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Clinical risk in rehabilitation: an exploratory investigation in Campania Region

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Key words: Clinical risk, rehabilitation, errors, management
Parole chiave: Rischio clinico, riabilitazione, errori, management

Abstract

Background: *Clinical risk management is a comprehensive programme that encompasses all the measures implemented to improve the quality of the healthcare service and ensure patient safety, which is based on learning through error. This process is intended to bring about ongoing improvements in clinical practice, starting with risk identification, before moving on to risk assessment and analysis, in order to reduce risks where possible. When clinical risk management is applied in rehabilitation, the first step involves identifying errors by assessing adverse events, which are considered to indicate the existing risk. Our work aims to explore the characteristics of the clinical risk in rehabilitation so as to learn more about its extent, its components, and its implications for the user.*

Methods: *Our study involved numerous workers operating in four different branches of rehabilitation – speech therapy, physiotherapy, psychomotor education and occupational therapy – at forty-nine private rehabilitation centres in the province of Naples, an area that has not been studied before. A questionnaire was drafted regarding the main errors committed in the rehabilitation sector. It was then distributed and collected in again, after which the results were analysed and outcomes measured. Out of a total of 556 questionnaires distributed, 493 were returned (88.6% response rate.)*

Results: *The study revealed that for all the rehabilitation branches considered, the macro-category of errors linked to technical and professional aspects accounted for the highest percentage of the total errors (39%). In this study, the most frequent errors linked to technical and professional aspects were: wrong dose errors, treatment planning errors and functional assessment errors.*

Conclusions: *There is an evident need to take action in order to manage the clinical risk in rehabilitation: to promote a concept of errors as opportunities for learning and improvement; to maintain the focus on both individual responsibility and on any systemic failings; to share fundamental values such as transparency, collaboration between workers, communication with patients, and a commitment to ongoing improvements in healthcare quality.*

Introduction

Clinical risk management is a comprehensive programme that encompasses all the measures implemented to improve the quality of the healthcare service and ensure patient safety, which is based on learning through error. The introduction of risk management in the delicate field of healthcare has led to the awareness that risk management is a systematic process of current and potential risk identification, assessment and handling, with the objective of increasing patient safety, improving outcomes and indirectly cutting costs, as well as reducing foreseeable adverse events.

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The risk profile, that is to say all the risks facing the healthcare organisation, has a unique nature and composition characterised by the objectives of the organisation itself. Therefore, the risk profile is dependent on the corporate mission, as well as on the internal and external characteristics of the organisation's operating environment (1). In healthcare, the risk profile is characterised by the extent of the *clinical risk*, defined as the probability of a patient falling victim to an adverse event, that is to say harm or discomfort that can be attributed, often unintentionally, to the medical care provided during his or her hospital stay, which may lead to a longer stay, deteriorating health, or even death (2). Healthcare is described as 'a risky business' (3) and is therefore a field in which patient safety plays a fundamental role, demanding increased attention on all levels, from all healthcare professionals. Although some areas are particularly subject to adverse events – such as operating theatres, wards, and accident and emergency departments – there are unfortunately no 'zero risk' areas of healthcare (4). While it is true to say that 'to err is human' and that all healthcare professionals work in an environment that presents an 'intrinsic risk', we can with statistical certainty also state that rehabilitation professionals can make mistakes too (5). What remains to be done is to establish the extent, the incidence and the type of harm these mistakes can cause to patients. Some authors claim that this matter has never been properly explored in rehabilitation for cultural reasons (6), perhaps because of a lack of awareness among professionals of their increased professional responsibility, due to a negative interpretation of the same, or because of insufficient involvement in the processes of guaranteeing patient safety and improving clinical quality (7). If we were to define a responsible person as someone who attempts to predict the possible effects of his or her conduct on others, it becomes apparent that risk assessment is an act required of all professionals who perform their duties responsibly. In fact, rehabilitation professionals can only guarantee patient safety and improve clinical quality if they are able to recognise and analyse risky and potentially harmful events in their professional practice. The objective of this work is, first and foremost, to explore the characteristics of clinical risk in rehabilitation so as to learn more about its extent, its components, and its implications for the user. Given the lack of tools for reporting errors specific to the rehabilitation sector, we also set ourselves the objective of designing a specific incident report form for use in this field. In greater detail, we will seek to identify the distribution of errors within each branch included in the analysis on the basis of the error types set out in the classification introduced in the study design. We will subsequently analyse the frequency at which the reported errors occur.

