A Web-based 'Patterns of Care Study' System for Clinical Radiation Oncology in Korea: Development, Launching, and Characteristics

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Purpose: We report upon a web-based system for Patterns of Care Study (PCS) devised for Korean radiation oncology. This PCS was designed to establish standard tools for clinical quality assurance, to determine basic parameters for radiation oncology processes, to offer a solid system for cooperative clinical studies and a useful standard database for comparisons with other national databases.

Materials and Methods: The system consisted of a main server with two back-ups in other locations. The program uses a Linux operating system and a MySQL database. Cancers with high frequencies in radiotherapy departments in Korea from 1998 to 1999 were chosen to have a developmental priority.

Results: The web-based clinical PCS system for radiotherapy in www.pcs.re.kr was developed in early 2003 for cancers of the breast, rectum, esophagus, larynx and lung, and for brain metastasis. The total number of PCS study items exceeded one thousand. Our PCS system features user-friendliness, double entry checking, data security, encryption, hard disc mirroring, double back-up, and statistical analysis. Alphanumeric data can be input as well as image data. In addition, programs were constructed for IRB submission, random sampling of data, and departmental structure.

Conclusion: For the first time in the field of PCS, we have developed a web-based system and associated working programs. With this system, we can gather sample data in a short period and thus save, cost, effort and time. Data audits should be performed to validate input data. We propose that this system should be considered as a standard method for PCS or similar types of data collection systems.

Key Words: Radiotherapy, Patterns of care study, Web, Clinical QA

Introduction

Korean radiation oncologists agree that certain clinical QA

tools are required. Some characteristics of the basic structure of radiation therapy in Korea have been incorporated into the development of the Patterns of Care Study (PCS) system.

First, cancer has been the leading cause of death in Korea for more than a decade (Fig. 1), and therefore, public interest is increasing not only in terms of cancer cure but also for good cancer management and QA. The number of new cancer patients included in hospital-based statistics continues to increase at a rate of 5~10% per annum. When we compared the frequency of new cancer incidence in 2002 to that in

1984, uterine cervix and stomach cancer were found to have to decreased, but over the same period rectal, liver, lung, and breast cancers increased by 1.3 to 2.0 fold (Fig. 2). These features demonstrate that we are well on our way toward developing a westernized pattern of cancer incidence.

Second, two peaks are evident in the frequency curve of cancer cases by age for females, but only one for males. The first peak for women occurs at rather a young age, around 40, and seems to be largely due to breast cancer; moreover, the

magnitude of this peak continues to increase year by year.

Third, among a total of 20,226 cases, only about 25% of all new cancer cases, were treated by radiation therapy in the year 2000[1,2]. This rather low percentage is probably due to the large number of stomach and liver cancer cases, which are not routinely prescribed radiotherapy. About 45% of new cancer cases were originated in the gastrointestinal organs as the stomach, liver, colorectum, and pancreas (Table 1).

Fourth, we have very limited resources. In Korea, there are 53 radiotherapy facilities and 152 trained radiation oncologists on staff. Moreover, the number of medical physicists and
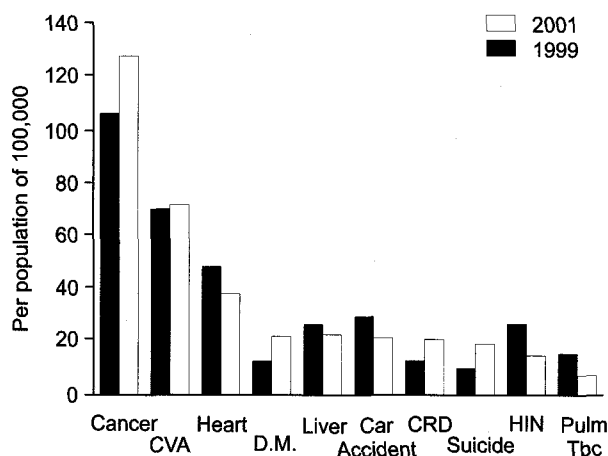

