Toward a Platform for Structured Data Acquisition in Oncology: A Pilot Study on Prostate Cancer Screening

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Keywords

Data acquisition · Data integration · Data element ·
Synoptic reporting · Clinical decision support system

Abstract

Introduction: Physicians spend an ever-rising amount of time to collect relevant information from highly variable medical reports and integrate them into the patient's health condition. **Objectives:** We compared synoptic reporting based on data elements to narrative reporting in order to evaluate its capabilities to collect and integrate clinical information. **Methods:** We developed a novel system to align medical reporting to data integration requirements and tested it in prostate cancer screening. We compared expenditure of time, data quality, and user satisfaction for data acquisition, integration, and evaluation. **Results:** In a total of 26 sessions, 2 urologists, 2 radiologists, and 2 pathologists conducted the diagnostic work-up for prostate cancer screening with both narrative reporting and the novel system. The novel system led to a significantly reduced time for collection and integration of patient information (91%, $p < 0.001$), reporting in radiology (44%, $p < 0.001$) and pathology (33%, $p = 0.154$). The system usage showed a high positive effect on evaluated data

quality parameters completeness, format, understandability, as well as user satisfaction. **Conclusion:** This study provides evidence that synoptic reporting based on data elements is effectively reducing time for collection and integration of patient information. Further research is needed to assess the system's impact for different patient journeys.

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Introduction

An aging society with multimorbid patients requires an interdisciplinary management that is able to evaluate an ever-increasing amount of data. This evaluation includes collecting, cleaning, mapping, and transforming data in accordance with the intended purpose and finally the provision of meaningful information [1]. In patient care, multiple clinical departments acquire a variety of data which are stored in various formats and IT systems. Summarizing and presenting all of this information in a consistent and easily retrievable manner are a key component to gain a holistic understanding of the patient's health status and facilitates communication between treating physicians [2].

The heterogeneity of data in terms of syntax (e.g., free text notes, images, and laboratory values), format (e.g., PDF and DICOM), and semantics (e.g., meanings or interpretations) complicates data integration in healthcare [3–5]. Missing documentation standards in healthcare cause patient data to be highly variable and patient records in 1 hospital to look different from data of similar patients receiving similar treatment in another hospital [6]. As a result, physicians and researchers are faced with considerable challenges to integrate disparate data from various sources [7].

A promising approach to improve information quality in medical reports is synoptic reporting [8]. Synoptic reporting is a clinical documentation method that unifies data entry with defined data elements. Data elements are units of information that have a precise name, definition, and representation terms [9]. Instead of the current standard of highly variable narrative reports, information is entered in a standardized manner. This way of documentation is suitable for different purposes like medical history, radiological, and histological examinations, and it has already been shown that such reports are more accurate, clearer, and coherent than narrative reports [10]. The broadest application of synoptic reporting is currently in oncologic pathology [11–16], radiology [17, 18], and operative reports in surgery [19, 20]. An essential prerequisite for the successful expansion of this reporting method is the development of international standards based on the best available evidence. Pathology, as the discipline with the longest experience in the application is driving the development of international standards in synoptic reporting. The International Collaboration on Cancer Reporting and the College of American Pathologists have established international standardization processes for the development of synoptic reports that are based on the best available evidence [21]. Synoptic reporting based on data elements enables the reuse of information for multiple purposes. Information can be presented according to requirements of the respective recipient, like the referring physician, multidisciplinary team (MDTs) meetings, or clinical research [2]. In this study, we developed a novel system to align synoptic reporting to the data integration requirements and compared it with the current standard.

Methods

In order to gain a deep understanding of the requirements for data acquisition and integration at our institution, we focused, as an example, on the diagnostic work-up in prostate cancer screening. To objectively describe this case, we engaged in a set of work-

shops together with Roche Healthcare Consulting. In these workshops, we mapped the information flow, stakeholders, resources, times, and standards along the patient's journey. Based on this process map, we designed our solution approach. Since we work in an academic setting, the use of data for research purposes was included in the system design.

