A Comparison of the Effectiveness, Cost and Efficiency of Four Formative Evaluation Conditions

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Abstract

Formative evaluation, as part of the instructional design process, is the systematic collection of data for forming decisions to revise instructional materials. This study compared the effectiveness, cost and efficiency of four formative evaluation conditions: a) revision based on learner data (RLD), b) revision based on expert data (RED), c) revision based on both learner and expert data (RBD), and d) revision without data (RND). Two more conditions were present in the study: materials in draft (MID) and no treatment (NT). The NT condition consisted of students who were tested without exposure to the instructional materials. The instruction that was formatively evaluated was a six-page article describing the relationship between diet and cancer. The article was written by chemistry professors for an "undergraduate chemistry course for non-science students". Undergraduates (n=187) provided the effectiveness data. They randomly received one of the four formatively evaluated versions of the article, read the article, answered questions on an objective test, and indicated their confidence with respect to their responses. Professional revisors (n=8) provided cost data. Each revisor provided cost estimates for all formative evaluation conditions. Efficiency was provided by combining effectiveness with cost data. Effectiveness differences were found between the MID and RLD, and the MID and RBD. The mean test scores, as well as the mean confidence-weighed test scores, of both RLD and RBD were significantly higher than those of the MID. Cost differences indicated three levels of cost. RND was the least costly formative evaluation condition. RLD and RED were equivalent in cost and more costly than RND. RBD was the most costly formative evaluation condition. With respect to efficiency, RLD was recommended. RLD was the least costly condition that was significantly more effective than MID. This study presented a framework for future effectiveness, cost and efficiency comparisons. Also, results have provided knowledge that can contribute to the development of a set of validated effectiveness, cost and efficiency guidelines for formative evaluation.

Résumé

Évaluation formative dans le développement de matériaux pédagogiques est l'accumulation systématique des données afin de pouvoir décider comment réviser des matériaux pédagogiques. Cette étude compare les résultats d'apprentissage, les coûts et l'éfficacité de quatre conditions d'évaluation formative: a) révision basée sur des données d'élèves (RLD), b) révision basée sur des données d'experts (RED), c) révision basée sur des données d'élèves et d'experts (RBD) et enfin, d) révision basée sur aucune donnée (RND). Deux autres conditions étaient présentes dans cette étude: matériaux brouillon (MID) et aucun traitement (NT). La condition NT était composée par des étudiants qui ont été examinés sans avoir lu l'article pédagogique. L'instruction qui a été évaluée formativement était un article de six pages qui décrit la relation entre le regime et le cancer. L'article a été rédigé par des membres de faculté qui sont des professeurs de chimie dans un programme de chimie de premier cycle pour des étudiants non-inscrits dans un programme de sciences. Des étudiants du premier cycle (n=187) ont fourni des résultats d'apprentissage. Ils ont reçu au hasard un des quatre articles évalués formativement ou matériaux brouillon, l'ont lu, ont répondu à des questions objectives et ont indiqué leur confiance en regard de leurs réponses. Des réviseurs professionels (n=8) ont fourni des données de coûts. Les données d'éfficacité ont été fournies en combinant les données d'apprentissage avec les données de coûts. Des différences d'éfficacité ont été constatées entre le MID et le RLD ainsi que le RBD. Les résultats d'examen des RLD et RBD ainsi que les résultats d'examen relié à la confiance des RLD et RBD étaient statistiquement plus élevés que ceux du MID. Des différences de coûts démontraient trois niveaux de coûts. RND était la condition d'évaluation formative la moins coûteuse. RLD et RED étaient équivalent et plus coûteux que le RND. RBD était la condition d'évaluation formative la plus coûteuse. Quant à l'éfficacité, le RLD a été recommandé. RLD est la condition qui est la moins coûteuse et la plus effective que le MID. Cette étude a dévéloppé la structure des analyses futures d'apprentissage, de coûts et d'éfficacité. De plus, les résultats ont fourni une connaissance qui pourrait contribuer au développement d'un ensemble de critères validés d'évaluation formative.

N.B. L'usage du masculin s'applique autant aux femmes qu'aux hommes.

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CHAPTER 1

INTRODUCTION

Formative evaluation, as part of the instructional design process, is the systematic collection of data for forming decisions to revise instructional materials (Dick & Carey, 1990; Flagg, 1990; Geis, 1987; Tessmer, 1993). It is a two-stage process that consists of data collection and revision (Dick & Carey, 1990; McAlpine & Weston, 1991). The reasons for employing formative evaluation are to 1) make instructional materials more effective before they are distributed to learners and 2) periodically verify the effectiveness of instructional materials once they have been put to use.

The instructional design literature is in general agreement that formative evaluation is a necessary component in the instructional design process. Andrews and Goodson (1980) compared forty instructional design models (models ranging from the year 1965 to 1979) and discovered that formative evaluation was recommended in 38 of them. Le Maistre (1991), in a review of 11 instructional design texts, found that they all recommended data collection and revision (i.e., formative evaluation). A comparison of 12 instructional design models was also conducted by Stolovitch (1982). Data collection, the first stage in formative evaluation, was observed through three types of data: learner feedback data (learners' verbal or written comments), student posttest scores and expert review data (experts' verbal or written comments). Of the 12 models, collecting learner feedback data was recommended 10 times, collecting test score data was

recommended 11 times, and collecting expert review data was recommended 4 times. In all 12 models, these data are then used to revise in the second stage of the formative evaluation process.

In practice, however, rarely are instructional materials formatively evaluated (Britton, Van Dusen, Gulgoz & Glynn, 1989; Pflieger, Chomienne, Bordeleau & Stolovitch, 1979). It is worth noting two reasons for the limited use of formative evaluation in the instructional design process. First, little empirical information exists to help instructional designers select an effective formative evaluation process that would optimize learning outcomes (McAlpine & Weston, 1991). Second, due to this lack of information, formative evaluation may be perceived as providing few benefits and high costs (see Bowler, 1978). This lack of effectiveness information combined with the perceived high costs undermines the efficiency of formative evaluation.

Definition of Key Concepts

Effectiveness of formative evaluation refers to the improvement of learning outcomes, measured with a retention test, after instructional materials have been formatively evaluated.

Cost of formative evaluation refers to the resources required to formatively evaluate instructional materials. Examples of such resources include time and money.

Efficiency of formative evaluation refers to the relationship of effectiveness and costs (Rossi & Freeman, 1985). It is the "consideration of decision

alternatives in which both costs and outcomes are taken into account in a systematic way" (Levin, 1988, p.51). Therefore, as Gropper (1975) suggested, the goal of efficiency, when formatively evaluating instructional materials, is to maximize the effectiveness of the materials while minimizing the costs.

Purpose of Study

To understand the interaction between the effectiveness, costs and efficiency of formative evaluation, this study examined four formative evaluation conditions. Specifically, it compared four data collection combinations while maintaining revision constant. The four formative evaluation conditions under investigation were: 1) revising with learner data (**RLD**), 2) revising with expert data (**RED**), 3) revising with both learner and expert data (**RBD**) and 4) revising with no external data (**RND**). In RND data were not collected from either learners or experts. Instead revisers internally generated their own data while revising. RND was included because, in practice, revisions are often conducted without the collection of external data (e.g., textbook publishing).

Research Questions and Hypotheses

Three research questions have guided this study:

Q1. Which formative evaluation condition most **effectively** improves instructional materials?

Q2. Which formative evaluation condition is least **costly**?

Q3. When effectiveness and costs are compared, which formative evaluation condition is most **efficient**?

To answer these research questions, four hypotheses were tested. The hypotheses were divided into three categories: one examining effectiveness, one examining cost and one examining efficiency. The number of each hypothesis was matched with its respective research question.

Effectiveness Hypotheses

H1a. Any formative evaluation condition renders instructional materials more effective than materials in draft (MID).

H1b. There are no effectiveness differences among the formative evaluation conditions.

Cost Hypothesis

H2. There are no cost differences among the formative evaluation conditions.

Efficiency Hypothesis

H3. There are no efficiency differences among the formative evaluation conditions.

Organization of Thesis

In Chapter 2, the formative evaluation literature is reviewed. In the literature review, formative evaluation is described conceptuaily, studies that have examined its effectiveness, cost and efficiency are reviewed, and a rationale for conducting the present study is provided.

In Chapter 3, the methodology of this study is described. Specifically, the design, participants, materials, procedure and analyses used to produce effectiveness and cost data are described.

Results of the tested hypotheses are reported in Chapter 4. The statistical treatments of these hypotheses are reported, and the main findings are stated and supported with tables and figures.

In Chapter 5, the results are discussed. Implications of the results are interpreted, examined, qualified, and compared to those of previous formative evaluation effectiveness, cost and efficiency studies. Recommendations are made regarding the most efficient formative evaluation condition. Finally, the contributions of the present study are summarised, limitations are discussed and recommendations for future studies are suggested.

CHAPTER 2

LITERATURE REVIEW

The literature review is divided into four parts. In the first part a conceptual framework for formative evaluation is described. This framework is organized according to the stages of formative evaluation. In the second part, the literature on the effectiveness of various formative evaluation conditions is reviewed. In the third part, studies that have investigated cost and efficiency among conditions are reviewed. Finally, in the fourth part, limitations that emerge from the reviewed literature are summarised in a problem statement.

Conceptual Framework:

The Two Stages of Formative Evaluation

For the purpose of this study, formative evaluation of instructional materials has been conceptualized as having two stages: data collection and revision. In the data collection stage, data may be collected from learners, from experts, or from a combination of both these sources. It is also possible that no external data be collected at all. In such instances, the reviser is understood to use internal data as the basis for revision decisions. In the revision stage, it is expected that expert sources revise.

According to McAlpine & Weston (1991), conceptualizing a clear distinction between the data collection stage and the revision stage allows for greater control in research studies of the formative evaluation process. This added control can provide more information and more internal validity on the

effectiveness of formative evaluation. For example, by separating data collection and controlling revision, it may be possible to verify whether learners, experts, both, or neither of these conditions are responsible for generating more effective instructional materials.

Previous studies (e.g., Golas, 1983; Kandaswamy, Stolovitch & Thiagarajan, 1976; Wager, 1983) and texts (e.g., Dick & Carey, 1990; Gropper, 1975) have also conceptualised formative evaluation to consist of two distinct stages, data collection and revision. However, most studies on formative evaluation have focused on controlling data collection while leaving revision uncontrolled (Dick, 1977; McAlpine & Weston, 1991). Due to this lack of control, it is difficult to determine whether the data collection or revision stage is responsible for generating effective instructional materials.

This section of the literature review describes in further detail the two stages of formative evaluation: data collection and revision. In the data collection stage, learner and expert data sources are elaborated upon whereas in the revision stage, expert revision sources are discussed.

Stage One: Data Collection

Data collection is the first stage of formative evaluation. In this stage, data can be collected on draft instructional materials from either learners or experts, or a combination of the two sources (Weston, 1991).

Learner data are collected from learners who are representative of the population for whom the materials are intended. Expert data (or expert review

data) can be collected from different kinds of experts, for example, subject matter experts (SMEs) or target population experts (TPEs) (Dick & Carey, 1990; Geis, 1987; Saroyan & Geis, 1988). SMEs can be expected to generate feedback on the content of instructional materials whereas TPEs can be expected to generate feedback on whether instructional materials are appropriate for the intended learner (Kandaswamy, 1980; Thiagarajan, 1978).

The primary distinction between learners and experts is their role in the data collection stage. Learners usually take on the role of learning but may also critique. The learner role is often measured through pretests, posttests, questions embedded in the materials, etc. The critic role entails judgements about materials provided through feedback comments, questioning, debriefing, etc.

Experts, who are viewed as more capable of judging instructional materials, usually take on the critic role (Geis, 1988). Experts are expected to review instructional materials and provide data on aspects of the materials that fall within their area of expertise (Dick & Carey, 1990; Saroyan, 1989). However, recent empirical findings contradict this notion. Tremblay (in progress) found that TPEs provided as much content-based data as did SMEs. Duy (1990) further found that experts may not limit their critique to their acknowledged area of expertise.

Stage Two: Revision

Revision is the second stage of formative evaluation. In this stage, the literature recommends that the data collected in the previous stage be used to

guide revision (Gropper, 1975). Revisions are usually conducted by experts. These experts include professional revisers, editors, instructional designers, instructors, or authors (Dick & Carey, 1990; Gropper, 1975). There are many instances, however, where instructional materials are revised without external data (e.g., Golas, 1983; Montague, Ellis & Wulfeck, 1983).

If revisers are not provided with data, revisers may take on the role of critics as well as revisers (Le Maistre, in progress; Saroyan, 1989). For example, when experts were asked to revise without any data, Le Maistre (in progress) found that they first chose to critique the instructional materials and then revised them.

Research on the Effectiveness of Formative Evaluation

The formative evaluation condition that most effectively improves instructional materials has been an ongoing topic of research. However, a distinction must be made between literature that recommends a condition based on an analysis of information about that data source (e.g., Carroll, 1988; Henderson & Nathenson, 1976; Nevo, 1985; Stolovitch, 1982; Weston, 1987) and research that recommends a condition based on empirical effectiveness comparisons (e.g., Dupont & Stolovitch, 1983; Golas, 1983). The former recommends a condition based on data about that source or based on data comparing two sources, whereas the latter recommends a condition by using data to revise instructional materials and then testing these materials on learners. Therefore, research on the effectiveness of formative evaluation will be discussed

in two parts. The first part will review studies that have made effectiveness recommendations based on an analysis of the data collected during formative evaluation (i.e., based on the data itself), and the second part will review studies that have made effectiveness recommendations based on empirical comparisons among formative evaluation conditions (i.e., based on learning outcomes).

Effectiveness Recommendations Based on Analyses of Data

Researchers who base their effectiveness recommendations on information about a data collection source have not agreed on the most effective source. The disagreement is based on the fact that different researchers have focused on different formative evaluation conditions. Those researchers that have focused on learner conditions have subsequently made recommendations in favour of such conditions. Those that have focused on expert conditions have subsequently made recommendations in favour of these conditions. Those that have focused on both learner and expert conditions have subsequently made recommendations in favour of both conditions. The arguments supporting these individual recommendations will be dealt with separately.

Recommendations for Learner Data

It is recommended by some that learner data be used to revise instructional materials since learners will be the ones to ultimately use these materials (e.g., Henderson & Nathenson, 1976; Carroll, 1988). Researchers argue that experts frequently fail to identify problems experienced by learners, while frequently detecting problems that do not really exist (Henderson & Nathenson,

1976). Therefore collecting data from learners, who closely represent the instructional material's target population, will result in more effective revisions (Carroll, 1988).

Recommendations for Expert Data

Others (e.g., Nevo, 1985) recommend that experts be used to collect data. Nevo (1985), for instance, argues the following: Experts are in a better position to provide data when instruction is in the stages of development since expert feedback can be obtained without testing the instructional materials. Such expert feedback is valued because it adds to the credibility of formative evaluation. Furthermore, collecting expert review data is less time consuming and therefore less costly.

Recommendations for Both Learner and Expert Data

Still others (e.g., Dick & Carey, 1990; Geis, 1987; Stolovitch, 1982; Thiagarajan, 1978; Weston, 1987) recommend collecting data from both learners and experts. Some researchers further recommend that expert review data be collected from both SMEs and instructional design experts (IDEs) before learner feedback data is collected (Stolovitch, 1982; Thiagarajan, 1978). This ensures that learners are exposed to both accurate content and an effective format that may facilitate the identification of problems. Dick & Carey (1990) recommend collecting data from both learners and experts. However, if a choice must be made, they recommend that data be collected from learners since the instructional materials are intended for them.

Since learner and expert data are qualitatively different (Geis, 1987; Weston, 1987) Weston (1987) suggests that both learners and experts provide data. Both should provide data on comprehensiveness, objectives and organization while experts alone should provide data on content accuracies and current thinking in a field. Revisions may be less effective if data are collected only from learners or experts (Weston 1987).

Summary

The aforementioned arguments supporting one or more formative evaluation conditions are based on information gathered about the conditions. To determine the most effective condition, data should be used to revise instructional materials and then the revised materials should be tested on learners. In the next section, studies that have done this are described.

Effectiveness Recommendations based on Empirical Comparisons

Effectiveness studies on formative evaluation will be divided into two categories: (1) draft-formative-evaluation comparisons and (2) among-formative-evaluation comparisons. Draft-formative-evaluation comparisons have compared formatively evaluated instructional materials to the original MID, whereas among-formative-evaluation comparisons have compared two or more formative evaluation conditions.

Examples of Draft-Formative-Evaluation Comparisons

Studies that have compared the effectiveness of the results of different formative evaluation conditions to MID have consistently found that formatively

evaluated instructional materials are more effective (e.g., Baker, 1970; Baghdadi, 1980; Kandaswamy, Stolovitch & Thiagarajan, 1976; Wager, 1983). Baker (1970) had ten instructional design graduate students design a lesson (on any topic) to be administered to grade five students. The lessons, along with test scores, were randomly distributed among the ten instructional design students. The instructional design students revised the lessons and they were re-administered to a different group of grade five students. Results showed significant improvements on the posttest scores. As a result, Baker concluded that the revised materials were more effective than the MID.

Kandaswamy, Stolovitch and Thiagarajan (1976) randomly distributed learner pretest-posttest data on an eighth grade mathematics lesson to four individual high school teachers acting as revisers. The revised version and the MID were administered to students and findings indicated that test scores of the revised versions of the instructional materials were higher than those of the MID. Baghdadi (1980) replicated Kandaswamy, Stolovitch and Thiagarajan's (1976) study and found similar results: Formative evaluation improved the effectiveness of the instructional materials when compared to the unrevised materials.

Wager (1983) had four formative evaluation graduate students revise instructional materials consisting of a ninth grade mathematics lesson, using learner test data. These materials were then randomly distributed to learners. Pretest-posttest scores indicated that the learner condition improved instructional materials when compared to MID.

Montague, Ellis and Wulfeck (1983) applied instructional quality inventory (IQI) procedures to a Navy radioman course that described several types of Navy call signs. IQI uses a classification system developed by experts (see Montague, Ellis & Wulfeck, 1983) and does not require data. The classification system acts as a job aide by adding structure to the revision task since no data are provided. The revised version and the MID were administered to students and findings indicated that test scores for the revised versions of the instructional materials were higher than those for the MID.

The results of empirical draft-formative-evaluation comparisons can be summarised as follows: Formative evaluation produces instructional materials that are more effective than those in draft. However, these studies have not been comprehensive. These studies have failed to compare more than one formative evaluation condition. Furthermore, the condition that has been compared to MID has predominately been learner-based. Research on the effectiveness of all possible combinations of formative evaluation conditions, when compared to MID, has not been done. Also, draft-formative-evaluation comparisons have not been conducted with higher education materials. It remains to be seen whether formative evaluation is as effective with higher education materials as it is with grade school materials.

Examples of Among-Formative-Evaluation Comparisons

Studies that have compared effectiveness among formative evaluation conditions have reported consistent findings. Dupont and Stolovitch (1983)

compared the effectiveness of instructional materials formatively evaluated with data collected from learners and data collected from experts. The learner data consisted of a retention test collected from 90 college students (An ability test was also included, however, effectiveness in the present study was only concerned with retention). The expert condition was not clearly defined (i.e., whether experts consisted of SMEs, TPEs, etc.). Revisers, consisted of professional staff members with some revising experience. The results of the retention test did not indicate a significant difference between materials formatively evaluated with learner data as opposed to expert data.

Golas (1983) compared two formative evaluation conditions: a learner condition and revising without external data. The learner condition consisted of test data while those revisers revising without any data used instructional editing guidelines which included the attributes of effective instruction developed by experts. These editing guidelines, similar to the job aide discussed in Montague, Ellis and Wulfeck (1983), add structure to a revision task when data is not provided. The instructional materials consisted of a U.S. Army training lesson. Seventy learners (U.S. Army soldiers) were randomly assigned to one of the two groups, were instructed to work through the materials, and were administered a posttest. Golas found no significant difference between the mean posttest scores of instructional materials revised with learner data and instructional materials revised without external data.

The findings of among-formative-evaluation studies suggest the following:

Effectiveness differences among-formative-evaluation conditions are non-existent. However, as with draft-formative-evaluation comparisons, these studies have not been comprehensive. They have never compared more than two formative evaluation conditions at a time, and RBD has never been empirically tested against other conditions. Furthermore, neither Golas (1983) nor Dupont and Stolovitch (1983) reported whether there were differences between MID and the formative evaluation conditions.

The Dupont and Stolovitch (1983) study is the only one to date that has investigated formative evaluation in a higher education setting. It is also the only study to date that has empirically compared learner conditions to expert data conditions. Golas' (1983) study is the only one to date that has empirically compared learner conditions to instructional materials revised without any external data.

Summary

In summary, the findings of empirical studies that have investigated the effectiveness of formative evaluation can be summarised as follows: 1) Learner data collection conditions have improved instructional materials when compared to MID and 2) no differences in effectiveness have been found among the following formative evaluation comparisons: learner and expert, and learner and no data. This study will comprehensively expand on and re-investigate these effectiveness findings.

Research on the Cost and Efficiency of Formative Evaluation

Most instructional design (e.g., Briggs & Wager, 1981) and formative evaluation texts (e.g., Lawson, 1975; Gropper, 1975) prescribe that efforts for improving effectiveness should produce benefits that outweigh costs. However, such texts provide little information on the procedures to accomplish this. At most, they recommend that materials be formatively evaluated until differences in costs outweigh differences in effectiveness, that is, until it is no longer efficient (e.g., Lawson). However, information on the efficiency of formative evaluation has not been provided by these sources.

Formative evaluation efficiency prescriptions can be found in published journal articles (e.g., Golas, 1983; Lowe, Thurston & Brown, 1983; Montague, Ellis & Wulfeck, 1983). Although this literature is the most complete to date, it is not comprehensive since it has not empirically compared the cost and effectiveness of all possible formative evaluation conditions. This literature, which is reviewed below, is organized in a similar manner to the effectiveness literature. The first part will review studies that have made efficiency recommendations based on an analysis of effectiveness and cost data collected during formative evaluation (i.e., based on the data itself), and the second part will review studies that have made efficiency recommendations based on empirical effectiveness and cost comparisons among formative evaluation conditions.

Effectiveness Recommendations Based on Analyses of Data

Lowe, Thurston and Brown (1983) argue that collecting learner data from

only one learner, a strategy they termed "the clinical approach" (pp.8), was least costly and therefore most efficient. Cost data were collected by keeping track of the time (in hours) required to formatively evaluate instructional materials with one learner. Drawing from the literature that suggests that any formative evaluation condition improves the effectiveness of instructional materials, Lowe, Thurston and Brown (1983) prescribed that the least costly condition is the most efficient one. It was for this reason that they recommended the clinical approach.

Effectiveness Recommendations based on Empirical Comparisons

Montague, Ellis & Wulfeck (1983) found that the costs of formative evaluation would be "considerably reduced" (pp. 13) if an Instructional Quality Inventory (IQI) was applied in the instructional design process. Cost data were collected by keeping track of the time (in hours) required to formatively evaluate instructional materials with an IQI. This study concluded that instructional materials revised with an IQI were more effective than those in draft, and since an IQI required less time to conduct than other formative evaluation conditions, it is therefore more efficient than other conditions.

Golas (1983) compared the cost and efficiency of two formative evaluation conditions: one using learner data and one without external data but using instructional editing guidelines. She found that using editing guidelines was less expensive than collecting data from learners. Cost data were collected using a model that compiles instructional costs through a functional cost analysis. The functional costs consisted of those accrued in data collection and revision. Golas

concluded that revising with editing guidelines was just as effective as revising with learner data, however less costly and therefore more efficient.

Summary

Rarely have efficiency recommendations been based on empirical dollar costs and market value comparisons. According to Levin (1983), two elements must be present when evaluating the efficiency of an educational project: (1) dollar costs (instead of time, effort, etc.) and (2) market value costs (instead of costs encountered in non-market settings, such as research-based costs). The lack of either one of these two elements will render an efficiency analysis artificial.

Formative evaluation costs should 1) be compared to effectiveness data generated from comprehensive effectiveness studies, 2) reflect the real dollar costs of formatively evaluating instructional materials (see Lawson, 1975) and 3) not reflect inaccurate costs encountered in a research-based environment. Using accurate costs in formative evaluation efficiency comparisons, and comparing these costs to empirical effectiveness data (see Komoski, 1974) may increase the perceived usefulness of formative evaluation research and may ultimately result in the increased use of formative evaluation.

Problem Statement

The rationale for this study extended from the limitations of previous research on formative evaluation. Previous studies have failed to conceptually separate data collection and revision, and have failed to control factors in data collection and revision, therefore producing findings that were weak in internal

validity. This study is the fourth in a programme of research that has consistently separated data collection and revision, and has controlled sources in data collection and revision, in an attempt to increase internal validity.

