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Momentum Builds After 4th International Symposium on Pet Contraception

Alliance for Contraception in Cats & Dogs and Found Animals Foundation Convene Experts and Advocates From Around the World

Portland, Oregon, May 17, 2010 – From April 8 to 10, 2010, 185 attendees from 25 countries convened in Dallas, Texas, to focus on advancing new tools to humanely and effectively manage populations of pet and un-owned cats and dogs. Experts in reproductive biology and other related scientific disciplines presented the newest research and discussed perspectives with industry experts in animal health drug development. Veterinary leaders joined with animal welfare and advocacy groups, foundation representatives, public health officials and others to assess the tools currently available for use. Together, these stakeholders looked at where we are, what is possible, and what is needed to advance non-surgical methods for controlling cat and dog reproduction around the world. A post-meeting survey generated high praise for the symposium; many felt inspired by the international involvement and excited about real progress using current approaches, and fresh science with real promise to deliver new technologies in the future.

A comprehensive list of speakers and attendees, session summaries, recorded presentations, posters and related think-tank reports are also currently available (or will be available by the end of May 2010) to view or download free of charge at www.acc-d.org/4thSymposiumProceedings.

Resources to Advance New Science, and a New Tool Available Now

After the symposium, a survey of the attendees indicated that 88% felt more hopeful that we will see progress in this area and 81% said they are now more interested in being involved in this effort. Contributing to high levels of enthusiasm were two key developments in the last two years.

The Michelson Prize & Grants in Reproductive Biology, launched in October 2008 by Found Animals Foundation, is inspiring researchers worldwide to focus on the goal of finding new non-surgical approaches to reproduction control. A \$25 million prize is offered for a single-dose sterilant for male and female cats and dogs. Another \$50 million in grant funding is offered for research with promise to advance progress toward that goal. Thirty-five attendees reported that they are likely to submit research proposals for possible grant funding.

I am convinced that excellent researchers working all over the world, supported by the Michelson Grants, will eventually develop such a treatment. This conference convinced me that it has to be possible to develop such a method in the coming years.

– Auke Schaeffers-Okkens, DVM, PhD, Dipl-ECAR, renowned veterinary researcher from the Netherlands



In separate news, EsterilSol™ from Ark Sciences, a product providing permanent sterilization for male dogs through a single treatment, is now available in Mexico and for limited use in other countries. Ark Sciences provided training in EsterilSol administration and veterinarians from international animal aid programs shared their field experiences and advice with those interested in using this technology.

The symposium was invigorating and refreshing. I have come back to Kenya ready to get down to work to make a difference in the lives of the thousands of stray and unwanted dogs and cats in the country, armed with new information on spay/neuter campaigns as well as powerful and effective new drugs.

– Ismail Thoya Ngoka, BVM, Kenya Society for the Protection and Care of Animals

In addition to general sessions, two symposium tracks were offered to build on these developments: The Michelson Prize and Grants Track focused on science to create new tools, and the Field Implementation Track explored special considerations for feral and free-roaming cats and ways to put existing tools to effective use.

Key Highlights – Overall

- The symposium connected a diverse community. This symposium brought together a very unique mix of stakeholders: 37% identified themselves as scientists (29% with an academic institution, the others with a private company), 20% as animal welfare advocates, 15% as practicing veterinarians, 8% with animal health pharmaceutical companies, 7% with foundations or investors, 2% work in public health, 2% are students, and 11% identify themselves as “other.”
- The caliber of attendees was exceptionally high. Special addresses featured CEOs of leading animal welfare nonprofits: Ed Sayres of the American Society for the Prevention of Cruelty to Animals (ASPCA), Wayne Pacelle of the Humane Society of the United States (HSUS), and Gregory Castle of Best Friends Animal Society. Keynote speakers from the scientific community included Dr. Stephen J. O’Brien, head of the Laboratory of Genetic Diversity at the National Cancer Institute of the National Institutes of Health (NIH), and Dr. Charles Rupprecht, chief of the Rabies Program at the Centers for Disease Control (CDC). Attending scientists represented esteemed institutions, including the Smithsonian, the National Institute of Immunology in New Delhi, India, Scripps Research Institute, Howard Hughes Medical Institute, and City of Hope, all newly involved in this area.
- There is increased recognition of the need for birth control alternatives for cats and dogs among researchers and industry. An international panel of animal advocates shared their challenges in humanely controlling pet populations in diverse communities around the world, from Bhutan to Colombia to the U.S. Dr. Andrew Rowan, CEO of Humane Society International and a member of the ACC&D Board of Directors, moderated the panel, noting that of the estimated 685 million dogs in the world, over 40% are stray or “community” dogs rather than pets. Panelist Dr. Elly Hiby, head of companion animals for the World Society for the Protection of Animals, built on ACC&D’s priorities for new products, commenting that “while a permanent sterilant would be



