Part VIII Appendix
Appendix I

Evidence in the treatment of head lice: drowning in a swamp of reviews.

Hilde Lapeere, Robert H Vander Stichele, Jean-Marie Naeyaert.

were within normal limits. A 2-dimensional echocardiogram showed normal ejection fraction and valvular function, without evidence of pericardial effusion. A cardiac event recorder showed normal sinus rhythm, with frequent episodes of trigeminy associated with symptoms of palpitations. Results of an exercise stress test were suboptimal but showed no evidence of inducible ischemia.

Therapy with atenolol produced fatigue, and verapamil was substituted. Since treatment with verapamil, a calcium channel blocker, was initiated, the frequency of palpitations has decreased. At the time of writing, it has been 12 weeks since the patient received the smallpox vaccine.

Historically, generalized vaccinia and encephalitis have been the most concerning complications associated with smallpox vaccination [1, 2]. In general, cardiac adverse events associated with smallpox vaccine or any other vaccine are rare [3, 5]. Although not proven, there has been a well-documented causal association between smallpox vaccine and "myopericarditis," a term referring to the presentation in patients of myocarditis, pericarditis, or both [4, 6]. This term has been used by the Centers for Disease Control and Prevention (CDC) for surveillance purposes to describe persons reported to have chest pain and electrocardiogram changes within 30 days after vaccination and without evidence of other causes [7]. Dysrhythmia may be a manifestation of inflammation within the myocardium or myocardial conduction system and has now been included in the case definition of myopericarditis [8].

Recently, significant cardiac events (angina and myocardial infarction) associated with coronary artery disease following smallpox vaccination have been reported. However, the causal connection has been difficult to confirm, because most of these patients had several preexisting risk factors for coronary artery disease [4]. Autopsy findings of reported fatalities failed to demonstrate disseminated vaccinia infection or myopericarditis [8].

There have been at least 7 cases of post-vaccination cardiac dysrhythmia (supraventricular tachycardia, atrial dysrhythmias, and frequent or sustained premature ventricular contractions) reported to the CDC [7]. Most cases have been associated with clinical myopericarditis and have ranged from mild to severe, whereas several have been asymptomatic in nature [7].

Although our patient did not have overt signs of myopericarditis manifest by chest pain and ST segment changes, she did have a new onset of symptomatic palpitations after receiving the smallpox vaccine. In the absence of any other overt explanation, her symptoms may have been manifestations of mild or asymptomatic myopericarditis.

Persons receiving smallpox vaccine should be informed that myopericarditis may be associated with the vaccine and that medical attention should be sought for chest pain, shortness of breath, or other symptoms of cardiac disease. Because a causal relationship between smallpox vaccination and serious cardiac events cannot be excluded, the CDC guidelines recommend that patients with a history of cardiac problems should not receive the smallpox vaccine [4].

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References


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Clinical Infectious Diseases 2003;37:1579–80

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Evidence in the Treatment of Head Lice: Drowning in a Swamp of Reviews

Ste—We read with interest the article by Jones and English [1] entitled “Review of Common Therapeutic Options in the United States for the Treatment of Pediculosis Capitis.” We would like to point out that there are currently no uniform guidelines on which a review of head lice treatment should be based, which has led to the publication of conflicting reviews in major medical journals, such as Lancet, New England Journal of Medicine, British Medical Journal, and Cochrane Database of Systematic Reviews (Cochrane Reviews) [2–6].

Two systematic reviews of the topical treatment of head lice with insecticides were published, one by Vander Stichele et al. [5] in 1995 and another in a Cochrane review by Dodd in 1999, which was later revised in 2001 [6]. The 2 reviews used different methodological approaches and had different results. We noticed that the current review by Jones and English [1] was based on the 1999 Cochrane review and that the earlier review by Vander Stichele et al. [5] was completely ignored.
The review by Vander Stechel et al. [5] identified 28 clinical trials, of which 7 met the inclusion criteria. They also identified 11 unpublished trials that compared the efficacies of permethrin and malathion [5]. Data from these trials were withheld by the manufacturer, thus causing an important publication bias.

