ON DATA ORGANIZATION AND COLLECTION POLICIES IN THE INFORMATIONAL SYSTEMS OF THE GERMAN CANCER SOCIETY'S CERTIFICATION PROGRAM

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<u>Abstract:</u> In order to improve the quality of treatment for cancer patients, the German Cancer Society implemented the certification of cancer centers, including rigorous data collection. The data are reviewed following a systematic collection-verification-storage-reporting pathway to make them usable for analyses of care quality across centers and improving of the certification criteria. The assessment of the input data from the centers leads to several output products for the centers. Our example shows that high quality data managing processes in a newly-established, growing certification system need to be constantly reviewed and formatively evaluated over time, requiring lots of efforts and resources.

Keywords: German Cancer Society; data collection; database; benchmarking; health care; certification

I. INTRODUCTION

The beginning of systematic patient outcome data collection was in the early 1960's, when Warren Warwick, a pediatrician from Minnesota, received a significand amount of money from the Cystic Fibrosis (CF) Foundation to collect reports on every patient treated at the thirty-one CF centers in the United States that year. The reason for this initiative was that a young pulmonary specialist claimed to have a much higher survival rate among CF patients than the national average. This was a claim that had to be verified and backed up with accurate data. The outcomes showed that the young doctor was correct. Now the important question was, how does he achieve this and how can other centers learn from his techniques and improve their own outcomes [1].

This is also the most important feature of a hospital certification program: to compare rigorously collected data from centers, to calculate results, all this in order to make the centers improve themselves by improving patient care quality. It all starts with an accurate data collection in order to have accurate and comparable results. By making these results public, the centers can see their position among other centers and can make changes or improvements in their treatment approaches in order to achieve better results.

According to [2], the number of accreditation programs has doubled every five years since 1951, with

Europe now accounting for half of the world's accreditation programs.

To ensure high standards of oncological care, the German Cancer Society introduced a certification system for cancer centers in 2003. The first implementation of cancer centers was for breast cancer (later called "Breast") [3]. It was then shortly followed by certifications for colorectal cancer ("Colorectal") [4], prostate cancer ("Prostate") [5], pancreatic cancer ("Pancreas") [6], gynecological cancer ("Gyn") [7], lung cancer ("Lung") [8], skin cancer ("Skin") [9], head and neck cancer ("Head and Neck") [10] and neurological cancer ("Neuro") [11]. Starting with 2015 the certification of liver and stomach cancer centers is also possible. Clinics that combine several organ cancer centers can additionally apply for a certificate as an "Oncology Center". At the present time, the certification system of the German Cancer Society is available not only in Germany, but in Austria as well as in Swiss and German speaking areas of Italy. The certification system requires a high standard data collection from the certified centers. Most of the data required for the certification are based on primary cancer cases. The collection is realized by OnkoZert, the independent quality assurance institute that organizes the auditing process on behalf of the German Cancer Society. This article presents the information flow of the raw patient data from the hospitals to the certification system and back as a report to the centers.

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Audit year 2015 / Indicator year 2014 Basic Data: Colorectal (For explanatory notes on the indicators please go to www.xml-oncobox.de)		D KREBS	KG GESELLSCHA	FT
Registration no.		Ì	Specimen certific	ate)
Centre				0
Location				
Contact person		Creation date		1
		Date of first certification		8
		Indicator year	2014	
State/country				
Cancer registry	8	Cooperation with cance	er registry	0
Tumour documentation system		XML-OncoBox Da	ırm	0
an nation into the source of	da.	No		

Primary cases	Ope	rative		Not operative	Not operative	
of colorectal cancer	Elective	Emergency	Endoscopic	palliative	curative	Total
Primary cases 🛙	1	i i	0			0
Colon	L	i i				
Rectum	l	8 8			n 3:	

