

Helen Nicely, Ph.D.
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CAREER SUMMARY

Researched and wrote documents about pain, diabetes, osteoporosis, rheumatoid arthritis, lupus, nephrology, neurology, immunology, oncology, cardiology, microbiology, organ transplantation, and rare diseases. Projects were based in clinical, regulatory, medical affairs, medical writing departments, and were also focused on advisory board development with key opinion leaders, QC, MSL training, publication planning, manuscript analysis, market analysis and business development.

EXPERIENCE SUMMARY

- ◆ Basic *in vivo* and *in vitro* bioscience research, post-marketing data analysis. 30+ manuscripts & 6 med info letters; 13 publications in market research; 2 review papers & case reports; 4 grants
- ◆ Extensive third party & corporate in-house medical writing, editing, PowerPoint preparation, QC & reviews
- ◆ Organizational leadership, mentoring
- ◆ Research team management including scientific staff recruiting
- ◆ Business development (lead finding, fund raising, business planning, presentations)
- ◆ Market research & analysis, competitive intelligence

WORK HISTORY HIGHLIGHTS

Sr. Manager of Global Medical Communications and Publications **Horizon Pharma (formerly Raptor Pharma)** **February 2016 to present.**

- Working with medical writing vendors, print vendors, and MSLs.
- Operated Datavision, EndNote and SharePoint for Medical Affairs
- Medical information management

Sr. Medical Writer **Depomed, Inc. (6-month contract via EPM Scientific), Newark** **August 2015 to February 2016.**

- Writing and submitting manuscripts, abstracts, slide sets and posters on 4 pain therapeutics, Lazanda®, Gralise®, Nucynta® IR and ER, and Cambia® (Adobe In-Design/Excel) to journals and congresses, respectively.
- Publication management and document review management. (Veeva)
- NDA-related literature searches. (Endnote/ Ovid).
- Working with medical writing vendors, print vendors, and MSLs.
- Training of newly recruited Associate Director.

Sr. Medical Writer **CareDx, Inc. (9-month contract via Real Staffing), Brisbane** **October 2014 to July 2015**

- Writing and submitting manuscripts, abstracts and protocols on predicting heart and kidney transplant rejection by gene-expression profiling by RT-PCR and cell-free DNA detection. Working with the IT department, designing and writing a customer Web Portal User Guide for AlloMap® diagnostic testing, due for roll out mid-2015.

Sr. Market Research Analyst

High Tech Business Decisions, Inc. (contract work conducted from June to July, 2014)

- Questionnaire development, conducted market research interviews of thought leaders, report-writing for study entitled "*Biopharmaceutical Contract Manufacturing 2014: Improving Markets, Services, and Technologies.*"

Sr. Medical Writer/Project Management

inVentiv Health Clinical CRO (dedicated writer for Eli Lilly US, China and Japan) February 2013 to May 2014

- Manuscripts, abstracts, and posters, writing and preparation with graph plotting in Sigma Plot and Excel for autoimmune diseases, bone, muscle, joint diseases, and diabetes.

Publication Project Manager/Sr. Medical Writer/EndNote Librarian

Ipsen Biopharmaceuticals, Inc., Brisbane

Medical Affairs Contractor

2011 to Feb 2013

- Management of MSL-related development of medical communication documents including posters and manuscripts relating to Increlex[®] for IGF-1 deficiency, Somatuline[®] for acromegaly and neuroendocrine tumors, and Dysport[®] for cervical dystonia.
- Writing medical information letters for neurological, off-label queries regarding Dysport & phase 4 Dysport protocols. eCTD training for submissions process.
- Draft manuscript review process conducted with vendors, internal stakeholders/authors and external authors/key opinion leaders, as well as timely submission to journals and scientific meetings.
- Preparation of monthly publication summaries, executive summaries and dashboards. Archiving pdfs of reprints for use by personnel within company.

Sr. Medical Writer/Publication Planning

BioMarin Pharmaceutical Inc., Novato

Medical Affairs, Business Development & Clinical Departments.

