A comparison of 33 European national HTA and decision making systems using archetypes and taxonomies: a model for progressive alignment?

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Introduction

Rising costs of healthcare expenditure and ever-growing consumer demand creates a greater need for more rationalised healthcare spending [1-3]. This has resulted in growth of Health Technology Assessment (HTA) internationally due to its ability to bridge the gap between health policy and science.

The role of HTA agencies and the HTA processes performed can vary greatly between jurisdictions as a result of different political, social and financial factors.

Study aims

- Characterise the regulatory review and decision-making systems for new pharmaceuticals across Europe through the development of standardised process maps and to categorise these through the application of a novel taxonomic structure

- Categorise the diversity of the different HTA systems by identifying sub-groups with common elements of process (ie, archetypes) that could be used to describe general characteristics common to the different systems within each archetype

- Examine how these archetypes could be useful in practice, for example by the identification of groups of countries where work-sharing would be feasible

Methodology

A novel mapping methodology has been refined to create process maps by layering three tiers of information [4-5]:

Step 1 identifies the key agencies and indicates their interactions with other agencies and the drug sponsor. Numbered discs indicate the order of the process and a light blue border highlights agencies that are within government

Step 2 determines where 7 predefined core functions are performed within the system. A colour-coded tab is then overlaid onto the agency, or agencies, that perform the function

Step 3 evaluates the processes performed by HTA agencies. Icons have been created for 6 chosen key HTA activities. The HTA core function tab includes a toolbox to display an icon for each of the key activities an agency performs
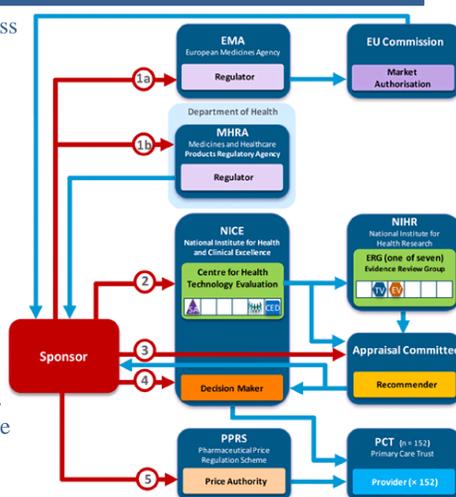

Figure 2: Process map for England

- The final process map (Figure 2 is validated by an agency representative or an expert within the field of HTA and date stamped

- The process maps for 33 European jurisdictions were compared to create taxonomic sets to represent the variation in a system organisation and different approaches for HTA processes

- The confluence of the two taxonomic sets identified distinct groupings to form 8 archetype groups

- The differences between the archetype groups were assessed to identify factors that could affect potential collaborations or information sharing

This study was conducted primarily using information from public sources and peer-reviewed journals. Information was also sourced from the International Drug Regulatory affairs compendium (IDRAC ®; Thomson Reuters)
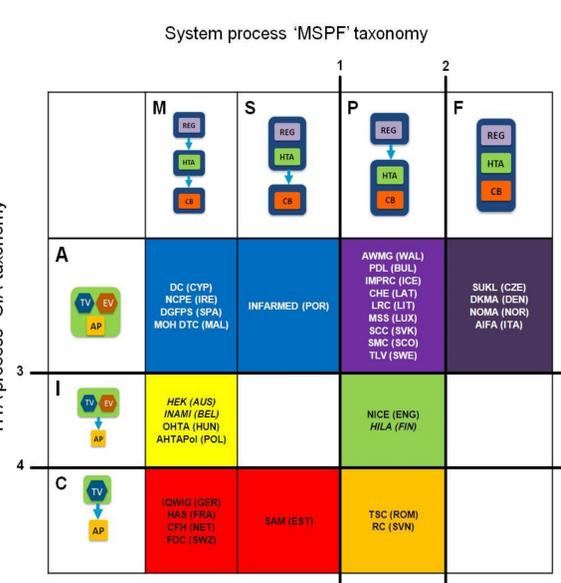
Summary

Figure 1: Geographical locations of archetypes

- A systematic mapping methodology has produced process maps for the national regulatory, HTA and decision-making systems for New Active Substances (NASs) in 33 European jurisdictions

- This research has produced two taxonomic sets for non-ranking method of classification of HTA agencies/ committees according to: 1) their position within the national system, and 2) the relationship between assessments for therapeutic value, economic value and appraisal

- The confluence of the two taxonomic sets has been reviewed to determine 8 unique archetype groupings

- The architectural and organisational differences of the taxonomic groups was assessed to consider potential conflicts of interest for potential collaborations or information sharing

