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A Monte Carlo simulation to validate the EAR cut-point method for assessing the prevalence of nutrient inadequacy at the population level

B de Lauzon[1,]*, JL Volatier[2] and A Martin[2]
[1]INSERM, U258, 16 avenue Paul-Vaillant Couturier, 94807 Villejuif Cedex, France: [2]Agence Française de Sécurité Sanitaire des Aliments, Maisons-Alfort, France

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Abstract

Objective: The aim of this study was to validate the EAR cut-point method for assessing the prevalence of nutrient inadequacy at the population level.
Design and subjects: Different methods for estimating the prevalence of inadequate intake were compared: the cut-off point method, with cut-off points at the Recommended Dietary Allowance (RDA), 0.66 RDA, 0.50 RDA and the Estimated Average Requirement (EAR); the probability approach; and a Monte Carlo simulation. In total, 591 men and 674 women, aged 20–55 years, were included in the analyses.
Results: The prevalence of inadequate intake as estimated by the EAR cut-point method was similar to the prevalence of inadequacy estimated by both probabilistic methods. The cut-point method with RDA, 0.66 RDA and 0.50 RDA as cut-off limits induced an over- or an underestimation of the real prevalence of inadequacy.
Conclusions: Probabilistic methods consider both the intake variability and the requirement variability, and, as a result, their estimation should be closer to the real prevalence of inadequacy. The use of the EAR cut-point method yields a good estimation of the prevalence of inadequate intake, comparable to the probability approach, and limits over- and underestimation of the prevalence induced by other cut-off points.

Keywords
Nutrient inadequacy
Recommended Dietary Allowance
Estimated Average Requirement
Monte Carlo simulation

The 'Recommended Dietary Allowances (RDAs) are recommendations for the average daily amounts of nutrient that population groups should consume over a period of time'[1]. They are typically based on the estimation of individual requirements in the population. The Estimated Average Requirement (EAR) represents the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life-stage and gender group[2]. To take account of the variability of requirements in the population, the upper level of requirement defined by the RDA is set at the average plus two standard deviations (+2SD) in the expectation that this meets the needs of all but 2–3% of the individuals, with the assumption of a Gaussian distribution of the requirements[3].

The estimated average requirement was defined for each gender and life-stage group, taking into account net requirement for a nutrient and absorption of this nutrient. Net requirement is the level of intake that allows maintenance of adequate physiological status. A specific criterion of adequacy was defined for each nutrient. So, nutrient requirement refers to a particular class of individuals of specific sex, age, physiological status, body size and activity, consuming a specified type of diet[3]. However, requirements were assessed only for a limited group of individuals, therefore uncertainty might remain on the statistical distribution of requirements. Moreover, RDA refers to an intake over a long period of time, i.e. to usual intake. Consequently, an estimation of the usual intakes in the population should be the first step in assessing the nutritional status of a population using dietary surveys[4].

As a direct calculation of the prevalence of inadequacy is impossible, because the requirements are unknown at the individual level, different methods of estimation have been used. The National Research Council (NRC)[4] and then Beaton[1] developed a method for estimating the prevalence of nutrient inadequacy at the population level: the probability approach. Nevertheless, the probability approach is not frequently used to assess the nutritional status of a group. In fact, many surveys have used fixed cut-off points to estimate the prevalence of nutrient inadequacy[5–11]. With this method, an intake below a fixed proportion of the RDA is assumed to be inadequate. However, there has not been a clear rationale for the selection of the threshold. More recently, Carriquiry[12]

*Corresponding author: Email delauzon@vjf.inserm.fr © The Authors 2004

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presented a geometric approach that justifies the use of the EAR cut-point method[2].

Estimating a prevalence of inadequacies of intake in nutritional studies raises two questions. First, is it possible to find a threshold which is statistically or biologically justified? Secondly, is it possible to validate the EAR cut-point method, developed by Carriquiry, by another approach, for instance the Monte Carlo approach, and to compare its results with those of the Beaton probability approach?

Methods

Subjects

We used data from the INCA (Individual and National Food Intakes) Study, which was the second national dietary survey in France. Data from 1985 adults (aged 15 years and over) and 1018 children (aged 3–14 years) were collected. This sample was representative of the French population[13].

