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11:00 AM - Urinary Tract Infection Treatment and Prevention
  Dr. Gary Oswald

Saturday, May 20, 2017, Room 3DE
1:45 PM - Stuck in the Stone Age: What you need to know
  Dr. Jody Lulich
3:15 PM - To Pee or Not to Pee, The Sr. Pet Dilemma
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Table of Contents

Anesthesia
Mike Barletta, DVM, MS, PhD, DACVAA
Acute pain and nociception: A case based discussion ...... 1
Anesthesia for patients with respiratory diseases............ 3
Anesthesia machines and breathing systems: How they work and what you should know........................................... 5
How to test and troubleshoot the anesthesia machine ...... 8
Local anesthetic blocks for dental procedures ............... 10
Local anesthetic drugs: How they work and why we should use them ....................................................... 11
Understanding capnography: A case based discussion ... 14
Understanding the ECG: A case based discussion ............ 16

Behavior
John Ciribassi, DVM, DACVB
Canine body language: But what do you really mean?...... 18
Fear-based aggression: I’m afraid of you so I would like to eat you................................................................. 19
Feline elimination disorder: Making litter the letter of the law................................................................. 21
Resource guarding: What’s mine is mine and what’s yours is mine .................................................................. 25
Separation anxiety: Can’t you just quit your job? .......... 27
Sibling rivalry: When roommates come to blows .......... 31

Beth Strickler, MS, DVM, DACVB
Changing behavior pharmacologically:
Which drug do I use? ....................................................... 36
How do animals learn: What’s all that psychobabble? ..... 38
How to efficiently create and implement behavior treatment plans .......................................................... 40
When the thunder rolls: Managing storm and noise phobia ................................................................. 41
Why can’t we all just get along? Managing feline aggression in the home .......................................................... 43
Why won’t my clients do what I ask? Motivating the behavior client ........................................................... 45

Canine Sports Medicine and Rehabilitation
Nic Cabano DVM, MS, DACVS, DACVSMR
Case study: Rocky’s abdominal evisceration .....................No Proceedings Required
Common working dog rehabilitation modalities:
Discretion is the better part of valor ......................................No Proceedings Required
Common working dog surgical procedures:
Elite athlete injuries and their management .....................No Proceedings Required

Garret Pachtinger, VMD, DACVECC
Common coagulopathies ........................................... 101
Cardiovascular emergencies in the ER/ICU ................. 104
Common emergency procedures .................................. 108
Effusion confusion ..................................................... 113
Endocrine emergency: The GREAT pretender!
Hypoadrenocorticism ................................................ 115
Feline lower urinary tract disease .................................. 117
If you can’t take the heat...you are probably a bulldog!
Heat stroke in the ER ................................................ 120
Lyme disease: Treating acute and chronic manifestations ................................................................. 123

Dawn Boothe, DVM, MS PhD, DACVIM, DACVCP
Antimicrobial decision making: Interpreting culture and susceptibility data .................................................. 65
Antimicrobial resistance: The state of affairs in dogs and cats ................................................................. 69
Compounded medications: Getting more complicated ......... 73
Does reading that package insert REALLY make a difference? ................................................................. 77
Pharmacogenomics: The role in drug interactions and adverse drug events ............................................. 81
Targeted drug therapy: Enhancing efficacy and safety ...... 85
The MIC is the key: Designing antimicrobial dosing regimens ................................................................. 89
Treating urinary tract infections: The new and the old ...... 91

Critical Care
Kari Santoro Beer, DVM, DACVECC
All about the pain train: Safe analgesia in the ER ............ 97
All bleeding stops eventually:
Common coagulopathies ........................................... 101
Cardiovascular emergencies in the ER/ICU ................. 104
Common emergency procedures .................................. 108
Effusion confusion ..................................................... 113
Endocrine emergency: The GREAT pretender!
Hypoadrenocorticism ................................................ 115
Feline lower urinary tract disease .................................. 117
If you can’t take the heat...you are probably a bulldog!
Heat stroke in the ER ................................................ 120
Lyme disease: Treating acute and chronic manifestations ................................................................. 123

Kari Santoro Beer, DVM, DACVECC
Emergency approach to the hemoabdomen ................... 125
Head trauma without headaches ................................... 127
Medical management of thoracic trauma ..................... 129
OMG, Acute Kidney Injury!! What do I do now? ........... 132
Should I use plasma for that? The truth about FFP ............ 135
Stabilization and ER management of blocked cats ......... 137
The highs and lows:
ER management of diabetic crises ................................ 139
What’s new with fluids in 2017? .................................. 142

Cardiology
Kristin Jacob, DVM, DACVIM
Mitral valve disease in dogs - Truly epic ......................... 47
Systemic hypertension: How low can you go? ................ 49
Why is evaluating chest radiographs so difficult?
Cardiac case-based interpretation tips to make your life easier ................................................................. 52

Neal Peckens, DVM, DACVIM
A practical approach to arrhythmias ............................... 54
Syncope: Diagnosis and management .......................... 58
The clinical utility of NT-proBNP in veterinary cardiology ................................................................. 62

Clinical Pharmacology
Dawn Boothe, DVM, MS PhD, DACVIM, DACVCP
Antimicrobial decision making: Interpreting culture and susceptibility data .................................................. 65
Antimicrobial resistance: The state of affairs in dogs and cats ................................................................. 69
Compounded medications: Getting more complicated ......... 73
Does reading that package insert REALLY make a difference? ................................................................. 77
Pharmacogenomics: The role in drug interactions and adverse drug events ............................................. 81
Targeted drug therapy: Enhancing efficacy and safety ...... 85
The MIC is the key: Designing antimicrobial dosing regimens ................................................................. 89
Treating urinary tract infections: The new and the old ...... 91

