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Research Article

The influence of digital clinical documentation on patient safety in a university hospital

Der Einfluss einer digitalen klinischen Dokumentation auf die Patientensicherheit in einem Universitätsklinikum

Abstract

The ultimate goal of digitalization in healthcare is optimized, safe and efficient patient care. To achieve this goal, the E-Health Act stipulates that every patient receives a digital data pool with all health-relevant information that all healthcare providers can access. In this way, competencies are to be combined and costs and time expenditure can be reduced. The basis for this project is a digital documentation of all medical facilities. The Department of Oral and Maxillofacial Surgery at Göttingen University Hospital has been working with a digital patient file in the Meona software since June 2020. In this study, 100 analog and 100 digital patient files were analyzed to clarify whether digital documentation can contribute to greater patient safety. Using common statistical mean and group comparisons, data quality and quantity of both sample groups were compared.

The analysis revealed superior quality of the digital documentation compared to the paperfiles. The better overview, traceability and readability that result of digitally documented clinical data offer great advantages in the area of patient and employee safety. When it comes to medication, the digital file is also superior to the analog file thanks to e.g. its precise orders and color markings. The digital signature and perfect readability also offer advantages in terms of communication as well as legal protection. Digital documentation therefore represents an elemental part on the way to safe and optimized patient care.

Keywords: documentation, patient safety, oral and maxillofacial surgery, digitalization

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Zusammenfassung

Höchstes Ziel der Digitalisierung im Gesundheitswesen ist eine optimierte, sichere und effiziente Patientenversorgung. Das E-Health-Gesetz sieht zum Erreichen dieses Ziels vor, dass jeder Patient einen Datenpool mit allen gesundheitlich relevanten Daten erhält, auf den alle Akteure des Gesundheitswesens zugreifen können. Auf diese Weise sollen Kompetenzen vereint sowie Kosten- und Zeitaufwand gesenkt werden. Grundlage für dieses Vorhaben ist eine digitale Dokumentation der medizinischen Einrichtungen. In der Abteilung für Mund-, Kiefer- und Gesichtschirurgie des Universitätsklinikums Göttingen wird seit Juni 2020 mit der digitalen Patientenakte in der Software Meona gearbeitet. In dieser Studie wurden 100 analoge und 100 digitale Patientenakten miteinander verglichen, um zu klären, ob eine digitale Dokumentation zu einer größeren Patientensicherheit beitragen kann. Mittels gängiger statistischer Mittelwert- und Gruppenvergleiche wurden Datenqualität und -quantität beider Stichprobengruppen verglichen.

Die Analyse ergab eine überlegene Qualität der digitalen Dokumentationsform. Die bessere Übersicht, Rückverfolgbarkeit und Leserlichkeit der Einträge in digitaler Form bieten große Vorteile auf dem Gebiet der Patienten- und Mitarbeitersicherheit. Auch in Bezug auf die Medikation

ist die digitale Akte durch präzise Anordnungen und farbliche Markierungen als Kontrollinstanz der analogen Akte überlegen. Die digitale Signatur und einwandfreie Leserlichkeit bieten außerdem Vorteile hinsichtlich Kommunikation und rechtlicher Absicherung. Eine digitale Dokumentation stellt somit einen elementaren Baustein auf dem Weg zu einer sicheren und optimierten Patientenversorgung dar.

Schlüsselwörter: Dokumentation, Patientensicherheit, Mund-, Kiefer-, Gesichtschirurgie, Digitalisierung

1 Introduction

Digitalization is nowadays an integral part of our society as well as an ongoing topic in the healthcare sector. There are many concrete advantages and visions of digitalization regarding healthcare. Digitalization stands for time, personnel and cost efficiency, but the focus in the healthcare sector should above all be on optimizing patient care. The electronic patient file is intended to represent a common data pool of all health-relevant patient data, to which all people involved in the care process have access [1]. The basis for the implementation of this project is a digital documentation of all health facilities.
The level of digitalization in most German hospitals is lagging behind compared to other European countries [1]. The Hospital Future Act now promotes the digital expansion of German hospitals [2]. Since many projects are currently still being planned or implemented, there is so far little literature or experience reported on the introduction of digital patient files in German hospitals. The University Hospital Eppendorf (UKE) in Hamburg is a pioneer in Germany when it comes to digitalization. Planning for the electronic patient file has already started in 2006. In 2011, the UKE was the first hospital in Europe to receive the highest level 7 in the Electronic Medical Record Adoption Model (EMRAM). Their recommendations for successful implementation include standardized processes, the integration of all areas under professional supervision and support during the implementation process, as well as appropriate operational organization and cost structure for the digitalization project [3].
In July 2019, the University Medical Center Göttingen (UMG) decided to introduce Meona as a new hospital information system (HIS) including a digital patient file. The company Mesalvo Freiburg GmbH offers the clinical software for implementing interoperability as part of the telematics infrastructure (TI) for German hospitals. Meona functions as a closed network to which only registered users with an electronic medical profession/practice ID have access. With an extensive repertoire of interfaces and proven technologies, the software can be integrated into existing HIS and subsystems [4].
The aim of this work is to analyze and compare the clinical documentation on a normal ward before and after the digitalization measure. Previous studies have found inadequate quality of clinical documentation in terms of completeness, clarity and traceability [5]. It is assumed that paper documentation can no longer meet the prevailing requirements for medical documentation [6]. This article aims to discuss the hypothesis as to whether digital documentation can contribute to greater patient safety. Further the article is intended to give a short impression about the experiences during the implementation process.

