# ETHICAL, LEGAL AND SOCIAL IMPLICATIONS
## of LEARNING HEALTH SYSTEMS

# SYMPOSIUM

**The Learning Health System in Practice**

**November 9, 2018**

**MICHIGAN MEDICINE**
UNIVERSITY OF MICHIGAN

Department of Learning Health Sciences

# [ELSI-LHS]



A "learning health system" is a health system that is set up to continuously self-improve. At all levels of scale, learning health systems use technologies, people, processes and infrastructures to link data and analysis to knowledge and practice. The Ethical, Legal & Social Implications of Learning Health Systems (ELSI-LHS) Symposium provides a forum to bring together scholars investigating and practitioners engaged in using health-related data, to generate computable knowledge, put that knowledge into practice, and evaluate the outcomes.

The goal of ELSI-LHS inquiry is to enable health improvements while forging a deliberate path toward equity and justice.

The ELSI-LHS collective supports this goal year-round through research, education and service— engaging with such themes as trust, systems ethics and equity.

In its first two years, the ELSI-LHS symposium considered the vision and enabling technologies of learning health systems. Today we'll investigate use cases and lessons learned from emerging learning health systems and learning health system technologies to address chronic diseases such as cancer— exploring *learning health systems in practice.*

# [past and future]



*"Equity in the learning health system is not built without concerted effort."*
—Patricia Kingori 2016



*"The symposium is emerging as home for a new and important group of scholars, lawyers and policy analysts – among others. Thoughtful presentations and debates are precisely the way to ensure that we do a good job identifying and addressing ELSI issues."*
—Kenneth Goodman 2017



*"The ELSI-LHS enterprise is part of a larger project of balancing individual vs. collectivist ethics."*
— Joon-Ho Yu 2017



*"The success of [the LHS] vision will depend on the health care system members' (patients') continued trust in the system. So it seems important to carefully consider policy proposals that could potentially affect that trust."*
—Scott Kim 2016

## Looking ahead...

We are currently putting in a grant proposal seeking funding for continuing these ELSI-LHS symposia. We would love to partner with other programs and training grants, and help to build a strong ELSI research network in this area.

If you'd like to be a part of our conference grant, this research network, or to collaborate on future paper or grant sprints and projects, please contact Jody Platt.

jeplatt@umich.edu
#elsilhs

# ELSI-LHS SYMPOSIUM AGENDA 2018

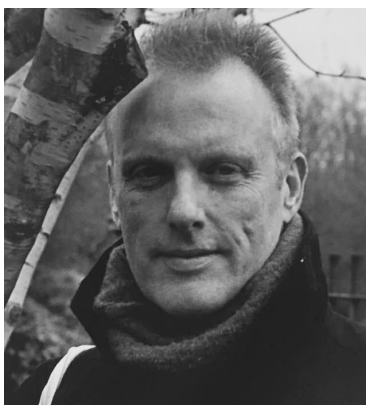| | | |
|---|---|---|
| **8-8:30** | **BREAKFAST + REGISTRATION** | |
| | **Welcome** | |
| 8:30-9 | Charles Friedman<br>Jodyn Platt<br>Kayte Spector-Bagdady | **Opening remarks** |
| | **Session 1: Reports from the Field** | **Moderator**<br>**Discussant** |
| 9-10:30 | Brendan Delaney • Establishing a Learning Health System for Cancer Diagnosis in Primary Care<br><br>Romesh Nalliah •  Improving Resource Utilization in Dental Clinics<br><br>Michelle Meyer • Objecting to Experiments that Compare Two Unobjectionable Policies: Experimental Evidence and Implications for Learning Health Systems | Tricia Piechowski<br><br>Joyce Lee |
| **10:30** | **15- MINUTE BREAK** | |
| | **Session 2: Equity and Ethics** | |
| 10:45-12:15 | Jeremy Sugarman • Lingering and Emerging Ethical Issues for Pragmatic Clinical Trials and Learning Health Systems<br><br>Anya Prince • Prevention, Coercion, or Both?<br><br>Shawneequa Callier • The Roles of Race and Representation in Learning Health Systems: Potential Future Approaches to Reduce Health Disparities | Julie Harris-Wai<br><br>Erica Marsh |
| **12:15-1:15** | **LUNCH WITH SPEAKERS** | |
| | **Session 3: Empirical Studies in and for ELSI-LHS** | |
| 1:15-2:45 | David Magnus • Biospecimen Exceptionalism Revisited: Uses of Genetic Data and EHR Data in the Learning Health System<br><br>Kirsten Ostherr • Privacy and Sharing in Metaclinical Health Ecosystems<br><br>Nov. 8 ELSI-LHS Paper Sprint Report | Dorene Markel<br><br>Reshma Jagsi |
| | **Conclusion** | |
| 2:45-3:15 | Jodyn Platt & Kayte Spector-Bagdady • Closing | |
| *Post your photos and take-aways at #elsilhs* | | |