Figure 1. Sheet "basic data" for colorectal certification

II. MATERIALS AND METHODS II.1 ELECTRONIC QUESTIONNAIRE – MICROSOFT EXCEL

Cancer Centers that wish to be certified by the German Cancer Society need to be reassessed annually before the audit takes place. Among others, every certified center must annually fill out an electronic questionnaire (using Microsoft Excel) with the centers' aggregated patient data. There are certain requirements which have to be fulfilled. These requirements are set as indicators with a numerator and a denominator. For example, the indicator for postoperative tumor board for breast cancer centers is made up from the denominator "operative primary cases" and the numerator "operative primary cases which were presented in the postoperative tumor board". All indicators are the same, regardless the country where the audit takes place. The electronic questionnaire has strict rules that ensure a high data quality, and warns the centers if some data are not plausible or below the given limit. These indicators must then be commented and an action plan has to be suggested. An action plan has to contain the measures taken by the centers to correct their results (including treatment of the patients if this is the cause of the indicator failure). In addition, after submission to OnkoZert and the auditors, the data and the comments are verified for validity, quality and plausibility. The indicators are set by the German Cancer Society's Certification Committee for each organ. The electronic questionnaire usually has five sheets.

The first sheet is called "basic data" and it refers to the general information about the centers and the basic information about patient categorization and cancer staging (Figure 1).

The second sheet called "indicator questionnaire" refers to the required indicators which have to be filled out (Figure 2). Most of the indicators are set with a numerator, denominator and percentage and some only as a number. Above the indicators a calculator similar to a traffic light shows to what extent are the indicators fulfilled. There are five categories of fulfillment presented with different colors in the first two columns: "OK and plausible" - white, "OK and plausibility unclear" - light grey, "target not met" - dark grey, "incorrect" and "incomplete" - black. The number of indicators for each category and the percentage are displayed. Incorrect and incomplete indicators are usually not accepted by the certification system and the data management. There is also a special category of optional indicators; these are not calculated in the traffic light and can be left empty. For the mandatory indicators, in case they are in one of the categories "OK and plausibility unclear" or "target not met", the centers must write the cause of the deficit and an action plan.

The third sheet called "data deficits for indicators" refers to a page similar to a to-do list, which tells the centers where they have problems regarding the indicators (no figure provided). This sheet is a résumé of the problems from the former sheet.

The fourth sheet called "matrix" refers to a matrix which must be filled out with data referring to previous years (no figure provided). The matrix contains data from the follow-up of the patients. Here, there is also a traffic light which measures the completeness and validity of the follow-up data. The traffic light contains the same categories and colors but counts the problematic cells. The structure of the matrix is dependent on the organ type of the certified cancer center.

The fifth sheet called "data deficits for matrix" refers to a to-do list for the matrix (no figure provided). This sheet is a résumé of the problems from the former sheet.

Prior to the audit, each center sends the electronic questionnaire to the auditors and to OnkoZert. The auditors generally verify the plausibility of the indicators and the given explanations. OnkoZert verifies the integrity of the file, the completeness, the validity of the indicators, the plausibility of the connections between the indicators, the existence of the explanations and action plans. OnkoZert and the auditors communicate with each other on this matter. If there are some problems or implausible data, these are discussed with the center and, if possible, corrected by the center before the audit takes place (Figure 3). In rare cases this only happens just after the audit.

II.2 "ELECTRONIC INDICATOR QUESTIONNAIRE" APPLICATION

Finally, the information gathered from the hospitals is then imported in a web application, EKB (Elektronischer Kennzahlenbogen = Electronic indicator questionnaire), see also www.kennzahlenbogen.de. EKB is built using Microsoft technologies and some proprietary frameworks (3rd party). Overall, the technology is based on the programming language C# (C Sharp), also developed by Microsoft.

