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[Opinion]**Evidence under threat:
Risk communication in an era of alternative facts**

Bruce Hugman

Uppsala Monitoring Centre 2017, Sweden

In his hilarious and alarming book, *Spurious Correlations*, Tyler Vigen, demonstrates that there is an almost perfect match between the divorce rate in the State of Maine and the per capita consumption of margarine; between US spending on science, space and technology and suicides by hanging, strangulation and suffocation. How many people might fall for these almost perfectly aligned trends based on multiple data-points and neat graphics? Well more than we should feel comfortable with, for sure.

Alternative facts, fake news and falsely attributed causality belong to an ancient human tendency: the urge to mislead or manipulate friends and foes for some kind of advantage.

Since ancient times, churches, governments, companies, institutions, interest groups, charlatans, quacks and everyday individuals have continued to make havoc with the truth for nefarious purposes. Today, I will explore some of the ways in which our perceptions of reality are being manipulated and corrupted in the 21st century; I'll make some suggestions about the principles underlying the strenuous defence we as (much of the time) rational thinkers and scientists need to mount against the tsunami threatening to overwhelm rationality and good sense.

There are several ways of making havoc with the truth: the most basic is lying – asserting something that is known not to be true by the person lying; the thief denying the theft, the politician denying the sexual relationship; the pharmaceutical company denying the adverse effects in their data; James W Johnston, the CEO of R J Reynolds telling a Congressional Committee, 'Cigarette smoking is no more addictive than coffee, tea or Twinkies'. Lying is in some senses manageable: it has an essential relationship to the truth (that is, being its opposite), and usually, through investigation or the passage of time, the truth will out, one way or another; history unmasks lying and calls liars to account. That, of course, presupposes a culture in which truth is valued and can be spoken.

All other forms of half-truth or untruth – propaganda, spin, disinformation, alternative facts, junk science, fantasy and fabrication are much more problematic, because they may have only a slight toehold in the realm of truth or no connection with it at all. In a long tradition of popular and academic discourse, these are all encompassed in the previously vulgar term, *bullshit*, which is now commonly used as short-hand for all kinds of chicanery in communication. Such chicanery is insidious because it infects perception of the truth; it is slippery, it cannot be argued away when there are no facts or evidence to contest, or when it is motivation and not facts or evidence that are in contention; facts and evidence are cherry-picked or

disregarded or disparaged as irrelevant to the message: vaccinated babies become autistic; homeopathy works; medicine is a conspiracy against the laity; our anti-depressant is safe; the government is keeping its promises; immigrants are milking the state; climate change is a hoax; GMO foods will destroy us. Philosopher Harry Frankfurt, in his influential book *On Bullshit*, writes: 'Bullshit is a greater enemy of the truth than lies'; and we have great reason to fear it.

Irrational beliefs, like climate-change denial, are not based on the narrow kind of evidence we call data (we might say, 'facts') but on political or belief-based conviction. While the tentative, non-linear progress of science rarely asserts certainty, there is an overwhelming scientific consensus about many issues, including climate change, but healthy scepticism about uncertain issues, or past errors, can degenerate into cynicism about the whole enterprise and the motives of those who promote it. Data is a specialized category of testimony, which, along with first-hand experience, is the broad evidence we accumulate, first- and second-hand, from our lives and the experience of others, that shapes our beliefs and behaviour. Frighteningly, much of the testimony to which modern audiences are exposed is unadulterated rubbish [bullshit].

We know that most of our preferences and responses to the external world are driven by what is known in neuropsychology as System 1- reflexive rather than System 2 reflective, instinctive rather than evaluative. Reflexive agility is highly adaptive in evolutionary terms, but it is not a friend of the scientific method.

Primary group affiliations exercise enormous power over us. If personal identity is based on shared beliefs, especially in a group with charismatic or celebrity endorsement, then loyalty will be consolidated by powerful social processes, and group beliefs are likely to be intensified by external threat, criticism or challenge. Having social support, from an evolutionary standpoint, is far more important than knowing the truth. The louder we decry the beliefs of dedicated vaccine-sceptics, the more our positions are likely to polarize; the more assertive we are in promoting the data, as a tactic of persuasion, the more will the data, and us and our affiliations be questioned, disparaged or vilified.

There was a time when most people seemed to accept that there was a difference between experts and laypeople and that, on the whole, experts and professionals could be trusted to give good advice and keep you safe. In recent years, there has been a critical loss of respect for those claiming to have knowledge, expertise and experience. The 'fourth estate' of journalism has often fuelled this new cynicism. Self-seeking politicians, greedy bankers and incompetent economists, dishonest commerce, fraudulent science, wicked doctors, the rise and fall of health theories and fads, have all contributed to public cynicism and weariness with those who set themselves up as experts; people who have, so often, been misguided or wrong. Who can we trust? Increasingly, people say they trust family, friends and peers above so-called experts.

We are all, to some extent in some kind of bubble, though yours and mine are, of course, more mature, rational, porous, and evidence-based than those of many others – aren't they? On the other hand, if you feel that Jenny McCarthy or Joseph Mercola or Nigel Farage or Donald Trump speaks for you, then you sign up and join a powerful, vocal community; drift further and further away from rationality and what was once the moderate common ground where issues might have been debated. Preaching to the converted – they to theirs, we to ours – doesn't change anything, of course. They would say, dismissively, of me and the analysis I am presenting to you in this environment, 'Well, he would say that, wouldn't he?'

The liberating and democratising impact of social media and the internet has also given rise to a race of self-styled experts, whose idiosyncratic, anecdotal, belief-based postings attract attention and approval and

spread rapidly round the world. Likes, friends, followers, sharing, re-Tweeting and instant videos, can give spurious weight and authority to pure bunkum ('miracle' cures and medical disasters among them) while an often hungry and pliant audience can be quickly whipped into enthusiasm for all kinds of weird and irrational causes. Within this turmoil of dynamic, glibly-communicated material, serious science and traditional experts can hardly hope to be visible or audible. Traditional media have played their part in creating this toxic environment; institutional oversight and peer-review have failed to provide a sufficient bulwark even in our own sphere.

In 2002, George W Bush's chief of staff, Karl Rove, chided a reporter by saying: 'People like you are in what we call the reality-based community. You believe that solutions emerge from judicious study of the discernible reality. That's not the way the world really works any more... We're an empire now, and when we act, we create our own reality.' (This is chillingly close to O'Brien's assertion of the The Party's definition of reality in Orwell's 1984.)

Arron Banks, the multimillionaire behind Leave.EU, the campaign for Brexit, cheerfully attributed their success to the mantra "facts don't work". Speaking after his referendum triumph, he said: "The Remain campaign featured fact, fact, fact, fact, fact. It doesn't work. You've got to connect with people emotionally. It's the Trump success."

Kellyanne Conway at the White House this year, following this mode of thinking, launched herself on the world with her 'alternative facts' about countable crowd numbers at presidential inaugurations.

'Fake news' – while a feature of all human societies in the sense of 'fabricated news' has also acquired the meaning of 'news I disapprove of', irrespective of its representation of reality; the term takes us one degree further from knowing the truth.

The fundamental Enlightenment value of 'dispassionate secular reason' and its powerful offspring, the scientific method, are not what primarily drive world affairs or the thinking of most human beings. Below the veneer of rationality and civilized restraint, a tempest of emotions, images, prejudices and narratives is constantly in the making, a tempest – of violence too - that can be unleashed by dramatic events or manipulative leadership.

Homeopaths, climate-change deniers, ideologues of all kinds, emphatically don't believe in Enlightenment values or in the 'reality-based community.' But what they do, and do supremely well, is connect with people sentimentally, emotionally, and with the inner turmoil and frustration modern life generates. And they tune into the new vilification of expert advice and of élites and social privilege which have so conspicuously frustrated promises of the good life for all.

With our acts of faith, as scientists, in the intelligibility of nature, the scientific method and the power of data, we have largely missed the boat on which the great majority of the world's population are sailing. While the expertise of plumbers and engineers, even some health professionals, remains largely valued, where expertise and data tread on the coat-tails of political priorities or common prejudices and preferences or the emotions generated by heart-wrenching stories or popular campaigns, they are under threat. On the whole people do not yearn for the data

concerning a class of events to which a vivid anecdote belongs and which has prompted their tears.

The usual forms of assertive scientific or public health communication often have perverse effects because they do not take account of – often are in culpable ignorance of - the context, mood, preoccupations and priorities of audiences; issues way beyond data overwhelm attention, and swamp frail shoots of analysis. The platform of broad belief and testimony on which people build their lives may not accommodate the narrow evidence of data at all. For us, the dilemma is that data alone (and almost certainly patient information leaflets) cannot provide the quality of answers that patients are looking for and they do turn elsewhere for the reassurance and confidence they are seeking.

In this environment, stories and scandals, conviction or revelation of one form or another, tend to knock scientific knowledge into a cocked hat.

So, from being dangerously on the back-foot, what can we do to recover? Here are some tentative thoughts about tactics, many of them based on good evidence:

First: arguing, cascading facts and debunking myths are unlikely to have much effect.

We must articulate the case for change in ways that appeal to the values that are important to the audience and their own ways of thinking about the world, rather than trying to change their world view altogether. 'You cannot,' Ben Goldacre wisely remarks, 'reason people out of a position that they did not reason themselves into.'

We must put the pragmatic arguments that might be most likely to win hearts and minds front and centre rather than arguments that address what we find morally objectionable or outrageous about the views of others. Start there; start with addressing the fundamental deficiency of Joan Williams' 'class cluelessness.' (The perception of élitist detachment and indifference has been a major cause of alienation and discontent.)

We must avoid polarisation and explore ambivalence: not everyone is 100% committed to any one position; if we attack, we will alienate potential waverers as well as core believers; we must seek those who might be persuadable.

Abandon crude binary perspectives (yes/no; right/wrong); adopt more measured processes of exploratory conversation.

What can we all agree on? Find a consensus starting point and a common ground beyond language (the (important) health literacy bandwagon goes no further than language; even if we speak the same language, how can we begin to identify the areas of common *feeling* and *values* we might have that drive the language we use?)

We must co-opt the power of stories and anecdotes. The world of bullshit and fake news is driven by vivid, memorable, colourful headlines, memes and images and by very short stories; we have to learn to compete; we have to abandon lecturing and didacticism and tired old bureaucratic language and methods. If we want to pick holes in the stories people tell themselves, we have to find ways of filling the gaps, so the stories are complete. An incomplete story is less tolerable than untruth.

Change passive listeners into active participants in scientific discussion; involve patients in every stage of planning and research; identify and promote champions from amongst those we hope to influence; depoliticize differences of opinion; reclaim the world of facts.

If mood and context determine memory and affect, as evidence suggests they do, then we must create enabling moods and contexts; populist leaders are expert at this – rallies, festivals, communities, the badges and privileges of membership, safe and comfortable spaces, enabling and inspiring leadership.

Make sure that messengers are liked and trusted; find people most like the audience, or most finely attuned to audience values and emotions (this is just what Trump and the Brexit campaigners did).

We need to be much more alert to the complexities of reasoning and memory and to the varied and unpredictable ways in which people assess risk – ways that are not at all like those of scientists. We must find ways of expressing and communicating risk that are simple, vivid and meaningful to lay audiences. These will vary immensely across populations and must answer the questions that matter to patients and to all citizens.

A radical thought from Dan Kahan: 'Many of the difficulties in effective science communication, we believe, are a consequence of forms of communication that needlessly put people in the position of having to choose between using their reason to be who they are and using it to know what is known by science.' We must try and respect and protect the integrity and identity of those we disagree with; disparagement is not a tool to facilitate change.

Nevertheless, we must continue, meticulously and conscientiously, to promote the scientific method, the integrity of its practice, the primacy of evidence and the uncompromising nature of facts and to insist that public policy should be unashamedly evidence-based, and promoted confidently and proudly as such.

Following the enlightened decision of Taiwan to introduce critical thinking and propaganda awareness as a specific field of study in its schools, we must address the intellectual weakness of much of the education of children and proclaim and nourish Enlightenment values and skills, the scientific method, statistical literacy and bullshit-detection at every stage.

An eloquent conclusion from a Guardian Opinion piece April 2017: 'It is not enough to understand the world. The point is to change it. And that requires all the skills of politics and of cultural warfare that some scientists shun and many believers in science practise rather badly...for that to happen there will need to be political sophistication as well as political force on the part of all the supporters of enlightenment.'

We are to blame for not having taken the threats seriously enough. There is a tough road ahead.

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[Original]

Are there more incidents in the emergency department during the months of overload? Review through the back to the emergency service (ES).

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Abstract

[Objective] To analyze the discharge reports of the patients who return to consult in the ER within 1 week after an initial care, in search of possible incidents in the first attention. Compare the data between two months with different care load.

[Material and method] We reviewed the medical history of all patients who attended our emergency department in February 2017, and who returned at least one visit in the next 7 days. Of these, 370 cases were analyzed to explore the existence of some failure in the first attention and the presence of security incidents. The data source has been the computerized report. They have been analyzed by doctors of the emergency service.

[Results] Of the 4355 patients seen, 368 were identified as case. Of these, 305 (83.7%) came for some cause related to the first visit. Safety incidents were found in 32 cases, 8.7% of the re-tests (confidence interval 5.8-11.6%). Regarding the repercussion it has had on the patient, in 26.6% there was physical damage that required additional treatment and in 53.3% it has needed additional tests to check consequences. 48.1% of those incidents have been considered avoidable.

In 2013, there were 24 incidents of 366 re-examinations (6.56% with ic = 4.1% -9%). There were no significant differences with to this year ($p = 0.12$).

[Conclusions] 8.7% of incidents have been evidenced in patients who recover within a week in the emergency room, without a significant increase compared to months of lower healthcare burden.

1. Introduction

Emergency services (ES) have a high potential risk for security incidents. The conditions of work are conducive to making mistakes, clinical decisions must be made sometimes quickly and without sometimes having all the information, in a high pressure environment^{1,2,3}.

If this is the natural working environment, when conditions are worse due to increased attendance, difficulty of entry or delays in general care, the risk of error increases and consequently, the appearance of security incidents could also be greater^{4,5,6}.

The problem is how to quantify it, because in studies of safety incidents performed in the emergency department, we find an important disparity of results, depending on the method used⁷.

One of the sources classically used for its detection and study is the declaration of security incidents, although as some authors point out, it gives partial information, since it is not a widespread practice, and it is estimated that less than 10% of events are declared^{8,9}.

Another approach would be to study the cases of patients who return to consult to ES in short-term¹⁰. Previous studies of safety incidents in the emergency department indicate that between 3 and 7% of consultations originate in a previous incident and, in turn, that more than 20% of incidents occurring in the emergency department result in requiring at least one new assistance^{11,12}. We had explored this data source 4 years ago to analyze safety incidents in a relatively quiet month and we wanted in this study to compare data from a month with overload in ES.

2. Material and method

This study is a retrospective descriptive study in two different periods of time. This study was conducted in a public hospital emergency department

The medical history of all patients attended in our emergency department in february 2017 and who returned at least one visit in the next 7 days, were reviewed. All of them were analyzed to explore the existence of some failure in the first attention and the presence of security incidents. The data collection was performed by the healthcare staff (doctors) of the emergency department itself (internal evaluation). The cases considered as safety incident were review for two person.

The result was compared with a study with the same methodology made in june 2013. In february in 20 days had more than 10 patient waiting for an admisión an 10% more patient that the annual average. In june 2013 ther was not problema with the admisión any day. As statistical method, we used the Chi-square test to compare proportions. The level of significance was 95%.

3. Results

In February 2017 4355 patients were seen in our service. Of them, 368 (8,4%) were identified as case because returned in the seven next days of the first visit. Of these, 305 (83.7%) came for some cause related to the first visit and the rest (53 cases) because a different motive.

Safety incidents were found in 32 cases, 8.7% of the re-tests (confidence interval 95% 5.8-11.6%). Regarding the repercussion it has had on the patient, in 26.6% there was physical damage that required additional treatment and in 53.3% it has needed additional tests to check consequences. The effects that have occurred in the patient have been related to general effects in 50% of cases and the medication in 33.3%. The 48.1% of those incidents have been considered avoidable.

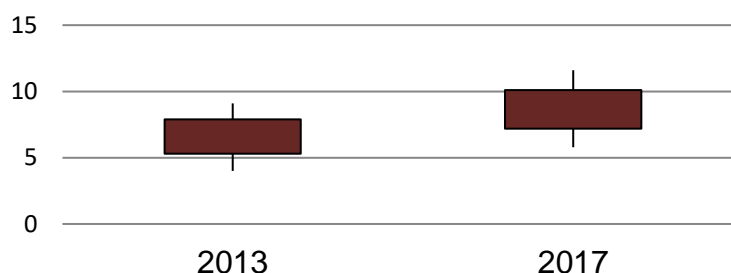
In June of 2013, there were 24 incidents of 366 re-examinations (6.56% with in = 4.1% - 9%). There are no significant differences between both of them ($p = 0.12$). See Figure 1.

4. Discussion

The method of revision reconsults allows comparing results as a source of data that does not depend on the will of the notifiers, as in the case of voluntary declaration. In addition, it allows to review all the cases of a period of time to be a accessible number of cases. Regarding the results obtained, although no significant differences were evidenced, if more incidents of patient safety were found in the month of greatest overload.

As limitation of this study, we can say that the percentages of incidents are low in the two months and this may help to show no statistical differences. Another limitation to compare is the 4 years between the two periods of time. In this time in this service we have worked on improving patient safety and this may have had a positive impact.

Grafic 1: Diferences between the safety incidents found in the two periods of study.
($p=0,12$)



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[Original]

Falling in Hospitalized Patients under the Influence of Soporific Agents: An Analysis of Public Adverse Event Reports on the Web

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Abstract

[Objective] Falling is an adverse event caused by patient-related factors such as age and muscle weakness. The use of soporific agents in the presence of such factors has a significant impact, and the role of nurses in administering such medications cannot be ignored. We analyzed information regarding hospital falls that occurred after administration of soporific agents, and examine some preventative measures for patients

[Methods] In April 2017, we searched for reports on patients who fell while under the influence of any drug. Of a total of 497 search results, we selected the 229 that corresponded to patients who received soporific agents. We then classified the reports by characteristics of fallen inpatients, fall-related injuries, time frames of occurrence and some circumstances of the fall, method of administering soporific agents, and Improvement measures against falls. We used descriptive statistics and the chi-square test for analysis.

[Results] Approximately 83% of falls occurred during the late-night time frame, between 2200h and 0600h the next day. The behavioral purpose of inpatients was usually excretion. Half of the events occurred in patients over 80, and approximately 60% of fall-related injuries were fractures. 56.3% of fallen inpatients used soporific agents regularly. On Improvement measures, excretion assistance and inpatient education was described in about 70% of all cases, respectively. But only a few measures involved insomnia interventions such as warm baths for the feet.

[Conclusions] Aging, cognitive or gait disturbance, and disease are falling risks, as is the use of soporific agents. Because fall risk assessments are carried out continuously, doctors, nurses, and pharmacists should engage in patient-specific conferences on the use of soporific agents. Moreover,

it is important to provide sleep assistance that does not rely on soporifics by enlisting the cooperation of shift workers and families.

Key words: falling, soporific agents, improvement measures, insomnia, hospitalized patients, nurses

1. Introduction

Patient falls are the most common adverse events in hospitals and healthcare facilities.¹⁾²⁾ These incidents result in additional treatment and extension of hospitalization for fall-related injuries. Damage due to falls range from minor to serious; examples of the latter include fractures, excessive bleeding, subdural hematomas, brain contusion, and even death.²⁾³⁾ Since 2008, in the USA, the Centers for Medicare & Medicaid Services do not reimburse hospitals and healthcare facilities for fall-related injuries sustained within them, based on the premise that the injuries could reasonably be prevented through the application of evidence-based guidelines.⁴⁾⁵⁾ Therefore, the high costs of falls represent unreimbursed expenses for medical facilities.⁶⁾ In Japan, under the universal coverage system, most medical costs are covered by public health insurance, paid to the hospital. However, patients are responsible for 10–30% of the cost of care as a self-payment. Consequently, patients who fall experience both unexpected suffering and cost. Hence, establishing preventive measures against patient falls is an important issue for medical institutions.¹⁾³⁾

Preventing falls requires assessing and managing patients at risk for falls, and implementing interventions on the patients assessed risk.^{5,7} Risk factors contributing to falls are broadly categorized into intrinsic factors and extrinsic factors, and falls are commonly due to interactions of those risk factors.⁵⁾⁸⁾⁹⁾ Intrinsic factors can be defined as those related to patient characteristics such as age, gender, fall history, medical condition, impaired mobility or gait, visual/auditory impairment, musculoskeletal deficits, nutritional deficiencies, and cognitive impairment; Extrinsic factors are those related to the environment as the physical environment of the hospital, medications, supportive and assistive equipment in bathrooms, lighting, and footwear.⁶⁾⁹⁾⁻¹¹⁾ Because intrinsic factors are related to patients' characteristics, they cannot be easily eliminated. By contrast, it should be possible to review the medicines taken by each patient or improve the recuperation environment. For example, items such as "keeping hospital bed brakes locked" and "place patient bed in low position" related to extrinsic risk factors were

mentioned by nurses in top 10 highly effective preventive intervention against falls.¹²⁾ And medications such as opioids, neuroleptic agents, benzodiazepines and tricyclic antidepressants were identified as extrinsic factors leading to increased fall risk.¹³⁾ Use of certain medications has a significant impact, and the role of nurses in administering such medications cannot be ignored. In particular, previous drug studies suggested that the appropriate selection of hypnotic or soporific drugs might be important for reducing the number of patient falls.¹⁴⁾⁻¹⁶⁾ Based on these findings, the authors proposed that pharmacists should recommend about selection of hypnotic or soporific drugs to physicians.¹⁵⁾¹⁶⁾

Soporific agents are generally used when patients complain of insomnia, as a remedy medicine rather than as a component of a treatment regimen. Although anti-hypertensives are therapeutic medications that must be taken every day, soporific agents do not need to be taken if inpatients are not insomnia. What measures could be implemented by nurses in order to prevent falls by patients under the influence of soporific agents?

The objective of this study was to analyze information regarding hospital falls that occurred after administration of soporific agents, and to examine some preventative measures for patients.

2. Methods

2.1 Design

Retrospective descriptive research design using secondary data based on public adverse event reports on the Web.

2.2 Public Adverse Event Reports on the Web

Based on Japanese laws and regulations, medical adverse event information is collected by the Japan Council for Quality Care in the Project to Collect Medical Near-miss/Adverse Event Information.¹⁷⁾ In January 2010, in response to numerous requests from medical institutions participating in this project, and researchers, and many other stakeholders, the Japan Council for Quality Care developed a Web-based search system that enables event information to be perused and downloaded without disclosing the

medical institution or date of occurrence.¹⁷⁾ Event information is retrieved in the 'event' category, but since the date of occurrence could not be specified in the search system, all cases since January 2010 were included. This service is available only in Japan.

The number of medical institutions participating in this project increases every year. At the end of 2015, medical institutions subject to reporting requirements (209 government institutions) and voluntarily participating medical institutions totaled approximately 1400 institutions. However, not all adverse events at those institutions will be reported. Medical adverse event information that is subject to reporting indicated by the Japan Council for Quality Care is defined as follows; a) apparent errors in treatment or management that resulted in the patient's death or mental or physical disability, or required unexpected treatment, treatment to an unexpected extent, or other medical procedure; b) suspected errors in treatment or management that resulted in the patient's death or mental or physical disability, or required unexpected treatment, treatment to an unexpected extent, or other medical procedure; c) other than events described in a) and b), information conducive to the prevention of medical adverse events and their recurrence at medical institutions.¹⁷⁾

The downloaded event information sheets can be printed individually. The front of the information sheet describes case ID, occurrence time frame, patient, persons involved, and summaries and severity of the event by category code. The reverse side describes the objective of the treatment provided, summary of the event, overview of factors behind the adverse event, and measures for improvement. Some cases are described in detail and others briefly, so the information obtained is non-uniform. Reporting to the Japan Council for Quality Care should take place within two weeks of the event, requiring efforts of the medical institution staff to identify events and prepare reports. The reported information constitutes valuable data that contribute to medical safety.

2.3 Data Collection

In April 2017, information regarding hospitalized inpatient falls under the influence of soporific agents and discovered by a nurse was retrieved. Information retrieval was limited to inpatients in departments of internal medicine in order to exclude factors such as limitation of body movement due to surgery or trauma, or the influence of sedative drugs. Data was recovered by clicking on nursing care categories on the event

summary, and then departments of internal medicine (internal medicine, cardiovascular medicine, respiratory medicine, neurology, etc.) and 'nurse' were selected from the pull-down menu related to clinical departments and the person involved. Psychiatry was excluded. A total of 497 hits were retrieved by entering "falling" and "under influence of medicine" in the keyword box. Among all cases identified, we selected those in which soporific agents were specified. Because administration by injection is usually performed for sedation rather than promotion of sleep onset, cases involving injection were judged as irrelevant to the objective of this study, and were excluded.

