STAKEHOLDER RECOMMENDATIONS

Stakeholder management & dialogue

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EUROPEAN REGIONAL DEVELOPMENT FUND
EUROPEAN UNION

Interreg
Baltic Sea Region

BFCC
Baltic Fracture Competence Centre

- Life Science Nord Management GmbH (Germany)
- Stryker Trauma GmbH (Germany)
- University Medical Center Schleswig-Holstein (Germany)
- University Medicine Greifswald (Germany)
- Sahlgrenska University Hospital (Sweden)
- ScanBalt fmba (Denmark)
- Lithuania University of Health Sciences (Lithuania)
- LifeScience Krakow Klaster (Poland)
- University Hospital in Krakow (Poland)
- University of Tartu (Estonia)
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- Bone Index Finland Ltd. (Finland)
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BFCC—BALTIC FRACTURE COMPETENCE CENTRE

The Baltic Fracture Competence Centre (BFCC) is a pan-Baltic fracture cooperation network fostering innovation within fracture management. The project consortium consists of a transnational cross-sector partnership involving five hospitals, three companies from the medical technology industry, a university, three clusters and one technology transfer organization.

Due to an ageing society, the need for innovative products and clinical procedures for fracture treatment is increasing as a response to age-related fractures and co-morbidities such as osteoporosis, infections and non-unions. Innovations in fracture management must reduce the cost of care or clearly improve quality of care.

Clinicians will support the innovation process by identifying the clinical needs to ensure user-oriented product development. The collaboration between hospitals across countries will foster the innovation of clinical procedures through the exchange of best practice in fracture management influenced by different national, organizational and regulatory conditions.

However, clinicians and companies often lack insight information about total cost and effectiveness of fracture management and causes of adverse health outcomes in the hospitals. To overcome this information gap, the BFCC will develop and implement a transnational fracture registry with five hospitals from Estonia, Germany, Lithuania, Poland, and Sweden, respectively, providing evidence about fracture treatment in the clinical »real world« and reveal clinical needs as well as potentials for innovation.

The BFCC will publish two innovation reports. The Innovation Report No 1 deals with trends in the surgical treatment methods of proximal femur fractures. The Innovation Report No 2 based on results and findings from registry data analysis will identify innovation needs and potentials.

PHOTO: Shutterstock

1. INTRODUCTION

Stakeholder (SH) dialogues, either via individual consultations, workshops or discussions during public conferences, are helping business as well as projects to

- find better solutions for complex problems by incorporating input from a wide variety of experts,
- integrate different expertise and generate new insights, creating a wide support for the project,
- create effective long-term win-win situations,
- deal with sustainability in an effective way,
- overcome information asymmetry between partners and stakeholders caused by a lack of transparency, and
- identify **new technologies** for future innovations.

Therefore, to build up a pan-Baltic Fracture Management Community, support from external specialists is needed to compile input for the development phase and regarding sustainability aspects in particular, if such a project involves, amongst other aspects, capacity building and knowledge transfer between the countries of the Baltic Sea Region (BSR), the development of a fracture registry and a **collaboration platform.** The Baltic Fracture Competence Centre (BFCC), has aimed to establish and involve a Stakeholder Group (SH Group) from the beginning of the project.

This SH Group consists of representatives from all relevant sectors, mainly medical device industry and clinicians, but also includes politicians and patients, to collect extensive information, to review project outcomes, and to identify the needs and requirements along the value chain of fracture management from an outside perspective. It should be highlighted that the project also established a project advisory board (PAB) during its runtime consisting of four experts for data, registries and fracture management. Input from PAB members was always very valuable regarding project development and its sustainability.

Companies wanting to develop new products, services and technologies may have entirely different needs regarding e. g. patient support groups, researchers and hospitals (clinicians). Only if all possible groups are heard and involved at an early stage, the BFCC project and its **sustainability** can be successful — which was one of the goals within the project.

