

ORIGINAL ARTICLE

Modelling the resource implications and budget impact of new reimbursement guidelines for the management of cow milk allergy in Finland

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ABSTRACT

Objective: To assess the impact of the decision by Kela (The Social Insurance Institution) to adopt guidelines for the management of food allergies in children, developed by the Finnish Medical Society Duodecim, as the basis for reimbursing clinical nutrition preparations for the treatment of cow milk allergy (CMA) in Finland.

Methods: A decision model was constructed using published clinical outcomes and clinician-derived resource utilisation estimates. The model was used to estimate the net resource implications and associated costs of Kela's new policy for the annual cohort of 1443 new CMA sufferers over the first 6 months following referral to a specialist. The analysis was conducted from the perspective of Kela, patients and Finnish society.

Results: Kela's new policy for reimbursing clinical nutrition preparations for the treatment

of CMA is expected to increase healthcare resource use, including a 10% increase in the number of specialist visits over the first 6 months following referral. Consequently, Kela's 6-monthly expenditure on 1443 new CMA sufferers following referral is expected to increase by 12% from €889 389 to €992 761. Additionally, parents' costs are expected to increase by 10% and fathers' absenteeism from work to increase by 11% within the first 6 months following referral.

Conclusion: It is important to validate guidelines in clinical practice before their implementation. Within the limitations of our model, Kela's new criteria for reimbursing clinical nutrition preparations for the treatment of CMA is expected to increase healthcare resource use in paediatric departments in public hospitals in Finland and increase costs to Kela, patients and Finnish society.

Introduction

Finland has a population of 5.1 million individuals, with 66% of the population living in towns and the remainder living in rural areas¹. The nation is divided into 452 municipalities, with a median population of 6000 inhabitants. These municipalities have a mandate

to raise taxation and are responsible for both funding and providing health services for their residents^{1,2}. Primary healthcare is provided in public health centres and access to a specialist is by referral from a health centre, with the exception of emergencies². Specialised medical care (secondary and tertiary care) is provided in hospitals, through outpatient and inpatient depart-

ments². Public hospitals are owned by federations of municipalities (i.e. hospital districts), of which there are 20 such districts in the country with a catchment population ranging from 70 000 to 800 000 inhabitants¹. The private healthcare system complements the public system and provides mainly outpatient care. The majority of physicians working in the private sector are specialists, who have a full-time appointment in a public hospital or health centre. Visits to a private specialist do not require referral from a health centre and physicians working in private clinics can send patients to either a public or private hospital. However, there are only a few private hospitals in Finland, providing approximately 5% of the hospital days in the country².

Kela (The Social Insurance Institution) is the organisation responsible for reimbursing healthcare in Finland³. It reimburses a range of costs including clinicians' fees, examination and treatment charges, hospitalisation, medicines and clinical nutrition preparations. Reimbursement is not calculated on the basis of actual costs, but on a schedule of fixed charges indicating the maximum cost covered. Additionally, Kela reimburses part of the cost of private sector services³.

Cow milk allergy (CMA) is an adverse reaction to protein in cow's milk, involving the immune system⁴. Its incidence in infancy in western industrialised countries has been estimated at 2–3%⁵. Symptoms of CMA generally appear within the first few months of life. An infant can experience symptoms either very quickly after feeding (rapid onset) or not until 7–10 days after consuming cow milk protein (slower onset)^{6–8}. The slower-onset reaction is more common and symptoms may include loose stools (possibly containing blood), vomiting, refusing food, irritability, colic, skin rashes and failure to thrive. This type of reaction is more difficult to diagnose because the same symptoms may occur with other health conditions. Most children will outgrow this form of allergy by 2 years of age. Rapid-onset reactions appear suddenly with symptoms that can include irritability, vomiting, wheezing, swelling, hives and bloody diarrhoea. In rare cases anaphylaxis can occur, however this is more common in nut and shellfish allergies⁵. Several tests can be used to inform a diagnosis of CMA, including a stool test, RAST test, skin prick test, and patch testing^{8,9}. However, these tests may yield both false positives or false negatives.