2.4 Data Analysis

Researchers created a summary table based on nominal data extracted from the described information. A total of 23 items were classified into the following three categories:

1) Inpatient information: age, gender, disease resulting in hospitalization, cognitive disorders, and disability.

2) Circumstances of the fall: fall-related injury and injured site, time frame of occurrence, signs leading to identification of the inpatient's fall, inpatient's actions before the fall, excretory behavior status, general condition, special symptoms and medical care status, method of administering soporific agents, and overview of factors behind the fall.

3) Improvement measures: inpatient guidance, assistance with excretion, behavior detection, shock mitigation, restraints with respect to getting out of the bed, soporific agent management, and insomnia intervention (referring to the prior literature¹⁸⁾⁻²⁰⁾).

We examined whether the terms described had the same meaning, and then classified and aggregated them. Because general condition was not directly expressed, it was categorized by researchers as worse, stable, or recovering, based on the description of special symptoms (debility, fever, anemia, hypoxia, etc.) and medical care status (discharge planned, rehabilitation, fall history). Because researchers had between 7 and 25 years of nursing experience, we judged that we could accurately assume inpatients' general conditions. Nominal data was assigned numerical values for analysis. Descriptive statistics and chi-square tests were performed using SPSS Statistics version 21.0 for Windows (IBM Corporation). The significance level was $p < .05$.

2.5 Ethical Considerations

The Japan Council for Quality Care clearly states that adverse event reports on the Web will be sent

not only to the medical community but also to Japanese society as a whole, thus creating a virtuous circle of further improvements in medical safety.¹⁷⁾ In 2011, we consulted with the organization by phone to discuss the pros and cons of using event information on the Web as analytical data in nursing research. Because the medical institution and date of occurrence are kept private,

anonymity of information is guaranteed. For data extraction and classification, researchers reviewed each other's work to ensure the reliability of data interpretation.

3. Results

In total, we analyzed 229 cases corresponding to the objective of this study.

Table 1: The characteristics of fallen inpatients and the fall-related injuries (n=229)

age n (%)	gender n (%)	hospitalization diseases n (%)	disorders n (%)	fall-related injuries n (%)
80 or over 120	male 57 (25.0)	cancer 18 (7.9) respiratory 34 (14.8) cardiovascular 28 (12.2)	cognitive 19 (8.3) physical 33 (14.4) both 19 (8.3) no description 48 (21.0)	fracture 75 (32.8) laceration 19 (8.3) braindamage 15 (6.6) others 11 (4.8)
	female 63 (27.5)	others 40 (17.5)		
60 to 79 102	male 55 (24.0)	cancer 37 (16.2) respiratory 19 (8.3) cardiovascular 14 (6.1)	cognitive 10 (4.4) physical 25 (10.9) both 12 (5.2) no description 56 (24.5)	fracture 60 (26.2) laceration 19 (8.3) braindamage 9 (3.9) others 14 (5.7)
	female 47 (20.5)	others 32 (14.0)		
59 or younger 7	male 3 (1.3)	cancer 1 (0.4) respiratory 2 (0.9)	cognitive — physical 3 (1.3) both 1 (0.4) no description 3 (1.3)	fracture 4 (1.7) laceration 2 (0.9) braindamage — others 1 (0.4)
	female 4 (1.7)	cardiovascular — others 4 (1.7)		
80 or over 120 (52.4)	male 115 (50.2)	cancer 56 (24.5) respiratory 55 (24.0) cardiovascular 42 (18.3)	cognitive 29 (12.7) physical 60 (26.2) both 32 (13.7) no description 108 (47.1)	fracture 139 (60.7) laceration 40 (17.5) braindamage 24 (10.5) others 26 (11.3)
79 or younger	female 114 (49.8)	others 76 (33.2)		

p=chi-square test

3.1 Characteristics of Fallen Inpatients

Table 1 showed the characteristics of fallen inpatients and the fall-related injuries. Approximately half (52.4%) of the subjects were over 80 years old, and the male/female ratio was approximately 1. Diseases responsible for hospitalization were broadly classified as cancer (24.5%), respiratory (24%), cardiovascular (18.3%), and other (brain, neurological, kidney, etc.). The former three serious diseases accounted for about 67% of all cases. The percentage of cancer was significantly higher between the ages of 60 and 79 than in inpatients aged 80 years or older ($p = .001$), likely representing the most probable age range in which inpatients receive cancer treatment. Approximately 53% of inpatients had cognitive disorders (dementia, nightly delirium, etc.) or

disability (walking, vision, hearing etc.), of which about one quarter had both types of disorders.

3.2 Circumstances of Falls

As shown in Table 1, approximately 60% of fall-related injuries were fractures; in 56.2% of fracture cases, the injury site was the femur. Approximately 10% of falls resulted in subdural hematoma or cerebral hemorrhage. Three inpatients died from their falls.

Many institutions in Japan turn off their lights around 2100h; therefore, soporific agents are most often administered to inpatients by nurses around that time. As shown in Figure 1, approximately 83% of falls occurred during the late-night time frame, between 2200h and 0600h the next day, presumably due to sustained drug effects. The

behavioral purpose of inpatients who fell during the late-night time frame was usually excretion (75.1%), significantly higher than during other time frames ($p = .002$).

The analysis results on other circumstances of falls are shown in Table 2. Approximately 46% of fallen inpatients were able to engage in excretory behavior by themselves, whereas the remainder required assistance (including use of nighttime portable toilets / urinals). There was no relationship between self-excretion behavior and age or gender. As a matter of course, fallen inpatients with disabilities had a higher rate of requiring assistance ($p < .0001$). However, about two-fifths of fallen inpatients who were able to engage in excretory behavior by themselves had a cognitive or physical disability. Dangerously, about one-sixth of fallen inpatients requiring assistance for excretion were overconfident that they could walk, and there was a tendency to engage in excretory behavior by themselves without calling nurses. General condition was 'stable' or 'recovered' in 64.2% of inpatients, and the remainder was 'worse'. Fallen inpatients who were stable or recovered had a significantly higher rate of self-excretion behavior ($p = .028$). The percentage of female inpatients over 80 years of age that were stable or recovered

was significantly higher ($p = .006$), and but this was not related to self-excretion behavior.

Signs leading to identification of falls were falling sounds and inpatients' voices (28.4%), followed by nurse calls from other inpatients in the same room

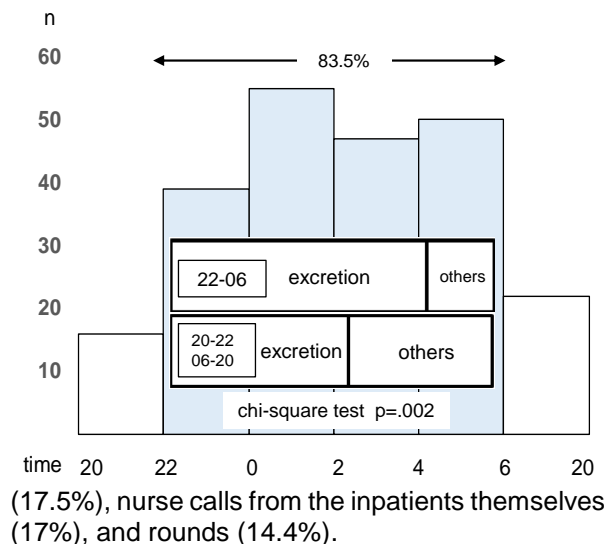


Figure 1: Time frames when inpatient falls occurred and behavioral purposes of inpatients who fell

Table 2: Circumstances of falls, administration of soporific agents and overview of factors behind the fall (n=229)

circumstances of falls	general condition		disorder		administration of soporific		overview of factor behind falling			age		gender		
	worse	stability /recovery	presence	no descrip.	regular	other than	descrip.	no descrip.	no attention	80 or over	60 to 79	male	female	
excretion behavior n (%)	self-support	30 (13.1)	76 (33.2)	40 (17.5)	66 (28.8)	66 (28.8)	40 (17.5)	55 (24.0)	4 (1.7)	47 (20.5)	54 (24.3)	47 (21.2)	52 (22.7)	54 (23.6)
	assist/portable (uninal)	52 (22.7)	71 (31.0)	81 (35.4)	42 (18.3)	63 (27.5)	60 (26.2)	75 (32.8)	11 (4.8)	37 (16.2)	66 (29.7)	55 (24.8)	63 (27.5)	60 (26.2)
general condition n (%)	worse	—	—	44 (19.2)	38 (16.6)	39 (17.0)	43 (18.8)	44 (19.2)	7 (3.1)	31 (13.5)	32 (14.4)	46 (20.8)	49 (21.4)	33 (14.4)
	stability/recovery	—	—	77 (33.6)	70 (30.6)	90 (39.3)	57 (24.9)	86 (37.6)	8 (3.5)	53 (23.1)	88 (39.6)	56 (25.2)	66 (28.8)	81 (35.4)

p=chi-square test

3.3 Administration of Soporific Agents and Overview of Factors Underlying the Fall

As shown in Table 2, 56.3% of fallen inpatients used soporific agents regularly: as-needed use or first dose (24%); increased use or multiple soporific

agent use (17.5%). A few cases were self-managed by inpatients. Approximately 40% of fallen inpatients who regularly used soporific agents had stabilized and recovered their general condition, and were significantly more likely to regularly use soporific agents than fallen inpatients with worse condition (p = .046).

In 56.8% of all cases, use of soporific agents was described as contributing to the risk of falling. Conversely, in 36.6% of cases, it was specified that soporific agents did not contribute to falling risk,

and the remaining cases emphasized other risk factors. In relation to excretion behavior, the percentage of cases in which soporific agents were described as risk factors was significantly higher in inpatients requiring assistance with excretion, and the percentage of cases in which soporific agents were not recognized as contributing to the falling risk was higher among those capable of self-excretion (p = .043). There was no relationship with general condition or age, sex.

Table 3: Described improvement measures for inpatient fall

measures described by more than about half of cases			measures with few cases described		
improvement measures	description	no description	improvement measures	description	no description
	n (%)			n (%)	
assisstance with excretic	165 (72.1)	64 (28.0)	shock mitigation	56 (24.5)	173 (75.5)
accompaniment	50 (21.8)		improving bed surroundings	38 (16.7)	
urination	46 (20.6)		floor mat installation	14 (6.0)	
toilet assistance	44 (19.2)		lower extremity training	3 (1.3)	
setting portable toilet or urinal	25 (10.9)		protective clothing	1 (0.5)	
inpatient guidance	143 (62.4)	86 (37.6)	restraints with respect getting out of the bed	37 (16.2)	192 (83.8)
instructions on use nurse calls	73 (31.8)		using four bedrails	20 (8.7)	
explanation of fall risk	17 (7.4)		not using portable/urinals	7 (3.1)	
guidance on footwear	13 (5.7)		controlling bodily sensations	6 (2.6)	
combination	40 (17.5)		warning posters	4 (1.8)	
behavior detection	113 (49.3)	116 (50.7)	insomnia intervention	10 (4.4)	219 (95.6)
bed-leaving sensor	60 (26.2)		moving inpatient to a quiet room	3 (1.3)	
frequent visitation	24 (10.5)		activities during the day	3 (1.3)	
moving inpatient to monitor room	7 (3.0)		listening feelings staff workshops	3 (1.3)	
combination	22 (9.6)		warm baths	1 (0.5)	
soporific agent management	108 (47.2)	121 (52.8)			
observation of effect	38 (16.6)				
explanation of drug action	33 (14.4)				
reviewing use	31 (13.3)				
discontinuation reducing dose	6 (2.6)				

3.4 Improvement Measures

On improvement measures for inpatient falls are shown in Table 3. Improvement measures aimed at preventing falls were classified into seven categories. Measures continued from before the fall were also included. Excretion assistance (accompaniment, urination induction guidance, toilet assistance, setting portable toilet or urinal) was described in 72.1% of all cases. Inpatient education, such as instructions on the use of nurse calls, guidance regarding footwear, and explanation of fall risk was described in 62.4% of cases; behavior detection (installation of a bed-leaving sensor, frequent visitation, moving the inpatient to a room that is easier to monitor) in 49.3% of cases; and management of soporific agents (observation of pharmacological effect, explanation of drug action, reviewing use, discontinuation or reducing dose) in 47.2% of cases. Measures described at lower rates were shock mitigation (environmental improvement in the bed surroundings, floor mat installation, lower extremity training, protective clothing) in 24.5%; restraints with respect to getting out of the bed (using four bedrails, not using portable toilets or urinals, controlling bodily sensations, warning posters) in 16.2% of cases; and insomnia intervention in 4.4% of cases. Specific measures for insomnia intervention were described as the following: moving the inpatient to a quiet room, promoting activities during the day, listening to the inpatient's expressing their feelings, warm baths, consultation with specialists, or staff workshops.

4. Discussion

We analyzed information related to 229 reported cases of hospital falls. We base our arguments about fall prevention on the results of this analysis.

4.1 Conferences about Soporific Agents

Falls occurred during movement of inpatients due to excretion during the late-night time frame, when the medicinal efficacy of the soporific agent was sustained. We inferred that inpatients who took soporific agents and subsequently fell during the night were trying to excrete in a state of insufficient arousal. Although more than half of fallen inpatients required assistance for excretion, we inferred from the signs that led to the identification of the falls that these inpatients had not called a nurse, and had moved without waiting for assistance. Falling could have been avoided if the inpatients had received assistance from a nurse. Many cases noted the nurses' beliefs that inpatients would request nurse assistance. However, because an inpatient's

thinking ability and judgment power differ between daytime and nighttime, when the effect of soporific agents is sustained¹⁶⁾, we assume that the inpatients did not think of calling nurses at night in the same manner that they would during the day. It should be considered that even inpatients capable of self-excretion behavior and those whose general condition was stable or recovered might not necessarily call nurses. It should be considered that inpatients capable of self-excretion behavior and those whose general condition was stabilized or recovered are the same. This was manifested in improvement measures aimed at inpatient education, e.g., encouraging the use of nurse calls and practicing excretion assistance. All of the inpatients in our study carried some risks of falling, including one-half of all cases that were over 80 years old, two-thirds that had a serious illness, one-half that had cognitive or physical disability, and two-fifths that had worse general condition. In recent years, ultrashort-acting soporific agents with lower muscle-relaxant activity have become available, and the effects on fall prevention have been described.¹⁶⁾ However, we wonder whether the use of soporific agents is appropriate for end-stage cancer patients who use narcotics or for patients with chronic respiratory disease with hypoxia. Because fall risk assessments are carried out continuously, doctors, nurses, and pharmacists should engage in patient-specific conferences on the use of soporific agents. Nurses should act as representatives for patients and coordinate these conferences.

4.2 Nursing Care for Patients in Insomnia

The inability to sleep is burdensome for patients. In this study, more than half of fallen inpatients regularly used soporific agents, and those who had stabilized or recovered their general condition were more commonly frequent users than those in worse general condition. As a matter of course, the percentage of self-excretion behavior was also high in the former class of inpatients. Therefore, both inpatients who regularly used soporific agents and night shift nurses expected that inpatients would be able to go to the toilet as usual. It could be inferred from the results that many patients with self-excretion behavior were included in cases in which nurses specified that soporific agents did not contribute to the risk of falling. For elderly people and patients with worse general condition, drug adverse effects are more likely to be noticeable. Even though it is known that the use of soporific agents is a factor of falling risk, in practice, nurses

are often unable to deny requests for these drugs from patients.

Although patient falls are adverse events, some have argued that falls do not represent errors, but instead the quality of medical care.²¹⁾²²⁾ In the United States, the American Nurses Association, a professional nursing organization, collects large quantities of data, with information about falls by hospitalized patients used as an indicator of nurse-sensitive quality in a hospital (National Database of Nursing Quality Indicators).⁶⁾²³⁾ In Japan, the Japanese Nursing Association started collecting information as a project related to the Database for Improvement of Nursing Quality and Labor (DINQL) in 2016. If patient falling is an issue related to quality of nursing, it should be prevented by proper nursing care. Should nurses be able to provide patients with nursing care for insomnia so that they can sleep without taking soporific agents? Nursing care for patients with insomnia includes a diverse range of approaches, including providing a proper sleeping environment, foot bath / shower or massage before bedtime, providing hot drinks, changing the patient's mood, playing soothing sounds, promoting daytime activities, sunbathing, and listening to the patients' feelings.²⁴⁾²⁵⁾ In this study, the improvement measures for excretion assistance and patient guidance were described frequently, but descriptions of insomnia intervention were provided in less than 5% of cases. A previous study in Japan also reported that nurses very rarely provide foot bath or massages for patients with insomnia.²⁶⁾ Foot baths have been demonstrated to aid the onset of sleep in patients who complain of insomnia.²⁷⁾⁻²⁹⁾ This form of therapy is a basic nursing skill that can be carried out even by nursing students. However, limited nursing resources during the night shift might prevent widespread implementation, because there is a risk of interfering with excretion assistance, infusion treatment, or emergency response. Recently, electric footbaths for medical treatment that can be handled without specialized training have become available at relatively low prices. Thus, it might be possible for patients themselves, their families, or nursing aides to perform foot baths before bedtime, even if the night shift nurses cannot. Transcending from soporific agent-dependent care of patients with insomnia is required, given the risks associated with its use.

5. Conclusion

Falling in hospitalized inpatients under the influence of soporific agents occurred during the

late-night time frame, when the effect of medicines was sustained, largely due to movement for excretory purposes. Aging, cognitive or gait disturbance, and disease are falling risks, as is the use of soporific agents. Nevertheless, patients at risks of falling still took soporific agents. Because fall risk assessments are carried out continuously, doctors, nurses, and pharmacists should engage in patient-specific conferences on the use of soporific agents. Improvement measures for fallen patients included excretion assistance, patient education, behavior detection, management of soporific agents, but rarely included therapy for insomnia, such as foot bath before bedtime. Transcending from soporific agent-dependent care is required by considering the adoption of medical footbaths that patients or their families can administer, as well as the use of nursing aides.

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[Original]**Evaluation of inter-rater reliability and accuracy of the Fall Risk Behavior Assessment Tool (FRBA-Tool) for prediction of the risk of fall****Akiko Hiyama¹, Keiko Nakamura²**

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Abstract

Nurses are expected to assist patients in maintaining their activity, but often must also restrict activity to prevent fall. To ensure safety in hospitalized patients while maintaining activity, we developed the Fall Risk Behavior Assessment Tool (FRBA-Tool) and verified its predictive accuracy in a case-control study. To improve the utility of the tool, we conducted a survey of inter-rater reliability and a prospective investigation of verified prediction accuracy. The inter-rater reliability was examined by determining the kappa-statistic for evaluation of 86 patients by 43 nurses in 14 general wards at 3 hospitals. Assessment of the accuracy of prediction of fall risk was performed over 4 months in 11 general wards at 4 hospitals. Logistic regression after adjustment for age showed that all 18 items of FRBA-Tool were associated with fall. A receiver operating characteristic curve was used to evaluate the predictive performance of FRBA-Tool. Ethical approval for the study was granted by the institutional review board. Inter-rater reliability was high for the 18 items of FRBA-Tool ($\kappa=0.53-1.0$). Based on logistic regression analysis, item scores were weighted and a total score cut-off point of 5 was obtained (AUC 0.81, 95%CI:0.71-0.90). Using this cut-off, FRBA-Tool had a sensitivity of 80.0% (95%CI: 0.63-0.98), specificity of 74.8% (95%CI: 0.71-0.78), positive predictive value of 3.17 (95%CI: 2.46-4.08), and negative predictive value of 0.27 (95%CI: 0.12-0.61). This study shows that FRBA-Tool has adequate reliability and accuracy for assessment of fall risk in hospitalized patients.

Key word: fall prevention, risk assessment, risk behavior.**2. Introduction**

Patient falls are the most common type of accident during hospital stays. In Japan, falls account for up to 19.3% of overall accidents, and 10% of fallers

experience a serious injury or death¹). Although the average number of days of hospital stay in Japan is 16.5 days²), which is longer than in other

countries, among 50% patients over 75 years old have a remarkable aging population³⁾.

Falls occur when patients do not control their posture due to various fall risk factors. These factors are intrinsic and extrinsic in nature⁴⁾. Intrinsic factors are attributed to the individual characteristics of the patient, i.e., a history of falling, reduced vision, unsteady gait, poor balance, altered mental status, cognitive impairment, decreased functional ability, and chronic disease. Extrinsic factors are attributed to environment of the patient, i.e., poor lighting, condition of the ground surface, type of foot covering, inadequate assistive devices, structural design of bathrooms and grab bars, design of furniture, and improper use of assistive devices.

Fall risk assessment tools evaluate the risk of fall, and utilize intrinsic or extrinsic fall risk factors⁵⁾. Although several fall risk assessment tools based on fall risk factors have been developed, one focused on the expertise of nurses has not been developed to date. Therefore, we aimed to develop a new fall risk assessment tool to assess the daily behavior of patients. In a previous study, the validity of the fall risk assessment tool we developed was confirmed retrospectively.

Therefore, we conducted a survey of inter-rater reliability and a prospective investigation of the prediction accuracy of the tool.

3. Method

1) Research design

The reliability and accuracy of the fall risk behaviors assessment tool was determined using a survey of inter-rater reliability and a prospective investigation.

2) Setting

This study was conducted at four JCQHC (Japan Council for Quality Health Care) certified hospitals in Sapporo City, Hokkaido, Japan; i.e., subjective hospitals that demonstrated satisfactory compliance with the applicable JCQHC accreditation standards. The Medical Care Act in Japan classifies General beds as those not involved in Psychiatric, Infectious disease, Tuberculosis, or Long-term care. The four hospitals were teaching hospitals with 80 to 312 beds, including general beds.

3) Sample and data collection

A fall was defined as an unexpected event in which the participant comes to rest on the ground, floor, or at a lower level.

Inter-rater reliability

The sample consisted of 86 patients who were cared for by 43 nurses in 14 general wards at 3 hospitals in Japan. To assess inter-rater reliability, two nurses applied the Fall risk behavior assessment tool independently on the same day to a convenience sample of patients who had been admitted to the unit from December 2014 to April 2015.

Assessment of the accuracy of prediction of fall risk

The sample consisted of 642 patients in 11 general wards at 4 hospitals. A total of 2,449 patients were admitted to the wards between May to September 2015. Patient who did not have the ability to move were excluded from the study, as they were considered to not exhibit significant risk behavior for falls.

We collected the average length of stay, number of new admitted patients per month, bed occupancy rate, the number of nurses, the number of assistant nurses, the number of nursing aides using in the hospital's nursing system and adverse event reports.

The instrument used for data collection was organized to collect 2 types of data: (1) general and medical information and (2) fall-related information. General information included gender and age. Medical information was collected to provide the medical diagnosis from medical chart. Fall related data included fall rate, score of the fall risk behavior assessment tool and score of the fall risk assessment tool.

The fall risk assessment tool was part of the electronic nursing support system and was the standard Japanese tool. The fall risk assessment tool consisted of 41 items that had been endorsed for use in hospitals by the Japanese Nursing Association (JNA). Specifically, the items included: (1) age, (2) history of disease, (3) perception (3 items), (4) motor function (4 items), (5) mobility (5 items), (6) cognition (4 items), (7) medication (5 items), (8) elimination (8 items), (9) treatment stage (5 items), (10) personality (5 items). A patient's fall risk level was determined as low, medium or high. A patient with ≤ 9 points would indicate a low fall risk, and ≥ 20 points would indicate a high fall risk; other points would be considered a medium fall risk.

4) Fall risk behavior assessment tool (FRBA-tool)

The FRBA-tool was used to predict falls due to the patient's behavior in hospitals, which had developed quantitative analyses based upon the behaviors of previous inpatients who had fallen.

The FRBA-tool consisted of 18 items that could predict the fall risk of the patient based upon observation of their behavior (Table.1). Patients were assessed with binary scores, 0 or 1, by the nurses. The nurses then indicate the presence of each risk behavior by placing a check mark next to each of the risk behaviors identified.

Prior to this study, a retrospective study had been carried out to modify the FRBA-tool, which had high accuracy to predict fall risks. The retrospective study found that the FRBA-tool had good prediction accuracy with a sensitivity of 84% and specificity of 63%.