Previous studies have also not been comprehensive. No single study has compared more than two formative evaluation conditions at a time. This study compared four formative evaluation conditions among each other and to MID. Also, few studies have made use of materials intended for higher education. The materials used in this study were developed in higher education to be used by undergraduates.

Finally, few studies have accurately examined costs among formative evaluation conditions and compared these costs to effectiveness data. This study examined both effectiveness and cost data, providing a measure of efficiency among the formative evaluation conditions. At a time when effectiveness and costs are of much concern in all aspects of education, efficiency information is necessary if formative evaluation is to have any influence on the development of instructional materials.

CHAPTER 3

METHODOLOGY

This chapter is divided into four parts. The first part describes this study in the context of a research programme, the second part outlines how effectiveness data were collected and analyzed, the third part outlines how cost data were collected and analyzed, and the fourth part outlines how effectiveness and cost data were combined to produce efficiency data. Parts 2 and 3 are further divided into five sections: design, participants, materials, procedure, and analyses. Part 4, since it combines effectiveness and cost data, is composed of one section: analyses.

Part 1: The Research Programme

This study is the last in a programme of research on formative evaluation of instructional materials. Using the same draft instructional material, each study has made use of prescribed task instructions to collect data from different sources (Israeloff, 1992; Rahilly, 1991b; Tremblay, in progress) and to revise the instructional materials (Le Maistre, in progress). The overall goal of this research programme has been to provide research-based effectiveness and efficiency guidelines when formatively evaluating instructional materials. This programme of study differs from other studies (e.g. Dupont & Stolovitch, 1983; Golas, 1983; Wager, 1983) in that many sources in the formative evaluation process have been controlled and independently studied.

The learner data in the present study were provided by Rahilly (1991b).

Demographically similar undergraduates provided the research programme with learner pretest and posttest scores (i.e., learners in the role of learners) as well as learner feedback data (i.e., learners in the role of critics). The expert data were provided by Israeloff (1992) and Tremblay (in progress). Demographically similar subject matter experts and target population experts provided the research programme with expert review data (i.e., experts in the role of critics). Demographically similar instructional designers then used combinations of learner and expert review data to revise the draft instructional material (i.e., experts in the role of revisers) (Le Maistre, in progress).

As a result of these studies, the revised materials represented the outcomes of four formative evaluation conditions: 1) instructional materials revised with learner data (RLD), 2) instructional materials revised with expert data (RED), 3) instructional materials revised with both learner and expert data (RBD), and 4) instructional materials revised with no data (RND). Two more conditions were added: (5) materials in draft (MID), and (6) a no treatment (NT) condition. The NT condition consisted of students who were tested without exposure to the instructional materials. This condition was included for baseline comparisons (see Bordens & Abbott, 1991) and to ensure that learners were not familiar with the content of the instructional materials (Dick, 1986). The MID condition was included for draft-formative-evaluation comparisons.

Part 2: Effectiveness[1]

Design

In the effectiveness study, experimental research methodologies were used. Of the three true experimental designs described by Campbell & Stanley (1963), pretest-posttest, posttest-only, and Solomon four-group, the posttest-only design was selected.

Independent Variable: Formative Evaluation Conditions

The independent variable consisted of six categorical conditions: NT, MID, RND, RLD, RED, RBD. The four latter were the formative evaluation conditions under investigation.

Dependant Variable: Effectiveness

Two measures of effectiveness were used, test scores and confidence-weighted test scores. Confidence-weighted test scores were included because: a) the advantages of weighting for confidence have been documented in the testing literature[2] however confidence weights have never been used in formative evaluation and b) they could be used to verify the internal validity of the effectiveness findings (see Bordens & Abbott, 1991).

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[1] Effectiveness research question and hypotheses.
Q1. Which formative evaluation condition most effectively improves instructional materials?
H1a. Any formative evaluation condition renders instructional materials more effective than MID.
H1b. There are no effectiveness differences among the formative evaluation conditions.

[2] There are several advantages to confidence-weighing test items: a) Controls for guessed answers. b) Increases the reliability of tests (Anderson, 1982; Friedland & Michael, 1987; Wen, 1975). c) Increases examinees ability to assess the correctness of answers (Anderson, 1982; Pressley & Ghatala, 1988; Sieber, 1979). d) Has a positive correlation with learners' understanding of the instructional materials (Kulhavy, Stock, Hancock, Swindell, & Hammrich, 1990).

Participants

A total of 198 McGill University undergraduates participated in the study. Participants were solicited from several large lectures (e.g., Chemistry for Non-science Students, Political Science, Math Curriculum and Instruction, etc.) and were randomly assigned to one of the six conditions. The students were told that they were participating in an "evaluation of instructional materials" study and that the materials were being evaluated and not the students themselves. They understood that participation was voluntary, that they could stop any time without prejudice, and that they were to sign a consent form that satisfied McGill University's Faculty of Education Ethics Committee on the use of human subjects in research. Participants were paid $10.00.

Of the 198 students that participated, 11 students (5.61%) misunderstood the task instructions and therefore their test scores could not be included in the analyses. The most common errors included neglecting to answer all the items on the test.

Of the final pool of 187 students, 115 were female (61.5%) and 72 were male (38.5%). Participants were between the ages of 17 and 33. As Table 1 indicates, participants in all formative evaluation conditions were demographically similar. A series of one factor completely randomized analyses of variance (ANOVAs) were conducted among the six conditions. Results indicated no significant differences in age and declared grade point average (GPA) among the conditions. Chi-square tests for sex, degree program, year of study, and declared

Table 1

Learner Demographic Characteristics (n=187)

	Formative Evaluation Conditions											
	NT		MID		RND		RLD		RED		RBD	
Demographic Characteristics												
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Age	19.40	1 25	19 62	2 80	20.20	2.82	20 10	1.72	20.12	2.18	19 83	1 91
$F(5, 177) = .65, p > .05$												
Grade point average (GPA)	3 38	29	3 22	35	3 23	.32	3 24	.69	3 02	67	3 38	29
$F(5,65) = 92, p > .05$												
	N	%	N	%	N	%	N	%	N	%	N	%
Sex												
Female	20	10 7	19	10 2	19	10.2	17	9.1	26	13 9	14	7.5
Male	10	5 3	12	6 4	12	6 4	14	7.5	8	4 3	16	8 6
$\chi 2(5, N = 187) = 6 93, p > 05$												
Current University Degree												
B A.	14	7 5	10	5 3	14	7.5	13	7.0	15	8.0	17	9 1
B Sc	11	5 9	11	5 9	11	5 9	10	5.3	8	4 3	7	3 7
B Com	0	0	0	0	0	0	1	5	0	0	0	C
B.Ed.	5	2.7	10	5.3	6	3 2	7	3 7	10	5 3	4	2 1
Other	0	0	0	0	0	0	0	0	1	5	2	1.1
$\chi 2(20, N = 187) = 19 97, p > 05$												
Current Year												
U1	25	13 5	26	14 1	23	12 4	18	9.7	24	13 0	20	10 8
U2	2	1.1	5	2 7	5	2.7	10	5 4	8	4.3	9	4.9
U3	2	1.1	0	0	1	.5	3	1.6	1	5	0	0
U4	1	5	0	0	1	5	0	0	0	0	1	.5
$\chi 2(15, N = 185) = 17 85, p > 05$												
Academic Performance												
As	8	4 5	8	4 5	11	6 1	10	5.6	8	4 5	8	4.5
Bs	21	11.7	21	11.7	18	10.1	19	10 6	22	12 3	19	10 6
Cs	1	.6	1	.6	1	.6	1	.6	0	0	2	1.1
$\chi 2(10, N = 179) = 3 59, p > 05$												

academic performance also indicated no significant difference among participants from the six conditions. Therefore, random distribution did succeed in creating six demographically similar groups.

Materials

Each student received a materials package comprising three parts. The first part contained specific instructions, practice exercises, demographic questions, and a consent form. The second part contained the treatment. The third part contained two measures of effectiveness: a test and confidence scales to generate confidence weighted test scores.

Treatment: Instructional Materials

The instructional materials were the MID and the four revised versions of a six-page article entitled The Diet-Cancer Relationship. This article was written by chemistry professors (subject matter experts) and is currently used in a course they teach: an undergraduate chemistry course for non-science students. The instructional materials could also be used for independent study.

Effectiveness Measures:

1) Retention Test

The retention test, developed by Fenster, Harpp & Schwarz (1990) and Rahilly (1991b), consisted of 30 items: 13 true or false statements and 17 multiple choice questions. The test, graded out of 30, measured students' ability to recognize specific key concepts. Therefore, it measured declarative knowledge at lower levels of the cognitive domain.

2) Confidence-weighted Test

Also included in the test were 30 confidence scales, one per test item. These confidence scales required students to indicate their degree of confidence regarding the correctness of their responses using a four-point Likert scale ranging from not confident, somewhat confident, quite confident, to very confident. Figure 1 provides a sample true or false statement, a sample multiple choice question, and a sample confidence-weighing scale.

Procedure

Students randomly received one of six materials packages. Randomization was obtained by shuffling the materials packages before they were distributed to the students (Table 2 provides a breakdown of the number of participants in each experimental condition). Students were informed that their materials package could be different from that of the person sitting next to them. Students who received an article were instructed to read the article and answer all the items on the test without referring to the article. Students in the NT condition were informed to answer the items on the test to the best of their ability. All students began the procedure simultaneously and worked through the materials package at their own pace. Data collection sessions did not exceed one hour.

Analyses

Per item confidence weights were combined with the test responses to produce a confidence-weighted test score. This was done using a procedure recommended by Echternacht (1972): Correct answers with corresponding high

Figure 1

Sample True or False Statement, Multiple Choice Question, and Confidence-weighing Scale

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5. T F **Consumption of naturally occurring carcinogens is an environmental factor which may cause cancer.**

Not at all Somewhat Quite Very

1.....2.....3.....4

18. **Nutritional guidelines for the population as a whole:**
    a) Neglect regional differences in the food availability making their application impossible.
    b) May be improperly applied leading many scientist to object to their recommendation.
    c) Do not consider foods from differing cultural origins.
    d) Ignore individual differences in height, weight and bone size.

Not at all Somewhat Quite Very

1.....2.....3.....4

Table 2

Number of Participants in the Formative Evaluation Conditions

Formative Evaluation Condition	Completed	Spoiled
a) No treatment (NT)	30	1
b) Materials in draft (MID)	31	1
c) Materials revised without data (RND)	31	4
d) Materials revised with learner data (RLD)	31	1
e) Materials revised with expert data (RED)	34	2
f) Materials revised with both sets of data (RBD)	30	2
Totals	187	11

confidence ratings received more weight than correct answers with corresponding low confidence ratings. On the other hand, incorrect answers with corresponding low confidence ratings received more weight than incorrect answers with corresponding high confidence ratings. The four point confidence scale combined with the possibility that an answer was either correct or incorrect created a range of eight possible weights. The weights ranged from 4 (i.e., a highly confident correct response) to -4 (i.e., a highly confident incorrect response). Zero was not included.

The test scores with eight possible confidence weights resulted in a total range of confidence-weighted test scores from -120 to 120 grades. For example, if a student scores 30 out of 30, and is very confident on all responses, then this student will score 120 on the confidence-weighted test score. If, on the other hand, a student scores 0 out of 30 on the test, and this student is also very confident that these responses are correct, then this student will score -120 on the confidence weighted test.

A one factor completely randomized analysis of variance (ANOVA) as well as various post-hoc tests were selected to test H1a and H1b. The one-tailed Dunnet post-hoc test was selected for H1a and the two-tailed Tukey post hoc test was selected for H1b. The rationale for selecting these tests is described below.

The Dunnet post-hoc test was selected to test H1a since many statistical sources in the behavioral sciences recommend using it when multiple pairwise comparisons between the MID and formative evaluation conditions are made

(e.g., Glass & Hopkins, 1984; Hopkins & Chadbourn, 1967; Kirk, 1982; Keppel, 1973; Pagano, 1986; Winer, 1971). The one-tailed option was selected because statistical sources (e.g., Bordens & Abbott, 1991; Hopkins & Chadbourn, 1967; Keppel & Zedeck, 1989) recommend it when alternate research hypotheses are being tested.

For H1b, the Tukey post-hoc test was selected since many statistical sources recommend using it with designs that involve paired, multiple contrasts (e.g., Glass & Hopkins, 1984; Hopkins & Chadbourn, 1967; Kirk, 1982; Keppel, 1973; Winer, 1971), such as among-formative-evaluation comparisons. The two-tailed option was selected because many statistical sources (e.g., Bordens & Abbott, 1991; Hopkins & Chadbourn, 1967; Keppel & Zedeck, 1989) recommend it when null research hypotheses are being tested.

Part 3: Cost[3]

Design

Quasi-experimental methodologies were used to collect cost data. Since participants had to estimate the cost of a number of formative evaluation conditions, a within-subject (often called repeated measures) design was used.

Independent Variable: Formative Evaluation Conditions

The independent variable consisted of four conditions, rather than the six

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[3] Cost research questions and hypotheses.

Q2. Which formative evaluation condition is least costly?
H2. There are no cost differences among the formative evaluation conditions.

used for the effectiveness study, since the NT and MID conditions did not include formative evaluation.

Dependant Variable: Cost Estimates

The dependant variable consisted of the four cost estimates.

Participants

Eight demographically similar professional revisers, all instructional designers, provided cost information on the four conditions. They were chosen because they had already worked with the instructional materials and were experts in the business of designing and revising instruction.

A series of one factor completely randomized ANOVAs revealed nonsignificant differences in years of experience and number of instructional design courses. Chi-square tests of university training and experience with providing cost estimates also revealed no significant differences across instructional designers. Table 3 summarises the demographic characteristics of the instructional designers.

Materials

Cost information, on the draft instructional materials, was collected with a four-item questionnaire. The questionnaire described the four formative evaluation conditions and then requested that participants provide four dollar cost estimates; one for each condition.

The questionnaire, along with a cover letter, the article in draft, a short description of the four conditions, and a stamped self-addressed envelope was

Table 3

Instructional Designer Demographic Characteristics (n=8)

Demographic Characteristics	Instructional Designers	
	M	SD
Years of experience $F(6, 1) = .22, p>.05$	9.25	3.80
No. of Instructional Design courses $F(6, 1) = 1.46, p>.05$	1.88	.78
	N	%
Degree		
M.A. in Ed. Tech.	6	75
Ph.D. in Ed. Tech.	1	12.5
Other	1	12.5
$X^2(12, N = 8) = 16, p > .05$		
Experience in providing cost estimates		
Every day	0	0
A few times per week	0	0
At least once per week	0	0
At least once per month	1	12.5
A few times per year	5	62.5
Less often than the above choices	2	25
Never	0	0
$X^2(4, N = 8) = 1.6, p > .05$		

packaged so that it could be mailed to instructional designers. Instructional designers were provided with telephone numbers in the event the instructions were unclear.

Procedure

Ten participants were solicited by telephone, and all agreed to provide cost estimates. The package was mailed immediately and a reminder was mailed ten days later. Eight participants returned the questionnaire (80% response rate).

Analyses

Since each instructional designer provided cost estimates for all four formative evaluation conditions, a within group single factor analysis of variance (ANOVA) was used to test H2 in order to control for the repeated measures factor (Keppel & Zedeck, 1989). Univariate F-tests were then used to test for significant cost differences among the formative evaluation conditions.

Part 4: Efficiency[4]

Analyses

Nagel's (1983) efficiency score method was used to test H3. Efficiency, in formative evaluation studies, refers to the relationship between the effectiveness and cost of a formative evaluation condition. The most efficient condition will be the one that maximizes effectiveness while keeping costs at a minimum.

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[4]Efficiency research questions and hypotheses

Q3. When effectiveness and costs are compared, which formative evaluation condition is most efficient?
H3. There are no efficiency differences among the formative evaluation conditions.

CHAPTER 4

RESULTS

In this chapter the tests of the hypotheses are provided. The findings are reported in three parts, effectiveness, cost and efficiency findings.

Part 1: Effectiveness Findings

While comparisons between NT[1] and the other conditions are not of interest in this study, a preliminary analysis was conducted to determine whether the learners were familiar with the content of the instructional materials. The resulting significant differences between the NT and the other conditions, for both test scores and confidence-weighted test scores, indicated that learners were not familiar with the content of the instructional materials.

Hypothesis 1a (H1a)

Any formative evaluation condition renders instructional materials more effective than MID.

H1a was rejected.

Test Scores

A one factor completely randomized analysis of variance (ANOVA) indicated a significant difference in test scores across the conditions at $\alpha = .05$, $F(5, 181) = 12.60$, $p < .05$. A one-tailed Dunnett post-hoc analysis found that the

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[1] All conditions.

NT = No treatment.
MID = Materials in draft.
RND = Revision not based on data.
RLD = Revision based on learner data.
RED = Revisions based on expert data.
RBD = Revisions based on both learner and expert data.

test scores for only RLD[2] and RBD were significantly higher than test scores of MID. Mean test scores for MID, RLD and RBD conditions were 19.32, 21.32 and 21.47 respectively. The mean test scores are summarised in Table 4 and graphically illustrated in Figure 2.

Confidence-weighted Test Scores

A one factor completely randomized ANOVA indicated a significant difference in confidence-weighted test scores across the conditions at $\alpha = .05$, $F(5, 181) = 16.44$, $p < .05$. A one-tailed Dunnett post-hoc analysis found that the confidence-weighted test scores for only RLD and RBD were significantly higher than test scores of MID. Mean confidence-weighted test scores for MID, RLD and RBD conditions were 30.13, 44.90 and 48.23 respectively. The mean test scores are summarised in Table 4 and graphically illustrated in Figure 3.

Hypothesis 1b (H1b)

There are no effectiveness differences among the formative evaluation conditions.

H1b was accepted.

Test Scores

A one factor completely randomized analysis of variance (ANOVA) indicated a significant difference in test scores across the conditions at $\alpha = .05$, $F(5, 181) = 12.60$, $p < .05$. However, a two-tailed Tukey post hoc test indicated

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[2] All conditions.

NT = No treatment.
MID = Materials in draft.
RND = Revision not based on data.
RLD = Revision based on learner data.
RED = Revisions based on expert data.
RBD = Revisions based on both learner and expert data.

Table 4

Results of Analyses: Test Scores (n=187) and Confidence-Weighted Test Scores (n=187)

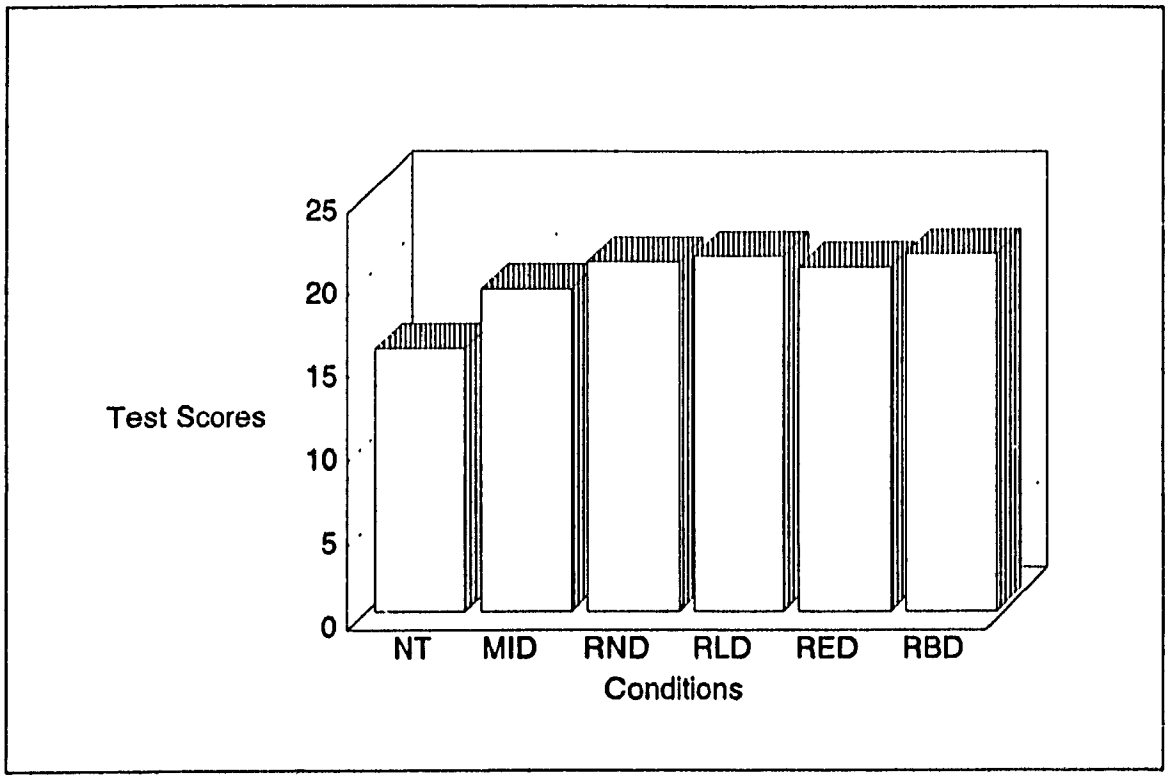
	Formative Evaluation Conditions											
	NT		MID		RND		RLD		RED		RBD	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Test scores[A] (o to 30)	15.70	2.89	19.32	3.64	20.97	3.51	21.32	3.02	20.65	3.95	21.47	3.23
Confidence-weighted test scores[A] (-120 to 120)	7.77	13.37	30.13	19.08	40.39	21.15	44.90	17.94	40 32	25.87	48.23	20 04

Note:

[A]Significant difference was found between MID and RLD and between MID and RBD.

Figure 2

Effectiveness Findings: Mean Test Scores Among Formative Evaluation Conditions

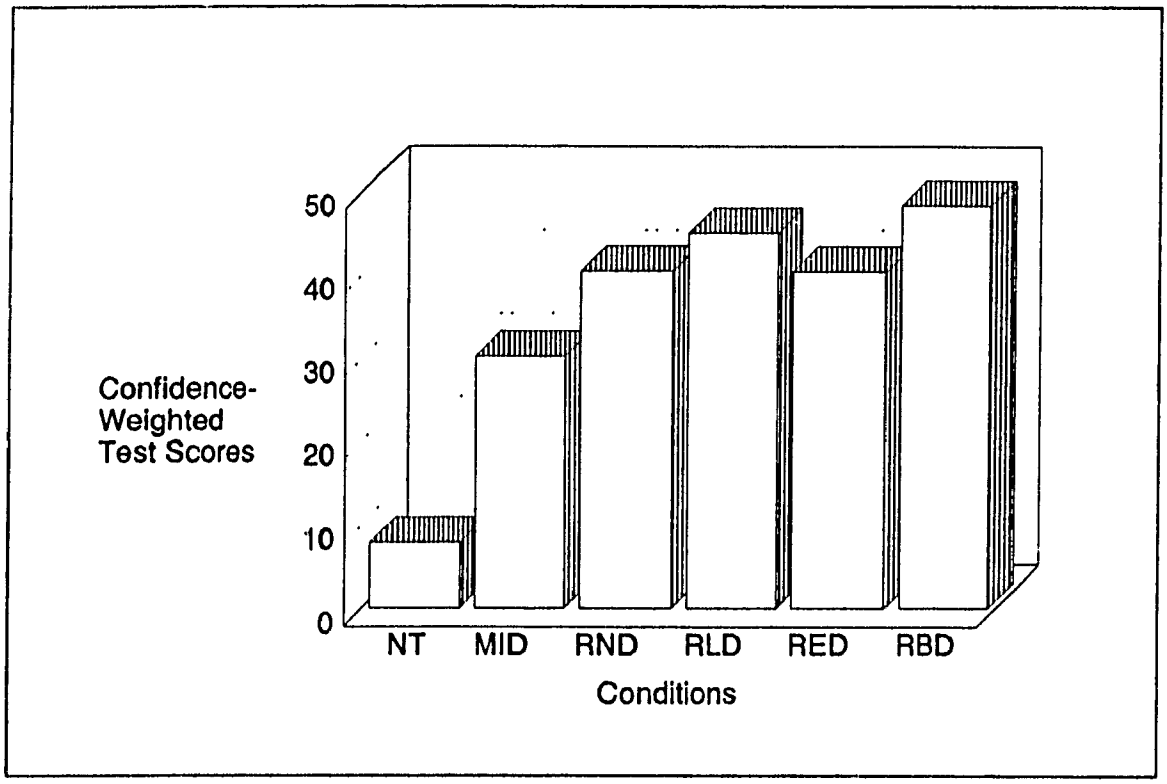


Note: 1. Test scores have a possible range of 0 to 30.

