ABSTRACT

HEALTH COMMUNICATION AT THE NATIONAL CANCER INSTITUTE

by Christine E. Theisen

The purpose of this report is to describe and evaluate the Graduate Health Communications Internship I completed at the National Cancer Institute from Jan. 8, 2001 through June 29, 2001. I describe two major projects I worked on—editing a book and beginning and managing an Intranet database project. I examine the latter by viewing my work and processes through the Anderson Problem-Solving Model and then by theorizing about how the model applied to my work and situation.
HEALTH COMMUNICATION AT THE NATIONAL CANCER INSTITUTE

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Chapter 1—An Introduction
After being accepted as a Graduate Intern in Health Communications with the National Cancer Institute (NCI), www.cancer.gov, I worked from January 8, 2001 to June 29, 2001 in the Communications Coordination office of NCI’s Office of Communications (OC). In this chapter, I describe:

- My job and how my work contributed to the office
- My role in the office
- The structure and culture of the organization I worked for

My Job with NCI
When I went through NCI’s interview process, I was offered three different positions and had to decide among an internship with the usability group, the press office, or Communications Coordination. The compelling reasons I chose Communications Coordination were: 1) that I liked the interview I had with Anne Lubenow, who would be my supervisor, 2) that the office was new and had few staff members so I thought I would have some freedom to determine the work I would do, and 3) that I was told I would have to be a self-starter and able to work independently.

Because NCI’s Graduate Health Communication Internship program is well established and places interns in various departments throughout the Institute, interns are not give specific titles within the offices they join. I was “the intern in Nelvis’ office.” Nelvis Castro is Associate Director of Communications Coordination and Anne Lubenow’s direct supervisor. Please see Appendix A for a copy of the then-current NCI/OC organization chart. Note that Dr. Sieber is listed twice, once in her position as the Director of NCI’s Office of Communications and again in a temporary position overseeing the new office of Technologies and Services.

When I accepted the intern position in Communications Coordination, the office desperately needed more staff but had only a general idea of what work I might do. The actual position they had hired me to fill was nebulous. I helped design my internship beginning the end of my first week. As I will describe later in this report, my work on two major and one minor project helped smooth the initial growth of Communications Coordination as a vital and integral part of NCI’s Office of Communications.

My Role in the Office
When I arrived, Communications Coordination was a brand new office, an outgrowth of a recent reorganization of the entire NCI Office of Communications. The office had few employees because it had been developed to fill a newly identified need—coordinating communication among all the various NCI divisions—and the challenge of finding appropriate staff while waiting for the end of the federal hiring freeze meant that the office stayed small throughout my time there.

I initially reported to Anne Lubenow, Acting Director of the Issue Management Branch. She was my official mentor, but because she went on maternity leave half way through
my internship, I switched to reporting to Nelvis. Unofficially, I also received direction and support from Julie Cheh, a Fellow with whom I shared an office.

**NCI, OC, and Communications Coordination’s Structure and Culture**
Because the office in which I worked had so few people, I am able to describe its structure completely. I will do so from the top down, discussing the NCI culture, then the Office of Communications, and then describing how Communications Coordination fits into the culture of NCI as a whole.

*The National Cancer Institute*
The National Cancer Institute is the largest institute within the National Institutes of Health, which is a part of the U.S. Department of Health and Human Services. Alone among the institutes, NCI has its yearly budget approved directly by Congress. See Appendix B to see how NCI fits within the structure of NIH, relative to the other institutes. Dr. Richard Klausner, a well-known researcher who commonly testifies before Congress on cancer-related issues and is often asked to speak around the nation, currently runs NCI.

*NCI’s Office of Communications*
Dr. Klausner named Dr. Susan Sieber, a research pharmacologist with an extensive background at NCI, Director of NCI’s Office of Communications during the recent reorganization. Although Dr. Sieber does not have a communications background, she was named to head OC as part of an overall move to run all parts of NCI, including the Office of Communications, on a model that more closely resembled the structure of NCI’s research divisions. Before the reorganization, OC would have been headed by someone with a pure communications background; not necessarily a person used to overseeing the complex budgetary and political ramifications of work completed within a division.

In addition, Dr. Sieber works very closely with Dr. Klausner; their offices are adjacent to each other within NCI’s front office. The Office of Communications is housed under the Office of the Director, which is one of the eight entities that comprise NCI. See Appendix C for a specific description of how the Office of Communications fits within NCI. Although the Office of Communications shares space with the Office of the Director, Dr. Klausner was absent from most of my experience at NCI. We never shared an elevator and I never saw him on either of the two floors. This contrasted with the Assistant Director, whom I often saw talking to people in their offices.

*Communications Coordination*
Although Communications Coordination is brand new, Nelvis Castro, who heads the office, has a decade of experience with NCI’s OC in all its various incarnations. Before taking on Communications Coordination, Nelvis headed the Health Promotions Branch. She is highly respected throughout the Institute and was specially selected to get Communications Coordination off the ground. Before working for NCI, Nelvis worked as an account executive at a consulting firm.
Anne Lubenow is next in the office hierarchy. She is a former intern with a master’s in public health who has working in NCI’s Office of Communications for over four years. Nelvis and Anne have worked together in other offices and function well as a team. Anne works from a smaller office than her position entitles her to, simply so she can be right next door to Nelvis. They often conduct business by shouting from office to office; and when they attend meetings together, Anne finishes Nelvis’ sentences. Their closeness belies the way the office is actually run. Nelvis is the epitome of a hands-off manager; when she welcomed me she described the attributes of employees who fit well into her group—people who don’t require a lot of direction and who are willing to take on responsibility on their own.

Nelvis and Anne’s personalities set the tone for the entire office. From the first day, it was clear that I might be integral to helping select the projects I might work on, but that the tone—show me you’re good, ask questions only when you need to, don’t take up too much of our time—had already been determined. After my initial conversation with Nelvis, I was assigned to Anne, who gave me a listing of all the projects she was working on and told me to let her know what I might be interested in jumping into. No possibility was held back, but neither was I told what to do.

Before I could start on projects, I was assigned to read all the NCI introductory materials: the Bypass Budget (the popular name for The Nation’s Investment in Cancer Research, the formal request for funding that goes to Congress yearly, the description of NCI’s defined Extraordinary Opportunities (areas in which NCI could have more impact with a more focused approach, often associated with items Congress identified each year as significant when determining funding for NCI), and the NCI Fact Book (facts and figures about cancer and about how the Institute is run).

When, after four days, I finished, I went to Anne to request my first project, editing the second version of a book known informally as the Pink Book, and more formally as Making Health Communication Programs Work: A Planner’s Guide. (Please see Chapter 2 for an extended description of this project.) Throughout my internship in Communications Coordination, my work was “assigned” in this way. I approached Anne or Nelvis about projects I was interested in, and they told me how I might be able to contribute.

Also during the first week, Nelvis told me that she would want to meet with me within a month or so, once another office member was back from vacation, to discuss the start of a project that was a priority of NCI’s Director. Besides my initial conversation with Nelvis and this direction, we did not really interact until after Anne left on maternity leave in April.

With and Without Anne
Before Anne left on maternity leave, she acted as a sounding board for me but did not directly supervise any of my activities. I was free to go to her with questions, as I was with Nelvis, and she was always helpful and made time for me, but she didn’t check up on my work regularly. Because she was the person in charge of most of the projects I
worked on, being able to spend a few minutes a week asking her questions and touching base made my work seem very connected to the rest of the office.

After Anne went on maternity leave, I didn’t have the same connection to the overall goals of the office because Nelvis did not spend the amount of time Anne did updating me on what was going on throughout OC. At first I was nervous, because I knew I did not have anyone I could run my ideas by. Gradually, I began to feel comfortable and realized that having Anne gone was a unique opportunity. Throughout the second half of my internship I became surer of my work and myself. I asked more questions of and worked more closely with Nelvis, and was able to take on leadership positions in some of my projects that I likely would not have been able to otherwise, such as managing the repository project, being responsible for all work on the Pink Book, and serving on SPN panels. (Please see Chapters2–4 for more information about these projects.)

**The Remainder of This Report**

In the remainder of this report, I describe the projects I worked on during my internship, how I spent my time, and how I applied the processes I learned during my MTSC coursework (viewing them in the framework of Paul Anderson’s Problem-Solving Model) to the major project on which I worked. The Anderson Problem-Solving Model is a model of broad activities designed to help a person resolve the problems that often occur in the management of projects designed to communicate specialized information.
Chapter 2—Description of Projects

In this chapter I will describe each of the five projects that I worked on at NCI—the three projects that were assigned specifically through Communications Coordination, and the two projects that were separate. I will also estimate the amount of time spent on each project and other smaller tasks I completed throughout my internship.

Communications Coordination Projects

As I mentioned in Chapter 1, Communications Coordination assigned me two major projects and one that turned out, time wise, to be minor. Below I describe the personal and organizational importance of these projects. At the end of this section, I describe some general, non-project specific, work I did in Communications Coordination.

Major Projects

- Editing the Pink Book, formally known as Making Health Communication Programs Work: A Planner’s Guide. This book was originally published by NCI in 1989 and, though currently out of print, is considered the “bible” by public health programs and community health workers in government and in non-profit organizations throughout the country. It is used in practice and as a textbook. Anne mentioned her work on the Pink Book to me during our first meeting, and when I first needed a project, I asked if she would like me to edit it.

At that time, the original Pink Book had spent three years under revision. During those years, five people had worked on the book, most section by section. The purpose of my work on the Pink Book was to bring all the sections together, fill in missing information, and edit the book for consistency. The end purpose of the project was to complete the revision; have it approved; and print, promote, and distribute the book.

Anne had been receiving calls and questions about the Pink Book since the revision process began in 1998. Public health instructors, other government agencies, and many not-for-profit agencies had used the original book for years and were eagerly awaiting the second version, which was to include references to using new technologies. No one in NCI’s Office of Communications believed that the revision would ever be finished and printed, and many senior staff felt the pace of the project put NCI in a bad light.

I did much of my work with Elaine Arkin, a writer, consultant, and former NCI OC Health Promotions Branch manager who authored the first version of the book and continues to write for many government organizations. On this project, I reported directly to Anne, but worked more often with Elaine, going over my revisions and asking her for sources or more information when necessary.

My work on the Pink Book consisted of completing three different levels of edit on each of the sections. I developed an elaborate computer filing system to ensure that one version of a section did not become mixed up with another. This project was time, brain, and computer intensive and causes me to spend many hours sitting at my
computer, staring at the screen, and concentrating on how I could best get across the point that needed to be conveyed. I loved it.

