Evaluation of methodological variations in the event simulation approaches of published health economic models in the context of obesity therapy and prevention

(Evaluation methodischer Vorgehensweisen zur Simulationen klinischer Ereignisse im Kontext der Prävention und Behandlung der Adipositas)

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DGGÖ – Deutsche Gesellschaft für Gesundheitsökonomie –
9. Jahrestagung, Universität Basel 2017

Introduction

- Obesity is a **multifactorial, chronic disorder** that has, according to the WHO, reached **epidemic proportions** globally and is a major contributor to the global burden of chronic disease and disability [1].
- Obesity is defined as abnormal or excessive fat accumulation that may impact health. According to the **WHO definition**, a BMI ≥ 25 and < 30 is overweight; **a BMI ≥30 is obesity** [1].
- In 2014, worldwide, more than 1.9 billion adults (≈39%), were overweight. Of these, **over 600 million adults (≈13%) were obese** [2].
- **Overweight and obesity are leading risks for global deaths**. In 2010, worldwide, it has been estimated that around 3.4 million adults died (≈ 6% of total deaths per year) as a result of being overweight or obese.[3]
- In addition, **44% of the diabetes cases**, **23% of the ischemic heart disease case**s and between 7% and 41% of certain cancer cases are attributable to overweight and obesity [4].

Objective

- Given this clinical and its associated economic burden, it is of major interest for healthcare decision makers to identify cost-effective programs or interventions for obesity prevention and therapy.
- Decision analytic modelling is particularly relevant in the case of obesity due to the chronic nature of the obesity associated risk factors, morbidities and related mortality; which requires long-term observations that are often not provided by purely empirical evaluations; hence **several decision analytic models have been applied**.
- The objective of our research **was to determine and compare the methodological variations in the event simulation approaches of published health economic decision models**.
- The **focus** was set **on cardiovascular diseases** (CVD); **type 2 diabetes** (T2D) **and stroke** as cohort studies have demonstrated that these diseases are three of the most important consequences of obesity [5].