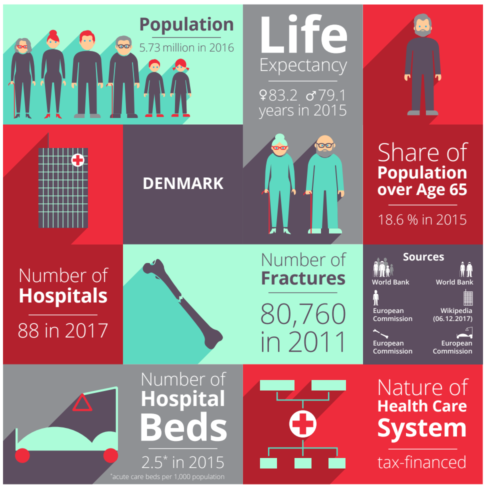
The stakeholder dialogue is based on either individual consultation or joined workshops. The addressed topics cover all aspects of the BFCC project, including registry management, review of the BFCC common minimal data set, data protection issues and eHealth, needs for the collaboration and competence platform as well as discussions about **clinical and industrial needs** in general. Not only discussions on medical device and registry were taken — stakeholders were also involved in development of the BFCC web-based knowledge platform. Further Needs & Requirements can also be found in the BFCC Collaboration Manual.

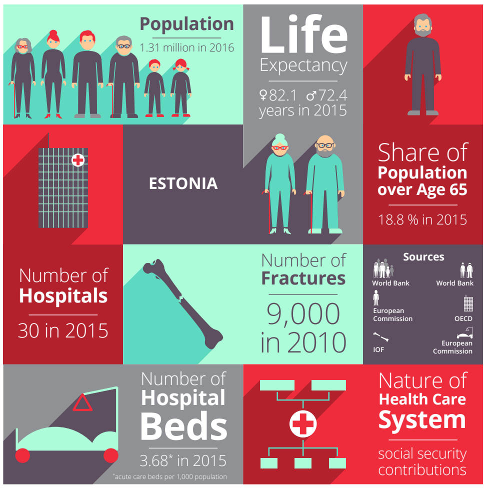
2. DIFFERENCES BETWEEN COUNTRIES IN THE BSR—WHAT ABOUT COUNTRY PROFILES IN FRACTURE MANAGEMENT AND HEALTH CARE?

Stakeholder management, communication as well as internal and external collaboration depend, even more if talking about a transnational level, on personal experiences but are also influenced by politics and social structures within the respective country. This often ends up with different point of views between countries and different challenges which have to be solved to find a common solution for a pan-Baltic (or transnational in general) approach — not only in the field of medical care. Therefore, the BFCC has compared the different project countries regarding costs, population and the general health care situation. Some of the following figures summarise the analysed outcomes, which also are published on the BFCC website (www.bfcc-project.eu).

DENMARK

ESTONIA





3. THE BFCC STAKEHOLDER GROUP

The BFCC SH Group includes industries with different areas of expertise such as trauma devices, imaging technologies, pharmaceuticals, single-use surgery devices, wound care and many more. Clinicians and university representatives are experts in fracture treatment, data protection, eHealth aspects and registry management, among others.

The BFCC Stakeholder Group consists of more than 430 people across countries of the BSR with different expertise and background who participated in workshops and innovation dialogues or were contacted individually. However, the community might be even **larger,** since due to the transnational approach, not all individual consultations and talks »by chance« (e. g. at international conferences) about the project can be monitored.