	Plausible 0,00% (0)		
OK	Plausibilty unclear 0,00% (0)	0,00% (0)	Processing quality
Target	Target not met		0,00% (0)
Dofostivo	Incorrect 0,00% (0)	100.0	09/ (25)
Defective	Incomplete 100,00% (25)	100,0	0% (25)

Figure 2. Sheet "indicator questionnaire - traffic light"

The application has a three-layer architecture [12], described as follows:

- Interface or Front End. It is responsible for defining 1) the graphical interfaces and taking/sending data from/to the user. Graphical interfaces are implemented using ASP .Net Web Forms technology. For additional features, appearance, and performance, some additional frameworks that are not related to Microsoft have been used. For the client scripting jQuery and Javascript were used. For additional controls or improvements of native controls the DevExpress controls and utilities suite have been utilized. DevExpress is a framework that builds over technologies Microsoft offering improved performance and esthetics related to controls and their functionality.
- 2) Logic Layer or Business Logic Layer. It is responsible for processing the received data, saving this data to the database, generating statistics, reports or exports based on the imported data. The used programming language is C#. DevExpress was used for reporting. For the excel exports EPPlus Framework has been used and to export PowerPoint the OpenXML SDK 2 Framework.
- 3) Data Layer. It is responsible for the communication with the database and for creating C# objects that are used to manipulate the data. Here, the use of the nHibernate Framework has been combined. nHibernate is an ORM Framework (Object-relational Mapping). This framework facilitates the translation of the database information into objects which the application can easily use. The Data Layer communicates with a Microsoft SQL Server Express 2008 R2 database. This Database engine is a free, lighter and simplified version of the MS SQL Server. It allows the storage of data measuring 10GB.

In addition to this architecture the EKB web application also includes a web service. The purpose of web services is to serve EKB data to various consumers in a safe way. The only actual consumer is the Data-WhiteBox application. The web service is implemented with Microsoft WCF Technology (Windows Communication Foundation) and the data is transmitted through the HTTPS encrypted protocol.

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Figure 3. Information flow



Figure 4. Relation graphic of the "Elektronischer Kennzahlenbogen"

The EKB application is installed on a dedicated server, hosted in Germany. A dedicated Server means that we have permanent access to it and we can use it as needed. The server is a computer with a Quad-Core processor with 8GB RAM and with a Windows Server 2008 R2 operating system. The applications hosted by the server run on an Internet Information Services (IIS) client server, version 7.5. This client server allows the hosting of a large number of web applications or web sites. Figure 4 presents the relational structure of the EKB data base.

III.3 "DATA-WHITEBOX" APPLICATION

Data-WhiteBox is a Windows application (it runs just on the latest Microsoft operating systems) built with Microsoft Win Forms technology and also with the DevExpress framework and programmed with the help of C# programming language. Data-WhiteBox can be considered a consumer application, which means that the application only brings and interprets data from other sources. In our case, the data is brought trough WCF web service from the EKB web application. Data is brought sequentially by the web service and it is temporarily stored in data structures inside the Data-WhiteBox application. These will be called and used at the appropriate time by the internal processes of the application.

The graphical interface of the application is built with the help of DevExpress Win Forms technology. The native Microsoft Win Forms controls are improved by those from the DevExpress library (Figure 5).

Regarding the exported documents, this application also uses EPPlus for the excel creation and exporting and OpenXML SDK 2 for the manipulation and exporting of the PowerPoint Benchmarking reports, that feed back information to the centers and the public annually.

The application is built on the principle of Model-View-Presenter (MVP). MVP is just a way of organizing, separating and fragmenting the task attributions for a better organization, understanding and maintenance. The Views are responsible for retrieving data from the user, for displaying results to the user and for communicating with the graphic controls. The Models are responsible for storing and manipulating basic information received from EKB. The Presenters are a link between the View and Model. They are responsible for the coordination of events triggered by the user, by loading and sending data and by performing complex operations.

The Data-WhiteBox application uses all the data stored in the EKB database and verifies the data quality, calculates basic statistics, generates different graphs and reports, and generates annual general benchmarking reports as well as specific individual reports.

The Data-WhiteBox application takes all individual data from EKB database. These data are categorized by organ, audit year and by indicator. Every individual number has an exact location in the database.

Firstly, the application makes a quality verification of the data. Data which are not correct, or are missing will not be included in the analysis.

Then, the application makes basic calculations (basic statistics) from which result i.e. the min, max, mean, median. These figures refer to an individual indicator/year/organ every time – and use the data from

all the centers certified in a certain year and with valid data. These values are compared to the target values that have to be achieved for every indicator. Based on the centers' results, certain graphs are generated which represent the results of a specific indicator. There are pie charts, scatterplots, bar charts, point charts and boxplots.

