

March 2015

AMWA's MISSION is to promote excellence in medical communication and to provide educational resources in support of that goal.

## Newsletter of the Northern California Chapter of the American Medical Writers Association

# PACEMAKER

### IN THIS ISSUE

Highlights ..... 1

Medical Writer Certified (MWC™) Credential ..... 2

CORE—Clarity and Openness in Reporting: E3-Based: A User Manual to Benefit CSR Writers ..... 3

Upcoming Events... 4

The Word Witch: Find and Browse... 6

Don't Wreck Your Bod!..... 8

Job Search and Your Online Persona..... 9

Microbiome Science at the Tipping Point... 10

List of Northern California Board of Directors ..... 12

## HIGHLIGHTS

### National News You Should Know

Medical writers should be aware of two upcoming and important changes to our professional landscape:

- 1 The medical writing certification credentialing program (see page 2).
- 2 The development of a user manual for CSR writers that complements International Conference of Harmonisation (ICH) E3 guideline, Structure and Content of Clinical Study Reports, and its subsequent 2012 Question and Answer (Q&A) update (see page 3).

### Upcoming Pacific Southwest AMWA Chapter Conference

Meeting Alert! Consider attending the Pacific Southwest Chapter Conference in San Diego on 1–2 May 2015 (see page 4).

### Learn How to Use MS Word to Easily Search and Navigate Through Documents

The Word Witch (aka Maggie Norris) introduces the Navigation Pane and shows you how to use it to make your life in MS Word easier. Check it out on page 6.

### Is Your Online Persona All That It Can Be?

Enhance your job search with the tips for creating an online persona provided by our Northwest AMWA Chapter colleague Susan Caldwell (see page 9).

### Missed the Northern California AMWA Chapter Presentation on the Human Microbiome?

Read the summary on page 10 and download the slides from our chapter website.



By  
Nancy  
Katz,  
PhD

*Nancy Katz is a past president of the NorCal AMWA Chapter and is an active presenter at DIA meetings. She recently completed a 4-year term as a core committee member of the DIA Medical Writing Special Interest Area Community and now serves as chair of the SIAC's E3 task force. More information is available at [IllyriaConsulting.com](http://IllyriaConsulting.com).*

**The Medical Writing Certification Commission (MWCC)**, in collaboration with AMWA, announced the launch of the Medical Writer Certified (MWC™) credentialing program and the Medical Writing Certification Examination (exam) that defines the scope of medical writing practice and distinguishes individuals in the field. The following areas are evaluated during the exam:

- Ability to gather, evaluate, organize, interpret, and present information.
- Awareness of best practices.
- Respect for ethical standards.
- Basic health care knowledge.

You qualify for the exam when you meet the following requirements:

- A bachelor's degree in any field of study.
- Minimum of 2 years of full-time work experience or the equivalent (eg, 4 years of documented part-time work at 20 hours/week) within the past 5 years. Experience must be in a paid capacity in the field of medical writing.

By earning the credential of MWC™, you can

- Give an employer or client increased confidence in your credibility and knowledge of medical writing.
- Show your commitment to continued professional development in the field of medical writing.
- Increase your marketability and opportunities for career advancement.

### Future Exam Dates and Locations

- September 2015, AMWA 75th Annual Conference, San Antonio, TX.  
**Application Deadline: 30 June 2015.** Exam Registration Deadline: 2 September 2015
- Spring 2016, Drug Information Association (DIA) Medical & Scientific Communications Annual Forum. **Application Deadline: 15 December 2015.**
- October 2016, AMWA 76th Annual Conference, Denver, CO.  
**Application Deadline: 30 June 2016.**
- November 2017, AMWA 77th Annual Conference, Orlando, FL.  
**Application Deadline: 15 December 2016.**

### Get Started Today

To obtain the Applicant and Candidate Handbook, the Application form, the Letter of Reference Request Form, and to pay the \$150.00 application (fee) (AMWA members receive a \$25.00 discount in the AMWA store), visit <http://www.amwa.org/mwc>.

If you plan to take the exam in September 2015, you may need a few months to acquire the documentation you need to apply for the exam, so get started now.



## CORE—Clarity and Openness in Reporting: E3-Based A User Manual to Benefit CSR Writers

By  
Nancy  
Katz,  
PhD

**The European Medical Writers Association (EMWA) and AMWA** are collaborating to develop an open-access end-user resource that will complement the International Conference on Harmonisation (ICH) E3 guideline, *Structure and Content of Clinical Study Reports*, and its 2012 Question and Answer (Q&A) update. This commitment is intended to benefit the many stakeholders who participate in the process of advancing therapeutic options. These include medical writers, the pharmaceutical industry, regulators, and patients.