ideal, even a contraceptive lasting one year could be of use, especially in dog populations getting annual rabies vaccines.”

As a member of the industry community, my eyes were opened regarding the real need for the development of the kinds of drugs that can put an end to the animal overpopulation problem, not only for pet animals, but for feral animals as well.

– Stephanie Arnold, DVM, Virbac Animal Health

Key Highlights – Setting the Stage for New Work

Several sessions provided key background to inform new science and field work:

- Theriogenologist Dr. Michelle Kutzler’s 90-minute workshop on reproductive biology discussed unique aspects of cat and dog reproduction to consider when designing birth control options.
- Dr. Iris Reichler’s presentation about spay/neuter focused on understanding the non-reproductive medical and behavioral effects of surgical sterilization as a benchmark for evaluating non-surgical alternatives. She pointed out the trade-offs of positive and negative impacts.
- Dr. Wolfgang Jöchle and Dr. Beverly Purswell collaborated on a review, presented by Purswell, of the history of approaches and targets for research aimed at advancing non-surgical alternatives.
- ACC&D Board of Directors chair Dr. Linda Rhodes shared a summary of what has been commercialized to date, noting that at ACC&D’s first symposium in 2002 there were no dog or cat contraceptive drugs on the market. Since that time, products in the areas of both chemical castration and GnRH agonist drugs have received regulatory approval and have been marketed for male dogs, with the latter working in females as well. In addition, two GnRH vaccines have been approved, one for male dog health issues (benign prostatic hypertrophy) and the other for contraception in deer. Given the significant time and funds needed for both research and regulatory approval, it is encouraging to have seen this amount of progress in less than a decade.
- Dr. Safdar Khan from the ASPCA spoke about what may be required by regulatory authorities to demonstrate safety of a new product, and a brief review of the regulatory pathway(s) for this unique category of animal health products was presented by consultant David Petrick, VMD, Esq.

Key Highlights – Michelson Prize and Grants Track

- Found Animals Foundation representatives and selected speakers provided an overview of the Michelson Prize & Grants program and offered direction on how to compete successfully for a grant. Dr. Shirley Johnston, Found Animals’ director of scientific research, shared the status of grants awarded: Of 102 letters of intent received since January 2009, 33 full grant proposals have been invited and reviewed. Seven of those have been recommended for funding for a total potential of \$3.5 million. Of those, three have been awarded, totaling \$1.5 million, and another four are under negotiation. Found Animals urged attendees to be worldwide ambassadors, bringing other researchers into this work.