In Figure 6 the colors represent the following: light grey for centers without noted problems for an indicator during the audit process; dark grey for centers which had at least one observation or one improvement indication from the auditor or the center had explained a data deficit and black for the centers with at least one deviation from the standard or the center has made up for his own an action plan to repair the existing problems. These kind of charts are checked by the German Cancer Society and they prepare comments for each indicator based on the centers' values. These comments appear then in the benchmarking reports.

Since data management for the colorectal centers is the most advanced we have counted how many times a center sends us the electronic questionnaire until it is valid. This statistic was done over a period of three years and refers not only to the total number of electronic questionnaires, but also to the moment in time related to the audit. We also counted the filling out rate of the quality indicators by all centers and the tumor documentations systems used by the colorectal centers.

III. RESULTS

Figure 7 presents the history of the data management system within the certification system of the German Cancer Society. As shown, the collection of the data (marked with light grey) is actually the main information about patient data. With the help of two assessment tools (marked with black) we manage to return to the centers 10 types of reports and instructions (marked with dark grey). The different elements are described further below.

For each organ there is a classification table (Tables 1 to 9). Each row shows the evaluated year and to which extent the centers got in the benchmarking report and how many centers sent valid data for the indicators. The definitions of the indicators are not subject of this article.

A = Certification year / Data year

B = Certified locations

C= thereof "locations with first certifications" not in the benchmarking report

D = thereof ,locations with certificate suspensions" not in the benchmarking report

E = thereof "locations with documentation problems" not in the benchmarking report

F = Locations in the benchmarking report - Absolute

G = Locations in the benchmarking report – Percentage

H = Filling out indicators - Absolute median / Absolute average

I = Filling out indicators - Percentage median / Percentage average

In the Lung tables (Table 9) instead of "locations" are meant "centers".

To give an example of how the data are transferred: in audit year 2012 there were 230 certified colorectal cancer

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Figure 6. Example of bar charts for one indicator



Figure 7. History of data management in the certification system

center locations. Prior to the audit OnkoZert had received 250 versions of electronic questionnaires and 25 versions after the audit. This was a total of 275 electronic questionnaires. From the 230 certified locations 205 didn't need to send a corrected version to OnkoZert after the audit. In audit year 2013 there were 253 certified locations. Prior to the audit OnkoZert had received 486 versions of electronic questionnaires and 216 versions after the audit. This was a total of 702 electronic questionnaires. From the 253 certified locations 124

didn't need to send a corrected version to OnkoZert after the audit.

Compared to audit year 2012 the percentage of totally sent files from the centers has grown by 232,1%. Also the percentage of files sent after the audits has grown to 785,5% (Figure 8).

The percentage of locations which didn't have to resend the files after the audits took place had fallen to 55%.

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Figure 8. Evolution of questionnaires handed to OnkoZert by the colorectal cancer centers

Table 1. Benchmarking Breast

А	В	С	D	Е	F	G	Н	Ι
2014/2013	277	3	1	-	273	98,6%	273 / 256,31	100,00% / 93,89%
2013/2012	274	5	-	1	268	97,8%	267 /249,51	99,62% / 93,10%
2012/2011	267	8	-	3	256	95,9%	255 / 249,93	99,60% / 97,63%
2011/2010	261	3	-	6	252	96,6%	247 / 245,40	98,01% / 97,38%
2010/2009	258	8	-	4	246	95,4%	239,5 / 232,56	97,36% / 94,53%

					0			
А	В	C	D	E	F	G	Н	I
2014/2013	276	15	2	2	257	93,1%	257 / 255,10	100,00% /
2013/2012	266	9	-	4	253	95,1%	253/243,16	100,00% /
2012/2011	257	16	-	11	230	89,5%	230/227,37	100,00% /
2011/2010	233	24	-	5	204	87,6%	203 / 199,18	99,50% /
2010/2009	199	33	-	5	161	80,9%	158 / 155,32	98,13% /