Because I initially thought that my work on the Pink Book would be the major project of my internship, I tracked my hours by task, which included a computer edit (to standardize formatting), a substantive edit (to be sure everything read well and information coordinated across sections), a clean edit (a double check to be sure everything was in the right place), and other associated tasks such as familiarizing myself with the material, and creating a style sheet. Please see Appendix D for the Pink Book spreadsheet. As another part of my process, I reported to Anne approximately twice a month on my progress. This was another way that I was allowed to pursue my own work but still keep in touch with Anne to let her know my progress. In these update reports, I gave a minimum of information; Anne most wanted to know about the progress I was making. Please see Appendix E for a sample report. At the end of my internship, I wrote short reports to Anne on each of my projects, to let her know where my work ended and what would need to be done next. Writing these last reports was especially crucial because Anne had not yet returned to work when I left. See Appendix F for my final Pink Book report to Anne.

• Creating a repository of cleared information about cancer. This is the project that is a priority of Dr. Klausner’s, the one Nelvis mentioned to me my first week. As Nelvis originally described it to me, the repository was to be a database that NCI employees could use to find scientifically cleared information about cancer for responding to phone calls, writing talking points, or sending requested information to Congress.

Although Nelvis told me that the repository would be a big project, I didn’t realize that it would become the major project of my internship until I began asking more questions and brainstorming. At the beginning of the project, my role was to envision and create the database, using interviews and meetings with potential users to guide my design. By the middle of my internship, we had organized substantial contractor support and my new role became project manager.

I selected the repository project to describe more fully later in this report not only because of its size and because I ended up managing it, but because creating the repository was the project most central to the organization in which I work.

Minor Project

• Creating a Communications Toolkit for groups experiencing health disparities, such as rural populations without access to doctors, many African American communities, and Hawaiian Islanders. This project was exciting and also fairly central to the goals of NCI/OC/CC, but because Julie and I began working on it late in my internship, we didn’t progress very far. As with the repository, Nelvis originally described this project. The purposes of the toolkit were to provide a model of best practices, to include information from the Pink Book about program planning, and to support first the Special Populations Networks (described in the next section). Toolkits are, in general, a priority at NCI, which uses this buzzword to describe sets of tools
(anything from online help to pre-produced forms) and information that helps other accomplish NCI-identified goals. The eventual format of this Toolkit was fluid; it might be paper-based, on CD-ROM or the Web, or a combination of the three.

The entirety of my work on this project was conceptual. Because the original idea for and description of this project were nebulous, Julie and I ran into a challenge when we presented Nelvis with our proposed outline of the Toolkit. Our vision of what it might contain turned out to be very different from her vision. Julie and I both left the meeting feeling discouraged and unenthusiastic about our new direction.

To keep the project moving, we turned to researching best practices and tried to determine whether any similar toolkits had been developed. I also spent time talking about the project’s structure with K. “Vish” Viswanath, an expert in NCI’s Health Communication & Informatics Research Branch, who was working on a different toolkit. By the end of my internship, this project was still in the research phase. We were working closely with the NCI librarian to search various databases for reports of effective programs, and not necessarily just those that applied to cancer. Please see Appendix G for my final report on this project.

**General Work in Communications Coordination**

After Anne left, I served as more of a sounding board for Nelvis. I wrote short items at her request, proofed items she’d written and, at one point, wrote the justification to hire another Fellow for the office.

**Other NCI Projects**

- **Reviewing first year non-competitive renewal reports and pilot project applications for the Special Populations Networks (SPN).** The Special Populations Networks program was begun to “build relationships between large research institutions and community-based programs and to find ways of addressing important questions about the burden of cancer in minority communities.” This new program is part of a wider set of projects, endorsed by NIH, to help reduce the incidence of many diseases and to increase treatment available for those diseases across the nation. The SPN program was designed specifically to bring together already-organized community groups experiencing health disparities (the rural poor, many ethnicities, and any other groups not receiving the care or screening they need) with universities and other partners. The goals are two: 1) to foster cancer awareness among these groups, and 2) to support minority enrollment in clinical trials. NCI researchers believe that fulfilling these goals will increase underserved populations’ knowledge about cancer and create equal treatment options for all people with cancer.

Many people question whether supporting minority enrollment in clinical trials is a good thing. Because of past government abuses, such as the Tuskegee study (in which many African American men with syphilis were observed, but not treated for the disease), the idea of trying to increase minority enrollment can sound like the government trying to use already-underserved populations as “guinea pigs.” From the little I observed at NCI, I believe that this is not the case. On the Institute level, NCI
has stated a commitment to and funded research to reduce health disparities, in addition to trying to increase minority enrollment in clinical trials. The primary goal of increasing minority enrollment is followed by a secondary goal: Make sure that all people receive all the screening and treatment they need. Although it may seem that the first goal unfairly singles out groups of people; meeting it is necessary to achieving the second.

The SPN program was at the end of its first year during my internship. The groups were required to submit non-competitive renewal applications to NCI before they could progress to second year activities. Because the SPN program is only a year old and understaffed, people from both NCI and universities associated with SPN groups were invited to help review the applications. In Anne’s place, I served as a secondary reviewer on non-competitive renewal reports from three of the Special Populations Networks. The purpose of the review was to evaluate whether the Networks had fulfilled the requirements of the first year of a five-year development plan, to give the Networks constructive critiques, and to identify areas in which NCI’s SPN team could provide more support. I wrote a review for each report, scored it, and presented my reviews to the panel. The result of this review panel was that each SPN was granted funding for a second year.

A few months after I served on the first panel, I was asked to serve on another, this on reviewing SPN pilot project applications. According to the five-year timeline created for the SPNs, the second year of funding was earmarked for the SPNs to design pilot projects to: 1) gather information, or 2) further the stated goals of the program. The largest amount an SPN could request was $50,000. Pilot project applications might be for: 1) funding to increase communication within an SPN so that all the local groups could work better together, or 2) funding for a science education project being conducted in schools.

In this second review, I was primary reviewer for three applications and secondary reviewer for two. Again, I wrote a report for each, scored it, and then presented my reviews to the panel—along with detailed descriptions of the projects for which I was the primary reviewer. The review panel granted funding to 24 applications; the remaining 18 pilot project applications were not funded. Of the three applications for which I was primary reviewer, none received funding. The SPN team gave the groups that did not receive funding suggestions on how to revise their applications before submitting.

Being asked to, and serving, on these panels was important both to me and to NCI. I found it very gratifying to be able to combine knowledge and expertise from my undergraduate sociology degree with my MTSC coursework. Finding reviewers is crucial to the SPN program, which has a large initial five-year budget and must be able to show progress before submitting a request for additional funding at the end of that term.
Writing for the Journal of the National Cancer Institute (JNCI). Immediately after I accepted my internship position at NCI, I attended the 2000 annual conference of the American Medical Writers Association. By a fluke, I ended up sitting in the general session next to a woman whose name badge had NCI on it. Katherine Arnold is a former NCI health communications intern and currently the Deputy News Editor for JNCI. Although I hadn’t accepted the internship in the press office, I asked her about the possibility of writing for JNCI during my time at NCI. She told me to contact her once I started.

For the past five years, JNCI has been moving slowly from being a government publication of NCI to a private publication of Oxford University Press with a Managing Editor named by the Director of NCI. The news section, which was once almost entirely written by NCI press office staff, is now written by a combination of freelancers and NCI staff. Katherine has twice monthly meetings with press office staff about upcoming articles, but there is some question as to whether or not they will continue to write for JNCI once the journal has switched completely to the aegis of Oxford University Press. As the changeover is made, writers in the press office have found it increasingly difficult to spend time writing for JNCI. My availability and intern status gave JNCI more text for less money.

As an intern, I wrote and published three articles in JNCI. The first announced the availability of an updated Breast Cancer Risk Assessment Tool, the second was an article about scientific and lay understanding of the word “chemoprevention,” and the third was a retrospective and update on items that had been report in JNCI’s news section in 1991. Please see Appendix H for official citations and to read the text of these articles.

Time Estimates
The pie charts below show how I spent my time, both by project and by task. The first shows estimates of the time I spent on each project mentioned above.
The second shows estimates of how I spent my time by task. I’ve defined the tasks and subtasks in the following way:

- Manage (plan project, coordinate and supervise contractor work)
- Write
- Edit
- Contact (meetings, e-mail, phone calls)
- Interview (applicable to both JNCI and initial repository research)
- Proof
Chapter 3—Description of Major Internship Project

In this section, I describe my work on the repository, also known as Cancer Content. I describe how the project came about, the role Cancer Content is due to play within NCI, and the way work was completed on the project. Although I will use Paul Anderson’s Problem-Solving Model to analyze my work on this project in Chapter 4, I plan to describe my work on Cancer Content in this chapter in the phases through which this project progressed.

Introduction

As a part of restructuring NCI’s Office of Communications, Communication Coordination was developed to coordinate communication among the numerous divisions within NCI. Because the Institute is so large, even employees within a single division often reproduce work. In the Office of Communications, redundant requests for information come to employees who spend valuable time looking for answers that may or may not exist, or recreating documents that have been stored elsewhere.

NCI recently identified cancer communications as an area of Extraordinary Opportunity. Because of this emphasis and the existing communication challenges within the Institute, Dr. Klausner tapped Nelvis and the new Communications Coordination office to create a repository of scientifically cleared information about cancer that could be accessed by all NCI employees. To make it most accessible to all employees, the repository was envisioned as an Intranet site backed by a database.

Phases

Repository Project Phase 1—My introduction to the project
As I mentioned in Chapter 2, Nelvis spoke to me about this project the first week I was at NCI. After this brief description of the project, I went away and wrote a list of questions I hoped would guide both my understanding and general development of the project. See Appendix I for these questions, which show how unformed even the idea of the repository was at that time. Before I could learn more, Donna Kerrigan, the NCI clearance officer, had to return from vacation. As clearance officer, Donna maintains copies of many of the documents Nelvis imagined would be housed within the repository. Once she was back at work, Nelvis, Donna, and I had the first official meeting about the repository.

Repository Project Phase 2—Initial steps
I ended up asking my questions of Nelvis when the three of us met. It turned out that most were not relevant at all and that my understanding of what she wanted was far from her vision. I had been thinking very long term, and, in addition to design and content ideas, had included ideas for ways to easily convert Cancer Content to the new cancer identification system NCI will likely adopt—naming different cancers by specific genetic markers rather than by where they occur in the body. Nelvis’ view was much more focused on getting the project underway as quickly as possible. Although I would have liked to do more long-term planning, Nelvis’ ideal schedule did include planning up front.
After the three of us met together, and before I created the original project plan, I interviewed a number of people throughout NCI whom Nelvis had identified as integral to developing Cancer Content as a viable product. The name Cancer Content was suggested early on by Donna, who, along with many others, was reluctant to use the word repository in everyday conversation.)