2006 to 2010

- Corporate publication planning with internal stakeholders/authors, external authors/key opinion leaders and external vendors.
- Abstracts, posters, case reports, review and management guidelines were written about lysosomal storage disorder, mucopolysaccharidosis VI (Maroteaux-Lamy syndrome) with and without enzyme replacement therapy Naglazyme[®].
- Early Access Program-related writing on research of tetrahydrobiopterin (Kuvan[®]) for PKU and other Kuvan[®] - related abstracts and posters. Further diseases supported were mucopolysaccharidosis IVA (Morquio Disease) using GALNS and Lambert Eaton Myasthenia Syndrome using Firdapse[®].
- Updated an amendment and conducted QA of a phase 2 protocol for tetrahydrobiopterin applied to peripheral arterial disease and intermittent claudication, while the Clinical Department was short-staffed.
- Business development projects involved developing and presenting PowerPoint slide shows to upper management regarding potential candidate indications (ALS & cystic fibrosis).

Regulatory Medical Writer

(Ad hoc Interim Manager)

Scios Inc./ a Johnson & Johnson company, Fremont

Clinical Department

May 2005 to August 2006

- Regulatory documents were written and edited according to ICH guidelines and J&J PRD guidelines.
- Documents included phase 1 and phase 3 protocols for subcutaneous delivery of Natrecor[®] and an outcomes trial, respectively, and two clinical study reports (CSR) in phase 2 and 4, as well as updates of the Natrecor[®] investigator's brochure. One CSR involved a trial on subjects with congestive heart failure undergoing coronary artery bypass graft and receiving Natrecor[®] during anesthesia (NAPA). Another CSR involved the renal protection and diuretic effect of Natrecor[®] compared to furosemide.
- QC and QA of CSRs were conducted in collaboration with J&J Global Support QA department.

- Worked with a team to create SOP, template and guidance for clinical study report preparation.
- Helped beta-test a new in-house electronic document system based on Documentum software and later took training to use the final version.

Supervisor & *ad hoc* Interim Manager of 5 contract medical writers

Founder of Medical Writing Department

Reviewer of applicant directors' and medical writers' writing exercises.

Staff Scientist/Medical Writer and Grant Writer

Buck Institute for Age Research, Novato

Neuroscience and Proteomics Lab. 2003 to 2004

- Grant writing and writing scientific papers about proteases, especially those involved in Alzheimer's Disease. Grant was written about proteomics of opioid action and addiction.

Lab Manager, Research Associate, and

Neuroscience Postdoctoral Fellow

Forbes Norris MDA/ALS (Lou Gehrig's disease) at CPMCRI

Research Center, San Francisco. 1993 to 1998

- Writing grants, abstracts, posters, meeting notes, and manuscripts
- Necropsy of humans and animals for electron microscopy and immunohistochemical testing.

Experimental Scientist,

(Thyroxine Assay Development)

Biocircuits, Inc. Burlingame. 1992 to 1993

Visiting Scientist, Developmental Biology

(Rheumatoid Arthritis)

Genentech, Inc. South San Francisco. 1990 to 1991

Research Scientist

(Glomerular Nephritis)

University of London, St Mary's Hospital, London, UK. Department of Nephrology

1989-1990

Forensic Scientist

Metropolitan Police Forensic Laboratory, London, UK. Department of Microbiology

1979 to 1980, then 1981-1982.

CONSULTING HIGHLIGHTS

Biopharmaceutical Consultant

Nicely Done Research

1999 to present

Market research, competitive intelligence, analysis and report writing for dozens of repeat biopharmaceutical, and contract manufacturing clients, medical device and original equipment manufacturer (OEM) printed-circuit board industry. Presentation of market research results to clients.

Sr. Market Research Analyst

HighTech Business Decisions, Inc. (DBA Nicely Done Research)

1999 to present

Questionnaire development, conducted market research interviews of thought leaders, report-writing on pricing of contract manufactured biopharmaceuticals and technical trends in the CMO industry. Development of a high-throughput screening market research study: "HTS: Improved Screening, Adapted Technologies and Enhanced Assays."