Country

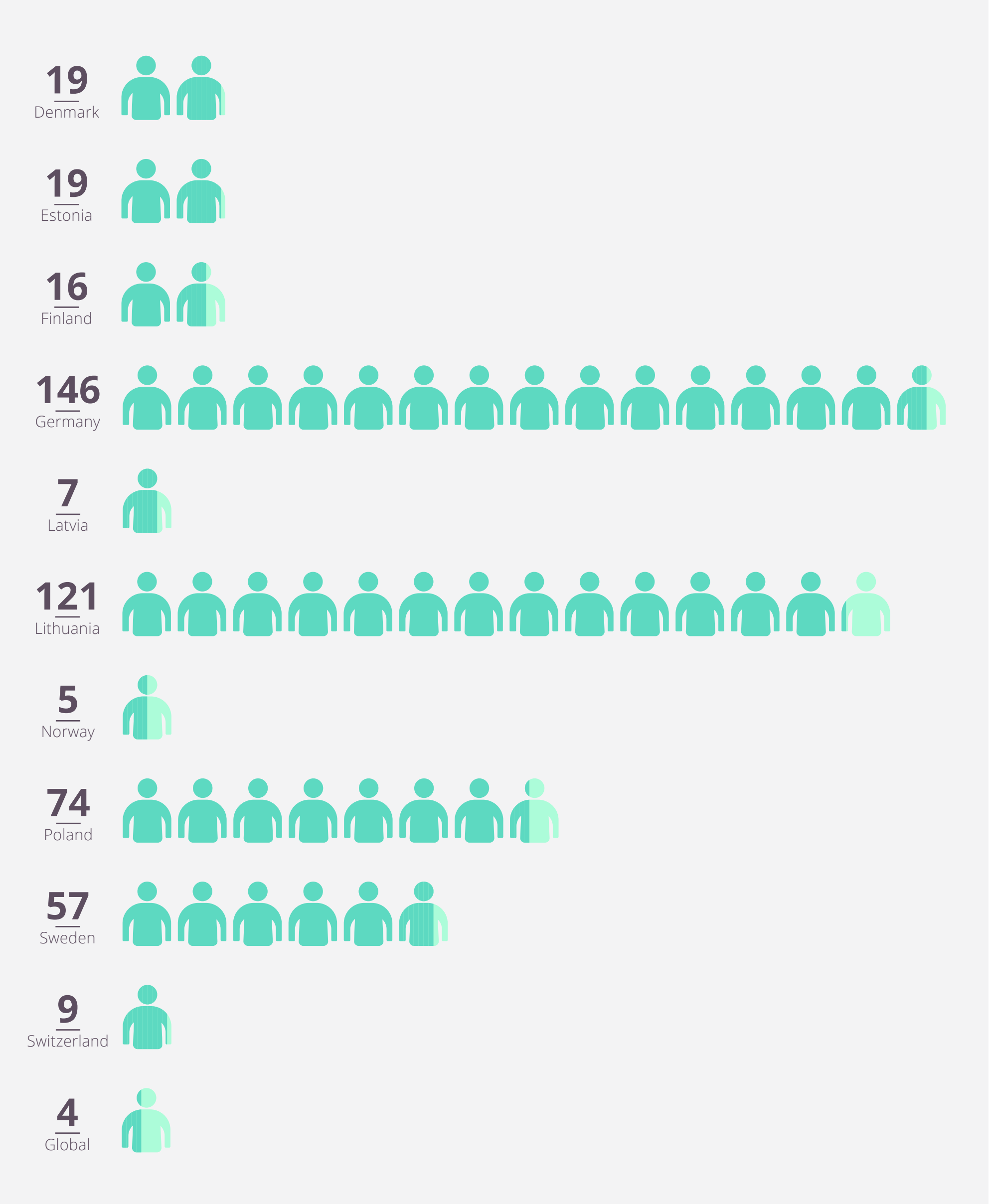
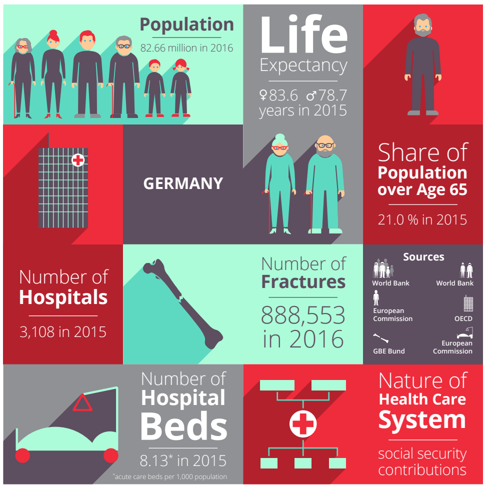


Figure 1: Distribution of stakeholders in the BSR and beyond of the BFCC project

Figure 1 shows the distribution of stakeholders in each BSR country and beyond. Most stakeholders are from Germany, since the work package lead and the lead partner of the project with its network is located in Germany as well. With the expertise of Lithuania and Poland, the project consortium attained a very high number of experts in the field of fracture management, too. A great success is that the project did not only reach collaboration partners and stakeholders in the respective and active countries of the BFCC, but stakeholders in other countries like Latvia, Norway and other global countries as well.