As I conducted the first interviews, I took copious notes. People were interested in the project and tended to come up with lots of ideas. I had to type the notes immediately after conducting an interview, because inevitably there was more information (including non-verbal signals) than I could write down. The process of interviewing and the resulting notes provided the basis for the initial project plan, which is attached in Appendix J. As was common with many of the documents I created for Anne and Nelvis, I was simply asked to bring them a certain type of document—in this case, a project plan. When I did, I usually found most of the content was what they had expected, but the format, which I normally borrowed from one of my MTSC projects, was not. Because I was never given a format to follow, each new document I created for Cancer Content subsequently underwent a few revisions just to bring it into the expected governmental form. I suggested that templates be created for each type of document, but was told it would be too time consuming that people just learned as they went along.

Once I had begun to brainstorm about the form of Cancer Content, had interviewed the group that would constitute the first project review team, and had begun to realize the enormity of this project, I was thrilled to hear from Nelvis that NCI OC’s new support contractor, Matthews Media Group, Inc. (MMG), would be doing most of the day-to-day work of creating Cancer Content. I would be the project manager in place of Anne, who was about to go on maternity leave.

*Repository Project Phase 3—Beginning to work with contractors*

To introduce the MMG team to the project, Anne and I set up a large meeting that included Nelvis; all the NCI employees I had interviewed; and the MMG project manager, editor, and computer support personnel. The meeting was a madhouse. Everyone I had interviewed had been uniformly excited by the idea of the repository, but most had their own ideas about how it should be structured and what information it should contain, based on the needs of their particular office. During this meeting, everyone was happy to share their opinions and the meeting soon devolved into everyone describing (over each other) what they wanted from Cancer Content.

After that meeting, Anne and I reassured the contractors that the project was not as unmanageable as the debate at the meeting had made it seem. Initially, I had a hard time directing the contractors. I am used to, and very comfortable with, talking with anyone face-to-face. Calling the project manager on the phone to give feedback on a component of the project or to ask for another component of the project to be added to the assignment was very challenging. Using the telephone, and being unable to see people’s reactions, was what made those first calls difficult. When Anne went on maternity leave a week earlier than anticipated, I just had to jump in. It was the best thing that could have happened.
During the last meeting Anne attended before she went on maternity leave, we talked with the contractors about our vision for the site. Based on my earlier brainstorming, I sketched a quick outline of the way the site might be structured. From there, we slowly began working together to define what Cancer Content would look like. The first step was to develop a site map.

Repository Project Phase 4—Creating and refining a site map
Because the site map would define the structure of Cancer Content, I focused specifically on its development once I began managing the project. The sketch I created went up on the MMG project manager’s wall and formed the basis of the first site map. (See Chapter 4 for a print version of the sketch.) After MMG produced the first complete version of the site map, I took it back to all the people I had originally interviewed for feedback. Although some found it challenging to follow the format of the site map, all were able to give specific suggestions about ways the site map could be improved. Nelvis’ feedback was especially crucial; she suggested including a section specifically to describe NCI priorities. This focus on NCI priorities and project later became a guiding principle in the development of Cancer Content.

Once I got feedback from the original interviewees on the site map, I combined and condensed all of their comments and prepared one copy of NCI’s feedback for the next meeting with MMG. That next meeting was a turning point in my relationship with the contractor and marked the way the rest of the project would run. I ran the meeting. Four MMG employees attended, including the Managing Vice President responsible for the entire OC support contract, and the directions and opinions I gave to them were taken as Communications Coordination’s word. Anne had said that I would be project manager in her place; that day was the first I felt that I was managing the project. The very specific feedback I gave on the site map gave them the direction they needed to create a strong second iteration of it.

Repository Project Phase 5—Beginning content development
With a second iteration of the site map underway, we selected three modules for development. Because Cancer Content was being developed at the request of Dr. Klausner, all of the initial development was covered under the Communications Coordination budget. Once a start had been made, the plan was to present the initial stages of the project to Dr. Klausner and the Strategy Team for approval. Thinking of areas that were most important to Dr. Klausner and the Strategy Team members, Nelvis made a political decision and selected Lung Cancer, Molecular Targets, and Survivorship (current hot topics) as the first three modules to be developed.

Since the beginning of the project, I had been collecting electronic versions of cleared material from Donna Kerrigan and filing each according to topic. Once the first three modules were selected, I forwarded all the applicable materials to MMG. At their suggestion, they began not only to organize the documents that had been forwarded, but also to develop talking points that would be the basis of each module. Talking points, or lists of bulleted items that lay out exactly what a speaker will say, are very big at NCI,
and, I imagine, throughout the federal government. The goal was to develop sets of
talking points for each of the three modules that would cover outside questions,
information needed for speeches, and internal inquiries quickly and on a “serve yourself”
basis. Users would be able to link from talking points to the source documents from
which the information came, such as a research report or the NCI Fact Book, or just be
able to lift and use the talking points as cleared text themselves.

Like the site map, the talking points went through a number of iterations. At first, we
asked MMG to use a set of NCI-developed talking points as a guide. However, the
structure of the resulting talking points was stilted and filled with government-speak.
After consulting with Donna to be certain that clearance would not be a problem, I
advised MMG that they could tighten the language. I also directed MMG to put a priority
within the talking points on NCI’s achievements and successes rather than giving general
information on each topic. This would help to differentiate Cancer Content from other
sites employees might search for information, and would also help further the work of
another OC group that was then creating a “brand” and new logo for NCI.

We developed a detailed process to approve each set of talking points as cleared content.
This was important because the talking points were the only text included in Cancer
Content that did not come directly from Donna Kerrigan’s cleared files. Having this
process in place early on meant we could plan for timely additions to the database. See
Appendix K for a copy of the flowchart detailing the clearance process. An example of a
set of talking points See Appendix L for a copy of the Molecular Targets talking points as
they currently exist during development. This example, which includes more specific
information on where items were found than would appear in the final version, shows
both text and some of the structure. The first list of points is a selection from the sections
that follow. These points would appear on the first page of the molecular targets section
of the site.

**Repository Project Phase 6—Planning for presentation**
The site map and the content of the first three modules of Cancer Content are due to be
presented to Dr. Klausner or the Strategy Team in late September or early October. At the
end of my internship, in June, we were beginning to discuss the most effective ways to
present the proposed structure of Cancer Content. Because Communications
Coordination is only seeking approval to continue development, and is not supposed to be
presenting a final product, we decided to make the presentation paper-based rather than
computer-based.

In order to present the most persuasive argument that Cancer Content development be
continued, we will supplement the comments made by the original interviewees by
conducting user testing of the site map and the Lung Cancer module talking points. The
results of that testing will be used to refine the site map and the contents of the first three
modules, which will be used to present Cancer Content to NCI’s leadership. The first
landmark of the project’s success would be approval granted to continue the project and
the direct funding for the project moved from the Communications Coordination budget
to a larger source of funding.
Chapter 4—Analysis of my Process For Work on Cancer Content

In this section, I use Paul Anderson’s Problem-Solving Model to analyze the process I used to bring the words “the repository project” from an unformed idea to the beginning structure of a workable product called Cancer Content. On paper, the Anderson model looks quite linear, with numbered activities and designated subtasks; I found each activity necessary to the process I used, but at least within the context in which I completed my work, I also found that I did not progress linearly through anything. My process and subsequent progress with the project developed nearly on its own as I attempted to apply what I’d learned to the situation I faced.

Using the Anderson Model to view this particular project, I decided that the model is most usefully imagined three dimensionally rather than as the two-dimensional grid presented to us during the MTSC program. Although I knew that the Anderson Model was recursive, I was surprised by the extent to which I found myself conducting all the designated activities at one time. The following description of my process shows how this worked.

Introduction

Before I discuss how I followed Anderson’s Problem-Solving Model in my process for work on Cancer Content, I will describe the context in which the work was completed. Some of this information may seem similar to the Chapter 1 description of the culture in which I worked, but I will add details here that are applicable to this project specifically rather than to my place of employment in general, because each new project brings a new set of dynamics within any group.

Context

As described earlier, this project came to me first through a passing mention by Nelvis. She mentioned it to me because developing this repository of information was one of Dr. Klausner’s main goals for the newly created Communications Coordination. From the time she mentioned the project to me to the time she and Donna and I met, I had worked primarily on the Pink Book, and mostly on my own. I still puzzle at why this high-visibility project was given to an intern—and can only guess that it was because the office was understaffed, both Nelvis and Anne already had too much work, and I’d proven myself able to bring initiative to the project (the Pink Book) on which I was working.

Within the Institute, there has been a general move to create more accessible and user-friendly computer-based methods for sharing information. While I was at NCI, the press office launched a new site (www.newscenter.gov) designed primarily to share with reporters and the public the information, press releases, and breaking news they dealt with every day. The main NCI Web page (www.cancer.gov), notoriously clunky, is currently undergoing a major revision. With NCI so large and spread out (members of the Institute work on three different campuses) the move to create a comprehensive Intranet site that would be responsive to the communication needs of the many employees who must answer inquiries or develop talking points for upcoming speeches made sense.
Although Communications Coordination was tasked with creating this repository, Nelvis was not given complete control. The plan was to develop an outline and perhaps a prototype of the repository, present this to Dr. Klausner or the NCI Strategy Team, receive approval, and then create, with additional funding, what had been modeled. Our initial objective was to develop the outline and a prototype for presentation. After receiving approval, more specific objectives would be set. My work as an intern on this project ended long before the presentation was scheduled.

Problem-Solving Activities
Of the five activities specified in the Anderson Problem-Solving Model, four of them include the word solution. This might give the false impression that a “solution” is a goal that can always be reached and that signifies an end. One particular solution might be reached, but in many cases, a solution or the testing, implementing, or evaluation of that solution will reveal or create another problem. I talk about the activities in this section in the order in which they are listed; truly, the process is more like a game of Tetris. One problem (the falling shape) leads to a solution (deciding where to place it), a test of that solution (rotating or moving the shape to check it against the landscape below), implementing the solution (putting the shape in the place you intended), and evaluating the solution (Did more lines disappear?). More than one activity is happening at a time, and decisions you made earlier in the game affect the whole game. Similarly, each problem you identify, and each solution you design, test, implement, and evaluate during a project, has the same long-term effect. There will always be another problem, another solution, and another chance to use as a guide all the activities this model describes.