2 Material and methods

2.1 Data collection

As part of this work, a sample of 100 analog and 100 digital files from the UMG Clinic for Oral and Maxillofacial Surgery (OMS) was analyzed with regard to documentation quality and quantity. The data was collected by retrospectively evaluating data from patient files documenting a stay in the OMS ward between January 2nd, 2019 and December 16th, 2020. The introduction of Meona within the OMS department took place on June 1st, 2020. To select the files, the four most common ICD codes were determined from a list of all inpatients in 2019 and 2020 (Table 1). Patient selection was random within the respective main diagnosis. Similar numbers of files were selected from the analog and digital groups in order to create a premise for comparability.

2.2 Assessment of readability

Readability is an important aspect of comparison between the two patient groups. In order to be able to approximately quantify readability, a scoring system was developed. For that readability is assessed in three categories: 2 = readable, 1 = at least one word is difficult to read and 0 = at least one word is illegible. In this way, legible entries receive the highest possible score (2). The highest possible overall score per document examined is calculated from the number of documents in the collective multiplied by two. For example, if a document is present 80 times in the analog patient file collective, the highest possible score is 160, which would then correspond to a readability of 100%. Readability results from the quotient of achieved points and maximum achievable points. This model was successfully tested using 30 randomly selected files.

2.3 Statistical procedures

The statistical tests were carried out using Microsoft Office Excel 2019. The significance level was set at 0.05 for all statistical tests. The statistics were supplemented

Table 1: Most common ICD codes with the number of files included in the data collection

Number of cases in research period	ICD code	Designation	Number of analog files	Number of digital files
172	S02.4	Fracture of the cheekbone and upper jaw	36	34
125	K10.28	Other specified inflammatory conditions of the jaws	33	35
103	K07.1	Anomalies of the jaw-skull base ratio	18	20
121	K02.1	Caries of dentin	13	11

by descriptive analyzes where appropriate. The unpaired t-test was used to compare two groups (e.g. analog vs. digital). The data was previously examined for variance homogeneity or heterogeneity using the Levene test. If the p-value was <0.05, the t-tests were carried out assuming equal variances and if the p-value was >0.05, the t-tests were carried out assuming different variances. For group comparisons of more than two groups (e.g. comparisons of the main diagnoses), the Analysis of Variances (ANOVA) was used. If homogeneity of variance was violated, Welch's ANOVA was used. Tests should be considered robust regardless of the normal distribution of the data [7], [8]. For group comparisons for binary questions, the Pearson chi-square test (2 groups, variable size >5) and Fisher's exact test (>2 groups, variable size <5) were used.

3 Results

3.1 Allergies

Documentation of allergies was planned on several documents as part of the analog recording process. In addition to the medical and nursing admission document, the same information had to be entered on the curve sheet. If the stay lasted longer than seven days, the allergy also had to be transferred to the next curve sheet (a curve sheet covers seven days). Thus information about allergies had to be recorded on three to four different documents. In the digital documentation, this information is recorded once by the doctor and can then be seen in the header of the curve and, if necessary, highlighted in color. A Fisher's exact test showed significant differences in the frequency of allergy information in the different documents, p=0.001. At 89%, information about allergies was given most frequently in Meona. It was documented second most frequently in the analog medical admission document. The information was also found more frequently on the first curve sheet than on the second curve sheet. Only 66%, which is the least amount, had information about allergies on the nursing admission document (Table 2).

3.2 Documentation of vital parameters

Using t-tests assuming different variances, significant differences between analog and digital documentation were determined with regard to the frequency of documenting the vital parameters. The days of a patient's stay were counted on which no measurement of blood pressure (RR), heart rate (HR) and temperature was documented, $t(175) = 2.21$, $p=0.028$; $t(178) = 2.95$, $p=0.004$; $t(165) = 2.65$, $p=0.009$. All three values were documented more frequently in Meona with an average of 2.1 days without documented measurement than in the analog with 2.5 to 2.7 days without documented measurement. Welch's ANOVA also showed significant differences in the number of days with missing documentation of vital signs between the different diagnosis groups. This applies to both the analog (RR: $F(3, 43) = 4.65$, $p=0.007$; $F(3, 43) = 2.88$, $p=0.047$; temperature: $F(3, 44) = 2.88$, $p=0.047$) and the digital (RR: $F(3, 36) = 4.31$, $p=0.011$; HF: $F(3, 36) = 6.53$, $p=0.001$; temperature: $F(3, 36) = 4.84$, $p=0.006$) sample (Table 3). Descriptively, it was noticeable that with diagnosis K07.1 (anomalies of the jaw-skull base relationship) the documentation of all three vital parameters in analog and digital form was most often missing. The most common documentation was analog for diagnosis K02.1 (dentin caries) and digital for diagnosis S02.4 (fractures of the cheekbone and upper jaw).
During the analysis of the analog files, discrepancies in the recording of heart rate and temperature were also noticed. This information should be entered into a two-column table every day using crosses. The values can then be read using the scales on the left edge of the document. The information here was partly misleading because different colors (red and blue) and/or columns were used inconsistently. Pulse and temperature information could not be clearly differentiated in 20% of the cases.