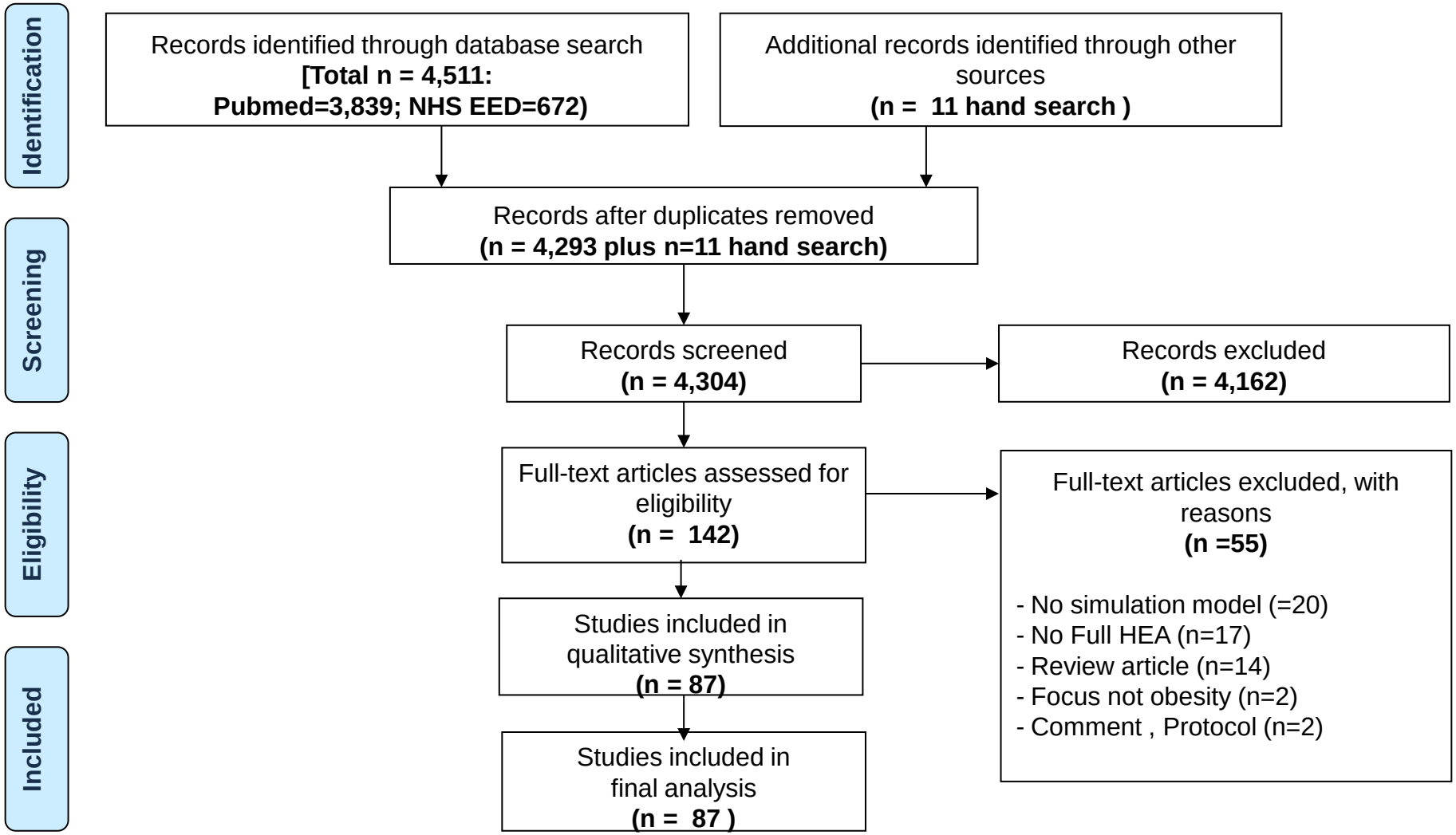
Methods

- This **systematic review** was conducted according to the **PRISMA guidelines**.[6]
- To identify relevant published decision models for full health economic assessment in context of obesity, the Pubmed Database and the NHS Economic Evaluation Database (which includes MEDLINE, EMBASE, CINAHL, PsycINFO and PubMed) have been searched (May 2015).
- For the data extraction a predefined template was developed and used **in order to summarize information on the obesity associated events simulation approaches**.
- This included the following information: **CVD / T2D / stroke incidence simulation approach, CVD / T2D / stroke simulation of the intervention effect**, event-specific mortality simulation, rating on whether reprogramming is possible on the basis of the data / information provided, and information on the validation of the event simulation.

