

# Investigations in Patient Education Resources & the Generation of Generic Templates for Computerized Patient Education for Cancer Patients

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## **Acknowledgement and Endorsement**

This report has been written by me and has not received any previous academic credit at this or any other institution.

I would like to express my thanks and gratitude to Dr. Raza Abidi for his guidance and advice. Also, I would like to thank Dr. Grace Paterson for her help during the internship.

(signature)

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## Executive summary

The aim of the report was to complete the MHI- internship requirement. This internship was accomplished in NICHE research group under supervision of Dr Raza Abidi. The major purpose of the internship was to apply health informatics concepts and theories. This was during the evaluation of two different patient educational materials and generation of templates, thus providing general guidance for health professionals in producing patient educational materials. Several phases were accomplished during the project. The first study aimed to evaluate online websites against certain criteria. These criteria were website reliability and website content readability. The author used different measures to assess readability such as SMOG F-K Grade and FRE. Other criteria such as sponsorship, audiences, currency and factual information were used to assess website reliability. In addition, the author used DISCREN tool for reliability and treatment choice appropriateness. This study concluded that reliability of these websites was not an issue within the study sample; rather readability was the main issue. Therefore, the author suggests some recommendations that could help to improve patient interaction with these websites during the research study. These recommendations were;

- Readability of patient educational materials should be below the sixth grade, matched with population literacy and easily understood.
- Recommendation of Patient tailored education materials.
- Physician or patient-educator should have a role in directing patient to reliable- evidence based resources to aid patient in taking informed decisions related to their health.
- Websites should use interactive tool or illustrations to increase patient understanding of the provided material.

The second study was similar to Study I; however, it differed in resource format. This is because, in Study II, the format was patient information leaflets (PILs), which are widely used in hospitals and clinics. In Study II, the author used similar criteria to Study I to evaluate PILs. Study II reached the same finding as those of Study I. Thus, readability was the barrier towards production of valuable materials that would enable patients to make an informed decision. Thereafter, the author made comparisons between the two studies. This comparison was followed by generation of five templates whose contents were abstracted from the educational materials from Study I and II. The main objective of generating these templates is to aid health professionals in producing valuable health education materials. However, these templates were retested with another set of materials to ensure that they produce complete coverage of educational concepts. The last phase in the project was the generation of Cancer Patient Educational Materials that acted as artifacts for the previous templates produced in the second phase of the project.

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## **1. Introduction**

Technology advancement has contributed a lot in the modern society. This is because many people utilize the online resources such as websites, forums, blog posts and others for gathering information regarding their health. However, the sources of information are diverse in their nature and content. Moreover, information quality and reliability varies significantly (University of Oxford & The British Library, 1998). The need for accurate and reliable information is in strong demand by health care professionals. This is particularly by patients as this information directly affects their health. Consequently, this internship has three distinct parts that are different in nature, but similar in their aims. This aim is to investigate patient education resources and generate useful templates for the same purpose. The first part dealt with evaluation of cancer patient educational materials in online formats, i.e. websites, and portable file formats, e.g. leaflets and pamphlets. The second part generated patient educational templates for aiding health professionals in the education process. The third part was the development of Patient Educational materials for cancer. This will be used to aid health professionals in educating cancer patients in order to make informed decisions related to their health.

## **2. Description of the organization**

NICHE (kNowledge Intensive Computing for Healthcare Enterprises) research group is a research group supervised and directed by Dr. Raza Abidi, Director of Health Informatics Program, Computer Science Faculty, Dalhousie University. NICHE group has interests in several areas of researchs such as knowledge management and semantic web, Health Informatics, Intelligent information and service personalization, and Health Data Mining (NICHE Research Group, 2011).

NICHE group makes different contributions in different projects, such as computerising clinical guidelines (CPG) and Clinical Pathways, developing Clinical Decision Support Systems (CDSS), and personalizing of medical education provided for patients using appropriate tools (NICHE Research Group, 2011). In addition, NICHE provides consultation services regarding use of technology in health related projects and mentors students during their required training or internship.

## **3. Description of the work performed at the organization during internship**

The internship encompassed three different project parts. The first one is known as the evaluation of patient-oriented cancer information available online either as websites or Patient Information Leaflets (PILS) and this part is divided into studies I and II. The second part is the generation of patient-oriented cancer educational templates, while the third one is entitled as generation of

Cancer Patient Educational Materials. The duties of the author during the project will be described below in various sections.

### **3.1. Description of internship duties**

Internship duties entailed the following:

- Utilization of intensive literature review to allocate the scientific basis for designing and running the research studies.
- Evaluation of readability and quality of patient educational materials by using readability metrics and quality measures.
- Data collection, evaluation, statistical analysis, and mining by using Microsoft Office Excel®2007 and WEKA® Data mining softwares.
- Interpretation and analysis of research results.
- Comparisons between two different educational resources that are being highly utilized among patients.
- Identification and extraction of essential patient- educational information from different resources to serve as the basis of medical educational contents for a template.
- Generation and testing of patient- educational templates.
- Creation of Patient Educational materials based on the generated templates.

### **3.2. Summary of the work**

As mentioned before, the project started with evaluation of patient-oriented cancer information available online either as websites, or as Patient Information Leaflets (PILs). This project phase covered the two studies, I and II. Study I aimed to evaluate websites that offer patient- oriented educational materials, from different aspects such as readability and reliability. This study concluded that reliability of these websites was not an issue within the study sample; rather readability was the main issue. In Study II, the design was nearly the same as Study I; however, the materials that were evaluated were Patient Information Leaflets. Study II reached the same finding as those of Study I. Thus, readability was the barrier towards production of valuable materials that would enable patients to make an informed decision. The second phase was the generation of patient-oriented cancer educational templates that standardized educational materials and produced comprehensive materials that served patients need. In this phase, five templates were produced for different purposes. The last phase of this project was the creation of Cancer Patient Educational Materials that acted as artifacts for the previous templates produced in the second phase of the project.

## **4. Analysis on the way work is related to Health Informatics**

The author used different knowledge and skills that have been acquired during studying in Master of Health Informatics at Dalhousie University. The author utilized skills acquired on Research Method course in analyzing the research project. These skills helped in the design of the research

project as the author identified the required study designs that were suitable for the study. Furthermore, this course helped in identifying the required calculations that were appropriate for the study. In addition, it helped in literatures review that has the integral part in finding the essential criteria that helped in evaluating websites and PILs scientifically.

In addition, statistics course aided the author in analyzing and interpreting the results. It also helped in choosing the statistical measures that were appropriate for the studies. Data Mining course was tremendously helpful in extraction of additional information from the statistics. For example, WEKA software was used to visualize data and find any relationships between different attributes in data set. The statistical data helped in identifying the relationship between Affiliation and overall DISCREN Evaluation in study I.

Project management course had a significant impact in managing the project through managing the timeline, deliverables and work-breakdown and planning for this internship. Knowledge management course played the integral part in the internship since the main aim of the internship was evaluating existing knowledge especially in Study I and II. Furthermore, it helped in extracting, acquiring and organizing knowledge, i.e. templates generation. Nevertheless, the abstraction of patient educational concepts from Study I & II during templates generation was a pure knowledge management that transformed into knowledge representation in the form of generic templates.

## **5. Research problem and proposed solutions**

According to the research study, cancer is highly associated with North Americans' early mortality (Arocha, Friedman & Hoffman-Goetz, 2006). During different stages of a cancer patient's journey, the patient is in strong need for information that enables him or her to make an informed decision regarding their case (Arocha, Friedman & Hoffman-Goetz, 2006). Thus, this paper aims to evaluate cancer information that is patient oriented between two different formats, i.e. websites and online pamphlets, according to several criteria.

### **5.1. Barriers for Patient Education**

The author identified various problems that represent barriers for patient education. One of these barriers is the readability issues of educational information provided for patients from different resources since their readability level did not match with the literacy level of the population. As study I and II indicated that readability level is greater than 11 and 10<sup>th</sup> grade level in SMOG and F-K grade scales. That means only people with education level of 10<sup>th</sup> grade are able to read and comprehend the information provided. This is considered as a real issue as some experts recommend a readability level of sixth grade that is fairly understood by the public who have limited literacy (Arocha, Friedman & Hoffman-Goetz, 2006). However, the number of researches that extensively research readability level of patient educational materials has significantly increased in the last decade (Calderón, Smith & Baker, 2007). Although of these extensive literatures regarding readability, a few researches proposed solutions or tools that help health practitioners to produce easy readable educational materials (Calderón, Smith & Baker, 2007).

The other barrier is the improper searching ability for patients to allocate valuable information (Mortensen & Yeung, 2012). That does not mean that patient cannot search well but it means that patient is unable to evaluate medical information provided in different resources. Although, patients in general lack the ability to evaluate medical information in both resources as they are lacking the essential knowledge to assess the contents of these resources, they can evaluate the resources in term of their reliability and creditability. That is only possible in case the patient is well prepared to receive training from the health educators.

## **5.2. Evaluation of patient oriented cancer information available online**

This phase is consisted of two studies, I and II. The author analysed these two studies in the following sections.

### **5.2.1. Study I “Evaluation of patient-oriented cancer information available on Websites”**

#### **5.2.1.1. Study I objective**

Study I aimed to evaluate websites that offer patient- oriented educational materials, from different aspects such as readability and reliability.