Fig. 1. The major leading causes of death in Korea; based on data obtained from the Korean National Statistics Office. Cancer is the most common cause of death and account for 24.4% of all deaths. Note; CVA: Cerebrovascular accident, DM: Diabetes mellitus, CRD: Chronic respiratory disease, HTN: Hypertension.
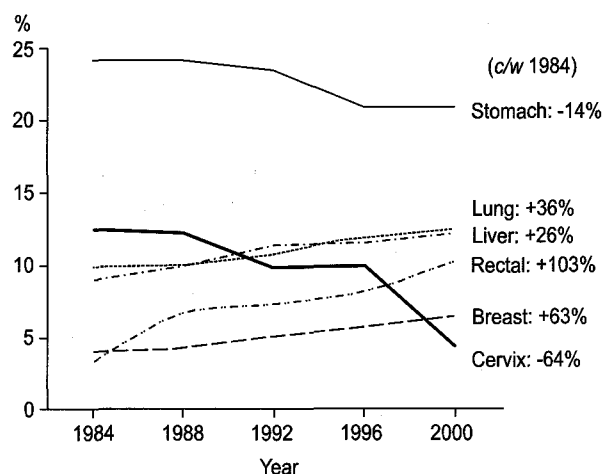

Fig. 2. Changing patterns of tumors registered in 131 major Korean hospitals; from the Korean ministry of health and welfare.

Table 1. National Tumor Registry 2000 in Korea*

	All	No (%)	Male	No (%)	Female	No (%)
1	Stomach	17,439 (20.8)	Stomach	11,761 (24.5)	Stomach	5,678 (15.8)
2	Lung	10,230 (12.2)	Liver	7,825 (16.3)	Breast	5,409 (15.1)
3	Liver	10,214 (12.2)	Lung	7,809 (16.3)	Uterine cervix	3,803 (10.6)
4	Colorectal	8,648 (10.3)	Colorectal	4,897 (10.2)	Colorectal	3,751 (10.5)
5	Breast	5,444 (6.5)	Bladder	1,666 (3.5)	Thyroid	2,469 (6.9)
6	Uterine cervix	3,803 (4.5)	Esophagus	1,394 (2.9)	Lung	2,421 (6.8)
7	Thyroid	2,921 (3.5)	Hematologic	1,320 (2.7)	Liver	2,389 (6.7)
8	Hematologic	2,366 (2.8)	Pancreas	1,120 (2.3)	Ovary	1,480 (4.1)
9	Bladder	2,045 (2.4)	Prostate	1,057 (2.2)	Hematologic	1,046 (2.9)
10	Pancreas	1,893 (2.3)	Kidney	891 (1.9)	Pancreas	774 (2.2)
All		83,846		48,005 (57.3% of all)		35,841 (42.7% of all)

*This is not a population-based registry but a hospital based-registry. The number represents the new cancer patients in 2000 among 131 major hospitals in Korea (Korean Ministry of Health and Welfare, 2002).

residents are below requirement. What is more, these resources are unevenly distributed geographically, and are more concentrated in larger cities like Seoul, Busan and Daegu.

The need for radiation oncology seems to be receiving favorable attention in the current Korean medical environment. The number of radiotherapy cases has increased from 5 to 7% per annum since 1992. We believe that certain important background factors promote this positive change, namely, the positive attitude of cancer patients and of their family members, the need for high-quality medical care, the application of adjuvant or combined radiotherapy for liver or stomach cancer, in some hospitals, and the installation of high- technology systems.

The Korean Society for Therapeutic Radiology and Oncology (KOSTRO) started clinical QA studies by competitive selection and peer review from 1998. Two basic QA care pattern studies for breast cancer and cervix cancer have been reported[3]. In addition, a large number of radiotherapy facilities participated in two physics QA studies upon the photon and electron output of linear accelerators.[4] KOSTRO have also surveyed basic personnel, apparatus availability and type, and the distribution of radiotherapy patients every 2 to 3 years, for more than 15 years. However, these activities have not been influential in terms of standardizing or promoting clinical QA.

We need systematic data that shows nation-wide patterns of radiotherapy structure, process and results. We started to develop a system for PCS in Korea in 2002. As developed, the PCS system enables clinical quality assurance to be studied in the field of radiation oncology.[5~9] It was and remains our aim to establish a standard tool for clinical quality assurance that defines the basic parameters of the radiation oncology process, one that provides a solid system for cooperative clinical studies, and which offers a useful standard database for comparisons with other nations.

The main principle underlying the PCS system is the saving of time and effort, because the number of radiation oncologists is restrictively limited in Korea. Thus, we have developed a web-based PCS system for the first time in the radiation oncology field, and here report upon the structure and function of the developed system.

Materials and Methods

We decided upon priorities during the development of the PCS system based on the number of radiotherapy cases (Table 2). We chose, cancers of the lung, breast, rectum, esophagus and larynx, and brain metastases as the initial target cancers for the PCS system for radiotherapy in Korea for the first year of its operation, 2002.

