

Guidelines Regarding §16 of the German Transplantation Act – Initial Experiences with Structured Reporting

Die Richtlinien zur Organtransplantation gemäß §16 Transplantationsgesetz (TPG) – Erste Erfahrungen mit strukturierter Befundung

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ABSTRACT

Purpose To transfer the report sheet from the guidelines regarding the German Transplantation Act to a standards-compliant report template and to evaluate it in the clinical routine.

Materials and Methods The template was developed using the freely available software brackets.io. It was implemented in the clinical routine using a reporting platform developed in-house. Interfaces to the department RIS and PACS allowed for integration into the usual reporting workflow. The evaluation period was 70 days.

Results Developing the template for implementation of the guidelines was possible without any difficulties. The content of the report sheet provided in the guidelines was transferred one to one. Additionally, a text field was included to allow for

further remarks. In the period under review, 7 radiologists performed 44 evaluations in line with § 16 of the German Transplantation Act. Users of the template, referring physicians and the employees of the transplantation office reported a high degree of satisfaction.

Conclusion Implementing report sheets that are required by law (e. g. in the guidelines regarding § 16 of the German Transplantation Act) in the clinical routine electronically is easy and achieves a high degree of acceptance. The standard supported by the German Radiological Society (IHE – "Management of radiology report templates") allows for a quick response to the growing demand for structured and standardized reporting.

Key Points

- Report sheets as required by law can easily be incorporated electronically into the clinical routine.
- Templates for structured reporting as supported by the German Radiological Society allow for a quick response to the growing demand for standardized reporting.
- Radiologists as well as referring physicians report a high degree of satisfaction with the electronic version of the report sheet.

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ZUSAMMENFASSUNG

Ziel Übertragung des Befundungsbogens aus den Richtlinien zum Transplantationsgesetz (TPG) in ein standardkonformes Befundtemplate und Evaluation in der klinischen Routine.

Material und Methoden Das Template wurde mit der frei verfügbaren Software brackets.io erstellt. Die Implementierung des Templates in die klinische Routine erfolgte mithilfe einer in Eigenentwicklung programmierten Befundungsplattform. Schnittstellen zu RIS und PACS erlaubten eine Integration in den gewohnten Befundungs-workflow. Die Evaluationsperiode erstreckte sich über 70 Tage.

Ergebnisse Die Erstellung des Templates für die Umsetzung der Richtlinien war ohne Schwierigkeiten möglich. Der vorgegebene Befundungsbogen wurde hierbei inhaltlich eins zu eins abgebildet. Zusätzlich wurde ein Freitextfeld hinzugefügt, um ergänzende Anmerkungen zu ermöglichen. Im beobachteten Zeitraum wurden von sieben Radiologen 44 Auswertungen gemäß § 16 TPG erstellt. Sowohl die Nutzer des Templates als auch die beteiligten Zuweiser und Mitarbeiter des Transplantationsbüros berichteten insgesamt über eine hohe Zufriedenheit.

Schlussfolgerung Die elektronische Implementierung gesetzlich (etwa in den Richtlinien zu § 16 TPG) geforderter Befundungsbogen in die klinische Routine ist einfach umsetzbar und zeigt eine hohe Akzeptanz. Der von der Deutschen Röntgengesellschaft unterstützte Standard (IHE „Management of Radiology Report Templates“) erlaubt eine schnelle Antwort auf die zunehmenden Forderungen nach strukturierter und standardisierter Befundung.

Introduction

The amended version of the organ transplantation guidelines pursuant to § 16 of the German Transplantation Act took effect on 5/17/2016, assigning radiology a special role in the evaluation and documentation of the disease stage and course in patients with hepatocellular carcinoma and thus in the determination of an indication for liver transplantation [1]. The guidelines require a standardized radiology report sheet for this purpose (► Fig. 1). Information regarding the number and morphology of liver lesions suspicious for HCC is to be provided in this sheet. Similar efforts to create partially standardized report sheets are increasingly being made in other contexts, e. g., in the certification of oncological centers. The amendment of the guidelines does not provide details regarding the implementation of this report sheet but it can be assumed that a paper version of the sheet will be used at many clinics.

Therefore, it seems desirable to meet these requirements with suitable technical tools that not only simplify documentation and archiving but ideally also support the radiology workflow and that can be flexibly adapted to changing and growing demands.

