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NUTRITION SESSIONS
From scientific knowledge to intervention studies : How to enhance F&V consumption?

In brown, sessions no validated by their authors

SESSION 3

F&V INTERVENTIONS TO REDUCE CARDIOVASCULAR DISEASES

Chair: **K.T. Khaw**

- The importance of F&V in the prevention of cardiovascular disease. **F.J. He**
- Are supplements equivalent to dietary micronutrient consumption? **J.V. Woodside**
- Effects of F&V consumption on plasma blood pressure: intervention study. **L. Dauchet**
- F&V and cardiovascular disease risk: what should we do? **K.T. Khaw**

The importance of F&V in the prevention of cardiovascular disease

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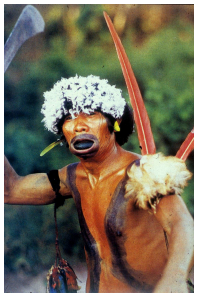
Cardiovascular disease is the leading cause of death and disability worldwide. The two major forms of cardiovascular disease are stroke and coronary heart disease. It is estimated that, worldwide, over 16 million people die of cardiovascular disease each year, that's equivalent to approximately 30 deaths every single minute. In addition to this, there are approximately another 20 million people who suffer a stroke or heart attack but survive. Many of these people will have to live with different degrees of disability for the rest of their lives and many of them would require long-term very costly medical care. Therefore, the primary prevention of cardiovascular disease is a major public health priority.

A number of risk factors for cardiovascular disease have been indentified. To tackle cardiovascular disease, all of these modifiable risk factors should be dealt with. We should lower blood pressure, lower cholesterol, stop smoking, eat more fruit and vegetables, do more exercise and reduce obesity. Today I am going to talk about the evidence for the increase in the consumption of fruit and vegetables to prevent cardiovascular disease.



I would like to begin with the studies in a very few tribes that still exist in the world. This is one such man, a Yanomama Indian from the border of Venezuela and Brazil living an evolutionary lifestyle. They mainly live on fruits, vegetables, roots and occasionally monkeys that they can catch. In their diet, there is no salt, very little fat and no refined carbohydrate. They are aggressive, very fit and have a lot of stress. In such populations, the average blood pressure and cholesterol are much lower than those in the developed countries. And in such populations, their blood pressure does not increase with age and there is no evidence of cardiovascular disease. Some people may argue that the Yanomama Indians die at a younger age before they develop a high blood pressure and cardiovascular disease. However, ecological studies have compared age-matched populations and showed that the populations that still have evolutionary lifestyles, have a significantly lower blood pressure, and the major cause of death for the Yanomama Indians is infectious disease.

A number of case-control epidemiological studies have specifically looked at the relationship between fruit and vegetable consumption, or some surrogate markers of fruit and vegetable consumption, and cardiovascular disease. So far, there have been 16 studies on coronary heart disease and 1 study on stroke. Most of these studies have shown a significant inverse association. In other words, a higher consumption of fruit and vegetables was associated with a lower risk of cardiovascular disease.

The largest case-control study is the INTERHEART study. It included over 15,000 cases of acute myocardial infarction and approximately the same number of controls. Only first acute cases of myocardial infarction were included in order to minimize any potential bias due to changes in diets or lifestyles following a coronary event. The study was carried out in 262 centres from 52 countries. The investigators used standardised methods for data collection across the world. The results showed that individuals who ate fruit and vegetables daily, compared with those who did not had a 30% lower risk of myocardial infarction after adjusting for all of these confounding factors.

Prospective studies have the advantage of eliminating any potential selection bias or recall bias which are more likely to occur in case-control studies. There have been over 20 prospective cohort studies looking at fruit and vegetable consumption and the subsequent occurrence of cardiovascular events. We have recently carried out a meta-analysis of these cohort studies. We included studies that had reported relative risk of stroke or coronary heart disease and their corresponding 95% confidence interval. For inclusion, studies had to provide the frequency or amount of fruit and vegetable consumption in relation to the relative risks. We excluded studies that reported a mixed healthy diet where the effect of fruit and vegetables could not be separated. We also excluded studies that reported only surrogate nutrients of fruit and vegetables rather than fruit and vegetables themselves.

For each individual study, we grouped fruit and vegetable consumption into 3 standardized categories, that is: less than 3 portions per day, 3 to 5 portions per day and over 5 portions per day. The corresponding relative risks of stroke or coronary heart disease were also grouped accordingly. We used random-effect model to calculate the overall relative risk.

This table shows the number of studies included in the meta-analysis.

	Stroke	**CHD**
Number of cohorts	**9**	**13**
Number of participants	**257,551**	**278,459**
Number of events	**4,917**	**9,143**
Duration of follow-up (yr)	**13**	**11**

He et al. Lancet 2006;367:320 & JHH 2007;21:717.

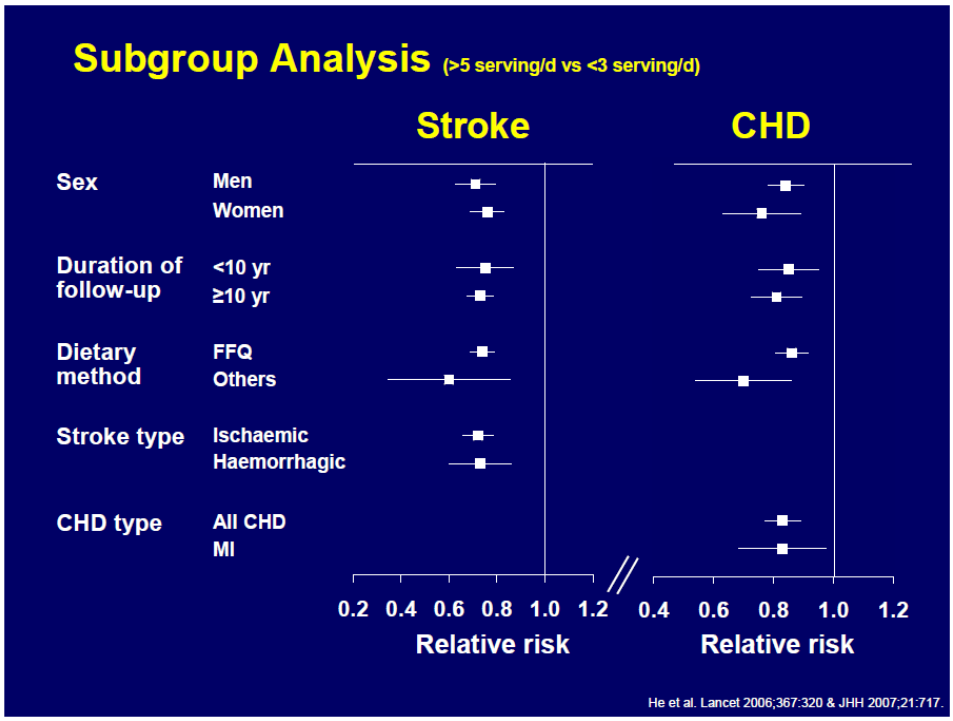
For stroke, 9 cohorts met the inclusion criteria; there were over 257,000 participants with an average follow up of 13 years. A total 4,917 strokes occurred. For coronary heart disease 13 cohorts met the inclusion criteria, there were over 278,000 participants with an average follow up of 11 years. A total of 9,143 coronary events occurred.

The results showed that an increased consumption of fruit and vegetables was related to a reduced risk for both stroke and coronary heart disease.

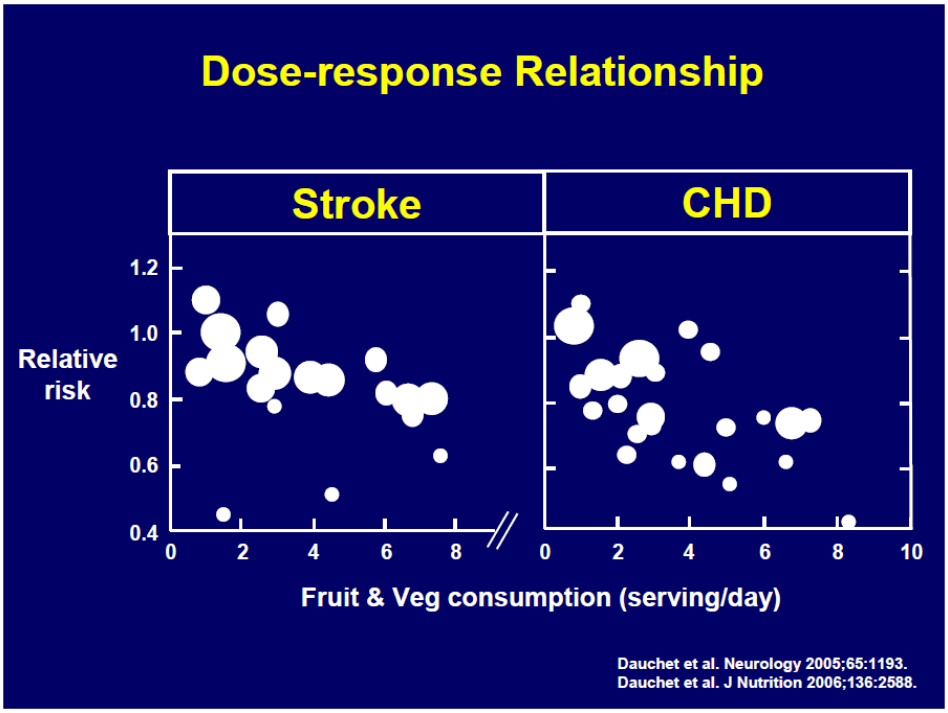
This figure shows the relative risk of stroke and coronary heart disease. Compared to the individuals who had less than 3 portions of fruit and vegetables per day,

individuals with 3 to 5 portions per day had an 11% lower risk of stroke and 7% lower risk of coronary heart disease. Individuals who had more than 5 portions per day had a 26% lower risk of stroke and 17% lower risk of coronary heart disease. All of these relative risks were adjusted for potential confounding factors.

This figure shows the sub-group analysis comparing individuals who had more than 5 portions per day with those who had less than 3 portions per day. The vertical lines are the relative risk of one, and these squares indicate the relative risk for the subgroups. If this square is on the left side of this vertical line, this indicates a protective effect. You can see that a higher consumption of fruit and vegetables had a significant protective effect for all of these subgroups. In other words, there was a significant protective effect for both stroke and coronary heart disease irrespective of gender, duration of follow up or dietary assessment methods. For stroke, there was a significant protective effect for both ischemic and haemorrhagic stroke. For coronary heart disease, the effect was significant for myocardial infarction alone or when all coronary events were considered together.



Another recent meta-analysis of cohort studies was the carried out by Dr. Dauchet and colleagues. Their papers were published around the same time as ours. They used a different statistical approach to analyse their data. These figures are from their papers. The y axis is the relative risk for stroke or coronary heart disease, and the x axis is the portions of fruit and vegetables per day. You can see that there is a clear dose-response relationship. So the higher the consumption of fruit and vegetables, the lower the risk for both stroke and coronary heart disease.

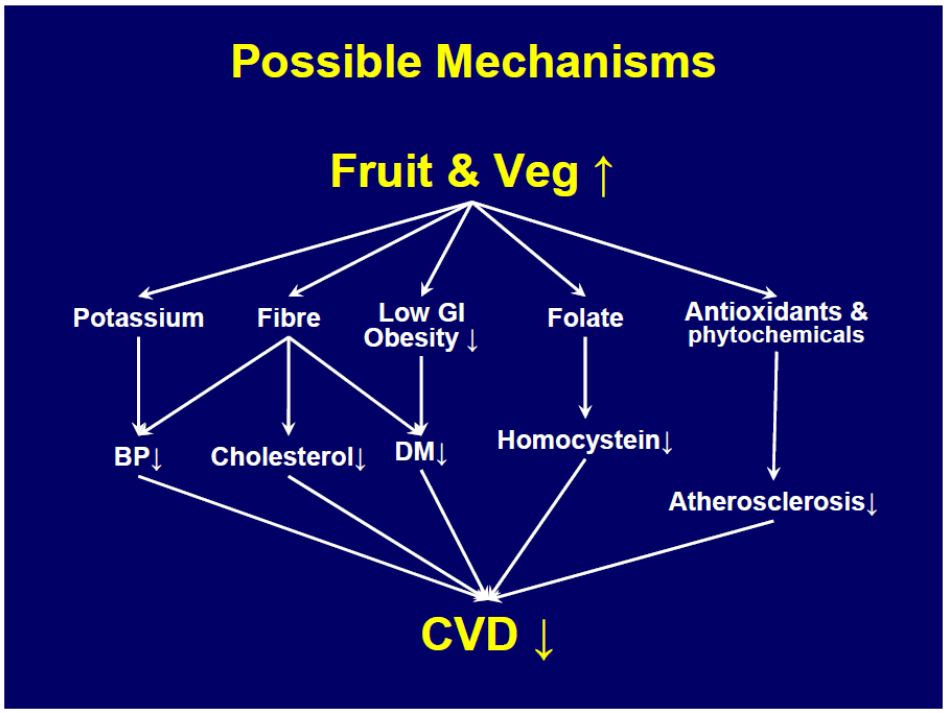


Outcome trials would provide stronger evidence. However it is extremely difficult to carry out long-term randomized trials on any dietary or lifestyle interventions on cardiovascular disease outcome. It is therefore not surprising that there is no randomized trial looking at fruit and vegetables alone on the primary prevention of cardiovascular disease. However there are a couple of randomized trials that have looked at the effect of an increase in the consumption of fruit and vegetables in combination with other healthy diets or lifestyles, particularly in individuals who had survived cardiovascular events. These trials have provided further support for an increase in the consumption of fruit and vegetables to prevent cardiovascular disease.

The Lyon Diet Heart Study is a good example. Over 600 individuals who had survived an acute myocardial infarction were randomized into 2 groups: the experimental group and the control group. In the experimental group, all participants were given advice by research dieticians on how to follow a Mediterranean diet which is rich in fruit and vegetables, olive oil, fish and low in red meat. Cream and butter were replaced with rapeseed oil based margarine. In the

control group, participants did not receive any specialist's advice from the research team, apart from the routine dietary advice from their own doctors. After four years of follow up, the experimental group had a 70% reduction in cardiac deaths and nonfatal myocardial infarction. It is a huge reduction. Although this outcome was not solely attributable to fruit and vegetables, this study clearly suggested that an increase in the consumption of fruit and vegetables in combination with other healthy diets reduces cardiovascular disease.

How do fruit and vegetables protect against cardiovascular disease? The mechanisms are likely to be multiple.



Fruit and vegetables are rich sources of potassium, folate, fibre, antioxidants and many phytochemicals. Randomized trials have shown that an increase of fruit and vegetable consumption leads to an increase in 24-hour urinary potassium excretion and a fall in blood pressure. Clinical trials have also shown that potassium supplementation had a similar blood pressure lowering effect. We all know that raised blood pressure is a major cause of cardiovascular disease, therefore the blood pressure lowering effect of potassium is likely to be an important mechanism for the protective effect of fruit and vegetables on cardiovascular disease. Increasing evidence also suggests that the potassium may have a direct effect on reducing cardiovascular risk which may be independent of but additive to the effect of the potassium on blood pressure.

Dietary fibre may reduce cardiovascular disease through its effect on blood pressure, cholesterol and reduce the risk of diabetes. As we have heard in the earlier session this morning, fruit and vegetables play an important role in the management of obesity, therefore reducing the risk of diabetes and cardiovascular disease.

Dietary folate may reduce cardiovascular risk through its effect on plasma homocystein levels. Antioxidants and bioactive phytochemicals may prevent the development of atherosclerosis.
I am going to briefly talk about one of these mechanisms that are potassium and cardiovascular disease. The earliest study on potassium and stroke was reported by Professor Khaw & Professor Barrett-Connor. In a prospective cohort study they followed up 859 men and women from Southern California for 12 years. They found that a 10 mmol increase in potassium intake, which is equivalent to 1 to 2 portions of fruit and vegetables per day, was associated with a 40% lower risk in stroke mortality after adjusting for all of these confounding factors including blood pressure. Later on, a number of larger cohort studies have confirmed Professor Khaw's findings. Recently an outcome trial on potassium was published. This trial was carried out in almost 2000 elderly veterans who lived in a veterans' retirement home in Northern Taiwan. In this veterans' home, 5 kitchens provided all food for all participants, and these 5 kitchens were randomized into two groups. In one group, the normal salt, which is sodium chloride, was used as usual. In the other group the normal salt was replaced with a potassium-enriched salt which is higher in potassium chloride and lower in sodium chloride. With this intervention there was a 76% increase in potassium intake and a 17% reduction in sodium intake in the intervention group. After two and half year of follow up, the high potassium group had a 40% reduction in cardiovascular disease mortality. This randomized trial clearly demonstrates that an increase in potassium intake and a reduction in sodium intake reduce cardiovascular disease mortality.
To summarize, ecological studies, case-control studies, prospective cohort studies, and secondary prevention trials have consistently demonstrated the importance of fruit and vegetables in the prevention of cardiovascular disease. Studies have also shown a clear dose-response relationship, so the higher the consumption of fruit and vegetables, the lower the risk of cardiovascular disease. Additionally, the protective effect of fruit and vegetables has a strong biological basis. Taken together, the totality of evidence strongly supports a causal relationship. In other words, a low consumption of fruit and vegetables is a cause of cardiovascular disease.

How much fruit and vegetables are we eating now? The average fruit and vegetable intake in most developed countries is between 3 and 4 portions per day. It is even less in developing countries. This figure shows the average fruit and vegetable consumption for adults from the Health Survey for England from year 2001 to 2006. The bar in yellow indicates the intake for men and the bar in blue is for women. From 2001 to 2006 there has been a small increase in fruit and vegetable consumption, but even in 2006 the average intake was only 3.3 portions per day for men and 3.7 portions per day for women.

This figure shows the proportion for adults who consumed 5 or more portions of fruit and vegetables per day; the data was again from the Health Survey for England.

From 2001 to 2006 there has been a small increase in the percentage of individuals who consumed 5 or more portions of fruit and vegetables per day. But even in 2006, only less than one third of adults had fruit and vegetable intake reached the recommended level of 5 or more portions per day. And over two thirds of adults had fruit and vegetable intake below the minimum recommended level.

In conclusion, what I have shown you today is that cardiovascular disease is the leading cause of death and disability worldwide. A low consumption of fruit and vegetables is an important cause of cardiovascular disease. Currently in most developed countries the average fruit and vegetable intake is between 3 and 4 portions per day and less than one third of adults have the intake reached the recommended level. These figures are even lower in developing countries. Therefore greater efforts should be made to increase fruit and vegetable consumption in the whole population. If the recommended levels are achieved, the benefits will be very large in terms of reducing the appalling burden of cardiovascular disease worldwide. Furthermore an increase in the consumption of fruit and vegetables may have other beneficial effects, for example, reducing the risk of some cancers and some other chronic diseases. I would like to finish with this statement from the World Health Organisation. This was based on an analysis from Dr Lock and colleagues: *"Worldwide, up to 2.7 million lives could potentially be saved each year with sufficient global fruit and vegetable consumption".*

Q&A

PUBLIC: The data of the meta-analysis which represented that low fruit and vegetable consumption among men and women was associated with a higher risk of CVD and stroke was independent of the consumption of other food groups and other co-variables associated with a risk of CVD?

KT KHAW: The question is: was the relationship between fruits and vegetables and cardiovascular disease in the observational studies independent of other food associated with CVD?

FJ HE: Almost all of the observational studies have adjusted for confounding factors as much as possible. However, we can not exclude the possibility that some un-measured factors may still have some confounding effect on the association between fruit and vegetable consumption and cardiovascular disease. But it is unlikely that all results from the observational studies were due to the confounding effect of the un-measured factors.

PUBLIC: One of the notable things you raised was that there is a suggestion that the relationship is stronger for stroke than coronary heart diseases. Do you think this is real?

FJ HE: I am not aware of any studies that have directly compared the effect on stroke with the effect on coronary heart disease, but one of the mechanisms for the protective effect of fruit and vegetables is through the blood pressure lowering effect. Because blood pressure is more closely related to stroke compared to coronary heart disease. So it is likely that fruit and vegetables may have a greater effect on stroke than coronary heart disease, but this is only based on speculations. The statistical comparisons are better to be made within a study to compare the effects on different cardiovascular outcomes.

PUBLIC (American Cancer Institute): I noticed you lumped all the data together after 5 servings and I wonder if you have any evidence that there are some benefits when you actually increase the number of servings from 5 to 9 or from 9 to 11. Is there any kind of evidence of any benefits out there?

FJ HE: We were not able to look at this in our meta-analyses. But some studies did have a higher fruit and vegetable consumption from 1 to 10 portions per day and they have shown a clear dose-response relationship, so the higher the consumption of fruit and vegetables, the lower the risk.

PUBLIC (American from the Cancer Institute): Typically when you have that high amount of consumption there are few fruits and vegetables that predominate. What fruits and vegetables are we talking about when you increase from 3 to 5 to 9 to whatever number? Are there really some fruits and vegetables that really help more than others?

FJ HE: The information on this is very limited in the literature. Some studies did suggest that green leaf vegetables, cruciferous vegetables, citrus fruits have a greater effect, but further studies are still needed to clarify this. I think we need to remember that the beneficial effect of fruit and vegetables is due to the combination of many nutrients contained in fruit and vegetables. It is unlikely that any single fruit or vegetable could provide the whole complex biochemical compounds contained in a variety of fruit and vegetables. Based on the available evidence, I think we should eat a wide variety of fruit and vegetables.

PUBLIC (Eric LEMERCIER, Groupe MedAlliance Europe, Producteur de Fruits et légumes) : Je suis un petit peu inquiet sur les tenants qui sont aujourd'hui donnés par les orateurs toujours sur la véracité de ce que peut apporter les fruits et légumes. On est toujours un peu sur une réserve de « peut être », « c'est probable », « c'est une liaison ». Comment pensez vous que l'on puisse aujourd'hui à valider chez les consommateurs d'accroître justement leur consommation quand nous même aujourd'hui nous n'arrivons pas à dire clairement si les fruits et légumes apportent réellement un bien fait avec des preuves à l'appui ? J'ai cette sensation qu'on est

toujours sur des réserves. C'était moins démontré tout à l'heure mais on se pose toujours la question : « c'est probable qu'il y ait une liaison », « mais », il y a toujours ce « mais ». Si nous même nous ne sommes pas convaincus du bienfait des fruits et légumes sur la santé des consommateurs à travers le monde comment ces consommateurs eux-mêmes peuvent-ils être convaincus ?

FJ HE: I know that there are still some uncertainties in these areas, but I believe, based on the available evidence, the evidence is strong, particularly when looking at the different types of studies - ecological studies, case-control studies, prospective cohort studies, secondary prevention trials and also studies on mechanisms, have consistently shown the importance of fruit and vegetables. So the evidence is strong. Now how to convince the consumers? There will be a session to discuss this.

Are supplements equivalent to dietary micronutrient consumption?

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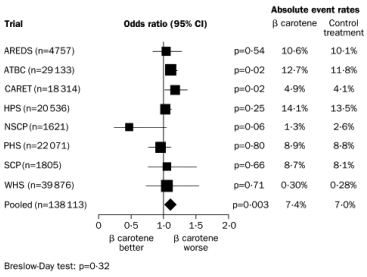
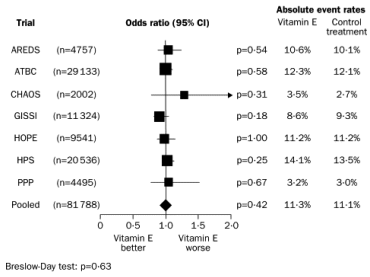
The outline of the presentation will be as follows: I am going to first talk about the evidence that micronutrient supplementation reduces cardiovascular disease risk and then looks at the evidence that increasing dietary micronutrient intake reduces cardiovascular disease risk. Throughout the presentation, I will concentrate on randomized controlled trial evidence wherever possible.

Clinical micronutrient deficiency is by now uncommon in the developed world. However, it has been proposed that sub-optimal intake of certain micronutrients could be associated with increased cardiovascular disease risk. Therefore, if we increase micronutrient status that will be theoretically linked with reduced cardiovascular disease risk.
How do we increase micronutrient status? We have a number of options: we can use micronutrient supplements, we can increase the consumption of micronutrient rich foods or finally we can fortify our food with the micronutrient of interest. I am not dealing with food fortification within this presentation.
What evidence do we have linking increase micronutrient status, by whatever means, with reduced cardiovascular disease incidence? We have a number of different strands of evidence. Firstly we can look at the increased micronutrient status in animal models, and whether that produces a change in CVD risk. We can look at increasing micronutrient status in healthy subjects and look for a change in cardiovascular disease biomarkers. We can carry out observational epidemiological studies and look at whether increased intake of a particular micronutrient is associated with reduced risk of cardiovascular disease. Finally we can carry out the randomized controlled trials of micronutrients - intervention studies with clinical end points where we look for a change in cardiovascular disease risk. I will concentrate in this presentation on the last two strands of evidence, and as I said primarily on randomized controlled trials where they exist.
This slide is included just to introduce the fact that we do have wealth of observational evidence linking increased micronutrient status with reduced risk of cardiovascular disease and it has been reviewed extensively over the years, this by Fairfield and Fletcher in 2002 in JAMA. That wealth of observational evidence led into a series of randomized control trials of isolated micronutrient supplements. A number of micronutrients have been tested, including B-group vitamins but because of the limited time today, I am only going to look at antioxidant vitamin supplementation and cardiovascular disease.
Randomized control trials started to be reported in the mid to late nineties and since then they have been subjected to meta-analysis as the data from the various RCTs

were reported. Largely these studies have reported no effects of antioxidant vitamin supplementation on cardiovascular disease risk.



β-carotene



Vitamin E

This is a meta-analysis carried out in 2003 showing that the supplementation of β-carotene in fact seems to lead to an increased risk of cardiovascular disease and for vitamin E there seems to be no effect of supplementation with vitamin E on cardiovascular disease end points.

Miller et al. in 2005 attempted to look at the dose-response relationship between vitamin E supplementation and all cause mortality rather than cardiovascular disease mortality in randomized controlled trials. They showed some evidence of a dose response effect; the higher doses of vitamin E seemed to be harmful, while at lower doses there seemed to be some evidence of a small protective effect. Further work carried out by a Danish group published in JAMA last year and published as a Cochrane review this year looked at the effect of antioxidants supplementation on overall mortality. They classified trials as having a low risk of bias if generation of allocation sequence was reasonable, if there was a blinding of allocation etc, and they classified a total of 47 trials as having a low risk of bias. Using those 47 trials they showed a small increase in risk of mortality for those taking antioxidant supplements versus placebo with a relative risk of 1.05. They then looked at the effect of individual antioxidant supplements, excluding the selenium trials because they showed some evidence of benefit, and once they excluded those trials, β-carotene, vitamin A, vitamin E, either singly or in combination, all significantly increased mortality.

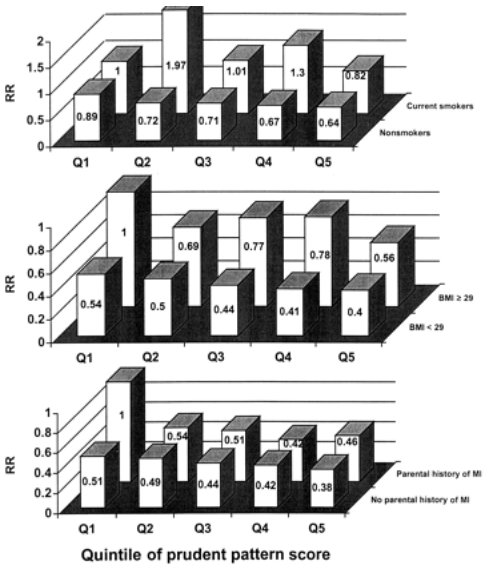
Now not all studies have been negative. We have the *AREDS* study which used a cocktail of antioxidant vitamins and showed a reduced progression from early stages of age-related macular degeneration (AMD) to the later stages of AMD. We also have the *SPACE* study which looked at the effect of vitamin E on cardiovascular disease endpoints in stage renal disease patients and showed a reduced proportion of patients with cardiovascular end points in the intervention versus placebo groups. However, by and large, these intervention studies with antioxidant vitamins have been negative and there has been great debate as to why these clinical trials have been negative. There has been criticism of these trials themselves; firstly they used an isolated antioxidant rather than a whole food or rather than a panel of antioxidants. There has been debate about the dose used, whether it was too low or too high etc. There has been debate over the duration of treatment with the antioxidants and the

duration of follow up after treatment with the antioxidants. There has been debate over the initial micronutrient status of the subjects invited to take part in these studies and their dietary intake and debate over the extent and distribution of existing disease. For example antioxidants have been shown to protect against LDL oxidation which is one of the crucial early stages in the development of atherosclerosis where a lot of human studies have recruited people who were quite advanced in the cardiovascular disease pathway in that they were already at a high risk of the disease e.g. they had high blood pressure levels or they were smokers. So there has been much debate about the design of the trials that have been carried out.
There has also been debate over two more general issues. Firstly, on the micronutrient used - it has been proposed that it is the foods themselves rather than the isolated nutrients that are protective. We find a complex mixture of antioxidant micronutrients and other bioactive components in fruits and vegetables. Maybe these are more effective than large doses of a small number of micronutrients. There is also the issue of confounding in observational studies where we did see an association between antioxidant intake and cardiovascular disease outcomes. It has been proposed that this association may have been confounded by other lifestyle behaviours, despite best efforts to control for these confounders. For example, it has been shown that a high intake of antioxidants is associated with a better overall diet, is associated with increased physical activity, with not smoking and with higher social class. And it has been proposed that the adjustments made to the analyses of the observational studies simply could not control fully for that confounding. It is therefore actually perhaps one of these other lifestyle factors that are causally linked with a reduced risk of cardiovascular disease.

It has also been proposed that it may be a combination of these things that is having a reduced effect on cardiovascular end points and that it is total diet and lifestyle pattern that is crucial. That is summarized quite effectively in an editorial that appeared in Lancet in 2004 where Forman and Altman said: “The effect on diseases with long latency periods of pharmacological doses of specific micronutrients over a few years in middle-aged adults is a different scenario from physiological doses of the same micronutrients provided as part of a balanced diet on a lifelong basis, starting in childhood.”

The second part of the talk looks at the evidence that an increase in dietary micronutrient intake will reduce cardiovascular disease risk. There are a number of approaches to study dietary patterns, for example looking at people who consume a vegetarian diet, looking at increased fruit and vegetable intake, looking at the Mediterranean diet and finally looking at combined health behaviours. Each of these dietary changes, will involve an increase in micronutrient intake, although there will also be a change in intake of other nutrients. It is actually difficult to definitely establish whether a health benefit is directly due to the increase in micronutrient intake but these are the approaches that have been taken.

Firstly dietary pattern analysis: this arose from a realisation that we do not consume nutrients in isolation, we do not consume foods in isolation but we consume an overall diet and concentrates therefore on that overall diet rather than one nutrient. A number of statistical techniques can be used to determine dietary patterns - most commonly principal component analysis but also cluster analysis or reduced rank regression. These aggregate food items and groups based on the degree to which these are correlated with each other and consumed together and that produces a summary score for specific dietary pattern. Now the dietary pattern produced depends on the data but it commonly produces a number of patterns. One is usually called the prudent pattern that can be characterized by higher intake of fruit, vegetables, legumes, whole grains, poultry and fish. And the western pattern which is characterized by higher intakes of red and processed meats, sweets, desserts, potatoes, chips and refined grains. This sort of analysis has been applied to a number of observational studies with heart disease end points.



This is one of the first occasions where dietary pattern analysis was applied by Hu et al. in 2000 and you can see that this is looking at the quintile of prudent pattern score by smoking status, BMI, and parental history of myocardial infarction and looking at multivariate relative risks going from low to high prudent pattern score. And you can see that classified by smoking status, BMI or parental history of MI, you can see that the relative risks tend to decrease as the score for the prudent dietary pattern increases.

It is crucial to show that these dietary patterns are associated with change in micronutrient status and we have done some work in this area using a relatively small cross sectional study on healthy men who were 30-49 years. We carried out principal components analysis to pull out dietary patterns and we found 5 dietary patterns. The first pattern which we called the healthy pattern was characterized by increased intake of wholemeal bread, high fibre breakfast cereals, fruit and vegetables and that healthy pattern was positively associated with folate, α-carotene, β-carotene and lycopene status and negatively associated with homocysteine. Therefore we can say that dietary patterns are associated with a change in micronutrient status.

Moving on to the vegetarian diet, the largest study of the vegetarian diet so far carried out was a pooled analysis of 5 prospective studies by Key et al. They ended up with 76'000 subjects with just under 30'000 were vegetarians and they showed that mortality from coronary heart disease was 24% lower in vegetarians than in non-vegetarians with no significant difference in mortality from cerebrovascular disease and cancer. Now it is clear that the vegetarian diet is a heterogeneous dietary pattern

but it tends to be that vegetarians have higher micronutrient intakes than non-vegetarians.

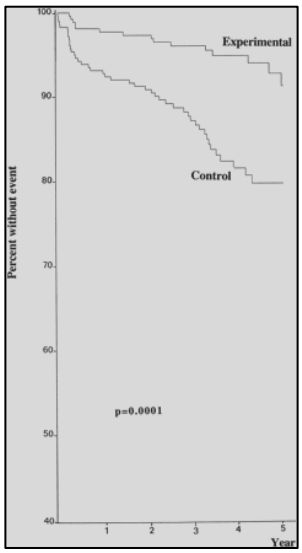
Moving on to fruit and vegetable intake and coronary heart disease and cardiovascular disease, it has been shown as we have heard previously from Dr He that increased consumption of fruit and vegetables is linked with reduced risk of CHD, CVD and all cause mortality and these studies have been subjected to meta analysis from Dr DAUCHET and Dr HE. The evidence is less consistent for cancer.

Again it is crucial to show that if we increase fruit and vegetable intake we increase micronutrient status. Zino et al. in 1997 randomized subjects who ate 3 or less portions of fruits and vegetables a day to either continue to eat less than 3 or less portions of fruits and vegetables a day or to increase to 8 portions per day. They actually saw an increase to nearly 8 in self reported numbers of servings per day. They saw that that produced a significant increase in β-carotene, α-carotene and vitamin C. It was shown by Brouwer et al. in a separate intervention that a diet high in Citrus fruit and vegetables increased folate status. There have been a number of randomized control trials of fruit and vegetables consumption on intermediate end points for cardiovascular disease or risk factors for cardiovascular disease. I am sure Luc will concentrate on this in a little more detail in his presentation but this was a study made by John et al. which was a 6 months RCT of advice to increase fruit and vegetables intake to at least 5 a day. They saw a significant reduction on systolic and diastolic blood pressure. Similarly the DASH study published in the late nineties looked at the effect of a fruit and vegetable-rich diet or a fruit and vegetable-rich and low-fat dairy product-rich diet versus control diet on blood pressure. For fruit and vegetables only they saw a significant a reduction in systolic and diastolic blood pressure but a further decrease on systolic and diastolic blood pressure when the fruit and vegetable-rich diet was combined with the low-fat dairy product-rich diet.

We have carried out some work in this area and in fact we are currently carrying out five fruit and vegetable intervention studies with clinically relevant endpoints. This is the first one to complete the other four are ongoing. It was called the "FAVRIT study" and was looking at the effect of dietary intake of fruits and vegetables on vascular function. We recruited 112 subjects with mild hypertension and they went on 1 portion of fruit and vegetable daily for a period of four weeks. They were then randomized to continue one portion a day or to consume 3 portions a day or to consume 6 portions a day for a period of 8 weeks. We measured vascular function at the start and end of the intervention period. We saw a dose-dependent effect of increased fruit and vegetable consumption on our primary end point which was forearm blood flow responses to intra-brachial acetylcholine, an endothelium-dependent vasodilator. This is an established index of vascular endothelial function. There was a significant dose-dependent improvement in endothelial function and this was associated with an increase in vitamin C, and increase in lutein and an increase in β-cryptoxanthin. So we were changing micronutrient status and then seeing these effects on endothelial function. Interesting, we did also see a trend that it was affecting blood pressure which may be of interest for the next presentation.

The Mediterranean diet has been associated with improved all cause mortality or survival and a number of large studies have confirmed this. This year in a large American population (the first to test this in a non-Mediterranean population) adherence to the Mediterranean diet score was associated with an increase in survival or reduced all cause mortality. There have been a number of interventions with Mediterranean style diets. This one is by Esposito published in JAMA in 2004 looking at the effects of 2 years of Mediterranean diet on features of the metabolic syndrome in people with the metabolic syndrome. They showed a significant change in HOMA score, significant improvement in endothelial function, reduction in high sensitivity CRP, reduction in IL-6 and there was a significant reduction in the number of the patients with the metabolic syndrome in the intervention group compared to the control group.

Again, we heard about the Lyon Heart study 605 participants recruited within 6 months of first MI randomised to receive the standard dietary advice or the Mediterranean diet and there was 5 year follow up.



There was a marked early separation in the survival curves this is with the end points on MI and CVD death and significant separation in these curves. What I am trying to link back to is what effect the Mediterranean diet has on micronutrient status. In the Lyon Heart study the experimental group reported an increased intake of fruit and vegetables that led to increased vitamin C intake and an increase in measured plasma vitamin C and E. Esposito in the metabolic syndrome intervention reported an increased fruit, vegetable nut and legume intake but they did not assess biomarkers.

Our research group would like to carry out a repeat of the Lyon Heart study in a Northern Europe Population and in an era where pharmacological therapy for cardiovascular disease is quite different to when the Lyon Heart study was carried out. But we consistently have been asked the question will non-Mediterranean countries adopt the Mediterranean diet particularly will Northern Irish people eat a Mediterranean diet. We have done a pilot study to try to see whether we can achieve a change in diet. We took 61 myocardial infarction and unstable angina patients and randomized them to either receive (1) conventional dietary advice received by every patient after MI. This is similar to Mediterranean dietary advice but less specific in terms of fat-intake or (2) Mediterranean dietary advice using a similar way of delivering the dietetic advice but with more contact (they were seen with one month, one week one month and four months after their MI) or (3) Mediterranean dietary advice with behavioural counselling which was the same advice delivered at the same time points so the same intensity advice but this time with a personal adjusting of the dietary advice depending on the person whether they were ready to change their diet. Therefore the dietary advice was not delivered as a whole, but rather

suggestions for change were made depending on whether that person was ready or not. We carried out dietary biochemical assessment at baseline and then at 6 months and then at 12 months after receiving this advice. I am only reporting our primary end point which was change in Mediterranean diet score and we actually saw that at 6 months and at 12 months there were no significant differences between our ways of delivering the dietary advice. We had thought that greater intensity of dietary advice and the more personal way of delivering the dietary advice might influence uptake but in fact it did not seem to. But we did achieve a significant increase in Mediterranean diet score with all of our groups both at 6 months and 12 months no matter what way we delivered the dietary advice. In terms of micronutrient status we observed significant increases in vitamin C status in these two more intensive dietary advice groups. We also saw trends toward an increase in carotenoid status.

Finally briefly looking at analysis of combined health behaviours which has been published by our chair here, professor Khaw - I think that this is a very interesting approach in terms of not looking at an isolated micronutrient not even looking at the whole diet approach but looking at a whole diet and lifestyle approach and it may leads to differences in the way we conduct intervention studies in the future. Carried out in the EPIC Norfolk cohort, 20'000 men and women with no know cardiovascular disease or cancer at the baseline were used in the analysis and a score was calculated - participants scored 1 point for current non-smoking, 1 point for not being physically inactive, 1 point for moderate alcohol intake, and 1 point for having plasma vitamin C that was more than 50 umol per litre - this was supposed to be reflective of a high fruit and vegetable intake. They were followed up for 11 years and for cardiovascular end points there was a significantly increased risk of CVD for those with none of those behaviours compared to those with all four health behaviours. This is a novel and useful approach linking diet and lifestyle factors and disease risk.

To go back to the original question is supplement use equivalent to dietary micronutrient consumption - we need to place this in context by examining the use of vitamin supplements throughout the general population. When the National Diet and Nutrition Survey in the UK was carried out in 1986/87, 17% of women, 9% of men reported taking supplements. By 2000/01 this had gone up to 40% of women and 29% of men reporting taking supplements. I certainly think at the moment that the evidence favours dietary advice to increase micronutrient consumption, e.g. to increase intake of fruit and vegetables etc. And that is supported by the NIH State-of-the-Science Conference Statement on Multivitamin/Mineral Supplements just published last year when they said that "the present evidence is insufficient to recommend either for or against the use of multivitamin minerals by the American public to prevent chronic disease".

In conclusion, the micronutrients supplementation trials published to date have largely been negative therefore the supplementation with isolated micronutrient does not seem to be equivalent to dietary micronutrient consumption**.** Cardiovascular diseases are multi factorial in origin and complex in aetiology, so our approach in either prevention or treatment must take account of this. We think that consideration of overall diet and lifestyle pattern is likely to be necessary to effectively reduce CVD incidence.

Q&A

PUBLIC: I wonder if I could comment on the folate story with regard to cardiovascular disease. I know that the cancer fields have become controversial, there have been some disturbing findings, what is the chance that this could happen for stroke and coronary heart disease?

JV WOODSIDE: There are no findings so far of an adverse effect on coronary heart disease or stroke end points. In fact there was a meta-analysis published last year showing that in certain subgroups for example those who had low folate and those initially who did not live in countries where folic acid fortification was taking place that there were beneficial effects of B-vitamin supplementation on stroke. I am not aware of any meta-analysis looking at CHD end points but overall again you are seeing the majority of the trials are negative. Therefore currently there would appear to be no effect of B-vitamin supplementation on CHD endpoints with some possibility of small benefit in certain sub-groups for stroke.

Effects of Fruits and Vegetables on plasma blood pressure: interventions studies

Luc DAUCHET
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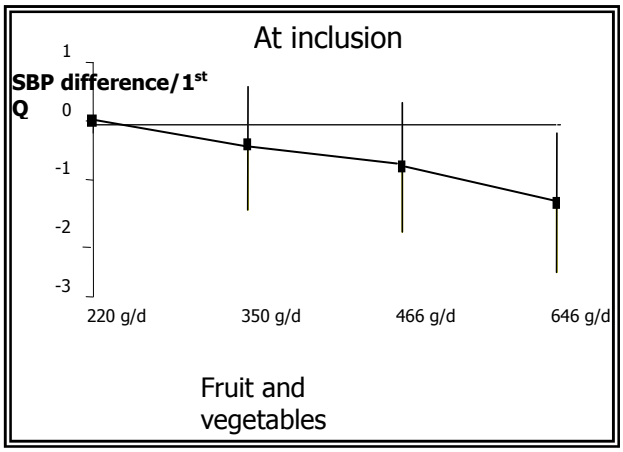
Je vais peut être introduire ma présentation en répondant à une question qui a été posée tout à l'heure. On a vu qu'il y avait un certain nombre d'arguments en faveur d'un effet protecteur des fruits et légumes sur les maladies cardiovasculaires, comment passer de ce faisceau d'arguments à une certitude de l'effet des fruits et légumes sur les maladies cardiovasculaires ? D'une façon scientifique, d'une manière générale, la seule manière de démontrer une causalité c'est de faire des essais d'intervention. Pour prouver l'effet des fruits et légumes sur les maladies cardiovasculaires il faudrait faire des essais randomisés d'intervention avec un groupe témoin et un groupe pour lequel on augmente la consommation de fruits et légumes et on voit l'effet sur les maladies cardiovasculaires. Ce type d'étude est très difficile à réaliser, peut-être impossible à réaliser ; par contre on peut étudier dans des essais d'intervention l'effet des fruits et légumes sur la pression artérielle avec des résultats qui sont obtenus à beaucoup plus court terme avec des populations plus faibles.

Comment étudier la relation entre la consommation des fruits et légumes et la pression artérielle ? La première chose est de vérifier que cette relation existe dans les études d'observation. Ce qui permet de retrouver une association mais qui ne prouve pas l'effet des fruits et légumes, il peut y avoir quantité de facteurs de confusion dont on a déjà parlé dans les exposés précédents. La seule façon d'établir un lien de causalité c'est de faire des études randomisées et des essais d'intervention. On ne peut évidemment pas tester l'effet global des fruits et des légumes entiers comme on testerait des vitamines ou des médicaments contre placebo en double aveugle mais on peut quand même faire des essais d'intervention contrôlés avec un groupe témoin et un groupe d'intervention. On va voir qu'il y a deux grands types d'essais qui sont réalisés soit avec une alimentation complètement contrôlée soit avec des interventions et des conseils nutritionnels.

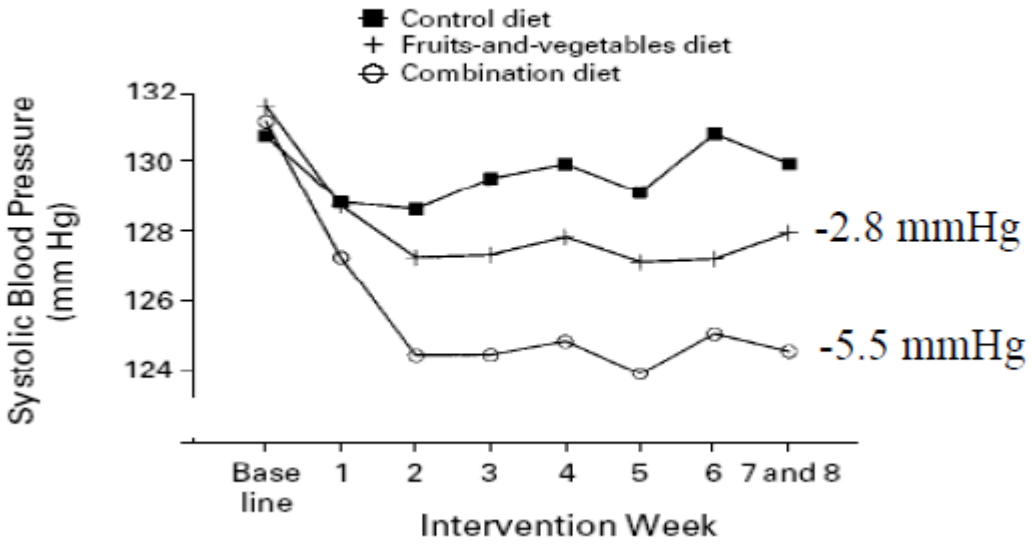


Tout d'abord les études d'observation, je vais vous montrer quelques exemples, il y en a de nombreux autres. Par exemple ici on a en France dans la population de SU.VI.MAX une inclusion dans l'étude, les grands consommateurs de fruits et légumes de l'étude avaient une pression artérielle qui était plus basse en moyenne que les faibles consommateurs avec une différence relativement

modérée mais significative de 1,4 mmHg (millimètre de mercure).
Il est à noter qu'au cours du suivi la pression artérielle des personnes qui consommaient beaucoup de fruits et légumes a moins augmenté que celles qui en consommaient peu, elle a augmenté de 2 mmHg en moins que ceux qui en consommaient peu ce qui indique également un effet ou du moins une association à long terme.
On retrouve des résultats similaires aux Etats-Unis dans la cohorte CARDIA où on retrouve une association entre consommation d'aliments végétaux et risque de survenue d'hypertension. Après 15 ans de suivi, le risque de survenue d'hypertension était diminué de 30% chez les grands consommateurs de produits végétaux. C'est une association que l'on trouve dans des populations très différentes. Un dernier exemple : dans une population de femmes iraniennes où la proportion de femmes hypertendues est également plus faible chez les grandes consommatrices de fruits et chez les grandes consommatrices de légumes. Donc des résultats qui sont trouvés de manière consistante dans les études d'observation. On voit donc une association entre consommation de fruits et légumes et faible pression artérielle dans l'étude d'observation. Néanmoins comme il s'agit d'observation il peut y avoir des facteurs confondants, quantité de facteurs liés à la consommation de fruits et légumes qui peuvent être d'autres consommations alimentaires ou d'autres habitudes de vies qui peuvent expliquer cette association d'où la nécessité de faire des études d'intervention.

Le premier type d'intervention que je vais vous citer sont les études portant sur des régimes complètement contrôlés où on contrôle totalement l'alimentation des sujets qui sont inclus dans l'étude et qui sont tirés au sort dans les différents groupes. Ce type d'étude est très difficile et très lourd à mener, il y en a relativement peu, peut-être des nouvelles qui vont arriver. La principale et la plus connue est la « DASH Study » (Dietary Approach to Stop Hypertension). Dans cette étude, 450 sujets ayant une pression artérielle normale, haute ou une hypertension modérée ont été inclus. Ils ont été tirés au sort en trois groupes et devaient chacun suivre un régime, une alimentation différente pendant 8 semaines et chacun des sujets devait au moins consommer un repas sur le lieu du laboratoire et recevait une glacière avec le reste de ce qu'il devait consommer dans la journée. Les personnes devaient consommer ce qu'on leur donnait et rien que ce qu'on leur donnait, ce qui était quelque chose de très contraignant à la fois pour l'investigateur et pour le sujet. Cette étude DASH a évalué trois régimes : un régime témoin qui correspondait à peu près au régime américain moyen, un régime fruits et légumes correspondant au même régime que le groupe témoin mais avec une consommation plus importante de fruits et légumes en moyenne d'environ 10 fruits et légumes par jour et enfin un régime combiné qui incluait une consommation de fruits et légumes mais également de produit laitiers pauvres en graisse et un apport réduit en graisse saturée. Cette étude a montré qu'après 8 semaines de suivi la pression artérielle systolique était diminuée de 2,8

mmHg dans le groupe fruits et légumes par rapport au groupe témoin. Il y avait des résultats similaires sur la pression artérielle diastolique.



Les sujets ont été tirés au sort donc la seule chose qui puissent distinguer le groupe témoin du groupe fruits et légumes c'est la consommation de fruits et légumes. Ce qui nous donne quasiment la preuve de l'effet des fruits et légumes sur une diminution de la pression artérielle. On n'est pas tout à fait au même niveau de preuve qu'un essai randomisé en double aveugle contre placebo mais on y est presque. Il est à noter que le régime combiné avait un effet plus important que le régime fruit et légumes d'où l'importance d'autres éléments d'alimentation que les fruits et légumes. Cette étude DASH nous donne donc une preuve expérimentale de l'effet des fruits et légumes sur la pression artérielle. Néanmoins, on est là dans des conditions expérimentales avec des régimes totalement contrôlés donc une intervention qui ne peut pas être appliquée au grand public. Ce qui est intéressant de savoir est : est-ce que des recommandations qui inciteraient les sujets à augmenter leur consommation de fruits et légumes pourraient avoir un effet sur la pression artérielle ?

On arrive à un deuxième type d'étude d'intervention qui a été réalisé concernant les fruits et légumes. On n'est plus là dans un régime totalement contrôlé où l'on fournit l'alimentation aux sujets mais c'est l'effet de conseil alimentaire visant à augmenter la consommation de fruits et légumes. Il y a beaucoup d'essais portant sur les interventions alimentaires, peu portent exclusivement sur la consommation de fruits et légumes. La principale est l'étude d'Oxford dans laquelle 700 sujets ont été inclus et tirés au sort entre un groupe d'intervention et un groupe témoin. Le groupe d'intervention était encouragé à augmenter la consommation de fruits et légumes et il recevait des conseils nutritionnels pendant 25 minutes à l'inclusion de l'étude ainsi

que des aimants à mettre sur le frigo et un livret pour mesurer leur alimentation en fruits et légumes et un rappel téléphonique à deux semaines et un courrier à trois mois, quelque chose d'applicable au grand public ou au moins à certaines populations. Le groupe témoin, il leur a été demandé de ne rien changer à leurs habitudes. Les résultats de cette étude ont montré au bout de 6 mois de suivi une augmentation de la consommation de fruits et légumes dans le groupe d'intervention donc d'un peu plus d'1 portion, un peu moins d'une portion et demie, 1,4 portion. Par contre dans le groupe témoin il n'y a pas eu d'évolution de la consommation de fruits et légumes tel qu'il leur a été demandé. La différence de consommation entre les deux groupes était donc d'1,3 portion de fruits et légumes. On est dans une différence, vous voyez, qui est beaucoup plus faible que ce qu'on a pu obtenir dans l'étude DASH puisque le régime était totalement contrôlé. Malgré cette différence relativement modérée, un effet a été retrouvé sur la pression artérielle avec une diminution significative de la pression artérielle systolique à 3,4 mmHg dans le groupe d'intervention par rapport au groupe témoin et une diminution également significative de la pression artérielle diastolique. Cette étude nous démontre l'efficacité à moyen terme, de l'incitation à consommer plus de fruits et légumes dans la population ,sur la pression artérielle.

F & V in free living individual : The Oxford Study

Self-reported intake of F&V, blood pressure and body weight

	n	Baseline, mean (SD)	Change at 6-months' follow-up, mean (SD)	Between-group difference in change (95% CI)	p for adjusted difference
Self-reported daily intake of fruit and vegetables (portions)					
I	329	3·4 (1·7)	1·4 (1·7)	1·3 (1·1 to 1·6)	<0·0001
C	326	3·4 (1·5)	0·1 (1·3)		
Systolic blood pressure (mm Hg)					
I	344	130·2 (19·7)	−2·0 (13·5)	3·4 (1·3 to 5·5)	<0·0001
C	346	129·3 (19·6)	1·4 (14·6)		
Diastolic blood pressure (mm Hg)					
I	344	79·2 (11·4)	−1·6 (8·7)	1·4 (0·1 to 2·7)	0·02
C	346	79·9 (11·9)	−0·3 (8·7)		
Weight (kg)					
I	344	76·1 (13·8)	0·6 (2·6)	0·0 (−0·3 to 0·5)	0·1 (−0·4 to 0·6)
C	346	75·6 (14·9)	0·6 (2·6)		

I=intervention group. C=controls.*Adjusted for baseline value and sex.

John et al Lancet 2002

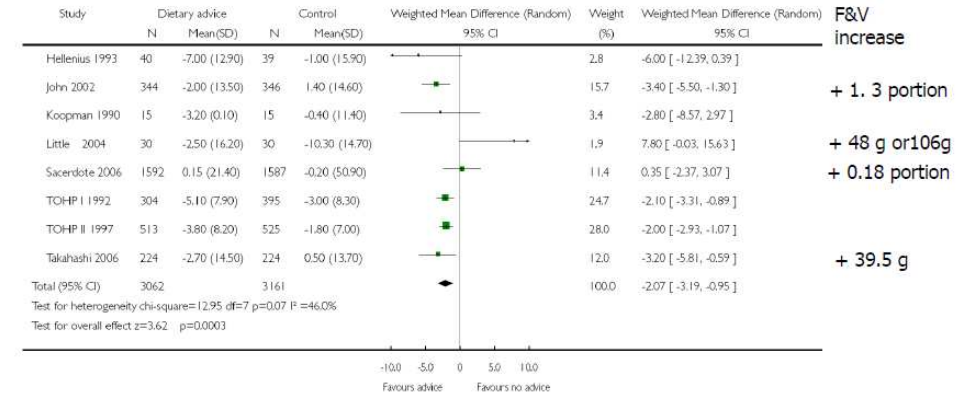
Une deuxième étude qui ne porte pas spécifiquement sur les fruits et légumes qui est « The Women Health Initiative study », mais qui nous apporte des informations intéressantes en raison de la très grande taille de cette étude qui porte sur à peu près 50 000 femmes avec une intervention qui consistait à augmenter la consommation de fruits et légumes et de céréales, de réduire l'apport en graisse avec des formations en groupe qui ont été réalisées auprès des sujets. Les groupes témoins recevaient

simplement le guide d'alimentation pour les américains. Les résultats de cette étude ont montré, après 1 an et 6 ans de suivi, une augmentation de la consommation de fruits et légumes dans le groupe d'intervention par rapport au groupe témoin qui est du même ordre de grandeur que celle retrouvée dans l'étude d'Oxford avec un peu plus d'une portion par jour. Par contre, les résultats portant sur la pression artérielle sont plus décevants. Il y a une diminution significative de la pression artérielle dans le groupe d'intervention par rapport au groupe témoin mais cette diminution est très faible 0,17 mmHg donc n'est significative que grâce à la taille très importante de l'échantillon. Pourquoi ne retrouve-t-on pas les mêmes résultats que dans l'étude d'Oxford ? Difficile de répondre à cette question et on peut émettre plusieurs hypothèses. Une des choses intéressantes à constater est que la pression artérielle a en réalité diminué dans le groupe d'intervention de 2 mmHg ce qui est à peu près du même ordre de grandeur de ce que l'on trouvait dans l'étude d'Oxford mais elle a diminué aussi dans le groupe témoin. Peut être qu'il y a eu des changements d'habitudes dans le groupe témoin du fait de rentrer dans l'étude, c'est difficile d'en juger.

Il y a d'autres essais de plus faible taille portant sur les études d'intervention nutritionnelle et la pression artérielle systolique. Il ya une méta-analyse récente qui a été réalisée par le groupe COCHRAN. Quasiment aucune ne porte exclusivement sur les fruits et légumes, toutes ne portent pas sur les fruits et légumes et quand il y a une incitation à consommer plus de fruits et légumes, la difficulté c'est d'arriver à obtenir une différence entre le groupe d'intervention et le groupe témoin qui soit suffisamment importante. (…) d'où la difficulté parfois d'interpréter le résultat de ces études.

F & V in free living individual : Other intervention studies

Any dietary intervention versus no intervention, outcome systolic blood presssure, change from baseline



Brunner et al Cochran collaboration 2008

On a vu que les essais avec des régimes complètement contrôlés nous prouvent l'effet des fruits et légumes sur les maladies cardiovasculaires. Les essais portant sur les interventions nous montrent que cet effet peut être obtenu par des interventions auprès des sujets, auprès des patients, auprès du grand public. Et, les études d'observation sont également intéressantes car elles nous permettent d'avoir les informations sur une durée de suivi plus longue et sur une population plus importante. L'ensemble de ces résultats sont cohérents et montrent les effets de la consommation des fruits et légumes sur la pression artérielle.

Alors pourquoi les fruits et légumes diminuent-ils la pression artérielle ? Il y a évidemment de nombreuses hypothèses sur les constituants des fruits et légumes. Le potassium joue un rôle probablement important. L'effet des antioxydants est plus discuté, on pourrait citer les fibres, on pourrait évoquer l'effet combiné des constituants des fruits et légumes. Il y a l'effet propre des fruits et légumes et également probablement un effet de substitution qui n'est pas négligeable. Évidemment, quand on demande aux personnes d'augmenter leur consommation de fruits et légumes ça se fait au détriment d'autres aliments. L'effet positif vient-il du fait d'augmenter la consommation de fruits et légumes ou de consommer moins d'autres aliments ? L'exposé de Barbara ROLLS nous a bien montré ce matin que quand on augmente la consommation de fruits et légumes on modifie le reste du comportement alimentaire. Donc, ici, les études d'intervention ne permettent pas parfaitement de trancher entre ces deux effets puisque même dans l'étude DASH les fruits et les légumes étaient remplacés par des snacks dans le régime témoin pour atteindre le même niveau calorique. Après tout, que ce soit l'effet propre des fruits et légumes ou un effet de substitution peu importe, ce qui compte c'est le résultat final pour les sujets d'où l'intérêt des fruits et légumes pour diminuer la pression artérielle.

Enfin, les recommandations sur les fruits et légumes ne doivent pas faire oublier les autres recommandations habituelles pour la pression artérielle. On a vu dans le régime DASH que l'effet du régime combiné était supérieur à celui des fruits et légumes. Une autre étude menée par la même équipe que celle de DASH a montré qu'un effet additif de la diminution de la consommation de sel par rapport à celui du régime DASH et enfin dans l'étude PREMIER qui a comparé les recommandations portant sur les recommandations habituelles donc perte de poids, diminution de consommation de sel et diminution de la consommation d'alcool avaient des résultats qui n'étaient pas significativement différents de celles portant sur les régimes habituels plus le régime DASH. Donc, la consommation de fruits et légumes est un apport supplémentaire dans la lutte contre la pression artérielle mais ne doit pas faire oublier les autres recommandations.

