Linking Science and Policy

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This article is based on the keynote presentation given at the 2013 Better Foods for Better Health Symposium sponsored by the Fondation Mérieux and highlights lessons learned and pathways forward in using science to develop policy, including regulations. Key lessons include that science is necessary for developing policy but not sufficient, the challenges associated with prevention, the relevance of the food and agriculture sectors to improve nutrition, the need to rethink the role of foods and nutrients in health, and the importance of multidisciplinary approaches to solve nutrition problems. Principles for moving forward are based on the significance of nutrition for public health, the importance of investing in nutrition research that can be used as a basis for development of policy, the need for diagnostic tools that help motivate behavior to maintain health and prevent disease, the use of nutrition knowledge to improve the food supply, and recognition that behavior will determine the success of nutrition strategies.


In order to provide a framework for my comments on lessons I have learned and pathways forward in ensuring food and nutrition maintain health and reduce risk of disease, it is useful to briefly describe my background. Between 2004 and 2013, I served as director of Nutrition, Labeling, and Dietary Supplements at the US Food and Drug Administration (FDA). This office oversees the development of policy and regulations for dietary supplements, labeling (including nutrition labeling), food standards, infant formula, and medical foods and represented the United States in 2 Codex Alimentarius committees (Food Labeling and Nutrition and Foods for Special Dietary Uses). Prior to FDA, I was a member of the faculty at the University of California, Davis, in Nutrition and Food Science and served as dean of the College of Agricultural and Environmental Sciences. These positions have given me the opportunity to look at the food system from several different perspectives, especially with regard to the role of science in the development of policy and regulations related to foods. At the beginning of my academic career, my focus was on the science, with the belief that if we get the science right, the policy will follow. Experiences with serving on the Dietary Guidelines for Americans Advisory Committee as well as committees for the Institute of Medicine—National Academy of Sciences reaffirmed the importance of having quality science to support decision making in development of policy. However, the experience on these committees made it clear that scientists must not be passive with regard to the interpretation and use of scientific information in the development of policy and regulation. With the move to FDA in 2004, my responsibilities became more directly in line with using scientific information for development of policy and regulations. In addition to work on policy and regulation for the United States, scientists at FDA are also actively involved on the international policy development level, especially through the Codex Alimentarius. This organization sets international standards and guidelines that are used by many countries, in particular developing countries, to develop their regulatory framework for foods.

One way I characterize my position at FDA was to keep the science intact until political and other factors would determine what was feasible to move forward into policy. The interface between science and policy is a point of tension. This tension can be healthy, resulting in a dialogue that leads to appropriate decisions that are feasible and enforceable and reflect good science. However, the tension can also be unhealthy in which science is simply used to justify political decisions. The objective of this article was to share some of the lessons I have learned in this process and identify some important principles for moving forward.

LESSONS LEARNED

1. Science is necessary for developing effective regulation and policy but not sufficient.

Science alone does not determine regulatory action.
After moving to the FDA, I frequently encountered questions from colleagues in nutrition about why something had not happened or had not been done by the regulatory agencies, especially because the science now supported a new or different approach. The response to that question comes from understanding that the policy and regulatory process is, by design, a slow, deliberative process requiring multiple forms of input and that it is not science alone that determines policy or regulatory action. Regulatory actions require a combination of legal analysis, economic analysis, and stakeholder involvement as well as scientific support to develop the political will that will result in agreed-upon policy, including development of regulations.