In the present paper, we took into account only adults aged 20–55 years, not including pregnant women. Therefore, our sample consisted of 591 men and 674 women. Most of our analyses were performed among only those subjects who did not underreport their usual intake (409 men and 482 women). The extent of underreporting was estimated by using the concept of 'cut-off values' developed by Goldberg *et al.*[14]. This method is based on the ratio between the observed energy intake and the estimated basal metabolic rate for a specific energy expenditure level. Goldberg *et al.* determined the lowest value of the ratio that is compatible with a normal lifestyle. Individuals with an energy intake below that value were assessed as underreporters.

Dietary information

This investigation lasted seven consecutive days, with each subject recording his daily food consumption in a diary. Then, the food intake data were converted into total energy and nutrient intakes using the CIQUAL (Data Center on Food Quality) food composition database. Only vitamin A, vitamin C, vitamin B_6, vitamin B_9 (folate), vitamin E, calcium and magnesium were included in the analysis. The French RDAs were used as dietary reference intakes. The requirement coefficient of variation was assumed to be 10% for vitamin B_6 and magnesium, 20% for vitamin B_9 and 15% for the other nutrients. Dietary supplements were not taken into account, because dietary supplement use was still relatively rare in 1999 and it was difficult to estimate nutrient intake from dietary supplements.

Adjusting intake distributions

Reasons for adjusting intake distribution

An individual does not have a constant dietary intake from day to day. His daily intake varies both in the amount and the type of foods and drinks consumed (intra-individual variation). This is the reason why 1-day dietary intake data cannot reflect the usual intake of individuals[15]. Moreover, variations exist also between persons in their nutrient intake averaged over time (inter-individual variation). Nevertheless, RDA refers to a nutrient intake over a long period; it is thus useful to estimate usual intake in a population before assessing nutritional status. In 1986, the NRC[4] proposed a measurement error model on observed daily intakes to remove the effects of day-to-day intake variability, when usual intake distribution was estimated. This model was developed further by Nusser *et al.*[16] at Iowa State University (ISU).

A simplified version of the ISU–Nusser procedure

According to the recommendations of the EFCOSUM project[17], the Nusser procedure can be summed up in three steps (Table 1). First, if data are not normally distributed, they must be transformed by the two-parameter Box–Cox function. Second, in this normal scale, the variance can be reduced and the usual intakes defined. Third, to define the usual intakes in the original scale, we must use a back transformation[17].

The cut-point method

Fixed cut-off points

Some authors have used different proportions of the RDA to estimate the prevalence of inadequate intake in a population, even if there has not been a clear rationale for the selection of the level. To understand the impact of the choice of a specific threshold on the results, several cut-off points should be compared: one, two-thirds and one-half

Table 1 Main steps of the Iowa State University–Nusser procedure for two nutrients: vitamin A and calcium

		7-day average intake		Daily intake		Transformation parameters		Usual intake in normal scale		Usual intake	
	Sex	Mean	SD	Mean	SD	λ	ω	Mean	Variance	Mean	SD
Vitamin A (μg)	Men	1445	877	1445	2209	0	0	7.14	0.07	1311	339
	Women	1220	780	1220	2024	0	0	6.95	0.10	1102	361
Calcium (mg)	Men	922	325	921.8	493	0	184.4	6.97	0.07	911	289
	Women	817	267	817.0	407	0	408.5	7.09	0.04	809	235

SD – standard deviation.