Table 1. Fall risk behavior assessment tool (FRBA-tool)

	check
1 Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction	<input type="checkbox"/>
2 Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure	<input type="checkbox"/>
3 Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs	<input type="checkbox"/>
4 Moving hastily, due to urinary urgency and performing of a task under pressure	<input type="checkbox"/>
5 Moving while lightheaded, due to a semiconscious state, in the absence of sedative or psychotropic drugs	<input type="checkbox"/>
6 Moving without selecting an appropriate moving assistance tool	<input type="checkbox"/>
7 Moving unstably, due to interference by a tube for intravenous drip or an IV stand	<input type="checkbox"/>
8 Moving with a lack of attention to safety, due to poor concentration	<input type="checkbox"/>
9 Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment	<input type="checkbox"/>
10 Moving unstably, due to impaired posture adjustment, asynergy	<input type="checkbox"/>
11 Moving without paying attention to footwear, clothing, linens	<input type="checkbox"/>
12 Changing the center of gravity through movement, such as a sudden change of direction and position	<input type="checkbox"/>
13 Moving unstably, due to interference by a tube for intravenous drip or an IV stand	<input type="checkbox"/>
14 Starting to move without reliable grip on the support apparatus	<input type="checkbox"/>
15 Moving obstacles or steps with uncontrolled body balance	<input type="checkbox"/>
16 Moving without paying attention to a slippery floor	<input type="checkbox"/>
17 Moving with insufficient balance control, due to impairment of the upper limb	<input type="checkbox"/>
18 Reaching over something or leaning forward in an unstable body posture	<input type="checkbox"/>

5) Ethical consideration

Ethical approval was granted by the Institutional Review Board of the researcher’s institute. The data collection forms were anonymized, with no reference to names or identification numbers.

6) Data analysis

SPSS 22.0 software (IBM Corp, U.S.) was used for the data analysis. Inter-rater reliability was calculated using the kappa index at 95% CI. Descriptive statistics were calculated for the sample characteristics: gender, age, hospital days, diagnosis. The FRBA-tool score was examined using logistic regression. Logistic regression, after adjustment for age, identified 18 items that were associated with falls. The prediction accuracy of the FRBA-tool was assessed based on the

sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the area under the receiver operating characteristics curve (ROC). Sensitivity referred to the number of fallers that were correctly identified by the FRBA-tool, divided by the total number of fallers. Specificity referred to the number of non-fallers that were correctly identified by the tool, divided by the total number of non-fallers. PPV was the rate of actual fallers compared with the prediction of falls: sensitivity/(1- specificity), and NPV was the rate of actual non-fallers compared with the prediction of non-falls: (1-sensitivity)/specificity. The ROC plots the 1-specificity vs. the sensitivity, and the area under the ROC represents the AUC.

The validity of the FRBA-tool method was used to determine the correlation with the fall risk assessment tool. Study design and subjects

The mean age of the 86 patients was 81.0 years (SD 10.4, range 38-96 years). The mean nursing experience of the 43 nurses assess patients was 7.9 years (SD 7.1, range 3-30 years). The Kappa index for each of the items is shown in Table 2.

4. Result

1) Inter-rater reliability

Table 2. Kappa index in the prediction of fall risk by using FRBA-tool

	Kappa	P
1 Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction	0.49	<.01
2 Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure	0.71	<.01
3 Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs	1.00	<.01
4 Moving hastily, due to urinary urgency and performing of a task under pressure	0.81	<.01
5 Moving while lightheaded, due to a semiconscious state, in the absence of sedative or psychotropic drugs	1.00	<.01
6 Moving without selecting an appropriate moving assistance tool	0.55	0.04
7 Moving unstably, due to interference by a tube for intravenous drip or an IV stand	0.57	0.02
8 Moving with a lack of attention to safety, due to poor concentration	1.00	<.01
9 Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment	1.00	<.01
10 Moving unstably, due to impaired posture adjustment, asynergy	0.60	<.01
11 Moving without paying attention to footwear, clothing, linens	0.75	0.03
12 Supporting the body with those that have not been fixed	0.63	<.01
13 Changing the center of gravity through movement, such as a sudden change of direction and position	1.00	<.01
14 Starting to move without reliable grip on the support apparatus	0.65	0.05
15 Moving obstacles or steps with uncontrolled body balance	0.53	0.09
16 Moving without paying attention to a slippery floor	0.57	0.06
17 Moving with insufficient balance control, due to impairment of the upper limb	0.57	0.03
18 Reaching over something or leaning forward in an unstable body posture	0.59	0.02

2) Accuracy of the fall risk

In wards, the mean duration of the hospital stay was 15.7 days, the mean number of new hospital patients was 77.5, the mean number of new patients leaving was 81.4, the bed occupancy rate was 92.3%, the mean number of working nurses was 25.4, the mean number of working assistant nurses was 0.3, the mean number of working nursing aides was 2.9. Of the patients, the mean age was 51.3 years (SD30.4); 348 were male and 289 were female. The common primary medical diagnoses were related to pneumonia (4.5%), Colorectal polyp (3.6%), hip fractures (3.2%), humerus fracture (2.5%), cataract (2.0%).

A total of 20 falls and 622 non-falls were recorded. Of the fallers, 6 (33.3%) were male and 12 (66.7%) were female, with no significant difference between genders. The mean age of the fallers was 64.3 years (SD 27.2) compared with 43.1 years (SD29.2) for the non-fallers (table 3).

Sixteen items showed significant differences among the fallers compared with the non-fallers (Table 4).

Based on logistic regression analysis (Table 5), the item scores were weighted and a total score cut-off point of 5 was obtained (AUC 0.81, 95%CI:0.71-0.90). Using this cut-off, the FRBA-Tool had a sensitivity of 80.0% (95%CI: 0.63-0.98), specificity of 74.8% (95%CI: 0.71-0.78), positive predictive value of 3.17 (95%CI: 2.46-4.08), and negative predictive value of 0.27 (95%CI: 0.12-0.61). The FRBA-tool and the fall risk assessment tool score showed a moderate correlation ($r=.44$, $P <.01$).

Table 3. Characteristics of the prospectively study participants

	Faller	Non-faller	P
Age (Mean, SD)	64.3(27.2)	43.1 (29.2)	<.01
Hospital days	15.3 (9.4)	8.8 (8.7)	<.01
Gender (Frequency, %)			
Men	6 (33.3%)	342 (55.3%)	0.91
Women	12 (66.7%)	277 (44.7%)	

Analysis of age and hospital days : n=541, Mann-Whitney U test

Analysis of gender : n=637, Chi-squared test

Table 4. Comparison of items of FRBA-tool between the faller and no-faller groups

	Faller (n=20)		Non-faller (n=619)		P
	Yes	No	Yes	No	
1 Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction	6	14	533	89	<.01
2 Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure	7	13	513	109	0.07
3 Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs	9	11	570	52	<.01
4 Moving hastily, due to urinary urgency and performing of a task under pressure	12	8	528	94	<.01
5 Moving while lightheaded, due to a semiconscious state, in the absence of sedative or psychotropic drugs	9	11	540	82	<.01
6 Moving without selecting an appropriate moving assistance tool	12	8	544	78	<.01
7 Moving unstably, due to interference by a tube for intravenous drip or an IV stand	10	10	497	125	<.01
8 Moving with a lack of attention to safety, due to poor concentration	14	6	522	100	0.12
9 Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment	9	11	524	98	<.01
10 Moving unstably, due to impaired posture adjustment, asynergy	9	11	551	71	<.01
11 Moving without paying attention to footwear, clothing, linens	13	7	555	67	<.01
12 Supporting the body with those that have not been fixed	12	8	539	83	<.01
13 Changing the center of gravity through movement, such as a sudden change of direction and position	11	9	540	82	<.01
14 Starting to move without reliable grip on the support apparatus	13	7	542	80	<.01
15 Moving obstacles or steps with uncontrolled body balance	9	11	535	87	<.01
16 Moving without paying attention to a slippery floor	10	10	528	94	<.01
17 Moving with insufficient balance control, due to impairment of the upper limb	6	14	520	102	<.01
18 Reaching over something or leaning forward in an unstable body posture	10	10	536	86	<.01

Chi-squared test

Table 5. Results of logistic regression model predicting fall by FRBA-tool

	OR	95% CI	p-value
Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction	8.345 [2.05 , 34.00]	0.003
Moving with insufficient balance control, due to impairment of the upper limb	13.36 [3.45 , 51.80]	0.000

Stepwise regression analysis using method of maximum likelihood, Adjusted for 18 FRABA-tool item and age, OR means odds ratio, CI means confidence interval, n = 642

Table 6. Measures of precision for FRBA-Tool

	95%CI
Sensitivity	0.800 [0.625 , 0.975]
Specificity	0.748 [0.713 , 0.782]
Accuracy	0.749 [0.716 , 0.783]
Positive likelihood ratio	3.169 [2.463 , 4.079]
Negative likelihood ratio	0.268 [0.118 , 0.606]

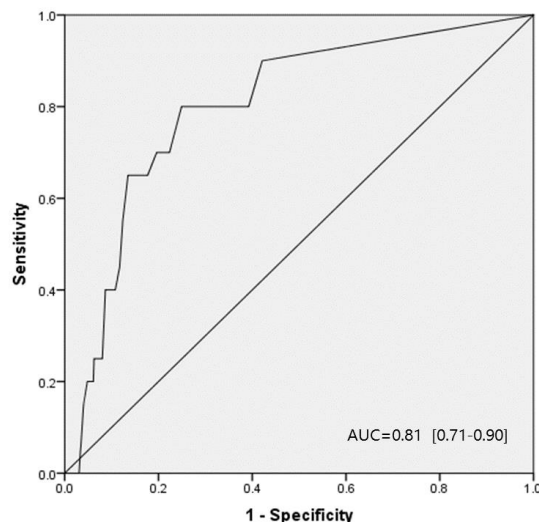


Figure 1. ROC curve of FRBA-Tool

5. Discussion

The fall risk assessment tool was developed in hospital from the perspective of internal factors (i.e., gender, diagnosis, type of medicine, frequent toileting, etc.)⁵⁾. The existing tool for the assessment of fall risk has a disadvantage in that it requires high nursing competency, if it will not be used without nursing judgment of the patient's activity. We argue that the fall risk assessment tool should be used for daily behavior assessment; not only for risk level evaluation. Assessing the daily behavior of patients enables effective improvements to nursing practice to prevent falls. In previous studies, the relationships between risk assessment and nursing practice were unclear.

It is important for the use of the tool to help nurses provide effective nursing practice. In clinical application requirement, fall risk assessment tool must have statistically significant prediction accuracy and reliability and content validity⁶⁾. Focusing on prediction accuracy, the St. Thomas's Risk Assessment Tool (STRATIFY)⁷⁾ and Morse Fall Scale (MFS)⁸⁾ are widely prevalent as fall risk assessment tools for inpatients; in a meta-analysis of fall risk assessment tools, STRATIFY has the highest reported sensitivity (80%), MFS has the highest reported specificity (68%)⁹⁾. When considering the comparison with the result of the meta-analysis, the FRBA-Tool is considered to have good sensitivity and specificity. Inter-rater reliability test shows that the FRBA-Tool has moderate reliability. Considering that the outcome of the behavioral assessment could be affected by individual nursing competencies, the result of the inter-rater reliability test was found to be clinically correct. In addition, the inter-rater reliability in our study was acceptable as compared with the Kappa index for each item in earlier study¹⁰⁾.

Furthermore, in comparison with the JNA tool, there was a moderate correlation, which indicated that the FRBA-Tool has content validity.

This study has several limitations, including selection bias. In the prospective design study that explored the prediction accuracy of fall risk in Japan¹¹⁾, the participation rate was 36.2%. Although in this study, the participation rate was 39.1% of the acceptable rate, it would be recommended to increase the rate and the number of fallers in future studies.

This study indicates that, the FRBA-Tool has high accuracy and reliability despite the limited sample size. Based on the high accuracy it is considered

that behavioral assessment might be closer to "why the patient might fall".

6. Conclusion

The inter-rater reliability in our study was acceptable; as compared using the Kappa index for each item. The accuracy of the fall risk behavior assessment tool for a general ward of hospitalized patients showed a sensitivity of 80.0% (95%CI: 0.63-0.98) and specificity of 74.8% (95%CI: 0.71-0.78), a positive predictive value of 3.17 (95%CI: 2.46-4.08), and a negative predictive value of 0.27 (95%CI: 0.12-0.61). This study shows that FRBA-Tool has adequate reliability and accuracy for the assessment of fall risk in hospitalized patients.

Conflict of interest

The authors have declared that there is no conflict of interest.

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[Original]

Relationship between professional employment as a practicing dietitian and health status among graduates of a department of food science and nutrition

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Abstract

[Objectives] There is no research on the health of the subjects who graduated from the training facility of the dietitian. The purpose of this study was to clarify the period of professional employment of nutritionists and their health status after graduation.

[Methods] 111 subjects who graduated from a nutritional training facility from March 1975 to March 1984 and have the professional employment experience (occupational or nutritional knowledge of the nutritional field) were eligible for the study. As a measure of health (QOL), the SF-36(version 2) Japanese version was used. The differences between eight scaled scores and 3 summary scores in tertile of professional employment were performed tests for trend with adjusting the age, presence of stress, marital status, disease history, and sleep conditions.

[Results] Physical functioning, physical role functioning, and vitality scores tended to be higher as a longer professional work period of (p for trend = 0.007, 0,006, and 0,029). No significant differences were found in the summary score during the professional period.

[Conclusion] It was suggested that the use of nutritional knowledge learned at nutritional training facilities would have a good impact on physical fitness.

1. Introduction

In Japan, the increasing number of lifestyle-related diseases such as cancer, heart disease, stroke, and diabetes has become a serious problem. In order to prevent the development and progression of lifestyle-related diseases, nutritional and dietary habits are important in preventing lifestyle-related diseases and improving the quality of life.

In training facilities for nutritionists and dieticians who play an important role in promoting health in Japan, it is necessary not only to acquire scientific

expertise and technologies related to food and health, but also to acquire the ability to practice appropriate nutrition education for the promotion of health and prevention of disease. Therefore, it is anticipated that students at nutritional training facilities are practicing healthy and good dietary habits in their diet. It has been reported that nutrition proficiency is positively correlated with the perceived adequacy (quality, quantity, coverage and importance) of nutrition training of medical students¹⁾.

We clarified that the relationship between the experience of professional employment and the number of years of experience after graduating from nutritional training facilities is more preferable than that of Japanese nationals in the same age period, but that the experience of professional employment after graduation and the number of years of experience have affected the eating habits that are more preferred²⁾.

The purpose of this study was to clarify the period of professional employment of nutritionists and their health status after graduation.

2. Methods

Subjects

Investigation requests were submitted to people who graduated from a nutritional training facility from March 1975 to March 1984. From August to September 2012, 224 participants received the questionnaire. According to a survey from August to September 2012, questionnaires were collected from 206 participants (collection rate: 92.0%). The analysis was carried out by the analysis of 111 participants of the professional employment experience (occupational or nutritional knowledge of the nutritional field) of 206 participants.

This study was conducted after approval of the Otsuma Women's University Life Science Research Ethics Committee on September 27, 2013 (25 – 005).

Assessment of health status

As a measure of health (QOL), the SF-36(version 2) Japanese version was used³⁾⁴⁾. SF-36 is a set of generic, coherent, and easily administered quality-of-life measures. The SF-36 consists of eight scaled scores: physical function, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning, and mental health. The SF-36 dimensions can also be divided into three categories: Physical Component Summary (PCS), Mental Component Summary (MCS), and Role / Social Component Summary (RCS) which

represent the physical functioning and wellbeing, emotional wellbeing, and ordinary relationships with others, respectively⁵⁾.

Statistical analysis

The subjects were classified into tertile (less than 9 years, 9 years or more, and more than 25 years) by the professional employment period. The differences between eight scaled scores and 3 summary scores in tertile of professional employment were performed tests for trend with adjusting the age, presence of stress, marital status, disease history, and sleep conditions. Statistical significance was less than 5% in all assays and SAS (version 9.4, SAS Institute Inc, Carney, NC, USA) was used for analysis.

3. Results

The characteristics of the subject for tertile of professional employment are shown in Table 1. The longer the professional employment period, the longer the period of employment. In the 25 years or more group, the duration of employment and the duration of professional employment were almost unchanged. Age, physique, Marital status, experience in nursing care, and annual income did not differ of tertile. The Number of children is significant in the results of the chi-square test, but the characteristics of tertile of professional employment are unclear.

Table 2 shows the eight scaled scores obtained from SF- 36 for subjects who have been classified into tertile by professional employment. Physical functioning, physical role functioning, and vitality scores tended to be higher as a longer professional work period of (p for trend = 0.007, 0,006, and 0,029).

The summary scores of the subjects who were categorized into tertile of professional employment were shown in Table 3. No significant differences were found in the summary score during the professional period.

Table 1. Characteristics of subjects by professional employment years (n=111)

	less than 8 years	8-25 years	25 years or more	p value ¹⁾
Number of subjects (n)	37	37	37	
Age (year)	55.3±3.0	56.0±4.0	56.3±3.2	0.4682
Height (cm)	156.6±6.0	158.5±5.1	157.3±4.6	0.3157
Weight (kg)	52.6±6.5	53.1±7.8	53.5±7.8	0.8865
BMI	21.4±2.4	21.1±2.5	21.6±2.6	0.7077
Working period (years)	14.4±11.3	19.4±7.4	34.1±4.2	<0.0001
Professional employment period (years)	3.5±1.9	16.2±4.3	34.0±4.2	<0.0001
Marital status				
Unmarried	0	2 (6.3)	1 (2.9)	0.0734
Married	36 (100.0)	26 (81.3)	31 (91.2)	
Divorce	0	3 (9.4)	0	
Bereavement	0	1 (3.1)	2 (5.9)	
Number of children				
3 or more	1 (2.8)	3 (8.1)	4 (11.1)	0.0458
2	9 (25.0)	13 (35.1)	4 (11.1)	
1	13 (36.1)	7 (18.9)	12 (33.3)	
none	13 (36.1)	14 (37.8)	16 (44.4)	
Experience in nursing care	17 (47.2)	13 (40.6)	14 (41.2)	0.5047
Income				
Less than 6 million yen	13 (38.2)	11 (31.4)	9 (27.3)	0.2971
6 million to 10 million yen	10 (29.4)	14 (40.0)	15 (45.5)	
10 million or more	11 (32.3)	10 (28.6)	9 (27.3)	

1); ANOVA or chi-square test

Table 2. Health concept assessed by F-36 and professional employment years (subscales)

	less than 8 years	8-25 years	25 years or more	p for trend ¹⁾
	mean ± SD	mean ± SD	mean ± SD	
Physical functioning	86.1 ± 15.1	90.1 ± 9.5	91.9 ± 7.1	0.007
Physical role functioning	83.4 ± 21.6	91.4 ± 16.5	94.4 ± 11.9	0.006
Bodily pain	70.2 ± 24.8	72.7 ± 21.1	75.3 ± 20.2	0.427
Social role functioning	62.3 ± 17.6	64.9 ± 14.2	65.7 ± 16.7	0.440
General health perceptions	62.7 ± 13.8	66.2 ± 15.9	64.5 ± 16.3	0.264
Vitality	82.4 ± 19.9	87.5 ± 20.8	92.2 ± 13.3	0.029
Emotional role functioning	87.8 ± 18.3	91.9 ± 14.9	91.0 ± 15.0	0.379
Mental Health	75.4 ± 12.9	78.8 ± 16.0	74.9 ± 13.3	0.938

1); Test for trend adjusted for age, presence of stress, marital status, prior history of disease, sleep conditions.

Table 3. Health concept assessed by F-36 and professional employment years (Summary Score)

	less than 8 years	8-25 years	25 years or more	p for trend ¹⁾
	mean ± SD	mean ± SD	mean ± SD	
Physical health	47.1 ± 12.4	49.1 ± 9.0	51.0 ± 8.1	0.130
Mental health	50.2 ± 7.0	47.6 ± 6.9	48.3 ± 6.1	0.090
Role / Social health	50.7 ± 8.9	49.1 ± 8.2	47.9 ± 7.7	0.211

1); Test for trend adjusted for age, presence of stress, marital status, prior history of disease, sleep conditions.

4. Discussion

There has been a report on the health after the graduation of the medical doctor and the nurse using the SF- 36⁶⁾. However, there is no research on the health of the subjects who graduated from the training facility of the dietician. This study is the first report on the relationship between the duration of employment of professional workers after graduation nutritionist training facilities and their health.

The results of the study, in which the scores of physical functioning, physical role functioning, and vitality were high in a group of long professional employment periods after graduation, are consistent with the fact that professional employment experiences are more likely to be related to the more preferred lifestyle, particularly dietary habits²⁾. The use of nutritional knowledge to work might have led to the high scores of physical functioning, physical role functioning, and vitality.

There was no significant difference in physical health of the summary scores from professional employment periods because of the lack of expertise related to the physical health of bodily pain and general health perceptions.

There were no significant differences in scores on mental health, such as emotional role functioning, social functioning, and mental health. This is probably because of the impact of stress on a variety of reasons, apart from the healthy life of mental health. However, the mental health and social functioning score of the subject of this study were higher than the standard value of the Japanese⁷⁾, the degree of mental health, which maintains a high.

The subject of this study took a variety of professional occupations after graduating from a nutritional training facility. For example, dieticians of hospitals, geriatric health facilities, schools, nursery schools and teacher of a nutritionist training facilities. It is likely that there is a

difference in the amount of work in the workplace by type of employment, the magnitude of their responsibility to work, communication in the workplace. These differences are not limited to occupational types and may vary by workplace. Since there was no data about detailed work environment is obtained in the present study, it was not possible to take into account these effects.

In conclusion, it was suggested that the use of nutritional knowledge learned at nutritional training facilities would have a good impact on physical fitness.

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[Original]

Communication between nursing students and nurses during practicums

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Abstract

Objectives: We examined the actual circumstances of poor reporting, communication, and consultation in communication between nursing students and nurses.

Methods: A questionnaire survey of nursing students was conducted to examine the times situations, and reasons for poor communication that negatively affected patients; coping strategies; and how to address such problems in the future. Simple tabulation was performed for the times and situations, and classification was performed for the reasons, recommendations, and how to address such problems in the future.

Results: Of 53 nursing students, 44 felt there was poor communication between nursing students and nurses, and 18 responded that this had a negative effect on patients. Poor communication occurred most frequently in the third year, and the most common situation in which it occurred was reporting. The reasons given for poor communication were “personal relationships with nurses” and “factors related to students.” Specific situations indicated in the responses were “factors related to nurses,” “the practicum environment,” “factors related to students,” and “effects on patients.” The coping strategies mentioned in the responses were “prompt students to act on their own initiative,” “form personal relationships with nurses,” and “not possible to address the problem.” Mentioned as ways to address such problems in the future were, “an instructional attitude that shows respect for students” and “the realities of instruction.”

Discussion: The atmosphere of the busy medical setting has given rise to inadequacies in nursing student reporting, communication, and consultation, which has affected patients. As a result, nursing students realized the importance of communication.

Keywords: nursing students, nurse, clinical training, communication, safety, questionnaire

I. Introduction

Two-way communication in the clinical setting is important from the perspective of healthcare safety. Yoshida et al. ¹⁾ stated that although nursing students are instructed to work closely with lead nurses in their clinical practicums through contact, consultation, and reporting, if cooperation does not go well and what the lead nurses intend to convey is not conveyed or if the nursing students forget to communicate information, patient safety cannot be maintained. Because of the demands of their work, nurses in the clinical setting cannot spend sufficient time with nursing students. Although the students, who have little practicum experience and undeveloped communication skills, learn much by communicating with nurses, seeing how busy the nurses are makes the students nervous and prevents them from actively trying to converse with the nurses.

Based on these observations, we examined times and settings in which poor communication between nursing students and nurses negatively affected patients, the reason for the poor communication, how the problem was handled, and how to address it in the future.

II. Methods

1. Definitions of terms

Communication in this case was limited to reporting, communication, and consultation between students and nurses. Poor communication was considered to have occurred in situations where accurate information could not be conveyed to the appropriate party at the appropriate time through reporting, contact, or consultation, the necessary measures to address the situation were taken too late, and the patient was negatively affected.

2. Working hypotheses

Students feel overly nervous due to factors such as the heavy workload of nurses and the tensions of the medical setting. Moreover, they do not know what they do not know due to their ignorance and therefore do not take the initiative to ask questions, which results in yet poorer communication.

3. Survey methods

1) Subjects

Sixty fourth-year nursing students who had completed practicums in their first to third year.

2) Anonymous, self-administered questionnaire survey administered by the detention method

Multiple-choice questions were used for the time and setting of the negative effect on the patient as a result of poor communication, and free text was used for the reason for the poor communication, how the problem was handled, and how it would be addressed in the future.