En conclusion, il y a une relation dans les études d'observation de manière générale entre consommation de fruits et légumes et pression artérielle. Les études avec des

régimes contrôlés montrent les effets des fruits et légumes sur la pression artérielle. Et enfin les études portant sur les recommandations montrent l'effet de ces recommandations et des ces incitations et conseils pour manger plus de fruits et légumes sur la pression artérielle. Donc un effet démontré de manière expérimentale de l'augmentation de la consommation de fruits et légumes sur la pression artérielle.

Q&A

KT KHAW: I think like Dr WOODSIDE also suggested, perhaps one of the possibilities if you can not do the large scale end point trials is to do more mechanistic studies looking at intermediate risk factors like blood pressure or endothelial function of inflammation. Do you think there is one way we can go to strengthen the evidence as requested?

L DAUCHET: Oui tout a fait, c'est la diapositive que nous a montré le Dr He tout à l'heure où elle concluait un effet de causalité. Effectivement, à défaut d'avoir un essai randomisé qui prouve les effets des fruits et des légumes il faut additionner les arguments qui sont des arguments épidémiologiques. Est-ce qu'on trouve la relation de manière générale ? Est-ce que cette relation est plausible au niveau biologique et pour ça, il y a les classiques critères de Hill pour essayer d'argumenter une causalité quand on ne peut pas avoir des faits randomisés. Tout à l'heure le Dr He nous a bien montré ça, on a un certain nombre d'arguments, mais évidemment on n'arrive pas à la preuve absolue, mais en accumulant les arguments on peut arriver à suffisamment de conviction pour recommander de consommer plus de fruits et légumes.

PUBLIC (Eric LEMERCIER, Groupe MedAlliance Europe, Producteur de Fruits et légumes) : Je vous ai bien entendu et très bien compris. Est-ce que ça peut justement un peu plus expliquer un petit peu le paradoxe qu'on a aujourd'hui ? C'est à dire que les Etats du monde entier mettent en avant la consommation des fruits et légumes par le biais de la communication. Je parle déjà principalement pour la France où on essaie de faire dans ce sens, je suppose que c'est aussi pareil dans les pays du monde entier. Est-ce qu'il n'y a pas un paradoxe entre le fait qu'on n'arrive pas aujourd'hui à apporter comme vous le disiez des preuves convaincantes et d'ailleurs on le voit bien nous, au niveau des produits qu'on doit apporter au consommateur en tant que fruits et légumes, c'est ne serait-ce que les allégations qui aujourd'hui reste encore très vastes. On n'arrive pas à informer je dirais, le consommateur aujourd'hui des raisons d'en consommer 5 par jour, oui mais pourquoi ? Pour l'instant on l'informe de la situation mais on n'informe pas spécialement du pourquoi de cette consommation tout ça parce que les allégations sont très floues aujourd'hui. Je relève d'ailleurs, sauf erreur de ma part, que l'AFSSA ne sont pas présents aujourd'hui parce qu'ils auraient peut-être pu nous en parler un peu. Le fait de ne pas informer aujourd'hui correctement le consommateur, lui ne modifiera en aucun cas sa consommation. Le fait de dire il faut consommer oui, pourquoi ? Et j'ai beaucoup

apprécié notamment le Dr He justement de par ses propos qui avait un peu plus de véracité dans le sens où effectivement, il y a une cause, il y a un effet. Même s'il n'est pas rempli à 100% on sait pertinemment que la consommation de fruits et légumes dans le monde entier ne pourra faire que du bien, on n'est pas non plus dans un mensonge.

L DAUCHET : C'est toute la difficulté de passer de la recherche scientifique à l'application et au message. Au niveau de la recherche scientifique on ne peut que citer l'ensemble des arguments que nous avons, qui est un faisceau d'arguments quand même relativement solide. On ne peut pas dire « c'est totalement prouvé » si on n'a pas la preuve. On a un faisceau d'arguments relativement solide. Après, la communication auprès du grand public est difficile, ça devient autre chose, on ne peut pas communiquer des choses aussi complexes. Je pense qu'on n'a pas attendu d'avoir des preuves pour agir, il y a quand même pas mal de chose qui sont faites pour consommer plus de fruits et légumes, le message « consommer 5 fruits et légumes par jour » est quand même bien reconnu dans la population. Je ne sais pas si on peut aller beaucoup plus loin.

PUBLIC (Eric LEMERCIER, Groupe MedAlliance Europe, Producteur de Fruits et légumes) : J'ai plutôt l'impression qu'en France on se base sur des chiffres qui environnent les 320 g, je fais peut-être un petit peu erreur au niveau de la dizaine de gramme, alors qu'on sait pertinemment que en France on a une surconsommation chez les seniors qui avoisinent plutôt les 600/700 g, une consommation quasi inexistante chez les jeunes parce qu'on est dans une génération aujourd'hui de fast-food et de boissons gazeuses. Ces chiffres donnent une moyenne, on sait aujourd'hui que l'alarme doit être tirée non pas pour les seniors mais plutôt pour les jeunes qui arrivent qui sont déjà une génération de jeunes et ceux qui vont arriver derrière. On sait que là on est en sous-consommation et on ne peut pas tirer d'une moyenne pour mettre en place des faits et des choses à réaliser. Si vraiment on veut aller dans la profondeur du problème, on voit bien qu'effectivement en France la consommation chez les jeunes est de 0 et à présent je crois 0.1 et c'est insignifiant sur la base de produits frais bruts. On peut aussi dissocier les légumes et les fruits en 4ème ou en 1ère gamme. Là on n'est pas sur des faits qui me semblent vraiment réels où on peut entamer notamment des négociations que ce soit avec les pouvoirs politiques qui effectivement, de leur vue à eux ne peuvent pas être convaincus comme ils devraient l'être quand on voit comment l'OMS tire le signal d'alerte au niveau mondial. On a l'impression que la locomotive va vite mais que certains wagons n'arrivent pas à prendre la bonne vitesse. Moi qui ait certainement beaucoup moins d'ancienneté que vous dans ce domaine de fruits et légumes, c'est vrai qu'il y a beaucoup de choses qui m'interpellent dans ce que j'entends, dans ce que je lis, dans ce que je peux voir.

L DAUCHET : Je pense que c'est un peu compliqué. Ce que vous essayez de nous faire dire c'est de dire voilà, on a la preuve absolue des effets des fruits et légumes

pour pouvoir faire bouger les politiques et que ça aille vite. On peut vous dire on a beaucoup d'arguments qui sont convaincants, on ne peut pas vous dire plus que ce qu'on a mais pour autant il est vrai qu'il ne faudrait pas attendre. On peut parler du tabac, si on avait attendu d'avoir la preuve absolue pour le tabac, on aurait réagi beaucoup trop tard donc ce n'est pas pour autant qu'il ne faut pas agir. Après, c'est un problème de décision politique qui doit décider en fonction des informations qu'ils ont mais on ne peut pas leur donner plus que ce que l'on a.

KT KHAW: I think you made a very clear illustration of why we are bringing together the scientific evidence, and the rest of this meeting is about how we translate the scientific evidence into policy and action which I think many of the people here will have much more expertise on.

PUBLIC (Serge HERCBERG): Je voudrais juste fournir quelques éléments de réponse à la question posée par mon voisin. Je crois qu'aujourd'hui en termes de politique nutritionnelle de santé publique, notre problème n'est pas tant d'arriver à convaincre la population que manger des fruits et légumes est bon pour la santé, je crois que les arguments qui sont tout de même repris et donnés sont suffisants pour que les campagnes qui sont faites puissent avoir un impact dans la connaissance. Notre problème n'est pas simplement de convaincre, c'est de pouvoir arriver, les problèmes sont plus en termes d'accessibilité, en termes de pouvoir d'achat, en termes disons d'autres facteurs. Les campagnes qui sont faites en France ont montré qu'elles étaient bien connues et reconnues, le public sait que manger des fruits et légumes est bon pour la santé, la difficulté qu'il y a c'est de traduire des connaissances en application pratique. Je crois que c'est un des points qui va être largement vu dans les jours qui viennent. Je crois que la réponse n'est pas tant de l'affirmation scientifique qui serait suffisamment convaincante pour faire bouger les comportements, les comportements doivent bouger par d'autres éléments et ce sont souvent des facteurs d'environnement sociologique, culturel, économique qui sont plus en cause que la connaissance simplement du rôle des fruits et légumes.

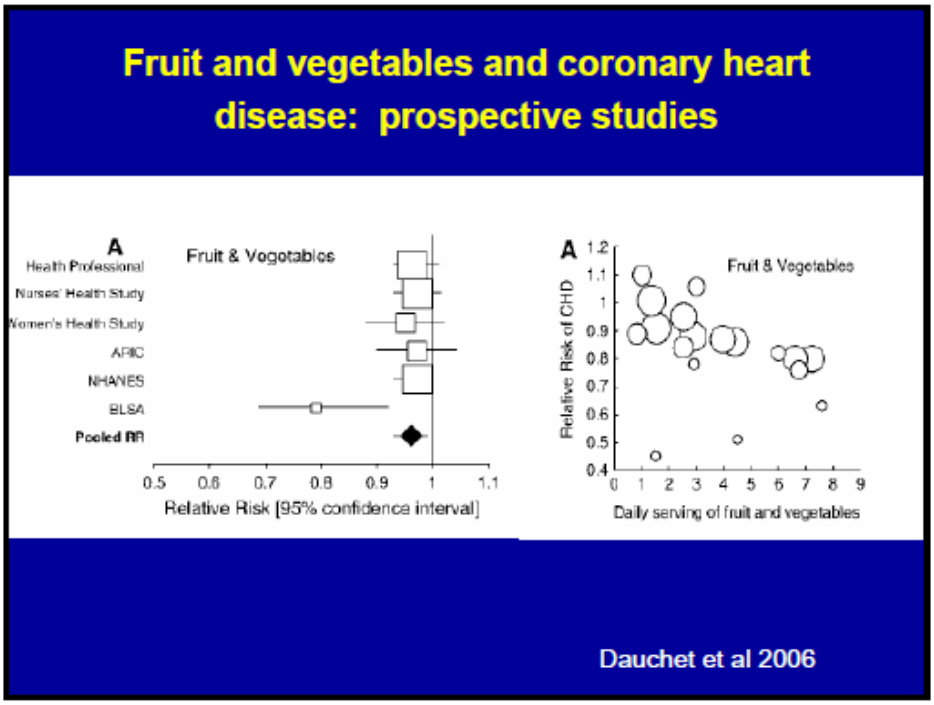
KT KHAW: I think that is why we are all here at this meeting to understand what we can do to translate the evidence to practice.

F&V and cardiovascular disease risk: what should we do?

Kay-Tee KHAW
Clinical Gerontology, University of Cambridge, UK

I will summarize some of the discussion and raise some of the issues that have perhaps already been raised by our audience in terms of how we deal the evidence. In terms of assessing the evidence it is a combination of the wealth of evidence including experimental and metabolic studies. Of course, the hard evidence may be the randomized trials and control trials with hard clinical end points but these are the hardest types of evidence to obtain.

The strength of the evidence relies therefore not only on biological plausibility but on how strong and consistent the evidence is across different human populations because of course we are trying to make generalised recommendation globally not just to our particular populations. We have heard earlier from Dr He and other speakers about the observational data. This is the Dr Dauchet's meta-analysis you have seen earlier suggesting a fairly consistent relationship in observational studies between fruit and vegetable intake and coronary heart disease.



This is Dr He's meta-analysis from the Lancet showing very consistent finding also for stroke and a dose-response relationship in the higher intake of fruits and vegetables associated with greater risk reduction in stroke. We also heard from Dr Woodside and I think that is an issue raised also by Dr Milner in his questions about understanding mechanisms much better. Why is it? What are the biological reasons

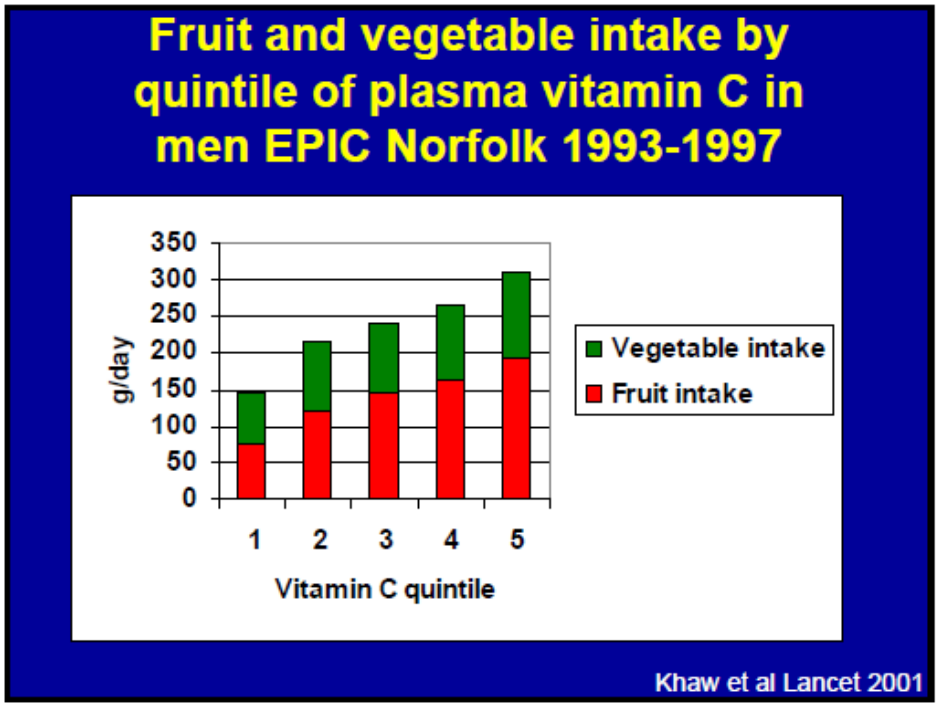
that fruit and vegetables may have an impact on cardiovascular risk? And we heard a huge amount about some of the many potential biological mechanism such as the inflammatory action as well as the blood pressure lowering factors that may be related to many of the different component of fruits and vegetables. And fruits and vegetables have hundreds of bio active components. I think it is rather intriguing that most of the early trials perhaps focussed on the antioxidant vitamins when potentially there are many other biological factors that could be looked at that perhaps we haven't though enough about. We have been a little set back perhaps because some of these single supplement trials that we have been chosen may not have selected appropriately the nutrients in fruit and vegetables that may be responsible and may need far more biological understanding of which of the components may have bioactive effects on cardiovascular risk.

We heard from Dr Woodside about the isolated trials and we also heard a little bit about the possible randomised trials including fruit and vegetables but there are no isolated trials with fruit and vegetables alone and that is our difficulty in term of dietary changes. You have seen this before, the univariate supplemental trials on beta-carotene, vitamin E have not been encouraging. Even for folate, despite the observational studies suggesting benefits for stroke, secondary prevention trials for coronary heart disease suggested perhaps an adverse slightly increase for supplementation folate so, again discouraging in term of the single factor supplementation. And, as Dr Woodside has suggested, some of the explanation may be that single supplements taken way beyond their physiologic doses may actually have adverse effect, pro-oxidant effect for example. Different isoforms, of, beta-carotene, trans or cis beta-carotene may also have different biological actions so maybe the compounds in foods may not be the same as those used in supplements. Additionally there may be interaction with other factors in free living populations.

What about the food based trials? I suppose the elephant in the room is the Women Health Initiative, this huge trial done in the States which was targeted at low fat but you can see did not really change cardiovascular disease risk.
Now why, in this particular trial was there not any observed effect?
Apart from lowering fat it was also meant to increase fruit and vegetable intake. One suggestion was that it was too short term, it is too late to intervene, and it was not specific at least in term of the fat because all the trials that have targeted fat that have had an effect on coronary heart disease risk have changed the poly unsaturated to saturated fat ratio. The Women Health Initiative did not change that it only lowered total fat. Another explanation may be too little change, particularly for the dietary interventions and in this context and may be in the American context when you ask people to increase fruit and vegetables they may not increase the particular fruits and vegetables that may have most direct impact on health. Again this returns to an issue, is it cruciferous vegetables or if individuals increase foods like peas and sweet corn may that does not have the same impact as green leafy vegetables. We do not

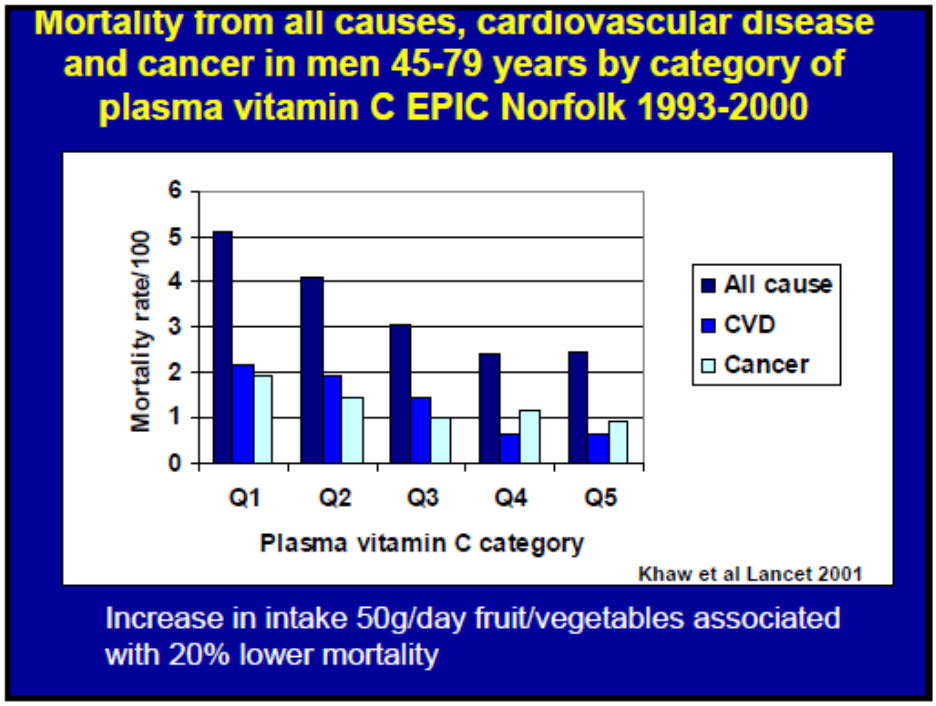
know whether the American context increasing fruit and vegetables intake as it was self reported might not have the same impact in different communities where the range of fruit and vegetables may be very different. Just to emphasize, the change in fruit and vegetables self reported in this intervention study was really very small and the average baseline was still below the 5 servings a day that is generally recommended. So, on average they did not achieve the target, fruit and vegetables intake that might be used in dietary recommendations.

One question that was raised yesterday by Dr Schatzkin was perhaps we are not measuring fruit and vegetables adequately and perhaps we should have better biomarkers of fruits and vegetables intake. I think Dr Jenab is going to talk about it this afternoon in relation to cancer risk but this was one of the reasons we tried to used different biomarker for fruits and vegetables intake rather than relying on self report which we know is really differential according to social class, education etc and maybe biased. We used plasma-vitamin C not because we believe vitamin C is the bioactive responsible compound in fruits and vegetables but because human do not manufacture vitamin C so the only source of vitamin C in our blood is from dietary intake that is primarily fruits and vegetables. You can see this relationship between vitamins C, blood levels and fruits and vegetables intake in our population in Britain. So vitamin C is a good biomarker and I am not talking about supplementation because in the analysis we excluded people who were taking vitamin C supplementation.



We used quintiles because this is a demonstration of usual free living population intake of food and I think the point that we wanted to make here was that it is not

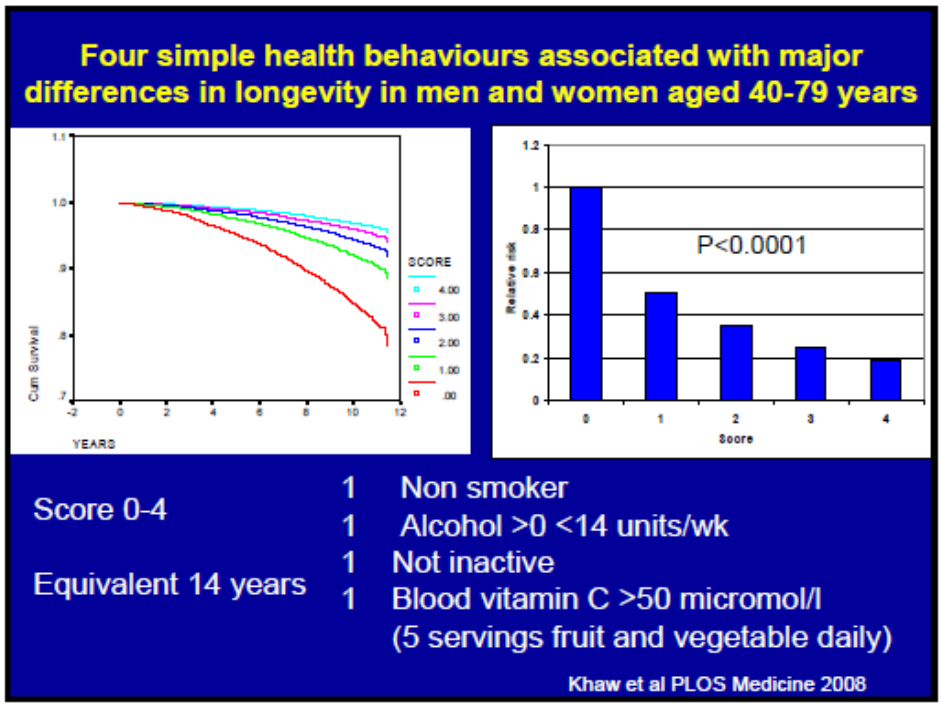
just the relationship with cardiovascular disease that we think is relevant for public health, people are not just interested in that, they are interested in total health. You can see the very strong relationship with total mortality, people who are in the top 20% or top 40% for plasma vitamin C the highest intake of fruits and vegetables not only have half of cardiovascular mortality but also half the total mortality compared to the people in the bottom 20%.



The magnitude of this was an increase of about 1 serving a day of fruits and vegetables associated with the 20% lower mortality. So within the normal habitual range in a free living population there is demonstrable relationship with mortality. But of course, we go back to the trials, and we heard again about the Lyon Heart Study which showed a 70% lower mortality. This was done in France so maybe it is a different pattern of fruits and vegetables because what happened in the Lyon study was in the subset where they did biomarkers, they were able to document apart from reported diet, biological change, a rise in the vitamin C an indicator of fruits and vegetables intake and interestingly enough a decrease in white blood cell count, a marker of inflammation, but without a big impact on the classical risk factors blood pressure and cholesterol with Mediterranean diet. This was, of course, not only associated with the change in type of fat but also with an increase in fruit and vegetables intake as we have heard from the earlier speakers.

One of the big criticisms in making any sort of lifestyle recommendations is firstly that people who eat a lot of fruits and vegetables also have other health behaviours, they are more likely to be physically active, they less likely to be smokers so they are all correlated. Fruits and vegetables is just a marker of a healthier lifestyle. To

address this, we did a health behaviour score where each of these lifestyles where independently scored so that addresses the confounding issue of lifestyle. The second is that often it is argued these behaviours are not feasible because we cannot possibly eat all this fruits and vegetables or do all these physical activities so we wanted to address feasible behaviours that were within the reality of free living populations and as you can see these are the scores: 1 point for each of these 4 healthy behaviours, two of them nutritional, one: moderate alcohol intake and the second is fruits and vegetables about 5 portions a day as indicated by our biomarker. Physical activity, not difficult, it was not being totally sedentary so anything beyond a total couch potato was one score for physical activity and of course, non smoking.



You can see the additive relationship of these very small differences in lifestyle. The people who had four behaviours, the relative risks across had one fifth the subsequent mortality and these are the survival curves according to the number of health behaviours equivalent if you practised 4 four healthy behaviours to be 14 years younger in term of chronological age for life expectancy compared to 0 health behaviour. 25% of our population had four health behaviours so a very small difference and feasible change seems to have impact on health outcomes.

What does it mean in terms of recommendations? We have heard questions about: how good is the evidence and is it enough to make public policy recommendations? We have heard from many speakers already about the huge burden of cardiovascular disease in the world and the biggest burden comes from developing countries. We also heard about the huge impotence to prevent cardiovascular disease but clearly putting the world population on blood pressure lowering medication is not a feasible public health policy. We need to understand what public health interventions might

have substantial impact on moderating the future epidemic of cardiovascular disease particularly in low and medium income countries where individual interventions are not feasible. We need public health interventions.
And we know that cardiovascular disease is hugely preventable, we only have to look at time trends, look at the US, this is a period of just 40 years this is not genetic differences these are huge environmental changes which have affected different populations differently. The US shows a precipitate decline in cardiovascular disease; Britain started lower but declined later but they also had a decline; Japan and Spain, South European countries have had low rate and they continue to decline but in sharp contrast; Mauritius and Russia, both examples of emerging economies have had this massive increase. If we could simply turn around some of those trends to reflect those that we see in some of the other countries we will be talking about as Dr He highlighted millions of potential events prevented in a year.
I come back to a statement that was made by Austin Bradford Hill in relation to smoking. How many of us believe that smoking is not causally related to health? I should think nobody. Smoking evidence was not based on any randomised trials whatsoever. When talking about the need to act in the absence of randomized trials we know we can never get a 100% certainty but certainly the evidence for fruits and vegetables is about as good as any other evidence that is available and there is no evidence so far at all that there is any harm from changing fruit and vegetables intake. As we heard from our earlier speakers there is a huge amount of evidence much more than for many other nutrients that high fruits and vegetables intake is beneficial not only for cardiovascular disease but for total health, for total mortality. The magnitude of a feasible change about 5 servings daily which is totally achievable and we heard from Barbara Rolls about how we can achieve that is about 20 to 30% lower cardiovascular disease risk and there is substantial potential public health impact particularly in the context of other health behaviours. So we really emphasize that the WHO global strategy on disease recommends an increase in fruit and vegetables intake within a totally achievable range as well as some of the other dietary changes and of course stopping smoking and increasing physical activity.

What will be interesting, I think, from the rest of this conference is to understand how perhaps we can achieve some of these changes.

SESSION 6

F&V CONSUMPTION TO REDUCE CANCER RISK

Chairs: **A. Schatzkin**

- Introduction. **A. Schatzkin**
- Changing dietary habits after a cancer: a systematic review of the literature. **T. Norat**
- Biomarkers of F&V intake and cancer risk. **M. Jenab**
- Vegetables and genetics: feeding studies in cancer prevention. **J. Lampe**
- What about mechanisms? **J. Milner**

Introduction

Arthur SCHATZKIN
National Cancer Institute, Division of Cancer Epidemiology and Genetics, Bethesda, Maryland, USA

(…) I will make a couple of very brief introductory remarks. We heard this morning very strong evidence that fruit and vegetable consumption plays an important role in obesity and in cardiovascular disease. Now, it is not necessarily true that fruit and vegetables have to be good for everything. They do not necessarily make you live to be 125, they are not necessarily going to make your kids get higher paying jobs, they won't necessarily improve you tennis performance. It would be wonderful if fruit and vegetables intake, in fact, did reduce your risk of cancer, but as you heard that has been a problematic field and the evidence is controversial, inconsistent at times, and changing over the last several years. Even if it were true that fruits and vegetables do not play a substantial role in malignant disease as you have heard, they play a substantial role in other chronic non-communicable diseases.
With our four speakers, we are going to approach the fruit and vegetables cancer problem from several different levels. We are going to have Dr Terea Norat presenting on cancer survivors. She will look at the epidemiologic evidence that fruit and vegetables consumption can play a role in long term prognosis for those who have been diagnosed with cancer. Then we have Mazda Jenab, who is going to talk about the important role of biological markers in relation to fruit and vegetable intake. He will discuss some of the difficult issues about how well we measure what people eat, how much fruit and vegetables they consume. Dr Johanna Lampe will be talking about feeding studies, with a particular emphasis on studies of the role of polymorphisms in metabolizing genes. She will discuss how understanding fruit and vegetables intake in relationship to chronic disease and cancer can be enhanced by these kinds of nutrition-gene studies. Finally John Milner will talk about underlying mechanisms and the importance of looking at genetically susceptible subgroups.

Changing dietary habits after a cancer: a systematic review of the literature

Teresa NORAT
Division of Epidemiology, Public Health and Primary Care, Faculty of Medicine Imperial College, London, UK

(…) I will base my talk on the literature review that was conducted for the global report of the American Institute for Cancer Research and Work Cancer Research Fund which was published last year and this year it includes detailed chapter with an extensive review of clinical-trials on dietary interventions and nutritional-based interventions on cancer survivors.

Cancer survivors is anyone who has been diagnosed with cancer, and there is a continual stage for cancer survivors that go from previous treatment to during treatment, recovering treatment, preventing recurrence, second primaries and living with advanced cancer and each of these stages have different requirements. It is importance to notice that there are important differences between nutritional research for cancer prevention and after cancer prevention. Currently, the most important difference is in the amount of evidence that has been collected. We have strong and substantial evidence that nutrition is related with cancer prevention and hundreds of studies that support these evidences while now we still have limited evidence of the relationship of nutrition with endpoint after cancer diagnosis. Another important difference between prevention and after cancer studies is that in the population in general there is modest interest in behavioral change for cancer prevention while in cancer patients there is keen interest in behavior change for improvement of quality of life, for improvement of result of treatment, for prolonging life expectancy. An the other important difference is that there is little commercial interest in studies on cancer prevention while there is much more commercial interest in studies on cancer survival mainly for the further applications in dietary supplements.
Patients, cancer survivors are highly motivated to seek information about food choices, physical activity and dietary supplements however in fact few survivors are actually making these changes.

American Cancer Society's SCS-II (N=9,105)
Cancer Survivors'Adherence to Lifestyle Recommendations

Cancer Group	Physical Activity (%)	5-A-Day (%)	Smoking (%)
Breast	37.1	18.2	88.1
Prostate	43.2	15.6	91.6
Colorectal	35	15.9	91.3
Bladder	36	16.3	82.6
Uterine	29.6	19.1	91.1
Skin melanoma	47.3	14.8	89

Abbreviation: 5-A-Day, consumed five servings of fruits and vegetables each day.

Blanchard et al. Journal of Clinical Oncology, 2008; 26(13) pp. 2198-2204

This is a study that was conducted by the American Cancer Society in more than 9'000 individuals and they investigated the adherence to lifestyle recommendations. In fact, non smoking was the recommendation that was made by most of the individuals the cancer survivors included in the study but other lifestyle behaviour like physical activity and the recommendation of 5 serving of fruits and vegetables were made by a limited number of cancer survivors. Then the question would be: Is adherence to lifestyle behaviour related to health-related quality of life? This was also investigated in this study where the researchers related health quality score which is based in physical and mental domains with the adherence to guidelines for cancer prevention. We could see that the mean score was higher for individuals that adhere to the recommendation for smoking, stop smoking for all cancer sites also was higher for individuals that adhere to the recommendation of being physically active and the score was also higher in individuals cancer survivors that adhere to the recommendation of consuming five servings of fruit and vegetables per day. When we analyse the clusters of the recommendations cancer survivors that adhere to the three recommendations have a higher health related quality score in average compare to cancer survivors that adhere to only two of these recommendations, either smoking and physical activity or smoking and high consumption of fruit and vegetables. These individuals have also higher health related quality score compare to the individual cancer survivors that only adhere to the smoking recommendation and higher score than individuals that did not meet any criteria.

<u>What is the evidence of nutritional interventions in cancer survivors?</u>

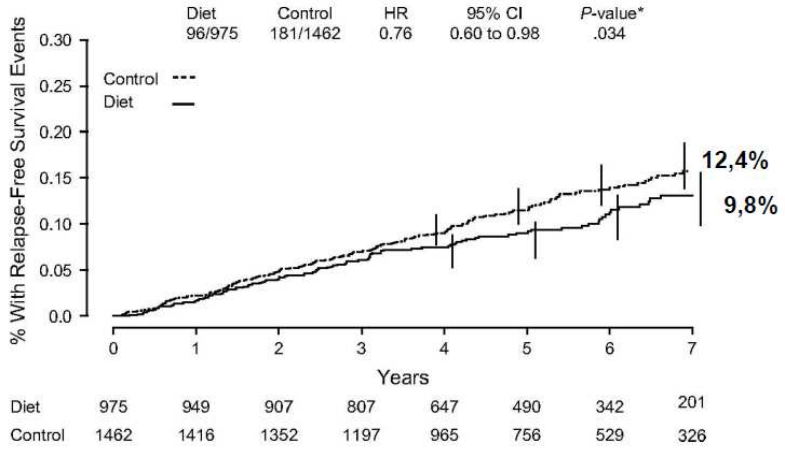
I will present the results of the meta-analysis that were conducted by the literature review did in Bristol for the Work Cancer Research report. This group retrieved all the published intervention-trials in cancer, nutritional-based intervention trials and they retrieved 53 trials in different cancer sites. (…) The pool had a ratio of 0.89, it is not significant and what we can see regarding the quality of the studies is that the number of individuals included in the studies is relatively low in addition we had a low number of cases. The interventions were missed, many of the interventions were

dietary advices (…) and some interventions also included liquid dietary supplements and different endpoints were evaluated in different cancer sites. This evidence is in reality inconclusive; it does not rule out the possibility that there is a beneficial effect.
In a second part showing the summaries of clinical trials for antioxidants we had some trials with a higher number of individuals and better quality and the relative estimated risk was 0.99 so this indicates that probably antioxidants supplementation in cancer survivors does not modify all cause mortality. Finally the clinical trials with retinol do not provide any overall evidence of any beneficial effect on cancer survival.
The results of the meta-analysis on cancer mortality is very striking in the low number of clinical trials that could be included in this ratio and overall there is no evidence of dietary interventions and beneficial effect o f dietary interventions on cancer mortality. There are some suggestions on the three results on the healthy dietary interventions but nothing for antioxidants and retinol. The main conclusion that can be taken from these analyses is that we need more studies and we need the quality of these studies.

Regarding physical activity, 23 trials were retrieved; half of the trials were in breast cancer survivors. There were several randomize controlled trials in breast cancer and there was consistent evidence of many benefits in particular increased muscular strength, decreased fatigue, fewer treatment side effects in patients with breast cancer. Overall the recommendation is to do 30 min physical activity in addition of the normal physical activity. These results are very consistent but the effects on prognosis are still unknown. With respect to bodyweight, there was enough evidence regarding on obesity and risk of breast cancer recurrence and the conclusion of the panel of experts is that overall recurrence risk increased by 78% among obese women (BMI>30) compare with normal weight (BMI<25). And, the increased risk of recurrence in women with higher body mass index and obese women was observed in different subgroups: in postmenopausal women, in premenopausal, estrogen receptive positive negative and even in women with Tamoxifen use.
I will present the result of two important trials that were published after the meta-analysis for the Work Cancer Research Fund.

The Women's Intervention Nutrition Study (WINS)

Kaplan-Meier estimates of relapse-free survival

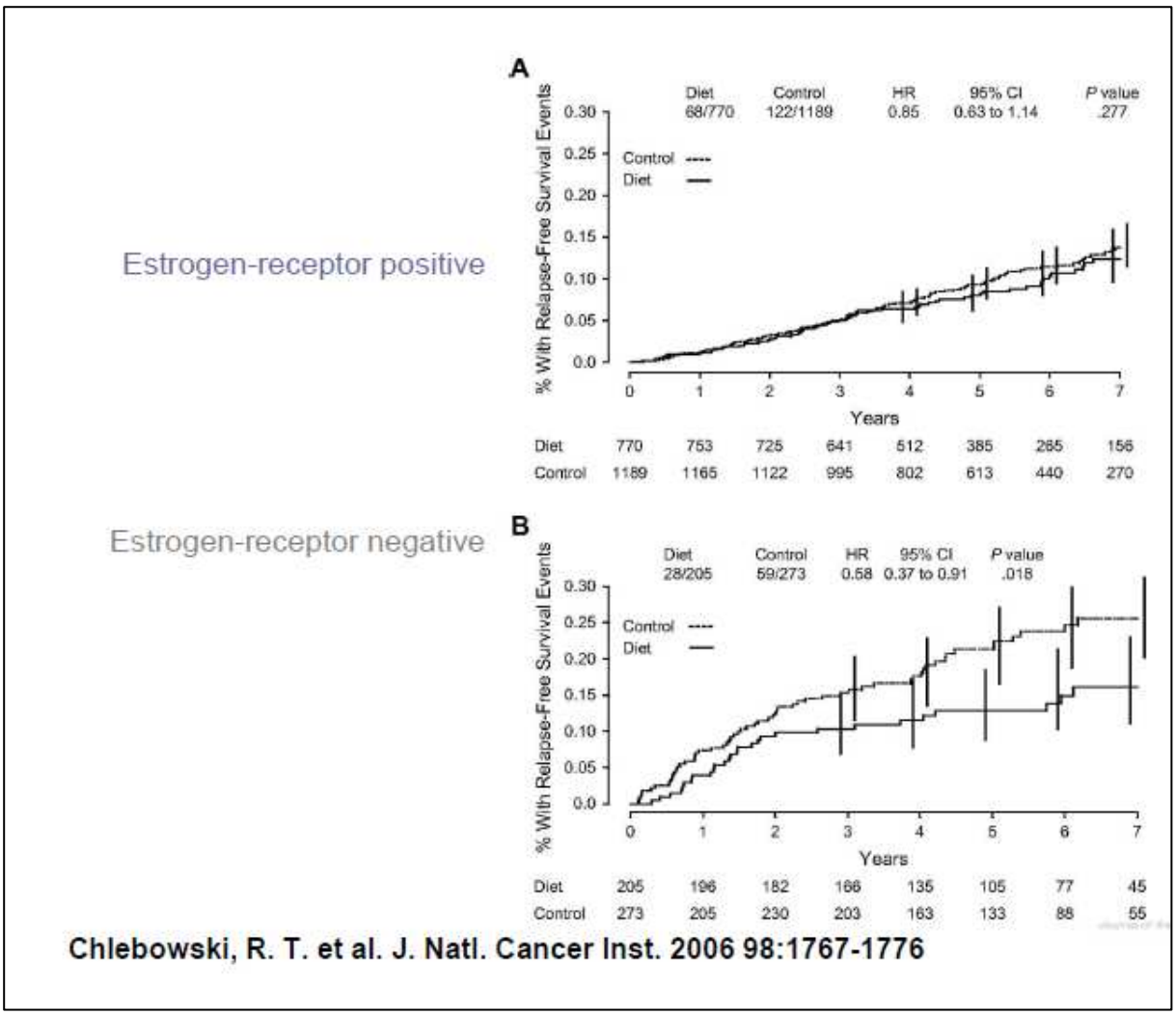


Chlebowski, R. T. et al. J. Natl. Cancer Inst. 2006 98:1767-1776

JNCI

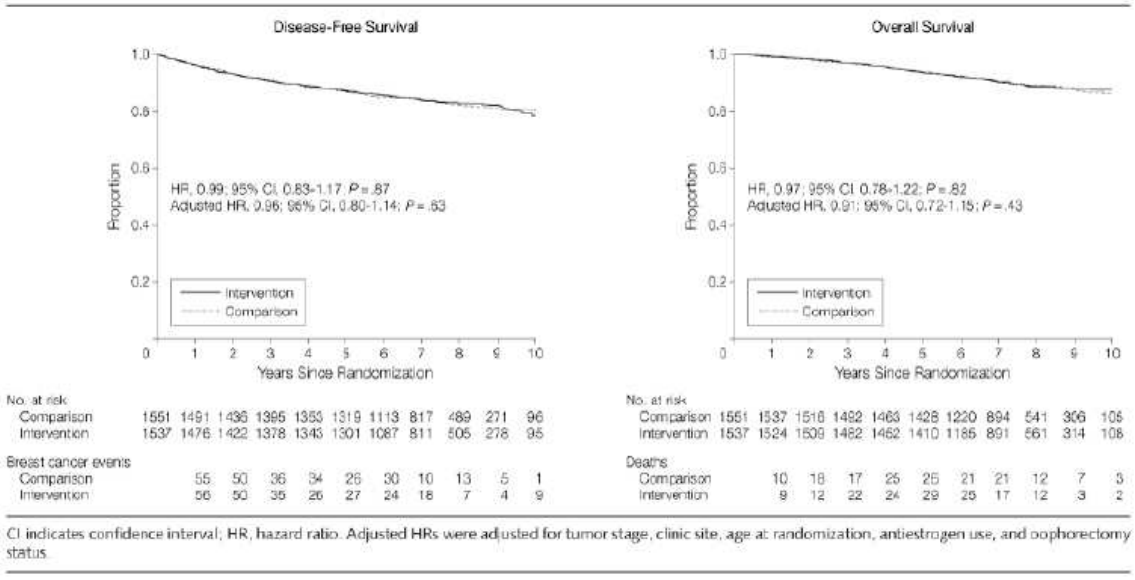
One of the trials is a trial on diet change after survival of breast cancer in The Women's Intervention Nutrition Study (WINS); it is a big trial in more than 2'000 women. The intervention consisted in low fat diet (15% kcal from fats) the diet was calculated on the advice to keep energy intake at a level that maintain weight so the trial was not designed to loose weight but was designed to low intakes of fats from diet. The primary outcome was relapse-free survival. The controlled group received the general control dietary guidelines.

After more than 5 years of follow up in the intervention group there was a 24% reduction in risk of relapse in the intervention group the group with a low fat diet compared to the group with dietary advice. This reduction in risk was observed mainly in women with oestrogen-receptor negative breast cancer.



The second important trial that was recently published was the Women's Healthy Eating and Living (WHEL) Randomized Trial which is a trial on testing the effect of a diet rich in fruit and vegetables in cancer survivors. The intervention group received advices of consuming five vegetables servings, 16 ounces of vegetable juice, 3 serving of fruits, 30 grams of fiber and calories from fat between 15 to 20% while the controlled group received a standard dietary advice (5 servings of fruit and vegetables, 20g of fiber, less than 30% of calories from fat).

Kaplan-Meier Estimates of Disease-Free Survival and All-Cause Mortality by Diet Group



CI indicates confidence interval; HR, hazard ratio. Adjusted HRs were adjusted for tumor stage, clinic site, age at randomization, antiestrogen use, and oophorectomy status.

Pierce et al.JAMA. 2007 Jul 18;298(3):289-98

In this trial, no significant difference was observed in cancer all-cause mortality in the two groups. There was also no difference in disease-free survival. So, these two trials pose now the question why there is difference.

How to explain the difference in the two trials?

One trial in which we observe that diet low in fat and rich in fruit and vegetables increase survival (WINS) while in the other trial (WHEL) we do not observe it. There are many possible explanations. One explanation is that in the WINS women intervention group that reduced intake of calories from fat the reduction that they attained was more important than the reduction of fat intake that was observed in the WHEL group. In fact, the average intake of fat in the WINS intervention group was about 20% of energy from fat in average wile in the WHEL group it was closer to 26/27%. There was also a difference in weight in the intervention and control groups in the WINS trial although it was not the end of the trial whereas in the WHEL trial the trial of high fruit and vegetables intake there was no difference in weight between the intervention and the control group. So, probably either lower dietary fat or lower weight could account for the survival benefits in the WINS study. But we need more trials to confirm this founding.

I would like to add some notes on vitamin and mineral supplement. I took some information from a review that was recently published of studies that were published between the years 1999 and 2006 about the consumption of vitamin and mineral supplement in cancer survivors. This study reports between 64 and 81% of cancer patients consume multivitamin or mineral. Multivitamin particularly was

reported between 26 and 77% of the cancer survivors. It was new there was a change in supplement use after diagnosis between 14 and 32% of the cancer survivors and 89% started using megavitamins. Only about 3% of the patients received dietary supplement as "not beneficial at all" and what I think is very striking is that between 31% and 68% of the cancer survivors never discuss their choice of multivitamins or mineral use with their physician. The reasons why they do not discuss are not known, the paper could not explore why. This is very important and it is not known if the use of multivitamin and mineral supplement on cancer survivors can have a beneficial or a harmful effect. We all know the results of the two important trials of β-carotene in smoker men that reported an increase in lung cancer. We have some evidence for studies in cancer survivors for example that the use of multivitamin or mineral supplement can be either beneficial of harmful but we need more evidence. Folic acid for example can be involved in progression of cancer in colon or colorectal polyps. Another example of trial, α-tocopherol during radiation in head and neck cancer was associated with higher recurrence of cancer. On the contrary, 35% improved survival was reported in a trial in small-cell lung cancer patients using multivitamin supplements. So the message is that "Vitamin use during treatment is controversial and potentially harmful" this is the message of the American Cancer Society but is at the same time "a daily, multivitamin supplement in amounts equivalent to recommended daily value could be a good choice for anyone…who cannot eat a healthful diet". And the NCI urges patients to avoid vitamin and mineral supplements while undergoing treatment or to take supplements only under physician's guidance. The World Cancer Panel notes that do not support the use of high-dose supplements of micro-constituents as a means of improving outcome in people with a diagnosis of cancer. And the panel of WCRF that cancer survivors talk with their physician or a qualified nutrition professional for advice.

Finally these are the recommendations of the World Cancer Research Fund based on the review that was conducted.

These recommendations are summarized as be as lean as possible within the normal range of body weight, physically active as part of every day life, limit the energy-dense food and avoid sugary drinks, eat mostly foods of plant origin, limit intake of red meat and avoid processed meat and limit alcohol drink.

And as recommendations for the future: to develop large-scale trials with longer follow-up are required, they need to focus research on diet and supplements and impact on outcome for 'survivors', they emphasise the fact that thy are confounding variables and heterogeneity of patients make appropriate trial design extremely difficult, should consider Quality of Life in outcomes and will need great care and thought by multidisciplinary team of experts.

As a conclusion we can say it may seem reasonable to assume that following guidelines for cancer prevention would also favorably affect cancer recurrence of survival rates and this is a prudent advice. However, few data are available to directly support this assumption. Persons who have been diagnosed with cancer may be at increased risk for other cancers and for cardiovascular disease, diabetes, and osteoporosis. So the advice in the absence of more evidence is that the guidelines established to prevent those diseases are especially important for cancer survivors

Q&A

A SCHATZKIN: We are all convinced that we do not have enough evidence on beneficial effect on cancer survivals but at this point is not that fruit and vegetables do not do anything for cancer survivors, we just do not have very much evidence.

T NORAT: We do not have very much evidence and the strongest evidence we have is a negative trial that I presented, the WINS. We need to designed better clinical-trials and one possibility is we need to focus on groups of population that maybe would respond better to the therapy. The issue would be how to identify those groups of population that probably would respond to behavior changes, maybe not everybody can respond. But we need more trials anyway, the evidence is limited.

A SCHATZKIN: There were some debates in the field around nutrition, diet and cancer survival as to whether observational studies, epidemiologic studies can play an important role. The concern is for example the prospective cohorts' studies around the world now have recruited enough cases breast cancer, prostate and other cancers that the individual that develop cancer can be followed prospectively. You have got information on diet, physical activity, body size and so on to see what effect or what association those factors have on prognosis and mortality on those who have been diagnose. The concern is that -and I know the Bristol group raised this- those observational studies are quite subjective in confounding, like clinical pathologic characteristic. Arguably the most important factors for survival are spread of disease, treatments and so on. And the data available in the observational studies on those factors may not be good enough. Therefore, some people may argue that the only good data in these areas are going to come from randomized trials. I do not know if you could comment on that.

T NORAT: I think that we should use the information from the cohort studies and in ethic we are thinking how to use this information. It would be very difficult because it was not designed for that so we do not have the mechanism to follow the patients except for second cancers or for mortality but we do not have the way to follow the people for example for cancer recurrence in the same way as we have it for cancer incidence. And we do not have detailed information about cancer and we do not have detailed information about the stages but also about characteristics of cancers like for example breast cancer they can be a big difference between estrogen-receptor positive cancers as we already saw and estrogen-receptor negative cancers and we do not have set up that yet in our studies. But I think that interventions in cohort studies are valuable source of information as it is now for the association with cancer incidence and we have to try to recuperate information and to control.

PUBLIC (American man): (…) there are actually two studies that show a relationship of fat intake and breast cancer risk and that is the Women Health Initiative in the WINS project and both of those start seeing a separation after about 4 and half years. I wonder why in fact you might see this kind of time line before you see a response. Do you think that would also be true about other nutrients that it would take that long to see a response? Then I want a make another general comment about the WHELS project. I think a little more diverse population; some women were a little greasier, prior breast cancer risk and that also may be a very important of variable of why you did not see response.

T NORAT: Yes and there were more women with complete surgery. There were differences.

PUBLIC (American man): There is at least some data coming out now some populations even in that project that looks like that some people may have been more responsive than others. We may need to start thinking about some population.

T NORAT: I agree with that.

PUBLIC (French man): How do you explain that cancer survivors do not follow the dietary recommendations about fruit and vegetables in one side and at the other side mineral and supplementations? Why do they believe that supplementation is better for them than fruit and vegetables?

T NORAT: I do not have explanations why they do not follow the dietary advice and why they think that consuming more vitamin supplements will be beneficial for health. I do not have any explanation, it is not known. I think this an important element topic of research.

Biomarkers of F&V intake and cancer risk

Mazda JENAB
IARC, Lyon, France

Higher consumption of fruits and vegetables has been suggested to be associated with a decreased risk of many cancers. This hypothesis was supported for several cancer sites in the WCRF Expert Review of 1997, but since then the accumulating evidence suggests a decrease in confidence in this hypothesis, as highlighted by the conclusions of the IARC Review of 2003 and the most recent WCRF Expert Review of 2007. These overall conclusions may well be correct, but there may also be some other potential explanations.

One of those has to do with how dietary intakes are assessed. All methods of dietary assessment are associated with some degree of inherent measurement error to do with for example, the type and amount of foods consumed, portion sizes, recipe ingredients, food combinations, cooking methods, reporting biases and even nutrient estimation. If we consider all of these uncertainties and add them up, the end result is a considerable amount of systematic and random measurement error that really can not be ignored in any situation.

A solution to the problem of dietary measurement error is to acquire an "independent" observation of dietary intake or a measure of "true" intake, i.e. dietary biomarkers. The underlying assumption of dietary biomarkers is that the biomarkers will lead to a better classification or ranking of subjects for the intake of a particular food or food component than would a dietary measure. Many nutrition epidemiologists have dreamt about an ideal biomarker, but the reality is that such an entity does not exist. But, if it were to exist it would be specific, sensitive, valid, reproducible and applicable to many populations with different dietary patterns. Many of the biomarkers that are currently used in nutritional epidemiology fit some of these criteria, but not all of them.

Fruits and vegetables are hypothesized to have an effect on cancer risk in large part because of their phytochemical components, many of which are often utilized as dietary biomarkers. We know that many of these phytochemicals have properties that may affect cancer risk by way of various biochemical pathways and mechanisms. We also know that the phytochemical levels might be different in different tissues or organs interest.

But, the question at hand is what may affect the levels of these biomarkers in the blood? The blood level might be affected by a variety of different factors, such as intake levels, dietary patterns, dietary habits, changes with cooking, bioavailability from the GI tract, interaction with other dietary components (for example, non-heme

iron is better absorbed in the presence of vitamin C) or the presence of variety of lifestyle factors such as smoking, physical activity or alcohol consumption. Something that we do not know very much about is genetic variability, and how it may affect the metabolism, rate of absorption and excretion of these biomarkers, or how these factors may differ between people and populations. All of these factors can affect the exposure, concentration and availability of the biomarkers of interest.

Something else that we do not know very much about is how these biomarkers and nutrients may act synergistically, addictively or even antagonistically, and how such variation may impact the assessment of cancer risk.

Another aspect that may affect the measurement and utility of biomarkers are analytical factors. In other words, issues to do with the biological sampling - the type of biological sample, how it was obtained, how it was treated, how it was stored, how many freeze-thaw cycles it went through, and so on. The stability of the biomarker during processing and decay over time in storage and the laboratory methodology used to assess that biomarker are also part of the issue, as are, of course, costs.

In general, the main considerations for many dietary biomarkers are: Does the biomarker approach really substitute for an assessment of whole fruit and vegetable intake? And does a dietary assessment provide sufficient information to preclude the use of a biomarker or is a biomarker approach preferable? In most cases, the answer is that they are both necessary and provide very useful information.

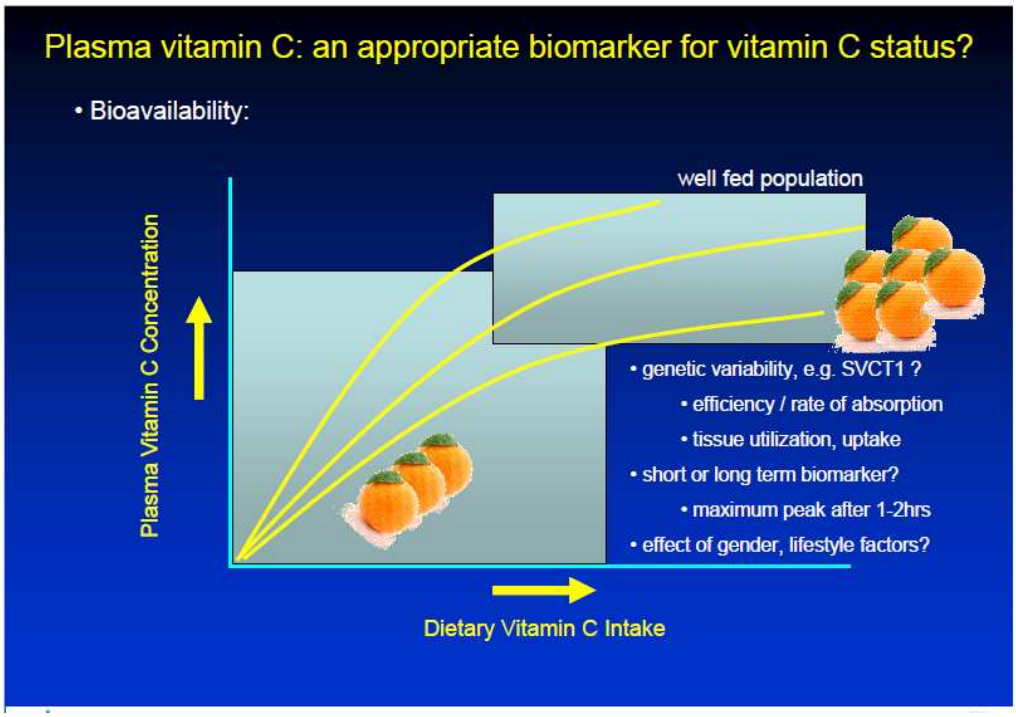
To illustrate these points I am going to use some examples of common biomarkers: vitamin C, carotenoids and tocopherols.

Vitamin C is an important water soluble nutrient, with a variety of different functions, the most important of which appear to be its antioxidant abilities, and its ability to scavenge nitrite and to inhibit in vivo nitrosation and n-nitroso compound formation.

But, the question is: is plasma vitamin C an appropriate biomarker of the level of fruit and vegetable intake or the level of vitamin C intake? Many studies have been performed to assess this question. The overall conclusion appears to be that there is only a moderate correlation between plasma vitamin C levels and dietary intakes. In general, plasma vitamin C has correlations of about 0.3 with total fruit intake, a lower correlation with total vegetable intake and a slightly better correlation with assessments and estimations of dietary vitamin C intake. But in general, these correlations are very moderate.

That is in part explained when we look at the dietary sources of vitamin C. We observe there is a wide range of sources ranging from about 3mg/100g up to 0/100g. If a dietary assessment method does not assess the full range of fruits and vegetables that provide vitamin C in a particular population then that can lead to considerable errors if vitamin C is used as a biomarker of fruits and vegetables intake in that population.

Another aspect to consider is bioavailability. In a perfect world, bioavailability of intake would equate exactly to plasma vitamin C concentration. But in reality the curve has a linear range and a non linear range or plateau at higher intakes.



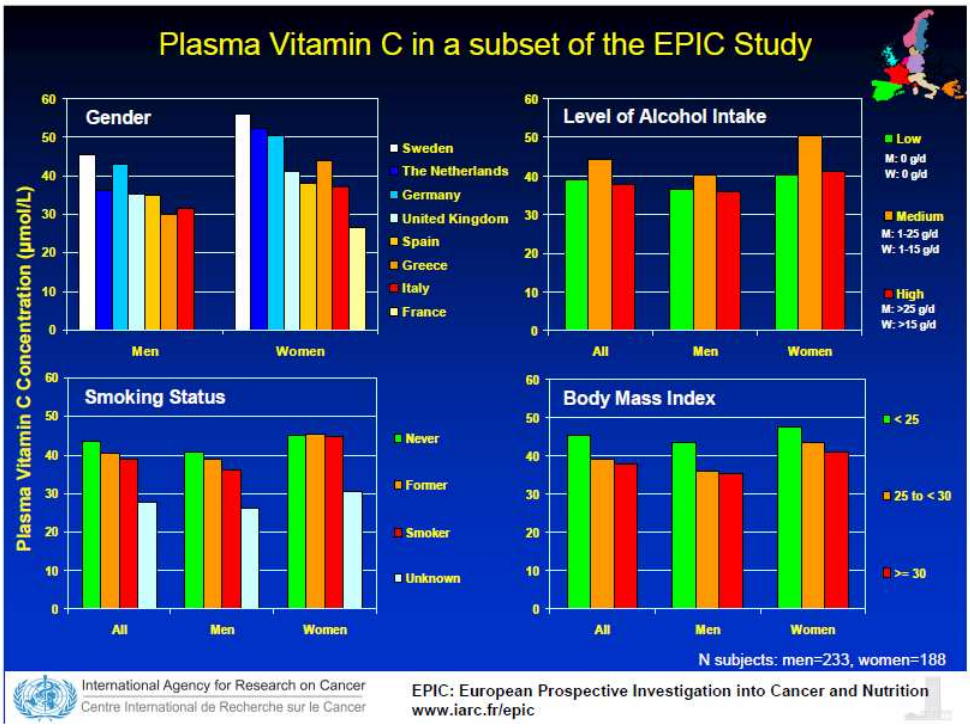
If you look at the linear range which is often seen at lower intake levels of vitamin C (approximately up to 90 to 100 mg/day intake or about three oranges per day): the vitamin c transporter protein is not saturated, the absorption is at a maximum and the renal excretion is at a minimum. However if we consider a population such as a well fed vegetarian population which has a high intake of a variety of fruits and sources of vitamin C we see that they may likely fall into the plateau range. So for a population in the linear range vitamin C might well serve as a good biomarker of fruit and vegetable intake. But for subjects who are in this plateau range, vitamin C may not correlate well with the dietary intake because no matter how much they consume, they will still be at a plateau. Although, even at this level, vitamin C may still be informative for assessing cancer risk and the ranking of subjects.

Another aspect that I mentioned before is genetic variability, for example, as applicable here, in the vitamin C transporter protein. This may affect the efficiency,

rate of absorption, tissue utilization, and uptake of vitamin C. This results in different curves for different subjects and different populations. How do we compare them if we do not know anything about the genetic variability affecting blood vitamin C levels?

Another aspect is: is the biomarker a short or long term biomarker of intake? Vitamin C is maximally absorbed after 1 to 2 hours after ingestion. So it is a short to moderate term biomarker of dietary fruits and vegetables intake. This may not be a problem for a population that has a constant intake of fruit and vegetables but it may be a problem for a population that has inconsistent levels of intake.

Another aspect is: how do lifestyle factors affect the concentration of the biomarkers in the blood? This is something I would like to illustrate by presenting some unpublished data from the EPIC study where we measured plasma vitamin C in a sub-set of subjects.