#### **5.2.1.2. The research design**

The preliminary study aims to evaluate the patient-oriented cancer educational materials available online for the public, and it is designed as a cross-sectional, descriptive, retrospective study. In addition to that, it helps to identify the required content for designing a template for patient education purposes. The author categorized them into three phases:

- Phase I is characterized by finding the criteria to evaluate the educational material for patients on the web by searching literature.
- Phase II is characterized by finding websites that offer educational material for patients to make an informed decision.
- Phase III involves evaluating the chosen websites based on the scientific criteria.

#### **5.2.1.3. Phase I**

According to literature, several criteria should be considered to evaluate websites’ credibility and quality of information provided (Medical Library Association, 2012, University of Oxford & The British Library, 1998 & Arocha, Friedman & Hoffman-Goetz, 2006). These criteria can be divided into two main categories:

- Criteria related to website reliability.
- Criteria related to website content readability.



## Criteria related to website content reliability

According to Medical Library Association (MLA) Guideline (2012) for content evaluation for websites providing medical information for patients, the following criteria are used:

- *Sponsorship*: This can be identified from the URL of the website as .org (organization), .edu (educational institution), .gov (governmental) and .com (commercial). It is essential to assess the credibility of the website. It is vital to know who is writing or editing the website's content, to know who funds the website. All of this information can be identified by checking the URL itself (org, gov, edu and com) or (about us) icon.
- *Currency*: This can be identified by the last revision date of the website content in order to ensure that up-to-date information, as health information is in a continuous change over the time.
- *Factual or evidence- based Information*: It means that one should clearly stated facts found, thus retrieve them from scientific literature. One can access the information through finding provided references for this information. Furthermore, it can be assessed by the judgment of the material's evaluator, who can infer whether the information provided is scientific, or author opinion especially in case he has a clinical background.
- *Audience*: The website should clearly state the audiences to whom this medical information is directed to, i.e. patients or health professionals.

In addition to the above reliability measures, some websites hold certificates or seals such as HONcode and Information Standard from certificating bodies. For example, the HONcode seal means these websites are certified by Health On the Net Foundation that assesses the website credibility by ensuring that the basic ethical standards are met by the website developer (Health on the Net Foundation, 2011a). Holding these seals reveals the credibility of the websites. However, few websites hold this seal as it is not a mandatory requirement for websites to get this seal to publish health information. HONcode (2011b) has eight principles that a website should meet before getting the certification. These eight principles are:

- *Authoritative*: This means that author of the information should be a qualified medical practitioner or an organization.
- *Complementarity*: It means it should not replace medical advice. Instead, it should be considered complementary along with doctor advice. It can be indicated by using a statement like, "The information provided on (web site name) is designed to complement, not replace, the relationship between a patient and his/her own physician." (HONcode, 2011b).
- *Privacy*: In case the website requires patient specific data that include his identity information, the privacy and confidentiality should be maintained. Furthermore, the patient or visitor should be familiar with privacy policy of the website.
- *Attribution*: In case there is information that is obtained from other references, it should be cited well and the date of last revision should be mentioned.
- *Justifiability*: It means any claims of benefits of certain procedure or therapy should be justified by evidence from a reliable source.
- *Transparency*: The contact information of the one that maintains the website should be clearly provided in case a patient or visitor wants additional information or needs further clarification.

- *Financial disclosure:* It means the funding sources of the websites, if any, should be stated.
- *Advertising policy:* It means that the website should have an advertising policy that differentiates it from editorial policy, and the website should declare in case it receives any funds from advertisements.

Health information contents can be evaluated with respect to their quality in terms of reliability and treatment choice appropriateness using DISCREN instrument. DISCREN tool was developed by University of Oxford, and The British Library to help consumers and health professionals to evaluate health related data and treatment choice for written publications (University of Oxford & The British Library, 1998). However, recent research has used it to evaluate web-based information directed for patients who will or have had surgery for diverticular disease (Mortensen & Yeung, 2012).

### **Criteria related to website content readability**

The research study reveals various tools and formulas that one can use to assess website readability. It is significant to clarify the meaning of readability before introducing any tool. The National Cancer Institute defines readability “as the determination by systematic formulae of the reading comprehension level a person must have to understand the written materials” (Badarudeen and Sabharwal, 2008, p.200). It can be determined by using SMOG, Flesch Kincaid Grade level (F-K Grade) and Flesch Reading Ease (FRE) measures. According to Arocha, Friedman and Hoffman-Goetz (2006), the readability level should be below the sixth grade for easy understanding by the layperson. SMOG is used frequently to assess health information while using of F-K will add more confidence to the study results (Arocha, Friedman and Hoffman-Goetz, 2006). FRE measures the degree of the difficulty of the passage (100 easy to 0 difficult), and it has been modified to generate F-K to calculate Reading Grade level (RGL) (Arocha, Friedman and Hoffman-Goetz, 2006).

#### **5.2.1.4. Phase II**

This phase is characterized by finding websites that offered educational material for patients to make informed decisions. The websites are found by using the popular search engine Google® and the search keywords were “Cancer Patient Information.” The search engine retrieved (67,400,000 results). However, the first 100 websites were selected for analytical purpose in order to match certain inclusion criteria to produce 25-30 websites that represent the sample.

### **Inclusion criteria**

- It should be a website.
- It should be mainly patient oriented and it can be both patient and health professional directed.
- It contains information for any cancer type or any cancer related data.

Preliminary evaluation based on inclusion criteria to the nature of these websites was performed first in order to allocate the required sample size.

### 5.2.1.5. Phase III

This phase is the integral part of this study as it contains the evaluation process of the websites based on scientific criteria in Phase I.

#### Methodology

Regarding readability, tools such as SMOG, Flesch Kincaid Grade level (F-K Grade) and Flesch Reading Ease (FRE) were used to assess readability of these websites. An online readability calculator was used from Online-Utility.org (2009). For assessing quality of information of websites' contents regarding appropriate treatment options and assessing reliability, DISCERN tool was used (<http://www.discern.org.uk/>) (Mortensen & Yeung, 2012).

Other data, such as sponsorship, audiences, information, currency and any certificating seal, were assessed manually, thus entered using Microsoft Office Excel®2007. Data coding was used to facilitate transferring and use of data mining software to ensure data uniformity, and decrease data preparation phase that is usually time-consuming in mining any data set. Further modification was done using WEKA® Data mining software, to enhance data preparation e.g. discretization of continuous data as SMOG, F-K grade and FRE into nominal data.

### 5.2.1.6. Results

Readability results are represented in Table 1 below. The quality results that are based on DISCERN tool are 38.46%, 42.30% and 19.23% of High, Moderate and Low quality websites respectively.

Readability measure	Mean	Maximum	Minimum	Comment
SMOG	11.958	15.28	7.55	Represent education grade level required for understanding and comprehend the materials
F-K Grade	10.822	15.51	6.98	Represent education grade level required for understanding and comprehend the materials
FRE	49.175	68.2	23.51	FRE indicates the difficulty level on a scale of 100 where 100 is easy

*Table 1-* represents readability results for Study I.

### **5.2.1.7. Analysis**

Readability is an issue within the study sample. From table 1, the means of SMOG and F-k Grade are high. That means it is only appropriate for people at senior high school levels and above. This can be explained by the extensive use of medical terminology, instead of patient-friendly vocabulary.

Regarding holding a certificate from bodies such as HONCode and Information Standard, only six websites, and four websites out of total 26 websites hold HONCode and Information Standard respectively. Only one website complies with these two standards at the same time.

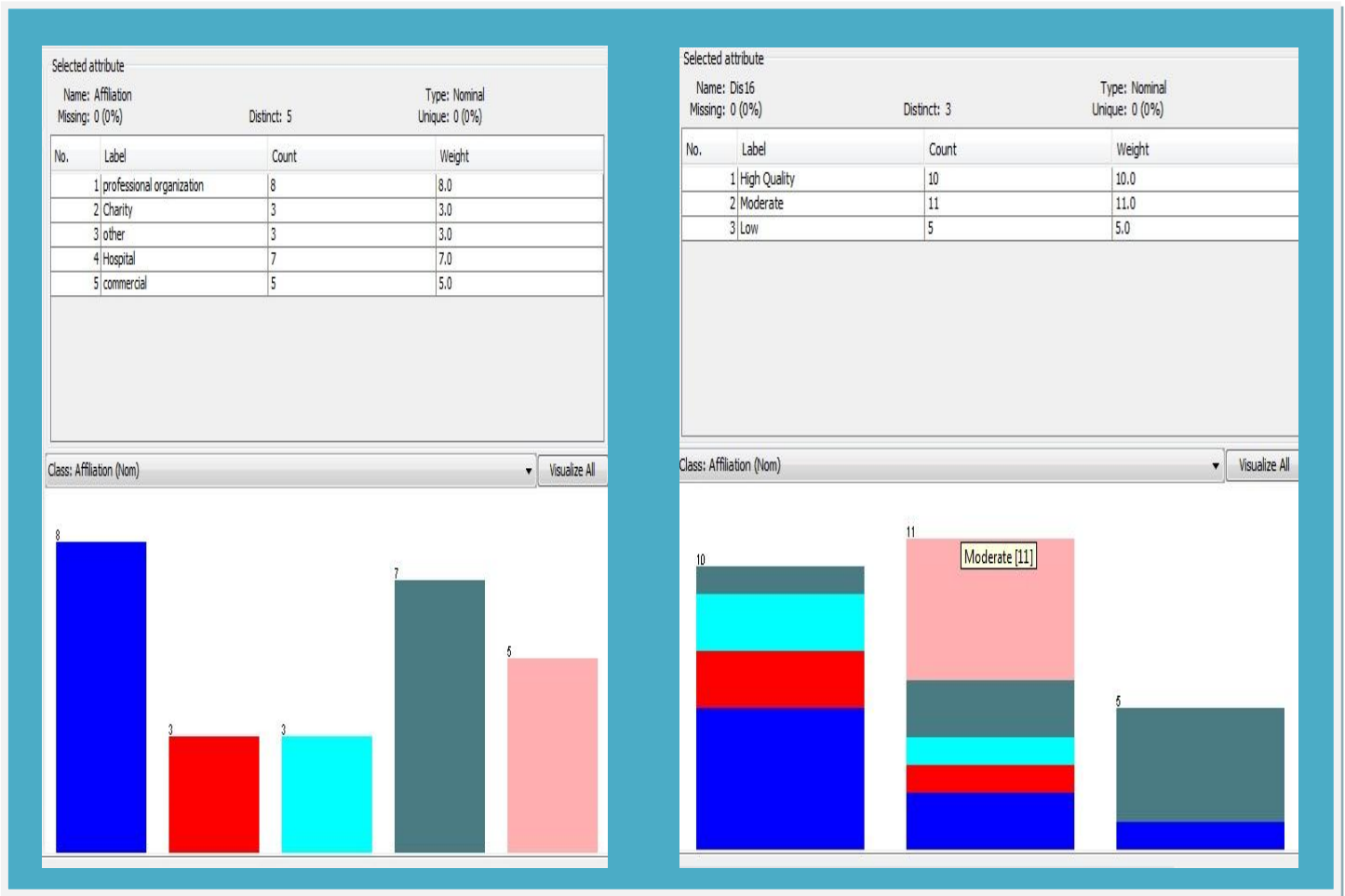
Based on DISCREN instrument for evaluating health information reliability and treatment choice assessment, ten websites are considered high, eleven moderate and five low qualities. Consequently, the websites of moderate to high quality represent the vast portions of the study.