Materials and methods

During the first phase of the research, a questionnaire was drafted comprising a list of twenty-one items, corresponding to twenty-one possible errors in a rehabilitation environment. The study participants were asked to indicate their gender, profession, years of seniority, workplace, unit in which they work and type of work contract. When completing the questionnaire, they were required to select, from among the adverse events listed, those that had occurred at any time during their careers. For each type of adverse event, they were asked to indicate the number of times it had occurred, where it occurred and the severity of its effects on the patient. A space was also provided to describe the adverse event or to add comments. The study participants were given assurances regarding their anonymity. They were also given a guide to help them complete the

questionnaire. Our classification features a total of twenty-one error types, grouped into seven macro categories:

- Code 1: errors linked to structural aspects and the rehabilitation setting;
- Code 2: errors linked to information;
- Code 3: errors linked to organisational, bureaucratic and administrative aspects;
- Code 4: errors linked to technical and professional aspects;
- Code 5: errors linked to relationship aspects;
- Code 6: errors linked to the application of and adjustment to specific current legislation;
- Code 7: miscellaneous errors.

We provided for eleven classes of adverse events that could arise as a result of the abovementioned errors. The reporting tool was designed on the basis of two clinical risk studies conducted in the rehabilitation sector in Italy: the study conducted by Bertozzi and Amici on clinical risk in physiotherapy (8), and the study conducted by Scarton on clinical risk in speech therapy (9). Our study focused on workers operating in four different branches of rehabilitation – speech therapy, physiotherapy, psychomotor education and occupational therapy – at forty-nine private rehabilitation centres in the province of Naples, which work in partnership with the Italian national health service. Having decided to use a very vast setting in order to explore all the errors that may have occurred in rehabilitation practice, the sample also included professionals from a number of hospital facilities, local health authority units and private clinics in the province of Naples with whom we came into contact. Workers who operate on an occasional basis, without a permanent contract, were excluded from the study sample.

The questionnaires were distributed and then collected during the second phase, after which the results were analysed and outcomes measured. Out of a total of 556 questionnaires distributed, 493 were returned (88.6% response rate). However, it should be noted that three of the questionnaires returned did not include any details about the respondent, while forty-nine respondents claimed that they had never made a mistake at any point in their career.

Results

Table 1 clearly shows that the group of survey respondents is representative of all seniority levels, including young workers alongside those with more than thirty years of experience. Table 2, which features the main descriptive statistics of the variable in the two groups, shows the mean seniority of the healthcare workers analysed to be around nine and a half years, with a modal value of ten years.

An accurate assessment of the various components of the clinical risk in rehabilitation necessarily involves an examination of the following variables:

- the total number of errors that a worker claims to have committed throughout his or her entire career (Y);

Table 1 - Distribution of respondents by gender and years of seniority

(rel. fr. %)	years of service							
Gender	[0.2]	[3.5]	[6.9]	[10.15]	[16.25]	[26.35]	not stated	
M	3.40	5.22	6.12	5.22	4.31	0.91	0.68	25.85
F	10.20	17.91	13.61	15.42	14.29	0.68	2.04	74.15
Total	13.61	23.13	19.73	20.63	18.59	1.59	2.72	100.00

Table 2 - Descriptive statistics for the 'Years of Seniority' variable

Mean	9.3566434
Median	7
Mode	10
Sample standard deviation	6.93300
Sample variance	48.06643
Kurtosis	0.45014
Asymmetry	0.98585
Range	34
Minimum	1
Maximum	35
Sum	4014

- the number of errors in a certain macro category that a worker acknowledges having committed throughout his or her entire career (*Y1, Y2, Y3, Y4, Y5, Y6, Y7*);

- the number of errors associated with a certain item that a worker acknowledges having committed throughout his or her entire career.