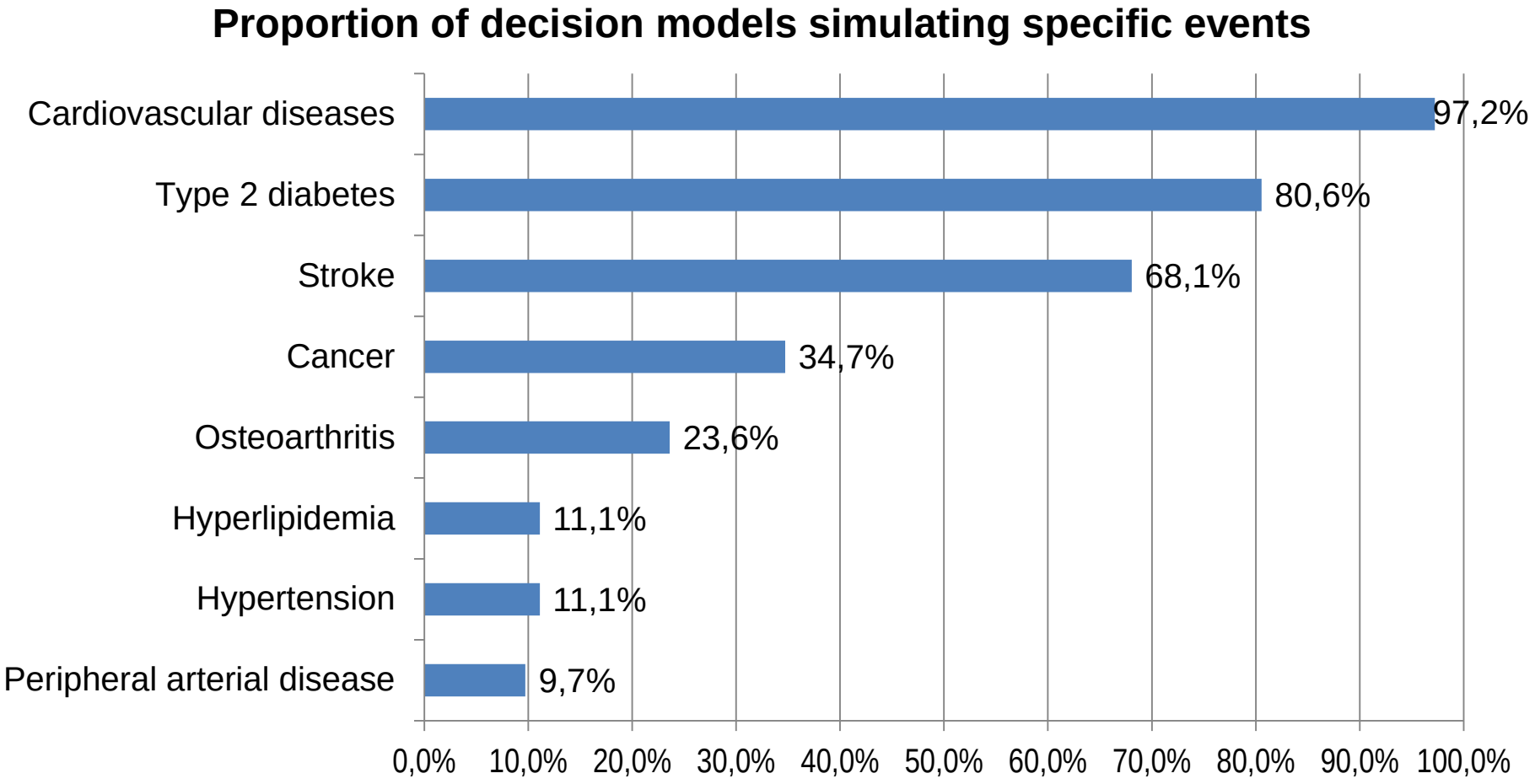
Eligibility Criteria

- Eligibility Criteria: Eligible studies were decision models for full economic assessment in the context of obesity.
  - **Full health economic assessments** (HEAs) were defined as "the comparative analysis of alternative courses of action in terms of both their costs and consequences" **according to Drummond et al**.[7].
  - **Decision models** were defined as “an analytic methodology that accounts for events over time and across populations, that is based on data drawn from primary and/or secondary sources, and whose purpose is to estimate the effects of an intervention on valued health consequences and costs” **according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)** Task Force on Good Research Practices – Modeling Studies [8]; hence health economic evaluations alongside a clinical trial have been excluded.
  - **Obesity was defined** as “a BMI greater than or equal to 30”, **according to the WHO criteria**.[1]

Flow Diagram



In 72 of 87 (83%) models obesity associated events were simulated



The percentages presented above are calculated on the basis of the 72 decision model that simulate obesity associated events; the 15 remaining decision models that were excluded simulated no events

Results

- Out of the 87 decision models identified
  - **72 (83% of the total) simulated obesity associated events**;
  - and **68 (78% of the total) of these models simulated at least one of the key obesity associated events (CHD, T2D and/or stroke)**.

- Looking at the single events we have identified
  - **60 decision models (69% of the total) that simulated CVD**;
  - **53 decision models (61% of the total) that simulated T2D**
  - and **48 decision models (55% of the total) that simulated stroke**;
  - only **39 (45% of the total) decision models simulated all three events**.