3) Survey period

July 17, 2016 to July 29, 2016

4. Analysis methods

1) Simple tabulation was performed for age, sex, whether the subject felt that communication was poor, and the time and setting of the negative effect on the patient as a result of poor communication.

2) The reason for the poor communication, the setting in which it occurred, how it was handled, and how it would be addressed in the future were classified by category.

5. Ethical considerations

The subjects were given written and oral explanations regarding the purpose and methods of the study, that the survey was anonymous and that they could not be identified, that participation was voluntary, and that anonymity would be ensured. After the data were tabulated, the questionnaires were shredded.

III. Results

Questionnaires were recovered from 53 of the 60 participants (recovery rate, 88.3%), and 53 provided valid responses (valid response rate, 100%).

Forty-four participants (83.0%) indicated that they felt communication was poor, eight (15.1%) indicated that they did not, and one did not respond (1.9%). In descending order, 10 responses (76.9%) indicated that the negative effect on the patient occurred during a specialized practicum, and three responses (23.1%) indicated it occurred during the basic practicum.

Regarding the setting of poor communication that affected the patient, 13 participants provided multiple responses (36 responses). In

descending order, there were seven responses (19.4%) for the morning report and five (13.9%) for each of the following four settings: during announcement of the practicum objectives and action plan, during a vital signs report, during an afternoon report, and during cleaning assistance.

1. Reasons for poor communication

Responses were obtained from 15 of 18 respondents (26 responses). As is indicated in Table 1, classification by category resulted in the extraction of the two categories “relationship with nurses” and “student-related factors” and the three subcategories “an atmosphere indicating that nurses were under a heavy workload,” “the attitudes of nurses made approaching them difficult,” and “unable to convey well what I wanted to say.”

2. Specific settings in which participants felt communication was poor

Multiple responses were obtained from 13 of 18 respondents (34 responses). Classification by category resulted in the extraction of the four

categories “nurse-related factors,” “practicum environment,” “student-related factors,” and “effect on the patient” and the five subcategories “attitude of nurses,” “context of poor communication,” “situation in which I felt communication was poor,” “delay in taking action,” and “put a burden on the patient.”

3. What types of communication should there have been

Multiple responses were obtained from 14 of 18 respondents (21 responses). As is indicated in Table 2, classification by category resulted in the extraction of the three categories “students acting on their own initiative,” “forming relationships with nurses,” and “unable to manage problems” and the five subcategories “do not hesitate to consult with nurses about questions,” “accurately convey information about requirements,” “confirm important points with the nurse,” “attempt to engage in two-way communication,” and “do not know how to manage the situation.”

Table 1. Reasons for poor communication (n = 26)

Category	Subcategory	Content
Relationship with nurses (23)	An atmosphere indicating that the nurses were under a heavy workload (20)	Nurses appeared to be under a heavy workload (14)
		It seemed that the nurses had no time to spare (1)
		The ward as a whole was in a state of commotion (1)
		Could not take time to speak with nurses (1)
		Nurse issued an instruction and then disappeared (1)
		Could not contact the nurse because the patient strongly insisted that the nurse not be called (1)
		Could not leave the patient and was therefore unable to contact the nurse (1)
	The attitudes of nurses made approaching them difficult (3)	Was repeatedly told by the nurse to leave it until later (1)
		Nurse was irritated (1)
		Was yelled at (1)
Student-related factors (3)	Unable to convey well what I wanted to say (3)	Although they were actually wrong, I could not argue with the nurse (1)
		Unable to speak to the nurses unless spoken to (1)
		Unable to put into words what I wanted to say (1)

(Multiple responses)

Table 2. What types of communication should there have been (n = 21)

Category	Subcategory	Content	
Students acting on their own initiative (18)	Do not hesitate to consult with nurses about questions (11)	Consult about things I don't know; do not make independent decisions (7)	
		Immediately consult if anxious about something (2)	
		Aggressively ask questions (2)	
	Accurately convey information about requirements (5)	When information should be communicated or something is not understood, this is communicated on the spot (1)	Urgent information is communicated even when nurses appear busy (1)
			I communicate my opinions (1)
			If there is something I don't understand, I call a nurse (1)
			Act with respect for the patient's wishes (1)
			Confirm important points with the nurse (2)
	Confirm important points with the nurse (2)	Confirm important points several times (1)	Confirm with nurses even if they appear busy (1)
			Confirm important points several times (1)
Forming relationships with nurses (2)	Attempt to engage in two-way communication (2)	Actively greet nurses (1)	
Unable to manage problems (1)	Do not know how to manage the situation (1)	Converse frankly and be friendly (1)	
		Ignorance: don't know what they don't know (1)	

(Multiple responses)

4. When in the position of accepting students, how should one interact with them

Multiple responses were obtained from 53 of 53 respondents (110 responses).

As is indicated in Table 3, classification by category resulted in the extraction of two categories, “communication that shows respect

for students” and “actual instruction,” and six subcategories, “active involvement with students,” “attitude of acceptance of students,” “create an atmosphere that mutually facilitates conversation,” “understanding and interacting with students,” “provide instruction that is clear and consistent,” and “adjust the time devoted to teaching.”

Table 3. When in the position of accepting students, how should one interact with them (n = 110)

Category	Subcategory	Content
Communication that shows respect for students (82)	Active involvement with students (41)	Spoken to by nurse (13)
		Listen to students and their reports (9)
		Be concerned (4)
		Nurses' ideas should also be communicated (2)
		Make arrangements to allow communication (2)
		Create relationships (2)
		Respond well when spoken to (2)
		Listen attentively to students' ideas (1)
		Offer praise (1)
		Do not ignore students (1)
		When talking with students, stop what you are doing and focus on the communication with eye contact (1)
		Provide care together (1)
		Let the students know beforehand that do not hesitate to ask questions or confirm their understanding (1)
		When been greeted, make sure to greet back (1)
	Attitude of acceptance of students (32)	Interact gently (13)
		Interact with a smile (4)
		Make the practicum enjoyable (2)
		Control your emotions and do not take it out on students (2)
		Do not say unreasonable things (2)
		Interact with time to spare (1)
		Nurse does not interact with students based on their mood at the moment (1)
		Interact politely (1)
		Interact in a manner that doesn't elicit unpleasant feelings (1)
		Do not make students uncomfortable (1)
		Accept students pleasantly (1)
		Do not assume an intimidating attitude (1)
		Interact with an attitude of mutual problem-solving (1)
		After a relationship of trust has been established to a certain degree, interact in a more demanding way (1)
	Create an atmosphere that mutually facilitates conversation (6)	Create an atmosphere conducive to starting a conversation (3)
		Create an atmosphere and environment conducive to consultation (3)
	Understanding and interacting with students (3)	Interact while understanding that the practical skills of the student are undeveloped (1)
		Attempt to understand what the student is thinking (1)
		Understand that students are here to learn (1)
Actual instruction (28)	Provide instruction that is clear and consistent (18)	Provide thorough instruction on subjects that are not understood (5)
		Ask whether there is anything they do not understand (3)
		Wish to impart knowledge (2)
		Provide advice on what is desirable to learn and on learning (2)
		Provide accurate instruction (1)
		Ask other staff about any questions students have that you cannot answer (1)
		Provide instruction on nursing care that gives first priority to the patient (1)
		Wish to provide future-oriented instruction (1)
		Opinions and information provided by different nurses are reconciled to provide consistent instruction (1)
		Advice is provided on points such as the significance of observations (1)
		Adjust the time devoted to teaching (10)
	When busy, set time for making reports (2)	
	Designate a specific time (2)	
	Let students know when you are too busy to talk to them (1)	
	If unable to respond soon, let them know you will talk to them later (1)	
	Make some time if help is needed to plan a program (1)	

(Multiple responses)

IV. Discussion

During their practicums, nursing students have experienced misunderstandings of some sort in their communication with nurses. One reason for this is that the students become overly stressed from seeing the circumstances of the nurses, who are busy every day, and from the tension of the medical setting. Moreover, they are unaware of what they do not understand due to their lack of experience and therefore do not take the initiative to ask questions. Consequently, to elucidate the types of communication that nursing students desire from nurses, we conducted a survey that was limited to communication between nursing students and nurses and focused on reporting, contact, and consultation, which are particularly important forms of communication.

Based on the results, following is a discussion of the questionnaire categories in order.

1. Have you ever felt that communication was poor?

Approximately 80% of the students acknowledged that communication with nurses was poor. In a study of field practicum instructors who were perceived by nursing students as being effective or ineffective, Yamada et al. ²⁾ reported that of the 69 participants, 66 (96%) expressed positive opinions and 69 expressed negative opinions. Based on the results of the study, it was inferred that the 20% of students who responded that communication was good included some who had confidence in their communication skills.

2. Have you ever felt that poor communication negatively affected the patient?

Approximately 40% of the students responded that poor communication had caused negative effects on patients. In a survey of nursing students regarding near-miss incidents conducted by Eguchi et al. ³⁾ the authors reported that 86 of the 87 participants said they had experienced a near-miss incident. Moreover, a total of 607 near-miss incidents were reported, indicating that each participant had experienced approximately seven near-misses. In the present study, the number of such incidents reported was half or fewer than the number reported by Eguchi et al. ³⁾ The reason for this was inferred to be that there were fewer such responses in the present study because it was limited to communication with nurses. In an

article on individual and institutional memory, Sugiura et al. ⁴⁾ stated that for each type of memory, repeated recall while the memory is retained is effective in converting it to memory that is retained longer and that episodic memory is the type of memory that is most easily lost in cases where there is aggressive memory loss, as in the case of dementia. Based on these studies, it was surmised that preferential forgetting occurred among students in the present study who were not left with a strong impression of poor communication with nurses. It was also surmised that even if poor communication results in a feeling of discomfort in the patient, that experience may disappear from memory if the problem is resolved on the spot. Moreover, because the threshold for discomfort varies depending on the individual, the results were thought to have reflected differences in sensitivity of the individual students.

3. Time when it was felt that poor communication had a negative effect on the patient

Approximately 80% of respondents said a negative effect on the patient occurred during a specialized practicum, and approximately 20% said such an effect occurred during the basic practicum. In a survey of nursing students regarding near-miss incidents, Okamoto ⁵⁾ reported that the number of such reports by year in school was 69 for first-year students, 68 for second-year students, and 24 for third-year students, 161 incidents in total. Thus, the results indicated that the number of near-miss incidents decreased and medical safety improved as the number of years in school increased. The results of the present study indicated that under the condition that the cause was poor communication with nurses, there were many cases of poor communication between nurses and nursing students during the third-year specialized practicum, which continued for half a year during the students' time in school. The reason for this was surmised to be that third-year students spend 2 weeks each in each ward for half a year, where they communicate with a different nurse each day, and consequently, the practicum ends before the relationship needed for good communication can be established. Moreover, because the opportunities to apply nursing skills increased, the chances to work closely with nurses through means such as instruction and reporting inevitably increased. Consequently, the opportunities to sense that

communication was poor and that patients had been negatively affected also increased.

4. Settings in which it was felt that communication was poor

The responses of the students regarding the settings in which poor communication occurred varied widely. The five most common settings were during the morning report, which was reported by approximately 40% of the participants, and during announcement of the practicum objectives and action plan, during a vital signs report, during an afternoon report, and during cleaning assistance, each of which was reported by approximately 30% of the participants. Thus, of the five most common settings, three involved reporting. These results showed that of the three types of communication examined -- reporting, contact, and consultation -- many students felt that poor communication occurred during reporting.

Cleaning assistance was included among the five most common settings as a nursing support setting. Cleaning assistance is performed daily because it is important for preventing infection, and it is the type of patient-related nursing care that gives students their most frequent involvement with nurses. This was surmised to be the reason why students felt that communication was poor in this setting.

5. Reasons for poor communication

Approximately 90% of the students said the reason was their relationship with nurses. In this category, responses were obtained that indicated the causes were an atmosphere in which the nurses appeared to be under a heavy workload and an attitude on the part of the nurses that made approaching them difficult. The response that the cause was an atmosphere in which the nurses appeared to be under a heavy workload was related to the settings in which the students felt that communication was poor. The morning is the busiest time for nurses because they replace night-shift nurses, and it is therefore a period of intensive nursing care, treatment, and testing. This makes it difficult for nurses to spare time to listen to the reports of students and provide them with instruction. Thus, students who said that their relationship with nurses was a reason for poor communication tended to think that this was because of problems with the schedules of the nurses and wards.

On the other hand, the approximately 10% of students who said that student-related factors were a reason for poor communication tended to

feel that they themselves were responsible and said they were unable to communicate what they wanted to well. A survey on the assertiveness of nursing students conducted by Azuma et al. ⁶⁾ found that for each subject the highest number of situations in which they were unable to say what they wanted to say was 36 situations in which the students were unable to communicate with a staff nurse. In addition, there were 13 situations in which they were unable to say what they wanted to say because they were subjected to aggressive language, such as when they encountered intimidation or a dismissive attitude on the part of a nurse, and seven situations in which their communication skills were undermined by factors such as a lack of confidence or nervousness. There were also many students in the present study who thought that the causes of the problem lay more with the nurses than with the students. It was therefore inferred that the apparent busyness of the nurses was a factor in the impaired communication between the nursing students and nurses.

Nursing students learn many nursing skills in university before their field practicum. During this time, the students imitate their teachers as models and strive to address what they do not know by acquiring skills through dialogue with teachers and other students. However, this training does not encompass items such as reporting, contact, and consultation with nurses, and the students therefore have no experience in these areas. Students who lack life experience find it difficult to communicate with nurses, who are the objects of the students' admiration and nervousness, in areas such as reporting, contact, and consultation, for which they have no models or experience.

6. Specific settings in which participants felt communication was poor

Approximately 30% responded that this involved nurse-related factors and approximately 30% said it involved the practicum environment. Thus, 60% of the students overall indicated the problem was related to the ward, and the most common of these responses (eight responses) concerned the heavy workload of nurses. However, in a survey of nursing students regarding the assertiveness of such students, Azuma et al. ⁷⁾ reported that the most common reason given for the students' not saying what they wanted to say was that they were subjected to aggressive language by the clinical instructor. Examples included not speaking because the student missed the appropriate time to do so due

to one-sided instruction (seven situations), because the instructor was dismissive (one situation), and because the student's pride was hurt by the instruction they received and they became overly self-critical (two situations). There were few reasons given that concerned the heavy workload of the instructor (three situations) or the students' inability to express themselves well (two situations). Thus, the results differed from those of the present study. However, a point of commonality with the present study was that many students felt that poor communication was caused by the attitude of the nurses.

Besides the reporting setting, a commonly cited situation was one in which the nurse instructed the student to wait and did not return and could not be contacted, and the patient was kept waiting. These descriptions portray the present condition in the clinical setting as being one in which smooth communication with nurses is difficult.

With regard to the effect on patients, six of the 13 respondents said they felt poor communication put a burden on the patient, suggesting concern over its effect on patients. These findings indicate that the three categories of nurse-related factors, the practicum environment, and student-related factors are all directly linked to an effect on the patient. Consequently, by being aware of the viewpoint of nursing students and creating an environment that enables smooth communication between students and nurses, nurses can in the future reduce the burden on the patient and provide nursing of higher quality as a single medical team that includes nursing students.

7. What types of communication do you think there should have been?

Ninety percent of the students responded that students should act on their own initiative. This suggested that many students saw a need to act boldly so that reporting, contact, and consultation can be performed when necessary for the welfare of patient or when the student is conflicted over whether something should be reported. On the other hand, one student responded "do not know" to the question. The free-text responses indicated that in the absence of an orientation on matters such as the mechanism for reporting established by each ward, nursing students actually could not decide how to proceed and were unable to process the situation by themselves when the survey was conducted.

8. When in the position of accepting students, how should one interact with them?

Approximately 80% of the students responded that communication should show respect for students. Yamada et al.⁸⁾ reported that students' eagerness to participate in practicums had increased as a result of the instructors' involvement in improving student morale and due to language and attitudes on the instructors' part that reflected an acceptance of the feelings of students, respect for their independence, and an enthusiasm for instruction. As with these study results, the results of the present study suggest that students are aware that the responses of the nurses who are their instructors affect their eagerness to learn, and many students hope that nurses will try to communicate in a manner that shows respect for students when providing instruction in the clinical setting.

Kaminski et al.⁹⁾ reported nine responses (60%) indicating that students prone to causing incidents cannot think flexibly and have a narrow outlook, three responses (20%) indicating that such students are excessively nervous and panic in the clinical setting, and two responses (13.3%) indicating that they implement techniques based on preconceptions and without adequate understanding. As these authors noted, the nervousness of nursing students in the clinical setting, an unfamiliar environment in which they lack experience, has been cited as a factor that gives rise to incidents. However, as indicated by the typical free-text responses regarding the types of communication that indicate respect for students, such as taking the initiative to start conversations with students and interacting with them in a gentle manner in the course of their work as nurses, the nervousness of nursing students may be reduced if they build good relationships of trust with nurses during their field practicums.

V. Conclusion

The results of the survey indicated that many students felt that communication was important. They portrayed a situation in which nurses under a heavy workload cannot take time to interact adequately with students, and the students are hesitant around the nurses and find it difficult to actively approach them. Based on these findings, it was concluded that practically all of the working hypotheses were supported.

Nurses play a very important role in field practicums, and many students felt that

communication with nurses was poor. Moreover, the findings highlighted the fact that nurses are deeply involved in the various emotions and misunderstandings that arise during practicums. The results showed that when they are in the position of instructing students, nurses need to remember the viewpoint of students and accept their feelings while being mindful of creating an environment in which communication with students proceeds smoothly from the nurse's viewpoint.

This study was a compilation of research conducted by nursing student Kako Murakami as part of her training. Therefore, it was an opinion survey of students conducted by a student, which enabled the frank opinions of the students to be gathered and the status of communication between nursing students and nurses in field practicums to be understood. However, because only students were surveyed, a discussion that compared the findings with the opinions of nurses was not possible.

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[Original]

**Comparison of back pain among physiotherapists and nurses
in the Maribor region of Slovenia**

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ABSTRACT

Back pain commonly occurs among healthcare workers, especially among physiotherapists and nurses. 45 physiotherapists and 45 nurses from various healthcare institutions from Maribor, Slovenia took part in the research. We found no statistically significant difference in the occurrence of back pain between the two professions in the last year ($p=0,517$) and that back pain occurs more frequently among healthcare professionals employed in institutions with immobile patients ($p=0.03$). Representatives of both professions are equally exposed to the manifestation of back pain. As expected, healthcare professionals who work with immobile patients and have more years of service had more back pain. We discovered that ergonomic knowledge didn't affect back pain occurrence so we believe that the only amelioration of this problem lies in the use of assistive devices for patient transfers.

Keywords: back pain; nurse; physiotherapists; ergonomics, ergonomic assistive device

Introduction

Absence from work due to pain has become a global problem and an indicator of the health of the population¹. More than 100 million Europeans suffer from chronic musculoskeletal pain, which is not only the most common cause of absence from work, but also the cause of reduced quality of life². The prevalence of musculoskeletal injuries and long-lasting absence from work is high among the professions that involve handling high loads, including physiotherapists and nurses. Damage to muscles and other structures of the spinal column is the result of excessive force produced by pushing, pulling or lifting heavy objects. When working with the patient, healthcare workers repeatedly find themselves, in a poor posture situations, which in combination with shift work causes damage and overloads back muscles. Healthcare workers are exposed to excessive forces on the spine in all fields: in the hospital environment, emergency room, homes for the elderly, etc^{3,4}.

The prevalence of pain in the lumbar spine (slightly less in the cervical spine) is high among healthcare workers. The annual prevalence of pain in the lumbar spine is between 45-77 % and can lead to serious consequences, such as

reduced quality of life, inability to work, sick leave and premature retirement. The most common causes for the occurrence of back pain are manual labour and frequent handling of patients, which nurses and physiotherapists encounter daily in their work⁵.

Improper lifting of heavy loads is responsible for not only the indisposition of a health professional, but also creates deficits in institutions and, consequently, an even greater burden on the remaining workers⁶. In addition, healthcare workers with pain in the spine have difficulties handling patients. They can cause additional injuries to the patient (e.g., a patient could fall during a manual transfer, because healthcare worker could not hold him)⁷. Nearly 66 % (N = 1600) of health workers experience pain in the lumbar spine. As noted, the most exposed are nurses (77.1 %) and physiotherapists (72.7 %)⁸. Gropelli and Corle⁹ found that the most common pain from which healthcare workers suffer is lumbar spine pain. These authors also observed that approximately 22 % of episodes of pain in the lumbar spine repeat. Alnaser¹⁰ found in a systematic review of the literature, that the majority of injuries to healthcare professionals are the result of patient handling (transfer, etc.) and

that younger and less experienced healthcare workers are more susceptible to back pain. Souza and Alexandre¹¹ also note that pain in lumbar spine predominates among healthcare workers (59 %) and is followed by pain in shoulders (40 %), knee (33 %) and neck (28 %). Mierzejewski and Kumar¹² found 49.2 % of physiotherapists experienced spinal pain due to the nature of their work, and that onset of pain was in the first five years of service. Shehab¹³ found 57 % of 100 physiotherapists experienced back pain. Alnaser¹⁰ found that most respondents who felt pain in the back were employed in the fields of orthopedics (34%) and neurology (24%). As Gropelli and Corle⁹ noted, nurses and physiotherapists accept pain in the spine as an inevitable part of their job. Most of them thought that injuries could only be reduced by carefully carrying out patient transfers. As the authors say, the survey clearly shows the need for education in this area, changes in the working environment and protocols to prevent injuries are inevitable. Manual transfer of the patient is one of the main reasons for the high prevalence of low back pain among healthcare professionals. Hazards during lifting and handling of patients include the weight of the patient, the patient's size, body shape, the presence of deformations, the functions of the lower extremities, and coordination. During patient transfer, physiotherapists and nurses often find themselves in an unsuitable posture. The cause of the problem may lie in lack of knowledge in the field of manual handling of transfers and ergonomic technical aids¹⁴. De Castro¹⁵ says that one cause for difficult transfers is the presence of chest or abdominal drains (e.g. in patients after surgery) and venous catheters. The cognitive function of the patient is also important, because those who do not understand the instructions may have difficulties participating in the transfer.

Healthcare professionals should devote full attention to the avoidance of manual transfer and use ergonomically technical devices as often as circumstances permit. However, if manual transfer is unavoidable, they must execute the procedure following ergonomic principles. During transfer of the patient, compression force on the L5 / S1 intervertebral disc should not exceed 3400 N (approx. 346 kg). Research shows that

the use of simple ergonomic assistive devices (turntables, belts and boards) reduce the aforementioned compression force on the intervertebral disc, to only 1800-2600 N (approx. 183-265 kg)¹⁶.

Methodology

In an analysis of existing findings, we carried out a review of databases in order to obtain information about topics that relate to the study. In the empirical section we used a quantitative method of work. We used a questionnaire consisting of open- and closed-type questions with one or more possible answers, based on the Likert scale. Questionnaires were distributed to physiotherapists and nurses personally.

To test the hypothesis we used bivariate statistical tests– Chi square test, Mann-Whitney U-test and Fisher's Exact test. For statistical analysis, we used the computer program IBM SPSS, version 21.

The research instrument that we used is a combination of questionnaires by authors Shehab¹³ and Kopec¹⁷. The questionnaire consists of 24 questions of open and closed types, and arguments that respondents had to assess using the Likert scale.

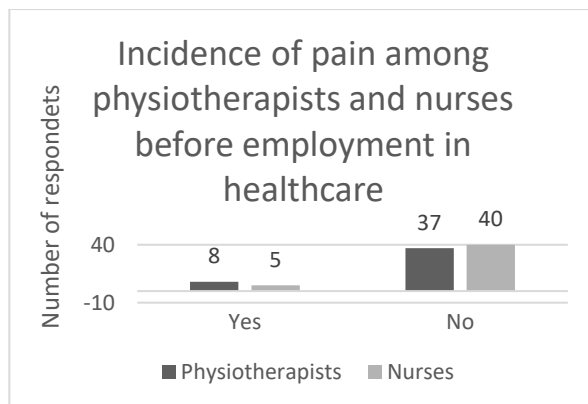
The study included 90 health professionals (45 physiotherapists and 45 nurses) employed in different wards of the University Clinical Centre Maribor, the Dr. Adolf Drolc Health Centre in Maribor, the Danica Vogrinec Home for the elderly and the Hrastovec social care institution.

The survey was conducted in June 2016 in the aforementioned institutions. Before carrying out the research, we obtained the necessary approvals from the institutions. Inclusion of respondents in the study was voluntary; respondents were given the option of refusing cooperation. The survey was completely anonymous.