The main conclusion in Vander Stechel et al. [5] was that there is only sufficient evidence available on the efficacy of permethrin and that evaluation of the efficacy of malathion and carbaryl requires more evidence. Lindane and natural pyrethrins were considered to have lacked sufficient efficacy [5].

The review by Jones and English [1] was based on the Cochrane review by Dodd [6], which was published in 1999 and revised in 2001. The objective of the Cochrane review was “to assess the effects of interventions in the treatment of head lice” [6]. Inclusion criteria for randomized controlled trials were the presence of live lice or “lice and eggs” (not just eggs alone) and the absence of treatment with any other pediculicide during the month preceding enrollment. An additional inclusion criteria was that lice and eggs should not be removed by combing after treatment with a pediculicide. The Cochrane review identified 71 trials, of which only 3 met the selection criteria—2 placebo-controlled trials by Taplin et al. [7, 8] and 1 comparative clinical field study by Burgess [9]. On the basis of the results of only 3 trials, the Cochrane review concluded that effectiveness was proven for permethrin, malathion, and synergized pyrethrins [6].

Many people who are working in this area are rather disappointed by the Cochrane review on head lice interventions [10]. Indeed, the 3 accepted trials were conducted in developing countries and involved populations who do not reflect infested patients in the United States or any other developed country, as was mentioned by Jones and English [1]. Furthermore, the definition of infestation that was used excluded several studies, because many researchers take it for granted that only patients with live lice or eggs are included in such studies. Every trial that did not explicitly mention this criterion was excluded, even if the inclusion of patients was properly done. The selection of trials and the assessment of quality can be heavily biased by personal communication. The Cochrane review also ignored 2 trials referenced in Vander Stechel et al. [5], and it still has not solved the publication bias mentioned above.

We also have remarks on the recommendation by Jones and English [1] to use formic acid to remove nits. This recommendation is based on a single study by DeFelice et al. [11], in which an “after- pediculicide nit removal system” (containing a formic acid cream rinse and a metal comb) was tested. Control and treated sites were combed with plastic and metal combs, respectively. The comb type alone (i.e., independent of the formic acid rinse) could account for the greater number of nits removed from the treated site.

Another important aspect in the treatment of head lice, which was not discussed in the review by Jones and English [1], concerns the bug-busting (i.e., wet-combing) method. The revised version of the Cochrane review states that bug busting is “ineffective” [6]. This conclusion is based on a trial by Roberts et al. [12]. In this pragmatic trial, the efficacy of bug busting was compared with that of malathion 0.5%. This study showed a cure rate of 78% for malathion and 38% for the bug-busting method. The authors jumped to the conclusion that “policies advocating bug-busting as first-line treatment for head lice infestations are inappropriate for the general population” [12, p. 543]. This conclusion is found repeatedly in new reviews on head lice treatments [4, 6]. However, until now, only 1 small efficacy trial with insufficient power, in which the efficacy of bug busting was compared with that of phenothrin lotion, has been performed [13]. Larger efficacy trials should yield valuable information. Conclusions about bug busting should not be based on the results of a pragmatic study, because every kind of treatment—chemical, as well as bug busting—can lead to bad results in a pragmatic study [14].

Other comments on the trial by Roberts et al. [12] are that its outcome depended on local resistance patterns to malathion. In regions where head lice are highly resistant to malathion, bug busting could perform better than the chemical treatment. Additional advantages of bug busting that were not taken into account include its low cost and the fact that it can be repeated over and over again without any side effects [15–17].

The bug-busting method cannot be written off because it was shown to be less effective than a chemical method in a pragmatic trial. An efficacy trial with sufficient power should be done first to determine the actual therapeutic value of bug busting.