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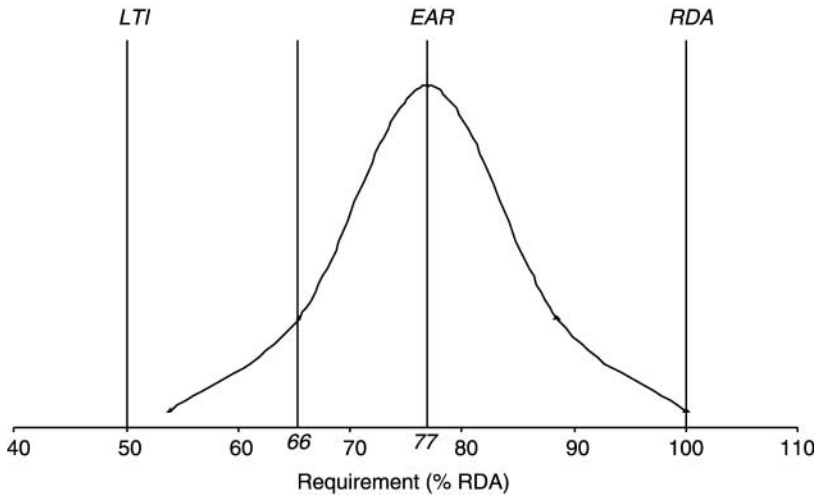

Fig. 1 Theoretical distribution of requirement at the population level. Requirement was assumed to be normally distributed, with average at 0.77 RDA and coefficient of variation of 15%. RDA – Recommended Dietary Allowance; LTI – Lowest Threshold Intake; EAR – Estimated Average Requirement

of the RDA, often defined as the lowest threshold intake (LTI; equivalent to RDA – 2SD).

Figure 1 presents these cut-off points and their relationship with the requirement distribution.

The EAR cut-point

More recently, Carriquiry *et al.* presented another cut-off point: the EAR cut-point. The requirement is supposed to be normally distributed around the estimated average requirement, which is 'the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group'[2]. The direct relationship between EAR and RDA can be described by the formula:

$$\mathrm{RDA} = \mathrm{EAR} + 2\mathrm{SD}_{\mathrm{Req}},$$

where $\mathrm{SD}_{\mathrm{Req}}$ denotes the standard deviation of the requirement. Moreover, it is assumed that the coefficient of variation is about 15%; thus the recommended intake is equal to 130% of the average requirement[3]. Consequently, the average requirement corresponds to 100/130 = 77% of the recommended intake. The EAR cut-point method is a short cut derived from the probability approach.

Geometric approach

Figure 2 shows a plot of usual intake and requirement of a hypothetical group of individuals introduced by Carriquiry[12]. The 45° line represents individuals whose usual intake equals their own requirement. To estimate the prevalence of inadequate intake at the population level, a calculation of individuals who are over the 45° line is required. Unfortunately, it is rarely possible to know the requirement of a particular individual in a dietary survey. As a result, an estimation of the prevalence of inadequacy by another method is needed.

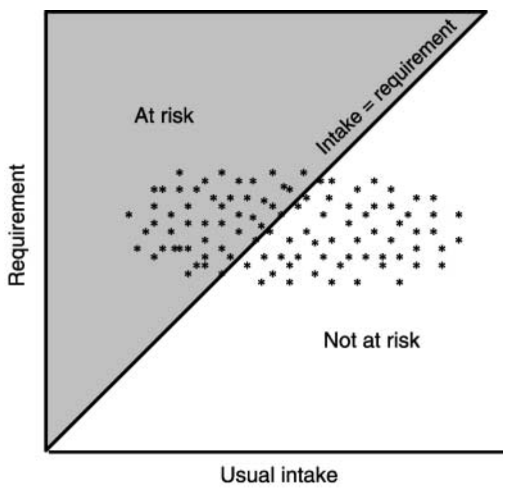

Fig. 2 Plot of usual intake and requirement for a hypothetical group of individuals. The 45° line represents points where usual intake equals requirement[12]

By using an arbitrary cut-off point, intakes are considered to be inadequate when they are below the cut-off point. Consequently, the group of individuals who are declared to have an inadequate intake does not entirely correspond to the group of individuals who really have an intake below their own requirement (Fig. 3a). Indeed, some individuals are declared to have an inadequate intake, whereas their usual intake is above their own requirement (triangle B). Furthermore, some other individuals seem to have an adequate intake but, in fact, their intake appears to be below their own requirement (triangle A). So, this confusion may induce a bias in estimating the prevalence of inadequate intake; i.e. an under- or an overestimation of the prevalence. However, if the cut-off point is fixed on the EAR, the number of individuals in triangles A and B may be equal and thus the bias decreases (Fig. 3b).