# [contributors]

**Shawneequa Callier, JD, MA • George Washington University**

Professor Callier is an Associate Professor in the Department of Clinical Research and Leadership and Director of Doctoral Research in the Translational Health Sciences Ph.D. program at the George Washington University School of Medicine and Health Sciences (SMHS). She teaches courses in bioethics and health care law in a variety of SMHS programs. She is a Professorial Lecturer in Law at the GWU Law School and Special Volunteer at the Center for Research on Genomics and Global Health, National Human Genome Research Institute, National Institutes of Health. Prior to joining the GWU faculty, she completed a post-doctoral fellowship at the Center for Genetic Research Ethics and Law, an interdisciplinary center for excellence funded by the National Human Genome Research Institute and located in the Bioethics Department of Case Western Reserve University's School of Medicine. Earlier in her career, Prof. Callier practiced health care law as an attorney in Washington, D.C. and interned at the World Health Organization and the Nuffield Council on Bioethics where she examined international healthcare ethics policies and human genetics laws and guidelines.

**Brendan Delaney, MD · Imperial College, London**

Dr. Delaney is a practicing GP in Rotherhithe, and has an academic background in Clinical Research Informatics (CDISC standards and eSource), Clinical Trials, HTA, Modelling and Patient Safety. Brendan's previous appointments include Wolfson Chair of General Practice at King's College London, and Chair, Reader, Senior Lecturer, Lecturer at the University of Birmingham. His main focus of research is on The Learning Health System, using informatics tools to link both knowledge generation and knowledge utilization to routine healthcare IT systems, with a particular emphasis on decision support for diagnosis and the role of Artificial Intelligence in creating, curating and improving diagnostic evidence. He is associate editor of the Journal "Learning Health Systems," a member of the UK Health Informatics Research Network College of Experts, Farr Institute Primary Care Lead, as well as a member for the MRC Methodology Research Panel and Vice-chair of the CRUK Early Diagnosis Expert Review Panel.

**Charles P. Friedman, PhD · University of Michigan**

DLHS  IHPI  MM  SI  SPH

Dr. Friedman is the Josiah Macy Jr. Professor of Medical Education and Chair of the Department of Learning Health Sciences at the University of Michigan Medical School. He joined U-M in 2011 as Professor of Information and Public Health, and Director of the Michigan health informatics program. Dr. Friedman's academic interests have intertwined biomedical and health informatics with the processes of education and learning. His department is a "first in the nation" medical school academic department dedicated to the sciences of learning at all levels of scale: from learning by individuals, to learning by teams and organizations, and learning by ultra-large scale systems such as entire nations. Prior to coming to Michigan, Dr. Friedman held executive positions at the Office of the National Coordinator for Health IT (ONC): from 2007-2009 as Deputy National Coordinator and from 2009-2011 as ONC's Chief Scientific Officer. While at ONC, Friedman oversaw a diverse portfolio that included the initial funding for the SMART platform. Prior to his work in the government, Dr. Friedman was Associate Vice Chancellor for Biomedical Informatics, and Founding Director of the Center for Biomedical Informatics at the University of Pittsburgh.

