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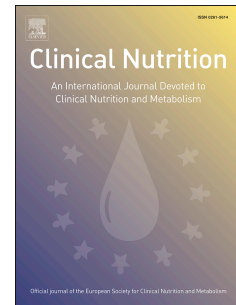
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Title Page

Proposed standard model and consistent terminology for Monitoring and Outcome Evaluation in different Dietetic Care settings: Results from the EU-sponsored IMPECD project

Running head: Monitoring, outcome evaluation and impact in dietetics

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List of abbreviations

DALY: Disability-Adjusted Life Years
DCP: Dietetic Care Process
EFAD: European Federation of Associations of Dietitians
EU: European Union
HEI: Higher Education Institute
ICF: International Classification of Functioning, Disability and Health
IMPECD: Improvement of Education and Competences in Dietetics
M&OE: Monitoring and Outcome Evaluation
NCP: Nutrition Care Process
NDA: National Dietetic Association
ONS: Oral Nutritional Supplements
PHN: Public Health Nutrition
QoL: Quality of Life
RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance
SFA: Saturated Fatty Acid
SMART: Specific, Measurable, Achievable, Results-oriented, Time-bound
TPN: Total Parenteral Nutrition
WHO: World Health Organization

Abstract

Background & Aims: Dietetic interventions contribute to certain health objectives and other outcomes, but are mostly part of a multimodal and multidisciplinary approach what makes evaluating the actual effects of dietitians involvement rather complex. Although monitoring and outcome evaluation (M&OE) can provide routine data to prove the effectiveness of dietetic interventions, this has not been established yet in different dietetic settings.

Methods: A comprehensive framework for M&OE in dietetics was developed by dietetic experts from five European higher education institutes for dietetics in the course of the EU sponsored project “Improvement of Education and Competences in Dietetics (IMPECD)”.

Results: Firstly, clear definitions on M&OE are proposed to facilitate the use of consistent terminology, with a specific emphasis on the term “impact” covering macro-level outcomes such as cost-effectiveness. Secondly, the Dietetic Care Process (DCP) was merged into a logic model to demonstrate the position of M&OE in relation to intervention planning and implementation, in both group and individual settings. Thirdly, selecting the appropriate indicators is indispensable to monitor and evaluate outcomes, and requires a high level of dietitians’ critical reasoning. A categorized overview of indicators is provided to support this process. Lastly, the consortium developed a checklist to give dietitians a handle on what elements could be included in their M&OE plan and trigger them to perform M&OE in practice.

Conclusions: Innovative M&OE models may help dietitians to demonstrate their effectiveness in improving clinical outcomes and justify their role in health care.

77 **Keywords**

78 dietitians; training; efficiency; dietetic intervention; nutritional counselling

ACCEPTED MANUSCRIPT

1. Introduction and objectives

Dietetic care and therapies are becoming continuously more important, not only in acute disease but also in the background of the steadily rising health cost concerning chronic non-communicable diseases world-wide (1). Idiosyncratically, exactly those steadily increasing health costs ask for cost-containing measures in health care and often services related to nutrition are first sacrificed when cost reductions are warranted. For example, in 1991 29% of US-American hospitals with more than 150 beds had well-established nutrition support teams (2). A decade later, these services were almost non-existent as they failed to demonstrate being cost-effective. Inability to prove efficacy of dietetic intervention has led to a reduction of dietetics workforce by about 25% in Germany between 1995-2015, with reduced availability of full time dietetic positions (3), also due to a general lack of scientific evidence proving the efficacy of the dietetic intervention. So far, meta-analyses have suggested only modest benefits of dietetic interventions, that were derived from a small number of studies (4) and long-term benefits of these interventions are unknown (5).

Qualified dietitians and experts in the field of dietetics are well placed and can effectively contribute to achieve health objectives and outcomes such as an improvement in nutritional and functional status, reduction in morbidity, higher quality of life (QoL), health care cost-savings and may result in healthier workplaces (6-10). For instance, Sun et al. (11) revealed through their meta-analysis of 69 studies a larger relative weight loss and a lower cost of intervention (per kilogram of weight loss) in dietitian-delivered lifestyle interventions as compared to those delivered by non-dietitians. In the Netherlands, dietetic intervention was shown to lead to savings in health care costs and to increase productivity and QoL (6). Similarly from an institutional perspective, a Belgian study demonstrated sustained improvement of nutritional care and reduction of total parenteral nutrition (TPN) in

hospitalized patients when treatment by a dietitian was embedded in the existing structures (7, 8). It is often difficult to separate the benefits achieved by the involvement of dietitians on health outcomes, as they usually work in collaboration with other health care professionals as a part of a multi-modal intervention, with primary emphasis during hospitalization being on drug treatment (12). Since randomized clinical trials on nutrition are expensive and time-consuming (13, 14), one possible strategy is to use well-controlled routine data to enhance the grade of evidence of effectiveness of dietetic interventions for various outcomes, and at the same time serve as quality assurance measure (15).