Diagnostic Work-Up in Prostate Cancer Screening

This study was conducted at the University Hospital Basel, Switzerland. The diagnostic work-up of the screening program includes patient history, PSA, MRI, targeted biopsy, and the initial survey of SF36, IPSS, and NIH-CPSI as surveys conveying the baseline for patient-reported outcome. Patient history, MRI, and biopsy results are documented in a traditional narrative report in 3 different systems (CIS, LIS, and RIS). SF36, IPSS, and NIH-CPSI were recorded paper-based, scanned, and stored in electronic medical record in the CIS. PSA is either visible via the hospitals LIS or, in the case of external assessment, documented manually during anamnesis in the EMR. After all examinations were completed, the results were evaluated by a specialist in urology. Any detected prostate cancer was discussed in the interdisciplinary tumor board of the genitourinary cancer center at the University Hospital Basel. During the tumor board, there is no visualization of the examination results. All information is read out of the respective reports and only mentally merged. The result of this integration is not documented.

From Retrospective Mapping to Prospective Standardization

The novel system is an in-house development and consists of a frontend, backend, SQL database, NoSQL database, and RESTful API. The frontend provides an overview of all patients included in the screening program, forms for each documentation step, reporting engines for the MRI and biopsy report, a data integration tool, and a dashboard for clinical decision-making. The forms for data entry ensure that all information along the patient's journey is entered in a structured and consistent manner using data elements. Data elements are standardized information units that have a unique name, attributes, and predefined relations to make them comparable and support their exchange between information systems. The solution provides forms for each documentation step (SF36, SPSS, NIH-CPSI, medical history, PSA, MRI report, and biopsy report). The recorded data elements of prostate MRI are based on the Guidelines for Multiparametric Prostate Magnetic Resonance Imaging PI-RADS v2 and recommendations [22]. Figure 1 shows the data entry form for the MRI report.

The recorded data elements of the biopsy of the prostate are based on the International Society of Urological Pathology Consensus Conference [23]. Figure 2 shows the data entry form for the biopsy report. All recorded data elements are stored in centralized SQL and NoSQL databases. Patient identifying data, such as name and date of birth were stored in the SQL database. Nonpatient identifying data, such as survey and examination results were stored in the NoSQL database. This split between databases allowed fast and safe exchange of information for research requirements, like in a multicenter trial. A referencing system ensured fixed links between related information within an examination as well as predefined links between related information across examinations, which have to be validated by a specialist. The use of a NoSQL database enabled fast queries for both clinical needs that require all information from 1 patient and research needs that re-

Fig. 1. Screenshot of the novel radiology user interface showing available reports (left), data entry form for the MRI report (middle) and automated report (right).

quire specific information from multiple patients with certain conditions. Queries of predefined research questions, for instance correlation between ADC values and Gleason scores, could also be executed web-based via the RESTful API.

The software provides summarized data in a patient overview that reduces manual data consolidation efforts. The patient overview displays how many examinations are completed along the patient's journey. Upon completion of all examinations along the diagnostic work-up, the data integration tool is available. Usually during MDTs, all examination results are reviewed in order to facilitate a treatment decision. The referencing system supports predefined links to integrate related information across examinations and departments, for example, assign MRI features of a tumor to its corresponding features from the biopsy. These context-specific links of functionally related information are integrated into the software to enable automated data evaluation (risk assessment, relevant statistics, and research questions) in real time. The case dashboard summarizes all information according to the needs of the decision-making process. To take full advantage of the system's ability to provide statistics and address research questions, predefined queries are provided in the backend.

Since traditional narrative reports represent the current standard for information exchange between physicians, the novel solution uses synoptic reporting to avoid additional effort for data acquisition in routine clinical workflow. The report engine consists of a library of standardized text modules that were compiled into

a report according to a predefined set of rules. Depending on the data elements entered, the corresponding text modules are composed to a coherent report.