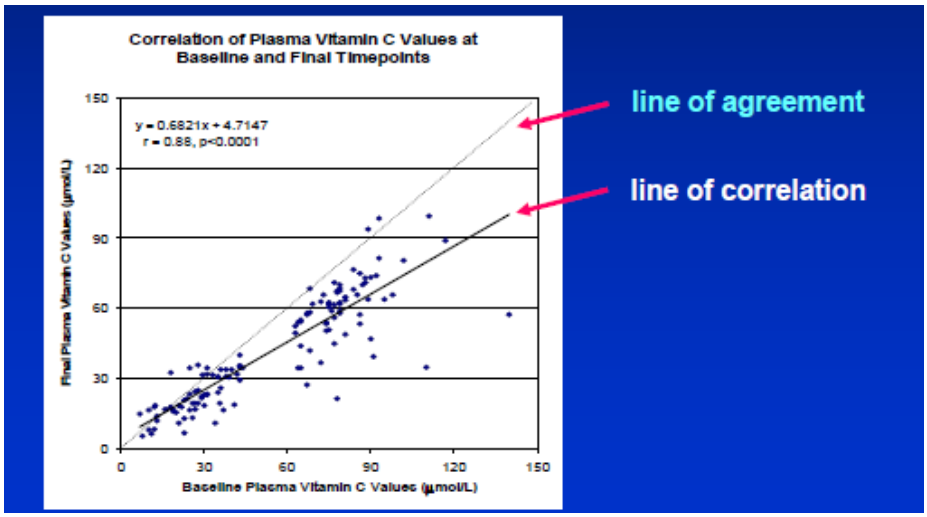


Here we observe variability between the 10 EPIC countries in terms of vitamin C levels; also by gender. There is also variability by lifestyle factors such as the level of alcohol intake, smoking status and body mass index. The point here is simply to illustrate that these variables may affect the correlation of plasma vitamin C with dietary measures of fruits and vegetables. This may also have an impact on the assessment of vitamin C with cancer risks.

I mentioned before that analytical factors could affect vitamin C. Vitamin C is in fact one of the most labile nutrients and issues of how the biological sample was processed, how it was collected, how it was stored, and what analytical method was

used could all affect the measured plasma vitamin C level. Another aspect that is not well studied is the decay of vitamin C over time in biological samples that are in storage. We studied this within the EPIC study.

This graph shows the baseline vitamin C level as compared to the final vitamin C level for the same subject after up to 11 years in frozen storage at minus 196° C. If there was no decay we would expect that the before and after measurements line up along the line of agreement. But in fact the line of correlation is lower indicating that there is some decay after frozen storage.



The degree of decay is illustrated by this table:

EPIC	Average loss of plasma vitamin C from baseline to final time points (%)	
Plasma Vitamin C at Baseline	Men	Women
Lowest Quintile	8.2 (p=0.2406)	17.6 (p=0.0003)
Highest Quintile	24.6 (p<0.0001)	24.2 (p<0.0001)

We see that the rate of decay is dependent on the concentration of vitamin C at baseline. So, lower concentrations of vitamin C at baseline have a lower decay and higher concentrations of vitamin C at baseline have a higher percentage of decay. This could have an impact not only on the correlation of the vitamin C with the dietary variable but could also impact the ranking of subjects as we assess cancer risks.

Another group of compounds that I would like to talk about are the carotenoids and tocopherols. These are also used as biomarkers of fruits and vegetables intake and like vitamin C it is thought that they may act as antioxidants and limit free radical mediated damage. I would like to use these compounds to illustrate another point: is it sufficient to measure one biomarker from a class of compounds? Do all compounds in a same class have the same effect? Are there synergistic, additive or antagonistic effects - something that we do not know much about? All of these could affect the

concentration or availability in the tissues or organs of interest. Here again, I would like to present some data from the EPIC EURGAST Study.

The EURGAST study is a component of EPIC that focuses on gastric cancer. EPIC is a large prospective cohort of 520,000 subjects from 23 centres in 10 European countries where we have detailed dietary and lifestyle data as well as biological samples collected. Using the biological samples, we conducted a nested case-control study of 238 incident gastric cancer cases matched to 626 controls; we used validated, country-specific dietary questionnaires and measured vitamin C, carotenoids and tocopherols in their plasma using the most recent methods.

This graph presents the odds ratio for gastric cancer risk for a battery of carotenoids, α-tocopherol and vitamin c for the bottom versus the top quartile of plasma concentration.

Plasma Analyte	Bottom vs. Top Quartile (ug / dL)	OR (95CI)
α-Carotene	< 3.2 vs. ≥ 9.0	1.19 (0.71-1.99)
β-Carotene	< 12.0 vs. ≥ 26.5	1.13 (0.69-1.86)
Canthaxanthin	< 0.4 vs. ≥ 1.6	0.80 (0.44-1.45)
Lutein	< 14.6 vs. ≥ 28.9	0.73 (0.43-1.37)
Lycopene	< 17.8 vs. ≥ 44.7	0.63 (0.36-1.09)
β-Cryptoxanthin	< 5.8 vs. ≥ 18.7	0.53 (0.30-0.94)
Zeaxanthin	< 3.2 vs. ≥ 6.7	0.39 (0.22-0.70)
Total Carotenoids	< 70.5 vs. ≥ 135.9	0.69 (0.39-1.21)
α-Tocopherol	< 1022.0 vs. ≥ 1393.7	0.59 (0.37-0.94)
Vitamin C (μmol / L)	< 29.0 vs. ≥ 51.0	0.55 (0.31-0.97)

Carotenoids/Tocophérols: Jenab et al, BJC 95:406, 2006 ; Vitamine C: Jenab et al, Carcinogenèses, 27:2250, 2006

As you can see, for α-carotene and β-carotene there is a non statistically significant positive cancer risk association, whereas for the other carotenoids we observe a negative association which is strongest for zeaxanthin. The point illustrated is that if we had just looked at β-carotene, we may have thought that they have a possible positive risk association, whereas when we consider a few more carotenoids we see that the picture is a bit different. Here, we only considered 7 common carotenoids but in reality there are about over 600 different carotenoids in fruits and vegetables and over 40 that are possibly found in human blood. We have not considered any of the other carotenoids and we have no idea what the overall total carotenoid effect may be. The variable of total carotenoids shown here is just a very basic sum of the concentrations of the individual carotenoids we measured. We have no idea how these individual carotenoids interact with each other and whether the different levels of carotenoids have the same effect in terms of antioxidant activity, for example.

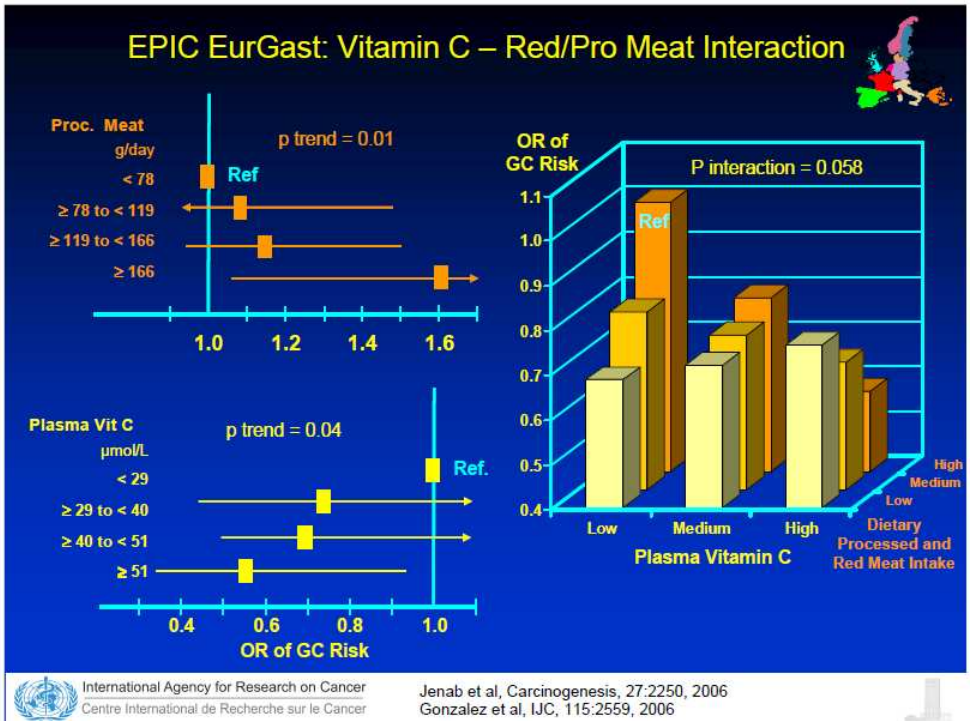
Here, α-tocopherol and vitamin C showed a negative association with gastric cancer in our data set. It is important to point out that for all of these biomarkers, no gastric risk associations were observed for the corresponding dietary variables. So, had we just considered the dietary questionnaire variables, we would have concluded a null disease risk association.

I mentioned earlier that vitamin C is important because it acts to inhibit endogenous N-nitroso compound formation in the gastrointestinal tract. N-nitroso compounds are formed from intake of dietary nitrate which comes from a variety of different dietary sources particularly from processed meats. We have to ask, would a high intake of vitamin C reduce the positive gastric cancer risk association that we observe with higher intake of processed meats? Within the EPIC EURGAST data set using dietary questionnaires we observed that higher intake of processed meat is associated with an increase in gastric cancer risk. We also observed, as I described earlier, that higher plasma concentration of vitamin C is associated with a decrease in gastric cancer risk. When we consider the two variables together we observe a statistically significant interaction which seems to suggest that the negative effect of vitamin C on gastric cancer risk is strongest in the presence of higher intake of processed meats. I put this up to illustrate the point that the population that we are looking at for a particular biomarker may be very important. In this case, the effect is strongest in high meat eaters. This example also illustrates how biomarker and questionnaire data can be combined to address relevant hypotheses.

In summary, both biomarkers and dietary assessment methods provide very useful information. Biomarkers and dietary assessment methods are both associated with various errors and limitations. We need to: improve dietary assessment methodology, improve and update how we compute nutrients, improve our understanding of the metabolism of existing biomarkers, identify new biomarkers of fruit and vegetable intake and most important of all, improve our knowledge of nutrient metabolism and nutrigenomics in particular. It is fair to conclude that only enhanced information from both dietary assessment methods and biomarkers can improve our knowledge of the association between fruit and vegetable intake and cancer risk.

Q&A

PUBLIC: Can you explain a little bit the slides about meat interaction?



M JENAB: If look at the interaction graph, our reference category is the category of low vitamin C and higher meat consumption and we see that the strongest effect as we move from low to high plasma vitamin C concentration is actually in those who have a higher dietary meat intake. This suggests that the gastric cancer protective effect of vitamin C is strongest in this population and it suggests that vitamin C may be acting, as the hypothesis suggests, by inhibiting N-nitroso compound formation from dietary nitrate which is higher in this population that eat a higher amount of processed meat than those who eat a lower amount of processed meat.

A SHATZKIN: Are you concerned about how well you measure meat while you measuring all this? Perhaps you have more than one dietary factor eaten that is measure with error?

M JENAB: Sure, that is a concern as well. However in the EPIC study we have prospectively built a mechanism to calibrate the dietary questionnaire measures and we have that mechanism from a subset taken much standardised 24 hour recall which we use as a gold standard to calibrate the dietary questionnaires. Now the data that I provided here is not calibrated, the data just come from the dietary questionnaires. However when we look at the calibrated data the association is exactly the same and so this gives a little bit of confidence in the meat data that we are observing.

A SHATZKIN: You argued for better biological markers for fruit and vegetables intake, are you optimistic that we will come up with such better biological markers? And do you see work going on to get them? Some of the other speaker might answer at some other degree.

M JENAB: I am not aware of much work going on, they may well be but I am not aware of identifying new biomarkers. But I am very optimistic that we can learn how to better interpret and better utilise these existing biomarkers.

PUBLIC: I guess in this context we do have biomarkers now that are relevant to fruit and vegetables consumption, I am wondering if there has been much done with regard to trying to use them together in compilation. You talked about the carotenoids and that capacity of whether or not expanding beyond to give a broader picture of exposure of that being done and how it has been done?

M JENAB: I am not aware of that being done but I think it is what we need to do. A major limiting factor may be the cost associated with analysing these compounds and also the amount of blood that is required to analyse these compounds. In a cohort study blood is very precious so you have to use very minute amount to work with. Perhaps for a lot of phytochemicals that I put up we need to develop better methodology to analyse them in much smaller amounts of blood.

A SHATZKIN: Do you see any potential in combining not only the biomarkers as you just discussed but combining the biomarker data with the self reported data whether it is food frequency questionnaire or even some of the new approaches to get multiple 24h recalls whether it is combined biological markers of fruit and vegetables intake with your self-reported data to even get perhaps a more accurate approach of true intake?

M JENAB: That is what I am actually trying to illustrate with this interaction graph where we look at data from dietary questionnaires and data from biomarkers together and my conclusion, the final sentence, stated exactly that we need enhanced information from all the various sources enable to get a better understanding on what is going on.

Vegetables and Genetics: Feeding Studies in Cancer Prevention

Johanna LAMPE
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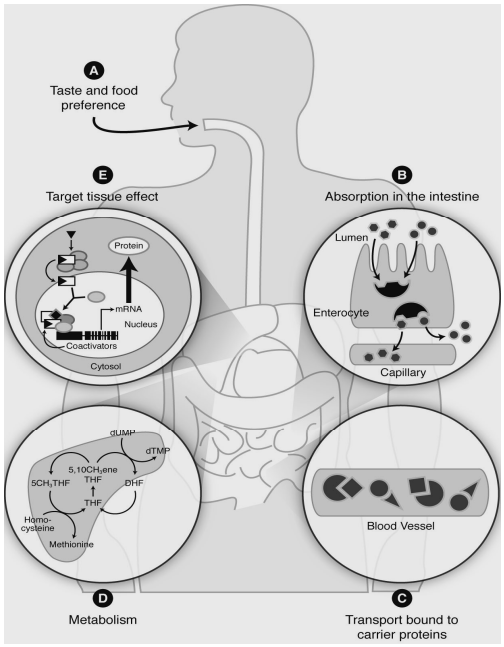
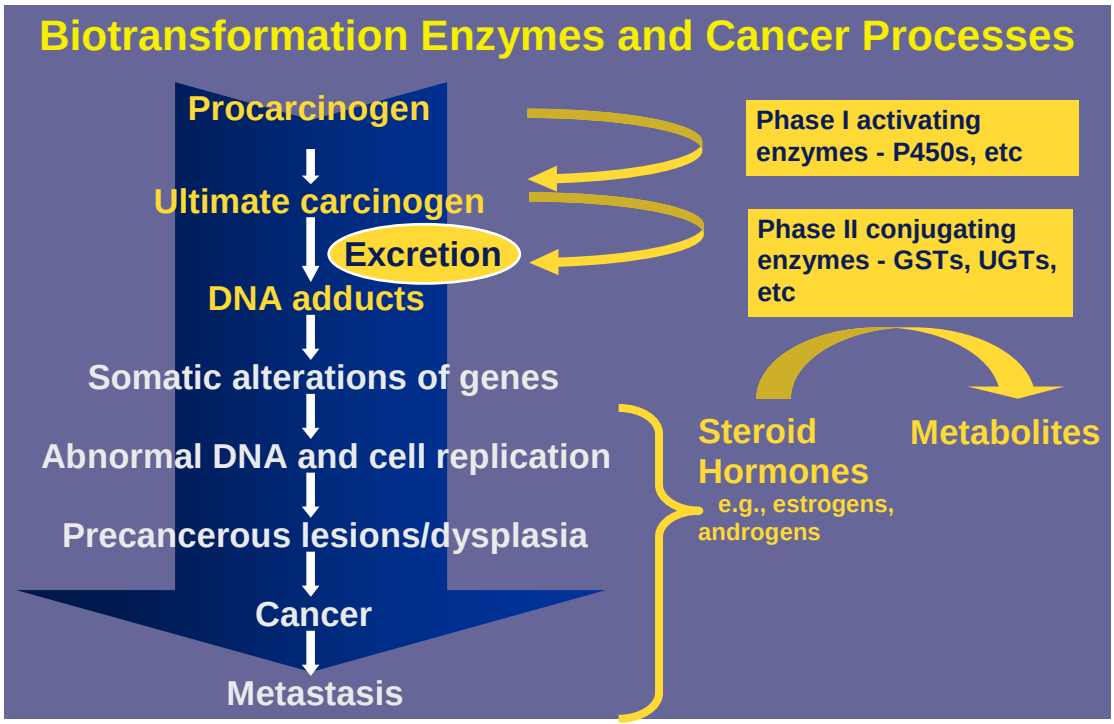
(…) I would like to pick up where Mazda Jenab left off with regards to some of the issue related to variation in response to fruit and vegetables, particularly focusing on some of the work that we have done in the context of exposure to different types of vegetables. One of the buzz words of nutrition these days is "nutrigenomics," which includes the concept that genetic variation can influence response to diet. We tend to think of this primarily in the context of the human genome both from the stand point of variation with regards to genetic variation. However, and I think Dr Milner will talk a little bit about this, more and more, other aspects of genomics may also come in to play. The variation in our epigenome is where genes are being expressed depending on whether or not promoter regions are methylated. Another genome that only recently has begun to receive more attention is the genome of our bacteria. In relation to diet, the gut bacteria have an important role and contribute to differences in response to diet. In that context all of these factors can contribute to cancer risk.
Because of the time limitation, I will focus primarily on host genome with regards to its impact on affecting diet, but you can also think about this in a much broader context. Genetic variation may contribute to individual response coming to the point even from the stand point of the food choices that we make. There are data to show that our food choices, whether or not it be fruit and vegetables, or whether it be how adventurous we are in our eating, is under some genetic control. There are some elegant twin studies that show differences between monozygotic and dizygotic twins, suggesting a genetic component to food preferences. Similarly food tolerance -- a prime example being lactose tolerance in adults -- absorption, transport, metabolism and the effect at the level of the target tissue are influenced by genetic variation and differences at all these points may play a role in our overall response to diet.



In the case of cancer, one of the points whether there is probably the most data with regard to genetic variation is in the area of biotransformation enzymes. These are groups of enzymes that are thought about typically in their role in handling potential carcinogens.

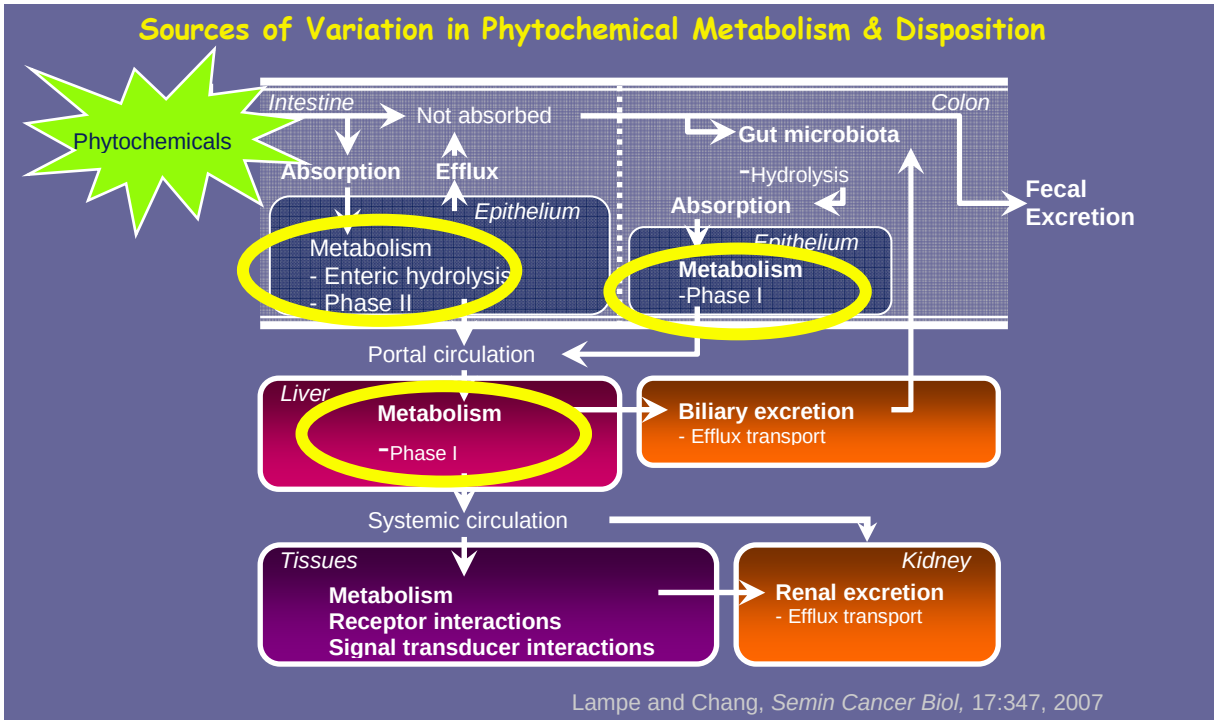
Most of the possible carcinogens exist in the environment not as carcinogens in and of themselves. If they are metabolised either by P450s in the phase of activation and not conjugated and excreted, they can contribute to the initial processes of carcinogenesis. At the same time, these enzymes are also involved in metabolism of



endogenous compounds. For example, the steroid hormones are conjugated and excreted in urine and bile and because of their proliferative effects can affect some of the downstream aspects of the cancer process. Therefore, these enzyme systems are receiving quite a bit of attention with regards to the cancer story. From the stand point of fruits and vegetables, we know from a wide body of literature that phytochemicals can modulate these enzymes. At the same time, these compounds in fruit and vegetables are also metabolised by these enzymes, so it is quite a complex story, especially when we add the layers of genetic variation on top of it.

If you think about all the various points at which we can find variation in phytochemical metabolism, there are absorption and handling by gut microbiota and metabolism by either phase I or phase II enzymes, which can occurred at the level of the intestinal epithelium, in which case many of these compounds will be pushed right back to the lumen of the intestine and be excreted and will not even be absorbed beyond that point. Otherwise, if the compounds are absorbed, they can be metabolised in the liver. There are also other points which genetic variation can

contribute to differences in exposure, including excretion systems and interaction at the level of the tissue.



One of the approaches to try to get at some of this genetic variation in metabolism is to use controlled feeding-trials. This helps to reduce some of the variation from environmental factors that are a concern in observational studies, and allows for greater focus on the genetic pieces that may play a role. The utility of this type of study is that you can:

- control intervention and the background diet;
- test dose-response, which helps to establish a biomarker level in relation to a particular fruit and vegetable exposure;
- conduct genetic studies, selecting particular genetic variants in such a way as to have sufficient statistical power to really ask the question of whether of not people with a certain variation respond or do not respond. Typically, with this type of study we often rely on whoever we have in the study and in post–hoc analyses attempt to evaluate whether or not there is a genetic interaction with regards to particular genotypes. Unfortunately, with many of the polymorphisms, the prevalence is relatively low, maybe 10 or 20% and as a result you end up with only a handful of individuals who are less common variant. A priori participant selection on the basis of genotypes gives you a chance to expand the sample of those rarer variants and gives better power;
- monitor intermediate markers of susceptibility

Unfortunately, because of the complexity of providing all the food to study participants and the costs of conducting such studies certainly these are not the types of studies that can be used to evaluate cancer as an outcome. That requires a behavior-based intervention trial. But, we can use feeding studies to set the stage for

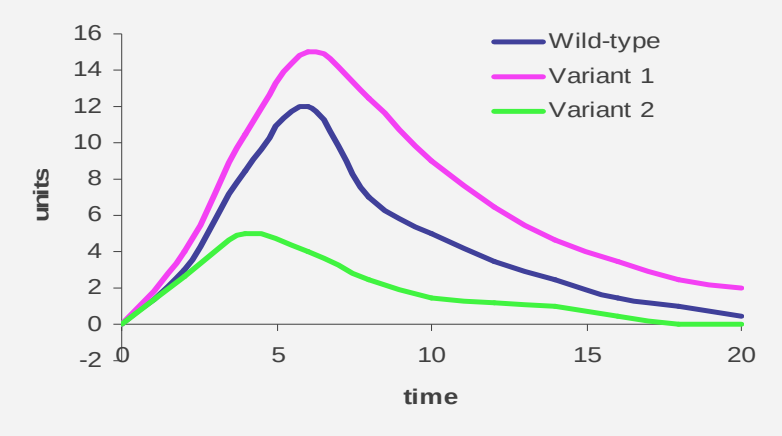
establishing some of the biomarker relationships and they can help us to target some of our prospective intervention strategies in the future.

There are several studies of the interaction between genetic variation and cancer-causative agents. For example the NAT2 polymorphism affects response to a diet of well-cooked red meat. Individuals who rapidly acetylate the compounds in cooked meat are more likely to have DNA damage in the colorectal mucosa compared to if they were not consuming the red meat and compared to the individuals who have a slow NAT2. So there is difference in response in the intermediate marker of risk. Similarly, in a study looking at the mutagenicity of urine from individuals fed red meat fried at high temperatures, individuals who had the UGT1A1*28 polymorphism tended to have more mutagenic urine than the individuals who did not have this genetic variant. UGT1A1 is in the UDP-glucuronosyltransferase family and the UGT1A1*28 polymorphism results in 50 to 60% the amount of enzymes than those of the individuals who have the wild type allele. These data suggest that the UGT1A1*28 variant results in poorer conjugation of compounds such as polycyclic aromatic hydrocarbons and may contribute to higher mutagenicity.

From a genetic stand point we have to keep in mind the totality of the diet in that we are not only dealing with exposure to a mixture of carcinogens and mutagens, but also protective agents. In many cases these compounds are all handled by the same groups of enzymes. So, in the context of, for example, high meat intake one genotype may be highly protective but at the same time those individuals may be handling the phytochemicals in the fruit and vegetables very differently, that is they may be clearing them more rapidly and not gaining the same possible protection from the phytochemical as somebody who has a different genotype.

If you think about this in the context of doing a pharmacokinetic study of a particular phytochemical, you might imagine that if you have somebody who has the wild type genotype, that is the enzyme is functioning normally with regards to clearance of a particular phytochemical and you might see a pattern that is the dark blue line of the graph.

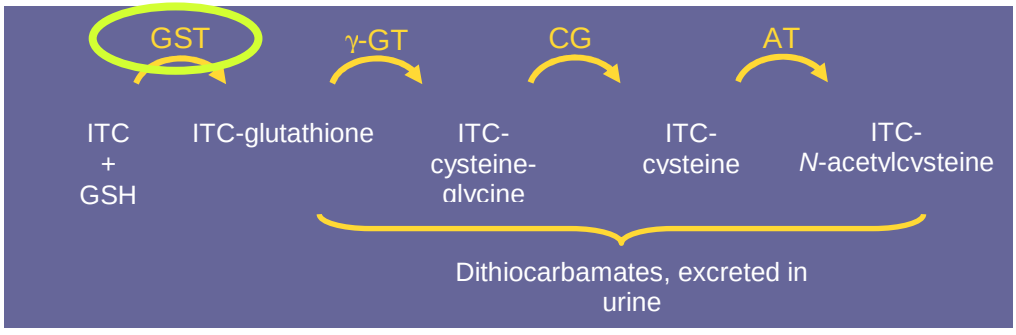
Theoretical Effect of Polymorphic Conjugating Enzymes on Phytochemical Pharmacokinetics



- Polymorphic enzymes with lower activity prolong exposure (Variant 1)
- Polymorphic enzymes with higher activity shorten exposure (Variant 2)

And, if you have a polymorphism which results in lower activity this may prolong exposure to the compound. In contrast, if you have a variant that produces a more active enzyme you may see more rapid clearance as in the case of the bright green. So, in the context of clearance of phytochemicals these polymorphic enzymes may give you very different results. Unfortunately there are few studies that have been done to evaluate this. Nonetheless, we know that in the context of drug metabolism that this occurs for a number of drugs and there is no reason to believe that this would not impact exposure to phytochemicals; however, we do not have much data to support this.

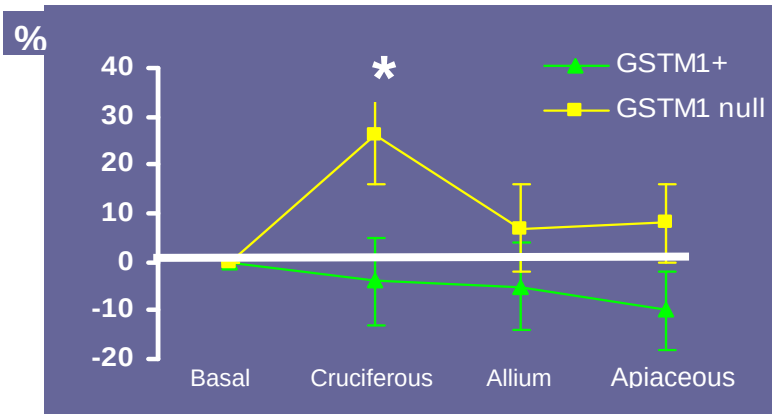
One area of phytochemical metabolism that has received a bit of attention is metabolism of the isothiocyanates from cruciferous vegetables. These compounds are present in crucifers as glucosinolates. They are hydrolyzed to isothiocyanates, which are the bioactive compounds, and then the body rapidly degrades them. The first step of the process is conjugation of the isothiocyanates by glutathione S-transferases and a series of subsequent enzymatic steps that degrade the compounds further.



The glutathione S-transferases (GST) come in many forms, the major ones being alpha, mu, pi and theta, of which mu, pi and theta play some roles in regard to metabolism to the GSTs. Also mu and theta in humans are highly polymorphic; there are very common genetic variants that result in complete lack of formation of the

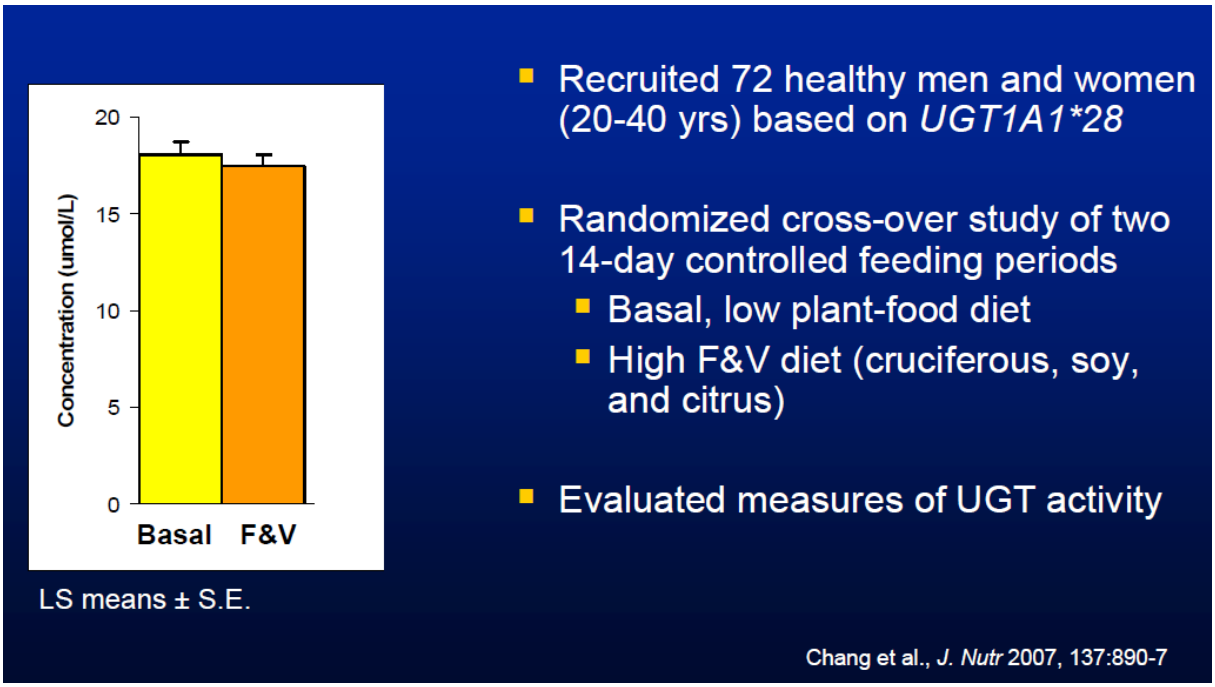
enzymes, such that you do not produce any GSTM1 or if you have another polymorphism you do not produce any GSTT1. The prevalence of the GSTM1-null genotype can be as high as 60% of the population depending on what population. This suggests that, for the most part, we do just find without these enzymes, but in the context of a certain exposure this lack of GST might be a problem.

Seow et al. presented the following hypothesis:
"Based on our understanding of the biological interaction of GST and isothiocyanates, we would expect that individuals who are null for GST and who therefore less readily conjugate and excrete these compounds, would have greater amounts of isothiocyanates at the tissue level, and hence would experience a greater protective effect."



In the context of the available observational data on the interaction of cruciferous vegetable exposure and the GST polymorphisms, the data are very mixed. Depending on which population you look, at some find that individuals who are GSTM1-null or T1-null are protected in the context of exposure to cruciferous vegetables. Typically, in western populations, we see the inverse, with on GSTM1+ and GSTT1+ being protective. We conducted a controlled feeding trial of different botanical groups of vegetables in individuals who were GSTM1+ and GSTM1-null and we saw that among the individuals who where M1-null there was an increase in serum GST-α, suggesting a potential for a greater effect of cruciferous vegetables in the GSTM1-null individuals.
At the same time, in the last couple of years, we now have pharmacokinetic studies from Gasper and colleagues that look at sulforaphane pharmacokinetics in individuals who were GSTM1-positive and GSTM1-null. They found the opposite of what we have been hypothesizing; that is, the individuals who are M1-null actually excrete larger amounts of the metabolized sulforaphane, as well as suforaphane itself, whereas those individuals who are M1-positive excrete less. More recently, a larger study by Steck and colleagues looked at the effect GSTM1 genotype, as well as GSTT1, GSTP1 and GSTA1 genotypes, on isothiocyanate excretion. Essentially they found no overall effect of the genotypes except that there tended to be a higher proportion of individuals who where excreting high amount of isothiocyanate if they were M1-null. These results are in keeping with the data of Gasper et al., but do not support the hypothesis that lower excretion and higher circulating levels of the isothiocyanates would be found in the M1-null. These results suggest that we still have a long way to go to really understand the relationships between these enzyme systems in relation to genetic variation.

Another area of interest with regards to the Phase II conjugating enzymes are the UDP-glucuronosyltransferases, which are major glucuronidators of steroid hormones and therefore in the context of hormone-dependent cancers may play a role as far as determining life-time exposure to steroid hormones. We have examined the effects of diet on UGT1A1 which is important in glucuronidating endogenous estrogens, as well as polycyclic aromatic hydrocarbons and heterocyclic amines in well-cooked meat. One of our big challenges in these types of studies is actually being able to measure enzyme activities in humans, where invasive strategies are not appropriate. It would be nice to have a liver biopsy, but that is not an option. This requires that we have surrogate biomarkers that we can use to evaluate the activity of these enzymes. In the context of UGT1A1, serum bilirubin is conjugated primarily by UGT1A1 so it serves as a nice marker.



In this study we examined the effect of a diet low in plant foods -- essentially devoid of all fruits and vegetables, spices, herbs -- compared to the same diet supplemented with a mixture of cruciferous vegetables (e.g. broccoli cauliflower and cabbage), as well as soy foods and citrus fruits (e.g. grapefruit, oranges etc). Looking at UGT activity, overall there was no difference in serum bilirubin as the result of the fruit and vegetable intervention compared to the basal study. However, when you break this down by UGT1A1 genotypes, among individuals who are wild type intact for the enzyme (i.e. have the optimal enzyme activity), in both men and women we see no response to the fruit and vegetable intervention and in individuals who carry one of the 28 alleles similarly no difference. However when you look individuals who are homozygous variant and have substantial reduction in the UGT activity, you see that the addition of fruit and vegetables results in significantly higher clearance of serum bilirubin, but only in the women. Interestingly, here we focus on genetic differences

but we also find that there are often sex differences in response to diet and I think we have to keep this in mind in designing studies and interpreting our data.

So there are many questions that we need to consider with regard to the interaction between genetic variation and fruit and vegetable intake. We need to consider not only the impact of human genetics on response to fruit and vegetables, but also the modifying effects of other environmental factors that contribute to cancer risk. Which of the polymorphisms are important in relation cancer? We are now to the point technically where we can interrogate the whole genome and we can go after every single nucleotide polymorphism in every person, and really get down to the minutia. However in the context of cancer risk in populations which are the ones that we need to focus on? Also, on a more global level, the relationship between diet and cancer risk differs in various part of the world. Given the differences in prevalence of polymorphisms between populations and the differences in diet, we also may be able to strengthen our understanding by integrating data from various populations around the world.

In summary, studies have suggested that genetic polymorphisms in enzymes involved in phytochemical metabolism and disposition may contribute to some of the interindividual variation with regards to risk for cancer. We need to continue to identify the various sources of genetic variation that is affecting response to fruit and vegetables in order to understand better their impact on cancer risk. Also, many of the phytochemicals are metabolized by gut bacteria and the effects of genetic variation in microbial populations also warrant attention. I would submit that we certainly have not used controlled feeding studies to the fullest extent to try to address these issues and would encourage those of you who do controlled feeding trials to build in opportunities to evaluate some of the genetic factors that may contribute to differences in phytochemical metabolism, as well as differences in response to the interventions.
(…)

Q&A

A SHATZKIN: You mentioned all the work is going on now with the all genome association studies going on with multiple cancers. Are they going to help much with the kind of things that you were showing us with the feeding studies and the bio transformation enzymes?

J LAMPE: I do not know. I think one the issues is that they may help as far as informing what genotypes may want to look at in the context of the feeding studies. I am not sure that doing *genome mite scans* in the context of a feeding study would be that useful unless you have got a very large study because you are going to end up

with so much data and you are going to be slicing and dicing into such small numbers than to make comparisons that hold up statistically I am not sure that we can go there. But I think and I hoping that some of the works that comes out of the other studies will help to guide where we may want to focus on and try to get out some of the specifics.

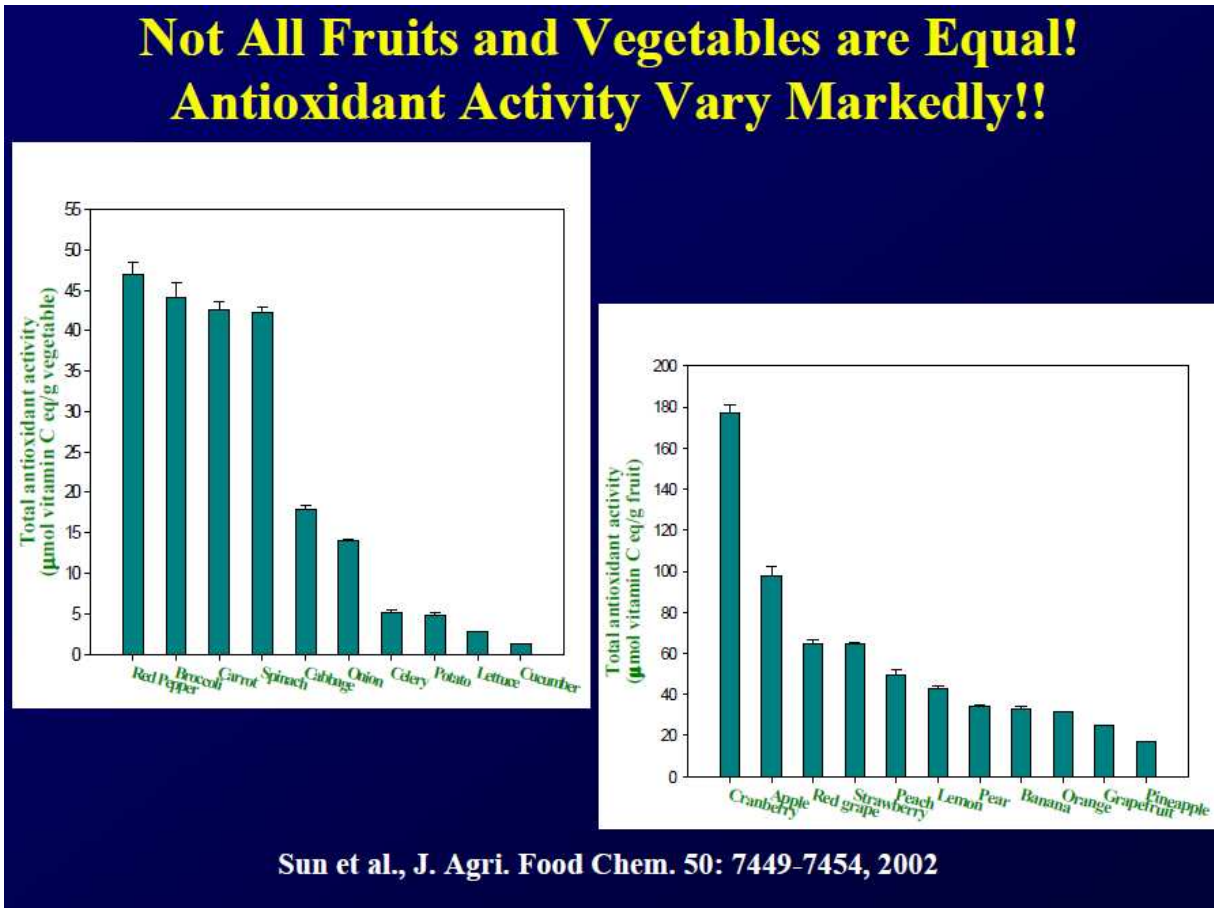
A SHATZKIN: With more work going on to improve the way we assess diet in fruit and vegetables and with more work going on in biological markers what Dr Jenab said, is there a case to be made that these big prospective cohort studies need to be genotyping everybody as well to actually zero win or in the correct relationship of fruit and vegetables and cancer?

J LAMPE: I think there is a place particularly in the context be a fact with regards with both handling of carcinogens as well of handling of chemo protective agents for the extend that we need to be genotyping for every single one of them. I think that we can do that but we will probably find that there are going to be certain of these genes where it is very important in the context of some of the UGTs relation to the exposure to some of the phytochemicals that are heavily glocoronidated that they may play a major role. Similarly sulfation of many of the flavanoids may be affected by polymorphism in these. I think that we do not know the extend of how broadly we want to be genotyping but at the same time the combination of the controlled feeding trials to try to get what is the degree of difference such as what is the genotype that is associated with the genotype in a controlled environment and then you wan intake that to the observational work.

What about mechanisms?

John MILNER
Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Health and Human Services, Rockville, USA

I think we already can say that diet is important for cancer prevention. It is typically recognised that about 30% of cancers relate to dietary habits. While there is wealth of evidence from preclinical models and from human investigations, that there is a lot of variability across studies. We do not always obtain consistent results, making interpretation difficult if not impossible. Part of that comes from a lot of variability in the food supply and with a lot of variability in genetic across individuals. One of the ways we attempt to integrate the benefits of food is to deal with a specific process, such as the antioxidant potential.



What is quickly observed is that not all food is equivalent in their antioxidant potential. Certainly not all vegetables and not all fruits are equivalent. Lump of all of this together as fruit and vegetables is inappropriate. Maybe it would be wiser to highlight specifics about individual food items and their overall benefits, especially as they relate to the cancer process. Again the food supply it is quite variable since

the content is highly dependent on the growing conditions and the type of fruit and vegetable being examined.

The effectiveness as an antioxidant is highly dependent on the molecule that is being modified. Figure (2) provides evidence that not all the compounds are equivalent. In fact while some are very effective in blocking peroxides while others are much more effective in modifying nitrogen radicals. So we have a combination of information to begin thinking about the anticancer properties of fruits and vegetables. The next issue is whether the response is a result of one or multiple processes; I submit to you it is multiple.

Speciation Is Bioactive Component is Important!!

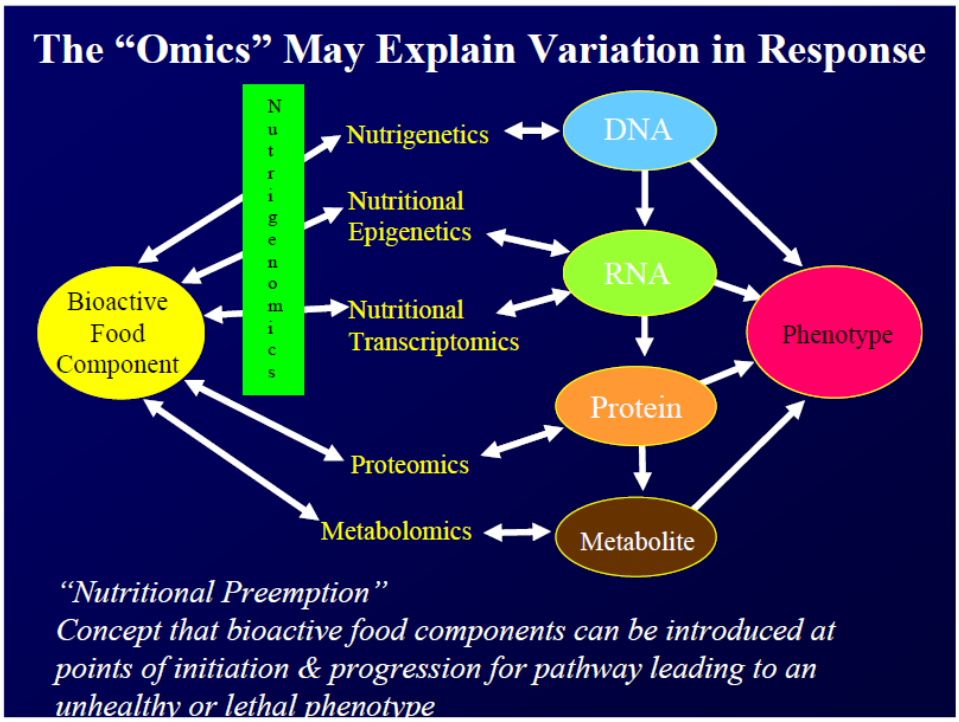
Radical scavenging - flavonoids

Scavenging rate constants of flavonoids for oxidizing radicals

Substance (trivial name) (*substitution pattern*)	Rate constant ($x10^8 M^{-1}s^{-1}$) $^{\bullet}OH$	$^{\bullet}N_3$	*t*-BuO$^{\bullet}$
Flavanols			
(+)-catechin (*3,5,7,3',4'-penta-OH*)	66	50	1.35
(-)-epicatechin (- " -)	64	51	-
Flavanones, Dihydroflavonols			
naringenin (*5,7,4'-tri-OH*)	210	52	2.65
dihydrofisetin (*3,7,3',4'-tetra-OH*)	67	56	-
eriodictyol (*5,7,3',4'-tetra-OH*)	117	47	0.8
dihydrokaempferol (*3,5,7,4'-tetra-OH*)	58	89	0.95
dihydroquercetin (*3,5,7,3',4'-penta-OH*)	103	43	1.0
Flavylium salts (anthocyanidins)			
pelargonidine chloride (*3,5,7,4'-tetra-OH*)	45	62	-
Flavones			
apigenin (*5,7,4'-tri-OH*)	135	48	3.0
luteolin (*5,7,3',4'-tetra-OH*)	130	41	5.7
Flavonols (3-hydroxyflavones)			
kaempferol (*3,5,7,4'-tetra-OH*)	141	88	6.0
quercetin (*3,5,7,3',4'-penta-OH*)	51	66	6.6

The reaction of flavonoid aglycones with the electrophilic radicals $^{\bullet}OH$ or $^{\bullet}N_3$ are at the diffusion-controlled limits but within the same region for almost all investigated compounds. The anti-oxidant principle is based on the number and position of the various hydroxy groups. Other oxidizing radicals, *e.g.* *t*-BuO$^{\bullet}$, $O_2^{\bullet-}$, ROO$^{\bullet}$, *etc.* also react effectively with flavonoids, all forming the same transient aroxyl radicals. (Bors W *et al.* (1992) in: *Free Radicals and the Liver*, Csomos & Feher, eds, Springer, Berlin, pp. 77.)

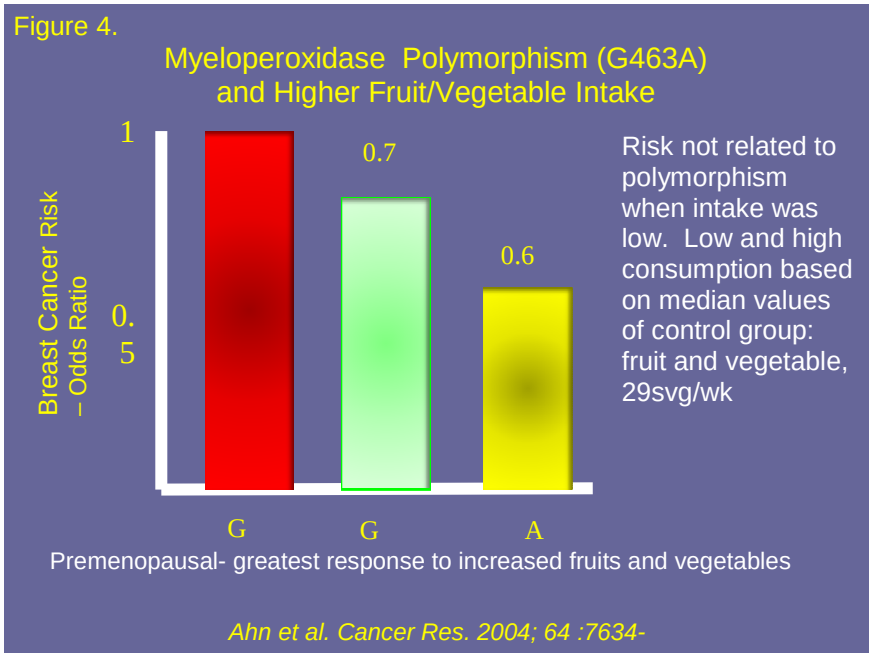
Step back and realize that we are not all the same we are in fact enormously different individuals. There are not perfect role models for understanding the effects of diet on the cancer process. If you are not aware of this difference between a little Chihuahua and a Dalmatian dog it is partially due to a polymorphism in IGF. Thus a slight change in gene expression can have a profound effect on phenotype and it is certainly the case when it comes to human investigation. I am quite surprise today in the all topic in nutrigenomics that we need to start thinking that the genes do set a tone for the actions of food components but it is not only the genes it is also the food compounds interaction with epigenomic events, as well as the formation of a message at MRNA.



That collectively is referred to as nutrigenomics clearly all of those impact phenotype. The downstream from that are actually the proteomics and metabolomic. Those are clearly influenced by bioactive food component that we consume on a daily basis. It would be not nice if in fact there was a linear response from genes all the way down to metabolome but that is not reality. In fact, there is enormous variability and you can not just look at one of those components but you have to look at multiple components. That means that bioinformatics is really going to be a key for us to understand that individuality in response and who is really going to benefit and who is not going to benefit from intervention strategies. I might just point out by the way that the mind set at least what we have been talking about the MCI is that in fact not all people are going to respond identically and by knowing something about the "omics" as we defined them we are actually able to intervene at different points. That is a concept called nutritional preemption. Knowing something about the individuals gives an important strategy for intervening.

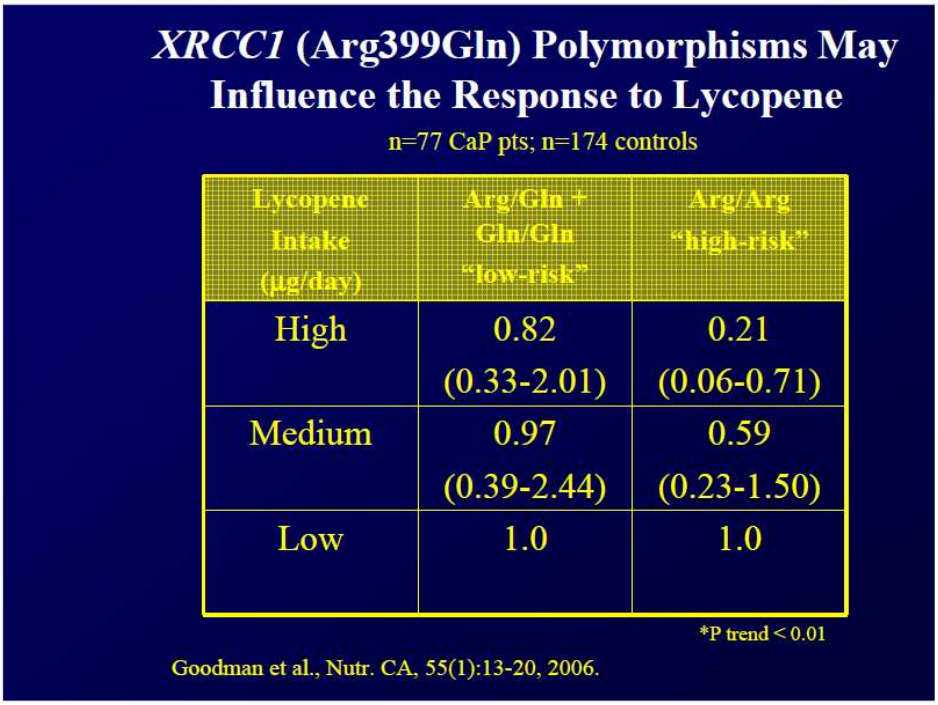
That also applies that not all people should get the same type of intervention. Some will benefit far more than others. As you already heard from Dr Lampe there is certainly some evidence out there that the gene polymorphism can set a tone for the response to food components. I will show you a couple of quick examples. By the way there are 30'000 genes and probably somewhere between 5 and 8 million SNPs (polymorphisms) so we clearly have got a massive undertaking to understand all of that genetic that is out there and remember that is not the genetic component.

Nevertheless there is some evidence that those polymorphisms can influence the response to food or food components. The example of Myeloperoxidase is associated with the release of oxygen radical from with cells; simply put a burst of oxygen is associated with an inflammatory type of response. What is interesting from the data on the Figure 4 is that the polymorphisms with the AA allele appeared to be much more responsive to higher fruit and vegetable intake in the diet that those that have GG allele. The *heterozygote* is somewhere in the middle. It turns out that this is about 30, 35% of the population so in fact if we are talking about health benefits of fruit and vegetables it may well be a subpopulation.



We have a subgroup that is much more responsive and for the other people it does not appear to really matter. From a collection of total fruits and vegetables that may be the case but I suspect that is much more complex than that. In fact, the response to a specific food such as tomatoes (or Lycopene) another polymorphism that is associated with the response will likely surface.

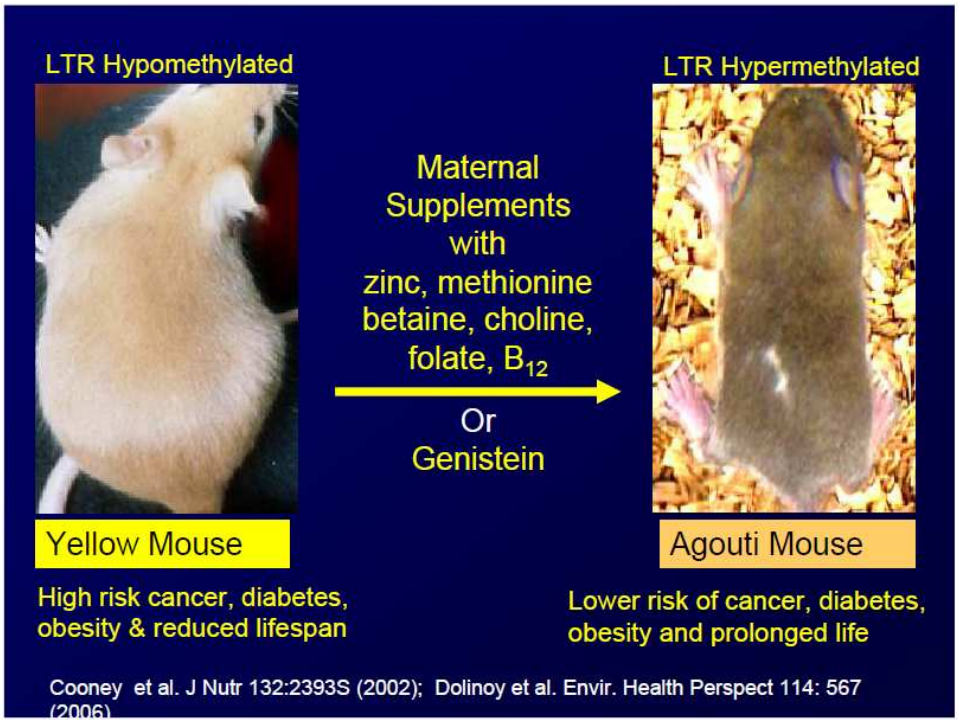
In this case it his is actually a DNA repaired gene. What you can notice with this one is the low risk of the arginine/glutamine or glutamine/glutamine groups you have the homozygote and the heterozygote and it does not really matter how much tomato is consumed. However, in the other group what happen is that there is about a 5 fold difference in risk depending on whether a low or a high consumer.



That means that for clinical studies one must take into consideration the variation in genotype by not characterizing the genes one is examining a mixed population and does not really understand what is being examined or observed.

Life is little bit more that just genes, in fact epigenetic processes can also dictate the overall behavior to diet. It includes methylation reactions, as well as the *histone* homeostasis, which is involved obviously how we coil the DNA. A number of nutrients can modify both of those processes. From A to Z, can modify methylation reaction; energy consumption can modify methylation reaction the classic is folic acid deficiency causing global hypomethylation in a site specific hypermethylation. But as I said there are lot nutrients that are out there that also modify that process.

Some of the most compiling evidence of this process is modifying by diet comes from preclinical studies in the rodent model. This is the Agouti model that demonstrated that if one takes a little yellow mouse and feeds her a typical diet she will give birth to other yellow mice. That is not surprising! However, if one fortifies the diet with component that modifies methylationthe color of the offspring changes to ajouti. You can notice at the top of the picture there is a hypermethylation that occurs on the long term repeating unit and that is the reason there is a change in the hair color. But that is not what is really important. What is really important is the yellow mice are obese, have high frequency of diabetes and have an increased cancer risk. When you fortify the mom's diet the offspring have a lowest risk of diabetes, obesity and cancer.



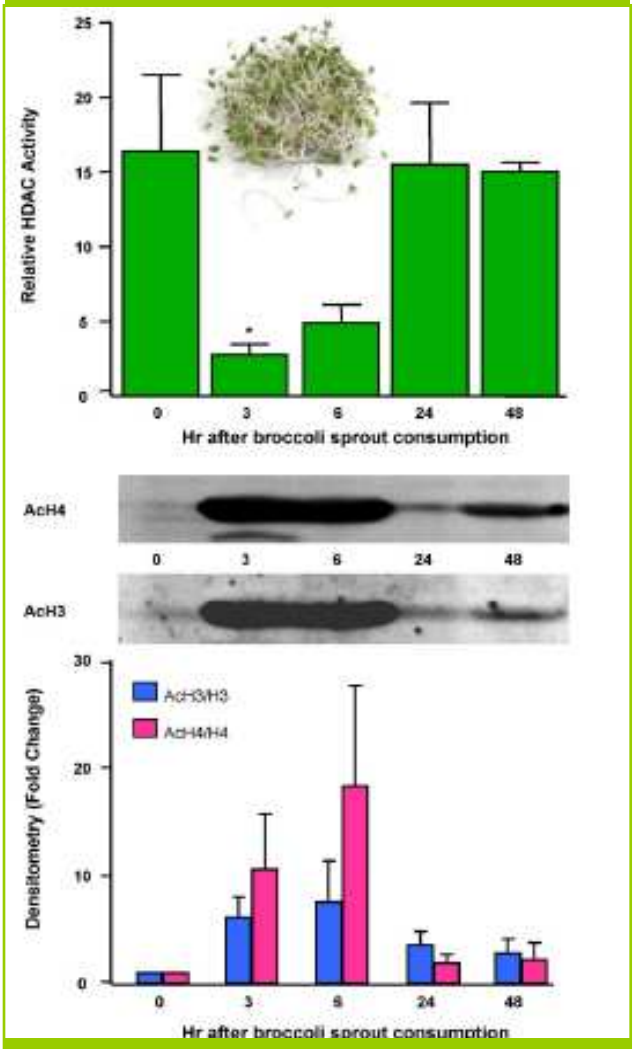
What is interesting is the change in methylation reaction that you can also bring about by adding genistein to the diet, genistein from soya beans. Genistein does not supply a methyl group, so these are changes that are occurring in methylation and this is probably some signal of the nuclear factor that is leading to this change.

Let's point out why it is so intriguing. We heard this morning about feeding a children and what happen to the offspring etc. of those children. I want to point out that if you actually over feed a mouse the offspring have a propensity to overeat for 7 generations. If you underfeed a mouse the offspring has a propensity to under eat for about 5 generations. Why? Is it methylation products that are being modified for generations? If so, it is not what you are eating now but actually what you mom's mom mom's mom ate that is setting the tone for your cancer risk and we have not even started to thing about those kinds of variables in humans.