The process to mandate nutrition labeling on packaged foods in the United States provides a useful example. In 1990, the Nutrition Labeling and Education Act was enacted and gave the FDA legal authority to mandate nutrition labeling. Although the legislation created a legal framework for FDA to move forward with nutrition labeling, a scientific analysis was needed to justify the regulations that were proposed; an economic analysis was needed to demonstrate that the benefits of such a requirement would exceed the costs of implementing the labeling; and a legal analysis was required to illustrate significant government interest (ie, the public health benefit) justified requiring speech in the form of mandatory labeling on food packages (ie, the legal analysis for labeling requirements needs to consider the legal authority granted to FDA through legislation plus First Amendment considerations of compelling or suppressing speech). In addition, stakeholders, including both consumer advocacy groups and the food industry, supported moving forward with a federally mandated approach in order to have uniform requirements rather than approaches that differed state-by-state. Because of the political will created by these factors coming together, mandatory nutrition labeling moved through the steps of legislation, proposed rule, comment period, and final rule in a short window of time, and Nutrition Facts began to appear on most packaged foods by 1994. In contrast, one can look at the timing for updating nutrition labeling. The FDA indicated in 2005 and 2007 its intent to update nutrition labeling to reflect new nutrient reference values from the Institute of Medicine as well as changes in food intake patterns within the population. In this case, a strong scientific justification can be made for updating nutrition labeling, but other factors are less compelling—new legislation does not require an update, ie the FDA is updating based on its own initiative; the economic analysis must consider the cost of changing nutrition labeling in the cost-benefit analysis; stakeholders have varying concerns with regard to what, if any, changes should be made to current labeling; and the work on revising regulations for nutrition labeling must be prioritized with other activities of the agency (eg, implementing the Food Safety Modernization Act). Thus, it is more difficult to create the political will to move such a project forward quickly, even though scientifically it is the right thing to do. The proposed rule was published in 2014; however, at least 7–9 years have passed since FDA first indicated its intent to make revisions and the changes will not be finalized until a final rule is published sometime in the future.

**Political will and many other factors including a scientific, economic, and legal analysis are needed to move regulations forward.**

At the international level, mandatory nutrition labeling serves as an example of the difficulty of generating the political will to move forward. The Codex Committee on Food Labeling discussed a guideline for mandatory nutrition labeling that could be used by member countries. Member countries that have already implemented mandatory nutrition labeling strongly supported such a guideline; however, many developing countries cited concerns about costs to implement such labeling and how such information would be used in their countries. Although all countries recognized the importance of nutrition labeling in addressing risks for diet-related disease, including inadequate nutrient intakes as well as risk of chronic noncommunicable diseases (NCDs) (eg, diabetes, cardiovascular disease, obesity), the political will to translate this understanding into a guideline for mandatory nutrition labeling did not exist.

2. Understanding nutrition for health promotion and disease risk reduction focuses on prevention.

From the earliest understanding of nutrient deficiencies to the current focus on bioactive food components and dietary patterns, the knowledge and understanding of nutrients and/or bioactive food components have been used to focus on prevention strategies, including recommendations for certain food and dietary patterns, fortification of the food supply, and promoting the use of dietary supplements. Although such strategies are inherently positive (ie, to prevent or reduce risk of disease and maintain health), they must be considered in the context of the challenges related to implementing prevention strategies. Dr Harvey Fineberg captured this challenge in the title of his article in JAMA: “The Paradox of Disease Prevention: Celebrated in Principle, Resisted in Practice.” Multiple reasons for this paradox exist, and in nutrition, the following are particularly important to acknowledge:

- Successful nutrition interventions typically must measure when something does not happen; that is, a nutrient deficiency disease does not occur or NCDs are delayed or
do not occur, or complications due to NCDs are mitigated. In addition, nutrition strategies are often most effective on a population basis rather than on an individual basis. For example, changes in the food/nutrition environment or default conditions or addressing barriers due to socioeconomic status may create better choices for the population as a whole, but individual choice will vary. Thus, while population data may suggest change in appropriate directions for prevention of disease, it is more difficult to assess meaningful change at the individual level.

• Health tends to be an abstract concept for most individuals, and we typically do not have robust biomarkers to validate a healthful status that are accessible to individuals. In contrast, disease is more visible to individuals and more likely to motivate behavior to address the problem. Most biomarkers that are available tend to measure disease risk (e.g., blood pressure or low-density lipoprotein cholesterol concentration) rather than maintaining health.

• Several reasons are economic in nature. For example, the medical system generally benefits economically when individuals are sick and need care, not when they are healthy. Economically, disease is often framed as a cost, whereas prevention is framed and evaluated based on cost savings. However, effective prevention programs cost money. In other words, the cost of a prevention program may be apparent, but if effective, it can be difficult to determine the cost savings (i.e., what was prevented?). In addition, there can be a disconnect between who pays the cost to implement effective prevention programs and who gains the benefit of that cost savings. Although a prevention program may target behavior change in certain areas and be successful in achieving that change, to fully understand the effectiveness of the intervention, the behavior or action that replaced the undesirable behavior or action and the consequences of the replacement must be determined to evaluate whether the behavior modification will improve health.