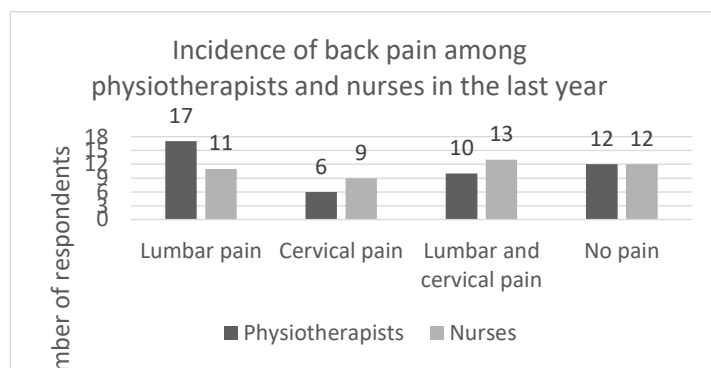
Results

The study involved 45 physiotherapists (50% of all respondents). The study included four male (8.9 %) and 41 female (91.1%) respondents. 30 physiotherapists (66.7%) were employed in the hospital, 9 (20%) were employed in the health centre, 3 (8.6 %) were employed in the home for the elderly and 3 (8.6 %) were employed in social care Institution. The average age of

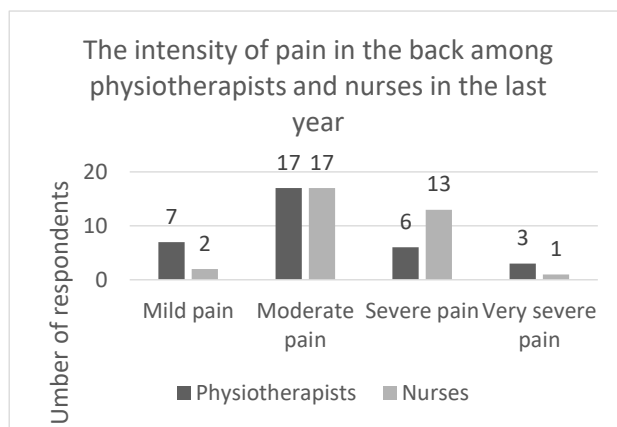
Graph 1: Comparison of incidence of back pain among physiotherapists and nurses before employment in healthcare.



Graph 2: Comparison of incidence of back pain among physiotherapists and nurses in the year leading up to study.



Graph 3: Comparison of the pain intensity in the back between physiotherapists and nurses.



physiotherapists was 41.40 ± 9.48 years, the minimum age was 24 years, maximum age 61 years. On average all physiotherapists were in

direct contact with the patient (direct labour) 7.02 ± 1.16 hours per shift, the minimum contact was 4 hours and maximum contact with patients was

8 hours per shift. The average length of service of physiotherapists was 17.43 ± 10.22 years, the minimum was 1 year, and the maximum 37 years. The mean body mass index (hereinafter referred to as BMI) was 23.85 ± 3.59 , the minimum was 16.46 and maximum BMI was 35.16.

The study also involved 45 nurses (50 %). The study included five male subjects (11.1 %) and 40 female (88.9 %) subjects. 12 nurses (26.7 %) were employed in the hospital, 12 (26.7 %) were employees of the health centre, 10 (22 %) were employed in the home for the elderly and 11 (24.4%) were employed in the socialsecurity institution. The average age of nurses was 40.80 ± 10.10 years, the minimum was 21 years, maximum 56 years. On average all nurses were in direct contact with a patient for 6.97 ± 1.37 hours per shift, the minimum contact with the patients was for 2 hours and maximum contact with the patient was for 8 hours per shift. The average length of service of nurses was 20.10 ± 11.21 years, the minimum length was 1 year and maximum length of service was 37 years. Mean BMI was 25.10 ± 4.27 , the minimum was 17.47, and the maximum BMI was 37.04.

Graph 1 shows 37 physiotherapists (82.2%) had back pain before they started working in healthcare and 8 physiotherapists (17.8%) had pain in the back before they began working in healthcare ($p < 0.001$). 40 surveyed nurses (88.9%) stated that they did not have back pain before they started working in the healthcare and 5 (11.1%) nurses had pain in the back before they started working in healthcare ($p < 0.001$).

Graph 2 shows 17 physiotherapists (37.8%) felt pain in the lumbar spine in the last year, 6 respondents (13.3%) felt pain in the cervical spine and 10 respondents (22.2%) felt pain in both lumbar and cervical spine. 12 respondents (26.7%) had had no pain in the back in the last year ($p = 0.134$). The graph shows that 11 nurses (24.4%) had felt pain in the lumbar spine in the last year, 9 respondents (20%) had felt pain in the cervical spine and 13 respondents (28.9%) had felt pain in both lumbar and cervical spine. 12 respondents (26.7%) had experienced no back pain in the last year ($p = 0.855$).

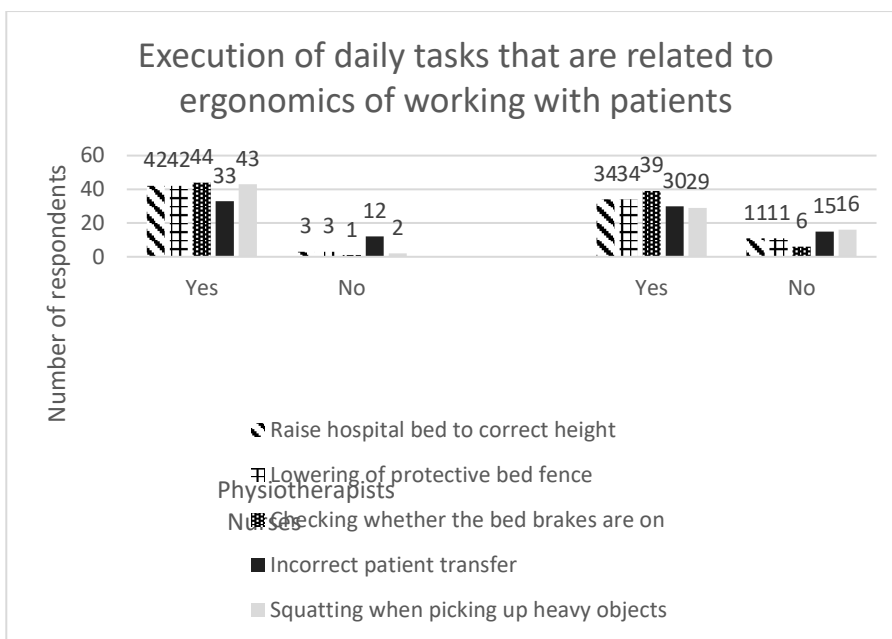
Graph 3 shows 7 physiotherapists (15.6 %) experienced mild pain (according to subjective assessment), 17 respondents (37.8 %) experienced moderate pain, 6 respondents (13.3 %) experienced severe pain and 3 respondents (6.7%) experienced very severe

pain. 12 respondents (26.7%), had no back pain. Among those surveyed nurses who had had a back pain, 2 nurses (4.4 %) experienced mild pain (according to subjective assessment), 17 respondents (37.8 %) experienced moderate pain, 13 respondents (28.9 %) experienced severe pain and 1 respondent (2.2 %) experienced very severe pain. 12 respondents (26.7 %) had had no back pain in the last year. Among 20 physiotherapists (44.4 %) back pain persisted for 1 week or less, 7 respondents (15.6 %) had back pain for 2-4 weeks and 6 respondents (13.3 %) had back pain for more than 4 weeks. 12 respondents (26.7 %) had no back pain. Among 19 surveyed nurses (42.2 %) back pain persisted for 1 week or less, 11 respondents (24.4 %) had pain for 2-4 weeks and 3 surveyed nurses (6.7 %) felt back pain for more than 4 weeks. 12 respondents (26.7%) had no back pain.

Physiotherapists were on sick leave due to back pain on average 1.66 ± 4.56 days per back injury event, absence from work lasted from a minimum of 0 to a maximum of 20 days. 39 respondents (86.7 %) who experienced back pain did not take sick leave. 1 physiotherapist (2.2 %) was absent from work for 7 days, 2 respondents (2.2 %) were absent for 10 days, 2 respondents (4.4 %) were absent for 14 days and 1 respondent (2.2 %) was absent for 20 days. Among nurses, sick leave lasted on average 2.91 ± 8.29 days per back injury event, the minimum absence from work was 0 days with a maximum of 45 days. 38 nurses (84.4 %) who experienced back pain took no sick leave. 1 respondent (2.2 %), was absent from work for 7 days, 1 respondent (2.2 %) was absent for 10 days, 2 respondents (4.4 %) were absent for 14 days, 1 respondent (2.2 %) was absent for 20 days and 1 nurse (2.2 %), was absent from work for 45 days.

42 physiotherapists (93.3%) were familiar to ergonomic principles in working with patients, 2 physiotherapists (4.4%) were partly familiar with ergonomic principles and 1 physiotherapist (2.2%) had not been introduced to ergonomic principles in working with patients ($p < 0.001$). 38 surveyed nurses (84.4%) were familiar with ergonomic principles in working with patients, 1 respondent (2.2%) was partly acquainted, and 6 respondents (13.3%) were not acquainted with ergonomic principles in working with patients ($p < 0.001$).

Graph 4: Comparison of execution of common daily tasks performed by physiotherapists and nurses.



Graph 4 shows that 42 physiotherapists (93.3 %) raise the hospital bed to the correct height when working with a patient and 3 physiotherapists (6.7 %) do not raise bed to the correct height. 42 respondents (93.3 %) lower the protective bed fence when working with the patients and 3 respondents (6.7 %) do not lower the bed fence. 44 physiotherapists (97.8 %) always check whether the bed brakes are on and 1 person (2,2 %) does not check the bed brakes. 33 respondents (73.3 %) do patient transfers incorrectly (lifting the patient up from the bed and abruptly transferring him to the chair). 12 physiotherapists (26.7%) do patient transfers correctly. To pick up heavy objects from floor 43 physiotherapists (95.6%) use the right technique (squatting), 2 persons (4.4%) do this activity incorrectly. 34 surveyed nurses (75.6%) raise the hospital bed to correct height when working with a patient. 11 nurses (24.4%) do not raise the bed to correct height. 34 respondents (75.6%) lower the protective bed fence when working with the patient. 11 persons (24.4%) do not lower the bed fence. 39 respondents (86.7%) always check whether the bed brakes are on and 6 subjects (13.3%) do not check bed brakes. 30 respondents (66.7%) do patient transfers incorrectly (lifting the patient up from the bed and abruptly transferring him to a chair), 15 persons (33.3%) do patient transfers correctly. To pick up

no statistically significant relationship between the occurrence of spinal pain and lifting the

heavy objects from floor, 29 respondents (64.4%) use the right technique (squatting), 16 persons (35.6%) perform this activity incorrectly.

Hypothesis 1: Pain in the back is more common among nurses than physiotherapists.

Based on the statistical test we found that there is no statistically significant difference in the occurrence of back pain between the two professions in the last year, therefore we can discard hypothesis 1 ($\chi^2(3) = 2.277$ and $p = 0.517$).

Hypothesis 2: Pain in the back in both professions occurs frequently due to a lack of knowledge of ergonomics at work with the patient.

To test hypothesis 2 we used chi-square test. The hypothesis will be tested on the basis of the answers to the 24th question of the questionnaire, which consists of 5 sub-questions. Participants had to confirm or to reject the statement regarding the knowledge of handling the patients. We analysed and statistically tested each sub-question.

The first statement was: "I raise the hospital bed to a suitable height." 54 physiotherapists and nurses who raise the hospital bed to a suitable height had had back pain in the last year and 22 respondents had had no back pain in the last year. 12 physiotherapists and nurses, who raise the hospital bed to a suitable height, had had back pain in the last year and 2 respondents had had no back pain in the last year. Based on the statistical test we found

hospital beds to the suitable height ($\chi^2(1) = 1.300$, $p = 0.254$).

The second statement was: "I always lower the security fence on the hospital bed." 54 physiotherapists and nurses who lower the security fence on hospital bed when working with patients had had back pain in the last year and 22 participants had had no back pain. 12 physiotherapists and nurses who lower the security fence on hospital bed when working with patients had had back pain in the last year and 2 had had no back pain. Based on the statistical test we found that there is no statistically significant relationship between the occurrence of back pain and lowering of the security fence on hospital bed when working with patients ($\chi^2 (1) = 1.300$, $p = 0.254$).

The third statement was: "I always check whether the brakes on the hospital bed are engaged." 60 physiotherapists and nurses who check if the brakes are engaged had back pain in the last year and 23 respondents had no back pain. 6 physiotherapists and nurses who check if the brakes are engaged had back pain in the last year and 1 respondent had no back pain. Based on the statistical test we found no statistically significant relationship between the occurrence of back pain and use of the brakes on the hospital bed ($\chi^2 (1) = 0.595$, $p = 0.441$).

The fourth statement was: "When doing a patient transfer I lift the patient up from the bed and transfer him abruptly to chair." 44 physiotherapists and nurses who perform the patient transfer incorrectly had had back pain in the last year and 19 respondents had had no back pain. 22 physiotherapists and nurses who performed the patient transfer correctly had had back pain in the last year and 5 respondents had had no back pain. $\chi^2 (1) = 1.310$ $p = 0.252$ ($p > 0.05$). Based on the statistical test we found no statistically significant relationship between the occurrence of back pain and incorrect transfer of the patient ($\chi^2 (1) = 1.310$ $p = 0.252$).

The fifth statement was: "I squat to pick up heavy objects from floor." 50 physiotherapists and nurses who use the correct technique to pick up heavy objects from the floor had had back pain in the last year and 22 respondents had had no back pain. 16 physiotherapists and nurses who use the correct technique to pick up heavy objects from the floor had had back pain in the last year and 2 respondents had had no back pain. Based on the statistical test we found no statistically significant relationship between the occurrence of back pain and the use of leg

strength to lift heavy objects from the floor ($\chi^2 (1) = 2.784$ $p = 0.095$).

Hypothesis 3: The incidence of back pain does not vary according to years of service.

The Table 1 shows that the group of health workers who had pain in the back in the last year, also had a higher average rank (49.89), suggesting that these workers have more years of service. The hypothesis is discarded based on a statistical test, because there was no statistically significant relationship between length of service and the presence of back pain ($U=502.00$, $p=0.008$).

Hypothesis 4: Back pain occurs less frequently among nurses and physiotherapists who work in health centres and clinical departments with ambulatory patients.

The fourth hypothesis will be verified by Fisher's Exact Test, due to there being too few respondents in some categories. Firstly, we will look at the distribution of the respondents according to the place of employment and the incidence of back pain. To help us with our statistical analysis, we divided data from all venues into two groups. In first group we merged all data from respondents who work with less ambulatory patients. In second group we merged all data from respondents who work predominantly with more ambulatory patients. Therefore, we divided places of employment into two separate groups according to ambulatory capabilities of patients.

Table 2 shows that 16 respondents (17.8 %) of both professions who work predominantly with less ambulatory patients experienced pain in the lumbar spine in the last year, 13 respondents (14.4 %) felt pain in the cervical spine, 21 respondents (23.3 %) felt pain in both cervical and lumbar spine, and 19 respondents (21.1 %) felt no pain. 12 respondents (13.3 %) of both professions who work predominantly with ambulatory patients, experienced pain in the lumbar spine in the last year, 2 respondents (2.2%) felt pain in the cervical spine, 2 respondents (2.2 %) felt a pain in both cervical and lumbar spine and 5 respondents (5.6%) felt no pain. Based on statistical analysis, we found a statistically significant relationship between back pain and place of employment. The hypothesis is confirmed, by a statistically significant connection between the two variables (Fisher's Exact test= 8.809, $p=0.03$).

Table 1: Average range of respondents with and without back pain compared to length of service.

Back pain in the last year		N	Average range
Years of service	Back pain	66	49,89
	No pack pain	24	33,42
	Sum	90	

Table 2: Relationship of physiotherapists and nurses to place of employment and presence of back pain.

Place of employment		Pain in lumbar spine	Pain in cervical spine	Pain in lumbar and cervical spine	No pain	Total
		Less ambulatory patients (count, %) Expected count	16 (17,8) 21,5	13 (14,4) 11,5	21 (23,3) 17,6	19 (21,1) 18,4
	Ambulatory patients (count, %) Expected count	12 (13,3) 6,5	2 (2,2) 3,5	2 (2,2) 5,4	5 (5,6) 5,6	21 (23,3) 21,0
	Total count and % Total expected count	28 (31,1) 28,0	15 (16,7) 15,0	23 (25,6) 23,0	24 (26,7) 24,0	90 90,0

Discussion

In this study we wanted to determine whether back pain in the back is more common among nurses or physiotherapists and determine the effect of ergonomic knowledge on the incidence of back pain. We also studied the impact of years of service and influence of workplace on the incidence of back pain.

We found that 73.3% of all respondents had back pain in the last year. Among the physiotherapists, there were 73.3% of those who had back pain. The same is true for nurses, of whom 73.3% also had back pain in the last year. According to our results, both profession are equally prone to back pain. Alperovitch-Najenson, Treger, and Kalichman¹⁸ found that 73.1 % of 26 physiotherapists and 43.9 % of 54 nurses had had back pain in the last year ($p = 0.004$). Pain in the cervical spine was more frequent among physiotherapists (57.7%) than among nurses (40.4%) ($p = 0.135$).

We found back pain among majority of physiotherapists (82.2%) and nurses (88.9%) occurred only after commencement of their profession ($p = 0.006$). The most common site of pain among physiotherapists (37.8 %) in the last year was the lumbar spine. Among nurses (28.9 %), the most common sites of pain were the cervical and lumbar spine. We found pain among

physiotherapists (44.4 %) and nurses (42.2 %) generally lasted for 1 week or less.

Shehab¹³ found that 70 % of 100 physiotherapists experienced back pain in the last year. The average age of the participants was 35.9 ± 8.5 years (minimum age was 23 years, maximum 58 years), 41 % were employed in a hospital. Landry¹⁹ also noted that 70.9 % of 344 healthcare workers had back pain in the last year. The research was conducted in one of the Kuwaiti hospitals. Sopajareeya²⁰ conducted a study and obtained similar results to our study. The study included 265 nurses and found back pain occurred among 61.5% of nurses in the last year. Karahan⁸ investigated the incidence of back pain among physiotherapists and nurses. The survey enrolled 1,600 physiotherapists and nurses and obtained similar results to our study. Their results showed that 77 % of physiotherapists and 72.7 % of nurses had episodes of back pain in the last year.

We have found that the place of employment has an impact on the incidence of back pain. Those physiotherapists and nurses who work in environments with less ambulatory patients, also have more problems with back pain ($p = 0.03$). Furthermore, those physiotherapists and nurses with more years of service have more back pain ($p = 0.008$). Al-Eisa and Al-Abbad²¹ did

a study on a sample of 155 nurses in Saudi Arabia and found that a higher incidence of back pain among nurses with more years of service. The findings of the authors Shehab¹³ are exactly the opposite. They found that generally physiotherapists (38 %) with low back pain had less than 5 years of work experience. The authors believe that is due to improper body mechanics and lack of experience with the techniques of handling patients.

Conclusion

Nurses and physiotherapists are highly exposed to the risk of developing back pain. Almost three-quarters of the representatives of the two professions experienced back pain in the last year, a share comparable with the findings of other studies. In addition, we highlighted the fact that the majority of physiotherapists and nurses developed back pain when they started working as physiotherapist or nurse. As expected, we demonstrated that the place of employment has an impact on the incidence of back pain. It is understood that, in institutions with less ambulatory patients, the risk of back pain is increased. In these institutions the medical staff are especially burdened because of frequent patient transfers (from bed to bed, from bed to wheelchair, etc.), which are in most cases manual without the use of ergonomic assistive devices. We also note that the length of service has an impact on the incidence of back pain. This means that physiotherapists and nurses with more years of service are at increased to develop back pain.

We are surprised by the finding that knowledge of health professionals in the area of ergonomics does not have a large impact on reducing the incidence of back pain, despite the fact that the majority of respondents were aware of the ergonomic recommendations for work (by formal education or employer). Despite the results, we believe that knowledge of the theory of ergonomics is very useful, but it is not enough. Apparently, the (correct) use of ergonomic assistive devices is inevitable if we want to reduce the incidence of back pain.

We believe that educational institutions have an important role in lowering the incidence of back pain among healthcare workers. Their goal should be educating students not only how to correctly execute manual patient transfers, but also about proper body mechanics. In addition, it is important that student physiotherapists and nurses are acquainted with and well trained in the use of a variety of ergonomic assistive devices. Furthermore, healthcare providers (hospitals,

homes for the elderly, etc.) have an important role in meeting the need for at least basic ergonomic assistive devices (movable patient lift, sliding board, low friction mat). In this way, we can provide a safer work environment for healthcare professionals, increase patient safety, and decrease the risk of additional injuries.

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[Original]

Protein p-53 Isoforms in Genetic Events of Chronic Lymphocytic Leukemia

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ABSTRACT

Background. Recent, endogenous somatic gene therapy research is a basic of trial clinical and therapeutic trial. The DNA, is used to treat a disease arising as a result of mutations in chromosomal regions. In the past few years, this method has been included in the treatment of Chronic Lymphocytic Leukemia (CLL), acute lymphocytic leukemia, [ALL], or multiple myeloma [MM].

Aim. In this study are presented the latest researches in the field of molecular medicine, in terms of Chronic Lymphocytic Leukemia (CLL), emerged from the P53 gene deletion in human lymphoma genome.

Method. In recent years proved that the best technique in the investigation of malignant lymphocytes is the Fluorescence in situ hybridization (FISH). This method is used as an alternative to chromosomal banding, a conventional application in molecular medicine.

Previous results. In the literature it was registered, in previous years, on an international study, conducted on 109 cases of CLL, 79 cases (72.5%) who had more genetic abnormalities: the remaining 30 cases (27.5%) had normal results, using FISH technology. The majority of patients, 67% (53.79) had a single anomaly and the remaining 33% had two or three genetic abnormalities. The chromosomes 14q32 /17p translocations in LLC genome, which appeared similar to some common, had demonstrated abnormalities involving IGH gene, located on chromosome14q32.

Conclusion. The frequencies of P53 gene mutations and deletion in CLL can be categorized as individual biomarkers in proteomic and genomic profile for this type of leukemia that can be implemented in targeted patient treatment of personalized medicine.

Keywords: P-53 gene, lymphocytic leukemia, apoptosis, fluorescence in situ hybridization.

1. INTRODUCTION

Chronic Lymphocytic Leukemia, (CLL), occurs in middle aged and elderly person, affecting men to women in approximately 2;1. Many patients are asymptomatic when the disease is diagnosed. Patients with minimal evidence of disease, ie, lymphocytosis only, are considered to be early stage of disease, while those demonstrating compromise of bone marrow function as anemia or thrombocytopenia, are in advanced stages [1, 2, 3]. The diagnosis of CLL can be established initially by optical microscopy morphology combined with immune-phenotyping: monoclonal antibodies in the panel of lymphocytic membrane receptor of B lymphocytes CD5 +, CD 19+, CD20 + and CD23 +, CD28 with B lymphocytes which express IgM or IgD heavy chains or immune-globulins with light chains kappa or lambda. Hypo-gamaglobulinemia occurs initially o during the course of the disease in most patients with LLC [4, 5].

Various biological and genetic markers also have prognostic values in CLL. Clonal chromosomal abnormality by technique FISH can be detected until 80% from patients with LLC. The most clonal abnormalities involves long arm q of chromosome 13, and band 13q14, with relative good prognostic, trisomy 12, deletions 11q22-q23, 7q21-q23 and deletion 17p13, last associated with more advance disease or shortened survival times [6, 7, 8].

Objective of this study is to present the latest researches in the field of molecular medicine, in terms of CLL, emerged from the P53 gene with deletions or translocations in human lymphoma genome and the prognostic and treatment of this diseases, in function of damages of P53 gene. Also, are following the correlations between characteristics LLC disease and response to treatment with tyrosinekinase inhibitor treatment until the indication of alogenic stem transplantation.

2. DESIGN

In recent years was proved that the best technique in the investigation of malignant lymphocytes is the Fluorescence in situ hybridization (FISH). The method is a gene analysis technique (recombinant DNA technology) and consists of coupling a fluorescent-labeled nucleic acid probes with a specific chromosomal region, (In situ hybridization with digoxigenin or fluorescent classical dye, molecular genetics and genomics). The method is used to identify the chromosomal abnormalities and its numerical and structural sites.