I said histone were also important. I want to point out that there is some evidence that several food items certainly regulate this process, including fiber, garlic and there is some evidence of sulforaphane. These food items are then important for modifying cell signals or setting a tone for whether pro- and antitumorigenic genes are being expressed.

These are some data from a human feeding study with broccoli sprouts. These are pretty high in sulforaphane, about 100 times higher than the *flower*. Providing causes a 90% reduction in histone deacetylase: within 3 hours, which is incredible. Within 24 hours it goes back up to a supposedly normal amount. What is interesting when it comes down to potentially modifying the risk of cancer by changing gene expression patterns? However, we do not really know what that means for growing child or reproducing woman. These are issues that we need to start thinking about. There are target populations who will really benefit from this and there is some other population that might place at risk because of these intakes.

Histone Deacetylase Activity Inhibited by SFN-rich Broccoli Sprouts in Humans



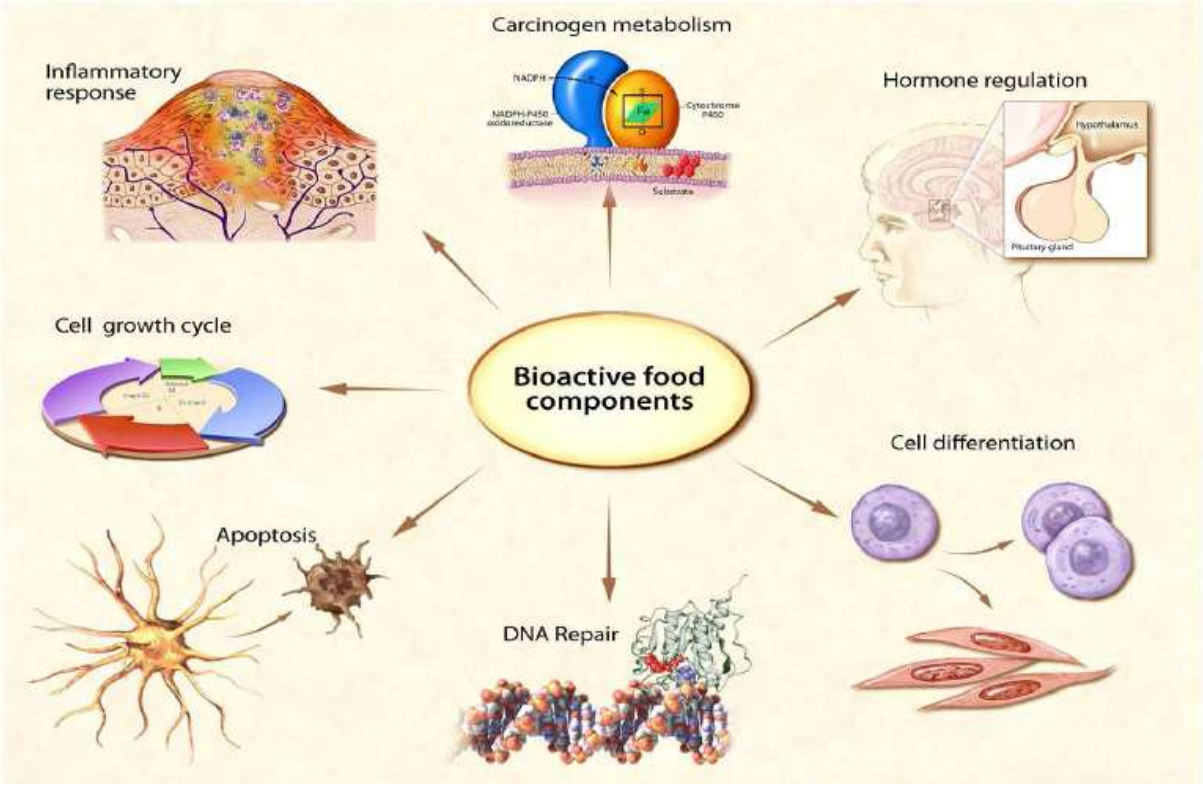
Dashwood RH, Ho E. Semin Cancer Biol. 2007 May 5

Talking about exposure we have a lot of data indicating that we can actually modify gene expression patterns change the message in the DNA just by the *bolus* of a food. Many cells processes modify dependant on the timing, on the exposure and we can see it in humans, we can see it within 3 hours after consuming foods. We are now seeing if you give a high carbohydrate versus high protein cereals that you can pick up changes in with cells within 3 hours.

Is it where we have got to be moving? I believe so! We actually can undertake *bolus* studies to provide clues about subpopulation that are going to be really responsive and those who are not going to be responsive to an intervention. I think that is what we are going to be headed and if you actually think about the old days of vitamins literature that is what we did. We identified those responders by testing a *bolus* challenge.

I have to say something about proteomics. I think that is the new wave of research as it relates to diet and cancer prevention. Multiple changes in proteins including phosphorlyation, thiol regulation, etc. can modify the behavior of proteins. More information is needed to understand if the response in a tumor is similar to what

occurs in normal cells. Regardless, these changes are going to be important to tell us about what processes are being modified. When it comes to processes some of the most important are provided in the next slide.



We have identified some of those processes that we believe are the most critical for explaining the cancer process. They can go everywhere form the DNA repaired down at the bottom all the way until the top to the inflammatory. Any one of these processes can be important for determining overall cancer risk or tumor behavior. Which one of these processes is modified first? This is the question that is before us. And what is the effective concentration of a bioactive constituent from a fruit or vegetable that is needed to lead to that change? This is related to the overall question that is before us today, namely when are fruits and vegetables most beneficial and to whom.

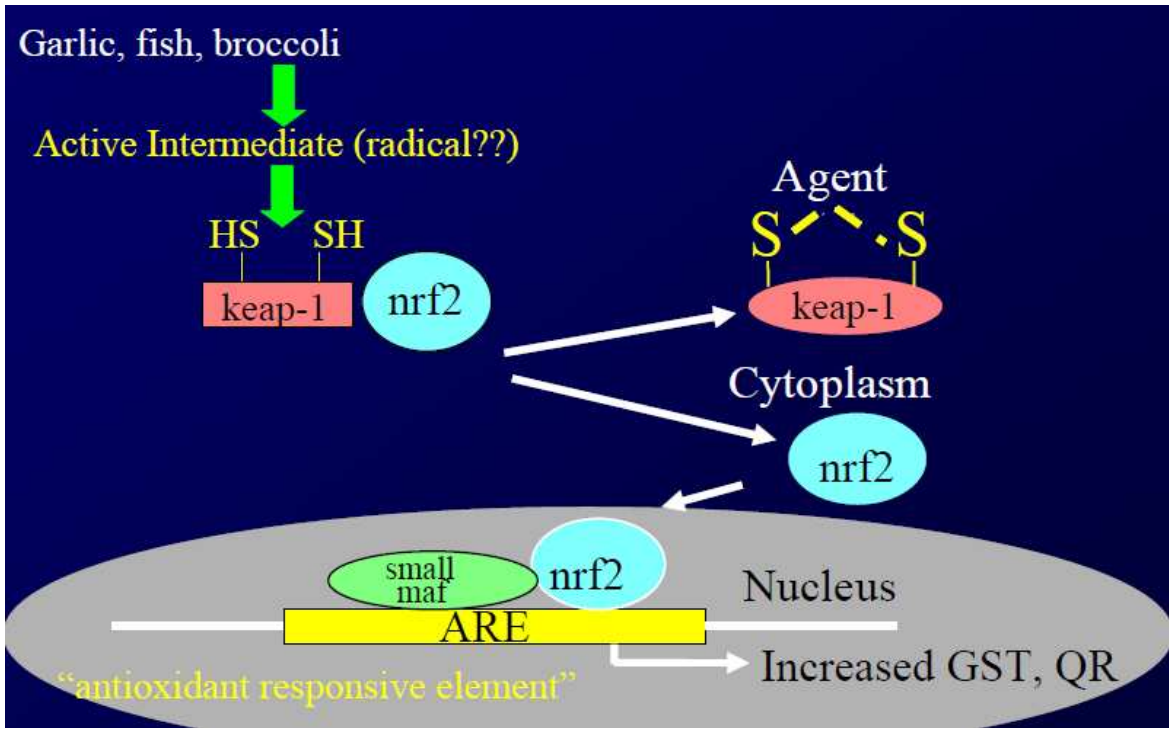
If you take that DNA repaired that I mentioned was one of those critical processes we actually already have some data that you can change that "destruction" of the DNA by intervening with fruits and vegetables. The problem with this study is that there are relatively few literatures. Since there was *no wash-out period* between the interventions one can not really tell which food item per se is leading to a change. How much inflammation is occurring after these interventions, how much (dose) is needed to get this kind of response? I think those are the issues that we have got to be talking about in the future.

We need to think also about something else. What is the process that really needs to be modified? Are we modifying the normal cell or we are modifying the neoplastic

cell? We have a lot of evidence that we can actually add a lot of food components to normal cells and it does not do very much until you get to super concentration. But neoplastic cells tend to be much more responsive. In the non-neoplastic high concentrations are needed before anything is observed. For example with allyl sulfur, one of the active components that are in garlic, it slows down cell division. That is probably because of a change in thiols in proteins, what I mentioned earlier as a regulator site. Interestingly, allyl sulfur actually modifies *ferritin* concentrations. *Ferritin* is an iron source. Allyl sulfur is causing iron to be released from *ferritin* then the iron serves to enhance the *fenton* reaction to generate free radicals. That means that allyl sulfurs are not serving as antioxidants, but serving as *prooxidants* and absolutely when it gets the concentration high serving in *prooxidants* and lead to the *reduction in cell division and apoptotic* response. That is not limited that allyl sulfurs since the same type of response occurs with flavonoids. When I think of those antioxidants when provided in high concentrations they actually serve as prooxidants and lead to free radicals generation, in part because of the unsaturation in those molecules.

So we have got many things going on in the cell but we need to remember when are we actually looking at the response? Are we looking at it as a normal response or a neoplastic response? I think this is something we really did not take enough time teasing apart.

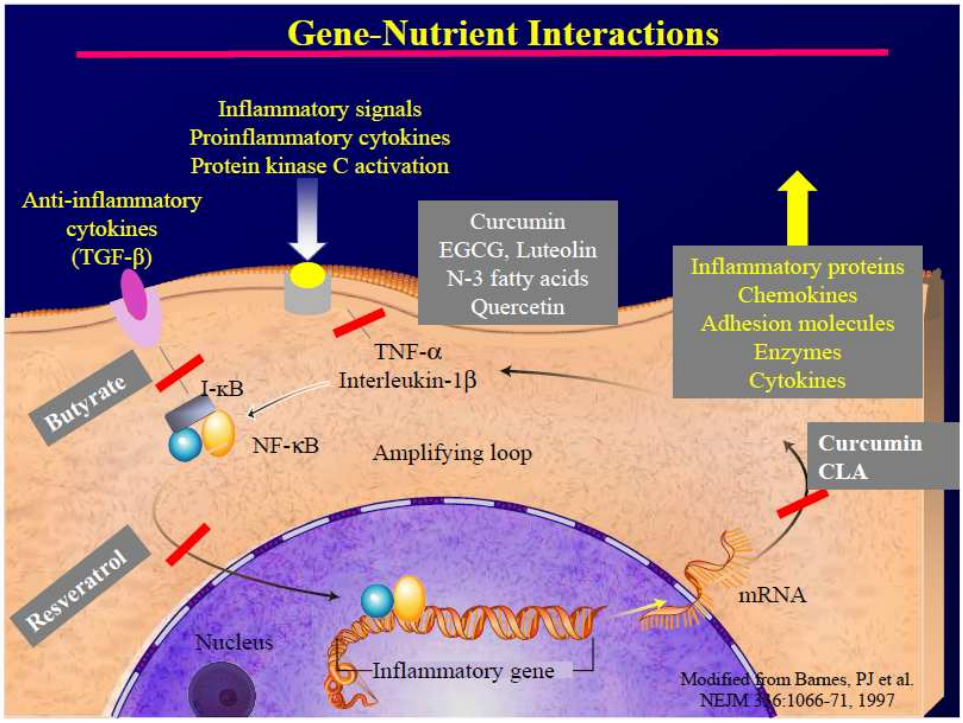
Dr Lampe provided you some evidence that we can give a lot of food items that block Phase I and Phase II enzymes; there is no question about that. There are relatively few deficiencies per se that lead to an increase in cancer. Actually I only know of two, one is a *methyl donor* insufficiency that leads to increased hepatic *cancer* "spontaneous *hepatic cancer"* and the other is more recent study that suggest that when you feed a low vitamin D, low calcium diet increases colonic tumors when fed longterm. But for the most part we are really not looking at deficiencies causing tumor, we are looking supplemental nutrients modifying the risk of cancer.



One of the molecular targets that have been identified when it comes to modifying the risk of cancer is the all nuclear transcription factor NRF2. It is a very interesting nuclear transcription factor that promotes the formation of glutathione S-transferase and oxido-reductase activity. Food items cause NRF2 to dissociate going to the nucleus and to promote the formation of these detoxication enzymes. Multiple food items can do that such as garlic allyl sulfurs, selenium from fish and sulfloratane from broccoli.

The problem is if one has not done a very good analysis of the eating pattern and only examines on food such as broccoli, and therefore not considered selenium from fish and other of these food items that are modifying this process false conclusion may be reached since they have the same site of action. Activities can only increase so much so if I eat a lot of broccoli does that mean that I get no benefit from garlic or vice versa? These are issues we need to start spending some time dealing with and we haven't done enough to understand these inter-relationships at this point.

One of the topics that is really hard these days is the inflammatory risk response.

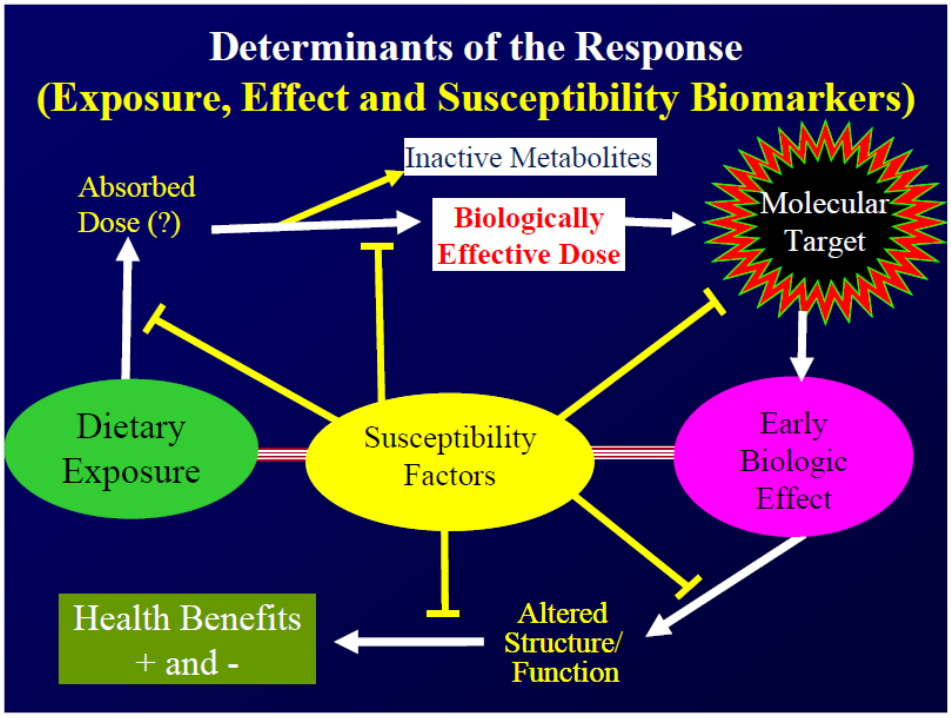


Remember in a normal process we need to have a normal inflammatory reaction but when it gets out of control the process cycle goes at a very rapid rate. When it goes at rapid rate we typically have an increase in cancer risk. Some people argue 40 to 50% that the cancers are associated with an increase in inflammatory process. That means that when I have that process those food components become even more important. That means that somehow I need to monitor the insult that is causing the inflammation (bacteria, virus, excess calories, etc.) to predict a benefit from the food. From this slide you see that there are a lot of items including fiber (butyrate) to conjugating linoleic acids (from animal products) to the spice curcumin that can modify the process. Again interactions of food are very important in determining the overall response. If you look at curcumin literature considerable variability if found in the decrease the inflammatory response. Individual variability probably comes down to the absorption of the curcumin and the metabolism of the curcumin as well as the degree of insult fostering the inflammatory process.

These processes cross talk I though I would show an example from a colleague the author Elaine Lanza who is actually working on various projects that relate to fiber and its relationship to the inflammatory process as well as its ability to modify factors that are associated with insulin and RGF. I just want to point out that NF-κB can modify such signals that are associated with insulin as well as all the downstream within associated with insulin.

So one of the issue that I want to raise with you is why would Mother Nature allow fruits and vegetables to modify multiple processes? Why would so many processes change simultaneously? That is probably one of the benefits of food, over drugs.

Food actually influence multiple targets not just a single target. For foods to have multiple targets it is all logical that there is some intracellular change that is leading to this. Could it be intracellular calcium? Could it be pH? Could it be all kinds of things that are actually turning out the signal that is changing many things inside the cells? I do not think that we know the answers to it but those are again questions that need to be addressed. We have to step back and ask ourselves what kind of information we really know, need to have to determine whether we have a response. This comes down to 3 biomarkers that are:
- certainly *Exposure* (dietary exposure or biological indicators);
- *effect*, we need to know what we are trying to modify that is the cellular process, what is the target within that process that we really trying to modify ;
- and then the *susceptibility biomarkers* those are really nutrient interaction and gene nutrient interaction that determine the overall response.



Indeed this is an incredibly complex area that we need to know a lot more about. There a lot of food that are in the food supply that could conceivably modify the cancer process but there are few that likely deserve a lot more attention. We can list them from the well known Time Magazine (January 21, 2002) with adding a few extra foods in there:

- soya beans,
- tomatoes and lycopene,
- spinach and the folic acids,
- broccoli and sulforaphane,
- garlic and allyl sulfurs,
- nuts and some very interesting flavonoids and interesting proteins,

- salmon- n-3 fatty acids,
- oats with fiber and flavonoids,
- blueberries for antioxidants,
- curcumin,
- green tea probably does not matter if it is green or black tea,
- red wine that I prefer to wash it down over the green tea!

I will finish with one slide about the future. I think we need to develop some predictive models because not everybody is going to respond the same way. That means a personalized approach to nutrient and cancer prevention. We are going to use strategies that are built along the "omics" and in fact we are going to deal with nutritional preemption. We have got a lot of people involved in this and not only the people that are eating these food items but the food industry, government and academia need to build partnerships!

Q&A

PUBLIC (from Puerto Rico): Based on the information you showed us today I am concerned about the recommendation of the National Cancer Institute regarding to avoid supplementation for everybody when we do not really know that is going to help for some people. What do you think about it?

J MILNER: That is a great question. If you look at the World Cancer Research recommendation, those are the global recommendations, there are the Public Health recommendations that I think are appropriated for the general message. The use of supplements is generally considered to not place anybody at risk. However, I think what we are headed to much more about personalized approach such that some individuals may really benefit from higher intakes either from foods or supplements. The message is for the public but most want to know I «What about me??" I want to know what I should be consuming. What I said to you at the end is that yes I want those recommendations that are globally but I want those focused on the 12 items that are back there because I think that is really where most the information is going to come from. The confusing part of my presentation was I just told that not everybody is going to respond the same way.

PUBLIC (Philip JAMES): I think you are now making people very depressed John because you are requiring a wealth of new techniques which are totally reasonable. But if you take a slightly different view, I mean if you look across the world you started off with Doll and Peto analysis which is amazingly crude if I remember correctly but they actually had a variation of 20 to 70% of from diet and they plumbed for an average of 35%. You appear to be focusing on a personalized process because you are trying to discriminate for example within a particular country the

discriminent which lead to those individuals developing cancer. What if you look in a different way across the world and you see 10 to 100 fold differences? Can we not begin to use your analytical approaches in a much more illuminating way because you could ask the question are those 10 to 100 fold differences explained by your key genetic differences or responses? Or could it be explained by diet? Because if you are thinking in practical terms, you might be able to come out with a much more coherent general case years before you could come up with your specific individualized approach to prevention.

J MILNER: I am not disagree with that and I think in fact that if you start looking at the gene polymorphism they do vary by population and we are going to see some variance here. We need to go back and start looking at it from that context that may lead to some important clue. As I said there are 30 000 genes and probably 8 to 10 millions SNPs, so it is very difficult to conclude anything at this point. I have to admit to a large extend except for a couple of studies and few other that most evidence is guilt by association. We need to go back to those apparent responsive populations and do a quick intervention studies that incorporates some relevant biomarkers. That was my point with the transcriptomic issue; if we are going to identify population we can do some of those challenge tests and get some real clues about actually sub-population rather than individual responses. I think that is what we headed.
I indicated the World Cancer Research indicated that with higher calcium intake there was about a 20% reduction in colon cancer. If you look at the data per se it is pretty iffy. But, if you start look at the vitamin D receptor the 20 % now moves to about a 3 to 4 fold change in risk, depending on the polymorphism that is there. Now, I actually have a subgroup that I need to be dealing with because there are the one that are going to be the most responsive to calcium and I think there are going to be some of these genes we can identify very quickly and actually start talking about subpopulation. Such interventions may be far more important in one area of the world that it is in another.

A SCHATZKIN: I will just sneak a comment. Even if it is true that there are subgroups that are more responsive to calcium or whatever or let say to sodium to cardiovascular disease or even smoking for cancer and maybe this is an extension of what Phil was sort of getting at, does it make sense it would be great if we had all of the information that would enable us to identify all the genetic variation that determine response. It may be incredibly complicated as I believe you were suggesting John even so complicated that it would be intractable. Does it not make sense therefore that we make overall Public Health recommendations about fruit and vegetable intake, sodium consumptions, smoking recognizing that there would be genetic intrinsic personal variation? But by shifting the exposure in the population as a whole you end up saving lots and lots of lives although there would be lots of variation in the population du to how people respond.

J MILNER You still may not get enough into some populations that would need more and benefit most. That is the only issue with a public health versus personalized approach. I think the Public Health message that says we need to eat more fruits and vegetables are appropriate. However we are not hogs I still think we have to be headed to this more personalized approach. In the old days we talked about type 4 hyperlipoproteonemia as a carbohydrate induced elevation in cholesterol, which is about 20% of the population or maybe a little bit less. When you tell people to eat a low fat diet they are immediately consuming more carbohydrates and those individuals are in increased risk and we fail to talk about those vulnerable individuals! I think we need to start talking about it; we need to start talking about individuality and responsiveness to individuals. Maybe the word "individual" is wrong, it is truly "subpopulations". But I think we need to start dealing with and I do not think "one size fits all". There is a lot of individual responsiveness and some people as I showed you are going to get a little response and others may get a lot. The lycopene story presented is a good example, if we only *recommended to the general public to consume a little more* it might actually not benefit one group as much since they may need considerably more. .

PUBLIC: Je vais continuer sur vos propos. J'ai vu à travers votre étude que sur le produit brocoli les résultats étaient plus que probants. Vous faites certainement allusion à la recherche du groupe SEMINIS sur une graine puisque c'est le premier ensemencier mondial qui vient effectivement de découvrir, qui a mis au point un brocoli qui serait à plus de 50 fois d'après ce qu'ils disent dans des teneurs d'antioxydants pour éradiquer les radicaux libres. Nous sommes nous-mêmes un groupe de producteurs de fruits et légumes sur l'Europe et nous sommes justement en train de nous développer puisque l'entreprise a une vocation de la santé et de bien-être en passant par la nutrition. Est-ce qu'aujourd'hui vous nous inciter à continuer dans cette direction qui va bien-sûr par une culture différente du produit, le groupe SEMINIS en est la preuve avec son brocoli, le résultat est là puisqu'il sera donc à la commercialisation en début d'année 2009 à travers le monde entier. Inciter vous encore des producteurs et des groupes de recherches à aller dans ce sens c'est-à-dire de faire la recherche génétique de produits d'antioxydants ? On sait que des cultures particulières telles qu'à base de sélénium renforcent se type de produits.
J'ai une seconde question plus simple.
Pour information personnelle, dans toutes les études qui nous ont été montrées par les orateurs aujourd'hui il est vrai qu'il aurait été bon de connaître par rapport à ce que vous venez de dire, qu'elles étaient dans les études les produits qui étaient étudiés car c'est vrai que bien souvent on donne la dénomination fruit et légumes, on sati qu'un brocoli ou un chou n'aura pas du tout la même consonance en matière d'antioxydants qu'un agrume donc il est vrai que les résultats des travaux peuvent effectivement avoir une différence et cela il faut le savoir, de 30 à 70%. Pour les

novices tels que nous-mêmes il est souhaitable d'avoir des précisions sur les produits qui sont étudiés.

J MILNER: As I said these are my opinions and not necessarily those of the National Cancer Institute. I will answer your question by saying that I think there is an opportunity to discuss specialized products for health benefits. I think that you are right that the broccoli sprouts are one example and I think we are going to find a similar approach for a lot of foods. You can find certain seeds from oats and wheat that have higher content of flavonoids and it may well be developing those who are better products and overall that would be a benefit. The part of me that says be careful is over indulgence of any of these nutrients can be harmful and there probably is a subgroup that is placed at risk from exaggerated intakes of any nutrients. We have to be cautious with this, we have to do some testing of these things but I think that is were we headed. If we can actually show that some of these products really are effective and that there are really doing something, why not. And I do not care if it lycopene or any other kind of compound in the food supply but I will say to you we have to be careful. I don't think many of us would have ever thought that folic acid was going to create a problem but I am not sure we know how much of a problem it is at this point. But there may well be a subgroup that is placed at risk, in this case increased cancer. You heard about this morning with the Vitamin E story; excessive vitamin E might be harmful to a subgroup and might increased risk of cardiac problems. We are going to have to think about how to use nutrigenomics to identify vulnerable populations.

A SCHATZKIN: We have raised a number of methodological as well biological issues. There certainly is potential in the future that fruit and vegetables intake will reduced the risk of cancer and perhaps mortality from it but there are clearly works to be done.

SESSION 11

EFFECTIVE INTERVENTION STUDIES TARGETING CHILDREN

Chairs: **C.Perez-Rodrigo** and **Ch. Rowley**

- Determinants of F&V consumption. **C.Perez-Rodrigo**
- School fruit and vegetable schemes: an international review of effectiveness. **K. Lock**
- New Zealand's Fruit in Schools program, a public/private partnership in action. **P. Dudley**
- Results of the Pro Children Study. **S. Te Velde**
- Free school fruit might give long term effects – Results from the Norwegian intervention study FVMM. **E. Bere**

Determinants of F&V consumption

Carmen PEREZ-RODRIGO
Community Nutrition Unit, Bilbao, Spain

We know that food habits in general are complex in nature. If we look particularly in habits in children and young people there are many areas of interests that are influencing what they eat, what they would like to eat and what they do. Particularly the family is very important especially when they are very young. Then when they come at school age, school becomes very important. Also the friends and Peers make a strong influence, community where they live and we can not forget either about the personal factors that are important in diet and the environment surrounding them, including mass media, marketing and publicity that they are exposed to. All these areas of influences have been arranged and have been tried to be understood, by different models and theories all waiting the determinants involved. In more recent years, ecological models have gain more attention. Such models like for instance the ANGELO framework focus on environment divided with the microenvironment looking into groups of people and the macro environment as the broader infrastructure surrounding people. There is also a classification regarding the type like physical environment such as the food available and easy to access, sociocultural environment like social norms, subjective norms, parental influences, peer pressure etc., the economical environment as cost related issues or the political environment.
We focus on children and adolescent eating behaviour and we look at the different areas where they live. The household level, the school level, the neighbourhood where they live and the city and municipality are the main areas of interest we should look into both the way of understanding the way they eat and how they eat what they eat but also with the main focus by understanding this we would be able to better tailor the kind of intervention we are more likely to be effective.

Micro and macroenvironmental correlates of dietary intakes among children (3- to 12-year olds)

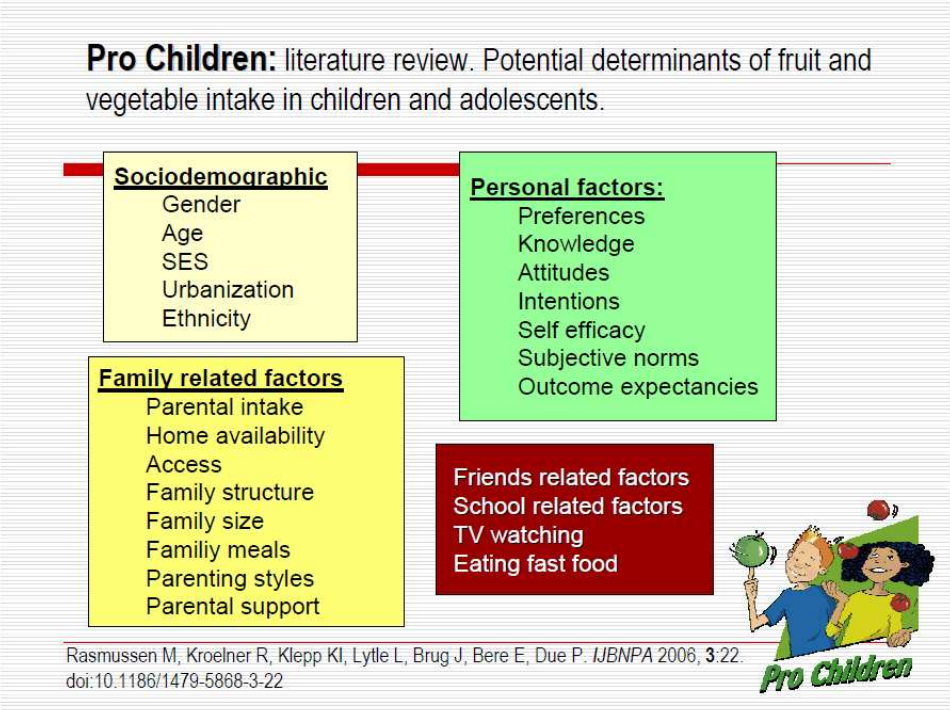
Home/household Physical		Sociocultural	
Energy			
Accessibility to food	Neg	Parental intake	
Minutes foods present at home		Parenting practices	
Fat (total fat, energy percent fat)		Control/restriction/discouragemer	Neg
Accessibility to food		Encouragement/assistance/prompts	
Minutes foods present at home		to increase food intake	
Fruit, juice, vegetables		Food as reward	
Availability	**Positive**	Parents' negative statements	Neg
Accessibility	**Positive**	about foods	
Home FJV barriers	Neg	Family support	
Television on during meals	Neg	Minutes spent eating at home	
Snacks, fast food		No meals eaten out	
Television on during meals		Marital status parents	
Soft drink		**Food presentations/food offers**	**Positive**
Television on during meals	Neg	Fat (total fat, energy percent fat)	
Availability		**Parental intake**	**Positive**
Sociocultural		Parenting practices	

van der Horst K, Oenema A, Ferreira I, Wendel-Vos W, Giskes K, van Lenthe F, Brug J. A systematic review of environmental correlates of obesity-related dietary behaviors in youth Health Education Research 2006; doi:10.1093/her/cyl069

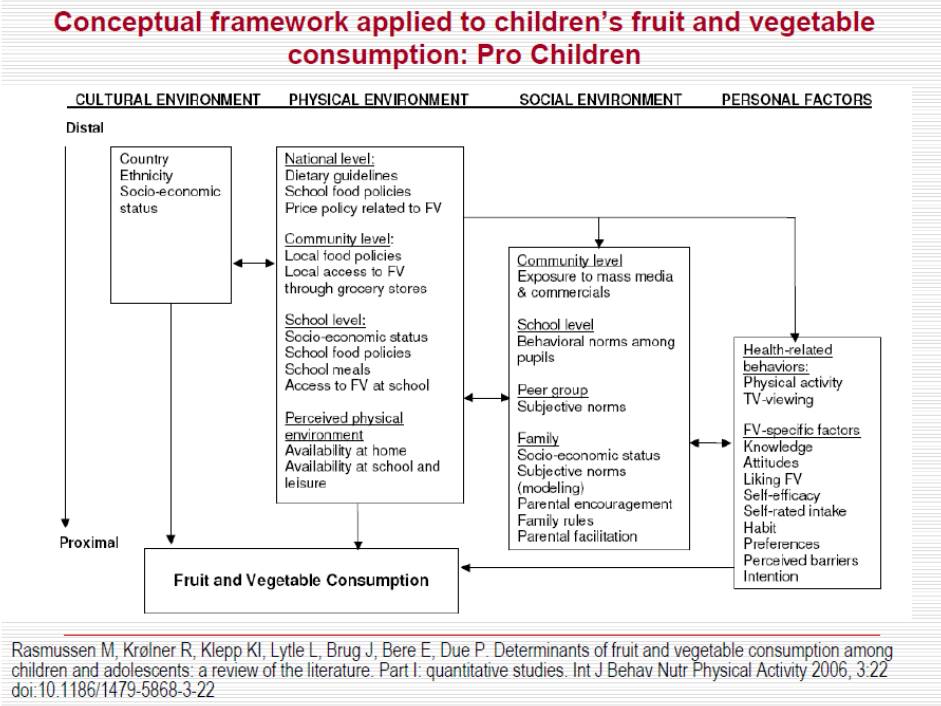
We already have some evidences build looking into micro and macro environments surrounding children in relation to what they eat.

For instance in this comprehensive literature review on evidence conducted in the Netherlands are looking into data behaviours related to obesity and already in this review conducted in 2006 we could see that F&V appeared and the family environment to micro/macro environment especially where are high level at home and easy to access have a positive influence in the amount and types and variety of F&V that children consume. On the other hand some of the features like for instance barriers to access of F&V or TV view on during meals and longer TV exposure have a negative impact on consumption of F&V among children.
The Pro Children study is an European funded survey and intervention that was conducted between 2002 and 2006 and it was focused on 10 to 12 years old children and we are looking into F&V consumption in determinant influencing those. On the other hand, we tested a pilot intervention and its effectiveness.

There 5 different blocks of determinants on F&V consumption namely socio-demographic factors like gender, age, socioeconomic levels, urbanisation and ethnicity, personal factors such as preferences; knowledge, attitudes toward F&V, intention, self-efficacy, subjective norms and outcome expectancies; family related factors like parental intake, home availability and access, family structure, family size, family meals and also some other factors that were identified such as friends related factors, school related factors, TV viewing or eating fast-food.



We constructed model trying to explain on how to harmonize all these different factors looking into the environments that we defined as a cultural environment, the physical environment, the social environment and personal factors and linking those together and how they influence F&V consumption in this specific population group.



Rasmussen M, Krølner R, Klepp KI, Lytle L, Brug J, Bere E, Due P. Determinants of fruit and vegetable consumption among children and adolescents: a review of the literature. Part I: quantitative studies. Int J Behav Nutr Physical Activity 2006, 3:22 doi:10.1186/1479-5868-3-22

In order to investigate determinant factors, we had 3 different approaches. The first literature review was conducted looking into determinants of F&V in children age 6 years to 12 years and the literature review went back up to 1966 up to 2004. So it included a long period of time on all surveys conducted in that period. Following on the slides some of the conclusions of what evidence we do have relating determinant factors for F&V consumption in children.

Summary of potential determinants of fruit and vegetable consumption among children and adolescents. Determinants included in at least three papers.

Determinant variable	Association/group with highest level of intake	No association
Sociodemographic factors		
Gender	Girls: (27 studies)	18 studies
	Boys: (4 studies)	
Age/grade	Neg. assoc: (9 studies)	9 studies
	Pos. assoc: (3 studies)	
Family-related factors	Pos. Assoc (38 studies)	19 studies
	Neg. assoc: (3 studies)	
Race/ethnicity	Assoc (15 studies)	6 studies
Urbanisation	Rural (3 studies)	1 study
Personal factors		
Preferences	Pos. assoc: (11 studies)	-
Nutritional knowledge	Pos. Assoc (6 studies)	1 study
	Neg. Assoc (1 study)	
Attitudes	Pos. assoc: (3 studies)	-
Intentions	Pos. assoc: (2 studies)	2 studies
Self-efficacy	Pos. assoc: (6 studies)	2 studies
Outcome expectations	Pos. assoc: (1 studies)	4 studies
Perceived barriers	Low barriers: (1 studies)	2 studies
Subjective norms (perception of others'attitude on own diet)	Pos. Assoc (3 studies)	

Rasmussen M, et al. Int J Behav Nutr Physical Activity 2006, 3:22 doi:10.1186/1479-5868-3-22

We know that gender is an influence factor and most of studies show that girls tend to have higher consumption of F&V than boys do. Also age is an influencing factor although in this sense not all the studies show the same kind of evidences. In some studies it is younger children who eat more F&V and then it decreases consumption, in other studies it is not the case. Family-related factors show a positive association, so when there is a higher consumption in the whole family children also have higher consumption of F&V. Ethnicity is not a unique trend, there are controversial results although it seems like more socio-economical related factor and regarding urbanisation the results are not conclusive either although is some studies in rural areas the consumption was higher. Regarding personal factors, it is quite unanimous that children who have a higher preference or a wider scope, more variety of preferences do consume a higher amount of F&V. When children are more aware about the nutritional relevance and know more the nutritional recommendations guidelines on F&V they eat more. Also a positive attitude for F&V has been also seen as a positive influence. Intentions is not conclusive so some studies say yes, intentions are important for consumption of F&V while others are not having the same conclusions. Self-efficacy in different domains, there is evidence that it is associated with higher consumption while outcome expectations did not that much so different constructs have been assess. Perceived barriers, in one study it was associated when low barriers exist then the consumption is higher. And the subjective norms, the perception of other's attitude on our own diet is associated positively with a higher consumption of F&V. If we look into other domains like family related factors, is seems like when the family eats more F&V, the variety, the home availability and access so parents acting as models have a positive influence on what children eat. Family structure, is seems like 2 parental families have positive influence on consumption compared to other family models while there is no conclusions regarding family sizes. The frequency of family meals also has a positive influence so the families who eat more often together the main meal at home of outside home but they eat together more frequently, this has also a positive influence on the amount of F&V children eat. Regarding the influence of friends, the perceived friend intake so when children perceived the colleagues, their friends eat more F&V then they also tend to eat more F&V and that is the positive association than has been observe at least in the studies showing that. School-related factors and particularly about the availability of F&V has a positive influence either on the school meals basis of other F&V schemes. So as long as F&V are more available and accessible in the school then children tend to consume and eat more F&V. On the other hand when competing foods exist in the schools either by means of the kind of food offer served in the schools meals, in the canteen or by vending machines or any other means then this has a counteracting, a negative influence on the amount of F&V children have. According to this review, the longer hour the TV exposure, there was a negative association with F&V consumption.

However, as I said previously, in the Pro Children study we conducted this literature review but we also investigated by means of qualitative methods determinant factors of F&V consumption and we concluded similar results. Personal Factors like taste preferences, knowledge, awareness were really relevant factors and the Family Environment mainly the availability and access, modelling by parents, have an important influence as well as to School F&V availability, schools norms and peer influences.
But, we also by means of a questionnaire investigated the influence of the different factors and I want to show you results from the analysis of the exposure to TV watching and the relationship with F&V consumption in the Pro Children study. You can see how TV viewing is really different matter and the Southern European countries like Spain and Portugal more often watch TV during dinner and are more often exposed to TV.

The proportion of children reporting having seen TV ads during the previous month and the kind of food items and beverages that they were exposed to by means of advertising and publicity, here I would like to highlight that if you look at the number of adverts regarding F&V children were exposed to is approximately half the number of the kind of adverts they were exposed related to candies, soft drinks or other matters.

However, in this Prochildren study we could see a positive association between exposure to F&V TV ads of children and a higher consumption. It was an immediate effect where exposure to TV ads on F&V positively influence attitude towards F&V and produce a higher liking for F&V and that was the mediating model on how this influence the amount reported of F&V consumed. However other studies have shown that longer TV exposure and longer exposure to TV ads in general, not specifically to F&V TV ads that we showed in the Pro Children study, has a negative effect on F&V consumption.
So we can say that the evidence existing related to F&V consumption is solid fully age, gender, socioeconomic level, preferences, self-efficacy, knowledge, family consumption and modelling, availability and access at home, habit strength. Regarding parenting styles this is not so conclusive as it has been less investigated and apparently there is a positive effect of the kind of authoritative feeding that is when norms and rules are established at home but at the same time some kind of encouragement and support for the children that seems to be positively associated with a higher consumption of F&V while, a negative association for a more authoritarian kind of feeding where only norms with no support or encouragement is exposed at home. More recent research is focusing on the availability and access of F&V in neighbourhoods still little research has been published but it is interesting as it more focusing being place into that and it seems like small neighbourhood food stores and their fresh produce availability and good local availability, own vegetable garden, may have a positive influence particularly on low food insecurity.

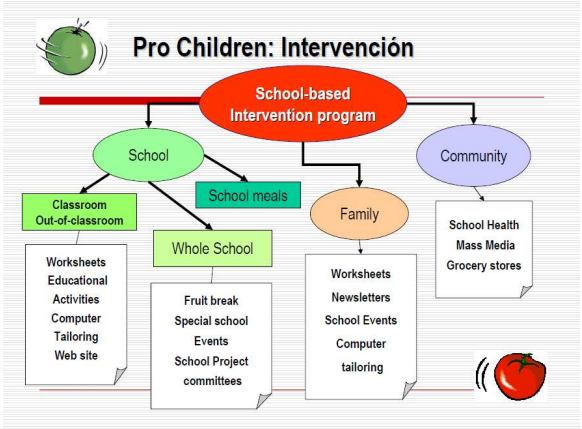
To end the presentation, I would like to highlight that this investigation of the determinants of F&V consumption is important firstly to understand why the situation is like it is but specifically because we have evidence that F&V consumption particularly among children and young people is below desire levels and action is needed. Some kind of interventions is needed to be divided in order to tailor to the needs and to cultural factors and to design more effective intervention we need certainly to understand that. In the Pro Children program, in the intervention that we

Identified changeable important determinants of fruit and vegetable consumption in Pro Children intervention

Determinants		
Personal	**Social**	**Environmental**
Awareness of importance of fruit and vegetable intake for health and well-being	Parental facilitation and direct encouragement	Availability and accessibility of fruit and vegetable at home
Positive taste preferences for different fruits and vegetables	Parental modelling behaviour	Availability and accessibility of fruit and vegetable in the school
Awareness of own fruit and vegetable intake	Peer modelling behaviour	A fruit and vegetable promotion school environment
Awareness of recommended intake levels	Teacher support	Neighbourhood support
Self-efficacy and skills for asking for fruit and vegetable		
Self-efficacy and skills for preparing fruit and vegetable		
Self-efficacy and skills for obtaining fruit and vegetable		
Self-efficacy and skills for keeping fruit and vegetable fresh		
Familiarity with different fruits and vegetables		

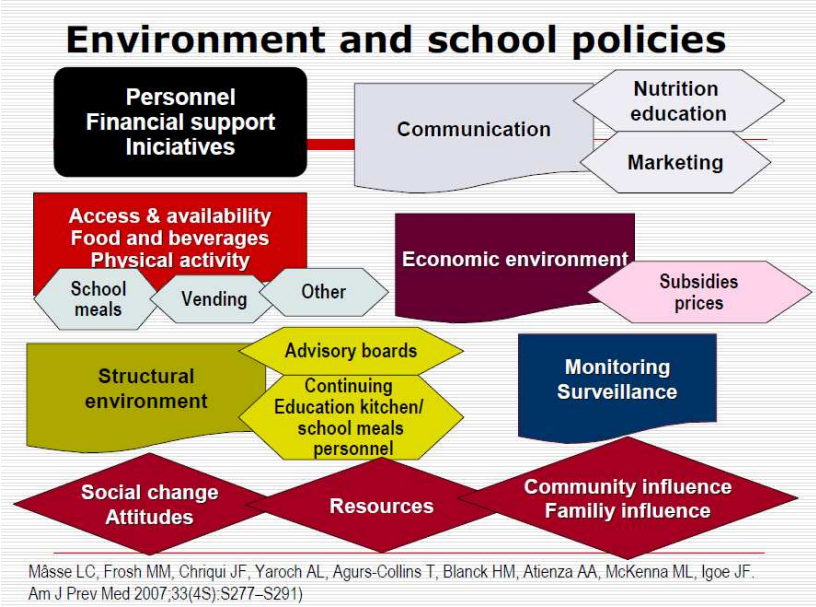
Pérez Rodrigo et al, Ann Nutr Metab 2005;49:267–277

tested we followed an intervention model procedure and that is we tried to understand the determinants that were relevant for the kids we were working with and try to look into those determinants which were able to be change within the time framework that we had that was 2 school years. According to those that we selected summarized in this table are the personal, social and environmental domains we tried to design the learning objectives that could be achieved to the program and try to identify which were the best teaching tools in the educational methods that could better suit to achieve the objective. So, this is just a flavour of the complex matrix that we came out with looking at the different determinant domains on the kind of learning objectives that we have divided and which are the most appropriate methods that should be used.



Therefore we ended up with a complex set for the intervention divided into three different blocks namely the school area, the school component looking into class rooms and out of the class room activities as well as whole school issues including school meals where they were existing, a family component and a community component.

In fact the school setting provides a wonderful opportunity for interventions if we have groups of children families and teacher together, all children attend school although all have the rights we must be aware that not 100% of children attend everyday regular school but most children attend to school. They spend many hours everyday, at least 5 days/week for 9 months/year and this for many years so this is a lot of potential. Additionally there is a potential for environmental intervention by means of school meals, vending opportunity, physical activity and also to influence the family environment. So there are different options including food planning and preparation development skills, school gardens and F&V schemes are other opportunities. But, the key thing is that interventions to be effective it is not just on a short term of a pilot testing that it should be desirable that when interventions work they could be sustainable in a long run. So a number of features should be focused in terms of school and environmental school food policies.



So unless there is an appropriate infrastructure and adequate budgeting and adequate resources this can not be effective in the long term and this is the big challenge that we need to face.

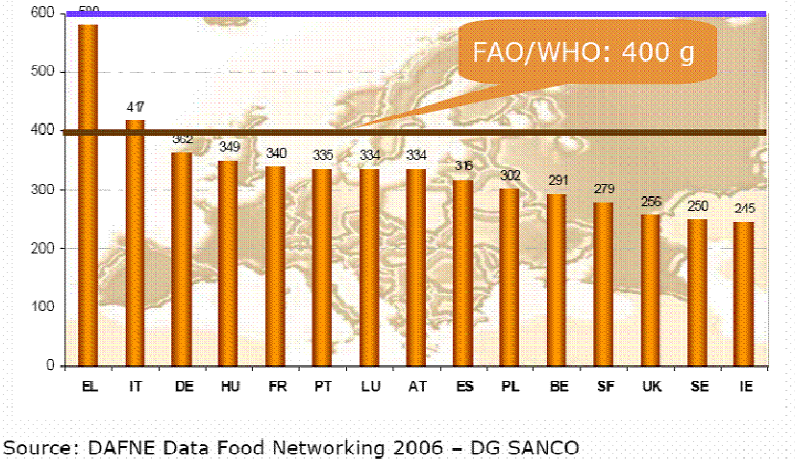
C ROWLEY (President of the session): The thing that strikes me with all the interventions that are out there is that is seems that the more we know, the more we really need to know and we need to keep out these things and look what these determinants are.

School fruit and vegetable schemes: an international review of effectiveness

Karen LOCK
London School of Hygiene and Tropical Medicine, UK

I want to talk to you about a systematic literature review that myself and colleague Joia de Sa at the London School of Hygiene and Tropical Medicine did last autumn. And we did it specifically to fit in the EU school F&V scheme impact assessment process. Obviously it is important at any point to have various pieces of information when you are planning policy and only one piece of that is scientific information on the effectiveness of such schemes. We were pleased that we were able to help and we felt that the important questions for us to answer were: Do school F&V schemes improve childhood nutrition and health? How are they organised? And how can we identify any necessary factors for success? I will show you how we were able to answer some of these questions.

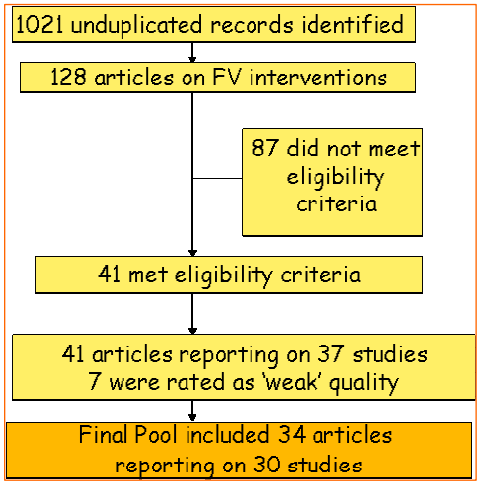
Consumption of F&V (g/day per capita). Strong difference between Member States. Under the level recommended by the WHO and the FAO (400 g per day)



Source: DAFNE Data Food Networking 2006 – DG SANCO

To the question why increase FV intake via schools I think it is obvious, there are poor F&V intake in children, we had some associations from recent cohort followed up in the UK that there is an association with higher childhood F&V intake and low risk of adult stroke in cancer as well as adult link with low intake and higher risk of diseases and schools are the obvious setting to target children.
This graph shows the consumption of F&V in Europe in adults and we saw information showing that we know in Europe that it is below the recommended levels.

The current systematic literature review that I am going to be presenting the evidence from, as I said we started looking at studies that were published or that we could retrieve to August 2007. We looked at studies looking at nutrition or food interventions that incorporated fruit and vegetables and that had to be a core component of them, in any children under 18 years in school or pre-school settings. They had measure FV intake but we did look at secondary outcomes including attitude and knowledge to FV. We basically looked at only those with an experimental or quasi-experimental design i.e. they had to have a control group so



we could be clear that the impact of any intervention was due to only those in the interventions group. I am not saying that is the only model of how you should evaluate a School Fruit Scheme depending on your requirements and there have been plenty of schemes that we did not wish to include in our review including the New Zealand one that is an excellent schemes and has been very well evaluated but because we set this sort of scientific criteria material for the evaluation of a control group we had to not include them. So just because they are not include is does not means these School Fruit schemes are not well evaluated but we just wanted to make sure that the absolute results we can be certain of in terms of improve the intake were due to interventions. The picture is just a summary that we managed to find over a thousand records which eventually were when we sort of filter them down were 128 articles on F&V, 87 did not this eligibility criteria, some I just mentioned. And eventually we rejected another 7 papers because they were rated 'weak' in terms of scientific quality (…). So the Final Pool we looked at was 34 articles with reporting on 30 studies and I am pleased to certify that on the panel today we have got lots of experts that did these studies so they can give you much more details on some of the schemes. I think that if you have to retain one thing of this paragraph, all we need to know is that school based F&V schemes are effective and increasing intake and that is one message that is pretty straight forward. Of 22 studies, over 70% showed statistically significant increases in intake and that was in all age groups. No studies showed reduction in intake which is also a very important finding. As far as I am concerned you can not do any harm in terms of F&V intake. We did not bother to do what in scientific terms is a sort of projectionist approach that sort of work out what is the average intake that all these schemes could do but we can just give you a range. So, they were ranged from 0.3 to 0.99servings/day in terms of the impact they had on children intakes of F&V. That compares well with recent meta-analysis which pooled 7 US studies by Howerton in 2007. They found that between these 7 studies, an increase of 0.45 servings a day as an average were after pooling these 7 studies. The other key point to take away with us is that there is some evidence now that FV interventions in schools can result in long term dietary changes and I think that is important in the fact that they are effective because that is the all point. When we finish the interventions, is that going to be long term impact? That is a key for policy. We know that the consistency studies have followed up of over 2 years. We also hear about the Norwegian school food scheme that had 3 years follow up and is incredibly successful.

In terms of summary of findings they are all in the main report if you go to my webpage. As you see major studies were on younger children surprisingly most 23 and only 7 on older children. Again if you look though the list of names, most of them are actually in Europe and US and very few, in fact non from developing countries and that is particularly because of the way the interventions were designed, it is not that we did not find any. There were some gardening interventions from other countries, not in Europe and the US. Some of them had very big studies, 11 on younger children were over a thousand participants so it is good evidence as well. You can actually see that a lot of them looked at secondary outcomes including impact on overweight and obesity, physical activity, TV viewing hours etc.

AGE of CHILDREN	Younger (5-11)	Older (11-18)
Total number of studies	23	7
Note: numbers of countries in which studies were in younger children >23 as one study was multi-sited (Pro children, te Velde et al).	Ireland (2) Netherlands (3) Norway (1) New Zealand (1) Scotland (1) Spain (1) UK (6) USA (10)	Belgium (1) Norway (2) USA (4)
Number of participants		
<1000	12	3
>1000	11	4
Secondary outcomes		
Anthropometry/Obesity	5	4
Physical activity	5	4
Reduced TV viewing hours	2	1
Micronutrient intake	0	2
Cholesterol	1	0

What we found is that School F&V schemes are incredibly diverse. The interventions that have been planned or the national programs that have been ruled out vary considerably. The picture in black and white is actually one I found of UK cooking class where they were told to prepare vegetables in schools for the girls in 1917 so we are not actually novel in this. It has been 90 years in the planning.

Types of interventions

But what we can tell if we look at the interventions is that there is a huge range of types of interventions between young and old. A lot of them unsurprisingly had 7 interventions among the younger providing F&V either free or subsidised and that included 2 national schemes, the UK and the Norwegian schemes. Because most of them had actually been planned from Public Health departments, a lot of them had classroom based curriculum or education components both in young and old age groups. But the nice thing is that a lot of them had many components and that includes school wide policies in terms of campaigns, school gardens etc. specifically policies on what you can buy and sell in schools as well as F&V including changes in the school food

	Younger (5 – 11)	Older (11 – 18)
FV provision (free or subsidised) inc 2 national evaluated programmes	7	3
Classroom based e.g. •Curriculum/ education •tasting •prizes/rewards	17	7
School wide e.g. •school media campaign •school garden •school nutrition policy	13	5
Teacher training	6	3
School food service •staff training •lunch modification •verbal encouragement	8	4
Peer leaders	2	1
Parents involvement	11	3

service and teacher training. And there are numbers that involved peers or parents as well.

Just to summarize in very brief overview of the interventions on Younger children and we randomly chose 5 to 11 years old as meeting most of the school designs around the world for younger children, 16 on 23 led to sustained increased intake in that group. A lot of them did provide F&V and that seems to be important for young but also for older children. Tasting was important and all had some education e.g. classroom activities or something to increase motivation and knowledge in that age group. Some used psychological rewards and models and one of the best known is the 'Food Dude'. So there were different ways they involved the multi components interventions.
In terms of older children the key finding and I think that goes against what a lot of people are saying is actually that you can make an impact on older children. Even if the teenagers' intake of F&V decrease dramatically in many countries, 70% of studies that were done on older children were effective. Most countries are focusing on the younger age groups but I think we should not ignore the older age groups, you can make a difference and that is an important age group. There are a lot of tacking studies that show what you are eating in this period tracks through in terms of healthy eating into your adulthood. So I think it is an important age group not to ignore. They also looked at secondary health benefits, several studies showed reduction in junk food intake which as well increase F&V intake. On the 4 studies looking at obesity out of the 10 lot, only one on older children was really done with sufficient power and over sufficient length for time to show any change and that was the only study that showed reduced overweight as well as increased F&V intake. I do not think that is because F&V schemes are unnecessarily important of reducing overweight and obesity, I just do not think they bring adequate designs to show that yet. There were more focused on health education in the older age group and less focusing on the reward and marketing and that is unsurprising peer issues and parents.

There are two points I want to raise. One important in planning schemes in terms of school F&V availability as shown in terms of determinant of intake is important in changing both the food environment and the diet. As I said there was a provision of free or subsidises F&V in 10 studies. In other studies, availability and access or exposure were actually increased in a number of ways and that is tasting (through the Food Dudes in Ireland), school gardening schemes, cooking, school food service modification, environmental modification as what was in vending machines and, changes in what children can bring to schools in their pack lunches and very other ways as well of changing the availability and accessibility of F&V.
To come back on this word 'multi-component interventions', it is a dreadful word concocted by scientists to summarize the fact that often health promotions or interventions in public health, they try to regroup things all together because it is

logical. We know about the determinants, it is important to change environment, it is important to change knowledge, to motivate in different ways. So you obviously got to tackle attitudes in a multiple approach and we defined as having 2 or 3 (or more) program elements in a program. 75 % of the studies that we looked at had multiple components and these have been shown in other studies, previous reviews of F&V interventions not just in schools and reviews of obesity interventions to be probably the most effective approach to both of them tackling overweight and increase F&V consumption. Unsurprisingly, as well as F&V, education was the majority of this sort of this extra component delivered in the studies, 6 on 7 studies on older children and 17 of 23 in the younger.

Everyone always says, usually the scientists, what is the important bit of the multi-component interventions? Can we not just find out what is the best bit of the multiple component and we do that bit? Obviously is actually quite hard to distinguish the effectiveness of different parts of the interventions and only one randomised control trial TEENS study in the USA in older children explicitly studied the impact of different levels of exposure to a multi-component intervention. Each groups sort of have a add on, one started we just environmental modifications then it added on some education then it added on both of those plus having some peer role models. The first two quite interestingly against the control group showed the school environment and plus the education showed no impact but if you added in peers, peer trained, peer leaders to support it as well it showed a significant increase. Unfortunately this was not sustained at 2 year follow up but it is a way of actually looking at components and how maybe the additive effect is very important.

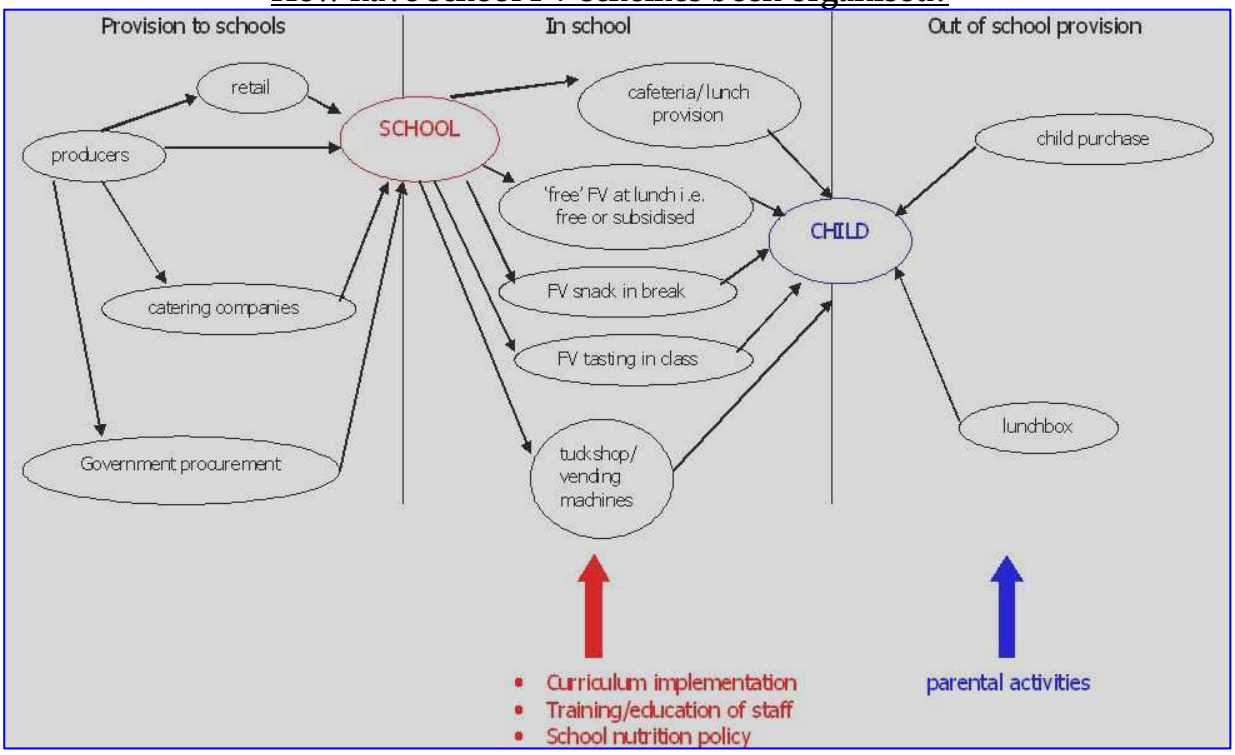
To summarize that part, school F&V schemes clearly childhood nutrition and health. But I think the important thing is that they can also potentially provide other social benefits and specifically reducing social and health inequalities.