3.3 Medication

With regard to the documentation of the medication, some aspects relevant to patient safety were observed, starting with the precision of the order.
In 49% of the paper files examined, the order for at least one medication was ambiguous with regard to dosage or time of dispensing (e.g. missing unit). This resulted in a statistically significant difference compared to Meona with 100% complete information, χ^2 (1, N=200) = 68.46, p<0.001 (Table 4).
There were also major differences in the employees' signatures. The t-tests carried out assume different variances. In Meona every administration of medication could be traced using the user name whereas analogously only 40% of the administrations were marked with a signature, $t(93) = -17.74$, $p<0.001$.

Table 2: Comparison of analog and digital: information on allergies

	Document	Information available	Information not available	Number of documents in the collective	Available in
Analog	Admission document doctor	70	15	85	82.35%
	Admission document care	66	34	100	66.00%
	Curve sheet 1	78	22	100	78.00%
	Curve sheet 2	20	9	29	68.97%
Digital	Curve in Meona	89	11	100	89.00%

Table 3: Comparison of analog and digital: days without documentation of vital parameters per patient stay, structured by main diagnosis

Analog n=100	**Average length of stay**		**Days without RR** N=254		**Days without HR** N=270		**Days without temperature** N=271	
ICD code	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
S02.4	5.67	4.11	2.31	1.45	2.39	1.48	2.44	1.58
K10.28	6.86	4.10	2.61	1.90	3.03	1.93	2.79	2.09
K07.1	6.66	1.22	3.44	1.58	3.17	1.34	3.67	1.64
K02.1	2.90	1.53	1.77	0.93	2.08	1.04	1.92	0.95
In total	5.88	3.68	2.54	1.64	2.70	1.60	2.71	1.77
Digital n=100	**Average length of stay**		**Days without RR** N=210		**Days without HR** N=212		**Days without temperature** N=216	
ICD code	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
S02.4	4.90	3.12	1.71	0.84	1.59	0.82	1.74	0.83
K10.28	6.80	3.40	2.23	1.26	2.34	1.24	2.34	1.24
K07.1	6.44	0.65	2.70	1.13	2.75	1.12	2.70	1.03
K02.1	2.97	0.56	1.82	0.98	1.91	0.94	1.91	0.94
In total	5.66	2.98	2.10	1.12	2.12	1.13	2.16	1.09

Annotation. Green background: most frequently documented, red background: least documented. n= sample size, N= number of days without documented measurements within the whole sample, M= mean, SD= standard deviation

Table 4: Comparison of analog and digital: clarity of the medication order

	Clear	Not clear	In total
Analog	49	51	100
Digital	100	0	100
In total	149	51	200

Table 5: Comparison of analog and digital: medication administration with signatures

	Drug administrations	Administrations with signatures [%]	
		M	*SD*
Analog (n=100)	Antibiotics (N=830)	99.06%	3.08%
	Other (N=3002)	21.44%	28.58%
	In total (N=3832)	40.14%	32.72%
Digital (n=100)	In total (N=3671)	100.00%	0.00%

n= sample size, N= total amount of administrations within the sample

Within the analog documentation there was a significant difference between signatures when administering antibiotics and other medications, $t(94) = -25.65$, $p<0.001$. The administration of an antibiotic was signed off in almost 100%, whereas other medications were signed off in only 21% (Table 5).

Another observation that was noticed in the analog patient file was incongruence between the curve sheet and