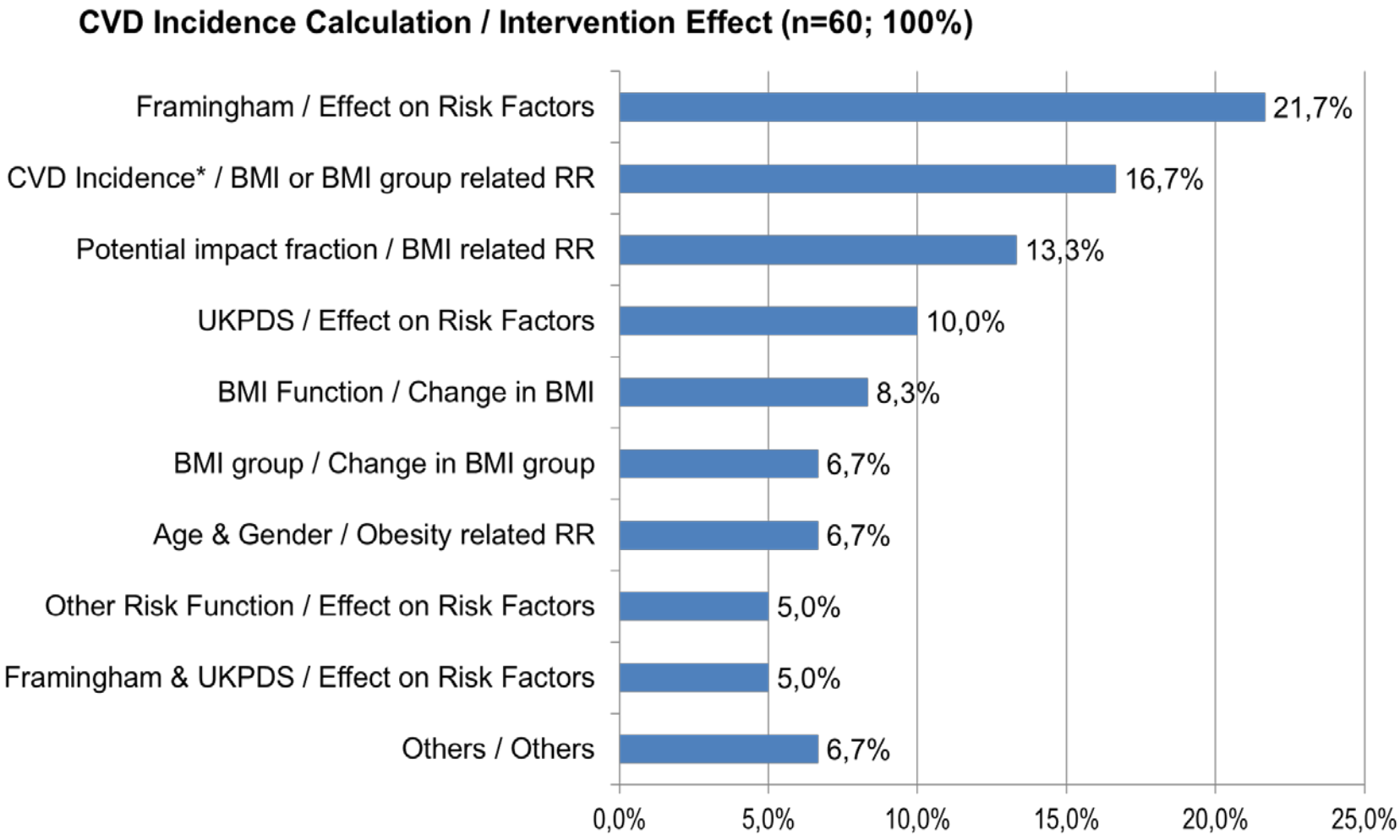
Categorization of Incidence Simulation

- Potential Impact Fraction (of obesity on events)
- Risk Functions (e.g. Framingham, UKPDS, others)
- Incidence Estimation
  - based on BMI function
  - based on BMI group
  - based on Age & gender
  - based on multiple factors
- Others