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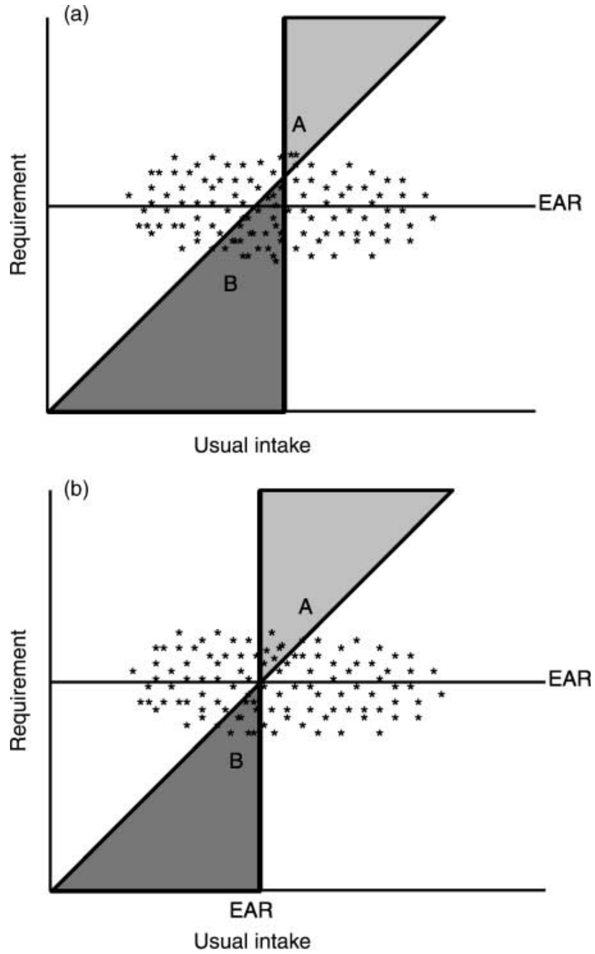

Fig. 3 Plots of usual intake and requirement for a theoretical group of individuals: (a) the number of points in triangle A is less than the number in triangle B; (b) the number of individuals in triangle A equals the number in triangle B[12]. EAR – Estimated Average Requirement

Validity conditions

Comparing usual intake with the EAR specific to a nutrient could solve the problem of assessing the prevalence of inadequacy in a group, as long as some conditions are met:

1. intake of and requirement for the nutrient are assumed to be independent[2];
2. the requirement distribution is symmetrical around the EAR; and
3. the variability in intakes among individuals in the group is greater than the variability in requirements of the individuals.

In addition, the actual prevalence of inadequate intake should be smaller than 90–92% and greater than 8–10%.

Consequently, this method does not work for energy, where intake and requirement are not independent, and for iron, whose requirement is not symmetrical around the EAR.

Probabilistic methods: Monte Carlo simulation and probability approach

As probabilistic methods take into account both requirement and intake distributions, they seem to give less biased estimations of the prevalence of inadequate intake. So, the prevalence of inadequate intake, estimated by the probabilistic methods, will be taken as a reference in the validation of a cut-off point.

Parametric estimation of requirement: the Monte Carlo simulation

The main problem in assessing the prevalence of inadequate intake comes from the impossibility of knowing the requirement of particular individuals for a nutrient. However, the requirement distribution in the population is supposed to be known.

A simulation refers to an analytical method meant to imitate a real-life system. The Monte Carlo simulation randomly generates values for uncertain variables over and over again. For each uncertain variable, the possible values are defined with a probability distribution. The type of distribution selected is based on the conditions surrounding that variable. In this study, a requirement was assigned to each individual of the population by a Monte Carlo simulation. This simulation was a randomisation, which took into account the requirement distribution in the population. As a result, the shape, the mean and the variance of the requirement distribution must be well identified. We assumed the requirement distribution to be normally distributed, with the EAR as average and a coefficient of variation of 15%. Requirement was randomised to each individual with the SAS function RANNOR independently of intake. Then, the proportion of individuals whose usual intake was below their simulated requirement estimated the prevalence of inadequate intake.