One possibility for meeting these demands is to create structured IT-based report sheets, the advantages and disadvantages of which are being increasingly discussed by radiological societies particularly recently [2–5]. The majority of professional societies are in favor of greater standardization and structuring of radiological reports [6]. As a result of the Reporting Initiative of the Radiological Society of North America (RSNA), numerous developments were initiated resulting in the preliminary publication of the IHE-MRRT profile (Integrating the Healthcare Enterprise, Management of Radiology Report Templates) [7, 8]. This profile provides the technical details for the development of structured report templates. Templates are to be created as simple HTML5 files with the IHE profile defining some restrictions. Dynamic elements can be added, e. g. per JavaScript, to support radiologists [9].

Structured reporting according to IHE MRRT currently plays only a limited role in the clinical routine. This could be due to the early development stage of the profile, the lack of support by major manufacturers and the lack of German templates. The German Radiological Society has defined the resolving of this issue and promoting of structured reporting as one of its central projects in the coming years (<http://www.befundung.drg.de/>).

At the University Medical Center Mainz, we were able to develop our own in-house open-source platform (www.mrre.org) for using IHE-compliant report templates [10]. The reporting platform was programmed in HTML/PHP/MySQL and offers a generic approach allowing use of any IHE-MRRT-compliant report template. Such templates can already be downloaded from the RSNA website (<http://www.radreport.org>), for example.

The goal of the present study was to transfer the sheet required by the guidelines regarding the German Transplantation Act to a dedicated MRRT-compliant template and to evaluate the use of the template in the clinical routine.

Materials and Methods

The free software Brackets (<http://brackets.io>) was used to create and test the template (HTML and JavaScript). When creating the template, standards compliance was ensured with the help of the published MRRT profile [8]. In addition, the fields of the template were assigned RadLex codes where possible. The corresponding RSNA website (<http://purl.bioontology.org/ontology/RADLEX>) was used as a reference.

The template was then imported into the above-mentioned reporting platform and was able to be used there after radiologists received brief training regarding the creation of structured reports (► Fig. 2). The already established interfaces between the reporting platform, RIS (i-Solutions Health GmbH, Mannheim) and PACS (Sectra AB, Linköping, Sweden) allowed simple integration into the clinical routine [10]. Reports created with the help of the reporting platform could be sent as a DICOM-PDF to the hospital-wide PACS so that they could be viewed by employees of the transplantation office at any time. At the same time, all entries made in the template were automatically saved in the dedicated database of the reporting platform and were accessible for additional analysis and evaluation.

Once the amendment to the guidelines regarding the German Transplantation Act came into effect, all report requests were electronically processed with the created template. The evaluation period was 70 days from May to August 2016.

User feedback was collected and documented particularly in the development phase both in joint meetings and during use. For more objective evaluation of user satisfaction, participants were asked after conclusion of the evaluation period to complete

IV Anhang
IV.1 Anlage 1 – Dokumentations- und Verlaufsbogen hepatozelluläres Karzinom (HCC) für die Lebertransplantation

Patientenname	ET Nummer/Datum	Initiales HCC:	Verlaufsbericht (Rezertifizierung):
		Ja <input type="radio"/> Nein <input type="radio"/>	Ja <input type="radio"/> Nein <input type="radio"/>
Anzahl der HCC Knoten			
Malland-Kriterien erfüllt	Ja <input type="radio"/> Nein <input type="radio"/>		
HCC Diagnose gesichert	Ja <input type="radio"/> Nein <input type="radio"/>		
Leberzirrhose gesichert	Ja <input type="radio"/> Nein <input type="radio"/>		
Eingesetztes Verfahren	MRT <input type="radio"/> CT <input type="radio"/>		
	ggf. US <input type="radio"/> (Befund beifügen)		

Läsion 1			
Größe der Läsion (größter Durchmesser, Pseudokapsel der portalen oder verzögerten Phase nicht in Messung einbezogen)	Segment	Kontrastphase der Messung	
		späarteriell <input type="radio"/> portalvenös <input type="radio"/> verzögerte Phase (ca. 120–180 sec nach Applikation) <input type="radio"/>	
Späarterielle Phase	stark anreichernd	Ja <input type="radio"/>	Nein <input type="radio"/>
Portalvenöse Phase	früh auswaschend	Ja <input type="radio"/>	Nein <input type="radio"/>
	„Pseudokapsel“	Ja <input type="radio"/>	Nein <input type="radio"/>
Verzögerte Phase (ca. 120–180 sec. nach Applikation)	auswaschend	Ja <input type="radio"/>	Nein <input type="radio"/>
	„Pseudokapsel“	Ja <input type="radio"/>	Nein <input type="radio"/>
	makrovaskuläre Invasion (Tumorthrombus)	Ja <input type="radio"/>	Nein <input type="radio"/>