Categorization of Intervention Effect

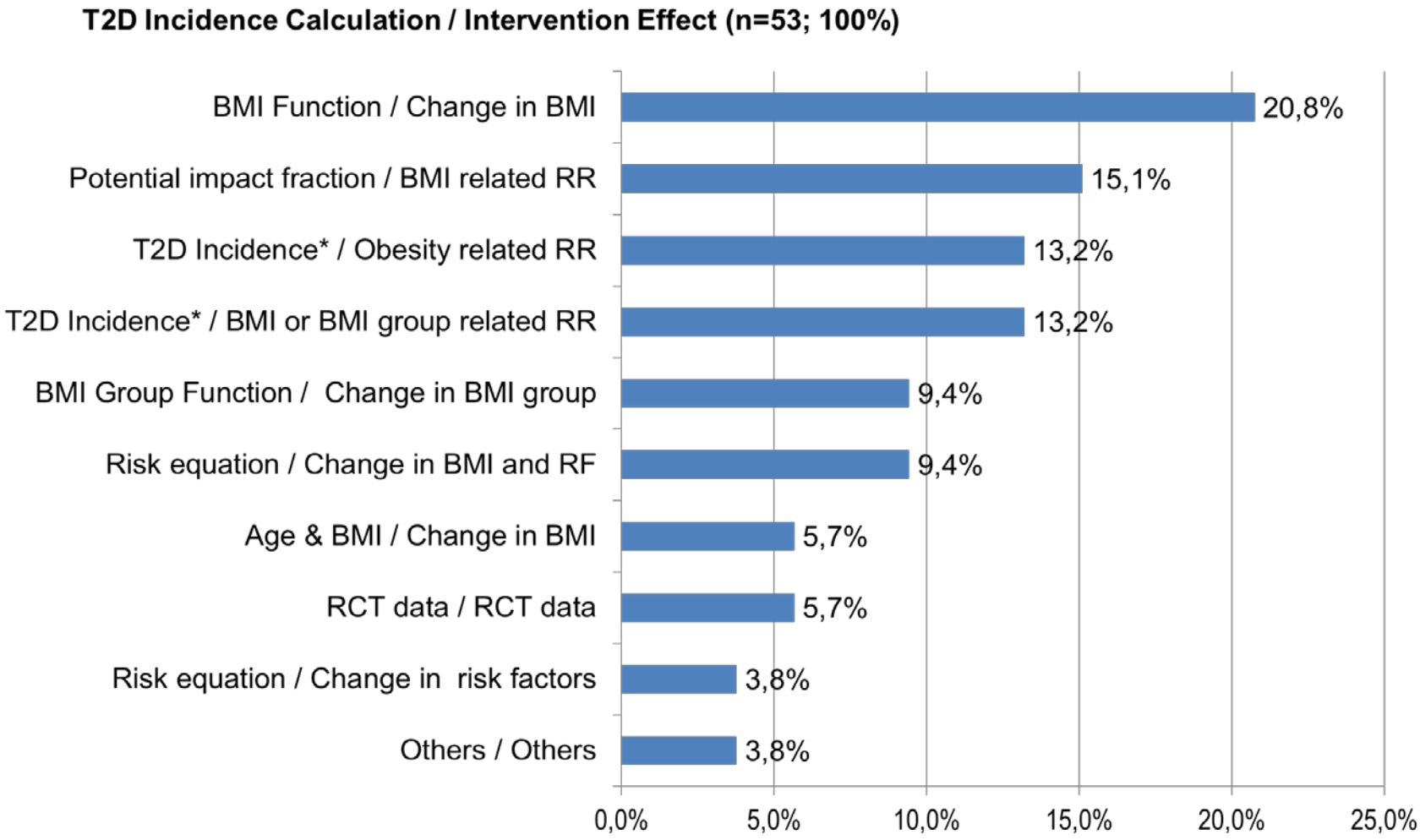
- Effect on Risk Factors (risk factor based incidence)
- BMI related relative risk [RR] (BMI based incidence)
- BMI group related RR (e.g. BMI<25;25-30;>30 etc.)
- Change in BMI (BMI based incidence)
- Change in BMI group (BMI group based incidence)
- Obesity related RR (higher RR with obesity)
- Others