We are also concerned about the way ivermectin is almost “promoted” as a quick fix for treating head lice in the review by Jones and English [1]. The reviewers should have adopted a more critical attitude toward the use of ivermectin for treating head lice. Head lice are still no official indication for the use of ivermectin, and nothing is known about the long-term effects of ivermectin in the battle against head lice.

The controversy on the interpretation of research on head lice treatment was discussed during the 2nd International Congress on Phthiraptera (Brisbane, Australia) in July 2002, but, unfortunately, no criteria for conducting quality trials and performing systematic reviews were formulated. Although the debate is ignored in scientific literature, the need for a uniform reference standard on the basis of which reviews on the treatment of head lice can be conducted still stands.

It is our opinion that a review should be a critical analysis of all available information. All evidence should be taken into account, including that from published and unpublished trials. It is high time for an international group of experts to define
Part VIII: Appendix II | Incidence of scabies in Belgium

References


Low Antibiotic Resistance in Respiratory Pathogens in a Remote Area in Southern Sudan That Was Isolated by Civil War for 18 Years

Sina We obtained 120 naopharyngeal swab samples from outpatients with symptoms of respiratory infection within a 5-day period at a rural hospital in Maupurdit, a remote area in southern Sudan where there are ~50,000 refugees from the civil war. This is the only hospital in an area similar in size to Slovakia (~50,000 km²), and it serves 80–100 outpatients and 60 inpatients daily in 4 bed departments. The hospital had been isolated until the year 2000 because of 18 years of civil war in south Sudan; in that area, there had been no access to health care and medication.

Collected samples were immediately cultured on transport medium (Difco, Oxoid) and were transported by air within 24 h to the Reference Laboratory of Antibiotic Resistance (University Hospital Nitra, Slovakia). Of 120 swabs, 117 were positive for a bacterial pathogen, as follows: Staphylococcus aureus, 19%; Staphylococcus pyogenes, 12%; Streptococcus pneumoniae, 7%; Klebsiella pneumoniae, 9.8%; Moraxella catarrhalis, 9.8%; Haemophilus influenzae, 9.8%; Flavobacterium violaceum, 5%; and Neisseria flavescens, 15%. The following was also noted: 0% of pneumococci were resistant to penicillin or erythromycin, 0% of S. pyogenes strains were resistant to erythromycin, and 0% of H. influenzae strains were resistant to ampicillin. The absence of antibiotic resistance in this small, 5-day, pilot surveillance study can be explained by the isolation of the area resulting from 18 years of civil war, total lack of infrastructure and communication systems, and absence of antibiotics, even as over-the-counter drugs. Furthermore, until the year 2000, no health care at all was available in the area.

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Appendix II

Short Report – Incidence of scabies in Belgium.

**Hilde Lapeere**, Jean-Marie Naeyaert, Jozef De Weert, Jan De Maeseneer, Lieve Brochez.

Accepted with revisions
SHORT REPORT

Incidence of scabies in Belgium.

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Summary

A prospective survey on scabies in Ghent, Belgium was performed in 2004. Sixty-four individual cases were reported, corresponding to a crude incidence rate of 28 per 100,000 inhabitants. The incidence was higher in the elderly (51 per 100,000 in persons over 75) and a higher incidence was also found in immigrants (88 per 100,000). More than 40% of the registered scabies patients had symptoms for more than 4 weeks at the time of presentation. In 54% of the consultations, the patient had already consulted a physician for his/her skin problem. Of this group, 44% had not yet received any scabeticidal treatment, indicating that scabies was not yet diagnosed or that an inappropriate treatment was prescribed. The observations suggest that the diagnosis and/or treatment of scabies in this region can still be improved.
SHORT REPORT
Incidence of scabies in Belgium

Scabies is an infectious skin disease caused by *S. scabiei* var. *hominis*. According to the WHO, approximately 300 million persons per year develop scabies worldwide [1].