Study Design

To evaluate the novel solution for routine clinical use, it was compared to the current routine practice in regards of data quality, effort for data acquisition, integration, and evaluation. To reduce possible confounds due to case variations, each specialist, in a real clinical practice scenario, compiled the same set of cases for data acquisition, integration, and evaluation once using the current methods (narrative reporting) and once with the proposed solution. In order to avoid previous opinion bias, all cases were first compiled using the standard and afterward using the proposed solution. As in a similar previous study, a washout period of 4 weeks was instantiated between the sessions to reduce this bias [24]. Participants received training on how to use the solution before the actual investigation.

The solution was applied to the screening's entire diagnostic pathway from anamnesis in urology to the pathologically confirmed diagnosis. All departments involved in this pathway (urology, radiology, and pathology) contributed to the study. Each department provided 1 resident and 1 senior consultant to test the software. All users had several years of experience in narrative reporting and no prior experience in usage to the novel software. The 30-min introduction to the novel software included finding and

The screenshot displays a software interface for pathology reporting, divided into three main sections: available reports, data entry form, and an automated report.

Left Panel (Available Reports): A sidebar titled "Berichte" (Reports) with a list of reports. The first report is "1. Probe | 22 | Gleason 3+4". Below this, there are three prostate cross-section diagrams labeled "Lokalisation Basis", "Lokalisation Mid", and "Lokalisation Apex". Each diagram shows the prostate with various zones labeled: AFS, TZ a, TZ p, PZ a, PZ p, CZ, and PZ m. The "Lokalisation Mid" diagram has a pink highlight on the PZ p zone.

Middle Panel (Data Entry Form): A form for entering biopsy data. It includes fields for "Biopsiedauer" (6 Minuten) and "B-Nummer" (22). Below this, there are fields for "Stanzent +", "Tumervolumen", "1. Gleason", "2. Gleason", "Ki67", "PTEN", "ERG +", and "ERG -". The "Entzündung" (Inflammation) section has a dropdown menu set to "h-g PN" and several checkboxes: "Intraduktales Karzinom", "Pn1" (checked), "L1", "V1", "Kapselüberschreitung", "Infiltration NVB", and "Infiltration Samenblase".

Right Panel (Automated Report): A text area showing an automated report for "22 Prostatamitte rechts (Stanzbiopsie)". The report text includes: "Adenokarzinom der Prostata in 6 von 6 Stanzent (80 %). Gleason 7a (3+4), WHO / ISUP Grad 2. Perineuralscheideninfiltration (Pn1). Proliferationsrate 5 %." Below this, there is a "Bericht Kopieren" (Copy Report) button.

At the bottom right of the interface is a "Speichern" (Save) button.

Fig. 2. Screenshot of the novel pathology user interface showing available reports (left), data entry form for the biopsy report (middle) and automated report (right).

opening a case, documentation of an exam, the report engine, the data integration tool, and the patient dashboard. For each case, the participants were instructed to perform their respective tasks in the screening process using the 2 methods (current vs. proposed solution). In both scenarios, the goal of a procedure recommendation after pathologically confirmed diagnosis was the same.

During the development of the software, the value of MRI in the screening program was investigated. Since the patients in this screening program undergo all the examinations that were covered by our novel system, these patients were selected for testing the software. At the beginning of the evaluation, 13 patients completed the screening's entire pathway to the pathologically confirmed diagnosis. All these cases were included in the evaluation, which resulted in 26 observation sessions reviewing the same twice. Characteristics of the selected cases are listed in Table 1.

The entire screening process was examined for expenditure of time, data quality, and user satisfaction. For each task, the time for both methods was recorded. Time per case was evaluated in total and separated for each specialty (urology, radiology, and pathology). Prior to the study, all necessary data elements for the treatment decision were defined. Based on the predefined data sets, both methods were evaluated for completeness. Furthermore, the perceived data quality was evaluated using a questionnaire for contextual information quality (completeness, relevance, timeliness, and usefulness) and representative information quality (for-

mat, consistency, and comprehensibility). A questionnaire-based survey was used to evaluate a qualitative acceptance of the new system compared to the previous workflow [25]. The defined data elements and surveys are provided in Tables 2–5.