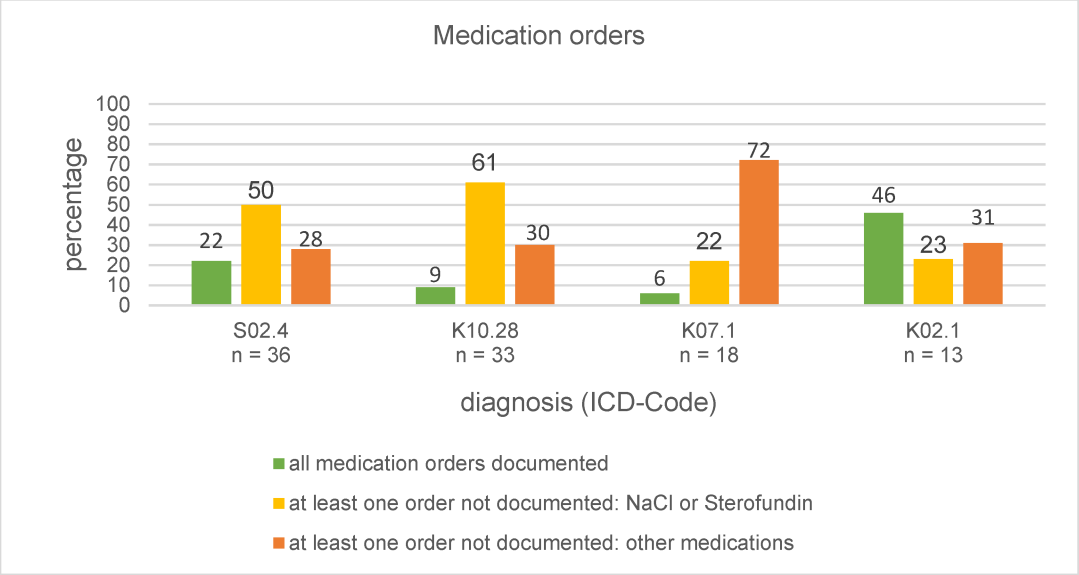

Figure 1: Percentage of patient cases with medication where the order has not and the administration has been documented in the analog patient files
n= sample size

the order sheet. It happened that medication was documented as administered in the chart, but no corresponding order could be found. Figure 1 shows that in 82% of the analog cases examined, at least one medication was found on the curve sheet that was not preceded by a corresponding order. For the medications whose order was not documented, a distinction could be made between solvents or infusions such as sodium chloride (NaCl)/Sterofundin® and other medications. In 45% of hospitalizations either NaCl or Sterofundin® was administered without appropriately documented orders. In 37% it was a different medication (with or without NaCl/Sterofundin® in combination). Descriptively NaCl or Sterofundin® were administered without a documented order more than twice as often to patients associated with the diagnoses S02.4 (fractures of the cheekbone and the upper jaw) and K10.28 (other specified inflammatory conditions of the jaw) than to patients associated with the other two diagnoses. The diagnosis in which another medication was by far most frequently administered without a documented order was K07.1 (abnormalities of the jaw-skull base relationship) at 72%. In almost half of the patient files containing the diagnosis K02.1 (dentin caries) all medications administered were preceded by an appropriately documented order. This is where the most thorough documentation took place.

Figure 2 shows the distribution of drug types of the remaining non-ordered drugs. The “Other” category includes nasal spray, dexpanthenol (Bepanthen®) and magnesium. The two most commonly administered painkillers were ibuprofen and metamizole (Novalgin®). Descriptively, patients of the analog documentation group diagnosed with K07.1 (anomalies of the jaw-skull base relationship) mainly received analgesics, antiemetics, sedatives, nasal spray and dexpanthenol (Bepanthen®). Regarding patients diagnosed with K10.28 (other specified inflammatory conditions of the jaws), the 30% (cf. Figure 1) was mainly due to analgesics and sedatives. 31% of patients diagnosed with K02.1 (dentin caries) predominantly received painkillers without documented medical orders. Regarding diagnosis S02.4 (fractures of the cheekbone and upper jaw) it was noticed that, in addition to analgesics and sedatives, medications that tend to be long-term medication (e.g. antihypertensives) were often affected by not being documented as ordered as well.

Table 6 shows the number of administrations of medications that were not documented as ordered per patient stay in the analog patient files. Welch ANOVA showed statistically significant differences in the number of NaCl or Sterofundin® administrations without associated documented order between the diagnoses, $F(3, 36) = 7.50$, $p<0.0001$. The number of these administrations in patients with the diagnosis K10.28 (other specified inflammatory conditions of the jaws) was almost three times as high as that of the other sample groups. Overall, there was an average number of 8.8 administrations per patient stay. With regard to the administration of other medications without documented order, no significant difference between the diagnoses could be found using ANOVA, $F(3, 96) = 1.02$, $p>0.05$. In average there were 1.3 doses of non-ordered medications administered per patient stay. Descriptively, the diagnosis K10.28 (other specified inflammatory conditions of the jaws) with an average of less than one dose fell behind the other three with around two doses each (Table 6). In Meona, it is not possible to document a medication as administered unless there is a corresponding order documented in advance. This way the documentation is much more stringent at this point.