Clinical Pharmacology
Dawn Boothe, DVM, MS PhD, DACVIM, DACVCP
Antimicrobial decision making: Interpreting culture and susceptibility data .................................................. 65
Antimicrobial resistance: The state of affairs in dogs and cats ................................................................. 69
Compounded medications: Getting more complicated ......... 73
Does reading that package insert REALLY make a difference? ................................................................. 77
Pharmacogenomics: The role in drug interactions and adverse drug events ............................................. 81
Targeted drug therapy: Enhancing efficacy and safety ...... 85
The MIC is the key: Designing antimicrobial dosing regimens ................................................................. 89
Treating urinary tract infections: The new and the old ...... 91
Experience Elanco at Booth #1002
Dentistry
John Lewis, VMD, FAVD, DAVDC
Complications of extractions and how to avoid them........................................... 144
Feline dentistry: Stomatitis, tooth resorption, and more.. 146
In the dark: Dental radiograph interpretation ......................................................... 149
It’s like pulling teeth: Surgical extraction techniques .............................................. 153
Making the diagnosis: Dental hyperplasia .............................................................. 156
Open wide: Dental exam and common oral pathology........................................... 158

Dermatology
Paul Bloom, DVM, DACVD, DABVP
Atopic dermatitis: The new paradigm and how it changes the way we treat it................................. 162
Canine cutaneous adverse food reactions: Diagnosis and treatment............................................. 170
New drugs in veterinary dermatology – updates and debates............................. No Proceedings Required
Quick, easy, and profitable dermatologic tests for small animal practice................................. 174
Resistant bacteria are coming to your neighborhood - MRSA, MRSP, MRSS: Proper antibiotic use in small animal dermatology – what should we be using? (Part 1) ................................................................. 179
Resistant bacteria are coming to your neighborhood - MRSA, MRSP, MRSS: Proper antibiotic use in small animal dermatology – what should we be using? (Part 2) ................................................................. 179
Simplified diagnosis and management of autoimmune skin diseases – including discussion of immunosuppressive therapy ................................................................. 187
What is new about canine demodicosis?............................................................................. 193

Anthea Schick, DVM, DACVD
Be among the first to know! News flashes from the North American Veterinary Dermatology Forum ................................................................. 199
Common skin tumors and treatments ........................................................................... 202
Cryotherapy in practice .................................................................................................. 204
Dermatology diagnostics: Review and updates on the many ways to obtain and interpret skin and ear samples........................................................................................................... 207
Fun with fungus: New ideas on managing ringworm ..................................................... 210
Managing atopic dermatitis ........................................................................................... 213
Primary secretory otitis media ......................................................................................... 215
Unlocking the mysteries of the ear: Diagnosing otitis and dealing with chronic otitis................................................................................................................................. 217
When to refer: Tricks on managing difficult cases and where dermatologists can help ................................................................................................................................. 222

dvm360 Full Circle
Andrew Roark, DVM, MS and Tasha McNerney, BS, CVT, CVPP, VTS (Anesthesia/Analgesia)
Epic fails in team harmony .............. No Proceedings Required
Top traps that vets set for techs .. No Proceedings Required
What Hall & Oates taught me about veterinary medicine........................................... No Proceedings Required

Andrew Roark, DVM, MS and Meghan Leigh Pierson Customer service crash course ... No Proceedings Required
Technician gold in the exam room ................................................................................. No Proceedings Required
Wowing clients who aren’t in the building ................................................................ No Proceedings Required

Endocrinology
Karen Eiler, DVM, DACVIM
Canine hypothyroidism: A review and what’s new .................................................... 162
Feline hypothyroidism: Diagnosis, treatment, and where dietary management fits in ................................................................................................................................. 170

Exotics
La'Toya Latney, DVM
Clinical approach to Ferret lymphoma.................................................................. 228
Exotic animal owners 101: How to increase your clientele ............................................. 231
Managing head trauma in exotic pets ............................................................................ 233
The ‘phys’ behind the physical exam in reptiles ............................................................. 241
Updates in small mammal medicine ............................................................................. 243

Expert2: The Power of Interaction – Cool views in virtual microscopy
Steven Stockham, DVM, MS, DACVP
Red cell cadavers in anemic blood (Part 1) ................................................................. 247
Red cell cadavers in anemic blood (Part 2) ................................................................. 252
What are the cells from that lump? .............................................................................. 257
White cell cadavers of leukocytosis ............................................................................. 259
Cases of cavitary effusion: What’s filling that space? ................................................. 262
Cases of cavitary effusion: What’s filling this space? ................................................. 265

Fear Free℠ Practice
Marty Becker, DVM
A look inside a wildly successful practice that’s been Fear Free℠ for over five years ................................................................................................................................. 272
Top 10 things to avoid in a Fear Free℠ practice ......................................................... 274
Top 10 things to do to provide true Fear Free℠ veterinary visits ..................................... 274
Gastrointestinal Medicine
David Twedt, DVM, DACVIM
Acute pancreatitis in dogs.............................................. 346
Diseases of an often forgotten organ: The esophagus.... 350
Helping cats that have chronic vomiting............... 353
Those troublesome chronic diarrhea cases............... 357
Update on feline liver disease ....................................361
What's new? Emerging liver diseases ......................... 365
Assessing abnormal liver enzymes activities:
A clinical approach ..................................................369
Chronic hepatitis in dogs: The latest updates............373
Common liver diseases in dogs.................................377

