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Original Article

Managing Clinical Risk in Romania

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Abstract

Background: The indicators for adverse events screening, developed by Wolff in Australia, use ready available data in order to identify "red flag" cases that might need to be reviewed by clinicians in terms of medical documentation.

Methods: In this study, the 8 indicators developed by Wolff were used in the process of screening the electronic patient records from the 41 district hospitals in Romania. Data used is the Romanian Minimum Basic Data Set for 2006 collected at the National School of Public Health and Health Services Management, the institution in charge with data collection and processing. From the 8 indicators selected by Wolff, only one could not be used due to lack of data in the Romanian Minimum Basic Data Set.

Results: The distribution of these indicators in the 41 district hospitals shows wide differences among hospitals. This could represent an indication of higher clinical risk at some hospitals, but they can mean as well errors in the collection and management of data from the electronic patient records.

Conclusion: The study shows that the indicators can be used by hospitals for benchmarking clinical risk, although a better standardization and monitoring of data reporting is necessary in order to increase their validity. The Minimum Basic Data Set represents an accessible instrument for identification and measuring of clinical risk, but for purpose of utilization at national level we recommend at first the validation of data used to build the indicators, followed by the testing of the sensibility, specificity, and the positive and negative predictive values.

Keywords: *Clinical risk, Patient safety, Risk indicators, Adverse events, Romania*

Introduction

Genuinely defined by Hippocrates's oath „first, do no harm", and then evolving in its meaning until it became a distinct area of research, clinical risk is commonly defined nowadays as the probability of a patient of being victim of an adverse event, suffering a loss of health outcomes as a consequence of the way that an episode of care was provided. The loss of health outcomes might be caused by delivery of hospital care, resulting in a prolonged length of stay, poorer health status at discharge or even death of the patient (1). At its origins may lay an avoidable or unavoidable error, generating a potential harm. When errors are avoidable it means that better care could have been provided within the limits of reasonable resources availability, and thus, clinical risk could have been minimized.

Clinical risk is the subject of a large number of international studies. Assessment methodology vary widely and results often are not comparable between countries. However, a merging conclusion from most studies is that between 1/3 and 1/2 of the adverse events are preventable (2). This means that clinical risk management could play an important role in controlling the level of avoidable errors. Actions to be taken include identification and measuring of clinical risk, application of corrective interventions and monitoring the results (3).

From an organizational behavior point of view, the dominating culture in healthcare organizations is that of concealing errors, so that main barrier to improvement are the prevailing culture of „name and blame" surrounding the occurrence of healthcare events, lack of user-friendly error-reporting mechanisms, and fear

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of litigation if errors are acknowledged and reported. However, organizations are changing, and the modern approaches in regard to medical errors are: first openly admit mistakes, report them while they occur (by means of an "incident reporting system") because they can add value to the process of quality improvement. Moreover, benchmarking of clinical risk indicators between hospitals or in-hospital wards became a common approach to patient safety improvement.

One of the easiest instruments to use in order to minimize clinical risk and improve patient safety is the utilization of ready available patient clinical data. Although generally data is gathered for more "important" purposes, such as financing, one cannot overlook the benefits of using the data for quality improvement. Calculation of risk indicators for hospitals, hospital wards or patients may be regarded as a screening method for signaling problems and issues that require further analysis, and more laborious processes (for example auditing the patient clinical chart) (4, 5).

Such opportunity was seized in Romania, since a case-based financing mechanism was implemented starting with 2002 and it is currently used by means of collecting electronic patient data from all hospitals. Demographic and clinical data is collected as a Minimum Basic Data Set (MBDS) and then processed to produce DRGs (Diagnosis Related Groups), the base for the financing of acute hospitals or for some types of day-hospitalizations"

Beside the purpose of financing, we proposed a different utilization of the data from MBDS, as a quality improvement instrument, by pursuing with a study on clinical risk management. Such a process, not expensive, could be a quick way to draw attention of the Romanian health professionals on the clinical risk and patient safety, even if they consider, at this time, that the lack of resources is the main cause that affects patients' safety (6).

