INTRODUCTION

Medical devices play a crucial role in the continuing advancement of healthcare, providing new solutions that challenge existing paradigms and revolutionize the way treatments are administered. The medical devices industry is now seen as one of the fastest growing ones, with the technological advances driven by an increasingly demanding market with growing patient population and legislative requirements, amplifying health policy reforms, and tough quality and regulatory hurdles. A multitude of medical devices appears on the market every year, where medical devices are defined by the European Commission as “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be administered.”
used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.

To enter the market, a device manufacturer must demonstrate that it is safe, that it produces value to patients and society at a reasonable cost, that it has potential to bring significant savings to the healthcare system, and that the risks associated with its use are acceptable when weighed against the benefits to patients. Health Technology Assessment (HTA) is the scientific discipline to systematically collect evidence on the effects, risks and health economic consequences of new medical technologies. Over the past decades, it has been difficult for small and medium sized companies (SMEs), that constitute around 75 percent of the medical device industry, to implement HTA in their business process. Those SMEs operate under constant financial pressure.

However, although HTA is not a core activity in most SMEs it is expected to become more important in the near future. A recent Dutch report reflects on the need for generating clinical evidence on safety and efficacy before market launch of medical devices, as do other policy documents such as the recently revised regulations in the EU urging for collection of clinical evidence throughout the market lifetime of a device. All these developments witness the current debate on safety of medical devices and the problems identified in the current regulatory framework.

So far, knowledge on HTA in SMEs is limited. In 2012, Craven et al. explored the levels of health economics knowledge within English SMEs. The results revealed that 60 percent of SMEs representatives had low or no HTA experience. Clinical trials and cost analyses or cost-effectiveness studies were the most highly cited means by which SMEs aim to demonstrate value of medical devices to the purchasers. However, those methods were reported as having no formal influence on the decision-making process within SMEs.

Ideally, HTA should be conducted as early as possible in the device development process. That way the development can either emerge or be stopped without major financial drawbacks for the company. The requirements of the stakeholders should constitute a base for an assessment and can be used to prioritize the development of medical devices most likely to succeed among others. At the same time, medical device manufacturers could use the early evidence gathered to enhance the efficiency of the use of research and development (R&D) resources within the company.

This aim of this study was to analyse whether and how medical devices manufacturers in the Netherlands perform an early assessment of medical devices that would allow them to meet the requirements of potential stakeholders. The Dutch medical device industry market was chosen, because of the large amount of public-private partnerships present in that market, e.g. The Centre for Translational Molecular Medicine (CTMM).

METHODS

EXPLORATION OF EARLY HTA ASSESSMENT METHODOLOGIES IN SELECTED COMPANIES

Four areas of an early assessment of the medical devices were subject of this study and incorporated in the

![Figure 1](Image)
structured interviews: (1) analysis of the clinical context of medical device use; (2) market analysis; (3) stakeholders analysis; and (4) financial and health economic evaluation of new medical device. In addition, the interviews were held so that a better understanding of the specific role of early assessments in companies could be elaborated. A detailed map of the four topics for early assessment as well as the specific elements is provided in figure 1.

The analysis of the clinical context of medical device included the criteria used by the companies to evaluate clinical impact and the clinical need for the novel medical device, e.g. the underlying disease state and disease severity. The market analysis as a part of an early assessment in this research was assumed to be based on the analysis of main competitors and the analysis of the future users. The stakeholders’ analysis was assumed to be based on the opinions of the experts, and the opinions of the decision makers. Finally, in the financial and health economic methods the company financial prospects as well as the buyer and societal perspective were analyzed. The list of methods presented during the interviews was extracted from the literature, and it was complemented during the validation of the interviews, and during the interviews themselves, as participants were asked to add methods if they thought any were missing. In general, specific methodologies (e.g. the Headroom method) were not explicitly included, as some of them might not be familiar to the medical device companies employees, so short description of the practical aims and results of those methods were used instead. During the interviews participants were asked to select those methods from the list which are being used in the company to assess medical device. Finally, the participants were asked to indicate at which stage the company started and finished specific assessments as well as which assessments were carried out iteratively throughout the development cycle. Six roughly defined medical device development stages were: (1) idea generation; (2) before prototype development starts; (3) during the prototyping; (4) gathering evidence on device effectiveness and efficiency; (5) device marketing; and (6) post-marketing surveillance.