Human-Animal Bond: Data to Transform Practice
Steve Feldman; Patrick Flynn, DVM; Laird Goodman, DVM; and Rebecca Johnson, PhD, RN, FAAN, FNAP
HAB panel discussion .......................No Proceedings Required
One hour HAB: Overview of HAB in science, society, and veterinary healthcare
................................................................................ No Proceedings Required
Patrick Flynn, DVM
The pet effect: Wonder and why of connection
..............................................................................No Proceedings Required
Laird Goodman, DVM
Bond-centered practice: Applying and prescribing the HAB...........................................No Proceedings Required
Rebecca Johnson, PhD, RN, FAAN, FNAP
Be healthy, get a pet: The human health benefits of pet ownership ..................No Proceedings Required

Neurology
Fred Winger, VMD, MS, DACVIM
A pain in the neck: Cervical myelopathies.................. 380
CSF: Who, what, when, where, how?.......................... 382
Dizzy now? Vestibular syndromes ............................. 383
Intervertebral disc disease: What is a generalist to do? ........................................No Proceedings Provided
I've fallen and I can't get up: The acute lower motor neuron patient .......................... 385
MRI-what's this big deal ...........................................388
Neuro-localization basics – 4th year 101 ..................... 390
Status Epilepticus in the 21st century .........................392
The Gait Game: A neurolocalization review ..............395

Nutrition
Deborah Linder, DVM, DACVN
Do I need a therapeutic food? A nutritionist’s approach to selecting diets in disease ..................397
Making client communication appetizing: Talking with owners about nutrition ................. 400
Parenteral or enteral feeding? Nutrition for hospitalized patients .....................................402
Should we still give a dog a bone? Nutritional management of dental disease .......... 405
To cook or not to cook? When to choose home-cooked diets for pets .................................407
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*Studies show Simparica starts killing ticks in 8 hours and is ≥96.9% effective for 35 days against weekly reinfestations of Ixodes scapularis, Amblyomma americanum, Amblyomma maculatum, Dermacentor variabilis, and Rhipicephalus sanguineus.1,2

SAROLANER (sarolaner) Chewables

FOR ORAL USE IN DOGS ONLY

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:
SAROLANER is a flavored, chewable tablet for administration to dogs over 6 months of age according to their weight. Each tablet is formulated to provide a minimum sarolaner dosage of 0.91 mg/lb (2 mg/kg) body weight.

Sarolaner is a member of the isoxazoline class of parasiticides and the chemical name is 1 improbable to humans.

Mode of Action:
The active substance of SIMPARICA, sarolaner, is an acaricide and insecticide belonging to the isoxazoline class of parasiticides. This class of compounds has a unique mode of action, making it different from that of traditional ectoparasite treatments. Sarolaner binds to and blocks the neuronal chloride channel (GABA) receptor, resulting in uncontrolled neuromuscular activity leading to death in insects or acarids.

Indications:
SIMPARICA kills adult fleas, and is indicated for the treatment and prevention of flea infestations (Ctenocephalides felis), and the treatment and control of tick infestations (Amblyomma americanum [lone star tick], Amblyomma maculatum [Gulf Coast tick], Dermacentor variabilis [American dog tick], Ixodes scapularis [black-legged tick]) for one month in dogs 6 months of age or older and weighing 2.8 pounds or greater.

Dosage and Administration:
SIMPARICA is given orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg) body weight.

Flea Treatment and Prevention:
Treatment with SIMPARICA may begin at any time of the year. Effective flea control can be achieved through simultaneous treatment of all dogs and cats in a household with an approved flea control product.

Contraindications:
There are no known contraindications for the use of SIMPARICA.

Warnings:
Not for use in humans. Keep this and all drugs out of reach of children and pets. For use in dogs only. Do not use SIMPARICA in cats.

Precautions:
SIMPARICA may cause abnormal neurologic signs such as tremors, decreased conscious proprioception, ataxia, decreased or absent menace, and/or seizures (see Animal Safety). The safe use of SIMPARICA has not been evaluated in breeding, pregnant, or lactating dogs.

Adverse Reactions:
SIMPARICA was administered in a well-controlled US field study, which included a total of 479 dogs (385 dogs treated with SIMPARICA and 164 dogs treated with active control) once monthly for three treatments. Over the 90-day study period, all observations of potential adverse reactions were recorded. Table 1. Dogs with adverse reactions

Table 1. Dogs with adverse reactions

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>sarolaner</th>
<th>sarolaner</th>
<th>active control</th>
<th>active control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>3</td>
<td>0.95%</td>
<td>9</td>
<td>5.50%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2</td>
<td>0.63%</td>
<td>2</td>
<td>1.20%</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>1</td>
<td>0.32%</td>
<td>2</td>
<td>1.20%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>1.80%</td>
</tr>
</tbody>
</table>

Additionally, one female dog aged 8.6 years exhibited lethargy, ataxia while posturing to eliminate, elevated third eyelids, and inappetence one day after receiving SIMPARICA concurrently with a heartworm preventative (ivermectin/pyrantel pamoate). The signs resolved one day later. After the day 14 visit, the owner elected to withdraw the dog from the study.

Clinical Pharmacology:
Sarolaner is rapidly and well absorbed following oral administration of SIMPARICA. In a study of 12 Beagle dogs, the mean maximum plasma concentration (C_{max}) was 100 ng/mL and the mean time to maximum concentration (T_{max}) occurred at 3 hours following a single oral dose of 2 mg/kg to fasted animals. The mean oral bioavailability was 96% and 107% in fasted and fed dogs, respectively. The mean oral T_{1/2} values for fasted and fed animals was 10 and 12 days, respectively.