The study aims to evaluate the opportunity of using the minimum basic data set (MBDS) as an instrument for clinical risk management, besides other data such as nozocomial infections, adverse events following blood transfusions, adverse events from medication, patient complaints, malpraxis claims. Also, the study aims to find out how the validity of Wolff indicators calculated for Romania (using MBDS) can be improved. The objectives were as follows:

1. To select some clinical risk indicators that can be calculated from the actual MBDS
2. To determine the clinical risk profile of similar hospitals based on the selected indicators
3. To perform an analysis on the variability of clinical risk of each hospital.

Materials and Methods

Wolff and his team performed a number of studies in Australia on discharge data (clinical and administrative) in order to build specific indicators for the screening of patient clinical chart (7). Consequently, a more detailed revision of the patient clinical chart was performed by Wolff in his study for those hospitalizations in which more of these indicators appeared simultaneously. Eventually the analysis yielded with a conclusion upon the occurrence or not of a clinical error to the patient (8). The eight indicators are presented in the Table 1. They are used in our study as criteria to signal the existence of potential adverse events in our patient clinical charts.

Data used is the Romanian MBDS for 2006 from the National School of Public Health and Health Services Management (NSPHHSM). As the process of revision of patient files showing more than one indicators could not be performed at NSPH-HSM level, the study merely shows the presence of the indicators in the files of the selected hospitals and indicates hospitals with possibly higher clinical risk.

From the indicators selected by Wolff (9), only one [I8] could not be used due to lack of data regarding „ Booked for the operating theatre and cancelled" in the Romanian MBDS.

Table 1: Set of clinical risk indicators developed by Wolff

No.	Indicators	Wolff	Romania
I1	Death	yes	yes
I2	Return to operating theatre within 7 days	yes	yes
I3	Transfer from general ward to intensive care	yes	yes
I4	Unplanned readmission within 28 days from discharge	yes	yes
I5	Cardiac arrest	yes	yes
I6	Transfer to another acute care facility	yes	yes
I7	Length of stay greater than 21 days	yes	yes
I8	Booked for the operating theatre and cancelled	yes	no

Some differences in the way data is recorded in Romania have to be mentioned, as they influence the meaning of some of the Wolff indicators above:

- I3 („Transfer from general ward to intensive care"): in Romania this does not mean always a deteriorating health status of the patient which would normally require a transfer to Intensive care, but also it can be a patient needing simply an anesthesia; that happens because in Romania an Intensive Care ward *tout court* does not exist. Instead, there is a merged Anesthesia and Intensive Care ward, which means that not all patients admitted need intensive care".
- I4 („Unplanned readmission within 28 d from discharge"): this indicator was calculated for cases when patient was readmitted without referral from specialist, and also when admitted as emergency, without having established a link between morbidity of patient at first episode and that of the readmission.
- I6 („Transfer to another acute care facility"): indicator was calculated including transfers to any hospital, as in Romania the MBDS does not specify which type of hospital patient is transferred to.

Data from NSPHHSM was used to calculate the indicators for the 41 district hospitals in Romania, for the 2006 discharges. The selection of hospitals was made on the criteria of high volume and complexity of cases, which may imply a potential higher clinical risk.

Results

The 7 clinical risk crude indicators calculated for the 41 Romanian hospitals are presented in the Table 2 (hospitals sorted in descending order by the total no. of cases).

Because the hospitals do not have the same departments (wards) and treat different pathology (as reflected in the cases complexity- casemix index CMI), it means that it is necessary to perform an adjustment of the crude values of these 7 indicators, in order to reflect the difference in treated pathology. In our study we performed this adjustment with the variation of the hospital casemix index (CMI) compared to the national CMI level (0.7627 in 2006). The hypotheses we made was that a more complex pathology is more likely to generate a higher rate of errors, and so a higher clinical risk."

The 7 indicators calculated for the 41 Romanian hospitals and adjusted for the CMI are presented in the Table no. 3. For example. it could be observed that hospital MS01 has a crude indicator for I1 at 1,295 deaths (table 2). Because his complexity reflected by CMI is higher than the national average (0.9209 compared with 0.7627), it means that the adjusted I1 indicator should be lower than the crude one -1,073 deaths in Table 3.

Based on the table 3, the further analysis of the 7 clinical risk indicators in this study was performed on the indicators adjusted for the CMI.