As we know children form low socio-economic groups traditionally have lower FV intake. The Norwegian School fruit scheme study is the only one that explicitly looked at the differences groups of different SES and showed that a free-scheme is clearly the way forward to reducing health inequalities in terms of intake of F&V. In terms of the discussions around food prices and how this is going to impact on everything I think actually free school fruit schemes are important mechanism to ensure diet quality and food security of these low income groups. Rather than thinking we are going to loose the battle because of this, I think probably it is an important mechanism.

Finally, how the School F&V schemes have been organised? In terms of how they have been organised, this is just a summary slide.

Field to school 'fork':

How have school FV schemes been organised?



We tried to look at field to what I call the school 'fork'. On one side is the provision to schools and this came in a number of different ways. Producers might supply retailers that supply schools, producers might supply schools directly of producers might supply the catering companies that provide school meals and producers supply the government procurement. So there were complicate ways of just getting the F&V to schools. Once you are in schools, the numbers of schemes have different way of getting the F&V from one it has been delivered to the children's mouth both in terms of café and lunch provision, free provision, snack programs, tasting in class, vending machines, tuck shops that I said was influenced again down there by the education and curriculum component to try to stimulate it and school nutrition policies. Then in terms of child, there were out of school provisions both in terms of child purchase and also lunch box because like in the Food Dudes school scheme in Ireland that is about what children bring in for their school lunches because the reality is there are lots of different lunch provisions in schools across Europe.

To summarise, what factors affect delivery and impact? Clearly the supply chain is what every schools in a F&V scheme has thought about when we staring up new school fruit schemes in the EU for new member states these are the things we need to consider and analyse, what are the key point in each member states. In terms of the supply chain who is the purchaser? Is it the school or is it the government? Are we going to get the supply direct from wholesalers/producers/retailers or via government procurement? There are completely differences in school systems around the world, both in terms of school meal provision and school food policies on what junk food can we have in schools, it you can have vending machines, whether

children bring pack lunches. This is quite important because there are a number of studies and I know they had to deal with this in the Pro Children study and had a model across multiple countries, some of them had school lunch programs and some did not. In Ireland, the Food Dudes schemes had to work with the school food system that does not have a school lunch program where children actually bring their lunch in whereas in England, we have a school lunch program. So, you obviously got to design the system completely differently depending on that. Free versus paid, snack versus meal are different ways you can give kids the F&V. Target groups, a lot of people because of logistics and finance go for selected age groups, why not all years? How often do you give it, everyday, some days, short period of time? Ideally everyone would like to continue and make this sustainable like the EU proposals. And what partnerships have you got? The has been key, the English scheme had trouble to start with because it did not make the right partnerships work and it had to set up a new supply chain from scratch after sort of ignored the agricultural sector. It is important to get the partnerships right. On the strength of current evaluations, there is no single best approach to all those and it clearly has to be flexible and adaptable to the context of country and to the diet school food system and also the supply chain system.

The last mention that we had to do is we looked at cost-effectiveness. Only one study looked at cost-effectiveness and it is an economic modelling study from Norwegian Directorate of Health. It shows some evidence that actually even a small very minus increase life long of 2.5g/day over the lifetime of F&V consumption is significantly cost-effective and makes a very large health care savings. Unfortunately it is in Norwegian so I had to get it translated: '*providing a free school fruit programme to all pupils grade 1-10 would be cost-effective if it resulted in a lifelong increase in mean fruit and vegetable consumption of only 2.5g/day*' *(Sælensminde, K. Frukt og grønnsaker i skolen Beregning av samfunnsøkonomisk lønnsomhet. Oslo: Sosial-og helsedirektoratet; 2006.)*

The important question are do school fruit and vegetable schemes improve childhood nutrition and health? The answer is yes. We also looked at the importance at how they are organised and what are the necessary factors for success. We know in the EU school fruit measure could increase added value by increasing availability particularly around the low consumers, reducing social inequalities as long as it is flexible. It is ending on good news and we have to congratulate the US Farm Bill for this $1 billion funding over 10 years for their F&V snack program. And we are hoping that something similar by the end of the year can be announced in Europe.

C ROWLEY (President of the session): We should remember simple things: they are effective, they are no reduction and some evidence of long term change and those are the positive things we need to get out. The other thing is that there are a lot of different ways to get to these results with all the cultural and organisational differences. I am a bit disappointed the trial studies were not included but we forgive you on that one.

New Zealand's Fruit in Schools program, a public/private partnership in action

Paula DUDLEY
'United Fresh/5+ A Day Charitable Trust', Birkenhead, Auckland

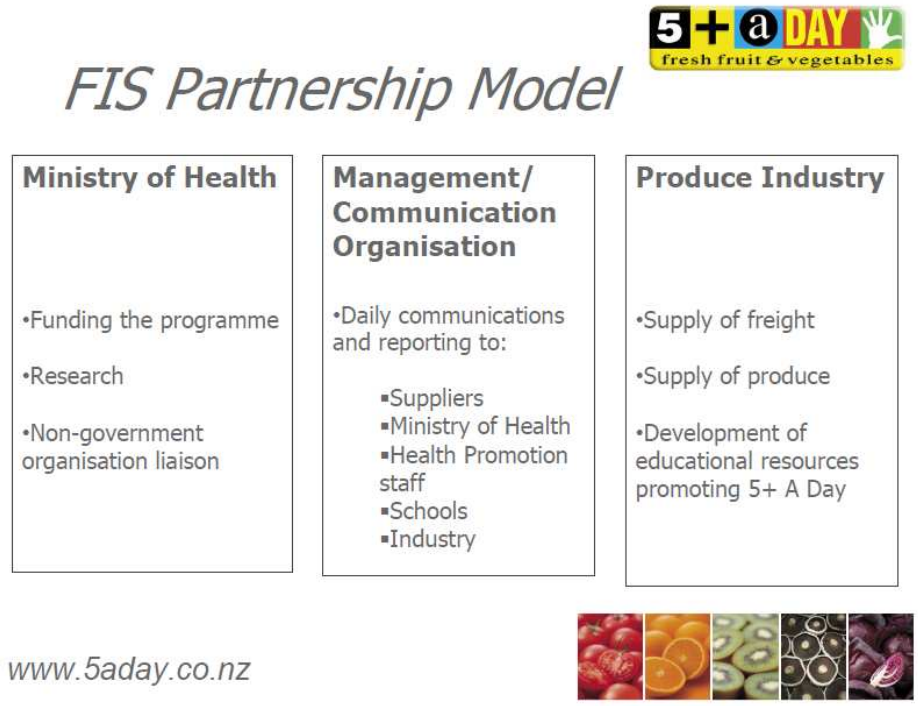
I am going to present New Zealand's Fruit in Schools program and I am going to take a practical approach to that, as a case study, hopefully to give you insights of lessons we have learnt and successes we have had since we launched the program in New Zealand (NZ).
As an overview of what I will present I am going to touch on the NZ health policy landscape, the timeline it took to get to our partnership operating, the program design, the numbers that are currently involved at this stage and the possible roll out that might happen by 2009, the Government has funded an evaluation and it is half-way through so I will give you un update on that and finally the benefits of the public/private partnership.

This is the Health Policy Landscape:
- 2000: *New Zealand Health Strategy* that is our overarching strategy and identifies raising the consumption of F&V as a priority (as do all the policies).
- 2002: *National Children's Nutrition Survey* that was a piece of research with over 3000 children involved in NZ that showed that only 40% were eating the recommended 2 servings of fruit a day and 60% were eating 3 serving of vegetables. So the government wanted to act on that as it also showed that 1/3 of our children are overweight or obese.
- 2003: *Health Eating Healthy Action Strategic Framework and Background released*
- 2004: *Healthy Eating Healthy Action Implementation Plan*
- 2006/07: *HEHA implementation and Mission On*
- 2007: *Select Committee Inquiry into Obesity and Type 2 Diabetes* that went on to recommend that the Fruit in Schools program was recommended to every single school in NZ.

For the timeline everything came together as far as the industry wanted to implement a Fruit in Schools program and the Government wanted to address the obesity issue. In 2002 we had an international meeting very similar to this conference which included a workshop on Fruit in Schools and NZ got to learn from countries such as the UK and America who had Fruit in Schools (FIS) programs implemented. Then we came back to our Ministry of Health and proposed a FIS program in 2003 just after the National Children's Nutrition Survey was released proving to be perfect timing for the Government to implement such a scheme. Then we were lucky enough to host the International Fruit and Vegetable Symposium and our Government partnered with us and the WHO, helping credibility, which was great. This is actually where IFAVA was born. In 2004 we piloted the scheme to test the

practicalities of the scheme to make sure that we could get freight to the remote areas and that fruit would stand out of cool storage because it gets very hot in the summer. So we got to roll out from the first phase in 2005 and now, is has not been confirmed but it does look like phase 4 will roll out as well this year so that is all good news for everyone involved.

What did we actually propose to our government? We took a proposal along with all the components in place. We suggested that they fund a piece fruit or a vegetable. To make that clear, we call the program Fruit in Schools however we actually provide F&V which is great from the industry perspective as well because if you represent industry as I do, they do not want to just be fruit, they want it to be F&V. This works out well for health anyway. In NZ schools are rated by decile from decile 1 to decile 10. Decile 1 is the highest deprivation area and this is where we targeted FIS. We gave the government the cost estimate of absolutely everything that we thought might be involved, the fruit, freight, the accountancy, the management, the communication on a day-to-day basis. We actually created a formula we could give to the government to estimate costs. We created a formula that came out with a cost of 37 NZ cents per day per child and that is probably about 0.17€. So, what we were offering was a tangible project that we would run if the government would fund it. It was in line with a number of their health policies.



We worked together on a partnership model and we saw there were three components that needed to be addressed. The Ministry of Health would be responsible for funding the program, and the research, evaluation and coordinating the non-government organizations such as the Cancer society and the National Heart Foundation. They would also fund local people on the ground to visit the schools,

called the Health Promoting Schools Coordinators. Then, we saw the need for a management communication component because there were a lot of stakeholders involved and the industry made it quite clear that they did not want the schools ringing the local wholesale supplier with questions. The produce industry was there to supply the fruit and freight and United Fresh provided their umbrella by putting the local producers and the local wholesalers together with health promoting fruit in schools coordinators and the schools on the ground. That has worked very well. Since 1994 we have produced resources promoting good health via 5+ A Day and we now distribute resources to fruit in schools as well.

Regarding the program design, as I said, a steering group was set up with all the stakeholders involved, all the NGOs, the Ministry of Health, and United Fresh as the industry. It was quite clear to everyone that just providing fruit would change the immediate environment but to make sustainable change the program had to go further. So in NZ they decided to report around the Health Promoting Schools framework. The schools focus on four areas: healthy eating, physical activity, Sunsmart and Smokefree. The fruit is not actually the whole program but is the reward for working toward becoming Health Promoting Schools. The schools signed contracts to say that they would work towards this in order to join the program.

This is where we are at the moment with over 60,000 children a day eating F&V. We deliver twice a week which is working well. In some areas where the rolls are really tiny and really remote we might even do a once a week delivery. When FIS was proposed to the industry some were excited, however quite a few of them actually felt that is devaluing the products by giving it away. Those people have done a full

turn around. Twelve million pieces of produce are now being delivered into schools. They now love the program and they see it for what it is, it is marketing for them to attract consumers of tomorrow. The roll-out looks like it would be coming by 2009 and then we will be sending out 100,000 pieces of produce every day. That would include the most deprived schools to decile 2 and that is over 20 million pieces of fruit and vegetables each year.

As I said, the government funded an evaluation. They took baseline data at phase 2 which provides some good results. The evaluation is and will be completed in 2009. They are monitoring the attitude, changes to attitude and behaviours toward healthy eating. The findings so far have included: an increased awareness in the importance of healthy eating, increased knowledge about healthy eating, and more children reporting that they are actually eating more F&V. With the evaluation group, there are 51 schools in total and there are seven control group schools. They have seen a large decrease and positive attitude toward F&V. The report will be available next year and we will ask our government to put it on the IFAVA website so people can share it.

As part of the communication and management component of the program we have a wealth of anecdotal information. We gather information daily as we call the schools everyday to make sure that everything is going well. Dental health is improving, concentration has improved, skin infections have halved, and children are bringing more produce to school in their lunchboxes. Also, toilet paper consumption has increased.

Now to the all important benefits of the program for the three partners: for the Ministry of Health - they have been able to capitalize on the industry's expertise as far as freighting the produce, and selecting appropriate produce. There have been cost benefits because of economies of scale due to using United Fresh as one focal point to the industry rather than the Ministry contracting individual local suppliers. We also have centralized reporting and control so we can keep an eye on the program everyday. The fruit quality management is not as simple as that and we have learnt that. The public/private partnership is also a quantifiable project that government can put toward their health strategies.

The benefits to the industry are that obviously we are seeing consistent rateable business as long as the contracts and the contract run for 3 years. The children are getting exposed to the products. And anecdotally we have seen that children are now asking their parents for these products. We are getting reports back from the schools that these children would not actually bring in F&V to school at all before the intervention. Now they are actually bringing fruit to school as well at getting a piece of fruit at school, we could not ask for better. The "feel good factor" can't be underestimated; the industry just loves it now. They are champions of FIS.

Benefits to United Fresh and the National 5+ A Day Program: the partnership and FIS has huge benefits for us as well. Our credibility is strengthened to the point that about a month ago we went to a research company to ask to do some more

awareness research and some understanding research for 5+ A Day and they looked a bit uncomfortable and said they just done all that for 5+ A Day for another company. This company shared the results and reported that 95% of all NZ are aware of 5+ A Day. As far as the traceability and the accountability for the producers supplying the fruit they all have to become members of United Fresh so that has grown our membership base.

This is a Maori proverb that I think wraps up our School program very nicely that basically means that when you share knowledge we will achieve much more together and in this case it is for
the heath of NZ children.

Na to rourou
Na taku rourou
Ka ora te manuhiri

With your basket
And my basket
The visitors will be fed

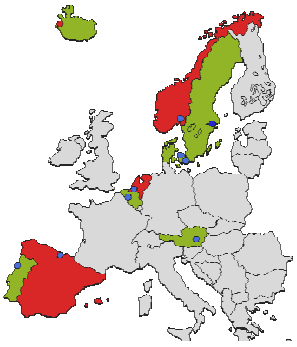
www.5aday.co.nz

C ROWLEY (President of the session): For me these sorts of things are very exiting to hear how these programs are going throughout the world. When I first started the Go for 2&5 and talking to people about why industry should get involved, how Horticulture Australia should be involved and I remember talking the Agriculture conference and they asked be why industry should get involved? And I said because NZ got one and that was the reason to drive it, if NZ can do it, we needed to be able to do it. Industry needs to be involved.

Results of the Pro Children Study

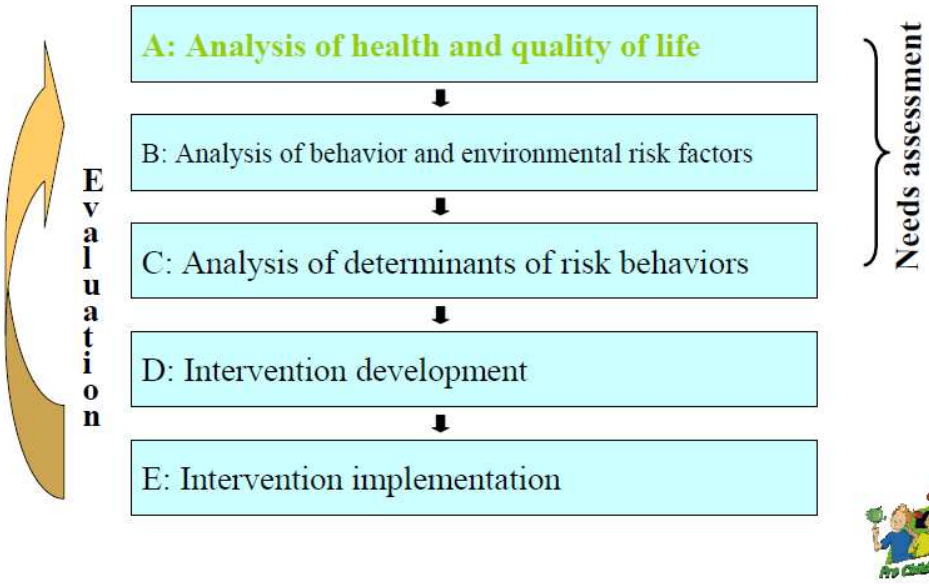
Saskia Te VELDE

My presentation is about Pro Children study and I would like to acknowledge my co-authors that are Johannes Brug, Marianne Wind, Mona Bjelland, Carmen Perez Rodrigo, Knut-Inge Klepp and the rest of the Pro Children team.



As you all know F&V can have health benefits specially related to metabolic diseases and certain cancers so that is one of the reason to promote F&V intake and that is the reason why we started the Pro Children project in 2002 and finished in 2006. Nine European countries were involved: the northern European countries, some in the middle to southern European countries. Norway, Spain, Iceland, Denmark, Portugal, Austria, the Netherlands, Sweden and Belgium were involved.

When we started all this we had in mind this simple Model for Planned Health Education & Promotion.



This gives you the steps you have to take design a plan in scientific based health promotion campaign. It starts with analysing the health and quality of life in the population. We did not actually do it but we know from the literature and from health surveys that most prevalent diseases in the western countries are cardiovascular diseases and cancer and overweight. The next step you have to do is make an analysis of the behaviour and environmental risk factors that are associated with those diseases. Again, form the literature we knew that F&V intake is one of the risk factors that can be associated with increased prevalence of cancers and cardiovascular diseases. Following this model, the Pro Children study consisted of several sub studies. First of all we started by doing review studies.

There was first of all a review on the literature on behaviour change theories that is good to provide a framework and that we could use to design our intervention. The

second review was on the determinants and the review on interventions studies that could give us some good strategies. The next step was to develop instruments which could assess F&V intake so we can collect new data. Then we did some qualitative studies and Carmen Perez-Rodrigo presented you the results. We did some focus groups interviews also to get an idea of what the children would tell us about what they think is a main determinant of why they eat or do not eat F&V. And we did some interviews with the teachers, what they thought was good strategy to promote F&V intake. Then we did cross-sectional surveys and I will present some results later on. We did this cross sectional survey in the nine countries and we assessed F&V intake in the children and their parents and we also assessed what the main determinants were. So, the first days of the Pro children study was a cross sectional survey conducted in all 9 countries. We took random sample of primary schools except in Belgium and Austria; it was primary schools from selected areas. We conducted school based surveys so one of the project when we went to the schools or we sent the survey to the schools and children completed the surveys and the supervision of the teacher were one of the project workers. They also had one questionnaire to be completed by one of the parents that was most often the mother. The questionnaire consisted of a general part asking about age, gender, birth date; parts that was the 24h recall asking about what F&V they ate previously and then a F&V frequency questionnaire assessing their usual F&V intake.

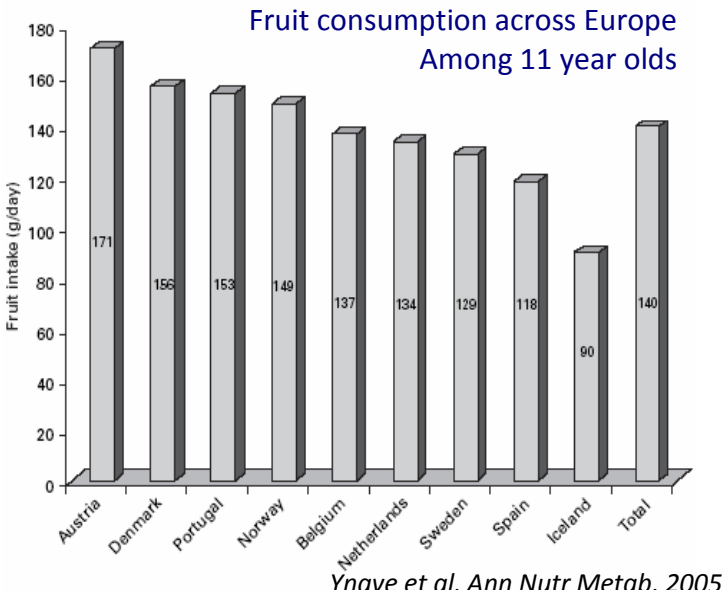
Characteristics of the cross-sectional sample

	Countries									
	All	Austria	Belgium	Denmark	Iceland	Netherlands	Norway	Portugal	Spain	Sweden
Sample size	13,305	1,692	1,343	1,919	1,196	1,105	1,196	2,134	1,313	1,407
Boys	6,680 (50.2)	805 (47.6)	728 (54.2)	978 (51.0)	629 (52.6)	511 (46.2)	607 (50.8)	1,012 (47.4)	705 (53.7)	705 (50.1)
Age (mean ± SD), years	11.4 ± 0.48	11.0 ± 0.59	11.5 ± 0.46	11.4 ± 0.38	11.3 ± 0.33	11.7 ± 0.46	11.3 ± 0.30	11.5 ± 0.45	11.4 ± 0.44	1.4 ± 0.47
Age range	8.8–13.8	8.8–13.5	10.3–13.8	9.5–13.2	9.8–12.1	10.3–13.6	10.4–13.4	10.8–12.8	9.8–13.8	9.8–13.6
Number of classes/ schools	723 classes/ 375 schools	73 classes/ 23 schools	73 classes/ 50 schools	105 classes/ 59 schools	68 classes/ 32 schools	62 classes/ 49 schools	73 classes/ 52 schools	128 classes/ 27 schools	64 classes/ 37 schools	77 classes/ 46 schools
Response rate	90.4%	95.3%	84.5%	92.0%	88.7%	79.7%	89.5%	98.4%	94.7%	84.2%

Note that response rate is the number of students' questionnaires returned, in relation to total number of students in participating classes. Thus, attrition consists of students being absent on the day the survey was carried out, as well as students present but denying to participate, or not being allowed to participate by their parents. Figures in parentheses indicate percentages.

Some characteristics of the cross-sectional sample, to show you the sample size, at the beginning we had a large amount of children taking part in the study, a bit more that 13 thousand and it varies between about 1,100 to more than 2,000 in Portugal. As you can see the mean age was around 11 years old, you can also see the number of classes and the response rates which are quite good.

These are the results which show the mean fruit consumption among 11 year olds and you can see the highest consumption was reported by Austrian children and the lowest consumption was reported by children form Iceland which was not very surprising because there are not so many F&V available in Iceland. On average the children consumed about 140 grams of fruit which is below the recommendations.



Yngve et al, Ann Nutr Metab, 2005

Table 5. Percentage of 11-year-old children with fruit plus vegetable intake ≥ 400 g, by gender and country

Country	Total		Girls		Boys	
	n	%	n	%	n	%
Austria	400	24.1	212	24.3	188	23.9
Belgium	253	19.1	108	17.8	145	20.3
Denmark	394	21.2	218	23.7	176	18.7
Iceland	92	7.8	36	6.4	56	9.1
Netherlands	130	11.9	77	13.1	53	10.5
Norway	202	17.5	109	19.2	93	15.8
Portugal	453	21.4	227	20.4	226	22.5
Spain	125	9.7	45	7.5	80	11.6
Sweden	250	18.3	136	19.7	114	16.8
Total	2,299	17.6	1,168	17.9	1,131	17.3

Yngve et al, Ann Nutr Metab, 2005

Too many children do not meet the recommendations

Presented in a slightly different way, we calculated how many children met the recommendations given by the World Health Organisation and less than 20%, about 17/18% of the children met the recommendations showing the importance of campaigns promoting F&V intake.

As I said we also assessed what are the most important determinants of F&V intake and this table present results form the low Countries which are the Netherlands and Belgium for fruit intake.

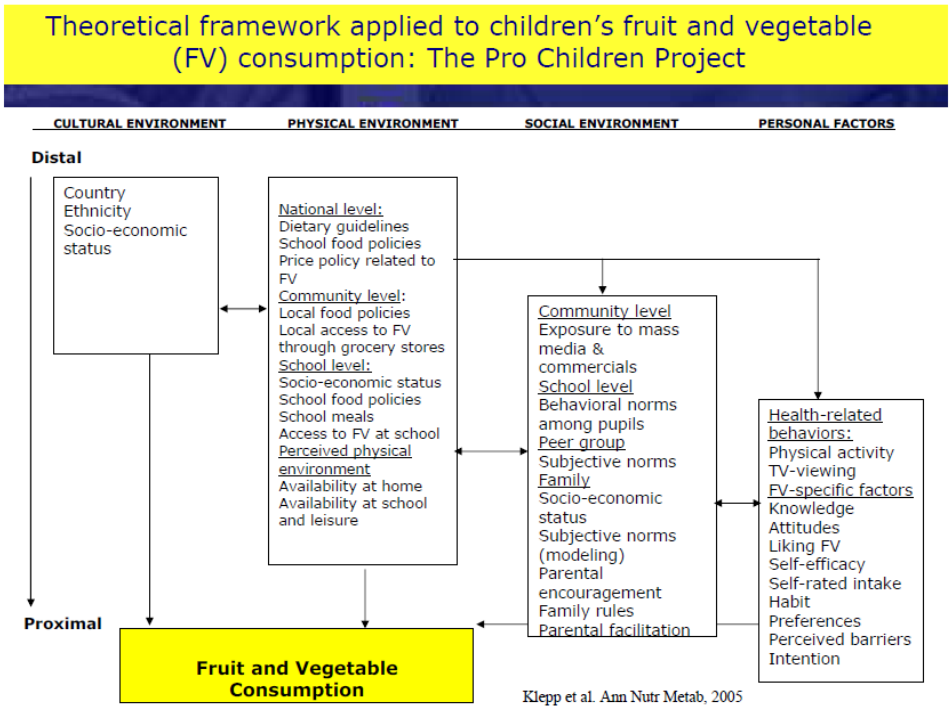
BLOCK OF VARIABLES Variable	Number of items	Adjusted R^2 = 0.03 Beta	 P value	Adjusted R^2 = 0.16 Beta	 P value	Adjusted R^2 = 0.24 Beta	 P value	Adjusted R^2 = 0.34 Beta	 P value
DEMOGRAPHICS									
Country (0 = the Netherlands; 1 = Belgium-Flanders)	1	−.03	.13	−.06	<.01	.03	.16	.05	<.01
Gender (0 = boys; 1 = girls)	1	.15	.00	.07	.00	.06	.00	.05	<.01
Age (range: 10.3-13.8)	1	−.01	.66	.00	.94	.00	.94	.01	.60
Parent's country of origin (0 = both parents born in Belgium/the Netherlands; 1 = at least one parent born in other country than Belgium/the Netherlands)	1	−.09	.00	−.07	.00	−.04	.03	−.04	.02
Family status (0 = two-parent family; 1 = one-parent family)	1	−.05	.02	−.06	.00	−.04	.03	−.04	<.05
PHYSICAL ENVIRONMENT									
Availability at Home*	1			.13	.00	.07	.00	.01	.60
Availability at School*	1			.03	.20	.01	.52	.01	.48
Bring to School*	1			.31	.00	.24	.00	.16	.00
Availability at Friends'*	1			.05	.01	.00	.95	−.01	.64
SOCIAL ENVIRONMENT									
Modeling*	3					.21	.00	.14	.00
Active Encouragement*	2					−.04	.10	−.02	.27
Parental Facilitation*	1					.08	.00	.04	.03
Parental Demand*	1					.15	.00	.12	.00
Parental Allowance*	1					−.01	.57	−.01	.80
PERSONAL									
Knowledge (0 = does not know recommended intake level; 1 = knows recommended intake level)	1							.17	.00
Attitude*	2							.01	.60
General Self-efficacy*	2							.12	.00
Liking*	2							.18	.00
Preferences*	12							−.02	.47
Perceived Barriers*	4							−.07	<.01

*(−2 = fully disagree; +2 = fully agree)

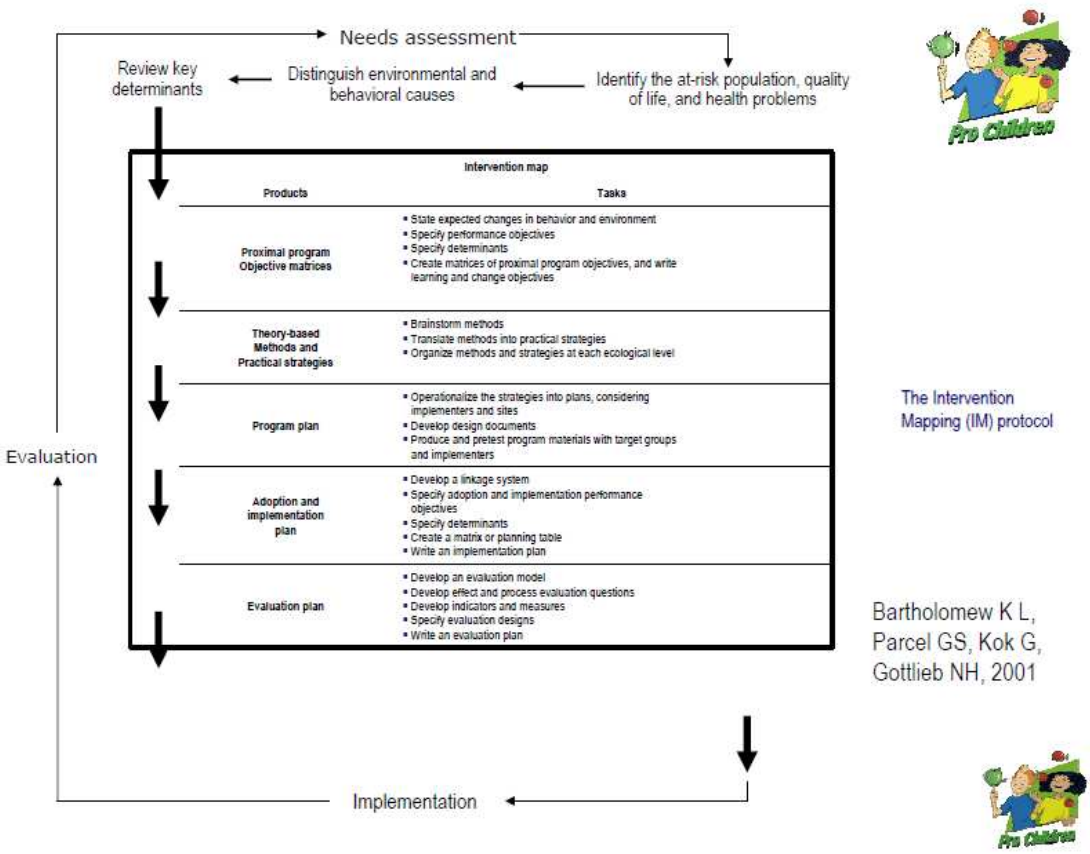
(Wind et al, J Nutr Educ Beh 2006).

We looked at determinants from different domains. You can find demographic variables, the Physical Environment variables, the Social Environment variables and the Personal variables. The green arrow show significant associations with fruit intake and you can see that variables from the different domains all relate to F&V intake. You can again find gender, age but also bring to school and nearly all social variables so parents are very important and of course knowledge and self-efficacy for fruits. In a table with vegetable intake more or less same variables came out.

This brings us to next step of health promotion which is the intervention development. Coming back to the main aim of the Pro Children study, it was to develop, implement and test evidence and theory-driven strategies to promote the consumption of fruits and vegetables among school children (10-12 year olds) and their parents and we aimed to increase F&V intake by 20%.



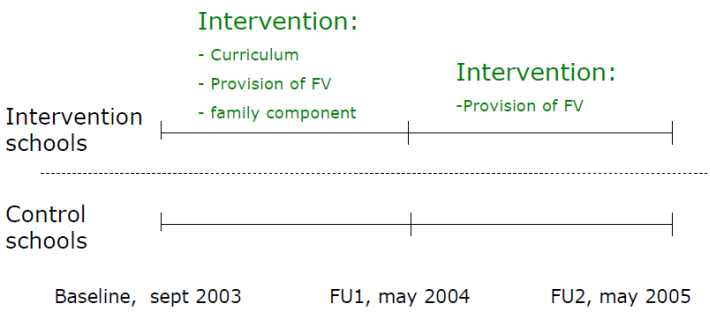
This model guided the development of the intervention and presents all variables that might be or are important according to literature and qualitative researches. You can find the different categories cultural environment, physical environment, social environment and personal factors and you can also see that those variables listed on the left-hand are more distal from the child that the variable on the right hand side.
We used the intervention mapping approach to design the intervention. This approach is described by Bartholomew et al. and results for the Pro Children study are reported by Carmen Perez-Rodrigo. We aimed at improving knowledge of the recommendations, improving better attitudes toward eating F&V, improving self-efficacy by giving them skills to eat F&V and also to improve availability and accessibility both at home and at school. The Pro Children intervention was a multi component intervention which was explained in the previous presentation. It consisted of the classroom component, school component and the family component.
The next graph is the scheme for developing interventions that shows you the different steps. We had to write down the objectives, we selected strategies, how we could aim at improving knowledge etc. and we described the program.



In the classroom component, we used a taste testing to expose the children to various fruits because sometimes they only knew apples and did not know what a mango taste like. There also educational materials as exercises with fruits. The school component consisted of a free provision of F&V during the breaks like a snack. And the family component consisted of various activities; the children brought home some homework assignments that they had to do together with the parents. For instance they had to go to the supermarket or they had to prepare a recipe. There was also a website which the parents could visit and they could do the tailored feed back tool so they could get advice on how to improve their F&V intake. And there were some newsletters that the children brought home which gave the parents all sorts of tools on how they could motivate the children or support the children improving their F&V intake.

Now I will come to the evaluation of the intervention that has been reported in the British Journal of Nutrition. We used the evaluating design that was a cluster randomised control trials meaning that schools were the level of randomisation. The intervention was only implemented in three countries that were Norway, Spain and the Netherlands.

Basically this picture represents the design.



We had two groups, the intervention schools and the control schools and we did an assessment of F&V intake and their determinants before intervention started then we implemented the intervention during one school year so between September and May. Then we did our first follow-up measurement and one year later we did our second follow up measurement. During the second year, there was only free provision of F&V; there were no educational materials and no newsletters. The schools were recruited for participation and after their agreement they were randomised as control and intervention schools. In total, 1,472 children had complete data on all three measurements and we used the 24h recall questionnaire to evaluate the intervention.

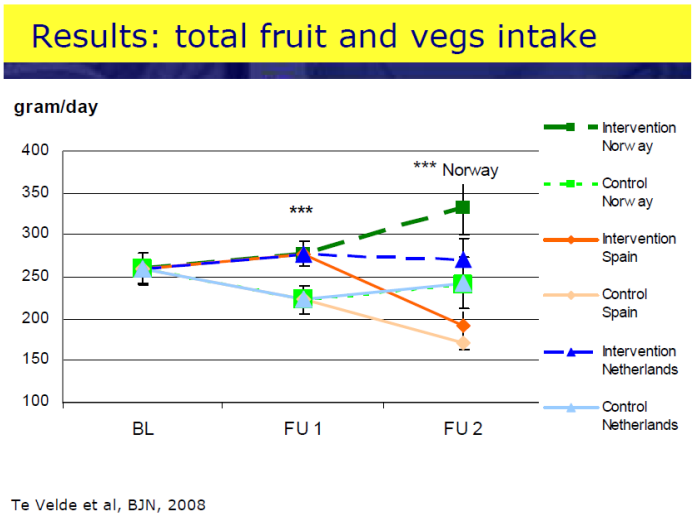
These are some descriptive statistics from the study population. Again you can see that the mean age was about 11 years old, there are slightly more girls than boys and you some data about the family structure and educational background of the parents.

Table 1. Demographic characteristics of the intervention and control group

	Intervention	Control	*P*
Subjects			
Norway (*n*)	231	281	
Spain (*n*)	286	205	
Netherlands (*n*)	281	188	
Age (years)			
Mean	10·8	10·7	<0·001
SD	0·54	0·54	
Boys (*n*)	365	333	
Boys (%)	45·7	49·4	0·088
Families (*n*)	792	669	
Family structure			
Subject lives with both own parents (%)	76·4	77·9	0·271
Subject does not live with both own parents (%)	23·6	22·1	
Subject lives with two adults (%)	85·7	86·8	0·295
Subject lives in single-parent family (%)	14·3	13·2	
Family educational level (*n*)	701	544	
< 7 years (%)	8·3	8·1	0·918
7–9 years (%)	25·2	17·8	0·002
10–12 years (%)	26·0	31·4	0·036
> 12 years (%)	40·5	42·6	0·452

We analysed our data using regression analysis, multiple-level analysis taking into account that the children were clustered within schools.

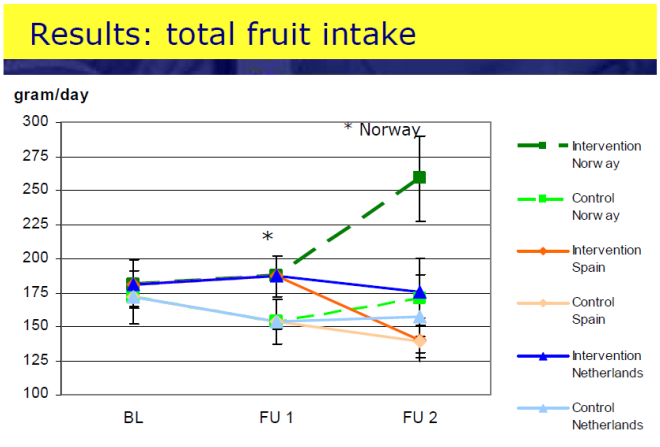
This graph shows the total F&V intake. You can see the F&V intake in grams per day which is adjusted for age and gender and the axes you see the three measurements: baseline, first follow up and second follow up. The different lines represent the different countries and the different groups. So dark green is the intervention group in Norway, lighter green is the control group. We have dark and light orange for Spain and blue for the Netherlands. As you cans see, after one year the intervention groups increase their intake while the controls decrease their intakes and this difference was significant. After another year where children were only provided with free F&V but not with educational materials only the Norwegian children further increased their intake while the other children remained stable or lower their intake. In the second follow up only a difference in Norway between intervention and controls schools was statistically significant. This graph has been made from the results on fruit intake and the results on vegetable intake.



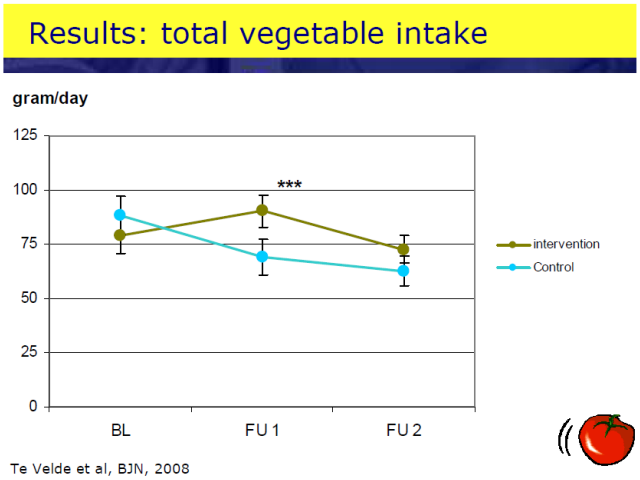
Te Velde et al, BJN, 2008

On the total fruit intake results graph, again we can see that only significant differences in all countries at first follow up and at second follow up the Norwegian children increase their fruit intake while the other children from the Netherlands and Spain decrease or more or less stabilised their intake and there was no significant difference at second follow up.

For the vegetable intake there was no different picture between the three countries so these are the three countries together. Again intake is on the y axis and the different measurement on the x axis. You can see a significant difference after one year but this disappear after two years.

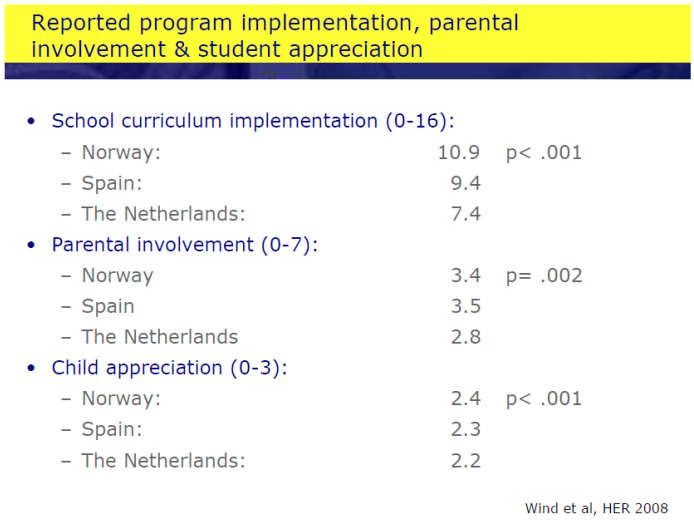


Te Velde et al, BJN, 2008



Te Velde et al, BJN, 2008

We did not only evaluate the intervention regarding the intake but we also wanted to know how well the program was implemented in order to explain our findings. So we asked teachers to complete logbooks and other questionnaires and we scored the teacher implementation of the school curriculum. The score could range between 0 and 16 which is actually the number of lessons that could be implemented. We also asked the parents about their involvement in the program with a score between 0 and 7 which is the number of activities that were organised. We asked them about homework assignments and the newsletters. We asked them if they visited the website and did computer tailoring and we asked them about whether they went to parental meetings or other activities at school. And finally we asked the children how they appreciated the program. There were 9 items questions asking about it.



Here are the results for the different countries on the different process measures. As you can see, in Norway, most curriculum lessons were implemented; almost 9 of the 16 lessons were implemented in Spain and the Netherlands scored worst with only a little bit more than 7 lessons on average implemented and the difference between the countries was significant. Regarding the parental involvement, Spain and Norway scored best significantly better than the Netherlands with more parents involved in the activities. And, regarding the child appreciation we can see that the average scores are closed to 3 so meaning that the children appreciated the project very much, they liked the various activities they did in the class room which is a positive thing.

I come to some conclusions, first regarding the implementation. We did some analysis relating the rate of implementation to the change in F&V intake in the children and we found that the schools or the countries where the project was best implemented, the most changes were achieved in the F&V intake. Also among the parents we found that when parents where more involved in the studies, they increase most their own F&V intake. However, we also saw that the implementation was rather low especially in my country the Netherlands. I think we found some good results after one year but not after two years. The rate of implementation might be one of the explanations especially because we saw that results were best in Norway where I think the program was best implemented as they had a special teacher which can devote all his/her time to the project while in the two other

countries teachers had to do this as an extra task. Another thing regarding the parental involvement, it is very important to get the parents involved because they act as role models and we also saw in the previous presentations that parents are important and the parental variables are important in the determinants. They can play a role model, they can support their children, and they make F&V available in homes and make them accessible. My final conclusion can be that because we did not find a sustained effect, it can be results of not that good implementation. Regarding vegetable intake it might be that the home environment important for the vegetable intake. At the schools the children were provided mostly with fruit and not as much vegetables.

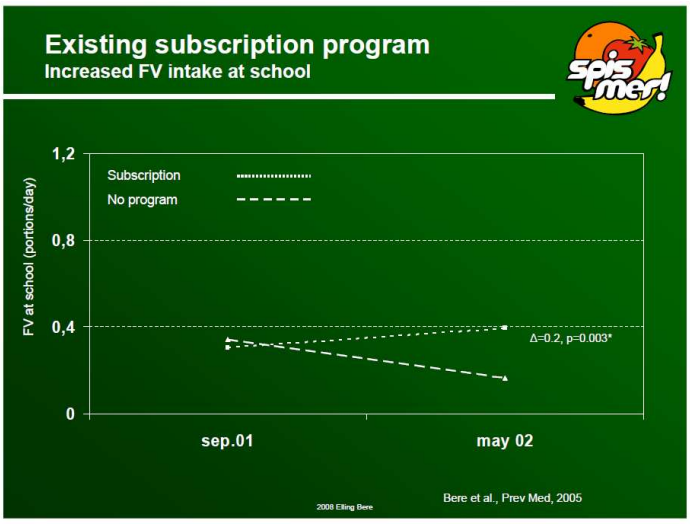
Free school fruit might give long term effects – Results from the Norwegian intervention study FVMM

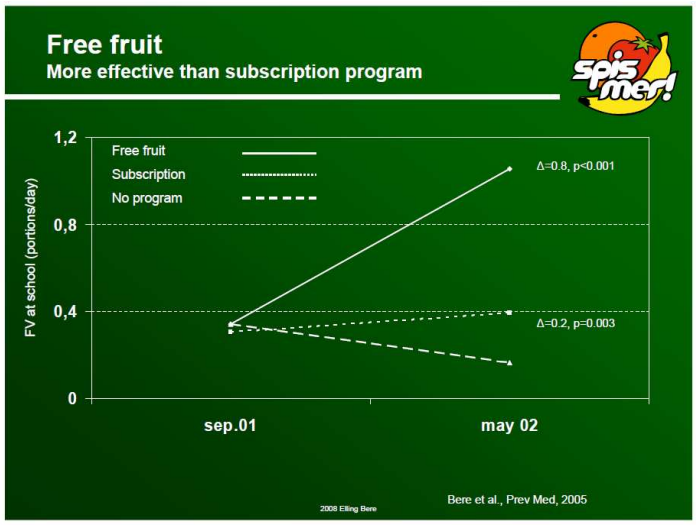
Elling BERE
University of Agder, Faculty of Health and Sport, Norway

This project is a research project, it is a Norwegian project. The reasons this project was applied for using kind of the same of the Pro Children. While the Pro Children was applied with EU money at the same time the project was in NOK but Oslo applied also for money in Norwegian Research Council. We started this program a bit earlier then the Pro Children project but the methodology and the design of the study is rather similar to Pro Children but what I will focus on in the presentation it the effect of the Norwegian School Fruit program that we had evaluated and also the effects on this program with fruits provided for free.
There is an existing School Fruit Program in Norway, it is a subscription program offered to all Norwegian elementary schools. Since it is a subscription program it has a cost, parents or the children, probably the parents have to pay NOK 2.50 a day which is approximately 0.30€. The program is also subsidised by the Norwegian Government and that is an important thing you should keep in mind, for those pupils who do subscribe they get NOK 1.00 per pupil per day. It happens like this: we pupils go to get the fruits, most of the time the fruit mostly provided is apples and they eat it during lunch or after the lunch. We included 38 schools randomly chosen in 2 different counties and almost 2,000 pupils participated in the project. The intervention for this project lasted for 1 year. We were able to give free fruits to 9 of the 38 schools so all the pupils at those schools were able to participate in this program for free. And of course when you offer something for free people do not say no so all the pupils wanted to participate. Then the remaining 29 schools had to choose to subscribe or participate to the normal existing program and 9 schools did and the remaining 20 schools did not participated in this program during the school year. The fruit was not provided before October so we collected the data in September 2001 before the program started and then again we collected data in May 2002 when the program was running so at the time they got the fruit at school and then again in May 2005 so that is three years after the end of the intervention.

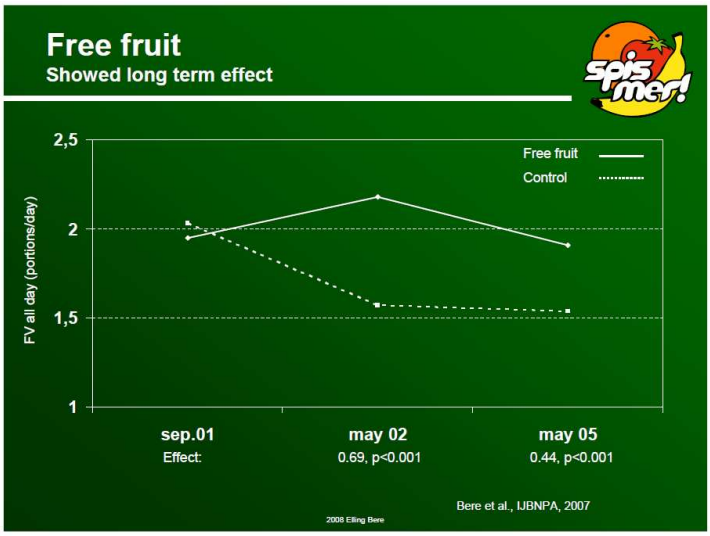
I will present basic points based from the results of this project. The first point is that providing free fruit was much more effective in increasing children's fruit and vegetable intake than the existing subscription program. The reason why the subscription program is not effective is first of all because few schools want to participate. Less than half (41%) of the schools in Norway participated in this program. The second reason is that at participating schools few students want to subscribe. In total and this is number from 2006, only 12% of the Norwegian school population from 1st to 10th grades did participate in this program. I think the figures are a bit higher now but not that much. The effect of this existing program is

therefore limited. On the first graph we can see on the white axis that there an increase in intake of F&V at school. And you can see in those schools providing the school fruit program, the pupils increase in average their intake with 0.2 portions due to the school fruit program. It is a significant effect but it is not very large. Then looking at the schools that were provided with free fruit (second graph) the effect is about 0.8 portions compared to schools not participating in the programs. So the effect of free school fruit is of course larger than the subscription program due to the fact that everybody wanted to have free school fruit.

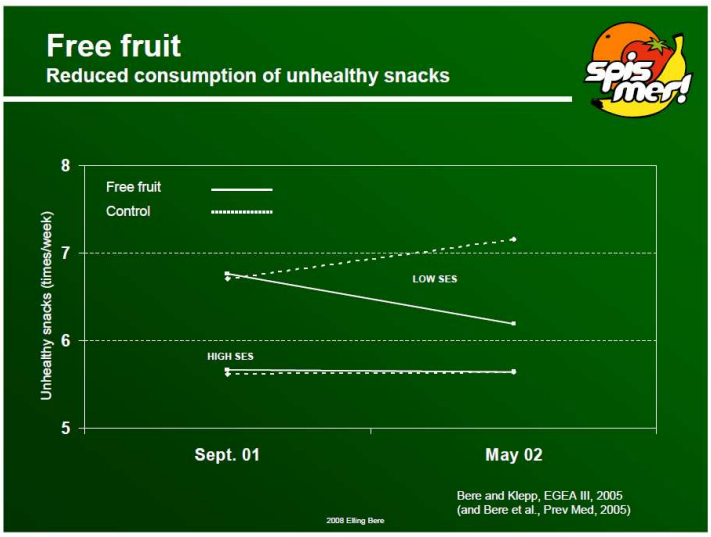




The second point is that we saw long term effects. These pupils given free school fruits for one year eat also more F&V than the controlled pupils three years later.
This is a different picture on the last graph as it is F&V all day, still important and the control group is combined from the 20 control schools and also including the 9 schools participating in the existing program because the effect of that program was rather limited. So as you can see there is still an effect three years after they were provided with free fruits. Partly, this can be explained by a higher subscription rate because those schools participating in the School Fruit program for free in 2002, some schools also participated in existing program in 2005 so three years later. Then those pupils who were given free fruits, they participated or subscribed in much higher rate than pupils not given free fruit for a year. So something has happened but this fact does not explain the full difference 2 years later.

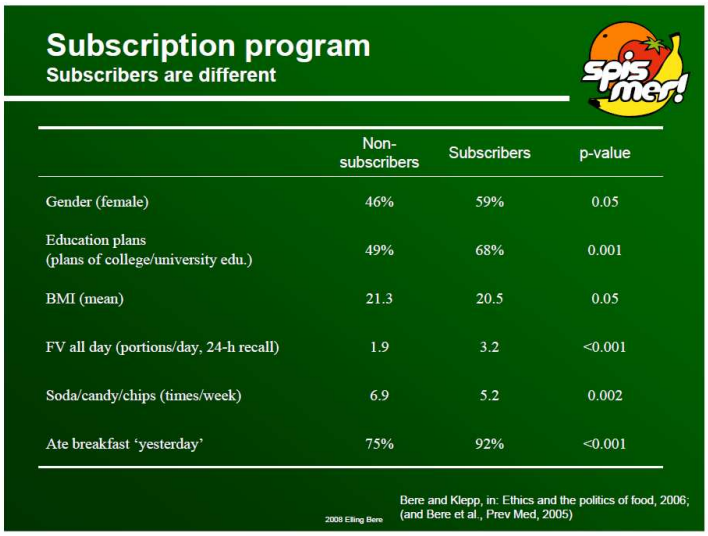


We now get more money so we will do another follow up in 2009 so that will be 7 years after the free school fruit launch to see if there is really effect also when they have finish elementary schools and when there is no subscription program offered. The cost benefit analysis has been conducted by the Health Department in Norway. They wan tot find out how, what effects free school fruit program would have for 10 years. How large the increase in lifelong F&V intake should be in order to be economically profitable or to at least not cost to the nation? Such analysis is based on assumptions. They have biases but the point here is that the amount of lifelong increase in F&V intake is so small, it is only 2.5 grams, you can almost not measure it on a kitchen weight and certainly we can not measure it using our 24h recall and FFQ. So the amount of lifelong increase is very little. We will continue with this cohort. On the last graph the effect was about 0.4 portions per day in our studies about 80 grams so that would be about 30 grams effect on the free school fruit for one year is about 30 grams when measured 3 years later. So it would be exiting to see how the effect will develop and if there is an effect and that is of course a really important thing to look at.



The third thing is that we also saw that some students reduced their intake of unhealthy snacks when they were given free fruits. We made a scale out of soft drinks including sugar, candy and potato chips.

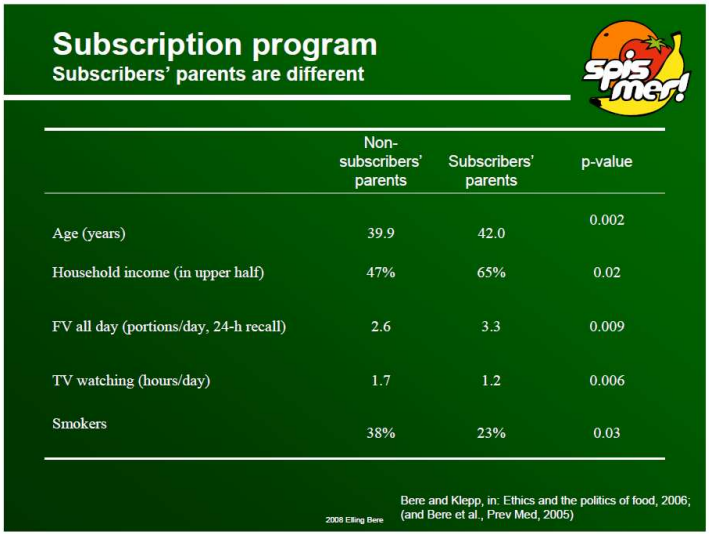
The interesting thing is that this effect was not for all children but was for those children with parents without high education so it was only among the children with a low socioeconomic status. Thos children with low SES eat in average much more unhealthy snacks than the children of parents who have education. So, this is also an interesting effect. We did not see any long term effect of this snacks intake.



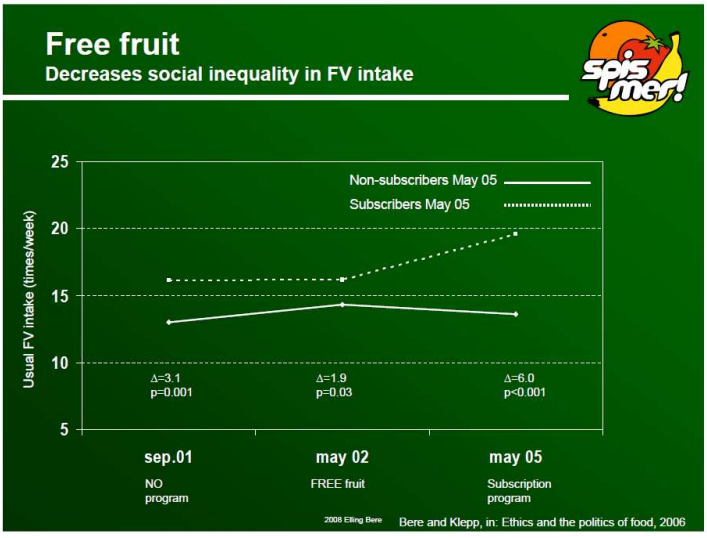
Then the social inequalities, because the subscription program, the pupils and the parents had to chose to subscribe or not to subscribe.

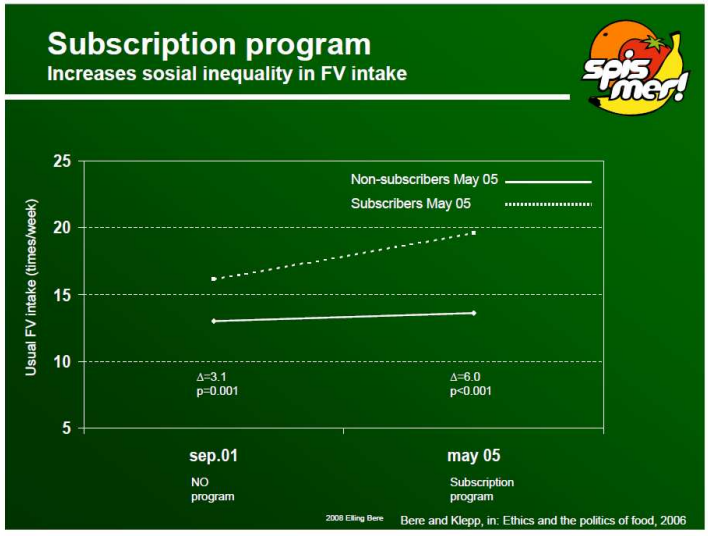
There is a very clear difference between those who subscribed and those who did not. Girls subscribed in higher degree, those with education plans subscribed in higher degree. The subscribers have a lower BMI, they eat more F&V before the project starts, they eat less unhealthy snacks and have a more regular meal pattern.

It is not only the children, it also the parents. Subscriber parents are older than non subscribing parents, they are richer they eat more F&V, they watch less television and fewer of them smoke. So there is a clearly different group that subscribed and those are healthier. Therefore the subscription program works among those that do not really need this. The people we really want to reach are the ones that do not subscribe in that program.



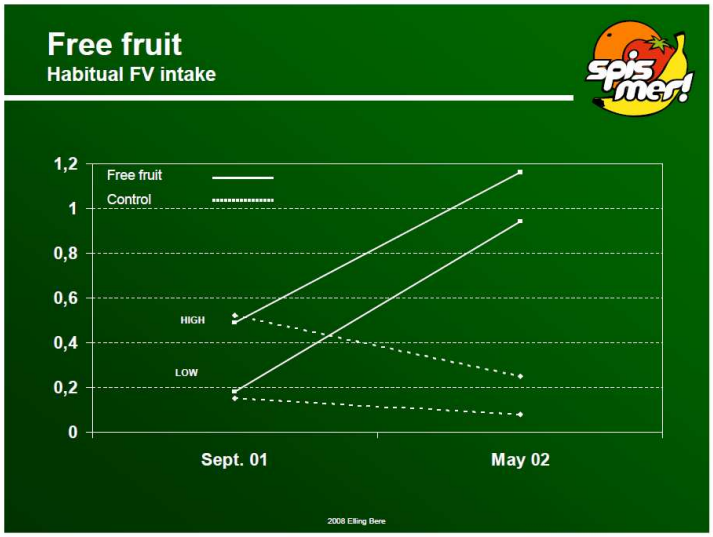
Presented in a slightly different way, this is a sub sample of the school cohort I will tell you late why I chose this sub sample but the point is that we have divided them among subscribers and non subscribers in 2005. There is a large difference in F&V intake in 2005 between the subscribers and the non subscribers. This is again a different scale as it is based on fruit frequency measures. What you can also see is that those two groups are also different in September 2001 that is 2 and a half year earlier. What is interesting here is that these pupils also participated in the school fruit for free in 2002 and when you see what happened when they participated for free was that the difference between the subscribers and non subscribers in 2005 was smaller than it was initially in 2001.