**INTERVIEW DESIGN AND SELECTION OF PARTICIPANTS**

This research was based on semi-structured face-to-face interviews with key-informants within medical device companies in the Netherlands. “Key-informants” in this study were defined as those people within the medical device companies who have experience-based and/or professional-based knowledge on different aspects of the medical device development and/or implementation, e.g. assessment practices, regulatory access, reimbursement.

After designing the interview format, all questions were pilot tested by experienced representatives in academic science and in the medical device industry, based in the Netherlands (3 people), and in the United Kingdom (1 person). The objective of the validation was to make sure that the questions covered the full range of methods and that the content of the questions will be easily understandable to the key-informants, i.e. in case of no scientific background in the early assessment of medical devices topic.

The participants of this study were selected with the use of the convenience sample method, based on the structured search of biomedical companies online. In total 91 companies were selected. The Chief Executive Officers (CEOs), or Managers within the topic of interest, of those companies were identified with the use of LinkedIn service and contacted via the telephone, with the use of the number provided on the companies websites. During the phone conversation the CEOs were first introduced to the research topic and asked about the willingness of their company to participate in the study. After the approval of the CEOs, the researchers scheduled the face to face structured interview with the CEOs themselves, or contacted the person indicated by the CEOs as the key-informant. In total 36 CEOs were interested in the participation, with one large company indicating two people from two different departments as key-informants for the interviews. 37 face-to-face structured interviews were conducted. Before the interviews, the interviewer explained the purpose and format of the interview to the participants. The interviews lasted on average around 50 minutes. The interviews were audio recorded with participants’ permission. The results of the interviews were analysed with the use of the SPSS Statistics 21.0 software. The script of the interviews is presented in Appendix 1.

**RESULTS**

**COMPANY AND PARTICIPANTS CHARACTERISTICS**

The interviews revealed that the majority of the companies commission their own employees as well as external consultants for the early assessment (reported 19 times). 15 participants reported that an early assessment is being performed only by people employed by the company, while only three stated that early assessment activities are fully performed by an external
consultant. Interviews revealed that the main reason for the companies to search for an external help for the early assessment of medical devices is the lack of an expertise within the company (N=18). Some participants stated that hiring external assessors is more efficient, e.g. cheaper (six participants), or more time-efficient (mentioned twice). Internal assessments are mostly performed by an individual employees assigned to particular tasks (N=22), or performed within the specialized departments within the company, e.g. R&D and Sales and Marketing department (N=14). Six participants stated that an early assessment in their companies is performed by assigning particular tasks to multiple people. Finally, two participants admitted that they are not sure how an early assessment was organised within their company. The characteristics of the interviews participants is presented in table A1 in Appendix 2. The characteristics of the companies participating in the interviews is presented in table A2 in Appendix 2.

**AN EARLY ASSESSMENT METHODS USED WITHIN THE COMPANIES**

**An overall assessment activities conduction**

When asked to indicate the start of the assessment activities based on six roughly defined medical device development stages, it seemed that clinical context and market assessment have the highest priority, as both start at idea generation for the majority of companies. A smaller number of companies also start stakeholder analysis (n=18) and financial and health economic evaluation at the idea generation, while more companies postpone this to later stages. Figure 2a presents an overview of the stages where an assessment within four areas of an early assessment started as reported within the Dutch medical devices industry.

When asked to indicate when the assessment activities stop, the majority of the participants (reported 30-31 times) indicated all the areas of an assessment activities last until the post-marketing surveillance. Figure 2b presents an overview of the ending time of an assessment activities within four areas of an early assessment as indicated by the interviews participants.