Sarolaner is distributed widely; the mean volume of distribution (Vds) was 2.91 L/kg intravenous dose of sarolaner. Sarolaner is highly bound (>99.9%) to plasma proteins. The metabolism of sarolaner appears to be minimal in the dog. The mean time of sarolaner elimination from dogs is biliary excretion with elimination via the feces.

Following repeat administration of SIMPARICA once every 28 days for 10 doses to Beagle dogs at 1X, 3X, and 5X the maximum intended clinical dose of 4 mg/kg, sarolaner systemic exposure was dose proportional over the range 1X to 5X.

Mode of Action:
The active substance of SIMPARICA, sarolaner, is an acaricide and insecticide belonging to the isoxazoline group. Sarolaner inhibits the function of the neurotransmitter gamma-aminobutyric acid (GABA) receptor and glutamate receptor, and works at the neuro muscular junction in insects. This results in uncontrolled neuromuscular activity leading to death in insects or acarids.

Effectiveness:
In a well-controlled laboratory study, SIMPARICA began to kill fleas 3 hours after initial administration and reduced the number of live fleas by 96.2% within 8 hours after flea infestation through Day 35. In a separate well-controlled laboratory study, SIMPARICA demonstrated 100% effectiveness against adult fleas within 24 hours following treatment and maintained 100% effectiveness against weekly re-infestations for 26 days. In a study to explore flea egg production and viability, SIMPARICA killed fleas before they could lay eggs for 35 days. In a study to simulate a flea-infested home environment, with flea infestations established prior to the start of treatment and re-infestations on Days 7, 37, and 67, SIMPARICA administered monthly for three months demonstrated >96% reduction in adult fleas within 14 days after treatment and reached 100% on Day 60. In well-controlled laboratory studies, SIMPARICA demonstrated 99% effectiveness against an initial infestation of Amblyomma americanum, Amblyomma maculatum, Dermacentor variabilis, Ixodes scapularis, and Rhipicephalus sanguineus 48 hours post-administration and maintained 96% effectiveness 48 hours post-re-infestation for 30 days.

In a well-controlled 90-day US field study conducted in households with existing flea infestations of varying severity, the effectiveness of SIMPARICA against fleas on Day 30, 60, and 90 when compared to baseline was 99.4%, 99.8%, and 100%, respectively. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/grydermatitis and pruritus as a direct result of eliminating fleas.

Animal Safety:
In a margin of safety study, SIMPARICA was administered orally to 8-week-old Beagle puppies at doses of 0, 1X. 3X, and 5X the maximum recommended dose (4 mg/kg) at 28-day intervals for 10 doses (8 dogs per group). The control group received placebo tablets. None of the neurologic signs were observed in the 1X group. In the 3X group, one male dog exhibited tremors and ataxia post-dose on Day 0; one female dog exhibited tremors on Days 1, 2, and 5; and one female dog exhibited tremors on Day 1. In the 1X group, one male dog had a seizure on Day 61 (3 days after dose); one female dog had tremors post-dose on Day 0 and abnormal head coordination after dosing on Day 140; and one female dog exhibited seizures associated with the second and fourth doses and tremors associated with the second and third doses. All dogs recovered without treatment. Except for the observation of abnormal head coordination in one dog in the 5X group two hours after dosing on Day 140 (dose 6). There were no treatment-related neurologic signs observed once the dogs reached the age of 6 months.

In a separate exploratory pharmacokinetic study, one female dog dosed at 12 mg/kg (3X the maximum recommended dose) exhibited lethargy, anorexia, and mild neurological signs including ataxia, tremors, disorientation, hypersalivation, diminished proprioception, and absent menace, approximately 2 days after a third monthly dose. The dog was not treated, and was ultimately euthanized. The first two doses resulted in plasma concentrations that were consistent with those of the other dogs in the treatment group. Starting at 7 hours after the third dose, there was a rapid 2.5 fold increase in plasma concentrations within 41 hours, resulting in a C_{max} more than 7-fold higher than the mean C_{max} at the maximum recommended use dose. No cause for the sudden increase in sarolaner plasma concentrations was identified.

Storage Information:
Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).

How Supplied:
SIMPARICA (sarolaner) Chewables are available in six flavored tablet sizes: 5, 10, 20, 40, 80, and 120 mg. Each tablet size is available in color-coded packages of one, three, or six tablets.

References:
Zoetis Inc., Kalamazoo, MI 49007
Made in Switzerland Revised: March 2017
50070900A&P

Additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth/
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Oncology
Sue Ettinger, DVM, DACVIM
Canine MCT: One size does not fit all
Easy ways to improve chemotherapy treatment in your practice
Essential tips for splenic masses
Let’s talk about cancer: Breaking the news
Osteosarcoma survival guide
Ready, set, go pink: The veterinary mammary cancer edition

Launch Pad Learning - Oncology
Cancer tools you can use tomorrow:
Canine lymphoma
Feline GI lymphoma

Ophthalmology
Mark Bobofchak, DVM
Eyelid Disease and Surgery
Glaucoma Update
The Canine Lens: Clarification of a cloudy topic

Heather Kaese, DVM, MS, DACVIM, DACVO
Feline Ophthalmology: What’s new in treating the feline eye?
Ocular examination: Lids to retina
Ocular pharmacology: Ulcers to uveitis to glaucoma

Rustin Sturgeon, DVM, DACVO
An ocular surgery for everyone! A review of enucleation and perioperative pain management
Avoid diabetic disasters with increased ocular vigilance

