

THE EFFORT TRIAL AND EVIDENCE-BASED MEDICAL NUTRITION

Featuring :: Prof Philipp Schütz, MD, MPH

TRANSCRIPT

Maura: Malnutrition continues to be a global problem, especially in adult hospital patients. People with malnutrition have poorer outcomes, and that includes length of hospital stay, increased complications, increased readmission rates, increased health care costs, and decreased quality of life. The good news is that evidence shows how proper nutrition care for hospital patients—by this, I mean early nutrition screening, assessment and intervention—how all those things can really change this trajectory and improve outcomes—not just for the patient but also for the healthcare system.

Maura: Now, healthcare professionals in hospital settings see malnourished patients each and every day, and they do their best to provide evidence-based nutrition care to improve their patients' care, health and outcomes. But this new evidence on the impact of nutrition screening and intervention can really aid in this care and begin to chart a path that helps decrease the number of malnourished patients across the globe.

Maura: I'm Maura Bowen, podcasting for the Abbott Nutrition Health Institute. I'm here today with Professor Philipp Schütz, a board-certified internist and endocrinologist in Basel, Switzerland. Dr Schütz and a team of researchers recently conducted the EFFORT trial. If you haven't heard of it, EFFORT stands for the Effect of early nutritional support on Frailty, Functional Outcomes, and Recovery of malnourished medical inpatients Trial (EFFORT). The landmark trial was published in Lancet in 2019 and it provides much needed new evidence on the power of nutrition.

Maura: With all that said, Dr Schütz, welcome! We're really excited you can join us today.

Dr Schütz: Well, thank you very much. I'm glad to be here to talk about this important topic with you.

Maura: Before we start, can you tell us a little bit about yourself, your current role, and what brought you to this area of focus in your career?

Dr Schütz: Yes, sure, I'm happy to. I'm head of a large medical university unit at a tertiary care center in Switzerland. And for my background, I'm an endocrinologist and also a specialist for clinical nutrition, and an internist. And so obviously, I've seen a lot of patients that come with both problems. Elderly patients and patients, polymorbid, and a lot of these patients have also metabolic disease and also nutritional disease, and so we've realized for a long time that once patients get malnourished—when they lose weight, and they lose muscle mass, their outcomes are really predicted to be getting worse. But it was for a long time unclear whether this was something we just had to accept, and we have to focus on the medical diseases or whether we can actually do something for their nutritional status. And this is what brought me and our time to the question of how effective in the end is it to treat all of these medical inpatients with nutritional support. Can we actually impact outcomes such as mortality or complications. And this is how we started the EFFORT trial, which had the focus on the problem of inpatient malnutrition

Maura: There are many trials in the literature on the benefits of nutrition screening and nutrition intervention. Why did your research team want to do the EFFORT trial? What were you hoping to show?

Dr Schütz: Yes, so when we started to look into this problem, we actually did a systematic search and meta-analysis to look at all the different trials. And we realized there are a lot of trials as you just mentioned, and most of these trials were small in number and didn't have the statistical power to show that nutrition can impact medical outcomes such as mortality or morbidity. And I think today when we talk about evidence-based medicine, it's really important for physicians to know that actually these treatments are effective in reducing clinical adverse outcomes of really improving the health of patients. So the EFFORT trial is really the first large trial that was powered to show the effect of nutritional support on clinically endpoint such as mortality and complication rates.

Dr Schütz: So we really wanted to do a landmark trial to understand if malnutrition in the end is a modifiable condition and whether nutritional support is effective in actually influencing these important outcomes.

Maura: Can you tell us a little bit about the methodology you followed for the EFFORT trial and what specifically you did in your trial in terms of nutrition screening and intervention?

Dr Schütz: Yes, so the EFFORT trial was really a pragmatic trial. Within all the different hospitals that participated, we started by doing a nutritional risk screen. All medical inpatients that went to the medical ward were screened for malnutrition. And we used the nutritional risk screen 2003, which is a broadly-used risk screen in Europe but also in the US. And so we screened these patients. And patients that nutritionally at risk were eligible to be part of the trial. And so we have a couple of exclusion criteria. We didn't want have any surgical patients or ICU patients or patients with terminal disease. We didn't want to include them in the trial. But other than that, we had a really broad patient population.