So this indicates how a free program works on the different groups and how it is compared to the subscription program. A free program tends to reduce the effect while subscription program increase the effect in social inequalities in F&V intake.

When we measured the effect of the intervention we checked to interaction with social status, gender, and so on in order to see a statistically different effect in the different groups. We had not seen any such effect except for the one I told you about, the unhealthy snacks. So with the graphs I have stratified on usual F&V intake and you see those with a low intake and those with high baseline intake there is a huge difference in F&V intake at schools before the program starts. There is also a difference while the program is running but both groups increase their intakes. The important thins is that those that are eating little F&V are also increasing their intake substantial and those are the ones we really want to reach.



In conclusion, Free School Fruit is more effective than the existing subscription program. Free school fruit show long-term effects. Free school fruit decrease consumption of unhealthy snacks at least in a part of the cohort. And free school fruit tend to reduce social inequalities.
For the happy news, last year the Norwegian government decided to give some pupils free school fruit so all pupils in Norway from grade 8th to grade 10th have now Free School Fruit every school day. We hope that they will continue and we also hope that they want to include the classes we want to grade 7th. One of the reasons at least the politicians decided to give Norwegian schoolchildren free school fruit was that in 2005 we had an election and before the elections the three parties that are now in the government all wanted to a free school meal not only free school fruit. So, that kind of made it easy for them to at least give some children free school fruits.
Just a final point I want to make not about the fruit but in Norway we import 95% of fruit and I think the amount that we import is increasing. We only half of the fruit that we should, the recommendations are at least two portion a day. But the funny thing not really funny but calculations have been done is that there are enough blueberries in Norwegian forests to meet all the daily portions of fruits every day and I think it is kind of stupid that we import that much.

Q&A

PUBLIC (Corinna HAWKES, Freelance Consulting and Research or the University in London): I have a question for all the speakers about taste. In any of the studies that you have done did you evaluate whether the children liked the F&V more than what they had been offered before? Where is the taste element in that? Did they found it tastier or else? Because I heard anecdotes that, let's face it, not all F&V taste that great, sometimes it is not such great quality and how important was it to make it really tasty in the success of the interventions?

C PEREZ-RODRIGO: In Pro Children we really included tasting preferences as part of the intervention component. We included tasting activities and we also suggested taste testing at home preparing recipes based on F&V that they could prepare whether at home or in the schools and then share it together as part of the tasting activities. In the evaluation we looked to that. But, certainly from the literature we can tell you that preferences is really a strong predictor of the amount consumed and it should be insisted and not just on limited actions but over time on the tasting activities, an higher exposure to wide variety of F&V both at home and at the schools.

S Te VELDE: I remember we looked at the effects at the preferences and taste and what I do know is that the children already had a high level of liking fruits so it was hard to improve the liking of fruits. But, for vegetables it could be a bit better. We had some results on the liking of vegetables but I do not know them by heart but I know it is an important issue.

PUBLIC (Robert PETER, from Danish Cancer Society): Just a comment because I have done a lot of work with running school F&V schemes and I thing one of the biggest issues is taste. If the children do not like the F&V then the program do not work very well so we have done a lot of research on how children taste effect of the varieties that we choose. Availability, accessibility is key but I thing, taste, quality, seasonality, freshness is really key to work in school fruit schemes.

PUBLIC (Ron LEMAIRE, 5 to 10 program in Canada and IFVA chair): I have a question on impact on home consumption. I know there has been a reference, comments about Food Dude where it has seen impact on increased consumption at home, an impact to also the educators that were involved in the program. Have you seen any research that has shown either positive impact at home and/or negative? Whether the responsibility of the parents in a free schemes happening basically is seen as now being transferred to the institutions as opposed to the home?

K LOCK: As I pointed it out, the problem is that there are a lot of interventions that have looked at different combinations of components; some were free, some with

subscriptions plus or minus parents, plus or minus education. So we can not actually say. There have been a number of studies I showed between younger and older children and again the parents were involved in different ways. It is not easy that we get parents to do activities for themselves or actually doing activities for the children or reporting on what happened at home. It does seem to be a positive thing but we can not say whether or not it is essential or whether it adds a significant amount of extra in terms of intake. I think it seems anecdotal about what you are saying that is are we transferring responsibilities to the institution by doing school F&V schemes and it does not seems to be any evidence of that. Actually there numerous examples that by raising awareness through schools and through children and very big branded product, promotion products and schemes it actually seems to have beneficial effects even wider than schools and parents. So that is only anecdotal, sorry about that.

C PEREZ-RODRIGO: In the Pro Children program, at least in the interventions in Spain we had a discussion regarding this because we started the provisions of free F&V in the schools which were already provided through school meals but an additional component of provision of Fruit for fruit break. The debate was about the schools really complained that whether they should be providing this or it should be more highly encouraged the participation of families who would provide the fruit so that the children bring themselves the fruit to schools. We had this debate. I can not remember the reference on an intervention providing free F&V in schools that was observing a shift so that overall consumption did not change because since family thought the children have it in the schools then they provided less at home.

PUBLIC (Christina POLLARD from Australia): A lot of the programs are being conducted in countries where you had high awareness programs or campaigns promoting increasing awareness of the amount and types of F&V should be eating. I am assuming there is some awareness of the general community that is very important of F&V that people should be eating more. That multi component approach where perhaps there are other interventions together with school schemes and interventions, that would create an environment that would encourage increased consumption across the board. I just wanted to comment about the multi-component strategies and where school programs fit or may fit?

K LOCK: Apart from my main research, it is exactly what Carmen Perez was presenting on the sort of environmental, the wider environment and what Pro Children had studied in more obstruent determinants. Absolutely, there is lot of research and very various people have been looking at this sort of wide environmental determinants and of course that the whole F&V schemes are just one part of that. That is why the Pro Children study is very innovative because it was looking at individual family schools and the wider environment.

PUBLIC (Anne-Marie SOUQUET du Réseau de Prévention de l'Obésité Pédiatrique en Ile de France) : Nous sommes en effet très concernés par les F&L mais je voulais attirer l'attention sur cette distribution de fruits et prendre simplement le cas particulier que je connais bien qui est non seulement la France mais plutôt Paris. Puisque dans Paris on a plus de 80% des enfants qui mangent à la cantine et nous avons aussi ce qu'on appelle des commissions menus etc. Dans le menu normal d'un enfant qui mange à la cantine, il a déjà à sa disposition au moins 2 fois par semaine le fruit puisqu'en France on mange un repas complet et chaud à midi. Donc, dans la lutte que nous avons, puisqu'il faut recadrer ça dans le cadre de la prévention de l'obésité, on a beaucoup parlé même au niveau européen de la distribution de ces fruits mais ce qui est important est de savoir quand est-ce qu'on va les donner. On a moins parlé des légumes qui sont tout aussi important. Je voudrais faire le parallèle par rapport à cette distribution de fruits avec la distribution de lait qu'on a eu en France après la guerre dans les années 50 parce qu'il existait une carence réelle en lait. Le gouvernement a donc permis une distribution gratuite de lait dans les écoles, ce qui était très bien au départ et qui petit à petit à eu un biais. De lait on est passé à rajouter des petits gâteaux, on a donné ça en plein milieu de la matinée ce qui fait que maintenant nous, on se bat, en on est là actuellement pour qu'on supprime cette fameuse collation du matin qui facilite l'effet pervers de faciliter le grignotage et qui est passé du lait avec des petits biscuits avec même du saucisson parfois. Donc maintenant notre but est de supprimer complètement la collation pour éviter ce souci de grignotage. On sait aussi que si on mange trop de fruits, il ne faut pas oublier la teneur en sucres des fruits donc attention, des fruits oui mais 2 ou 3 fruits par jour attention. C'était une réflexion que je voulais vous livrer pour voir si vous aviez d'autres commentaires.

C PEREZ-RODRIGO: I think the evidence show that overall in most countries and in most places, children and young people in this particular population group right now it would be desirable. Of course they might be groups of people who are eating often F&V so this is ok and we are just trying to maintain this consumption at level but this is not the case for most people. So, any strategies in trying to get higher consumption levels would be welcome. And I think strategies need to be comprehensive, multifaceted and multi component to be effectives. So we are now focusing a lot on environmental actions like the provision of increasing availability and access to F&V because it has been proved that this contributes to enhance consumption and particularly to decrease inequality in access to F&V and I think that this is the sort of main key fact. However, the provision of F&V only is probably not likely to be effective, it should be complemented by other action like educational strategies and we have seen from the review on determinants that self-efficacy is very important. Being aware of the amount that each one is consuming and what would be recommended levels is also important. What the children experience in the schools and in the family is very important. So, there are a lot of component that should be looked at and should be included and not only, not just the provision of

F&V. The provision increases access and increases availability and that is also very important and is also very important for disadvantage groups. I think it is just looking to population we are working with and look into which are the specific needs and the specific characteristics of this particular group. We really believe in working in Pro Children where we were working in 3 very different countries: one Nordic country the Netherlands which is quite up North in Europe and Spain in the South of Europe, all with different cultural backgrounds and different SES conditions even in the participation both in intervention and control schools and we have to be keep all these factors in mind. It is essential in any interventions and health promotion that we look into these factors and try to choose what is likely to be more effective and more adapted to the real life. And also looking and I think this is very important, to sustainability and not just for a pilot intervention that would be concluded after few months but looking in the long term. Other considerations regarding the content of sugar and displacement for the fruit, I think that should be part of the overall intervention.

K LOCK: On the Paris experience it was interesting you were saying about the milk scheme and I think most of European countries now are getting rid of school milk for the reasons you pointed out. But if you did not hear the presentation by Barbara Rolls, I will recommend you look at her research which seems to show that actually introducing F&V as a snack or F&V in the meal which is what is obviously you do in France, is going to be good. People are going to eat less, less high density energy food and hopefully tackle overweight and obesity so I do not think you have to worry about increasing snack provisions as long as it is F&V and putting them in the meals as well. But also I think you are right, when we looked through the systems in the Pro Children studies, every school system is different. Some have school meals, some do not. Some have snacks programs, some no. We are solely focus on snack programs.

PUBLIC (Helen MUEHLHOFF from FAO): I would be very interested to know from the panel what readiness there is in European countries, the Ministries of Education to actually integrate food and nutrition education into the curriculum. I think we have seen and heard from these various studies that there are obviously some very excellent efforts ongoing but they seem to all be on a pilot scale. So, I would like to know what initiatives are there in place to integrate food and nutrition education into the curriculum to provide children not only knowledge but also the skills and the motivation that they need to change their dietary habits in a longer term.

P DUDLEY: The New Zealand program is not a pilot and the curriculum has fully been liked through the health promoting schools and bringing to home involved into the provision of the F&V. There are going to be about 100 thousand children by probably the end of 2008 and as I said before is getting well evaluated.

K LOCK: (…) When I look just in terms of F&V schemes, there were number of coexisting nutrition and education programs running alongside these schemes that are already embedded depending on the school system. We did not look at them in particular, some of them were not necessarily focused on F&V obviously there was various nutrition intervention initiatives. I suppose what you have been hearing here is that only those ones that are specific to the school F&V schemes that we have discussed so I think there is a difference and you are right. Some people have integrated the F&V programs within a wider nutrition education curriculum and some have stand alone education components but absolutely sustainability will be ideal to have everything integrated. I do not know if someone now has done the analysis in that respect in detail.

PUBLIC: The Food Dude program did show that based on evaluation in terms of teachers and parents that there was an increase in terms of portions that children were bringing to school and this as such that there was a clear demonstration of the positive effect beyond the children themselves and also the families as well as the teachers. This was a 12 months evaluation but I think that is a quite important one and I think we need to expand that to other programs. About the school milk, Karen Lock said we were going to stop it, absolutely not; on the contrary we want it to be a success therefore we have directed it into more healthy types of diary products with low fat and that is the reason why we changed completely the system. I do not want to suggest that diary products are unhealthy, that is certainly not the case. I think about almost diets include also diary products. We are trying to change it from high fat to low fat with more healthy results. The last issue about whether there is a nutrition policy, in fact I think this is an important thing and the school Fruit Program on an EU based could be sort of the start or an initiative which could also inspired because we are asking for a national strategy and this would also include obviously, taking into account wider aspect that just the consumption of F&V.

SESSION 15

F&V NUTRIENT PROFILING: WHAT ARE WE GOING TO BE ABLE TO SAY IN THE FUTURE?

Chair: **A. Martin**

- Introduction? **A. Martin**
- Nutrient profiling of foods: a systematic approach. **M. Rayner**
- Validating nutrient profile models. **J.L. Volatier**
- Nutrient profiles, pleasure, and cost. **A. Drewnowski**
- How to communicate nutrient profiles to the consumer?
    - AFSSA point of view. **A. Martin**
    - EFSA Representative. **L. Heng**
    - Consumer's association representative. **Ch. Pernin**

Introduction

Ambroise MARTIN
Faculty of medicine, Lyon, France

My name is Ambroise Martin, I am a professor of nutrition, and biochemistry also, in a medical school and in Lyon in France. I am a member of the expert committee of the French Food Safety Agency, and I chaired the working group of nutrient profiles. I am also a member of the NDA panel, Nutrition Dietetic Products and Allergy, in the European Food Safety Authority. And I am also member of the working group of claims in this agency.

So as most of you already know, nutrient profiles is a very hot topic in the European context since the publication of the new regulation of claims, and the introduction of nutrient profiles as a condition for the food to be able to bear a claim. Since the first discussions about the introduction of nutrient profiles, there have been many, many works on that in the scientific community. Since a long time, nutritionists, dietitians, use nutrient profiles. But they use them in a qualitative way to do counseling of the patient, and the challenge for the nutritionist was to develop nutrient profiles in a quantitative way in a regulatory context. And also, there is a constraint of a timeframe because the nutrient profiles system should be adopted by the Commission by the end of January of the next year. So for the moment, theoretically, Member States are negotiating what could be the European system.

So we do not know what could be the final result. We can give some indications about what has been done in some countries, for example, in the U.K. and in France, but there are many, many other systems. And the list compiled by the FSA indicated about 38, perhaps 40 now, different systems in the literature, including the gray literature.

So the first presentation will be given by Mike Rayner about the development of the food standard agency model, and as an example of a systematic approach, how to answer to the questions which are in the regulation. And then a presentation will be given by Jean-Luc Volatier because science cannot answer to all these questions. And one of the ways for the input that science can have, is to try to assess the result of the system, how can we be sure that the system gives the right result and the expected result, and so on. So there will be something about that by Jean-Luc Volatier.
Then the third presentation by Adam Drewnowski about things which are not in the regulations, but which could have very important consequences for the consumers about pleasure and cost in relation to nutrient profiles.

So it is a logical order, and I propose to be on time and to stop at 7, to begin with the first presentation. Before that, just a word. The presentation will take about 15

minutes, so I think we will have 5 minutes for discussion. It could be, perhaps, interesting to reserve after each presentation to have few, very specific questions about the presentation, perhaps to have more time after the first 3 presentations for general discussion when you will have a clearer a view of all the problematic.

Nutrient Profiling of Foods: A Systematic Approach

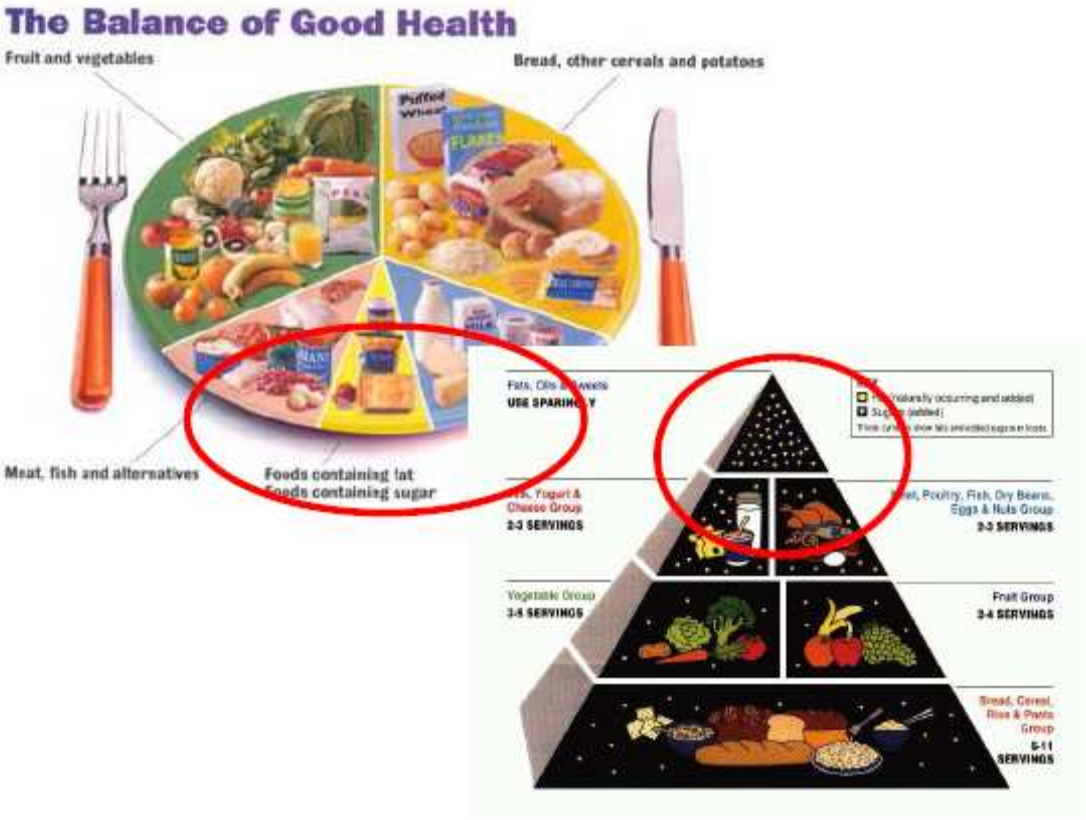
Mike RAYNER
British Heart Foundation Health Promotion Research Group, University of Oxford, UK

Thank you very much, the organizers, for inviting me to speak about the nutrient profiling of food, a systematic approach. Because I am the first speaker, I have the luxury of introducing the subject to you, so the aims of my talk are going to be to define nutrient profiling, what do we mean by nutrient profiling? Look at some things that are around why we need it, then to talk what systems are developing models, and that's the main body of my talk, and then briefly to talk about validating and comparing nutrient profiling models.

So, what do we mean by nutrient profiling? Well, this is our definition in a publication by Michael O'Neil, 2004. We think nutrient profiling is a science of categorizing foods according to any nutritional composition. And this means that nutrient profiling can provide definitions of terms applied to food such as high or low in a nutrient like fat. High or lower in a nutrient relative to foods of the same category, but in this talk most likely I'm going to be talking about these last 2 types of definitions generated by nutrient profiling models. Healthier and unhealthy, per se, or less healthy and healthier, per se, and also healthier and less healthy by comparison by foods in the same sorts of categories. I think it's important to distinguish these 2 meanings of the term, "healthier" and "less healthy."

How I think nutrient profiling works is by coming out with definitions of things like the healthiness of foods. But, of course, food by itself cannot be 'healthy,' it's only a person that's 'healthy.' So the concept, healthiness of a food, is a theoretical construct related to the healthiness of a diet, and in turn, the healthiness of a diet is related to the health of people.

The healthiness of foods has quite long been talked about, even though people have generally said there is no such thing as healthy or an unhealthy food, only healthy or unhealthy diets. These are food guides, and the food guides, you always have food in the food guide which people should eat less of, at the bottom of the plate in the British model, or at the top of the pyramid in the American model. So I think the concept of the healthiness of a food isn't such a radical concept as it might seem.



Why do we need definitions of things like healthiness of a food? Well, largely because of increasing emphasis on the marketing of food, and the need to regulate the marketing of food, not just the advertising of food, as we heard about yesterday, but also the product, itself, its composition and its labeling, the place where it's made available through vending machines and schools, etc. But also the price of food. And I think as we move towards more and more of a problem with obesity there are increasing emphasis on trying to regulate the way foods are marketed. In particular, the unhealthy foods, not just the healthy foods like fruits and vegetables which we have been talking about most these few days.

My group got interested in nutrient profiling largely through helping the Food Standards Agency in the U.K. to develop a nutrient profiling model for the definition of an unhealthy food for the purposes of regulating foods to children. And this document is the new regulations put out by Ofcom, the broadcast regulator in the U.K. which sets new rules for advertising of foods to children. And these rules only apply to unhealthy foods, junk foods or whatever you like to call them. And the nutrient profiling model that we developed for the FSA is the basis for these rules. That model is summarized on this side, some of you might have seen yesterday. Basically, it defines an unhealthy food on a basis of 7 components: energy, saturated fat, total sugar, sodium, protein fiber, and fruit, and vegetables, and nuts. You score points for the top 4 nutrients, and use points for the bottom 3 components, and you end up with a score. And if you score more than 4, you are deemed to be less healthy

or unhealthy food. And similarly with drinks, although the scoring system is different for them. And less than 4 you are a healthy food and you can be advertised to children on television.

It classified foods in this sort of way; this is just a sample of foods. Some of these foods clearly aren't controversial. Most people would agree that a Mars bar, perhaps, or a jam donut are unhealthy foods, and a peach or lettuce are healthy foods. But there are some more controversial foods on this table such as cheddar cheese. Well, cheddar cheese is a good example of where the model creates controversy around the classification of foods, which we can go into later.

How do we develop this model? This is the main point of my talk, is that we developed a systematic approach to developing a nutrient profiling model. A planned staged approach. Lots of people in the past have developed nutrient profiling models, but quite often, these are done rather randomly. So what we tried to do was develop a more open and transparent way of developing a model. And we proposed that you needed to go through these 7 steps. The nutrient profiling model had to fit or relevant to the purpose for which it was to be used, in our case, the advertising of foods to children. You had to look at the group or population the purpose was relevant to. You might need different models for food advertising aimed at children, than you would need for food advertising aimed at adults, for example.

But the big issue, of course, one of the most controversial issues in relationship to a nutrient profiling model, is whether they should be across the board, or a food category-specific. And I'll try to explain in the next slide what that means. Our model categorizes foods across the board. It ranks foods from the most healthy, in this case the apple, and the least healthy, in this case, the chocolate cake. And it puts foods roughly on that spectrum. Apples, avocadoes, skim milk, whole milk, olive oil, butter, fruit cake, and chocolate cake. Category-specific, however, would do the following, it would rank the healthier foods as apples, and less healthy foods as avocadoes, the skimmed milk as healthier, the whole milk as less healthy, the olive oil as healthier, the butter as less healthy, the fruit cake as healthier and the chocolate cake as less healthy. And clearly, they are 2 very different types of conceptual models here around the categorization of food. And I think to some degree, it's a matter of choice whether you choose a category-specific or an across the board model.

As Ambroise said, we've looked at existing models around the world, we think it's about 38-40 at the moment, and half of those, roughly, use a food category-specific approach, and the other half use an across the board approach. But the category-specific models use a wide range of numbers of different categories, ranging from 71 in the case of the model underlying the Australian Tick program run by the Australian Heart Foundation, to 3 in the case of the nutrient profiling model underlying the rules around the U.S. health claims.

The next stage in the systematic approach is to decide on the nutrients. Again, this, I think, is rather simple compared to some of the other decisions in this approach. But of course, there is a whole range of possible nutrients, 100's, I think, which you could include in the model. This is just some, and to show you some of the types of options you might end up with. Our model, as I said before, involves 7 components, those highlighted in red here. Other models involve more components. This is the nutrient profiling model underlying the Kraft Sensible Solution endorsement scheme which has 18 different components.

There is some similarity between models, generally they use saturated fat, generally they use sodium, they use either energy or total fat, and they often involve, not just negative nutrients, nutrients that we'd like the population to cut down upon, but also positive nutrients which we'd like people to eat more of, such as fiber and vitamins and minerals.

The next decision that has to be made is in relationship to the base, the reference quantity on which the model is constructed. You have basically 3 options here, the per 100 grams, the per serving, and the per 100 kilo-joule base. Our model uses a per 100 gram base. And because of this relationship between healthiness of foods and health, the healthiness of foods in nutrient profiling is defined by the nutrient composition. But the nutrient composition isn't the *only* thing which affects the nutrient composition or the healthiness of a diet. It's also affected by things like the serving size and the frequency of consumption, and also the combination of foods

which you eat. For example, one of my illustrations is strawberries which are, on the face of it, quite healthy. But because I generally eat them with cream, the combination of strawberries and cream makes strawberries less healthy. And you can think of lots of examples around spreads and bread, and breakfast cereals and milk, and so forth. Basically you have to choose whether to incorporate these things like serving size, frequency of consumption, or combination, within your model. And some people do and some people don't include serving size criteria within their model. If you don't choose a serving model, you do run into some problems with foods which come in small servings, but which are high in fat or sugar or salt, such as [...] and honey. But also, some foods benefit from a per 100 gram model, such as meat with cheese-based ready meals. But generally, when constructing models, it's the people who do badly under the model who complain, rather than the people who do well under the model.

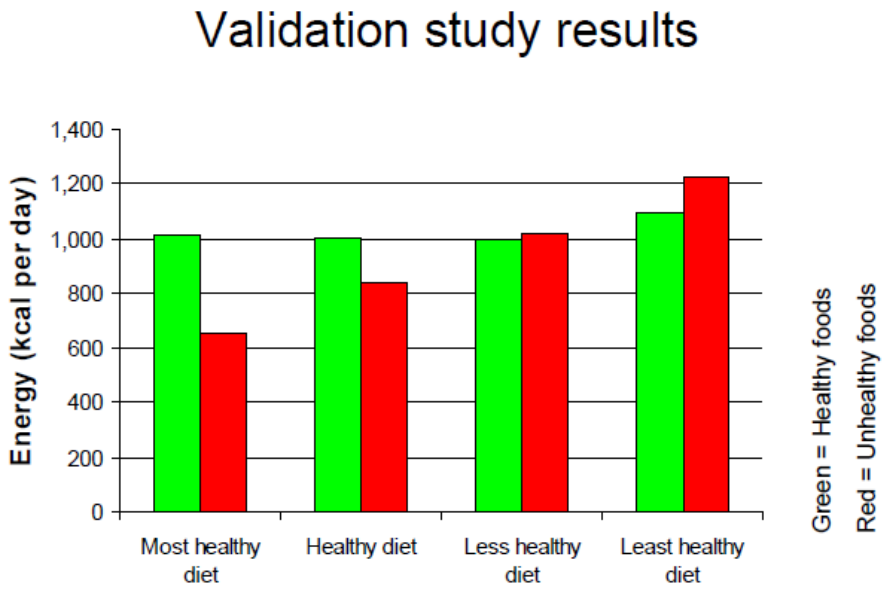
Finally, validating and comparing models. It's all very well and good having a systematic approach or a logical and transparent way of constructing a model. But how do you know whether the model is doing what we'd like it to do?

We've come to the conclusion that there are 3 different ways of validating nutrient profiling models. And I know Jean Luc is going to talk about some of these later. We think there are 3 methods of validity testing based on epidemiological approaches, to the validity testing of new scores like a quality of life score or even species diversity score for an environment. Content validity, criterion validity, and construct validity defined in these ways.

Content validity is really just taking into account all the important dimensions that need to be measured by your new measure, your new score. And that's partly addressed by developing a systematic and consensual approach to the development of the model. Perhaps more interesting are these 2 latter methods, criterion validity and construct validity testing. Criterion validity is comparing how your new measure measures against or compares against a gold standard. But because I think nutrient profiling is a very new field, we don't actually have a gold standard for which to measure new nutrient profiling models against. We have tried to do that in relationship to things like the views of nutritionists, but you can see that the views of nutritionists aren't necessarily a gold standard, they are quite subjective. So perhaps what we've been leaning towards as the best way of validating nutrient profiling models is to use construct validity testing, examining the relationship between the new construct and other constructs. So going back to that model, looking at how the construct of the healthiness of foods relates to the healthiness of a diet, and to health, ultimately.

And briefly, to summarize the results of our validation study of the construct validation study of our model which we developed for the Foods Standards Agency,

what we did here was divide people in the U.K. into 4 groups, depending on the quality of their diets, defined by a validated diet quality index. We divided into the most healthy diets, the healthy diets, the less healthy diets, and the least healthy diets, and looked to see where they were getting their energy from, in terms of the foods that we defined as healthy or less healthy by our model. And this graph shows that the people with the least healthy diet get most of their diets from least healthy foods, and the people in the most healthy diet get most of their energy from the healthier foods defined by our model. So this, I think, gives us some hope that the model is actually measuring a real construct related to the healthiness of foods, and gives us some degree of certainty, validity, if you like, for the model.



Source: **Aramebepola C, Scarborough P, Rayner M.** Validating a nutrient profile model. Public Health Nutrition, 2008,11:371-9.

The issue that people are now struggling with is how do you compare different models, really? Because it's all well and good saying that you've got a good model, but how, amongst the 38 models that we've come up with in our review, which is the best? I'm not really going to offer you any solutions to this problem; I think it's a really very difficult problem which people are still struggling with. But I do think it matters. This slide shows you that if you are trying to relate to the construct healthiness of a food to the healthiness of a diet, not all foods in an unhealthy diet are unhealthy. Clearly, here is a typical British breakfast. Tomatoes are defined as healthier by our diet. You can have a very unhealthy breakfast, and still have *some* of your foods, as healthier foods. [...] [...] is in this instance.

I think it does matter how models categorize foods, this is just a brief, looking at 3 of our models from our recent review showing that the 3 different nutrient profiling models do classify foods differently. Our model is the top one. [...] Choices model is the next one down, and the Swedish keyhole system, the model underlying that is the bottom one. And you can see at the extremes like your bread and cola, models

generally agree with one another, but there are lots of foods in the middle like ham, and ratatouille, and baked beans which are classified differently by different models. Does it matter that these foods in the middle, between the 2 extremes, are classified differently by different models?
This slide shows that different models generally agree, again, on the extremes. So here, I've plotted the scores generated by our model against the scores generated by a model developed by Adam Drewnowski, a naturally nutrient-rich score on the bottom. It's quite a good correlation between the 2 scores. The unhealthiest ones on our scoring system, toffees, are at the top of the model on the left. And the healthy one, celery, is at the bottom right. And you can see from this that we and Adam agree on celery and toffees. But we don't agree on things like whole meal bread and apples, ham and bran flakes. Our model classifies whole meal bread and apples as healthier, whereas NNR doesn't. And our model conversely, classified ham and bran flakes as being unhealthy, but the NNR model classifies [...] as healthy. And this is because they are based on slightly different principles. Our model pays bigger attention to the negative nutrients in the model, the saturated fat, and the sodium, and the energy density of the foods. Whereas, the NNR pays more attention to the positive nutrients, the micro nutrients in food. So depending on your choices and your approach to the development, you do end up with different classifications on your model.
And just to look at 3 different other models, there is more agreement between some models and others, so our model agrees very strongly with the Swedish keyhole scheme, but not so well with the [...] Choices model.

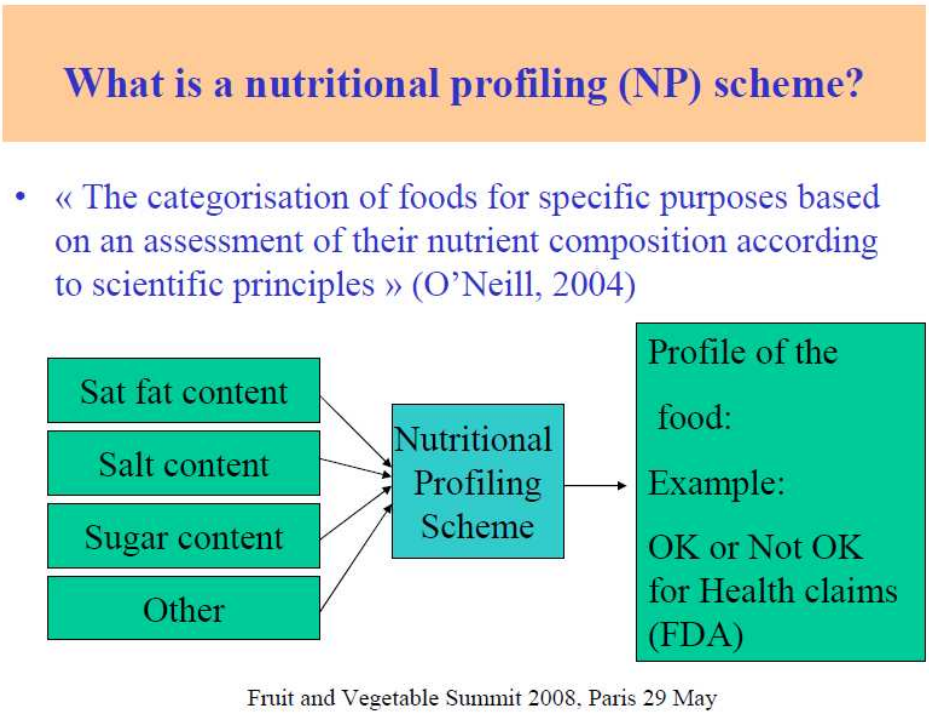
So just to leave you with some questions, really, for pondering. The big issue is can we relate healthiness of foods to health? Again, not just looking at the relationship of the healthiness of the foods to the healthiness of a diet, but to health overall. I think this is an unresolved and yet to be answered research question. Another big issue for me is how do we define categories for category-specific models if you choose to have a model which has different criteria for different categories? And nobody has really come up with a solution to that problem. There again, lots of different options, in terms of the actual categories, and in terms of the numbers of categories. Is one model sufficient for all purposes? I think this is an important issue. The model we developed was for the advertising of foods to children, regulation of the advertising of foods to children. Would it work for health claims? And is there a good model method for comparing models? At the moment, I think we need more research effort to come up with better ways of comparing models, not just looking at the data, looking at the way different models categorize foods. So 4 questions which you might like to think about for the rest of the session. Thanks.

A. MARTIN (President of the session): We move to the next presentation by Jean-Luc Volatier who is the Head of the Unit in the Food Consumption and composition of the French Food Safety Agency.

Validating Nutrient profile models

Jean-Luc VOLATIER
AFSSA, Maisons Alfort, France

So I will try to add on to Mike's presentation on validating nutrient profile (NP) models to put more scientific information in the choice of the different systems that exist at the European level. A nutritional profile is a kind of black box that uses information on the food composition and content to define a profile that is okay or not okay for health claims.



There are for instance, profiling systems by the FDA, the FSA and others. The purposes are very different from one system to another. And the criticisms that are usually sent to these NP schemes are that there is a lack of objective agreements to choose a system, and that there is a lack of scientific validation. The results that have been shown depend on the profiling method chosen. A more general criticism is that there are no bad or good foods from a nutritional point of view, but only favourable or unfavourable diets.

Because of the new regulation on health claims in Europe, there is a kind of revival of work, after the works that were done in the 80's or in the 90's in the U.S., to do more research on this question of validation of nutrient profiling scheme.

So most of the existing nutrients profiling schemes for the moment have not been really validated because they have been considered more as a risk management tool, and not a completely scientific issue. But some choices of the parameters that are

used in the nutrient profiling schemes may be considered as self-validating. It is the case, for instance of the maximum percentage of fat in a food product that can be derived from the rate of desirable reduction of the percentage of fat to achieve the recommendation, for instance, of less than 35% or less than 30% of energy from fat. So there are some criteria that are easier to validate than others.

And some nutrient profiling systems are more or less directly derived from this kind of recommended intakes. But on the other side, if you consider different systems, you can see that you can profile the same foods differently. For instance, if you consider ordinary cornflakes in the FSA WXY system that has been shown by Mike, the profile is "less healthy". For the FDA profiling system for health claims it is "okay". And for the Dutch "Tripartite" system, it's considered as "exceptional". So you can also show contradictions, for instance, for boiled potatoes. There are a lot of foods like that whose profiles are different according to the systems. The question is: is it possible to find some profiling systems that are preferable to others, for a certain point of view, for a certain aim of regulation?

So I don't have exactly the same categorization of the different methods of Mike Rayner. The traditional one is to use expert advices; it's based on nutritionists opinions and it is a qualitative method. There are also validation methods based on nutritional surveys, and the group of Mike Rayner organized this type of survey, which is different from the first one because it's a quantitative method based on the rating, the opinion of experts, about the quality of foods on a nutritional point of view. But the problem is that this approach is linked to the culture of the country where the survey is done.

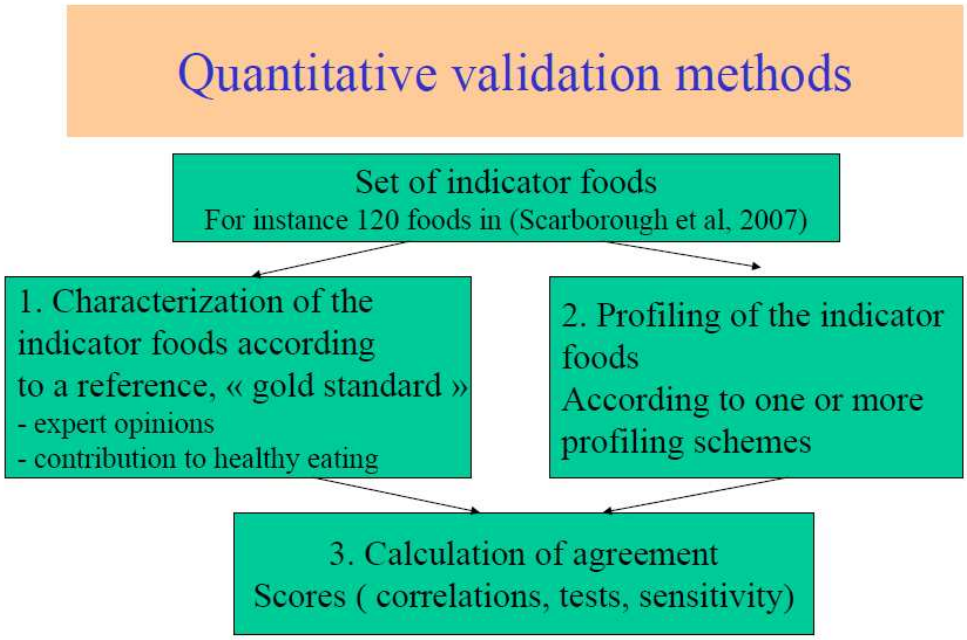
Then we have a new set of category of validation methods that are developed in different research groups, based on trying to make a link between intakes and profiling of foods, with the idea that we are more able to qualify a diet from a nutritional point of view, than foods. This approach is based on mathematical modeling and I will show you part of what we've done to try to validate 3 systems of nutrient profiling in 5 countries, in trying to measure links between quality index of the diets with the profiles of the foods.

There is also a fairly new approach which is also very promising, but also very recent, which is to try not to consider diets in real life, but to build theoretical diets that are associated, or not, to nutritional recommendations, and use these diets as a way of qualifying the foods that participate, or not, to the diet and then try to see if food with a good profile are well-linked to these theoretical diets.

And finally, there are also testing method that are more in the field of feasibility, easiness to use, that are considered also as a part of the validation. So there are different techniques of nutrient profile validation according to different aims, and of

course, it's necessary, probably, to combine the different validation types.

Most of these validation methods are based on a kind of gold standard and a set of indicator foods that could be used as a gold standard for qualifying the systems. For instance, in the method of Mike Rayner with the initial survey, we have 120 foods and they are characterized by the opinion of the surveyed experts, and then you compare it to the profile of these foods using different profiling schemes. And then you calculate different agreement scores, and it's a method of the validation.

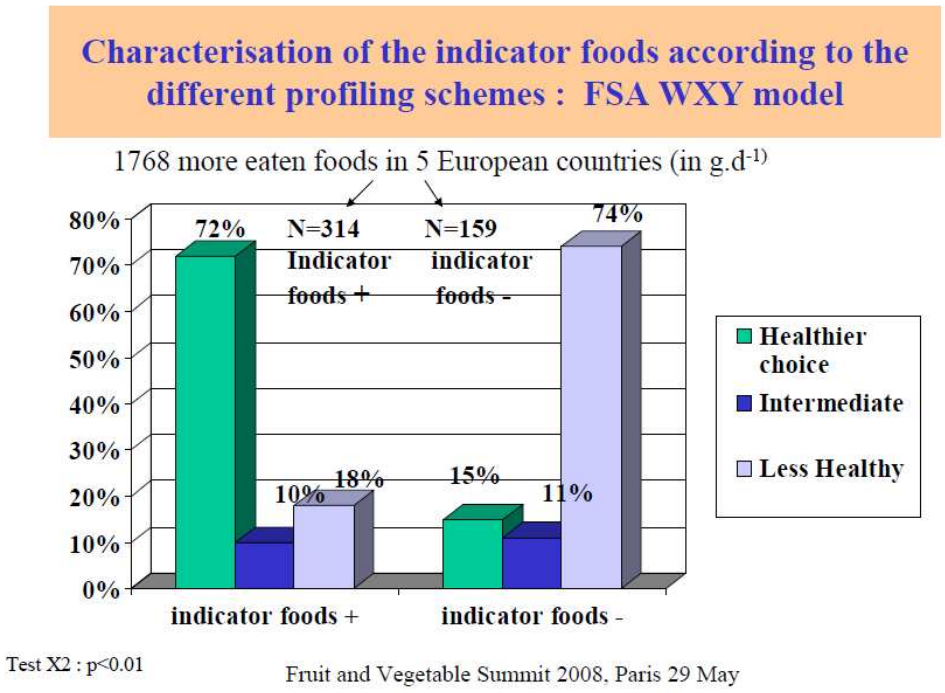


Fruit and Vegetable Summit 2008, Paris 29 May

In our group, it was a European group, we tried to define the gold standard, this time not on the opinion on experts, but on defining healthy diets based on the Eurodiet European recommendations, and then identify the foods that are associated positively or negatively to this healthy diet. So this gold standard allowed us to identify in 5 different countries, Belgium, Denmark, France, Ireland, Italy, a lot of individual foods that are mainly fruits and vegetables-based products, or dairy products, or cereal products for the foods that are associated to the healthy diets. On the other side, meat and meat products, fats, cakes and pastries, and potato-based products are negatively associated to the healthy diets. But these indicator foods that were identified in the different countries, are a minority of the foods eaten, so there were a lot of foods that we are not able to qualify either as positively or negatively associated to a healthy diet. Another problem is that we found that these indicator foods were different from a country to another. That shows that the validation method based on indicator foods are country-specific because there are broad differences of habits between EU countries.

The second part of the validation is a comparison between these "gold standard" and

profiling schemes. For instance, the FSA WXY model that was presented in the first presentation is very well correlated with our indicator foods. We are sure here that among 1768 more frequently eaten foods in the 5 countries, we see that we had for those foods that we are able to qualify, 314 indicator foods positively associated with a healthy diet, 72% of them were profiled as "healthier choice" by the FSA model. So there is a good agreement. On the other side, among the 159 indicator foods that were negatively associated to the healthy diet, 74% of them were quoted as "less healthy" by the WXY model. So you see that there is an overall good agreement. The problem is that this overall good agreement is always on a limited number of foods. We find the same result, for all the models. So there are very little differences of validation results between the different profiling schemes that do exist.



There are other approaches that are developed, so this approach based on the work of Arambepola and the work of Mike Rayner, trying to link the profiles of foods to food based dietary guidelines and to quality indexes and we can see in this paper that there is a good agreement because fruit and vegetables products that should be eaten a lot, according to guidelines, are mainly classified as healthier foods by WXY model. So this type of validation study are slightly different from the others that I presented to you, and it brings results that are very, very close, in fact.

There are new ongoing research and validation of nutrient profiles; in particular a new method based on the definition of optimal diets that allow meeting nutritional endpoints. The method of Nicole Darmon which begins to be published, but it's an ongoing work, is based on the use of linear programming with nutrient intakes as a constraint, and a range of energy intake compatible with the usual intake as an

output. The interest of this approach is to use diets that really meet nutritional endpoints as "gold standard". So there is no need in this approach to find individuals who are really linked to these endpoints. You have a kind of "pure ideal diet" that is really linked to the nutritional endpoints on the nutrients, on vitamins, minerals, and so on. And then for these diets, there are no confusing factors that bring artificial association between foods with good profiles and foods with less good profiles. That was the problem also, that was quoted by Mike.

The inconvenience of this approach is the risk of selecting diets that are unachievable considering socioeconomic constraints. So there is a need to study these diets and introducing socioeconomic constraints in the study of these diets.

So in conclusion, you can see that the question of the validation of nutrient profiles is an ongoing research sector. There are different quantitative validation methods for profiling systems that have been proposed in the last 2 years, some of them very recently. And they are based on quantitative surveys on expert opinions, association or contribution of foods to nutrient intakes according to dietary surveys. The contribution of the food to the diet seems to be a better criterion than the association because of the correlation that can be linked to artificial correlation, like the fact that you may eat at the same time bread and jam, for instance. So contribution to the diet is a better criterion. There are definitions of theoretical diets now meeting nutritional endpoints as a golden standard. And this can bring the possibility to analyze a contribution of profiled foods to these diets.

About the question of fruits and vegetables-based products, all these approaches are converging, especially for the profiling of these foods. They are mainly profiled as "healthy". Most of the difficulties are for intermediate foods that are fruits and vegetables-based products. How to consider them? One of our problems is that these approaches are country-specific and there is a need of a country by country validation if a model is used at the international or at the European level. Thank you for your attention.

Q&A

PUBLIC: Did I understand correctly that the gold standard that you're using in your model is one which is derived from ILSI and they are a food-dominated organization. Do you think this gold standard has a scientific credibility? Why did you choose it?

JL VOLATIER: This gold standard is based on the Euro diet recommendations as a basis, which are independent recommendations. Then there is a methodology to provide from this Euro diet recommendations a categorization of the foods and the gold standard. And I participated in this group, so I feel free to say that we had

absolutely no pressure, no attempt by the industry to influence the work of the participating researchers. So even if it has been done in an ILSI group, all the researchers who published the paper were from the public sector and we had really no problem to say what we wanted to say.

A. MARTIN: It's a very interesting point. It's somewhat auto claim, auto proclamation as a gold standard *[laughs]*. It was the best at the moment because when it was developed only the expert judgment was used. But we can say also that there is some type of circular validation because Euro diet criteria has been established by experts who also considering many things. So perhaps the true gold standard will be the direct comparisons to health. But for the moment, we have not the methodology to do that. So it's a very stimulating area for research. Any other questions?

Nutrient Profiles, Pleasure, and Cost

Adam DREWNOWSKI
School of Public Health and Community Medicine, University of Washington, Seattle, WA

Good afternoon, ladies and gentlemen. My presentation today has got 2 very, very simple aims. I'm going to be talking about nutrient profiling in relation to nutrition, cost, and pleasure. And I want to do 2 things. I want to introduce the Nutrient-Rich Foods Index, and I want to apply the Index to a problem in public health, and the problem is the selection of new foods for the WIC package. WIC stands for Supplemental Nutrition Program for Women, Infants, and Children. And the foods allowed under the WIC package in the United States are being evaluated this year for the first time in 35 years. So this is a clear case to apply nutrient profiling to a concrete example in public health.

And let me just say this up front, the way that nutrient profiling in the European Union and in the United States is very different. The motivation in European Union has been the imminent arrival of nutrition and health claims. Only foods with favorable profiles will be allowed such claims. Foods with unfavorable profiles will be disqualified. This is not the case in the United States. Nutrition and health claims have been allowed for some time. The Food and Drug Administration already has criteria for which foods are healthy and which foods can, or cannot, carry such claims. Those criteria are based by nutrient content and do not involve a total composite score. So the nutrient profiling in the sense of thorough composite score is being used largely to give consumers an easy at-a-glance method to identify nutrient-dense foods. This concept was mentioned in the 2005 Dietary Guideline for Americans, this concept was mentioned in the Food Guide Pyramid. The feeling is that the current nutrition panel in the United States is overly complex, and I view nutrient profiling essentially as the bridge between the dietary pyramid and the food label. And this is an at-a-glance index that is science-based, consumer-driven, and let's not forget, cost-conscious.

So this is the Nutrient-Rich Food Index. We are using 9 beneficial nutrients known to be good for health. They are protein, fiber, vitamin A, vitamin C, calcium, and iron, as well as vitamin E, potassium, magnesium. And we are using 3 nutrients to limit saturated fat, added sugar or sodium. All are expressed as mean percent daily values per reference amount of food. So the actual score is a simple arithmetic sum of percent daily values.

So looking at this EFSA scheme, there are a number of potential decision-points you have to make in deciding how you want to construct your score. I will want to deal with only 3 of those because other speakers have mentioned those. I will mention the disqualifying and the qualifying nutrients, our decision to base the score on reference

amounts, and our method of validating the score.

So here, notice that we are using more beneficial nutrients than many other scores, but again, the number is limited, it's only 9. We are basing the score on reference amount with a very specific way of validating it with respect to an independently obtained measure of a healthy diet.

And here we were able to benefit from previous experience of the Food and Drug Administration because Food and Drug Administration already has 6 nutrients that come into the definition of healthy foods. And those are protein, fiber, vitamin A, vitamin C, calcium, and iron. This means we included them in our score. The Dietary Guidelines have a number of nutrients identified as nutrients of concern, and so these were our guidelines of what to include among the beneficial nutrients. The nutrients to limit, again, the Food and Drug Administration also lists a number of nutrients which would disqualify a food from carrying a health claim, and of course, European Union also lists 4 of the same nutrients as being potentially disqualified. So the actual choice of the nutrients was fairly easy. And I'll show you later on of how we validated this choice.

This was a bit trickier, because you may have noticed that the British score is based on 100 grams, the French score is based on the combination of 100 calories and 100 grams, and of course, serving size as government-mandated does not exist in the European Union at this time. On the other hand, the Food and Drug Administration already operates using serving sizes. And in fact, all the American food labels are calculated per serving size. To make things difficult, there are 139 different serving sizes in existence. But there is a short cut, because when you plot the serving sizes against energy density of foods, you start realizing that the serving sizes are, in fact, an inverse function of energy density. So the serving size for sugar is 4 grams, for oil it is 15 grams, for cheese it is 30 grams, for vegetables and fruit it is 85 grams, yogurts 220, juices 240, and as a result, you have a very nice inverse relation between energy density of foods and serving sizes, which means that calculations based on serving size and those based on 100 calories would be almost exactly the same. So I suspect that the French score based on 100 calories will reflect the nutrient density of foods more closely because of the nutrient to calorie ratio, and this is very similar to what we are doing in the United States basing everything on serving size.

We then tested a number of alternative algorithms because we had, as in the French score, a positive component and a negative component. There are various ways in which those can be calculated and combined, and here we used a comparison to a healthy diet as a way of validating our approach. What we did was to take data from the National Health and Nutrition Examination Survey. For each subject, we calculated the mean nutrient-rich score for all the foods consumed by that subject on that day. We then calculated the Healthy Eating Index for that subject on the same

day independently. The Healthy Eating Index is again, a government-created measure of a healthy diet in the United States. You may argue whether or not it is accurate, whether it truly reflects a healthy diet, but be it as it may, this is right now the government-based gold standard. And we used regression analyses adjusting for gender, race, and ethnicity to see what percent of the variants was accounted for.

This is the Healthy Eating Index, it is food-based, it is based on adherence to the pyramid, and to the Dietary Guidelines for Americans. It is a 100-point scale with these components, and you calculate it independently, and then compare your score values to the Healthy Eating Index values. And these are our percents of variants accounted for. There are 2 or 3 interesting things. One, is the [...] score based only on the nutrients [...], does not account for too much of the variants. So if you have a score based only on saturated fat, added sugars, and sodium, it doesn't really truly reflect the total nutrient quality of the food. You start getting better results as you increase the number of beneficial nutrients, going from 5 to 6 to 9. And then something else happens. As you start loading up the Index with more nutrients, going beyond 11, to 12, to 15, to 23, the actual comparison to a healthy diet diminishes and you start losing discriminating power. So we actually use this method to test a number of alternative indices and arrive at the best fit. And this is why our Index is based on 9 beneficial nutrients, and 3 nutrients the limit. And not on 15 nutrients, 16 nutrients, 23 nutrients. All of those possibilities have been tried and rejected. And many of those indices are published in the literature.

So, let me move on to the next issue, how can we use such indices to improve public health? And here, I'm not talking about labeling; I am talking about how to allow consumers to recognize nutrient-rich foods at a glance. Or more to the point, how to allow WIC dietitians to identify such foods and put them on the list for the new WIC package? WIC package, as I mentioned, is undergoing a revision. WIC families starting sometime next year will be offered more whole grains, a greater variety of vegetables and fruit, less fat, less saturated fat, and less sugars. This is a major development; the WIC package has not been updated or modified in the past 35 years. Now WIC package is a form of food assistance, and these foods, the allowed foods, the approved foods, are provided to women, infants, and children under the age of 5, free of charge. The State of Washington spends $100 million per year on WIC foods, the State of California spends $800 million a year on WIC foods, so these are huge issues of commercial and industrial, and of course, nutritional concern.

Right now, what's permitted in Washington State are cereals, including fortified cereals, juices, frozen juices, juices fortified with calcium. But the only fresh vegetable permitted, and only to breast-feeding women, are carrots. Nothing else, just carrots, that's it. And then you have milk, cheese, peanut butter, beans, chicken, and canned fish. You will figure out from that that the major concern with WIC 35 years ago, was to provide adequate protein. So this is the old WIC package. And in fact, those foods

had never really been coded. I plotted here the currently permitted WIC foods against their protein content and notice that you have your carrots, and tomato juice and V8 juices are permitted, milk powder, formula diet, eggs, tuna, cheese, peanut butter, cereals, energy density on a horizontal axis, calories per 100 grams, protein content over here, a fairly limited number of foods. Here you have the same currently permitted WIC foods, and their fat content. Peanut butter is the only one with high fat, there is some fat in cheese, cereals, eggs, tuna, and milk. Again, tomato juice and carrots. And here you have sugar content, of course, the cereals are pre-sweetened and do contain sugar. Peanut butter has some sugar. Milk powder, juices with some added sugar, again milk, and then carrots and tomato juice. But this is a nutrient by nutrient profile focusing on protein and fat and sugar, the way that WIC dietitians have been selecting those foods.

So the issue here is, how do we apply the nutrient-rich food score to the new WIC package, and how do we demonstrate that the nutrient profile of the new WIC package is substantially improved? So these are now the new WIC foods. There are federal guidelines for what those foods are going to be, but each state has some discretions of what to allow. So, for example, what is going to happen, that fresh or processed food will be introduced without limitation, same with fresh and processed vegetables, and $6-8 per month will be specifically earmarked for fruit and vegetables preferably fresh. It is right now not certain whether or not certain individual states would permit only fresh fruit and vegetables, or will they permit canned fruits and vegetables, which contain some sodium and their nutrient profile, may not be as favorable?

Now, of course, the WIC package has to be cost-neutral. Which means you can improve nutrition, but you can't pay more, says United States Congress, so as a result the total package has to come to the same price for the individual states. So as a result, the amounts of dairy products, the amount of cheese, and so on, are going to be reduced, and the monies of these are going to be taken up by vegetables and fruit, very likely fresh.

So the issues about cost and enjoyment and cultural issues are now coming in big, because the WIC population may not respond to foods which are highly nutritious, but either unfamiliar, not liked, or too expensive. So right now, what everyone is trying to do is to put together a package which will balance all those things that will be cost-neutral. The question is whether fresh, frozen, or canned vegetables will be used. What container of package size will be used? WIC is very specific; you can only buy whole wheat bread in 16 oz packages. The problem is, nobody makes that. So federal regulations specify that this has to be done, this does not exist, and industry is moving in to create this for the purpose of WIC. What are the lowest cost options? What about using organic produce? And then, of course, we need to allow for taste preferences, and the foods need to be culturally appropriate. So that nutrient

profiling is merely a component of the process. Other foods or other considerations come into the choice of foods, as well.

Let me show you briefly how this works for nutrient profiling. We begin here with sub-score based on the beneficial nutrients only. And here you have energy density and the nutrient-rich 9 score of the new WIC foods, and this is just the beneficial components sub-score based on the 9 beneficial nutrients. Notice, of course, that this is energy density; this is now the nutrient profile. You have a whole variety of vegetables and fruit, you have dried fruit, as well, these are now the cereals, you had them before, the cheese and peanut butter, the tuna, but the entire picture has now changed because the vegetables and fruit are now allowed without limits.

Now how about a sub-score based on saturated fat, added sugar, and sodium? This is now the negative component. And this is what happens, first of all, this is energy density and sugar content of new WIC foods. This is, of course, the total sugar content, and cereals are sweetened, but vegetables and fruit and juices do contain sugar. And this is one reason, actually, why now our Nutrient-Rich Food score, we are using added sugar and not total sugar. Because when you start looking at added sugar, this is what happens, take a look. This is now total sugar in vegetables and fruit, this is now added sugar. So as a result, if you use added sugar, the score changes completely. There is going to be some dried fruit here, I think these are dried cranberries with added sugar, there is going to be some, again, fruits and vegetables with added sugar, and of course, the cereals. So the score changes depending on whether you use added sugar or total sugar.

And now this is [...] complete sub-score, these are now some of the canned vegetables with sodium content which lowers their score. So you can see, if you want to introduce a new food into a WIC package, you can use this 2-dimensional graph to see where a new food will fit in. Right now, one issue is whether or not yogurts ought to be accepted into the WIC package. The Institute of Medicine recommended that they are included. The State of California has not made a decision. The question then is, where will yogurts fit in, and how do they balance nutrition and cost?

So this is now the composite, Nutrient-Rich Food Index applied to the WIC foods, and you see you have your skim evaporated milk over here, dried fruit, cereals, peanut butter, cheese, and this wide range of vegetables and fruit, but there are some juice drinks with added sugar, which do not score quite so well, they scored below zero.

So this is the new WIC package, and let me just conclude by showing you how the new WIC package relates to other foods and food supply scored according to this same method. Still the Nutrient-Rich Food score. These are the WIC foods, these are, of course, the vegetables and fruit included in WIC. You see where they are favorable

nutrient profile, low energy density. These are now meats, some of them do not score quite so well. Fish scored better. Some with high energy density is bacon. This is liver and organ meats. Here you have dairy products, again, a nice separation. Skim milk, 1% milk, 2% milk, whole milk, plain yogurt, and of course, the cheeses are over here with higher energy density. And of course, saturated fat and sodium content, there is very little you can do about that. Here you have cereals, including fortified cereals and sweetened cereals over here with a more negative score. And here you have the fats and sweets, all of them below the line, you can do nothing about those because they do contain either saturated fat or sugar or sodium, or in some cases, all three, and no beneficial nutrients. So this is a nice way, a kind of visual way, at looking at the new WIC package and seeing where the new foods will fit in.

And of course, there is a reason for showing you this because there is going to be, of course, a relation to cost. So for example, when you compare the previous foods, just go back here, the sweets and fats to the WIC foods, you see that the WIC foods actually will make a difference and they will have changed the nutrient profile of the food supply of the women, infants, and children in a positive direction.

So finally, lets us take a look at the cost issue. And this is going to be a problem where, again, nutrient profiling can help, perhaps in combination with linear programming of the kind just mentioned by Jean Luc Volatier. These are now prices from Seattle supermarkets. Energy-dense foods, which are energy-rich, but nutrients-poor, are cheaper. On the other hand, the more nutrient-rich foods, those that score higher on the Nutrient-Rich score, tend to be more expensive. But that does not necessarily apply to all foods. There are going to be gradations within each food group because you can go from fresh shellfish and fish to things like canned fish, and actually the WIC package does allow for canned sardines, mackerel, tuna, and salmon. You can have for dairy products, milk, and yogurt, and some cheeses. So there is going to be a whole range of food prices. Notice that each increment of the scale is a ten-fold difference, which means that the final WIC package will be chosen using both nutrition and cost, using methods much like this. These are now grains which tend to be less expensive. These are now vegetables and fruit. Notice that salad greens are expensive, but there are other vegetables and fruit that are not. Here are beans and here are nuts. Nuts are right now not part of the WIC package. Could be. There are ways of selecting foods for nutrient density and cost.

So to conclude, the new WIC package, by inclusion of vegetables and fruit, will improve the nutrient density of the diet, and I think nutrient profiling is one way to help states select WIC foods for inclusion, and this is a way of balancing the nutrient density of individual foods with preference and acceptability of those foods, and of course, the food costs. And much more work needs to be done on fitting this together in some kind of mathematical model, perhaps using linear programming or some other way of calculating the best foods for the price. That is for you an introduction

of how nutrient profiling can be used *directly* for consumer information in the service of public health in a way that really has nothing to do with food or nutrition labeling. It can be useful anyway. Thank you.

