Testing the plausibility of a taxonomy for medical devices in the logic of HTA

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INTRODUCTION

Despite the general debate on the extent to which medical devices (MDs) require tailored assessment methods, no categorization exists that considers devices from the viewpoint of HTA. With the aim of providing policy-makers and researchers with an orientation guide on how to approach the assessment of MDs, the presented work includes the following steps:

(1) Developing a taxonomic model that (i) groups MDs for HTA purposes by building upon existing classification schemes to (ii) provide a tool for evaluating and how assessment methods can be modified to achieve best results depending on the taxonomic position.

(2) Plausibility testing of the taxonomy based on identified HTA reports, which sets the focus of the poster.

METHODS

(1) Development of a taxonomic model

We analysed exiting classification schemes in combination to inform a comprehensive taxonomic model.

(2) Plausibility testing

(a) Identification of reports

We systematically identified European HTA institutions (based on \cite{1}) and searched for publicly available reports. These were screened and matching documents were downloaded and inventoried in Microsoft Excel.

(b) Selection of reports

Reports were eligible if they focused on a MD (alone or within a procedure) and were evidence-based and systematically developed between the years 2004 and 2014.

Excluded were:

\begin{itemize}
  \item Other types of evidence-based documents (clinical guidelines etc.),
  \item Reports that focus on the treatment of a disease exploring several different technologies,
  \item Reports on telemedicine and screening applications only focusing on the intervention as a whole,
  \item Reports that focus on the treatment of a disease exploring several different technologies,
  \item Exclusion of HTA reports that (i) groups MDs for HTA purposes by building upon existing classification schemes to (ii) provide a tool for evaluating and how assessment methods can be modified to achieve best results depending on the taxonomic position.
\end{itemize}

(c) Assignment of taxonomic position

The technologies evaluated in included reports were assigned a taxonomic position in the model developed in step 1. At this point in the work no distinction was made between tests with a purely diagnostic compared to a prognostic nature.

1) RESULTS

A matrix in table format was created based on relevant aspects from the existing classification schemes, incorporating elements of risk (as described in EU-Directives 90/385/EEC, 93/42/EEC, 98/79/EC) and role/functionality (as described in OECD Classification of Health Care Functions \cite{2}) of device types (A, B, C). Active implantable devices (IV) as well as in-vitro diagnostics (V) were assigned separate rows. The matrix further incorporates a distinction between the diagnostic (A1-C1) or therapeutic (A2-C2) nature of devices, which can be crucial for HTA purposes.

The relevance of different device categories in regard to HTA was considered quite variable and was color-coded in the matrix, including high (‘green’), intermediate (‘yellow’) and low (‘red’). ‘Green’ fields were those where no MDs and assessments would be expected.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
\textbf{Classification criteria of EU-Directives according to risk aspects:} & \textbf{Assessive technology devices (directly used by patients) A1} & \textbf{Artificial body parts (implanted by medical device) B1} & \textbf{Medical devices for the assistance of medical professional C1} & \textbf{Assessive technology devices (directly used by patients) A2} \\
\hline
\textbf{93/42/EEC} & \textbf{Thermometer} & \textbf{Stethoscope} & \textbf{Walking frame} & \textbf{Spotula} \\
\hline
\textbf{90/385/EEC} & \textbf{Pulse oximeter} & \textbf{Ultrasound} & \textbf{Hearing aid} & \textbf{Dental crown} & \textbf{Tracheal tube} \\
\hline
\textbf{98/79/EC} & \textbf{X-ray, PET-CT} & \textbf{Insulin pen, Contraceptive} & \textbf{Dental implant} & \textbf{Laser} \\
\hline
\textbf{90/385/EEC} & \textbf{ICD: heart analyser} & \textbf{Condoms with spermicide} & \textbf{Cardiac stents, arterial laser} & \textbf{Angioplasty balloon catheter} \\
\hline
\end{tabular}
\end{table}
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2) RESULTS

Insights related to the plausibility of the taxonomic model:
- Reports sometimes assessed more than one technology (n=69) and sometimes these technologies belonged to different categories (n=13).
- Some reports assessed a technology which fall in more than one field (n=14) such as implantable cardioverter defibrillator (ICD), these were counted twice in figure 2.
- For one originally grey fields (B1/III) we identified a technology.
- For one originally green field (A2/III) and one red field (A1/I) no report could be identified.

Main findings:
Overall, the distribution of identified reports on the matrix generally confirm that the taxonomy is plausible. Only one report was identified for one grey field where no HTAs were expected. The majority of reports in the sample addressed technologies from the green fields, considered of high relevance. Relatively few reports were available for the red fields considered of low relevance. Some correlation to risk level and type of device is apparent, at least for devices that are implanted or serve to assist medical professionals.

Further steps:
In-depth analysis of reports corresponding to specific taxonomic positions regarding methodological approaches adopted so far and if/how these vary by taxonomic position is ongoing. As assessing MDs can be inefficient in some cases or particularly complex in others, we are exploring for example the purpose and methodology of those reports carried out for devices theoretically considered of low relevance for HTA (red fields). Furthermore, interviews with HTA institutions about the usefulness of the taxonomy and suggestions for refinement are being conducted.

REFERENCES

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