Some reports on the epidemiology of scabies are based on nationwide reporting systems [2-5]. Other resources such as army databases [6, 7], sentinel practice networks [8, 9] or patient files [10-12] have also been used. Few countries have an obligatory reporting system. In Belgium, the reporting of scabies to the Health Inspection is mandatory since 1995. These data are published quarterly on the website of the Health inspection [13] and seem to suggest that there has been a resurgence of scabies in Belgium. The incidence has increased from 125 individual cases (or a relative incidence of 2.1 per 100,000 inhabitants) in 1995 to 449 cases (7.5 per 100,000) in 2001. Since then, the incidence has decreased again to 231 cases (3.8 per 100,000) in 2005. However, it is suspected that these data are incomplete because of underreporting by physicians to the Health Inspection.

Insight in the epidemiological and clinical profile of scabies patients can be helpful to adapt the management of scabies to the current needs. The information in many of the epidemiological studies mentioned above is not applicable because these reports are often outdated [2, 10, 11, 14, 15] and/or based on a specific population [7]. The current survey presents data on the incidence of scabies and the socio-demographic and clinical profile of scabies patients in Ghent. This industrialized city in the northern part of Belgium has 229,377 inhabitants of which 6.9% are of a non-Belgian origin [16]. Demographic characteristics, patient history and clinical information on all new scabies patients that consulted a physician in Ghent between January 1st 2004 and December 31st 2004 was collected by means of a prospective survey. The survey was conducted using a self-developed questionnaire that contained questions about demographic characteristics (sex, age, nationality) and patient history (was the patient referred, since when did he have symptoms, had the patient already consulted another physician before). The physician was asked which elements were suggestive for the diagnosis of scabies in each patient (contact persons with scabies, nocturnal itch, family members or contacts with itch, scabies burrows, papules, erythema, flakes, crusts, scratch lesions, impetigo). Finally, the survey contained questions about which treatment was prescribed and how many contacts of the index patient were treated. Approval for this project was obtained from the Ethics Committee of the Ghent University Hospital (2003/295).

All dermatologists (n=32), GP’s (n=344) and pediatricians (n=75) in Ghent were invited to
participate in this survey. The questionnaire and an accompanying letter were sent by mail in December 2003. The survey was also promoted during a local press conference in June 2004.

Eighteen different physicians returned sixty-nine completed forms, reporting 64 scabies patients. Twenty-four (38%) cases were registered by physicians working at the dermatology department of the University hospital, 27 (42%) cases by other dermatologists and the remaining 13 (20%) cases by GP’s.

The recorded 64 cases correspond to a crude incidence rate of scabies in Ghent of 28 per 100,000 inhabitants (95% CI 22/100,000 – 36/100,000). An equal number of men and women were reported. The highest incidence rates were found in children less than 5 years of age (5 cases corresponding to 50 per 100,000, 95% CI 22/100,000 – 116/100,000), in young adults between 15 and 24 (9 cases corresponding to 35 per 100,000, 95% CI 19/100,000 – 67/100,000) and in the elderly (11 cases in persons over 75 corresponding to 51 per 100,000, 95% CI 29/100,000 – 91/100,000). (Table 1)

Incidence rates were almost 4 times higher in immigrants (14 cases or 88 per 100,000, 95% CI 53/100,000 – 148/100,000) than in persons with a Belgian nationality (50 cases corresponding to 23 per 100,000, 95% CI 18/100,000 – 31/100,000) (P< 0.001, Fisher’s exact test). About 70% (95% CI 59% - 81%) of the reported scabies patients lived in a family, 16% (95% CI 9% - 26%) lived alone and 14% (95% CI 8% -25%) was residing in different institutions.