Neal Wasserman, DVM, DACVO
Management of complicated corneal ulcers: What to do when antibiotics aren’t working

Orthopedics
David Dycus, DVM, MS, DACVS, CCRP
A surgeon’s perspective on the current trends in managing osteoarthritis
It’s a puppy, what could go wrong? Developmental orthopedic conditions
Regenerative medicine in orthopedics: A new approach to an old problem

Pain Management
Michael Petty, DVM, CVPP, CVMA, CCRT, CAAPM
Acute on top of chronic pain in geriatric patients
An update on NSAID use and safety
The business of pain management
The use of cannabidiols for the treatment of pain
Launch Pad Learning - Pain Management
Myofascial pain therapy and massage for successful surgical and pain treatment outcomes
Perioperative anesthesia and pain control – with Mary Ellen Goldberg, BS, LVT, CVT, SRA, CCRA

Parasitology
Rick Alleman, DVM, PhD, DABVP, DACVP
Part I: Ticks, Tick Pathogens, and the Veterinarian in One Health
Part II: Ticks, Tick Pathogens, and the Veterinarian in One Health

Richard Gerhold, DVM, MS, PhD
Update on tick-borne diseases of humans: Focus on One Health
Cough it up: Respiratory parasites of animals
Migrating heartworm: Diagnostics and treatment
Neospora, Toxoplasma, and coccidia: Microscopic monsters
Update on tick-borne diseases
Wildlife diseases important for practitioners to know

Richard Goldstein, DVM, DACVIM (SAIM), DECVIM-CA
The Latest on Lyme: Optimizing prevention through total tick control and vaccination

Public Health in Primary Care Practice: People are animals, too!
Audrey Ruple DVM, MS, PhD, DACVP
Chikungunya, West Nile, and Zika, oh my!
Emerging zoonotic viruses and the One Health approach
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The veterinarian’s role in public health
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Shelter Medicine
Amanda Dykstra, DVM
Are dogs really “socratly aware?” New research results on scrotal vs. prescutal castration................................................51
Feline herpesvirus-1: A review and exploration of the role stress plays in upper respiratory infections......................514
Trap-neuter-return and Shelter-neuter-return: What have we learned recently?.................................................................520
Launch Pad Learning - Shelter Medicine
Investigating and responding to an outbreak:
Sudden death in shelter cats.................................................................523

Social Media and Digital Marketing
Bill Schroeder
25 big digital marketing hacks ............................................................527
Monitoring digital marketing: How to check your ROI .... 528
SEO basics: How to convert “prospects” into “clients”...530
Sharing your message: Storytelling in your practice........532

Soft Tissue Surgery
Christopher Adin, DVM, DACVS
5 skin closure techniques that you should be using in practice Proceedings Not Provided
Challenging cases in oncologic surgery: When to cut and when to quit Proceedings Not Provided
Is it septic? What you need to know about acute abdomens Proceedings Not Provided
It’s huge! How to handle masses of the liver and spleen Proceedings Not Provided
Kidney and urethra stones in cats: A decision-making tree Proceedings Not Provided
Refractory incontinence in dogs: Stop the leak Proceedings Not Provided

Toxicology
Tina Wismer, DVM, DABVT, DABT
Everyday household hazards .............................................................534
Fascinating topics in clinical toxicology ........................................538
Intoxications of marijuana and new cannabinoid products ........541
Myths and misconceptions in toxicology ........................................544
Toxicity of human medications ......................................................547
Toxicity of veterinary medications .....................................................551
Treating tough toxins .....................................................................554

Urology
India Lane, DVM, MS, Ed. D, DACVIM
Angry bladder tumors: Practical diagnosis and management ........558
Big, angry prostate: Update on canine prostatic disease ..............560
Little angrier bladders: Options for refractory FIC .........................563
Little angry bladders: First steps for nonobstructive FIC ..............567
Little, leakier bladders: Options for refractory incontinence ........570
Little, leaky bladders: First line medical management of canine urinary incontinence .....................................................573

USDA/NVAP
Module 2: Role of agencies, health certificates Proceedings Not Provided
Module 3: Overview of foreign animal, program, and reportable diseases Proceedings Not Provided
Module 7: Foreign animal disease detection in Category 1 animals Proceedings Not Provided
Module 9: Interstate and international health certificates for Category 1 animals Proceedings Not Provided
Module 25: Using behavior to assess animal welfare Proceedings Not Provided

Veterinary Hospice and Palliative care
Dani McVety, DVM
Avoiding career burnout ................................................................577
Compassion fatigue or ethical fatigue? ......................................578
Creative euthanasia: What to do when you don’t know what to do ...............................................................................580
Euthanasia: What words you should – and should not – be using .........................................................................................583
The art of euthanasia and the science of death .........................587
The ethics of euthanasia: Is it a convenience or not? ......593

Veterinary Informatics in General Practice
Sonnya Dennis, DVM, DABVP; Jonathan Lustgarten, MS, PhD, VMD; and Pamela Okerholm, MS
Better data saves pets: How informatics can help pets and practices ..............................................................594

Julie Green, DVM, MS
Your master problem list: Working for or against you? ....595

Veterinary Leadership
Karen Bradley, DVM; Kimberly-Ann Therrien, DVM; and Sarah Wooten, DVM
Girlfriends’ guide to surviving a veterinary career: Best advice you NEVER GOT! .........................................................599
Squeezing out of the gender #wagegap ........................................599
Veterinarians against for humanity: A career adventure game for (un)conventional professionals .........................................................603

Betsy Charles, DVM, MA
Emotional Intelligence 101: The three hours no one got—and everyone needed—in vet school ..........................................................607

The ethics of euthanasia: Is it a convenience or not? ......593

xiii
You think that a lawsuit could never happen to you?