Monitoring and outcome evaluation (M&OE) can play a pivotal role to achieve dietetic goals and can be used to demonstrate successes achieved by dietetic interventions (16-18). However, it has still not been established in the field of dietetics, especially involving behavioural therapies. Data collection is a key element throughout the whole process of M&OE. It enables dietitians to show that the patient or client needs have been met. At the same time, adequate clinical data underpins the effectiveness of the treatment while information on costs and resources are essential for economic evaluations. In order to provide these adequate data, assessment methods should be simple, affordable, time-saving and available in daily practice, but satisfactory enough to be accepted by the health care system.

The EU sponsored project “Improvement of Education and Competences in Dietetics (IMPECD)” (19) aims at establishing innovative and holistic models for dietetic training at higher education institutes (HEIs) in Europe. The IMPECD consortium is composed of five European Universities of Applied Sciences (UAS) offering an academic dietetic education programme, which are UAS St. Pölten (Austria), Artesis Plantijn University College Antwerp (Belgium), UAS Fulda (Germany), Hanze UAS Groningen (Netherlands) and UAS

Neubrandenburg (Germany). Besides this, all respective National Dietetic Associations and the European Federation of Associations of Dietitians (EFAD) are members of the project's "sustainability and impact board" and ensure most appropriate dissemination of the IMPECD project results.

The current paper builds on the IMPECD philosophy and objectives to provide novel unified didactic models for the main dietetic fields (clinical nutrition, nutritional counselling, public health) (20, 21). By addressing all fields of dietetics, beneficiaries of dietetic interventions will not always be ill persons, i.e. patients. Therefore, the more neutral term "client" will be used throughout the present report to cover both patients or healthy persons taking part in dietetic interventions. In particular, the focus will be on the aspects of monitoring and evaluation, which will enable the future dietitians to incorporate research to tackle challenges in their daily practice. Although dietetic care process (DCP) or nutrition care process (NCP) models are already available (22-25) and include similar steps and aspects of monitoring and evaluation (26), these models lack details of specific procedures and use a different terminology (see online supplement S1). The overall objective of this paper is to develop a comprehensive model, which can provide a framework encompassing not only the perspectives of the client, but also includes data collection at a macro-level. This will help optimizing dietetic strategies to improve health, support therapies and demonstrate their economic relevance. The ultimate purpose is to offer some tools and stress the importance of M&OE to improve the value of dietetic interventions.

2. Definitions of Monitoring and Outcome Evaluation (M&OE)

Monitoring and Outcome Evaluation (M&OE) benefit from clear definitions of the underlying general concepts.

a) Intervention outcomes

Generally, health intervention goals are defined by formulating desired health outcomes. A general definition of a “health outcome” is *“a change in the health of an individual, or a group of people or a population, which is wholly or partially attributable to an intervention or a series of interventions”* (27). Outcomes can apply to an individual (clinical setting or prevention), group setting (community) and institutional/population level (service provider) (28), and demonstrating outcomes achievement can be used to improve the relevance of dietitians and their profession by resolving or improving an identified health problem (23). In 2016, the most commonly reported objectives of dietetic primary care in the Netherlands were: influence the clients’ eating behaviour, the disease as such, QoL and the clients functioning (29). Unfortunately, an internationally standardized set of outcomes and their measurement for nutrition related conditions is often not available (30).

b) Monitoring, outcome evaluation and impact

Conducting an activity does not necessarily mean that the desired results from that activity are achieved. M&OE are essential in various quality systems (31-38), but the applied terminology unfortunately is rather complex, limited or inconsistent. Online supplement S1 provides an overview of useful general descriptions of M&OE components based on to develop the suggested definitions in the present article.

To overcome inconsistent use of terminology for dietetics application, we suggest to use the common term “monitoring” over “process evaluation”, the term “outcome evaluation” over the general term

“evaluation” and the term “impact” to demonstrate outcome achievements on a larger scale in time or organizational level (32). The IMPECD consortium summarized specific characteristics of monitoring, outcome evaluation and impact (Table 1) and proposes the following definitions:

Monitoring: *“Systematically conducting ongoing checks whether preselected indicators are changing within acceptable limits during an intervention. The aim is to check the intervention implementation and client adherence, as well to track progress towards the a priori determined goals and outcomes, and feedback on it.”*

A lack of progress or the appearance of new issues can be reviewed to determine whether the diagnosis is still valid or the planned intervention still adequate. Indicators connected to monitoring are called “monitoring indicators” and include the clients’ facilitating factors and barriers during the implementation.

Outcome evaluation: *“Systematic assessment of indicators to check whether a priori determined goals and objectives, defined as SMART (Specific, Measurable, Achievable, Results-oriented, Time-bound) outcomes, have been achieved within the set timeframe (yes/no). While some outcomes can be evaluated during the actual timeframe of the intervention, the main outcome(s) are always evaluated at the end of the intervention period.”*

The aim is to decide whether the intervention was successful or not. This can be, in dietetic practice, expressed in terms of effectiveness and supports any further action that might be needed.

Indicators connected to outcome evaluation are called “outcome indicators”. In human clinical research, outcome indicators are synonymous for “endpoints” and “readouts” in basic research.