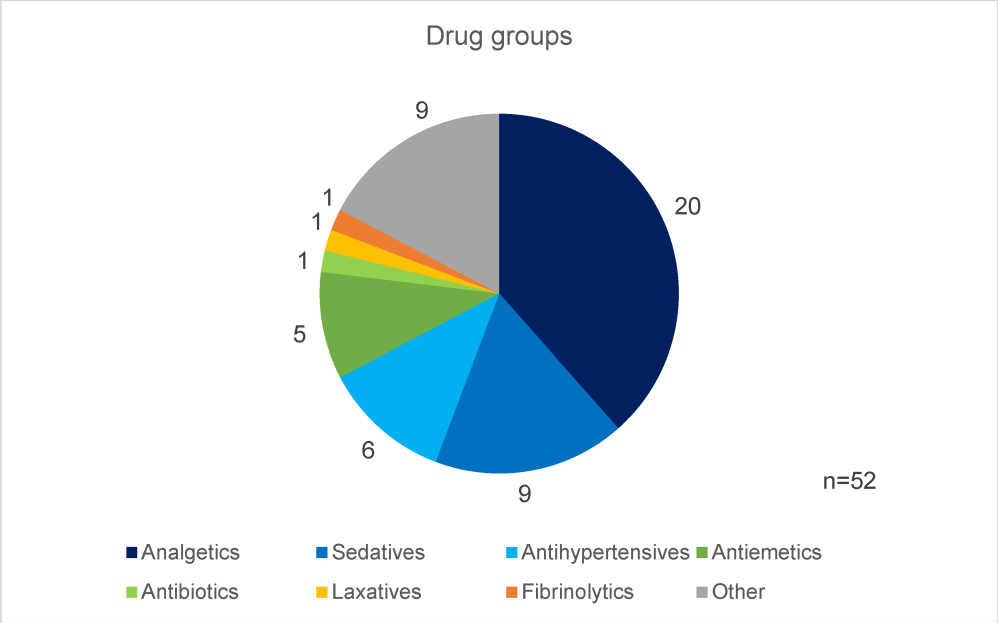

Figure 2: Overview of medications without documented order in the analog patient files
N= total amount of medication with documented administration but no documented order within the analog patient files

Table 6: Number of administrations of medications with missing documentation of order per patient stay in the analog patient files

	NaCl/Sterofundin® (N=878)		**Other medications** (N=131)	
ICD code	*M*	*SD*	*M*	*SD*
S02.4	5.86	8.72	1.89	4.88
K10.28	15.79	14.31	0.79	1.65
K07.1	6.28	6.97	1.72	2.61
K02.1	2.54	4.43	2.54	1.13
In total	8.78	11.38	1.31	3.31

n=100 (sample size), N= total amount of documented administrations within the sample

3.4 Readability

Descriptively, the readability of the doctor's orders and visit notes in the digital file was significantly better than in the analog patient sample. This particularly applies to medication orders. Of an average of six medication orders documented in the paper file per patient stay, only around a third could be read correctly.

3.5 Orders and doctor's visit notes

Below, entries in the analog document for doctor's visit notes and orders (both types of entries are shown on one sheet) were compared with entries in the digital line "visit notes" in Meona (different from the analog file there are separate tabs for visit notes and orders in Meona, nevertheless orders happen to be entered in the tab for visit notes as well). For the analysis, a doctor's visit note was understood to be a documentation of findings during the medical visit. Orders contain information about further clinical procedures.

Since the ordering of medications takes up a very large part of the total orders in both collectives, these were not taken into account here to improve comparability.

With regard to the number of entries, the t-test, assuming different variances, showed a significant difference between the analog and digital patient files, $t(186) = -2.44$, $p<0.05$. While an average of 4.6 visit notes per patient and stay were documented in Meona, there were only an average of only 3.6 visit notes per patient and stay in the paper files.

Two-sample t-tests assuming different variances also showed significant differences in the classification of entries into isolated orders (excluding medications), isolated findings and mixed entries. In the paper file, an average of 2.1 isolated orders were made per patient per stay, in Meona only 1.1, $t(189) = 5.30$, $p<0.001$. However, isolated findings were found significantly more frequently in the "visit notes" in Meona with 1.2 entries than in the paper files with 0.3, $t(134) = -5.37$, $p<0.001$. The same applies to entries that contain both the order and the findings. In Meona there were an average of 2.4, whereas analogously there were only 0.8 mixed entries on average, $t(145) = -7.04$, $p<0.001$. Unassessable

Table 7: Comparison of analog and digital: average doctor's visit notes and orders per patient stay

	Total amount		Orders		Findings		Mixed		Cannot be assesed	
Analog	364		214		31		78		40	
Digital	463		110		116		235		2	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Analog (n=100)	3.64	2.48	2.14	1.55	0.31	0.61	0.78	0.99	0.40	0.97
Digital (n=100)	4.63	3.21	1.09	1.24	1.15	1.44	2.35	2.00	0.02	0.20