I will focus my discussion here on the first three activities mentioned in the Anderson Problem-Solving Model: 1) Define Problem, 2) Design Solution, and 3) Test Solution, because these are the activities that I spent the most time on during my internship. I will spend little time discussing Implementing Solution, because I left NCI before anything substantive was implemented, but will write at some length about ways in which I built Evaluate Solution into the steps of my process. I will further limit my discussion, once I start talking about Design Solution, to an interim solution critical to the development of Cancer Content. Elucidating and evaluating my process of completing this interim solution will give the reader an excellent example of how I evaluate my process overall.

Define Problem
This activity was definitely the most challenging. During my second meeting with Nelvis, she described the project to me so broadly that I went away and used all I knew at the time about NCI’s resources to write a list of questions, the answers to which I hoped would help me understand how Nelvis defined the problem. What I discovered was that Nelvis hadn’t really defined the problem herself, except that her office was to produce something that would fulfill Dr. Klausner’s wishes. Talking with Dr. Klausner was not an option.

Even after, through brainstorming, conversations with Nelvis and Donna, and some decision-making, I defined the problem as three-fold and detailed my conceptualization of the situation in a document, I found that new problems cropped up, such as dealing
with re-conceptualizations of the project Nelvis gave me even as work progressed. My process was not a linear one of defining a problem, designing, testing, implementing, and evaluating a solution, but of continually defining a problem, redefining a problem, proposing a solution, and then finding another problem.

While I am certain that this situation is common for brand new projects of this size, I believe that my process was also somewhat dictated by the culture of the office in which I worked. Both Nelvis and Anne work from a similar hands-off model—give a little direction on a project, see what the subordinate comes back with, and then give feedback on that, but never meet together to describe their vision of a project.

Throughout the early part of my process (before Anne went on maternity leave), each step that required defining the problem, such as:

- Determining what form the repository should take,
- Determining what the structure of the repository should be,
- Deciding what type of information should be included, and
- Deciding what format(s) the information would be presented in,

took the same amount of back-and-forth to make each decision. Just before Anne went on maternity leave and for the rest of my internship, defining each problem became easier. I believe this was because Nelvis and Anne had determined that I was able to manage this project and associated contractors on my own. I then used feedback from future users and our contractors to define each problem. About once a month, Nelvis inquired about the project, I gave her informal, oral updates whenever she asked. This process seemed to fulfill her needs.

One of the easier parts of defining the problem was defining the audience. Nelvis knew that she wanted this site to be internal. From there, we had to determine who might make most use of the site and who would be called upon most often within offices to answer questions or draft a new communication. To begin to define the audience, I conducted a series of personal interviews about what the repository might become with representatives from different offices throughout NCI, chosen because they either had a need for a system like the repository or because their expertise would be useful as we developed it. These interviews set the stage for defining the second level audience, which we planned to focus on once we received approval to continue developing the repository.

**Design Solution**

The most important solution that we designed during this project was an interim design of the structure of the eventual repository. This part of the process was the longest of my involvement with the repository project because we focused nearly exclusively on creating, refining, and finalizing the site map before beginning to develop content. The process began at our second meeting with the contractors. This was the last meeting (early April) that Anne attended, and she let me take the lead. The contractors and NCI were new at working together, and I was having a hard time orally describing the format I believed we might start with for the repository. After a couple of attempts, I grabbed a
pen and walked over to a nearby easel and began sketching a simple flowchart of how the categories we’d been talking about might be broken down. As I mentioned earlier, that flowchart went up on the MMG project manager’s wall and inspired all the work that followed. See a print representation of the flowchart on the following page.
First Cancer Content Flowchart:

HOME
- Cancer by type
- NCI General Information
- Cancer related Topics
- Treatments

General Information
- Funding
- Trials
- RFAs
- Statistics
- General Links
- Legislative Activity

Cancer related topics
- Environment
- Genetics

Treatments
- Agents under development

Cancer by Type
Search for the type of cancer
A B C D E F G ...

Or type in your search term here

Lung Cancer
Overview/talking points
- Bullet
- Bullet
- Bullet

Funding
Trials
RFAs
Statistics
General Links
Legislative Activity
The broad categories we had been talking about came from my interviews with the selected NCI representatives. I had gone to their offices and described our vision for the repository, then asked how they might use it, what content they had to share, and what information would be the most useful to them. It was from my interview with Nelvis that I took the most definitive breakdown of major categories, but I still had to translate those notes into the flowchart I drew during the meeting.

Based upon the initial drawing and notes from the interviews I conducted, an MMG Web developer began creating a site map. This began the part of my process that provides the best example of working closely with the Anderson Problem-Solving Model. The site map was an interim project solution, to be used both as a piece that the audience could react to and as a road map to structure the rest of the project. Getting it “right” was a long process that involved not only Design Solution (or a small part of it), but also Test Solution, and developing future plans for Implement and Evaluate Solution.

Test Solution
Throughout development, we tested the site map both informally, by putting it under scrutiny at a team meeting the contractors and I had each week, and formally. After MMG produced the initial draft of the site map, Nelvis and I evaluated it and went back to the contractors with feedback about what should be moved, which sections needed to be rethought, and where there might be information missing. After we worked with the contractors to produce a couple of revisions, we began to test formally. See Appendix M for the initial draft of the site map.

I contacted all those who I had interviewed about the project initially, plus some other people Nelvis mentioned whose positions within the Institute would mean that their approval gave us some institutional buy-in. I designed the test so that I would send a paper copy of the then-current site map to the interviewee, request feedback, comments, and notes all over the paper, and follow up with and interview within two days.

The response I received was incredible. Most people had spent at least an hour on the site map, had written extensive comments on their copy, and were very happy to tell me exactly what they thought. I believe that this initial buy-in was easy because: 1) I had already interviewed most of these people, 2) they had already expressed interest, and 3) many of the higher-level people I spoke with knew the project was important to Dr. Klausner. The enormous amount of feedback I received from these interviews made it impossible to simply bring the notated site maps back to the contractor; I created, in essence, a testing report by organizing and writing everyone’s applicable comments together on one copy of the site map. This copy was used as a discussion piece during the next team meeting. Please see Appendix N for a copy of the reviewed site map with my comments.

At the next meeting with the contractors, we went over the site map in detail, discussing points that had been made by more than one person, evaluating what components should be included, and defining new directions, where necessary. We also talked about fantasy items, things or features that would be great to include but that were not appropriate for
early development, such as a link to the Cancer Information Service (a telephone service that provides information about cancer), or a detailed section tracking funding NCI provided to researchers. See the final site map in Appendix O; it was created after this meeting.

I tried to accomplish two things by gathering all the interview responses together. One, I was trying to ensure that the contractors did not end up feeling the way they had when they attended that first, really large meeting about the repository, the one that became a free-for-all with each person trying to be sure that their ideas would be included. Two, I was completing an initial evaluation of the responses I’d received. From earlier interviews, I knew that some of the people whose knowledge we were using to help design the repository had very distinct ideas about what it should include. When I compressed the testing feedback onto one document, I took out references to materials that people thought should be included but were only mentioned because they would help that particular person or office. I had to keep in mind that I was designing the repository to be useful to all offices throughout NCI.

Implement and Evaluate Solution
In this short section, I will describe future plans for implementing and evaluating different solution components of Cancer Content. Because my internship ended before these activities took place, I will not be able to include details, but I am able to talk about the plans I helped develop for both processes.

Because we could not move forward until we received approval from Dr. Klausner or the Strategy Team, actually implementing Cancer Content was something I envisioned but would not see. The plan, subject to much change, of course, was that MMG would develop both the Intranet site and the database to back it. The site would go live in October and the event would be accompanied by an internal advertising campaign. We planned to have processes in place for clearing and adding new documents, and for making sure that out of date documents did not stay on the site.

Testing and evaluating go hand-in-hand in my process. Testing, such as the testing of the site map that I described in the previous section, naturally has evaluation as a result. The testing I planned for later in the project will serve the same purpose and will encompass more than the site map. The next phase of testing will occur before the most crucial round of evaluation—presentation of Cancer Content to Dr. Klausner. The testing will follow a format similar to that used to test the site map. Employees who agree to test will receive materials and instructions and will then undergo a structured interview. Many components may be included, such as the site map, the talking points developed for a specific module, and a scenario asking testers to find information based upon the talking points from another module. From this testing, we hope to gain statistics and quotes about how useful the material we’ve developed will be. We are also hoping that this testing will point out any trouble spots that can be fixed before making the presentation for approval.

Assuming Dr. Klausner grants approval to continue developing Cancer Content, the next phase will be to build the site itself, using the site map as a guide. The talking points that
have been developed and the source documents that have been gathered for each of the initial three modules will be flowed into the database built to support the site. NCI and MMG will then conduct a third round of testing, this time computer-based, to evaluate the usability and functionality of the site. Only after those final revisions are made will the Anderson Problem-Solving Model’s fourth activity kick in. Implement Solution in this case means that the site goes live. After that, were I still managing the project, the Anderson Model would provide a guide as I defined new problems that cropped up, and designed, tested, implemented, and evaluated new solutions.

Conclusion

When I began to develop an outline of this report, I mentioned to my committee chair that I didn’t see how I would ever be able to apply Anderson’s Problem-Solving Model to the process that I used working on Cancer Content. In the particular government context in which I worked, my work felt both slowed and predetermined. I might want to spend time analyzing my audience or trying to fully understand the problem—my boss would want me to forge ahead. Going over my process as I created an outline of this report has, however, changed my mind. I found the activities in the Problem-Solving Model necessary to my process of creating the first structure of a new project. The issues the Problem-Solving Model does not address, such as gaining buy-in or finding yourself the target of someone else’s anger and frustration at how a project is being run (quote from one interviewee, “Why did they have to bring contractors in? It’s crazy to spend all of this money! You could have done this by yourself!”) are just as important to good project management.

The interviewee who made the comment above had worked for NCI for many years in a job in which he had control over his day-to-day work. He was unhappy about the recent Office of Communications reorganization, seeing it as additional bureaucracy without benefit. He was excited about the repository project until contractors were brought in. At another time, he said, “You could just do this yourself.” I doubt it—no one person could create what our team was achieving. I’ve added this description to show that my challenge was working with a person so unhappy, not with gather divergent opinions together.

