Network of Agencies for Health Technology Assessment (INAHTA)**
**National Coordinating Centre for Health Technology Assessment (NCCHTA) National Horizon Scanning Centre**
**National Institute for Health and Clinical Excellence (NICE):**
**NHS Quality Improvement Scotland (NHS QIS)**
**Trip Database.**