The PCS center was charged with the development of the on-line PCS system, including, the general structure and function of the web site, and the study items for common demographic items such as radiotherapy number, age, and gender, and for comorbidities and brain metastasis. Five task groups were assigned to develop the web-based PCS tools for cancers of the lung, breast, rectum, esophagus and larynx. Five co-workers organized five to ten group members, and took charge of the task groups. Other medical specialties have not been involved in the development of this program because we focused on the radiotherapy process and technology and we believe that the system is best served by incorporating basic information on surgery and chemotherapy from the medical record.

The structure and methods of the Korean PCS for radiation therapy are shown in Fig. 3, which shows that the scope and the extent of the PCS were designed to increase the number

Table 2. Patterns and Proportions of New Radiotherapy Patients in Korea*

Primary tumor site	No. of cases (%) in '98	No. of cases (%) in '96
Lung	2,920 (14.4)	3,087 (16.1)
Uterine cervix	2,442 (12.1)	2,689 (14.0)
Head and neck	2,010 (9.9)	2,005 (10.5)
Breast	1,749 (8.6)	1,574 (8.2)
Colon and rectum	1,702 (8.4)	1,595 (8.3)
Bone metastasis	1,667 (8.2)	1,244 (6.5)
Brain and spinal cord	924 (4.6)	1,095 (5.7)
Brain metastasis	909 (4.5)	794 (4.1)
Esophagus	794 (3.9)	753 (3.9)
NHL or Hodgkin's	581 (2.9)	513 (2.7)
All	20,226	19,200

*Korean Society for Therapeutic Radiology and Oncology (2000)

of tumor types, participating hospitals, and active members.

Results

1. System (Fig. 3)

The main system has a web-based multi-user structure. The main server (Compaq proliant server DL360, memory 512 MB, HDD 72 G, Raid O mirroring) is maintained at constant temperature and humidity inside the Korean Internet Database Center (KIDC) with a 100 Mbps dedicated line service protected by a double physical firewall. We maintain one backup

mirror inside and two outside the KIDC. The web domain for the Korean PCS for radiation oncology can be found at *www.pcs.re.kr*.

Software for our web-based PCS function is based on the Linux 7.2 operating system, an Apache 1.3.27 web server, a Sendmail mail server, Mysql-UDF for DBMS, PHP4.23 + Zend optimizer + gd for language, and an IR5.0 browser. Standard PCS resolution is set at 1024 * 768 with 16-bit high color. We use the Coconut security system and Supercert SSL (Secure Sockets Layer) encryption technology to safeguard information.
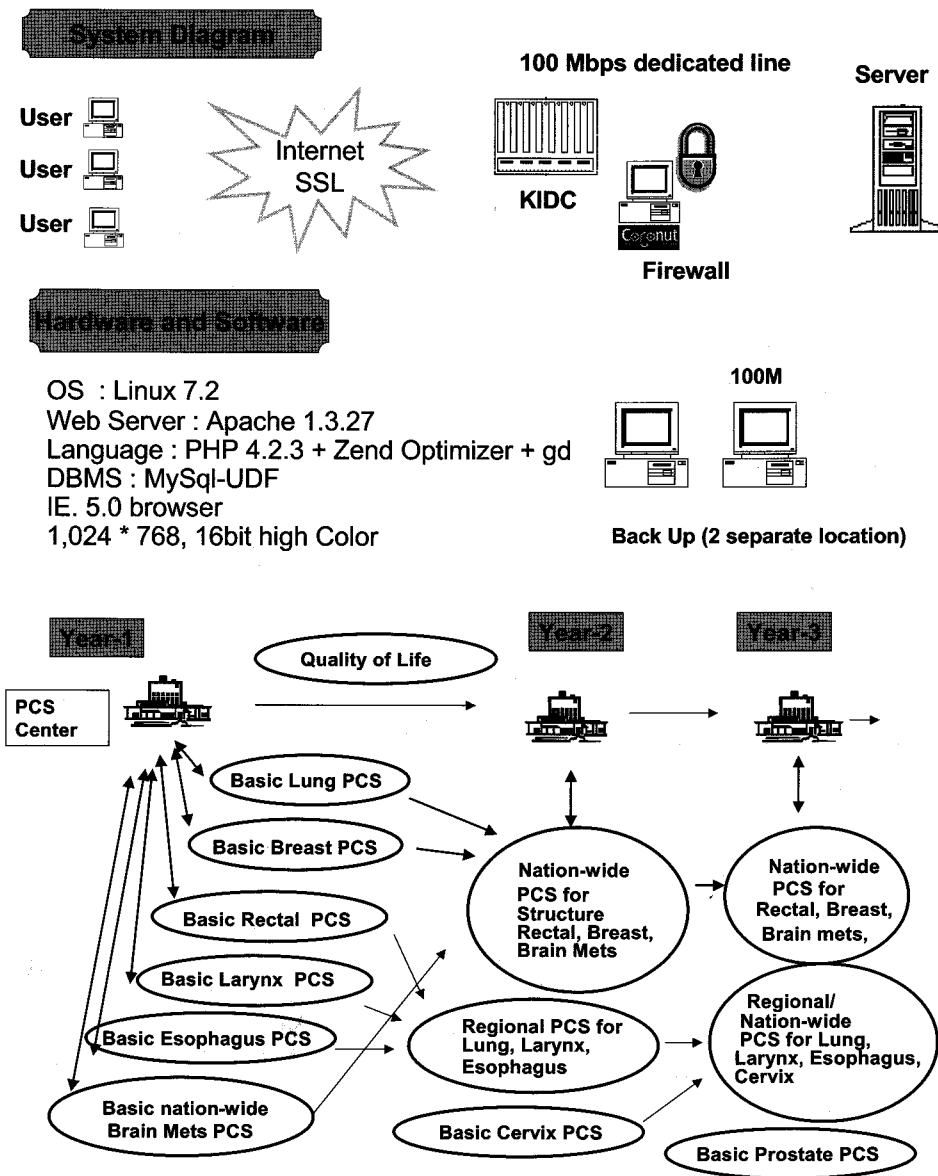
System Diagram