Affiliations of the websites are hospitals (7), commercial websites (5), professional organizations (8), Charities (3) and others (3) as private publisher and private webs. All the websites offered their services to the public without any charges except one website, which offer general information. However, for access to detailed information, it requires a subscription.

Some results were obtained through analyzing in case there are any correlations between different variables in the study such as Affiliation, DISCREN overall Score. The first correlation is between Affiliation and Overall DISCREN Evaluation for the websites. Websites that hold commercial affiliation have moderate quality with DISCREN scoring instrument, while hospitals' websites form the significant part of websites with low quality. Furthermore, professional websites have varied qualities between high, moderate and low quality. However, they represent the main part of high quality websites. Figure 1 represents clearly this correlation between these variables.

It seems that there is no significant correlation between the website ranking and its affiliation. However, commercial websites hold intermediate to the last rank rather than first one. In addition, "other website" category (private website and private publishers) are classified in the first rank mainly. Moreover, professional websites were ranked as the first, intermediate and last as can be seen in Figure 2.

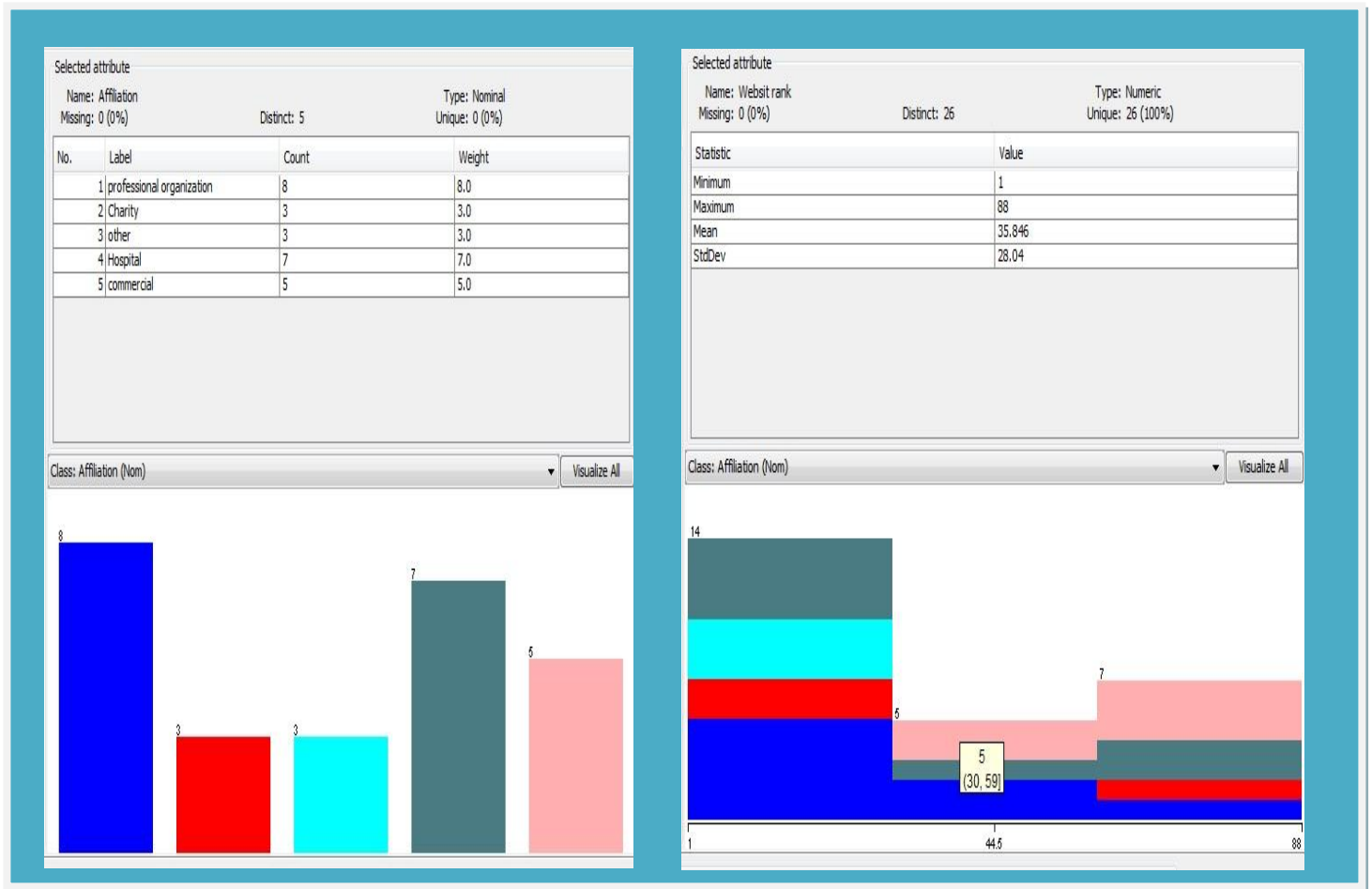
When comparing overall quality and currency of the websites, low quality websites provided information that is not up to date or does not emphasize the last revision date for their materials. On the other hand, few websites that are considered high and moderate quality were not dated as can be seen from Figure 3.



**Figure 1-** represents relationship between Affiliation and overall DISCREN Evaluation.

Most of the websites give detailed information regarding most cancer types; however, a few websites are specialized in one type of cancer, such as testicular, pancreatic and prostate cancer. For commercial websites as MSN® and EverydayHealth®, their information is provided by a private company specialized in health information (Healthwise®) that gathers and compiles the information from National Cancer Institute (NCI).

Few websites offer downloadable materials for patients for further discussion with their healthcare providers. Few websites have interactive tools, illustrations or Youtube® videos in order to facilitate the understanding of the materials.



**Figure 2-** represents relationship between Affiliation and Website Rank.

Regarding the content of the websites, most of the websites provide information about cancer type, diagnosis, symptoms and treatment (type, side effects and mode of action) remission, coping, support and additional resources. However, the level of the information varied from general description to detailed one. Most of the websites provided factual information regarding cancer-related data and no single website provided any opinion information. However, some websites that hold hospital affiliations have some bias regarding some modes of therapy that are in current use, in their facilities with some advertisement of their experts.



**Figure 3-** represents relationship between Overall DISCREN Evaluation and Currency criteria. *N.B. in currency (label 0) means not dated while (label 1) means is dated.*

### 5.2.1.8. Study I Conclusion

Readability of websites within the study sample is high, and it is difficult to be understood by layperson due to the extensive use of medical jargon. In addition, the quality of health information varies from high to low level and from the detailed description to a general one.

### 5.2.2. Study II “Evaluation of Patient Information Leaflets (PILs) available online”

### **5.2.2.1. Study II objective**

Study II aimed to evaluate Patient Information Leaflets (PILs) that offer patient- oriented educational materials, from different aspects such as readability and reliability.

### **5.2.2.2. The research design**

This study is similar to study I; however, it differs in inclusion criteria. It is a preliminary study, which aims to evaluate Patient Information Leaflets (PILs). The PILs offers online cancer information for patients, and it is designed as a cross-sectional, descriptive study. In addition, it helps to identify the required content for designing a template for patient education purposes.

This covers two phases:

- Phase I is characterized by finding PILs that offer educational material for patients to make an informed decision.
- Phase II involves evaluating the chosen PILs based on the scientific criteria as in Phase I in Study I.

### **5.2.2.3. Phase I**

This phase involves finding PILs that offer educational material for patients to make informed decisions. The PILs are found by using the popular search engine Google®. The search keywords were “cancer patient information”; however, search was restricted through using the advance search tool by specifying the type of format (file type: pdf). The search mechanism retrieved 2,020,000 outcomes. However, the first 35 results were selected for analysis in order to match certain inclusion criteria until getting 10-15 leaflets that represent the sample.