FINLAND

GERMANY



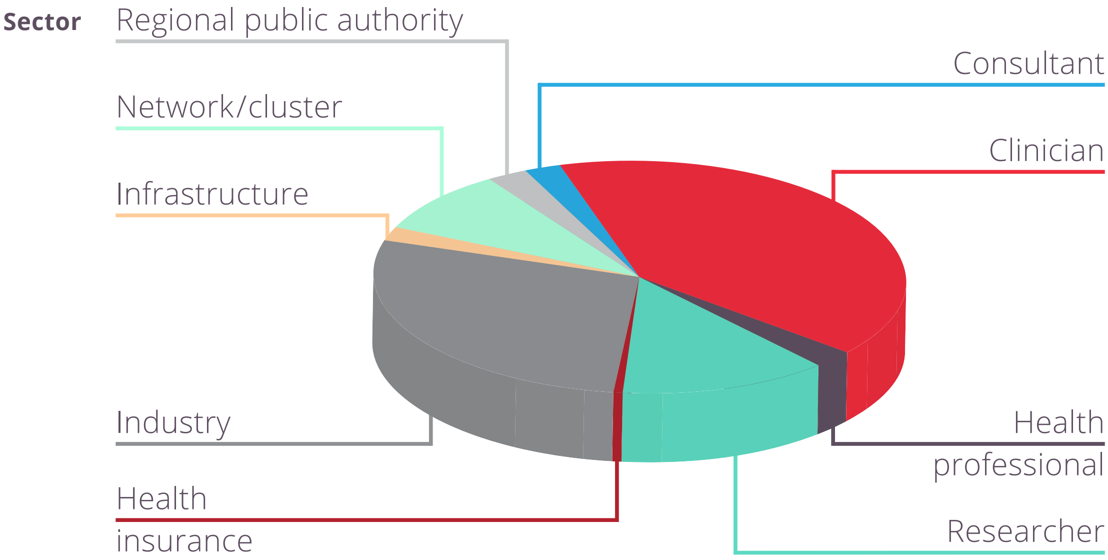


Figure 2: Distribution of stakeholders in the BSR for respective sectors

In figure 2, you can see the distribution of stakeholders of the different sectors in the project: Industry and clinicians have the strongest interest in the BFCC project, which is more than reasonable. However, to build up a registry, a stronger involvement of public authorities and patients might be helpful.

With this report, we want to summarise key findings of the consulted stakeholders so far by individual talks (e. g. conferences, appointed personal meetings and calls) and workshops that took place at the different BFCC partner sites in the BSR.

4. IDENTIFIED CHALLENGES

Regarding the minimal data set, which has been published in June 2017, stakeholders from the industry replied that some items are not suitable for them. Some reported that, if the information of the product that was used in surgery is not collected, the fracture register will hardly give a company substantial value, besides the general value of collecting the patient information. However, it was of common understanding that collecting too much data for different industry expertise will increase work for the clinicians, which might be critical for quality assurance.

Clinicians reviewed the data set and mainly recommended a continuously external review and minimisation of the data set. With a larger data set the probability of more mistakes raises and may lead to decreased data quality, and more values within the data set increases time to enter them. Quality of the data entered has a higher priority than quantity. Moreover, it has been discussed that documentation of the patient consent should be as easy as possible within the registry — to further decrease clinician's workload.