A 13

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Klinische Angaben

ET-Nummer

initiales HCC ja nein

Verlaufsbericht ja nein

HCC gesichert ja nein

Leberzirrhose gesichert ja nein

aktuell eingesetztes Verfahren vom

zusätzlich zweites Verfahren ja nein

Anzahl HCC-Knoten

extrahepatische Manifestation ja nein

Läsionen

Läsion 1

Größe der Läsion mm

Segment

Seriennummer

Bildnummer

Kontrastphase der Messung

Verhalten arteriell ja nein

Verhalten portalvenös ja nein

Verhalten verzögert ja nein

Pseudokapsel ja nein

makrovaskuläre Invasion ja nein

Läsion 2

Größe der Läsion mm

Segment

Seriennummer

Bildnummer

Kontrastphase der Messung

Verhalten arteriell ja nein

Verhalten portalvenös ja nein

Verhalten verzögert ja nein

Pseudokapsel ja nein

makrovaskuläre Invasion ja nein

BEKANNTGABEN DER HERAUSGEBER

Läsion 2			
Größe der Läsion (größter Durchmesser, Pseudokapsel der portalen oder verzögerten Phase nicht in Messung einbezogen)	Segment	Kontrastphase der Messung	
		späarteriell <input type="radio"/> portalvenös <input type="radio"/> verzögerte Phase (ca. 120–180 sec nach Applikation) <input type="radio"/>	
Späarterielle Phase	stark anreichernd	Ja <input type="radio"/>	Nein <input type="radio"/>
Portalvenöse Phase	früh auswaschend	Ja <input type="radio"/>	Nein <input type="radio"/>
	„Pseudokapsel“	Ja <input type="radio"/>	Nein <input type="radio"/>
Verzögerte Phase (ca. 120–180 sec. nach Applikation)	auswaschend	Ja <input type="radio"/>	Nein <input type="radio"/>
	„Pseudokapsel“	Ja <input type="radio"/>	Nein <input type="radio"/>
	makrovaskuläre Invasion (Tumorthrombus)	Ja <input type="radio"/>	Nein <input type="radio"/>

► Fig. 1 a Report sheet taken from the guidelines regarding organ transplantation pursuant to § 16 of the German Transplantation Act. b IHE MRRT-compliant implementation in HTML5 without design information and with disabled JavaScript.

Klinische Angaben

Z.n. atyp. Resektion bei HCC, gelistet zur LTX, AFP-Anstieg. Im MRT V.a. Rezidiv (12mm).

ET-Nummer

initiales HCC ja nein

Verlaufsbericht ja nein

HCC gesichert ja nein

Leberzirrhose gesichert ja nein

aktuell eingesetztes Verfahren CT vom 17.05.2016

zusätzlich zweites Verfahren ja nein

Anzahl HCC-Knoten MRT vom 26.04.2016

extrahepatische Manifestation ja nein

Läsionen

Läsion 1

Größe der Läsion 11 mm

Segment 8

Seriennummer 7

Bildnummer 37

Kontrastphase der Messung verzögert

Verhalten arteriell ja nein

Verhalten portalvenös ja nein

Verhalten verzögert ja nein

Pseudokapsel ja nein

makrovaskuläre Invasion ja nein

Bemerkungen: schwer von einem Artefakt durch den ventral legenden Clip zu differenzieren. Außerdem keine art. Hypervaskularisation.

Klinische Angaben

Z.n. atyp. Resektion bei HCC, gelistet zur LTX, AFP-Anstieg. Im MRT V.a. Rezidiv (12mm).