Table 2. Benchmarking Colorectal

Table 3. Benchmarking Gyn

А	В	С	D	E	F	G	Н	Ι
2014/2013	112	9	-	-	103	92,0%	39 / 59,50	37,86% / 57,76%
2013/2012	100	14	-	-	86	86,0%	86 / 85,85	100,00% / 99,83%
2012/2011	80	8	1	-	71	88,7%	70 /69,85	98,59% / 98,39%

Table 4. Benchmarking Prostate

А	В	С	D	Е	F	G	Н	Ι
2014/2013	95	4	-	-	91	95,8%	91 / 88,32	100,00% / 97,06%
2013/2012	95	2	4	1	88	92,6%	87 / 80,10	98,86% / 91,03%
2012/2011	92	8	-	4	79	85,9%	77 / 71,16	97,46% / 90,07%
2011/2010	80	15	-	3	62	77,5%	59 / 55,64	95,16% / 89,74%

Table 5. Benchmarking Lung

А	В	C	D	E	F	G	Н	Ι
2014/2013	39	2			37	94,9%	37 / 36,95	100,00% / 99,88%
2013/2012	38	3	-	-	35	92,1%	35 / 34,66	100,00% / 99,05%
2012/2011	34	5 centers (with 1 location) + 1 center (with 2 locations) + 2 separate locations	-	1 center (with 1 location) + 1 center (with 2 locations) + 2 separate locations	24	70,6%	24 / 23,76	100,00% / 99,02%

Table 6. Benchmarking Skin

А	В	С	D	E	F	G	Н	Ι
2014/2013	43	1	-	1	41	95,3%	41 / 34,52	100,00% / 84,20%
2013/2012	41	3	-	-	38	92,7%	38 / 32,08	100,00% / 84,44%
2012/2011	39	1	-	3	35	89,7%	35/34	100,00% / 97,14%

Table 7. Benchmarking Pancreas

А	В	С	D	Е	F	G	Н	Ι
2014/2013	68	16	-	-	52	76,5%	55 / 50,85	100,00% / 92,47%
2013/2012	50	7	-	1	42	84,0%	42 / 41,72	100,00% / 99,34%
2012/2011	43	10	-	1	32	74,4%	32/31,35	100,00% / 97,98%

Table 8. Benchmarking Head and Neck

А	В	C	D	Е	F	G	Н	Ι
2014/2013	26	2	-	-	24	92,3%	24 / 24	100,00% / 100,00%
2013/2012	13	1	-	-	12	92,3%	12 / 8,35	100,00% / 69,61%
2012/2011	10	4	-	-	6	60,0%	6/6	100,00% / 100,00%

Table 9. Benchmarking Neuro

А	В	С	D	Е	F	G	Н	Ι
2014/2013	16	4	-	-	12	75,0%	12/12	100,00% / 100,00%
2013/2012	8	1	-	-	7	87,5%	7/7	100,00% / 100,00%

Table 10. Tumor documentation systems

Tumor documentation systems	2014 / 2013	2013 / 2012	2012 / 2011	2011 / 2010
GTDS	25,68%	24,51%	24,13%	23,61%
Ondis	8,95%	9,09%	7,39%	6,44%
Alcedis MED	8,56%	8,70%	8,56%	8,58%
ODSeasy / ODSeasy Net	8,17%	6,72%	4,28%	3,00%
megaMANAGER	6,23%	9,49%	15,57%	18,88%
onkodok (XAXOA)	4,28%	3,56%	3,89%	-
c37.CancerCenter	2,72%	2,37%	-	-
KoReDos	2,33%	1,98%	-	-
CREDOS	1,95%	1,58%	-	-
megaMANAGER eDoc	1,95%	-	-	-
ODOK (Agfa)	1,95%	4,35%	-	-
StuDoQ	1,95%	-	-	-
KRAZTUR	1,56%	1,58%	-	1,72%
Tudok (Tumorzentrum Regensburg)	-	1,58%	-	-
ODOK (KIS-Anbindung ORBIS)	-	-	2,72%	3,43%
Q-Tudok	-	-	-	3,00%
	12.02.01	14 (00)	17.100	10.020
In-house developments (MS Excel, MS Access etc.)	13,23%	14,62%	17,12%	18,03%
Other (systems used in less than four centers)	10,51%	8,30%	11,67%	7,73%
Hospital information system extensions	-	-	2,72%	2,58%
Tumor documentation exclusively by cancer registry	-	1,58%	1,95%	3,00%