- The three primary technologies represented by grant applications have been immunization against GnRH, targeted delivery of cytotoxins to pituitary or gonadal cells, and silencing of genes coding for proteins that are essential in the reproductive cascade (essentially “turning off” genes that are required for reproduction). This track featured sessions on each of these areas, although it was noted that the foundation is open to approaches outside these categories. As Johnston explains: “Attendees at the 4th symposium included many scientists from fields of human medicine and basic reproductive biology who can help advance the field of animal non-surgical contraception.”
- Dr. Linda Rhodes chaired the session on cytotoxin conjugates, with speakers including leading researchers from human contraceptive centers. Dr. Joseph Tash and Dr. Kathy Roby from the Interdisciplinary Center for Male Contraceptive Research and Drug Development at the University of Kansas have an approach known as “KU-AS-272” that is working to sterilize male rats. This is a potential single-dose anti-spermatogenic agent, targeting Sertoli cells, with specific effects on a protein target that is also thought to be critical for ovarian granulosa cell functions, and therefore may also work in females. Additional studies on female mice have demonstrated a disruption in egg development. These researchers are hopeful to advance this approach to be able to sterilize cats and dogs.
- Speaker Dr. John Herr is the director of the Center for Research in Contraceptive and Reproductive Health at the University of Virginia. The University of Virginia and Merck recently announced that they have entered into a strategic research collaboration to characterize reproductive enzymes and develop novel drugs for female contraception. The new collaboration focuses on non-steroidal small molecule drugs that would target reproductive cells more selectively than steroids, with possibly fewer side effects. In his session, Dr. Herr outlined the reproductive cell and molecular biology of an oocyte-specific contraceptive target, SAS1R. Although this target is likely not suitable for a single-dose sterilant, the characterization of SAS1R serves as a model for the types of questions important to identify for validating a sterilant target. Dr. Herr and others discussed using a technique called “phage panning,” where scientists are discovering proteins that are unique to primordial cells in the ovary and testis that may be good targets for specific delivery of toxins to induce sterility.
- Dr. William Ja (Scripps Institute), who is trained in molecular biology and biochemistry, and is establishing his first independent laboratory this year, spoke about “FSH Receptor Ligand-Cytotoxin Conjugates: Potential for Permanent Chemosterilization.” This approach — to neutralize the action of a key hormone of pituitary origin essential for normal functioning of the gonads of both sexes — is of great interest. Years of attempts to eliminate the source of gonadotropin in the pituitary by using a cytotoxic approach and GnRH as a carrier ligand have failed after initial successes, possibly because of the regenerative capability of the gonadotroph cells in the pituitary gland.

Dr. Ja really inspired our audience as a leader of a new generation of researchers. The Michelson Prize piqued his curiosity; his intellect and training qualified him to try and answer key questions. Dr. Ja’s approach seeks to neutralize the action of a key hormone of pituitary origin critical for normal functioning of the gonad. Of particular appeal is that his proposed method could evaluate in vitro the effectiveness and safety of potential



cytotoxic constructs without involving animals at an early stage. He epitomizes the bright newcomers we have hoped to attract to this cause.

– Shirley Johnston, DVM, PhD, DACT scientific director, Found Animals Foundation

- The session on “Silencing Genes That Control Reproduction” was chaired by Dr. Stephen O’Brien, and for that reason and more was much anticipated by Dr. Wolfgang Jöchle, science advisor to both ACC&D and Found Animals: “This is an approach many feel might bring a solution to seemingly insurmountable problems to control reproduction across species for both males and females. Yet its mechanisms and specific problems are understood only by a few, represented by this session’s speakers. It is incredibly inspiring to have them start to imagine how to approach this.”
- Dr. John Rossi (City of Hope) provided an introduction and overview about this field of research by talking about “Functions and Therapeutic Applications of Small RNAs.” Approaches to gene delivery were addressed by Stanford’s Dr. Mark Kay, who spoke about “Vector-Based Strategies for RNAi Expression in Whole Mammals.” This involved the use of viral vectors and new non-viral vectors and mini-circle DNA plasmids. Since body defenses can limit gene transfer and block access to specific tissues, new strategies had to be developed. As a result, using these RNAi-based vectors, human pathogenic viruses and endogenous genes were blocked in animal models of human diseases. Progress along these lines in therapy and disease management was presented and some ideas of application to animal sterilization proposed.
- Since the master control center for reproduction resides in the hypothalamus, it will be challenging to deliver siRNA across the blood-brain barrier, particularly targeting the GnRH-producing neurons. Dr. Gregory Disson from Oregon Health Sciences University is one of the scientific collaborators trying to surmount this hurdle, supported by the first Michelson Grant awarded. During his session, “Progress in siRNA Targeting in the Central Nervous System: Where Are We on Proof of Principle,” he shared that viral vectors can be used and adeno-associated virus (AAV) vectors of a distinct serotype have been shown to cross the blood-brain barrier and transduce neurons and astrocytes locking into distinct receptor type epitopes. Combined with AAV, this could carry the agents to the neurons to suppress GnRH.
- In the session called “Immunological Approaches to Sterilization of Cats and Dogs,” chaired by Dr. Stephen Boyle (co-founder of ACC&D and head of its scientific advisory board), presenters discussed ways to address key issues for vaccine-based approaches: improving the percentage of animals responding to treatment and increasing the duration of effect.
- In Dr. Scott Coonrod’s session, “Viral Particle-Based Display of Multiple Antigens for Companion Animal Immunosterilization,” he explained his research based on using virus-like particles (VLPs) that mimic parvovirus capsids with antigens incorporated from the target disease. It has been shown that the body recognizes and mounts a robust immune response to some antigens embedded in VLPs. His approach was to incorporate two antigens involved in reproduction into a VLP, to stimulate both antibody production and cell-mediated immunity.