Nutritional formulas for infants with CMA include soy-based milk or hypoallergenic formulas. Soy-based formulas contain proteins found in soybeans. They also contain the same vitamins and minerals as those found in cow's milk-based formulas¹⁰. Hence, the nutritional value of the two formulas is comparable. Two major types of hypoallergenic formulas are available: extensively hydrolysed formulas and elemental

formulas. Extensively hydrolysed formulas (eHF) contain milk proteins which have been pre-digested, making them less allergenic than the whole proteins contained in regular formulas¹¹. Elemental formulas, such as Neocate (SHS International, Liverpool, UK) contain only amino acids in the absence of any protein and thus are not allergenic^{12–14}. Partially hydrolysed formulas are not recommended for use in infants with CMA since they are not considered truly hypoallergenic and can still provoke a significant allergic reaction¹⁵.

Mothers of affected infants who are being breast-fed are advised to eliminate dairy products from their diet under the close supervision of a dietician, because a strict diet must be followed to ensure adequate intake of nutrients while eliminating cow milk protein. However, in practice, this is not always done. In many European countries, and in Australia and New Zealand, mothers of formula-fed infants are often advised to feed either a soy protein-based formula or an eHF to those >6 months of age, but to initially feed only an eHF to those <6 months of age. Those infants who cannot tolerate soy would generally be switched to an eHF and those who cannot tolerate an eHF would generally be switched to an elemental formula.

In 2004, the Finnish Medical Society Duodecim¹⁶, under the auspices of the Ministry of Social Affairs and Health in Finland, produced guidelines for the management of food allergies in children¹⁷. With effect from 1 December 2005, Kela adopted these guidelines as the basis for reimbursing clinical nutrition preparations for the treatment of CMA. Before 1 December 2005, Kela reimbursed the costs of healthcare associated with managing CMA without any restrictions and 75% of the cost of prescribed clinical nutrition preparations for the treatment of affected infants³. On the 1 December 2005 the new policy was implemented for reimbursing clinical nutrition preparations for the treatment of CMA. In addition, the reimbursement rate for the cost of prescribed clinical nutrition preparations for treating CMA was reduced to 72%³.

Clinicians involved in managing infants with CMA in Finland have anecdotally found that the new guidelines have created additional workload, in terms of clinician time and resource use, and have led to a delay in diagnosis. Parents have also complained about additional costs they are incurring. Consequently, the authors decided to assess the resource implications and budget impact of the new policy to Kela, patients and Finnish society.

Methods

Study objective

To assess the budget impact of Kela adopting the Finnish Medical Society Duodecim's guidelines for the management of food allergies in children as the basis

for reimbursing clinical nutrition preparations for the treatment of CMA. The study was conducted from the perspective of Kela, patients and Finnish society.

Decision model

A decision model was constructed in Crystal Ball (Decisioneering Inc., Denver, CO, USA) which depicted the treatment patterns and associated resource use attributable to managing new CMA sufferers before and after the 1 December 2005 (Figure 1). The model was used to simulate the management of a cohort of new CMA sufferers over the first 6 months following referral to a specialist in Finland.

Model inputs – clinical outcomes

Based on a range of published studies, the intolerance to soy and eHF in the model was estimated to be 23%^{7,18–28} and 12%^{7,21,23,26,27,29–34}, respectively.

Model inputs – resource use

There are five university hospital clinics in Finland that are considered to be clinical reference centres². The model is based on the management of new CMA sufferers before and after the 1 December 2005 by paediatricians at two of these centres in Finland: the Department of Paediatrics, University Clinic Turku and the Skin Allergy Hospital, University Clinic, Helsinki. Additionally, the model incorporates the management of new CMA sufferers at an allergy centre in Turku and an allergy clinic in Tampere.

Management of infants < 6 months of age at time of diagnosis

The model assumes that before 1 December 2005, new CMA sufferers would initially be treated with an eHF by a specialist. All infants would have a follow-up specialist visit after 1–2 weeks. Those infants who become symptom-free would undergo a cow milk challenge to confirm the diagnosis. Those infants who remain symptomatic would return to the specialist and be treated with an elemental formula and at a subsequent clinic visit would undergo a cow milk challenge to confirm the diagnosis.