The following relations are therefore valid:

Y = Y1 + Y2 + Y3 + Y4 + Y5 + Y6 + Y7
Y1 = Y1.1 + Y1.2
Y2 = Y2.1 + Y2.2
Y3 = Y3.1 + Y3.2
Y4 = Y4.1 + Y4.2 + Y4.3 + Y4.4 + Y4.5 + Y4.6 + Y4.7 + Y4.8 + Y4.9
Y5 = Y5.1 + Y5.2 + Y5.3
Y6 = Y6.1 + Y6.2
Y7 = Y7.1

The Y variable is a discrete variable. Moreover, as it regards interviewees who declared at least one error, it can never have a value of 0 and is configured as a 'zero truncated variable' in keeping with the statistical terminology used in international literature (10). Data regarding the values provided by the sample for this variable is compiled in Table 3 and Table 4, while Figure 1 features a bar chart that can be interpreted with the help of Table 5 showing the Distribution of frequencies for classes with absolute frequencies and relative percentages.

Table 3 - Y variable indicators

Sample mean	35.53968
Standard error	2.02083
Median	19
Mode	2
Standard deviation	42.43748
Sample variance	1800.94
Kurtosis	4.42023
Asymmetry	2.07028
Range	221
Minimum	1
Maximum	222
Sum	15673
Count	441
Coefficient of variation	1.194087
Semi-amplitude 95% confidence interval	3.971684

Table 3 reveals that $\sum_{i=1}^{441} Y_i = 15673$ and $\overline{Y} = 35.53968$. It emerges that the group of 441 rehabilitation workers reported a total of 15,673 errors, meaning that each of them could have been responsible for around thirty-five errors, on average, during the course of their careers. A rough average based on the field of variation and the interquartile range resulting from Table 4 reveals how the variability of the calculation quantified by Y is very strong. If we then consider the very high values assumed in

Table 4 - Y variable quintiles

10th percentile	3
1st quartile	8
Median	19
3rd quartile	44
90th percentile	97
95th percentile	128

Table 5 - Distribution of the total number of errors by place of occurrence

	abs. fr.	abs. cumul. frequency	rel. fr.	rel. fr. %
Other spaces	1841	1841	0.1175	11.7463
Inpatient facilities	929	2770	0.0593	5.9274
Outpatient facilities	11781	14551	0.7517	75.1675
Gym	1107	15658	0.0706	7.0631
Not stated	15	15673	0.0010	0.0957
	15673	Total	1.0000	100.0000

the sample by the standard deviation and the variance, we can add that the Y variable is characterised by overdispersion (11).

A combined assessment of the bar chart in Figure 1 and the skewness and kurtosis indices in Table 3, suggests that the Y variable has an abnormal and asymmetrical distribution.

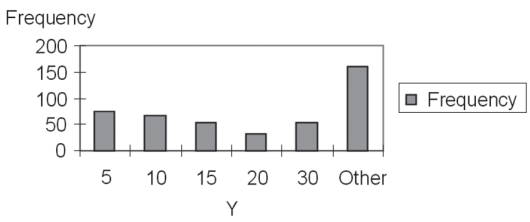

Figure 1 - Y variable bar chart

As already mentioned, the overall number of errors reported by the group as a whole amounted to 15,673. Table 5 indicates that these mainly occurred in outpatient clinics, which accounted for 75.17%.