While invaluable and essential, the 1995 E3 Guideline and its subsequent 2012 Q&A are written broadly and cannot be expected to provide detailed work instructions or transmit the experience of the many writers who have successfully authored and submitted E3-compliant CSRs to regulatory bodies worldwide. Hence, a user manual elucidating E3 and its Q&A was conceived.

*The all-new CORE Reference is scheduled to be available by mid-2016. CORE will take the form of a user manual intended to assist CSR authors, thereby complementing E3 and the Q&A update. The development of the CORE Reference considers all available resources, including unpublished recommendations from the 2012 Q&A consultation process.*

The CORE Reference will be developed in close collaboration with relevant stakeholders, including members of the medical establishment, patient advocates, industry representatives, and regulators. Stakeholder participation will mine the collective experience of the community, thus encouraging broad acceptance of the interpretations and recommendations that will be captured in the user manual. Individual stakeholders will endorse the CORE Reference after providing approval of the final document.

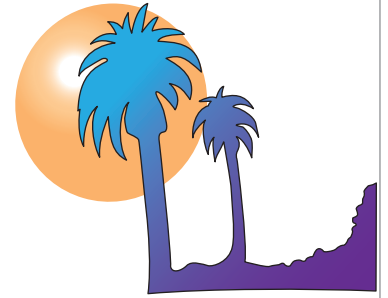
The CORE Reference project began as a detailed review of ICH E3, led by the EMWA Budapest Working Group (BWG). It has evolved into the international EMWA-AMWA partnership with global reach. Original members of the BWG are

- Sam Hamilton (BWG Chair, EMWA Vice President)
- Art Gertel (EMWA and AMWA Fellow, AMWA Past President)
- Walther Seiler (EMWA and AMWA member)
- Aaron Bernstein (EMWA Past President and AMWA member)

Nancy Katz, past president of our Northern California Chapter, is one of the stakeholders and will keep you updated during this process.

## UPCOMING EVENTS

### PACIFIC SOUTHWEST CHAPTER CONFERENCE 1–2 MAY 2015 • San Diego, California



Attend the conference for small-group workshops, networking opportunities, and provocative conversations with writers, editors, scientists, and other medical communicators in fun-filled and historic San Diego Old Town, home to numerous food, shopping, entertainment, and cultural venues.

#### OPEN SESSIONS

- Preparing a Clinical Study Report
- Setting Up a Freelance Business
- Using Storytelling Skills to Tailor Communications for Different Audiences
- Panel Discussion: Medical Communications Careers

#### PLUS—2 WORKSHOPS!

- Outlining for Writers and Editors, led by Sue Hudson
- Effective Paragraphing, led by Helen Hodgson

#### WHERE

Courtyard Marriot in Old Town, San Diego, California  
2435 Jefferson Street  
San Diego, CA 92110

For details visit the AMWA Pacific Southwest Chapter website at

<http://www.amwa-pacsw.org/announcements.html>

**Onsite registration will not be available,** so register online now and save.

Conference fees received by March 25, 2015:

\$165 Members, \$195 Nonmembers

Conference fees received by April 25, 2015:

\$195 Members, \$225 Nonmembers

Deadline: Paying by check? Payments by check must be received by April 25, 2015. Online registration is required: [www.123signup.com/event?id=ypttv](http://www.123signup.com/event?id=ypttv).



## UPCOMING EVENTS

Save  
the  
Date

### AMWA Annual Meeting

Save the Date for AMWA's 75th Annual Conference

30 September – 3 October 2015, in San Antonio, Texas

Grand Hyatt San Antonio

600 E Market Street, San Antonio, TX 78205

The AMWA Annual Conference is the ultimate resource for medical communicators around the world, offering educational and networking opportunities beyond compare in the field. The General Session Speakers will be Ivan Oransky and Jay Ingram.

There's no room at the Alamo. Make your reservations at the Grand Hyatt San Antonio today via the national AMWA website.



