**Background**

Rising costs of healthcare expenditure and insatiable consumer demand creates a greater need for more rationalised healthcare spending [1]. This has resulted in faster growth of Health Technology Assessment (HTA) internationally due to its ability to bridge the gap between health policy and science. For this study HTA is defined as:

> "A form of policy research that systematically examines the short- and long-term consequences, in terms of health and resource use, of the application of a health technology." [4] (Figure 1)

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. Healthcare systems can also be characterised by the welfare state ideology from which they originated.

**Study Aims**

- To characterise the regulatory review and decision-making systems for new pharmaceuticals across Europe through the development of standardised process maps and to categorise these according to an established taxonomy
- To 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 structural characteristics common to the different systems within each archetype
- To 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 [5-6]:

- **Step 1** identifies the key agencies (blue boxes) and indicates their interactions with other agencies and the drug sponsor (red box). Numbered discs indicate the order of the process and a light blue border highlights agencies that are within government (Figure 1)
- **Step 2** determines where seven predefined core functions are performed within the system. A colour-coded tab is then overlaid onto the agency, or agencies, that perform the function (Figure 2)
- **Step 3** evaluates the processes performed by HTA agencies. Icons have been created for six chosen key HTA activities: Scientific Advice (SA), Therapeutic Value (TV), Economic Value (EV), Reimbursement Rate Setting (S), Public Consultation, Coverage with Evidence Development (CED). The HTA core function tab includes a toolbar to display an icon for each of the key activities an agency performs (Figure 3)
- The final process map (Figure 4) 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

This study was conducted by using information from primarily public sources and peer reviewed journals. Information was also sourced from the International Drug Regulatory affairs compendium (IDRAC) [9, Thomson Reuters]

**Results**

- National HTA agencies for 31 countries were characterised into two taxonomic sets (MSPF and CIA) and compared by grid (Figure 5)
- 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 6). This has resulted in seven archetypes, plus an eighth archetype (8X) was created, to represent systems that used external HTA (Figure 6-7).
- The potential for further work sharing collaborations were first evaluated between taxonomic sets (Figure 6). The potential for conflicts of interest and suitability of data sharing identified from the taxonomies was applied to the archetype groups (Figure 7).

**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
- The proposed progressive alignment approach could help facilitate the European Network of HTA’s overall aim of alignment [7]
- This study found no association between the taxonomic sets and archetype groups when compared against GDP and GDP purchasing parity values or a country’s geographical location
- 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.

**Impact and Future Studies**

- 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 systems
- The process maps have been compiled to create the interactive Cardiff University / CIRS Atlas which is now available online and as an iPad app (Figure 8-10) [8]
- An abstract for a professional poster presentation of this study has been accepted for the forthcoming HTAi 10th annual meeting in Seoul, June 2013 (Figure 11)
**Figure 1:** Mapping methodology step 1

**Figure 2:** Mapping methodology step 2

**Figure 3:** Mapping methodology step 3

**Figure 4:** Process map for England

**Figure 5:** Confluence of taxonomies to create archetypes

- National HTA agencies for 31 countries were characterised into two taxonomic sets (MSPF and CIA) and compared by grid (Figure 5)

**Figure 6:** Identifying factors to overcome to facilitate work sharing between taxonomic sets

The final regulatory, HTA and coverage 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.

- **Figure 7:** Potential for work sharing between archetype groups

- **Figure 8:** CIRS Atlas App menu

- **Figure 9:** An abstract for a professional poster presentation of this study has been accepted for the forthcoming HTAi 10th annual meeting in Seoul, June 2013 (Figure 11)

**Figure 10:** HTAi 10th Annual meeting

- A benchmarking study for Canadian payer agencies is currently in progress. This project has been initiated with support from the Canadian Agency for Drugs and Technologies in Health (CADTH) and Alberta Health (Figure 12).