Table 6, which provides detailed information on error distribution by severity, indicates that the consequences were mild in 40.16% of cases, while around 14% of the errors produced serious consequences. It should also be noted how more than half of the errors (51%) produced moderate or serious consequences.

Failure to declare the consequences of the error was a rare phenomenon, with only 0.06% omitting this information.

An analysis of the errors by macro category reveals that the majority of adverse events (39%) were linked to errors concerning technical and professional aspects (see Table 7).

Table 6 - Distribution of the total number of errors by severity of the consequences

	abs. fr.	rel. fr.	rel. fr. %
Near miss	1368	0.0873	8.7284
Mild consequences	6294	0.4016	40.1582
Moderate consequences	5870	0.3745	37.4529
Serious consequences	2131	0.1360	13.5966
Not stated	10	0.0006	0.0638
	15673	1.0000	100.0000

Table 7 - Distribution of the total number of errors in Rehabilitation by error macro category; estimated mean annual frequency of the generic and specific error for each macro category

Error macro category	abs. fr.	rel. fr.	rel. fr.%	Mean frequency of occurrence during a one-year period of activity
1	976	0.062273	6.23	0.24
2	2729	0.174121	17.41	0.67
3	2712	0.173036	17.30	0.67
4	6016	0.383845	38.38	1.48
5	2165	0.138136	13.81	0.53
6	786	0.05015	5.01	0.19
7	289	0.018439	1.84	0.07
	15673	1.0000	100.00	3.86

In this study, the most frequent errors linked to technical and professional aspects were: wrong dose errors, treatment planning errors, and functional assessment errors. *Macro category 2*, concerning errors linked to information, accounts for 17.41% of total events. It is the second biggest macro category in order of importance after that linked to technical and professional aspects. *Macro category 3* concerning errors linked to organisational, bureaucratic and administrative aspects, reaches almost the same level of importance, accounting for 17.30% of total events. The non-negligible percentage of the total errors represented by this macro category was certainly determined by the quantity of errors attributable to lack of communication with other rehabilitation team members (item 3.2). Moreover, item 3.2 accounts for the highest percentage out of the total (10.30%), as shown in Table 8. Tables 7 and 8 provide basic data for estimating the frequency of each error type over a set period of time. Choosing one year as the time period, an index that expresses the mean frequency of occurrence (of a specific error type across the entire rehabilitation sector) is given by the following ratio:

total number of a certain error type reported by the sample / total years of seniority of the group

In order to avoid distortion when calculating this type of ratio, it is important to exclude any responses that make no mention of the years of seniority. However, these responses do not need to be excluded when calculating the percentage of a specific error type out of the total errors, because in this case the seniority datum is not needed and does not produce any distortion. The value of these estimation indices is reported in the final column of Tables 7 and 8. The last line of this column reveals that a rehabilitation professional commits an average of 3.86 errors per year.

Discussion and conclusions

The study highlights interesting and unique aspects of the clinical risk in rehabilitation. It was conducted by means of a qualitative and quantitative statistical survey, which represents an innovation in the panorama of studies conducted in this field in Italy. To date, surveys regarding the clinical risk in rehabilitation have only been conducted on a very small number of professionals working in a certain branch or within a single facility. Our study involved numerous workers operating in four different branches of rehabilitation at various facilities in the province of Naples, an area that

Table 8 - Distribution of the total number of errors in Rehabilitation by error item; estimated mean annual frequency of the generic and specific error for each item