2. RLD and RBD are significantly different from MID. All other differences (with the exception of NT) are not significant.

Figure 3

Effectiveness Findings: Mean Confidence-Weighted Test Scores Among Formative Evaluation Conditions



Note: 1. Confidence-weighted test scores have a possible range of -120 to 120.

2. RLD and RBD are significantly different from MID. All other differences (with the exception of NT) are not significant.

that this difference was not among any of the formative evaluation conditions.

Confidence-weighted Test Scores

A one factor completely randomized ANOVA indicated a significant difference in confidence-weighted test scores across the conditions at $\alpha = .05$, $F(5, 181) = 16.44$, $p<.05$. However, a two-tailed Tukey post-hoc test found that this difference was not among any of the formative evaluation conditions.

Part 2: Cost Findings

Hypothesis 2 (H2)

There are no cost differences among the formative evaluation conditions.

H2 was rejected.

A within group single-factor ANOVA indicated a significant difference in cost estimates among the formative evaluation conditions, $F(3, 21) = 11.17$, $p<.05$. The Univariate F-tests found that RND was the least costly formative evaluation condition. RLD and RED were statistically equivalent in cost and more costly than RND. RBD was the most expensive formative evaluation condition. The progression of conditions, from least to most expensive, was: RND < RED ≈ RLD < RBD. Mean cost estimates for this progression were \$586.25, \$809.38, \$987.50 and \$1300.00 respectively. Cost-estimates are summarised in Table 5 and graphically illustrated in Figure 4.

Table 5

Results of Analyses: Costs (n=8) Among the Formative Evaluation Conditions

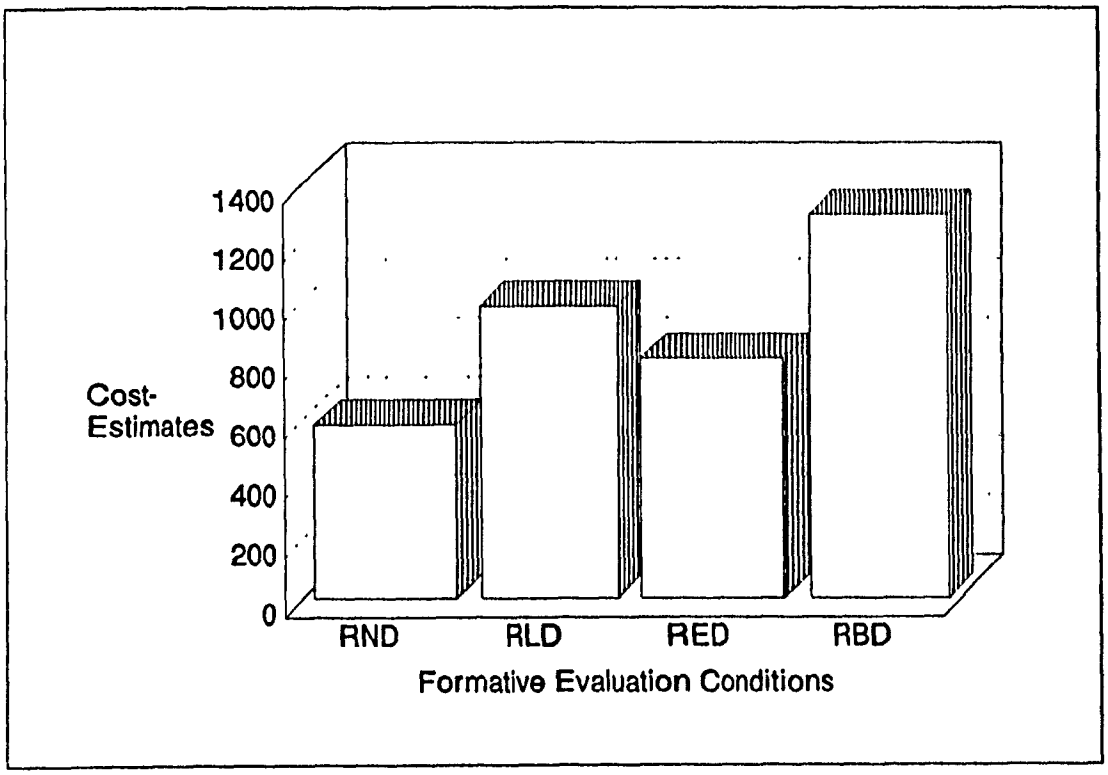
	Formative Evaluation Conditions											
	NT		MID		RND		RLD		RED		RBD	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Costs[A] (in dollars)	---	---	---	---	566	277	809	371	988	513	1300	713

Note:

[A]Significant difference was found between all combinations except RLD and RED.

Figure 4

Cost Findings: Mean Cost-Estimates Among Formative Evaluation Conditions



Note: 1. Cost estimates are in dollars.

2. All cost estimates are significantly different, except RLD and RED.

Part 3: Efficiency Findings

Hypothesis 3 (H3)

There are no efficiency differences among the formative evaluation conditions.

H3 was rejected.

RLD and RBD significantly improved instructional materials when compared to MID, and no significant difference was found between RLD and RBD in terms of effectiveness. However, RBD is significantly more costly than RLD. Therefore, if the intent is to maximize effectiveness and minimize costs, then RLD is the most efficient formative evaluation condition.

CHAPTER 5

DISCUSSION AND CONCLUSION

Overview

Three questions were addressed in this study:

Q1. Which formative evaluation condition most effectively improves instructional materials?
Q2. Which formative evaluation condition is least costly?
Q3. When effectiveness and costs are compared, which formative evaluation condition is most efficient?

In this chapter these questions are answered by examining, qualifying and drawing inferences from the results. In the first section, the main findings are summarised. In the next three sections each research question addressed in this study is examined in detail. In the remaining three sections, recommendations for practitioners are made, the study's contribution to knowledge is reviewed, and limitations are discussed as well as recommendations for future studies.

Summary of Main Findings

The main findings can be summarised as follows. Specific formative evaluation conditions, when compared to MID, significantly improve instructional materials. RLD[1] and RBD generated instructional materials that were significantly more effective than MID. Differences in effectiveness among the formative evaluation conditions were not found. These results were consistent

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[1] All conditions.

NT = No treatment.
MID = Materials in draft.
RND = Revision not based on data.
RLD = Revision based on learner data.
RED = Revisions based on expert data.
RBD = Revisions based on both learner and expert data.

across both measures of effectiveness, that is, test scores and confidence weighted test scores.

Cost differences were found among the formative evaluation conditions. Results indicated three levels of costs. RND was the least costly formative evaluation condition. RLD and RED were statistically equivalent in cost and more costly than RND. RBD was the most costly formative evaluation condition.

A comparison of cost and effectiveness outcomes provided efficiency information. Since RLD and RBD both significantly improved instructional materials when compared to MID and since no significant difference was found between RLD and RBD, then cost became an important factor in determining the most efficient condition. As RBD was significantly more costly than RLD, then RLD was the most efficient formative evaluation condition. These findings are discussed in more detail in the sections to follow.

Interpretation of Effectiveness Findings

The effectiveness of various formative evaluation conditions can be compared in two ways; by making draft-formative-evaluation comparisons and by making among-formative-evaluation comparisons. This distinction was made since information provided by these two types of comparisons is different. Draft-formative-evaluation comparisons provide information as to whether particular formative evaluation conditions are more effective than the MID, whereas among-formative-evaluation comparisons provide information as to whether particular formative evaluation conditions are more effective than others.

Draft-formative-evaluation Comparisons

Both effectiveness measures (i.e., test scores and confidence-weighted test scores) indicated that only the formative evaluation conditions RLD and RBD, when applied to MID, improved instructional materials. This finding is consistent with previous research findings (e.g., Abedor, 1971; Baker, 1970; Kandaswamy, Stolovitch & Thiagarajan, 1976; Wager, 1983) indicating that learner data significantly improve MID.

Previous draft-formative-evaluation studies have only compared learner data to MID while claiming that any kind of formative evaluation will improve instructional materials. However, one cannot assume that *all* conditions will render instructional materials more effective than MID based on these previous findings. As the results of the present study indicate, only the conditions that make use of learner data (i.e., RLD, RBD) improve MID. The implication is that learner data, whether used alone or in combination with other data, will significantly improve MID. It was only through the comparison of combinations of learner and expert data sources that such findings could have surfaced.

A Rationale for the Effectiveness of RLD and RBD

We cannot conclude without asking *why combinations of data that include learners are more effective in formatively evaluating MID.* Nathenson and Henderson (1977) provide two rationales for collecting data from learners and these will be discussed in light of the present findings. (1) Learners may be in a better position to detect problems in the materials than are experts since learners

more closely represent the instructional material's target population (Nathenson & Henderson, 1977). The present findings provide support for this rationale. Since only the formative evaluation conditions that included learner data were effective, then learners must have been more capable of detecting problems in the materials. (2) Experts will frequently detect problems that do not really exist (Nathenson & Henderson, 1977). The present findings cannot validate the accuracy of this assertion. It may indeed be possible that experts detect problems that do not really exist, or it may be that the problems identified by experts do not drastically hinder learning. In order to determine *why* learner data sources are more effective than expert data sources, an in-depth analysis of both the quantity and quality of data produced by these data sources is essential.

Israeloff (1991) compared the quality and quantity of data produced by experts and learners and found that experts identified more problems in the instructional materials whereas learners provided revisers with more detail on the problems they identified. Israeloff's (1992) findings, combined with the findings of the present study, indicate that the qualitative nature of data provided by learners is more effective in improving instructional materials than the quantitative amount of data provided by experts. Experts provide revisers with many problems, but little detail on the nature of such problems whereas learners provide revisers with more detail on identified problems. This allows revisers to more accurately understand the nature of the problem and therefore rectify it. These findings may provide an explanation for the effectiveness of learner conditions.

Among-formative-evaluation Comparisons

The two effectiveness measures did not indicate a difference among the four formative evaluation conditions. This finding is consistent with previous among-formative-evaluation comparisons (e.g., Dupont & Stolovitch, 1983; Golas, 1983). Dupont and Stolovitch (1983) found no significant effectiveness differences on a retention test between instructional materials formatively evaluated with learner data and instructional materials formatively evaluated with expert data. Golas found no significant effectiveness differences on a retention test between instructional materials formatively evaluated with learner data and instructional materials formatively evaluated without external data. These consistent findings strengthen the internal validity of among-formative-evaluation comparisons.

Interpretations of Cost and Efficiency Findings

Formative evaluation is a time-consuming and therefore costly endeavour (e.g., Brenneman, 1989). However, formative evaluation is not equally costly among the four conditions. Since RLD and RBD significantly improved the effectiveness of the MID, and since RLD was less costly than RBD, then RLD was the most efficient formative evaluation condition.

These findings suggest a positive relationship between the number of data sources used and the cost of formative evaluation. Previous findings (e.g., Golas, 1983) support this notion. Although RND requires much work on the part of the revisers, it does not require that any data be collected and therefore is still less expensive than the other conditions. Revisers rated both RLD and RED,

conditions that require data collected from learners or experts, equally expensive and more expensive than RND. Finally, when professional revisers were asked to collect data from learners and experts, they rated RBD as the most expensive condition.

However, collecting data from the least costly source is pointless unless the effectiveness of that source is considered. Previous studies that have examined the efficiency of formative evaluation have assumed that any type of formative evaluation will render materials more effective, therefore the emphasis has been on choosing the least costly method. However, comprehensive effectiveness studies had never been conducted and unless several conditions are compared in the same study, knowledge on the efficiency of formative evaluation is limited.

The *estimation* of costs is another fundamental consideration in determining the efficiency of various conditions (an assumption is made that calculating precise costs is a complex procedure in formative evaluation, therefore we contend with estimates). The accuracy (as opposed to the comprehensiveness) of efficiency analyses should follow from two recommendations: First, costs should not be collected in a research setting. Instead costs should reflect the real market costs of formatively evaluating instructional materials. Second, costs should be expressed in dollars, and not time or effort. Accurate dollar cost estimates may increase the worth of formative evaluation efficiency studies. Practitioners who employ formative evaluation are not interested in costs accrued in a research setting and administrators who budget for formative evaluation are more

concerned about dollar costs than time.

Recommendations for Practitioners

The present research findings coupled with previous findings suggest recommendations for practitioners. These recommendations are directed at professional revisers, editors, instructional designers, instructors, and authors who plan to use formative evaluation when developing or revising instructional materials.

These efficiency recommendations are based on the findings of the present study in the context of the research programme and in the context of the literature. Since the intent was not to develop an extensive description of these recommendations, they have been listed in point form.

1. Collect data from learners because this condition has been found both effective and efficient.
2. Use a small group to collect test data or a dyad to collect verbal feedback data. The dyad requires that two learners work through instructional materials identifying problems in a synchronous and interactive manner (see Medley-Mark & Weston, 1988). The dyad has been found as effective as a small group, more effective than a one-to-one, and less costly than either a small group or a one-to-one (Rahilly, 1991b).
3. Use these data to revise. Since revising is a comprehensive and complex task, an inexperienced reviser is referred to sources such as Debert (1979), Dick and Carey (1990), Gropper (1975) and/or Tessmer (1993) for assistance.

4. Periodically verify the effectiveness of the materials.

Contributions of Study

This study has contributed research-based knowledge on the effectiveness, cost and efficiency of four formative evaluation conditions. With respect to effectiveness, findings indicate that not all formative evaluation conditions significantly improve the effectiveness of materials in draft. Only those that collect data from learners have been found to significantly improve the effectiveness of instructional materials. The internal validity of the effectiveness findings was increased by separating the data collection and revision stages thus making it possible to control revision.

This study also introduced a procedure whereby test scores were weighted for confidence. This procedure is well established in the testing literature (see Anderson, 1982), but was not previously used in formative evaluation studies. As a result of weighing test scores for confidence, an additional measure of effectiveness was provided: confidence-weighted test scores. In this study, confidence-weighted test scores were used to increase the internal validity of the formative evaluation effectiveness findings.

With respect to cost and effectiveness, since differences were found, it was possible to recommend an efficient formative evaluation condition.

Finally, this study provided effectiveness, cost and efficiency knowledge on formative evaluation in a higher education setting. This is an area of education in which little formative evaluation research has been conducted.

Limitations and Recommendations for Future Studies

The limitations of this study suggest recommendations for future studies. The first limitation deals with generalizability and external validity. The research population was restricted to undergraduates. It is not known whether using a different population would have produced similar results. Future studies should be conducted with different populations of learners.

Also, it is uncertain whether results can be generalized to other types of instructional materials. The instructional material used in this study was developed by professors in higher education for undergraduates. Furthermore, it was of a topical nature (i.e., the relationship between diet and cancer is a contemporary concern). Future studies should be conducted with different instructional materials.

This study was only concerned with retention as a measure of effectiveness. Both test scores and confidence-weighted test scores, although providing different information, tested students' ability to remember key concepts in the instructional materials. Future studies should measure learning in other areas (e.g., Dupont & Stolovitch, 1983), since learning incorporates more than just the recollection of information. Future studies should therefore be conducted with different types of effectiveness measures.

Finally, future formative evaluation studies can vary revision rather than data collection. For example, different types of revisers can be compared. Due to the lack of empirical revision research, such exploratory studies would provide

much information on revision and would add to our knowledge of formative evaluation.

Concluding Remarks

Results of this study provide both research and practical implications. With respect to research implications, this study presented a framework for future effectiveness, cost and efficiency analyses. Although many studies have compared the effectiveness of formative evaluation, few have provided information on costs and efficiency. Furthermore, the efficiency framework presented in this study can be altered and applied to a multitude of other areas apart from formative evaluation.

With respect to practical implications, knowledge on the effectiveness, cost and efficiency of formative evaluation was provided. Such knowledge can contribute to the development of a set of validated effectiveness, cost and efficiency guidelines for professional revisers, instructional designers, and course instructors. This may ultimately result in the increased use of formative evaluation and in the improved effectiveness of instructional materials.

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Appendix A:

Materials in draft (MID)

- 1 -

THE DIET CANCER RELATIONSHIP

"Sound nutrition is not a panacea. Good food that provides appropriate proportions of nutrients should not be regarded as a poison, a medicine, or a talisman It should be eaten and enjoyed." This statement by the Food and Nutrition Board of the National Research Council in the U.S in a 1980 publication called "Toward Healthful Diets" raised more than a few eyebrows. Reaction from consumer groups was furiously negative. These groups along with many individuals objected to the conclusion that no specific dietary advice was appropriate for all citizens. The recommendation of a balanced diet with moderation in consumption did not sit well with people who were convinced that a great many of the ills of North American society are related to improper nutrition. A document detailing the evils of food additives, the benefits of vitamin supplementation and the virtues of "organic" foods would undoubtedly have received more favorable reaction. Science however cannot deal with emotions, beliefs or anecdotal evidence; it must be based on facts stemming from well controlled and reproducible experiments. Unfortunately in the area of nutrition it is very difficult to design and carry out studies which lead to conclusive results. Accordingly many reports of results are speckled with phrases like "may cause", "is consistent with", "is associated with"; all of which imply uncertainty. The difficulty of providing "proof" one way or another in the areas of food science and nutrition leaves the door open to a variety of opinions not only among the alarmists and self styled authorities but among nutritional experts as well.

Indeed, just two years after the above mentioned report the National Research Council issued a new document entitled "Diet, Nutrition and Cancer" with more specific recommendations reflecting the state of knowledge and information pertinent to the diet and the incidence of cancer. The guidelines now recommended a reduction of fat intake from about 40% to 30% of total calories, a reduction in the consumption of cured, pickled and smoked foods and an increase in the consumption of whole grain cereal products as well as fruits and vegetables, especially those rich in carotene. Vegetables belonging to the cabbage family were highly recommended but vitamin supplementation was not advised. The new report was in turn also criticized. Many scientists believe that not enough is known about the diet-disease connection to warrant specific guidelines for the population as a whole and furthermore the suggestion was made that if the guidelines were improperly applied they could lead to nutritional deficiencies. In light of the ongoing controversy it is appropriate to examine the studies and the kind of data that have lead to the debated recommendations. An examination of this controversy also serves to underline the need for a basic scientific understanding of chemical and nutritional concepts. Familiarity with terms like "minerals", "vitamins", "fat", "fiber", "carotene" etc. is essential for an objective and critical discussion of the relationship between diet and cancer.

There appears to be little doubt that many cancers are environmentally related. Epidemiological studies have clearly shown large differences in cancer rates between countries. For example, breast and colon cancer rates in many areas of the world are less than one fifth that in North America. The Japanese in turn have the highest incidence of stomach cancer in the world. Immigrants from other countries to the U.S. and Canada however experience the local cancer rates, suggesting an environmental influence.

Perhaps the best demonstration of this environmental effect comes from a study made public in 1984 by the National Cancer Research Institute of Japan. An epidemiological study spanning 16 years and involving over 100,000 men clearly showed that the incidence of cancer was greatest among those who smoked, drank alcohol, ate meat regularly and did not consume vegetables daily. Indeed the absence of vegetables from the diet appeared to increase the risk of a wide variety of cancers. The results of the survey are summarized below:

RELATIVE MORTALITY RATES

Smoking	Drinking	Meat	Vegetables	
No	No	No	Yes	1.0
No	Yes	Yes	No	1.1
Yes	Yes	Yes	Yes	1.7
Yes	Yes	No	No	1.8
Yes	No	Yes	No	1.8
Yes	Yes	Yes	No	2.5

The protective effects of vegetable consumption are dramatically illustrated by the above data; in fact even in the high risk group (smokers, drinkers and meat eaters) the risk of cancer can be reduced by one third if vegetables are regularly eaten. This protective effect may be manifested through the fiber, Vitamin C or carotene components of the vegetables as discussed below.

Accordingly many cancer experts now estimate that as much as 90% of North American cancers are environmentally determined and that a large fraction of these should therefore be avoidable. "Environmental" must not be confused with "man made"; in the present context the word is used to differentiate from "genetic" factors. Cigarette smoking and toxic wastes are environmental and obviously "man made", but exposure to sunlight and the consumption of naturally occurring carcinogens can also be termed "environmental". In fact, Bruce Ames of the University of California (Berkeley) has concluded after a survey of the scientific literature that most of the carcinogens that non-smokers encounter in their daily life come from natural foods and cooking methods. For example celery and parsley contain a carcinogen which becomes activated by light; mushrooms, beans and even alfalfa sprouts contain compounds which may increase the risk of cancer. Cooking, especially when food is browned or burned adds carcinogens to the diet. On the other hand, suggests Ames, food also appears to contain natural anti- carcinogens like Vitamins C and E, selenium and carotene which may decrease the risk of the dreaded disease. The fact that cancer rates aside from those related to smoking have remained almost constant over the years appears to imply that the "natural" components of the environment may be more important than the "man made" factors in inducing cancer.

In a controversial article in Science, 221, 1256 (1983), Ames produced summarized the many natural foods (above) which contained various carcinogens. In this same article, he also indicated that there were many foods which were also anti-carcinogens. The main idea here was that a minimum of the questionable foods coupled with a reasonable amount of the "good" ones (vide infra) would provide as good a balance of risk/benefit as could be achieved in this very complex area. Ames was criticized by a group of 18 academics, union officials and environmentalists in a 1984 letter to Science for "trivializing" cancer risks. Ames recently published a summary of relative risk factors for cancer by a careful (but controversial) examination of the literature. The resulting index called HERP (Human Exposure dose/Rodent Potency dose). This index considers two questions: How much of the material causes considerable rates of cancer in lab animals, and how much of it might an average person be exposed to over a lifetime? The rankings do not predict a person's actual chances of developing cancer, but show comparisons. If the relative ranking of tap water is 1.0, then peanut butter (2 tablespoons/day) is 30

(aflatoxin risk) as is comfrey tea (1 cup/day) (symphytine, a natural pesticide is present). One pack /day of cigarettes is rated at 12,000 while the risk of cancer from PCBs (once used in electrical transformers) is 0.2. Needless to say, such a detailed list has created concern and discussion and will stimulate research in the future.

Since the second World War some 50,000 synthetic chemicals have been introduced into the environment with about 500 new ones coming into use every year. Many of these are mutagenic or carcinogenic in lab tests yet the cancer epidemic that many scientists (even Bruce Ames at one time) have predicted has not materialized. Accordingly there is widespread, though certainly not universal, belief that most cancers are caused by natural carcinogens. Many of these carcinogens are produced by plants as natural pesticides to ward off insects. Ironically the current practice of breeding insect resistant plants in order to minimize the use of synthetic pesticides may actually be introducing new carcinogens into the diet. It is also a fact of course that not everyone gets cancer even though everyone consumes natural carcinogens.The explanation for this apparent inconsistency may lie in the possibility that whereas chemicals isolated from food can cause cancer, the whole food does not. Mutagens and "anti- carcinogens" are often present in the same food. For example the potentially harmful effects of the psoralens in parsley and celery may be counteracted by the carotene and vitamin components of these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment. The following summarizes the current state of knowledge in this important area.

The Dietary Fat-Cancer Relationship

The above mentioned recommendation to reduce the fat content of the diet stems mostly from correlations noted by epidemiologists. A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer. It must be pointed out however that such associations do not imply cause. For example a similar correlation exists between gross national product and breast cancer. Although the "per capita" correlation of dietary fats with cancer is strong, there appears to be no conclusive correlation of individual fat consumption and cancer. There may be other variables in the relationship as well. Hormones like estrogen have been linked with cancer. Does the fact that women are having fewer and later pregnancies influence the average estrogen levels ? Could it be the added calories and not the fat per se which is instrumental? The human feeding studies which would be needed to clarify the situation can never be ethically done but studies in animals do suggest that higher levels of fat intake cause mammary tumors. Theoretically the argument can be put forward that fats cause cancer by undergoing oxidation in cells leading to the production of cancer causing reactive species called free radicals. These free radicals then damage the DNA of the cell, leading to improper replication. If this mechanism is correct, unsaturated fats may pose a greater risk since they are more easily oxidized. Some studies have indeed shown an association between cancer and "trans" fatty acids which are produced when vegetable oils are converted into margarine. Adequate Vitamin E , beta carotene and selenium consumption may prevent the oxidation of fats.

Dr. Keith Ingold at the National Research Council in Ottawa has in fact shown that Vitamin E is the major "free-radical trapping" anti-oxidant in human blood. Beta carotene can also act as an anti-oxidant, especially at low oxygen concentrations such as are found in cells. It is noteworthy that this important research started out as an investigation into why engine oils break down upon exposure to oxygen in the car's engine; a nice demonstration of how important results can come from seemingly "unimportant" research. Similarly the antioxidants BHT and BHA which had originally been developed to prevent fats in cereals from going rancid (and incidentally have been much maligned) may turn out to have an important role in not only the prevention of cancer but in actually slowing down the aging process.