NON-PROFIT VOLUNTEERING

Communication Director (State of California Award)

Pacifica Beach Coalition (2013 Cox Hero award-winning, 2014 Chicken of the Sea award-winning, 2015 Fog Fest: Most Creative Walking Group, non-profit organization)

December, 2012 to present

Project management of communications, including grant writing, blogs, email messages, press releases and articles relating to Pacifica & Daly City's coastal environmental protection strategies.

Director

Skyline Palisades Residential Association

January 2007 to present

President

Daly City Coastal Coalition (non-profit organization)

June 2007 to present

Project management of coastal environmental protection strategies. Influencing a network of Public Works, Waste Water Management, Police, City Manager, local schools, Pacifica Tribune, Patch and Riptide, and Pacifica Beach Coalition. Embracing the goals of dedicated volunteers in making a difference to protect and nurture marine wildlife; having an impact through education, inspiration and leadership, responsibility and stewardship; and creating a sense of community in support of a long-term vision that brings enjoyment and appreciation to all.

EDUCATION

Ph.D. Ear, Nose and Throat Pathology, University of London, England 1990

Thesis: Primary Tissue Culture of Human Laryngeal Carcinoma and Interaction with Native Lymphocytes

B.S. Microbiology (with honors), University of Surrey, England 1982

Internship: 1-year in forensic science at the Metropolitan Police Forensic Lab, London, England.

Thesis: Staphylococcus aureus: A Study Related to its Potential Use in the Forensic Examination of Face Masks

UC Berkeley Extension Courses Completed:

- Grammar, Mechanics and Usage for Editors, 2011
- Protocol Development, 2006
- Molecular Biology, 1992

American Medical Writers Association (AMWA)

- Core Curriculum Accreditation with specialty in writing and editing, 2012

AWARDS

New York, New Jersey Society of Interventional Pain Physicians. Pain Medicine Symposium 2015: Evolving Pain Therapies. EPoster (Vanita Spagnolo et al) picked as slide set for oral presentation, awarded one of 4 top abstracts submitted: Dosage-Dependent Effectiveness of Treatment of Breakthrough Cancer Pain with Fentanyl Pectin Nasal Spray.

State of California Earth Hero Award, 2014: Communication Director for Pacifica Beach Coalition & founder of Mussel Rock Stars, a volunteer beach cleanup group.

Dove Press: Favored Author Program Status for Yang Y, **Nicely H et al**, 2015 paper: In-patient cost of treating osteoporotic fractures in mainland China. 1052 article reviews in first 12 weeks of publication.

American Diabetes Association Congress 2013: Best poster award for Skrivanek Z *et al*, 2013 poster: Dose-finding results in an adaptive trial of dulaglutide combined with metformin in type 2 diabetes (AWARD-5).

Orphanet. **Highly accessed** Review: Mucopolysaccharidosis VI. Valayannopoulos V, **Nicely H** *et al*, 2010 review paper. 24,781 total accesses April 2010 to June 2015; 404 in month of June 2015; 4761 from June 2014-June 2015.

PUBLICATIONS, POSTERS AND PODIUM PRESENTATIONS

(Maiden name: Helen S.L. Wang)

2015

Schmidt P. Safety information on serotonin syndrome for tapentadol IR and tapentadol ER administration. Poster outline created for agency to draft poster. American Academy of Pain Medicine. February 18-21, 2016. Palm Springs, CA.

Schmidt P. Metabolism of tapentadol-the data to date. Poster outline created for agency to draft poster. American Academy of Pain Medicine. February 18-21, 2016. Palm Springs, CA.

Schmidt P. Secondary endpoints in the phase 3 trial of tapentadol ER. Poster presented at PAIN Week, Las Vegas, Sept 8, 2015. Poster development, graphs, tables and layout.

24 June, 2015 A Pacifica Tribune Letter to the Editor, by **Helen Nicely**: July 4: Red, White, Blue... and Green! http://www.mercurynews.com/pacifica/ci_28368549/july-4-red-white-blue-and-green.

Komocsar W, Blackbourne J, Halstead C, Winstead C, Wierda D. Fully human anti-BAFF inhibitory monoclonal antibody tabalumab does not adversely affect T-dependent antibody responses in cynomolgus monkey (*Macaca fascicularis*): A summary of three pre-clinical immunotoxicology evaluations. J Immunotoxicol 2015, Jan 14: 1-13. Written by **Helen Nicely**.