Dr Schütz: And so once patients entered the trial, they were randomized either to the control arm—and this was just the standard of care. The nutrition arm, where patients were allowed to get any sort of nutrition, but we didn't have a team looking at their nutritional goals or providing them with oral nutritional supplements or any kind of specialized nutrition formula. So the intervention group, we had a nutrition protocol which was administered by our team—the nursing team and a registered dietitian. And basically, we defined for each patient individualized goals—so we had protein goals—we then defined an individual strategy on how to reach these goals. So of course one patient may prefer to work with oral supplements, other patients had other preferences such as working more within the hospital kitchen. And for some patients, it was even needed for a certain amount of time to use enteral nutrition to reach these goals. So in the end, we compared what is the risk of patients to die or have severe complications, and whether he was treated just by usual nutritional care or whether we use the nutritional strategy to reach these goals. So we were very pleased to see in the end that the nutritional intervention was very effective in our trial, and it reduced the risk for severe complications by about 4%. So we had a number needed to treat in the trial of about 25, so we needed for 25 patients that were receiving nutritional support, we were able to prevent severe complication. The same was true for mortality—we had a number needed to treat of about 40, so for 40 patients that were treated according to protocol, we were able to prevent one death in the trial.

Maura: What did you expect to find in the data?

Dr Schütz: From the previous literature, we found that a lot of studies have shown that nutrition is quite effective in improving weight and nutritional outcomes. But we were not sure how effective it was really in reducing mortality and also complications. So in the end we found that our nutritional protocols was very effective and had a strong effect on clinical outcomes. IN the end, this was the ultimate proof we needed to show that malnutrition is really a disease and condition we can be active about, and we can improve patients' health states by using nutritional treatment plans. So I think it was a very important trial because it did have a lot of patients, and there was a lot of statistical power to show that nutrition is working and a very effective treatment.

Maura: Can you go into a little more detail about what the data did show and how you cross-checked it against what you expected?

Dr Schütz: Yes, sure. So, we found that we had different end-points. We looked at worst outcomes, which was combined endpoints. And we found that nutrition reduced the risk of adverse outcomes within 30 days from 27% to 23%. We also found a lower risk of mortality in patients who were treated with our nutritional treatment protocols. Patients also had better functional outcomes—so the risk to have a decline in their functionality was reduced. We also looked at quality of life using the E25D quality of life score, and we found a significant improvement in quality of life in over 30 days in the trial. So basically, nutrition was very effective in reducing mortality risks and improving outcomes, and in functionality and quality of life. So I think the results are very positive and really show these patients have strong benefits from nutritional intervention.

Maura: How do you think these findings positively add to the base of evidence showing the benefits of good nutritional care?

Dr Schütz: That's a great question. When we started the EFFORT project, we did a meta-analysis, and we found that there is quite a lot of trials, many of these trials are small, and a lot of them really didn't look at mortality and did not find significant results. There was also the NOURISH trial published recently, which also was a large, US-based trial, and EFFORT and NOURISH both showed nutrition is effective in reducing mortality in this patient population. So we have recently finished a meta-analysis, where we gathered all the randomized control data around nutritional interventions in medical inpatients. The meta-analysis basically shows that the nutritional intervention produces about a 25% reduction in the risk of mortality. This is very similar to the results we found in the EFFORT trial. So I think when we look globally at the problem of malnutrition, these new trials now very much support that nutritional treatment has a positive effect on patient outcomes and particularly can reduce mortality strongly by about 25%, and I think this is an impressive number.

Maura: Did anything surprise you about your findings?

Dr Schütz: Well, I think it was hard at first to know whether patients would stay active in the trials, because nutritional care is difficult—it needs a lot of team effort. It needs the patient on board, but also the nursing team, the dietitian team on board—and so we found that in most of our patients, we were able to reach their nutritional goals within this trial. And I think this was a positive experience for us, to see that if you work together with the dietitian team, the nursing team, but also the hospital kitchen and the patient, the team effort you have there, the end result can be very positive.

Maura: I would say our listeners would definitely agree with that. You and other authors went on to publish a new meta-analysis and systematic review by Gomes and others in November 2019 in JAMA Network Open, is that right? Can you tell us what this review showed and how it was different from previous reviews on nutrition intervention in malnourished patients?

Dr Schütz: Yes, so there are a lot of different reviews out there, and a lot of them have been more qualitative or not found conclusive results. I think it was mainly based on the lack of larger trials, which can prove in the end the benefits of nutritional intervention. So with our meta-analysis that was published last year, we really did an up-to-date literature search. We included the EFFORT trial, which was the largest trial with more than 2,000 patients. But there were also other large trials such as the NOURISH trial. And so in the meta-analysis, we found consistently that nutritional support in patients who were malnourished and in the hospital that this was very effective and reduced mortality by about 25%. We also found that the risk of hospital readmission once the patient gets discharged is reduced by about 25%. And we also had the length of hospital stay shortened in the nutritional intervention group for the patient groups who had established malnutrition.