- NIH researcher Dr. John Schiller inspired attendees about the potential of immunocontraception, sharing his success with creating a human papilloma virus (HPV) vaccine (with the technology currently commercialized by both Merck and Glaxo Smith Kline), which provides long-lasting (i.e., multi-year) immunity. As he notes in his abstract, “The human papilloma virus-like particle vaccines consistently induce high titers of virus neutralizing antibodies in humans that have remained highly protective in the six years since the initiation of trials” in more than 98% of treated women. He expressed enthusiasm for using a VLP-GnRH to achieve contraception with a long multi-year duration and a high percentage of responders. This reinvigorated many attendees who have witnessed decades of obstacles to successfully suppressing GnRH for an extended period of time using immunocontraception. As Schiller expressed it, “The challenge for immunocontraception will be to display GnRH, or other fertility target antigens, at high density on the surface of virus-like particles and generate antibody responses that remain in the protective range after their long-term plateau levels have been reached.”
- Another promising technology was described by Dr. Kent Van Kampen of Vaxin who reported on viral vector vaccines. His lab has demonstrated the feasibility of using adenoviral vectors that express antigens to induce antibodies that block fertility. This approach is already widely used for vaccines against infectious diseases and also for the control of cancer, diseases of the endocrine system, and even Alzheimer’s disease. The focus of his talk was exploring the mainly non-scientific obstacles to development, including intellectual property and regulatory hurdles to prove safety, efficacy and good manufacturing, all of which cost substantial amounts of money.

Scientific Think-Tank Reports Debuted at Symposium Suggest Direction for Research

ACC&D convened two interdisciplinary scientific think-tanks in late 2009 in the areas of gene silencing and immunocontraception, with the support of Found Animals Foundation and the Animal Assistance Foundation. The two events each gathered over a dozen participants, including leading scientists in relevant fields who had never met or worked together before. The purpose of these events was to identify key obstacles and opportunities in these two areas and to suggest appropriate research agendas to advance permanent or long-acting birth control methods for cats and dogs. These recommendations were debuted at ACC&D’s 4th International Symposium and several scientific leaders were there to speak about the ideas shared in the think-tank meetings.

To access these think-tank reports, visit www.acc-d.org/ThinkTanks.

Key Highlights – Field Implementation Track

Focus on Feral and Free-Roaming Felines. Presenters, panelists and attendees participated in an interactive session to identify priorities for contraceptives and non-surgical sterilants for this unique population. In the U.S. particularly, feral cats are a key target for population control, with estimates ranging from 9 to 90 million un-owned cats in the U.S., approximately 95% of which are not sterilized. Recommendations from these creative and wide-ranging discussions included the following:



- While a permanent sterilant may be ideal, many participants could see value in a contraceptive with a three-year duration, under some circumstances. Seventy-three percent of participants recommended that ACC&D take action to advance a single-treatment, three-year contraceptive if and when the technology becomes available.
- Panelists and audience members expressed concern about existing hormonal (generally progesterone-like) contraceptives being used by some feral cat caregivers. It was acknowledged that there is demand for contraceptives that can be delivered in food, despite the risks associated with the unapproved oral progesterone-like drugs and with administering drugs in food. Therefore, education about risks, including side effects, is critical.
- Clipping the tip of one ear is the common method for identifying a feral cat as sterilized. This method could not be used with a contraceptive or non-surgical sterilant that does not require anesthesia. Identifying or developing new methods for identifying feral cats as infertile is a key challenge and one that participants urged ACC&D to make a priority.

Chemical Castration of Male Dogs

This session focused on an existing product that provides permanent sterilization of male dogs in a single treatment. The daylong session offered a one-of-a-kind opportunity for participants to learn more about these approaches from Ark Sciences, the company that developed EsterilSol, as well as from veterinarians and leaders of international animal welfare organizations experienced with EsterilSol or its U.S. predecessor, Neutersol®. Opportunities and challenges presented by this approach were discussed at length and audience members were encouraged to ask questions and express concerns — a critical element of the program because the product has been the subject of many rumors. Guidance was offered to help organizations determine whether this approach would be a meaningful addition to their population control programs.