Yang Y, Du F, Ye W, Chen Y, Li J, Zhang J, **Nicely H**, Burge R. In-patient cost of treating osteoporotic fractures in mainland China. Clinicoeconomics and Outcomes Research. 2015;7:205-212. **Dove Press Favored Author Status Award** related to metrics: 1052 article reviews in the first 12 weeks of publication. http://www.dovepress.com/articles.php?article_id=21316&l=5wlIMA64gYiJtdL1k4pnDbal474978

Deng M, Elashoff B, Pham M, *et al*. Comparative utility of gene expression profiling test score variability, endomyocardial biopsy and echocardiography to predict clinical events in heart transplant recipients. Written by **Helen Nicely**. Not yet submitted.

Crespo-Leiro M, Stypmann J, Schulz U, *et al*. Non-invasive gene-expression profiling test (GEP): the CARGO II European-based multicenter trial. Written by **Helen Nicely**. Not yet submitted.

Crespo-Leiro M, Stypmann J, Zuckermann A, *et al*. Performance of gene expression profiling variability in discriminating heart transplant patients at risk for future clinical events. Written by **Helen Nicely**. Not yet submitted.

January 7, 2015: Pacifica Tribune Article: **Helen Nicely**. Holiday clean-up at Mussel Rock brings out an amazing team.

February 18, 2015: Pacifica Tribune Article: **Helen Nicely** & Julie Walters. Join the Pacifica Beach Coalition.

Hiller D, Grskovic M, Beausang J, *et al*. Donor-derived cell-free DNA is stable in non-rejecting heart transplant recipients in the CARGO II multicenter trial. Abstract accepted for oral presentation at American Transplant Congress 2015, Pennsylvania, USA. I participated in writing and submission to congress.

Grskovic M, Beausang J, Hiller D, *et al*. Plasma levels of donor-derived cell-free DNA increase with rejection and often decrease in organ transplant recipients. Abstract accepted for oral presentation at American Transplant Congress 2015, Pennsylvania, USA. I participated in writing and submission to congress.

Teuteberg J, Shullo M, Wolf T, *et al.* Clinical use of gene-expression profiling to monitor for rejection after cardiac transplantation-which patients and when? Abstract accepted for oral presentation at American Transplant Congress 2015, Pennsylvania, USA. I participated in writing and submission to congress.

Kanwar M, Yee J, Ewald G, *et al.* Correlation of longitudinal gene-expression profiling (GEP) score to cytomegalovirus (CMV) infection: Results from the Outcomes AlloMap® Registry (OAR). Abstract accepted for oral presentation at American Transplant Congress 2015, Pennsylvania, USA. I participated in writing and submission to congress.

Sulemanjee N, Prasad P, Wolf T, *et al.* Can gene-expression profiling score help explain the adverse clinical outcomes seen in gender-mismatched heart transplants? Abstract accepted for oral presentation at American Transplant Congress 2015, Pennsylvania, USA. I participated in writing, and submission to congress.

Teuteberg J, Wolf T, Prasad P, *et al.* Gene-expression profiling to monitor for rejection-which patients are being offered this strategy? Abstract accepted for poster presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

Sulemanjee N, Prasad P, Wolf T, *et al.* Gender-mismatched heart transplants and gene-expression profiling score-lessons from the Outcomes AlloMap® Registry (OAR). Abstract accepted for poster presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

Kanwar M, Yee J, Ewald G, *et al.* Correlation of longitudinal gene-expression profiling (GEP) score to cytomegalovirus (CMV) infection: Results from the Outcomes AlloMap® Registry (OAR). Abstract accepted for poster presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

Crespo-Leiro M, Zuckermann A, Stypmann, *et al.* Increased plasma levels of donor-derived cell-free DNA correlate with rejection in heart transplant recipients: the CARGO II multicenter trial. Abstract accepted for poster presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

Mohacsi P, Crespo-Leiro M, Zuckermann A, *et al.* Donor-derived cell-free DNA is stable in non-rejecting heart transplant recipients in the CARGO II multicenter trial. Abstract accepted for oral presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

Stypmann J, Vanhaecke J, Zuckermann A, *et al.* Donor-derived cell-free DNA decreases following effective treatment of acute cellular rejection in heart transplant recipients: the CARGO II multicenter trial. Abstract accepted for oral presentation in the International Society for Heart and Lung Transplantation congress, Nice, France. I participated in writing and submission to congress.