During my internship, I used the Anderson Problem-Solving Model to help me design a method for communicating specific information. I used people skills and learned-on-the-job management techniques to make the process go smoothly. Combining both, I helped create a strong start for a new product—Cancer Content.
I left the National Cancer Institute at the end of June 2001, when my internship term was complete. Since then, many changes have occurred within NCI and OC. Dr. Klausner resigned his position and is now working as head of a think tank, and Dr. Sieber retired. I began to work for Matthews Media Group, Inc., the company that provides the contractor support I described in chapters 3 and 4 of this document. Because of my familiarity with two projects from Communications Coordination, editing the Pink Book and creating Cancer Content, I have been asked to join the teams working on these projects.

I co-manage work on the Pink Book and am pleased to say that a second version of *Making Health Communication Programs Work: A Planner’s Guide*, should be on the shelves in early 2002.

I also continue work on Cancer Content. This project has had periods of inactivity since I left NCI, because Dr. Klausner left the Institute and none of his pet projects (like Cancer Content) has been receiving attention. Nelvis, after consulting with the new head of CO, has decided that we will move ahead slowly with this project and wait until the newly-named NCI Director takes office before planning any presentation or request for additional funding. Although this project has slowed, I believe that all of the evaluation components I suggested will be included as Cancer Content is developed.

On the last day of my internship at NCI, a few friends and I went upstairs to take photos of each other in front of the official NCI sign. We had taken a couple of group shots when a secretary came out and asked us if we’d like to take any pictures with Dr. Klausner—and we did. He greeted us in his office and posed for a few photos with the group. He asked all about our experiences as interns and talked with us for a few minutes. It was really nice to finish my internship by meeting the person I’d been hearing about, and working for, but had never seen.
Appendix A: January 2001 NCI/OC Organization Chart
Appendix B: NIH and NCI

The National Institutes of Health (NIH), comprised of 27 different institutes and centers and the Office of the Director, is one of 8 health agencies within the U.S. Department of Health and Human Services. Institutes and centers include:

National Cancer Institute
National Eye Institute
National Heart, Lung, and Blood Institute
National Human Genome Research Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Kidney and Digestive Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Library of Medicine
National Institute of Biomedical Imaging and Bioengineering
Warren Grant Magnuson Clinical Center
Center for Information Technology
National Center for Complementary and Alternative Medicine
National Center for Research Resources
National Center on Minority Health and Health Disparities
John E. Fogarty International Center
Center for Scientific Review

The National Cancer Institute is the largest of all of NIH’s institutes and centers, both by funding and by sheer size of workforce.
Appendix C: NCI and OC

The National Cancer Institute is organized into the Office of the Director, one Center, and six Divisions, each specializing in a different aspect of cancer research. These groups are:

Office of the Director
Center for Cancer Research
Division of Cancer Biology
Division of Cancer Control and Population Sciences
Division of Cancer Epidemiology and Genetics
Division of Cancer Prevention
Division of Cancer Treatment and Diagnosis
Division of Extramural Activities

Within this organization, the Office of Communications falls under the Office of the Director.
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<th>Task</th>
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Appendix E: Sample Pink Book Report

2/02/01
Report: Pink Book Project Status
Christine Theisen

**Accomplishments**
- Completed Introduction/Overview
- Completed Stage 1
- Implemented tracking system
- Followed NIH plain language guidelines
- Lowered printing costs by reducing the size of each document
  - Introduction/Overview by 9%
  - Stage 1 by 10%
- Increased Flesch Reading Ease score for each document
  - Introduction/Overview from 31.8 to 37.1
  - Stage 1 from 35.8 to 37.3

**Process**
For each section, in order, I am doing the following:
1. Reading and accepting previous edits
2. Completing a computer edit
3. Completing a substantive edit / Rewriting
   - In the active voice
   - Using parallel construction
   - To fit a more coherent layout

As I work, I have also created the following:
- A task and time sheet,
- A style guide,
- A milestone schedule, and
- A list of questions.

**Progress**
Completed:
- Introduction/Overview
- Stage 1

In progress/ongoing:
- Stage 2
- Task and time sheet
- Style guide
- List of questions
Appendix E: Sample Pink Book Report

**Schedule/Milestones**
Based upon my work to date I project a Pink Book complete date of April 13, 2001. Please see the following schedule:

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Appendix F: Final Pink Book Report

Pink Book
End of Internship Status Report
Christine Theisen

General
- All sections have been reviewed with Elaine Arkin

Meeting with Graphics
- “Layflat” design chosen for printing
- New layout – agreed 2 column, white space at top, san serif font
- Donna Bonner suggested using photos instead of graphics and updating almost all

MMG Support
- The new “wheel” has been finalized
- Still working on the mammogram graphic (in place of behavior change table)
- Still working on changes to mass media/audience table
  - It’s been reviewed by 3 MMG people
  - We’ve switched the focus to larger media outlets and away from racial/ethnic generalizations

Current Status
- Bernard Glassman has provided an update to the tailoring section
- A few examples (including sections from the Partnership notebook) still need to be included – the file is in your office
- Stage 4 has been sent to John Burklow for review
- Waiting for other reviewers to respond; have sent message to reply to Anne Lubenow
- Have talked with Arline Sanchez re: sending Dr. Rimer a copy as FYI

Upcoming
- Add final examples
- Incorporate reviewer comments
- Finalize mammogram graphic
- Deliver appropriately for layout then PDF development
- Develop soft promotion plan and evaluation
- Plan printing and distribution
Appendix G: Final Toolkit Report

Health Disparities Communication Toolkit
End of Internship Status Report
Christine Theisen

General
• Julie and I have worked on this together. She has all of our materials.
• Development plan under revision
• Have worked with “Vish” Viswanath to help refine ideas

Current Status
• We are in the second phase of research - looking for already-evaluated communication programs
• We have pulled a set of articles which need to be evaluated
• Judy Grosberg is supposed to be conducting a second search for us, but may need to be reminded

Ideas for Development
• SPN interviews
• Digital divide interviews (contact Vish)
• Focus groups
• Verification/interviews of research findings
Appendix H: Citations and JNCI Articles

Updated Breast Cancer Risk Disk Available
Journal of the National Cancer Institute, Vol. 93, No.8, 581, April 18, 2001
© 2001 Oxford University Press

Chemoprevention: What’s in a Name?
Journal of the National Cancer Institute, Vol. 93, No. 10, 743, May 16, 2001
© 2001 Oxford University Press

Whatever Happened To…? Looking Back 10 Years
Journal of the National Cancer Institute, Vol. 93, No. 14, 1049-1050, July 18, 2001
© 2001 Oxford University Press
Updated Breast Cancer Risk Disk Available
Christine Theisen

The Breast Cancer Risk Assessment Package, first developed by the National Cancer Institute in 1999, is now available in a revised second version. More commonly known as the “risk disk,” the tool is used by physicians and other clinicians to help determine an individual woman’s 5-year and lifetime risk of developing invasive breast cancer.

The major change to the risk disk, which originally included data applicable only to African-American and Caucasian women, is the inclusion of risk assessment data applicable to Hispanic women. There is not yet enough data about other minority groups to include on the disk.

A survey of users revealed that physicians and other clinicians wanted to be able to use the tool in new ways, and this led to other changes in the disk. For example, physicians can now save individual patient records. The revised tool also allows physicians to save data on all their patients and search the records for specific subsets of women, such as women who had their first child before the age of 20 or women who take birth control pills.

Women also benefit from the change to the Risk Assessment Package. In the first version, a woman’s risk was compared with that of a woman who had no risk factors, and women did not find that comparison useful. A woman’s individual risk is now compared with women in her age range who have an average risk of developing invasive breast cancer.

Additionally, the Risk Assessment Package allows physicians and other clinicians to print individual records directly from the screen so that women can keep a copy of their 5-year and lifetime estimated risk assessments.

The Breast Cancer Risk Assessment Package CD Version, which contains both English and Spanish language versions of the tool, can be ordered or accessed online at http://www.cancer.gov/publications, or it can be ordered by telephone at 1-800-4CANCER (1-800-422-6237).
Appendix H: Citations and *JNCI* Articles

**Chemoprevention: What’s in a Name?**
Christine Theisen

As focus and funding for cancer research broadens to find more ways to prevent the beginning of the carcinogenic process, the concept of chemoprevention becomes increasingly important.

Chemoprevention is the use of pharmacologic or natural agents that inhibit the development of invasive cancer either by blocking the DNA damage that initiates carcinogenesis or by arresting or reversing the progression of premalignant cells in which such damage has already occurred. But there is concern that the word chemoprevention may be misunderstood by the public.

Michael B. Sporn, M.D., coined the term chemoprevention in a 1976 article in *Federation Proceedings* when writing about the work his group was doing with vitamin A analogues. Sporn, then of the Carcinogenesis Program at the National Cancer Institute, and others were doing the first work with agents that could be used to prevent cancer. The work in his laboratory was on animals, and clinical trials in people had not begun.

"In terms of writing the article it became apparent to me that we needed a new term," said Sporn, now of Dartmouth Medical School, in a recent interview. "The word chemoprevention includes prevention of initiation, promotion, and progression of carcinogenesis to cancer."

Chemoprevention is a word now used extensively among both researchers and clinicians. Sporn’s coining of the term was integral to solidifying the concept of chemoprevention as an important area of research in the prevention of human cancer, said Peter Greenwald, M.D., Dr.P.H., chief of the NCI’s Division of Cancer Prevention.

"The idea of chemoprevention started taking hold in the early 1980s," Greenwald said. That is to say, the concept took hold in the scientific community. The word "chemoprevention" may not be catching on with the public. Some see it as potentially self-contradictory; they equate "chemo" with cancer treatment and "prevention" with being free of cancer. Others read "chemo" and think sickness, and then read "prevention" and think health.

In an NCI focus group study of attitudes toward participation in prevention research that involved women at increased risk of breast cancer, the women had these reactions to the word chemoprevention:

"Sounds gross. You think of chemotherapy and throwing up, and all the things that go with it."
Appendix H: Citations and JNCI Articles

"You also don’t relate the word ‘chemo,’ whether it’s therapy or prevention, with health. If you are doing ‘chemo,’ then you’re sickly, or sick."

The issue of terminology has come up in chemoprevention trials, such as the National Surgical Adjuvant Breast and Bowel Project’s Study of Tamoxifen and Raloxifene and its predecessor, the Breast Cancer Prevention Trial.

"The Breast Cancer Prevention Trial Participant Advisory Board recommended that we not use the word chemoprevention," said Lori Garvey, director of public relations and communication for NSABP. "They said it’s not participant-friendly." NSABP does use the word chemoprevention in its research protocol but does not use it in any documents intended for the public.