Colon cancer has also been associated with high fat, high cholesterol diets. Once again though, epidemiological studies in individuals have yielded inconsistent results. Animal feeding studies in turn have shown that dietary fat promotes colon cancer. Furthermore, populations with high rates of colon

cancer have increased levels of bile acids in the feces; these have been associated with cancer and are known to be formed in larger amounts in high fat, high cholesterol diets. In summary, the evidence may appear to be somewhat circumstantial, but the recommendation to reduce fat content by 25% does not represent a risk as long as a balanced diet is maintained.

The Cured Foods-Diet Association

Once again population studies have shown that cancers of the stomach and esophagus are more common in countries such as China, Japan and Iceland where the diet is high in foods that are salt cured and smoked. There is no doubt that smoke contains cancer causing compounds and salt has been reported to promote gastric cancer in rats. Sodium nitrite, a pickling agent and preservative used in cold cuts, hot dogs, ham, etc. has been linked with the potential formation of nitrosamines, known carcinogens, in the body. Based upon these observations, limiting the intake of such cured or smoked foods would appear to be wise. Yet, even this recommendation has been challenged. It has been pointed out that the death rate from stomach cancer has been declining in North America while the consumption of processed meats has been rising. Furthermore, nitrite addition is so strictly regulated now that only minimal amounts are used; in fact the amount of nitrite now added can only prevent growth of the clostridium Botulinum organism if it is used in conjunction with salt. It is also true that most of the "smoked" foods presently marketed are smoked with liquid smoke. This is made by passing smoke through water; since the carcinogenic compounds do not dissolve in water foods "smoked" by this process are safer than "naturally" smoked foods. Although credence can be given to these criticisms, it must also be pointed out that foods high in smoke flavor and nitrites are generally high in fat and thus in calories-perhaps enough of a reason to minimize consumption.

The Selenium-Cancer Association

Selenium is a mineral required by the body in "trace" amounts. It plays a role in the activity of the enzyme glutathione peroxidase, an enzyme which protects cells from damage by oxidation. Consistent with this activity is the observation that mammary cancer in rats fed a high polyunsaturated fat diet can be inhibited by selenium. Selenium is found in the soil and is absorbed by crops. High soil selenium areas correlate inversely with cancer but these areas are also less populated and differ from low soil selenium areas in several respects. Indeed lung cancer rates are lower in countries where tobacco contains more selenium. Mexican and Colombian tobaccos have three times as much selenium as American and British tobaccos. Some correlations between blood selenium levels and cancer have also been noted and preliminary research has shown that the selenium content of hair and nails may reflect blood levels. High intake of selenium can be toxic and the presently available information does not warrant the recommendation of supplements.

The Cancer- Vitamin C and E Connection

The evidence for this association is essentially anecdotal although both of these vitamins are anti-oxidants and therefore could behave as anti- carcinogens. Vitamin E has been reported to reduce mutations in some bacterial systems and Vitamin C does block the conversion of nitrites to nitrosamines. For the latter reason Vitamin C is added to hot dogs. Similarly since both tomatoes and lettuce contain Vitamin C they can conceivably do more than just dress up the appearance and flavor of a bacon sandwich. Indeed a BLT may be the best way to consume bacon. There is however no evidence that either Vitamin E or C can prevent cancer.

The Cancer-Vitamin A Connection

Remember the stories about eating carrots to see better? This may be stretching the point, but the vitamin A in carrots does play an essential role in the chemistry of vision. Furthermore, the vitamin and its precursor compound (beta- carotene) may also protect the body against cancer. The rationale for this belief lies in the fact that vitamin A plays an important role in the control of cell differentiation and in that both vitamin A and especially beta-carotene are efficient scavengers of chemical species called free radicals. Since loss of cell differentiation is a basic feature of cancerous cells and since free

radicals are unstable, highly reactive chemicals which can damage our genetic materials (DNA and RNA) there is good reason to suspect that these two nutrients may have a protective effect against cancer.

Vitamin A itself can be obtained from animal products such as liver, eggs and meat or it can by synthesized by the body from. beta carotene. Many green vegetables produce this bright orange compound but the richest sources are pumpkins, spinach and of course carrots.

In 1975 a major epidemiological study showed that Norwegian men consuming more than the average amount of vitamin A had less than half the rate of lung cancer as compared with men having below average consumption of the vitamin. Similar findings were also reported in the following 5 years from scientists in Japan, Singapore and the United States.

A further study (Nov. 1981) published in the British medical journal Lancet supported the hypothesis that the pro-vitamin A (beta carotene) and not the vitamin itself was the beneficial factor. The study showed that there was an inverse relationship between intake of dietary beta-carotene and lung cancer in 1,954 middle aged male smokers over a period of 19 years. Intake of preformed vitamin A did not show a significant effect.

Unfortunately, studies on vitamin A are often limited due to its toxicity. High levels of vitamin A lead to liver damage, headaches, lack of appetite, hair loss, menstrual problems and retarded growth in children -- problems sometimes seen among vitamin and health food faddists. On the other hand, optimal investigative approaches are possible with beta carotene since there are no known serious side effects, even with doses so high as to cause and obvious orange skin coloration. In recent years synthetic analogs of vitamin A have been prepared in an effort to reduce its toxicity. These safer compounds are now being tested with high risk groups to determine if other forms of cancer can be prevented. One such group consists of albino children in Africa who have a 100% risk of developing skin cancer. In addition, at the present time the U.S. National Institute of Health has invited all male physicians between the ages of 40 and 85 to participate as subjects in a placebo-controlled general study of beta- carotene and cancer.

A major report on this issue published in the New England Journal of Medicine, March 1984 (by the Harvard School of Public Health) explained that although the protective effect against lung cancer of beta-carotene is strongly supported by many studies, there are indications that these effects may not apply to other types of cancer.

In conclusion, it should be noted that the main cause of lung cancer, smoking, also increases one's risk of several other serious diseases, including atherosclerosis -- a primary cause of death in North America. However, there is no evidence that either vitamin A or beta carotene affects this condition in any way.

<u>The Cancer-Fiber Connection</u>

Roughage? Unappetizing, tasteless, completely indigestible but... it fights cancer!

It all started with Dr. Dennis Burkitt's 20-year observation of diets and incidence of colorectal cancer in rural Africa. The British surgeon noted that although cancer of the lowest five to six feet of the intestine is very prevalent in the western world it is almost nonexistent among people in Africa consuming a high fiber diet. In Canada, about 100,000 people get colon cancer every year, half of whom die within the same year. The same high frequency of this malignancy has been found in the U.S., Scotland, Denmark and especially New Zealand, countries which consume the highest amounts of meat and animal fat around the world.

The incidence of this type of cancer appears to be 100 times more prevalent in the lowest 1% of the small intestine. This leads scientist to believe that carcinogens are not swallowed with our food but are produced in the colon from material in the feces. It has been suggested that bile acids (biomolecules

naturally released into the gut in response to the presence of fat in the diet) are chemically altered by bacteria to produce carcinogens. High colon cancer areas have been found to be much more abundant in colorectal cancer patients than in control groups. In a recent study conducted by Dr. Tracy Wilkins, a microbiologist at the Virginia Polytechnic Institute in Blacksburg, a chemical mutagen, named faecapentaene, was isolated from the feces of about 20 per cent of the white residents of Johannesburg. The same compound was detected in less than 2 per cent of the rural population. The diet of the urban community is very similar to ours (high in refined carbohydrates and fat), whereas that of the rural population is low in meat and fat and high in fruits and vegetables. Although most carcinogens are mutagens not all mutagens are carcinogens, and therefore the presence of faecapentaene does not necessarily mean that it is the cause of cancer. Dr. David Kingston, a chemist at the Virginia Polytechnic Institute, has synthesized this compound and its cancer-causing potential will now be investigated in laboratory animals.

These findings certainly support the theory that fiber, which increases the rate of feces elimination, should lower one's chances of developing cancer of the colon. . However, there are some inconsistencies in the findings related to the effects of fiber. For instance, in a Canadian study published in 1980 higher consumption of dietary fiber was shown not to have any significant effect on cancer whereas in Puerto Rico high consumption was associated with higher incidence of colon cancer. Such.discrepancies may be related to the extremely heterogeneous nature of dietary fiber. Dietary fiber is a mixture of indigestible chemicals: cellulose, hemicellulose, lignin and pectin.. Preliminary studies have shown that wheat bran and fiber from citrus fruits protect laboratory animals against chemically-induced colon cancer. Since citrus fruits are also an excellent source of vitamin C (a scavenger of carcinogenic free radicals) an orange a day, or even the traditional apple a day, may not be such a bad idea.

GUIDELINES FOR AN ANTICANCER MENU

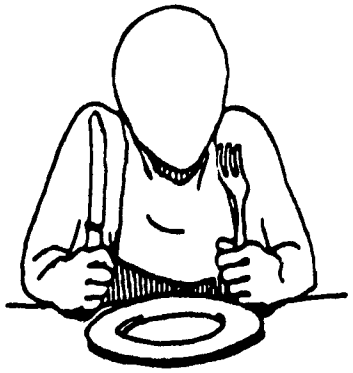
-decrease consumption of fats, nitrite-cured meats, smoked or charcoal-broiled meats and large amounts of alcohol.

-increase consumption of foods rich in dietary fiber,. beta carotene, vitamins A, E and C and the mineral selenium (megadoses of dietary supplements are presently not recommended).

-consume often, cruciferous vegetables such as cabbage, broccoli, Brussels sprouts and cauliflower.

RECENT REVIEW

A recent summary which gives a balanced report is from Scientific American, November, 1987, p. 42.



Appendix B:

Materials revised without data (RND)

1

THE DIET CANCER RELATIONSHIP

Introduction

Do you ever dream that eating pizza, potato chips, and drinking beer does not pose a cancer risk? Well, according to numerous studies, it is not what you eat, but the combinations of foods eaten which may increase or decrease the chances of getting cancer.

The objective of this article is to make people better consumers of food with respect to nutrition and cancer. Some more specific objectives include: You will be able to interpret research findings about the relationship between diet and cancer and to evaluate the conclusions of these research findings. This will allow you to decide for yourself which cancer risks you are willing to live with, and which you are not. Also, you will be able to look at what ever comes up in research studies and be able to link this information to other issues of interest or concern.

In order to achieve these objectives, we will explain what cancer is, what causes cancer, and how a nutritious diet can help prevent cancer. Then, we will differentiate what is meant by "environmental cancers" and "man made" cancers. A brief review of recent cancer research will be discussed and then the relationship between various ingredients in our diet and cancer will be discussed. But first, we will start with a small exercise to quiz knowledge in this complex area.

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Exercise 1: "Hit" or "Miss"

Below is an exercise that examines how much you know about the relationship between diet and cancer. Next to each statement, indicate whether the information is a "hit" (i.e., true) or a "miss" (i.e., false). The answers are on the last page.

(hit or miss)

1. _____ Alcohol consumption increases the risk of cancer.
2. _____ Vitamin A does **not** protect the body against cancer.
3. _____ A reduction in the consumption of cured, pickled and smoked foods is **not** recommended to reduce the risks of cancer.
4. _____ Most cancer-causing carcinogens that non-smokers encounter in their daily life come from natural foods.
5. _____ Fiber in your diet accelerates the formation of certain cancers.

What is Cancer

Cancer is a malignant mass of tissue that spreads in the body. Cancer is caused by loss of cell differentiation and chemical species called free radicals. Loss of cell differentiation is a basic feature of cancerous cells and reactive species called free radicals are unstable, highly reactive chemicals which can damage genetic materials and can cause cancer. Theoretically the argument can be put that cancer is caused when substances undergo oxidation in cells leading to the production of cancer causing reactive species called free radicals.

Some food substances, like fat, cured foods, smoked foods, are carcinogenic; that is, they can cause cancer. Some other food substances, like selenium, vitamins, fiber, are helpful in the prevention of cancer. It appears that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of cancerous synthetic carcinogens in one's diet and in the environment. A good place to start is understanding the difference between "environmental" factors and "man made" factors.

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The "Environmental" and "Man Made" Cancer Debate

There appears to be little doubt that many cancers are environmentally related. Epidemiological studies have clearly shown large differences in cancer rates between countries. For example, breast and colon cancer rates in many areas of the world are less than one fifth that in North America. The Japanese in turn have the highest incidence of stomach cancer in the world. Immigrants from other countries to the U. S. and Canada however experience the local cancer rates, suggesting an environmental influence.

Accordingly many cancer experts now estimate that as much as 90% of North American cancers are environmentally determined and that a large fraction of these should therefore be avoidable. "Environmental" must not be confused with "man made". For example, cigarette smokeing and toxic wastes are "man made", but exposure to sunlight and the consumption of naturally occurring carcinogens can be termed "environmental".

Since the second World War some 50, 000 synthetic chemicals have been introduced into the environment with about 500 new ones coming into use every year. Many of these are mutagenic or carcinogenic in lab tests yet the cancer epidemic that many scientists (even Bruce Ames at one time) have predicted has not materialized. Accordingly there is widespread, though certainly not universal, belief that most cancers are caused by natural carcinogens. Many of these carcinogens are produced by plants as natural pesticides to ward off insects. The explanation for this apparent inconsistency may lie in the possibility that whereas chemicals isolated from food can cause cancer, the whole food does not. Mutagens and "anti-carcinogens" are often present in the same food. For example the potentially harmful effects of the psoralens in parsley and celery may be counteracted by the carotene and vitamin components of these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment. The following summarizes the current state of knowledge in this important area.

Did you know that ...

Ironically the current practice of breeding insect resistant plants in order to minimize the use of synthetic pesticides may actually be introducing new carcinogens into the diet. It is also a fact of course that not everyone gets cancer even though everyone consumes natural carcinogens.

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Research on the Diet Cancer Relationship

Unfortunately in the area of nutrition it is very difficult to design and carry out studies which lead to conclusive results. Accordingly many reports of results are speckled with phrases like "may cause", "is consistent with", "is associated with"; all of which imply uncertainty. The difficulty of providing "proof" one way or another in the areas of food science and nutrition leaves the door open to a variety of opinions not only among the alarmists and self styled authorities but among nutritional experts as well.

In 1982, National Research Council issued a document entitled "Diet, Nutrition and Cancer" with specific recommendations reflecting the state of knowledge and information pertinent to the diet and the incidence of cancer. The guidelines now recommended a reduction of fat intake from about 40% to 30% of total calories, a reduction in the consumption of cured, pickled and smoked foods and an increase in the consumption of whole grain cereal products as well as fruits and vegetables, especially those rich in carotene. Vegetables belonging to the cabbage family were highly recommended but vitamin supplementation was not advised. The new report was in turn also criticized. Many scientists believe that not enough is known about the diet-disease connection to warrant specific guidelines for the population as a whole and furthermore the suggestion was made that if the guidelines were improperly applied they could lead to nutritional deficiencies. In light of the ongoing controversy it is appropriate to examine the studies and the kind of data that have lead to the debated recommendations.

Perhaps a good demonstration of the relationship between cancer and consumed goods comes from a study made public in 1984 by the National Cancer Research Institute of Japan. An epidemiological study spanning 16 years and involving over 100, 000 men clearly showed that the incidence of cancer was greatest among those who smoked, drank alcohol, ate meat regularly and did not consume vegetables daily. Indeed the absence of vegetables from the diet appeared to increase the risk of a wide variety of cancers. The results of the survey are summarized on the next page:

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Relative Mortality Rates

Smoking	Drinking	Meat	Vegetables	
No	No	No	Yes	1. 0
No	Yes	Yes	No	1. 1
Yes	Yes	Yes	Yes	1. 7
Yes	Yes	No	No	1. 8
Yes	No	Yes	No	1. 8
Yes	Yes	Yes	No	2. 5

Note:
1. Your relative mortality rate increases if you smoke, drink, and eat meat.
2. Not all combinations of smoking, drinking, eating meat, and eating vegetables are present. What are some other combinations that may exist? Where would the relative mortality rate of these other combinations fall?

The protective effects of vegetable consumption are dramatically illustrated by the above data; in fact even in the high risk group (smokers, drinkers and meat eaters) the risk of cancer can be reduced by one third if vegetables are regularly eaten. This protective effect may be manifested through the fiber, Vitamin C, or carotene components of the vegetables. Each of these items will be looked at in more detail later on; however, this piece of research demonstrates how eating vegetables can counteract the risks of cancer.

In fact, Bruce Ames of the University of California (Berkeley) has concluded after a survey of the scientific literature that most of the carcinogens that non-smokers encounter in their daily life come from natural foods and cooking methods. For example, celery and parsley contain a carcinogen which becomes activated by light; mushrooms, beans and even alfalfa sprouts contain compounds which may increase the risk of cancer. Cooking, especially when food is browned or burned adds carcinogens to the diet. On the other hand, suggests Ames,

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food also appears to contain natural anti-carcinogens like Vitamins C and E, selenium and carotene which may decrease the risk of the dreaded disease. The fact that cancer rates aside from those related to smoking have remained almost constant over the years appears to imply that the "natural" components of the environment may be more important than the "man made" factors in inducing cancer.

In a controversial article in Science, 221, 1256 (1983), Ames summarized the many natural foods (above) which contained various carcinogens. In this same article, he also indicated that there were many foods which were also anti-carcinogens. The main idea here was that a minimum of the questionable foods coupled with a reasonable amount of the "good" ones (vide infra) would provide as good a balance of risk/benefit as could be achieved in this very complex area. Ames was criticized by a group of 18 academics, union officials and environmentalists in a 1984 letter to Science for "trivializing" cancer risks. Ames recently published a summary of relative risk factors for cancer by a careful (but controversial) examination of the literature. The resulting index was called HERP (Human Exposure dose/Rodent Potency dose). This index considers two questions: How much of the material causes considerable rates of cancer in lab animals, and how much of it might an average person be exposed to over a lifetime? In other words, the index is calculated in two steps. First, the quantity of cancerous material required to cause cancer in lab animals is estimated. Then, the amount of human lifetime exposure to this material is estimated. Therefore, the rankings do not predict a person's actual chances of developing cancer, but show comparisons. If the relative ranking of tap water is 1. 0, then peanut butter (2 tablespoons/day) is 30 (aflatoxin risk) as is comfrey tea (1 cup/day) (symphytine, a natural pesticide is present). One pack /day of cigarettes is rated at 12, 000 while the risk of cancer from PCBs (ones used in electrical transformers) is 0. 2. Needless to say, such a detailed list has created concern and discussion and will stimulate research in the future.

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Table 1: Relative Ranking of Cancerous Materials

tap water	1
peanut butter (2 tablespoons/day)	30
comfrey tea (1 cup/day)	30
One pack/day of cigarettes	12, 000
PCBs (ones used in electrical transformers)	0. 2

Exercise 2: Carcinogenic and Non-Carinogenic Foods

Which of these foods may be carcinogenic? Which are likely non-carcinogenic? The answers are on the last page.

Food	Carcinogenic	Non-carcinogenic
1. smoked meat	___	___
2. carrots	___	___
3. barbecued spare ribs	___	___
4. cabbage	___	___
5. parsley	___	___

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Familiarity with terms like "minerals", "vitamins", "fat, "fiber", "carotene" etc. is essential for an objective and critical discussion of the relationship between diet and cancer.

Table 2

Term	Description	Found in ...
minerals	inorganic substances found in nature	mainly vegetables
vitamins	a group of organic substances necessary for growth and regulation of the body	occur naturally in minute quantities in a variety of plants and meats
fat	organic compounds composed of carbon, hydrogen, and oxygen	meat tissues, dairy products, nuts
fiber	a complex of substances of plant origin that are not absorbed nor digested by humans	roughage, broccoli, beets, bran, apples
carotene	a red or yellow pigment converted by the body into vitamin A	pumpkin, spinach, carrots

These five important ingredients in our diet have been shown to have links with cancer. The next sections look at these ingredients. The ingredients have been grouped into two categories: those that increase the risk of cancer, and those that reduce the risk of cancer.

Evidence of Increasing Diet Cancer Relationship

Diets high in fatty, cured, or smoked foods can increase your chances of developing cancer. The relationship between foods in each of these categories and cancer will be dealt with in more detail below.

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The Dietary Fat-Cancer Relationship

A couple of hamburgers and a fry? Delicious, mouth watering, and fatty! The above mentioned recommendation to reduce the fat content of the diet stems mostly from correlations noted by epidemiologists. A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer. It must be pointed out however that such associations do not imply cause. For example, a similar correlation exists between gross national product and breast cancer. Although the "per capita" correlation of dietary fats with cancer is strong, there appears to be no conclusive correlation of individual fat consumption and cancer. There may be other variables in the relationship as well. In other words, there is no clear connection between diets and cancer. This is because other factors may be involved.

Did you know that ...

Some studies have shown an association between cancer and "trans" fatty acids. These acids, which are easily oxidized, are produced when vegetable oils are converted into margarine.

Hormones like estrogen have been linked with cancer. Does the fact that women are having fewer and later pregnancies influence the average estrogen levels? Could it be the added calories and not the fat per se which is instrumental? The human feeding studies which would be needed to clarify the situation can never be ethically done but studies in animals do suggest that higher levels of fat intake cause mammary tumors. Theoretically the argument can be put forward that fats cause cancer by undergoing oxidation in cells leading to the production of cancer causing reactive species called free radicals. As you read earlier, these free radicals then damage the DNA of the cell, leading to improper replication. Adequate Vitamin E (found in vegetable oils), beta carotene (found in spinach and carrots) and selenium (found in seafood, milk, grains) consumption may prevent the oxidation of fats.

Colon cancer has also been associated with high fat, high cholesterol diets. Once again though, epidemiological studies in individuals have yielded inconsistent results. Animal feeding studies in turn have shown that dietary fat promotes colon cancer. Furthermore, populations with high rates of colon cancer have increased levels of bile acids in the feces; these have been associated with cancer and are known to be formed in larger amounts in high fat, high cholesterol diets. Therefore, the evidence may appear to be somewhat

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circumstantial, but the recommendation to reduce fat content by 25% does not represent a risk as long as a balanced diet is maintained.

The Cured Foods-Diet Association

Pickled vegetables and lean, almost fat-free smoked meat is not unhealthy, right? No, wrong! Once again, population studies have shown that cancers of the stomach and esophagus are more common in countries such as China, Japan and Iceland where the diet is high in foods that are salt cured and smoked. There is no doubt that smoke contains cancer causing compounds and salt has been reported to promote gastric cancer in rats. Sodium nitrite, a pickling agent and preservative used in cold cuts, hot dogs, ham, etc. has been linked with the potential formation of nitrosamines, known carcinogens, in the body.

Yet, even this recommendation has been challenged. It has been pointed out that the death rate from stomach cancer has been declining in North America while the consumption of processed meats has been rising. Furthermore, nitrite addition in foods is so strictly regulated now that only minimal amounts are used.

Did you know that ...

Most of the "smoked" foods presently marketed are smoked with liquid smoke. This is made by passing smoke through water; since the carcinogenic compounds do not dissolve in water, foods "smoked" by this process are safer than "naturally"smoked foods.

Evidence of Decreasing Diet Cancer Relationship

Diets high in selenium, vitamins, and fiber can decrease your chances of developing cancer. The relationship between foods in each of these categories and cancer will be dealt with in more detail below.

The Selenium-Cancer Association

Selenium is a mineral required by the body in "trace" amounts. It plays a role in the activity of the enzyme glutathione peroxidase, an enzyme which protects cells from damage by

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oxidation. Consistent with this activity is the observation that mammary cancer in rats fed a high polyunsaturated fat diet can be inhibited by selenium. Selenium is found in the soil and is absorbed by crops. Indeed lung cancer rates are lower in countries where tobacco contains more selenium. High soil selenium areas correlate inversely with cancer but these areas are also less populated and differ from low soil selenium areas in several respects. Mexican and Colombian tobaccos have three times as much selenium as American and British tobaccos. Some correlations between blood selenium levels and cancer have also been noted and preliminary research has shown that the selenium content of hair and nails may reflect blood levels. High intake of selenium can be toxic and the presently available information does not warrant the recommendation of supplements.

The Cancer- Vitamin C and E Connection

There is no evidence that either Vitamin E or C can prevent cancer. The evidence for this is essentially anecdotal although both of these vitamins are antioxidants and therefore could behave as anti-carcinogens. Vitamin E has been reported to reduce mutations in some bacterial systems and Vitamin C does block the conversion of nitrites to nitrosamines. For the latter reason Vitamin C is added to hot dogs. Similarly since both tomatoes and lettuce contain Vitamin C they can conceivably do more than just dress up the appearance and flavor of a bacon sandwich. Indeed a BLT may be the best way to consume bacon. Since citrus fruits are also an excellent source of vitamin C (a scavenger of carcinogenic free radicals) an orange a day, or even the traditional apple a day, may not be such a bad idea.