Impact: *“Evaluation of outcomes on a macro-level of time (e.g. sustainability, long term effect), organizational level (surpassing the client’s perspective e.g. for a certain professional field or*

society in general) and resources (e.g. financial impact by cost-effectiveness analysis)."

Outcome indicators connected to impact can be called "impact indicators".

Examples of impact indicators are: body weight two years after completion of the intervention, reduction in disability-adjusted life years (DALY) as a result of dietetic interventions for diabetes, reduction in costs of par(enteral) feeding in a hospital, ...

It may take a very long period for impact to become apparent, and impact measurement can be confounded as observed changes could also be attributed to other factors than the intervention (35). Nevertheless, assessing impact is crucial for all professional practice.

Monitoring and outcome evaluation (M&OE): *"The process of planning and performing monitoring and outcome evaluation through data collection and analysis".* M&OE includes impact assessment and enhances continual professional improvement by reflection (37) and *sharing experiences with peers.*

	Monitoring	Outcome Evaluation	Impact
Systematic approach as part of dietetic routine			
Ongoing process during implementation of intervention; multiple measurements possible	X		
Mid-term alterations of intervention are possible	X		
Performed at the end or after the intervention (single measurement); yes/no as answer of achievement		X*	X
Professional improvement (life-long learning and sharing experiences with peers)	X	X	X

Performing measurements			
Indicators predetermined at the start of intervention	X	X	X
Prognostic value towards target (= achievement of intermediate goals)	X		
Client reported measurements can be used	X	X	
Measures are ideally hard and objective (not client reported)		X	X
Standardized Terminology			
Process parameters / process indicators / progress indicators / monitoring indicators / process evaluation / formative evaluation / performance evaluation	X		
Summative evaluation / outcome parameters / outcome indicators / outcome evaluation		X	X
Impact indicator / impact evaluation			X
Effectiveness		X	X
Cost-effectiveness			X
Micro- or meso-level (client or group)	X	X	
Macro-level (time, organizational or resources level)			X

Table 1: Characteristics of monitoring, outcome evaluation and impact according to the proposed IMPECD definitions.

(* depends on a priori set timing of the outcome)

c) Efficacy, effectiveness and efficiency

The following IMPECD descriptions are based on and adapted from (36, 39-43):

Efficacy: *“The extent to which a dietetic intervention yields the desired outcomes under ideal conditions.”* It refers to internal validity and answers the question if the intervention ‘can’ work, derived from research results (ideally from well controlled clinical trials).

Effectiveness: *“The extent to which a dietetic intervention yields the desired outcomes with normal dietetic/clinical practice”.* It refers to external validity and answers the question if the intervention also works in practice in daily life settings. Routine data from practitioners can be used to gauge effectiveness.

Cost-effectiveness = efficiency: *“The effect or value of a dietetic intervention in relation to its costs (direct and indirect) and resources (individual or from society) needed to produce the desired outcomes”.* It answers the question if the intervention is meritable and can be justified. We recommend using the clearer term “cost-effectiveness” over the older term “efficiency” to avoid confusion with the previous terms.

Efficacy-effectiveness gap (EEG): *“Possible discrepancies and complementary scientific evidence on efficacy and effectiveness”.* Its paradigms are described in a publication by Nordon et al (40).

Table 2 shows some examples of dietetic intervention outcomes and one of their indicators. These examples are only illustrative for the terminology and therefore not intended to give an exhaustive summary of all indicators involved.

In some cases, outcomes are directly related to the behavioural change of the client caused by the dietitians’ counselling, e.g. when the outcome deals with reducing saturated fatty acid (SFA) intake.

The main health outcome ‘normalisation of serum cholesterol’ can actually be caused by many factors (e.g. change in medical drugs, other medical condition), but proving that ‘decreased intake of SFA’ took place prior to ‘normalisation of serum cholesterol’ provides the causal link to the effects of dietetic advice. Only if the cause-effect relationship is established, the clinical outcome can be

regarded as dietetic intervention outcome. Health promotion campaigns often have multiple outcomes and many indicators from various sources, which are often summarized in a matrix.

Outcome	Example of Monitoring indicator	Example of Outcome indicator
10% body weight reduction after 1 year of intervention	Body weight at each consult	Body weight after 1 year
A reduction of saturated fatty acid (SFA) intake to less than 10% of daily energy intake after 6 months	Intake of food items rich on SFA by food frequency questionnaire after the second consult	Intake of SFA and energy by 7day-food record after 6 months of intervention
Reduction of serum LDL to reference values after 1 year	Available clinical chemistry reports and/or assessment of SFA intake and eating pattern at each consult	Clinical chemistry report on serum cholesterol concentration after 1 year
80% of elementary schools have implemented a high quality health promotion policy within 9 years from now	Percentage of schools with minimum 2/10 (e.g. involvement parents) achieved criteria for high quality health promotion after 3 years	Percentage of school with minimum 5/10 achieved quality criteria after 9 years
Improved nutritional status of a malnourished haemodialysis client	Body weight, presence of oedema, bioimpedance vector analyses (BIVA), 24 hr recall	Normalisation of nutritional status (absence of malnutrition signs, improved

	to detect a reduced energy, protein, and micronutrients intake every two weeks, Serum albumin and inflammation (CRP) every 3 months	body cell mass) after 6 months
Normalisation of defecation and gastro-intestinal complaints in a client with constipation	Dietary history (fibre and fluid intake), physical activity or exercise, and Bristol stool chart after 1 and 2 months	Absence of Rome III criteria after 6 months

Table 2: Outcome evaluation: Examples for monitoring and outcome indicators concerning dietetic intervention outcomes

3. Merging a “dietetic care process” into a logic model to understand M&OE

The IMPECD unified DCP model is shown in Figure 1 and includes five steps of dietetic assessment, diagnosis, planning, implementation of intervention (including monitoring) and outcome evaluation (19). The current NCP and DCP models implicitly follow a logic model construction, mostly in a circular (non-linear) visualization (22-24, 44).