The model assumes that since the 1 December 2005, new CMA sufferers would initially be treated with an eHF by a specialist. All infants would have a follow-up specialist visit after 1–2 weeks. Those infants who become symptom-free would undergo a cow milk challenge to confirm the diagnosis. Those infants who remain symptomatic would be given another eHF and have another specialist visit 1–2 weeks later. Those infants who become symptom-free would undergo a cow

milk challenge to confirm the diagnosis. If they remain symptomatic they would be treated with an elemental formula and would be expected to become symptom-free within 2 weeks. These infants would then have another specialist visit and undergo a cow milk challenge to confirm a diagnosis of CMA and an eHF challenge to confirm their intolerance to this formula. It is expected that one-third of the infants would react to an eHF in the clinic and then be prescribed an elemental formula. However, the other two-thirds are not expected to react to an eHF in the clinic. Hence, they would be switched back to an eHF for 1 week and parents would be asked to complete a diary card to document any symptoms. One week later the infants and their parents would return for another specialist visit and, depending on the symptoms documented in the diary card, may be treated with an elemental formula.

Management of infants > 6 months of age at time of diagnosis

The model assumes that before 1 December 2005, new CMA sufferers would initially be treated with soy or an eHF by a specialist. All infants would have a follow-up specialist visit after 1–2 weeks. Those infants who become symptom-free would undergo a cow milk challenge to confirm the diagnosis. Those infants who remain symptomatic with soy would be treated with an eHF and if they become symptom-free would undergo a cow milk challenge to confirm the diagnosis at a subsequent clinic visit. Those infants who remain symptomatic with an eHF would return for a follow-up visit to the specialist and be treated with an elemental formula and at a subsequent clinic visit undergo a cow milk challenge to confirm the diagnosis.

The model assumes that since the 1 December 2005, new CMA sufferers > 6 months of age would be treated as those < 6 months of age, except that infants have to be demonstrably intolerant to both soy and eHF before being treated with an elemental formula. The model also assumes that as with eHF, intolerance to soy is demonstrated in the clinic with a soy challenge.

Model inputs – reimbursement of clinical nutrition preparations

The following reimbursement rates for clinical nutrition preparations have been incorporated into the model.

- Before 1 December 2005, Kela reimbursed 75% of a clinical nutrition preparation, but since 1 December 2005, the reimbursement rate became 72%. Parents pay the remainder.
- Before 1 December 2005, a confirmed diagnosis of CMA was required in order for a clinical nutrition preparation to be reimbursed, but Kela would reimburse the preparation for a maximum of 4