**Julie Harris-Wai, PhD, MPH · UCSF**

Dr. Harris-Wai is a bioethicist and ELSI researcher at the University of California, San Francisco. She has a Ph.D. in Public Health Genetics from University of Washington and completed a fellowship in population health sciences with the Robert Wood Johnson Foundation's Health and Society Scholars Program. Her research focuses on strategies for incorporating diverse public perspectives into genomics research programs and health policies. She is currently leading community engagement efforts for the UCSF Prenatal and Pediatric Genomic Sequencing study (P3EGS). She recently completed two projects using deliberative community engagement methods to help inform decision-makers on policy changes in state newborn screening programs. Prior to returning to UCSF, Dr. Harris-Wai was a scientist at the Kaiser Permanente Division of Research, where she led bioethics and community engagement efforts for the KP Research Bank, a national biorepository, including over 200,000 KP members.

**Reshma Jagsi, MD, D.Phil · University of Michigan**  `CBSSM`  `IHPI`

Dr. Jagsi is Professor, Deputy Chair, and Residency Program Director in the Department of Radiation Oncology and Director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan. She graduated first in her class from Harvard College and pursued her medical training at Harvard Medical School. She served as a fellow in the Center for Ethics at Harvard University and completed her doctorate in Social Policy at Oxford University as a Marshall Scholar. An active clinical trialist and health services researcher, Dr. Jagsi's medical research focuses on improving the quality of care received by breast cancer patients, both by advancing the ways in which breast cancer is treated with radiation and by advancing the understanding of patient decision-making, cost, and access to appropriate care. Her social science research examines women's representation in the medical profession and  issues of bioethics arising from cancer care, including an NIH R01-funded deliberative democracy study of cancer patients' perceptions of the ethical implementation of learning health systems in oncology care.  She serves on the Board of Directors of the American Society of Clinical Oncology, the Steering Committee of the Early Breast Cancer Trialists Collaborative Group, the editorial boards of the Journal of Clinical Oncology and JAMA Oncology, and others. She was also elected to the American Society of Clinical Investigation.

**Joyce Lee, MD, MPH · University of Michigan**  `IHPI`  `MM`

Dr. Lee is a Physician, Designer, and Researcher, and the Robert P. Kelch, MD, Professor of Pediatrics at the University of Michigan. Her work focuses on the development of learning health systems using the methods of clinical informatics, quality improvement, and patient-centered participatory design; studies of collaborative innovation networks and patient-centered innovation, and integration of the maker movement into healthcare. Her work can be found at http://www.doctorasdesigner.com.

**David Magnus, PhD · Stanford University**

Dr. Magnus is Thomas A. Raffin Professor of Medicine and Biomedical Ethics and Professor of Pediatrics and Medicine at Stanford University, where he is Director of the Stanford Center for Biomedical Ethics and co-Chair of the Ethics Committee for the Stanford Hospital.  He is now Vice-Chair of the IRB for the NIH Precision Medicine Initiative ("All of Us.") He is the former President of the Association of Bioethics Program Directors, and is the Editor in Chief of the American Journal of Bioethics. Dr. Magnus received his Ph.D. in philosophy from Stanford and has published articles on a wide range of topics in bioethics, including research ethics, genetics, stem cell research, organ transplantation, end of life and patient communication. He has served on the National Research Council Ad Hoc Committee on the Bioconfinement of Genetically Engineered Organisms, as an "expert consultant" for the World Bank on food security and biotechnology and a consultant for the National Conference of State Legislators on cloning.  He was a member of the Secretary of Agriculture's Advisory Committee on Biotechnology in the 21st Century and serves on the California Human Stem Cell Research Advisory Committee. He is the principle editor of a collection of essays entitled *Who Owns Life?* (2002).