This method is unable to define individuals at risk, but it can estimate the prevalence of inadequate intake at the population level as follows:

$$P = \sum f_i(I_i < R_i) \quad \text{with } f_i = 1 \text{ if } I_i < R_i, \text{ else } f_i = 0$$

where I_i is the intake of individual i and R_i is the simulated requirement of individual i.

Probability approach

Definition. The probability approach was described by the NRC[4] and developed by Anderson[18] and Beaton[1]. This approach can take into account the variability in both usual intake among individuals and their nutrient requirement. It does not need any Monte Carlo simulation but a lot of assumptions on the parameters of the statistical distribution of the risk of intake inadequacy are made.

Risk curves. The first step of this approach is to compute a risk curve that links a risk with each intake level, under

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the assumed requirement distribution. Here, requirements are assumed to be normally distributed, and their average is the EAR. For iron, the risk curve would be different because iron requirements are not normally distributed[1].

The risk curve is obtained from the cumulative distribution function (CDF) of requirements. $F_R(.)$ denotes the CDF of the requirement for a specific nutrient, and is defined as:

$$F_R(a) = \Pr(requirements \leq a) \quad \forall a \geq 0.$$

Consequently, F_R takes values between 1 and 0. The risk curve is defined with the formula:

$$\rho(a) = 1 - F_R(a) = 1 - \Pr(requirements \leq a).$$

Each interval of intake is associated with a risk level. However, the variable of interest is not the risk associated with an intake level, but the prevalence of inadequate intake in the studied population. So, the prevalence P of inadequate intake is defined as:

$$P = \sum_{y=0}^{\infty} \rho(y) \times p(y),$$

where $p(y)$ is the probability to have y as usual intake and $\rho(y)$ indicates the risk of inadequacy associated with the level y of usual intake computed from the requirement distribution[12].

Beaton defined the risk curve (Fig. 4) on the following assumptions:

- requirements are normally distributed with an average set to 0.77 RDA and coefficient of variation of 15%;
- an intake below 0.45 RDA is associated with a risk of inadequacy of about 100%, contrary to an intake above 1.15 RDA, which is associated with a risk of about 0%; and
- the risk of inadequacy decreases with a rise in usual intakes between 0.45 and 1.15 RDA.

The risk curve could be significantly different if the requirement coefficient of variation is 10% (vitamin B_6 and magnesium) or 20% (folate) instead of 15%.

Validity conditions. The probability approach requires the knowledge of the requirement distribution (mean, SD and shape). Moreover, intake and requirement are assumed to be independent, in order to distinguish requirement from intake in the probability formula[12].

Generally, the requirement is assumed to be normally distributed[18–20]. Mean and SD of requirements are estimated from experimental data. Therefore, errors in these estimations could induce a bias in the estimation of the prevalence of inadequate intake. In the case of iron, for women of fertile age, requirements are not assumed to be distributed symmetrically around the EAR. For other nutrients like vitamin A or vitamin B_6, the normality hypothesis cannot be verified because of the small number of individuals who were used to estimate requirements in the population.

The probability approach is a method meant to estimate the prevalence of inadequacy in the population. However, the approach does not categorise any particular individual as having an adequate or inadequate intake. It is only able to assess the nutritional status of a group or population[21].

Data analysis

The data were analysed using the SAS statistical package (version 8.0; SAS Institute Inc., Cary, NC, USA). The