### **Inclusion criteria**

- It should be a leaflet in Portable Document Format (PDF).
- It should be mainly patient- oriented.
- It contains information for any type of cancer or any cancer related data.

Preliminary evaluation based on inclusion criteria to the nature of these leaflets was performed first in order to allocate the required sample size.

### **5.2.2.4. Phase II**

In order to evaluate PILS within the sample size, same tools as in Phase III in Study I such as online calculator for assessing readability, DISCREN instrument for document reliability and evaluating treatment options were used. Other criteria as sponsorship, currency, information and audiences were assessed. However, a criterion as holding certificate seal is not applicable here in study II due to the nature of PILS that differs from websites.



### 5.2.2.5. Results

Readability results are represented in Table 2 below. Regarding the quality of PILS with DISCREN tool, 8 of Moderate quality (80%) while only two out of 10 of Low quality (20%).

Readability measure	Mean	Maximum	Minimum	Comment
SMOG	11.688	14.04	9.43	Represent education grade level required for understanding and comprehend the materials
F-K Grade	10.337	13.16	8.82	Represent education grade level required for understanding and comprehend the materials
FRE	52.579	63.32	41.32	FRE indicates the difficulty level on a scale of 100 where 100 is easy and 0 is difficult

*Table 2-* represents readability results for Study II.

### 5.2.2.6. Analysis

With respect to readability measures, PILS within study sample were of high readability, i.e. only a person with grade 10th level and above can understand and comprehend the materials. Furthermore, the level of difficulty with FRE scale is relatively difficult with a mean of 52.579 (FRE indicates the difficulty level on a scale of 100 where 100 is easy, and 0 is difficult).

The contents of PILS varied according to its topic and its main purpose. Some of the PILS are full of details while others are relatively superficial and missing pertinent information. Moreover, the length of PILS is varied (from too-long 35 page and above to too-short 2 pages).

Most of PILS is produced either by professional organizations (6) or hospitals (4). All these PILS are directed for patients, their relatives or caregivers and no single PILS are directed to health professional plus patients. Numbers of PILS (7) are updated frequently, while only three are without any issue or reviewing date.

### 5.2.2.7. Study II Conclusion

PILS are significance tools for educating patients since it is convenient with respect of accessibility for patients. However, it has some limitations in term of readability and limited quantity of information provided. Thus, readability was the barrier towards production of

valuable materials that would enable patients to make an informed decision. PILs need more efforts to be a successful tool for educating patients and their relatives.

### 5.2.3. Logical Assessment between Study I & II

The comparison between study I & II is depending on two aspects:

- Parametric measures: that includes comparing readability measure and DISCREN evaluation criteria.
- Non- parametric measures: It includes the nature of these resources, and their results that were retrieved during the research.

#### 5.2.3.1. Comparison of parametric measures

Parametric measures that are being used in Study I and Study II are:

- Readability measures such as SMOG, Flesch Kincaid Grade level (F-K Grade) and Flesch Reading Ease (FRE).
- Reliability measures the DISCERN Results.

The comparison between study I and study II is represented in Table 3.

Measures	Study I	Study II
<b>SMOG</b>	11.958	11.688
<b>F-K Grade</b>	10.822	10.337
<b>FRE</b>	49.175	52.579
<b>DISCREN(High)</b>	10 (38.46%)	0 (0%)
<b>DISCREN (Moderate)</b>	11 (42.30%)	8 (80%)
<b>DISCREN (Low)</b>	5 (19.23)	2 (20%)

*Table 3-* parametric measures comparison between Study I & II

#### 5.2.3.2. Comparison of Non-Parametric measures

Initial research results were (67,400,000) and (2,020,000) for Study I and II respectively using Google® research engine. To explain this significant difference between these resources availability online is that PILs are mostly available as printed hard copies. The health professionals can hand them to patients during their visits. Sample sizes were 26 and 10 for Study I and Study II respectively.

Both websites and PILs provide information about sponsorship either from their URL link or (about us) icon for websites or from logos or others for PILs. All resources in Studies I and II contain accurate information; however, few resources in the two forms are not dated. In Study I, the audiences are varied sometimes patients only and health professionals together. However, in Study II all information is intended for patients only.

In Study I, websites are affiliated to professional organizations, hospitals, commercial, private publishers and private webs, charities and others. However, in Study II, the PILs are holding either hospital or professional organization affiliations.

### **5.3. The proposed solution**

#### **5.3.1. Generation of Generic Patient Education Templates for Cancer**

##### **5.3.1.1. Introduction**

Study I and II results in this report show that educational materials, either websites or pamphlets, are varied in their readability levels, quality and provided information. Consequently, there is an urgent need for addressing issues such as accuracy, easy accessibility, readable, high quality and organized information. Furthermore, one can achieve all these through identifying and extracting the essential contents from high to moderate quality sources. This is either using websites or PILs in generating templates that will help in accomplishing several purposes. These templates will have the most comprehensive educational concepts that high quality educational resources should contain.

##### **5.3.1.2. Objectives**

The main objective of generating this template is to aid health professionals in producing valuable health education materials. These materials will not replace or substitute medical advice; however, it will be a complementary. Moreover, it will fill any deficiency in education process during doctor and patient interactions. Thus, it will decrease the information gap between patient and his healthcare provider.

##### **5.3.1.3. Method**

By examining two educational materials types that the patients used and then directed through health practitioners such as websites and PILs, the required content for template for cancer patient education was identified. Three websites with high quality and three PILs with moderate quality were used. In addition to two of low quality materials, one website and one pamphlet were selected for comparison in terms of their content. Table 4, Appendix A represents the used websites and pamphlet links for generating the templates.

The author used grounded theory as a methodology for templates generation. The author collected the data, i.e. the contents of educational resources, then categorized (coding) these

contents into categories. After that, the author analyzed these categories for using as a basis of templates.

However, after generating these templates, there was a need for testing them. Consequently, the next step was testing that was done through having 2-4 additional educational resources. A new data set that contained all resources from Study I and II, was used for generating the templates. In order to eliminate selection bias, a stratified random method was used for sampling for retesting (Hulley et al, 2007). By this method, the dataset was divided based on the resource types, i.e. websites and PILs. Then, the author selected randomly the sample from every group. Thus, the sample represented all the two groups within the study. The contents of the chosen educational resources were compared against these templates in order to check the comprehensive coverage of educational concepts within these templates. The author carried out retesting that based on the following conditional rules:

- In case these contents match with template's concepts, so the template is satisfying.
- In case the template is not satisfied, the template should be updated with the missing categories.

This process was repeated four times with each template until all the four educational resources in retesting sample were used. Figure 4 in Appendix B represents the methodology that used for retesting.

#### **5.3.1.4. Results**

In general, some resources provided information under the following categories:

- Overview of cancer in general or sometimes called basics information.
- Other resources provided overview of specific cancer type (includes its location, organ involved and symptoms).
- Diagnosis of specific type of cancer (may include early detection, diagnostic test and stages if there are any).
- Treatment options (may include one or more, their indication, side effects and after treatment).
- Other sections (may include survivor resources, statistics, coping and other resources for more information).

However, some resources provided information for certain purposes such as for therapy or diagnostic test. Consequently, the information provided is slightly different from the ones intended for general purposes. The author tailored information used for the specific purposes. For example, for a certain therapy, the educational concepts used were for describing the therapy mainly while a little light was shaded on cancer description or other treatment approaches. In DISCREN tool, the educational material that provide information for certain treatment should mention at least a brief description for other treatment approaches for balancing and considering them as a high quality material (University of Oxford & The British Library, 1998). This intended to allow patients to make knowledgeable choices. This is through by weighing the benefits and risks from different options in order to become aware of the availability of other choices.

All resources that used are with high, moderate and low quality and readability level of 8th grade and above. However, one website of high quality contents was with grade 6th level. The difference between resources (both websites and PILs) with high quality and moderate from one side and others with low quality from the other side provided more details regarding their contents. Thus, the high and moderate quality resources were superior to others of low quality by providing comprehensive information in detail.

There were some differences in the presentation order of information according to the purpose of the material. For example, materials for general purpose tried to introduce patients first to the diseases, diagnosis and then therapy and so on. Therefore, one can conclude that it followed the same pathway exposed to patients during their journey with cancer.

### Testing templates

The results of comparing templates contents with testing set are in Table 5. Table 5 shows which templates that were coverage satisfactory and unsatisfactory during each test. For example, during Test 1 template 2 through 5 were satisfactory with their coverage of the educational concepts that were provided by educational material used in Test1. However, template 1 was not satisfactory with Test1, and there were missing concepts that were not included in template 1. Therefore, the missing concepts were added to template 1. Then in Test 2 same process was followed with all the templates, and any additional missing concepts were updated again in the unsatisfactory templates. The process of further retesting continued until all the comparison with retesting sample was completed.

Test number	Template1	Template2	Template3	Template4	Template5
Test (1)	Unsatisfied (Reasons of recurrence, Types of cancer, Staging system used & its definition)	Satisfy	Satisfy	Satisfy	Satisfy
Test (2)	Unsatisfied (Effect of cancer on organ and its function, and prognosis (outcomes))	Satisfy	Satisfy	Satisfy	Satisfy
Test (3)	Satisfy	Satisfy	Satisfy	Satisfy	Satisfy

<b>Test (4)</b>	Unsatisfied (Treatment indication, General treatment plan, and Before& after treatment instruction)	Unsatisfied ( Treatment indication, General treatment plan, and Before& after treatment instruction)	Satisfy	Satisfy	Satisfy
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**Table 5-** Represent template retesting results and the additional categories that were added to the templates.