**Dorene S. Markel, MS, MHSA · University of Michigan**  `DLHS`  `BREHM`  `MM`

Dorene Markel is Director of the Brehm Center at Michigan Medicine, which is focused on transforming the way research and collaborations are undertaken using a systems analysis approach, utilizing diabetes as a platform. She holds a faculty appointment in the Department of Learning Health Sciences and is playing a key role in initiating an LHS approach to diabetes care at UMHS. Her interests in ethics relate to human genetics, human-focused research and learning health systems. She serves as a coordinator and mentor to the Brehm Scholarship programs. Ms. Markel has been on staff at the UM Medical School since 1984 and has held leadership roles in growing the clinical and translational research enterprise at Michigan Medicine. She served as the Associate Director for Alliances and Collaborations for the Michigan Institute for Clinical and Health Research (MICHR) home of UM's NIH-CTSA grant, as the Director of Clinical and Translational Research at the University of Michigan Medical School and as the founding Managing Director of MICHR. She also played a key role in the development of the NIH Human Genome Center at the University of Michigan (then directed by Dr. Francis Collins), where she served as the Director of Human and Family Studies. Ms. Markel was the first Genetic Counselor to be employed by Michigan Medicine, and among the first nationally to specialize in neurogenetic conditions.

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### Erica E. Marsh, MD MSCI FACOG · University of Michigan    `IHPI`  `MICHR`  `MM`

Dr. Marsh is an Associate Professor of Obstetrics and Gynecology at the University of Michigan Medical School, Chief of the Division of Reproductive Endocrinology and Infertility, and Founder and Executive Director of the Women's Health and Reproductive Disparities (on-WHARD) Program at Michigan Medicine. She graduated from Harvard College *magna cum laude* and from Harvard Medical School, *cum laude,* in 2001. She completed her residency at the Integrated OBGYN Residency at the Brigham and Women's Hospital and Massachusetts General Hospital in 2005, and next completed a Reproductive Endocrinology and Infertility fellowship at Northwestern University before joining the faculty at Northwestern's Feinberg School of Medicine. In 2016, Dr. Marsh joined the University of Michigan, where she sees patients, teaches, mentors, and conducts basic science, population, health services and clinical research. Dr. Marsh has received millions of dollars in funding to support her research and has published on fibroids, abnormal uterine bleeding and reproductive health disparities. Her work is currently funded by the NICHD, NIMHD, PCORI and industry. Her research area of interest is Comparative Reproductive Health across populations, with a particular interest in abnormal uterine bleeding, uterine fibroids, and ovarian reserve. Dr. Marsh seeks to understand the challenges of these conditions from $360^0$, addressing their pathophysiology, epidemiology, clinical impact, and patient experience from symptoms and diagnosis to treatment. Among numerous research awards, she was named the 2015 Ira and Ester Rosenwaks New Investigator of the Year by the American Society of Reproductive Medicine. In addition to her roles of Division Chief, PI, and Founder and Executive Director of The onWHARD Group, she also serves as the Faculty Lead of Community Engagement for the CTSA at Michigan Medicine – the Michigan Institute for Clinical and Health Research (MICHR).

### Michelle N. Meyer, JD, PhD · Geisinger

Michelle N. Meyer, JD, PhD is an Assistant Professor and Associate Director, Research Ethics, in Geisinger's Center for Translational Bioethics and Health Care Policy. She chairs the IRB Leadership Committee and directs the Research Ethics Advice and Consulting Service and the Meyer Lab, which uses experimental and other methods to empirically investigate ethical, legal, and social aspects of science and health care. Dr. Meyer's research interests focus on the legal, bioethical, and policy issues that arise in the conduct of research and other learning activities (e.g., QA/QI). In particular, she has written and spoken about learning healthcare systems and the ethical imperative to study the consequences of policies and practices; the role of IRBs and alternative bodies and processes for overseeing research and other learning activities; informed consent effectiveness in research (and in clinical contexts); data privacy and data sharing; responsible science communication, and reproducibility in science.