EsterilSol offers significant advantages to many nonprofit and government agencies around the world, especially where veterinarians have little surgical training or limited access to appropriate surgery suites, or where dog owners resist the idea of having their dogs castrated. There was special interest in this training from a number of nonprofits in developing countries. With funding from the World Society for the Protection of Animals (WSPA) and the Parsemus Foundation, scholarships that covered the symposium registration as well as significant travel costs were provided to conference participants from Ecuador, Mexico, India, South Africa, Sierra Leone, the Philippines, Guatemala, Kenya and Ethiopia. ACC&D's EsterilSol Small Grants Program, discussed in this session, aims to help organizations like these begin using EsterilSol most effectively and efficiently, while gathering data to help future projects be even more successful.

[EsterilSol] is non-invasive, requires little equipment and can be administered anywhere. The dogs keep their testicles and we can release them quickly. We therefore have the capacity to sterilize larger numbers of dogs quickly, more efficiently and humanely.

– Emma Clifford, executive director of Animal Balance, an organization that works to control dog and cat overpopulation on islands such as the Galapagos, thereby minimizing impact on endangered wildlife



Complete administration instruction, including hands-on training in injection techniques used in male dogs, is especially important for the most safe and effective use of EsterilSol. With an audience of at least a hundred observers, Dr. Carlos Esquivel of Ark Sciences provided this training with four shelter dogs participating in an injection demonstration. (The dogs have all been placed for adoption.) EsterilSol grant recipients and other veterinarians experienced with EsterilSol assisted veterinarians from Chile, South Africa, Sierra Leone, Kenya and Turkey as they learned the injection process through hands-on training. Feedback on the session was quite positive, with 96% reporting that they would recommend it to someone interested in EsterilSol.

I think that the evidence-based information given out by the international panel helps open up veterinarians' minds to the possibility of implementing chemical sterilization as a valuable tool in the effort of reducing pet overpopulation.

– Carolina Alborta, DVM, Houston, Texas

In Summary

Linda Rhodes, VMD, PhD, vice president of AlcheraBio, LLC, and chair of the ACC&D Board of Directors, summarized the event: “This symposium clearly demonstrated the worth of bringing the key people together that are needed to discover, develop and demonstrate the value of non-surgical alternatives to spay/neuter for cats and dogs. I was particularly moved by the international efforts for pet population control, and applaud the dedication and perseverance of those ‘in the field.’ The need for a good alternative couldn’t be clearer, and with the inspiration of the Michelson Prize & Grants, we are attracting world class scientists to help tackle this problem. This meeting demonstrated fresh resolve and resources to make progress toward the goal of safe and effective products that will make a real difference.”

Attendees from the animal health pharmaceutical industry included AlcheraBio, LLC; Amplicon Vaccine, LLC; Ark Sciences; Biorelease Technologies; The Delta Consortium Regulatory Consulting; Elanco Animal Health; Innolytics; Merial Ltd.; Pfizer Animal Health; Schering-Plough Animal Health; Virbac Animal Health; Senestech, Inc.; Vaxin, Inc.; and MPM Capital.

Special Thanks

ACC&D’s 4th International Symposium would not have been possible without the support of its sponsors. Many thanks to presenting partner Found Animals Foundation and sponsors ASPCA, Humane Society of the United States, Animal Assistance Foundation, Erika Brunson and the Coalition for Pets & Public Safety, Parsemus Foundation, Best Friends Animal Society, Petfinder.com Foundation, Ark Sciences, Petco Foundation, World Society for the Protection of Animals, PetSmart Charities, Handsel Foundation, Summerlee Foundation, Morris Animal Foundation, Elinor Patterson Baker Trust, Elanco Animal Health, AlcheraBio, LLC, Marian’s Dream, Intervet Schering-Plough Animal Health and SPAY Colorado.###

See the following pages for additional quotes from symposium attendees.



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Other Quotes from Participants

I believe that the need for animal population control is urgent. We must develop practical, safe, effective and economical means of reducing conception in companion, feral and wild animals. This meeting highlighted the issues and offered hopeful solutions in the future.