100 Mbps dedicated line   **Server**

User   Internet SSL   KIDC

Firewall

Hardware and Software

OS : Linux 7.2
Web Server : Apache 1.3.27
Language : PHP 4.2.3 + Zend Optimizer + gd
DBMS : MySql-UDF
IE. 5.0 browser
1,024 * 768, 16bit high Color

100M

Back Up (2 separate location)

Year-1   **Year-2**   **Year-3**

Quality of Life

PCS Center

Basic Lung PCS

Basic Breast PCS

Basic Rectal PCS

Basic Larynx PCS

Basic Esophagus PCS

Basic nation-wide Brain Mets PCS

Nation-wide PCS for Structure Rectal, Breast, Brain Mets

Regional PCS for Lung, Larynx, Esophagus

Basic Cervix PCS

Nation-wide PCS for Rectal, Breast, Brain mets,

Regional/ Nation-wide PCS for Lung, Larynx, Esophagus, Cervix

Basic Prostate PCS

Fig. 3. Structure and methodology of Korean PCS for radiation therapy.
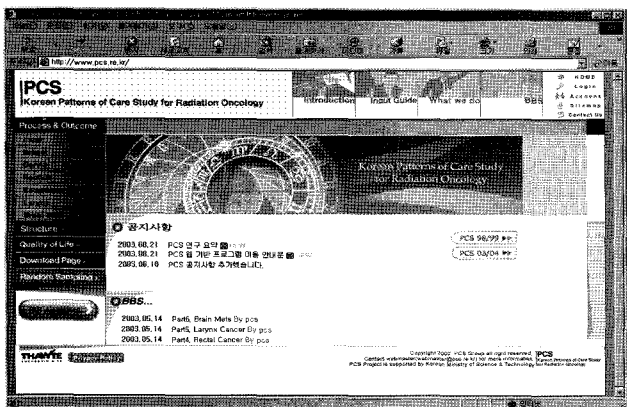
Fig. 4. The main page of the Korean PCS web site for radiation therapy can be found at www.pcs.re.kr.

Fig. 5. An image upload module in the web-based Korean PCS for radiation therapy.

2. Program

Two steps of security must be passed to enter the PCS system. Main contents of the system are; Structure, Process & Outcome, QOL, Download pages, Random sampling, and Introductory explanations with graphs (Fig. 4). A registered member may input information including; a user ID, password, name, department, institute, e-mail address and phone number, and choose a cancer type. A member of a participating department should input information on manpower, patient distribution, apparatus (e.g., manufacturer, model, year of installation or disassembly), energies of external radiotherapy machines, brachytherapy unit, or details of the planning systems. From such data, the long-term perspectives and dynamics of the apparatus and personnel in Korea can be understood.