**Clinical context assessment**

To analyze the clinical impact and need several performance indicators were of interest to the medical device developers: (1) potential device efficacy/effectiveness (N=32), (2) potential target population size (N=30), (3) safety and tolerability of the device (N=24), (4) patient satisfaction with the device (N=23), and (5) the severity of the disease that medical device is targeted at (N=15).

In order to evaluate these indicators, companies use different information sources, e.g. talking with the patients and clinicians (key-opinion leaders, KOL) (N=22), attending (clinical) conferences, events/trade shows (N=21), and reading scientific journals (N=20) (see figure 3).

**Market assessment**

The market analysis as a part of an early assessment in this research was assumed to be based on the analysis of the future users and the comparison to other interventions used for the disease. The majority of the respondents reported that the user analysis is mainly based on literature reviews of user needs (N=32), safety and
usability testing (N=31), and informal and/or accidental meetings with users (N=29) (see figure 4a). The analysis of the alternative medical devices and interventions is mainly based on experts (KOL) consultation (N=30), monitoring industrial news sources (N=27), and patent searches (n=26) (see Figure 4b).

**Stakeholders analysis**

The analysis of the stakeholders within the medical device industry is based on the views of the experts and key decision makers within the medical device field of application. The participants reported that two dominating methods were present to gather those opinions, i.e. informal discussions (N=22), and formal consultation (n=21) (figure 5).

**Financial and health economic evaluation**

With respect to the financial analysis, most participants reported that in their company an extensive financial analysis from the company perspective is conducted (N=34), followed by financial analysis from the buyer (health insurance or hospital) perspective (N=29). Finally, least interviewees reported a full health economic evaluation, i.e. an evaluation of the incremental societal benefits against the incremental costs to society (N=22).

The financial analysis from the company perspective is usually supported by three methods, i.e. price determination (N=31), net present value using discounted cash flow analysis (N=30), and return on investment analysis (N=29) (figure 6). The financial analysis from the buyer perspective is supported with the Budget Impact Analysis (N=29), and with the return on investment.
(N=21). Interviewees reporting on a health economic evaluation did mention cost-benefit analysis (N=18), cost-effectiveness analysis (N=16), and use the least – cost-utility analysis (N=7).

**DISCUSSION**

With the increasing regulatory demands for medical device SMEs and the need for efficient allocation of resources, a thorough understanding of the regulatory environment and its mechanisms to build the evidence at early stages of product development is required. This study interviewed key-personnel from medical device companies involved in R&D and market access and concluded that most companies do several assessments along the product development pipeline. Most of the assessment activities start early in the development of the medical devices (at the idea generation stage) and are conducted iteratively up to the post-marketing surveillance stage.
Although this research was not solely focused on SMEs, more than half of the companies participating in this study were SMEs (N=19), and 11 were micro-sized spin-off companies with less than 10 employees. Almost half of the interviews participants, which were selected as the “key-informants” in the topic, reported a medium level knowledge (N=18) of the medical devices health technology assessment procedures, and one fourth indicated low/basic knowledge. This led to the conclusion that, although early assessment is considered important, most companies do not have in-house capacity and knowledge to perform health technology assessment.

Previous research on the health economics activities within the English medical device industry performed by Craven et al.\textsuperscript{14} seems to confirm the findings of this research with regard to the varying levels of health economics knowledge within the medical device industry. The main recommendation of Craven et al. was actually to increase the focus on the education needs, and tools to support the application of various health economics/assessment tools within the industry.

With regard to the different areas of the assessment activities as distinguished in this study, it is clear that the current focus is on the evaluation of the clinical context of the medical device and the assessment of the potential market. These assessments are mostly performed informally with interviews and stakeholder meetings. The majority of the companies use only the conversations with the clinicians and patients (N=22) and attending clinical conferences and trade shows (N=21) as an actual source to inform the clinical context. No formal quantitative methods presenting the opportunities for new products and the needs of patients are performed, while these could contribute to the validity and quality of the information that is collected.