### **5.3.1.5. Templates**

The author generated varied templates that based on their purposes. The first one meant for universal function. The templates could be used at the beginning of diagnosis to educate patient about his case.

The second template is for providing information about cancer therapies in general or about certain treatments. For example, health specialist wants to introduce his patient to a new therapeutic protocol that is currently used in a clinical trial. The health specialist can use this template to provide his patient by the necessary information regarding all the therapeutic aspects of this new therapy. The purpose of that is to help his patient to make the right decision of whether to start this therapy or not.

The third template is for diagnostic tests that the patient may undergo in certain stages of his cancer. For instance, this template will help the patient to understand how to be prepared well for the test. In addition, it will help him to be aware of the risks of doing this test.

The fourth template is for coping information that patients need to cope with cancer symptoms or therapy side effects. Thus, coping template will introduce coping methods that patients can utilized to decrease the side effects of the disease or the therapy.

The fifth template provides information for dealing with cancer and cancer related issues in home like a home-based care. Patients or their caregivers can use this template in order to improve patient care within his household. This template can be used to provide information at the beginning of the diagnosis, either after the therapy or at the end-stage of the cancer.

The Author recommended certain guidelines within these templates, which includes;

- Use of patient-specific or patient-friendly vocabulary
- Do not exceed certain readability level (at least 6th grade level)
- Provide the references used for producing the educational materials
- Mention the issue date and last revision date
- Mention sponsor information for reliability consideration

In addition to the general guidelines, the content itself should be factual, non-opinion, evidence-based information that written by a medical expert. At last, the aim of publishing these materials should be mentioned. Appendix C included five of the templates.

#### **5.3.1.5.1. Cancer Patient educational artifacts**

The author generated two educational materials that acted as artifacts for two previous templates produced in the second phase of the project. These two templates were template two and three that are for specific therapy and specific diagnostic test respectively. The author used her knowledge as a pharmacist to assess the content for these artifacts. Appendix D included these artifacts.

#### **5.3.2. Other Potential Solutions**

##### **For Readability Matters**

The following are the potential solutions for issues of readability:

- Use of patient- friendly terminology to improve readability of materials provided to the patient, thus reducing the usage of medical jargon especially “Plain Language Thesaurus”. For Communication Health” it is a vocabulary introduced by the Centers for Disease Control and Prevention’s National Center for Health Marketing (Ianphi.org., 2012). This can help professionals to replace medical terms by a regular terms used by laypersons (National Center of Health Marketing, 2007).
- Use of certain tools that guide the physician and health educators to produce easy and readable materials is crucial. Calderón, Smith & Baker (2007), suggested a tool called FONBAYS that health practitioners can use to reduce the readability level of their materials. The guideline produced by Calderón, Smith & Baker (2007) for using the FONBAYS method is in Table 6, Appendix A.
- In addition, health practitioners can use the built in calculator for measuring readability in Microsoft Word® Software to test their written material before publish it for patients (Clauson, Zeng-Treitler & Kandula, 2010, & D’Alessandro, Kingsley & Johnson-West, 2001). The word processor of Microsoft Word® software can determine automatically FRE and F-K grade for any entered text (Arocha, Friedman & Hoffman-Goetz, 2006). Moreover, Health Literacy Special Collection (2011) has several tools and guidelines regarding how to produce educational materials for people with limited literacy. One of these tools is an online Wordscount® tool that gives statistics as readability measures for any written materials.

##### **Searching ability issues for patients**

Improper searching abilities by patients can be addressed using the following:

- Educate patients regarding search of medical information through introducing criteria to evaluate medical information materials. For example, DISCREN tool is designed to help patients, and consumers to evaluate the quality of medical information offered to them (Mortensen & Yeung, 2012 & University of Oxford & The British Library, 1998).

Therefore, in case physicians introduce DISCREN or another tool to their patients, it will be helpful to them. Therefore, when patient use this tool, he or she can know in case this resource contains valuable information or not.

- Health educators can have a valuable role in directing patients for a way to evaluate health information available online. For example, health educators can prepare public or private workshops to increase the patient's awareness of the dangerous effects that can happen to them from getting information from unreliable resources. In addition, they can direct and introduce their patients to the ways of evaluating health information such as the tutorial from National Library of Medicine (<http://www.nlm.nih.gov/medlineplus/webeval/webeval.html>).
- Health practitioners can have significant role in directing patients to valuable resources that have been evaluated before. For example, during patients encounter doctor can give a list of quality websites that the patient can access to get more information.

## 6. Conclusions

Patients are in strong need for accurate, reliable and readable information that aid them to take over the control on their health and to make informed decisions. However, the available resources are varied in their quality and readability to play that role. Study I in this project revealed that readability of the websites within the study was not appropriate for the literacy level of the population and was much higher than the recommended level by the experts. In Study II, the author reached the same conclusion with respect of readability of patient information leaflets (PILs). From Study I and II, the author concluded that readability was the barrier towards production of valuable materials that would enable patients to make an informed decision.

Physicians and healthcare educators can play a significant role in directing patients to reliable resources or by providing valuable materials. Using templates for producing health information directed for patients can play a significant role. It will aid health professional to identify the required fields that should be addressed to provide comprehensive educational materials for different purposes.



## 7. Recommendations

The following recommendations are specified for each type of patient educational materials were examined during this project.

### For websites

- Readability of patient educational materials should be below the sixth grade, matched with population literacy and easily understood.
- Recommendation of Patient tailored education materials.
- Physician or patient-educator should have a role in directing patient to reliable- evidence based resources to aid patient in taking informed decisions related to their health.
- Websites should use interactive tool or illustrations to increase patient understanding of the provided material.

### For PILs

- PILs are a significant source of information provided for patients; however, the need for improvement in their design and content is essential.
- They should be written in remarkably simplified language for easy understandings by patients with different literacy level.
- Their content should be convenient, and that means not to be too detailed or too superficial.
- They should have illustrations that aid in explaining any medical concept or any process.
- These PILs should direct the patient to additional resources in case there is need for that.
- Their length should be appropriate meaning that they should not be too short or too long.
- In addition, preparing standardized, complete and up to date templates will be perfect solution. Use of predefine template such as templates provided in Appendix C will help health professional. It will aid them to identify the required fields that should be addressed to provide comprehensive educational materials for different purposes.
- These PILs should be edited and reviewed by medical experts, who should ensure that these educational materials are written in clear and readable language.

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## 9. Appendix A (Tables)

Link	Type	Quality level	Readability level
<a href="http://www.cancer.net/">http://www.cancer.net/</a>	Website	High Quality	➤ 10 <sup>th</sup> Grade
<a href="http://cancerhelp.cancerresearchuk.org/">http://cancerhelp.cancerresearchuk.org/</a>	Website	High Quality	➤ 11 <sup>th</sup> grade
<a href="http://www.cancer.org/Treatment/index">http://www.cancer.org/Treatment/index</a>	Website	High Quality	➤ 6 <sup>th</sup> grade
<a href="http://www.birminghamcancer.nhs.uk/uploads/document_file/document/4cc5b6c8358e98756800016a/secondary_20liver_20cancer_20-_20final_20version_20pbcn_20dec_202009.pdf">http://www.birminghamcancer.nhs.uk/uploads/document_file/document/4cc5b6c8358e98756800016a/secondary_20liver_20cancer_20-_20final_20version_20pbcn_20dec_202009.pdf</a>	PILS	Moderate Quality	➤ 11 <sup>th</sup> grade
<a href="http://infotheque.muhc.ca/Files/14/1440en.pdf">http://infotheque.muhc.ca/Files/14/1440en.pdf</a>	PILS	Moderate Quality	➤ 9 <sup>th</sup> grade
<a href="http://www.homerton.nhs.uk/uploaded_files/GP_information/stomach_cancer_final_a4.pdf">http://www.homerton.nhs.uk/uploaded_files/GP_information/stomach_cancer_final_a4.pdf</a>	PILS	Moderate Quality	➤ 8 <sup>th</sup> grade
<a href="http://www.mdanderson.org/patient-and-cancer-information/index.html">http://www.mdanderson.org/patient-and-cancer-information/index.html</a>	Website	Low Quality	➤ 13 <sup>th</sup> grade
<a href="http://www.cancerscreening.nhs.uk/prostate/prostate-patient-info-sheet.pdf">http://www.cancerscreening.nhs.uk/prostate/prostate-patient-info-sheet.pdf</a>	PILS	Low Quality	➤ 8 <sup>th</sup> grade

*Table 4, Appendix A-* represents the used websites and pamphlet links for generating the templates.