The principle of this method consists in attaching to the target sequence a single-stranded DNA probes (about 40 kb) fluorescently labeled on the basis of the complementary with a target sequence of a chromosome. Hybridization of the probe with the cellular DNA is visualized in the fluorescence microscope equipped with excitation and emission filters, which enables the reading target as a specific signal. FISH technique allows the detection and chromosomal rearrangements complex. By FISH-engineering, can be detected the chromosome deletions: 7q, 13q, 11q, 13 q, 14q and 17p, from peripheral blood leukocytes or bone marrow. This test requires cell culturing and the analysis can be performed only in conditions in which leukocyte count is $> 10 \times 10^3 / \mu \text{L}$ and the percentage of immature cells is on blood smear is $> 20\%$.

3. PREVIOUS RESEARCHES RESULTS IN GENETIC PANEL OF LLC

3.1. Markers of LLC discovered by Flow Cytometry

In the previous literature it was registered, on an international study, conducted on 109 cases of CLL, 79 cases (72.5%) who had more genetic abnormalities; the remaining 30 cases (27.5%) had normal results, using the technique Florescence in situ Hybridization, (FISH). The majority of patients, 67% (53.79) had a single anomaly and the remaining 33% had two or three genetic abnormalities. The band chromosomes 14q32 17p translocations in LLC genome, which appeared similar to some common, had demonstrated abnormalities involving IGH gene, located in 14q32 region [9]. The 90 cases of CLL were analyzed for the presence of lymphocytic membrane receptor of B lymphocytes, CD38 and the 81 cases were placed in groups of prognosis. Nineteen (23%) of 81 were CD38 + with a poor prognostic. A similar percentage of cases CD38

+ was present in cases with deletions cromozomiale17q and 11q (33%), translocation (4q-11q (36%)) and cases results FISH normal were in percentage [33%]). CLL cases with trisomy 12 or isolated 13q- had the lowest percentage of CD38 + cases; 15% and 8%, respectively. ZAP-70 receptor was tested in 36 cases; 10 were positive [10].

3.2. Genetic Markers discovered by FISH Technology

Deletions of chromosomal region 13q14 were frequently associated with cases of CLL and lymphocytosis with monoclonal B cells may precede occasionally LLC or aggressive lymphomas and is suggested that this region contains a tumor suppressor gene, similar to gene P-53 with who combine their work. All this leads us to conclude that the appearance LLC deficiency occurs through a common P-53 gene and chromosomal region 13q14 gene.

CLL and Hodgkin Lymphoma (HL) are particularly dependent on their microenvironment and have associated signaling pathways and deletion of miR15/16 locus, common in specially, in CLL. Micro-ARN, miR15 and miR16 are located at chromosome 13q14, a region deleted in more than half of B cell chronic lymphocytic leukemia (B-CLL) [11]. Micro-RNA deletions, miR-15a / 16-1, both accelerate the proliferation of human B cells by modulating the expression of genes that control cell cycle progression. These results define the role of the 13q14, with deletions P-53 in the pathogenesis of CLL [12].

In another study methods were used FISH to detect cytogenetic features in 275 cases of B-CLL in 48 hospitals from China. The frequency abnormalities were as follows: deletion 13q (56.4%), trisomy 12 (34.5%), deletion of P-53 (33.5%) and 11q22 deletions (30.5%). It was evident that patients with P-53 deletion had lower levels of Hemoglobin ($P = 0.001$) and PLT ($P = 0.003$) compared to patients without the gene deletion P-53. [13]. In general, somatic mutations in the gene P-53, due to the influence of physical factors, chemical or biological infectious, over the years tend to predict clinical outcomes in cancer patients due to the central role of P-53, with the role of tumor suppressor gene. In the other conditions, in a recent paper were systematically explored the optimal conditions required for growth of tumor spheroids in hepatocarcinoma [14].

It has examined the morphological growth of each cell line. Also they were evaluated gene expression patterns of P-53 and E-cadherin, [CDH1] in selected cell lines. CDH1 is located on

the surface of cancer cells and plays an increasing important role in the formation of cell-cell contacts and is responsible for maintenance of cell polarity. In addition, CDH1 plays an important role in the physiology of the extracellular matrix (ECM), [15]. The role of adhesion molecules such as integrins and E-cadherin (CDH1), in signals transduction of intracellular cancer cells have been elucidated above. The presence of cell-cell contact and cell-matrix contacts play an important role in the modulation patterns of morphological and gene expression of cancer cells. The extracellular matrix (ECM) of a tumor microenvironment is composed of various glycoproteins and fibrous proteins that allow cancer cells to interact with each other and normal cells [16]. The characteristic surface roughness of the edge of the spheroid SNU-387 was much more prevalent as compared to the SNU-475 cell line [Fig. 1], [17]. With adjusting FISH with immune-fluorescence staining of the interphase cell lines showed protein p53 gene product P-53, with varying intensity and color CDH1 [18].

3.3. TP53 status and metabolic cellular response

In particular, mutant p53 proteins are known to exhibit a dominant-negative effect, which can lead to an abnormal accumulation in the nucleus. However, the dominant negative effect, typically depending on the specific position of the mutation in the p53 protein [19]. In the normal cells, suppressor gene P53 gene, coding proteins that bind to DNA and regulate the expression of genes, prevents the genome mutations. A mutation of the gene P-53 will inevitably lead to a process of carcinogenesis in which the cell divides endlessly [20]. In recent years proved that the best technique in the investigation of malignant lymphocytes is the

FISH technique and this method is used as an alternative to chromosomal banding, a conventional application in molecular medicine [21].

Identification of P53 gene mutations in regions of 17 chromosome of hematological neoplasm is important because these mutations have an impact on the clinical course of patients and requires an attitude adjustment therapeutic adequate [22]. However, the primary pathogenic event that leads to growth, proliferation and survival of B-cells in CLL is difficult to determine. Molecules involved in B cell receptor (BCR) signaling pathways and constitutes rise to cytoplasmic survival factors, acting in concert to confer resistance to apoptosis [23]

3.4. Biological Activities of the p53 Isoforms

Restoring function to p53 can induce lymphoma, apoptosis. Recent, endogenous somatic gene therapy research is a basic of trial clinical and therapeutic trial. The nucleic acid, DNA, is used to treat a disease arising as a result of mutations in chromosomal regions. In the past few years, this method has been included in the treatment of CLL, acute lymphocytic leukemia, [ALL], or multiple myeloma [MM], [24]. **Cancer genome sequencing studies confirm that P53 is the most commonly mutated tumor suppressor gene in human cancers. The majority of studies indicate that the presence of mutated P53 is associated with bad prognosis in various cancer types.** Five new P53 mutations were identified in six pedigrees from hereditary cancer clinics, (17p13.1), [25]. Mutations in the p53 gene are known primarily to inactivate properties onco-suppressor protein p53 wild type, losing the function of transcription (loss-of-function - FOL), and this can arm cancer cells with new oncogenes (gain-of-function -GOF). P5-53 when

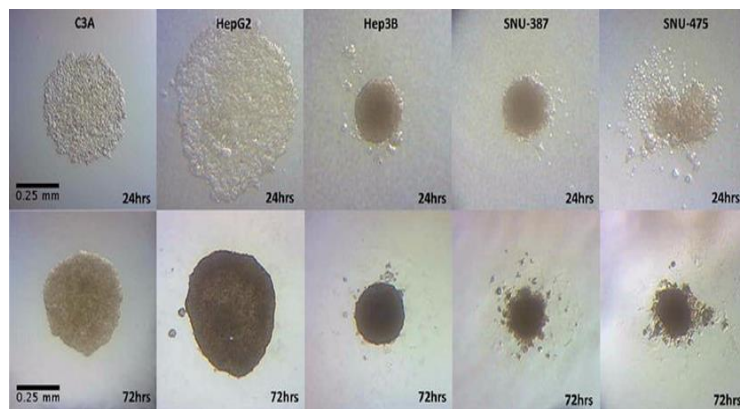


Fig. 1. Cellular lines with the spheroid formations and culture: a model system to understand cancer cell growth mechanics (Accepted figures reproduction: Pomo, M.J. Taylor, M.R. Gullap, RR. Influence of TP53 and CDH1

genes. Hepatocellular cancer spheroid formation and culture: a model system to understand cancer cell growth mechanics. *Cancer Cell International* 2016; 16:1-44 E-mail: rgullapalli@salud.unm.edu), 18].

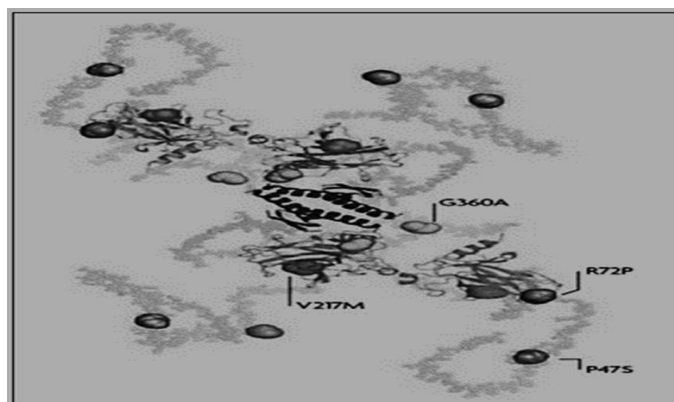


Fig.2.Three dimensional structure of p53 protein in its tetrameric isoforms in cancer. (Accepted figures reproduction; Three dimensional structure of p53 protein in its tetrameric isoforms in cancer. JC Bourdon, K Fernandes, F Murray-Zmijewski, G Liu, A Diot. p-53 isoforms can regulate p53 transcriptional activity *Genes & development* 19 (18), 2122-2137, Email: ku.ca.ednud@nodruob.j).

the gene exerts its function, glucose uptake is enhanced by a GOF producing shunt glucose transporter, Glut-1 on the surface of the cancer cell membrane [26]. Encoded by the mutated gene variants P-53 tumor suppressor proteins p53 isoforms function of oncoproteins they acquire assets, promoting tumor growth and metastasis. [27].

P-53 mutations are not present in normal cases and this induces exposure to a genotoxic allele. Therefore, mutant p-53 co-exist with wild-type (WT) p53, before losing the wild-type allele by loss-heterozygosity (LOH) [27]. During the development of the transformed cells, the p53 protein derived from the mutated allele P-53 coexists with the wild type (WT) allele of the p53 from the other for different periods of time, until the WT allele is generally lost through loss of -heterozygosity (LOH), resulting solely from the existence of only p53 mutant alleles. Moreover, mutant p53 protein, called "gain-of-function" (GOF), acquires new activities that help cancer aggression. Induction of p53 action is carried out largely by decoupling the p53-MDM2 interaction her, leading to increased levels of p53 [28].

3.5. Protein p-53 Isoforms and Cancer

Research has shown that this restoration

of function of the protein p-53 can result in regression of certain cancer cells without damaging other cells. For example, restoration of the function of endogenous p-53 can induce apoptosis in lymphoma while cell growth may be reduced to normal levels. Thus the pharmacological reactivation of p53 is presented as a viable treatment option to cancer [29]. The broad spectrum of phenotypes of P53 gene mutations cancer is supported by the fact that the p53 protein iso-forms have different cellular mechanisms of prevention against cancer [27]. Acetylation of p53 and phosphorylation is an important means of post-translational modifications and is indispensable for its activation that is a reversible enzymatic process, (Figure 2), [30].

-The both acetylation and deacetylation of p53 proteins are involved in the fine regulation of cellular responses to DNA damage and genotoxic stress large spectrum of cancer phenotypes due to mutations in the P-53 gene is also supported by the fact that different isoforms of p53 proteins have different cellular mechanisms in cancer. Mutations in P-53 gene can give rise to different isoforms protein p-53, preventing their overall functionality in different cellular mechanisms and thereby extending the cancer phenotype from

mild to severe [31].

At the molecular level, certain stimuli, such as genotoxic stress (DNA damage-inducing agents) and glucose deprivation, promote a series of reversible post-translational modifications (PTMs) of p53 including multisite phosphorylation of the transactivation domain (N-terminus). In addition to contributing towards the induction of p53, these events are thought to regulate p53-mediated transcription at individual promoters, possibly in a selective manner (the 'barcode' hypothesis).

Ser-15 phosphorylation also triggers a sequential series of additional phosphorylation events in p53 (including phosphorylation of Ser-9, -20, -46 and Thr-18) that contribute further to p53 induction and activation. These findings suggest that Ser15 phosphorylation is therefore a major focal point in the activation of p53. Ser15 phosphorylation is required to permit local acetylation of histones and relaxation of chromatin.

Mutation of Ser-15 to alanine results in partial failure of p53 to inhibit cell cycle progression. In this context the nuclear p-53 protein was shown that protect the cell of a malignant process, and only cytoplasmic p-53 protein, by its isoforms, in modified cytoplasmic medium, by high concentration of anaerobic ATP, drives at cancer, [32].

The current study showed that the level of p21 is strongly correlated with the activity of Mammalian Target Rapamycin (m-TOR) but not p53 status. The study was published in the February 2, 2016, online edition of the journal Nature Communication (www.cnio.es). By the Warburg effect, glucose maintains stability mutant p53 gene promotes cancer cell growth and generating a positive regulatory loop. This appetite for glucose to cancer cell, identify a potential therapy of

malignant diseases, which is currently under extensive investigation [33].

Protein p-53 plays an important role in the regulation of glycolysis that is showed experimentally. Most researches seems to indicate that, in line with its role as tumor suppressor p53 is able to fall glycolysis [34]. This activity can be regarded as an attempt to counteract the acquisition of p53 aerobic glycolysis, usually associated with the cancer cells. Of major concern, the p53 protein has been identified as an important regulator of glucose transport, and was repressing transcription has been shown to both receptors GLUT1. By contrast, the mutant p-53 does not affect the GLUT1 and GLUT4 receptor activity [35].

The broad spectrum of phenotypes of P53 gene mutations cause cancer is supported by the p53 protein isoforms Mutations in the gene P-53 can give rise to different isoforms of protein p-53, preventing their overview in different cellular functionality. This mechanism thus is extending the phenotypic of cancer from mild to severe [36]. Previous studies have suggested that expression of gene P-53 works like a watch and this has a circadian rhythm. Disruption of the circadian rhythms appears to be associated with accelerating the development of cancer. Current models are also useful for modeling protein isoforms of p53 mutations and their effects of oscillation could promote pharmacological drug discovery of chemotherapy in the treatment of CLL [37]. A mutant p53 protein will no longer bind DNA in an effective way, and, as a consequence, the p21 protein will not be available to act as the "stop signal" for cell division [38]. The expression the CDK gene, which encode protein p21, is tightly controlled by the tumor suppressor protein p53, through which this protein mediate the p53-protein dependent cell cycle G1, phase arrest in

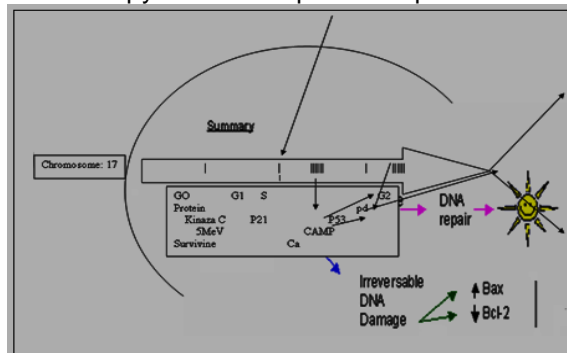


Figure 3. Current models are useful for modeling protein isoforms of p53 mutations and their effects of oscillation

response to a variety of stress stimuli, [39]. Current models are also useful for modeling protein isoforms of p53 mutations and their effects of oscillation could promote pharmacological drug discovery in chemotherapy in the treatment of CLL farmatokinetic, [40], [Figure 3].

3.6. The effect of Aurora-kinase A and B

Aurora kinases, enzymes A and B, play critical roles in regulating spindle assembly, chromosome segregation, and cytokinesis to ensure faithful segregation of chromosomes during mitotic cell division cycle. Aberrant expression of Aurora kinases, on the other hand, cause defects in mitotic spindle assembly, checkpoint response activation, and chromosome segregation leading to chromosomal instability. Aberrant expression of the Aurora kinases–p53 protein family signaling axes appears to be critical in the abrogation of p53 protein family mediated tumor suppressor pathways frequently deregulated during oncogenic transformation process.

Aberrant expression of the Aurora A kinases–p53 protein family signaling axes appears to be critical in the abrogation of p53 protein family mediated tumor suppressor pathways frequently deregulated during oncogenic transformation process. Phosphorylation of p53 serine-106 was shown to inhibit the interaction of p53 with MDM2 and prolong the half-life of p53 protein [42].

Aurora-kinase B has also been shown to interact with and phosphorylate p53 at multiple residues in DNA-binding domain. Similar to the effect of Aurora-A phosphorylation on p53 activity and stability, Aurora-B phosphorylations of p53 at serine-269 and threonine- 284 inhibit p53 transactivation activity, whereas phosphorylations at serine-183, threonine-211, and serine-215 accelerates the degradation of p53 through poly-ubiquitination-mediated proteasome pathway, [MDM2], [43,44].

4. NEW CANCER THERAPIES

Some studies showed that patients with cancer make antibodies against p53 proteins, but the frequency and magnitude of this response is still under debate [45]. The most advanced work used a long synthetic peptide mixture derived from p53 (p53-SLP; ISA Pharmaceuticals, Bilthoven, the Netherlands). The vaccine is delivered in the adjuvant setting and induces T helper type cells. About one-third of cases (30%) did not have recurrent chromosomal mutations, suggesting a

high degree of genetic heterogeneity and no clear mutational drivers of CLL [46]. Consistent with a role in disease initiation, global DNA hypomethylation and shortened telomeres were found to be significantly associated in early stage CLL tumors (Binet A) from untreated patients [47].

Similarly, methylation at the CDKN-2A gene, (INK4a/ARF) locus can epigenetically silence the expression of the p14ARF protein, and block the ability of activated oncogenes to stabilize the p53 response. Antibodies specific for total p53 and for p53 phosphorylated at three different sites within the activation domain were used in parallel analyses. This has led to a number of active clinical trials using immunization with large peptides derived from p53 and a search for evidence of a natural immune response to p53 in cancer patients. While it has been established for some time that cancer patients make antibodies to p53 the frequency and magnitude of this response is still debated.

A body of work using two mouse models has recently provided strong evidence that aberrant hypo-methylation promotes CLL development [48]. Thus, aberrant hypo-methylation of a single promoter may upregulate several micro RNAs possibly contributing to tumorigenesis .TET2 enzyme, conversely, is an enzyme that plays a central role in DNA demethylation by catalyzing the conversion of 5-mC to 5-hydroxymethyl cytosine (5-hmC). Recent studies have suggested strong cross-talk between histone modifications, transcriptional activity, and prior DNA methylation status on DNMT localization [49]. Treatments with specific methylation agents are used in combination with conventional anti-neoplastic chimio-therapy treatment. Somatic gene therapy has become a research table in clinical trials using a therapeutic DNA, for the treatment of diseases [50].In recent studies has included the method for the treatment of CLL [51].

In experimental models, disrupting the MDM2–p53 interaction restored p53 function and sensitized tumors to chemotherapy or radiotherapy. For example in hematologic malignancies, such as multiple myeloma, chronic lymphocytic leukemia (CLL), the induction of p53 – using a small MDM2-inhibitor molecule, nutlin-3 – can induce the apoptosis of malignant cells [52].

Nutlins are a group of cis-imidazoline analogs which have a high binding potency and selectivity for MDM2. Nutlin-3 displaces p53 by competing for MDM2 binding. It has also been found that nutlin-3 potently induces apoptosis in cell lines derived from hematologic malignancies and B-

cell CLL with frequent translocation 14q32- 17p, with a good therapeutic response [53].

4.1 Immune therapeutic success.

After the chemotherapy treatment, the tumor antigens are taken up by antigen presenting cells (APC) and are presented in the context of co-stimulatory molecules B7 from malignant cells. T cells recognize antigens to become activated. T cells can differentiate into memory T cells that can be reactivated in the presence of recurrent tumor. Another way of inhibiting cell identified after the CTLA-4 receptor is represented by PD-1 (programmed to the pH) and PD-L1, or ligand. Like CTLA-4, PD-1 is expressed only in activated T cells to stop their proliferation at a time, limiting the production of memory T lymphocyte type. However, in contrast to CTLA-4, PD-1 inhibits T cell responses by interfering with T cell receptor signaling, as opposed to out-competing CD28. There are ongoing clinical trials with anti-CTLA-4 (Ipilimumab, Med-Immune / Astra-Zeneca) plus anti-PD-1 or anti-PD-L1 in other types of tumors with preliminary data showing promising results [54].

Combination therapy can improve the anti-tumor responses. Recently, somatic gene therapy is based on climate science and therapeutic. DNA (either integrated into the genome plasmid or external) is used experimentally to treat a disease that occurs due to mutations in chromosomal regions. In recent years, this method has been included in the treatment of CLL, acute lymphocytic leukemia [ALL], or multiple myeloma [MM].

5. CONCLUSION

The studies of genotypic and phenotypic chromosomes aberrations by FISH method allow the identification of differential diagnosis at patients with CCL. The frequencies of gene mutations, deletions or translocations of P53, in CLL, can be classified as biomarkers of individual proteomic and genomic profile for this type of leukemia.

Identification of P53 gene deletions and mutations in regions of chromosome 17 in hematological malignancies is important because these mutations have an impact on the clinical management of patients and requires an attitude adjustment therapeutic adequate in a personalized medicine. Personalized treatments will be applied by combining diagnostic tools, knowledge databases and therapeutic drugs.

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[Short Communication]

**A lesson from the Aviation industry:
IT integration with EMR**

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Healthcare Organization of Veneto Region Italy

Abstract

Regione Veneto, Italy, Public Healthcare organization is adopting new strategies and tools for Risk Management. Similarly to the Aviation industry, our target is the transition from *Reactive* to *Proactive* clinical safety. Patient peculiarity such as allergies, diabetes, hypertension, ecc., which are stored in the individual electronic database, will be compared with patient treatment by means of collecting and processing data in order to detect latent problems and develop targeted actions for improvement. Related data flows are nowadays collected from claims, sentinel events and voluntary reporting. The novelty that we propose is to create a direct link among the electronic patient data (EMR, EHR), and a database of standards, guidelines and best practices in order to make all of the information

immediately available to professionals. A computerized dashboard will present several categories of data and taxonomies, each interconnected with a risk management section, indexed and processed into charts and graphs to highlight regional and local risks trends of adverse events. Like the flight data monitoring system (FDM) and the engine monitoring system (EMS) in airplanes, the software will automatically warn the user for risk parameters. A *big data* system will then support the operational units at each level from the front line to the top management, and will monitor not only the healthcare patient related risks but also communication and organizational issues, showing a *big picture* for decision makers. This will result in a benefit for safety, quality, reduction of litigation and insurance costs. The project will take into account all patient privacy related aspects.

Key Words: Clinical Risk, Error, Aviation, Information Technology, Proactive, EMR, HER, Appropriateness

Future important aspects of healthcare Safety will be more and more centered on the synergy between human performance, multi discipline teams and information technology; exchanges between industries, in terms of technology, and methodology, are essential to develop new skills. You will certainly remember, for example, that WHO adopted Surgery Safety Checklists in 2007 (http://www.who.int/patientsafety/safesurgery/ss_c_hecklist/en/), which originated from an aviation control method created in 1935 by a pilot of a Boeing B 17. Since then, numerous studies all over the world have shown the benefits of the checklist in healthcare.

Regione Veneto, Italy, Public Healthcare organization is adopting new strategies and tools for Risk Management and Patient Safety to anticipate errors through information and communication technology.

Similarly to the Aviation industry, combining incident reporting, information technology and training, our target is the transition from Reactive to Proactive clinical safety. The key word is: Prevention.

This will be done by collecting, processing and analyzing data in order to detect latent problems and develop targeted actions for improvement. Related data flows are nowadays collected from claims, sentinel events, voluntary reporting and via electronic support too.

The novelty that we want is to propose and establish is the addition of the electronic patient data (EMR, EHR) to this risk management electronic system. Patient peculiarity such as allergies, diabetes, hypertension etc. will be recorded in the individual electronic database and compared with patient treatment.

All this data will be integrated with a database of guidelines and best practices, so incongruent data will be immediately spotted and highlighted through an alarm system that will show up to all professionals involved in each care pathway. This indexed decision-support system will be able link research elements and clinical data (EMR, HER) to physicians who work directly on the patient; and will be used as a professional training and updating tool.

Moreover, for top and middle managers, a computerized dashboard will show several categories of data and taxonomies, each interconnected with a risk management section, indexed and processed into charts and graphs to highlight regional and local risk trends.