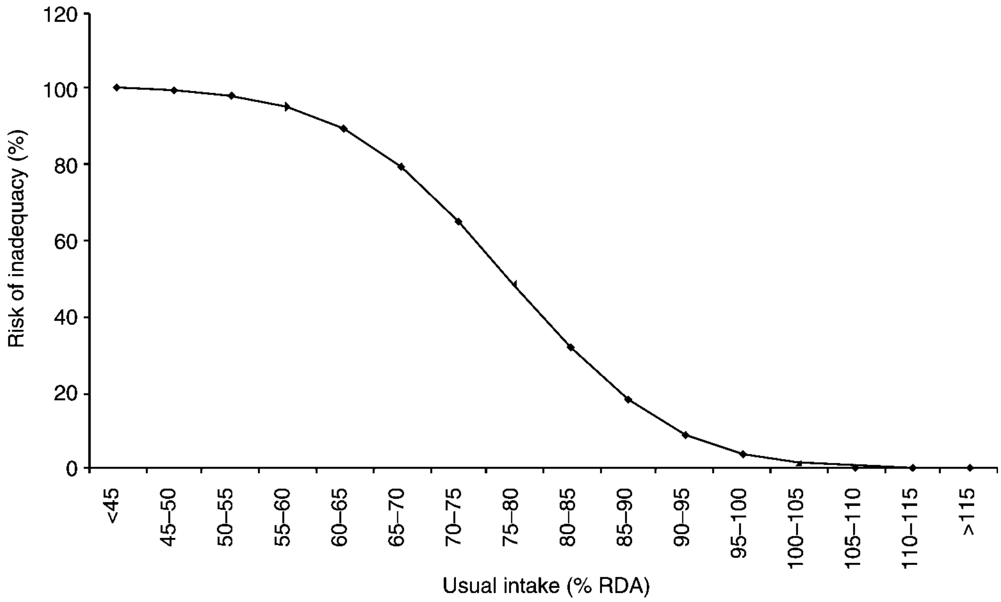

Fig. 4 Risk curve: cumulative distribution of risk of inadequacy. Requirements are normally distributed with the Estimated Average Requirement as expectation[1]. RDA – Recommended Dietary Allowance

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prevalence of inadequate intake was estimated by using both the cut-off point method, with 0.5 RDA, 0.66 RDA, RDA and EAR as cut-off points, and a probabilistic method.

Results

Comparison of different methods

First, the results from both probabilistic methods were analogous (Table 2) in average as well as in confidence intervals. In fact, both methods had taken into account the same requirement distribution (mean, SD and shape).

Assuming that the requirement distribution is well known, the estimation of the prevalence from a probabilistic method is an unbiased estimation. Consequently, results of both the probability approach and the Monte Carlo simulation were considered as the reference to validate the choice of a cut-off point.

When the RDA was used as cut-off point, the prevalence of inadequate intake was very high and exceeded the prevalence estimated by the probability approach; it was above 80% for four of the seven nutrients studied. As the RDA was defined as a level of intake where the requirements of 97.5% of a population would be satisfied, this increase in the prevalence should not be surprising. On the contrary, the prevalence was lower than the probabilistic methods when 0.66 RDA or 0.50 RDA was used as cut-off limit.

Impact of underreporting

Most dietary survey methods have been found to produce energy intake levels below expected needs. This fact indicates an underreporting of the food intake or a decrease in food intake over the study period. To examine the impact of underreporting in estimating the prevalence of inadequate intake by the EAR cut-point method, the prevalence estimated from all adults was compared with the prevalence estimated from adults for whom food intake estimation was acceptable. The difference between both prevalences of inadequate intake was found to be more important when the intake median of acceptable reporters was close to the RDA value (Fig. 5). The proportion of individuals who had an inadequate intake could increase by up to 17 percentage points, if underreporters were included in the studied population. It is therefore necessary to detect underreporting and to take it into account to decrease the bias in estimating the prevalence of inadequacy in the population[22].

Discussion

The assessment of nutritional status at the group level was developed here. All the methods presented in this study were able to assess the nutritional status of a group, but unable to distinguish individuals who had an inadequate intake. To evaluate the nutritional status of a particular individual, other methods should be used.

The prevalence of inadequate intake estimated by both the probability approach and Monte Carlo simulation was assumed to be close to the real prevalence of inadequate intake. Our results suggested that the use of RDA, 0.66 RDA or 0.50 RDA as cut-off point induced an over- or underestimation of the real prevalence of inadequacy. With 0.50 RDA as cut-off limit, the prevalence of inadequacy was very low. Indeed, an intake below 0.50 RDA corresponds to an intake level where the probability of having clinical signs of deficiency increases[3,23]. This