The web contents include subprograms for each tumor, and each subprogram has an identical structure, i.e., an eligibility check module, a demographic data module, specific data input modules, and an image upload module. The system accepts image files in jpg format only and a maximum of 5 image files (Fig. 5). A test version showed that an image file of 800 ×600 resolution is sufficient to read or differentiate fine structures in, for example, simulation films. One can button 'Save & Next step' or 'Save & Quit' after finishing each module. One can modify input data or input additional data into the next modules later.

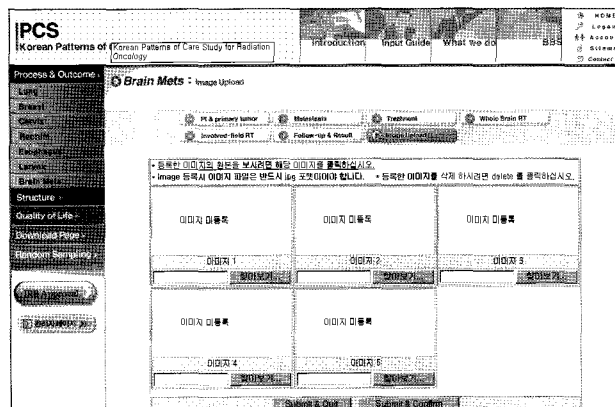The subprograms for each cancer have been designed to be user-friendly allowing data input by mouse for the large part, using some default values, conditional or logical flow, and automatic calculation of duration or survival. Some subprograms have a tree structure and accept sub-organs, such as, programs for post-mastectomy and breast conserving decisions in breast cancer, or supraglottic, glottic or subglottic laryngeal cancers.

To protect patient information, we excluded names, personal ID numbers, permanent or present addresses, and telephone/fax numbers from the system, and have observed the Guidelines for the Protection of Private Information and the Laws on the Utilization of Information Networks and Protection of Information issued by the Korean government.

The numbers of study items developed for non small-cell lung cancer, breast cancer after mastectomy, breast cancer after conservative surgery, laryngeal cancer, esophageal cancer, rectal cancer, and brain metastasis were 184, 167, 177, 132, 246, 89, and 84, respectively. Common demographic items were not included in the above figures.

The right to modify, or administer the database structure or process and output data has three hierarchies, manager, group manager and member. Each member can manage and download his data only using files in xls format, whenever he wishes, a group manager can manage his group data only, and the system manager can access all data without limitation. One can either input data directly from a keyboard monitor or print and complete a 'download form' and then place this data into the system later.

Discussion

Our web-based system for patterns of care study is a new and unprecedented tool in the field of clinical QA for radiation therapy. We highlight some characteristics of our system. First, this kind of computer or information technology application is a reasonable and inevitable solution to limited radiation oncology manpower in Korea. It saves time collecting data. Co-workers do not need to visit participating hospitals to summarize relevant medical records. Instead, each participating member inputs data into the system after accessing our web site. Co-workers then physically visit some or all of the participating hospitals to make an external data audit to confirm system validity.

However, there are some prerequisites for the use of this kind of tool. Participating members should be familiar with computers and the internet process. We believe our society members are familiar with the web and thus do not need an extended learning period. Participating members might spare time to summarize or input data, or provide a helping hand. Extra manpower should be found in each hospital or it can be provided by the PCS center.

A member can easily confirm database details at his level of access at almost real-time speed. Of course, on-line data modification or management is allowed, thus data security is important, and data must be protected from hackers or accidental release. We believe our system, which uses double firewalls, triple back-ups, and data encryption is both very powerful and effective.

One of the strong points of our system is that it can deal with both alphanumeric and image data. The type of image depends upon the tumor, but we believe simulation films, verification films, photos of the treatment set-up, or of a required patient position are good subjects. The creation of digital files using a digital camera is much better than file creation by scanning films or photos. It is encouraging that digital cameras and camcorders are gaining popularity.

We have not stratified radiotherapy departments by the annual number of patients as has been done in the USA or Japan, and we would like all radiotherapy departments to participate in this study. We regard a case as eligible for entry into the PCS when it fulfills current eligibility criteria and one fraction of radiotherapy or more has been administered. Case information selected from random sampling among eligible cases can be inputted as PCS data. We have established a target of 400 to 1,000 as the number of cases required per tumor. The number of target cases per tumor type per department was allocated using the power allocation technique with an a of 0.5.