At NCI, the Division of Cancer Prevention also uses different terms with different audiences. When speaking to basic research scientists, Greenwald said the division refers to "the chemopreventive agent program." In contrast, materials used to explain prevention research or to accrue patients to chemoprevention trials refer to "research to reduce clinical risk," or to "clinical trials to prevent cancer."

The distinction may be important, because NCI has 25 chemopreventive clinical trials in development.

Chemopreventive research as a concept has found its place in cancer research, thanks, in part, to the groundbreaking efforts of people like Sporn. "There is a continuum of chemoprevention, because we’re aiming to reduce cancer risk in people that are high risk, but also in the general population," said Greenwald. On the other end of the continuum, "the focus is on treatment of precancerous lesions."

"I believe that all forms of carcinoma are preventable if we can devise the appropriate chemopreventive agents," Sporn said.

As for use of the word chemoprevention while trials of those agents are ongoing, Greenwald said, "I think that gradually we may change. There could be an image (of the word chemoprevention) that’s a little misleading."
Appendix H: Citations and JNCI Articles

What Ever Happened To . . . ? Looking Back 10 Years
Christine Theisen

This is part of an occasional series that recalls some of the stories reported 10 years ago in the News section of the Journal.

The News reported in its Aug. 7, 1991, issue that the National Cancer Institute had signed agreements with private companies, research institutions, and the U.S. Food and Drug Administration to test foods for cancer prevention. The agreements brought resources together to support the NCI’s Designer Foods Program, which was started under toxicologist Herbert Pierson, Ph.D.

The Designer Foods Program aimed to "create food products fortified with natural phytochemicals found in fruits, vegetables, and other plants." The idea was to identify and isolate possible cancer-preventing agents in foods such as citrus fruits, soybeans, and garlic, and then develop those agents separately to be included in processed foods such as baked goods or salad dressings.

Ten years later, the Designer Foods Program no longer exists. However, scientists are still looking for what are now called the bioactive components of different foods. This means that scientists are not designing new foods. Instead, they are focused on naturally occurring constituents of foods that already exist.

"Pierson deserves enormous credit for showcasing the area and getting people to think about what I would call minor food components and their importance in health," said John Milner, Ph.D., chief of the Nutrition Science Research Group in NCI’s Division of Cancer Prevention. "Almost single handedly, he moved this area into a whole new dimension."

Researchers are now looking at foods’ bioactive components, as well as at how genes are involved in the processing of these components. Current research shows that there is considerable variety in the response that occurs in different people exposed to the same bioactive food components. In the near future, NCI will fund studies to look at how nutrients modify the genes involved in the cancer process. The plan is to have teams of investigators determine which nutrients and which genes are most important for study.

Mark Messina, Ph.D., who was director of the Designer Foods Program after Pierson, now researches soy and its possible benefits for anticancer activity and activity related to heart disease, osteoporosis, and renal function. The phytochemicals of most interest in soy are isoflavones.

"Soy is a unique dietary source of isoflavones, and I believe most of the hypothesized benefits of soy are due to the isoflavones," said Messina.
Appendix H: Citations and JNCI Articles

Milner believes that future research will allow for a move from observation to a more individual approach. "We are trying to unravel that mystery of what nutrients do and under what circumstance. We cannot assume that what is good for one person is necessarily good for another."

**Paclitaxel (Taxol)**

In the July 3, 1991, issue of the *Journal*, the News reported that scientists were probing Taxol’s mechanism of action in an effort to help develop a synthetic formulation of the drug. Taxol, known generically as paclitaxel, was under investigation at the time as a treatment for ovarian cancer. Earlier studies had shown it effective in stopping the growth of tumor cells.

The problem was that the paclitaxel molecule was derived from the bark of the Pacific yew. The Pacific yew, which grows primarily in the western United States, is a slow-growing tree. Because the Pacific yew had largely been ignored before its cancer fighting properties were identified, there were too few naturally occurring and easily harvestable trees available to produce the amount of Taxol that would be required to treat patients once the drug was approved.

Developers also encountered challenges from environmental activists worried that harvesting the yew trees would disturb the habitat of the northern spotted owl, which is on the endangered species list. Eventually, guidelines restricted the number of trees that could be harvested for paclitaxel production.

Since 1991, great advances have been made in both the synthesis and the use of paclitaxel. Early on, scientists recognized a need to develop a synthetic or semisynthetic form of paclitaxel using a method that would not require harvesting thousands of trees to create just 25 kilograms of the drug.

"The total synthesis of Taxol was a tour de force," said David Newman, Ph.D., a chemist in the NCI’s Natural Products Branch. The previous method of harvesting the bark of the Pacific yew tree and then isolating Taxol "never would have been a sustainable method for the production of large quantities of the drug," Newman said.

Under an NCI grant, a researcher developed an efficient way to produce the semisynthetic form of paclitaxel that is in use today by adding a side chain to the nucleus of the paclitaxel molecule. Basically, the nucleus of the paclitaxel molecule (compounds called baccatins) occurs about three times as often in the leaves or needles of the European yew and other yew species as does the whole molecule. Converting the baccatins, isolated from the leaves or needles, to paclitaxel by adding the side chain to the nucleus allowed sufficient amounts of paclitaxel to be produced.
"You no longer kill the tree by removal of the bark, and you can grow very large quantities of yew bushes for sustainable harvesting of the leaves," said Newman. This method is so effective that researchers no longer plan to pursue development of a completely synthetic form of paclitaxel.

In 1992, the FDA approved the use of Taxol as a treatment for women with advanced ovarian cancer. Since then, it has also been approved for use in the United States to treat advanced breast cancer, lymph node-positive breast cancer, non-small-cell lung cancer, and AIDS-related Kaposi’s sarcoma.

**Smoking Rates and Smoke in the Air**

On Feb. 6, 1991, the News reported on the possibility of the United States becoming a smoke-free society by early in the 21st century. This was the outlook of Donald R. Shopland, then coordinator of the National Cancer Institute’s Smoking and Tobacco Control Program. A few decades earlier, more than 60% of men were regular smokers, but by 1991, U.S. adult smoking prevalence was approaching 25%. The Environmental Protection Agency was soon expected to identify environmental tobacco smoke as a known human carcinogen.

Some of what was expected in 1991 has come about, but none of it without challenges.

Adult smoking rates are only slightly reduced. The Centers for Disease Control and Prevention reported in *2000-2001 Profile Of The Nation’s Health*, that the U.S. adult smoking prevalence is 24%—not the decrease that was hoped for. Researchers are not certain why.

"We do know that tobacco industry has increased its marketing of products," said Scott J. Leischow, Ph.D., chief of the Tobacco Control Branch at NCI. The stagnation of rates "may be related to a hardening of the target; one possibility is that we’re getting to a population of harder core, more dependent smokers. Another possibility is that the treatments we have available may not work as well in the real world as the clinical trials show that they do," Leischow added.

In 1992, the EPA classified environmental tobacco smoke as a known human carcinogen, but the report that the classification was based upon was partially vacated by a 1998 North Carolina District Court decision. The EPA reports that none of the findings concerning the serious respiratory health effects of secondhand smoke in children were challenged. In 1998, the Clinton Administration filed an appeal of the North Carolina District Court’s decision. The appeal is still pending.
Appendix H: Citations and JNCI Articles

Looking back 10 years shows minimal progress in reducing the adult smoking rates. What will the next 10 years bring? Healthy People 2010, a statement of national objectives for preventing threats to health, lists goals for smoking reduction among both adults and adolescents. For adolescents the goal is to reduce smoking rates from 35% to 16%. For adults over age 18 the goal is to reduce smoking rates by half, from 24% to 12%.

"My hope is that we redouble our efforts to encourage people to quit who are current smokers, improve access [to smoking cessation programs], and encourage treatments," Leischow said. "We know what treatments can work; the challenge is getting it implemented into healthcare systems and the communities. That’s a high priority for us."
Appendix I: Initial Repository Questions

Questions about Repository Project

1. CancerNet has non-scientific documents – what is different about what we are to provide? Audience or content?

2. We’ll be providing information to CSI, mass media, legislative office (any one else?) – where do they get their information now?
   a. Can I research their offices – how they get their info? Where from? How long it takes? Whether they adjust the material they get for different audiences? How long that takes?
   b. Do you have contact names in those offices?
   c. In those organizations?

3. The ByPass priorities don’t lend themselves to categories – were you speaking of Genes and the Environment, Cancer Imaging, etc?
   a. Or would you like info, by type of cancer, on state of science (We talked about screening, prevention, Dx, TX, research)?
   b. If so, will that be compatible with the eventual move to cancer diagnosis by molecular type rather than body area?
   c. May I design with that change in mind?
   d. Will the new designations be assigned in order of discovery, or by some other classification?

4. How will this information be available?
   a. Who will access it (will there be an intermediary)?
   b. Will it be available electronically?
   c. Should it be easily printable from electronic form?

5. If this information is to be used internally, how are we fulfilling the goal of partnering with other health organizations and the NIH? Will we provide info to all, get info from all, or act as a general NIH repository?
Appendix J: Initial Repository Project Plan

Core Cancer Information Repository
Project concept document/Action Plan -draft (3/13/01)

Situation

Problem:
- Requests (both internal and external) for the same information come to multiple offices.
- Employees waste time searching for materials that may or may not be available and producing materials others may already have created.
- No standards exist for information production, so materials are produced in various, and sometimes inappropriate, forms.
- NCI's image is not presented in a consistent manner to the public, Congress, the White House, etc.

Proposed solution:
Create a centralized repository of core information about cancer, which will be maintained and updated by the Communications Coordination office. The information the repository will be used as a resource by internal offices to accurately and rapidly meet their communication needs.

Purpose
- To create and maintain a central resource for non-scientific information requests
- To standardize the presentation of core information in the repository
- To provide information that accurately conveys NCI's image

Audience
NCI Divisions and program staff
NCI's Office of Communications, including:
- The Cancer Information Service (CIS)
- The Liaison Activities office
- The Press office
- The Office of Public Inquiries
The Legislative office

Process
The repository will be created as a password accessible intranet site on an NCI server. A quality control system will be developed to maintain and regularly update the site. All materials posted on the site will be scientifically and approved prior to posting, and the materials will match NCI's political position on each subject.
Appendix J: Initial Repository Project Plan

The information in and structure of the repository must meet the needs of all of its users. See the following guidelines:

- The information will be concise, current, and accurate.
- The information will be easy to find and easy to understand.
- The intranet site will be logically organized, cross-reference linked, and include appropriate help, if necessary.
- A standards document and style sheet will be created and used for consistent site updating.

