It is possible – establishing a web-based system in a major German university hospital to successfully measure patient reported outcomes using the International Council of Health Measurement data set

Abstract

Background:
Collecting patient reported outcome (PRO) data in a systematic way enables an objective evaluation of treatment and its related outcomes. By using the disease specific questionnaires developed by the International Consortium of Health Outcome Measurement (ICHOM) this allows for comparison between physicians, hospitals and even different countries.

Objective:
The aim of this pilot project was to establish a digital system to measure patient reported outcomes for new breast cancer patients who attended the Charité Breast cancer clinic. This approach should serve as a blueprint to further expand the PRO measurement to other disease entities and departments.

Methods:
In November 2016 we implemented a web-based system to collect PRO data at the breast center at Charité University hospital using the ICHOM data set. All new patients at the breast center were enrolled and were answering a predefined set of questions using a tablet computer. Once they start their treatment at Charité automated emails were sent to the patient at predefined treatment points. Those emails contained a web-based link through which they could access and answer questionnaires.

Results:
By now 541 patients have been enrolled and 2470 questionnaires initiated. 9.44% of the patients were under the age of 40, 49.7% between 40 and 60, 39.6% between 60-80 and 26.3% over the age of 80. The average return rate of questionnaires was 67%. When asked about preference regarding paper versus online questionnaires 6% of the patients between 50 to 60, 6% between 60-70 and 13% over 70 would prefer paper versions.

Conclusion:
Measuring PRO in breast cancer patients in an automated electronic version is possible across all age ranges while simultaneously achieving a high return rate.

Keywords: Breast cancer, patient reported outcomes, International council health outcome measurement

Introduction
In Germany, every year 70,000 women receive the diagnosis breast cancer. Almost thirty percent are under the age of fifty-five. Due to improved screening and treatment modalities there has been a significant improvement in overall survival in the last decade. Breast cancer specific mortality in Europe was reduced from 17.9 per one hundred thousand women in 2002 to 15.2 women in 2012 [4]. However, survival gains are often associated with a loss in physical functioning, increased morbidity and new challenges regarding the emotional, social and financial aspects of life [5,6,7,8]. Therefore, this increase in life expectancy for cancer patients must lead to an increased scrutiny regarding the long-term side effects of new and existing cancer treatments [9,10]. An important aspect in evaluating the effects of any therapy is the patients voice...
and perception. This applies all the more to cancer patients. The best way to address this aspect is by using patient reported outcome measures (PRO). The US Food and Drug Agency describes PRO as “any report coming directly from patients about a health condition and its treatment” [11]. Nowadays, using electronic media like smartphones and tablet computers measuring PRO data is much easier and less time and cost consuming than in the past. The use of PRO data allows for a real time evaluation of therapy concepts, and the monitoring of new treatments. At the same time, it is an easy way for long term follow up. Increasingly complex therapies in medicine are simultaneously requiring an increase in documentation – time missing in direct patient communication [12,13]. However, this time is essentially needed to adequately assess a patient’s situation and symptoms. PRO has been shown in multiple studies to help the clinician to adequately assess patient symptoms, save time for patient communication and therefore improve patient care and even survival [14,15].

Methods

After obtaining ethics approval from the Charité ethics commission (EA xy/cryz), we implemented a web-based system to collect PRO at the Charité Breast Center. Data capturing started in November 2016. The PRO collection was based on an international standard set for breast cancer outcome measures, which was developed by the International Consortium for Health Outcome Measurement (ICHOM). All new patients, who attended the breast clinic should be included into the PRO measurement. Afterwards, those who had a diagnosis of breast cancer and received their treatment at Charité Breast Center should be stratified into follow up. After patients registered at the clinic, they were asked by the receptionist, if they would be willing to participate and received a personal log in after they signed consent. The waiting time until their appointment was used to answer the ICHOM questions, as well as questions regarding their medical history on a tablet computer. After successful completion of the questionnaire, the answers and calculated PRO scores were immediately available for the treating physician for the upcoming consultation. During that, treating physicians had the option to add missing clinical data. If they decided not to record the clinical data necessary, it was later added by support staff. Once patients entered specific care pathways like chemotherapy or surgery, an automated process was started through which they received follow up emails containing the access code to their individual PRO measurement questionnaires.

From a technical standpoint the system for PRO collection, was installed on campus as an on-premise installation. It was therefore only available within the Charité network. The core system was supported by an additional patient portal, which acted as the outward facing tool, to interact with patients. The patient portal was hosted in a different environment to allow for online access. It enables patients to complete questionnaires from home using a secure connection.