In 43% (95% CI 31% - 52%) of the consultations, the patient had symptoms since 1 to 4 weeks. In 12% (95% CI 4% -20%) of the consultations, symptoms were present since 1 to 2 months and in 31% (95% CI 20% - 42%) for more than 2 months. In 54% (95% CI 42% - 66%) of the consultations, the patient had already consulted a physician for their skin problem. Of this group, 36% (95% CI 20% - 52%) (or 19% of the total group) had received a scabicide treatment and 44% (95% CI 22% - 56%) (or 25% of the total group) had received another type of treatment.

Nocturnal itching was the most frequently cited element in the patient history and was present in 87 % (95% CI 79% - 95%) of the patients. In 27% (95% CI 16% - 38%) of the cases scabies was diagnosed in contact persons of the patients and in 48% (95% CI 36% - 60%) itching was present in household members or other contactpersons.

Scratch lesions were the most frequent clinical finding (in 72%, 95% CI 61% - 83%). Burrows, erythema, papules and scaling were present in respectively 66% (95% CI 55% - 77%), 64% (95% CI 53% - 75%), 67% (95% CI 56% - 78%) and 61% (95% CI 49% - 73%) of the patients.

Skin scrapings were performed in 64% (95% CI 53% - 75%) of the patients and demonstrated mites, eggs or scybala in 70% (95% CI 56% - 84%). Permethrin cream was
prescribed for 53 patients. Six patients received ivermectin (in two cases combined with permethrin cream) and one patient benzyl benzoate emulsion. The treatment was not specified in 7 subjects.

This survey was performed using a self-developed questionnaire sent by mail. Several forms of bias could have an influence on the results of this type of survey and need to be taken into account. For instance, longstanding, “difficult” cases may be overrepresented because 38% of all cases were recorded at the University Hospital, leading to a referral bias. On the other hand, patients with difficulties to access health care might be underrepresented causing a diagnostic access bias. A spectrum bias is possible if only clear, definite cases of scabies were reported [17].

In 2004 we received information from 64 individual patients. During the same period, 39 scabies patients in this region were reported to the Health Inspection. These results suggest a possible under-registration by the Health Inspection. In a recent survey of knowledge and management of scabies in Belgium, respectively 40% and 55% of the participating dermatologists and GP’s admitted they rarely or never reported a patient with scabies to the Health Inspection [18]. Perhaps the obligation to report scabies is not sufficiently known or physicians might not value the notification of a disease which is not life threatening [19].

Even though a higher number of cases were reported in the current survey, the actual incidence could still be higher. Low response rates to physician surveys are common and might lead to a response bias if the characteristics of the reported patients differ from those that were not reported [20].

The completeness of registration can be assessed by comparing the collected data to other registries such as pathology reports, patient records, laboratories for clinical biology, morbidity databases, information from sentinel practice networks or sales figures of disease specific medication. However, biopsies are seldom taken if scabies is suspected and this diagnosis is not recorded in sentinel practice networks in Belgium. Samples are not sent to laboratories for clinical biology and the standard treatment for scabies, permethrin cream, is not only prescribed for scabies patients but also to treat asymptomatic contact persons.

In this survey no difference in incidence of scabies was found between men and women. Reports on sex differences in the incidence or prevalence of scabies are inconsistent [14]. Some authors observed that scabies occurs equally in men and women [2, 4] while others reported a higher incidence in men [11, 12] or in women [8-10].

The incidence of scabies in this region is comparable to crude incidence rates reported in Poland but is much lower than the incidence in the UK which was 233/100000 in 2003 [4, 8]. The age distribution for scabies in Ghent is similar to that observed in the UK where there is also a peak in children under 5 and young adults between 15 and 24 [8]. These incidence
rates are however difficult to compare because they are crude rates, not adjusted for age distribution and demographic profile of the populations.