Dr. Keith Ingold at the National Research Council in Ottawa has in fact shown that Vitamin E is the major "free-radical trapping" anti-oxidant in human blood. Beta carotene can also act as an antioxidant, especially at low oxygen concentrations such as are found in cells. It is noteworthy that this important research started out as an investigation into why engine oils break down upon exposure to oxygen in the car's engine: a nice demonstration of how important results can come from seemingly "unimportant" research.

Did you know that ...

The antioxidants BHT and BHA were originally developed to prevent fats in cereals from going rancid. This may turn out to have an important role in not only the prevention of cancer but in actually slowing down the aging

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The Cancer-Vitamin A Connection

Remember the stories about eating carrots to see better? This may be stretching the point, but the vitamin A in carrots does play an essential role in the chemistry of vision. Furthermore, the vitamin and its precursor compound (beta-carotene) may also protect the body against cancer. The rationale for this belief lies in the fact that vitamin A plays an important role in the control of cell differentiation and in that both vitamin A and especially beta-carotene are efficient scavengers of chemical species called free radicals. Since loss of cell differentiation is a basic feature of cancerous cells and since free radicals are unstable highly reactive chemicals which can damage our genetic materials (DNA and RNA), there is good reason to suspect that these two nutrients may have a protective effect against cancer. Vitamin A itself can be obtained from animal products such as liver, eggs and meat or it can by synthesized (that is, manufactured) by the body from beta carotene. Many green vegetables produce this bright orange compound but the richest sources are pumpkins, spinach and, of course, carrots.

In 1975 a major epidemiological study showed that Norwegian men consuming more than the average amount of vitamin A had less than half the rate of lung cancer as compared with men having below average consumption of the vitamin. Similar findings were also reported in the following 5 years from scientists in Japan, Singapore and the United States.

A further study (Nov. 1981) published in the British medical journal Lancet supported the hypothesis that beta carotene, and not vitamin A itself, was the beneficial factor in fighting cancer. However, a major report on this issue published in the New England Journal of Medicine, March 1984 (by the Harvard School of Public Health) explained that although the protective effect against lung cancer of beta-carotene is strongly supported by many studies, there are indications that these effects may not apply to other types of cancer. In other words, beta carotene may protect the body against lung cancer, but it does not protect the body against other types of cancers.

Unfortunately, studies on vitamin A are often limited due to its toxicity. High levels of vitamin A lead to liver damage, headaches, lack of appetite, hair loss, menstrual problems and retarded growth in children -- problems sometimes seen among vitamin and health food faddists. On the other hand, optimal investigative approaches are possible with beta carotene since there are no known serious side effects, even with doses so high as to cause an obvious

orange skin coloration. In recent years synthetic analogs of vitamin A have been prepared in an effort to reduce its toxicity. These safer compounds are now being tested with high risk groups to determine if other forms of cancer can be prevented. One such group consists of albino children in Africa who have a 100% risk of developing skin cancer. In addition, at the present time the U. S. National Institute of Health has invited all male physicians between the ages of 40 and 85 to participate as subjects in a placebo-controlled general study of beta-carotene and cancer.

The Cancer-Fiber Connection

Roughage? Unappetizing, tasteless, completely indigestible but... it fights cancer! Dietary fiber is a mixture of indigestible chemicals:cellulose, hemicellulose, lignin and pectin.

It all started with Dr. Dennis Burkitt's 20 year observation of diets and incidence of colorectal cancer in rural Africa. The British surgeon noted that although cancer of the lowest five to six feet of the intestine is very prevalent in the western world it is almost nonexistent among people in Africa consuming a high fiber diet. In Canada, about 100, 000 people get colon cancer every year, half of whom die within the same year. The same high frequency of this malignancy has been found in the U.S., Scotland, Denmark and especially New Zealand, countries which consume the highest amounts of meat and animal fat around the world.

The incidence of this type of cancer appears to be 100 times more prevalent in the lowest 1% of the small intestine. This leads scientists to believe that carcinogens are not swallowed with our food but are produced in the colon from material in the feces. It has been suggested that bile acids (biomolecules naturally released into the gut in response to the presence of fat in the diet) are chemically altered by bacteria to produce carcinogens. In a recent study conducted by Dr. Tracy Wilkins, a microbiologist at the Virginia Polytechnic Institute in Blacksburg, looked at to what extent intestinal cancer is caused by things we eat or by some kind of process. Dr. David Kingston, a chemist at the Virginia Polytechnic Institute, has synthesized this compound and its cancer-causing potential will now be investigated in laboratory animals.

These findings certainly support the theory that fiber, which increases the rate of feces elimination, should lower one's chances of developing cancer of the colon. However, there

are some inconsistencies in the findings related to the effects of fiber. For instance, in a Canadian study published in 1980 higher consumption of dietary fiber was shown not to have any significant effect on cancer whereas in Puerto Rico high consumption was associated with higher incidence of colon cancer. Such discrepancies may be related to the extremely heterogeneous nature of dietary fiber. Preliminary studies have shown that wheat bran and fiber from citrus fruits protect laboratory animals against chemically-induced colon cancer.

GUIDELINES FOR AN ANTICANCER MENU

-decrease consumption of fats, nitrite-cured meats, smoked or charcoal-broiled meats and large amounts of alcohol

-increase consumption of foods rich in dietary fiber, beta carotene, vitamins A, E and C and the mineral selenium (megadoses of dietary supplements are presently not recommended).

-consume often vegetables such as cabbage, broccoli, brussel sprouts and cauliflower.

Exercise 3: An Anticancer Meal

Develop an anticancer meal: breakfast, lunch or dinner. Give a rationale why you chose each food item on your meal. Remember, a minimum of the questionable foods coupled with a reasonable amount of the "good" ones provides as good a balance of risk/benefit as can be achieved.

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FURTHER READING

A recent summary which gives a balanced report is from Scientific American, November, 1987, p. 42.

ANSWERS TO THE EXERCISES

Exercise 1

(hit or miss)

1. ___*hit*_____ Alcohol consumption increases the risk of cancer.
2. ___*miss*____ Vitamin A does **not** protect the body against cancer.
3. ___*miss*____ A reduction in the consumption of cured, pickled and smoked foods is **not** recommended to reduce the risks of cancer.
4. ___*hit*_____ Most cancer-causing carcinogens that non-smokers encounter in their daily life come from natural foods.
5. ___*miss*____ Fiber in your diet accelerates the formation of certain cancers.

Exercise 2

Food	Carcinogenic	Non-carcinogenic
1. smoked meat	_x_	___
2. carrots	___	_x_
3. barbecued spare ribs	_x_	___
4. cabbage	___	_x_
5. parsley	_x_	_x_

Appendix C:

Materials revised with learner data (RLD)

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The Diet Cancer Relationship

"Sound nutrition is not a panacea. Good food that provides appropriate proportions of nutrients should not be regarded as a poison, a medicine, or a talisman. It should be eaten and enjoyed. "This statement by the Food and Nutrition Board of the National Research Council in the U.S. in a 1980 publication called "Toward Healthful Diets" raised more than a few eyebrows. Reaction from consumer groups was furiously negative. These groups along with many individuals objected to the conclusion that no specific dietary advice was appropriate for all citizens. The recommendation of a balanced diet with moderation in consumption did not sit well with people who were convinced that a great many of the ills of North American society are related to improper nutrition. A document detailing the evils of food additives, the benefits of vitamin supplementation and the virtues of "organic" foods would undoubtedly have received more favourable reaction.

The purpose of this article is to review the relationship between food consumption (that is, diet) and cancer. To do so, first, a review of diet-cancer research is provided, and second, the relationship between cancer and (1) fat, (2) **selenium**[1], (3) vitamins, and (4) fiber will be discussed. Guidelines for an anti-cancer menu are provided at the end.

Selenium: non-metallic elements often found in sulphur ores

Diet-Cancer Research

Science cannot deal with emotions, belief or anecdotal evidence; it must be based on facts stemming from well controlled and reproducible experiments. Unfortunately in the area of nutrition it is very difficult to design and carry out studies which lead to conclusive results. Accordingly many reports of results are

[1] Words with a star(*) are defined beside the text.

speckled with phrases like "may cause", "is consistent with", "is associated with"; all of which imply uncertainty. The difficulty of providing "proof" one way or another in the areas of food science and nutrition leaves the door open to a variety of opinions not only among the alarmists and self styled authorities but among nutritional experts as well.

National Research Council

Indeed, just two years after the above mentioned report the National Research Council issued a new document entitled "Diet,Nutrition and Cancer" with more specific recommendations reflecting the state of knowledge and information pertinent to the diet and the incidence of cancer. The guidelines now recommended a reduction of fat intake from about 40% to 30% of total calories, a reduction in the consumption of cured, pickled and smoked foods and an increase in the consumption of whole grain cereal products as well as fruits and vegetables, especially those rich in carotene. Vegetables belonging to the cabbage family were highly recommended but vitamin supplementation was not advised. The new report was in turn also criticized. Many scientists believe that not enough is known about the diet-disease connection to warrant specific guidelines for the population as a whole and furthermore the suggestion was made that if the guidelines were improperly applied they could lead to nutritional deficiencies. In light of the ongoing controversy it is appropriate to examine the studies and the kind of data that have lead to the debated recommendations. An examination of this controversy also serves to underline the need for a basic scientific understanding of chemical and nutritional concepts. Familiarity with terms like "**minerals**", "**vitamins**", "**fat**", "**fiber**", "**carotene**" etc. is essential for an objective and critical discussion of the relationship between diet and cancer.

Minerals: inorganic substances found in nature

Vitamins: a group of organic substances necessary for growth and regulation of the body

Fat: organic compounds composed of carbon, hydrogen, and oxygen

Fiber: a complex of substances of plant origin that are not absorbed nor digested by humans

Carotene: a red or yellow pigment converted by the body into vitamin A

3

Environmentally Related Cancers

There appears to be little doubt that many cancers are environmentally related. Epidemiological studies have clearly shown large differences in cancer rates between countries. For example, breast and colon cancer rates in many areas of the world are less than one fifth that in North America. The Japanese in turn have the highest incidence of stomach cancer in the world.

Immigrants from other countries to the U.S. and Canada however experience the local cancer rates, suggesting an environmental influence. This is because many of North America's immigrants take on eating habits similar to those of the local population.

Perhaps the best demonstration of this environmental effect comes from a study made public in 1984 by the National Cancer Research Institute of Japan. An epidemiological study spanning 16 years and involving over 100,000 men clearly showed that the incidence of cancer was greatest among those who smoked, drank alcohol, ate meat regularly and did not consume vegetables daily. Indeed the absence of vegetables from the diet appeared to increase the risk of a wide variety of cancers. The results of the survey are summarized below.

Table 1
Relative Mortality Rates

If you. . .				Then your relative mortality rate is...
Smoke	Drink Alcohol	Eat Meat	Eat Vegetables	
No	No	No	Yes	1. 0
No	Yes	Yes	No	1. 1
Yes	Yes	Yes	Yes	1. 7
Yes	Yes	No	No	1. 8
Yes	No	Yes	No	1. 8
Yes	Yes	Yes	No	2. 5

The protective effects of vegetable consumption are dramatically illustrated by the above data; in fact even in the high risk group (smokers, drinkers and meat eaters) the risk of cancer can be reduced by one third if vegetables are regularly eaten. This protective effect may be manifested through the fiber, Vitamin C, or carotene components of the vegetables as discussed below.

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Environmental Vs. "Man-Made" Cancers

Many cancer experts now estimate that as much as 90% of North American cancers are environmentally determined and that a large fraction of these should therefore be avoided. "Environmental" must not be confused with "man made". Cigarette smokeing and toxic wastes are obviously "man made", whereas exposure to sunlight and the consumption of naturally occurring **carcinogens** can be termed "environmental".

Carcinogens: any substance or agent that causes cancer

In fact, Bruce Ames of the University of California (Berkeley) has concluded after a survey of the scientific literature that most of the carcinogens that non-smokers encounter in their daily life come from natural foods and cooking methods. For example, celery and parsley contain a carcinogen which becomes activated by light; mushrooms, beans and even alfalfa sprouts contain compounds which may increase the risk of cancer. Cooking, especially when food is browned or burned, adds carcinogens to the diet. On the other hand, suggests Ames, food also appears to contain natural **anti-carcinogens** like Vitamins C and E, selenium and carotene which may decrease the risk of the dreaded disease. The fact that cancer rates aside from those related to smoking have remained almost constant over the years appears to imply that the "natural" components of the environment may be more important than the "man made" factors in inducing cancer.

Anti-carcinogens: any substance or agent that prevents cancer

Bruce Ame's Study

In a controversial article in Science, 221,1256 (1983), Ames summarized the many natural foods which contained various carcinogens, such as celery, parsley, beans, mushrooms, etc. . In this same article, he also indicated that there were many foods which were also anti-carcinogens, such as carrots. The main idea here was that a minimum amount of cancerous foods

coupled with a reasonable amount of the anti-cancerous foods would provide a good risk/benefit balance.

However, Ames was criticized by a group of 18 academics, union officials and environmentalists in a 1984 letter to Science for "trivializing" cancer risks. Ames recently published a summary of relative risk factors for cancer by a careful (but controversial) examination of the literature. The resulting index called HERP (Human Exposure dose/Rodent Potency dose). This index considers two questions: How much of the material causes considerable rates of cancer in lab animals, and how much of it might an average person be exposed to over a lifetime? The rankings do not predict a person's actual chances of developing cancer, but show comparisons. If the relative ranking of tap water is 1. 0, then peanut butter (2 tablespoons/day) is 30 (aflatoxin risk) as is comfrey tea (1 cup/day) (symphytine, a natural pesticide is present). One pack /day of cigarettes is rated at 12,000 while the risk of cancer from PCBs (once used in electrical transformers) is 0. 2. Needless to say, such a detailed list has created concern and discussion and will stimulate research in the future.

Contemporary Diet-Cancer Situation

Since the second World War some 50,000 synthetic chemicals have been introduced into the environment with about 500 new ones coming into use every year. Many of these are mutagenic or carcinogenic in lab tests yet the cancer epidemic that many scientists (even Bruce Ames at one time) have predicted has not materialized. Accordingly there is widespread,though certainly not universal, belief that most cancers are caused by natural carcinogens. Many of these carcinogens are produced by plants as natural pesticides to ward off insects. Ironically the current practice of breeding insect resistant plants in order to minimize the use of synthetic pesticides may actually be introducing new

carcinogens into the diet. It is also a fact of course that not everyone gets cancer even though everyone consumes natural carcinogens. The explanation for this apparent inconsistency may lie in the possibility that whereas chemicals isolated from food can cause cancer, the whole food does not. Mutagens and "anti- carcinogens" are often present in the same food. For example, the potentially harmful effects of the psoralens in parsley and celery may be counteracted by the carotene and vitamin components of these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment. The following summarizes the current state of knowledge in this important area.

The Dietary Fat-Cancer Relationship

A couple of hamburgers and fries? Delicious, mouth watering, and fatty!

The need to reduce the fat content of the diet stems mostly from correlations noted by epidemiologists. A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer. It must be pointed out however that such associations do not imply cause. Although the "per capita"correlation of dietary fats with cancer is strong, there appears to be no conclusive correlation of individual fat consumption and cancer. For example a similar correlation exists between gross national product and breast cancer. However, an increase in gross national product does not imply a direct increase in breast cancer, there are other variables in the relationship as well.

Hormones like estrogen have been linked with cancer. Does the

fact that women are having fewer and later pregnancies influence the average estrogen levels? Could it be the added calories and not the fat per se which is instrumental? The human feeding studies which would be needed to clarify the situation can never be ethically done but studies in animals do suggest that higher levels of fat intake cause mammary tumours. Theoretically the argument can be put forward that fats cause cancer by undergoing oxidation in cells. An example of this is when vegetable oils are converted into margarine. However, adequate Vitamin E, beta carotene and selenium consumption may prevent the oxidation of fats.

Dr. Keith Ingold at the National Research Council in Ottawa has in fact shown that Vitamin E is the major anti-oxidant in human blood. Beta carotene can also act as an antioxidant, especially at low oxygen concentrations such as are found in cells. It is noteworthy that this important research started out as an investigation into why engine oils break down upon exposure to oxygen in the car's engine; a nice demonstration of how important results can come from seemingly "unimportant" research. Similarly the antioxidants BHT and BHA which had originally been developed to prevent fats in cereals from going rancid may turn out to have an important role in the prevention of cancer.

Colon cancer has also been associated with high fat, high cholesterol diets. Once again though, epidemiological studies in individuals have yielded inconsistent results. Animal feeding studies in turn have shown that dietary fat promotes colon cancer. Furthermore, populations with high rates of colon cancer have increased levels of bile acids in the feces; these have been associated with cancer and are known to be formed in larger amounts in high fat, high cholesterol diets. In summary, the evidence may appear to be somewhat **circumstantial**, but the recommendation to reduce fat content by 25% does not

Circumstantial: not supported by evidence

represent a risk as long as a balanced diet is maintained.

The Cured Foods-Diet Relationship

Pickled vegetables and lean, almost fat-free smoked meat is not unhealthy right? Wrong!

Population studies have shown that cancers of the stomach and esophagus are more common in countries such as China, Japan and Iceland where the diet is high in foods that are salt cured and smoked. There is no doubt that smoke contains cancer causing compounds and salt has been reported to promote gastric cancer in rats. Sodium nitrite, a pickling agent and preservative used in cold cuts, hot dogs, ham, etc., has been linked with the potential formation of **nitrosamines**, known carcinogens, in the body. Based upon these observations, limiting the intake of such cured or smoked foods would appear to be wise. Yet, even this recommendation has been challenged. It has been pointed out that the death rate from stomach cancer has been declining in North America while the consumption of processed meats has been rising. Furthermore,nitrite addition is so strictly regulated now that only minimal amounts are used; in fact the amount of nitrite now added can only prevent growth of the Clostridium Botulinum organism if it is used in conjunction with salt. It is also true that most of the "smoked" foods presently marketed are smoked with liquid smoke. This is made by passing smoke through water; since the carcinogenic compounds do not dissolve in water, foods "smoked" by this process are safer than "naturally" smoked foods. Although credence can be given to these criticisms, it must also be pointed out that foods high in smoke flavour and nitrites are generally high in fat - perhaps enough of a reason to minimize consumption.

Nitrosamines: compounds containing -NO and $-NH_2$

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The Selenium-Cancer Relationship

Selenium, a mineral required by the body in "trace" amounts, is found in the soil and is absorbed by crops. Research studies have shown that high soil selenium areas correlate inversely with cancer. Indeed lung cancer rates are lower in countries where tobacco contains more selenium. Some correlations between blood selenium levels and cancer have also been noted and preliminary research has shown that the selenium content of hair and nails may reflect blood levels. However, high intake of selenium can be toxic and the presently available information does not warrant the recommendation of supplements.

The Cancer- Vitamin C and E Relationship

The evidence for this association is essentially anecdotal although both of these vitamins are antioxidants and therefore could behave as anti-carcinogens. Vitamin E has been reported to reduce mutations in some bacterial systems and Vitamin C does block the conversion of nitrites to nitrosamines. For the latter reason Vitamin C is added to hot dogs. Similarly since both tomatoes and lettuce contain Vitamin C they can conceivably do more than just dress up the appearance and flavour of a bacon sandwich. Indeed a BLT may be the best way to consume bacon. There is however no evidence that either Vitamin E or C can prevent cancer.

Table 2
Vitamin C and Vitamin E: A Comparison

Vitamin C	Vitamin E
- antioxidant	- antioxidant
- behave as anti-carcinogens	- behave as anti-carcinogens
- blocks the conversion of nitrates to nitrosamines	- reduces mutations in some bacterial bacterial systems

The Cancer-Vitamin A Relationship

Remember the stories about eating carrots to see better?

This may be stretching the point, but the vitamin A in carrots does play an essential role in the chemistry of vision. Furthermore, the vitamin and its precursor compound, beta-carotene may also protect the body against cancer. The rational for this belief lies in the fact that vitamin A plays an important role in the control of cell differentiation and in that both vitamin A and especially beta-carotene are efficient scavengers of chemical species called free radicals Since loss of cell differentiation is a basic feature of cancerous cells and since free radicals are unstable highly reactive chemicals which can damage our genetic materials (DNA and RNA), there is good reason to suspect that these two nutrients may have a protective effect against cancer.

Vitamin A itself can be obtained from animal products such as liver, eggs and meat or it can by synthesized by the body from

beta carotene. Many green vegetables produce this bright orange compound but the richest sources are pumpkins, spinach and, of course, carrots.

In 1975 a major epidemiological study showed that Norwegian men consuming more than the average amount of vitamin A had less than half the rate of lung cancer as compared with men having below average consumption of the vitamin. Similar findings were also reported in the following 5 years from scientists in Japan, Singapore and the United States.

A further study (Nov. 1981) published in the British medical journal Lancet supported the hypothesis that the pro-vitamin A (beta carotene)and not the vitamin itself was the beneficial factor. The study showed that there was an inverse relationship between intake of dietary beta-carotene and lung cancer in 1,954 middle aged male smokers over a period of 19 years. Intake of preformed vitamin A did not show a significant effect.

Unfortunately, studies on vitamin A are often limited due to its **toxicity**. High levels of vitamin A lead to liver damage, headaches, lack of appetite, hair loss, menstrual problems and retarded growth in children -- problems sometimes seen among vitamin and health food faddists. On the other hand, optimal investigative approaches are possible with beta carotene since there are no known serious side effects, even with doses so high as to cause an obvious orange skin coloration. In recent years synthetic analogs of vitamin A have been prepared in an effort to reduce its toxicity. These safer compounds are now being tested with high risk groups to determine if other forms of cancer can be prevented. One such group consists of albino children in Africa who have a 100% risk of developing skin cancer. In addition, at the present time the U.S. National Institute of Health has invited all male physicians between the ages of 40 and 85 to participate as subjects in a

Toxicity: the poisonous quality of a substance

placebo-controlled general study of beta- carotene and cancer.

A major report on this issue published in the New England Journal of Medicine, March 1984 (by the Harvard School of Public Health) explained that although the protective effect against lung cancer of beta-carotene is strongly supported by many studies, there are indications that these effects may not apply to other types of cancer.

In conclusion, it should be noted that the main cause of lung cancer, smoking, also increases one's risk of several other serious diseases, including atherosclerosis -- a primary cause of death in North America. However, there is no evidence that either vitamin A or beta carotene affects this condition in any way.

The Cancer-Fiber Relationship

Roughage? Unappetizing, tasteless, completely indigestible but... it fights cancer!

It all started with Dr. Dennis Burkitt's 20 year observation of diets and incidence of colorectal cancer in rural Africa. The British surgeon noted that although cancer of the lowest five to six feet of the intestine is very prevalent in the western world it is almost nonexistent among people in Africa consuming a high fiber diet. In Canada, about 100,000 people over 45 years of age, get colon cancer every year, half of whom die within the same year.

The same high frequency of this malignancy has been found in the U.S., Scotland, Denmark and especially New Zealand, countries which consume the highest amounts of meat and animal fat around the world.

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The incidence of this type of cancer appears to be 100 times more prevalent in the lowest 1% of the small intestine. This leads scientists to believe that carcinogens are not swallowed with our food but are produced in the colon from material in the feces. It has been suggested that bile acids (biomolecules naturally released into the gut in response to the presence of fat in the diet) are chemically altered by bacteria to produce carcinogens. High colon cancer areas have been found to be much more abundant in colorectal cancer patients than in **control groups**. In a recent study conducted by Dr. Tracy Wilkins, a microbiologist at the Virginia Polytechnic Institute in Blacksburg, a chemical mutagen, named faecapentaene, was isolated from the feces of about 20 per cent of the white residents of Johannesburg. The same compound was detected in less than 2 percent of the rural population. The diet of the urban community is very similar to ours (high in refined carbohydrates and fat), whereas that of the rural population is low in meat and fat and high in fruits and vegetables. Although most carcinogens are mutagens not all mutagens are carcinogens, and therefore the presence of faecapentaene does not necessarily mean that it is the cause of cancer. Dr. David Kingston, a chemist at the Virginia Polytechnic Institute, has synthesized this compound and its cancer-causing potential will now be investigated in laboratory animals.

Control group: group not given a treatment in an experiment

These findings certainly support the theory that fiber, which increases the rate of feces elimination, should lower one's chances of developing cancer of the colon. However, there are some inconsistencies in the findings related to the effects of fiber. For instance, in a Canadian study published in 1980 higher consumption of dietary fiber was shown not to have any significant effect on cancer whereas in Puerto Rico high consumption was associated with higher incidence of colon cancer. Such discrepancies may be related to the extremely heterogeneous nature of dietary fiber. Dietary fiber is a mixture

of indigestible chemicals:cellulose, hemicellulose, lignin and pectin. Preliminary studies have shown that wheat bran and fiber from citrus fruits protect laboratory animals against chemically-induced colon cancer. Since citrus fruits are also an excellent source of vitamin C (a scavenger of carcinogenic free radicals) an orange a day, or even the traditional apple a day, may not be such a bad idea.