3. The interface between nutrition and public health includes food science and agriculture.

As the public health challenges of obesity and overweight have become more prevalent around the world, criticism of the food sector has increased. In particular, concerns have been raised about the role that foods, which are high in energy density but low in the density of beneficial nutrients, may play in the etiology of NCDs. However, the food sector must be part of the solution. Availability of foods that are accepted and consumed and contribute positively to nutrition is a challenge for food science and agriculture. The primary determinants of consumer choice are taste, cost, and convenience, and these are the qualities of foods that are most obvious to consumers. Nutritional quality may be desirable, but it is not a visible attribute, and in most cases, consumers rely on information rather than direct experience to assess nutritional quality. Because the food industry understands the importance of taste, cost, and convenience to consumers, it can work to build these attributes into products that are recommended for a healthful lifestyle and take steps to diversify the food supply as well as to improve nutrient retention and availability in products that are appealing to consumers. In packaging and marketing foods, the industry has many opportunities to provide meaningful information to consumers that will help them use products to meet dietary recommendations.

Another dimension of this area is the recognition that food choice may be limited by socioeconomic status, and yet healthful foods need to be available to all sectors of the population. What role can food processing and technology play in making nutritious foods affordable, especially in situations where it is important to reduce food waste and provide adequate foods for urban populations?

4. Current policies and regulations delineate the role for foods in the health spectrum—do we have the right framework?

Two aspects of this lesson are important to consider: the spectrum between food and drugs and the balance in current policy between nutrients and foods. Most regulatory frameworks categorize drugs as intended to treat, cure, mitigate, or prevent disease and foods as intended to maintain health. As a dimension of maintaining health, foods are also recognized for their importance in providing essential nutrients to prevent nutrient deficiency diseases. With the introduction of health claims that can be used in food labeling, foods and food components are recognized as reducing risk for certain diseases. However, the overall nature of this framework is to draw a bright line between foods and drugs. If the prevalence of overweight and obesity, hypertension, diabetes, and prediabetic states is high in a population, is it reasonable to expect that such disease states are managed only by drugs, biologics, and medical devices, or is there a role for foods? Both Codex and the Federal Food, Drug, and Cosmetic Act include a proviso for foods for special dietary use (FSDUs). Foods reduced in sodium were initially categorized as FSDUs in Codex Alimentarius, but in the current marketplace, such a claim is regulated as a nutrient content claim. Likewise, gluten-free foods are categorized as FSDUs in Codex. US regulations appear to recognize that FSDUs may need to provide “particular dietary needs” because of certain conditions, “including but not limited to conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight.” A Federal Register Notice, which was subsequently withdrawn, provides an excellent perspective on FDA’s thinking about FSDUs, as it existed in 1996. The challenge can be illustrated with the introduction of probiotics in the marketplace. In some cases,
the claims for products might categorize the product as a drug (prevents or mitigates diarrhea), and yet the product itself is consumed as a food (eg, cultured milk). If a claim were to be made, what evidence is needed to support the claim, studies for a new drug or studies for a food for special dietary uses? Now that we have 20 to 30 years of experience with health and nutrition claims on food products, and in view of the prevalence of NCDs and risk for NCDs in the population, it may be time to explore whether a space between foods and drugs exists that requires the development of new policies and regulations so that foods can be used to mitigate risk factors that are prevalent in the population.

An article in the *Journal of Nutrition* highlights the impact of Casimer Funk’s 1912 article, in which he characterized the “vitamine theory” of disease. This theory emphasized how what was missing from the diet is linked to certain public health problems that were prevalent during that era (eg, beriberi, rickets, scurvy). Some key aspects of documenting these deficiency diseases were the requirements to isolate and characterize the chemical entity that was missing from the diet and to demonstrate that consumption of the compound needed to be ongoing (ie, it could not be consumed like a drug in which a certain dosage was used to cure the disease but was not needed in the long term). The concepts developed around the “vitamine theory” has guided thinking in nutrition for over a century even as the focus has shifted from deficiency diseases to concern about diseases associated with excess nutrient intake and interest in understanding the role of bioactive compounds in foods.