2014

September 9, 2014: Pacifica Tribune Article: **Helen Nicely** and Lynn Adams. Be a Part of the Solution, Help End Pollution-and Let's Make Trash Extinct on Coastal Cleanup Day, Saturday 20th September!

September 3, 2014: Pacifica Tribune Article: **Helen Nicely** and Lynn Adams. The 30th Annual Coastal Cleanup Day is September 20th.

Submitted: a paper that I researched and drafted: Sheng Z, Liao E, Chen Y. Sequential and combination use of anabolic agents (parathyroid hormones, PTH 1-34 [teriparatide] or PTH 1-84) and antiresorptive agents for optimal treatment of patients with osteoporosis at high risk of fracture. Chinese J Osteoporosis Bone Miner Res.

Submitted, a paper that I researched and drafted: Xie Z, Burge R, Yang Y, Du F, Lu T, Huang Q, Ye W, Xu W. Post-hospital discharge medical care costs and family burden associated with osteoporotic fracture patients in China from 2011-2013. Int J. Equity Health.

2013

January 2013: Pacifica Tribune Article: **Helen Nicely**. Pacifica Beach Coalition teams up with National Day of Service, attracts hundreds of volunteers to Linda Mar State Beach.

February 19, 2013: Pacifica Tribune Article: **Helen Nicely**. Barn owl released in Mussel Rock Park.

February 2013: Pacifica Tribune Article: **Helen Nicely** and Lynn Adams. Surf movies inspired and entertained.

March 12, 2013: Pacifica Tribune Article: **Helen Nicely**. Pacifica Beach Coalition announces that this year's Earth Day is all about sharks.

March 12, 2013: Pacifica Tribune Article: **Helen Nicely**. Volunteers dedicate Pacifica Beach Coalition sign on Westline Drive.

April 9, 2013: Pacifica Tribune Article: **Helen Nicely**. City Council issues proclamation in honor of Earth Day.

June 25, 2013: Pacifica Tribune Article: Myrna Faulds and **Helen Nicely**. Firework changes help wildlife.

July 3, 2013: Pacifica Tribune Article: **Helen Nicely**. Alternative ways to celebrate the 4th of July.

September 3, 2013: Pacifica Tribune Article: **Helen Nicely**. California Coastal Cleanup 2013 targets cigarette butt trash.

September 10, 2013: Pacifica Tribune Article: **Helen Nicely** and Lynn Adams. Countdown to California Coastal Cleanup Day, 21 September, 2013.

Yamamoto *et al.* Assessing the effect of baseline status or serum bone turnover markers and vitamin D levels on efficacy of teriparatide 20 µg/day administered subcutaneously in Japanese patients with osteoporosis. *J Bone Miner Metab* 2013;31:199-205. Slide set development from manuscript for Global Slide Bank by **Helen Nicely**.

Nakamura *et al.* Consistency of fracture risk reduction in Japanese and Caucasian osteoporosis patients treated with teriparatide: a meta-analysis. *J Bone Miner Metab* 2012;30:321-325. Slide set development from manuscript for Global Slide Bank by **Helen Nicely**.

Yoh *et al.* Quality of life in raloxifene-treated Japanese women with postmenopausal osteoporosis: a prospective, post-marketing observational study. *Curr Med Res Opin.* 2012;28:1757-1766. Slide set development from manuscript for Global Slide Bank by **Helen Nicely**.

Yoshitaka Isaka, Masako Nakano, Parag Garhyan, Tomonori Oura, Risa Nasu, Kenji Ohwaki, Masakazu Takeuchi, Ronan P. Kelly. Glucagon receptor antagonist LY2409021 effectively reduces fasting blood glucose in Japanese patients with type 2 diabetes mellitus during 28 days oral treatment. Oral Presentation to the Japanese Diabetes Society meeting in Kumamoto, Japan, May 16-18, 2013. Slide set development, all graphs, and tables created by **Helen Nicely**.