Summary

In summary:

It is very difficult to design and carry out studies which lead to conclusive results in the area of nutrition.

Recommendations include a) a reduction of fat intake from about 40% to 30% of total calories, b) a reduction in the consumption of cured, pickled and smoked foods, c) an increase in the consumption of whole grain cereal products, d) an increase in the consumption of vegetables belonging to the cabbage family.

Vitamin supplementation is not advised.

Many cancers are environmentally related and "natural" components of the environment may be more important than the "man made" factors in inducing cancer.

Some natural foods, such as celery, parsley, beans, mushrooms, etc., contain various carcinogens whereas there are many foods, such as carrots, which contain anti-carcinogens.

A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer.

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Smoked-foods and cured-foods contain cancer causing compounds and salt has been reported to promote gastric cancer.

Selenium areas correlate inversely with cancer.

Both Vitamin C and Vitamin E are antioxidants and therefore could behave as anti-carcinogens.

Vitamin A, and its precursor compound beta-carotene, may also protect the body against cancer.

Fiber fights cancer.

The main idea is that a minimum of the questionable foods coupled with a reasonable amount of the "good" ones should provide as good a balance of risk/benefit as can be achieved in this very complex area.

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Guidelines for an Anti-Cancer Menu

Table 3
The "Do's and Don't's" of an Anti-Cancer Menu

Do ...

... increase consumption of foods rich in dietary fiber,. beta carotene,vitamins A, E and C and the mineral selenium

... consume often, cruciferous vegetables such as cabbage, broccoli, brussel sprouts and cauliflower.

Don't ...

... consume megadoses of dietary supplements

... consume many foods that contain fat

... consume too much nitrite-cured meats, smoked or charcoal-broiled meats and large amounts of alcohol

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Recent Review

A recent summary which gives a balanced report is from
Scientific American, November, 1987, p. 42.

Appendix D:

Materials revised with expert data (RED)

1

THE DIET CANCER RELATIONSHIP

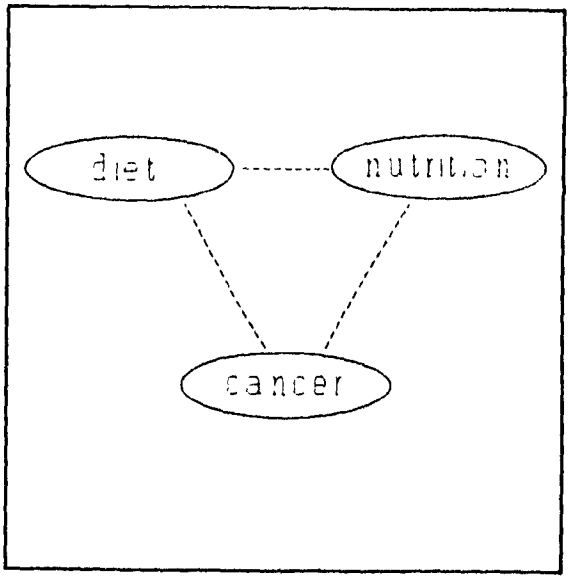
Do you ever dream that eating pizza, potato chips, and drinking beer does not pose a cancer risk? Well, according to numerous studies, it is not what you eat, but the combinations of foods eaten which may increase or decrease the chances of getting cancer.

The objective of this article is to make people better consumers of food with respect to nutrition and cancer. Some more specific objectives include: You will be able to interpret research findings about the relationship between diet and cancer and to evaluate the conclusions of these research findings. This will allow you to decide for yourself which cancer risks you are willing to live with, and which you are not. Also, you will be able to look at what ever comes up in research studies and be able to link this information to other issues of interest or concern.

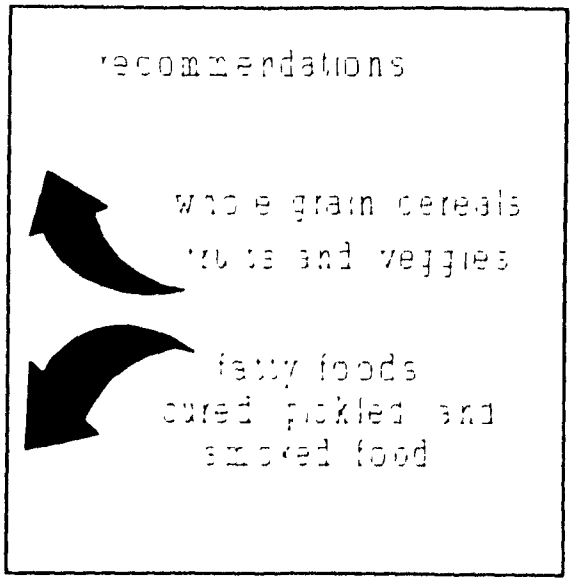
In order to achieve these objectives, we will look at some recommendations made by the National Research Council in the U.S.; we will discuss some international research finding; and we will also discuss some North American research findings. Then, we will examine the relationship between fat and cancer, cured foods and cancer, selenium and cancer, vitamins and cancer, and between fiber and cancer. Finally, guidelines for an anti-cancer menu are provided and further readings are suggested. Let us start by observing some of the findings of the National Research Council.

National Research Council Reports (U.S.)

"Sound nutrition is not a panacea. Good food that provides appropriate proportions of nutrients should not be regarded as a poison, a medicine, or a talisman. It should be eaten and enjoyed." This statement in a 1980 publication called "Toward Healthful Diets"[1] raised more than a few eyebrows. Reaction from consumer groups was furiously negative. These groups along with many individuals objected to the conclusion that no specific dietary advice was appropriate for all citizens. The recommendation of a balanced diet with moderation in consumption did not sit well with people who were convinced that a great many of the ills of North American society are related to improper nutrition. A document detailing the evils of food



additives, the benefits of vitamin supplementation and the virtues of "organic" foods would undoubtedly have received more favourable reaction. Science however often cannot deal with emotions, belief or anecdotal* evidence; it must be based on facts stemming from well controlled and reproducible experiments. Unfortunately in the area of nutrition it is very difficult to design and carry out studies which lead to conclusive results. Accordingly many reports of results are speckled with phrases like "may cause", "is consistent with", "is associated with"; all of which imply uncertainty. The difficulty of providing "proof" one way or another in the areas of food science and nutrition leaves the door open to a variety of opinions not only among the alarmists and self styled authorities but among nutritional experts as well.



Indeed, just two years after the above mentioned report a new document entitled "Diet,Nutrition and Cancer"[2] with more specific recommendations reflecting the state of knowledge and information pertinent to the diet and the incidence of cancer. The guidelines now recommended a reduction of fat intake from about 40% to 30% of total calories, a reduction in the consumption of cured, pickled and smoked foods and an increase in the consumption of whole grain cereal products as well as fruits and vegetables, especially those rich in

* All terms or concepts followed by a star (*) are defined in the Glossary at the back of the article.

carotene. Vegetables belonging to the cabbage family are highly recommended but vitamin supplementation was not advised. The new report was in turn also criticized. Many scientists believe that not enough is known about the diet-disease connection to warrant specific guidelines for the population as a whole and furthermore it was suggested that improperly applied guidelines could lead to nutritional deficiencies. In light of the ongoing controversy it is appropriate to examine the studies and the kind of data that have lead to the debated recommendations. An examination of this controversy also serves to underline the need for a basic scientific understanding of chemical and nutritional concepts. Familiarity with terms like "minerals", "vitamins", "fat, "fiber", "carotene" etc. is essential for an objective and critical discussion of the relationship between diet and cancer. Also, an observation of some international research demonstrates that different cultures have different types of cancers.

There has been much research on diet and cancer done outside North America. Regardless of whether these findings apply to North America, it is interesting to see what research is conducted internationally.

Diet Cancer Relationship - International Research

Much of the research on the relationship between food and cancer shows that chemicals isolated from food can cause cancer, the whole food does not. For example, the potentially harmful effects of parsley and celery may be counteracted by the carotene and vitamin components in these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment. The following summarizes some of the research on the diet-cancer relationship.

There appears to be little doubt that many cancers are environmentally related. Epidemiological* studies have clearly shown large differences in cancer rates between countries. For example,breast and colon cancer rates in many areas of the world are less than one fifth that in North America. The Japanese in turn have the highest incidence of stomach cancer in the world. Immigrants from other countries to the U.S. and Canada however experience the local cancer rates, suggesting an environmental influence.

4

Japanese Research

Perhaps the best demonstration of this environmental effect comes from a study made public in 1984[3]. An epidemiological study spanning 16 years and involving over 100,000 men clearly showed that the incidence of cancer was greatest among those who smoked, drank alcohol, ate meat regularly and did not consume vegetables daily.

Table 1
Relative Mortality Rates

If you...

Smoke	Drink Alcohol	Eat Meat	Eat Vegetables	Then your relative mortality rate is...
No	No	No	Yes	1.0
No	Yes	Yes	No	1.1
Yes	Yes	Yes	Yes	1.7
Yes	Yes	No	No	1.8
Yes	No	Yes	No	1.8
Yes	Yes	Yes	No	2.5

Notes:
1. Your relative mortality rate increases if you smoke, drink, and eat meat.
2. Not all combinations of smoking, drinking, eating meat, and eating vegetables are present. What are some other combinations that may exist? Where would the relative mortality rate of these other combinations fall?

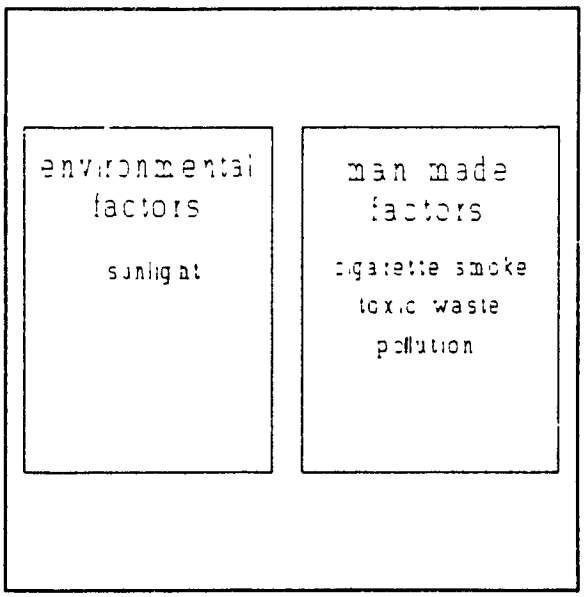
Indeed the absence of vegetables from the diet appeared to increase the risk of a wide variety of cancers. However, generalizations cannot be made for individual incidence of cancer are not easily predicted. The results of the survey, summarized below, provide a comparison between relative mortality rates and consumption of cigarettes, alcohol, meat and vegetables.

The protective effects of vegetable consumption are dramatically illustrated by the above data; in fact even in the high risk group (smokers, drinkers and meat eaters) the risk of cancer can be reduced by one third if vegetables are regularly eaten. This protective effect may be manifested through the fiber, Vitamin C, or carotene components of the vegetables as discussed later.

Much research on diet and cancer has also been done closer to home. The following summarizes the results of some of this research.

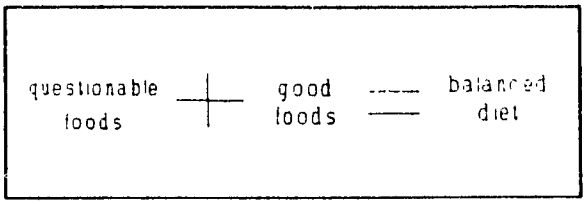
Diet-Cancer Relationship: North American Research

Many cancer experts now estimate that as much as 90% of North American cancers are environmentally determined and that a large fraction of these should therefore be avoidable. "Environmental" must not be confused with "man made". Cigarette smokeing and toxic wastes are "man made", but exposure to sunlight and the consumption of naturally occurring carcinogens is termed "environmental". In fact, Bruce Ames of the University of California (Berkeley) has concluded after a survey of the scientific literature that most of the carcinogens that non-smokers encounter in their daily life come from natural foods and cooking methods. For example celery and parsley contain a carcinogen which becomes activated by light; mushrooms, beans and even alfalfa sprouts contain compounds which may increase the risk of

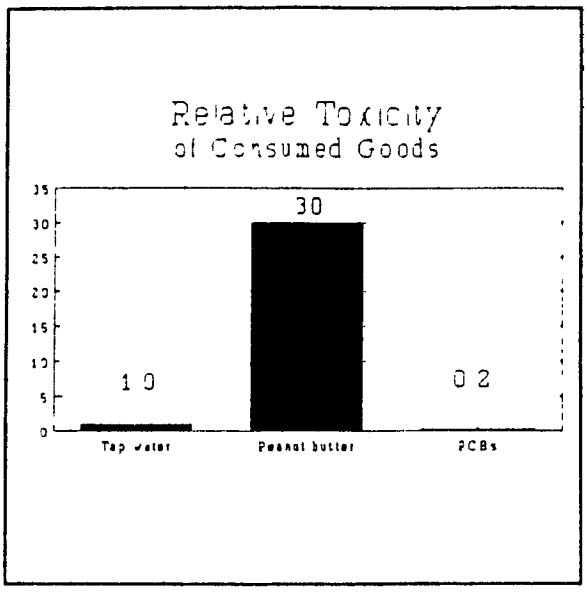


cancer. Cooking, especially when food is browned or burned adds carcinogens to the diet. On the other hand, suggests Ames, food also appears to contain natural anti-carcinogens like Vitamins C and E, selenium and carotene which may decrease the risk of the dreaded disease. Natural anti-carcinogens are "naturally" found in food. The fact that cancer rates aside from those related to smoking have remained almost constant over the years appears to imply that the "natural" components of the environment may be more important than the "man made" factors in inducing cancer. A research-based study, discussed below, attempted to find which foods were more cancerous and which are less cancerous.

In a controversial article[4], Ames summarized the many natural foods (above) which contained various carcinogens. In this same article, he also indicated that there were many foods which were also anti-carcinogens. The main idea here was that a minimum of the questionable foods coupled with a reasonable amount of the "good" ones would provide as good a balance of risk/benefit as could be achieved in this very complex area. Ames was criticized by a group of 18 academics, union officials and environmentalists in a 1984 letter to Science for "trivializing" cancer risks. Ames recently published a summary of relative risk factors for cancer by a careful (but controversial) examination of the literature. The resulting index called HERP (Human Exposure dose/Rodent Potency dose). This index considers two questions: How much of the material causes considerable rates of cancer in lab animals, and how much of it might an average person be exposed to over a lifetime? The rankings do not predict a person's actual chances of developing cancer, but show comparisons If the relative ranking of tap water is 1.0, then peanut butter (2 tablespoons/day) is 30 (aflatoxin risk) as is comfrey tea (1 cup/day) (symphytine, a natural pesticide is present). One pack/day of cigarettes is rated at 12,000 while the risk of cancer from PCBs (ones used in electrical transformers) is 0.2. Needless to say, such a detailed list has created concern and discussion and will stimulate research in the future.



Since the second World War some 50,000 synthetic chemicals have been introduced into the environment with about 500 new ones coming into use every year. Many of



these are mutagenic* or carcinogenic* in lab tests yet the cancer epidemic that many scientists (even Bruce Ames at one time)have predicted has not materialized. Accordingly there is widespread,though certainly not universal, belief that natural carcinogens cause most cancers. Many of these carcinogens are produced by plants as natural pesticides to ward off insects. Ironically the current practice of breeding insect resistant plants in order to minimize the use of synthetic pesticides may actually be introducing new carcinogens into the diet. It is also a fact of course that not everyone gets cancer even though everyone consumes natural carcinogens. The explanation for this apparent inconsistency may lie in the possibility that whereas chemicals isolated from food can cause cancer, the whole food does not because mutagens, which can cause cancer, and "anti-carcinogens", which fight cancer, are often present in the same food. For example the potentially harmful effects in parsley and celery may be counteracted by the carotene and vitamin components in these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment.

The following sections summarize the current state of knowledge in the important area of specific consumer diet items and cancer. The specific diet items discussed will be fat, cured foods, selenium, vitamins and fiber. The first two diet items, fat and cured foods, present a risk in contracting cancer. The remainder of the food items are "anti-cancerous". However, selenium can be toxic in large amounts. Let us look at each specific item.

8

The Dietary Fat-Cancer Relationship

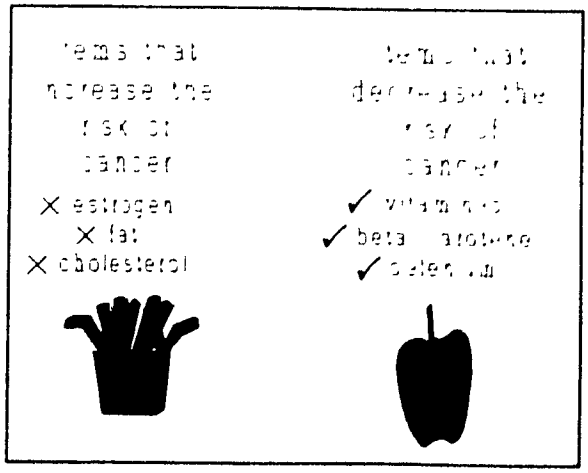
Types of cancers discussed: breast cancer, colon cancer.

A couple of hamburgers and fries? Delicious, mouth watering, and fatty!

The recommendation to reduce the fat content of the diet stems mostly from correlations noted by epidemiologists. A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer. It must be pointed out however that such associations do not imply cause. For example, a similar correlation exists between gross national product and breast cancer. Although the "per capita" correlation of dietary fats with cancer is strong, there appears to be no conclusive correlation of individual fat consumption and cancer because there may be other variables in the relationship as well. These other variables correlate with cancer, but not fat itself. Think of it as that old statistics riddle, A is equal to B, B is equal to C, but C is not equal to A!

Theoretically the argument can be put forward that fats cause cancer by undergoing oxidation* in cells. Unsaturated fats may pose a greater risk since they are more easily oxidized. Some studies have indeed shown an association between cancer and fat produced when vegetable oils are converted into margarine. Adequate Vitamin E, beta carotene and selenium consumption may prevent the oxidation of fats.

Dr. Keith Ingold has in fact shown that Vitamin E is the major "free-radical trapping" anti-oxidant* in human blood[5]. Beta carotene can also act as an antioxidant, especially at low oxygen concentrations found in cells. It is noteworthy that this important research started out as an investigation into why engine oils break down upon exposure to oxygen in the car's engine; a nice demonstration of how important results can come from seemingly "unimportant" research. Similarly the antioxidants BHT and



BHA which had originally been developed to prevent fats in cereals from going rancid (and incidentally have been much maligned*) may turn out to have an important role in not only the prevention of cancer but in actually slowing down the aging process.

Colon cancer has also been associated with high fat, high cholesterol diets. Once again though, epidemiological studies in individuals have yielded inconsistent results. Animal feeding studies in turn have shown that dietary fat promotes colon cancer. We must remember that studies done on animals are not always precise. If they are not, they may give some indications for further research. Furthermore, populations with high rates of colon cancer have increased levels of bile acids in the feces; these have been associated with cancer and are known to be formed in larger amounts in high fat, high cholesterol diets. In summary, the evidence may appear to be somewhat circumstantial, but the recommendation to reduce fat content by 25% does not represent a risk as long as a balanced diet is maintained.

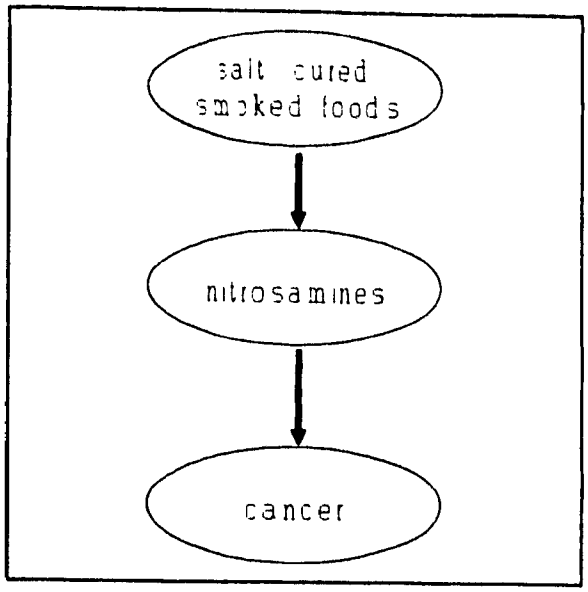
The Cured Foods-Diet Association

Types of cancers discussed: gastric cancer, stomach cancer.

Pickled vegetables and lean, almost fat-free smoked meat is not unhealthy right? No, wrong!

Once again population studies have shown that cancers of the stomach and esophagus are more common in countries such as China, Japan and Iceland where the diet is high in foods that are salt cured and smoked. There is no doubt that smoke contains cancer causing compounds and salt promotes gastric cancer in rats. Sodium nitrite, a pickling agent and preservative used in cold cuts, hot dogs, ham, etc. is linked with the potential formation of nitrosamines, known carcinogens, in the body. Based upon these observations, limiting the intake of such cured or smoked foods would appear to be wise. Yet, even this recommendation has been challenged. It has been pointed out that the death rate from stomach cancer has been declining in North America while the consumption of processed meats has been rising. Furthermore,nitrite addition is so strictly regulated now that only minimal amounts are used. It is also true that most of the "smoked" foods presently marketed are smoked with liquid smoke. This is made by passing smoke through water; since the carcinogenic compounds do not dissolve in

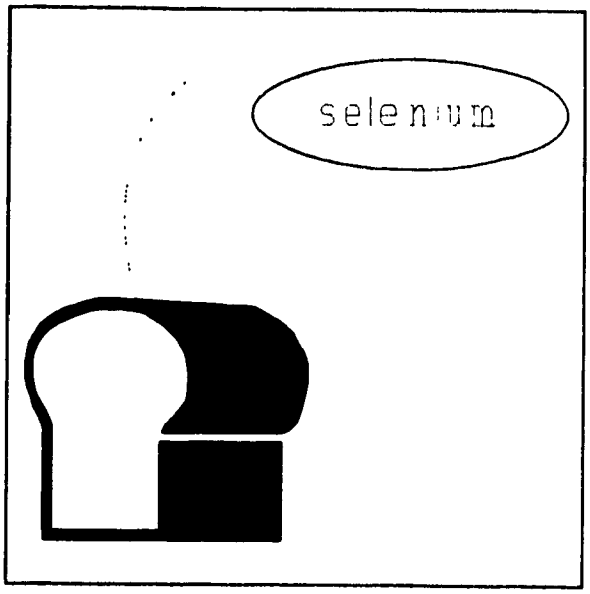
water foods "smoked" by this process are safer than "naturally" smoked foods.



In conclusion, research findings contradict themselves. However, it must also be pointed out that foods high in smoke flavor and nitrites are generally high in fat, perhaps enough of a reason to minimize consumption.

The Selenium-Cancer Association

Types of cancers discussed: mammary cancer.



Selenium, found in sea food, milk, and grains, is a mineral required by the body in little amounts. It plays a role in the protection of cells from damage by oxidation. Studies have shown that selenium has inhibited mammary cancer in rats fed a high polyunsaturated fat diet. Selenium is found in the soil and is absorbed by crops. High soil selenium areas correlate inversely with cancer but these areas are also less populated and differ from low soil selenium areas in several respects. Some correlations between blood selenium levels and cancer have also been noted and preliminary research has shown that the selenium content of hair and nails may reflect blood levels. High intake of selenium can be toxic and the presently available information does not warrant the recommendation of supplements.

11

The Cancer-Vitamin C and E Connection

The evidence for this association is essentially anecdotal although both of these vitamins are antioxidants and therefore could behave as anti-carcinogens. Vitamin E reduces mutations in some bacterial systems and Vitamin C does block the conversion of nitrites to nitrosamines. For the latter reason Vitamin C is added to hot dogs. Similarly since both tomatoes and lettuce contain Vitamin C they can conceivably do more than just dress up the appearance and flavor of a bacon sandwich. Indeed a BLT may be the best way to consume bacon. There is however no evidence that either Vitamin E or C can prevent cancer.

Vitamin	Source	Effects on Cancer
C	tomatoes lettuce citrus fruit hot dogs	blocks the conversion of nitrates into nitrosamines
E	vegetable oils whole wheat bread beef liver	reduces the mutations in some bacterial systems

The Cancer-Vitamin A Connection

Types of cancers discussed: lung cancer, skin cancer.

Remember the stories about eating carrots to see better?