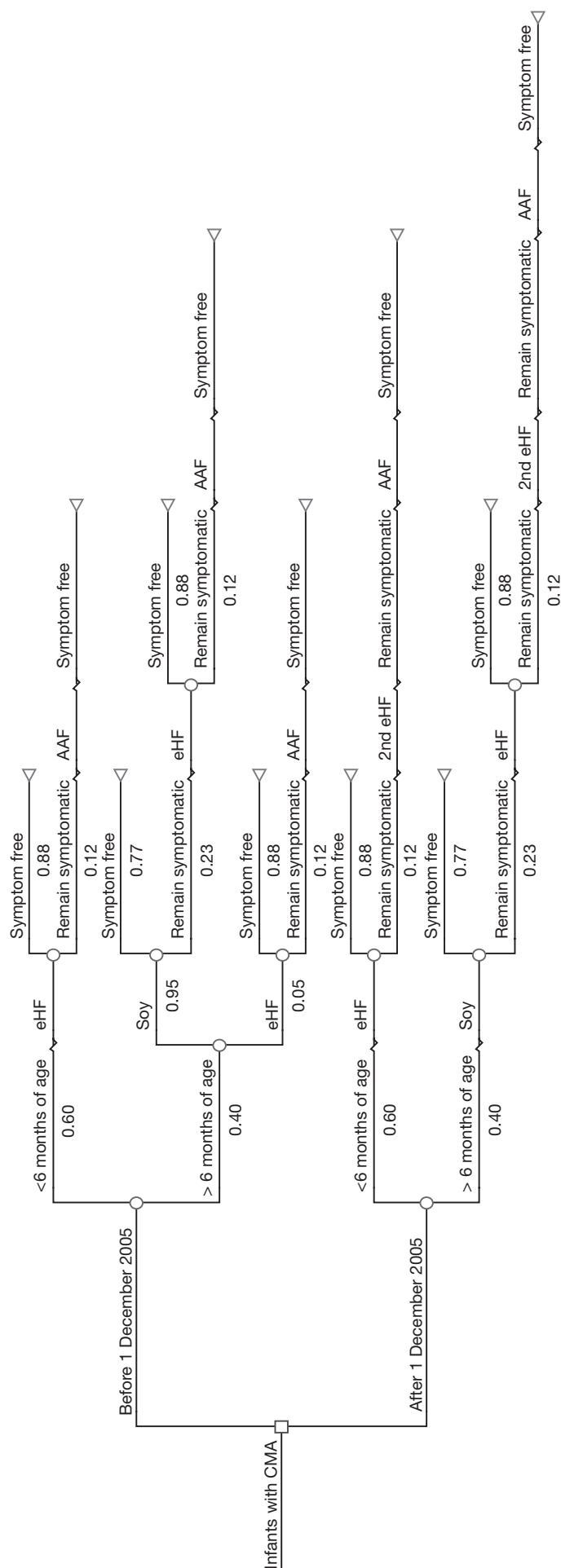


Figure 1. Decision model depicting the management of new CMA sufferers in Finland before and after 1 December 2005. Numbers denote the probability that a patient will follow a particular pathway. AAF, amino acid based formula; eHF, extensively hydrolysed formula

weeks prior to a diagnosis of CMA being confirmed. Since 1 December 2005, a confirmed diagnosis of CMA is required before Kela will reimburse a clinical nutrition preparation and there is no retrospective reimbursement.

- Before 1 December 2005, documented evidence of intolerance to soy and eHF was not required by Kela before an elemental formula would be reimbursed. Since 1 December 2005, Kela requires documented evidence of intolerance to eHF and soy before an elemental formula will be reimbursed for infants > 6 months of age and documented evidence of intolerance to eHF before an elemental formula will be reimbursed for infants < 6 months of age.
- Since 1 December 2005, if an infant is intolerant to one eHF, Kela requires documented evidence that the infant is intolerant to a second eHF before an elemental formula will be reimbursed.

Model outputs

The mean number of infants born in Finland is 57 700¹ per annum. The incidence of CMA among infants is 2.5%⁵. Hence, the annual number of new CMA sufferers in Finland was estimated to be 1443 infants. According to the four centres on which the model is based, 60% of infants with CMA are <6 months of age at the time of referral to a specialist.

The model estimated the expected levels of healthcare resource use for 1443 new CMA sufferers over the first 6 months following referral before and after 1 December 2005 and the associated net resource implications. Unit resource costs in euros at 2005/06 prices (Table 1) obtained from the centres that participated in this study were applied to the resource utilisation estimates within the model. This enabled the expected 6-monthly cost of healthcare resource use attributable to managing 1443 new CMA sufferers following referral to a specialist before and

after 1 December 2005 to be estimated. According to the interviewees, all infants are expected to be on an appropriate clinical nutrition preparation and be symptom-free at 6 months after the initial referral. Hence, a cost-minimisation approach was adopted. Such an analysis identifies the treatment strategy that achieves the same outcome for least cost.

The expected 6-monthly cost to parents of 1443 new CMA sufferers following referral before and after 1 December 2005 was also estimated.

The model also estimated the expected indirect cost to society as a result of parents of 1443 new CMA sufferers being absent from work over the first 6 months following referral before and after 1 December 2005, by assuming:

- All fathers of infants < 6 months take a day off when their child has a clinician visit or has to undergo tests;
- 33% of fathers of infants > 6 months take a day off when their child has a clinician visit or has to undergo tests;
- 70% of infants who are intolerant to soy and/or eHF undergo an eHF challenge in the home;
- 50% of fathers of infants undergoing an eHF challenge in the home miss half a week of work due to exhaustion;
- Annual salary of men in Finland in 2005 was €32 723¹.