Error item	abs. fr.	rel. fr.	rel. fr.%	Mean frequency of occurrence during a one-year period of activity
1.1	636	0.0406	4.06	0.15
1.2	340	0.0217	2.17	0.08
2.1	1577	0.1006	10.06	0.39
2.2	1152	0.0735	7.35	0.28
3.1	1092	0.0697	6.97	0.27
3.2	1620	0.1034	10.34	0.40
4.1	813	0.0519	5.19	0.20
4.2	684	0.0436	4.36	0.17
4.3	812	0.0518	5.18	0.20
4.4	874	0.0558	5.58	0.21
4.5	495	0.0316	3.16	0.12
4.6	506	0.0323	3.23	0.13
4.7	1008	0.0643	6.43	0.25
4.8	650	0.0415	4.15	0.16
4.9	174	0.0111	1.11	0.04
5.1	731	0.0466	4.66	0.18
5.2	697	0.0445	4.45	0.17
5.3	737	0.0470	4.70	0.18
6.1	445	0.0284	2.84	0.11
6.2	341	0.0218	2.18	0.08
7.1	289	0.0184	1.84	0.07
	15673	1.0000	100.00	3.86

has not been studied before. The group identified for the study meets the criterion of representativeness, meaning that it presents all the characteristics of the reference population. The extensive participation of the interviewees should also be mentioned. Scepticism regarding the effective completion of the questionnaires by the interviewees was unfounded given the very small number of missing responses recorded. This point was certainly influenced by the approach adopted by the reporting tool, which was based on a more synthetic and practical classification of errors than others formerly proposed, while still being comprehensive and precise. The study succeeded in its attempt to record the distribution of all the error types proposed in the classification, the severity of the consequences and the place of occurrence. It revealed that, for all the rehabilitation branches considered, the macro category of errors linked to technical and professional aspects accounted for the biggest percentage of the total errors (38.38%). The importance of the macro category of errors linked to organisational,

bureaucratic and administrative errors should not be underestimated. The predominant error in this macro category was failure to communicate with members of the rehabilitation team, which accounted for 10.34% of the total errors across the rehabilitation sector. This leads us to reflect on the role played by cooperation between workers in achieving adequate levels of efficacy and safety in the provision of healthcare services. As the study design provided for the indication of the years of seniority, it was also possible to estimate the mean frequency of each error over a set period of time for each branch. This represents another innovation in the panorama of studies conducted in this field to date. For each branch of rehabilitation, the calculation of the mean frequency of each error type over a one-year period represents an initial attempt at the problematic quantification of the clinical risk by means of numerical indicators. Speech therapy and physiotherapy were the branches with the highest annual mean frequencies. The high number of notes and comments providing a more detailed description of the adverse events demonstrates, first and foremost, that the workers entered fully into the survey. Moreover, these notes provide grounds for reflection on the causes of the errors and guidelines for the execution of future studies on the origin of adverse events. A more thorough analysis of the notes reveals the negative effects deriving from organisational and management shortcomings within the system, which created favourable conditions for the occurrence of an active error. It is therefore important not to overlook latent errors that, despite remaining concealed within the system, incapable of causing overt symptoms on their own can give rise to an adverse event when they occur in connection with other causative factors and in favourable conditions. In greater detail, the latent errors that emerged regarded poor maintenance of equipment, lack of rehabilitation tool uniformity, inadequate identification of roles and work organisation, excessively small, unhygienic and insufficiently private therapy areas, wrong dose errors linked to local health service prescriptions, and too many services per unit of time, with the consequent impossibility to communicate with other professionals. Some workers reported the existence of other types of errors, such as excessive empathy and the risk of burnout.

A meter for assessing the severity of the errors emerged for each branch.

For physiotherapists, the serious errors regarded:

- lack of communication with members of the rehabilitation team;
- sprains;
- epidural haematomas from falls;
- performance of manoeuvres resulting in femoral neck injuries in patients with osteoporosis.

According to speech therapists, the serious errors led to:

- delays in achieving the objectives as the result of an incorrect functional assessment;
- falls within the rehabilitation setting;
- lack of communication with other professionals.

The reported results may have been influenced by the following limitations apparent in the study:

- the setting was formed by professional environments with no tradition of participating in research studies, whose workers were not accustomed to reporting their errors;
- some interviewees may have doubted that their anonymity would be respected and, as a result, may have under-reported the events due to fear of their mistakes being discovered.