### Events Around the Country

#### AMWA Chapter Events

MID-ATLANTIC CHAPTER CONFERENCE

13 March 2015 • Gaithersburg, MD

INDIANA CHAPTER CONFERENCE

10–11 April 2015 • Indianapolis, IN

SOUTHWEST CHAPTER CONFERENCE

18 April 2015 • Dallas, TX

DELAWARE VALLEY CHAPTER  
CONFERENCE

25 April 2015 • Princeton, NJ

CAROLINAS CHAPTER CONFERENCE

1 May 2015 • Chapel Hill, NC

ROCKY MOUNTAIN CHAPTER  
CONFERENCE

6 June 2015 • Denver, CO

#### Drug Information Association

DIA 27<sup>TH</sup> ANNUAL EURO MEETING

13–15 April 2015 • Palais des Congrès, Paris

DIA 51<sup>ST</sup> ANNUAL MEETING

14–18 June 2015 • Washington, DC

# THE WORD WITCH: FIND AND BROWSE

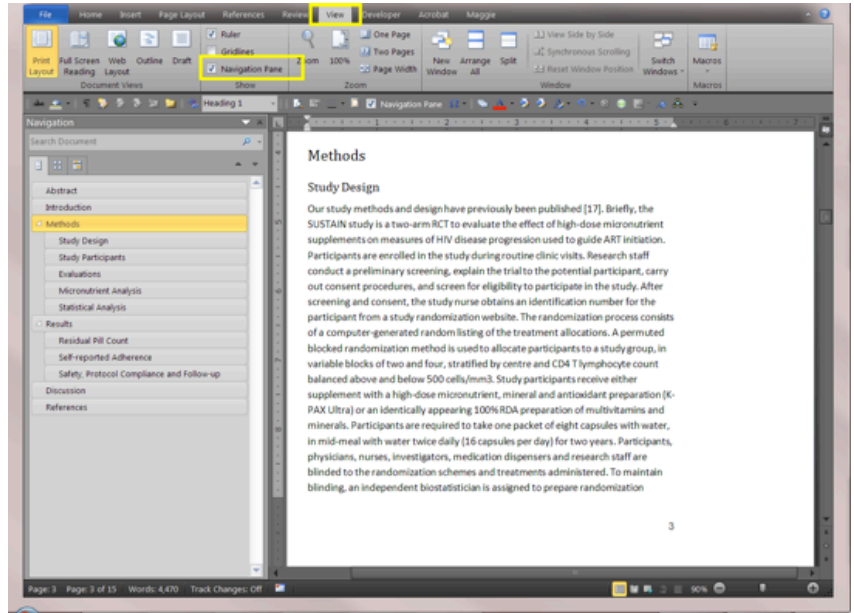


By  
Maggie  
Norris,  
BSc, ELS

Maggie Norris is a long-time member of the NorCal AMWA Chapter and currently serves on the Chapter Board

The **Navigation Pane** (Nav Pane) is one of several “task panes” that display optionally in the application window in Word 2010 and later. Some users discovered the Nav Pane when they set up their first **Find** in Word 2010. When the user executes a **Find** command (**Ctrl+F** or the **Find** icon on the **Home** tab), the Nav Pane opens automatically and displays on the far left (see screenshot 1).

Screenshot 1. Navigation Pane in the application window. The Browse Headings tab is displayed.



The Nav Pane is integrated with the **Find** function and offers access to the full range of **Find** options. In this tutorial, I show you a way to use the Nav Pane to efficiently perform one of those bothersome editorial tasks that usually comes near the end of development:

checking the abbreviations and acronyms versus the list of abbreviations and applying your style guide requirements for where and how abbreviations are included in the text.

## Basics

The Nav Pane has 3 tabs: **Browse Headings** on the left, **Browse Pages** in the middle, and **Find and Browse** on the right (see screenshot 2). Many writers of complex documents use **Browse Headings** to navigate efficiently, that is, to move instantly to a section or subsection, or to check the hierarchical structure of the entire document or of a particular section. When my screen is big enough, I work with the Nav Pane open so I can see the document structure.



Screenshot 2. Navigation Pane tabs: Browse Headings (left), Browse Pages (middle), Find and Browse (right).

## Procedure: Checking Abbreviations

For this exercise, we're going to use **Find and Browse**.

Select the first term in the abbreviations list (called the “search string” in this context) and press **Ctrl+F**. The Nav Pane opens with the search string displayed in the search field.

Open the **Find and Browse** tab, then click the search icon (magnifying glass). Word delivers a list of each instance of the search string in context (about 20 words or 90 to 100 characters). The passages containing the search string are easily readable in the pane (see screenshot 3). You can compare any instance with any other without moving around in the file.