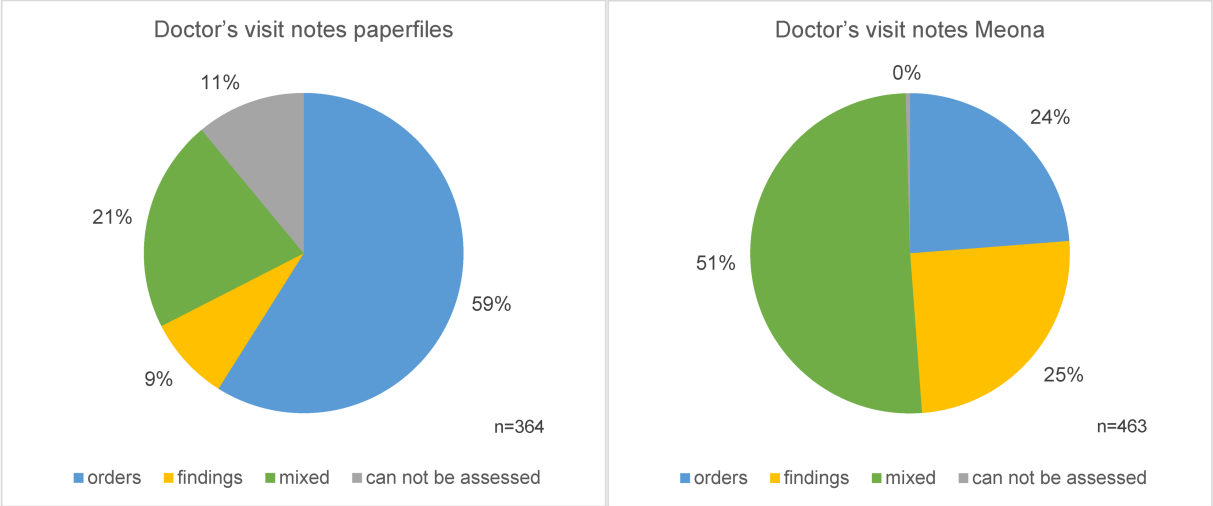

Figure 3: Comparison of analog and digital: distribution of doctor's visit notes contents (analog: sheet for orders and visit notes, digital: Tab "visit notes" in Meona)

entries (e.g. indecipherable or do not apply to the categories) occurred significantly more often in analog files than in digital ones, $t(107) = 3.82$, $p<0.001$ (Table 7). Figure 3 shows the percentage distribution of entries in the analog and digital patient sample.

4 Discussion

4.1 Discussion of the methods

Within the analysis of the patient files a retrospective review of clinical data was conducted. It should be mentioned here that the files examined are randomly selected samples, which may only partially reflect the overall situation. By selecting the files within the most frequently occurring ICD codes, the results can still be considered representative. It is also important to note that the digital files date from the period from the implementation of Meona to six months afterwards. The handling of the digital patient file in Meona may have developed further afterwards. Accordingly, the analysis can only show the comparison six months after introduction.

Concerning the assessment of the readability a weak point in the system that should be mentioned is that, if in doubt, the legibility of an entry could be classified as completely illegible based on one illegible word. In order to dampen this effect, the gradation 1= "at least one word is difficult to read" was used. Another point to counter this is that these are mostly entries of just a few words and an illegible word therefore makes up a high percentage of the total entry. In addition, the probability of finding an illegible word in the middle of otherwise perfect handwriting is comparatively low. What must be critically noted is that, despite intensive testing, the system is liable to a certain degree of subjectivity.

4.2 Discussion of the results

4.2.1 Allergies

The fact that the information about allergies should take place on at least three different documents within the analogously documented admission process is a strong indication that the individual processes and associated documents were not optimally coordinated with one another. A planned double or triple documentation costs at least twice the time that could be spent bedside [9]. At 89% (cf. Table 2), the allergy information was documented most frequently in Meona compared to the analog documents. This shows that requiring multiple documentation can lead to negligence. Although not systematically evaluated, transcription errors were repeatedly found in analog files. The most common observation was the lack of transfer of information from the first to the second curve sheet. Hartel et al. describe transmission errors in

over half of the cases examined [10] as well. Digital documentation avoids transmission errors and makes work more efficient [11].
Meona also offers a further advantage due to the overview of the most important health data on top of the digital curve, whereas the same information is spread over several pages within the paper files. A comparable level of clarity cannot be achieved here [12]. Providing important information such as allergies and infections in the header as shown in Meona can furthermore help improve patient and employee safety. The color marking also creates a quicker overview of potential dangers.

4.2.2 Documentation of vital parameters

A non-stringent and ambiguous documentation, as in this study in the case of pulse and temperature, makes the documentation itself invalid. Only consistent documentation can fulfill its purpose, which is often better implemented digitally. After examining 341 patient files, Paans et al. recommend the digital representation of the patient file to improve precision and consistency in documentation [13].