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Hilal Dogan, BVSc
Why the Veterinary Confessionals Project could help heal the profession - and you
.................................................................No Proceedings Required
Kimberly Pope-Robinson, DVM, CCFP
Diagnosing and treating frustration – yours (with seemingly uninformed, skeptical, or unappreciative pet owners) ............................................. 598
Top 10 tips: How to become a recovering perfectionist .600
Training for the marathon we call a career in veterinary medicine .................................................. 602
When the fearful animal is you: How to differentiate perceived threats from real danger ....................... 605
Launch Pad Learning - Wellness
The violinist and the veterinarian: How to acknowledge beauty and value in your work – when others may not .................................................................No Proceedings Required

Practice Management
Brian Conrad, CVPM
Ask the pet owner: A LIVE panel and learning session ....................No Proceedings Required
From recommendation to invoice:
The compliance cycle .................................................................Proceedings Not Provided
Girls just wanna have fun: Creating an enjoyable workplace .........................................................Proceedings Not Provided
Owning and running: If it were easy, everyone would do it ............................................................Proceedings Not Provided
Phone calls gone bad: Coaching receptionists (kindly) with recordings .............................................608
The new client treasure chest: Where can I find THAT? .................................................................Proceedings Not Provided
The world’s best managers share their top solutions .................................................................Proceedings Not Provided
What happens in the treatment area doesn’t stay there: How to communicate value for clients and their pets .................................................................Proceedings Not Provided
Launch Pad Learning - Practice Management
Forget the P&L: Sharing real numbers with your team .....................................................................................Proceedings Not Provided

Bash Halow, LVT, CVPM
Clear! Shock your team to life with these energizing strategies .............................................................. 610
Creating better expectations for interpersonal behavior in practice .......................................................... 612
How to accomplish goals in practice without losing your cool .................................................................. 613
Trends shaping veterinary practice and careers by 2020 and beyond .......................................................... 615
Launch Pad Learning - Practice Management
Client compliance builder workshop: Inspiring ideas to drive medical services ........................................ 623
Jeremy Keen, DVM
From veterinarian to betterinarian: How I improved my production .......................................................... 625
How to rock ‘n’ roll with your staff: Getting it done ............................................................................... 628
Oh, those clinic smells! What your clients’ senses are telling them ..........................................................630

Dave Nicol, BVMS, MRCVS
3 years, 3 continents, $1M earned: Lessons learned from an extraordinary journey ...........................................Proceedings Not Provided
7 elements to the perfect exam-room visit ...............................................................................................Proceedings Not Provided
9 leadership lessons that will change your life
(Part 1) .............................................................................................Proceedings Not Provided
9 leadership lessons that will change your life
(Part 2) .............................................................................................Proceedings Not Provided
Tips to unplug from the Matrix and take back your life .............................................................................Proceedings Not Provided
Why ego is crushing medicine (and business) and what you can do about it ............................................Proceedings Not Provided

Dave Nicol, BVMS, MRCVS and Andrew Roark, DVM, MS
Management happy hour .............................................................................................................................No Proceedings Required

Kathryn Primm, DVM
5 things you must ask before your boss retires ..................................................................................... 632
Finding new clients isn’t match.com, but you still want a good fit ................................................................ 634
How to grow – not fight – with local competitors ..................................................................................... 636

Bill Schroeder
Paid social media: The art of “pay to play” on social networks ..................................................................... 638
Protecting your practice with a great social media policy .............................................................................. 640
Why should corporations have all the fun? Use logo and colors to create a memorable experience ............ 642

Denise Tumblin, CPA
Online pharmacies: Take in the good, get rid of the bad ................................................................................. 644
The elusive 20% ROI: Can it be done? ........................................................................................................... 647
The inside skinny on boosting revenue ........................................................................................................... 651

Niqole Varani, DVM and Monica Perry, CVPM
Essentials of HR: Compensation ............................................................................................................... 655
Essentials of HR: Employee manual ............................................................................................................ 661
Essentials of HR: Hiring .............................................................................................................................. 666
Essentials of HR: Motivation and retention .................................................................................................... 679
Essentials of HR: Performance and termination ............................................................................................ 684
Essentials of HR: Training and the first 90 days ............................................................................................ 693

John Volk
Financial tools that can get clients to say ‘yes’ ............................................................................................... 702
How pet owners are changing and what it means to your practice ............................................................... 705
How to make pet insurance your practice’s new best friend ..................................................................... 708

Sarah Wooten, DVM
5 things associates should be doing now ................................................................................................. 710
Pimp my brain: A crash course in perspective taking .................................................................................. 712
Sharpen your soft skills, change your life ..................................................................................................... 713
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Technician Program

Benita Altier, LVT, VTS (Dentistry)
Advanced Periodontal Therapy for Veterinarians and Technicians ................................................... 741
Dental Radiographs – Tips and Tricks .............................................. 717
Dental Instruments: Care and Sharpening ............................................. 720
Oral Anatomy, Pathology, and Charting ................................................ 724
Regional Anesthesia for Veterinary Dentistry ........................................... Proceedings Not Provided
The Professional Dental Procedure for Veterinarians Technicians .......... 729

Paul Bloom, DVM, DACVD, DABVP
Technician’s role in the management of ear disease ........... 734

Dawn Boothe, DVM, MS PhD, DACVIM, DACVCP
The high points of medical marijuana and cannabinoids .............................................. 739

Sue Ettinger, DVM, DACVIM
What to do with lumps and bumps: Why wait? Aspirate! ............................................ 743