Zachary Skrivanek, Jenny Y Chien, Brenda Gaydos, Michael Heathman, Mary Jane Geiger, Zvonko Milicevic. Dose-finding results in an adaptive trial of dulaglutide combined with metformin in type 2 diabetes (AWARD-5). Presented to the American Diabetes Association Congress, 73rd Scientific Sessions, June 22, 2013, Chicago, IL. [Poster awarded best poster merit](#). Poster development, all graphs, tables, layout and blue background version created by **Helen Nicely**.

2012

William Downey and **Helen Nicely**. CMO Adoption of New Process Technologies. *Pharmaceutical Outsourcing*. Nov 29, 2012. <http://www.pharmoutsourcing.com/featured-articles/126023-CMO-Adoption-of-New-Process-Technologies/>

Ipsen Medical Information Letters for Dysport®:

Dysport® for Injection (abobotulinumtoxin A) in the Treatment of Patients with Pediatric Urologic Indications.

Dysport® for Injection (abobotulinumtoxin A) in the Treatment of Patients with Non-Neurogenic/Idiopathic Detrusor Overactivity.

Dysport® for Injection (abobotulinumtoxin A) in the Treatment of Patients with Neurogenic Detrusor Overactivity/ Neurogenic Overactivity.

Dysport® for Injection (abobotulinumtoxin A) in the Treatment of Patients with Bruxism.

Dysport® for Injection (abobotulinumtoxin A) in the Treatment of Patients with Benign Prostatic Hyperplasia.

Ipsen Information Letter for Dysport®:

Ipsen's Progress on Developing an Alternative to Animal Testing for Botulinum Toxin Products: (LD50 testing of Dysport®).

Ipsen Abstract:

ENDO 2012, abstract for poster at 94th Annual Meeting, Houston, TX. June 23-25, 2012. Efficacy and Safety in the Somatuline® Depot (Lanreotide) Injection for Acromegaly (SODA) Study Conducted in the US: Overall Year-1 Data and Comparison of Home Injection Versus Office Injection. Salvatori R, Woodmansee W, Clary C, Chang S, Bakker B.

November 2012: Pacifica Tribune Article: **Helen Nicely**. The "Big Flush" Kept Volunteers Busy Picking Up Beach Trash.

http://www.mercurynews.com/pacifica/ci_22037258/big-flush-kept-volunteers-busy-picking-up-beach

July 2012: Pacifica Tribune Article: **Helen Nicely**. Letter to the Editor about results of cleanup and gray whale sightings at Mussel Rock <http://fixpacifica.blogspot.com/2012/07/pacifica-tribune7312-letters-to-editor.html>

March 2012: Pacifica Tribune Article: **Helen Nicely**. Dog killed by coyotes at Mussel Rock Point.

<http://fixpacifica.blogspot.com/2012/07/pacifica-tribune7312-letters-to-editor.html>

March 2012: Pacifica Tribune Article: **Helen Nicely**. Beware of coyotes at Mussel Rock Park if walking your dog there. <http://fixpacifica.blogspot.com/2012/03/beware-of-coyotes-if-walking-your-dog.html>

2011

December 2011: Pacifica Tribune Article: **Helen Nicely**. If you go down to the woods today, you're in for a big surprise. Coyotes have moved in, and may be getting closer to our homes and pets.

August 2011: Pacifica Tribune Article: **Helen Nicely**. Reasons to respect coastal wildlife: The lost age of innocence. <http://www.pacificabeachcoalition.org/news-room/reasons-to-respect-coastal-wildlife>

NANETS 2011, abstract for poster at NANETS meeting, Minneapolis, Oct 20, 2011. An Ongoing Double-Blind, Randomized, Placebo-Controlled Clinical Trial, Investigating the Efficacy and Safety of Somatuline® Depot (Lanreotide) Injection in the Treatment of Carcinoid Syndrome: Update on the Current Status. Gomez-Panzani E, Chang S, Knowles N & Fohanno V.