4.2.3 Medication

For about half of the patients in the analog group, at least one medication order per stay was imprecise. Information on dosage, delivery time or frequency was missing. Incorrect orders are not uncommon [10], [14]. The fact that in around half of the patients at least one medication order was not complete in terms of dosage or delivery time or frequency may be due to the often fast-paced and hectic processes on the ward. In addition, there may be a prerequisite knowledge of the usual handling of certain medications. However, full information on dosage and administration is urgently necessary. The increasing number of medications on the market, some with similar names, are making the process of prescribing and administering medications increasingly complex. Possible mix-ups due to unclear documentation can have far-reaching health consequences. In addition, due to demographic change, practitioners are confronted with increasingly longer medication lists and drug interactions [15]. In Meona incomplete information on medication orders is not possible within the system. This guarantees precise documentation. The program also warns of possible interactions with existing medication. Such AI-supported warning functions contribute to increased patient safety [16]. This function also puts employees in a better position in the event of legal questions or similar issues and protects them from accusations of inadequate documentation.
Complete documentation includes signatures from the person issuing the order and the person executing it, as well as the time at which the measure was carried out [17]. Some of this information was not complete in the analog collective. McCarthy et al. already reported on the problem of missing signatures [5]. The reasons for the missing information in this study may vary. Omissions are conceivable as part of the often fast-paced work routine on the ward. The administration of medication was traceable in less than half of the cases (40%, cf. Table 5) of the analog documentation. The administration of antibiotics was signed-off five times more frequently (99%) than the administration of other medications (21%). The reason seems to be in the form of the analog curve sheet. Forms or pre-printed forms require to fill out the fields and blank spaces provided [18]. The lines titled “HZ” (Handzeichen = signature) in the “Antibiotics” section of the curve sheet form explicitly ask the person filling out the form to give a signature. The remaining categories such as “oral” or “iv” have no such label. A weakness of the document itself must therefore be highlighted here.
Since every employee in Meona has to verify themselves with their individual user name and an associated password, an electronic signature is automatically stored for each entry. The date is also automatically recorded by the system. Since both the date and the signature are always legible and clear, all documentation can be traced and is therefore compliant with the basic principles and guidelines of nursing documentation [19]. This creates great potential for greater safety for patients and employees. Even if every employee should always act to the best of their knowledge and belief, precise tracing using the electronic signature is another motivating factor to carry out and document every work step correctly. In addition, the better traceability also makes it easier for possible queries between different employees. Comprehensible documentation is also highly relevant in legal matters [20].
In addition, in the analog patient files, there was an increasing number of medications in the curve view that were documented as administered but were not preceded by a corresponding documentation of an order (82%, cf. Figure 1). A written order from the doctor for all therapies is necessary [20]. There are differences in the type of medication whose order has not been documented between the various main diagnoses. These can partly be explained by the different therapies.
The diagnosis K07.1 (Anomalies of the jaw-skull base relationship) is associated with a relatively invasive surgical procedure and often severe pain and swelling postoperatively [21]. The high rate of medication not ordered (94%) resulted from a mixture of analgesics, antiemetics, sedatives, nasal spray and dexpanthenol (Bepanthen®), which were used to treat the postoperative symptoms. The probability that one of the numerous emergency medications will be administered during the night shift, for example, without a written doctor’s order, is comparatively high. However, ordering medication as needed is the sole responsibility of the doctor as a therapeutic decision and may not be carried out without a corresponding order [20]. This is where Meona offers advantages. If a new medication is registered, it must be approved by a doctor. This can also happen if the doctor is not in the same location, as he can flexibly access the digital file in Meona from any UMG computer that is con-

nected to the patient network. This prevents, for example, telephone arrangements from being forgotten to be added to the file. Data protection is still maintained through password-protected access.

In patients diagnosed with S02.4 (fractures of the cheekbone and upper jaw), in addition to analgesics and sedatives, medications that tend to be classified as long-term medication (e.g. antihypertensives) were also affected. This could again be due to the often non-standard admission process for these patients via the emergency department. Here, the written instructions for admission medication can easily be ignored afterwards. Scanning the QR code of the patient's federal uniform medication plan and automatically transferring it to the digital patient file significantly simplifies this process. However, the medication plan often differs greatly from the actual intake medication from the anamnesis interview [22]. Consequently, an adequate anamnesis is still the key to safe patient care and its documentation.

Patients diagnosed with K10.28 (other specified inflammatory conditions of the jaws) should be given intravenous antibiotics postoperatively [23]. However, in the files examined, only the order of the antibiotic itself was documented. Information about the type, quantity and concentration of the solution in which it was to be administered was missing. However, the solvent NaCl was still documented on the curve sheet. This resulted in the high amount of NaCl (61%) that was documented as administered but not as ordered. At this point, Meona is significantly superior to analog documentation, as this information cannot be missing from the program.

For patients with the comparatively harmless diagnosis K02.1 (dentin caries), the medication documentation was probably most consistent because both the admission process and the ward stay can proceed comparatively according to plan and without complications.

4.2.4 Readability

It was foreseeable that there would be significant differences in readability between analog and digital documentation, as individual handwriting is no longer required in Meona. Although abbreviations that are understandable to a specialist are permitted in clinical documentation, all entries must be written clearly and legibly [24]. In a study by Hartel et al. the handwriting was rated as difficult to read in 52% and unreadable in 2% [10]. This shows that handwritten, illegible file entries are a known problem in clinical documentation. Digital documentation offers significant advantages here [25], [26].