The site will be organized into different topics. The following is a sample arrangement:

- Cancer by site
- Programs
- Environment

If the information is organized this way at the top level, the ByPass budget headlines can be used as subheadings within each section. For example:

Cancer by site → Breast Cancer → Progress → Opportunities → Challenges

Each subtopic (such as breast cancer in the example above) on the site will include general information, statistics, and links to sites where people can learn more.
Appendix K: Clearance Process Flowchart

DEVELOPMENT AND CLEARANCE FLOW

NEW MODULES

MMG develops new module

NCI/OC CC staff member reviews and approves

MMG submits to Clearance Officer (CO)

CO coordinates scientific clearance and makes changes to the electronic version of the document (7-10 days)

MMG copyedits as necessary, makes changes to the electronic version, returns to CO

UPDATES TO EXISTING MODULES

MMG or NCI identify the need to update Cancer Content material

Talking points: MMG drafts replacement or new talking point, and checks all talking points in series

New documents: MMG formats the document and copyedits as necessary

Updates to documents: MMG makes changes to the document

NCI repository staff member reviews and approves

MMG submits to CO

CO coordinates scientific clearance and makes changes to the electronic version of the document (1-2 days)

MMG copyedits as necessary, makes changes to the electronic version, returns to CO

CO makes changes using track changes

Does the CO have any additional changes?

No

MMG places in Cancer Content

Yes

MMG copyedits using track changes

MMG submits to CO
Appendix L: Molecular Targets Talking Points

MOLECULAR TARGETS TALKING POINTS

General
A molecular marker is a protein, gene, or other molecule that exhibits changes when a cell becomes precancerous or cancerous. When researchers investigate therapies designed to reverse or alter precancerous or cancerous molecular changes, the protein, gene, or other molecule involved is called a molecular target. (MMG)

Identification and Prioritization of Molecular Targets
Anatomy Project and the Director’s Challenge for Molecular Diagnostics, will aid in the discovery of molecular and other biological substances that researchers believe may be the earliest warning signals that normal cells are on the road to becoming cancerous. (NCI Press Office, NCI Announces Creation of Early Detection Research Network: Comprehensive Initiative Will Develop and Validate Early Detection Markers for Cancer, [http://newscenter.cancer.gov/pressreleases/detection.html](http://newscenter.cancer.gov/pressreleases/detection.html))

Preclinical Evaluation and Prioritization of Novel Targets
NCI aims to create unprecedented conceptual and functional links among drug discovery, development, and clinical testing to help researchers answer the necessary questions in pursuing a new drug’s effect on malignant or precancerous cells (Scientific Priorities for Cancer Research: Molecular Targets of Prevention and Treatment, [http://plan2002.cancer.gov/scptargets.htm](http://plan2002.cancer.gov/scptargets.htm))

Future of Molecular Therapeutics
NCI research is focusing on drugs that target the molecular differences between tumor and normal cells—the altered genes or proteins or corrupted pathways. Such drugs promise to be less toxic and more effective than current drugs. (Scientific Priorities for Cancer Research: Molecular Targets of Prevention and Treatment, [http://plan2002.cancer.gov/scptargets.htm](http://plan2002.cancer.gov/scptargets.htm))

Current Research
NCI is conducting clinical trials to further investigate Gleevec, a drug recently FDA-approved for use in chronic myelogenous leukemia. The trials are conducted in cooperation with Novartis Oncology, the drug’s developer. (NCI Press Office, FDA Approves Important New Leukemia Drug Offers Further Proof of Principles for Molecular Targeting in Cancer Treatment, [http://newscenter.cancer.gov/pressreleases/gleevecpressrelease.html](http://newscenter.cancer.gov/pressreleases/gleevecpressrelease.html))
Appendix L: Molecular Targets Talking Points

Identification and Prioritization of Molecular Targets


2. Recently, investigators observed a new molecular abnormality that is proposed to be associated with cancer: specific molecular changes seem to be uniform across all of the mitochondrial DNA in cells that are cancerous or precancerous. NCI’s Early Detection Research Network will develop a validation assay for this finding. (NCIDEA: National Cancer Advisory Minutes: September 12-13,2000, http://deainfo.nci.nih.gov/new-internet/advisory/ncab/115_0900/ncab0900.htm)

3. Advances in cancer research, including NCI programs such as the Cancer Genome Anatomy Project and the Director’s Challenge for Molecular Diagnostics, will aid in the discovery of molecular and other biological substances that researchers believe may be the earliest warning signals that normal cells are on the road to becoming cancerous. (NCI Press Office, NCI Announces Creation of Early Detection Research Network: Comprehensive Initiative Will Develop and Validate Early Detection Markers for Cancer, http://newscenter.cancer.gov/pressreleases/detection.html)

4. A cell’s signature changes during its transformation from a normal cell to a cancer cell. Cells surrounding an incipient tumor may also undergo changes. By reading the signatures of easily accessed cells, researchers may be able to develop simple, noninvasive tests to find cancers located deep within the body. NCI’s ultimate goal in developing signatures is to push back the detection and diagnosis of cancer to the earliest stages, allowing researchers to focus on intervention efforts. (Scientific Priorities for Cancer Research: Extraordinary Opportunities, Defining the Signatures of Cancer Cells: Detection, Diagnosis, and Therapy, http://plan2002.cancer.gov/scpsigs.htm)

5. To identify the changes in cell signatures linked to major steps of tumor development, NCI is building the complete molecular catalog of cancer through the Cancer Genome Anatomy Project (CGAP). Approximately 40,000 new genes have been discovered through CGAP’s main component, the human Tumor Gene Index. (Scientific Priorities for Cancer Research: Extraordinary Opportunities, Defining the Signatures of Cancer Cells: Detection, Diagnosis, and Therapy, http://plan2002.cancer.gov/scpsigs.htm)
Appendix L: Molecular Targets Talking Points

6. An NCI goal for the next several years is to develop molecular profiling or molecular signatures—the identification of patterns of gene and protein expression abnormalities that will someday enhance a clinician’s ability to predict the behavior of a particular cancer. The goal of NCI’s Director’s Challenge for Molecular Diagnosis is to develop a tumor classification system that is firmly based on the cell biology of cancers, rather than on microscopic appearance. (SIG, NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)

7. To develop and apply technology to advance molecular signatures research, NCI recently created the Innovative Molecular Analysis Technologies (IMAT) program. This program has awarded more than 80 grants to support research to develop and carry out pilot applications of instruments, techniques, and analysis tools that can be used to conduct molecular analyses of tumor samples. (NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)

8. The NCI initiative Toward a Molecular Classification of Tumors builds on the success of NCI’s Cancer Genome Anatomy Project (CGAP), which is compiling the first comprehensive index of genes that are expressed in breast, prostate, colon, and other cancers. The project uses information compiled through CGAP and other gene discovery projects as resources to discover which of the thousands of molecular changes in a tumor cell are most informative in determining how a tumor will behave. Investigators funded by this initiative are creating comprehensive molecular profiles of tumors using DNA, RNA, or protein-based technologies. (Scientific Priorities for Cancer Research: Extraordinary Opportunities, Defining the Signatures of Cancer Cells: Detection, Diagnosis, and Therapy, http://plan2002.cancer.gov/scpsigs.htm, NCI Press Office, the Director’s Challenge: Toward a Molecular Classification of Tumors, http://newscenter.cancer.gov/pressreleases/challenge.html)

9. NCI-supported investigators have discovered a gene, survivin, that shows promise as both a marker of cancer progression and as a possible target for therapeutic intervention. Survivin inhibits apoptosis, which is programmed cell death that eliminates damaged cells. Without apoptosis, damaged cells can develop into cancer cells. And, overexpression of survivin can actually cause these damaged cells to proliferate. (Approved content, Survivin—molecular document from Donna to Christine 5/30/01; NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)
Appendix L: Molecular Targets Talking Points

10. Supported by NCI and the National Human Genome Research Institute, the Tissue Array Research Program (TARP) uses tissue microarray technology to store hundreds of very small tissue samples on a single laboratory slide. Tissue microarrays permit scientists to test hundreds of tumor samples at once. They are an important tool in the search for and evaluation of molecular signatures. TARP:
   - Produces multi-tumor screening tissue microarrays for the research
   - Serves as an arraying facility for groups with unique tissue materials
   - Disseminates tissue microarray technology by providing training


11. To identify leads for cancer therapy and develop novel strategies for marker discovery, NCI is funding libraries of small molecules, peptides, and antibodies. The libraries can be screened to identify molecules (ligands) that either bind differently to tumor and normal cells or bind differently between tumors of varying malignant potential. These ligands can be used for new approaches to cancer diagnosis.


12. As cancer’s fundamental nature becomes more clear, the capacity to use imaging tools to detect the molecular changes associated with a tumor cell promises to vastly improve the ability to detect and stage tumors, select treatments, monitor the effectiveness of a treatment, and determine prognosis. An NCI goal is to accelerate development of such imaging methods.


Preclinical Evaluation and Prioritization of Novel Targets

1. NCI aims to create unprecedented conceptual and functional links among drug discovery, development, and clinical testing to help researchers answer the necessary questions in pursuing a new drug’s effect on malignant or precancerous cells:
   - Does the drug kill the cancer or effectively block its growth and spread?
   - What part of the cell’s complex machinery does it disrupt?
   - How is this disruption related to its anticancer effect?