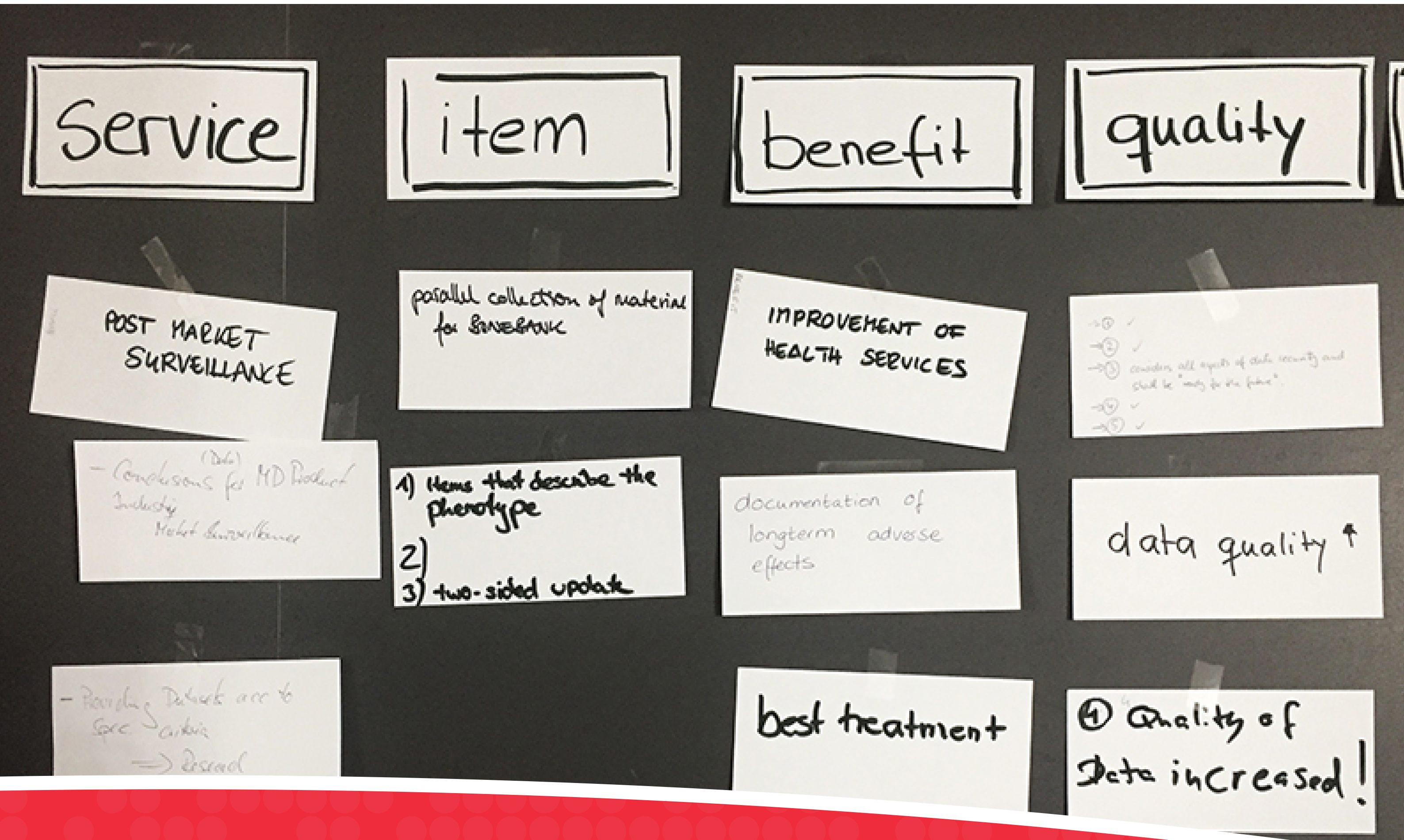
On the one hand, industry would like to have as many data as possible — this reflects the need to include more information for different treatment processes. Obviously, a fracture registry is needed to collect information on performance, safety and suitability of several industrial treatment processes for better collaboration, post-market surveillance, development of implant cards and an understanding of the total cost of care. The BFCC project challenges these issues to gather and collect all available products of the industrial project partners as this would increase the number of collected items within the BFCC data set.

It was suggested by many participants that the data entry should be somehow automated and linked to other registries

or hospital information systems. Furthermore, some stakeholders felt that for the data to be of **good quality** and worth buying for there has to be added value and the possibility to analyse it with information from other datasets: To get background information like nutrition, or hobbies and analyse it with information from the registry. However, most of the stakeholders were also quite positive and have recognised the strong potential of the registry and the overall BFCC project to offer valuable data and services to

- develop new products
- discover research opportunities
- optimise the fracture management and
- optimise definitions and understandings on an **international level.**

Within the consultations, competencies and interests of the BFCC stakeholder community have been analysed as well (see figures 3 and 4).