Results

Monthly increase in patients who participate in the PRO measurement since program implementation

Figure 1 shows the monthly increase in patients who were entered into the PRO evaluation at the breast center and agreed to participate after its implementation in November 2016. After an initial increase in January 2017 with 40 patients there was a drop in participation with the lowest rate in March 2017 with only four patients.
From July 2017 on there was a marked increase in patient numbers, a trend that continued from there on.

Figure 1. Monthly increase in patient numbers with PRO measurement since implementation

Table 1 compares the number of new patients entered into the PRO system with the total number of new patients seen at the Charité breast center. With the exemption of January 2017, where 34% of the new patients were added to the PRO system, the percentage of all new patients stayed below 20% until July 2017 with its lowest point with only 2% in March 2017. After July 2017 there was a marked increase in adding new patients almost continuously increasing and reaching its highest percentage in December 2017 with 74% of all new patients included in the PRO system.

<table>
<thead>
<tr>
<th>Month/Year</th>
<th>New patients seen at the Charité Breast Center</th>
<th>Number of new patients who participated in PRO Measurement</th>
<th>Percentage of all new patients who participated in PRO Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 16</td>
<td>105</td>
<td>13</td>
<td>12 %</td>
</tr>
<tr>
<td>Dez 16</td>
<td>90</td>
<td>7</td>
<td>8 %</td>
</tr>
<tr>
<td>Jan 17</td>
<td>116</td>
<td>40</td>
<td>34 %</td>
</tr>
<tr>
<td>Feb 17</td>
<td>124</td>
<td>10</td>
<td>8 %</td>
</tr>
<tr>
<td>Mrz. 17</td>
<td>166</td>
<td>4</td>
<td>2 %</td>
</tr>
<tr>
<td>Apr 17</td>
<td>104</td>
<td>20</td>
<td>19 %</td>
</tr>
<tr>
<td>Mai 17</td>
<td>139</td>
<td>25</td>
<td>18 %</td>
</tr>
<tr>
<td>Jun 17</td>
<td>112</td>
<td>9</td>
<td>8 %</td>
</tr>
<tr>
<td>Jul 17</td>
<td>116</td>
<td>55</td>
<td>47 %</td>
</tr>
</tbody>
</table>
Table 1 Increase in patients with PRO measurement compared to total number of new patients seen at the breast center

<table>
<thead>
<tr>
<th>Month</th>
<th>New Patients</th>
<th>Total Patients</th>
<th>Increase %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 17</td>
<td>108</td>
<td>54</td>
<td>50%</td>
</tr>
<tr>
<td>Sep 17</td>
<td>163</td>
<td>67</td>
<td>41%</td>
</tr>
<tr>
<td>Okt 17</td>
<td>93</td>
<td>59</td>
<td>63%</td>
</tr>
<tr>
<td>Nov 17</td>
<td>169</td>
<td>115</td>
<td>68%</td>
</tr>
<tr>
<td>Dez 17</td>
<td>117</td>
<td>86</td>
<td>74%</td>
</tr>
</tbody>
</table>

Only a small number of patients decline to participate in the long term follow up. Figure 2 shows the percentage of breast cancer patients who agreed to participate in the electronic follow up PRO measurement compared to those who did not want to participate. In the age group 20-30, 66.67% agreed to follow up, in the age group 30-40, 75% agreed to follow up. The highest number was seen in the forty to fifty years old patients with 90.91% followed and with 75.76% in the age group sixty to seventy years. Participation levels were the same with 75% in the age groups seventy to eighty years and above eighty years.

Figure 2 Number of patients who participate into follow up versus those who decline

Refusal Follow-Up  Number of patients who agreed to follow up

<table>
<thead>
<tr>
<th>Age groups (in years)</th>
<th>Number of Breast Cancer patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-30</td>
<td>12.5</td>
</tr>
<tr>
<td>30-40</td>
<td>25</td>
</tr>
<tr>
<td>40-50</td>
<td>37.5</td>
</tr>
<tr>
<td>50-60</td>
<td>25</td>
</tr>
<tr>
<td>60-70</td>
<td>12.5</td>
</tr>
<tr>
<td>70-80</td>
<td>0</td>
</tr>
<tr>
<td>über 80</td>
<td>0</td>
</tr>
</tbody>
</table>

12.5 %  25 %  37.5 %  25 %  12.5 %  0 %  0 %

92.50 %  90.91 %  75.76 %

Figure 3 shows the return rates of the online questionnaires completed by those patients who participated in the follow up PRO measurement. After an initial drop to 66.67% in February 2017 there was a continuous increase in the return rate from 54% in March of 2017 to 83% in September with then another slow decline in October 2017. November and December 2017 showed a steady return rate above 80% with 81% in November and 83% in December 2017.
Figure 3 Return rates of the digital questionnaires completed by patients who participated in the long-term PRO measurement.