William Downey and **Helen Nicely**. Biopharmaceutical Fill and Finish Contract Manufacturing. Pharmaceutical Outsourcing Sept/Oct 2011: 56-61.

William Downey and **Helen Nicely**. Single-Use Disposables Technologies in Biopharmaceutical Contract Manufacturing. American Pharmaceutical Review July/Aug 2011: 42-47.

Sean Turbeville, **Helen Nicely**, Douglas J, Rizzo T, Pedersen L, Orchard PJ, Horowitz MF, Horowitz EM, Veys P, Bonfim C, Seraihy AA. Clinical outcomes following hematopoietic stem cell transplantation for the treatment of mucopolysaccharidosis VI. Mol Genet Metab 102 (2011) 111-115.

2010

J. Pediatric Rehabilitation Medicine – **Helen Nicely**, editor of 2 issues, comprising 16 manuscripts as meeting proceedings from Promoting Bone Health in MPS VI: Framing New Therapies-a Meeting for MPS diseases held in 2008, published 2010.

Harmatz P, Hendriksz C, Giugliani R, **Nicely H**, Waite A, MPS VI CSP Investigators at 41 sites. Preliminary analysis of cervical cord involvement in Mucopolysaccharidosis VI patients aged <6 years old before and after enzyme replacement therapy with Naglazyme® (galsulfase). Podium presentation by first author at the Adelaide MPS/LSD meeting 2010. Abstract submitted also to ASHG 2010.

V Valayannopoulos, **H Nicely**, P Harmatz, S Turbeville. **Highly accessed**
Review: Mucopolysaccharidosis VI. Orphanet Journal of Rare Diseases and www.orpha.net.
http://www.ojrd.com/content/5/1/5. Epub 12 April 2010.

Paul Harmatz, Chris Hendriksz, Roberto Giugliani, **Helen Nicely** and the MPS VI Clinical Surveillance Program Investigators. Preliminary Analysis of Cervical Cord Involvement in Mucopolysaccharidosis VI Patients Aged <6 Years Old Before and After Enzyme Replacement Therapy With Naglazyme (Galsulfase). Abstract submitted to the 11th MPS/LSD meeting in Adelaide, Australia, June 2010.

Decker *et al.* **Helen Nicely** as project manager and editor. Enzyme replacement therapy for mucopolysaccharidosis VI: growth and pubertal development in patients treated with recombinant human N-acetylgalactosamine 4-sulfatase. J. Pediatr Rehab Med. Editorial contributions. 2010.

Harmatz *et al.* **Helen Nicely** as project manager and editor Enzyme replacement therapy for mucopolysaccharidosis VI: evaluation of long-term pulmonary function in patients treated with recombinant human N-acetylgalactosamine 4-sulfatase. J. Inherit Metab Dis 2010 6 Feb. Project management and editorial contributions.

Pederson D, Rizzo T, **Nicely H**, Turbeville S. Morbidity and Mortality following Hematopoietic Stem Cell Transplantation for the Treatment of Mucopolysaccharidosis VI. Poster submitted to ACMG 2010 and submitted to Adelaide MPS/LSD meeting 2010.

2009

K White, P Harmatz, R Lachman, S Turbeville, **H Nicely**. Orthopedic management in the mucopolysaccharidoses. Poster presented to ASHG 2009, Hawaii.

Peck D, Volz A, **H Nicely**. Ongoing observations of PKU patients treated with Kuvan (sapropterin dihydrochloride): An introduction to the PKUDOS registry for BH4-responders and BH4-non-responders and its subregistry PKUMOMS for pregnant or nursing PKU patients. Poster presented to NSGC (National Society for Genetic Counselors) Atlanta, Georgia. November, 2009.

T Kurczynski, B Wuebbels, D Reilly, **H Nicely**, Pat Pallansch. Long-term observations of the phenylketonuria patients in the PKUDOS registry and its subregistry PKU MOMS. Poster presented to ACMG 2009 Tampa, Florida.

V Valayannopoulos, M Raff, S Turbeville, **H Nicely**. A follow-up of Naglazyme enzyme replacement therapy in two cases of bone marrow transplantation failures in MPS VI patients. Poster presented to ASHG 2008, Philadelphia.