Sensitivity analysis

Probabilistic sensitivity analyses were undertaken using Monte Carlo simulations (1443 iterations of the model) by simultaneously varying the probabilities, resource use values and unit costs within the model. The probabilities were varied randomly according to a beta distribution by assuming a 20% standard deviation around the mean. The resource use estimates and unit costs were varied randomly according to a lognormal distribution by assuming a 20% standard deviation around the mean. Large standard deviations were used to reflect the uncertainties surrounding the inputs of our model. Additionally, deterministic sensitivity analyses were performed to identify how differences between criteria for reimbursing clinical nutrition preparations for the treatment of CMA would change, by varying the different assumptions in the model.

Results

From the perspective of Kela

Expected changes in healthcare resource use

The expected levels of healthcare resource use attributable to managing 1443 new CMA sufferers over the first 6 months following referral to a specialist

Table 1. Unit resource costs at 2005/06 prices

Resource	Unit cost in euros at 2005/06 prices
Outpatient visit with specialist	140.00
Outpatient visit with nurse	90.00
Cow milk challenge	70.00
eHF challenge	200.00
Soy challenge	200.00
Soy (per 3.10 litres)	10.97
eHF (per 3.57 litres)	23.62
Neocate (per 2.67 litres)	60.17

eHF = extensively hydrolysed formula

are shown in Table 2. This table illustrates that Kela's December 2005 policy on reimbursement of clinical nutrition preparations for CMA is expected to lead to a 10% increase in the number of specialist visits over the first 6 months following referral. It is also expected to lead to an 18% increase in the number of challenge tests and a corresponding 18% increase in the amount of secretarial time associated with completing the appropriate certification in order for parents to obtain reimbursement of their infant's diet.

Expected healthcare costs

The expected 6-monthly costs of healthcare resource use attributable to managing 1443 new CMA sufferers following referral are shown in Table 3. Since 1 December 2005, the 6-monthly cost of healthcare resource use attributable to managing 1443 new CMA sufferers following referral is expected to have risen by 12%. The increase is principally due to a 10% and 50% increase in the cost of specialist visits and challenge tests, respectively, which are partially offset by a 37% decrease in the cost of the eHF diet. However, Kela's expenditure on soy is expected to rise by 154% while that for elemental formula is expected to fall by 52%. Notwithstanding this, Kela's total expenditure on clinical nutrition preparations for 1443 new CMA sufferers is expected to fall by 34% (from €47 930 to €31 666) over the first 6 months following referral. Moreover, the acquisition cost of the clinical nutrition preparations was estimated to account for only 5% and 3% of the expected 6-monthly cost of managing new CMA sufferers before and after 1 December 2005, respectively.

The levels of resource use and corresponding costs were not affected by the infants' age at the time of presentation. If all 1443 new CMA sufferers were <6 months of age at the time of presentation, the expected 6-monthly cost of healthcare resource use following referral before and after 1 December 2005 was estimated to be €890 796 and €988 963,

respectively. In contrast, if all 1443 new CMA sufferers were >6 months of age at the time of presentation, the expected 6-monthly cost of healthcare resource use following referral before and after 1 December 2005 was estimated to be €887 278 and €998 458, respectively.

Sensitivity analyses

Sensitivity analyses (Table 4) demonstrated that the net impact to Kela of changing their policy on reimbursing clinical nutrition preparations for CMA is sensitive to the percentage of infants >6 months using eHF first-line, the probability of being intolerant to eHF and soy, the probability of undergoing an eHF challenge and soy challenge and the unit cost of a specialist visit. Nevertheless, we were unable to identify a plausible scenario in which the net impact to Kela would lead to a reduction in resource use and corresponding costs (Table 5).