ET-Nummer

initiales HCC ja nein

Verlaufsbericht ja nein

HCC gesichert ja nein

Leberzirrhose gesichert ja nein

aktuell eingesetztes Verfahren CT vom 17.05.2016

zusätzlich zweites Verfahren ja nein

Anzahl HCC-Knoten MRT vom 26.04.2016

extrahepatische Manifestation ja nein

Läsionen

Läsion 1

Größe der Läsion 11 mm

Segment 8

Seriennummer 7

Bildnummer 37

Kontrastphase der Messung verzögert

Verhalten arteriell ja nein

Verhalten portalvenös ja nein

Verhalten verzögert ja nein

Pseudokapsel ja nein

makrovaskuläre Invasion ja nein

Bemerkungen: Der zweite Herd (S5) ist ebenfalls abzugrenzen, allerdings ausgesprochen flau und daher schwer von einem Artefakt durch den ventral legenden Clip zu differenzieren. Außerdem keine art. Hypervaskularisation.

► Fig. 2 a Template within the reporting platform with data entered by the reporting radiologist. Lesions are only shown in the number needed and chosen, and help buttons are added through JavaScript. Tooltip shows how to choose the value for the respective field. b The final report in the HTML view. The formatting is preserved for the export as DICOM-Encapsulated-PDF and can be sent to the PACS.



► **Fig. 3** The reports are stored in the database and are readily available for graphical evaluation and analysis.

an electronic feedback form created via SurveyMonkey (<https://www.surveymonkey.de>). Responses were recorded using a 5-point Likert scale [11].

Results

A dedicated template for guideline implementation was able to be created without difficulty. In addition to reproducing the report sheet from the guidelines in MRRT-compliant HTML, several tools were added in JavaScript to simplify use in the clinical routine. Therefore, the number of fields displayed for lesion evaluation corresponds to the specified number of actual lesions instead of the fields for five lesions that are always displayed on the paper sheet and often remain blank. Moreover, a "comments" text field that was not included in this form in the sheet proposed in the guidelines was added. It became clear early on that it was essential to give the reporting radiologist the opportunity to add comments. This is important particularly when different radiologists need to perform structured documentation of re-staging examinations which can be numerous depending on the wait time for an organ. Moreover, a function that automatically suggests whether the patient currently meets the Milan criteria was implemented. This is intended not only to make the radiologist's job easier but also to eliminate a potential source of error. Internal rules were also added as a Tooltip so that the relevant criteria for a particular field are again displayed to the radiologist prior to every click on a field (► **Fig. 2a**). The template was developed so that it can be used even with JavaScript fully disabled since the IHE-MRRT profile allows the use of JavaScript but specifies that it is not necessarily supported by other reporting platforms. Development and completion of the template required approximately eight man hours.

The template was able to be imported into the reporting solution without errors and was able to be used immediately. The plat-

form allowed completely digital documentation and could be fully integrated into an existing RIS/PACS environment.

In the 70-day study period, 44 requests for evaluation and reporting according to the guidelines regarding the German Transplantation Act were made and processed by 7 radiologists with abdominal imaging experience.

Since all findings were stored in the database of the reporting platform, further reports can also be created, e. g., the percentage of patients with a solitary HCC (17 of 44 cases in our collective) (► **Fig. 3**).

In general, template users as well as participating referring physicians and employees of the transplantation office reported a high level of satisfaction already in the development phase. At the end of the evaluation period, 15 referring physicians and 7 radiologists participated in the electronic satisfaction survey. In general, both the referring physicians and radiologists were highly satisfied (median total = 4.5; median for referring physicians = 4; median for radiologists = 5). All surveyed radiologists and most referring physicians indicated that the electronic version was preferable to the paper-based one (median total, referring physicians and radiologists = 5). Also in relation to usability, clearness, and availability, there was a high level of satisfaction with the electronic version of the sheet (► **Table 1**). The complete digitalization and thus the lack of a need to switch media to use paper-based sheets were consistently specified as the greatest strengths. The most common critical feedback related less to the template than to a lack of clarity in relation to the content of the guidelines regarding the German Transplantation Act.

Discussion

The advantages of structured report templates have been documented many times in the literature [3]. Therefore, for example,

► **Table 1** Results of the questionnaires sent to radiologists and clinicians about the degree of satisfaction with the electronic report sheet from the guideline to the German Transplantation Act.