The financial and business case evaluations within the medical device industry seems to be well developed with return on investment as a main driver and price setting as the objective. Although such analysis is essential for business planning and attractive venture capital, it does not reflect the perspective of the society in which the medical devices will operate. The societal perspective, i.e. the question whether society is willing to allocate

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure5.png}
\caption{An overview of the methods used to gather the opinions of experts and decision-makers.}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure6.png}
\caption{An overview of the methods used to perform an economic evaluation from the company perspective.}
\end{figure}
scarce resources to implement and/or reimburse the new medical device, is at best only marginally performed or understood from the companies perspective. This is disappointing, as the business case might be unreliable if the societal benefits are not considered. Markiewicz et al. proposed a simple method to illustrate how the expected societal benefits of the new product can be used for value-based pricing.

The results of this study confirm that medical device industry is very specific. It is characterized with very high level of innovativeness, strong technology push and a not very well developed market access and pricing strategy. It is build up mostly from SMEs managed by executives with strong scientific or technical background and over-simplified view of business and management issues. That leads to the situation where other than technological advantages aspects, which significantly influence future implementation and adoption of medical device, e.g. the potential stakeholders requirements, are mostly overlooked. At the same time the majority of the SMEs within the medical device industry focus on the development of a disruptive technologies, for which it is difficult to find the way to economically viable products. A truly innovative medical device may offer the ability to significantly improve patients care, however proving safety, efficacy and regulatory compliance is often too challenging and costly for SMEs.

Inability of the SMEs to provide strong evidence of the potential societal value of their medical device under development makes it very difficult, or even impossible for most of them, to find investors willing to support their projects. As the healthcare resources are getting more and more stringent, the ability of a company to prove to potential investors that their technology will be cost-effective became a compelling argument supporting its future development. The development of medical device from concept to product on the market can take up to a decades and significant investment is often needed before the medical device can even reach the first stage of clinical investigation. In the same time the coverage and reimbursement by health insurance have a strong direct impact on the manufacturers attainable revenues. Although there is a debate going on how assessment of an innovation early in the lifecycle could provide answers for insurers on the issue of funding the new technology and allow early patient access, the direct collaboration between medical device industry and insurance companies is still in the learning phase.

Although medical device manufacturers are operating in high technology multi-stakeholder environments they often fail to recognize the importance of the stakeholders analysis and they face the challenge of finding the right people to collaborate with. For the medical device manufacturers it is therefore important to start an early dialogues with various stakeholders to understand the evidentiary requirements of various decision-makers involved in the implementation process. That could also help to better align perspectives on the potential value that the medical device could introduce to the healthcare system.

CONCLUSION

Although many methods seem to be in use within the medical device industry, there is no clear understanding of how those methods are conducted, what evidential requirements are to be met and how this supports the decision-making process in companies. To improve the assessment of the medical devices, a structured guidance of best practices would greatly benefit the industry as a whole.

ACKNOWLEDGMENT

This research was committed under a grant assigned by Province Overijssel and EU for NIRION Project within GO EFRO 2007–2013, and within High Tech Health Farm Program granted by Overijsselse Centra voor Research & Innovatie.

REFERENCES


harmonize regulatory and coverage perspectives. 

APPENDICES

Appendix 1. Interviews with MD companies executives.

I COMPANY BACKGROUND
1. What is your knowledge level on assessment of medical devices?
   - good/expert;
   - unmedium;
   - low/basic.

2. Who performs assessment of medical devices in/for the company you work for?
   - there are people in the company responsible for assessment performance;
   - we hire external companies/people to assess devices;*
   - we have both people in and outside the company assessing devices;*
   - other:

3. *Why does your company hire external company/people to perform the assessment?
   - there are no people capable of assessment performance in my company (lack of expertise);
   - there are no people assigned to perform assessment in my company (lack of tasks specification);
   - there is no time available to perform assessment in my company;
   - hiring external company is more efficient (e.g. cheaper);
   - other:

4. How does your company performs the tasks required for assessment of medical devices?
   - individual people assigned to particular tasks;
   - company department specialized in assessment performance;
   - ad hoc decisions on who is responsible for particular tasks;
   - particular tasks divided over multiple people.