As shown in Table 4, the most frequent among hospitals is the indicator I3- *Transfer from general ward to intensive care*, followed by I7- *Length of stay greater than 21 d* and I1- *Deaths*.
As shown in Table 4, some of the indicators have a very low frequency. The analysis per hospitals will be focused on the high frequency indicators (I1, I3, I5, I6, I7).
Indicator I1- *Deaths*, varies from 0% at hospital IF01, to 2.34% at hospital PH01 (Table 5). Higher percentages can be observed for hospitals in Bihor (BH01), Satu-Mare (SM01), Timiş (TM01). Indicators of hospitals from Maramureş (MM01) and Prahova (PH01) districts suggest higher clinical risk, which should be explored further, based on the medical documentation.
Because the indicator for *deaths* was adjusted for cases complexity, the explanation for such big differences could lie in different clinical risk, great variations of practice or poor registration of data.
Indicator I2 - *Return to operating theatre within 7 days*, has a very low frequency. In Table 6 are shown the no. of hospitals with the same number of cases.
Distribution of indicator I3- *Transfer from general ward to intensive care* presented in Table 7 shows that hospital with the lowest frequency are in districts of Covasna (CV01), Ilfov (IF01) and Maramureş (MM01) (0%), and those with highest frequency of transfers to intensive care are in Teleorman (TR01), Iaşi (IS01) and Hunedoara (HD01) districts (15-16%).
However we mention again that recording of patients transferred to intensive care in Romanian hospitals it does not have a precise meaning, as it includes also patients transferred for anesthesia services. In the same time, recording of patients transferred to intensive care is not compulsory, as under the DRG payment system intensive care services are included in the payment per case.
Regarding the indicator I4- *Unplanned readmission within 28 d of discharge*, it can be seen (Table 8) it has a low frequency (approximately 0.1%); we have chosen to mention in Table 8 the hospitals having more than 50 cases, and for which the indicator represents more than 0.2%.
Distribution of indicator I5- *Cardiac arrest* shows a variation between 0% (Ilfov- IF01 hospital) and 2.38% (Ploiesti - PH01 hospital). This one has an almost double frequency of I5 compared to the next hospital in the list, and almost 5 times more than the average for 41 hospitals.
In Table 9 it can be seen that the first 7 hospitals with highest frequencies of I5 account for 4,499 cases out of the total of 8,049. This suggests a potential higher clinical risk.
As for the situation of 0 cases encountered at Ilfov - IF01 hospital, this level can be explained by the localization of hospital nearby Bucharest, a major centre with emergency hospitals. So it can be interpreted that probably patients with lower clinical risk choose to come to this non-emergency hospital.
In Table 10, the distribution of indicator I6 - *Transfer to another acute care facility* shows a variation between 0% (hospitals from Braşov - BV01 and Mureş - MS01) and 2.87% (hospital in Ialomiţa - IL01).
Interestingly, although IL01, situated at 130 km from Bucharest has the highest transfer rate of patients to other hospitals, a similar hospital, BV01 has 0 cases of transfers. This great variation may indicate a reporting error at patient discharge.
This error related with the status of patient discharge may occur because sometimes, in cases when patients are transferred by other means and not by ambulance, the discharge is not recorded as transfer to other hospital, but simply as „discharged".
Distribution of indicator I7- *Length of stay greater than 21 d* is presented in Table 11. It varies between 0.47% (hospital Ilfov- IF01) to 4.79% (hospital in Sibiu- SB01). What should be further explored about this indicator is its interpretation as measure of clinical risk, since in Romania there is not yet a good separation of the care services for the chronic, terminal, palliative care or social cases.