Table 2 Prevalence of intake inadequacy according to three different methods

				Prevalence of inadequate intake (%)					
						% of individuals with usual intake below a cut-off point			
	Sex	Intake*	RDA	Monte Carlo†	Probability approach‡	RDA	EAR§	0.66 RDA	0.5 RDA
Vitamin C (mg)	M	75	110	66 (64–68)	66 (64–68)	81 (80–82)	67 (65–69)	58 (56–60)	40 (38–42)
	W	76	110	66 (64–68)	66 (64–68)	82 (81–84)	67 (65–69)	57 (55–59)	38 (37–40)
Vitamin B_6 (mg)	M	2.0	1.8	4 (3–5)	4 (4–5)	16 (15–18)	3 (2–4)	0 (0–0)	–
	W	1.6	1.5	9 (7–10)	9 (8–10)	29 (27–31)	7 (6–8)	0 (0–1)	–
Vitamin B_9 (folate) (μg)	M	288	330	29 (27–30)	29 (28–30)	76 (74–78)	25 (23–27)	17 (15–18)	2 (2–3)
	W	245	300	38 (36–41)	39 (37–40)	81 (79–82)	37 (36–40)	29 (27–31)	8 (7–9)
Vitamin A (μg)	M	1445	800	1 (0–1)	1 (0–1)	4 (3–5)	0 (0–1)	–	–
	W	1220	600	1 (0–1)	1 (0–1)	4 (3–5)	1 (0–1)	–	–
Vitamin E (mg)	M	8	12	75 (74–77)	75 (74–76)	96 (95–97)	79 (78–81)	60 (58–62)	23 (21–24)
	W	7	12	85 (84–86)	85 (84–86)	99 (98–99)	89 (88–90)	75 (73–77)	37 (36–39)
Calcium (mg)	M	922	900	25 (23–26)	25 (23–26)	53 (51–55)	23 (22–25)	12 (10–13)	2 (2–3)
	W	817	900	34 (32–36)	34 (33–36)	68 (66–70)	33 (32–35)	18 (16–20)	4 (3–5)
Magnesium (mg)	M	315	420	71 (69–73)	71 (69–72)	93 (92–94)	73 (71–75)	33 (32–35)	4 (3–5)
	W	251	360	81 (79–82)	81 (80–82)	97 (97–98)	84 (82–85)	44 (42–46)	7 (6–8)

RDA – Recommended Dietary Allowance; EAR – Estimated Average Requirement; M – men; W – women.
Numbers in parentheses represent the 95% confidence interval of the prevalence estimation.
* Average intake in the study population.
† Estimated prevalence of inadequacy from Monte Carlo simulation.
‡ Estimated prevalence of inadequacy from the probability approach.
§ Equal to 0.71 RDA for vitamin B_9, 0.83 RDA for vitamin B_6 and magnesium, and 0.77 RDA for the other nutrients.

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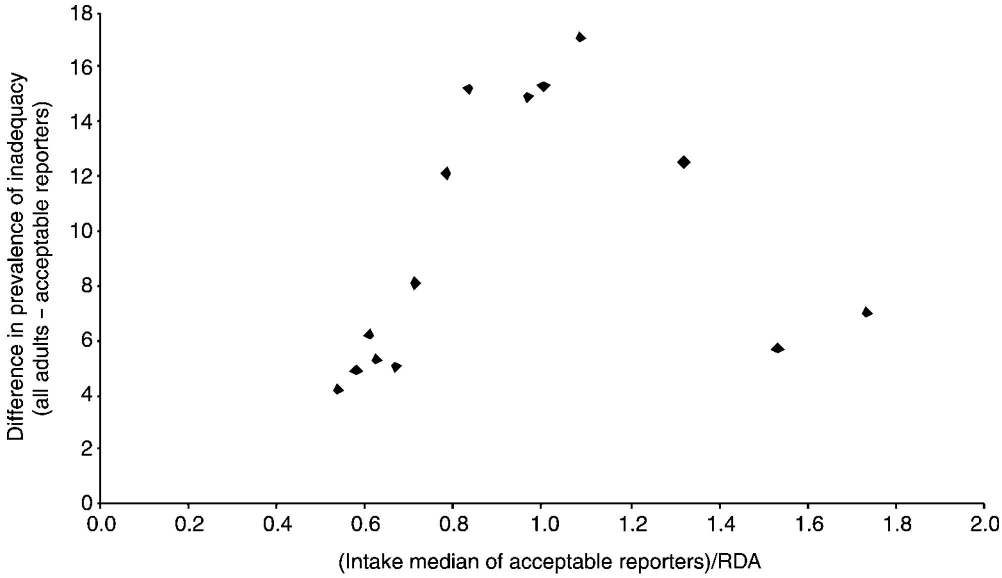