5. How many people does the company employ at the moment?
6. Which country does the company mainly operate in?

7. What is the number of medical devices your company now works on/offers?
   - On the market
   - In the development
   - Unsuccessful projects rate

8. What type of devices in the risk-based classification does your company mainly produce?
   - Class I: simple, low risk devices
   - Class II: more complex, higher risk
   - Class III: most complex, highest risk

II MARKET ANALYSIS
9. What does your company look at when performing market analysis?
   - clinical context of use (need analysis); (choose methods from LIST 1)
   - competitors (other companies operating in the area); (LIST 2)
   - future users (doctors, patients, hospital managers). (LIST 3)

List 1: CLINICAL CONTEXT OF USE
What sources does your company uses in the analysis of the clinical context of device use?

   - reading academic/scientific journals;
   - watching the activities of universities with departments engaged in medical devices R&D;
   - attending (clinical) conferences and events/trade shows, reading trade publications;
   - talking with patients/clinicians;
   - developing in-house suggestion schemes/idea repositories (e.g. intranet discussion boards);
   - following weblogs;
   - talking to insurance companies/hospital managers;
   - assessing the competitors activities;
   - using external companies trend reports;
   - looking at white papers.

List 2: COMPETITORS
How do you (or your company) keep track of the competition during medical device development?

   - keeping track of websites/blogs/other internet resources;
- talking with clinical experts/clinicians/health professionals;
- attending trade shows, reading trade publications;
- talking with insurance companies and hospital managers;
- using reports on trends from external companies;
- attending (clinical) conferences and events;
- keeping track of scientific publications in research journals.

**List 3: FUTURE USERS**

How does your company involve the future user perspective in medical device development?

- user analysis (i.e. analysis of published materials on user requirements, user needs);
- safety and usability testing;
- informal and/or accidental meetings with users;
- seeking contact with user organizations (i.e. patient groups);
- formal meetings with individual users;
- formal meetings with users in group setting;
- (semi)structured interviewing of multiple (>5) users;
- by offering online or in-house discussion opportunities;
- surveys/written questionnaires.

10. How do you or does your company estimate the potential of the medical device in the clinical context?

- the clinical impact (increase in effectiveness of care) of the new device; *(LIST 4)*
- costs of new device (for the company, for potential buyers, social costs); *(LIST 5)*
- opinions of experts and decision makers; *(LIST 6)*

**List 4: CLINICAL IMPACT**

What does your company include in the clinical impact analysis of a medical device?

- disease severity (e.g. life threatening);
- the size of the target population;
- the improvement of efficacy/effectiveness (of cure or care);
- the improvement of safety & tolerability (of cure or care);
- the improvement in patient satisfaction.

**List 5: ECONOMIC EVALUATION**

What methods does your company use to estimate costs from the company perspective?

- estimation of the future selling price of the device based on manufacturing cost, market place, competition, market condition, and device quality;
- estimation of the profitability of the project based on potential costs and revenues;
- estimation of the return on investment on medical device;
- estimation of how long it will take before the investment in the medical device will be recouped;
- comparison of different business cases for one device, or for different devices to select the device with the highest potential for the company;
- estimation of the profitability of the project based on potential costs and revenues while including the probability of achieving the revenues.

What methods does your company use to estimate costs from the buyer perspective?

- estimation of the financial impact of new device in its future setting (i.e. hospital, etc.);
- estimation of the future return on investment on new medical device for the buyer.

What methods does your company use to estimate costs from the societal perspective?

- cost-effectiveness analysis;
- cost-utility analysis;
- cost-benefit analysis.

**List 6: EXPERTS/DECISION MAKERS**

How does your company gather opinions of the experts and decision makers?