In evaluating bioactive compounds in foods, studies in which compounds are isolated and fed in controlled trials often do not duplicate observations when dietary patterns containing the compounds are consumed. Certain dietary strategies to reduce risk of chronic disease may focus on a single nutrient when a more complex dietary strategy is needed (eg, emphasis on sodium reduction with little education or focus on potassium intake and dietary patterns such as the DASH diet to reduce hypertension). The regulations that have been developed for nutrition labeling on foods as well as the claims related to nutrition and health are generally nutrient focused and reinforce targeting specific nutrients to change rather than food groups or dietary patterns. In addition, such emphasis on nutrients may be associated with development of fortified foods to which the single nutrient is added. In contrast to this focus on individual nutrients, nutrition recommendations have increasingly emphasized food groups and dietary patterns. Although food labeling lists ingredients, it is difficult for consumers to discern from an ingredient list whether a packaged food will make a meaningful contribution to intake of a food group in order to meet the recommended dietary patterns. New approaches are needed in food labeling for consumers to make links between advice in dietary recommendations such as the Dietary Guidelines for Americans or the DASH diet or USDA Food Groups and what is in the packaged food they purchase and use.

5. Linking better foods to better health requires a multidisciplinary strategy.

When the objective is to develop better foods for better health, the challenges in achieving this objective are multidimensional and will require expertise from many disciplines working together to address the issues. Too often nutrition problems, whether due to inadequate intakes or excess intakes, are defined by the tools available or by focusing on a single nutrient. For example, vitamin A deficiency is known to be a significant problem in many developing countries. Public health might define the problem as requiring the use of supplements; food science may define it as the need for fortified foods; plant science may focus on the need for cropping systems or genetic engineering of plants; nutritionists might evaluate the dietary sources of vitamin A or carotenoids; and economists may focus on socioeconomic factors associated with poverty or market access. Each discipline has a valid perspective; however, the tool should not be used to define the problem. In most situations, a reductionist approach is not useful, and a multidisciplinary team may be able to see these strategies as a portfolio of tools to define and address the problem.

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**Once problems are defined, a portfolio of tools may be needed to address them.**

It is important to note that working in a multidisciplinary manner can be challenging. Among the experts, there needs to be a common understanding of the strengths and weaknesses of each discipline so that dialogue and problem solving can be productive in addressing each situation. Difficulty occurs when the experts in 1 discipline try to speak for another discipline or define the problem to be solved in a manner that results in only 1 approach being acceptable. For example, a plant scientist may be able to define what is feasible for improving the nutrient content of plants or diversifying the production of plants to improve dietary patterns using traditional breeding techniques or genetic engineering. However, a nutritionist may be a more appropriate expert to define the causes of nutritional imbalance within a population.

**PRINCIPLES FOR MOVING FORWARD**

A part of learning is to also look for ways to move forward. From my experience in government, including international...
work in Codex, and in the university, looking to the future is best done by creating a framework that includes a set of principles or core beliefs that can be agreed upon and used to determine the barriers or issues that need to be addressed as well as the investments that will be necessary to achieve our purpose. I propose some principles below that I hope can be a starting point for discussion. In some cases, the principles may be stating the obvious, but that statement is important to recognize where there are points of agreement in thinking about how to build better foods for better health.

1. Consequences of malnutrition, whether due to over or under nutrition, are serious.

The media often covers controversies in nutrition, and the nature of the coverage may result in some individuals questioning the importance of dietary choices in maintaining or improving health and taking for granted the adequacy of the diet. Over a century of research has demonstrated the serious consequences of inadequate nutrient intake, including mental retardation and reduced capacity for work and learning, as well as public health problems (eg, scurvy, beri-beri, rickets, anemia). Likewise, dietary excesses are linked with poor quality of life and productivity as well as increasing healthcare costs associated with NCDs such as diabetes and cardiovascular diseases. As nutrition science moves into new areas, including understanding the role of nonnutrient bioactive compounds in foods and the potential value of foods in managing disease, controversy is useful to define the issues and experimental approaches that are needed; however, such controversies should not undermine the fundamental understanding of the significant role nutrition plays in maintaining health and well-being.

2. Ongoing investigation of the function and metabolism of nutrients and food components is critical for defining nutrition’s role in public health.