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Benchmarking Colorectal Cancer Centers 2015 (Audit year 2014 / Indicator year 2013)



1. Pretherapeutic case presentation

Figure 9. Example of report for an indicator for colorectal cancer centers

The Data-WhiteBox application, based on the data from the EKB database and on the graphs created using these data, generates annual benchmarking reports general and individual too. These reports (Figure 9) include, beside general information about the certified centers for a specific organ, statistical analysis referring separately to every indicators' results. The report is generated using a PowerPoint template containing the codes and positions for every figure and graph. There are qualitative and quantitative statistical values included. There are also information with only explicative value, but no statistical value. These can be remarks on the behalf of the German Cancer Society which provide further explanations regarding the indicator, its target value and why some centers with insufficient values still own a certificate.

The cancer centers use to document their patients in tumor documentation systems.

These systems can be software applications or different types of data bases in Excel or Access (In-house developments). The centers have the opportunity to

IV. DISCUSSIONS

The quality improvement of health care requires national and international quality improvement frameworks to guide various stakeholders to improve the quality of care provided in a systematic way to reduce unwarranted variation [13] [14]. At the beginning of the 20th century population-based cancer registries were first set up in Europe and the United States; 50 years later a WHO subcommittee recommended the registration of all cancer cases [15]. There is a great interest in moving from paperdocument the patients on their own or they can delegate this task to the regional cancer registries. Table 10 shows the percentages of the tumor documentation systems chosen by the colorectal cancer centers in the last four years (data years 2010-2013).

Table 11 presents the extent to which the colorectal cancer centers have cooperated with cancer registries in audit year 2014 / data year 2013.

Table 11	. Cooperation	with cancer	registries
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Cooperation with cancer registries	Percentage	
No cooperation	0%	
Minimal cooperation	29%	
Intensive / regular cooperation	52%	
Tumor documentation almost entirely		
made by cancer registry	19%	

based health records to electronic health records (EHR) in order to provide a reduction in costs, improved quality of care, the promotion of evidence-based medicine and record keeping, management of workflows, mobility ("Free Movement") and reliable information for endusers [16] [17] [18]. In 2004, the US President decided on the connection of patient data to the electronic version for all patients by 2014 [19], this resulted in a growing investment in information systems [20]. In order to assess, promote and guarantee efficient patient care safety an internationally recognized accreditation is needed [21] [22]. The introduction of indicators for clinical performance and their transparency enhances the goals of certification. The accreditation became nowadays an agent of government regulation [23] and analytics, graphs and tables determine a better decision making which shapes the future of medicine and care delivery [24].

The certification system of the German Cancer Society is an internationally unique model of certification for cancer centers, among others, because of the implementation of the data management which achieves a high level of transparency. The full certification process is described for example for gynecological and colorectal centers in Wesselmann et al. [25, 26]. Even though the German Cancer Society established the certification of the first centers in 2003, only in 2006 emerged the thought of systematically collecting data about the patients. At that time the centers were asked to provide some numbers in prose within the data entry form. One year later, a structured questioning of some indicators appeared on the last page of the data entry form [27] [28]. OnkoZert, the Certification Institute of the German Cancer Society started gathering these data, but they were not statistically evaluated, and also not stored in any data base. In 2009 OnkoZert started to manually verify and formally evaluate these indicators sent by the centers. This way, before each audit, the centers received a report containing the indicators which formally were miswritten or under the target values. This helped the auditors to have a starting point in the analysis of the tumor documentation at the clinics.