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Nine Steps to Readability Enhancement Using the FONBAYS Method

1. Identify compound sentences

- **A compound sentence has multiple clauses and, therefore, contains more than one thought.**
- **A clause is a simple sentence that links with another clause to make a complex sentence.**
- **The goal is to separate compound sentences into clauses that are easier to read and contain a single idea.**

2. Identify and separate compound sentences into clauses

- **Separate clauses at the words for, or, nor, because, and, yet, so (FONBAYS).**
- **Separate sentences at colons and semi-colons.**

3. Identify and reduce compound clauses

- **Compound clauses have more than one subject or object.**
- **Separate subjects or objects into separate clauses.**

4. Eliminate free modifiers or convert them into a clause

- **These words do not form the basic structure of a sentence.**
  - **Omitting them does not change the meaning of the sentence.**
  - **They may kept if they represent a clause.**
  - **They are separated from the rest of the sentence by a comma or commas.**
- Example: Born to wealthy parents, he was able to pursue his career without financial worries.*

5. Remove elements in parentheses

- **These are elements that are not part of the basic sentence structure.**
- **They may be omitted without changing the meaning of the sentence.**
- **They may be converted into an independent clause.**

6. Write an independent clause using each clause element

- **Make a simple complete sentence.**
- **May result in repetition of some sentence elements.**
- **Some repetition is good for enhancing comprehension.**

7. Identify clauses that may fit under one sub-heading

8. List similar clauses under one sub-heading

- **Example: Benefits to Society.**
- **Bullet independent clauses under sub-headings.**

9. Convert bullet into a vision friendly size and style

**Use 12' or 14 Pica Bookman Old Style font.**

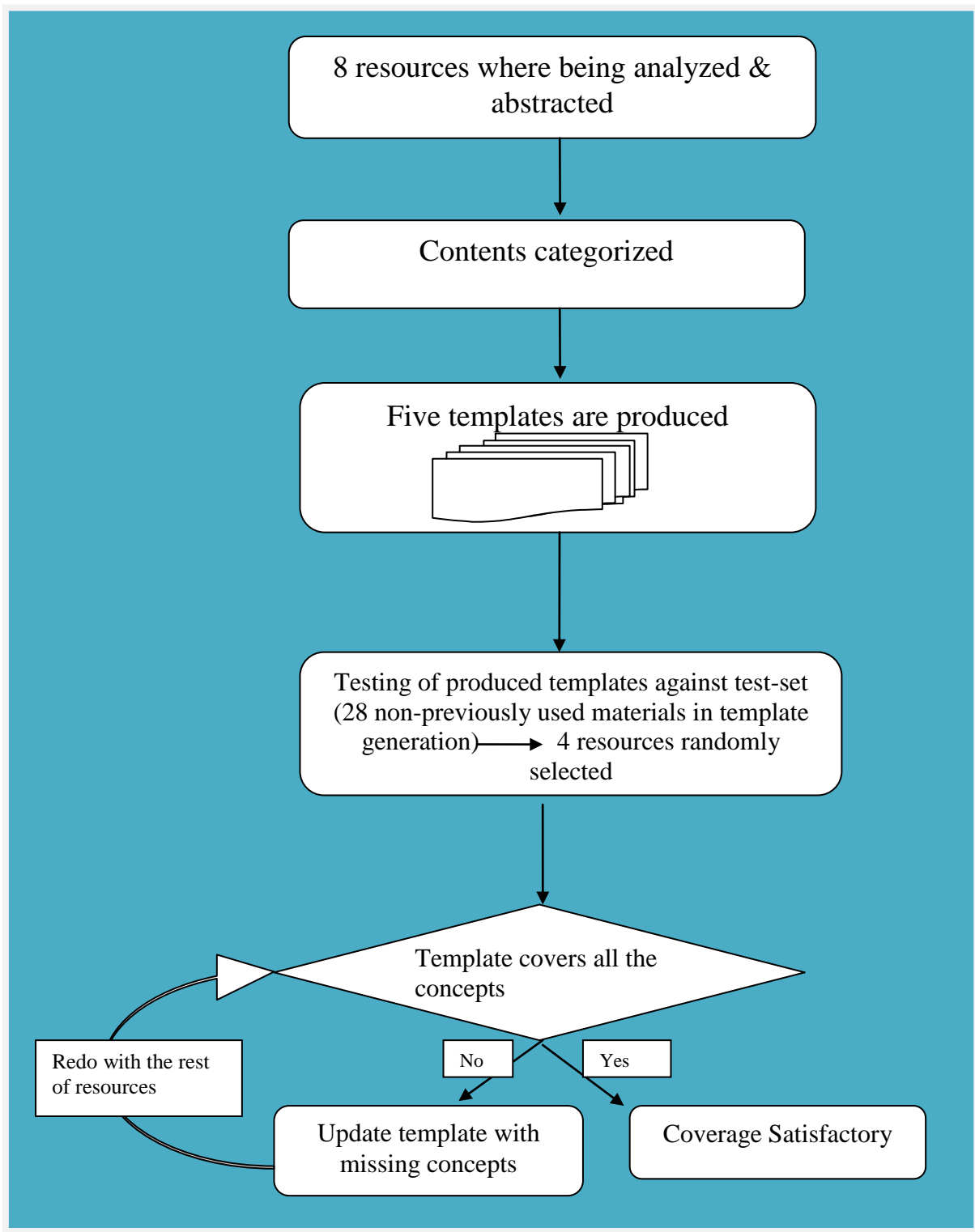
**Use 12 or 14 Pica Century Gothic Style font.**

**The readability of these instructions is F-K Formula 7.4 FREI 62.2 (Fairly easy to read)**

---

**Table 6, Appendix A-** contains Guideline produced by Calderón, Smith and baker (2007) for using FONBAYS method.

## 10. Appendix B (Figures)



*Figure 4-* represents the methodology that used for retesting of templates.

## 11. Appendix C (Templates)

### Template 1 For General purpose

#### Purpose of this pamphlet

- What is the aim of this pamphlet
- The information should be relevant
- The aim should be really covered within the pamphlet

#### Overview of location of cancer and its function

- Organ description
- Functions involved

#### Overview of cancer in general

- What is cancer?
- Different between benign and malignant

#### Over view of this specific type of cancer

- General description
- Facts and statistics
- Types of this cancer
- Effects of cancer on organ functions and health overall
- Risk factors
- Early detection and screening
- Symptoms

#### Diagnosis

- Diagnostic tests
- Further tests
- Benefits & limitation of test
- Stages ( staging system used & its definition)

#### Treatment planning

- Teams may involved in the treatment journey and their roles
- Consent/permission
- Second opinion

#### Treatment approaches

- Treatment options & general therapeutic plan in this cancer type

- Indication, Mode of action of each treatment, Benefits & risk of each therapy
- Before & after treatment instruction
- Effects of treatment on the overall quality of life
- Clinical trial option
- Complementary therapy
- Palliative therapy in case no treatment option
- Treatment by stage
- It should clearly mention if there is other treatment options
- Support for shared decision making, if there is uncertainty it should be mentioned

#### After treatment options & follow up

- What is the next step?

#### Recurrence

- Reasons for recurrence
- Therapeutic plan for recurrence

#### Prognosis and outcomes

#### Coping with cancer

- Coping physically
- Coping emotionally
- Dying with cancer( end-stage)

#### Questions section

- to be asked to healthcare provider
- Frequently asked questions and its answers

Other resources

## Template 1 For General purpose

- Reading lists & other resources
- Organizations & groups for support

General direction of writing PILS

- Readability level 6<sup>th</sup> and below

- Use of patient specific vocabulary
- Should be edited & reviewed by medical experts
- Facts only (no opinion)
- Reference should be mentioned
- Facts only (no opinion)
- Current information ( date of issue and reviewed frequently)
- Sponsor should be mentioned.



## Template 2 for specific purpose (e.g. specific therapy)

### Purpose of this pamphlet

- What is the aim of this pamphlet
- The information should be relevant
- The aim should be really covered within the pamphlet

### Organ associated with cancer

- Organ location
- Organ function

### Cancer overview

- What is cancer?
- General information about cancer

### Description of specific type of cancer

- What is this type?
- Statistics
- Symptoms
- Prevention and detection
- Diagnosis

### General therapeutic plan for this type of cancer

- What is usual start therapy?
- What is therapeutic plan for recurrence or secondary cancer?

### Description of treatment option in general

- E.g. general description of chemotherapy, surgery, radiation, etc.

### Description of specific type of treatment

- What is this specific therapy?

### Treatment indication

- Main indication and if there is other uses.

### How this treatment works?

- General description of mechanism of action

### Method of administration

- Is it locally or systemic therapy?
- Rout of administration

### Before & after treatment instruction

- Is there special procedure before or after treatment? E.g. taking antiemetic before chemotherapy

### Benefits of this treatment

- E.g. Is it eradicating cancer?

### Risk of this treatment

- Adverse effects

### Coping

- with treatment side effects
- with cancer symptoms

### After treatment & follow up

- What is the following step or steps?

### Treatment interaction with

- Other medications
- Herbal or food supplement
- Laboratory tests

### Special precautions

- For medication use

### Other resources

- Reading lists & other resources
- Organizations & groups for support

### General direction of writing PILS

- Readability level 6<sup>th</sup> and below
- Use of patient specific vocabulary

### **Template 2 for specific purpose (e.g. specific therapy)**

- Should be edited & reviewed by medical experts
- Reference should be mentioned
- Facts only (no opinion)
- Current information (date of issue and reviewed frequently)
- Sponsor should be mentioned.

## Template 3 for specific purpose (e.g. specific test)

### Purpose of this pamphlet

- What is the aim of this pamphlet
- The information should be relevant
- The aim should be really covered within the pamphlet

### Organ associated with cancer

- Organ location
- Organ function

### Cancer overview

- What is cancer?
- General information about cancer

### Description of specific type of cancer

- What is this type?
- Statistics
- Symptoms
- Prevention and detection
- Diagnosis

### Description of tests options in general

- E.g. general description of CT scan, MRI, etc

### Description of this test

- General information for this test

### Benefits of this test

- Is detecting size of tumor, its location?