Dr Schütz: So different clinically-relevant outcomes were significantly affected in a positive way by nutritional support. And so I think this meta-analysis is very important because it summarizes all the evidence we have from the different trials from different countries. I think we had about 50 different countries. So this is really a global picture of malnutrition showing that the treatment for malnutrition by use of nutritional intervention work and are very effective.

Maura: What does it take for clinicians to change their clinical practice? How can evidence like the EFFORT trial and the new meta-analysis impact change?

Dr Schütz: I think nutrition has been seen as just a supportive treatment, which a lot of physicians aren't aware it's a very effective treatment. Now nutrition is more difficult than just prescribing a patient another pill, because it really needs a team approach. First, you need your hospital to have an effective malnutrition screening in place, you need to identify the patient, then you need a team going to the patient, talking about nutrition, talking about his goals, understanding his situation. You also need the team to communicate with the kitchen—to bring the foods, to adapt the food to the patient's individual goals. And so it's a lot of team approach. A lot of it is logistics. It takes some EFFORT to really establish a good nutrition team in the hospital.

Dr Schütz: And so my recommendation is for physicians and clinicians to look into nutrition, to make sure that in their hospital they have a screening program in place, that their patients are all being looked after in regard to the nutritional goals they have.

Maura: I noticed you discussed the term “evidence-based medical nutrition” in your EFFORT publications. Can you tell us a little about more about this?

Dr Schütz: Evidence-based medicine has become the gold-standard for treatment, and it means that for each and any treatment that we give our patients, we need to have evidence that any treatment is effective, and is not associated with any side-effects. And also from a cost-effectiveness perspective, the treatment should be favorable. And I think the same standard in medicine for all our drugs and treatments, we should use the same standard for nutrition. So, the term “evidence-based nutritional therapy” underlines this goal that we also need to have strong evidence that our nutritional interventions is effective, safe and cost-effective.

Maura: When you look at all of this through the context of the COVID-19 pandemic around the globe, how has this affected patients in your hospital and their nutritional status?

Dr Schütz: Yea, I think Covid is an infection that has caused a lot of morbidity and mortality, particularly in the elderly polymorbid patients, and a lot of these patients are malnourished. And so if these patients are malnourished, they have very little reserve, and so if they get sick, if they get Covid-19, they are at high risk if they're malnourished. If they're malnutrition gets work, the malnutrition will have a very negative impact on their outcomes and increase their risk that the patient will not survive their hospital stay.

Dr Schütz: And so particularly for the Covid-19 patient, because of the vulnerable patient population that gets infected and comes to the hospital, we have to be very careful not only to focus on the infection Covid-19, but also to focus on attention to their nutritional health. It's something we can actually treat and positively influence, while for the Covid-19 infection, there's still uncertainty how well the infection is actually treatable with all the different drugs out there.

Maura: How, then, do you think the results of the EFFORT trial be used in care of these COVID-19 patients to optimize their nutritional therapy?

Dr Schütz: In the EFFORT trial, we really included the broad medical inpatient population, and we had about 400 patients who were coming to the hospital due to pneumonia. So it is a very similar patient population than the one we see now with Covid-19. And of course by that time we didn't have any Covid-19 patients in the EFFORT trial. We did have a lot of patients with COPD and a lot of patients with pneumonia and other types of infections. And so in the EFFORT trial, we saw that these patients with lung infections, other infections, COPD, if they were at risk for malnutrition, they had the benefit from nutritional intervention. And so we strongly believe that the same would be true now for the Covid-19 patient population.

Maura: Bringing it all home, what learnings from this trial can or should clinicians apply to their practice?

Dr Schütz: Well, I think first of all it's important that someone cares. You need in your hospital a nutrition care team. And you need to make sure patients are being screened. And if we identify patients at high risk for malnutrition, we need to have people caring for their nutritional support. So I think it's a lot of organizational points. You need to make sure they work. Who is doing the screening, who is reading the screening, what are you going to do. Once you find a patient at risk, who's going to take care of this patient, and how often are you going to see him to make sure that he keeps up with his nutritional support protocol. And I think it's really important that everyone on the hospital care team knows what is his or her role, and what are his or her responsibilities. And I think now for Covid-19 where we have very sick patients, old patients, and a lot of these patients are polymorbid and at risk for malnutrition, I think it's very important to care for these points in order to get the best possible outcomes for these patients.

Maura: Dr Schütz, thank you so much for your time today. You've been very informative and helpful. I hope you'll join us again with future updates on your research.

Maura: And to our listeners, thank you for joining us today. Be sure to visit [anhi.org](https://www.anhi.org) for more nutrition science education and resources, including more podcasts, which you can find on [anhi.org](https://www.anhi.org) under RESOURCES, and the PODCASTS & VIDEOS. Thanks everyone.