Are there any differences between our PCS program and the PCS programs used by other nations? The PCS program for rectal and laryngeal cancer, and brain metastasis was firstly developed in this field. Some of the study items for lung, breast and esophageal cancer differed. In addition, we have included Quality of Life issues[10] and a standard system for patient immobilization during radiotherapy, although they are not the standard PCS issues.

It was our intention to start PCS from May 2003 and to use radiotherapy patient data from 1998 to 1999. Our goal in the year 2003 is a nation-wide study of breast and rectal cancers, and local group studies on non-small cell lung, esophageal and laryngeal cancers. However, we postponed data collection until this July, because we experienced problems during the preliminary data collection period. It took a much longer than was expected gain acceptance of our system and to motivate our society members. We also found some technical bugs in the image upload process, the secondary checking of radiotherapy numbers, the calculation of duration, and in the internal logic of items used for statistical analysis. However, many members have shown a high level of interest in the system environment and appreciated the ease of data input. It usually takes 20~30 minutes to submit all data for a single case.

We will also establish a basic format for cervical and prostate cancers during 2003 or 2004. However, before launching the PCS, we decided to obtain approval from the Institutional Review Boards (IRB) of participating hospitals. We have yet to formulate general principles on the authorship of publications based on PCS data or on the duties and rights of PCS participants.

In summary, our PCS is equipped with a new web-based user-friendly system with data security, encryption, back up, data audit, protection of personal database, double entry

checking, and statistical analysis. The developed PCS system allows, an exact understanding of current status, details of current problems, the determination of future goals, and what can be done to achieve them. We also hope that the experiences and expertise gained during the development of our web-based system can be used to help establish similar systems for other medical societies or specialist groups.

We sincerely hope the developed system, improves our radiotherapy service and the clinical QA system, and that it gives rise to more rational standard guidelines and provides a solid frame of reference for the various activities within radiation oncology. Moreover, we are convinced that it will make a significant contribution toward improved cancer care and that it will aid those involved in randomized clinical trials in Korea.

Acknowledgements

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—— 국문초록 ——————————————————————————————

우리나라 임상방사선종양을 위한 웹 기반 PCS 시스템의 개발과 특성

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목 적: PCS 연구의 목적은 임상 방사선치료 QA의 표준 연구 수단을 구축하고, 방사선치료 과정의 기본 요소를 결정하고, 협동 임상시험의 기반을 제공하고, 외국과의 비교 연구를 위한 기본 자료의 구축에 있다. 우리나라 임상 방사선종양학의 PCS 연구기법으로서 구축한 웹 기반의 PCS 시스템의 개발 및 특성을 보고하고자 한다.

대상 및 방법: 본 시스템은 메인서버와 외부에 구축한 2중 백업서버로 구성되어 있다. 리눅스 운영 체제 및 MySQL 데이터베이스를 이용하여 프로그램을 완성하였다. PCS 대상이 되는 종양으로서의 개발 우선 순위는 1989년부터 1999년 사이에서 우리나라 전국의 방사선종양학과에서 치료빈도가 많은 순서를 근거로 결정하였다..

결 과: 2003년 초반에 웹 기반의 임상 PCS시스템이 구축되었다. 웹 주소는 www.pcs.re.kr이며, 우선 유방암, 직장암, 식도암, 후두암, 폐암 및 전이성 뇌종양을 대상으로 하였다. 완성된 개발항목의수는 1,000 항목을 상회하였다. 구축된 시스템은 사용자 편의성 충족, 기입 내용 중복 확인, 자료 기밀성, 자료 보존 및 사본 작성, 이중 백업, 통계 분석 지원 등을 구현하였다. 문자화된 자료 외에 영상 자료도 입력되도록 시스템을 구축하였다. 아울러, 임상시험승인 관련 양식 지원, 무작위 자료 추출, 방사선종양학과의 구조적 요소 파악 기능도 갖추었다.

결 론: 본 시스템은 PCS 분야에서는 최초로 구축되고 작동되는 웹 기반 시스템이다. 구축한 시스템을 통해서 단시간 내에 표본 자료의 수집이 가능하여 시간 및 비용을 절약할 수 있게 되었으나 구축자료의 신뢰도 확인을 별도의 검증 과정은 필수적이다. 본 연구팀이 개발한 본 웹 기반 시스템은 향후 PCS 연구 또는 자료 수집이 필요한 유사 연구 상황에 응용될 수 있는 표준적인 기법으로서의 활용되기를 희망한다.

핵심용어: 방사선치료, PCS, 웹, 정도 관리