From the perspective of parents

Since 1 December 2005, the 6-monthly cost incurred by the parents of 1443 new CMA sufferers following referral is expected to have increased by 10%. This increase is principally due to a 471% and 26% increase in their expenditure on the soy and eHF diets, respectively (Table 6).

Sensitivity analyses (Table 4) showed that the net impact on parents of the change in Kela's policy is relatively insensitive to changes in the inputs incorporated in the model and is principally due to the change in Kela's reimbursement rate for the diets (from 75 to 72%).

From the perspective of Finnish Society

The model estimated that fathers of 1443 new CMA sufferers would collectively miss 1065 weeks of work before 1 December 2005 and 1184 weeks of work after

Table 2. Expected levels of healthcare resource use attributable to managing 1443 new CMA sufferers over the first 6 months following referral to a specialist

Resource	Six-monthly amount (95% CI in parentheses) of resource use attributable to managing 1443 new CMA sufferers	
	Before 1 December 2005	After 1 December 2005
Specialist visits	4524 (4504; 6002)	4957 (4884; 6431)
Nurse visits	1443 (668; 2111)	1526 (785; 2232)
Secretarial time (h)	360 (334; 387)	424 (390; 463)
Cow milk challenge	1443 (1336; 1548)	1443 (1336; 1548)
eHF challenge	0	120 (78; 156)
Soy challenge	0	133 (67; 237)

h = hours
eHF = extensively hydrolysed formula

Table 3. Expected 6-monthly costs (euros at 2005/06 prices) of healthcare resource use attributable to managing 1443 new CMA sufferers following referral to a specialist (percentage of total cost is in parentheses)

Resource	Six-monthly cost (95% CI in parentheses) in euros at 2005/06 prices of healthcare resource use attributable to managing 1443 new CMA sufferers	
	Before 1 December 2005	After 1 December 2005
Specialist visits	604 569 (413 340; 1 029 556)	665 092 (444 537; 1 114 456)
Nurse visits	129 825 (47 550; 147 325)	137 371 (54 437; 156 560)
Secretarial time	6 091 (5637; 6539)	7 157 (6592; 7809)
Cow milk challenge	100 975 (84 861; 103 632)	100 975 (84 861; 103 632)
eHF challenge	0	23 957 (10 717; 24 722)
Soy challenge	0	26 542 (9778; 36782)
Soy diet	1 872 (564; 4500)	4 574 (2404; 8533)
eHF diet	31 690 (25 846; 36 238)	20 079 (13 263; 25 296)
Neocate diet	14 368 (11 324; 17 261)	6 833 (4669; 8755)
Total	889 389 (648 574; 1 288 078)	992 761 (711 926; 1 406 585)

eHF = extensively hydrolysed formula

Table 5. Two-way sensitivity analyses depicting the net cost (euros at 2005/06 prices) to Kela for different probabilities of being intolerant to extensively hydrolysed formula and soy. Shaded cell depicts the base-case value

	Probability of being intolerant to eHF											
	0.05	0.06	0.07	0.08	0.09	0.10	0.11	0.12	0.13	0.14	0.15	
0.15	45 199	50 979	56 759	62 539	68 319	74 099	79 879	85 659	91 439	97 219	102 999	
0.16	47 156	52 973	58 790	64 606	70 423	76 240	82 057	87 873	93 690	99 507	105 323	
0.17	49 114	54 967	60 820	66 674	72 527	78 381	84 234	90 087	95 941	101 794	107 648	
0.18	51 071	56 961	62 851	68 741	74 631	80 521	86 411	92 301	98 192	104 082	109 972	
0.19	53 028	58 955	64 881	70 808	76 735	82 662	88 589	94 516	100 442	106 369	112 296	
0.20	54 985	60 948	66 912	72 875	78 839	84 803	90 766	96 730	102 693	108 657	114 620	
0.21	56 942	62 942	68 942	74 943	80 943	86 943	92 944	98 944	104 944	110 944	116 945	
0.22	58 899	64 936	70 973	77 010	83 047	89 084	95 121	101 158	107 195	113 232	119 269	
0.23	60 856	66 930	73 004	79 077	85 151	91 225	97 298	103 372	109 446	115 519	121 593	
0.24	62 813	68 924	75 034	81 144	87 255	93 365	99 476	105 586	111 697	117 807	123 917	
0.25	64 770	70 917	77 065	83 212	89 359	95 506	101 653	107 800	113 947	120 094	126 242	