Table 2: The 7 clinical risk indicators (crude values), per 41 acute care hospitals, in 2006

Hosp. ID	No. cases	I1- No. Deaths	I2- No. Returns to theatre within 7 d	I3- No. Transf. from general ward to intensive care	I4- No. Unplanned re-adm. within 28 days of discharge	I5- No. Cardiac arrests	I6-No. Transfer to another acute care facility	I7- Length of stay > 21 d	CMI
MS01	79,105	1,295	0	7,934	1	540	2	3,090	0.9209
CT01	65,633	914	3	7,793	51	615	560	2,008	0.8333
GL01	63,496	1,230	0	2,592	0	183	48	1,657	0.8316
DJ01	58,788	823	13	1,792	130	244	294	1,844	0.8316
BC01	53,974	488	6	4,290	73	136	175	1,156	0.8101
PH01	52,344	1,271	1	5,202	27	1,293	106	1,107	0.7926
CJ01	50,735	788	0	1,584	15	378	275	2,656	0.8927
VL01	47,388	211	1	1,959	67	78	306	1,547	0.7605
BR01	47,039	769	0	7,116	0	172	316	979	0.8059
BV01	46,696	1,042	1	5,323	16	463	0	1,279	0.8523
AG01	46,581	436	0	3,518	2	101	189	964	0.7818
GJ01	45,935	89	0	2,455	1	19	203	762	0.6543
NT01	44,645	458	0	1,384	0	282	437	1,031	0.8085
OT01	44,581	191	0	4,788	26	65	214	927	0.7148
MM01	44,384	1,018	2	0	58	25	247	1,087	0.8044
SV01	43,647	557	2	4,873	18	43	318	878	0.9100
BH01	43,074	1,023	0	3,335	26	240	166	1,576	0.8761
TM01	43,005	1,116	27	437	123	792	545	2,059	0.9123
SM01	42,631	896	0	1,714	5	374	100	1,251	0.7426
MH01	40,918	238	0	1,233	24	52	170	1,002	0.7222
DB01	39,266	208	1	2,712	12	68	194	574	0.7532
BZ01	38,092	357	0	3,451	6	164	321	683	0.7151
IS01	37,597	477	1	8,540	3	219	270	1,036	1.1003
VN01	37,114	372	3	2,357	64	248	566	593	0.6994
CS01	34,821	267	1	1,731	6	91	396	604	0.7610
VS01	34,117	187	0	3,456	0	132	173	803	0.7743
SB01	33,914	549	0	1,385	0	214	112	1,745	0.8188
TL01	33,110	368	2	3,340	32	10	519	1,035	0.6497
BT01	32,359	374	10	3,772	72	99	375	616	0.8132
BN01	31,556	374	0	837	9	239	189	923	0.7247
AR01	29,064	502	1	1,608	36	270	80	1,520	0.8586
AB01	28,828	462	0	1,390	2	80	33	1,100	0.7629
SJ01	27,910	258	1	1,769	27	14	170	752	0.8346
CL01	25,493	132	4	1,773	106	12	411	322	0.6731
HR01	24,543	340	1	632	21	153	74	522	0.7956
IL01	23,730	231	0	2,931	0	72	656	273	0.7349
TR01	23,726	186	0	3,176	47	57	209	434	0.6881
CV01	23,721	317	0	0	0	118	33	517	0.8430
HD01	22,537	462	0	4,137	0	65	215	782	0.8735
GR01	16,906	169	1	1,267	13	58	50	451	0.6610
IF01	3,330	0	0	0	0	0	10	11	0.5406
Total	**1,606,333**	**21,445**	**82**	**119,586**	**1,119**	**8,478**	**9,727**	**44,156**	**0.8033**

Table 3: The 7 clinical risk indicators adjusted for CMI, per 41 acute care hospitals in 2006