As this verification evolved, the necessity of an instruction catalogue appeared for the interpretation of indicators, as the clinics and the auditors had sometimes different opinions about the significance of the indicators. As a result, in 2011 the first interpretation of the indicators for colorectal cancer was published [29]. In parallel, in 2009 OnkoZert created the electronic platform called "Elektronischer Kennzahlenbogen" [30], where the centers introduced their data on their own. In 2011, to be more flexible, but also more accurate, the electronic questionnaire as Excel file was introduced [31], [32] [33]. This demanded from the centers explanation for each inconsistency, insuring this way that every center tries to remain at the high standards set by the German Cancer Society every year. It also provides important international data, which then can be used to report the actual status on oncological care throughout Germany, but also other countries like Austria, Switzerland and Italy.

In 2012 the first benchmarking reports were realized for the cancer centers. For these, but also for the certification process it is important to show the trend regarding the results of the centers. The benchmarking report also shows the target value, median, maximum and minimum values. There is a highly representative chart for each indicator which provides an overview of each center's performance as compared to the target value and the median.

The boxplots containing data from previous years are an important statistical tool to show the ascending or descending trend of the centers compared to the target values. The boxplots show the scattering of the values. When the area of the boxplot is bigger, then the values are more scattered and inconsistent. That means the centers have big differences between the results for the same indicator. A smaller area of the boxplot shows that the centers are very close to each other in the achieved values.

Starting with 2013, the colorectal centers had received along with the common benchmarking report also two individual reports for better comparison with other centers but also with themselves over time [30].

Another innovation started in 2013 with the release of the XML-OncoBox for colorectal cancer centers. The XML-OncoBox is a verification tool developed for the clinics to check the plausibility and completeness of the patient documentation and has the purpose of comparability between centers by well-established algorithms. At the present moment, the XML-OncoBox is also available for breast and prostate cancer centers and can be downloaded for free [34].

Also in 2013, OnkoZert has programmed another platform, this time for the transparent presentation of the interdisciplinary network of each center. This application is called OncoMap [35] and it is widely used by patients and by self-help groups for localization of proper treatment possibilities near their home.

In 2014, the EKB was extended with the Data-WhiteBox, the internal statistical tool for rapid evaluations of the centers' data. Advantages of the three layer architecture: data integrity can be improved by the middle layer which can ensure that only valid data is allowed to be inserted, updated or deleted in the database; higher level of security can be achieved since the client does not have direct access to the database; changes to business layer or data layer only need to be updated on application server and do not have to be distributed to all clients; the application servers can be deployed on many machines, the database no longer requires a connection from every client; improved availability; hidden database structure; the workflow can be better organized and more programmers can work at the same time [12].

Also starting in 2014, there was a supplementary report given for the oncological centers. All common reports can be downloaded from the websites on the German Cancer Society and OnkoZert [36] [31].

Another way to ensure that the centers generate proper data for the audit is by the realization of the Auditcheck. This is a document created individually for each center prior to the audit, where OnkoZert verifies the entire documentation of the center and makes a résumé of the problems and inconsistencies found in the documents. This is first sent to the auditor who can add some comments if needed. Based on this Auditcheck the centers have a structured plan to correct the listed problems prior to the audit. This way the data quality is increased before the audit takes place.

The last innovation introduced in 2015 is the StudyBox, the platform of clinical study accreditation [37]. This government-funded application is promoted by the German Health Ministry with the purpose of access facilitation for patients, certified clinics and practices to clinical studies. The platform is now in a pilot phase for colorectal centers, but one of the goals is to accept patients for the clinical study indicators only if the patients were treated in accredited studies.

As seen in Figure 7 the milestones from the last 10 years can be classified in three groups: Input from the

centers, Output to the centers and Assessment tools. The actual status of the input is by the electronic questionnaire in Excel. With the help of the two assessment tools (EKB and Data-WhiteBox) we manage to return to the centers a diversified offer of products with the purpose of data quality improvement, and, this way, of patient care improvement, which is the main goal of the certification.