Discovering that a group of 441 rehabilitation professionals admits having committed 15,673 errors during the course of their careers, means we can state with certainty that rehabilitation is not free from risks to patients. Moreover, finding

that 13.60% of these errors caused serious consequences demonstrates not only that rehabilitation can harm patients, but also that said harm is not insignificant. In this sense, rehabilitation, like other healthcare disciplines, entails an intrinsic and often overlooked risk. It is no coincidence that Campania Region Decree No. 124 of 10/10/2012, which sets out rules for definitive institutional accreditation in accordance with Regional Law No. 23 of 14 December 2011, in the checklist of specific requirements to be met by rehabilitation centres, expressively requires that 'training is to be provided for all personnel, in order to promote the culture of preventing adverse events' and 'procedures for reporting adverse events must be identified, defined and adopted, and must meet the following criteria: what happened, where, when, how and why; what action has been implemented or proposed; what impact did the event have on the patient, on other people, on the organisation; which factors have or could have minimised the impact of the event. 'It also establishes that 'organisational measures and appropriate technologies must be identified for the reduction of adverse events' (12). Hence the need for rehabilitation facilities to undertake measures designed to manage the clinical risk: to promote a vision of errors as opportunities for learning and improvement (leaving behind the deep-rooted attitude of blame and culpability); to maintain the focus on both individual responsibility and on any systemic failings; to share fundamental values such as transparency, collaboration between workers, communication with patients, and a commitment to ongoing improvements in healthcare quality. To this regard, a specific form has been designed for reporting adverse events in rehabilitation. In the rehabilitation sector, clinical risk management coordinators will have the role of: promoting ongoing professional development; ensuring proper integration between professionals; encouraging, involving and giving responsibility to collaborators; carrying out proper risk analyses and assessments in order to manage critical events; adopting corrective strategies to reduce the risk of error and systematically support methods based on scientific evidence. The hope is that this work does not remain an isolated effort, but that, as highlighted in the European Union Council Recommendation on Patient Safety, a validation process is introduced for standardised adverse event reporting systems, specific to the rehabilitation system, such as the one we have proposed, worker training is promoted, a *culture of learning through error* is propagated, and further research is conducted regarding clinical risk in rehabilitation (13).

Riassunto

Il rischio clinico in riabilitazione: un'indagine esplorativa nella Regione Campania

Background: La gestione del rischio clinico è un processo che mira al miglioramento continuo della pratica clinica partendo dall'identificazione dei rischi, proseguendo con la loro valutazione e analisi, per arrivare alla loro riduzione, ove possibile. Volendo applicare questo processo in ambito riabilitativo, il primo passo è quello di identificare gli errori, attraverso la rilevazione degli eventi avversi, considerati segnalatori del rischio esistente. Lo scopo del nostro lavoro è quello di esplorare le caratteristiche del rischio clinico in riabilitazione per conoscerne le dimensioni, le componenti e le implicazioni per l'utente.

Metodi: La nostra ricerca ha coinvolto numerosi operatori di quattro branche della riabilitazione appartenenti a numerose strutture collocate in un ambito territoriale mai esplorato, che è quello della provincia di Napoli.

Risultati: Dallo studio è emerso che per tutte le branche della riabilitazione considerate, la macrocategoria di errori legati ad aspetti tecnico-professionali è risultata essere quella avente il peso in percentuale più elevato sul totale degli errori.

Conclusioni: Si evince la necessità di intraprendere azioni mirate alla gestione del rischio clinico in riabilitazione: sostenere una visione dell'errore come occasione di apprendimento e di miglioramento; mantenere viva l'attenzione sia sulla responsabilità individuale che sulle

eventuali inefficienze del sistema; condividere i valori fondamentali come la trasparenza, la collaborazione tra gli operatori, la comunicazione con il paziente e l'impegno per il miglioramento continuo della qualità assistenziale.

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