### Risk of this test

- Side effects of this test

### After test

- What is the following step or steps?
- Interpretation of test results

### Special precautions

- Some precautions that patient takes before, during or after test

### Depending on test result what is treatment options

- Therapeutic options after test results

### Other resources

- Reading lists & other resources
- Organizations & groups

### General direction of writing PILS

- Readability level 6<sup>th</sup> and below
- Use of patient specific vocabulary
- Should be edited & reviewed by medical experts
- Reference should be mentioned
- Facts only (no opinion)
- Current information ( date of issue and reviewed frequently)
- Sponsor should be mentioned.

## Template 4 (coping with cancer)

### Purpose of this pamphlet

- What is the aim of this pamphlet
- The information should be relevant
- The aim should be really covered within the pamphlet

### What is coping?

- General description of coping

### Coping types

- Coping with cancer symptoms
- Coping with treatment side effects

### Ways of coping

- Physically
- Practically
- emotionally

### Who could help with coping?

- if there is some organization that provide coping services

### Other resources

- Reading lists & other resources
- Organizations & groups

### Support Services

- Professional support (on-call nurse, pharmacists, others)
- Social support (online communities)

### General direction of writing PILS

- Readability level 6<sup>th</sup> and below
- Use of patient specific vocabulary
- Should be edited & reviewed by medical experts
- Reference should be mentioned
- Facts only (no opinion)
- Current information (date of issue and reviewed frequently)
- Sponsor should be mentioned.

## Template 5 (Home-Based Cancer Care)

### Purpose of this pamphlet

- What is the aim of this pamphlet
- The information should be relevant
- The aim should be really covered within the pamphlet

### Meaning of home-based cancer care

### Types

- Home-based cancer care After initial diagnosis
  - Life style changes (nutrition, social, work, etc)
  - Managing cancer symptoms (pain, fatigue, anxiety, etc)
  - Psychological and social support
  - Communicate cancer diagnosis with family, friends, work, etc.
- Home-based cancer care during and after treatments
  - Being ready for therapy ( e.g. bringing antiemetic medications before chemotherapy course)
  - Managing treatments side effects (hair loss, mastectomy, etc)
  - Treatment interactions with Over-the-counter medications (OTC), herbal and food supplements.
  - Quit or resume some activity that interact with therapy or therapy results
  - Dealing with treatment uncertainty
  - Complementary therapy
- **Home-based cancer care & dealing with recurrence**
  - Recurrence symptoms

- Home-based cancer care & remission and follow up
- Home-based cancer care & childhood cancer
- End-life stage / near the death
  - Palliative treatment/ managing pain
  - Spiritual support
  - Prepare for death
  - End – of life options

### Support Services

- Professional support (on-call nurse, pharmacists, others)
- Social support ( online communities)

### General direction of writing PILS

- Readability level 6<sup>th</sup> and below
- Use of patient specific vocabulary
- Should be edited & reviewed by medical experts
- Reference should be mentioned
- Facts only (no opinion)
- Current information ( date of issue and reviewed frequently)
- Sponsor should be mentioned

## 12. Appendix D (Cancer Patient educational artifacts)

### CMF Chemotherapy

#### Purpose of this pamphlet

- This pamphlet aims to give patient, his family or patient's care giver the essential information regarding CMF chemotherapy regimen in Breast cancer.

#### Overview of the Breast

- Female breast is made mainly from glands (lobules) that produce milk, ducts or tubes to carry milk to nipple, and fatty and connective tissues (1). In addition to that, breasts have a network of blood and lymph vessels. Blood vessels provide breast tissue by nutrients and oxygen. Lymph vessels remove waste products from breast. Lymph vessels are connected to lymph nodes (2). Lymph nodes are located under arms or inside the chest (1). This tiny bean-shaped nodes fight infection (2).

#### Cancer overview

- Mutation or abnormal changes in your genes that regulate cells growth can end up by having cancer (5). The mutation in these genes will result in uncontrolled growth of the involving cells and tumor will be formed (5). The tumor has two types that are benign and malignant (5). Benign tumors are not cancerous and not dangerous to the health and their cells do not spread to other tissues. On the other hand, malignant tumors are cancerous and dangerous to the health. If malignant tumor left without control it will spread to other surrounded tissues or other body parts (5).

#### Description of specific type of cancer

- Breast cancer is a tumor in breasts. It can occur in female and rarely in male. This cancer can attack surrounding tissue or spread to other parts of the body (1).
- Cancer can start from cells in the wall of ducts (Ductal cancers), lining cells of milk glands (Lobular cancers), or a few types can start in other tissues (1).

#### Statistics

- In 2011, in United States 226,870 women diagnosed with invasive breast cancer and 63,300 women with in situ breast cancer (2). The five-year survival rate is 99% for people having in situ breast cancer, and 23% for people having breast cancer spread to distant sites (2).

**Artifact 1-** represents cancer patient educational information provided for patients receiving CMF chemotherapy.

## CMF Chemotherapy

- After lung cancer, breast cancer is the second leading cause of death in women from cancer (2).

### Symptoms

Symptoms of breast cancer may include the following (5):

- swelling of all or part of the breast
- skin irritation or dimpling
- breast pain
- nipple pain or the nipple turning inward
- redness, scaliness, or thickening of the nipple or breast skin
- a nipple discharge other than breast milk
- a lump in the underarm area

### Prevention

- If woman has risk factors that are leading to breast cancer, some interventions are available to prevent breast cancer (2). For example, if woman has mutation in BRCA1 or BRCA2 genes, her doctor may take a prophylactic measure as removing her breasts to decrease chances of developing breast cancer (2).

### Diagnosis

- Usually diagnosis begins by that woman or her doctor notice unusual mass or any change in breast. To confirm that doctor can request diagnostic test or biopsy of the breast. MRI, diagnostic mammography and ultrasound are imaging tests that are used for breast cancer diagnosis (2). Sometimes doctor can order blood tests as Blood Tumor Marker Test (biomarker) that is used to diagnosed recurrent or metastatic cancer (2).

### General therapeutic plan for this type of cancer

- The treatment plan is usually put by a multidisciplinary team (different types of doctors working together). Treatment plan depends on patient's age, overall health, tumor's hormone receptor status and stage of cancer (2).
- In general for early- stage of invasive breast tumor, the breast surgical removal is recommended. After surgical removal of the breast, doctors usually start adjunctive therapy to prevent recurrence of the tumor. This adjunctive therapy includes but not limited to chemotherapy, radiation therapy and/or hormonal therapy (2). If in first place surgery is not appropriate, adjunctive therapy will be used (2).

## CMF Chemotherapy

- Therapeutic plan for recurrence or secondary cancer depends on the ways used for treating cancer when it was first diagnosed (2).

### Description of treatment options in general

- **Surgery** can be completely removal of breast (mastectomy) or partial removal of tumor and surrounding tissue while most of breast remains (lumpectomy) (2). Lumpectomy sometimes called breast-conserving surgery that usually followed by radiation therapy (2).
- **Radiation therapy** can be internal (brachytherapy) or external use of high energy x-rays or particles(external beam radiation therapy) to kill cancer (2). Radiation therapy is usually a set of radiation sessions for a period of time (2).
- **Chemotherapy** involves use of medications to kill or stop the growth of cancer cells. It is usually occur in cycles or session of treatments over a period of time. Chemotherapy can be taken as intravenously or orally (2). Patient may take ne drug or a combination of drugs as a chemotherapy course. More often combination therapy is effective than single treatment (2).

### Description of CMF

- CMF is chemotherapy regimen. It used to treat breast cancer as
- This regimen CMF acronym stands for three drugs are: Cyclophosphamide, Methotrexate and 5-Fluorouracil (5FU) (3).
- These three drugs work differently against breast cancer to kill cancer cells (4).

### Treatment indication

- This regimen is indicated for node-negative or node-positive breast cancer.

### How this treatment works?

- Each drug has different way of action. However, all together work to kill cancer cells (4).

### Method of administration

- Patient needs to have a blood test before getting the therapy. This blood test could be done before or at the same day of treatment session. If the result of the test is normal, you will start the therapy (3).
- You may be treated as a day patient. Your nurse will insert a cannula (a thin plastic-tube) in your hand or arm vein. Sometimes, it can be administered through insertion of a thin plastic tube into the vein near the collarbone (central line) or the vein in the crock of their arm (PICC Line) (3).



## CMF Chemotherapy

- Before therapy starts, you need to take antiemetic medications (anti-sickness that stops or reduce chemotherapy- induced nausea). The antiemetic medication can be given as tablets or as injection through cannula, central-line or PICC-line (3).
- After antiemetic administration, therapy starts. Each drug is given separately in this order Cyclophosphamide then Methotrexate and followed by 5-Fluorouracil. Cyclophosphamide can be given as oral tablet as a course of two week before the session starts. The session will take approximately one hour. After this hour, your cannula will be removed and you can leave to your home. If you have central or PICC- line you will be given special instruction to take after the line as it should be stay in place for the next session (3).

### Before & after treatment instruction

- Before therapy starts, you need to take antiemetic medications (anti-sickness that stops or reduce chemotherapy- induced nausea). The antiemetic medication can be given as tablets or as injection through cannula, central-line or PICC-line (3).
- After session completion, if you have central or PICC- line you will be given special instruction to take after the line as it should be stay in place for the next session (3).
- You will be provided by anti-sickness drugs to be taken at home, please stick to your health care provider advice. Anti-sickness drugs more effective to be taken before symptoms of nausea starts than after (3).