Harmatz P, Giugliani R, Schwartz IV, Guffon N, Teles EL, Miranda MC, Wraith JE, Beck M, Arash L, Scarpa M, Ketteridge D, Hopwood JJ, Plecko B, Steiner R, Whitley CB, Kaplan P, Yu ZF, Swiedler SJ, Decker C, MPS VI Study Group. **Helen Nicely** as project manager and editor. Long-term follow-up of endurance and safety outcomes during enzyme replacement therapy for mucopolysaccharidosis VI: Final results of three clinical studies of recombinant human N-acetylgalactosamine 4-sulfatase. Mol Genet Metab, 2008 Aug, Vol.94, Pages 469- 75, [PMID]: 18502162. Project management and editorial contributions.

April 8, 2008: Pacifica Tribune Article: **Helen Nicely**. My Turn. The Plastic Dilemma. The Answer to the Great Whodunnit: How plastics in the Pacifica Ocean and whales' stomachs are directly linked to Pacifica and Daly City's run-away recycling.

C Tiffit, V Proud, P Levy, K De Marco, **H Nicely**, S Turbeville. Enzyme replacement therapy in the home setting for MPS VI: A survey of patient characteristics and physicians' early findings in the United States. Poster presentation to 10th Annual MPS Society meeting, Vancouver, June, 2008. J. Infus Nurs 2009, Jan-Feb 32, p45-52.

2008

E Jurecki, M Schultz, **H Nicely**. Selection of phenylketonuria (PKU) patients by academic medical centers for sapropterin expanded access program (SEAP) and determination of response to sapropterin dihydrochloride (Kuvan™) therapy. Poster presented to AMCP (Academy of Managed Care Pharmacy), Kansas, October, 2008. Manuscript submitted to JMCP 2009.

H Bausell, E Jurecki, P Pallansch, A Schatz, K de Marco, A Volz, R Cady, S Turbeville, **H Nicely**. Preliminary analysis of safety data from the sapropterin expanded access program for PKU. Poster for GMDI (Genetics Metabolism Dietitians International), Atlanta, April, 2008. Manuscript submitted to JIMD 2009.

R Lachman, S Turbeville, **H Nicely**. Radiographic expression of mucopolysaccharidoses: Dysostosis multiplex. Poster: Society for Pediatric Radiology. 51st Annual Meeting & Postgraduate Course. Scottsdale, Arizona. May, 2008.

N Armstrong, H Bausell, E Jurecki, **H Nicely**, A Dorenbaum. Four classical PKU subjects with variable responses to Kuvan™. Poster presented to GMDI, Atlanta, April, 2008.

D Musson, C O'Neill, W Kramer, E Foehr, F Bieberdorf, S Kim, A Dorenbaum, S Turbeville, **H Nicely**. The Bioavailability of Kuvan™ (sapropterin dihydrochloride) from intact and dissolved tablets administered with or without food to healthy volunteers. Identical poster presentations to SIMD and GMDI, March and April, 2008 in Asilomar and Atlanta, respectively.

B Burton, H Bausell, E Jurecki, P Pallansch, A Schatz, K de Marco, A Volz, R Cady, S Turbeville, **H Nicely**. Preliminary findings of safety data from the sapropterin expanded access program for PKU. Poster for SIMD (Society of Inherited Metabolic Disorders), Asilomar, March, 2008.

S T Koseoglu, P Harmatz, S Turbeville, **H Nicely**. Reversal of papilledema and improved visual acuity with Enzyme Replacement Therapy (galsulfase) in MPS VI: a Case Report. Poster. Abstract book ACMG March, 2007, manuscript accepted by International Ophthalmology 2008.

P Harmatz, A Wen, **H Nicely**, S Turbeville, M Heard, K Hardy, C Decker. Tracheostomy reversal in an MPS VI patient due to improved pulmonary function while on enzyme replacement therapy. Poster presented to ACMG, Phoenix, AZ in March 2008.

Koseoglu ST, Harmatz P, Turbeville S, **Nicely H**. Reversed papilledema in an MPS VI patient with galsulfase (Naglazyme) therapy. Int Ophthalmol 2008 April 17.

2007

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