Logic models are often used to describe a systematic approach for interventions. Although such models have been used mainly for program development and evaluation, traditionally in an organizational context beyond the individual level, there is however no reason why such a model couldn't be applied in non-community settings, with goals to reach being set in terms of prevention as well as treatment targets (45). An evidence-based logic model provides a framework to link a problem (situation) to the intervention (its preparation and implementation) to the outcomes and final impact (31, 32, 34, 46). Such a model is mostly presented as a visual roadmap and enables the “theory of change” to be inferred, clarifying the theoretical concepts behind the model and explaining how and why the intervention will work and lead to the desired changes and outcomes over a specified period (47-49).

A logic model always includes actions of M&OE by formulating desired outcomes in a SMART way, and by that giving an outline of what relevant monitoring and outcomes indicators can be selected (32, 34).

A comprehensive model adopted to provide a workable framework for our M&OE purposes is given in Figure 2.

This model shows 6 different stages for the dietitian in practice:

- 1) What is the problem/situation and etiology? What are the sign/symptoms? What are the resources and barriers (input)?

Collection of data on resources is essential to demonstrate cost-effectiveness

2) What can you do about it? Plan intervention activities and produce output

What outcomes and impact do you want to achieve? Set goals in terms of outcomes.

Select a priori monitoring indicators and outcome/impact indicators, and their appropriate measures.

3) Implement the intervention

4) Monitor by measuring monitoring indicators. Feedback and, when designated, adopt the intervention or revise the preparation aspects (represented by the arrows)

5) Evaluate by measuring outcome (and impact) indicators: to what extent has the outcome/impact been achieved? (numerical or descriptive)

6) Feedback to improve; learn and share

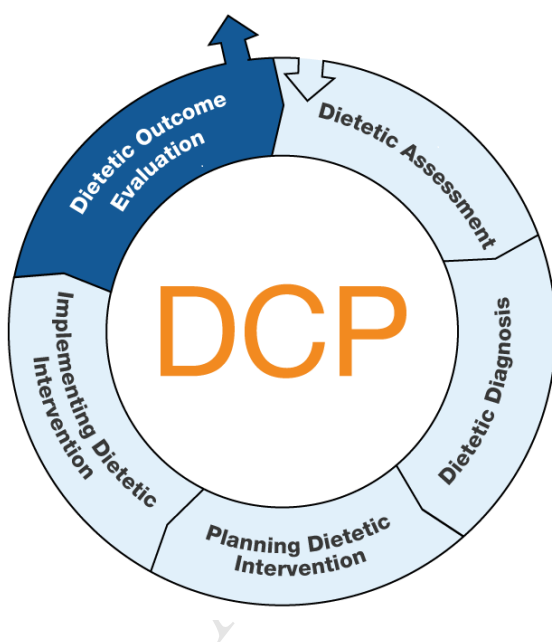


Figure 1: Working model of the Dietetic Care Process (DCP) used in the IMPECD project