Competencies

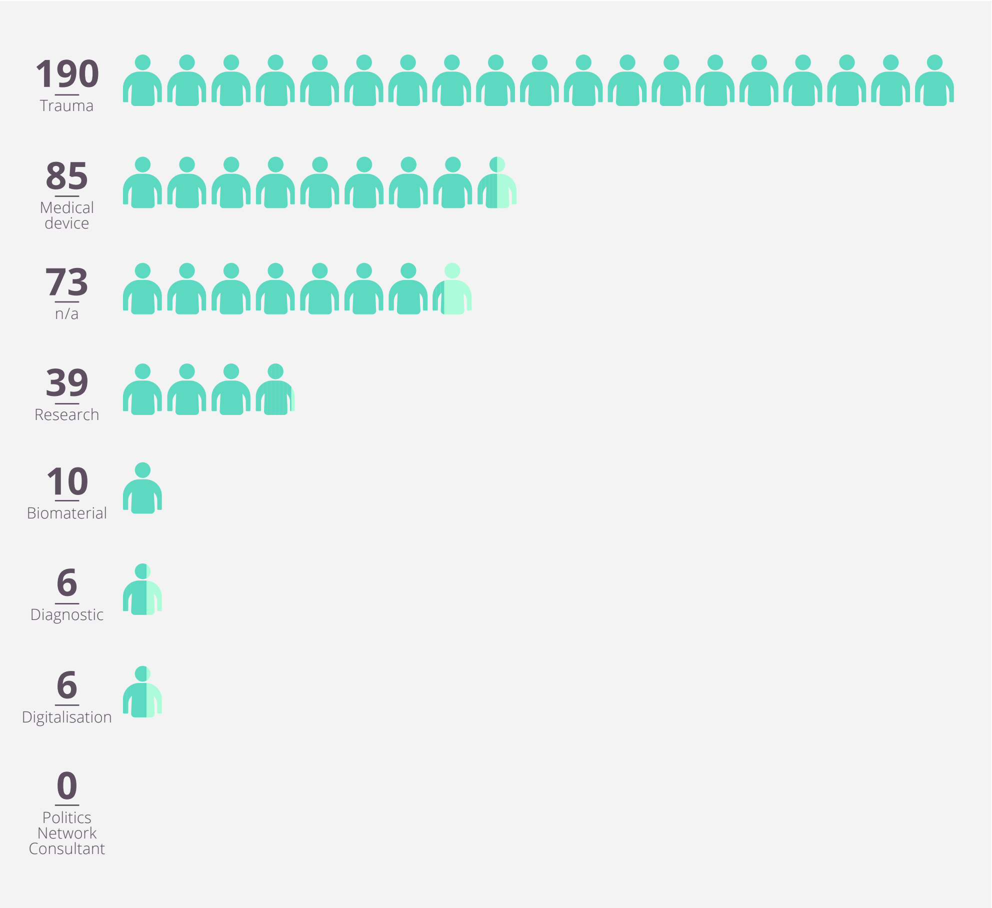


Figure 3: Distribution of stakeholders's competencies

Interests

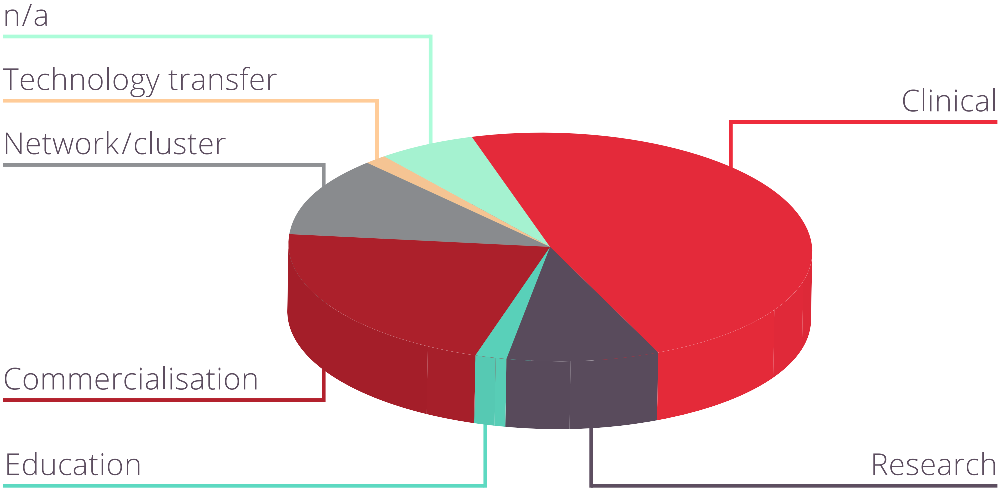
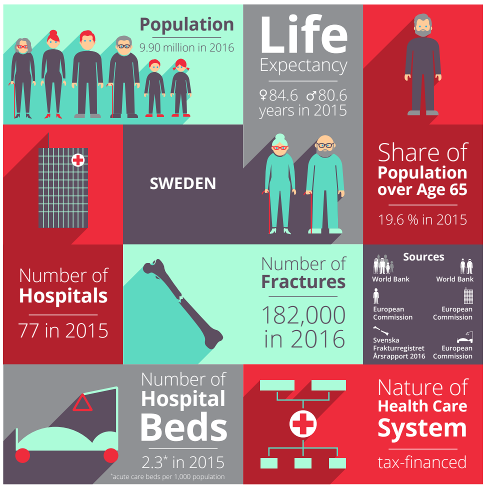


Figure 4: Distribution of stakeholders's interests for the future

POLAND

SWEDEN



5. DIFFERENT APPROACHES TOWARDS SUCCESS

To find a solution or an advice regarding the above stated issues, the project and the stakeholder network discussed quality management within the SH Group. How can clinicians be motivated to enter data (which takes longer than e. g. six minutes)? How can the industry be involved to gather data for their interests? There were different answers regarding these aspects, such as payment for the clinicians. Another option could be to increase the intrinsic motivation of clinicians and health professionals — that would include the need for an employee taking care of this specific task in the beginning of the extension stage of the BFCC registry beyond the project runtime. This could then lead to a self-motivating circle within the hospital, where young clinicians learn best practice from the experienced staff and entering the data becomes a regular everyday task. Clinicians and managers could also be motivated by the option to get quality reports of their (or the hospitals) performance out of the registry.

However, the motivation of clinicians to enter industry-related data that goes beyond the amount of data is still a discussion point for the future.

6. SUMMARY

The most important issues for the BFCC and its registry in the future have been identified as follows:

- There is always the risk that the data set required for input is too large and its quality too low — therefore, it's better to start small (few hospitals only), but in the right way (high-quality data)