### Benefits of this treatment

- Each drug in this combination has different way of stopping the growth of cancer cells, that's make it more effective to eradicate cancer cells after surgical removal of breast or as alternative therapy for surgery if it is not possible (2, 4).

### Risk of this treatment

The most common side effects for this regimen are the following;

- **Increase the risk of infection:** This regimen decreases your white blood cells that are responsible for your immunity. So, when your white blood cells count decreases, your risk of infection will increase. Contact your doctor when your temperature is above 38 °C (100.4 °F) or if you are feeling not well (3).
- **Bruising or bleeding:** This regimen decreases platelets count that results in bleeding or bruising from your nose or gum. In case your platelets count is too low, may you need platelets transfusion (3).

## CMF Chemotherapy

- **Anemia:** This regimen decreases your red blood cells that results in Anemia. May you will feel tiredness and breathless. In case your red blood cells count is too low, may you need blood transfusion (3).
- **Tiredness (fatigue):** This fatigue can starts at the end of the treatment and can stay for weeks after finishing your course (3).
- **Feeling sick (nausea) or being sick (vomiting)**
- **Sore mouth**
- **Taste changes:** May you will feel some changes in food tastes that will not stay for long time (3).
- **Diarrhea:** If you have diarrhea following your chemotherapy course, you are advice to drink plenty of fluids. In case you have severe diarrhea, your doctor will prescribe medication to stop or control diarrhea (3).
- **Eye problems:** This regimen may cause kind of eye soreness, redness and itchiness. If necessary, soothing eye drops will be prescribed for you (3).
- **Bladder irritation:** Cyclophosphamide may cause bladder irritation. To prevent that, you are advice to drink at least two litres of water in the first 24 hours following your session. Report any discomfort in urination or if there is any blood in your urine (3).

### Less common side effects

- Hair loss
- Skin changes
- Nail changes
- Liver changes
- Changes in the way your heart works

### Coping

#### With treatment side effects

- If you have diarrhea following your chemotherapy course, you are advice to drink plenty of fluids (3).
- For eye soreness, itchiness and redness, you can take soothing eye drops (3).
- To prevent bladder irritation drink at least two litres of water in the first 24 hours following your session (3).
- You may find sucking on ice soothing will reduce your moth soreness. Use of soft tooth brush and drink plenty of water may will be helpful (3).
- You may need to use wigs, headscarves, hats or turbans in case you have hair loss after chemotherapy.

## CMF Chemotherapy

### After treatment & follow up

- After therapy completion, it is recommended to follow up with your doctor to check your recovery and detect any sign of cancer recurrence (2). Follow up plan can include physical exams and/ or medical tests e.g. mammogram (2).

### Treatment interaction with

- CMF can interact with other prescribed medications or OTC (over the counter drugs), so consult your doctor or your pharmacist when you are taken other medication (3).
- CMF can interact with Herbal or food supplement, so consult your doctor or your pharmacist when you are taken any Herbal or food supplement (3).
- CMF can interact with alcohol, so stop taking it during your therapy (3).

### Special precautions

- It is advisable to take contraceptive during chemotherapy course as it has harmful effects on baby development during pregnancy (3).
- Chemotherapy can affect your fertility, so discuss that with your doctor.
- Breastfeeding should be stopped during therapy and after it for a few months, as there is risk that chemotherapy drugs are present in breast milk (3).

### Other resources

- [American Society of Clinical Oncology](#)
- [American Cancer Society](#)
- [Macmillan Cancer Support](#)
- [Cancer Chemotherapy Treatment Help](#)
- [Advanced Breast Cancer Community](#)
- [Bright Pink](#)

### Supporting Groups

- [BreastCancer.Org \(community groups\)](#)
- [The Macmillan Online community](#)
- [Young Survival Coalition](#)
- [SHARE: Self-help for Women with Breast or Ovarian Cancer](#)

## CMF Chemotherapy

### References

- 1) American Cancer Society. (2011). *Breast Cancer*. Retrieved from <http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-what-is-breast-cancer> Accessed on 17/07/2012.
- 2) American Society of clinical Oncology (ASCO). (2011). Breast Cancer. Retrieved from <http://www.cancer.net/patient/Cancer+Types/Breast+Cancer?sectionTitle=Overview> Accessed on 17/07/2012.
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## Blood tumor marker tests (Biomarker) for Breast Cancer

### Purpose of this pamphlet

- This pamphlet aims to give patient, his family or patient's care giver the essential information regarding Blood tumor marker tests for Breast cancer.

### Overview of the Breast

- Female breast is made mainly from glands (lobules) that produce milk, ducts or tubes to carry milk to nipple, and fatty and connective tissues (1). In addition to that, breasts have a network of blood and lymph vessels. Blood vessels provide breast tissue by nutrients and oxygen. Lymph vessels remove waste products from breast. Lymph vessels are connected to lymph nodes (2). Lymph nodes are located under arms or inside the chest (1). This tiny bean-shaped nodes fight infection (2).

### Cancer overview

- Mutation or abnormal changes in your genes that regulate cells growth can end up by having cancer (3). The mutation in these genes will result in uncontrolled growth of the involving cells and tumor will be formed (3). The tumor has two types that are benign and malignant (3). Benign tumors are not cancerous and not dangerous to the health and their cells do not spread to other tissues. On the other hand, malignant tumors are cancerous and dangerous to the health. If malignant tumor left without control it will spread to other surrounded tissues or other body parts (3).

### Description of specific type of cancer

- Breast cancer is a tumor in breasts. It can occur in female and rarely in male. This cancer can attack surrounding tissue or spread to other parts of the body (1).
- Cancer can start from cells in the wall of ducts (Ductal cancers), lining cells of milk glands (Lobular cancers), or a few types can start in other tissues (1).

### Statistics

- In 2011, in United States 226,870 women diagnosed with invasive breast cancer and 63,300 women with in situ breast cancer (2). The five-year survival rate is 99% for people having in situ breast cancer, and 23% for people having breast cancer spread to distant sites (2). After lung cancer, breast cancer is the second leading cause of death in women from cancer (2).

**Artifact 2-** represents cancer patient educational information provided for patients receiving Blood tumor marker tests (Biomarker) for Breast Cancer

## Blood tumor marker tests (Biomarker) for Breast Cancer

### Symptoms

Symptoms of breast cancer may include the following (3):

- swelling of all or part of the breast
- skin irritation or dimpling
- breast pain
- nipple pain or the nipple turning inward
- redness, scaliness, or thickening of the nipple or breast skin
- a nipple discharge other than breast milk
- a lump in the underarm area

### Prevention

- If woman has risk factors that are leading to breast cancer, some interventions are available to prevent breast cancer (2). For example, if woman has mutation in BRCA1 or BRCA2 genes, her doctor may take a prophylactic measure as removing her breasts to decrease chances of developing breast cancer (2).

### Diagnosis

- Usually diagnosis begins by that woman or her doctor notice unusual mass or any change in breast. To confirm that doctor can request diagnostic test or biopsy of the breast. MRI, diagnostic mammography and ultrasound are imaging tests that are used for breast cancer diagnosis (2). Sometimes doctor can order blood tests as Blood Tumor Marker Test (biomarker) that is used to diagnosed recurrent or metastatic cancer (2).

### Description of tests options in general

In general diagnostic tests for breast cancer can be divided into parts; imaging tests, surgical test, blood tests, test for tumor's genes and additional tests (2).

- **Imaging tests:** include diagnostic mammography, ultrasound and MRI.
- **Surgical test:** is mainly biopsy from breast tissue that surgically removed. It is followed by testing the tissue to determine type of cancer and its features (2).
- **Blood tests:** include serum chemistry panel that examines serum electrolytes but it is not specific for breast cancer. Blood tumor marker test is another blood test but it is specific for cancer. This test is to examine the presence of certain substance in blood. This substance is called sometimes biomarker or blood tumor marker that associated with cancer (2).
- **Testing tumor's genes:** include Oncotype Dx and MammaPrint. Both tests are used to look to tumor's genes and determine the risk for cancer recurrence (2).

## **Blood tumor marker tests (Biomarker) for Breast Cancer**

- **Additional tests:** are not usually used at the beginning of diagnosis but used for advance breast cancer. These tests are Bone-scan, special x-ray, Computed Tomography (CT) Scan and Position Emission Tomography (PET) Scan.

### Description of Blood tumor marker test

- Your doctor will ask for this test to check the level of a substance in your blood. This substance is called a biomarker. It is generally associated with cancer. It can be produced by tumor itself or your body in response for cancer. Presence of high level of this substance in blood may be as a result of cancer or some noncancerous condition. This test is not for use in early stages of cancer. It is used to determine the risk of cancer recurrence and metastasis of tumor to other body parts (2, 4).

### Benefits of this test

- Blood tumor marker test will help your doctor in treatment planning and tumor monitoring. It helps to confirm other test results (4).

### Risk of this test

- There are no known test side effects as your doctor will take a sample of your blood after that this sample will be examined in the laboratory to determine the level of the biomarker (4). However, this test has some limitations. The increase in the biomarker's level can be due to other reasons other than cancer. It can increase in a healthy person without any cancer. It is not helpful for early diagnosis as the level increases usually associated with advance cancer (4).

### After test

The biomarker level will help your doctor to adjust your treatment and to determine your prognosis (future chances of recurrence or complete remission) (4).

### Other resources

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## Blood tumor marker tests (Biomarker) for Breast Cancer

### Supporting Groups

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### References

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