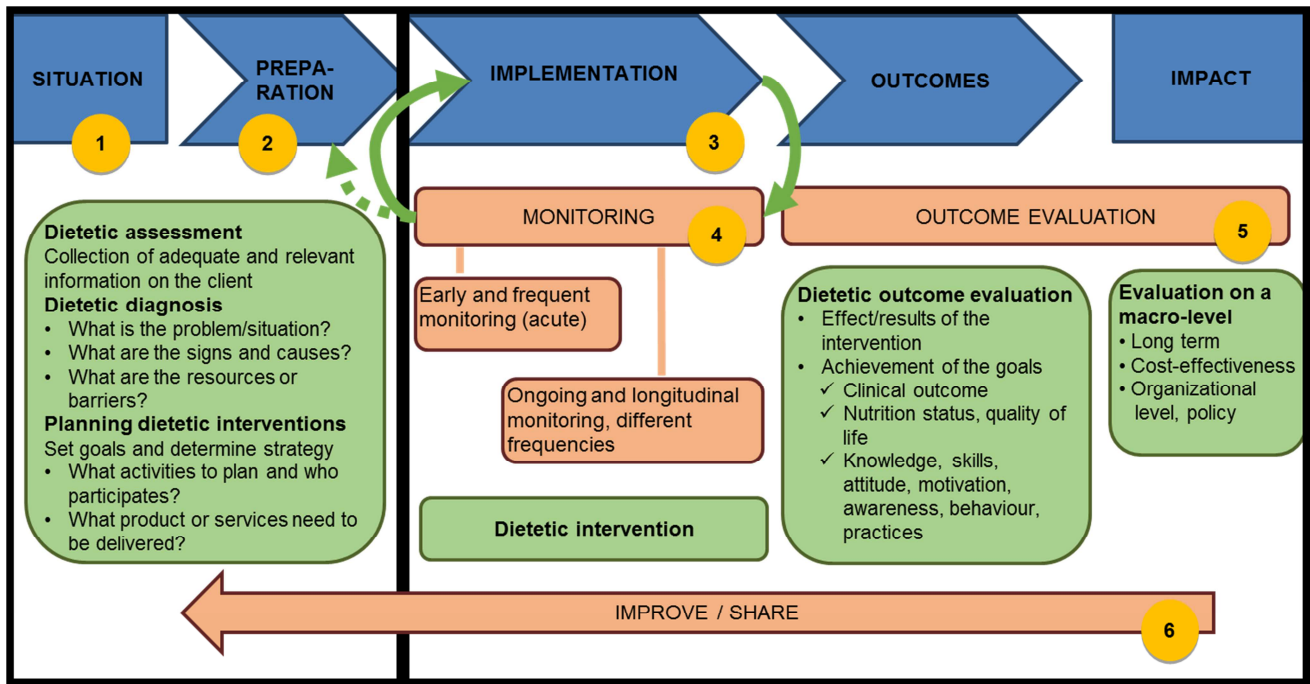


Figure 2: The comprehensive IMPECD logic model for dietetics. Blue boxes represent the steps in a logic model, green boxes the steps in a 'Dietetic Care Process (DCP)', red boxes the steps of 'monitoring and outcome evaluation (M&OE)'

4. M&OE and selecting indicators in different dietetic settings

As indicated by the second step of Figure 2, M&OE require setting goals and selecting those monitoring and outcome indicators relevant to the client. Outcome mapping is a useful tool to set intervention goals (50), which can be described in terms of preventing, maintaining, improving, normalizing, expanding or reducing certain monitoring and outcome indicators (38). Unfortunately, information on the type of indicators for M&OE in current NCP models (22-24) is limited to aspects of food intake, anthropometry, biochemical aspects and nutrition-focused physical findings. In order to come to a more holistic overview on the client, the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization (WHO) (51) was consulted, covering broader aspects of personal, social and environmental dimensions which are useful for M&OE (52). The result, as presented in Table 3, is a categorized overview of indicators developed by the IMPECD consortium for different dietetic settings. For counselling, the type of indicators needs to be linked to the counselling method used by the dietitian. Outcomes and indicators of eating disorders are not covered in this table as they have an important psychological dimension (53).

The list given in Table 3 is non-exhaustive as indicators can also be very case-specific. The selection of relevant indicators should be based on best practices and evidence-based guidelines (54). This part of M&OE requires a high level of dietitians' critical reasoning (37) and should be planned thoroughly, also taking into account available measurement options and equipment. In case a proposed indicator is not directly measurable, unavailable or unobservable in a given setting (e.g. individual cardiovascular risk), indirect (proxy) indicators could serve as alternative indicators (e.g. waist circumference and/or serum cholesterol values) (55). Obviously, validated measurement techniques are to be used by preference and, especially for outcome evaluation, sufficiently sensitive to attribute the measured effect to the intervention (56).

Furthermore, outcome indicators should be as “hard” as possible, that is reliable and confirmative for the health improvement or clinical situation of a client. In line with evidence-based medicine, “mortality” is the hardest outcome, nonetheless rarely applicable or meaningful in dietetic settings. “Soft” outcome indicators to detect changes in behaviour, e.g. increased energy intake, are often derived from questionnaires, without confirming a consequent improvement of health, disease or risk factors for disease. Nevertheless, soft outcome indicators may be important to link the work of the dietitian (e.g. improving dietary intake) to a consequent improvement of health or risk factors (e.g. reduced LDL-cholesterol level). In short, cause-effect relationships can be established by linking soft with hard outcome indicators. In addition, newer concepts in clinical nutrition recommend multidimensional approaches, meaning the addition of client centered outcome indicators, such as QoL, as well as cost-effectiveness into conventional outcome models, which are focused on clinical improvements only (57). Main advantages seen are related to the increasing relevance of client satisfaction and economic dimensions in today’s resource-constrained environments (57).

As not all outcome indicators have a quantitative measure, they may not be routinely captured or may be neglected. For instance, in dietetic counselling qualitative data concerning the progress of symptoms, functioning, well-being, behavioural aspects (knowledge, beliefs, attitudes), readiness to change and client satisfaction (30) rely highly on the dietitian’s professional judgement. In that case qualitative scales or client reported outcomes, typically short questionnaires, can be considered (55, 58). As with all other numeric indicators, it is also important to set target values for these indicators, with respect to their initial values. Within ICF-dietetics, impairments and progress can be estimated by using a coded system ranging from ‘no impairment’ to ‘light, moderate, serious or full impairment’ (38). Noteworthy, evaluation of satisfaction is challenging as it is multi-factorial and itself does not demonstrate the effectiveness of an intervention (55).