Richard Gerhold, DVM, MS, PhD
Testing beyond the fecal centrifugation .................................................... 746

Mary Ellen Goldberg, BS, LVT, CVT, SRA, CCRA
Feline physical rehabilitation and the veterinary technician ............................................. 747
How can I be a patient advocate in pain management for exotics and zoo animals? ............... 751
Obesity/weight management and physical rehabilitation .................................................... 755

India Lane, DVM, MS, Ed. D, DACVIM
Pertinent pee pills ........................................................................... 760

LaToya Latney, DVM
Post-operative patient management in herbivores ............................................ Proceedings Not Provided

Deborah Linder, DVM, DACVN
Finicky felines and picky pooches: Strategies for patient inappetence ........................................ 763

Debbie Martin, LVT, VTS (Behavior)
Kitten start right: Preventing behavioral problems in kittens ............................................. 767
Prevention is easier than treatment! The importance of preventive behavioral services .............. 770
Puppy start right: Preventing behavioral problems in puppies ............................................. 772

Tasha McNerney, BS, CVT, CVPP, VTS (Anesthesia/Analgesia)
Launch Pad Learning - Technician Clinical Program
Anesthesia basics and beyond: Things you learned in school but have forgotten ........................................ 775

Dani McVety, DVM
Your personal curb appeal: Body language for anyone! ................................. 778

Garret Pachtinger, VMD, DACVECC
Cats are not small dogs...and I’ll show you why......................... 782

Paula Plummer, LVT, VTS (ECC, SAIM)
Canine and feline diabetes ................................................................. 784
How to handle multiple emergencies ................................................... 786
ICU boot camp: What you should know on day 1 ....................... 790
In the trenches of transfusion medicine ............................................... 794
The unstable feline diabetic patient ...................................................... 796
What every technician should know about feline hyperthyroidism ............................................ 800

Kimberly Pope-Robinson, DVM, CCFP
Teams in the trenches - what 12-mile mud runs teach us about working in a veterinary hospital .... 804

Danielle Russ, LVT, BS, BA, AS
Being fearless in management ................................................... Proceedings Not Provided
Constructive criticism: Fact or fiction? ................................................... Proceedings Not Provided
Needs care, no $$$...what now? ................................................... Proceedings Not Provided

Kari Santoro Beer, DVM, DACVECC
Stabilization and monitoring of the critical patient ............................................ 805

Anthea Schick, DVM, DACVD
Allergies explained: How to help your clients understand why their pet is itchy and how we can help ........................................................................ 807

Oriana Scislowicz, BS, LVT
Beat back bullies in your practice ................................................... 809
Project you: Care and feeding for a long-lasting team .............................................. 810
Solve the Bermuda triangle of triangulated conversations ............................................. 811

Steven Stockham, DVM, MS, DACVP
Unidentified microscopic objects (UMOs): Red cell cadavers ................................... Proceedings Not Provided
Unidentified microscopic objects (UMOs): White cell cadavers................................... Proceedings Not Provided

Fred Wininger, VMD, MS, DACVIM
Managing acute spinal cord injury ....................................................... 812
Meet The Speakers

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Mike Barletta, DVM, MS, PhD, DACVAA
University of Georgia
Athens, GA

Behavior
John Ciribassi, DVM, DACVB
Chicagoland Veterinary Behavior Consultants
Carol Stream, IL
Beth Strickler, DVM, DACVB
Veterinary Behavior Solutions
Nashville, TN

Canine Sports Medicine and Rehabilitation
LTC Nic Cabano, DVM, MS, DACVS, DACVSMR
USAFA Academy
FT. Carson, CO

Cardiology
Kristin Jacob, DVM, DACVIM
CVCA Cardiac Care for Pets
Towson, MD
Neal Peckens, DVM, DACVIM
CVCA Cardiac Care for Pets
Leesburg, VA

Clinical Pathology
*Steven Stockham, DVM, MS, DACVP
Kansas State University
Manhattan, KS

Clinical Pharmacology
*Dawn Boothe, DVM, MS, PhD, DACVIM, DACVCP
Auburn University
Auburn, AL

Critical Care
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(Anesthesia/Analgesia)
Veterinary Anesthesia Nerds
Glenside, PA
Andrew Roark, DVM, MS
Cleveland Park Animal Hospital
Greenville, SC

Endocrinology
Karen Eller, DVM, DACVIM
VCA West Los Angeles Animal Hospital
Los Angeles, CA

Exotic Animal Medicine
*LaToya Latney, DVM
University of Pennsylvania
Philadelphia, PA

Feline Medicine
Elizabeth Colleran, DVM, DABVP
Chico Hospital for Cats
Chico, CA
Steve Dale, CABC
Steve Dale's Pet World
Chicago, IL
Sheilah Robertson, BVMS, PhD, DACVAA, DECVAA, DACAW, DECWMB (WSEL), CVA, MRCVS
Lap of Love Veterinary Hospice
Gainesville, FL
Craig Webb, DVM, DACVIM
Colorado State University
Fort Collins, CO

Gas trointestinal Medicine
David Twedt, DVM, DACVIM
Colorado State University
Fort Collins, CO

Human-Animal Bond
Steve Feldman
HABRI Foundation
West Lafayette, IN
Patrick Flynn, DVM
Zoetis
 Parsippany, NJ
Laird Goodman, DVM
Murray Hill Veterinary Hospital
Beaverton, OR
Rebecca Johnson, PhD, RN, FAAN, FNAP
Research Center for Human Animal Interaction
Columbia, MO