In the same way as the Flight Data Monitoring System (FDM) that monitors speed, altitude, vertical speed, acceleration etc. and the Engine Monitoring System (EMS) that monitors, in real time, engine parameters (see Fig.1), our software will automatically warn for possible risks such as

incorrect medical prescription to patients, allergies, conflicting therapies, ecc.

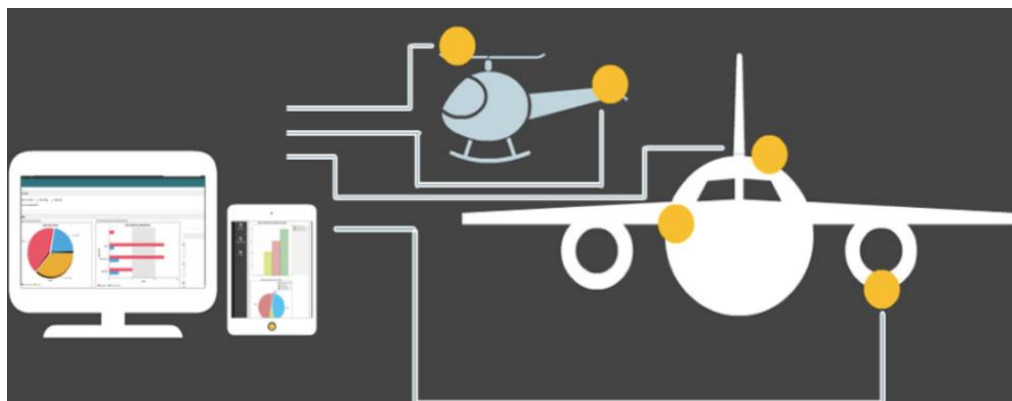


Fig.1

A big data system will then support the operational units at each level, from the front line to the top management and will monitor not only risks related to patient health, but also communication and organizational issues to avoid waste and duplication of prescriptions and materials and showing a big picture of trends for decision makers.

The IT clinical risk management function will be integrated with other databases and management systems such as drug administration, emergency room access, telemedicine and of course with known methods of analysis as Failure Mode and Critical Effect Analysis, Clinical Audit, Root Cause Analysis, ecc. (see Fig.2).

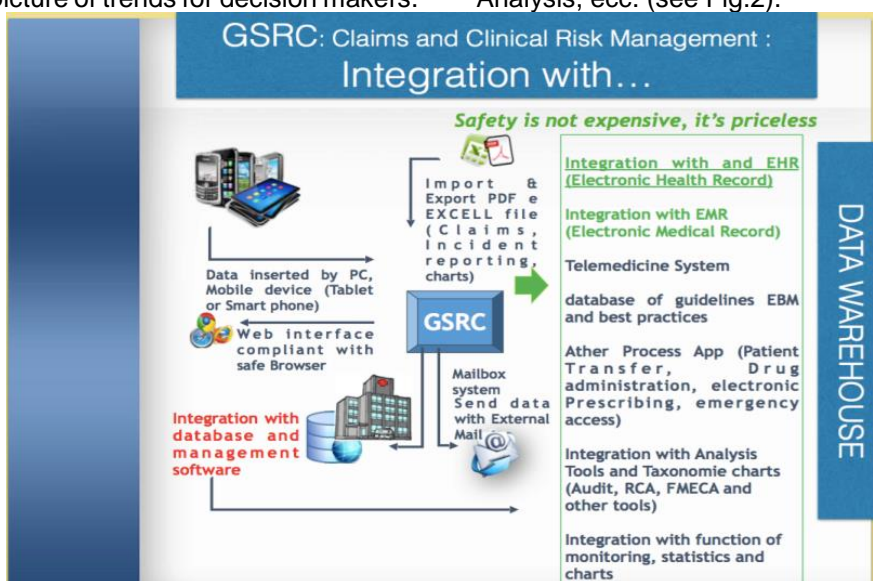


Fig 2.

A benefit for safety, quality, appropriateness, reduction of litigation and insurance costs will be the ultimate goal of this process.

The project has to take into account all patient privacy related aspects. Health professionals and managers will be trained on this new methodologies, including with simulation tools. The medium-long term target will include data collection and analysis of the Human Factors-Human Errors aspects as, for example, the Non Technical Skills

categories (<https://www.abdn.ac.uk/iprc/notss/>) and the Crew Resource Management factors (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3488012/>), all already considered and evaluated in the Aviation industry. This will require a culture-change and investments in training and staff engagement.

Below you will find a narration of a practical example, and a video can be found at the following link.

<https://vimeo.com/231504515/95ae7ca9af>

“Marco is riding his motorcycle when an insect bite causes a sharp and sudden pain in his left shoulder,

which makes him fall to the ground and causes a bad bruise. He is about to go to the emergency ward,

when he suddenly remembers that he has downloaded the INFO PS app on his phone (see Fig.3), which allows him to find the closest, more appropriate and most accessible emergency ward in real time.

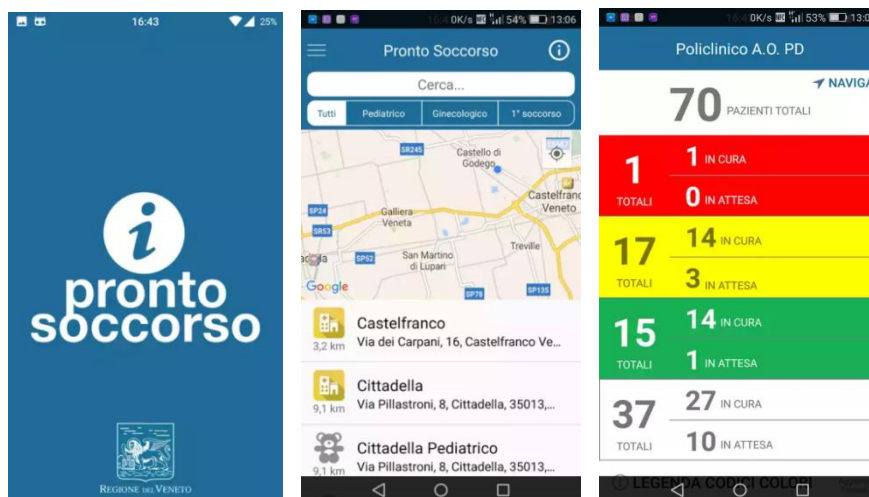


Fig. 3

Healthcare staff implements the triage checklist, without specifically mentioning the insect bite, and assigns the green code to the patient. The physician visiting the patient notices the insect bite that may have caused the acute pain and hence the fall. At this point, she accesses the patient record system. Suddenly, the patient has difficulty breathing.

The patient record indicates the patient's allergy to insect bites. Thanks to this quick access to personal and medical information, the physician can immediately intervene to limit the severe allergic reaction in progress and prevent anaphylactic shock.

The patient record also showed that the patient had received a tetanus shot a few months before this episode, which made it possible to avoid giving Marco unnecessary injections and wasting the resources of the healthcare system.

The emergency was resolved promptly thanks to the ICT system, data availability and a well-organized process.

Finally, the physician proceeds with the near miss reporting addressed to the organizational risk manager by completing the Incident Reporting Form, so that the organizational risk manager can verify the appropriateness and correct use of the triage checklist and the training of the healthcare staff”.

An integrated informatics system can therefore provide: clinical information essential for physicians; greater attention to the patient; more targeted clinical risk management and reduction of adverse events; better work organization and saving public resources

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[Short Communication]

**Successful Applications of High Reliability Organization Methods to Improve Patient Safety and Actions Required to Accelerate Progress
Use of High Reliability Methods to Improve Patient Safety**

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Abstract

[Purpose/Objective] Healthcare organizations worldwide are embracing the practices of High Reliability Organizations to improve Patient Safety. These efforts are being met with varying degrees of success. This paper summarizes which new practices are working well and where new thought processes are needed.

[Materials and Methods] Since the Institute of Medicine report emphasized the need for cross-industry learning in 1999 many new practices from High Reliability Organizations have been adopted by healthcare. Successful new practices and processes are resulting in improvements in outcomes, patient safety and safety culture. There are however some proven practices that have not been accepted or have failed to achieve widespread acceptance. Several of these initiatives have been reviewed to in order to identify the barriers to incorporation that remain.

[Results] As expected, the cultural differences between industries have had a large impact on the degrees of success, and the expected regulatory and legal challenges have hindered some progress. However, more fundamental factors have been identified and also play a role. These factors include contributors such as basic human behaviors and communications.

[Conclusions] Some early successes in the transfer of good practices from other industries have been realized. The impact of human behaviors and communications appear to require more attention. Although a new generation of Healthcare workers will facilitate much of the future change, new models to define and communicate future direction will be required. Many of these models already exist and should be incorporated into healthcare organizations today.

Keywords: Safety Culture, Human Error, High Reliability, Nuclear Power

The 1999 Institute of Medicine (IOM) report: To Err Is Human: Building a Safer Health System estimated as many as 98,000 deaths per year from medical errors.¹⁾ The authors suggested that experience from other high-risk industries should be used to improve healthcare safety. In the 10 years preceding that report, aviation accidents had continued to decrease with 1999 having less than 50% of the number of accidents that were occurring 10 years prior, even with an increase in the number of flights.²⁾ During that same period, the average number of significant events at United States (US) nuclear power plants decreased by more than 90%.³⁾ So how much progress has been made in applying the high-risk/high-reliability organization methods in healthcare? A 2016 study by Makary concludes the mean rate of death from medical error may actually be more than 250,000 per year.⁴⁾ While there is not a conclusion that performance has declined, Makary points out that a lot of work remains to be done. This article summarizes some of the progress that has been made in implementing practices from high reliability organizations (HRO) and identifies those areas that are continuing to present a challenge.

Since the IOM report was published many organizations have emerged with a mission to improve patient safety. A large variety of guidance has been made available and organizations across the world are adopting various approaches. In the US, the Agency for Healthcare Research and Quality (AHRQ) has published operational advice for hospital leaders on becoming a high reliability organization.⁵⁾ The Joint Commission has also identified steps needed for healthcare to move to high reliability.⁶⁾ Some organizations that have embraced the HRO principles have reported significant reductions in serious safety events.⁷⁾ Others have even attained goals of zero incidence of certain hospital acquired conditions.⁸⁾ While these successes are commendable, they are not the norm. Many organizations have still not embraced a goal of zero for harm events and some continue to focus on questioning the accuracy of the estimated medical error rate. Industries that have successfully produced HROs typically build their programs with the understanding that errors are normal daily occurrences that should be expected and factored into processes. Major programs must be designed so that human errors are tolerated. The underlying attitude should be that mistakes are inevitable but harm is preventable. This allows

the emphasis to shift from individual accountability and punishment to process improvement.

Although much progress has been made in using basic HRO practices such as checklists, timeouts, barcoding and Root Cause Analysis, the Joint Commission reports that the cultural changes necessary to truly reach high reliability remain out of reach for many organizations.⁹⁾ Many leaders still have not recognized that open communications, especially those associated with reporting potential safety incidents, are absolutely required for the HRO safety culture. The engine that drives and maintains a strong safety culture is a low-threshold reporting program. The communication of concerns, followed by feedback from leadership about corrective actions taken, creates the organizational learning and continuous improvement environment essential for a culture of safety. Also, lowering the reporting threshold and focusing on minor issues or good-catches shifts the entire organizational focus to a more proactive position. HROs emphasize reporting of the precursor conditions to more serious events in order to obtain leading indicators of risks versus using the lagging data collected after events have already occurred.

The barriers to creating a strong culture of safety are not small. In many cases, creating a culture of safety requires actions contrary to normal human nature. For example, we ask that errors be self-reported when humans naturally hide their weaknesses and imperfections. We ask for extreme attention to detail and formal communications when humans naturally scan the broader picture and use acronyms and slang in communications. Changing organizational outcomes requires a change in the team behaviors. Behaviors are governed by beliefs, and beliefs come from an individual's training and personal experiences. Therefore, to create the desired behavior changes that are key to a strong safety culture, leaders may need to change current beliefs. Work by Edmonson indicates that effectiveness of efforts to affect behaviors and create a learning environment will depend on leaders ensuring both accountability and psychological safety.¹⁰⁾ The psychological safety comes from members of the organization believing they are trusted, valued and their jobs are secure. In summary, leaders must build a culture that values open reporting, builds trust and drives for continuous process improvement.

Achieving these behaviors will enable healthcare organizations to become true HROs.

After the human behavior and cultural challenges have been incorporated into improvement efforts there will still be plenty of opportunities to make even more progress. A few organizations, such as the Children's Hospitals' Solutions for Patient Safety (SPS Network), have become advocates for greater transparency and are reporting their event trends on their external (public) website. The SPS Networks Hospital-Acquired-Conditions and readmissions rates are continuously updated and visible to all stakeholders.¹¹⁾ This approach has been very successful for the SPS network and is a key factor in moving healthcare quality and safety to the next level. In his new book, Makary proposes that healthcare must abandon the code of silence, embrace public reporting and support a high level of transparency because "transparency has the power not just to improve the experience of patients but to transform the business of healthcare in America".¹²⁾ In conclusion, it appears healthcare is gradually transforming into an industry of High Reliability Organizations. Progress was slow in the early years, due to initial questioning of the data and an overemphasis on human error. However, today we have begun to focus more on human behaviors and building a culture of safety. Further advances and higher levels of performance will be possible as we attain higher levels of transparency.

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[Short Communication]

Trial of Exchanging Mini-Medical-Records shared between Patient and Doctor for good patient-doctor relationship and reducing risk of medical law suit

Kazuhiro Okamura, MD, PhD

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Abstract

Printing and pasting all information from electric medical record on a notebook which is carried by patient will help the patient’s understanding and yield good patient-doctor relationship. As a result, medical law suit will decrease

Keywords: electric medical record, good understanding, patient-doctor relationship, law suit

1. How Mini-Medical-Records System started

Okamura Isshindow General Hospital is developing our own Electric Medical Recording System with Macintosh and 4thDimension since 1987. When we started full electronic medical recording system in 2001, I found old paper based chart system is superior in looking through the medical records. So, I started to print out electric file right after the completion of medical examination and cut and paste all records on A6 size note book like paper system.

I thought the patient will have better understanding of his diseases if he was given this notebook. If the patient himself keep the notebook, we do not worry about how and where to keep in the hospital.

2. Contents of Mini-Medical-Records System

Contents of Mini-Medical-Records System will include current diagnoses, past diagnoses, medical descriptions, prescriptions, ordered tests, all medical reports including radiology, physiology, biochemical and hematological reports. Discharge summary will be pasted at the time of discharge.

3. Sample of real case

- Cover page
- The name of the patient and ID are handwritten.
- Copyright statement is printed.
- Page 1 Behind the cover

All active diagnoses and deleted inactive diagnoses are shown.

- Page 2
- In cases of chronic diseases, doctor can paste basic medical knowledge such as criteria of hypertension and diabetes, if applicable.[Fig 1]

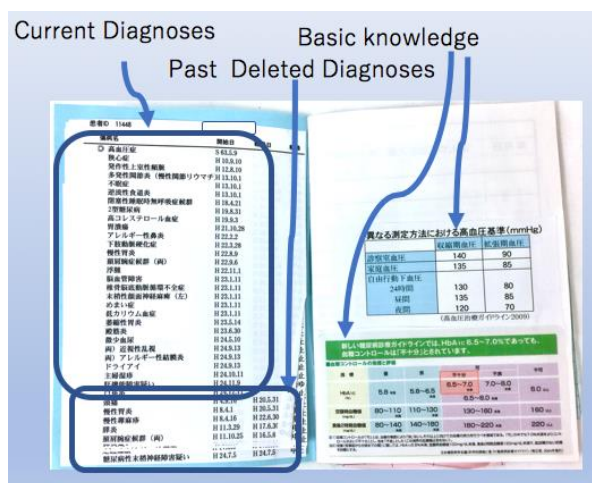


Fig 1: Page 1 and 2 of Mini-Medical-Record showing diagnoses and explanations of common diseases.

- After Page 2
- Descriptions of outpatient visit, prescriptions and lab tests ordered are pasted.

Radiology, physiology and endoscopic reports are also pasted.

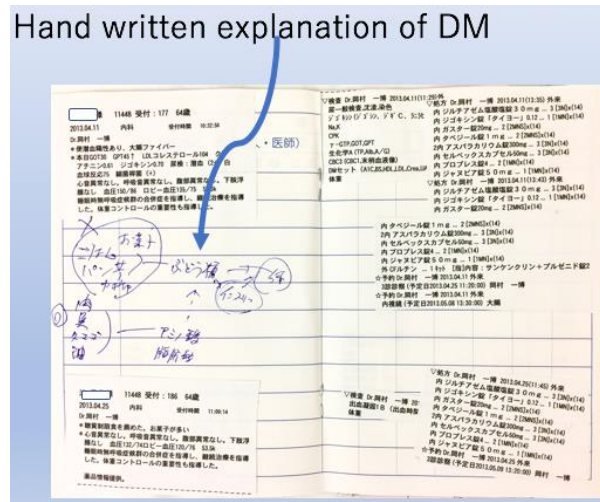
In case of admission, discharge summary is pasted on the right page at the time of discharge.

Sometimes a doctor can add hand writing explanation.

Patient can write down the results of home BP, blood glucose as well as his or her questions to the doctor.

Mini-Medical-Records System is bi-directional communication.[Fig 2]

Hand written explanation of DM



[Fig 2] Sometimes doctor can hand write on mini-medical-record. The patient can write his questions also.

- Last Page

Biochemical and hematological data are pasted on the last page of booklet.

4. Pros 6 Cons of Mini-Medical-Records System

This system will contribute to better understanding of the patient. Reliability to the hospital will rise up because everything is open and the patient knows hospital side cannot rewrite medical records. These better understanding of patients and reliability to the hospital will produce good patient-doctor relationship thus reduction of medical lawsuit will be acquired. As a matter of fact, we only had two mild suits in 15 years.

On the other hand, hospital staff have to print, cut and paste all documents. It is bothersome. Utilizing bar cord system is preferable to assure correct attachment as we do.

5. Conclusions

You may need some courage to disclose your medical writing and all medical information. Since disclosing all informations will be required at the law suit, it is all the same whether you disclose now or later. Mini-Medical-Record system will produce good patient-doctor relationship. It will lower law suit rate.

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[Short Communication]**Inflammatory colitis****Mei-Lin Lee, Yu-Feng Tian**

Chi Mei Medical Center, Surgery Department Tainan, Taiwan

An 80 year-old woman presented with lower abdominal pain for days. The patient had a history of end-stage renal disease, diabetes mellitus, and old stroke. On arrival, her vital signs were a temperature of 36.8°C, pulse rate of 83/min, respiratory rate of 25/min, and blood pressure of 122/75 mmHg. Physical examination was unremarkable except abdominal distention, and lower abdominal tenderness. Laboratory examinations were as follows: white cell count, 26400/mm³, aspartate aminotransferase, 65 IU/L, glucose, 372 mg/dl, C-reactive protein of 149.7 mg/L (reference value, < 3 mg/L). Computed tomography (CT) of abdomen revealed fecaloma in the rectum with inflammatory rectal wall and peri-rectal fat stranding (Figure 1), which was consistent with stercoral colitis. One episode of massive bloody stool developed during hospitalization, and the colonoscopy showed large linear circumferential ulcers with bloody clots and several red nipple signs found at rectal sigmoid colon. Her clinical condition was responded to conservative management with mesalazine enema, NPO, and parenteral nutrition. Several days later, the abdominal pain and distention gradually improved, and she was discharged uneventfully.

Stercoral colitis is an inflammatory colitis that is caused by increased intraluminal pressure from fecaloma on the walls of the sigmoid colon, where the vascular supply was the most vulnerable.^{1,2} Because of prolonged localized pressure and compromised vessel supply, pressure ulcers may

develop thereafter. Perforation of colon can occasionally occur due to the progression of pressure ulcers, and its associated mortality may be up to 35%.³ Early diagnosis of stercoral colitis is not easy because its manifestation may be non-specific. In this clinical condition, Abdominal CT can provide useful informations for diagnosis, such as the presence of fecaloma, pericolic stranding, perfusion defect, dense mucosa, colon wall thickening and proximal colon dilation.¹ Moreover, if the presence of extraluminal gas or an abscess is detected by CT, it should indicate the diagnosis of colon perforation, and suggest surgical intervention for life-saving.

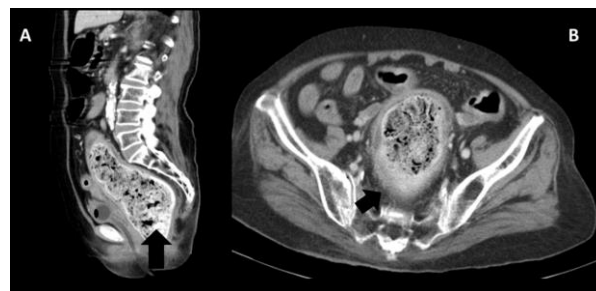


Figure 1 Computed tomography (CT) of abdomen revealed fecaloma in the rectum with inflammatory rectal wall and peri-rectal fat stranding.

Contact to the Author:

[Short Communication]**Self-expandable metal stent(SEMS) Enhance
The Patient Preoperative Life Quality****Chu-Li Tu, Chia-Lin Chou ,Yu-Feng Tian**

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A 78-year-old male present with anemia and constipation for 3 days. The patient had a history of chronic kidney disease, stage IV, diabetes mellitus and hypertension. On arrival, his vital signs were a temperature of 36.8°C, pulse rate of 83/min, respiratory rate of 18/min, and blood pressure of 122/75 mmHg. Physical examination was unremarkable except abdominal distention, and lower abdominal tenderness. Laboratory examinations were as follows: white cell count 10500/mm³, hemoglobin 114.4g/dl , hematocrit 35.3%, Red Blood Cell Count 4.25 10⁶/uL, glucose 202 mg/dl, carbohydrate antigen 199 42.7 U/mL, carcinoembryonic antigen 8.3 ng/mL. Computed tomography (CT) of abdomen revealed sigmoid colon carcinoma with pericolic invasion and suspicious peritoneal invasion, peritoneal carcinomatosis with ascites.

The self-expandable metal stent (SEMS) was done smoothly later. His clinical condition was responded to bowel decompression with SEMS. After two weeks, he received laparoscopic LAR successful and he was discharged uneventfully.

Bowel obstruction is a common complication of late-stage abdominal cancer, especially colon cancer. For a person experiencing a malignant obstruction, choosing between a emergency ostomy or the placement of a stent placed can often be difficult. To many, a stent will seem the obvious choice. After all, stents can be placed relatively easily, often with minimally invasive laparoscopic surgery and far shorter recovery time.

The SEMS has been increasingly used for the management of malignant colorectal obstruction, not only as a palliative method but also as a preoperative treatment in surgical candidates. In south of Taiwan, the SEMS was no common to use in the colon obstruction because expensive

equipment and Taiwan health insurance does not pay. In this case, emergency operation with colostomy can relief the symptoms. But if patient hesitate ostomy care and want to good life quality, SEMS offers another option.



Figure 1: bowel obstruction due to advanced colon cancer noted at sigmoid colon

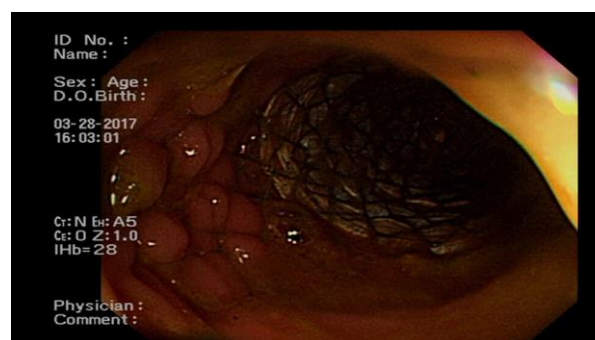


Figure 2: Advanced colon cancer with obstruction, Sigmoid colon, S/P stenting

Contact to the Author

[Short Communication]**The relationship between working patterns and dietary habit and weight gain during the pregnancy period**

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Abstract

[Background and Objective] In recent years, both women's labor and the population of double income rate has risen in Japan. A survey, Time Use and Leisure Activities in 2011, reported that those who work tend to have less time to do housekeeping compared to those who do not work. In this research, we investigated the influence that labor has on diet and weight gain during the pregnancy period.

[Method] The subjects were 149 pregnant women who were recruited at the National Center for Child Health and Development (NCCHD). Based on the amount of working hours per week, the subjects were divided into no work (n=80), part-time (n=22), and full-time(n=47) groups. Using medical examination data, a 3-day dietary record and weight gain during pregnancy we assessed their nutrient and food intake. Based on appropriate weight gain during pregnancy according to the BMI before the pregnancy by the Ministry of Health, Labor and Welfare we evaluated their weight gain, "appropriate", "high", and "low". Tukey's HSD analysis and chi-square test was used to compare the three groups.