Statistical Analysis

The Wilcoxon signed-rank test was used to compare case preparation time as a functional specialty (urology, radiology, and pathology) for the current method and the proposed solution. Cohen's *d* was used to compare responses to the survey questions. $p < 0.05$ was considered statistically significant. Analysis was conducted in R (R Core Team, 2014) and figures were produced using the package ggplot2 (Wickham [26]).

Results

Turnaround Time

The total turnaround time for the novel solution was statistically significantly lower than the current method (-2.95 min, $p < 0.001$). The paired analyses for turnaround times as a function of specialty showed statistically significant differences between the novel

Table 1. Case characteristics

Case number	Age, years	DRE	PSA, ng/mL	Prostate volume, mL	Highest PI-RADS	Highest Gleason	WHO/ISUP	Recommendation
1	60	NS	6.80	30	5	7a	2	RP/RT
2	73	NS	40.00	40	5	7b	2	RP/RT
3	75	NS	3.99	22	4	6	1	AS
4	74	S	3.02	60	4	7a	2	RP/RT
5	61	NS	2.18	28	4	6	1	AS
6	61	NS	1.38	26	3	7a	2	RP/RT
7	53	NS	2.88	23	4			Follow-up
8	51	NS	10.10	64	3			Follow-up
9	50	NS	0.41	20	4			Follow-up
10	59	S	0.43	15				Follow-up
11	73	NS	0.72	28	4			Follow-up
12	75	NS	4.35	26	4	HGPIN		Re-biopsy
13	60	NS	1.04	15	4			Follow-up

DRE, digital rectal exam; S, suspicious; NS, nonsuspicious; ISUP, International Society of Urological Pathology.

Table 2. Recorded data elements along the screening's pathway

Urology	Radiology	Pathology
Family history	Date of old exams	Biopsy duration
Digital rectal examination	Artifacts	Number of punches
Previous surgery	Diameter ap	Number of punches with cancer
5 α -reductase inhibitor	Diameter axial	Tumor volume
Testosterone replacement therapy	Diameter cc	Gleason the most
Urinary tract infection	Contrast agents	Gleason the worst
PSA	Lesion description	Ki-67
IPSS (1–8)	Reference series	PTEN
NIH-CPSI (1–9)	Reference image	ERG
SF36 (1–36)	Diameter	High-grade PIN
	Shape	Inflammation
	Localization	Intraductal carcinoma
	PI-RADS	Perineural invasion
	ADC	Vascular invasion
	Reference series	Lymphovascular invasion
	Reference image	Extraprostatic extension
	Contrast enhancement	Neurovascular bundles invasion
	Extraprostatic extension	Seminal vesicle invasion
	Neurovascular bundles invasion	
	Seminal vesicle invasion	
	Lymphnode invasion	
	Bone invasion	

IPSS, International Prostate Symptom Score; NIH-CPSI, National Institutes of Health-Chronic Prostatitis Symptom Index; SF36, short form (36) health survey; ADC, apparent diffusion coefficient; ap, anterior posterior; cc, craniocaudal; PTEN, phosphatase and tensin homolog; ERG, ETS-related gene; PIN, prostatic intraepithelial neoplasia.

Table 3. Survey results of the effect size for comparison of contextual information quality with the current method and novel solution

Construct	Item	Cohen's <i>d</i>	95% CI
Completeness	"The system provides me with complete information"	0.69	−0.63 to 2.01
	"The system produces comprehensive information"	2.28	0.63–3.94
Relevance	"Information within the system is applicable"	2.33	0.67–4.00
	"Information with the system is relevant for my job"	0.55	−0.76 to 1.86
	"In general, information within the system is relevant"	0.73	−0.60 to 2.06
Timeliness	The information provided within the system is up-to-date	2.03	0.45–3.62
	"The information provided within the system is received in a timely manner"	3.05	1.16–4.94
Usefulness	"Information within the system is informative"	1.70	0.20–3.20
	"Information within the system is valuable"	1.85	0.31–3.39

Positive values indicate an effect in favor of the novel solution. Values above 0.2 reflect a low, above 0.5 a medium, and above 0.7 a high effect size.