Traditionally, principles of M&OE are most established in public health nutrition and, for dietitians at least, to a lesser extent in the field of medical nutrition, but even there is room for improvement. A well-shaped M&OE model will not yet occur in nutritional counselling due to different approaches and methods of dietitians during the consult.

In public health nutrition, although the impact of unhealthy food environments on obesity and diet-related diseases is unquestionable and policies for prevention have been implemented in various nations, a recent review showed that only a relatively small proportion of the implementation of these actions is being assessed and evaluated (59). Some standardized evaluation frameworks and validated methods are well developed but often theoretical/conceptual (e.g. 'Public Health Nutrition (PHN) bi-cycle' (60) and the 'Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM)' framework (61)), and not harmonized to ensure that specific data can be compared across different countries, settings or over time (59). Attention should also be paid to investigate whether improvements in knowledge and attitudes result in actual behavioural change (62) and whether such beneficial changes can be attributed to the policy or to some other factor (59, 63). Depending on the target population and desired outcomes it is definitely recommended to always check whether certain organizations offer protocols with specific indicators, not only concerning non-communicable diseases (NCD) but also other nutrition-related problems (e.g. the WHO indicators for the comprehensive implementation plan on maternal, infant and young child nutrition (64)). In general, data are more available for short-term effects than longer-term impact as this implies morbidity or mortality and may take several years before a change can be observed (65). Furthermore, there is a relative lack of evidence on how best to address inequalities across different population subgroups (66). The ICF could be used in the formulation of policy goals and might provide an infrastructure for the systematic recording of data with regards to functioning and disability (52, 67).

Changing to the other side of the dietetic spectrum, medical nutrition is defined as nutritional therapies encompassing oral nutritional supplements (ONS) as least invasive approach followed by enteral tube feeding and parenteral nutrition (68). Medical nutrition mainly deals with malnourished patients or those who are at risk of malnutrition and it also includes the intensive care environment. In medical nutrition, with increasing invasiveness of the nutritional therapy, behavioural aspects are losing importance on the costs of complication monitoring. Strict and close monitoring of nutritional complications are especially important in the intensive care settings (69, 70) and patients who are at a risk of refeeding syndrome (71), and not only need advanced skills of a dietitian but also a multi-disciplinary team approach consisting of doctors, nurses and pharmacists. Such team approaches are commonly called 'nutrition support teams' (68). Still, the general concepts of M&OE do also apply in medical nutrition with predetermined outcome indicators being important to prove the efficacy, safety and cost-effectiveness of the medical nutrition therapies.

	<i>Categories of indicators</i>	<i>Specific examples</i>
<i>ALL DIETETIC FIELDS</i>	Diet history	Meal and snack pattern Fluid intake, fluid balance Nutrient intake, nutrient balance Energy intake - energy expenditure Current and previous diets and/or food modifications
	Clinical status	Medical history Current medical status Intake of medical drugs Clinical chemistry
	Nutritional status	Anthropometric data Body composition Nutrition-focused physical findings, e.g. dentition status, dysphagia/swallowing problems Physical activity, physical functioning, mobility
	Personal factors	Education / (health) literacy Social status, income Smoking Social participation, hobbies Family situation, number of children
	Adoption / implementation of the intervention	Participation rates, adherence to intervention
	Adverse outcomes and barriers/facilitators	Possible side effects, invasiveness
	Quality of Life (QoL)	Questionnaires on QoL, indicators of well-being (social, economic, subjective)
	Participants satisfaction	

	Costs and efforts, health care utilisation	<p>Satisfaction scores</p> <p>Financial data</p> <p>Time requirements</p> <p>Number/length of hospitalisations</p>
<i>Specific for</i> DIETETIC COUNSELLING	<p>Behaviour</p> <p>Environment</p> <p>Motivation and empowerment</p> <p>Social support</p> <p>Autonomy of the client</p>	<p>Food and nutrition knowledge</p> <p>Beliefs and attitudes about food and health, food choice</p> <p>Eating style</p> <p>Factors affecting behaviour (e.g. fatigue, emotional distress)</p> <p>Factors affecting access to food and food/nutrition-related supplies on a micro-level (e.g. kitchen infrastructure, household), meso-level (e.g. distance to food retail and supermarkets, neighbourhood, transportation, playground, workplace) or macro-level (e.g. pricing, advertising, media, policy, funded food initiatives)</p> <p>Stage of change: pre-contemplation, contemplation, preparation, action, maintenance.</p> <p>Thoughts, emotions, ambivalence and barriers of behaviour change</p> <p>Self-efficacy, self-management</p> <p>Awareness, engagement, decisiveness</p> <p>Support by relatives and friends</p>
<i>Specific for</i> PUBLIC HEALTH NUTRITION	<p>Behaviour</p> <p>Environment</p> <p>National strategic leadership and policies</p> <p>Supportive environments and programmes</p>	<p>See above</p> <p>See above</p> <p>Existence of national guidelines on diet and physical activity</p> <p>Regulatory frameworks on food marketing</p> <p>Number of schools participating in a health campaign, provision of counselling in primary care</p>