[Result] The part-time group had significantly higher intake of energy, compared with the full-time group (p=0.0365). And the part-time group had significantly higher intake of fat than the other groups (p<0.05). Compared to their weight gain, the ratio of "appropriate" was significantly high in the part-time group (p=0.0182), and the ratio of "low" tended to be high (n.s).

[Conclusion] This research indicated that the energy load during pregnancy was supplemented with fat in the part-time group, and this prevented low weight gain.

Key word: Pregnancy, Diet, Working pattern, Working hour, Gestational weight gain, BMI.

7. Background and Objective

In Japan, since the Basic Law for Gender Equality in Society in 1999 was enforced, An environment

for women to be active in society has been created, and Women working in recent years are increasing. The labor force populations of women in Japan was 27.16 million in 2006, and after 10 years it was 28.92 million people, more than 1 million people. Double income households in Japan increased from 9.07 million in 2006 to 112.9 million in 2016.¹⁾ The women's lifestyles diversified as women's social advancement increased in Japan. Marriage, pregnancy, childbirth are big turning points of women's lifestyle.

According to the 2013 Annual Report on the State of the Formation of a Gender Equal Society and Policies, the percentage of women who worked before marriage continued to work was 71.4%, among which the proportion of those who continue to work after the first child birth is 64.0%.²⁾ In addition, Japanese woman workers are characterized by a higher percentage of non-regular employees than Japanese man workers. According to the results of Longitudinal Survey of Adults in the 21st Century (2002 Cohort), the percentage of men and women after marriage who summed up part-time workers, contract workers and non-regular employees was 4.5% of men, 19.7%, which shows that the proportion of woman's non-regular employees is higher than that of men.³⁾ Pregnant women who are in any type of employment must manage their weight gain by taking appropriate diet for mothers' and children's health. The Ministry of Health, Labor and Welfare compiled several studies on the relationship between gestational weight gain and health risk. Extremely low weight gain during pregnancy increases the risk of low birth weight infant delivery⁴⁾⁵⁾, imminent abortion⁶⁾, premature labor.⁶⁾ Extremely high body weight gain increases the risk of pregnancy-induced hypertension⁶⁾, delivery of infants who were 4000 g or heavier⁷⁾, cesarean delivery.⁷⁾⁸⁾ According to Ministry of International Affairs and Communications on Time Use and Leisure Activities(2001), Japanese women are doing household work about five times as long as men, and 51% of household work time is spent on managing meal.⁹⁾ This shows that women mainly manage household meals. When comparing the household which the couple work and the household which the wife don't working, there is little difference in the husband's housework time. The husband of the household where the couple work has 4 hours and 8 minutes, and the husband of the household where the wife don't work is 5 hours and 42 minutes.⁹⁾ This might indicate that wives working reduces the time spent managing family's meal, which affect their diet.

Here, we investigated the relationship between working patterns and diet and weight gain during pregnancy period.

8. Method

Study design and subjects

We conducted this survey from January to December 2011 at the National Center for Child Health and Development (NCCHD, Tokyo, Japan). We were randomly recruited participants from the outpatient department of obstetrics during their first prenatal visit from 5 to 15 weeks of gestation. Of the 272 women asked to participate in our study, 248 (91.2 %) women finally consented to enrolment. Twenty-one (8.5 %) withdrew after initially participating and another twenty-seven were excluded from the analysis, because they had severe emesis (n 3) or unavailable FFQ (n 21) in early pregnancy, finally 203 women became participants. We conducted 3days-dietary record and the questionnaire about labor to subjects in the second trimester pregnancy. We analyzed 149 people who responded to meal survey in the middle of pregnancy (gestation 22 to 35 weeks) in the meal survey and answered questionnaire on labor. Institutional Review Board of the NCCHD approved this study (Institutional Review Board approval no. 461).

3-days dietary record

We used 3-days dietary record to assessed subject's nutrient and food intake. Subjects recorded the day, time, along with a detailed description of the food, the weight of the food. We required subjects to measure and record the weight of food as much as possible for the contents of the meal, and when measurement is impossible, to record it with an approximate amount (1 apple, 1 spoonful, 1 cup of cup etc.). Subject's dietary was recorded three non-consecutive days, including two weekdays and one weekend day. To improve the quality of the DR, the records were reviewed by nutritionists and missing values or vague answers were clarified according to our manual.

Working patterns

The questionnaire about labor consisted of questions about working hour and working days per week. We calculated subject's working hours per week using working hour and working days per week. Using the part-time standards used in the Monthly Labor Survey by Ministry of Health, Labour and Welfare, we defined a person who have a weekly working time less than 35 hours as part-time worker, and more than 35 hours as full-time. Based on the amounts of working hours per week,

the subjects were divided into no work (n=80), part-time (n=22), and full-time(n=47) groups.

Gestational weight gain

We calculated subject's weight gain during pregnancy from self-reported weight and weight at delivery. We evaluated whether or not the subject's weight gain during pregnancy is appropriate according to "the Maternal Optimal Weight Gain Chart" indicated by the Ministry of Health, Labor and Welfare. The chart shows the optimum weight gain during pregnancy as 9 to 12 kg for pregnant women with pre-pregnancy BMI less than 18.5, 7 to 12 kg for 18.5 to 25.0, and less than 5 kg for more than 25.0. We classified subjects into three patterns of weight gain in this study, "low", "appropriate" and "high".

Statistical analysis

We used Tukey's HSD analysis to compare nutrient and food intake of three group by their working style, and Chi-square test to compare weight gain. All analyses was performed by JMP9®(SAS Institute Inc., Cary,NC,USA).

9. Result

Characteristics

The participants' characteristics are shown in Table 1. Subjects were divided into part-time group (n=22), full-time group (n=46), No work group (n=80). Mean pregnancy age of three groups was 36.9 ± 2.9 , 35.4 ± 3.9 and 35.4 ± 3.9 years in the part-time group, the full-time group and the no work group respectively, this difference was not significantly ($p=0.256$). Mean working hour per week was 20.2 ± 9.6 hour in the part-time group and 43.3 ± 6.9 hour in the full-time group. The percentage of first-time births was 31.7% (n = 7), 23.9% (n = 11) and 26.9% (n = 21), and the percentage of those who graduated from university were 63.6% (n = 14), 60.9% (n = 28) and 68.8% (n=55) in the part-time group, the full-time group and the no work group respectively, these was not

statistically different (respectively $p = 0.164$, 0.572). The population of BMI less than 18.5 was 22.7% (n=5) of subjects, 28.3% (n=13) and 21.3%(n=17), wherea the percentage of BMI more than 25 was 0% (n=0) group, 4.3% (n=2) and 7.5% (n=6) in the part-time group, the full-time group and the no work group respectively, there was not statistically different ($p=0.615$).

Nutrient intake

Nutrient intakes of three groups by working patterns are shown in Table2. There were significant differences in energy, fat and salt intake among three group by working patterns. Mean of energy intake was 1917 ± 282 Kcal, 1705 ± 351 Kcal and 1792 ± 327 Kcal in the part-time group, the full-time group and the no work group respectively, the part-time group had statistically significant higher energy intake than the other groups ($p=0.037$). Mean of fat intake was 72.1 ± 14.8 g, 60.0 ± 18.6 g and 61.7 ± 17.4 g in the part-time group, the full-time group and the no work group respectively, the part-time group statistically significant higher had fat intake than the full-time and no work group ($p=0.027$, 0.038). There was no significant difference in saturated fatty acid intake between the three groups, but the part-time group had significant higher intake of mono-unsaturated fatty acid and polyunsaturated fatty acid than the other groups. Mean intake of mono-unsaturated fatty acids was 26.4 ± 5.9 g, 21.5 ± 7.6 g and 21.7 ± 6.5 respectively, and the part-time group had significantly higher intake compared with the full-time group and the no work group ($p = 0.017$, 0.013). Mean intake of polyunsaturated fatty acid was 13.6 ± 3.0 g, 11.2 ± 4.1 g and 21.7 ± 6.5 respectively, and the part-time group had significantly higher intake compared with the full-time group ($p = 0.025$). Mean intake of salt was 9.4 ± 1.5 g, 8.2 ± 2.4 g and 9.2 ± 2.5 g n the part-time group, the full-time group and the no work group respectively, and the no work group had significantly higher intake compared with the full-time group ($p = 0.046$)

Table 1: Characteristics of the study subjects (n=149)

	Part-time	n=22	Full-time	n=47	No work	n=80	ANOVA's p
	Mean	SD	Mean	SD	Mean	SD	
Age (y)	36.9	2.9	35.4	4.1	35.4	3.9	0.2568
	%	n	%	n	%	n	Chi-square test's p
Primiparity	31.8	7	23.9	11	26.3	21	0.1639
Education level							
collage or more	63.6	14	60.9	28	68.8	55	0.5724
Body Mass Index (kg/cm ²)							
<18.5	22.7	5	28.3	13	21.3	17	0.6147
18.5-24.9	77.3	17	69.6	32	71.3	57	
≥25	0.0	0	4.3	2	7.5	6	
Alchole intake							
less than once per month	90.9	20	97.8	45	95.0	76	0.5253
2-3 times per month	0.0	0	0.0	0	1.3	1	
2-3 times per week	0.0	0	2.2	1	2.5	2	
missinng	9.1	2	4.5	1	1.3	1	
Smoking							
no smoking	81.8	18	69.6	32	72.5	58	0.5108
smoking in the past	13.6	3	28.3	13	26.3	21	
missing	4.5	1	4.3	2	1.3	1	
Annual household income (yen)							
<400 million	0.0	0	4.3	2	8.8	7	0.1337
400-799 million	27.3	6	32.6	15	31.3	25	
≥800 million	63.6	14	63.0	29	60.0	48	

Part-time; working hours per week less than 35 hours, Full-time; working hours per week more than 35 hours, No work; no working hours per week

Food intake

Food intake of three groups by working patterns are shown in Table 3. There were significant differences in meat, egg and oil intake among three group by working patterns. Mean intake of meat was 93.9 ± 35.3 g, 70.0 ± 32.4 g and 82.3 ± 34.8 g n the part-time group, the full-time group and the no work group respectively, and the part-time group had significantly higher intake compared with the full-time group ($p=0.021$). Mean intake of meat was 38.3 ± 21.9 g, 24.7 ± 20.7 g and 28.6 ± 21.3 g n the part-time group, the full-time group and the no work group respectively, and the part-time group had significantly higher intake compared with the full-time group ($p=0.038$). Mean intake of oil was

14.4 ± 5.0 g, 9.3 ± 5.8 g and 10.4 ± 5.7 g in the part-time group, the full-time group and the no work group respectively, and the part-time group had significantly higher intake compared with the full-time group and no work group (respectively $p=0.0013$, 0.0096)

Gestational weight gain

Gestational weight gain of three groups by working patterns are shown in Table4. There was a significant difference in evaluation of gestational weight gain compared with three groups ($p= 0.018$). The highest population of "appropriate" was in part-time group (77.3%, $n=17$), the highest population of "low" was in full-time group (28.3%, $n=13$).

Table 2: Nutrient intake per day of three groups working patterns

		Part-time (n=22)		Full-time (n=47)		No work (n=80)		Tukey's HSD analysis		
		Mean	SD	Mean	SD	Mean	SD	Part-time vs Full-time	Part-time vs No work	Full-time vs No work
Energy	kcal	1917.1 ^a	± 282.0	1705.2 ^a	± 351.5	1791.6	± 327.3	0.0365*	0.2558	0.3288
Protein	g	67.6	± 15.3	61.9	± 14.3	65.8	± 12.9	0.2437	0.8514	0.2673
Total fat	g	72.1 ^{ab}	± 14.8	60.0 ^a	± 18.6	61.7 ^b	± 17.4	0.0216*	0.0376*	0.8559
Carbohydrate	g	243.9	± 36.6	226.6	± 49.1	239.6	± 44.0	0.2922	0.9141	0.2555
sodium	mg	3701.0	± 581.7	3224.2 ^a	± 942.6	3635.4 ^a	± 989.7	0.1178	0.9534	0.0445*
potassium	mg	2468.7	± 420.7	2444.5	± 842.8	2568.3	± 653.0	0.9900	0.8219	0.5959
Calcium	mg	525.9	± 150.6	536.9	± 177.3	545.4	± 199.0	0.9715	0.9005	0.9663
magnesium	mg	246.5	± 51.5	235.8	± 74.9	247.6	± 63.6	0.8043	0.9974	0.5944
Iron	g	7.9	± 1.8	7.4	± 2.6	7.7	± 2.5	0.7624	0.9634	0.7946
Zinc	mg	8.2	± 1.8	7.4	± 1.6	7.9	± 1.8	0.1833	0.7528	0.2724
Iodine	µg	309.1	± 76.2	283.4	± 67.7	302.4	± 79.1	0.3852	0.9277	0.3568
Retinol	µg	243.8	± 172.1	396.5	± 814.9	293.3	± 510.7	0.5827	0.9364	0.6141
Retinol Eq	µg	601.5	± 261.3	777.0	± 906.1	629.7	± 514.5	0.5413	0.9818	0.4265
VitaminD	µg	7.1	± 8.7	5.8	± 4.3	6.3	± 4.6	0.5902	0.8001	0.8495
VitaminE	mg	7.6	± 2.1	7.3	± 3.0	7.3	± 2.3	0.9167	0.9039	1.0000
VitaminB1	mg	1.0	± 0.1	0.9	± 0.0	0.9	± 0.0	0.1583	0.4959	0.5079
VitaminB2	mg	1.2	± 0.1	1.2	± 0.0	1.2	± 0.0	0.7140	0.7844	0.9712
niacin	mg	15.7	± 0.9	14.1	± 0.6	15.0	± 0.5	0.2943	0.7815	0.4373
niacin Eq	mg	28.3	± 6.5	25.6	± 6.6	27.3	± 6.2	0.2362	0.7755	0.3432
Vitamin6	mg	1.2	± 0.3	1.1	± 0.3	1.2	± 0.3	0.8783	0.9026	0.4274
VitaminB12	mg	6.9	± 9.1	6.2	± 5.1	6.6	± 6.3	0.9168	0.9771	0.9548
Folate	µg	323.5	± 86.2	323.8	± 144.8	316.2	± 97.1	0.9999	0.9619	0.9292
VitaminC	mg	112.6	± 37.0	106.2	± 55.2	120.4	± 53.0	0.8914	0.9769	0.9265
SFA	g	22.7	± 6.2	19.1	± 6.3	19.5	± 6.8	0.0831	0.1016	0.9435
MUFA	g	26.4 ^{ab}	± 5.9	21.5 ^a	± 7.6	21.7 ^b	± 6.5	0.0170*	0.0130*	0.9888
PUFA	g	13.6 ^a	± 3.0	11.2 ^a	± 4.1	11.6	± 3.3	0.0250*	0.0517	0.8077
Dietary fiber	g	14.1	± 3.1	15.2	± 7.3	14.5	± 5.4	0.7419	0.9518	0.7961
Salt	g	9.4	± 1.5	8.2 ^a	± 2.4	9.2 ^a	± 2.5	0.1228	0.9579	0.0455*
Alcohol	g	0.7	± 0.6	0.7	± 0.9	0.8	± 0.8	0.9673	0.9260	0.6822
caffein	mg	0.1	± 0.1	0.1	± 0.1	0.1	± 0.1	0.9673	0.9260	0.6822

Part-time; working hours per week less than 35 hours, Full-time; working hours per week more than 35 hours, No work; no working hours per week

^{a b}; The same alphabet indicates significant difference

*; p<0.05 **; p<0.01

10. Discussion

In this study, we divided pregnant women in 2nd trimester into three groups by their working patterns, and compared their nutrient intake, food intake and weight gain during pregnancy to investigate the relationship between working patterns and diet and weight gain in pregnancy. There are already many studies about the relationship between a shift work included night work and obesity, peptic ulcer disease and coronary heart disease.¹⁰⁾¹¹⁾¹²⁾¹³⁾¹⁴⁾

There are also studies about the relationship between a shift work included night work and pregnancy outcome.¹⁵⁾¹⁶⁾¹⁷⁾¹⁸⁾ However, there are no other reports about pregnant women's work pattern, consisted of no work, part-time and full-time, and diet and weight gain. Pregnancy is life events that diversify working situation for modern women. This study have a important meaning for modern women with diversified lifestyle to give safety and healthy birth.

The energy intake per day for pregnant women in the National Health and Nutrition Survey (2015) was 1,713 ± 573.6 Kcal, and the energy intake of

the subjects in this study was 1783 ± 332.8 Kcal, and there was no big difference in the average value.¹⁹⁾

The part-time group had significantly higher energy intake compared to the full-time group and had the highest proportion of those with the appropriate weight gain compared to the other groups. Compared to the other groups, the percentage of those who gained weight gain was the largest in the full-time group. Since the part-time group had significantly higher fat intake compared with the other groups, it can be inferred that they supplied for the necessary amount of energy by taking in higher fat intake. In food intake of three groups, the part-time group had significantly more meat and egg intake than the full-time group, and it has significantly more fat and oil than the full-time group and no work group. This showed that higher intake of meat, eggs, fats and oils contributed to significantly higher energy intake among part-time group. The full-time group had lower energy intake and higher percentage of those who had less weight gain compared with the other groups. There was a possibility that working hours restricted their

dietary behavior. It can be assumed that the part-time group had less time limit than the full-time group and more the opportunity to go out than no work groups. Based on this estimation, it is conceivable that the part-time increase the opportunity eating out, and taking out and eating snack. The Ireland's research indicated that eating out and take-out food have higher energy and fat than homemade meals among adult women, which may have contributed to higher fat intake of the part-time group in this study.²⁰⁾ The Dietary Reference Intakes for Japanese (2015 Edition) regulates the energy load during pregnancy.²¹⁾ Pregnant women should appropriately supply the energy load with carbohydrate and protein as well as fat for maternal and child health.

This study has following two limitations.

The first limitation is that we do not analyze subject's use of eating out and take-out in detail, although we referred to eating out and take-out. The second limitation is that this is a cross-sectional study at one point in the second trimester pregnancy. Pregnant women change physical condition and environment change throughout the first, second and third trimester, which influences their diet certainly. In this study, we investigated pregnant women in the second trimester avoiding influence of morning sickness, but in order to analyze pregnant diet in more detail, it is necessary to investigate diet and weight gain pregnancy the first and third trimester.

Table 3: Food intake per day of three groups by working patterns

	Part-time (n=22)		Full-time (n=47)		No work (n=80)		Tukey's HSD analysis		
	Mean	SD	Mean	SD	Mean	SD	Part-time vs Full-time	Part-time vs No work	Full-time vs No work
Grain	351.5	± 107.7	322.1	± 114.6	332.7	± 83.3	0.4758	0.7041	0.8251
Rice	214.9	± 86.0	194.1	± 98.1	196.9	± 73.7	0.6036	0.6447	0.9829
Bread	45.5	± 29.0	54.7	± 31.2	46.7	± 32.7	0.5019	0.9858	0.361
Noodle	39.1	± 46.2	44.8	± 51.6	51.2	± 48.3	0.8955	0.562	0.7557
Potatoes	33.2	± 32.5	29.1	± 27.0	40.2	± 39.8	0.8945	0.6876	0.2033
Sugar	7.4	± 5.5	6.0	± 6.0	7.0	± 6.5	0.652	0.9573	0.6587
Beans	56.1	± 49.4	53.9	± 67.6	60.3	± 64.8	0.9907	0.9596	0.851
Seeds	2.1	± 3.3	3.6	± 7.8	3.9	± 7.7	0.7035	0.5608	0.9734
Vegetable	249.7	± 103.0	258.0	± 138.9	236.6	± 88.2	0.9531	0.8708	0.5334
Fruits	128.5	± 74.8	130.8	± 120.8	167.0	± 108.1	0.9962	0.3045	0.1671
Mushroom	14.6	± 14.5	10.1	± 10.2	12.3	± 13.3	0.3489	0.7253	0.6084
Seaweeds	4.8	± 6.8	5.0	± 6.6	4.2	± 7.5	0.9873	0.9335	0.777
Seafood	46.3	± 42.4	46.0	± 30.0	48.2	± 31.9	0.9996	0.9683	0.9333
Fish products	2.2	± 6.6	5.7	± 9.5	3.8	± 8.6	0.2734	0.7259	0.4728
Meat	93.9 ^a	± 35.3	70.0 ^a	± 32.4	82.3	± 34.8	0.0209*	0.3412	0.1264
Red meat	52.0	± 31.6	41.6	± 27.5	42.9	± 31.5	0.3772	0.422	0.9706
White meat	25.0	± 27.2	15.4	± 20.0	25.6	± 27.7	0.3121	0.9939	0.0757
Processed meat	16.8	± 13.0	13.1	± 14.4	13.8	± 12.3	0.5117	0.606	0.9506
Eggs	38.3 ^a	± 21.9	24.7 ^a	± 20.7	28.6	± 21.3	0.0375*	0.1445	0.571
Dairy products	147.3	± 92.9	170.1	± 107.4	179.5	± 133.5	0.7436	0.5081	0.9054
Oil	14.4 ^{ab}	± 5.0	9.3 ^a	± 5.8	10.4 ^b	± 5.7	0.0013**	0.0096**	0.4926
Confectionaries	55.8	± 33.8	42.0	± 36.3	42.4	± 29.0	0.2232	0.1965	0.9975
Alchole	7.0	± 5.8	6.0	± 7.7	7.3	± 7.1	0.855	0.9804	0.5793
Tea	395.1	± 335.5	311.4	± 293.0	321.5	± 335.2	0.5748	0.6105	0.9841
Coffee	68.2	± 66.8	44.1	± 83.4	62.2	± 84.3	0.2549	0.761	0.2292
Other drinks	48.9	± 64.1	45.0	± 72.4	49.6	± 78.4	0.8404	0.9704	0.7402

Part-time; working hours per week less than 35 hours, Full-time; working hours per week more than 35 hours, No work; no working hours per week

^{a b}; The same alphabet indicates significant difference

*; p<0.05 **; p<0.01

Table 4: Evaluation of gestational gain according to "The Maternal Optimal Weight Gain Chart" indicted by the Ministry of Health, Labor and Welfare

	Part-time	n=22	Full-time	n=47	No work	n=80	Chi-square test's
Weight gain	%	人	%	人	%	人	p
low	4.5	1	8.5	4	21.3	17	
appropriate	59.1	13	59.6	28	52.5	42	0.0182
high	18.2	4	31.9	15	23.8	19	

The Maternal Optimal Weight Gain Chart shows the optimum weight gain during pregnancy as 9 to 12 kg for pregnant women with pre-pregnancy BMI less than 18.5, 7 to 12 kg for 18.5 to 25.0, and less than 5 kg for more than 25.0.

11. Conclusion

We investigated the relationship between working patterns and dietary habit and weight gain during the pregnancy period. The energy load during pregnancy was supplemented with fat in the part-time group, and this prevented low weight gain. The full-time group had significantly lower energy intake, which probably caused a lower weight gain. This indicated working pattern influence dietary among pregnant women in the second trimester.

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IARMM Purposes, Charters & Activities

Purpose

Because of rapid globalization of society and progress in technological innovations, problems related to global environment issues, life-style disease, community health, occupational health, medical accidents, food product health, international health, mental health and health problems for aging population are on the rise. Whilst we all recognize the importance of the practice of risk management sciences for prevention of those problems by risk assessment, it is essential to integrate interdisciplinary research in such fields as political economics, administration studies, sociology, environmental science, ecology, behavioral science, information science, education, ethics, epidemiology and statistics, not just to develop technologies to implement government policies and countermeasures. This Society, therefore, seeks to contribute to the promotion of scientifically sound countermeasures and solutions by encouraging the free exchange and interplay of international research activities. The most distinctive features of this Society will be:

- 1) Focusing on health risks associated with the occurrence of unpreferable health conditions, to carry out evidence-based health policy study by means of numerous analyses of countermeasures for preventive management of health risks.
- 2) To promote advancing the techniques and theory of "management" as required by the science of preventive medicine.

2002, April. International Association of Risk Management in Medicine

OVER ALL

A mailing list, and provide information by means of English journals and newsletter, etc., on internet. Planning to conduct education and research programs and symposia by lecturers. International electronic forum and electronic symposium are provided.

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1. The member (Conference President) who wishes to conduct the Special Conference of IARMM should submit the outline of the Conference to IARMM Congress Chairperson or President to make the contract with IARMM Chair and President.
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- ② Books and other monographs
Detels R, McEwen J, Beaglehole R, Tanaka H. *Oxford Textbook of Public Health. The Scope of Public Health. Fourth Edition.* Oxford: Oxford University Press, 2002.
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