- This research proposes a 'progressive alignment' approach would help preserve diversity of the HTA environment while providing the benefits of work sharing for more efficient HTA practices

- The CIRS Atlas is now available as an interactive iPad™ application and online web emulator

Discussion

- HTA alignment for work sharing has the potential to provide the European HTA environment greater cost and clinical efficiencies. However, it may be too soon to align HTA as the best practices might not be fully developed

- This study suggests an alternative progressive alignment approach that will provide the benefits of work sharing but also maintain diversity

- Archetype groups displayed some relationship with the welfare state ideology from which the health system originated

- These results conclude that HTA work sharing would be more efficient between agencies with similar processes rather than traditional groupings based on geographical location or a country's ability to pay

Results

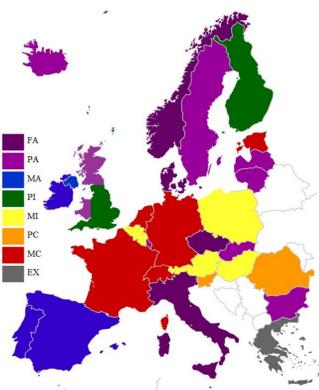System process 'MSPF' taxonomy

Figure 3: Confluence of taxonomies to create archetypes

Figure 4: Identifying factors to overcome to facilitate work sharing between taxonomic sets

A: Information sharing flow for HTA System 'MSPF' taxonomy

B: Information sharing flow for HTA process 'CIA' taxonomy

- The final regulatory, HTA and decision-making process maps for new medicines in 33 national European jurisdictions were compared to identify notable similarities and differences

- Although many European Nations still do not have a formal HTA system, 31 of the 33 systems required a therapeutic assessment for a coverage decision

- National HTA agencies/ committees for 31 jurisdictions were characterised into two taxonomic sets ('MSPF' and 'CIA') and compared by grid (Figure 3)

- The third aim of this study was to identify potential work sharing collaborations, therefore, the two groups with a single agency were merged with the most similar grouping (Figure 5).This resulted in the creation of seven archetypes, plus an eighth archetype (EX) to represent systems that used external HTA (Figure 3-4)

Provider / Recipient

Recipient \ Provider	MC	PC	MI	PI	MA	PA	FA	EX
MC	✓	?	X	X	X	X	X	X
PC	✓	✓	X	X	X	X	X	X
MI	✓	?	✓	?	?	?	?	X
PI	✓	✓	✓	✓	?	?	?	X
MA	✓	✓	✓	✓	✓	?	?	X
PA	✓	✓	✓	✓	✓	✓	✓	X
FA	✓	✓	✓	✓	✓	✓*	✓	X
EX	✓	✓	✓	✓	✓	✓	✓	X

Symbol	Description
✓	Information generated by provider group should be suitable for recipients needs.
?	Consider potential conflict of interests. Information provided by an agency with combined HTA and coverage body.
?	Consider potential conflict of interests. Recipient group may need an additional external appraisal.
X	Information from provider is unlikely to be appropriate for the requirements of agencies within this group.

Figure 5: Potential for work sharing between archetype groupings

- The potential for further work sharing collaborations were first evaluated between taxonomic sets (Figure 4).

- The potential for conflicts of interest and suitability of data sharing identified from the taxonomies was applied to the archetype groups (Figure 5)

Future studies

Figure 6: CIRS Atlas App menu

Figure 7: CIRS Atlas comparison tool

- The process maps have been compiled to create the interactive CIRS Atlas © which is now available online and as an iPad™ app (Figure 6-7) [6]

- The refined mapping methodology has now produced over 90 process maps for new medicines, oncology products, and medical devices at both national and regional level regulatory, HTA and decision-making systems

- The Atlas plans to extend coverage to include countries from Asia and Latin America (Figure 8-9)
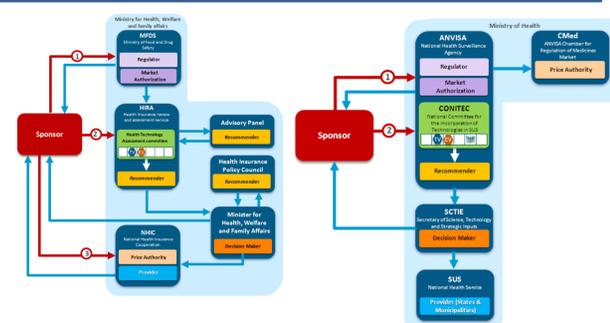

Figure 8: Process map for South Korea

Figure 9: Process map for Brazil

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