An ongoing investment in research is required to build the scientific knowledge that is necessary to understand the role of nutrition in health. Such research needs to include clinical observations and basic experimental studies in order to understand mechanisms. This knowledge is essential for building meaningful recommendations that are unlikely to change based on new information. Nutrition faces significant challenges in developing the research models that will enable us to move beyond the focus on single nutrients or food components. Our evolving understanding of nutrition has indicated that isolating components from the matrix of foods and dietary patterns may result in difficulty defining the importance of nutrition in health promotion and disease prevention. Research models are needed that allow an understanding of dietary interactions and the potential for individual variation, including genetic variation, in responding to diet.

The recent focus on the microbiome illustrates the complexity in conducting research to understand the interaction between dietary factors, the microflora, metabolism, health, and disease risk.

An additional challenge in building the research foundation that is needed in food and nutrition is the development of validated biomarkers. Biomarkers that are valid surrogate end points facilitate the ability to conduct human studies in nutrition. For example, reduction in low-density lipoprotein cholesterol is accepted as a surrogate end point for cardiovascular disease, and investigators can use this biomarker to conduct shorter clinical studies rather than longer studies that have incidence of disease as the end point. Biomarkers are also needed as surrogate measurements of food intake and developmental outcomes. Because of the importance of these tools in research, studies are needed to validate biomarkers for these purposes.

3. Regulation and policy in nutrition must be based on science and be effective in helping consumers.

The corollary of the previous principle is the use of science in the development of regulation and policy. As noted under lessons learned, science is necessary but not sufficient; however, science is a key component for creating the political will to support policies and regulations. If the science is debatable or readily challenged, those controversies will mire down the process and undermine the ability to move forward. To illustrate the problems of trying to develop policy when the science is still not well settled, the process to develop a definition for dietary fiber in the Codex Committee on Nutrition and Foods for Special Dietary Uses is an example. After many years of debate, certain components of the definition were left to national authorities (eg, how to determine the physiological benefit of an isolated fiber and whether to include polysaccharides of <10 sugars in the definition) because they could not be resolved based on current scientific information. Consequently, the definition will vary among countries and does not meet 1 of Codex Alimentarius’ goals of encouraging fair-trade practices. When decisions are not based on relevant scientific information, the risk of unintended consequences increases. For example, some countries have considered labeling for added or extrinsic sugars in foods; however, it is not known if that information will result in consumers paying less attention to calories and total sugar content of foods, which may be more important for energy balance and dental caries risk.

The importance of scientific evidence to support policy development is illustrated by the use of evidence-based systematic reviews to support recommendations by the World Health Organization (WHO) as well as government agencies. For example, the US Department of Agriculture and the Department of Health and Human Services have implemented a systematic review process to support the work of the Dietary Guidelines Advisory Committee, the US FDA
has posted guidance on the evidence-based review process used for evaluation of health claim petitions, and the European Union has published its guidelines for review of nutrition and health claims used in food labeling. The WHO has developed a process using GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) to develop systematic reviews that include meta-analysis that are evaluated by expert committees. The WHO is using the input from an expert committee to reevaluate and revise Technical Report 916 and publish guidelines that are used by many countries to develop their policies in food and nutrition. Because of this reliance on evidence-based systematic reviews, the demand for clinical and experimental studies in humans that provide scientific support for recommendations beyond the associations found in epidemiological or observations studies is increasing.

The second aspect of this principle is that regulation and policy should be effective in helping consumers by providing useful information for promoting public health. Government agencies have, as a part of their mission, to protect public health, and policies and regulations should support and facilitate that objective. If the role in protecting public health is transparent, the recommendations are more likely to be trusted by the public.

4. Development of new diagnostic tools and understanding the human genome provide new pathways to develop prevention strategies using nutrition and dietary patterns. Incidence of disease or distinct warning signs for risk of disease are typically more effective in motivating behavior change to manage or reduce risk than providing general advice. As better genetic tests and diagnostic tools become available, the knowledge gained by understanding who is at risk may provide incentives both to the healthcare system and to individuals to maintain health and motivate behavior change that could mitigate risk. Knowledge of who is at risk will enable better evaluation of when interventions can be effective at preventing or mitigating the impact of disease. Although health is an abstract concept to many consumers, more useful diagnostic tools may make it more tangible and thus desirable to maintain. The development of better tools using genetic and metabolic diagnostic tests may result in useful biomarkers to understand risk and the variability in nutrient needs/requirements.