Q&A

PUBLIC: So if I understand well, you never take account the content of phytochemicals, beneficial phytochemicals, in the food. And fruits and vegetables are not equal in their nutritional quality, so this is not taken into account in this model?

A DREWNOWSKI: Actually we have not taken into account the phytochemicals because the databases are not good, and in designing our nutrient-density profile, we wanted to make sure that the databases were complete and also open source. Which means anybody who wants, should be able to download the nutrient composition dataset, and calculate the nutrient-density index at home if they so wish. So for example, all our calculations are based on the food and nutrition dietary dataset, set for dietary studies, which you can download from the Web from the USDA. So using open source data is very important to us, and phytochemicals are generally not included. Maybe later.

PUBLIC: In addition, as far as I know, we have no reference values for the intake of phytochemicals. And since the system is somewhere based *[laughs]* to use reference values.

A DREWNOWSKI: Right.

PUBLIC: It's in addition, a difficulty.

PUBLIC: Yes, just as matter of interest, I hadn't actually realized that infant formula is part of the WIC package.

A DREWNOWSKI: Yes. Why is that the case? Well, infant formulas had been part of the WIC package before and they will stay. There are going to be limits on the use of infant formula after the age of 6 months, and I may have had them there someplace, I can't remember. They are certainly fortified, so they will come out well. Just like the fortified cereals, you know, the score does what you ask it to do. So anything that's fortified will score well.

PUBLIC: Adam, it might be important to note that breast-feeding women will get more money per month.

A DREWNOWSKI: Yes.

PUBLIC: $10 vouchers, I believe, if they breast-feed.

A DREWNOWSKI: Right.

A. MARTIN: Any more questions? Perhaps I have a question because perhaps I have missed something. I have not any headphones to capture the very good translations in French that we have, and thank you very much for the translations. And I apologize for my English. But I have not understood the clear answer to the question, is it not neutral as far as cost is concerned? The changes are neutral?

A DREWNOWSKI: Well, cost is not part of the score, but certainly--

A. MARTIN: But the new WIC package doesn't cost more than the previous one?

A DREWNOWSKI: Supposedly not, it's supposed to be cost-neutral, but as I say, each state has some discretion about what to allow. So for example, the $6-8 per person is a figure from the State of Washington. I understand it will be similar in the State of California.

PUBLIC (Philipp JAMES): Rather than talking about the general issue, I just wonder, Adam, if you calculated on the basis of what you know about the cost which you have there. What quantity of fruit and vegetables could somebody actually buy for the $6-8 per month? I've got no feel for that. In other words, does it remotely get anywhere near 400 grams a day per person?

A DREWNOWSKI: That's an excellent question; this has actually not been done. In fact, in doing this research, I was stunned to discover that nobody had applied nutrient profiling to the choice of WIC foods when the Institute of Medicine was doing the report. So we don't know at this point. So there are ways probably, of selecting the most nutrients you can for the $6-8, but that requires the techniques that Jean-Luc described, and has not been done. The other issue is whether or not yogurts ought to be included, the issue was cost. They were recommended by Institute of Medicine, it has not been implemented, California is now doing a study whether or not yogurts will give you enough nutrients for the money, and would they be accepted by the consumer? Again, that has not been done. The new WIC package is going to be introduced in June of this year, so time is running short.

PUBLIC: But that, Chairman, automatically means that when you talk about cost, you are not really talking about consumer costs and so on.

A DREWNOWSKI: No. It's costs to the State.

PUBLIC: You are talking simply about how to manipulate the package.

A DREWNOWSKI: Yes.

PUBLIC: So that it satisfies Congress not costing more money.

A DREWNOWSKI: Yes, yes. So for example, California is spending, you know several hundred million dollars a year, this is what they got, and they will not be spending any more. They want to reallocate foods *within* the system in some way so it's cost-neutral. And the question is how to do that? In my opinion, these techniques allow more precise calculation than just guesswork.

PUBLIC: Actually, it's Elizabeth from United States. Just to answer this question, USDA released a study in 2004 showing that consumers could eat 5 servings a day on less than a dollar a day. Now, that doesn't account for the changes in cost for foods, but

A DREWNOWSKI: Well, yes.

PUBLIC: Okay *[laughs]*.

A DREWNOWSKI: The USDA released a study, Elizabeth absolutely correct, suggesting that consumers could get 7 servings, or 6 servings, of fruits and vegetables for as little as 67 cents. But they based it on strange prices. What they did was to calculate the entire yearly outlay on, say, apples, $1,800,000,000. And then they calculated the amount of apples produced divided by one billion eight and came up with, you know, 67 cents per pound. So this is not how you necessarily do that. They were using global statistics of the average cost.

PUBLIC: Yeah, the other point that they often mention with the WIC program in the United States is that it is a 'supplemental' food package, it's not meant to provide everything.

A DREWNOWSKI: Absolutely correct, supplemental food package, yes.

PUBLIC: Because, Chairman, what that actually means, if I understand it, on a manipulated mass cost basis, about 10 days fruit and vegetable equivalents per month. And therefore, it has to be a supplement.

A DREWNOWSKI: anyway, yes.

How to communicate nutrient profiles to the consumer? AFSSA point of view.

Ambroise MARTIN
Faculté de médecine de Lyon, France

So thank you, I have to stop this very interesting discussion and to introduce myself and apologize because I was requested to give a brief overview of the French Food Safety Agency system, and I discover only a few hours ago, that the general title was, "How to Communicate Nutrient Profile to the Consumer." I remind you that in the regulation, theoretically, nutrient profiles are perfectly neutral, transparent for the consumers who will see only the result, if there is a claim or not on their product. But we have the chance to have a representative of a consumer association that is involved in the issue of nutrient profiles and perhaps he will give his advice more in line with the title...

The contribution of the French Food Safety Agency to the setting of nutrient profiles was prepared by a working group that I chaired the last year, and involving consumer representatives, which is not very usual in the French Food Safety Agency.

At the beginning of the work, we decided not to develop a nutrient profile system thinking that we have no time enough to do that and that there were already many systems on the market, if I can say. And we change our mind because we observed that we have in hand a system which was originally developed by Nicole Darmon to analyze the links between nutritional quality, food prices, and diet costs, and that this system could be adapted to the regulatory issue of claims. And also, since we were requested to answer the question laid down in the Regulation, the 5 questions about scoring, choice of nutrients, and so on, the questions that have already cited by Mike, we observed that in order not to have only a theoretical approach and to give a very theoretical answer, it could be useful to work on an actual system to give answers supported by some type of research.

This system is a system known as SAIN, which is a nutrition density score, the acronym is derived from French wording. It's an arithmetic mean of percent of the French recommended dietary allowances for qualifying nutrients for 100 kilocalories.

$$\text{SAIN} = \frac{\left(\frac{Nut_1}{ANC_1} + \frac{Nut_2}{ANC_2} \cdots + \frac{Nut_n}{ANC_n}\right)}{n} \times 100 \times 100$$

$$\text{ED}$$

y = number of qualifying nutrients
ED = energy density (kcal/100 g)
Nuti = quantity of nutrient i /100 g
ANCi = ANC of nutrient i for the general population (mean for male and female adults)
Nuti and ANCi are expressed in the same unit (g, mg or µg)

It's not necessary to develop the formula, of course, it appears to be complex, but with pocket computers it easy to perform now. It should not be a problem in practice.

The second dimension of the system is LIM, it is Limited Nutrient score, score based on 3 disqualifying nutrients which are calculated for a given quantity, 100 gram. So we have 2 reference bases, kilocalories for qualifying nutrients and grams for disqualifying nutrients.

$$LIM_n = \frac{\left(\frac{Nut'_1}{reco_1} + \frac{Nut'_2}{reco_2} + \cdots + \frac{Nut'_n}{reco_n} \right) \times 100}{n} \times 100$$

n = number of disqualifying nutrients
Nut'i = quantity of nutrient i /100 g
Recoi : daily recommended quantity of nutrienti

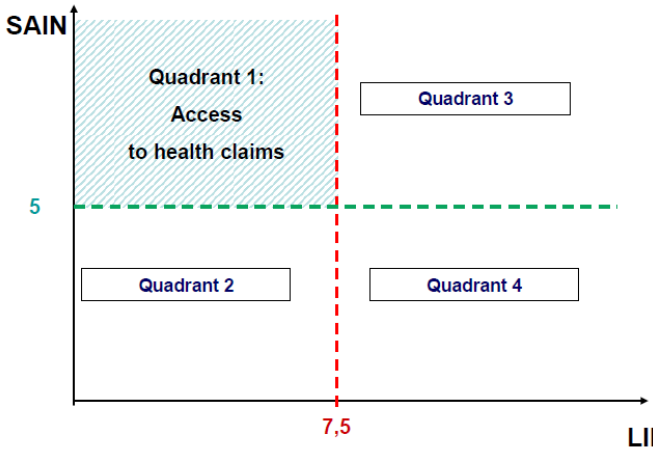
In the issue of the choices of nutrients, we tested many formulas, many different combinations, starting from 23 nutrients, and progressively reducing the number of nutrients in order to have a practical system, practical to implement in the real world. And finally we chose a formula containing 5 nutrients with the possibility of one optional nutrient. I come back later on that.

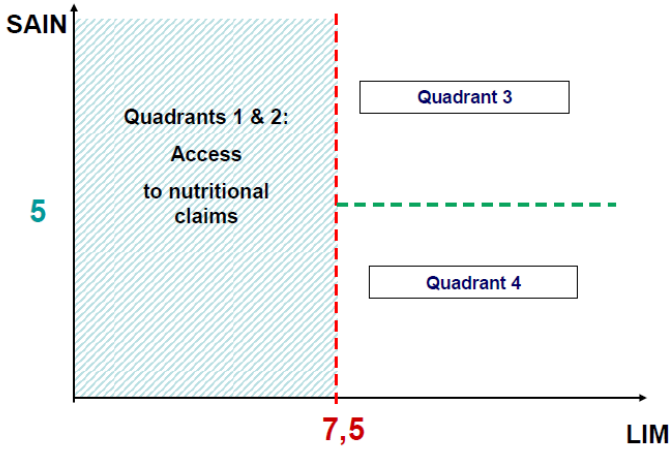
We also look for the relationship between the chosen nutrients and the other nutrients, and it appeared that the chosen nutrients displayed the best correlation with all the other nutrients, so that these proxy nutrients are really linked to the other nutrients which are not introduced in the model. The same thing was done for the LIM. We tested only, in this case, 2 different formulas, and chose the formula with 3 nutrients, sodium, saturated fats and added sugars. Dealing with the reference basis, the interesting point is the choice of 2 different reference bases, one for qualifying and the other for disqualifying nutrients, so that there is no compensation for nutrients, in contrast with other scoring systems using a single reference basis. Also, the advantage of an across-the-board system appears, from our experience, to be the easiness to justify the choice of the threshold for the score. And for example, for the optimal SAIN we considered that the optimal SAIN is 100% of the recommended dietary allowances for the general accepted number of 2000 kilocalories per day. So for one 100 kilocalories per day it leads to the adoption of a 5% of the RDA for 100 kilocalories. The same reasoning is made for the maximal LIM leading to the choice of the threshold value of 7.5% of the limit for 100 grams.

The result is four quadrant representation: because there is no compensation of qualifying nutrients and disqualifying nutrients, there is no need, like in the U.K. system, to add additional rule in order to discriminate between some foods, because the same result can be obtained with a food which is high in good nutrients and relatively high in bad nutrients, and a food which has no bad nutrients and a low level of good nutrients. And perhaps the nutritional interest is not the same.

The representation divides the food table in 4 quarters (1=high SAIN, low LIM; 2= Low SAIN, Low LIM; 3= High SAIN, High LIM; 4= Low SAIN, High LIM), and we

proposed that it's a choice, it can be contested or modified, that to be eligible to bear a claim, the food should be in the first quarter with a high SAIN and low LIM.





We also propose something different, which is not in the Regulation, but not prohibited by the Regulation, that we could be more generous for nutrition claims because promoting value, in term of selling, is less than health claim, and to accept all the foods which do not exceed the threshold for the LIM. In addition, it was interesting to demonstrate that a scoring system is perfectly compatible with the application of the derogation for nutrition claims which is in the Regulation. It was difficult to convince some of the members of the DG SANCO, for example, that it was possible to apply the derogation with a scoring system. It's perfectly clear from our experience and the same thing could be verified with the English system or any scoring system. It's very easy to apply the derogation.

The result of the SAIN-LIM system using the French Food database is presented on this slide. No time enough to comment on that, it's not very important because it depends on the specific composition of the database. And since an official database does not represent actual foods, it's not necessary to comment further.

Some points for discussion. The interest or the advantage of an across-the-board system, no categorization is needed, and Mike has made some comments on the difficulty of a priori categorization of all the foods present on the European market. The application of the derogation is possible and easy. And this system which is based, on one hand, on the nutrient density for the SAIN, and on, more or less, energy density for the LIM, take into accounts some very important ideas in the nutritionists' mind.

Also we observed that for ready-to-eat meals, for example, or composite dishes, there was a distribution in the 4 quarters around the thresholds, and we think that this fact highlights that some minor changes in the recipes of these composite dishes could allow for this food to move in the right quarter if it is the wish of the producer to bear a claim.

It's a tool which is obviously configurable. The choice of nutrients could be modified if we want, it could be modified, also, if there is a choice of a mixed system because the system is also compatible with a mixed system, across-the-board for all the food with specific derogations for specific categories. Also the references which are used could be adapted, we use French references, but of course, a population reference intake could be chosen. And so on.

The report has not yet been published, it will be published, I hope, within a few weeks or perhaps a few days, by the French Food Safety Agency (the report is available on the Afssa website (www.afssa.fr/NUT-RA-profils[1].pdf)). But since the report has been finished for the experts, we have continued to work, and specifically in the issue of validation, which is very important. And Nicole Darmon, in fact, has obtained very recent results that I want to show to you.

Linear programming is perhaps a tool which is underused in nutrition. It's a computer-based tool which, in theory, is very easy to use to answer to some questions. In order to achieve linear programming, we need 3 things. The first thing is a food database which contains what you want. Here, to answer to the first questions, the food database contains only the food eligible for health claim by the SAIN/LIM system. The second set of data you need is a set of constraints in order to obtain, in some way, a realistic diet. Thus we imposed nutritional constraints, the respect of the recommended dietary allowances, but also acceptability constraints, for example, portion sizes which have to be realistic. The third need is to define the objective function what you want, to minimize or to maximize, energy for example, while respecting the constraints. I show you the results about minimal and maximal achievable, but of course, if you have in your database, you have the prices, the cost of the food; you can minimize the prices and see if the diet can be achieved at a reasonable cost using foods eligible to bear claims. And the last step is to optimize: is it possible to fulfill all the constraints, and since the objective function is energy here, within which energy range?

So the first question was: *is it possible to fulfill nutrient needs by selecting only foods eligible to bear claims*? The second question was a reverse one: *is it possible to fulfill nutrient needs by selecting only foods not eligible to bear claims*? And only the foods in the database changes, nutritional constraints and the objective functions were the same. And the third question was: *is it possible to eat unhealthily, i.e. not respect the nutritional constraint by selecting only foods eligible to bear claims*? And so we change the nutritional constraint and introduced which could be considered as a nutritionist's nightmare, for example, we imposed to have a fat intake above 40% and so on. And the last question was: *is it possible to eat unhealthily by selecting only foods eligible to bear claims*?

So the answer to these different questions is: yes, for the first one; it's possible to build a well-balanced diet with a large energy range using only the food selected by the French system. And it is not possible, mathematically impossible, to fulfill nutrient needs by selecting the foods which are excluded by our system. Yes, it is possible to eat unhealthily by selecting only foods eligible to health claims, but within unrealistic energy range. And is it possible to eat unhealthily by selecting only foods not eligible to health claims? It opened a door which is already open, I think, but yes, it is possible within a large energy range.

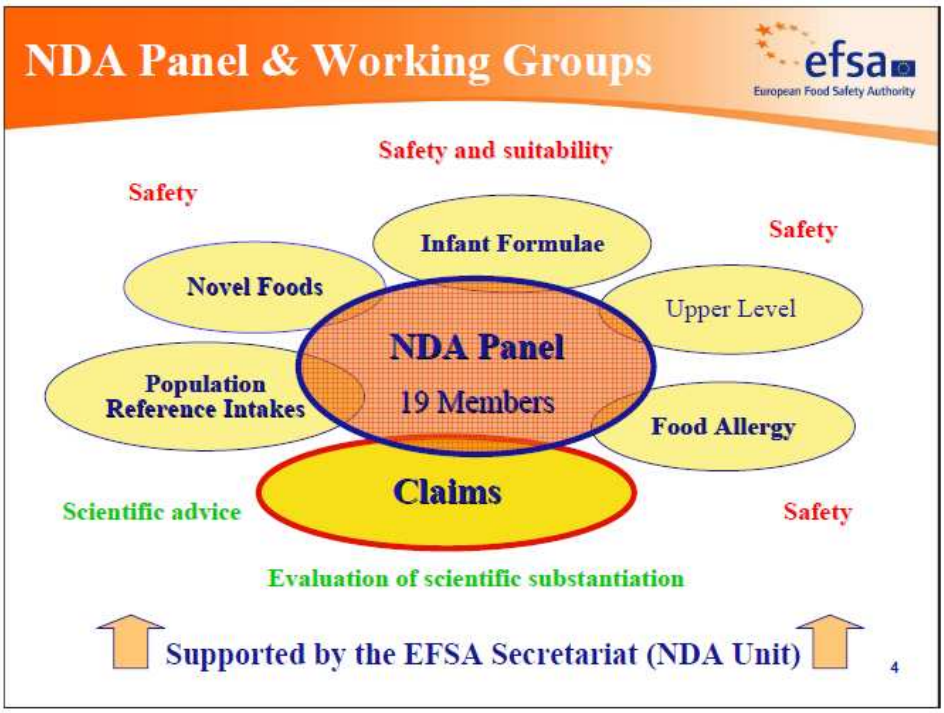
So we propose that this tool could be used as a complementary tool to expert judgment and the method already developed and perhaps to other methods, to assess or to compare the results of the different systems. For example, if it is impossible for fulfill healthy constraints, the system should be too strict. In the reverse situation, if it's possible to fulfill unhealthy constraints within a realistic energy range, the system is not strict enough. And if we compare the energy range needed to fulfill healthy and unhealthy constraints, we can rank the different systems according to their degree of severity, so we can give to the managers some objective arguments in the choice of the final systems. Thank you very much, it was the last slide.

How to Communicate Nutrient Profiles to the Consumer? EFSA representative

Leng HENG
European Food Safety Authority (EFSA), Parma, Italy

Thank you very much. My presentation today is on the EFSA's opinion related to nutrient profiles. Let's start with a brief background of the Panel and the EFSA tasks in the framework of the regulation on claim, then I will focus on the opinion on profiles.

Among the [...] scientific panels of EFSA, it is the Panel on Dietetic Products, Nutrition and Allergies, the so-called NDA panel, which has been mandate to deliver the scientific opinions of EFSA in relation to human nutrition, also as on claims and profiles.



These are the tasks of EFSA in the framework of the claims regulation. EFSA was request by the Commission to provide scientific advice and technical support on nutrient profiles. EFSA has provided scientific and technical guidance for health claims applications, and last, but not least, it is EFSA has to evaluate scientific substantiation of claims.

Now moving on to the profiles. The question, are all foods allowed to bear a claim? The regulations set out conditions for the use of nutrition and health claim, and [to avoid] that health claim must be, overall, nutritional status of a food product and mislead the consumer--only foods which comply with a profile, might bear claims.

As specified in the regulation, in accepting the profile, the Commission has to request EFSA for scientific advice, focusing on a number of issues you are familiar with. And these profiles should be based on scientific knowledge on diet, nutrition, and their relation to health.

EFSA [...] its opinion late January 2008 after 2 stakeholder consultation events. I'd like to stress that the advice from EFSA focused only on the size and the [...] nutrient profiles. So here is some general principle. In this context, the purpose of nutrient profiling is solely for the regulation for the claims, not for communicating to consumers.

The nutrient profile in the overall diet is an important factor in determining health. The profile or balanced diet is defined by nutrient intake recommendations. The panel identified 3 scientific criteria that can be used by policymakers in deciding which foods are eligible to bear claims. The potential of food to adversely affect dietary balance is the main scientific consideration. This consideration relates, in particular, to nutrients for which there is evidence of a dietary imbalance in EU populations that might be related to overweight, obesity, and diet-related disease. That includes nutrients that might be consumed to excess, as well as [...] intakes might be inadequate. And the dietary role of different food groups and their contribution of nutrients to the overall diet of the population must also be taken into account.

These are the [...] food groups that play important dietary role and [...] in food-based dietary guidelines. Finally the nutrient profile should be consistent with food-based dietary guidelines established in Member States.

So the question now is which nutrients to be included? The choice should be driven by the public health important for EU population. This includes nutrients generally which do not comply with the intakes recommendations. Of course, not all nutrients would have to be included; otherwise, we will run into overly complex schemes. The Panel also recommends that some nutrients might not be needed, or could be include for select products. For instance, trans fatty acid might be include for some food groups. But they are decreasing public health importance as intakes are declining in the EU due to the product reformulations.

Which type of scheme? The Panel evaluates different options and considered a nutrient profile for food in general, except for limit number of foods group that play important dietary role, might overcome the main disadvantage of the across-the-board category-based scheme. For the use of different reference quantities, as well as for the choice of threshold values or scores, the Panel outlined the advantage and disadvantage, each. And recommend that the choice should be based on pragmatic consideration relate to the need of each scheme.

The regulation also required the testing of the model to be applied. For this, there is a need to apply the model to the selection of foods on the EU market. This required a database of energy and nutrient contents [...] foods as purchased. Then the question is, there is a need to evaluate the outcome, does the model classify foods in the same way as by expert judgment? The classification of foods for their eligibility to bear claims can be done by using the 3-sided criteria already outlined. In addition, all the nonscientific criteria must also be taken into account. For instance, the need to promote innovation, the feasibility, and the easy of use for this scheme to apply.

The panel also outlined scientific limitations of nutrient profiles. It is rather difficult to set at an EU level, then at national level. Owing to the lack of uniform data in the EU for food composition and food consumption, there are differences in nutrient recommendations, also in the food-based dietary guidelines among Member States. There are differences in dietary habits and [...] EU. It is also difficult to apply to, in EU foods, the nutrient recommendation established for the overall diet. And the nutrient content of foods as purchased can change during preparation and cooking.

Finally, there is no data at all regarding the habitual intakes and pattern of consumption of individual foods. So this limitation outside the need for expert judgment to be used in setting profile, and the basis for judgment, should be transparent.

So in addition to the scientific opinion delivered, EFSA continue to provide technical support to the Commission. EFSA has developed a tailor-made food composition database, compiling cooperation with Member States industry. The database include

over 500 different foods select from 20,000 food [...] food composition database from 6 Euro Member State. The setting of this [...] require dynamic process allowing for repeat feedback between the Commission and Member States. This data may be used for testing different nutrient profiles in EU provide by the Commission.

Now, to conclude, I would like to clarify some confusion about the [...] of EFSA. It is not for EFSA to decide on which nutrients to be included. The different quantity, threshold value score, the scheme to be implement, the sample food to be test, the criteria to be used, and the specific profiling system to be adopt, these are to be decide by the Commission and Member State. Based on EFSA opinion, and the technical support provide by EFSA, by January 2009 the Commission and Member State will establish specific profiles, including exemption and [...] views. That's my presentation, thank you very much.

As you can see, in the European Food Safety Agency experts have nothing to do *[laughs]* as compared with the National Food Safety Agency where they have built national systems. It's a joke, of course! *[laughs]* As indicated by Leng, we have a huge task with substantiation of claims that we are very pleased that we have not to develop a specific system.

I propose that we continue directly to the consumer reaction and perception, and question and comments, and so on, because it was a vital of the last part of this session. And I hope perhaps we will have some time to have a general discussion.

Ch. Pernin is an active member in French consumer associations, there are 19 or 18 consumer associations which are [...] in the national level. But not all are involved in the field of nutrition, and the "Confédération du logement et du cadre de vie", will give the English translation, perhaps, is very active in his field.

How to Communicate Nutrient Profiles to the Consumer
Consumer's Association Representative

Charles PERNIN
Consommation Logement et Cadre de Vie (CLCV), Paris, France

Je vous prie de m'excuser, mais je vais m'exprimer en français. Je voudrais aussi m'excuser puisqu'à la différence des intervenants précédents, je ne parle pas anglais, je ne suis pas scientifique et je n'ai même pas de présentation, mais en revanche, j'essaierai d'être bref puisque j'ai cru comprendre que nous avions un horaire très serré.

Je voulais d'abord rappeler en quelques mots ce qu'est la CLCV. Nous sommes, comme le disait Ambroise, une des principales organisations de consommateurs en France et nous sommes bien sûr intéressés par toutes les questions ayant trait à la qualité de l'alimentation, nous sommes, par ailleurs, membre du BEUC qui est la Fédération Européenne des Associations de Consommateurs et nous avons donc travaillé sur cette question des profils.

Je voudrais aussi saluer la qualité des exposés scientifiques que nous avons eus aujourd'hui et je voudrais revenir d'abord brièvement sur le pourquoi de tout ce travail, pourquoi cette question des profils est-elle posée aujourd'hui au niveau européen ? Il faut bien le reconnaître, cet outil que sont les profils correspondait à la demande des associations de consommateurs françaises et européennes. Cet outil, comme vous le savez, a été défini pour permettre un meilleur encadrement des allégations nutritionnelles et de santé. Nos associations avaient en effet pu constater un certain nombre de dérives en matière de publicité et d'allégations nutritionnelles.

Ceci étant dit, ce qui me frappe, suite aux exposés auxquels nous venons d'assister, c'est que manifestement, il reste quand même dans la définition scientifique des profils un certain nombre d'incertitudes ou à tout le moins, une part d'arbitraire. On voit également qu'il y a une grande variété de systèmes, je crois que vous disiez que 38 ont été recensés. Et puis dans la logique même, dans l'approche même de cette évaluation de la qualité nutritionnelle, il y a des méthodes très différentes : avec ou sans seuils, par catégories ou sans catégories. Tout cela est finalement très riche, mais renvoie aussi un peu l'image qu'il n'y a peut-être pas encore, peut-être que cela viendra un jour, de certitudes absolues ou de consensus scientifique très ferme dans ce domaine. On l'a bien vu, ces systèmes seront finalement amenés à évoluer, à s'enrichir. La nutrition est une science où l'on en apprend apparemment tous les jours, on imagine même qu'un système défini aujourd'hui qui ferait consensus pourrait être amené à évoluer d'ici quelques années.

Ce constat nous amène finalement à une position, je dirais, de prudence quant à la question de savoir s'il faut communiquer ou non ces profils aux consommateurs. Faut-il communiquer ces profils aux consommateurs ? Je n'en suis pas absolument convaincu aujourd'hui pour les raisons que je viens d'évoquer.

Dans la définition des systèmes on a bien vu le rôle joué par l'EFSSA. Mais il y aura aussi des arbitrages presque politiques, qui relèveront en tous cas de la Commission Européenne. Pour l'instant, il nous semble que ce système devrait être utilisé dans l'objectif pour lequel il a été défini, c'est-à-dire l'encadrement des allégations nutritionnelles et de santé. On peut envisager à termes peut-être d'autres applications, par exemple, sur la publicité. En revanche, il ne nous parait pas faisable d'envisager à brève échéance l'utilisation de ces profils pour un étiquetage et une information nutritionnelle. D'ailleurs on peut même s'interroger sur l'utilité pratique pour un consommateur d'une information de type « profil nutritionnel » sur un produit. En effet, si l'on a un profil nutritionnel transversal à toutes les catégories, c'est à dire un seul système qui couvre toute l'offre alimentaire, on risque d'avoir quelque chose qui va nous dire : finalement, les fruits et les légumes, c'est bon, vous pouvez y aller, en revanche, les barres chocolatées, il faut avoir une consommation plus modérée, il me semble que l'intérêt pratique est finalement assez limité, ce sont des recommandations que l'on peut avoir par ailleurs de façon beaucoup plus générale par une sensibilisation bien menée. Si l'on a un système par catégorie, c'était l'exemple qui nous était présenté auparavant, on va être amené à dire : entre la charlotte aux fraises et la charlotte au chocolat, il vaut mieux manger de la charlotte aux fraises. Mais je ne sais pas quel sera l'impact réel en termes de santé publique : on peut imaginer qu'il y ait des gens qui ne consomment au dessert plus que de la charlotte aux fraises et ce n'est peut-être pas aussi ce que l'on souhaite Je pense que l'utilité pratique et l'impact en terme de comportement de consommateurs et en bénéfice reste à démontrer en ce qui concerne en tout cas une utilisation en tant qu'étiquetage nutritionnel.

Juste un point sur la question des fruits et légumes puisque c'était quand même le cadre général de ce sommet, d'une manière générale, pour les fruits et légumes la situation est assez simple puisque l'ensemble des systèmes sont conçus justement pour que les fruits et légumes puissent alléguer, en revanche, là où les profils nutritionnels pourront être très utiles, c'est pour peut-être encadrer la communication et la publicité qui se fait sur des produits transformés où il y a parfois un petit peu de fruits et légumes et où il y a, par contre, énormément de marketing et de publicité.
Je vous remercie.

Discussion

Pour rebondir sur ce que vient de dire M Pernin, le gros souci aujourd'hui justement pour favoriser une bonne consommation de fruits et légumes, ne serait-ce que d'abord en France, ce serait peut-être de penser à pouvoir mettre en allégation les fruits et légumes bruts, ce qui n'est pas le cas aujourd'hui et pourtant, on sait très bien que leurs valeurs nutritives et phyto-chimiques sont nettement les meilleures en produits bruts. C'est un premier point.

Le deuxième point, c'est effectivement de savoir que sur des produits élaborés – j'ai cru entendre tout à l'heure que dans le prochain process, il serait mis effectivement les plats élaborés et cuisinés ; on sait que les grosses multinationales aujourd'hui ensellent de façon très significative, pour des raisons de conservation ce type de plats, est-ce vraiment nécessaire de les induire dedans malgré, il doit être certain, une pression directe ou indirecte de ces multinationales et puis principalement de revenir sur les points de l'EFSA encore aujourd'hui, sur les allégations santé puisque l'on ait toujours repéré sur le fait qu'effectivement, on n'a pas de critères scientifiques qui nous affirment qu'un crucifère riche en antioxydant va quand même prévenir, je dis bien prévenir, dans une incertitude, c'est sûre, mais les radicaux libres, les effets carcinogènes qu'ils peuvent avoir, est-ce qu'il est envisagé par l' AFSSA et l'EFSA via ensuite la Commission Européenne d'élargir un petit peu les allégations rapportant bien sûr fonctionnelles et santé pour des produits bruts et élaborés. Bien sûr avec des vérifications qui se font de par les industriels, qu'ils soient nationaux ou régionaux. Aujourd'hui, je représente un énorme producteur européen de fruits et légumes, nous investissons des millions d'euros dans la recherche pour justement arriver à une consommation bien meilleure et on espère au-delà de l'Europe, néanmoins, on a aussi besoin d'avoir une « publicité », j'appellerai plutôt cela de l'information pour les consommateurs, je ne suis pas trop convaincu de l'effet de marquer les nutriments parce que je ne suis pas convaincu que le consommateur fait la différence aujourd'hui entre un lipide et autre chose et les lipides gras saturés, par contre d'avoir une allégation qui va dans le sens aujourd'hui pour le bien être de la santé des gens, je pense que l'on pourrait dynamiser correctement notre consommation de bons produits sains pour aujourd'hui et pour l'avenir.

Thank you very much for these comments. Would anyone like to comment?

...about profiles that you've seen, all the different profiling system that have been shown, like this LIM or other, show clearly that fruit and vegetables are high in the good sector of the composition that will then have a good profile. So I think on this--about your question about the quality as a composition of, it [show] composition of different fruit and vegetables and transform product, you know that there is a very big NOR report that was published last year, we have extensive [...] review of that, so I think it could be a reference, also, to discuss this point. ///

For me, if I can have a comment. For me, nutrient profile is only a tool, as it has been already said. And the good effect can be expected only if it is integrated in a current nutrition policy, nutrition education, and nutrition information. By itself, we do not expect that they will solve all the health problems. Mike? ///

Yeah, I just wanted to point out. I think the session today has made it seem that there is lots of disagreement amongst societies. But actually, I think we are moving towards a greater position of consensus. And we do now have some very good models, which are well-validated models, and also we do have most of the models classified, in things like fruit and vegetables, in the same way. So I think we shouldn't be left after today's presentations with the feeling that we are not getting anywhere, in terms of nutrient profiling. It's all very complicated. I think we are making progress, and we are moving towards much more consensual positions in defining healthy and unhealthy foods. ///

May I comment? I agree with that. I would say that more commonality came across. For example, our negative component is exactly the same as Ambroise's component. And we are also using linear programming to use nutrient profiling as a tool within the broader context of preferences in consumer behavior. So I think this is where the future is going, it's going to be a tool, but one of many, integrated within a healthy diet. ///

So the issue of claims, claims substantiation is another issue. From the prospective nutrient profile, there is no problem with fruit and vegetables. About what could be said [...] [...], there are 2 aspects. The first one is generic claims which can be used by any food containing the nutrients. For the moment we cannot say what could be the result of the evaluations, because we have not yet received the consolidated list by the European Commission, so we are not sure what we will have to assess or to substantiate. You have the results of the evaluation of the joint Healthcare Initiative, you have the results of the French [...] [...] about some generic claims. For the moment you have to wait for June or September 2009 to have the result of the European Food Safety Authority. And to wait for January 2010 to have the final decision by the Commission about the generic claims. But if you have specific research, of course you have another possibility to have specific claims. And EFSA has released in July last year a guidance document. So this document can help you to design the [...] studies which are weighted by the experts in order to judge if a claim is substantiated or not. So the frame is very clear. And again, claims and profiles are only a specific tool for specific things. Of course, if there is a genuine nutrition policy to promote fruit and vegetables by funding, for example, for interventions in school programs, in school [...], so there are many other ways. And perhaps you are not very happy with all the results of the process, but I can assure you that many people in this field are not happy at all, because there are some, we are winners and some are

losers on specific points. Sometimes they are the same, so. *[laughs]* ///

I am surprised that given the variety of applications, your last comments are extremely important. I mean, we are doing things in the European context, Europe is the biggest exporter and importer of food, shouldn't we be thinking of this in a general way, applicable to foods globally? Because if you are involved in claims and trade, that seems to be fundamental. And I just wonder whether we are just being manipulated by the Commission, dominated by small sector interest, in only positive claims. When, as we've seen by the WIC program, you know, there is a completely different perspective that we could have. I'm also surprised that Mike talked about categories as though they were valid, all these pyramids and plates, and so on, presupposed advice to change categories. So surely, we have to dispense with all categories. I'm very intrigued by how benign you are to fundamentally ridiculous propositions. ///

[laughs] /// It's alright. *[laughs]* /// I think there is sort of an emerging consensus that a scheme which applies to all foods would be simplest and makes a lot of sense. The AFFSA scheme, the U.K. FSA scheme, essentially have across-the-board schemes. But it seems to me that the Commission, in this instance, is pushing for categories. I'm not sure on what basis, and you're right, I mean, on what basis are they defining these categories which Heng pointed out. I think they are moving in the wrong direction in that way, but people need to talk to the Commission and persuade it to have an across-the-board scheme like the AFSSA scheme or the FSA scheme. ///

Interestingly enough, the FDA serving sizes, to some extent, correspond to food categories because they take into account the huge difference in serving sizes in things like sugars, and oils, and desserts, and juices, and so on. So it actually, my position is, it might be easier to introduce serving sizes in Europe than to engage in a yearlong debate of what food categories really are, which could be unproductive and go on for far too long. So it would be easier to introduce serving food sizes. ///

Yes, but to define serving sizes at the European level with 27 Member States. For the moment, it has been [charged] that it is an impossible task. But perhaps *[laughs]* they could change their mind because there are many, many discussions between the different food suppliers and so on, the categories, to try to define portion size at the manufacturer levels, perhaps. But for the moment, we have not, and it has been no longer discussed by the EFSA Panel. ///

So I think we have to stop, unless the buses are not here. Are they here? The buses are already here? Probably. So thank you very much for these very interesting discussions and comments. And enjoy your cocktail. Thank you.

SESSION 20

INTERVENTION STUDIES TO INCREASE F&V CONSUMPTION IN DISADVANTAGED POPULATION IN DEVELOPED COUNTRIES

Chair: **S Hercberg**

- Nutrition interventions in low-income groups: dearth of research on effective interventions. **AS Anderson**
- Effect of a targeted subsidy on intake of F&V among low-income women in the special supplemental nutrition program for women, infants and children. **D Herman**
- Providing an economic supplement for fresh F&V purchase. **H Bihan**

Dearth of research on effective interventions

Annie S. ANDERSON
Centre for Public health Nutrition Research, University of Dundee, Dundee, Scotland, UK

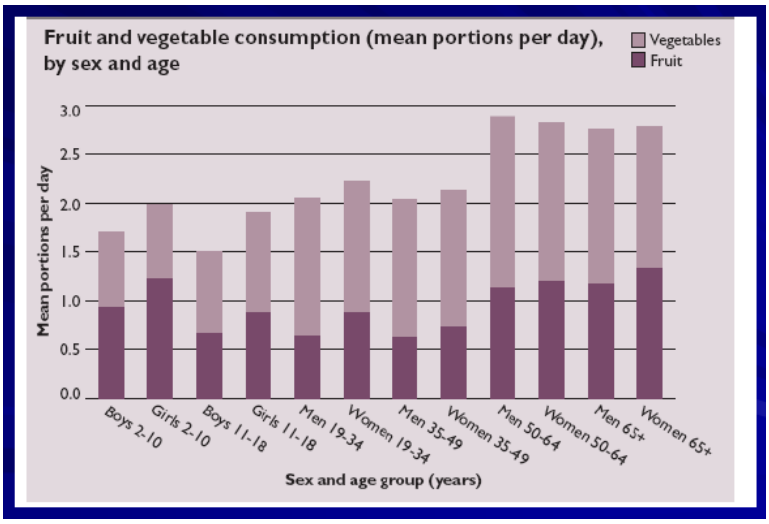
Thank you very much for the invitation to speak on this very interesting title, "Nutrition Interventions in Low-Income Groups: Dearth of research on effective interventions."

And what I'm going to do is reflect, firstly on the context of low-income groups, then look at issues that arise from diet interventions that have taken place in different settings. So I'm going to take quite a wide perspective on diet interventions. I'm going to reflect about some issues between research, practice, and policy, and that relationship. I'll talk about recent systematic review on behavior change in low-income groups, and then finish with some comments on a wider research agenda.

So let us start about the context of diet and issues surrounding low-income groups, and this is within a U.K. context. We have a recent publication, The Low-Income Diet and Nutrition Survey, which is a representative sample of low-income and materially deprived households in the U.K. There are many things I could say about this Survey, many things have been said, and many things have been said by the U.K. government saying that perhaps there aren't so many issues about low-income groups as originally we thought.

But I think there are some headlines that we need to take account of when we are designing diet interventions for this population. For example, 87% of women and 75% of men aged 50-64 have serum cholesterol levels above what is desirable, in terms of cardiovascular disease. So I don't think we can ignore this risk factor in this population. In terms of body mass index, and this is data for women, 30% of our low-income group are in the overweight category, 33% in the obese category. So in terms of need, in terms of dietary interventions, the case isn't hard to make.

When we look at the diet of these consumers, there are 2 major issues that can be flagged. One is that only 8% of men and 9% of women actually achieved the goal of 5-per-day, so there are some major challenges there.



And the other major difference in dietary intake between our group of low-income consumers and the

national population is intake of sugar. And we see a very notable social gradient. And this slide, if you look at the middle columns for men aged 19-64 in the low-income group on the dark bar, and the national population in the lighter bar; you can see that the low-income consumers eat considerably more sugar. So we have low fruits and vegetables, high sugar intake, and a range of risk factors associated with health.

Who are low-income consumers? We use one term to really describe a very diverse group within our community. They include lone parents, both mothers and fathers. They include unemployed, but also the employed. And I think it's very important to note that many of our low-income adults are in low paid short term jobs. They include manual works, they include pensioners. So we have a broad age spectrum within our communities. And they include ethnic minorities. So it isn't one population that we talk about when we say the "low intervention group."

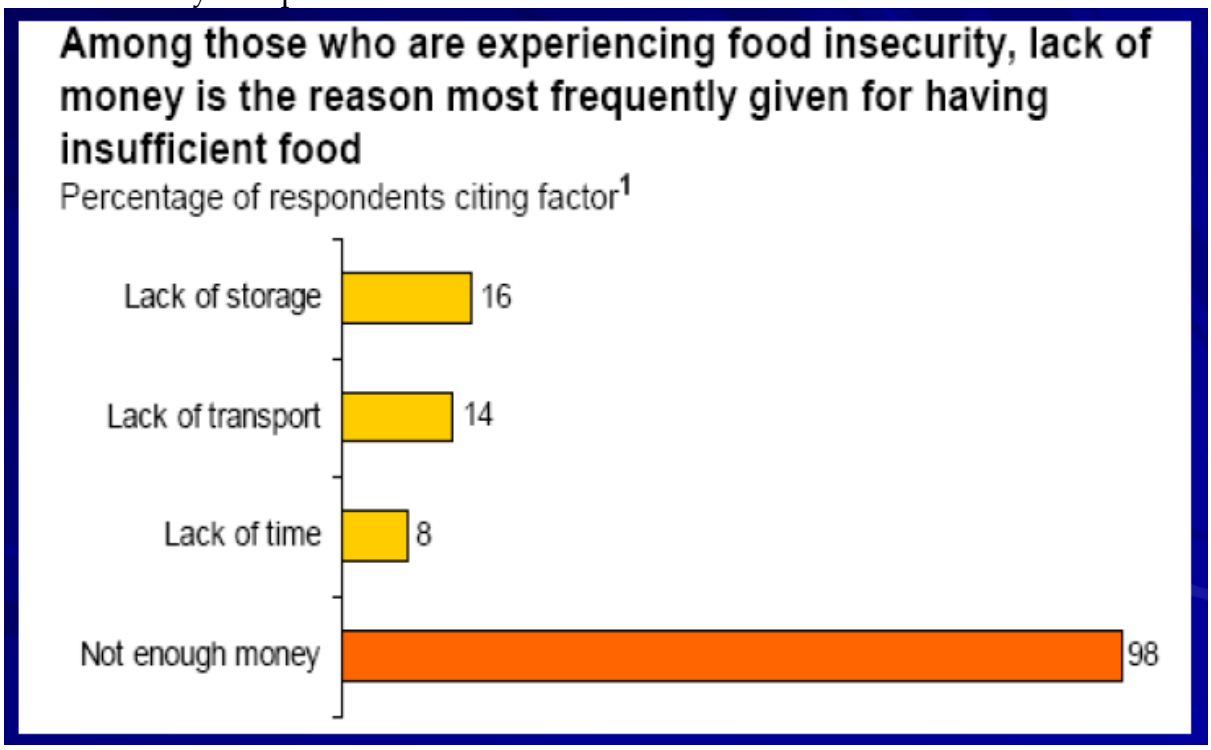
One other very striking finding about the Survey is this particular issue: limiting long term illness. By "limiting," it means limiting everyday activities, opportunities for work, leisure, and so on. 42%, that's almost half, in adults aged 45-54, claim report limiting long term illness. 60% in those aged over 55. This is a population who we are trying to intervene with who have circumstances that, actually, they are not very healthy, they are not very well. And that's both physical and mental health. And we need to take this into account, and this presents both challenges and opportunities for intervention settings.

Within the low-income group we can identify the poor and the poorest. So within the survey, 29% of the survey reported living in food-insecure households. And these are particularly women who are also able to demonstrate that women who lived in food-insecure households had a less healthy diet than those who were secure. It's harder to show this relationship for men, but it's clear for women. 39% reported that they were worried about food running out, and 36% reported they could not afford to eat balanced meals. So we have some very important considerations and concerns about trying to eat well in this vulnerable grouping.

Now, within this Survey there were a number of questions posed about issues about the relationship between money and food choice. So among those who were experiencing food insecurity, lack of money is the reason most frequently given for having insufficient food. And I think this graph depicts that very well. At the bottom line you have 98% of people saying they do not have enough money for food.

Respondents were also asked what factors they felt would facilitate the desire to changes in diet that they reported. Many people reported that they wanted, for example, to increase fruits and vegetables. And the overriding response was more money or reductions in price of food. There were other factors like individual

attitudes, like willpower, like self-discipline. And down at the bottom there, there were some factors like improving cooking skills, improving storage facilities. But let's not kid ourselves, at the top, the *strongest* factor that was presented was issues around money and price.



So let's put this together, in terms of summing up our starting point for interventions. We have a very diverse target group. There may be some very specific issues for women. They are diverse in their socioeconomic profile and their social characteristics. But there are people who are *very* poor, as well as being poor. These are people who are not well. There is unlikely to be one intervention that will fit the whole of our low-income community. Price is clearly an important issue in terms of personal budget. But there are other issues like support, like attitudes, self-discipline, and so on, which tells us that we perhaps need to think of both societal approaches and personal approaches. We need also to remember the wider aspects of food marketing that are likely to impact on these vulnerable communities. And finally, our governments would say the cost of interventions surely must be a major factor.

But when we think of costs of intervention, in particular on price, we need to balance that with the cost of ill health. And this is some data that was recently presented, in terms of restricting advertising to children. The impact of changing the increase of fruits and vegetables to 5 a day, reducing salt, cutting saturated fat, and what the impacts of that would be in terms of death avoided each year, and [...] affecting morbidity. So if we are going to talk about prices of interventions, these need to be balanced with the prices and costs of healthcare.

So let us turn now to a classical approach of how we might influence dietary

behavior. We think of micro environments working at the individual level, macro environments in a settings level, and also international environments. And let us start here with that wider, national environment. So in terms of what might impact on dietary choices, and this is dietary choices in the widest context here, we have to learn, I think, from work in tobacco. And we heard this morning about impacts of increasing tax on undesirable products. The tobacco work has certainly shown that young people and the poor are most responsive to price change. But actually, maybe we need to think of the other approach, which is lowering prices, lowering prices of fruits and vegetables, and what impact that much *wider* intervention would have on individual choice.

In terms of macro environments, we tend to think about community environments, and Phillip James mentioned this morning the North Karelia Project, the work in Finland. And this project, of course, which was initiated around over a 20-year period, was *very* interesting in terms of the effects both of fruits and vegetables, and the effects on mortality and morbidity. And we need to learn from that, but it's difficult to identify analysis by low-income groups. So there is an important issue about impacts on the *whole* of the population, and not just focusing on low-income communities.

Within the U.K., we've had a number of community-based interventions aimed at improving or reducing cardiovascular disease risk in different communities. These are some that have been undertaken over the years, Heartbeat Wales, Action Heart, Good Hearted Glasgow, Have a Heart Paisley, the latter two of which was undertaken in Scotland. And always the results of these studies say: it is very difficult to effect *major* change, so we are very ambitious about the risk factors that we try and change. There are complex interventions; it's very difficult to have good research design that allows us to compare the effect of our community group versus our control population, so we have a lot of contamination and overlap. And so many people feel that these sort of community studies, which have a lot of meaning and a lot of action at local community level, don't always produce the sort of research evidence that governments want to see, in terms of investing in health action and health promotion.

Focusing specifically on fruits and vegetables, we have our English Department of Health running a "5 A Day Program" which many of you will be familiar with. And the 5 A Day community initiatives are very much directed at local action within local communities. Very much bottom up work, which have been analyzed a lot, in terms of process. *Who gets the fruits and vegetables, how does it impact on knowledge, how does it impact on choice*? But not beyond that, what are the greater effects, in terms of hard health outcome measures? And it is always difficult when the relatively short term interventions are being carried out around fruits and vegetables and expecting to show hard health outcomes. So we need to be realistic about what our outcomes or

our impacts are, in terms of interventions.

Recently, we have seen a lot of work on retail initiatives around promotion and prices. We've recently undertaken some work with the Institute for Social Marketing at the University of Stirling, looking at direct marketing to low-income consumers. And this work was undertaken in conjunction with a major retailer in the U.K., the [Co-op] Supermarket. And within that database, it's relatively straightforward to identify low-income consumers because consumers have loyalty cards, and their background data on their household composition, and so on, is part of the data that the supermarket holds. We also wanted to target consumers who were main shoppers with that supermarket, and identify what we've deemed was "unhealthy" shoppers. And we had to identify certain food items that they selected on a regular basis which are generally high fat and high sugar items, as being people who were appropriate to target.

And our direct marketing meant that we sent leaflets, with quite significant money-off vouchers with recipes, which were aimed at increasing fruits and vegetables, and decreasing high fat milk and lower fat meat options. The recipes provided details of how to cook, for example, the lower fat meat *and* the importance of adding vegetables within recipes. The quite significant money-off vouchers, the level of voucher, was dictated or was informed by formative research with potential recipients.

And this intervention took place over one month to 45,000 consumers, so it was a significantly large intervention study. I'm not sure how well you can see all the changes here, but the intervention which took place over the month of May, when we look at the percentage intervention consumer base, we can see that during that month, for 4 of the products for which money-off vouchers were given, we did indeed *increase* the percentage of consumers purchasing those products.

Now, when I first looked at this data, I thought, ugh, it doesn't look very interesting, it doesn't look very significant, it's quite a small amount. The supermarkets, on the other hand, were hugely excited. Because it is really very important for them to get this sort of impact. And its good business and they think its worthwhile doing. So again, perhaps we need to learn about just how ambitious we are, perhaps, being with some of our interventions.

So the intervention did encourage purchase of the products, it increased the number of customers buying the healthy products. There is some switching from the high fat to the low fat product. But, of course, the effects were not sustained after the promotion ended. And here, of course, is a classical issue that we all have when we do intervention studies. Short term interventions, this is what our research always gets funded for. Where are the long term interventions that we need to be able to

demonstrate sustained effect?

So like any intervention, and that's true whether it's a drug or a community intervention, the intervention we can demonstrate is effective when it's there. If we remove it, it will not work. And that is very, very important.

Another retailer intervention that's being undertaken, this time in Scotland. It's not being undertaken by a research group. I came across this intervention on a Web search one day and also because I use my local shop. And it is part of the Scottish government's Healthy Living Program.

And the aim is to improve the supply of fresh products in neighborhood shops. So these are small, local shops, often in quite poor areas, and they are the sort of shops that people go to buy their bread and milk, perhaps not to do their major shopping. But we are hopeful, or the government is hopeful, that they may also pick up fruits and vegetables. And the type of work that's being done in these shops is to present, to market, the Healthy Living Program with providing stands of fruits and vegetables, providing chilled cabinets to provide a *range* of fruit and vegetables that *look* attractive, that the consumer meets as *soon* as they walk in the door, and even *before* they walk in the door. And to be honest, it's often the most exciting thing *in* some of these shops.

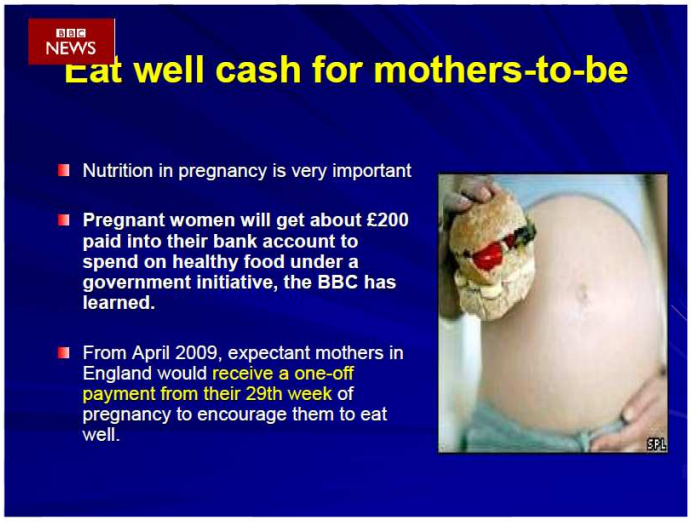
And a whole lot of initiatives went along with these promotions. A free piece of fruit every time a non-sugared drink was bought. A free fruit for every child accompanying a parent. Spend 2 pounds and receive a free piece of fruit. Now, the retailers, by their own admission, are not doing this primarily because they are interested in health. They want to increase their profits. The fruit here is not cheap. They want people to buy it. And it's marketed well. And this initiative has brought in business development managers, and tackled a lot of stores in deprived areas. They've also brought in store champions, and these store champions are somebody that can talk to the consumers, be friendly, and be part of the shop, quite different from what you find in national retailers.

And this is the sort of data that's available from that Initiative. And it's the percentage of sales increase for juice, yogurts, and a whole range of other products, as well. They have also done fresh fruits and vegetables, but I wasn't able to access the data. But they are very pleased, because retailers have found that they can market

these products, consumers will purchase more fruits and vegetables, and that includes low-income consumers, but they still make their profits. And there is an issue there about how, in fact, that can be incorporated with some sort of budgeting component, as well. But it reminds us that marketing is very powerful. Marketing can be used for positive purposes.

Okay and then turning to micro environments. And this is usually where most of our, perhaps, our intervention research will be found. And this is very much tackled at the individual - a lot of it is focused on women and children. And in the U.K., we have something called the Healthy Start Program which displaced our welfare foods program, and it's just started running over the last year. So pregnant women and children in the first 4 years of life, it offers coupons for women who are eligible for this program, and it is means-tested. So it is really targets the very poor, and any pregnant woman who is under the age of 18, so women must already be claiming social benefits to get on to this program. The vouchers that are available have just gone up to something like 3 pounds per week for milk, fresh fruits and vegetables, and for vitamin supplements. Now, this seems, on the surface, like a very worthwhile program. But when we look at research, we don't know what kind of effect this program will have. No baseline work has been done prior to the implementation of this program. And now, the Department of Health is trying to put some sort of research in, but it will be process, it will not be effect. So many of us who are working hard on research and trying to get an evidence-base, feel slightly frustrated that we have a government program that doesn't, perhaps, take account of effective evidence, and certainly optimal approaches, particularly around the cost of vouchers that's being provided.

And more recently, the English government also announced a special cash allowance for pregnant women who will get 200 pounds paid into their bank account, supposedly to spend on health food under a government initiative. And this, on the surface, sounds very good. It's going to be available for all women. But it doesn't come with any involvement of food. It is a check into the bank. So how does that affect? Where is the joined-up thinking there, in terms of trying to make some sort of effect and help the whole issue of trying to improve nutrition?



And I think this contrasts with the Women, Infant, and Children's program in the

U.S., which I think we will hear more about later, both in terms of the range of foods that WIC provides or woman have an opportunity to have, as well as the sum of money or vouchers that's related. Also in the U.S. we have the expanded "Food and Nutrition Education Program" which ties in an educational approach and builds on skills development. Again, something that we don't see in the U.K. We do, of course, see a lot of small scale community interventions around food skills development. This is one study that our group undertook a few years ago on the development and evaluation of a nutrition education for pregnant teenage women. These are a very, very vulnerable group. The city that I live in Scotland is the highest teenage pregnancy rate in the U.K., probably in Europe. And we were able to identify in a very short period, 120 young women who were eligible for a study of cooking skills, where we invited them in to eat, to cook, to bring their partners, their parents, and to also receive free food gifts. Of the 120 women we invited, only 16 were interested. So we think it's a wonderful idea, we think food skills are really, really important. These women have more important priorities in their lives. So we can think of many interventions, but we need to make sure that they actually relate to where people are at.

We also have a lot of schools initiatives going on in Scotland. For example, we have a free school meals scheme which has just been initiated as a pilot. And this has been rolled out for all children in primary schools in certain areas in Scotland, recognizing that the free school meals initiative that currently exists is only for poor children. So what happens if you take away that stigma and offer all children free school meals? We also have free fruit, we have milk, and we have mains-fed water coolers in schools, so we've lots of school work going on. What we don't have is research going on to show what the impact of that will be. And that raises this very thorny issue of that relationship between research and policy.

When we look at our academic texts, in terms of recommendations for community-based diet interventions, and this is returning again to the issue of women, we know that we should conduct qualitative research to determine what women would like to have, we should tailor programs to women's stage of life readiness to change, to specifics of groups rather than just a wide group. And that we also need to evaluate

policy and the environmental interventions. And this sounds like good common sense to a research community, but somehow it doesn't quite translate into what actually happens in practice.

Another study of cooking skills I'm going to talk about, which demonstrates another issue about undertaking research in vulnerable communities. A few years ago, we undertook a cooking skills project called the "Cook Well Project." You may, of course, have noticed that the direct marketing project we talked about was Buy Well. We like to add "well" and positive messages to our interventions. This project worked with existing community groups, people who were already coming to community centers, sometimes for literacy classes, sometimes for mother and toddler groups. But they existed as a group and we offered cooking skills programs. There was in interest in these programs being taken up. 93 participants in settings from across the country completed 50 7-day food diaries at 2 time points. The 3rd time point, with a further dropout of 40. The sort of impact, this cooking skills project had, and I'd really like you to notice the scales here, in terms of mean portions per week. And this is our intervention group. And we are talking in terms of fruit, about at Time 1, less then 2 portions per week - this is not per day - and the impact that our cooking skills intervention, which ran for 6 weeks, had. And really, the only significant impact was, in fact, on vegetables and salad, which went up slightly from 6 portions per week to about 7 portions. So the challenge is fairly significant.

However, there are other aspects of community interventions that emerge, including issues around confidence, including issues around self-efficacy. And when we look only at cooking skills, or when we look only at dietary intake, it doesn't really capture the whole impact of our community interventions. And these sorts of outcomes are things that we might be able to build on, to be able to *retain* our intervention groups. And there are big issues around data collection and undertaking research within low-income groups, and this is from our own findings, in terms of our studies and also from the low-income diet and nutrition study. We have issues about low literacy and numerously, English is not a first language for many people. There is often domestic chaos at undertaking surveys, we have to write everything down after it's consumed, is fairly challenging. We mentioned health before. Higher levels of obesity, higher levels of under-reporting. And really, we don't have much information about some of our most vulnerable group.

We mentioned that many people in low-income groups are unwell, and so why don't we have a health services approach to dietary interventions? Isn't this an appropriate setting, because many people will visit the primary care practitioners? We know in the U.S. that there have been various programs trying to tie in, for example, screening and interventions with some indications of important impacts on cardiovascular disease risk. And we know there are challenges around integrating clinical and lifestyle intervention, not least because our clinical colleagues are not

terribly skilled in lifestyle interventions.

But, I would like to focus on one intervention which is of interest. It's on fruits and vegetables, it is behavioral counseling to increase consumption of fruit and vegetables in low-income adults, a randomized trial undertaken by Andrew Steptoe and his colleagues in London, published in the British Medical Journal. It had all the designs for a classic trial. I use this paper quite a lot for teaching my students. An intervention group with brief counseling focusing on good theories of behavioral change, social learning, stages of change, tailored to the individual, personalized specific advice, 15-minute individual consultation versus nutrition counseling. A very brief intervention. The impact of the behavioral counseling demonstrated that the in low-income adults as significant increase in fruits and vegetables were possible. And this study didn't just look at reported intake, but also biomarkers. And the conclusion was that this brief individual counseling and primary care can elicit sustainable increases - this study was carried out over a year - in consumption of fruits and vegetables in low-income adults, at a level that would be clinically relevant. Is this research used in clinical practice? Has it been transferred out to our practice community? No. So there are real issues about research dissemination, even if we have effective interventions.