Fig. 5 Impact of underreporting in estimating the prevalence of inadequate intake depends on the position of the intake median of acceptable reporters compared with the RDA value. Each data point refers to intakes of the seven nutrients by men and women. RDA – Recommended Dietary Allowance

threshold is also able to detect states of deficiency, which could be valuable at the individual level, but it probably underestimates the prevalence of inadequacy at the population level, even if clinical signs are not visible yet.

Theoretically, the EAR cut-point would give the less biased prevalence of inadequacy. Indeed, with this threshold, the number of individuals who are falsely classified as having inadequate intake is assumed to be the same as the number of individuals who are falsely classified as having adequate intake. By comparison with the prevalence calculated by the probability approach, the prevalence of inadequacy estimated by the EAR cut-point method would be a good estimation of the real prevalence. When nutrient requirements are to some extent linked to intake, validity conditions of the EAR cut-point method are not respected, and estimation of the prevalence of inadequate intake would then be biased. The more the requirement and intake are strongly related, the more the estimation of inadequacy is biased. For example, a high protein intake affects vitamin B_6 status, and foods rich in vitamin B_6 are also high-protein foods. Vitamin B_6 requirement is therefore not totally independent of vitamin B_6 intake. To estimate an unbiased prevalence of vitamin B_6 inadequacy, it would be preferable to use another method, like the probability approach, which could take into account this association between intake and requirement. However, in the case of a minor association, the EAR cut-point method could give an acceptable first estimation.

This study refers to the concept of inadequacy, and a level of usual intake could be supposed to be inadequate without clinical signs. Moreover, we did not take into account possible metabolic adaptations. Indeed, the effects of a sub-optimal intake should be considered in a long-term perspective. The use of biological parameters in estimating the prevalence of inadequate intake might give lower results, but the prevalence would not reflect the same notion in both cases. Notions of inadequate intake and deficiency should be separated.

Moreover, it remained impossible to determine the degree of distance between intake and requirement for an individual. It might be important to develop a cut-off point that would be strongly correlated with the biological deficiency. Then, the justification for such a threshold would no longer be statistical, but biological.

The notion of inadequacy is based on the concept of requirement. Both the probability approach and the EAR cut-point method require knowledge of the requirement. Nevertheless, the requirement distribution in the population remains uncertain for most nutrients, and each uncertainty has an impact on the validity of the estimation of the prevalence of inadequacy. However, the EAR cut-point method requires a less precise knowledge of the requirement distribution than the probability approach. In fact, in the EAR cut-point method, requirements are assumed to be symmetrical around the EAR, and its variance to be below the variance of intakes, whereas the shape, mean and variance of the requirement distribution should be known in the probabilistic methods. As a result, the EAR cut-point method can give better results when information about requirements is approximate.

By using a probabilistic method, the estimation of the prevalence of inadequate intake could consider both the variability in requirement and the variability in usual intake. So, this evaluation of inadequacy prevalence should be used as reference. The mean and the SD of requirements define the risk curve. Each interval of intake is associated with a risk level. Results would therefore be

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more precise with a great number of small intervals of intake. The EAR cut-point method can be more easily used in estimating the prevalence. Moreover, its results are comparable to those produced by the probabilistic methods. Consequently, this method can be a valid estimation of the prevalence of inadequate intake. The benefit of using a probabilistic approach may not be evident, when the EAR cut-point method is valid. A Monte Carlo simulation can also be used in nutritional studies when the EAR cut-point method does not work. Indeed, simulating a requirement distribution conditionally with intake (for energy) or a specific requirement distribution (in the case of iron) would be possible.

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