	Surveillance system Reach of target population	National food consumption surveys Number or proportion of participants, response rate
<i>Specific for MEDICAL NUTRITION</i>	Food and Nutrient Administration Metabolic indicators Status indicators Impact indicators	Supplementation e.g. oral nutritional supplementation (ONS) Enteral tube feeding and parenteral nutrition Electrolyte status Blood glucose Lactate Liver enzymes Inflammatory parameters Actual energy intake versus prescribed energy intake Physical and cognitive functionality Muscle mass Tolerance of clinical therapies Number of Re-admissions In-hospital costs

Table 3: Categorized overview of indicators for monitoring, outcome evaluation and impact, for different dietetic settings and examples (non-exhaustive list)

5. Checklist for a dietetic M&OE plan

Dietitians' participation in outcome monitoring is of huge importance and can be promoted by providing ready-to-use tools and training. Even more, dietitians' involvement in outcomes research should be encouraged by keeping data collection methods as simple as possible (72). Within the IMPECD project a checklist for M&OE was developed (Table 4), in accordance with the steps derived from Figure 2, that could be used by dietitians in each setting, in the same way as existing checklists for intervention development and planning have been shown to be useful for the professional (73).

The answers from the checklist (Table 4) enables the dietitian to gain enough insight to construct a M&OE plan (34) in grid style (see online supplement S2). Some aspects with regards to timing and reporting aspects might be a potential barrier for M&OE, in particular for individual dietetic settings, are worth elaborating on.

a) Frequency and timing of measurements

Treatment protocols often include guidelines on the number and timing of consults and what indicators should be measured. The Dutch National dietary therapy guidelines recommend to collect data and information during the first consultation, halfway, when significant changes occur (in adherence, clients' status or situation) and at the end of the process. The last consult has to deal with outcome evaluation and long-term advice and point to yearly check (74). In practice, it is however often up to the professional judgement of the dietitian, based on the evidence-based prediction of expected effects and given that consultation time is limited and time and fees for follow-up consultation often lower (75).

Adherence to the intervention, in particular, should be monitored regularly, although evidence on the most effective strategies in achieving long-term adherence is scarce and improving adherence is not

universally effective but recommended to be individualized. For instance, there is no universal agreement about the frequency and timing of phenylalanine concentration measurements to assess dietary adherence in phenylketonuria (76).

b) Data collection and reporting strategy

During dietetic counselling a lot of information can be obtained by observing the client and asking questions (e.g. on their comprehension of the given dietary advice) during the consultation. Data could also be derived from self-monitoring, computer programs or apps, telephone or electronic follow-up (77). A mixed methods approach wherein the qualitative data provides understanding and application of the quantitative data can be recommended (34).

Sufficient time for data analysis and reporting should also be foreseen (35). Data registration can be done by various systems of client records (53, 78). Digital incorporation outreaches conventional paper formats when it comes to automation of analyses and incorporation into other formats such as electronic health records (79). Rossi et al. (80) showed that, in a population receiving haemodialysis, the implementation of an electronic system compared with a paper-based system resulted in significant improvements in the efficiency of nutrition care and effectiveness related to client outcomes.

Current software can include options for goal setting and to register and monitor all kinds of data like body weight, anthropometric data, biochemical data or data on client motivation. For M&OE, we recommend checking if the software is able to yield charts or reports showing evolution over time (i.e. the different consults). Commercial web pages (using search strings such as 'nutrition software') make comparisons between existing software for non-professionals and for professional use, but nevertheless, these internet searches are mostly in English and not always country-specific.

436 After the outcome evaluation, reporting is done in accordance with the M&OE work-plan that
437 defines the stakeholders, the content, the format and the frequency (37) (see online supplement Table
438 S2).

439

ACCEPTED MANUSCRIPT

	Setting intervention goals in term of desired outcomes
1	Intervention goals/outcomes are prioritized
2	Intervention goals/outcomes are set in agreement with the client
3	Intervention goals/outcomes (e.g. select from Table 3 column 2) have been defined in a SMART way (Specific, Measurable, Achievable, Results-oriented, Time-bound) and with target values where possible
	Selecting monitoring and outcome indicators
4	Appropriate modifiable indicators are selected (e.g. select from Table 3) and their reference standards for comparison
5	Appropriate and/or valid instruments to measure/assess indicators are selected and available. Preferentially quantitative measurements where possible, qualitative measurements where this is not possible or not existing
	Data collection: Measuring and assessment
6	Baseline values of indicators are determined/measured
7	Frequency and timing of measurements are determined
8	Data that can't be obtained internally are accessible externally
9	Measurements are preferentially done in a valid and reproducible way (under standardized conditions, following a protocol, using validated questionnaires)
10	Time and resources are foreseen to collect, register and analyse data
	Interpretation of data: M&OE reasoning
11	Deviations from target/reference values can be interpreted and counteracted (monitoring)
12	Decisions can be made on discharge, long-term follow-up, re-assessment or continuation of intervention (outcome evaluation)
13	The effectiveness of the intervention (including generalizability of effects) can be assessed.
14	The sustainability and impact at a level beyond the client can be assessed
15	Non-completion of intervention, non-participation and/or drop-out can be analysed
16	Professional improvement by personal reflection is performed
	Reporting
17	Professional improvement by sharing experiences with colleagues/peers
18	All data and results are documented in written form