Imaging
Eli Cohen, DVM, DACVR
North Carolina State University
Raleigh, NC
Jaime Rechy, DVM
North Carolina State University
Raleigh, NC
Robert Toal, DVM, DACVR
VCA SouthPaws Veterinary Specialists and Emergency Center
Fairfax, VA

Neurology
*Fred Wininger, VMD, MS, DACVIM
Veterinary Specialty Services
Manchester, MO

Nutrition
*Deborah Linder, DVM, DACVN
Tufts Cummings School of Veterinary Medicine
North Grafton, MA

Oncology
*Sue Ettinger, DVM, DACVIM
Dr. Sue Cancer Vet
Tarrytown, NY

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Eye Care for Animals
Cleveland, OH
Heather Kaese, DVM, MS, DACVIM, DACVO
Eye Care for Animals
Overland Park, KS
Rustin Sturgeon, DVM, DACVO
Eye Care for Animals
Overland Park, KS
Neal Wasserman, DVM, DACVO
Eye Care for Animals
Wheeling, IL

*Also participating in the Technician Program
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Orthopedics
David Dycus, DVM, MS, DACVS, CCRP
Veterinary Orthopedic and Sports Medicine Group
Annapolis Junction, MD

Pain Management
Mary Ellen Goldberg, BS, LVT, CVT, SRA, CCRA
Boynton Beach, FL

Michael Petty, DVM, CVMA, CVPP, CCRT, CAAPM
Animal Pain Center
Canton, MI

Parasitology
Rick Alleman, DVM, PhD, DABVP, DACVP
Lighthouse Veterinary Consultants
Alachua, FL

*Richard Gerhold, DVM, MS, PhD
University of Tennessee
Knoxville, TN

Richard Goldstein, DVM, DACVIM, DECVM
Animal Medical Center
New York, NY

Practice Management
Brian Conrad, CVPM
Meadow Hills Veterinary Center
Kennewick, WA

Monica Dixon Perry, CVPM
Veterinary Management Consultants
Evergreen, CO

Bash Halow, LVT, CVPM
Halow Tassava Consulting
New York, NY

Jeremy Keen, DVM
Desoto County Animal Clinic
Southaven, MS

**Dave Nicol, BVMS, MRCVS
Dave Nicol Veterinary Services
Brighton, UK

Kathryn Primm, DVM
Applebrook Animal Hospital
Ooltewah, TN

Andrew Roark, DVM, MS
Cleveland Park Animal Hospital
Greenville, SC

Bill Schroeder
InTouch Practice Communications
Schererville, IN

Denise Tumblin, CPA
Wutchett Tumblin and Associates
Columbus, OH

Niqole Varani, DVM, CVPM
Veterinary Management Consultants
Evergreen, CO

**John Volk
Brakke Consulting
Chicago, IL

Sarah Wooten, DVM
Sheep Draw Veterinary Hospital
Greeley, CO

Public Health in Primary Care Practice
Audrey Ruple, DVM, MS, PhD, DACVP
West Lafayette, IN

Shelter Medicine
Amanda Dykstra, DVM
University of Tennessee
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Soft Tissue Surgery
Christopher Adin, DVM, DACVS
Raleigh, NC

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Chesapeake Veterinary Surgical Specialists
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Benita Atlier, LVT, VTS (Dentistry)
Pawsitive Dental Education
Prosser, WA

Mary Ellen Goldberg, BS, LVT, CVT, SRA, CCRA
Boynton Beach, FL

Debbie Martin, LVT, VTS (Behavior)
Veterinary Behavior Consultations
Spicewood, TX

Tasha McNerney, BS, CVT, CVPP, VTS (Anesthesia/Analgesia)
Veterinary Anesthesia Nerds
Glenside, PA

Paula Plummer, LVT, VTS (ECC, SAIM)
Texas A&M University
College Station, TX

Danielle Russ, LVT, BS, BA, AS
Center of Veterinary Expertise
Suffolk, VA

**Oriana Scioldo, BS, LVT
CVCA Cardiac Care for Pets
Richmond, VA

Toxicology
Tina Wismer, DVM, DABVT, DABT
ASPCA Animal Control Poison Center
Urbana, IL

Urology
*India Lane, DVM, MS, Ed. D, DACVIM
University of Tennessee
Knoxville, TN

USDA/NVAP
Gillian Comyn, DVM
USDA-APHIS Veterinary Services
Richmond, VA

E. Scott Weber III, VMD, MSc, DACVPM, CertAquaculture
USDA-APHIS Veterinary Services
Richmond, VA

Veterinary Hospice and Palliative Care
**Dani McVety, DVM
Lap of Love Veterinary Hospice
Lutz, FL

Veterinary Informatics in General Practice
Sonnya Dennis, DVM, DABVP
Stratham-Newfields Veterinary Hospital
Newfields, NH

Julie Green, DVM, MS
Green Meadows Veterinary Service
Elkton, VA

Jonathan Lustgarten, MS, PhD, VMD
Red Bank Veterinary Hospital
New York, NY

Pam Okerholm, MS
Boston Benefit Partners
Boston, MA

Veterinary Leadership
Karen Bradley, DVM
Onion River Animal Hospital
Montpelier, VT

Betsy Charles, DVM, MA
Western University of Health Sciences
Pomona, CA

Kimberly-Ann Therrien, DVM
WVLDI Board Member
Banfield Pet Hospital
Palm Harbor, FL

Sarah Wooten, DVM
Sheep Draw Veterinary Hospital
Greeley, CO

Wellness
Hilal Dogan, BVSc
Veterinary Confessionals Project
Maui, HI

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