Using a digital way to measure PRO compared to a paper-based version is preferred in almost all age groups. Figure 4 shows the percentage of patients who would prefer a paper-based version of the questionnaire instead of a digital one. 100% of the patients in the age groups from twenty to forty years preferred a digital version while 3% of the patients in the age group forty to fifty years preferred a paper-based version. This increases to 6% in the age group between fifty and seventy years of age and then further increases to 13% for those patients between seventy and eighty years of age. Above eighty years of age, there was a 100% preference for paper-based questionnaires compared to digital questionnaires.

Fig 4 Preference regarding paper versus digital questionnaire according to age groups.
Discussion

Principal Results

Our study documents the successful implementation of measuring patient reported outcomes using the ICHOM data set for breast cancer in a German university hospital for the first time. During the implementation period we made numerous observations. First, it takes an at least six months period to implement and establish a working system, get all key stakeholders to adopt it, while simultaneously solve those technical problems which will arise during the implementation phase. Second, most patients, across all age groups are willing to participate in the initial measurement as well as in the long term follow up. Third, contrary assumption, most patients, even those above 60 prefer a digital survey over a paper-based way to answer the PRO questionnaires.

Our observation regarding the required time frame to establish a successful electronic PRO system is matched by previous publications coming from experiences in the United States of America [16]. One crucial point in establishing a successful digital program is to explain and educate all health care providers who will be involved in the collection of PROs about the purpose and benefit of PRO. While there is increasing interest and knowledge about PRO measurement there are concerns regarding workflow, increase in workload due to the additional measurements as well as data overload and creation of additional needs [17] [18] [19]. These findings are mirrored in our low patient accrual data in the first six months after implementation. It took this time to train, educate and convince all involved staff members from front desk staff up to the treating physicians. Once this barrier was broken there was a steady increase in breast cancer patients who would be followed with PRO measurement. Only a small percentage of patients declined to participate in the PRO follow up. The highest percentage who agreed to follow up was in the age group of the forty to fifty years-old women with an astonishing 92.5%. The lowest rate was found in the age group of the twenty to thirty years-old women with only 66.67% agreeing to follow up. This is in part because of the low numbers of patients we have in this age group.

In addition to the finding that it is possible to establish a successful PRO measurement program at a German Breast center this work showed for the first time that the majority of breast cancer patients treated in a German university hospital preferred a digital survey. Patients did not want to fill out questionnaires in a paper and pencil based version – despite contrary believes. In addition to this interesting finding we were able to show that we can simultaneously achieve a high adherence rate even in long term follow up. Similar observations have been made previously in the United States of America for example at Memorial Sloan Kettering Cancer Center [20] or the University of North Carolina [21].

Limitations

Since this is a retrospective analysis of an implementation trial it is not without limitations. In the beginning, reasons of patients' decline in participating were not systematically collected. Since this systematic approach was started only at a later point we currently don't have enough data on this matter but are collecting them now. Also, we did not have enough resources to be able to contact those patients who decided not to continue in the follow up. This point as well as the first are important aspects and we are currently addressing both of them and plan to publish the results in a following publication.
Comparison with Prior Work
While there is increasing interest in the potential of PRO measurements in almost all disease entities [22,23,24,25] there is still a lack of standards what to measure and how to measure it. The ICHOM initiative has therefore created a working group for a wide range of diseases with the goal to establish standard sets to compare outcomes between different providers, hospitals and even countries [26]. This is the first published work to show that the implementation of one of their standard sets – in our case for breast cancer - is feasible and lays the foundation for further improvements in the complex care of breast cancer patients.

Conclusions
The goal of this pilot trial was to create a template on how to establish a successful web-based PRO measurement at a German university hospital, setting the stage for what to expect and showing that it is possible to measure PRO in a digital manner in breast cancer patients of all age groups.

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Conflicts of Interest
Disclose any personal financial interests related to the subject matters discussed in the manuscript here. For example, authors who are owners or employees of Internet companies that market the services described in the manuscript will be disclosed here. If none, indicate with "none declared".

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Abbreviations
JMIR: Journal of Medical Internet Research
ICHOM: International Council on Health Measurements
PRO: Patient reported outcomes
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