eHF = extensively hydrolysed formula

Table 4. *One-way sensitivity analyses*

Scenario	Base-case value	Threshold value	Effect
From Kela's perspective			
Percentage of infants > 6 months of age using eHF first-line ranges from 0 to 100%	0%	—	The net additional cost to Kela ranges from €103 372 to €60 487
Percentage of cohort being < 6 months of age at time of referral ranges from 30 to 70%	60%	—	The net additional cost to Kela ranges from €107 276 to €102 071
Unit cost of a specialist visit ranges from €80 to €200	€140	—	The net additional cost to Kela ranges from €77 433 to €129 311
Unit cost of a cow milk challenge ranges from €50 to €150	€70	—	The net additional cost to Kela remains unchanged since the same number of tests are expected to be performed before and after 1 December 2005
Unit cost of an eHF challenge ranges from €50 to €250	€200	—	The net additional cost to Kela ranges from €85 404 to €109 361
Unit cost of a soy challenge ranges from €50 to €250	€200	—	The net additional cost to Kela ranges from €83 465 to €110 007
Probability of being intolerant to eHF ranges from 5 to 15%	12%	—	The net additional cost to Kela ranges from €60 856 to €121 593
Probability of being intolerant to soy ranges from 15 to 25%	23%	—	The net additional cost to Kela ranges from €85 659 to €107 800
From parents' perspective			
Percentage of infants > 6 months of age using eHF first-line ranges from 0 to 100%	0%	—	The net cost to parents ranges from €4277 to €6204
Probability of being intolerant to eHF ranges from 5 to 15%	12%	—	The net cost to parents ranges from €4741 to €4078
Probability of being intolerant to soy ranges from 15 to 25%	23%	—	The net cost to parents ranges from €3787 to €4399
From societal perspective			
Probability of infants exhibiting eHF intolerance in the clinic ranges from 15 to 60%	30%	—	The net societal cost arising from absenteeism from work ranges from €84 489 to €85 152

eHF = extensively hydrolysed formula

1 December 2005 during the first 6 months following referral. This equates to an 11% increase in the cost of lost productivity to Finnish society from €757 569 (95% CI: 572 393; 1 014 007) to €842 279 (95% CI: 636 315; 1 132 655). Nevertheless, this represents a negligible proportion of Finland's total GDP, which was estimated to be €143.5 billion in 2006¹.

Discussion

The guidelines for managing CMA, developed by the Finnish Medical Society Duodecim, did not incorporate any cost analyses and their impact on the efficiency of paediatric healthcare delivery was not assessed³⁵. Moreover, we were unable to find any studies that assessed resource use pertaining to CMA in Finland. Against this background, our analysis used clinical outcomes from published studies and resource utilisation estimates derived from clinicians at four key centres in Finland to construct a model that simulates the management of 1443 new CMA sufferers in Finland.

The model was used to assess the budget impact on Kela, parents and Finnish society of Kela's decision to use the guidelines as the basis for reimbursing clinical nutrition preparations for the treatment of CMA in paediatric departments in public hospitals. The period of the model was limited to 6 months, since in most cases patients are generally discharged back to their GP for subsequent management in the community at around this time. Additionally, the majority of infants with CMA outgrow this allergy by the time they reach 2 years of age⁵⁻⁷.

Our analysis found that Kela's decision to use the guidelines as the basis for reimbursing clinical nutrition preparations for the treatment of CMA is expected to increase the use of paediatric healthcare resources in Finland's public hospitals, which could have been used elsewhere within the system. Whilst our results are sensitive to some of the model's inputs (as outlined in the sensitivity analyses), the findings are due in part to all infants now requiring a confirmed diagnosis of soy and/or eHF intolerance before their clinical nutrition preparation will be reimbursed by Kela. Consequently, it now takes about 1 additional month for infants who remain symptomatic to be eligible for a reimbursable elemental formula, although this is not expected to have any deleterious long-term effect on clinical outcome.