Table 4. Survey results of the effect size for comparison of representational information quality with the current method using traditional reports and novel solution using charts

Construct	Item	Cohen's <i>d</i>	95% CI
Format	"The information provided within the system is well laid out"	3.15	1.22–5.07
	"The information provided within the system clearly presented on the screen"	3.26	1.30–5.22
Consistency	"Information within the system is accurate"	2.08	0.48–3.68
	"In general, information within the system is reliable"	1.95	0.38–3.50
Understanding ability	"Within the system, information is easy to comprehend"	2.27	0.62–3.92
	"Within the system, information that is clear in its meaning"	2.26	0.61–3.91

Table 5. Survey results of the effect size for user satisfaction of the current method and the novel solution

Construct	Item	Cohen's <i>d</i>	95% CI
Net benefits	"Using the system improves my content-related work"	3.42	1.40–5.43
Workarounds	"Instead of using the system, I often use alternatives"	−0.50	−1.80 to 0.81
Satisfaction	"Overall, I am satisfied with the system"	3.99	1.76–6.21

solution and the current method. Time for case evaluation in urology using novel solution decreased significantly compared to the current method (−3.49 min, $p < 0.001$). Reporting time in radiology using the novel solution significantly decreased compared to the current method (−3.29 min, $p < 0.001$) and reporting time in pathology using the novel solution decreased compared to the current method (−1.89 min,

$p = 0.154$). For a summary, please refer to Figures 3 and 4 and Table 6.

Information Quality

The objective evaluation for information completeness showed no missing information in either method. The results of the surveys on specific aspects of information quality are shown in Tables 3 and 4. The effect size

Fig. 3. Screenshot of the novel patient dashboard showing the available information in comprehensive charts. The risk assessment shows all information for each individual lesion (top left). NIH-CPSI (top right), quality of life (bottom left), and IPSS (bottom right) show results from the respective surveys.

Table 6. Mean and standard deviation values for total case turnaround times novel solution and the current method as a function of specialty

Specialty	Mean (standard deviation)			Difference, %	p value
	novel (min)	current method (min)	difference (min)		
Pathology	3.77 (2.87)	5.66 (3.85)	-1.89	-33%	=0.154
Radiology	4.18 (1.22)	7.47 (3.08)	-3.29	-44%	<0.001
Urology	0.36 (0.17)	3.85 (1.09)	-3.49	-91%	<0.001
Total	2.71 (2.46)	5.66 (3.24)	-2.95	-52%	<0.001

was calculated using Cohen's *d*. Positive values indicate an effect in favor of the novel solution. Values above 0.2 reflect a low, above 0.5 a medium, and above 0.7 a high effect size. The novel system demonstrated a high positive effect size on all evaluated dimensions of contextual and representational information quality. Content of information in the novel system was perceived to be more

complete, relevant, up-to-date, and useful. Representation of information in the novel system was perceived to be more clear, consistent, and understandable.

User Satisfaction

The survey results indicated that use of the novel solution resulted in overall higher ratings on all of the ques-

Fig. 4. Box plots for total case turnaround times novel solution and current methods as a function of specialty.

tions regarding ease of use and satisfaction. Synoptic reporting and the usage of charts for comprehensive information overview showed higher satisfaction, contributed to a statistically significantly improved patient evaluation, and reduced workarounds. Results for overall satisfaction across participants using Cohens's *d* are shown in Table 5.

Discussion

The integration of clinical information from multiple sources is essential to understand the patient's medical condition [27, 28]. Missing documentation standards and siloed information management increase the effort for physicians to integrate patient information [29]. The alignment of medical reporting to data integration requirements can reduce physician's effort to understand the patient's medical condition and improve subsequent treatment decisions [30, 31].