- For industry, post-market surveillance is of course a main interest regarding a fracture registry to gain knowledge about distribution of products, total cost of care, reasons for usage and new approaches to address clinical problems
- The example of social care data management in Scandinavia was given
- Uploading the patient consent should be as easy as possible to minimise clinicians' workload
- The inclusion of further industry-related values is beneficial
- The project should focus on selected, not too many, indications
- There is a strong need for an overall pan-Baltic fracture registry to improve collaboration, but the implementation has been identified as a challenging task
- Establishment of post-market surveillance reports for industry
- Patient-specific data to be collected for all products
- Development of implant cards
- Finding solutions for the GDPR regulations and the Medical Device Regulation (MDR)

7. CONCLUSIONS

- The BFCC project was of interest for in particular the implant manufacturers attending the meetings as well as for monitoring professional performance in hospitals
- Registries will play an import role in the post-market surveillance process
- The degree of awareness of the new Medical Device Regulations varied among the participants

PHOTO: Adobe Stock

KEY FACTS

- Duration: 36 months (2016–2019)
- Total budget: about EUR 3.6 million
- Programme: Interreg Baltic Sea Region
- Fund: European Regional Development Fund
- Flagship project of the EU Baltic Sea Region strategy

PROJECT PARTNERS

- Life Science Nord Management GmbH (Germany; Lead Partner)
- Stryker Trauma GmbH (Germany)
- University Medical Center Schleswig-Holstein (Germany)
- University Medicine Greifswald (Germany)
- Sahlgrenska University Hospital (Sweden)
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