We observed a remarkable high incidence in persons over 65 which is in contrast to the lower incidence usually found in the elderly [2, 4, 9, 12]. In a recent survey in the UK an increase in persons over 75 compared to persons between 65 and 74 was observed [8]. Older persons frequently require ambulant health care and are more often hospitalized or residing in institutions. Their multiple intense contacts with health care workers and fellow residents could predispose them to a higher risk of infection. Elderly patients with scabies require extra attention because they often have an atypical presentation and are at a higher risk of developing crusted scabies [21].

The incidence was almost four times higher in immigrants than in native Belgians. Nationality could be an indicator of socio-economic status or living conditions with a non-Belgian nationality reflecting a lower status or worse living conditions. Studies in Poland have shown a higher incidence of scabies in areas with a high level of unemployment and worse sanitary conditions [3, 4]. In a study in Italy the incidence of skin diseases in immigrants between 20 and 29 years of age was compared to the incidence in matched natives. The incidence of scabies was four times higher in immigrants than in native Italians. However, there was no difference when only the subpopulation of employed persons was analyzed. The level of unemployment was much higher in immigrants than in natives. This study illustrates that not nationality by itself but the associated different socio-economic status can contribute to the risk of getting scabies [22]. Another contributing factor could be a language barrier causing difficulties to access health care services [23, 24].

In 25% of the consultations, patients had already consulted a physician for their skin problem but were not yet treated with a scabicide, suggesting that the diagnosis of scabies was not yet established or that the patient was ineffectively treated. A recent survey on knowledge and management of scabies in the region showed that knowledge of GP’s and dermatologists was of an acceptable level [18]. However, the performance status of the participating physicians could have been biased with an over-representation of physicians who are interested in scabies. On the other hand, it is also possible that physicians do have sufficient basic knowledge but that they have difficulties to put their knowledge into practice. The current survey is perhaps a more realistic reflection of daily practice.

Skin scrapings were performed in 2 out of 3 consultations and were positive in only 70%. This diagnostic procedure is currently considered the gold standard for the diagnosis of scabies but has low sensitivity. Epiluminiscence microscopy has been advocated as a diagnostic aid [25]. The sensitivity of this technique also depends on the skills of the observer. Recently an ELISA has been developed to detect anti-bodies to the mite in the serum of scabies patients but the performance of this test was disappointing [26]. There is a
high need for diagnostic tests with a high performance because delay in diagnosis has been identified as a factor contributing to the development of epidemics [21]. The current survey suggests that there is still room to improve diagnosis and adequate treatment of scabies. In the management of scabies, extra attention should go out to vulnerable groups, especially immigrants, children and the elderly.
Figure 1: Reported cases of scabies in Ghent in 2004 and crude incidence rates. (n = 63).

<table>
<thead>
<tr>
<th>Age category</th>
<th>Number of cases</th>
<th>Crude incidence rate per 100,000 inhabitants</th>
</tr>
</thead>
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<tr>
<td>&lt; 4 years</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>5 – 14 years</td>
<td>5</td>
<td>21</td>
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<td>51</td>
</tr>
<tr>
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</table>
Acknowledgements

We would like to thank all physicians that participated in this survey.

This research was supported by a grant from Ghent University, BOF2002/DRMAN/007
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Curriculum Vitae
Curriculum Vitae

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Publications

A1 Articles in journals with peer-review system and international distribution.

- **Hilde Lapeere**, Lieve Brochez, Yves Vander Haeghen, Cyriel Mabilde, Robert Vander Stichele, Luc Leybaert, Jean-Marie Naeyaert. Method to measure force required to

- Joanna Ibarra, Frances Fry, Clarice Wickenden, Alice Olsen, Robert Vander Stichele, Hilde Lapeere, Maryan Jenner, Andrea Franks, Jane Leseley Smith. Overcoming health inequalities by using the Bug Busting ‘whole-school approach’ to eradicate head lice. Accepted for Journal of Clinical Nursing.


**A3 Articles in national journals with peer review system**


**A4 Articles in journals not included in A1, A2 or A3.**


Presentations

Oral presentations


- Skin infestations: Pediculosis capitis and scabies. Lecture at the Summer School Microbiology, fostered by the EADV. July 21st 2005, Vienna, Austria.