In this study, we developed a novel system to align medical reporting to data integration requirements and

compared it with the current standard. We evaluated the time required to report, review, and integrate patient data along the diagnostic work-up of prostate cancer screening. The usage of synoptic reporting reduced time for documentation of examination results compared to traditional narrative reporting, which is in line with previous studies [32]. Potential reasons include the reduced effort for text formatting [32, 33], correction of dictation errors (casus, numerus, and genus of word endings) [33], use of defaults (normal finding), automated calculations (prostate volume and tumor volumes in biopsies), proofreading for completeness, and consistency of the report [11, 13, 14]. The comparison of time savings between diagnostic departments showed greater time savings for radiology compared to pathology. This may be due to the longer reports in radiology, which allow for more time savings.

The urology department, which is responsible for review and integration of patient data, showed the greatest time savings of all departments. This can be explained by the usage of standardized definitions of information units

and semantic relationships among these information units in an embedded referencing system. Information could thus be organized in a patient-centric manner, relieving urologists from the high manual effort of reviewing and integrating from multiple sources. In our study, data elements recorded along the diagnostic pathway were automatically prepared in a visually easily consumable way for the complex decision-making needs of MDTs. Since this presentation is not yet a routine procedure, no comparisons to the conventional approach with regard to time savings were made. However, previous studies were able to show that this way of organization and representation of information reduced case preparation time for decision-making processes [24, 34]. Given an aging society, the interdisciplinary management of multimorbid patients may lead to MDTs becoming primary recipients of examination reports. Therefore, MDT's requirements for information use should be better addressed in clinical reporting. Although not examined in this study, the patient is another important recipient of integrated data. Patients face enormous challenges in capturing, understanding, and acting on information from narrative reports. Data elements prepared in an easily consumable format, without technical terms, could provide patients with valuable insights about their health status and help them take a more active and empowered role in their care.

The survey results indicate that synoptic reporting improved data quality in terms of completeness, clarity, and consistency compared to narrative reporting. This is in line with previous studies and widely acknowledged in the diagnostic disciplines [10, 16, 32, 33, 35, 36]. Several studies demonstrated increased completeness in synoptical reports across various cancer reports including the breast, colorectal, lung, and prostate [35, 37–40]. User satisfaction in our study achieved significantly higher values than the current method. This is consistent with previous studies showing that the high-level of clarity and consistency in synoptic reports leads to high satisfaction among oncologists, pathologists, and surgeons [41, 42]. The optimized representation of patient information in comprehensive dashboards allows physician to focus on best treatment decisions rather than searching through poorly organized electronic medical records to retrieve relevant clinical information.

This study has the limitation of being confined to a single institution. This makes it difficult to generalize to other institutions using other IT systems. We also had limited ability to assess inter-user variability since only 2

participants were observed within each specialty. Nevertheless, the results based on 26 observation sessions represent a sufficient sample of observations. It is also limited by the fact that we only studied the linear pathway of prostate cancer screening. However, it is consistent with previous studies on synoptic reporting in different settings [8, 12–14, 17, 36, 40, 41]. Our study can only serve as an initial assessment of the data integration requirements, as it does not reflect the full dynamics of the complex course of the disease.

Conclusion

Our study supports the hypothesis that synoptic reporting based on data elements is an effective method to reduce time for collection and integration of relevant patient information. Further work is needed to investigate the dynamics of complex courses of disease, multiple health conditions, and preparation of information in a suitable format for the patient.

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Statement of Ethics

This study does not investigate diseases or the human body and is therefore not subject to the Human Research Act. The study is approved by the Ethikkommission Nordwest- und Zentralschweiz (January 14, 2020) and exempt from the Ethical Committee approval. All patient data used in this study were completely anonymized and are therefore not subject to the Data Protection Act. Informed consent of the patients is therefore not required.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

M.H., B.S., H.S., and C.W. determined system requirements. M.H., J.L., and M.K. developed the system. M.H. and B.S. determined the study design. K.D.M., C.B., K.M., S.G.D., S.M., and C.W. collected the data. M.H., K.D.M., C.W., and B.S. created the manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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