### Romesh Nalliah, DDS, MCHM · University of Michigan    `DENT`  `MM`  `IHPI`

Dr. Nalliah has research expertise in process evaluation. He has studied various healthcare processes, educational processes and healthcare economics. His research studies were the first to use nationwide data to highlight emergency room resource utilization for managing dental conditions in the United States. Dr. Nalliah is internationally recognized as a pioneer in the field of nationwide hospital dataset research for dental conditions and has numerous publications in peer-reviewed journals. After completing a masters degree at Harvard School of Public Health, Dr. Nalliah's interests have expanded to include sports injuries, poisoning, child abuse, motor vehicle accidents and surgical processes (like stem cell transplants, cardiac valve surgery and fracture reduction). Dr. Nallliah's passion is that his reserch should inform an evolution of health education curriculum and practice. His broad expertise gives rise to opportunities to lecture to medical residents, nurse practitioners, students in medical, pharmacy and nursing programs about oral health. Dr. Nalliah's professional mission is to improve healthcare delivery systems and he is interested in improving processes, minimizing inefficiencies, reducing healthcare bottlenecks, increasing quality, and increase task sharing which will lead to a patient-centered, coherent healthcare system. Dr. Nalliah's research has identified systems constraints and his goal is to influence policy and planning to break those constraints and improve healthcare delivery.

### Kristen Ostherr, PhD, MPH · Rice University

Dr. Ostherr teaches film and media studies, focusing on historical and contemporary visualizations of health and disease in photography, documentary film, television, animation, advertising, medical imaging, and web-based media. Her current research focuses on the emergent field of mHealth (mobile health) media, concepts of algorithmic life and the quantified self, and design-based translations of data into story. With the support of an Andrew W. Mellon Foundation New Directions Fellowship, Dr. Ostherr recently completed an MPH degree at the UT-Houston School of Public Health. Her MPH research focused on the use of information and communication technologies in end-of-life care. Since 2012, Dr. Ostherr has been co-founder and director of the Medical Futures Lab, a collaborative center bringing together faculty from Rice, Baylor College of Medicine, and UT Health to reimagine medicine at the intersection of humanity and technology. Through the Medical Futures Lab, she team-teaches a series of "digital medical humanities" courses that train students to solve real-world healthcare problems through collaborative, participatory design practices.

### Tricia Piechowski, MSW, MA · MICHR    `MICHR`  `MM`

Tricia Piechowski, MPH, MSW, MA is an Administrative Program Director of the Community Engagement Program at the Michigan Institute for Clinical & Health Research (MICHR) within the University of Michigan's Medical School Office of Research. She works toward building equitable partnerships between community and academic partners in research. She develops trainings, creates funding mechanisms, provides consultations, and engages in other infrastructure building activities for partnership development to support community-engaged research. She has served as the Chair of the Community-Based Public Health Caucus (CBPHC) of the American Public Health Association (APHA) and is currently an academic program planner for the Caucus. She chairs the Washtenaw County DHHS Board, an active member of the Washtenaw County Success by 6 Great Start Parent Coalition, and is Adjunct Faculty at Wayne State University. She has an MSW in interpersonal practice with children and youth and MPH from the University of Michigan in Health Behavior & Health Education and an MA in African Studies from UCLA.

### Jodyn Platt, PhD, MPH · University of Michigan    `CBSSM`  `DLHS`  `IHPI`  `MM`

Dr. Platt is an Assistant Professor in the Department of Learning Health Sciences, Division of Learning and Knowledge Systems at the University of Michigan. She is trained in medical sociology, health policy, and public health. Her research currently focuses on informed consent in cancer and genomic studies, and the Ethical, Legal, and Social Implications (ELSI) of public health genetics, newborn screening, and learning health systems. She is interested in understanding what makes learning health systems trusted and the pathways for earning and sustaining trust, using qualitative and survey methods. She has led the planning and implementation of the ELSI-LHS symposia since they began in 2016 and chairs the ELSI initiatives in the UM Department of Learning Health Sciences including the ELSI working group of the pan-university UM Collaboratory.