19	All stakeholders are identified and informed (care-givers, target client/population, institution, funder, developer, policy maker)
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Table 4: The IMPECD checklist for monitoring and outcome evaluation (M&OE)

6. Discussion and conclusions

This paper examined monitoring and outcome evaluation in the perspective of different dietetic settings. Good intervention preparation alone does not ensure desired results, so progress needs to be monitored and goals need to be evaluated to deliver high-quality care (30). On the other hand, well planned and executed monitoring alone will not correct poor intervention designs (46). In this perspective, M&OE provide opportunities at regular predetermined check-points to validate the logic throughout a dietetic intervention and to make necessary adjustments where needed.

We promote a prominent position for impact as part of outcome evaluation. Performing cost-benefit analyses is an excellent way to demonstrate impact and is critical for the future development of dietetics. The added value of dietitians being in charge of delivering nutritional intervention has not been investigated in the past, although the awareness in this field is increasing. The limited available evidence shows favorable health effects and lower costs of dietitian-delivered interventions than in those delivered by non-dietitians (11). In primary care, consultations by a dietitian are shown to be particularly effective for improvement of certain outcomes such as diet quality, weight loss and diabetes management (15). A cost-benefit analysis doesn't necessarily have to occur in a traditional research environment and can be based on information derived from all kind of sources. For instance, data from the organizational level can be used, showing savings achieved through artificial feeding and provision of oral nutritional supplements, or showing higher productivity through less number of sick leaves taken and cost-savings due to less utilization of health-care resources. The studies on cost-effectiveness of dietitians mentioned in the current paper were also based on data delivered directly from dietitians (6-8).

Although we have suggested using terminology in a consistent way, it is better to remember that in a real-life setting monitoring and outcome evaluation merge together during the implementation

timeframe of the intervention (35). For instance, the achievement of a short-term outcome is part of outcome evaluation, while simultaneously assessing the progress of other (longer term) outcomes before they have been achieved belong to monitoring. Another example concerns the actual implementation of the intervention. Implementation and adherence are mostly not a goal as such but need to be monitored to gauge the effectiveness of the intervention. Adherence to dietetic intervention in real world settings might be low and improved by dietetic follow-up and by addressing personal and environmental factors (81, 82). Therefore, a thorough monitoring of adherence can be helpful to improve outcomes in all dietetic settings (81-85). Feedback and sharing insights from M&OE are crucial to working out strategies to improve adherence, dietetic outcomes (e.g. adequate intake of nutrients, weight gain), clinical outcomes (e.g. decreased cardiovascular events, improved tolerance of radiochemotherapy), overall outcomes (e.g. increased activities in daily living, increased QoL) and to achieve impact (e.g. cost savings, reduction in hospital length of stay). Collaboration with other (para)medical professionals (e.g. physiotherapists, psychologists) is known to be important in raising the success rate in achieving certain health outcomes (15).

The IMPECD model and checklist for M&OE presented in this paper offer useful tools for dietitians in different settings. Although useful checklists have been developed in the past for public health interventions (86, 87) and the current NCP models give information only on the general aspects of M&OE, this is to our knowledge the first time that M&OE has been clearly applied to dietetics by converging existing models into one comprehensive model. Furthermore, the IMPECD consortium translated these insights into a useful checklist suited for dietetic practice, covering the areas of medical nutrition, counselling and public health. This checklist can be seen as a starting point to inspire and trigger dietitians to perform M&OE in practice, and thus implicitly has the potential to serve real routine data collection and therefore may contribute to dietetic research. Those items in the list that would appear to be of less relevance to a certain dietetic intervention in practice, can be left

out or the list can be simplified following the dietitians own critical reasoning. This list is open to further analyses and syntheses by dietetic practitioners and researchers.

The frequency of measurements and a strategy for data collection and reporting are important aspects of M&OE. Although national dietary treatment guidelines for a specific disease may include instructions for client measurements (74), uniformly accepted guidelines on outcome measurement are often lacking. Beyond the individual dietitian's perspective, dietetic associations and their disease-specific commissions, nationally and internationally, could coordinate the standardized collection and analysis of data provided by its members. As underlined by Porter et al. (30), developing a minimum sufficient set of outcomes for every nutrition-related condition is crucial to demonstrate professional impact and justify medical reimbursement.

Providing an evidence of the effectiveness of dietetic interventions in improving health outcomes is of critical importance to justify the importance of nutrition in health-care. This can contribute to the dietitians' strategy for success by demonstrating their effectiveness and by that strongly claim their role in health care.

Statement of authorship

Vanherle K wrote the article, in close collaboration with Valentini L and Werkman A. Adam M, Baete E, Barkmeijer A, Gast C, Höld E, Kohlenberg-Müller K, Kolm A, Ohlrich-Hahne S, Ramminger S, Walters M, and Wewerka-Kreimel D revised it critically for important intellectual content. All authors revised and approved the submitted version of the manuscript.

Conflict of interest

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