Hosp. ID	No. cases	I1- No. Deaths	I2- No. Returns to theatre within 7 d	I3- No. Transf. from general ward to intensive care	I4- No. Unplanned readm within 28 d of discharge	I5- No. Cardiac arrests	I6-No. Transfer to another acute care facility	I7- Length of stay > 21 d
MS01	79,105	1,073	0	6,571	1	447	2	2,559
CT01	65,633	837	3	7,133	47	563	513	1,838
GL01	63,496	1,128	0	2,377	0	168	44	1,520
DJ01	58,788	755	12	1,644	119	224	270	1,691
BC01	53,974	459	6	4,039	69	128	165	1,088
PH01	52,344	1,223	1	5,005	26	1,244	102	1,065
CJ01	50,735	673	0	1,353	13	323	235	2,269
VL01	47,388	212	1	1,965	67	78	307	1,551
BR01	47,039	728	0	6,735	0	163	299	927
BV01	46,696	932	1	4,763	14	414	0	1,144
AG01	46,581	425	0	3,432	2	99	184	940
GJ01	45,935	104	0	2,862	1	22	237	888
NT01	44,645	432	0	1,306	0	266	412	973
OT01	44,581	204	0	5,109	28	69	228	989
MM01	44,384	965	2	0	55	24	234	1,031
SV01	43,647	467	2	4,084	15	36	267	736
BH01	43,074	891	0	2,903	23	209	145	1,372
TM01	43,005	933	23	365	103	662	456	1,721
SM01	42,631	920	0	1,760	5	384	103	1,285
MH01	40,918	251	0	1,302	25	55	180	1,058
DB01	39,266	211	1	2,746	12	69	196	581
BZ01	38,092	381	0	3,681	6	175	342	728
IS01	37,597	331	1	5,920	2	152	187	718
VN01	37,114	406	3	2,570	70	270	617	647
CS01	34,821	268	1	1,735	6	91	397	605
VS01	34,117	184	0	3,404	0	130	170	791
SB01	33,914	511	0	1,290	0	199	104	1,626
TL01	33,110	432	2	3,921	38	12	609	1,215
BT01	32,359	351	9	3,538	68	93	352	578
BN01	31,556	394	0	881	9	252	199	971
AR01	29,064	446	1	1,428	32	240	71	1,350
AB01	28,828	462	0	1,390	2	80	33	1,100
SJ01	27,910	236	1	1,617	25	13	155	687
CL01	25,493	150	5	2,009	120	14	466	365
HR01	24,543	326	1	606	20	147	71	500
IL01	23,730	240	0	3,042	0	75	681	283
TR01	23,726	206	0	3,520	52	63	232	481
CV01	23,721	287	0	0	0	107	30	468
HD01	22,537	403	0	3,612	0	57	188	683
GR01	16,906	195	1	1,462	15	67	58	520
IF01	3,330	0	0	0	0	0	14	16
Total	**1,606,333**	**20,361**	**78**	**113,541**	**1,062**	**8,049**	**9,235**	**41,924**

Table 4: Frequency of the 7 indicators among the 41 hospitals

	No. cases	No. cases I1	No. cases I2	No. cases I3	No. cases I4	No. cases I5	No. cases I6	No. cases I7
Total	1,606,333	20,361	78	113,541	1,062	8,049	9,235	41,924
%	100%	1.27%	0.01%	7.07%	0.07%	0.50%	0.57%	2.61%

Table 5: First 5 and last 5 hospitals as frequency of I1- Deaths

Hospital ID	% indicator I1 adjusted- No. *Deaths* in total no. of cases
IF01	0.00
GJ01	0.23
VL01	0.45
OT01	0.46
DB01	0.54
BH01	2.07
SM01	2.16
TM01	2.17
MM01	2.17
PH01	2.34
Total 41 hospitals	**1.27**

Table 6: Distribution of indicator I2 among hospitals

No. hospitals with the same no. of cases of I2	21	10	3	2	1	1	1	1	1
No. of cases of I2	0	1	2	3	4	6	10	13	27

Table 7: First 5 and last 5 hospitals as frequency of I3 - Transfer from general ward to intensive care

Hospital ID	% indicator I3 adjusted - *Transfer from general ward to intensive care*
CV01	0.00
IF01	0.00
MM01	0.00
TM01	0.85
HR01	2.47
IL01	12.82
BR01	14.32
TR01	14.84
IS01	15.75
HD01	16.03
Total 41 hospitals	**7.07**

Table 8: Number of cases of I4 and % of indicator among 6 hospitals with highest frequency

Hospital ID	No. Cases	I4 adj. – Unplanned readmission within 28 d of discharge	% indicator I4 adj. - Unplanned readmission within 28 d of discharge
DJ01	59,788	119	0.20
BT01	32,359	68	0.21
TR01	23,726	52	0.22
TM01	43,005	103	0.24
CL01	25,493	120	0.47
Total 41 hospitals	1,606,303	1.062	0.07