Now, I am going to wind up with just a last couple of slides. I recently came across a systematic review of low-income groups and behavior change interventions, published in the last month. 9,725 references were found, and the number actually included in the review was 13. And this isn't just healthy eating; this is smoking cessation, healthy eating, physical activity, and interventions that covered more than one behavior. So if my title was "Dearth of Research on Effective Interventions," probably these slides say it all. And at some point, people have probably got to say, if this is all that can be collected, what can we really say? But of course, people that are paid to do reviews like this, don't stop work if little is found. They say, well, what have we got from these small numbers of interventions, not all of which were effective? Well, it looks like intervention techniques in low-income groups that are most frequently used and found to be effective are "providing information" and encouraging "people to set goals". So that's the current evidence base from our behavioral research. However, I think many of us would argue whether that these do not provide the final or indeed only approach that might be utilized.
In conclusion, I think interventions need to look at both societal approaches and personal approaches. We need to listen to our low-income groups who say money is important, in terms of intervention. We need to understand something about 'promising' interventions, and not rely solely on our systematic reviews to inform evidence. We need to think about the length of interventions, about sustaining intervention effect, the sort of measures that we use in research, and fundamentally, that relationship between research and practice. Thank you.

Effect of a targeted subsidy on intake of F&V among low-income Women in the Special Supplemental Nutrition Program for Women, Infants and Children

Dena HERMAN
Nutrilite, USA

Mesdames et Messieurs,
Je voudrais d'abord remercier les organisateurs de l'invitation et je suis enchantée d'être ici parmi vous et de pouvoir vous présenter les résultats de mes recherches. Cette conférence est un évènement important et passionnant et c'est un honneur d'être ici entourée de personnes compétentes.

Okay, that's the end of my French. I will spare you any more. I'm here to talk to you today about an intervention project within the United States with "WIC participants" who are defined by the program as being, low-income or 185% of the U.S. federal poverty limit. I'm going to divide this presentation into 2 parts. First , I'm going to start with the research and our intervention project to increase fruit and vegetable intake, and then move to the policy piece of this, because this is, an intervention project which became a policy that is now being enacted in the United States. So I will divide this presentation into those 2 parts.

First of all, I'm not sure how many people in this room understand what the "WIC program" is, so I'd like to give you a brief background on what it does and who it does that for. It is a Special Supplemental Nutrition Program for Women, Infants, and Children, that is the formal name of the "WIC program." So it covers women from pregnancy into lactation, and all children up to the age of 5. It is an income-based program, a means-tested program, meaning entry into the program is determined, by your income level, 185% of the poverty limit in the U.S. Then you need to be in one of these critical groups of development pregnant or postpartum woman, infant, or child under the age of 5 years.

The Program provides special foods, high quality foods, to target pregnancy outcomes, in particular. The nutrients targeted as part of the food package are vitamins A, C, iron, calcium, and protein. This was based on a program that started, in the early 70's, and whose purpose was to reduce rates of both anemia and low birth weight. To that end, very particular foods are in this package. They are milk, eggs, cheese, dried beans or peanut butter, fortified cereals, and juice. The packages for pregnant women are approximately worth $55-60 US dollars.

Unfortunately, since the 70's, the food package has not changed, and that has been 34 years in coming. We haven't been waiting quite that long, but almost, to change the

food package. So I'm going to go ahead now with some of the explanation of this study.

We conducted this project for a number of reasons. One, an Institute of Medicine review of the WIC food package was being conducted, looking at the scientific basis for the foods that were included in the package, and the desire from the public health community to bring the package into alignment with the dietary guidelines. In addition, of course as I think everyone knows in the U.S. we are some of the fattest people. So the obesity epidemic and health consequences for obesity were another consideration for trying to get fruits and vegetables into the package. Finally, to evaluate the impact of providing an economic incentive to this low-income population, we provided money to people to increase access to fruits and vegetables.

These are the locations of the 2 intervention sites; they are in Los Angeles, and represent the largest WIC program in the United States. This Program serves 318,000 women a month, so quite a few people. These sites are relatively close, if anyone has been to the LAX Airport, Culver City is about 12 miles north, and Gardena is about 12-15 miles south, so in a pretty proximal area. One of these sites was a farmer's market, Culver City. The other was a supermarket chain in Gardena. And if you imagine, way up in the right-hand corner, that was our control clinic, in a place called Pomona which is very close to Riverside County, so out of the L.A. County area.

What we did was provide an economic incentive to increase fruit and vegetable intake. That incentive was worth $10. A $10 voucher was given per week to purchase fresh fruits and vegetables only. We carried that intervention out for 6 months. So that each family participating - and there were 200 at each of the 3 sites - received $240 for the entire intervention period. As I mentioned, one of the intervention sites was a supermarket, while the other was a farmer's market. We had 400 intervention families, and 200 control families participating. We followed them for a total of approximately 14 months. We had interviews conducted at recruitment, 2 months following recruitment to track baseline intake, at the completion of the intervention which was 6 months, and then an additional 6 months without any intervention to see if the fruits and vegetables consumption had somehow changed.

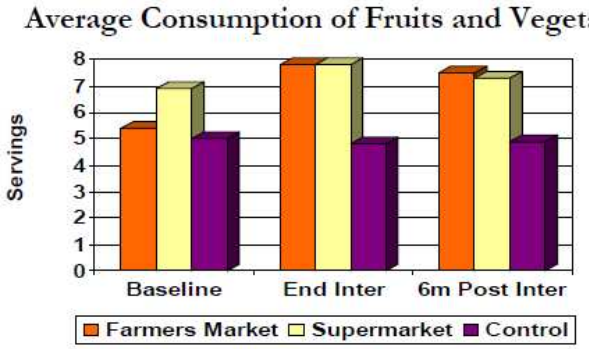
The eligibility criteria for the study were post-partum WIC participants who had just delivered within the last 2 months. They had to be at least 18 years of age, and English- or Spanish-speaking. Here are the demographic characteristics of the population. The most important facts are that they are of child-bearing age, on average about 27 years old, education is 9 years, income is roughly $1200 a month, and the family size about 4 people. Overwhelmingly, this population was Hispanic. But there were other ethnicities involved.

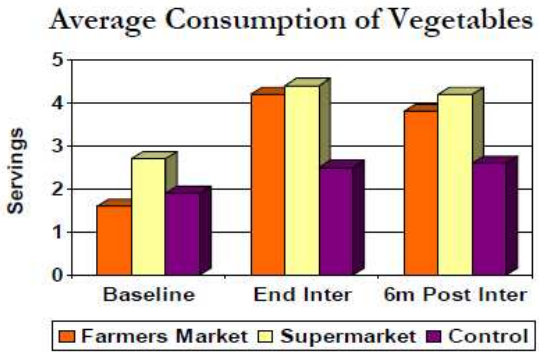
This voucher was redeemed at an incredibly high level, 88% in both the farmer's market and supermarket settings. This is highly unusual, if you speak to retailers. Usually a manufacturer's coupon is redeemed in the very best situation at about 20%. So when they saw 88%, they almost fell out of their chairs. It was quite impressive to them.

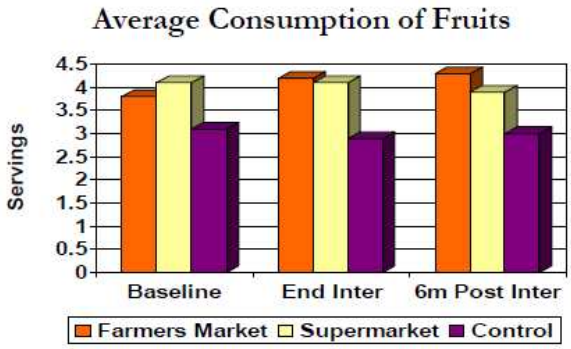
Participants purchased a very wide variety of fruits and vegetables, whether in the farmer's market site or the supermarket's site. I'm going to show you 2 lists now of first fruits, and then vegetables purchased by WIC participants. They ranged from bananas to papayas and melons, and every season really is encompassed here in this list. It wasn't just that they bought bananas and apples all year long; they really did purchase an incredibly wide variety. For vegetables, it's truly the same case. Carrots, tomatoes, obviously, you know, good sources of vitamin A and other nice phytonutrients, all the way down to very cultural items like chayote which is basically a pear-shaped vegetables, almost like a squash, it's very common in the Hispanic culture, to make a salad. I think you call it here, "choux choux." So a very wide variety of vegetables, as well. This is just to give you a little bit of an idea of the wide variety, but the fruits and vegetables were also very nutrient-dense. The nutrients that were targeted in the report set out by the IOM were increasing vitamins A, C, fiber, and potassium, nutrients seen as lacking in these very vulnerable populations during critical periods of development. And you can see from this list, the checkmark indicates a good or high source of that nutrient, that we had a very, very good representation for, actually, all of these nutrients, from many sources.

These are just the results that were brought out now in January of this year in the American Journal of Public Health, these are the final results. They show that there was an increase in fruits and vegetables from the baseline, beginning of the study, all the way to 6 months post-intervention. Meaning, that even though the economic incentive was taken away, these participants actually made a change in their eating habits and decided to carry out their own - they made some change in their spending patterns and consuming patterns. How do we know this? You are probably asking how these data come about. We did very intensive quantitative 24-hour recalls, 4 times throughout the period. So we have mountains of data, but we can tell you this fairly confidently that these are what the data look like.

Increase in Fruit and Vegetable Intake Sustained

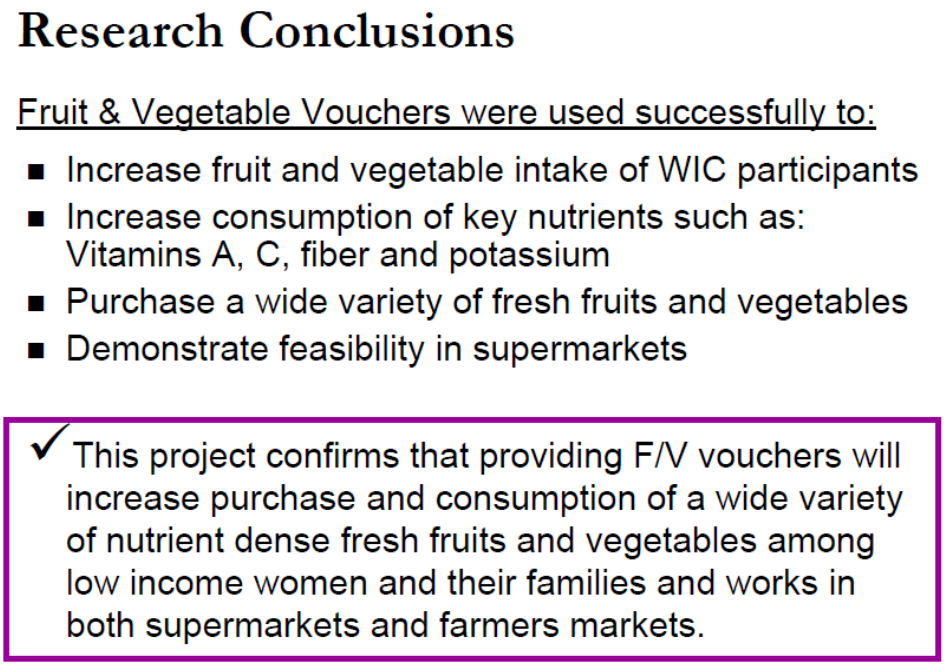






In the end, the increases in fruits and vegetables intake were relative to one serving of fruits and vegetables, one portion, per 1000 calories or 4,186 kilo-joules. Most people eat more than 1000 calories, so 2 servings for over 8,000 kilo-joules, which is really quite a nice increase, sustained increase, over the period of the study. You notice that the other 2 graphs below refer back to consumption of vegetables and fruits separately. I think the even more exciting part of this, because we heard so much at this conference how difficult it is to increase vegetable intake, the increases were actually realized primarily in the area of vegetables. So this was also another very nice outcome for us.

In conclusion, fruits and vegetables vouchers were successfully used. They increased fruits and vegetables intake of the participants, they increased the consumption of key nutrients such as vitamins A, C, fiber, and potassium, and participants purchased a very wide variety of fresh fruits and vegetables. We also demonstrated feasibility in supermarkets, and farmer's markets. So really, the study was able to confirm that providing economic incentives of fruits and vegetables vouchers will increase the purchase *and* consumption of a wide variety of nutrient-dense fruits and vegetables among low-income women and their families and this worked both in the supermarket and farmer's market settings.



So I'm just going to very briefly explain a couple more results because these really added to the mix. I'm going to talk to you more about policy. There are actually 2 more studies that followed on to this; one took place at the same time, the one in Calaveras County. Calaveras County is in the very north of California, and is a very rural community; we were in primarily in an urban setting. I didn't find out about this project, actually, until I had completely completed mine and found my colleague as we testified for the US Congress in Washington, D.C. They had a program very similar to ours, except it was a $5 voucher and carried out for 5 years. Participants also purchased a wide variety of fruits and vegetables with fruit and vegetable vouchers. They increased their consumption of fruits and vegetables, they somehow, miraculously, had the exact same redemption rate as us, 88%. They purchased primarily the fruits for snacks and the vegetables for dinner, and besides what we showed, they were also able to show that it worked well in a variety of settings, so not only the supermarkets. They only had one supermarket near the clinic where this was administered out of, and it was quite far for them. But they also were able to show this in small, independent markets and mom and pop type stores, so your corner, kind of, store here, was very successful in those settings. And in terms of New York State, they modeled a project based on our 2 studies, and also had equally similar results.

So moving on now to more of the policy piece of this presentation. As I mentioned early on, these projects were based, really, on the IOM report which came out in April 2005. And this report recommended changes to the food packages. These changes had been desired by the public health community for quite some time, but putting the pencil to paper and an authoritative body of scientists saying that, and

trying to bring the food package into compliance with the Dietary Guidelines, was their goal. They recommended their changes only based on current science, and those changes were to reduce milk, cheese, eggs, and juice, include vouchers for purchase of fruits and vegetables for all age categories - they actually recommended the $10 voucher per person per month. Their mandate, however, was to maintain cost neutrality, so they did have to cut some things out of the food package that were currently there, and replace those with fruits and vegetables. And the data from the current study were actually used to testify to support these recommended changes.

We faced a number of barriers trying to get these results to help move policy changes, to take research into action. The USDA officials and legislators did not want to believe that moms would even use these vouchers. It was money, how they would do the right thing, that they could buy nutrient-dense fruits and vegetables, to actually make those decisions for themselves, and to increase their fruit and vegetable consumption. They were all highly doubtful. There was also the concern that fruit and vegetable vouchers would be cumbersome at checkout. So we had many hills to climb.

But we superseded in the end. Thanks to a lot of people. These results influenced national policy. We had many briefings with the U.S. Congress and with USDA, both the officials, as well as the people who work within USDA. We had briefings with policymakers at USDA and also with the WIC division staff at the U.S. Department of Agriculture.

I have to say one more thing, going back to this. None of that would have been possible without the National WIC Association and Lorelei DiSogra here in the front seat. United Fresh got us there together with the legislatures and helped them actually see that these barriers could be overcome. Here is a photo of me next to Eric Bost, who was the Undersecretary for USDA at the time. Shirley Runnings, who is next to me, is the representative from Calaveras County. And Lorelei DiSogra is there in the red jacket. So we are all truly there, this is not - because I live in Los Angeles, this wasn't taken out of a film, it truly happened.

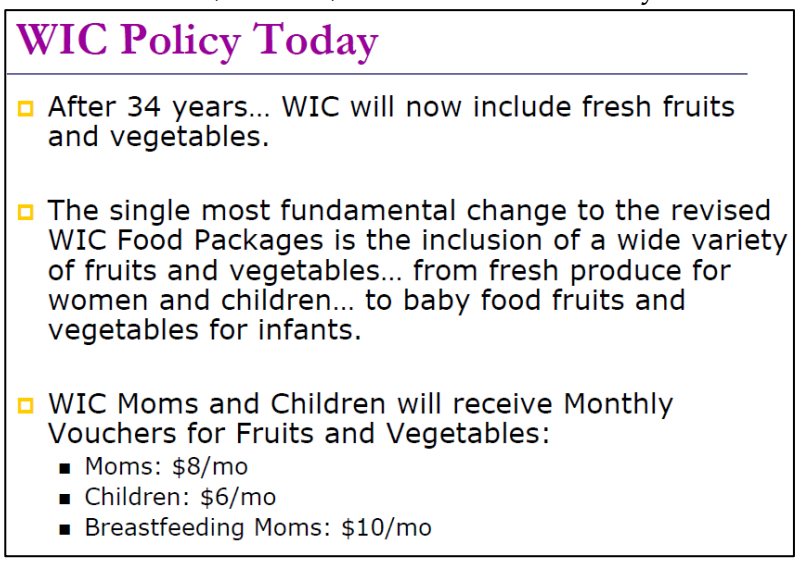
Results Influence National Policy

- Briefings with U.S. Congress
- Briefing with Policy Makers at U.S. Department of Agriculture
- Briefing with WIC Division Staff at U.S. Department of Agriculture

Lorelei carried this out, both before and after we came to D.C., but the results were relentlessly marketed. The 5 key messages that were brought to the legislators and other people, who needed to be informed, were that low-income moms valued these vouchers and redeemed them at very high

rates. They purchased a wide variety of nutrient-dense fruits and vegetables. They increased their consumption of fruits and vegetables and sustained it over the time. The vouchers were easy to use. Retailers loved these things, the supermarkets who participated trained all their personnel and they had basically no events, any problems whatsoever redeeming these. And the vouchers worked at the farmer's market, as well. There was no problem in getting them out.

So today, 34 years later, the WIC food package will now include fresh fruits and vegetables. It really is the single most fundamental change to the revisions of the WIC food packages, and ensures that women, infants, and children can buy a wide variety of fruits and vegetables. And for the infants, they are also encouraging fruits and vegetables from a very young age by providing baby food fruits and vegetables, so they can get acquire the taste, from early to encourage intake of fruits and vegetables.



The monthly vouchers for this program will be implemented as follows: pregnant mothers will get $8 per month, children $6 per month, and breast-feeding moms $10 per month. That perhaps doesn't seem like a lot, but realize that most families have, perhaps, 2 people on the program, so it does really contribute quite a bit to their ability to purchase fruits and vegetables.

So the exciting part. This is going to improve health, the health of 8 and a half million WIC mothers, infants, and children. WIC moms will have more than $500 million per year nationwide to buy produce to improve their public health. And it's going to improve access to fruits and vegetables, especially for low-income communities in inner cities, and in remote areas.

I'm going to speak just for a minute now back to Calaveras County to show you that the advent of these vouchers was not only good for the participants, themselves, but it actually caused community transformation, and was a great source of social justice. In Calaveras County, as I mentioned, they got a voucher for $5 monthly and it was carried out for 5 years. It did result in increase of availability and variety of fresh fruits and vegetables for sale in small markets. And this was quite remarkable because many of these tiny stores had no refrigeration and carried only potatoes and onions to begin with when this program first began. But after the vouchers were in

the store for awhile, these small stores increased their variety to include over 25 fresh fruits and vegetables. This increased access benefited the WIC families, but also the entire community because everyone shops at these small markets. So WIC was actually had a large part in that, because it increased access for everyone in the area. This shows that these WIC fruits and vegetables vouchers have the potential to transform access in inner cities and rural areas.

So, in conclusion, this small study in Los Angeles will actually have global implications. We are going to be able to offer fruits and vegetables vouchers to low-income families, and that should result in their increasing their fruit and vegetables consumption, improving their health, reduce the risk of obesity, and improve access to fruits and vegetables in these communities. As a final note, I want to just let you know that there are many nutrition programs in the U.S. This has also affected the ability to increase our funds for evaluating other programs, because there has just been so much goodwill behind this program, and the fact that there were real results that were achieved. So as an example, the food stamp program, which is a program that serves far more people in the U.S., will now have $20 million available to actually start an evaluation of that program to see how it can be improved. Thank you.

Q&A

S HERCBERG : Merci beaucoup Dena pour cette présentation extrêmement intéressante présentant des résultats spectaculaires et encourageants. Félicitations. Nous avons le temps pour quelques questions.

PUBLIC: I just have a very brief question which is, it was a fantastic presentation, a very positive message. What would be interesting to hear would be: how the vouchers were redeemed, was this an easy process? And did any of the shopkeepers rebel, you know, were they negative about it?

D HERMAN: Well, thank goodness I've answered this question a number of times, as it is one of the most common questions we have had to answer. It was very nice; actually, that no one rebelled. For the farmer's market, we had to work with the entire City of Culver City because it's a city action to put on a farmer's market, so I had multiple members of city government help us collect the money. What happens is there is a market manager, and the market manager pays the farmers, they turn in the coupons each market, and pay them, then the market manager goes back to the City, and had the vouchers counted again - they just had someone do this for us - just to verify the amounts were correct, and they'd send the coupons back to us. It was done completely out of goodwill, we did not pay them anything. And it went exquisite, it just worked incredibly well. And for the farmers, of course, it was great.

About $45,000 additional dollars came to them in 6 months. They were ecstatic. For the supermarket, we worked with a corporate headquarters in Los Angeles. It's a very large food chain; it's called Kroger's or Ralph's. And also we had a lot of support from them because $500 million, who doesn't want a piece of that pie? They were looking ahead. They thought this was going to work. For the supermarket, they also had before their eyes the fact that in the product department, they are going to have less shrink, so they will actually profit from that. And also getting more people into the supermarket is going to give them additional incremental sales. So they were very happy with those ideas to begin with, and then they also went out of their way to train all their personnel in the stores that we used. They collected our vouchers and anything that we did not redeem, that other 12%, because we had to pay up front, they gave back to us. And they gave us electronic reports, and there was not one incident at the checkout which you might think would happen. The participants were given instructions to use the $10, they weren't allowed to buy less, but they could buy more. The participants had to be taught how to use the vouchers, buy 5 pounds of oranges and whatever else. They had to think about things so they could go quickly through the line, because they didn't want anything hindering that process, and there was nothing. It went very well.

PUBLIC (Bill [...] from Los Angeles). I think you might have answered one of my questions. It sounds like it was Ralph's is the retailer that participated and not any of the other major retailers in the greater L.A. area like Vons or…, etc.

D HERMAN : No.

PUBLIC: And number 2 is, did you make any effort at all to give any kind of nutritional information, recipe information, to the recipients? And then the 2nd question would be, has there been any effort to follow-up what the recipients on actual consumption purchases, you know, post-study?

D HERMAN : Those are very nice questions. Let me start, it was Ralph's Food 4 Less, so we used the warehouse version of Ralph's because that was the store. It had to be, for research reasons, within 5 kilometers of the clinic that we were at. So it was at Food 4 Less that we used, because those were the ones that were in those areas.

Let's see, what was the other question?

PUBLIC: It was about the recipes and nutritional information on use of the items.

D HERMAN : Oh, right, I'm sorry. The piece that I left out about WIC is that it has actually 3 parts. One was the package of special foods that they offer, but they also offer referrals as they are an adjunct to health care, and they also have nutrition education classes, so every month participants come back, they have a nutrition

education class. And if you look at what they offer throughout the entire year, they have a very strong emphasis on eating fruits and vegetables, they do a whole thing on consumer education, so what to buy in their supermarket, looking for coupons, you know, just smart shopping. And they also do recipes because they have a number of units on healthy eating related to cancer prevention and diabetes prevention, etc. So within those contexts, these things were offered, but it was not part of our program. They are already offered at the WIC clinic.

PUBLIC: and then any follow-up with the recipients, as far as purchase of fruits and vegetables post-study?

D HERMAN : Right. Well, as I said, we offered the intervention for 6 months, and then we had 6 months where there was nothing. And all that time we were tracking purchase and intake. So for the length of the study, yes. After that, no. The WIC population being low-income is an incredibly mobile population. Also for just human subject's reasons, you have to get consent from everyone. After the period of study, you are not really able to contact subjects again. So theoretically, it would have been impossible; also we didn't have any more money *[laughs]*, so you might imagine, following people up after we had completed the study. So, no.

PUBLIC (Jane LAND from the U.K.): Thank you for your very interesting presentation. It's a related question, really. In your research, were you able to see whether the people using the vouchers were topping them up? Were they making cash purchases for fruits and vegetables that they might not otherwise have done?

D HERMAN : We didn't track purchase, whether cash or credit card. So you are talking about additional purchases to what we had, to what they showed through our program?

PUBLIC: Yes, yes.

D HERMAN : They definitely purchased more because - I am not sure how - but they redeemed these vouchers early in the month. We gave them $10 per week, but the $40 for the month was gone very early on. They came back to us usually a month later, we asked the question, did you use all your vouchers, and if you didn't, why? And they had all used them, it was kind of in a 2-week period they were gone. So they definitely did additional purchases because we tracked everything they ate through the 24-hour quantitative dietary recall. So looking at that, they definitely purchased additional fruits and vegetables. However, as I mentioned, the WIC food package is worth $60 dollars. So they had some incremental money available to them through the Program. But they definitely purchased more.

PUBLIC (Emily GOODWIN, U.S.): Could you please tell us the location of the study

in the State of New York?

D HERMAN : It was the entire State. Statewide.

PUBLIC (Emily GOODWIN): I see, thank you.

PUBLIC (Kristina POLAN from Australia): How long do women usually stay in the voucher system for when they get the vouchers? Because if I were a policymaker, I'd be looking at, you know, if you can increase consumption and then when you stop, you don't have to worry about it anymore.

D HERMAN : Well, actually women stay in for quite some time. You know, they come in at child-bearing age so between 24-45 years and they have a child and often have more children, so if they have 3 children, on average, we've done a dose of WIC computation, and on average it's 8-10 years.

PUBLIC: And the other thing was, does it encourage them to continue breast-feeding? That looked like that might have been one of the outcomes, which sounds great.

D HERMAN : Yeah. Well, that does, but there is also a very large push within WIC to breast-feed. It's one of the other big nutritional kinds of campaigns that go on within WIC. So I think the fruit and vegetables certainly encourage it, and they were actually used as an incentive to breast-feed, because people who breast-feed actually get some additional items, including fresh carrots, even now, before the new packages have been implemented. I should mention that this Program is being implemented now, as of December 2007 it was approved. New York will be the first state, most likely, to carry it out, and there will be a roll out all across the United States, with California implementing in October 2009.
...this type of work is often not reported in a research environment. And so we missed the opportunity to learn from that. But I would be very much in favor of trying to support better evaluation and research of those often very local, but community-driven, initiatives.

S HERCBERG : Merci beaucoup Dena pour cette présentation et cette discussion. Nous allons passer la parole au dernier intervenant, Madame le docteur Hélène Bihan. Elle est médecin endocrinologiste à l'hôpital Avicenne en Seine Saint-Denis, qui est un département proche de Paris, particulièrement confronté aux problèmes des populations défavorisées ; elle est également Chercheur au Centre de Recherches en Nutrition Humaine et elle va présenter les tous premiers résultats d'un travail expérimental fait dans le département de Seine-Saint-Denis sur l'efficacité d'un coupon en fruits et légumes à la fois sur la consommation des fruits et légumes et le statut nutritionnel des populations défavorisées.

Providing an economic supplement for fresh F&V purchase

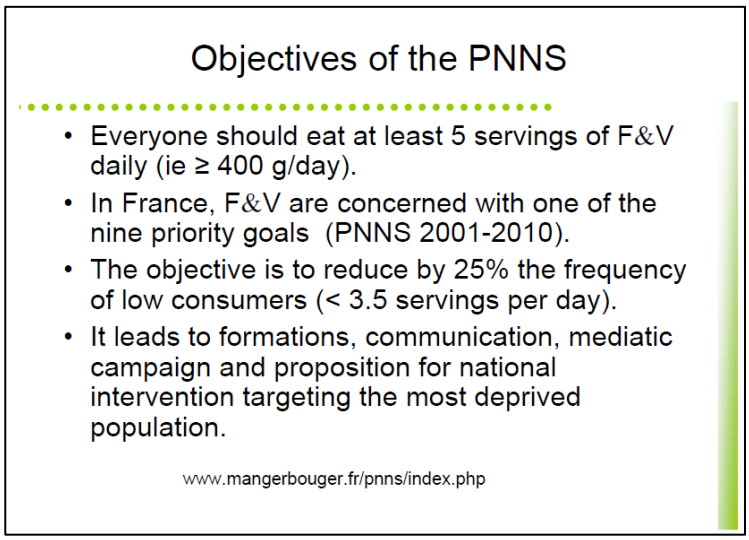
Hélène BIHAN
UREN, U557 Inserm, SMBH-Université de Paris 13, Bobigny, France

Je remercie tout d'abord les organisateurs de m'avoir également invité et je vais vous présenter ici les premiers résultats de l'étude que nous menons en France sur le même intitulé : l'évaluation de l'effet de supplémentation économique pour augmenter la consommation de fruits et légumes chez des sujets précaires.

Les données françaises sont peut-être moins importantes que les données que l'on a vues précédemment, notamment au cours de cette matinée et donc, je vous présente uniquement deux cohortes françaises pour vous montrer un peu la difficulté de la consommation des fruits et légumes chez les populations défavorisées.

On a tout d'abord la cohorte ENNS, ENNS est une enquête de population générale, qui montre que 22% des sujets consomment entre 3,5 et 5 portions de fruits et légumes par jour et 42,8% consomment plus de 5 fruits et légumes par jour. Si maintenant on regarde les données d'une population très précaire, puisqu'il s'agit de la cohorte ABENA, la cohorte ABENA est une cohorte d'environ 1000 sujets qui ont été interviewés, ce sont des sujets qui se nourrissaient essentiellement grâce à des aides alimentaires, donc, pour la plupart, ils étaient sans travail, mais pas sans domicile. Donc, dans cette cohorte, c'est une étude de 2004-2005, on voit que 4% des sujets mangent entre 3,5 et 5 fruits et légumes par jour et que 1,2% des sujets simplement mangent les recommandations de plus de 5 fruits et légumes par jour.

En France, le « programme PNNS », Programme National de Nutrition Santé, c'est un programme qui a débuté en 2001 dont l'un des principaux objectifs est l'augmentation de la consommation des fruits et légumes avec l'objectif sur le plan épidémiologique français de réduire de 25% la fréquence des petits consommateurs sachant qu'elle est actuellement d'environ 50% et c'est dans la population générale.



Là, nous allons nous intéresser à une population de personnes précaires. Dans les objectifs du PNNS, il y a des campagnes de publicité, de communication à la fois par

voie télévisuelle, par presse écrite et donc, une intervention qui va cibler des populations précaires.

L'objectif de notre étude est vraiment celui-là, c'est évaluer l'effet d'un supplément économique pour l'achat de fruits et légumes sur la consommation de fruits et légumes en tant que portion de fruits et légumes dans une population précaire avec les deux principaux objectifs intermédiaires qui sont de tester la faisabilité, on a déjà eu des questions qui vous intéressaient sur la communication précédente et puis les questions également d'acceptabilité à la fois des sujets inclus dans cette étude et des magasins qui allaient distribuer les aliments et recevoir les chèques.

Le protocole de l'étude est le suivant : l'équipe était installée quotidiennement au centre d'examen de santé ; le recrutement se faisait au centre d'examen de santé, qui est situé à Bobigny en Seine-Saint-Denis. Le centre d'examen de santé est un organisme qui dépend de la Caisse Primaire d'Assurance Maladie et qui propose à des personnes tout venant un bilan de santé gratuit de dépistage des pathologies. Au niveau de ce centre d'examen de santé, nous avons proposé à des personnes précaires d'être incluses dans l'étude. Je vais vous préciser ce qu'est le « score Epices », c'est un score de précarité typiquement français et donc, nous avons organisé l'étude afin d'inclure 300 sujets pour pouvoir essayer de montrer une différence de 30% de la consommation des fruits et légumes à la fin de l'étude, entre les deux groupes. Une fois que les sujets étaient inclus dans l'étude, ils bénéficiaient en plus du bilan standard fait par le centre d'examen de santé, d'un bilan nutritionnel pour évaluer les apports nutritionnels, le statut nutritionnel, notamment en vitamines - je vais vous le détailler également - et puis, nous faisions au niveau du centre d'examen de santé une randomisation, un tirage au sort entre un groupe de 150 personnes qui allait recevoir uniquement des conseils diététiques ; alors l'entretien diététique durait à peu près une trentaine de minutes et le deuxième groupe de personnes recevait toujours les mêmes conseils diététiques par les mêmes diététiciennes qui à ce moment-là de l'étude n'étaient pas au courant du groupe dans lequel allait se situer le sujet et à la fin de la randomisation, le sujet pouvait recevoir, donc pour la moitié des sujets, un groupe recevait les chèques fruits et légumes, je vais vous en parler également. Le tirage au sort était appareillé sur des facteurs tels que âge, sexes, et la composition des foyers ; le design de l'étude prévoit donc une réévaluation du statut nutritionnel du bilan clinique avec trois mois de l'étude et peut-être une prolongation, on en discutera.

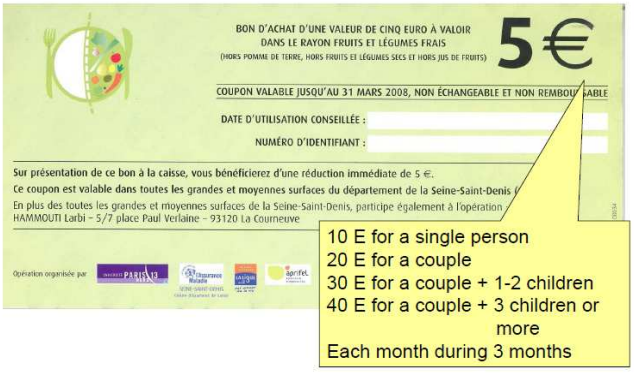
Qu'est-ce que le score de précarité, qu'est-ce que le « score Epices ? » Le terme Epices signifie : « Evaluation de la précarité et des inégalités de santé dans les centres d'examens de santé ». C'est un score qui a été créé en France, c'est vrai qu'à ma connaissance, il n'existe pas de score précis pour évaluer le niveau socio-économique dans les études internationales, on voit souvent les niveaux de revenus mensuels ou le niveau d'éducation ; en France a été créé ce score à partir de 42 questions

interrogeant les personnes sur le niveau socio-économique, les analyses statistiques ont permis de retenir 11 questions qui permettent donc d'évaluer la précarité avec un chiffre au total qui varie entre 0 personne non précaire et 100 personnes étant dans une situation de très grande précarité et ce score a été validé en 2002 sur 200 000 sujets qui consultaient les centres d'examens de santé français.

Voici très brièvement les 11 questions de ce score et vous allez pouvoir voir par exemple dans la question (4) : « est-ce que vous êtes propriétaire de votre logement ou le serez-vous dans le futur ? » - qui peut donc être une des questions permettant de situer un petit peu la personne ; d'autres questions comme par exemple la question (10) : « si vous avez des difficultés financières ou de santé, est-ce que quelqu'un va vous aider ? » C'est donc à partir de ce score, à partir de ce questionnaire de 11 questions qui sont assez simples qu'on définissait un niveau de précarité et nous proposions aux personnes ayant un score supérieur à 38,5 jugées précaires par la création du score de participer à cette étude.

Les données qui sont collectées dans l'étude comprennent à la fois un examen clinique réalisé au centre d'examen de santé pour avoir des mesures anthropométriques : le poids, la taille, le tour de taille, le tour de hanches et la pression artérielle, un bilan biologique pour les marqueurs nutritionnels classiques, bilan créatine anémique, bilan glycémique, bilan lipidique, la ferittinémie, et également un dosage des vitamines A et C corrélé à la consommation de fruits et légumes et autres vitamines qui peuvent définir des carences, vitamines B9, B12 et l'homocystéine.

Le volet « enquête diététique » comprenait deux parties : à la fois un questionnaire que le sujet remplissait seul comportant des questions sur son âge, son niveau d'éducation, son travail, des caractéristiques individuelles de perception de l'alimentation et puis les lieux habituels où le sujet peut faire ses courses et la deuxième partie de l'enquête était donc un rappel des 24 […] réalisés par la diététicienne avant la délivrance des conseils diététiques, donc, ces données sont collectées initialement lors de l'inclusion et à trois mois lorsque le sujet est re-convoqué au centre d'examen de santé. Ceci est le chèque ou le coupon fruits et légumes français, vous pouvez voir son montant de 5€, je vais vous expliquer également pourquoi et il s'agit d'un coupon qui est échangeable uniquement contre des fruits et légumes frais, donc au rayon frais, mais utilisable dans de nombreux magasins – pour rappel, vous voyez sur le coupon le logo de l'APRIFEL qui est le promoteur de



l'étude et que je remercie au passage – et le code barre qui permet l'utilisation du coupon dans tous les magasins qui disposent d'appareils permettant l'utilisation des codes barres.

Donc, nous avions choisi le montant de 5€ pour le montant du chèque avec une date d'utilisation qui serait ciblée à deux semaines afin justement de pouvoir favoriser l'utilisation des chèques tout au long du mois en mettant des périodes de deux semaines d'utilisation chèque, alors le montant qui était délivré aux personnes dépendait de la composition du foyer, une personne seule allait recevoir 10€ par mois, une personne en couple, 20€ par mois, un couple avec un ou deux enfants reçoit 30€ par mois et un couple avec plus de trois enfants reçoit 40€. Ces chèques étaient donnés initialement par les diététiciennes, puis remis ensuite par voie postale tous les mois pendant 3 mois.

Je vais vous présenter maintenant les premiers résultats qui sont des résultats encore très initiaux, l'étude est encore en cours, l'étude a débuté en décembre 2007, nous avons fini les inclusions fin avril et donc, nous avons pu inclure 302 sujets, et vous pouvez bien comprendre que tous n'ont pas pu être vus à trois mois. Dans les 302 sujets inclus, nous avons 135 hommes et 167 femmes dont l'âge moyen est de 45,5 ans, et le score Epice moyen, ce score de précarité est de 60,8 sachant que pour avoir une idée dans l'ordre dans la population générale consultant en France les centres d'examens de santé, le score moyen est de 25. Donc, je vous présente les résultats de ces 302 sujets quelque soit le groupe dans lequel ils ont été ensuite randomisés. Je vais vous montrer la répartition des sujets selon le travail, le niveau d'éducation puis le statut familial.

En ce qui concerne le travail, vous voyez que 33% des sujets travaillent à plein temps, mais que nous avions au total 40% des sujets, c'est-à-dire 20% des sujets qui étaient en recherche d'emploi, donc au chômage et 20% des sujets qui étaient bénéficiaires des minima sociaux, dont le RMI – cela pour les français.

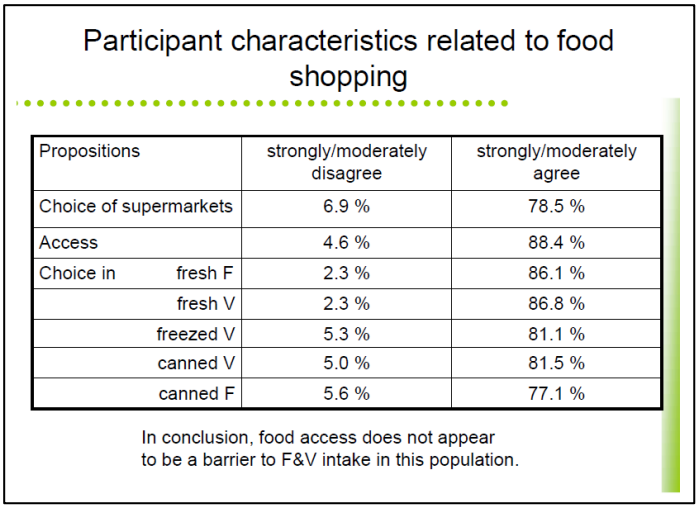
En ce qui concerne le niveau d'éducation, il s'agit d'une population qui est globalement peu éduquée, donc 67% avait moins de 12 années d'études, donc toujours pour les français, cela correspond à un niveau collège, donc en tout cas pas de niveau baccalauréat, on peut noter sur cette diapositive que 12% ont un niveau d'étude de stade universitaire, notre analyse était probablement, ce sont des personnes qui sont pour une grande part originaire de l'étranger et donc avaient un diplôme étranger qu'elles ne peuvent peut-être pas utiliser en France.

Le statut familial : 54% des personnes sont en couple, et nous voyons aussi que le pourcentage d'enfants dans les familles est de 63% des foyers qui comportent des enfants avec un nombre moyen de personnes de 3,5 par foyer.

Voici les résultats globaux de ces 302 sujets, sujets en situation de précarité, mais insérés quand même parfois par leur travail. Au niveau de la répartition des fruits et légumes : on voit d'emblée en prenant le nombre de portions de fruits et légumes entre 0 et 2 portions de fruits et légumes par jour, nous avons 68% de la population, donc 68% de très petits consommateurs et seulement 8,4% de cette population consomment plus de 5 fruits et légumes par jour – je vous rappelle les données françaises équivalentes de l'enquête nationale de nutrition santé qui rapportait 42% de consommateurs de plus de 5 portions de fruits et légumes par jour. Cela montre bien le niveau de précarité de ces populations et leurs difficultés de consommer les fruits et légumes. En, ce qui concerne la différentiation entre les fruits et légumes, on a l'impression que la consommation de fruits est un peu meilleure puisque donc 15% environ consomment plus de 3 fruits par jour, alors que la consommation de légumes est vraiment très faible, 51% consomment moins d'une fois par jour des légumes.

Quelques données au niveau de la situation socio-économique et donc la perception des sujets, de leur situation sociale et économique ; dans les questionnaires initiaux, 52% des personnes déclaraient avoir des problèmes financiers très importants et donc 40% estimaient ne pas avoir assez d'argent pour acheter quotidiennement des fruits et légumes. 16% déclaraient également avoir parfois manqué ou souvent manqué d'alimentation et seulement 28% n'avaient jamais été anxieux à l'idée de pouvoir manquer un jour d'aliments. A noter également que c'est une population dans laquelle l'accessibilité à la voiture est très faible, à la fois en tant que voiture personnelle et même voiture à disposition par des amis, donc 62% n'ont pas du tout d'accès à un véhicule.

Nous avons aussi un peu regardé les caractéristiques de leur ressenti par rapport à l'offre en fruits et légumes de la région dans laquelle ils se situent et contrairement à ce que l'on peut voir dans la littérature notamment américaine, ici, on a plutôt l'impression que les personnes sont contentes de l'offre de fruits et légumes qu'elles ont à disposition ; donc quand on regarde la proposition de choix des supermarchés proches de leur domicile, 78% nous disent qu'elles sont d'accord ou tout à fait d'accord à la question : « est-ce que vous trouvez qu'il y a suffisamment de magasin à côté de chez vous pour faire vos courses ? » De même, au niveau de l'accessibilité de ces magasins, 88% sont plutôt d'accord avec la notion d'accessibilité même s'ils n'utilisent pas la voiture, le réseau urbain de transports locaux leur permet de faire



Participant characteristics related to food shopping

Propositions		strongly/moderately disagree	strongly/moderately agree
Choice of supermarkets		6.9 %	78.5 %
Access		4.6 %	88.4 %
Choice in	fresh F	2.3 %	86.1 %
	fresh V	2.3 %	86.8 %
	freezed V	5.3 %	81.1 %
	canned V	5.0 %	81.5 %
	canned F	5.6 %	77.1 %

In conclusion, food access does not appear to be a barrier to F&V intake in this population.

leurs courses comme ils le souhaitent et en ce qui concerne maintenant le choix de fruits et de légumes au sein de ces magasins, ils estiment également qu'à la fois pour les fruits frais et les légumes frais, les légumes congelés ou les produits en conserve, il y a suffisamment de choix pour faire leurs achats. En conclusion de cette diapositive, il ne semble pas que l'accessibilité aux fruits et légumes soit une réelle barrière dans cette population.

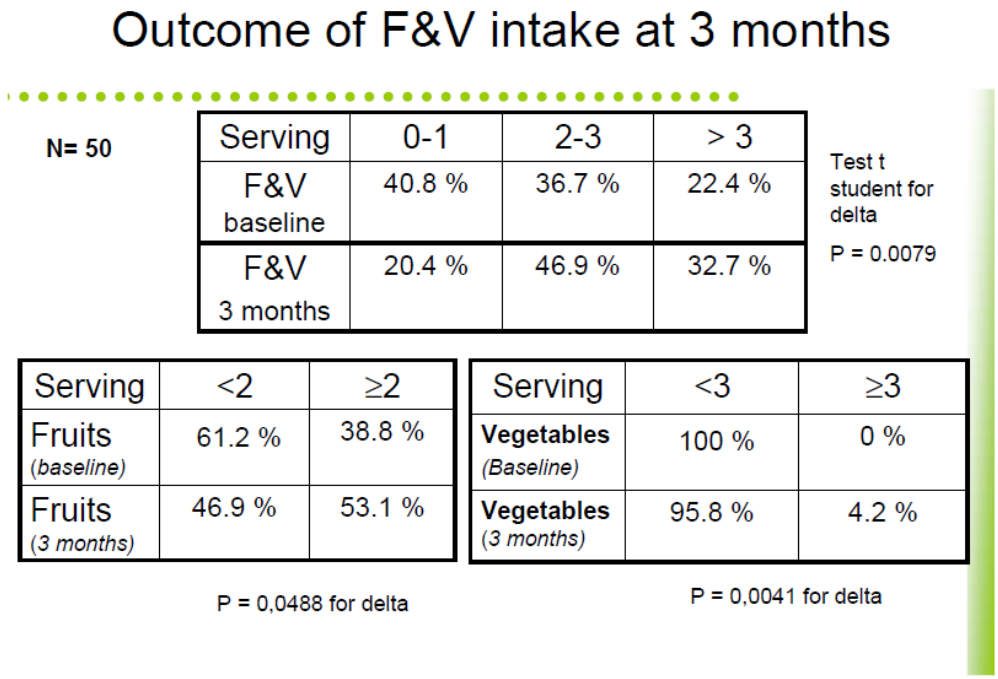
En ce qui concerne les facteurs plus individuels, perception de la consommation des fruits et légumes : « j'aime manger des fruits et légumes : est-ce que vous êtes d'accord avec cette réponse ? » 91% des sujets nous disent que : oui, ils aiment manger des fruits et légumes. Maintenant, qu'est-ce qu'il en est dans la réalité et que font-ils ? « Je mange sainement » : seulement 47% des sujets évaluent que leur consommation globale, leur alimentation globale est bonne pour leur santé et « je mange suffisamment de fruits et légumes » : 37%. C'est un peu les mêmes données que nous a présentées le Docteur Herman. « Je pense que les fruits et légumes sont d'un coût abordable » : 34% des sujets ont cette sensation et donc 70% trouvent que les fruits et légumes sont d'un coût trop élevé et le même pourcentage trouve qu'ils ne pourraient pas acheter plus de fruits et légumes.

En ce qui concerne les analyses préliminaires statistiques, on n'a pas remis en évidence de relations entre le niveau d'éducation, ni le travail et la consommation des fruits et légumes ; par contre , on met en évidence au sein de cette population une relation entre la consommation de fruits et légumes et la perception du coût des aliments, également avec la perception d'une alimentation saine, donc les personnes qui mangent le plus sainement sont aussi celles qui nous déclarent manger le plus de fruits et légumes et de même avec les critères motivation à manger des fruits et légumes et le plaisir de manger des fruits et légumes.

Les données cliniques et biologiques dont nous disposons actuellement sont beaucoup plus restreintes : 200 sujets, tout simplement parce que nous dépendons du centre d'examen de santé pour récupérer certaines des données. J'insisterais juste sur cette diapositive sur la différence de répartition entre des index de masse corporelle au niveau des hommes et des femmes, on peut voir pour les femmes dans la dernière colonne que 28% des femmes de cette population sont obèses, 45% sont en surpoids excluant l'obésité ; en ce qui concerne les hommes, 16% des hommes sont obèses et 39% en surpoids excluant l'obésité. Les données biologiques ont été mesurées initialement, mais je n'ai pas pour le moment les données de suivi, donc je passerais.
Egalement pour une partie des données qui concernent le statut vitaminique qui sont pour le moment les données qui ne correspondent pas vraiment aux vitamines les plus corrélées avec l'apport en fruits et légumes, mais il est vrai que le dosage de vitamines A et C est une de nos questions qui sera évaluée, donc la modification éventuelle du statut vitaminique A et C par rapport à la consommation des fruits et légumes à trois mois.

A trois mois, pour le moment, nous avons pu réévaluer seulement 50 sujets compte-tenu des obligations de recrutement ; 75% des sujets qui avaient été vus en tout début d'étude sont revenus pour faire le bilan à 3 mois ; 67% pour le moment des sujets du deuxième mois sachant que ce ne sont que des résultats préliminaires. On peut noter que quelques personnes n'ont pas de numéro de téléphone et c'est vrai, comme le disait les oratrices précédentes, c'est parfois une population qui est difficile à re-convoquer.

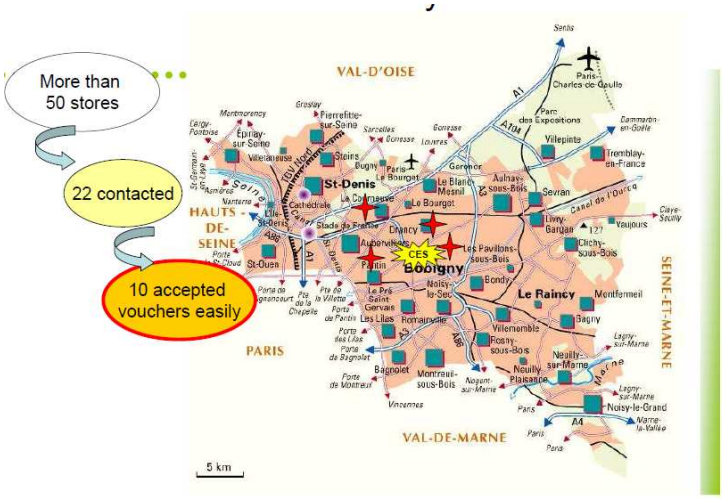
Voici la diapositive que vous attendez le plus et qui est la seule diapositive qui donne un petit peu une évolution : il s'agit des 50 premiers sujets et pour le moment, volontairement, nous n'avons pas fait de séparation des sujets entre les groupes recevant des chèques et les groupes ne recevant pas de chèques puisque les résultats sont encore trop préliminaires.



Là, ce que vous voyez, c'est l'évolution chez ces 50 sujets de la consommation en fruits et légumes initialement et à trois mois, quand on regarde la variable globale, 40% des sujets mangeait entre 0 et 1 portion par jour au départ de l'étude, ces 50 mêmes sujets ne sont plus que 20% à être des tout petits consommateurs à la fin de l'étude et l'on voit dans case supérieure à 3 portions par jour, on a une augmentation de la consommation des fruits et légumes chez ces 50 sujets avec une différence qui dès trois mois et pour un tout petit nombre de personnes est significative ; ceci se retrouve surtout au niveau des légumes puisque initialement tous les sujets consommaient moins de 3 portions de légumes par jour alors qu'à trois mois, ses 50 personnes, certaines, 4% mangent plus de 3 portions par jour et c'est une donnée significative. Pour les fruits, on a à peu près le même résultat, moins significatif, mais aussi une augmentation de la consommation des fruits. Je vous rappelle que

l'intervention dans les deux groupes contenait des conseils diététiques et c'est vrai que les diététiciennes étaient extrêmement motivées pour cette étude et investissaient leur rôle de diététiciennes comme un rôle très précieux et avaient vraiment, quelque soit le groupe puisqu'elles ne savaient pas initialement dans quel groupe allait se situer la personne, elles donnaient à toutes les mêmes conseils en leur délivrant les deux guides de recommandations alimentaires, le guide français du Programme National de Nutrition Français et un guide créé par l'APRIFEL qui permet de donner des conseils sur l'alimentation chez des personnes qui ont des petits revenus notamment en insistant sur la possibilité d'acheter des fruits et des légumes en conserve.

Une des questions qui est posée par cette étude, c'est la question de la faisabilité, c'est une question qui nous a été demandée dans l'organisation de l'étude avant de pouvoir envisager une extrapolation de l'étude ou de proposer des mesures nationales parce qu'il est vrai qu'en France, pour le moment, on n'a pas de programme national comme la WIC aux Etats-Unis et les programmes anglais, donc la question était la question de la faisabilité. L'acceptabilité à la fois au niveau des personnes : est-ce que les personnes recevant les chèques fruits et légumes allaient vouloir les utiliser ? Pour le moment, on n'a que de bons retours, tous les sujets sont très enthousiastes à l'idée de recevoir des chèques et nous ont vraiment fait un accueil enthousiaste lorsqu'on leur proposait de participer à l'étude ; les sujets qui ne recevaient pas de chèque, mais uniquement des conseils sont également enthousiastes ; pour le moment, dans les 50 sujets qui sont revenus, on a 25 sujets du groupe recevant des chèques, mais également 25 sujets qui appartenaient au groupe ayant reçu uniquement des conseils diététiques. L'utilisation des chèques par les personnes, c'est une des questions que nous nous posons également, à la fois, quels vont être les produits choisis ? Est-ce que l'on pourra évaluer avec l'analyse des tickets de caisse ? Les difficultés éventuelles rencontrées pour l'utilisation des chèques : est-ce qu'elles ont eu des barrières lors de leur utilisation, mais aussi quelles ont été les personnes du foyer bénéficiaires des chèques ?



Un mot de la faisabilité au niveau de l'organisation pratique sur le terrain : je vous montre ici une carte du département de la Seine-Saint-Denis situé au Nord-Est de Paris. En jaune, au centre, vous voyez le CES, le Centre d'Examen de Santé qui était l'endroit où nous recrutions les personnes et où avait lieu le bilan de santé. Initialement, plus de 50 magasins avaient été contactés plus ou moins directement pour participer à cette

opération, mais avec une campagne de publicité qui n'était pas très importante, ce qui peut expliquer parfois certaines barrières dont je pourrais reparler, mais au final, nous avons une dizaine de magasins qui acceptent extrêmement facilement les chèques pour lesquels maintenant les personnes sont bien orientées et n'ont plus de problème pour leur utilisation, donc toutes les personnes à qui on a délivré des chèques et qui sont revenues nous ont bien rapporté l'utilisation facile lors d'un passage en caisse sans aucun problème.

En conclusion de cette étude, cette population précaire de Seine-Saint-Denis, on voit que la consommation quotidienne de fruits et légumes est extrêmement basse puisque plus d'un tiers des sujets consomment moins d'une fois par jour des fruits et légumes, que ces sujets rapportent comme première barrière pas tellement des problèmes d'accessibilité ou de disponibilité des fruits et légumes dans les magasins environnants, mais plutôt une barrière économique pour les premières analyses et qu'il s'agit d'une des premières études françaises dans ce domaine qui avant de proposer des mesures plus larges sur le plan national va pouvoir évaluer l'efficacité de chaque fruits et légumes pour augmenter la consommation de fruits et légumes avec deux aspects intéressants, à la fois la consommation en tant que portion évaluée par les diététiciennes, mais également on espère peut-être voir un impact au niveau du statut vitaminique, notamment en vitamine A et C, à la fin des trois mois et l'on espère également grâce à la poursuite des soutiens pouvoir poursuivre cette étude : les premiers sujets qui sont revenus à trois mois étaient très volontaires pour revenir se faire évaluer à six mois sachant que ces sujets revus à trois mois ont bénéficié de nouveaux chèques à la fois en tant que remerciements de chèques fruits et légumes et que l'on attend un petit peu l'écho de cette étude pour savoir jusqu'à quand on va pouvoir la poursuivre. Je vous remercie.

Q&A

S HERCBERG : Merci pour cette présentation d'un travail expérimental qui est en cours et qui fournira sûrement des résultats d'information très passionnant. Nous avons le temps pour un petit nombre de questions rapides.

PUBLIC (Sandra MEYER from the European Association): Thank you very much for the excellent presentation, very interesting. For this study, the decision to exclude processed, frozen vegetable, canned vegetable, etc., was it a conscious decision or was it just a practical decision in term of who do we get on board for the supermarkets because in my local "Carrefour" the fresh green beans, the greatest part comes from Kenya and any frozen green beans you buy are normally frozen within 4 or 5 hours after the harvest and you have excellent nutrition values for example for frozen, but also for can products and you also bring in the cost aspect and before that over and over again today for this advanced layer of society

processed vegetables in particular are frequently at a stable price available all year around at very good prices, so would that also be an idea for the future to include these and to see if this has a different impact ? Thank you very much.

H BIHAN: Pour répondre à cette question, c'était une décision en effet plutôt pratique dans le sens où la mise en place de l'étude et justement l'idée de pouvoir la faire accepter par les magasins environnants nous a fait sélectionner le rayon fruits et légumes afin de faciliter la communication auprès des magasins et de faciliter aussi le discours auprès des personnes, donc, c'était simplement pour le moment des considérations pratiques.

PUBLIC: Je voudrais savoir quand cette étude prendra fin et ce qui était prévu peut-être comme prolongation, ou du moins qu'est-ce que vous espérez après sur le plan national ?

H BIHAN: Pour ce qui est de revoir les sujets à trois mois, on pense probablement avoir pu revoir tous les sujets en septembre, on a fini les inclusions en avril début mai, donc, c'est vrai que ces personnes vont être revues en juillet ou peut-être un petit peu décalé à cause de certaines contingences logistiques, donc à trois mois, pour la rentrée et puis en ce qui concerne la poursuite de l'étude, c'est encore des discussions en cours, les derniers sujets seront revus probablement en septembre et on devrait prendre une décision très prochaine pour savoir si les sujets qui ont été revus à trois mois, on peut continuer à les suivre à 6 mois, ce qui est vraiment notre désir et on attend des réponses.

PUBLIC: Et sur le plan national ?

H BIHAN: Sur le plan national, c'est une mesure qui avait déjà été discutée par le Professeur Hercberg au niveau national il y a quelques années lors de la mise en place du Programme National de Nutrition Santé et - il va répondra après moi - mais on lui avait initialement répondu que avant d'envisager une mesure nationale, il fallait justement prouver la faisabilité de l'étude et son efficacité, donc c'est ce que l'on fait dans cette étude, avec l'espoir de pouvoir le proposer sur le plan national.
La question est de savoir s'il est possible d'extrapoler ce type d'action qui a, bien évidemment un coût, 10€ par mois et par personne multiplié par 5 millions de personnes qui en France ont des revenus considérés comme insuffisants pour pouvoir avoir accès à une alimentation suffisamment riche en fruits et légumes amène à un coût qui est tout à fait considérable, donc c'est une opération pour laquelle sur les bases de travaux scientifiques, il est peut-être possible de convaincre des municipalités, des collectivités locales ou territoriales de s'investir ou des partenaires d'autres natures pour développer des actions ; pour l'instant le Ministère de la Santé et le Comité interministériel qui a décidé des choix d'orientation du deuxième programme national de nutrition santé n'a pas retenu l'idée d'une mesure

générale, mais soutient des initiatives qui pourraient avoir lieu au niveau des collectivités. Et je pense que les éléments d'informations issus de ces travaux, mais également de tout ce qui a été présenté dans d'autres expériences à travers le monde sont des éléments qui aideront à pouvoir dialoguer avec les pouvoirs publics.

PUBLIC (Laurence […], Fondation Louis Blondel) : C'est une question à Mesdames Anderson et Herman. J'aurais aimé savoir si les associations caritatives qui viennent en aide aux personnes défavorisées notamment sur le plan alimentaire ont été impliquées dans les études que vous avez montrées ou bien si elles ont des initiatives dans le sens de favoriser la consommation de fruits et légumes et quelles seraient ces initiatives éventuellement ?

AS Anderson: In this study I described, no charity organisation have been involved, but charity organisations are involved in many community food initiatives, but in the U.S. for all community-based research, at least relating to some aspects of food security, which often times involves also fruits and vegetables intake. So to some extent, that research is available. There is also many very large organizations like FAC, which is a Food Research and Action Coalition that stay very current with these are more of a policy advocacy organization, as opposed to a welfare organization. But they also tend to gather data from smaller groups who are working in this area, so we have some report of it, more often than less, in local news. But we didn't have any support, financially or otherwise, from welfare organizations.

D HERMAN: Thank you, as well. Most of what Dr. Anderson has said is also true for us. We did not have any welfare type of organizations involved. However, there are a number that are involved. And this type of work is often not reported in a research environment. And so we missed the opportunity to learn from that. But I would be very much in favor of trying to support better evaluation and research of those often very local, but community-driven, initiatives.

S HERCBERG : S'il n'y a pas d'autres questions, je vous propose que l'on clôture la séance et il me reste à remercier les speakers pour leurs excellentes présentations et je tiens à remercier l'audience pour sa participation active aux débats. Merci à tous.