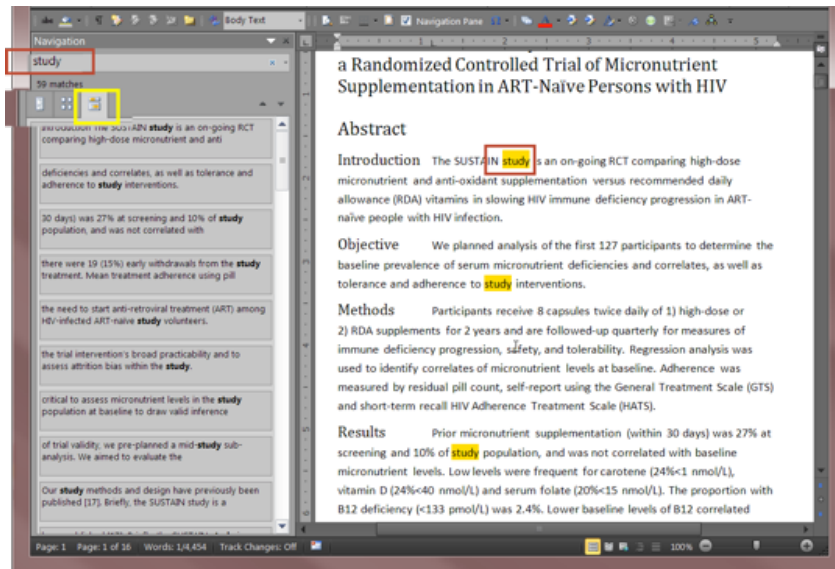


Search icon





## THE WORD WITCH: FIND AND BROWSE (Concluded)



Navigation Pane, Find and Browse

*Screenshot 3. Find and Browse tab with the search string “study” in the search field and instances of the search string highlighted in the document window.*

Drag the right border of the pane to expand it and fit as many items as possible in the same view.

Perhaps you will find that the first instance of the search string (abbreviation) is in the abbreviations list, the

second instance is the first use of the abbreviation in the text with the definition or expanded term in parentheses (and identical to the definition in the abbreviations list), and all subsequent instances are of the abbreviation alone (or per your style guide specifications). Congratulations.

Move on to the second and subsequent abbreviations and perform a search for each. At some point, you may find errors or imperfections: the definition or expansion not with the first use in text; an instance of the term defined or expanded in the text where it is not wanted; inconsistent renderings of the definition. Click the item containing the error to navigate to the corresponding place in the text to make corrections. Then move back to the **Find and Browse** pane to continue.

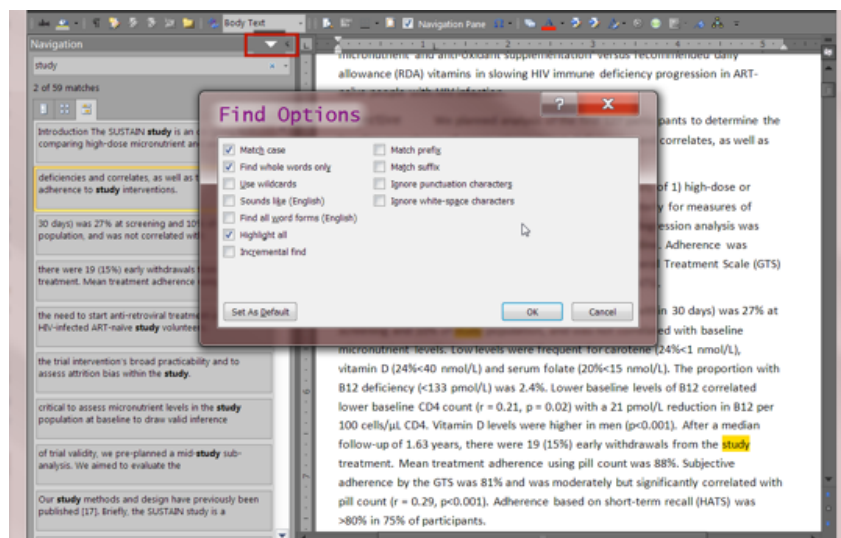
### Beyond the Basics

Other errors can creep into an abbreviation or acronym: a typing error could render it wholly or partly in the wrong case, for example, “NOaEL”; or the term may be pluralized, for example, “NOAELS.” That’s where **Find Options** can help.