Table 9: First 7 and last 7 hospitals as frequency of I5 -Cardiac arrest

Hospital ID	No. Cases	I5 adj. – No. cases cardiac arrest	% indicator I5 adj. – No. cases cardiac arrest
IF01	3,330	0	0.00
TL01	33,110	12	0.04
SJ01	27,910	13	0.05
GJ01	45,935	22	0.05
CL01	25,493	14	0.05
MM01	44,384	24	0.05
SV01	43,647	36	0.08
MH01	40,918	55	0.13
OT01	44,581	69	0.16
VL01	47,388	78	0.17
…	…	…	…
HR01	24,543	147	0.60
CJ01	50,735	323	0.64
VN01	37,114	270	0.73
BN01	31,556	252	0.80

Table 9: Continued…

AR01	29,064	240	0.83
CT01	65,633	563	0.86
BV01	46,696	414	0.89
SM01	42,631	384	0.90
TM01	43,005	662	1.54
PH01	52,344	1,244	2.38
Total 41 hospitals	1,606,303	8,049	0.50

Table 10: First 7 and last 7 hospitals as frequency of I6 - Transfer to another acute care facility

Hospital ID	No. Cases	I6 adj. – No. Cases Transfer to another acute care facility	% indicator I6 adj. – No. Cases Transfer to another acute care facility
BV01	46,696	0	0.00
MS01	79,105	2	0.00
GL01	63,496	44	0.07
AB01	28,828	33	0.11
CV01	23,721	30	0.13
PH01	52,344	102	0.19
SM01	42,631	103	0.24
…	…	…	…
TM01	43,005	456	1.06
BT01	32,359	352	1.09
CS01	34,821	397	1.14
VN01	37,114	617	1.66
CL01	25,493	466	1.83
TL01	33,110	609	1.84
IL01	23,730	681	2.87
Total 41 hospitals	1,606,303	9,235	0.57

Table 11: First 7 and last 7 hospitals as frequency of I7 - No. cases with Length of stay greater than 21 d

Hospital ID	No. Cases	I7 adj. - No. cases Length of stay > 21 d	% indicator I7 adj. – No. cases Length of stay > 21 d
IF01	3,330	16	0.47
IL01	23,730	283	1.19
CL01	25,493	365	1.43
DB01	39,266	581	1.48
SV01	43,647	736	1.69
CS01	34,821	605	1.74
VN01	37,114	647	1.74
…	…	…	…
VL01	47,388	1,551	3.27
TL01	33,110	1,215	3.67
AB01	28,828	1,100	3.81
TM01	43,005	1,721	4.00
CJ01	50,735	2,269	4.47
AR01	29,064	1,350	4.65
SB01	33,914	1,626	4.79
Total 41 hospitals	1,606,333	41,924	2.61

Discussion

It is well established that errors in healthcare cannot be completely eliminated due to the complexity of healthcare systems. However, they can be greatly reduced by means of an efficient management of clinical risk.

First step of clinical risk management is identification and analysis of risk. This step can be done with minimal effort and costs by utilizing the ready available data from patient records. Information gathered can be used for further auditing of the clinical files.

The set of indicators for screening adverse events (Limited Adverse Occurrence System or LAOS) developed by Wolff in Wimmera Base Hospital in Horsham Victoria, Australia shows how to use ready available data for identifying „alarm cases" which require further medical records review for establishing the occurrence of an adverse event. This study shows how the set of Wolff indicators can be ready to use for the screening of data collected as MBDS in Romania. The analysis performed on 41 hospitals (district hospitals) looked at the distribution of indicators among hospitals, followed by an adjustment of the indicators for the complexity of pathology treated in each hospital (measured by the CMI). Although only 7 of the 8 indicators had been calculated for the Romanian hospitals, the analysis developed in this study reveals important differences among hospitals regarding indications for potentially high clinical risk; but in the same time, these differences may also be a result of errors in data recording used for calculating the indicators.

The study shows that the indicators can be used by hospitals for benchmarking clinical risk among clinical wards, although a better standardization and monitoring of data reporting is necessary in order to increase their validity.

MBDS represent an accessible instrument for identification and measuring clinical risk. For purpose of utilization at national level we recommend first the validation of data used to build the indicators, and also the testing of the sensibility, specificity, and the positive and negative predictive values, after auditing the patient clinical chart". Limitations of the instrument can be surpassed if it can be integrated with other instruments of clinical risk, such as medical records audit, incident reporting etc.

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