question	n answer 1	n answer 2	n answer 3	n answer 4	n answer 5	median
radiologists (n = 7)	very dissatisfied	dissatisfied	indifferent	satisfied	very satisfied	
overall, how satisfied are you with the electronic version of the organ transplantation sheet?	0	0	0	3	4	4.5
	very poor	poor	no opinion	good	very good	
usability of the template	0	0	0	1	6	5
processing speed	0	0	0	3	4	5
reliability of the technical implementation	0	0	0	3	4	5
availability of completed sheets	0	0	0	0	7	5
	preferably paper-based		doesn't matter		preferably electronic	
do you prefer a paper-based or electronic version?	0	0	0	0	7	5
referring physicians (n = 15)	very dissatisfied	dissatisfied	indifferent	satisfied	very satisfied	
overall, how satisfied are you with the electronic version of the organ transplantation sheet?	0	1	2	5	7	4
	very poor	poor	no opinion	good	very good	median
clearness of completed sheets	0	1	2	6	6	4
availability of completed sheets	0	0	3	5	7	4
	preferably paper-based		doesn't matter		preferably electronic	median
do you prefer a paper-based or electronic version?	0	0	2	4	9	5

it could be shown that the report text contains significantly more relevant information for referring physicians and the satisfaction of clinical partners is significantly higher as a result of the use of structured report templates [15]. Similar results are seen in relation to the staging of rectal cancer and the description of cerebral lesions in multiple sclerosis or pathological findings in the intestine in Crohn's disease [16–18]. Although some manufacturers offer proprietary solutions for structured reporting, there is a lack of support for the IHE-MRRT standard.

Therefore, it seems logical to create an IHE-MRRT-compliant electronic version of the report sheet to meet the requirements regarding the documentation of patients with HCC that were updated as part of the guideline amendment and thus also to

demonstrate the practical feasibility on the basis of a current clinically relevant example. A corresponding template was able to be developed and used on a free and open-source reporting platform without difficulty. Corresponding to similar experiences in the literature, a high level of user satisfaction on the part of clinicians and radiologists could also be shown.

Some ambiguities in relation to individual sections of the report sheet published in the *Ärztblatt* were identified during the study period, thus necessitating internal clarification. However, there is a risk that this lack of explanations developed together with clinical radiologists and published in advance in the report sheets created to date in Germany may have led to a certain level of heterogeneity.

In our case the following rules were defined in coordination with clinical colleagues to ensure uniform report quality and results without making a claim to their general validity:

Verification based solely on imaging (according to S3 guidelines) was permissible for the diagnosis of HCC, while liver cirrhosis required histological confirmation. Only verified HCC lesions should be evaluated and the same number of lesions as specified under "number of HCC nodules" should be displayed and documented. According to the guidelines, verified lesions were (analogous to Li-Rads, <https://nrdr.acr.org/lirads/>) lesions > 2 cm with typical contrast enhancement behavior (arterial hypervascularization with washout or lesions between 1 and 2 cm with typical behavior on two images). Lesions < 1 cm were not taken into consideration unless there was a definitive histological result for the lesion. Similar rules were also defined by the United Network for Organ Sharing in the United States in order to include only lesions that are HCC lesions with almost 100% certainty in reports [12, 13]. A lesion previously defined as HCC-typical was still considered a lesion as defined by the guidelines following TACE (with only the vital part of the tumor being measured as in mRECIST [14]), while lesions treated on a curative basis (resection, local ablation) were no longer considered lesions.

Our results show that report templates corresponding to the IHE-MRRT profile allow a quick response to the increasing demands for structured and standardized reporting. Moreover, report templates make it possible to support radiologists with stored, explanatory notes and computer-based decision-making tools in order to achieve consistently high report quality.

In addition to the ideally higher report quality, report templates provide the further advantage that radiologists can help to establish a clinical database without additional effort as part of the daily routine. The stored information is readily accessible at any time and can thus be used with the patient's consent, for example, for clinical studies or for health services research (► Fig. 3).

This study also clearly shows that structured reporting can have a concrete effect on the clinical routine today – and not in what seemed like the distant future several years ago [19].

CLINICAL RELEVANCE OF THE STUDY

1. The amendment of the organ transplantation guidelines according to § 16 of the German Transplantation Act requires documentation using standardized report sheets for all HCC patients on the wait list for liver transplantation.
2. An electronic version of this required report sheet in a format supported by the German Radiological Society was easy to create and was able to be integrated into the clinical routine without difficulty.
3. On the whole, radiologists and referring physicians reported a high level of satisfaction. Particularly regarding availability and clearness, the electronic version provides definite advantages.
4. Structured reports also make it possible to create clinical databases and thus improve scientific interpretation.

Conflict of Interest

The authors declare that they have no conflict of interest.

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