5. Nutrition knowledge enables us to understand how to improve the quality of our food supply.

Food-based dietary recommendations need to be a key component in the development of food and agricultural policy. At the level of the individual, consumers must have the ability to choose products that help them meet the recommendations in a sustainable and affordable manner. Such choice is feasible only if nutrition recommendations are factored into planning at a community and national level for food and agriculture. Given today's marketplace, technology and innovation can have an important role in helping consumers meet food and nutrition recommendations. Food processing is recognized as a technology that can improve nutrient retention and availability as well as reduce spoilage and waste in the food system. In addition, innovative use of technology can facilitate the ability of all consumers regardless of socioeconomic status to have access to dietary patterns associated with health promotion and disease risk reduction.

6. Human behavior is a major determinant of the success of nutrition strategies.

The link between better foods for better health is behavior. Foods that are part of recommended dietary patterns and considered better choices are already available in the marketplace. Thus, the potential to link better foods to better health exists; however, that potential is realized only if consumers make choices consistent with recommendations. The policies that are currently in place with regard to nutrition focus primarily on providing consumers with information so that better choices are possible. However, information is used most effectively when adequate education is available to understand and utilize that information. This linkage raises the question of whether current education strategies are sufficient to use nutrition information effectively.

FUTURE SCENARIO

The 6 principles outlined above are intended to encourage discussion and thinking about the relevance of nutrition science in policy development. The value of developing principles that can be agreed upon is that these principles create a framework to consider what investments or actions are needed and what barriers or issues need to be overcome. A future scenario is useful to consider how such a framework might be used to think about what we would like to see happen.

The scenario, "Mary's Story," considers the interaction of personalized medicine and nutrition. Let us assume that by the year 2020 new innovative screening tools, including genetic information, are a part of routine health screening. As a consequence, Mary, who is in her 30s, has been identified as at risk for early heart disease. In the ideal version of this scenario, Mary is assigned to a clinic program to help her implement the prevention program that has been developed for her, and that program includes diet, exercise, and medication, as needed. Mary already has a good working knowledge of nutrition information and labeling because it was integrated into her school program, and she has been using the information before her diagnosis. The clinic teaches her how to adapt those skills for her particular program. In addition to the clinic program, she also has diagnostic tools that allow her to monitor her own progress...
and response to modifications she is making in her lifestyle. During the intervening years, research on food components has advanced, and the food industry has moved forward with several initiatives to develop products that target certain risk profiles such as Mary’s (i.e., FSDUs). In addition, food analysis has advanced so that more complete information is known about the components in various products. Mary responds well to the program and is able to delay the need for medications until her 70s by which time pharmacogenetics has advanced and is better able to target her specific metabolic condition.

However, just as there can be an ideal version of this scenario, the nightmare version of the scenario should also be considered. In this version, after her diagnosis, Mary is given a booklet with information about diet and exercise and told to follow the instructions and return in 3 months. She does not have a good understanding of how to use information in food labeling and is aware of the reports in the media that seem to indicate any proposed benefits of diet and exercise are controversial and confusing. Upon returning to the clinic, she agrees that medication is probably the more effective route for managing her condition. Research on food components has been mediocre because it is not clear how the research can be used to innovate new products and provide information about the effects of diet on managing disease risk. By the time Mary is in her 40s, she is hypertensive, prediabetic, and relying on medications to manage her condition. In her 50s, she has had to use the emergency room on occasion and taken time off from work and is beginning to consider if she should apply for medical disability to deal with her condition.

I prefer to end on the ideal scenario in which diagnostic and genetic information is used to motivate behavior change; our knowledge of food and food components has resulted in better foods for an at-risk individual; the person is educated in how to use nutrition information effectively; and the consequences are positive for her health and well-being.

**CONCLUSION**

All populations should have the opportunity to achieve better health based on the availability of better foods. From my perspective, we have learned many lessons in trying to achieve this goal, and it is important to use those learnings to develop a pathway forward. I appreciate the opportunity to share my perspectives on this important task.

**REFERENCES**