As shown in Figure 8, a big difference between the electronic questionnaires in audit year 2012 and 2014 for colorectal cancer centers can be seen. The situation changed radically in audit year 2013 compared to 2012 since the centers had started to accommodate with the electronic questionnaires and since these pointed out the implausible data. Another important reason was the active role taken by OnkoZert and the auditors prior to the audits to verify the excel files. OnkoZert was verifying them formally and the auditors medically. Also the auditors had a new task during the audit: this was the extensive verification of the tumor documentation [38]. This led to the fulmination of the files because implausible or invalid files were sent back to the centers for correction. In audit year 2014 there seems to be a slight descent in the overall sent files as the centers are getting used to this type of verification system.

Regarding the evolution of the tumor documentation systems, as seen in Table 10, it can be observed that colorectal cancer centers are starting to use more professional tumor documentation software applications and let go to the Excel and Access data bases. In audit year 2011 / data year 2010 the percentage of "self-made" data bases was of 18,03% and in audit year 2014 / data year 2013 of 13,23%. The slow descent is caused by the difficulties that come along with the change of an application, as the fields from one data bases. As the patient data should be transferred from one application to another, and this takes a lot of time and resources, the choice to change to other software products is made with a lot of care.

Table 11 shows that all colorectal cancer centers had some kind of cooperation with cancer registries in audit year 2014 / data year 2013. 19% of the centers leave the entire documentation in the hands of cancer registries. [39] In the data years from 2010 until 2012 some centers which had their patients entirely documented by cancer registries but didn't know the names of the applications used by these, have given the name for the application as "tumor documentation exclusively at the cancer registry". As of data year 2013 all centers knew the names of the documentation systems within the cancer registries, the option "tumor documentation exclusively at the cancer registry" has disappeared in Table 10. Also the hospital information system extensions got application names and disappeared from the table in the last two years.

Tables 1-9 show how many centers appear in the benchmarking reports. The range of included centers lies between 60% and 98,6%. This big gap has a few causes, from which the most important one is the permanent certification of new centers but also of new cancer types. The cancer type with the highest inclusion value was Breast in audit year 2014. Historically, Breast cancer centers were the first certified centers starting with 2003. In 2014 they have reached a saturation, as there were already 277 centers certified and only 3 centers were first certifications. The cancer type with the lowest inclusion value was Head and Neck in audit year 2012. As this certification type only started in 2011, and as these centers can only exist within an oncological center, it is understandable that the percentage is that low.

Similarly, it can be observed that within a cancer type most of the years present an ascending trend of the centers included in the benchmarking. This can best be seen at the types which are certified for a longer time.

On the other hand, not only the first certifications pull down the inclusion percentage. Also the centers with documentation problems play an important role. This is best seen in the older certification types. Centers from younger certification types, usually are modules like Pancreas, Neuro, Head and Neck. These centers appear in clinics where the tumor documentation systems are already implemented, so they do not have to put so much effort in this area. It is similar for Gyn centers as they appear most of the times in clinics were Breast cancer centers already exist. Among others, a main cause of documentation problems can be attributed to the change of a tumor documentation system as described above.

Tables 1-9 show for each organ that nowadays almost all centers can give data to almost every indicator, not like a few years ago [40]. The problems appear when new indicators are set. When the centers get used to an indicator, than they usually don't have problems with filling it out. For example, Lung centers in audit year 2014, with one exception, have filled out with 100% all of the indicators. But this doesn't mean that they have all reached the given limits [41].

Quality data is gathered using a lot of time, personnel and money resources, in a world where these resources are getting fewer, but the expected quality is getting higher. Only by the means of continuous data collection, analysis and correction can this be achieved [42].

V. CONCLUSIONS

This article doesn't discuss the medical impact of the indicators from the certified centers but the way data are gathered. This research shows that high quality data cannot be achieved quickly, they can only be achieved over time with a lot of effort and resources. Nowadays high data quality is expected and valid data is needed but the resources are more limited. The continuous collection of data and their analysis and corrections are of basic relevancy for the positive development of data management. All these can be done only by a tight collaboration between the German Cancer Society, the certifications commissions, the certification institute, the auditors, the tumor documentations system producers, the cancer registries, the centers and last, but not least, the tumor documentation personnel.

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