Overview of **CVD** event modelling approaches



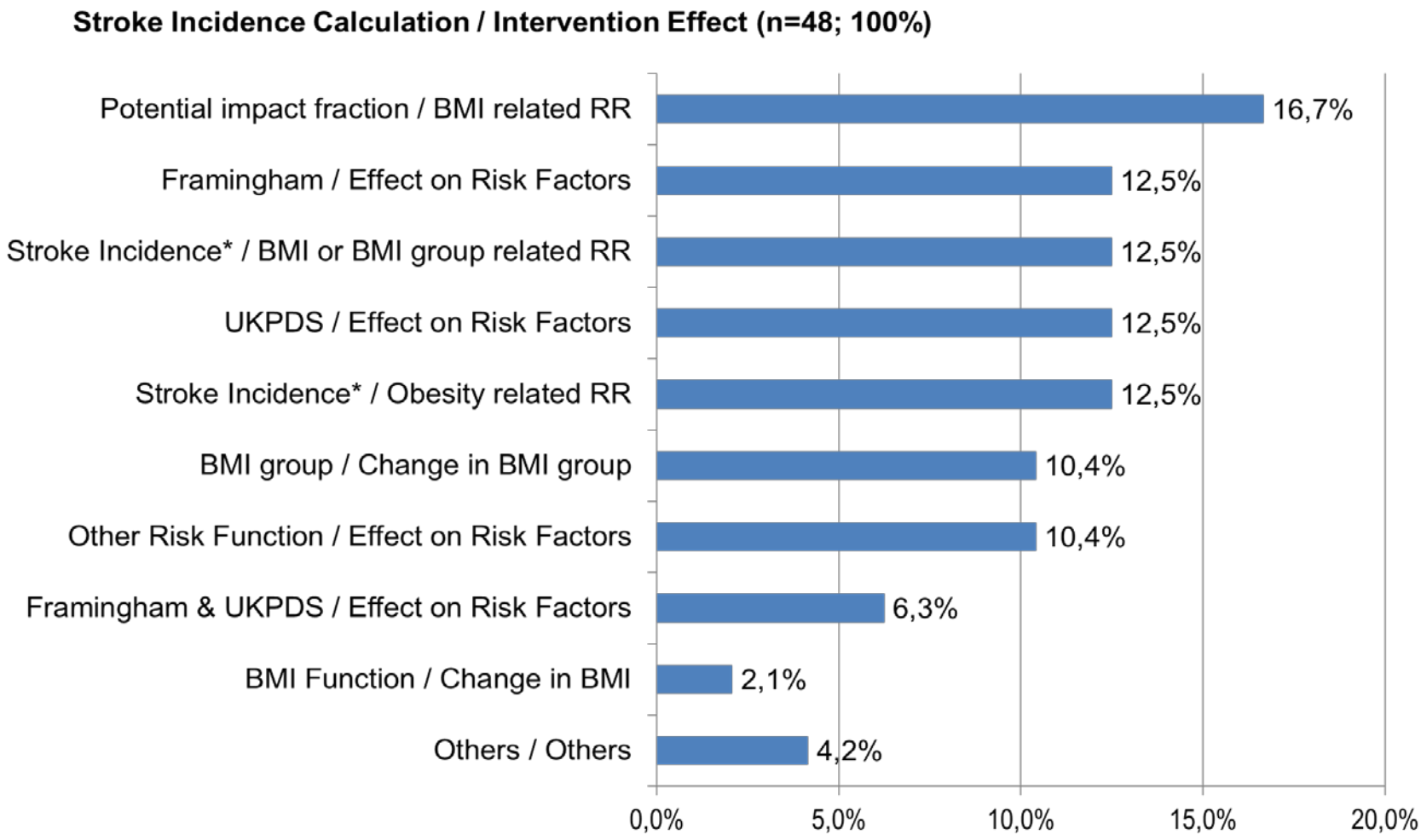
* Incidence calculation based on different factors; CVD = Cardiovascular Diseases; BMI = Body Mass Index; RR = Relative Risk

Overview of **T2D** event modelling approaches



* Incidence calculation based on different factors; CVD = Cardiovascular Diseases; BMI = Body Mass Index; RR = Relative Risk

Overview of **Stroke** event modelling approaches



* Incidence calculation based on different factors; CVD = Cardiovascular Diseases; BMI = Body Mass Index; RR = Relative Risk

Further Findings

- Considering those decision models that have simulated specific obesity related events (72 of 97) we have found that
  - **93% (56 of 60) simulated CVD–specific mortality;**
  - **44% (23 of 53) simulate a T2D-specific mortality rate**
  - **and 98% (47 of 48) simulate a stroke-specific mortality rate.**
- Reprogramming of the approach on the basis of the data / information provided in the related publications was estimated to be possible for
  - **45% (27 of 60) of the CVD event simulation approaches,**
  - **for 43% (23 of 53) of the T2D event simulation approaches**
  - **and for 38% (18 of 47) of the stroke simulation approaches.**
- Any validation procedures (internal, external or cross-validation) were described **for 22% (15 of 68) of the decision models that simulated CVD, T2D and/or stroke.**

Discussion

- Although we have identified a huge variation in the base risk and the intervention effect simulation approaches **we were able to identify and group comparable event simulation approaches**, in order **to provide insights on the frequency of their application** in the context of obesity.
- To **guide future modelling** in the field of obesity a **valuable next step** would be to **present more details on the identified key approaches, to reprogram them, and to compare the outcomes of these key event simulation approaches** when simulating comparable patient populations and comparable intervention effects.
- Furthermore **a comparison of these outcomes to epidemiological long-term studies (external validation) would be very interesting** in order to inform modelers and decision makers on the predictiveness of the identified event simulation approaches.

Conclusion

- We have identified a wide range of event simulation approaches to model obesity associated events.
- This highlights the need to develop recommendations and/or minimal requirements for model-based HEAs in the context of obesity prevention and therapy
- Future work on the comparison of these event simulation approaches (cross validation & external validation) is required in order to guide future modelling in the field of obesity.

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