Our results may be confounded by certain limitations within the model. The rates of intolerance to soy and eHF were based on a combination of published studies, and there was a lack of published data assessing resource use attributable to the management

of CMA. Therefore, this was obtained retrospectively by interviewing several consultant paediatricians at key centres. Consequently, the model used resource estimates for the 'average patient' and did not take into account such factors as gender and causes of CMA (IgE and non-IgE mediated CMA). The inherent variability and uncertainty of using data from sources, other than that collected prospectively, is depicted by the Monte Carlo simulations. The model excludes changes in quality of life and improvements in general well-being of sufferers and their parents as well as parents' preferences. Also excluded are changes in patients' behaviour. Consequently our study may have underestimated some of the impact of the guidelines.

Clinical guidelines are systematically developed statements designed to help clinicians and patients make informed decisions about appropriate healthcare for specific circumstances³⁶. The benefits of usable clinical guidelines enabling patients, practitioners, scientists and purchasers to make more informed decisions and share information more effectively has been well documented³⁷. However, before healthcare organisations adopt guidelines, there is an onus of responsibility on them to validate them and ensure they are clinically effective and cost-effective. Hence, before Kela decided to adopt the guidelines as the basis for reimbursing clinical nutrition preparations for CMA sufferers, the validity of the guidelines' recommendations in clinical practice should have been appraised³⁸. Adopting recommendations from guidelines without appropriate validation can lead to harm to patients or a waste of resources³⁹. Within the United Kingdom, appraising the validity of existing guidelines is being facilitated by the NHS Appraisal Centre for Clinical Guidelines and by the establishment of guideline development programmes, which use rigorous methods and include formal appraisal within the programmes – for example, the Scottish Intercollegiate Guidelines Network⁴⁰. Moreover, critical appraisal tools for guidelines are widely available⁴¹.

Food allergy represents an important source of patient morbidity and healthcare utilisation. Nevertheless, our literature search did not find any health economic studies on CMA. Hence, we believe this to be the first health economic study of CMA. One study has been published outlining a framework for measuring costs to society of IgE-mediated food allergy⁴². However, to our knowledge, no cost analyses have thus far been published. Another earlier study estimated the direct NHS costs of managing allergic problems in children and adults (i.e. allergic rhinitis, anaphylaxis, asthma, conjunctivitis, eczema/dermatitis, food allergy and urticaria/angioedema) in the UK to be >£1 billion per annum⁴³. Notwithstanding this, CMA represents a special case from Kela's perspective, since no other food allergy requires such sequential

Table 6. Expected 6-monthly costs (euros at 2005/06 prices) incurred by parents of 1443 new CMA sufferers following referral to a specialist (percentage of total cost is in parentheses)

Six-monthly cost (95% CI in parentheses) in euros at 2005/06 prices incurred by parents of 1443 new CMA sufferers				
Resource	Before 1 December 2005		After 1 December 2005	
Specialist visits	28 850 (26 725; 31 004)	(64%)	28 850 (26 725; 31 004)	(59%)
Soy diet	624 (192; 1495)	(1%)	3 564 (1917; 6407)	(7%)
eHF diet	10 563 (8575; 12082)	(24%)	13 331 (8846; 16 638)	(27%)
Neocate diet	4 789 (3717; 5784)	(11%)	3 378 (2323; 4309)	(7%)
Total	44 827 (40 896; 48 535)	(100%)	49 103 (44 083; 53 724)	(100%)

eHF = extensively hydrolysed formula

food challenges for a diagnosis. This may be because CMA is the only food allergy that requires treatments that are partially reimbursed by Kela. Consequently, no other food allergy warrants this type of health economic evaluation at the present time.

Conclusion

Within the limitations of our model, Kela's new criteria for reimbursing clinical nutrition preparations for the treatment of CMA is expected to increase healthcare resource use in paediatric departments in public hospitals in Finland and increase costs to Kela, patients and Finnish society.

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