This may be stretching the point, but the vitamin A in carrots does play an essential role in the chemistry of vision. Furthermore, the vitamin and its precursor compound (beta-carotene) may also protect the body against cancer. The rationale for this belief lies in the fact that vitamin A plays an important role in the control of cell differentiation* and that both vitamin A and especially beta-carotene are efficient scavengers of chemical species called free radicals. Since loss of cell differentiation is a basic feature of cancerous cells and since free radicals are unstable highly reactive chemicals which can damage our genetic materials (DNA and RNA), there is good reason to suspect that these two nutrients may have a protective effect against cancer.

Vitamin A itself can be obtained from animal products such as liver, eggs and meat or it can by synthesized by the body from beta carotene. Many green vegetables produce this bright orange compound but the richest sources are pumpkins, spinach and, of course, carrots.

Cancer-Vitamin A Research

In 1975 a major epidemiological study showed that Norwegian men consuming more than the average amount of vitamin A had less than half the rate of lung cancer as compared with men having below average consumption of the vitamin. Similar findings were also reported in the following 5 years from scientists in Japan, Singapore and the United States.

A further study[6] supported the hypothesis that the pro-vitamin A (beta carotene)and not the vitamin itself was the beneficial factor. The study showed that there was an inverse relationship between intake of dietary beta-carotene and lung cancer in 1,954 middle aged male smokers over a period of 19 years. Intake of preformed vitamin A did not show a significant effect.

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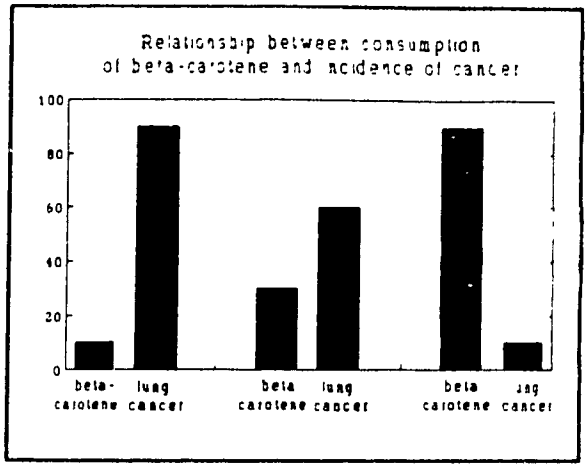


Unfortunately, studies on vitamin A are often limited due to its toxicity. High levels of vitamin A lead to liver damage, headaches, lack of appetite, hair loss, menstrual problems and retarded growth in children -- problems sometimes seen among vitamin and health food faddists. On the other hand, optimal investigative approaches are possible with beta carotene since there are no known serious side effects. In recent years synthetic analogs of vitamin A have been prepared in an effort to reduce its toxicity. These safer compounds are now tested with high risk groups to determine if other forms of cancer can be prevented. One such group consists of albino children in Africa who have a 100% risk of developing skin cancer. In addition, at the present time the U.S. National Institute of Health has invited all male physicians between the ages of 40 and 85 to participate as subjects in a placebo-controlled* general study of beta-carotene and cancer.

A major report[7] on this issue explained that although the protective effect against lung cancer of beta-carotene is strongly supported by many studies, there are indications that these effects may not apply to other types of cancer.

In conclusion, the main cause of lung cancer, smoking, also increases one's risk of several other serious diseases,including atherosclerosis -- a primary cause of death in North America. However, there is no evidence that either vitamin A or beta-carotene affects this condition in any way.

The Cancer-Fiber Connection

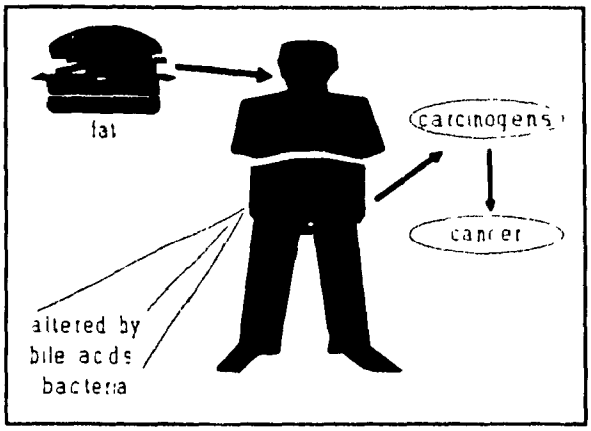
Types of cancers discussed: colorectal cancer, colon cancer.

Roughage? Unappetizing, tasteless, completely indigestible but... it fights cancer!

It all started with Dr. Dennis Burkitt's 20 year observation of diets and incidence of

colorectal cancer in rural Africa. The British surgeon noted that although cancer of the lowest five to six feet of the intestine is very prevalent in the western world it is almost nonexistent among people in Africa consuming a high fiber diet. In Canada, about 100,000 people get colon cancer every year, half of whom die within the same year. The same high frequency of this malignancy has been found in the U.S., Scotland, Denmark and especially New Zealand,countries which consume the highest amounts of meat and animal fat around the world.

The incidence of this type of cancer appears to be 100 times more prevalent in the lowest 1% of the small intestine. This leads scientists to believe that carcinogens are not swallowed with our food but are produced in the colon from material in the feces. It is suggested that bile acids (biomolecules* naturally released into the gut in response to the presence of fat in the diet) are chemically altered by bacteria to produce carcinogens.



High colon cancer areas are much more abundant in colorectal cancer patients than in control groups. In a recent study conducted by Dr. Tracy Wilkins, a microbiologist at the Virginia Polytechnic Institute in Blacksburg, a chemical mutagen, named faecapentaene, was isolated from the feces of about 20 per cent of the white residents of Johannesburg. The same compound was detected in less than 2 percent of the rural population.The diet of the urban community is very similar to ours (high in refined carbohydrates and fat), whereas that of the rural population is low in meat and fat and high in fruits and vegetables. Although most carcinogens are mutagens not all mutagens are carcinogens, and therefore the presence of faecapentaene does not necessarily mean that it is the cause of cancer. Dr. David Kingston, a chemist at the Virginia Polytechnic Institute, has synthesized this compound and its cancer-causing potential will now be investigated in laboratory animals.

Dietary fiber is a mixture of indigestible chemicals: cellulose, hemicellulose, lignin and pectin. Preliminary studies have shown that wheat bran and fiber from citrus

fruits protect laboratory animals against chemically-induced colon cancer. Since citrus fruits are also an excellent source of vitamin C (a scavenger of carcinogenic free radicals) an orange a day, or even the traditional apple a day, may not be such a bad idea.

These findings certainly support the theory that fiber, which increases the rate of feces elimination, should lower one's chances of developing cancer of the colon. However, there are some inconsistencies in the findings related to the effects of fiber. For instance, in a Canadian study published in 1980, higher consumption of dietary fiber showed not to have any significant effect on cancer whereas in Puerto Rico high consumption was associated with higher incidence of colon cancer. Such discrepancies may be related to the extremely heterogeneous nature of dietary fiber.

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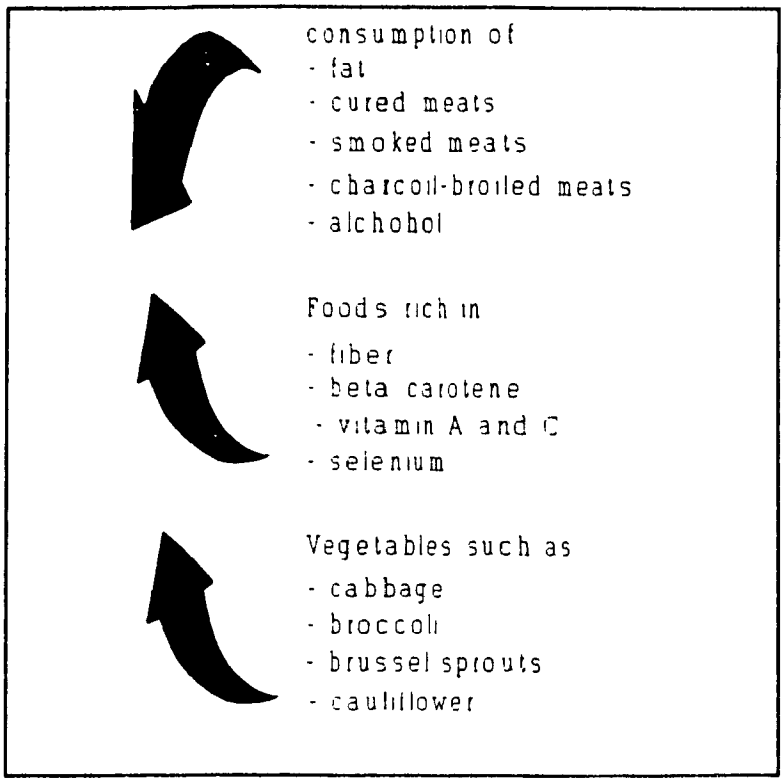
GUIDELINES FOR AN ANTICANCER MENU



RECENT REVIEW

A recent summary which gives a balanced report is from Scientific American, November, 1987, p. 42.

Another good source is Introductory Nutrition by Helen A. Guthrie.

GLOSSARY

Mutagenic: ability to cause mutations

Malignancy: cancer-causing tumor

Carcinogenic: any substance or agent that causes cancer

Cell differentiation: modification and specialization of cells as an organism grows

Epidemiologists: people who study the causes, distribution, and control of disease in a community

Oxidation. breakdown of molecules into unstable charged particles

Anti-oxidation: prevention of the breakdown of molecules into unstable charged particles

Placebo-controlled: inactive material given to subjects in a controlled experiment

Biomolecules: large, organic molecules found in organic substances

Anecdotal evidence: evidence not supported by experiments

ENDNOTES

1. Food and Nutrition Board of the U.S. National Research Council, 1980.
2. Food and Nutrition Board of the U.S. National Research Council, 1982.
3. National Cancer research Institute of Japan, 1984.
4. See Science, **221**, 1256, 1983.
5. National Research Council of Canada.
6. Published in the British medical journal Lancet, Nov. 1981.
7. Published in the new England Journal of Medicine, March 1984.

Appendix E:

Materials revised with both learner and expert data (RBD)

1

THE DIET CANCER RELATIONSHIP

Introduction

Chemists, nutritional experts and food faddists cannot agree on the strength of the relationship between our diets and cancer. This article attempts to review what is known in this very complex area. Specifically, we will differentiate what is meant by "environmental cancers" and "man made" cancers. Then, we will discuss some international research findings, and some North American research findings as well. Next, we will examine the relation between some "bad" foods and cancer: foods which contain fat and foods which are cured and smoked. Then, we will examine the relation between some "good" foods and cancer: foods which contain selenium, vitamins, and fiber. And finally, guidelines for an anti-cancer menu will be provided and further readings are suggested.

The objective of this article is to make people better consumers of food with respect to nutrition and cancer. Some more specific objectives include: (1) The introduction of the concept that there is a social response to what happens in the popular press, in lobby groups, and in special interest groups. These groups do not always agree with what the scientific community says. (2) You will be able to interpret research findings and to evaluate the conclusions of these research findings. This will allow you to decide for yourself which cancer risks you are willing to live with, and which you are not. Finally, (3) you will be able to look at research findings, and be able to link this information to other issues of interest or concern. Also, you'll be able to answer intelligently about some of the issues affecting diet, cancer, nutrition, and food faddism.

The central theme is that, with respect to the diet and cancer relationship, there is much controversy, there are many powerful interest groups with many differing convictions, there is much scientific evidence, and there are many food faddists. This is coupled with the fact that diet, nutrition and cancer are very sensitive social issues. To sort through these issues, let us start by reviewing some recent research that tries to understand the relationship between diet and cancer.

2

Overview of Recent Research on Cancer

"Sound nutrition is not a panacea. Good food that provides appropriate proportions of nutrients should not be regarded as a poison, a medicine, or a talisman. It should be eaten and enjoyed." This statement by the Food and Nutrition Board of the National Research Council, in the U.S., in a 1980 publication called "Toward Healthful Diets", raised more than a few eyebrows. Reaction from consumer groups was furiously negative. These groups objected to the conclusion that no specific dietary advice was appropriate for all citizens. The recommendation of a balanced diet, with moderation in consumption, did not sit well with people who were convinced that a great many of the ills of North American society are related to improper nutrition. A document detailing the evils of food additives, the benefits of vitamin supplementation and the virtues of "organic" foods would undoubtedly have received more favourable reaction.

Science however cannot deal with emotions, belief or anecdotal evidence; it must be based on facts stemming from well controlled and reproducible experiments. Unfortunately in the area of nutrition it is very difficult to design and carry out studies which lead to conclusive results. Accordingly many reports of results are speckled with phrases like "may cause", "is consistent with", "is associated with"; all of which imply uncertainty. The difficulty of providing "proof", one way or another, in the areas of food science and nutrition, leaves the door open to a variety of opinions not only among the alarmists and self styled authorities but among nutritional experts as well.

Indeed, just two years after the above mentioned report the National Research Council issued a new document entitled "Diet, Nutrition and Cancer", with more specific recommendations reflecting the state of knowledge and information pertinent to the diet and the incidence of cancer. The guidelines now recommended:

- a reduction of fat intake from about 40% to 30% of total calories
- a reduction in the consumption of cured, pickled and smoked foods
- an increase in the consumption of whole grain cereal products
- an increase in the consumption of fruits and vegetables, especially those rich in carotene

Vegetables belonging to the cabbage family were highly recommended but vitamin

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supplementation was not advised. The new report was in turn also criticized. Many scientists believe that not enough is known about the diet-disease connection to warrant specific guidelines for the population as a whole, and furthermore the suggestion was made that if the guidelines were improperly applied they could lead to nutritional deficiencies. In light of the ongoing controversy it is appropriate to examine the studies and the kind of data that have lead to the debated recommendations. An examination of this controversy also serves to underline the need for a basic scientific understanding of chemical and nutritional concepts. Familiarity with terms like "**minerals**[1]", "**vitamins**", "**fat**", "**fiber**", "**carotene**" etc. is essential for an objective and critical discussion of the relationship between diet and cancer. Familiarity with the concepts "**environmental**" and "**man made**" is also essential for an objective and critical discussion of the relationship between diet and cancer. Let us start by explaining these two latter concepts.

Definitions

Minerals: inorganic substances found in nature.

Vitamins: a group of organic substances necessary for growth and regulation of the body.

Fat: organic compounds composed of carbon, hydrogen, and oxygen.

Fiber: a complex of substances of plant origin that are not absorbed nor digested by humans.

Carotene: a red or yellow pigment converted by the body into vitamin A.

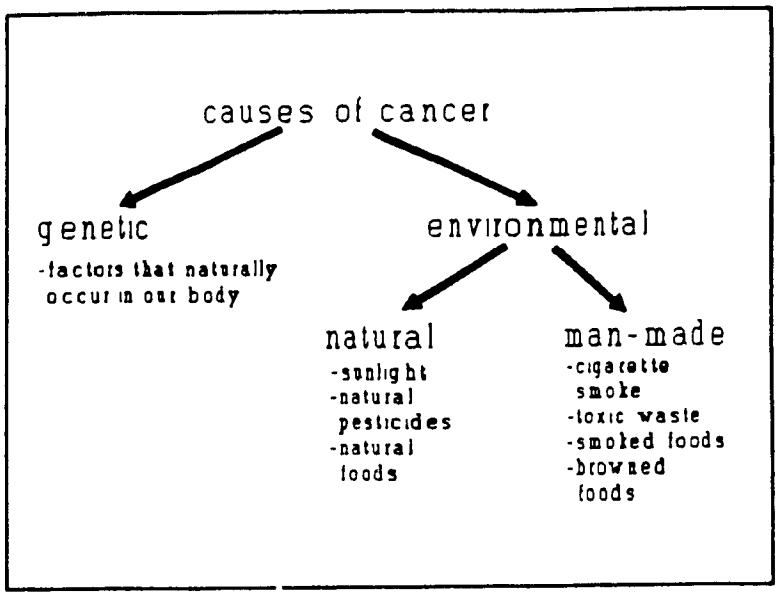
Environmental: substances produced outside our body. For example, neither sunlight nor cigarette smoke is produced in our body.

Man made: substances produced outside our body, that are not found "naturally" in nature. For example, cigarette smoke and toxic waste is man-made.

Environmental vs. Man Made Factors

Many cancer experts now estimate that as much as 90% of North American cancers are environmentally determined and that a large fraction of these should therefore be avoidable. "Environmental" must not be confused with "man made"; in the present context the word is

[1]Words in bold are defined in the boxes.



used to differentiate from "genetic" factors. Cigarette smokeing and toxic wastes are environmental and obviously "man made", but exposure to sunlight and the consumption of naturally occurring carcinogens can also be termed "environmental".

There appears to be little doubt that many cancers are environmentally related. Epidemiological studies have clearly shown large differences in cancer rates between countries. For example, breast and colon cancer rates in many areas of the world are less than one fifth that in North America. The Japanese in turn have the highest incidence of stomach cancer in the world. Immigrants from other countries to the U.S. and Canada however experience the local cancer rates, suggesting an environmental influence.

Japanese Research

Perhaps the best demonstration of this environmental effect comes from a study made public in 1984 by the National Cancer Research Institute of Japan. An epidemiological study, spanning 16 years and involving over 100, 000 men, clearly showed that the incidence of cancer was greatest among those who smoked, drank alcohol, ate meat regularly and did not consume vegetables daily. Indeed the absence of vegetables from the diet appeared to increase the risk of a wide variety of cancers. The results of the survey are summarized on the next page:

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Table 1
Relative Mortality Rates

If you. . .

Smoke	Drink Alcohol	Eat Meat	Eat Vegetables	Then your relative mortality rate is. . .
No	No	No	Yes	1. 0
No	Yes	Yes	No	1. 1
Yes	Yes	Yes	Yes	1. 7
Yes	Yes	No	No	1. 8
Yes	No	Yes	No	1. 8
Yes	Yes	Yes	No	2. 5

Notes:

1. Your relative **mortality rate** increases if you smoke, drink, and eat meat.
2. Not all combinations of smoking, drinking, eating meat, and eating vegetables are present. What are some other combinations that may exist? Where would the relative mortality rate of these other combinations fall?

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From this chart, we can conclude that:

Definition
Mortality rates: the death rate per 100,000 people

- the protective effects of vegetable consumption are dramatically illustrated.
- even in the high risk group (smokers, drinkers and meat eaters) the risk of cancer can be reduced by one third if vegetables are regularly eaten.

This protective effect may be manifested through the fiber, Vitamin C or carotene components of the vegetables as discussed below.

Research Closer to Home

Bruce Ames, of the University of California (Berkeley), has concluded after a survey of the scientific literature that most of the carcinogens that non-smokers encounter in their daily life come from natural foods and cooking methods. For example celery and parsley contain a carcinogen which becomes activated by light; mushrooms, beans and even alfalfa sprouts contain compounds which may increase the risk of cancer. Cooking, especially when food is browned or burned adds carcinogens to the diet. On the other hand, suggests Ames, food also appears to contain natural anti-carcinogens like Vitamins C and E, selenium and carotene which may decrease the risk of the dreaded disease. The fact that cancer rates, aside from those related to smoking, have remained almost constant over the years appears to imply that the "natural" components of the environment may be more important than the "man made" factors in inducing cancer.

In a controversial article in the journal Science, 221, 1256 (1983), Ames summarized the many natural foods which contained various carcinogens. In this same article, he also indicated that there were many foods which were also anti-carcinogens. The main idea here was that a minimum of the questionable foods, coupled with a reasonable amount of the "good" ones, would provide as good a balance of risk/benefit as could be achieved in this very complex area. However, Ames was criticized by a group of 18 academics, union officials and environmentalists in a 1984 letter to Science for "trivializing" cancer risks.

Ames recently published a summary of relative risk factors for cancer by a careful

examination of the literature. The resulting index called HERP (Human Exposure dose/Rodent Potency dose). This index considers two questions: How much of the material causes considerable rates of cancer in lab animals, and how much of it might an average person be exposed to over a lifetime? In other words, the index is calculated in two steps. First, the quantity of cancerous material required to cause cancer in lab animals is estimated. Then, the amount of human lifetime exposure to this material is estimated. Therefore, the rankings do not predict a person's actual chances of developing cancer, but show comparisons. If the relative ranking of tap water is 1. 0, then peanut butter (2 tablespoons/day) is 30 (aflatoxin risk) as is comfrey tea (1 cup/day) (symphytine, a natural pesticide is present). One pack /day of cigarettes is rated at 12, 000 while the risk of cancer from PCBs (once used in electrical transformers) is 0. 2. Needless to say, such a detailed list has created concern and discussion and will stimulate research in the future.

Since the second World War some 50, 000 synthetic chemicals have been introduced into the environment with about 500 new ones coming into use every year. Many of these are mutagenic or carcinogenic in lab tests yet the cancer epidemic that many scientists have predicted has not materialized. Accordingly there is widespread, though certainly not universal, belief that most cancers are caused by natural carcinogens produced by plants as natural pesticides to ward off insects. Ironically the current practice of breeding insect resistant plants in order to minimize the use of synthetic pesticides may actually be introducing new carcinogens into the diet.

It is also a fact of course that not everyone gets cancer even though everyone consumes natural carcinogens. In other words, these chemicals do get into our foods, but this does not necessarily present a cancer risk. The explanation for this apparent inconsistency may lie in the possibility that whereas chemicals isolated from food can cause cancer, the whole food does not. Mutagens and "anti- carcinogens" are often present in the same food. For example the potentially harmful effects of the psoralens in parsley and celery may be counteracted by the carotene and vitamin components of these foods. It appears then that attention to a scientifically balanced diet may be more important in warding off cancer than worrying about the trace amounts of synthetic carcinogens in the environment.

If we can draw one conclusion from this information, it is the fact that a minimum amount of questionable foods coupled with a reasonable amount of "good" foods provides as good a balance of risk/benefit as can be achieved. In other words. we do not have to restrain from

some of our favourite foods, no matter how cancerous they may be. Moderation, and a nutritional diet, may be enough to reduce the risks of cancer.

The following sections summarize the current state of knowledge in the important area of specific consumer diet items and cancer. The specific diet items discussed will be fat, cured foods, selenium, vitamins and fiber. The first two diet items discussed, that is fat and cured foods, present a cancer risk. The remainder of the food items are "anti-cancerous".

The Dietary Fat-Cancer Relationship

The above mentioned recommendation to reduce the fat content of the diet stems mostly from **correlations** noted by epidemiologists. A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer.

Definitions

Positive **correlation**: as one factor increases, so do the others

Negative **correlation**: as one factor increases, the others decrease

Breast Cancer

It must be pointed out however that such associations do not imply cause. For example a similar correlation exists between gross national product and breast cancer. Although the "per capita" correlation of dietary fats with cancer is strong, there appears to be no conclusive correlation of individual fat consumption and cancer. There may be other variables in the relationship as well.

Colon Cancer

Colon cancer has also been associated with high fat, high cholesterol diets. Once again though, epidemiological studies in individuals have yielded inconsistent results. Animal feeding studies in turn have shown that dietary fat promotes colon cancer. Furthermore, populations with high rates of colon cancer have increased levels of bile acids in the feces; these have been associated with cancer and are known to be formed in larger amounts in high fat, high cholesterol diets. In summary, the evidence may appear to be somewhat

circumstantial, but the recommendation to reduce fat content by 25% does not represent a risk as long as a balanced diet is maintained.

Free Radicals: Cancer Causing Reactive Species

Hormones like estrogen have been linked with cancer. However, the human feeding studies which would be needed to clarify the situation can never be ethically done, but studies in animals do suggest that higher levels of fat intake cause mammary tumors. Theoretically the argument can be put forward that fats cause cancer by undergoing oxidation in cells leading to the production of cancer causing reactive species called **free radicals**. These free radicals then damage some cells, which subsequently leads to their improper replication. Unsaturated fats may pose a greater risk since they are more easily oxidized. Also, some studies have indeed shown an association between cancer and "trans" fatty acids which are produced when vegetable oils are converted into margarine. However, adequate Vitamin E, beta carotene and selenium consumption may prevent the oxidation of fats.

Definition

Free radicals: highly reactive, electronically charged, organic molecules

In summary, fatty foods can cause breast cancer and colon cancer. This is because fats cause cells to oxidize, leading to the production of cancer causing reactive species called free radicals.

The Cured Foods-Diet Association

Population studies have shown that cancers of the stomach and esophagus are more common in countries such as China, Japan and Iceland, where the diet is high in foods that are salt cured and smoked. There is no doubt that smoke contains cancer causing compounds and salt has been reported to promote gastric cancer in rats.