Notice the tiny arrowhead to the right of the search icon. Click the arrowhead to open the **Find Options** dialog box (see screenshot 4). For the task at hand, less may be more; that is, fewer restrictions will generate a more comprehensive list of variations, some of which may be errors that need

to be corrected. For example, if **Match case** is not activated, a search for “NOAEL” will find “NOaEL.” If **Find whole words** is not activated, Word will find “NOAELS.” Experiment with the **Options** to discover which ones work best in your documents.

*Screenshot 4. Find and Browse tab with the Find Options dialog box.*



## Don't Wreck Your Bod!

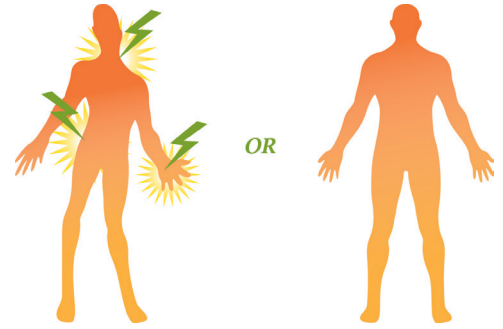


By  
Caren  
Rickhoff, BA

*Caren Rickhoff is the editor of the Pacemaker and Vice President of the NorCal AMWA Chapter. Her expertise includes more than 20 years of experience creating all forms of medical communications from manuscripts and presentations to regulatory submissions.*

Writers abuse their bodies. We all do it. We sit to think, we sit to write, we sit through meetings, we sit while commuting. We get lost in our work and forget to get up—for hours. It is no wonder we suffer from hand, wrist, back, and neck injuries as well as all-over fatigue.

We in the Northern California AMWA Chapter plan to provide a series about different aspects of the work environment that you can alter and manage to improve your quality of life and reduce injuries. Topics will range from preventing injuries at your computer work station to preventing visual discomfort.



**If you have suggestions or would like to contribute, please send an email to [vice-president@amwancal.org](mailto:vice-president@amwancal.org).**

For now remember: the most important and easiest thing you can do is

**GMT—Get Moving Today!**



**GET UP!**



**MOVE AROUND!**



**TAKE A BREAK!**

Take microbreaks every 20 or 30 minutes if only for 2 minutes; do a quick stretch, walk down the hall and back, look out the window (remember that there is a world out there), march in place. Moving literally extends your life.





By  
*Susan E.  
Caldwell,  
PhD*

*Susan Caldwell is a member of the Northwest AMWA Chapter and is a medical writer consultant in the Greater Seattle Area. Her specialty is writing regulatory documents of all types. More information is available at Biotech Ink, LLC, and on Susan's Biotech Ink Spots blog.*



Most of us are painfully aware of the tough US job market. The good news is that there are medical writing staff and contract jobs out there.

For those seeking a new staff or contract position, the question is how to most effectively do your search. In today's competitive job market, you must let hiring managers and recruiters know you're available and a great match for the target job. But how to do this?

Use the internet to accomplish your goals, whether you're a medical writer, hiring manager, or recruiter! Medical writers are a scarce breed, so it's hard for recruiters and managers to find the right writers for their open positions. The internet is their tool of choice for locating talented job candidates. Similarly, finding open medical writing positions on the internet is an important step in your job search. Contract and staff medical writing positions are very well represented on the major job boards. However, you should talk with recruiters, too; they have access to open positions that aren't even posted on the job boards.

If you want to compete for a contract or staff medical writing job, it's well worth the time to develop an online persona. Here are some suggestions:

**(1) Your Resume.** Put your resume on the job boards. If you're a medical writer, some of the boards you'll want to use are Monster.com, Medzilla.com, and Biospace.com. FlexJobs has many contract and permanent (including remote) writing jobs, if you're willing to pay a small fee for monthly access. If you're looking for contract work, make sure you say so, to avoid unwanted calls for permanent openings.

**(2) Your Networking Profile.** Develop your public profile on the networking sites, such as LinkedIn. A photograph in your profile will help people feel like they "know" you, and it makes you more approachable. Complete as much of your profile information as you're comfortable with, keeping in mind that the information will be public. Include any publications, coursework, special projects, and other information that can speak to your productivity, knowledge, and work experience. Similarly, start discussions that demonstrate your expertise, but you should be willing to follow them these threads and contribute as readers chime in.