2. NCI’s Rapid Access to Intervention Development program aims to efficiently move novel treatment interventions developed in academic settings to the clinic. The RAID program:
   - Makes NCI’s drug development resources available to investigators with molecules that hold promise for cancer treatment
   - Removes the most common barriers between laboratory discovery and clinical testing by providing resources for preclinical development of drugs and biological agents
   - Returns products developed through the RAID program directly to the originating laboratory for clinical trial testing

3. NCI’s Molecular Targets Laboratory (MTL) initiative focuses intensively on developing a resource of biological assays and chemical probes for biological studies of cancer. MTLs will emphasize collaboration between chemists and biologists in an effort to:
   - Produce libraries of potential anticancer compounds for public distribution
   - Develop screening assays suitable for high-throughput screening of chemical libraries for potential agents
   - Confirm a drug’s initial ability to alter the drug target in cancer cells

4. To encourage creative investigations for identifying, characterizing, and validating promising new molecular targets for cancer prevention and treatment, NCI has established Molecular Target Drug Discovery grants to:
   - Identify novel molecular targets
   - Validate targets as a basis for cancer drug discovery
   - Develop assays to detect the effects of agents on their targets

5. NCI supports new initiatives in drug development based on the last decade’s progress in understanding the biology of cancer cells. New technology—such as combinatorial chemistry and miniaturization of assays—will allow for the evaluation of thousands of compounds in a very short time, speeding up the process of identifying new candidates for evaluation in clinical trials. (SIG, NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)

6. NCI supports Interdisciplinary Research Teams (IRTs) that will develop new assays, probes, and technologies for molecular target assessment in the development of new agents against specific targets. NCI will support two or more IRTs focused on the development of mechanism-based assays of antiangiogenic activity. (SIG, NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)
Appendix L: Molecular Targets Talking Points

7. NCI will co-fund the expansion of technology in the National Beam Laboratories to enable researchers to rapidly determine the structure of important molecular targets, thereby permitting computer modeling of potential agents. (Scientific Priorities for Cancer Research: Molecular Targets of Prevention and Treatment, http://plan2002.cancer.gov/scptargets.htm)

8. The combination of newly developed chemical and biological combinatorial techniques are enabling scientists to create millions of chemically diverse structures with potential anti-cancer effects over the course of weeks or months, rather than years. Biotechnology advances are also enabling researchers to mix and match genes to design synthetic proteins, creating a new class of potential anti-cancer agents. To this end, NCI is continuing its support of six Biology-Chemistry Centers, which have screened hundreds of thousands of compounds. (Scientific Priorities for Cancer Research: Molecular Targets of Prevention and Treatment, http://plan2002.cancer.gov/scptargets.htm)

9. Drug development research areas that suggest opportunities of particular interest include:
   - Pathways directing apoptosis (programmed cell death), invasion, and metastasis
   - Multiple molecular components that drive the cell cycle or are responsible for the repair of damaged DNA

Future of Molecular Therapeutics

1. The most severe toxic effects of chemotherapy stem directly from their nonselective nature. Most available compounds that inhibit tumor cell growth also inhibit the growth of healthy cells. NCI research, therefore, is focusing on drugs that target the molecular differences between tumor and normal cells—the altered genes or proteins or corrupted pathways. Such drugs promise to be less toxic and more effective than current drugs. (Scientific Priorities for Cancer Research: Molecular Targets of Prevention and Treatment, http://plan2002.cancer.gov/scptargets.htm)

2. Approved in 1998 for treating late-stage breast cancer, Herceptin heralded the arrival of a revolutionary new class of drugs that take aim at the molecular changes that cause a cell to change from normal to cancerous. Herceptin targets a protein on breast cancer cells. Several NCI-sponsored clinical trials are evaluating whether Herceptin combined with other chemotherapies may improve treatment outcomes for gastric, endometrial, salivary gland, prostate, colorectal, ovarian, non-small-cell lung, and pancreatic cancers. (NCI FY 2002 Budget Congressional Justification, http://www.nci.nih.gov/admin/fmb/2002cj.pdf)
Appendix L: Molecular Targets Talking Points

3. Gleevec, an oral treatment for chronic myelogenous leukemia (CML) is the first FDA-approved drug that directly turns off the signal of a protein known to cause a cancer. Other FDA-approved molecular-targeting drugs interfere with proteins associated with other cancers, but not with proteins that directly cause the disease. NCI—in a cooperative research and development agreement with Gleevec developer Novartis Oncology—is further investigating the drug in clinical trials for people with CML. (NCI Press Office, FDA Approves Important New Leukemia Drug Offers Further Proof of Principles for Molecular Targeting in Cancer Treatment, http://newscenter.cancer.gov/pressreleases/gleevecpressrelease.html)

4. By reading cellular signatures accurately, researchers may be able to detect and diagnose cancers before they have a chance to invade nearby tissues. With the tools currently being developed, a single drop of blood from a patient’s finger may be all that is needed to:
   - Find a cancer
   - Assess the threat it poses by comparing its traits to profiles in an online library of tumor characteristics
   - Choose the best possible treatment
   - Monitor the patient’s recovery

5. Researchers are now working on learning new ways to characterize tumors more efficiently by determining which genes are active and inactive, and determining the levels of proteins that are present in a particular tumor. Such molecular fingerprinting will:
   - Markedly improve the specificity of cancer diagnosis by allowing differentiation among tumors at the molecular level
   - Lead to treatments targeted at cellular subtypes of different cancers

6. Continuing insight into how the immune system works at the molecular level is transforming cancer vaccine development, enabling researchers to create vaccines that target tumor cells with greater precision and result in less toxicity to normal cells. (Cancer Vaccine, approved content from zipped files)

Current Research
1. NCI is conducting clinical trials to investigate Gleevec, the drug recently FDA-approved for use in chronic myelogenous leukemia. The trials are conducted in cooperation with Novartis Oncology, the drug’s developer. (NCI Press Office, FDA Approves Important New Leukemia Drug Offers Further Proof of Principles for Molecular Targeting in Cancer Treatment, http://newscenter.cancer.gov/pressreleases/gleevecpressrelease.html)
Appendix L: Molecular Targets Talking Points

2. A study at NCI has reported promising results for the phase I testing of BL22, a recombinant immunotoxin that links cell-killing toxins to antibodies to guide the toxin to the cancer cell. The antibody portion of BL22 specifically binds to the CD22 receptor, which is found in abundance on the surface of many leukemia cells. The researchers reported that 11 of 16 patients with chemotherapy-resistant hairy cell leukemia (HCL) experienced complete remissions lasting up to 18 months with the drug without any major side effects. The drug also has promise for people with other types of leukemia. (High Response Rate of Hairy Cell Leukemia Patients to Immunotoxin Treatment Raises Hopes, approved content from zipped files)

3. NCI-supported researchers are investigating and developing novel products that will block formation of blood supplies for malignancies. NCI is also supporting research to:
   - Improve the effectiveness of existing anti-cancer agents
   - Develop new agents that inhibit molecular targets or pathways important for the initiation or maintenance of cancer
   - Develop new agents that inhibit bone invasion by cancer cells
   - Develop novel drug delivery systems that target certain organs, such as bone

4. To foster multidisciplinary research on cellular and molecular imaging, NCI has established 3 In Vivo Cellular and Molecular Imaging Centers and awarded 10 planning grants for additional centers. The centers will narrow the gap between the discovery of new cancer genes and intracellular pathways, and the translation of these discoveries into clinically useful, minimally invasive imaging approaches. (Scientific Priorities for Cancer Research: Extraordinary Opportunities, Cancer Imaging, http://plan2002.cancer.gov/scpimaging.htm)

5. An NCI-funded study at the University of Louisville is examining the molecular mechanisms of gonadotropin-releasing hormone (GnRH). The GnRH receptor (GnRHR) might play a key role in the regulation of hormone-responsive tumor growth. The study has the potential to provide the basis for the development of a new class of drugs for treatments of hormone-responsive tumors. (Molecular Characterization of GnRH Receptors, CRISP, http://commons.cit.nih.gov/crisp3/crisp_lib.query)

6. NCI is funding a study of the p53 tumor suppressor protein, which is often inactive in cancer cells because of genetic mutation. Because current therapies use primarily DNA-damaging agents in the form of radiation or chemotherapeutics, p53 plays a critical role in cancer’s response to therapy. The study is due to end in July 2001. (P53 Protein/Protein Interactions, CRISP, http://commons.cit.nih.gov/crisp3/crisp_lib.query)
Appendix L: Molecular Targets Talking Points

7. Ecteinascidin-743 (Et-743) is a novel drug that possesses extremely potent cytotoxicity against human cancer cell lines and human xenografts. The drug is particularly useful against a variety of sarcomas that generally lack alternative chemotherapeutic options. NCI-sponsored research at the Beckman Research Institute aims to identify a molecular target for Et-743. (Identification of a Molecular Target for the Anti-Tumor, CRISP, http://commons.cit.nih.gov/crisp3/crisp_lib.query)
Appendix M: Initial Site Map

Page One:

[Diagram of a site map with various sections and links, including Cancer by Type, Cancer-related Topics, and General Info, with a key explaining symbols for web pages, documents, and off-site resources.]
Appendix M: Initial Site Map

Page Two:

Repository of Cleared Information
Site Map
May 2, 2001

Cancer by Type
Click on a letter to find the content on a particular cancer:
A B C D E F G H I J K L M
Or enter a search term:
Search

Lung Cancer
Overview / Talking Points
Lung Cancer Documents
Funding
Trials
RFAs
Statistics
Legislative Activity

Lung Cancer Data
General
Environment
Genetics
Risk Factors
Links to documents in the Repository, sorted by Risk

Clinical Trials
Links to resources on other Web sites

RFAs
Links to resources on other Web sites

Statistics
Links to resources on other Web sites

Legislative Activity
Links to resources on other Web sites

Funding
Links to resources on other Web sites
Appendix M: Initial Site Map

Repository of Cleared Information
Site Map
May 2, 2001

Cancer-Related Topics
Click on a letter to find the content on a particular topic:
A B C D E F G H I J K L M...

Or enter a search term:
[search box] Search

General
Sort by date
Sort by cancer type
Links to documents stored in the Repository

Environment
Sort by date
Sort by cancer type
Links to documents stored in the Repository

Genetics
Sort by date
Sort by cancer type
Links to documents stored in the Repository

Risk Factors
Sort by date
Sort by cancer type
Links to documents stored in the Repository
Appendix N: Reviewed Site Map
Appendix N: Reviewed Site Map

Page Three:

Repository of Cleared Information
Site Map
May 4, 2001

Cancer-Related Topics
Click on a letter to find the content on a particular topic:

A B C D E F G H I J K L M ...

Or enter a search term:

[Search]

General
Sort by date
Sort by cancer type
Sort by topic
Links to documents stored in the Repository

Environment
Sort by date
Sort by cancer type
Sort by topic
Links to documents stored in the Repository

Genetics
Sort by date
Sort by cancer type
Sort by topic
Links to documents stored in the Repository

Risk Factors
Sort by date
Sort by cancer type
Sort by topic
Links to documents stored in the Repository

e.g. for environment
- environment
  - cancer clusters
  - electromagnetic fields
  - nuclear accidents
  - + more

Use CIS patient education materials (with others) as appropriate
http://consent.nih.gov/ncipub/default.asp
Appendix O: Final Site Map

Repository of Cleared Information
Site Map
June 16, 2001

[Diagram of Site Map with branches for different categories and options]

Please Note:
This site map is a draft intended to provide a visual reference for discussion. It will be updated as the site is developed.

Key:
[Symbol legend for different elements on the map]

Web page
Facsimile-protection