- building and analyzing potential buyers profiles;
- running a focus groups;
- organizing a public meetings;
– interviewing buyers and using buyers discovery;
– formal consultation;
– brainstorming sessions;
– informal discussions.

11. When does market analysis start?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

12. When does market analysis stop?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

13. How is, in your opinion, market analysis usually performed?
– one off exercise;
– iterative/repetitive process.

14. Has the market analysis of the medical device ever led its further development to be:
– accelerated;
– stopped;
– decelerated;
– altered;
– none of these;
– I don’t know.

III ECONOMIC EVALUATION

15. From which perspective(s) does your company estimate the costs aspects of the medical device?
– company perspective (e.g. production costs, profit margins, production capacity);
– buyer perspective (e.g. impact on hospital budget, spending and savings incurred by implementing the product in the setting);
– societal perspective (e.g. long term costs consequences on societal spending on health care and revenues with regard to working life years gained).

16. Has the analysis of the cost impact of a medical device from the company/buyer/societal perspective ever led its further development to be:
Company perspective: Buyer perspective: Societal perspective:
- accelerated; - accelerated; - accelerated;
- stopped; - stopped; - stopped;
- decelerated; - decelerated; - decelerated;
- altered; - altered; - altered;
- none of these; - none of these; - none of these;
- I don’t know. - I don’t know. - I don’t know.

17. When does your company start with the analysis of a medical device costs?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

18. When does analysis of medical device costs stop?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

19. How is, in your opinion, analysis of costs of a medical device usually performed in your company?
– one off exercise;
– iterative/repetitive process.

IV EXPERTS/DECISION MAKERS ANALYSIS

20. Who do you or your company consider experts or decision makers in medical device development process?
21. When are the opinions of experts/decision makers on medical device first gathered?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

22. When the gathering of opinions of experts/decision makers on medical device stops?
– idea generation;
– before the development of the device prototype starts;
– during the device prototyping;
– when gathering evidence on effectiveness and efficiency of the device;
– during marketing of the device;
– I don’t know.

23. Has the consultation of experts/decision makers ever led its further development to be:
– accelerated;
– stopped;
– decelerated;
– altered;
– none of these;
– I don’t know.

V RESPONDENT BACKGROUND
24. What is your age in years?
25. What is your education level?
26. What is your education background (Business management, Economist, etc.)?
27. What is your position in the company?
28. Which department within company do you work in?
29. How many years of experience (in that position) do you have?

VI USE OF MEDICAL DEVICE ASSESSMENT
What, in your opinion, are the uses of performing assessment for medical devices under development?
– increase understanding of design, usability and safety of a medical device;
– aid decision making with regard to design, usability and safety of a medical device;
– increase understanding of device impact (e.g. potential clinical and economic value);
– aid decision making with regard to device impact (e.g. uptake in the market).
Appendix 2. Table A1 presents an overview of the companies that participated in the study. Table A2 presents an overview of the participants of the interviews.

Table A1: An overview of the companies that participated in the study (N=36)

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Table A2: An overview of the participants of the interviews.

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<td>Vocation education</td>
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<tr>
<td>Education background</td>
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<tr>
<td></td>
<td>Economics</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Health sciences</td>
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<tr>
<td></td>
<td>Other (e.g. Medicine, Engineering)</td>
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</tr>
<tr>
<td>Respondents age</td>
<td>21-40</td>
<td>17</td>
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<tr>
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<td>41-60</td>
<td>16</td>
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<tr>
<td></td>
<td>more than 60</td>
<td>4</td>
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<tr>
<td>Experience years</td>
<td>&lt; 1</td>
<td>4</td>
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<tr>
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<td>11</td>
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<tr>
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<td>6-15</td>
<td>14</td>
</tr>
<tr>
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<td>&gt;15</td>
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<tr>
<td>Assessment knowledge</td>
<td>good/ expert</td>
<td>10</td>
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<tr>
<td></td>
<td>medium</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>low/ basic</td>
<td>9</td>
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