**(3) Your Website.** If you don't have a website, consider creating one if you are a contract medical writer. Your website is essentially a validation of your business, and potential clients will often look at your website before they call you about a project. And don't despair; you don't have to spend a lot of money to have a website. It doesn't need to be fancy, but it should contain the right information. Describe the kind of writing you do, your work experience, education, publications, and the services your clients can expect from you. And don't forget to include a photograph and your contact information.

**(4) Your Blog.** If you want to market yourself, but you don't want or need a website, blogs can be effective tools that let others see a little of who you are. Often more conversational and less formal than websites, blogs can help you project not only your credentials, but also your personality. Your blog can be very inexpensive or free to post, and you should write blog articles fairly frequently to keep the content fresh and your readers returning for more. If you have a website, too, be sure your blog links to your website, and vice versa.

After you begin bringing your online persona to fruition, you'll probably get noticed by hiring managers or recruiters. After that, of course, there's another challenge. It's up to you to convince the hiring manager that you're the perfect fit for their job opportunity. Your resume and online persona can get you an interview, but not the job.

Summary by  
Caren Rickhoff

**Chapter Program Presentation**  
**Speaker: Mohan Iyer, MS, MBA**  
**Chief Business Officer, Second Genome, Inc.**  
**Saturday, 7 February 2015**

During this presentation, Mohan Iyer reviewed the world of the human microbiome and how discoveries about it are being mined for new therapies to improve human health using activities at Second Genome as examples.

Below is a summary of the presentation. The slides of the presentation can be accessed on the chapter website.

**WHAT IS THE HUMAN MICROBIOME?**

The human microbiome consists of the microbes that live in and on the human body. The human body contains about 100 trillion microbes, that is, about 10 times more bacteria, fungi, and other micro-organisms than human cells.

Interest in the microbiome has exploded since 2007 as evidenced by the exponential growth in the number of publications. Interest is supported by the National Institutes of Health initiative titled the Human Microbiome Project (HMP) that was launched in 2008 with the mission of generating research resources enabling comprehensive characterization of the human microbiota and analysis of their role in human health and disease.

**IDENTIFICATION OF MICROBES WITHIN THE HUMAN MICROBIOME**

Historically, identification of members of the microbial community was almost entirely culture-dependent. That is, it was necessary to grow an organism in the laboratory, and specific microbial species were detected by plating samples on specialized media selective for the growth of that organism, or they were identified by features such as the morphological characteristics of colonies, their growth on different media, and metabolic production or consumption. Thus, the ranges of organisms that could be studied were limited.

The research landscape changed with the introduction of culture-independent, high-throughput techniques based on DNA/RNA analyses. Genomic technology breakthroughs are enabling us to finally study the structure and function of the microbiome in a culture-independent manner. These microbiome-profiling techniques allow analysis of community DNA extracted from a sample containing various microbes.

Early DNA/RNA analysis addressed questions such as

- What organisms are present and in what relative abundance?
- What is the function of the bacterial community?

Emerging techniques now involve analysis of extracted RNA (metatranscriptomics), proteins (metaproteomics), and metabolites (metametabolomics). Integration of data from these sources allows researchers to identify and elucidate the network of interactions between expressed genes, proteins, and metabolic products in a single sample:

- Metagenomics: defines what they do
- Metatranscriptomics/metametabolomics: defines what they are doing.
- 16S rRNA marker analysis: defines who they are.

### MICROBIAL COLONIZATION IN HEALTHY HUMANS

In humans, within bacteria, two phyla (divisions), the Bacteroidetes and the Firmicutes, dominate our microbiomes, with Proteobacteria and Actinobacteria ranking third and fourth.

At birth, we are “germ-free” and are colonized during the postnatal period. The gut microbiota of infants evolve toward an “adult-like” state during the first 3 years of life and remain relatively stable thereafter. By adulthood, our bodies become home to trillions of microbes comprising 500–2000 species in the gut microbiota alone.

The infant microbiome is shaped by the method of delivery:

- Microbiota of babies delivered vaginally are similar to the vaginal microbiota of their mothers.
- Microbiota of babies delivered by Cesarean section are similar to the skin microbiota of their mothers.

This leads to the question of what is the dominant factor in the development of the human microbiome: genetics or environment? A study conducted by Turnbaugh et al (2009) involving both identical and fraternal twins (54 pairs) examined the relative roles of human genotypes versus environmental exposure in shaping the gut microbiome. Key findings indicated that the environment had a greater effect than genetics, the microbiomes of identical twins were no more similar to one another than those of fraternal twins, and the microbiota of cohabitating adults (such as husband and wife) are more similar to each other than to related adults living separately.