4.2.5 Orders and doctor's visit notes

On average, one more doctor's visit note was written per patient stay in Meona than in the paper file. While there is a separate ordering function in Meona, in the paper file orders and visit notes are shown on the same document. The arrangement of medication often takes up a lot of space on the document. This could quickly give the impression that sufficient documentation has already taken place in this case. In comparison, the visit note line in Meona is separate from the orders. This means that even after medication and post-surgery instructions have been ordered using the ordering function, the impression quickly arises that the medical documentation obligation still needs to be followed up.

In contrast, entries documenting isolated findings were significantly more common in Meona. Flexible access to the documentation system plays a crucial role in adequate documentation [11]. In any case, accessing the patient files during or after the visit with a simple mouse click is much more efficient than leafing through often thick and unwieldy files and may also lower the inhibition threshold regarding additions. Another factor is the proposed text modules in Meona, which can at least partially replace typing a note with just a few mouse clicks. In a study by Maamri et al. many employees stated that they could write file entries faster using a computer than by handwriting [27].

4.2.6 Overall

The Mesalvo company has been growing steadily since it was created from the merger of the companies Meona and iSolutions in 2021 [28]. The system interfaces are based on the latest technology (IHE/HL7/FHIR) and are intended to enable seamless integration into existing IT system landscapes and ward specific applications [29]. Individual adjustments are possible to a certain extent and are reserved for the so-called key users. Nevertheless, as part of an acceptance survey by UMG employees, 14 doctors and two nurses out of 77 people surveyed stated a lack of interoperability and compatibility with other clinical software within the free text answers. Two members of the medical staff mentioned that the implementation of changes was too slow [30]. The lack of interoperability is a widespread problem in the context of digital medicine [31]. The UMG is aware of this vulnerability and fixing it is part of the digitalization strategy until 2025/2030 [32]. Overall, none of the employees surveyed at UMG wanted the paper documentation back. For further research and assessment, a new analysis and a new acceptance survey would be desirable at a later date after all planned areas of application have been introduced.

In order to make a recommendation for other hospitals regarding the introduction of a new HIS, a comparison of the interoperability competencies of different HIS would certainly be desirable. The switch to digital medical documentation often initially represents an additional stress factor for staff [33], [34]. Recommendations regarding the process of introducing a new HIS are therefore a reduced workload and an individual training offer. Dealing with the new program initially takes more time. So that this does not have to be compensated for in the form of overtime and thus causes staff dissatisfaction, the workload should be distributed among more employees in the introductory phase. The extent to which this

measure can be implemented in times of a shortage of skilled workers is questionable. With regard to the training for the new system, an individual concept should be developed that is tailored to the needs of the different age groups. Since employees of older generations are more critical of technical developments [35], they should be particularly motivated. Here, the basic handling of technical devices is often a training aspect that would only bore the digital natives. It is known that inadequate training contributes to increased stress levels among employees [33]. This was also evident in the acceptance survey. The key users included in Meona's training concept, who receive special training in advance and are considered experts for their ward, have also proven themselves. As part of the training of all staff, alternative appointments should be planned for missing people (vacation/illness).

The UMG plans to reach EMRAM level 6 by 2025. This requires further developments, especially in the areas of intelligent, patient-specific clinical decision support (CDS) and closed-loop medication. The piloting of closed-loop medication is on UMG's investment plan until 2023. The CDS is scheduled to be implemented between 2023 and 2025. Investment goals for the coming year include the implementation of mobile applications in everyday clinical practice, patient self-services, e.g. check-in, questionnaires, etc., and measures for better interoperability [32]. All of these aspects should be implementable within the framework of Meona as further software extension and updates. The rollouts are managed by the digitalization project team. The practical feasibility remains to be seen.

5 Conclusion

Overall, the comparison of analog and digital file samples confirmed that digital medical documentation can contribute to greater patient safety. In addition, it can also protect employees from allegations of poor documentation or legal issues.

The information about allergies serves as an example of how multiple documentation is not only time-consuming and therefore cost-intensive, but also results in poorer documentation quality. Digital documentation offers great advantages here as it can counteract multiple documentation. Meona's better overview and automatic color highlighting of potential dangers in the curve can also contribute to a safer environment for both patients and employees.

A central aspect of the clinical care process is medication safety. This study has shown that digital documentation can have a significantly positive impact on patient safety in terms of ordering and administering the correct medication. A more detailed and frequent documentation of pre- and postoperational findings implies a higher quality in patient observation and thus improving security during a patient's stay.

The digital signature and perfect readability of the digital patient file also offer advantages in terms of communication and legal protection.

In conclusion, it should be noted that digital documentation is an elementary building block on the way to safe and optimized patient care, although it requires much effort in implementation.

Finally, it must be taken into account that these results may only have limited significance and are closely related to the HIS Meona. An expansion of the data sets with data from other wards or settings would be desirable. Qualitative research methods or interrupted time series could also be used for additional investigation. Further research could include meta-analyses of different HIS and their advantages and disadvantages in comparison to analog documentation and amongst each other.

Notes

Competing interests

The authors declare that they have no competing interests.

Ethics

The authors declare that an ethics committee vote is not required.

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