Poster presentations


Grants & Prizes

- Roche Dermatology Prize “Fundamental Research Award 2006”.

- La Roche – Posay prize 2005 for the compensation of scientific research that has recently been published. This award was granted for the paper: “Method to measure force required to remove Pediculus humanus capitis (Phthiraptera: Pediculidae) eggs form human hair.”

- BOF mandate at the Ghent University 2002-2006 for scientific research in function of the PhD project “Development of an evidence-based management of pediculosis capitis and scabies”. 
Dankwoord
Dankwoord

Na een goede vier jaar is dit doctoraatsonderzoek afgelopen. Het onderzoek dat in deze thesis beschreven werd zou niet tot stand gekomen zijn zonder de hulp en aanmoediging van vele mensen. Nu is eindelijk het moment aangebroken voor een welgemeend woordje van dank.

Eerst en vooral wil ik mijn promotor en copromotor bedanken. Prof. Naeyaert, u hebt gezorgd voor de nodige faciliteiten om dit onderzoek tot een goed einde te kunnen brengen. Uw vertrouwen in dit onderzoek en in mijn capaciteiten hebben mij de nodige ruggesteun gegeven. Prof. De Maeseneer, uw enthousiasme, verfrissende ideeën en welgemeende interesse gaven mij telkens een nieuwe stimulans. De leden van de examencommissie wil ik bedanken voor de interesse waarmee zij dit werk gelezen hebben en de nuttige suggesties die zij gegeven hebben tijdens het afronden van deze thesis.

Ik wil in het bijzonder Prof. Dr. Robert Vander Stichele en Prof Dr. Lieve Brochez bedanken voor hun steun en begeleiding bij het oplossen van de vele, dagdагelijkse problemen en kleine crisissen. Bob, je hebt me geleerd om kritisch te kijken naar de geleverde resultaten en om het altijd nog iets beter te doen. Lieve, je hebt me heel wat praktisch tips gegeven, van het plannen van een nieuw onderzoeksproject tot het schrijven van een manuscript. Maar vooral je bemoedigende woorden als het wat moeilijk ging hebben me dikwijls gesteund.

Ik heb het genoegen gehad om tijdens de verschillende onderzoeksprojecten met heel wat mensen uit verschillende disciplines samen te werken. Dankzij het team van prof. Dr. Luc Leybaert kon het onderzoek naar de neten uitgevoerd worden. Prof. dr. Dirk Debacquer heeft voor verschillende projecten het nodige advies rond statistische verwerking gegeven. Sara, het was zeer aangenaam om met jou samen te werken aan het manuscript rond de grote luizenscreening. Met Fien en Filip ben ik aan de lange weg begonnen die moet leiden tot een aanbeveling. Dankzij hun enthousiasme is gans het proces toch net iets minder frustrerend. Daarnaast hebben heel wat patiënten, kinderen, scholen, CLB’s en artsen zich belangeloos ingezet om de vele projecten tot een goed einde te brengen, waarvoor mijn oprechte dank.

Ik wil van de gelegenheid gebruik maken om ook mijn ouders te bedanken. Ik besef dat ik dit alles niet zou bereikt hebben dankzij hun jarenlange steun en aanmoediging. Zij hebben stevige fundamenten gelegd waar ik mocht op verder bouwen.

Tot slot wil ik mijn echtgenoot Bert bedanken. Lieveke, jij hebt me gesteund op alle mogelijke vlakken, van praktische dingen zoals het maken van illustraties tot een troostende schouder als het allemaal niet meer ging. Jij hebt me gemotiveerd om door te bijten en dit werk tot een goed einde te brengen. Vanaf morgen begint een nieuw leven waarin we het weekend niet meer systematisch achter de PC zullen doorbrengen…