### WHAT HAPPENS WHEN THE NATURAL BALANCE OF MICROBES IN HUMAN BODY IS ALTERED?

Interrupting the natural balance of microbes by environmental factors, diet, or medications may lead to profound disruption and unintended consequences and may result in the increased incidence and prevalence of chronic conditions, such as autoimmune diseases, asthma and allergies, gastrointestinal (GI) disorders, infectious diseases, inflammation, and obesity and diabetes.

#### *Effects of Diet*

The type of diet clearly influences the type of microbial communities that are present in the human gut. For example, diet affects the type of microbes present in babies (Yatsunenko et al, Nature 2012): Breast-fed babies have more *Bifidobacteria* compared with formula-fed babies.

Different populations (eg, “Western” versus “rural”) also have different microbiomes: Pronounced differences in bacterial assemblages and functional gene repertoires were noted between United States residents and those in the Amazonas of Venezuela and in rural Malawi.

Gut microbiomes also differ between carnivore and herbivore mammals: animals consuming similar diets have similar microbiomes and amino acid metabolism differentiates herbivorous versus carnivorous gut microbiomes (Ley et al, Science 2008; Muegge et al, Science 2011). Results of an examination of mammalian gut microbes indicate that host diet and phylogeny both influence bacterial diversity, which changes from carnivory to omnivory to herbivory; that bacterial communities codiversified with their hosts; and that the gut microbiota of humans living a modern lifestyle is typical of omnivorous primates (Ley et al, Science 2008).

***Effects of Medications***

It has been long recognized that medications such as antibiotics can profoundly affect microbial populations in the body; however, scientists now have the tools to longitudinally study the details of such effects. For example, Second Genome-Merck published a study of post-antibiotic rebound of microbiota after a single dose of 30 mg/kg of clindamycin in Syrian golden hamsters followed for 20 days during which populations of microbial taxa were tracked using V4 16S rRNA gene sequence profiling. Results indicated the following:

- Rapid microbiome perturbation occurred with slower recovery.
- Complete return to baseline was not observed during the 20-day study period.
- The trajectory was dose dependent.

A 7-day course of clindamycin notably affected one subject's gut microbiome: for 9 months, the subject's gut contained only a clindamycin-resistant strain of *Bacteriodes thetaiotaomicron*; even 2 years after treatment, the flora had not regained their former diversity.

**MICROBIOME-BASED THERAPIES**

The advances in microbiome-profiling technologies and approaches are providing insights of not only the microbial community but also its interaction with a human host, which, in turn are leading to new therapeutic approaches. These approaches are based on revised disease definitions, novel targets, and enhanced understanding of the underlying pharmacology.

Pharmaceutical companies—small and large—are exploring these new approaches to address chronic disease states such as irritable bowel syndrome, autism spectrum syndrome, and metabolic diseases as well as infectious diseases.

As an example, Second Genome's focus is on development of an understanding of the mechanism of disease based on a microbiome drug discovery paradigm: identify a key microbe, identify a key metabolite, identify a pathway and target, and ultimately identify a drug. Second Genome is teaming with pharmaceutical giants such as Pfizer to develop new therapies using this model.

In summary, based on the availability of culture-independent investigative techniques, enhanced understanding of the microbiome and its relationship to functions of the human body, and increasing research initiatives by small and large government and independent organizations, the microbiome therapy market is no longer a niche market; it is an emerging one.

**Northern  
California  
Chapter  
Board of  
Directors,  
2014–2015**
**Elected Positions**

President: Arushi Sinha, PhD

Vice President: Caren Rickhoff, BA

Secretary: Barbara Arnoldussen, BSN, MBA

Treasurers: Kariena Dill, PhD, and Catherine Magill, PhD

Program Chair: Barbara Boughton

Membership Liaison: Dennis Bittner, PhD

**Non-elected Positions**

Immediate Past President: Maggie Norris, BSc, ELS

Jobs List Administrator: Dennis Bittner, PhD

**Chapter Committees**

Programming Committee: Barbara Boughton, Maggie Norris

Conference Planning Advisory Committee: Catherine Magill

Communications Committee: Mimi Wessling; Myrna Faulds; Suzanne Canada; Caren Rickhoff, Mayya Shveygert