Cured Foods

Sodium nitrite, a pickling agent and preservative used in cold cuts, hot dogs, ham, etc. has been linked with the potential formation of **nitrosamines**, known carcinogens, in the body. Based upon these observations, limiting the intake of such cured or smoked foods would

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appear to be wise. Yet, even this recommendation has been challenged. It has been pointed out that the death rate from stomach cancer has been declining in North America while the consumption of processed meats has been rising. Furthermore, nitrite addition is so strictly regulated now that only minimal amounts are used; in fact the amount of nitrite now added can only prevent growth of the Clostridium Botulinum organism if it is used in conjunction with salt.

Definition
Nitrosamines: compounds containing -NO and $-NH_2$

Smoked Foods

It is also true that most of the "smoked" foods presently marketed are smoked with liquid smoke. This is made by passing smoke through water; since the carcinogenic compounds do not dissolve in water foods "smoked" by this process are safer than "naturally" smoked foods. Although credence can be given to these criticisms, it must also be pointed out that foods high in smoke flavor and nitrites are generally high in fat and thus in calories-perhaps enough of a reason to minimize consumption.

In summary, eating cured and smoked foods may represent a risk in developing stomach cancer. However, research findings have shown inconsistencies between these relations.

The Cancer - Vitamin C and E Connection

The evidence for this association is essentially anecdotal although both of these vitamins are antioxidants and therefore could behave as anti-carcinogens. Vitamin E may reduce mutations in some bacterial systems and Vitamin C may block the conversion of nitrites to nitrosamines. For the latter reason Vitamin C is added to hot dogs. Similarly since both tomatoes and lettuce contain Vitamin C they can conceivably do more than just dress up the appearance and flavor of a bacon sandwich. Indeed a BLT may be the best way to consume bacon. There is however no evidence that either Vitamin E or C can prevent cancer.

Dr. Keith Ingold at the National Research Council in Ottawa has in fact shown that Vitamin E is the major "free-radical trapping" anti-oxidant in human blood. Beta carotene can also act as an antioxidant, especially at low oxygen concentrations such as are found in cells. It is

noteworthy that this important research started out as an investigation into why engine oils break down upon exposure to oxygen in the car's engine; a nice demonstration of how important results can come from seemingly "unimportant" research. Similarly, the antioxidants BHT and BHA, which had originally been developed to prevent fats in cereals from going rancid (and incidentally have been much maligned), may turn out to have an important role in not only the prevention of cancer but in actually slowing down the aging process.

In summary, the evidence for this connection is anecdotal. There is no evidence that either Vitamin E or C can prevent cancer, but both act to reduce the risks of cancer.

The Cancer-Vitamin A Connection

Vitamin A does play an essential role in the chemistry of vision. Furthermore, the vitamin and beta-carotene, which are both found in carrots, may also protect the body against cancer. The rationale for this belief lies in the fact that vitamin A plays an important role in the control of cell differentiation, and in that vitamin A and especially beta-carotene are efficient scavengers of chemical species called free radicals. Since loss of cell differentiation is a basic feature of cancerous cells, and since free radicals are unstable, highly reactive chemicals which can cause cell differentiation, there is good reason to suspect that these two nutrients may have a protective effect against cancer.

Vitamin A itself can be obtained from animal products such as liver, eggs and meat or it can by synthesized by the body from beta carotene. Many green vegetables produce this bright orange compound but the richest sources are pumpkins, spinach and, of course, carrots.

In 1975, a major epidemiological study showed that Norwegian men consuming more than the average amount of vitamin A had less than half the rate of lung cancer as compared with men having below average consumption of the vitamin. Similar findings were also reported in the following 5 years from scientists in Japan, Singapore and the United States.

A further study (Nov. 1981), published in the British medical journal Lancet, supported the hypothesis that the pro-vitamin A (beta carotene) and not the vitamin itself was the beneficial factor. The study showed that there was an inverse relationship between intake of dietary beta-carotene and lung cancer in 1, 954 middle aged male smokers over a period of 19 years.

Intake of preformed vitamin A did not show a significant effect.

A major report on this issue, published in the New England Journal of Medicine, March 1984 (by the Harvard School of Public Health) explained that although the protective effect against lung cancer of beta-carotene is strongly supported by many studies, there are indications that these effects may not apply to other types of cancer.

In conclusion, it should be noted that the main cause of lung cancer, smoking, also increases one's risk of several other serious diseases, including atherosclerosis -- a primary cause of death in North America. However, there is no evidence that either vitamin A or beta carotene affects this condition in any way.

The Selenium-Cancer Association

Selenium is a mineral required by the body in "trace" amounts. It plays a role in the activity of the enzyme glutathione peroxidase, an enzyme which protects cells from damage by oxidation. Consistent with this activity is the observation that mammary cancer in rats fed a high polyunsaturated fat diet can be inhibited by selenium. Selenium is found in the soil and is absorbed by crops. High soil selenium areas correlate inversely with cancer but these areas are also less populated and differ from low soil selenium areas in several respects. Indeed lung cancer rates are lower in countries where tobacco contains more selenium. Mexican and Colombian tobaccos have three times as much selenium as American and British tobaccos. Some correlations between blood selenium levels and cancer have also been noted and preliminary research has shown that the selenium content of hair and nails may reflect blood levels. High intake of selenium can be toxic and the presently available information does not warrant the recommendation of supplements.

In summary, small amounts of selenium may reduce the risk of cancer. However, high intake of selenium can be toxic.

The Cancer-Fiber Connection

Fiber does fight cancer. It all started with Dr. Dennis Burkitt's 20 year observation of diets and incidence of colorectal cancer in rural Africa. The British surgeon noted that although cancer of the lowest five to six feet of the intestine is very prevalent in the western world, it

is almost nonexistent among people in Africa consuming a high fiber diet. In Canada, about 100, 000 people get colon cancer every year, half of whom die within the same year. The same high frequency of this malignancy has been found in the U.S., Scotland, Denmark and especially New Zealand, countries which consume the highest amounts of meat and animal fat around the world.

This leads scientist to believe that carcinogens are not swallowed with our food but are produced in the colon from material in the feces. It has been suggested that bile acids (biomolecules naturally released into the gut in response to the presence of fat in the diet) are chemically altered by bacteria to produce carcinogens.

High colon cancer areas have been found to be much more abundant in colorectal cancer patients than in control groups. In a recent study, conducted by Dr. Tracy Wilkins, a microbiologist at the Virginia Polytechnic Institute in Blacksburg, a chemical mutagen, named faecapentaene, was isolated from the feces of about 20 per cent of the white residents of Johannesburg. The same compound was detected in less than 2 percent of the rural population. The diet of the urban community is very similar to ours (high in refined carbohydrates and fat), whereas that of the rural population is low in meat and fat and high in fruits and vegetables. Although most carcinogens are mutagens not all mutagens are carcinogens, and therefore the presence of faecapentaene does not necessarily mean that it is the cause of cancer. Dr. David Kingston, a chemist at the Virginia Polytechnic Institute, has synthesized this compound and its cancer-causing potential will now be investigated in laboratory animals.

These findings certainly support the theory that fiber, which increases the rate of feces elimination, should lower one's chances of developing cancer of the colon. However, there are some inconsistencies in the findings related to the effects of fiber. For instance, in a Canadian study published in 1980 higher consumption of dietary fiber was shown not to have any significant effect on cancer whereas in Puerto Rico high consumption was associated with higher incidence of colon cancer. Such discrepancies may be related to the extremely heterogeneous nature of dietary fiber.

In summary, dietary fiber is a mixture of indigestible chemicals: cellulose, hemicellulose, lignin and pectin. Preliminary studies have shown that wheat bran and fiber from citrus fruits protect laboratory animals against chemically-induced colon cancer. Since citrus fruits are

also an excellent source of vitamin C (a scavenger of carcinogenic free radicals), an orange a day, or even the traditional apple a day, may not be such a bad idea.

Conclusion

As is evident in the article, chemists, nutritional experts and food faddists cannot agree on how strong the relationship between our diets and cancer is. However, some overall generalizations can be made from the information presented in this article:

It is very difficult to design and carry out studies which lead to conclusive results in the area of nutrition.

Recommendations include a) a reduction of fat intake from about 40% to 30% of total calories, b) a reduction in the consumption of cured, pickled and smoked foods, c) an increase in the consumption of whole grain cereal products, d) an increase in the consumption of vegetables belonging to the cabbage family.

Vitamin supplementation is not advised.

Many cancers are environmentally related and "natural" components of the environment may be more important than the "man made" factors in inducing cancer. Some natural foods, such as celery, parsley, beans, mushrooms, etc. , contain various carcinogens whereas there are many foods, such as carrots, which are anti-carcinogens.

A strong correlation exists between per capita fat intake and breast cancer mortality in women as well as between fat intake and mortality from colon cancer.

Smoke-foods and cured-foods contain cancer causing compounds and salt has been reported to promote gastric cancer.

Food with selenium correlates inversely with cancer.

Both Vitamin C and Vitamin E are antioxidants and therefore could behave as anti-carcinogens.

Vitamin A, and its precursor compound beta-carotene, may also protect the body against cancer.

Fiber fights cancer.

The main idea is that a minimum amount of the questionable foods coupled with a reasonable amount of the "good" ones provides as good a balance of risk/benefit as could be achieved in this very complex area.

GUIDELINES FOR AN ANTICANCER MENU

- decrease consumption of fats, nitrite-cured meats, smoked or charcoal-broiled meats and large amounts of alcohol

- increase consumption of foods rich in dietary fiber, beta carotene, vitamins A, E and C and the mineral selenium (megadoses of dietary supplements are presently not recommended).

- consume often cruciferous vegetables such as cabbage, broccoli, brussel sprouts and cauliflower.

RECENT REVIEW

A recent summary which gives a balanced report is from Scientific American, November, 1987, p. 42.

Appendix F:

Task instructions (NT and all other conditions)

Instructions

Please read carefully.

This study is the last in a series of research projects concerned with how to improve instructional materials. We have gathered feedback from students and experts about an article titled "The Diet Cancer Relationship". Then, revisers have used this information to revise the materials.

Since you have been randomly assigned to the control group, your task is to provide us with information about your knowledge of the diet cancer relationship without having read the article. In order to do so, please:

1. Read and sign the consent if you agree to participate in this study.

2. Answer all questions on the "INFO SHEET" to the best of your ability.

3. Answer all the items on the objective test.

4. Hand in the Materials Package and collect your $10.00. Don't forget to sign the receipt.

Instructions

Please read carefully.

This study is the last in a series of research projects concerned with how to improve instructional materials. We have gathered feedback from students and experts about an article titled "The Diet Cancer Relationship". Then, revisers have used this information to revise the materials.

In order to evaluate the effectiveness of this entire process, we need you to do the following:

1. Read and sign the consent if you agree to participate in this study.
2. Answer all the questions on the "INFO SHEET" to the best of your ability.
3. Read the article at a comfortable pace.
4. Answer all the items on the objective test.
5. Complete the questionnaire
6. Hand in the Materials Package and collect your $10.00. Don't forget to sign the receipt.

Appendix G:

Consent, receipt, and demographic questionnaire (Info Sheet)

Part A: Consent

Please read and sign Part "A" now.

I understand that I am participating in a program of research conducted by Tino Bordonaro under the supervision of Dr. L. McAlpine and Dr. G. B. Isherwood.

I understand that the purpose of the study is to provide data to help evaluate the teaching module "The Diet Cancer Relationship", and that **my performance or ability is not being judged.**

I understand that my participation in this study is voluntary; there is no coercion based on my enrolment in any course, and the only inducement to my participation is $10.00 upon completion of the evaluation.

I understand that my identity will not be given on the materials I hand in, and that my score on the test will be aggregated with the scores of other participants.

I understand that the data gathered may be published.

I understand that I may withdraw from this study any time without negative consequences.

Signature _____

Date _____

Part B: Receipt

Please sign Part "B" when you have received payment.

I acknowledge receipt of $10.00 for participating in the evaluation of the teaching module "The Diet Cancer Relationship".

Signature _____

Date _____

This sheet will be torn off and put in a separate pile when you hand in the package.

INFO SHEET

Instructions:

Please answer each question to the best of your ability. If you do not understand a question, please ask.

Sex: _____ **Age:** _____

Mother Tongue: _____

Language of previous schooling:

Language of CEGEP (if you attended) -

_____

Language of High School -

_____

Do you have a D.E.C.? (CEGEP diploma):

No: _____ **Yes:** _____

If yes, what program? (e.g., Social Sciences, Creative Arts, etc.):

_____

Current studies:

Degree: (e.g., B.A.) _____

Major: _____

Year: (1st, 2nd, etc.)_____

Academic Performance:

Do you generally get -

A's _____ **B's** _____

C's _____ **D's and lower** _____

Grade Point Average (if known): _____

Did you take Chemistry while in High School?

No: _____ **Yes:** _____

If yes, list courses -

_____

_____

Did you take Chemistry in CEGEP?

No: _____ **Yes:** _____

If yes, list courses -

_____

_____

Appendix H:

Effectiveness measures:
Retention test and confidence-weighing scales

EXAMPLE QUESTIONS

INSTRUCTIONS

Please read each question carefully and circle the **best** answer. After you answer each question, please rate how confident you feel about your answer on the scale provided.

TRUE FALSE QUESTIONS

CONFIDENCE RATING

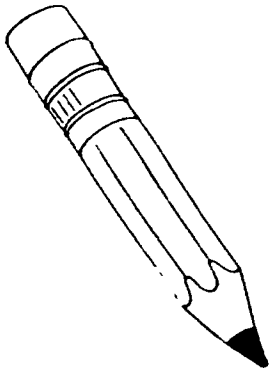
Not at all — Somewhat — Quite — Very

A. T F **Smoke contains cancer causing compounds** 1.....2.....3.....4

MULTIPLE-CHOICE QUESTIONS

B. **The C.N. tower is in:** 1.....2.....3.....4

a) Montréal
b) Calgary
c) Toronto
d) Vancouver



INSTRUCTIONS

Please read each question carefully and circle the **best** answer. After you answer each question, please rate how confident you feel about your answer on the scale provided.

			TRUE FALSE QUESTIONS	CONFIDENCE RATING (Not at all / Somewhat / Quite / Very)
1.	T	F	New National Research Council guidelines recommend a reduction in fat intake from about 40% to 30% of total calories.	1.....2.....3.....4
2.	T	F	The Japanese have the lowest rate of stomach cancer in the world.	1.....2.....3.....4
3.	T	F	Many cancers are caused by environmental factors.	1.....2.....3.....4
4.	T	F	An absence of vegetables from the diet appears to increase the risk of contracting a wide variety of cancers.	1.....2.....3.....4

				Not at all	Somewhat	Quite	Very
5.	T	F	Consumption of naturally occurring carcinogens is an environmental factor which may cause cancer.	1	2	3	4
6.	T	F	Consumption of burnt food does <u>not</u> add carcinogens to the diet.	1	2	3	4
7.	T	F	The risk of cancer can be reduced by one third if vegetables are eaten regularly.	1	2	3	4
8.	T	F	Anti-carcinogens and mutagens rarely occur in the same food.	1	2	3	4
9.	T	F	Individual fat consumption is highly correlated with cancer.	1	2	3	4
10.	T	F	Vitamin E is the major "free-radical trapping" anti-oxidant in human blood.	1	2	3	4
11.	T	F	No association exists between colon cancer and a diet high in cholesterol.	1	2	3	4
12.	T	F	Evidence indicates that Vitamin C and Vitamin E prevent cancer.	1	2	3	4
13.	T	F	A 1975 study of Vitamin A consumption among Norwegian men showed the following: Increasing Vitamin A consumption decreased the rate of lung cancer by more than 50%.	1	2	3	4

MULTIPLE-CHOICE QUESTIONS

Not at all | Somewhat | Quite | Very

14. **Controlled experiments repeated many times:** 1.....2.....3.....4
    a) Prove theories
    b) Are the hallmark of the scientific method
    c) Are as valid as the intuition of famous scientists
    d) Must be conducted in laboratory settings.

15. **Experiments in nutrition are difficult to carry out because:** 1.....2.....3.....4
    a) It is too difficult to find human subjects.
    b) It is difficult to provide "proof" based on results
    c) Governments will not fund the research.
    d) They require too much time and effort to be worthwhile.

16. **Consumption of which family of vegetables is highly recommended in the National Research Council's nutritional guidelines?** 1.....2.....3.....4
    a) Cabbage
    b) Legume
    c) Tuber
    d) Herb

17. **Which of the following was <u>not</u> recommended by the National Research Council?** 1.....2.....3.....4
    a) A reduction of fat intake
    b) A reduction of the consumption of cured, pickled and smoked foods
    c) Vitamin supplementation
    d) An increased consumption of whole grain cereals, fruits and vegetables

Not at all Somewhat Quite Very

18. **Nutritional guidelines for the population as a whole:** 1.....2.....3.....4
    a) Neglect regional differences in the food availability making their application impossible.
    b) May be improperly applied leading a scientist to object to their recommendation.
    c) Do not consider foods from differing cultural origins.
    d) Ignore individual differences in height, weight and bone size.

19. **Which of the following combinations of factors would result in the highest risk of cancer?** 1.....2.....3.....4
    a) Smoking, drinking and not eating vegetables
    b) Smoking and eating meat
    c) Smoking, drinking, eating meat and eating vegetables
    d) Smoking, drinking and eating meat

20. **Carotene, Vitamin C and Selenium are:** 1.....2.....3.....4
    a) Are all found in a glass of orange-juice
    b) Increase the speed of feces elimination
    c) All examples of anti-carcinogens
    d) Are found in DNA

21. **Professor Bruce Ames of the University of California at Berkeley has devised a scale of relative risk (the H.E.R.P.) index. It is associated with:** 1.....2.....3.....4
    a) The risk of contracting various forms of the Herpes Simplex virus.
    b) The likelihood of encountering naturally occurring cancer-causing agents found in the environment on a given day.
    c) Getting a variety of diseases and stands for High Environmental Risk Position.
    d) Various substances in food and other parts of the environment in terms of the likelihood of getting cancer.

Not at all Somewhat Quite Very

22. **Research indicates that the 50 000 chemicals introduced into the environment since the second World War have not caused a cancer epidemic. This leads scientists to believe:** 1.....2.....3.....4
   a) Improvements in the world diet has prevented the occurrence of many types of cancer.
   b) Cancer is caused by naturally occurring carcinogens.
   c) Concern about toxic waste dumps is unfounded.
   d) Human resistance to carcinogenic substances is improving.

23. **Breast cancer and colon cancer have been shown to be highly correlated with:** 1.....2.....3.....4
   a) A high sodium diet.
   b) An inadequate intake of Vitamin E.
   c) Per capita fat intake.
   d) Consumption of cured foods.

24. **Oxidation of fats in the cells:** 1.....2.....3.....4
   a) Is caused by excessive Vitamin C consumption
   b) Is caused by improper cell replication
   c) Is unrelated to dietary fat intake
   d) Produces free radicals

25. **Which statement is <u>correct</u> regarding unsaturated fats?** 1.....2.....3.....4
   a) Consumption of unsaturated fat increases the likelihood of breast cancer in women.
   b) Unsaturated fats may pose an increased risk of cancer as they are easily oxidized.
   c) Unsaturated fats are environmental anti-carcinogens.
   d) Consumption of unsaturated fats is the cause many forms of cancer.

Not at all Somewhat Quite Very

26. **Which of the following substances <u>will not</u> prevent the production of free radicals?** 1.....2.....3.....4
    a) Vitamin A
    b) Beta carotene
    c) Vitamin E
    d) Selenium

27. **Cancer of the stomach and esophogas are associated with:** 1.....2.....3.....4
    a) A high cholesterol diet.
    b) A high fat diet.
    c) Consumption of cured and smoked foods.
    d) Consumption of red meat.

28. **Selenium is a mineral required in trace amounts. What is its function?** 1.....2.....3.....4
    a) It prevents cancer of the esophogas.
    b) It is required in the digestive process.
    c) It assists in metabolizing beta carotene.
    d) It protects cells from damage by oxidation.

29. **Which of the following is true about Vitamin A:** 1.....2.....3.....4
    a) The precursor to Vitamin A, beta-carotene, is thought to be the important factor in reducing some forms of cancer.
    b) Intake of Vitamin A supplements was highly recommended by the National Research council to prevent many forms of cancer.
    c) Vitamin A is not ingested by the human body.
    d) Vitamin A is not toxic, even at high doses.

30. **The probability of contracting cancer of the small intestine and colon may be reduced by:** 1.....2.....3.....4
    a) An increase in Vitamin C consumption
    b) Eliminating BHT from the diet.
    c) Increasing consumption of dietary fiber.
    d) Increasing consumption of dairy products.

Appendix I:

McGill University Faculty of Education ethical approval

McGILL UNIVERSITY

FACULTY OF EDUCATION

CERTIFICATE OF ETHICAL ACCEPTABILITY FOR RESEARCH INVOLVING HUMAN SUBJECTS

A review committee consisting of:

a. Helen Perreault

b. William Ryan

c. Jeff Derevensky

has examined the application for certification of the ethical acceptability of a project titled:

The influence of different strategies of formative evaluation on improving the effectiveness of instructional materials.

as proposed by: Cynthia Weston
(Applicant) (Supervisor if applicant is a student)

to: SSHRC
(Granting agency, if any)

The review committee considers the research procedures, as explained by the applicant in this application, to be acceptable on ethical grounds.

(Signed)

a) Jeffrey L. Derevensky

b) HELENE PERREULT

c) DR. WILLIAM C. RYAN : William L. Ryan

Date Oct. 16, 1989 J. REBUFFOT

Appendix J:

Letter accompanying cost questionnaire

Centre for University Teaching and Learning
McGill University
3700 McTavish Street
Montreal Quebec H3A 1Y2

Centre d'enseignement supérieur
Université McGill
3700 rue McTavish
Montreal Quebec H3A 1Y2

Feb. 23, 1993

Jane Doe
1234 Street
City, Town
Province, A1B 2C3

RE.: Costs of Different Formative Evaluation Combinations.

Dear Jane Doe,

We are requesting participation in a cost-analysis study. A bit of background on our research: This study is the final part of an ongoing team research project concerned with the improvement of instructional materials through formative evaluation. This piece of research involves looking at the **costs** of collecting feedback and revising instructional articles. More specifically, we are concerned with comparing the costs across four different formative evaluation combinations (more information on these four combinations is provided).

The main reasons we are asking for your participation are: a) you are an experienced instructional designer, b) you have previously been involved providing us with formative evaluation information, and c) you have already worked with the instructional articles we are using.

The instructional article on which we are collecting cost data, titled The Diet Cancer Relationship, is a module from an introductory chemistry course for non-chemistry students from both Arts and Sciences. We have appended the article in its original (draft) condition. We ask that you please return the article along with your cost estimates.

Enclosed, you will find the four different formative evaluation combinations and a short description. **Please estimate how much you would charge for collecting data and revising each of these combinations.** This should only take a few minutes. Also, your identity will not be disclosed and your cost estimates will be aggregated with the estimates of other instructional designers. If you require any further assistance, do not hesitate to contact us.

Sincerely,

Tino Bordonaro
323-9461

Dr. L. McAlpine
398-6648

Appendix K:

Cost questionnaire

Costs of Four Different Formative Evaluation Combinations

Please estimate how much you would charge for collecting data and revising each of these combinations.

Combination 1: Revision using Learner Data

1. Collect: a) learner feedback comments from 5 learners,
   b) learner pretest and post-test scores from 10 learners.

   Learners must be undergraduate level students.

2. Use these data to revise the article.

Cost Estimate: Approximately how much would you charge to collect this data and revise the instructional article?

$ _____

Additional Comments: If any, please use space below.

Combination 2: Revision using Expert Data

1. Collect: a) expert review comments from 2 experts

   One expert must be a subject matter expert (SME).

2. Use these data to revise the article.

Cost Estimate: Approximately how much would you charge to collect this data and revise the instructional article?

$ _____

Additional Comments: If any, please use space below.

Combination 3: Revision using Both Learner and Expert Data

1. Collect: a) learner feedback comments from 5 learners,
   b) learner pretest and post-test scores from 10 learners.
   c) expert review comments from 2 experts

   Learners must be undergraduate level students.
   One expert must be a subject matter expert (SME).

2. Use these data to revise the article.

Cost Estimate: Approximately how much would you charge to collect this data and revise the instructional article?

$ _____

Additional Comments: If any, please use space below.

Combination 4: Revision using no data.

1. You are not required to consult with learners nor experts. In other words, the article is revised using only your expertise.

2. Revise article.

Cost Estimate: Approximately how much would you charge to revise the instructional article?

$ _____

Additional Comments: If any, please use space below.

On average, how often do you provide cost estimates for clients?

a) Every day
b) A few times per week
c) At least once per week
d) At least once per month
e) A few times per year
f) Less often than the above choices
g) never

Thank you for participating in the study
"Costs of Different Formative Evaluation Combinations".