– Kent Van Kampen, DVM, PhD, chief operating officer, Vaxin, Inc.

This was a well organized and executed meeting that brought together a wide range of individuals from diverse backgrounds that are linked in a common mission. I came away very inspired to continue working on this important issue.

– Scott Coonrod, associate professor of reproductive biology, Baker Institute for Animal Health, College of Veterinary Medicine, Cornell University

I have been to all the symposia organized by ACC&D and I found the methods proposed at this one to be the most promising. The Michelson Prize and Grants have stimulated a new subset of scientists studying reproductive processes to put their minds to helping this problem.

– Cheri Asa, PhD, director, AZA Wildlife Contraception Center, St. Louis Zoo

The presentation regarding the contraception program of many animal welfare groups in various islands, where the stray animals are really in a plight, really confronted the need of the contraception program and has given inspiration for development of successful birth control options.

– Vandana Chauhan, PhD candidate and research associate, Indian Institute of Technology, School of Medical Science and Technology, West Bengal, India

The symposium provided me the unforgettable opportunity to represent my notions in the field of pet contraception in front of the world renowned ace scientists and researchers, veterinarians, funders, humane workers and public health professionals, which helped me to make myself recognized in the ocean of knowledge. Above all, the light thrown on “The Michelson Prize & Grants Track” in the symposium has given me profound encouragement to establish myself as a pioneer in the big picture.

– Kuladip Jana, PhD, Bose Institute, Kolkata, West Bengal, India

The symposium was interesting, educative and most of all able to bring people of common interest to share experiences and strengthen linkages for the good of animals.

– Gudush Jalloh, DVM, director, Sierra Leone Animal Welfare Society (SLAWS)

Very professionally run. Attracted a diverse range of participants that injected great interest into the proceedings and kept the discussions focused and practical.

– Peter Howe, BVSc, MScMed, PhD, MACVSc, Vets Beyond Borders Inc., Australia



I found it heartening to see so many talented people, with such diverse backgrounds and varied expertise, coming together to apply their energies to finding innovative, pragmatic, and globally sustainable solutions to the pet overpopulation problem.

– John Boone, PhD, wildlife biologist and member of the Board of Directors, SPCA of Northern Nevada

I was impressed at the wide scope of the conference and the attendees and speakers from all over the world. The conference was a good reminder for those of us in the U.S. that there is not only a national crisis but a global one.

– Amanda Arrington, spay/neuter initiatives manager, Humane Society of the United States

This is my favorite conference because it brings people in animal welfare, science, veterinary medicine, and other fields together. Everyone focuses on solving the same problem and leaves with so many new ideas they would never have thought of on their own.

– Holly Anderson, veterinary student, Cornell College of Veterinary Medicine

I thought the symposium was a great gathering of a diverse group of people both nationally and internationally — NGOs, shelter medicine veterinarians, biomedical researchers, and field workers. It was great to see people come together in the name of animal welfare. I think the symposium did a commendable job at accentuating this idea of all of us working together to solve the pet overpopulation problem in a humane manner.

– Chumkee Aziz, veterinary student, Tufts Cummings Veterinary School

A source of inspiration and with excellent speakers. The food was also good, and the location was conducive to a good-level networking.

– Stefano Romagnoli, DVM, MS, PhD, Dipl-ECAR, professor, University of Padova, Italy

First class meeting.

– Roy Brenton Smith, DVM, treasurer, American Association of Feline Practitioners

I was impressed by the quality of the speakers discussing various possibilities of one non-surgical treatment for permanent or long duration contraception in dogs and cats. I am convinced that excellent researchers working all over the world, supported by the Michelson grants, will eventually develop such a treatment. It would be fantastic to have a non-surgical method for contraception for countries with a high overpopulation of dogs and cats, which leads to euthanasia of many animals and problems with human health, for example, due to rabies. But it would be also very important for the animals in countries where overpopulation is not a real problem. It is much better for the animal and more ethical if we can prevent an invasive surgery such as a castration or ovariectomy by a non-surgical contraception method, assuming that it is a safe method without nasty side effects. This conference convinced me that it has to be possible to develop such a method in the coming years.

– Auke Schaeffers-Okkens, PhD, DVM, Dipl-ECAR, veterinary faculty, Utrecht, the Netherlands