### Anya Prince, JD · University of Iowa

Professsor Prince's work explores the ethical, legal, and social implications of genomic testing, with particular focus on genetic discrimination and privacy rights, the intersection of clinical and research ethics, and insurance coverage of genetic technologies and interventions. She is a former Visiting Assistant Professor of Law at Indiana University's Robert H. McKinney School of Law, where she taught New Genetics: Ethical, Legal and Policy Issues and Employment Law. She has published a variety of articles in legal, bioethics, and medical journals, including the American Journal of Bioethics, Journal of Law, Medicine, and Ethics, and Genetics in Medicine, and she has presented and been an invited speaker at conferences across the country. She was recently awarded a Pathway to Independence Award (K99/R00) from the National Human Genome Research Institute to examine the use of genetic information by life, long-term care, and disability insurers. Before joining the legal academy, she served as a Post-Doctoral Research Fellow at the UNC Center for Genomics and Society (CGS) in the Department of Social Medicine at UNC-Chapel Hill School of Medicine as well as an intern on the UNC Hospital Ethics Committee. In 2015, she received the UNC's Postdoctoral Award for Research Excellence and received additional funding from the Skadden Foundation for her work on the hospital ethics committee.

**Kayte Spector-Bagdady, JD, MBioethics · University of Michigan**   IHPI   MM   CBSSM   MICHR

Kayte Spector-Bagdady is an Assistant Professor in the Department of Obstetrics and Gynecology at the University of Michigan Medical School and is also the Chief of the Research Ethics Service in the Center for Bioethics and Social Sciences in Medicine. At UM she also serves as Chair of the Research Ethics Committee, a clinical ethicist through CBSSM's Clinical Ethics Service, and a member of IRB Council. Her current work focuses on the limits of current governance structures over private biomedical data collection and sharing. Prof. Spector received her J.D. and M.Bioethics from the University of Pennsylvania Law School and School of Medicine respectively after graduating from Middlebury College. She is a former practicing biotech attorney and was Associate Director of the Presidential Commission for the Study of Bioethical Issues under President Obama (2010-2015).

**Jeremy Sugarman, MD, MPH, MA · Johns Hopkins University**

Dr. Sugarman is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, professor of medicine, professor of Health Policy and Management, and deputy director for medicine of the Berman Institute of Bioethics at the Johns Hopkins University. He is an internationally recognized leader in the field of biomedical ethics with particular expertise in applying empirical methods and evidence-based standards for evaluating and analyzing bioethical issues. His contributions to both medical ethics and policy include his work on the ethics of informed consent, umbilical cord blood banking, stem cell research, international HIV prevention research, global health and research oversight.



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| IHPI | Institute for Healthcare Policy and Innovation | SPH  School of Public Health |
| | | MM  Michigan Medicine |

**Little doodles.
Big ideas.
Please write on
your tablecloths!**

# [ready, set, sprint!]

This year we piloted a writing sprint as a part of the ELSI-LHS symposium. The goal of a writing sprint is to facilitate collaboration and produce meaningful deliverables (papers and grants) in a focused block of time, synthesizing ideas and pooling efforts relevant to a research area— in this case, ELSI-LHS.

The writing sprint methodology was developed by the University of Michigan School of Public Health Innovation Studio along with Andrew Ryan and colleagues at IHPI.  Writing sprints last two hours, and offer a collaborative space with a structured agenda that help members of our community participate in a focused team project to increase the impact of their work and disseminate findings.

Yesterday, (Nov. 8, 2018) we hosted 4 collaborative teams in the writing sprint.  Teams involved senior and junior faculty, graduate students, and staff focused on a topic of mutual interest.  Topics for papers and grants this year included :

(a) an application of critical race theory and the public health critical race praxis to ELSI-LHS;

(b) deliberative democracy as a method of engagement in health and science policy `CBSSM` ;

(c) the ethical considerations for performance feedback interventions to healthcare professionals and teams, and

(d) a proposal for the next three years of ELSI-LHS symposia.

Thanks to the participants! At time of printing: Karen Calhoun; Shawneequa Callier; Elizabeth Cope; Melissa Creary; Brendan Delaney; Raymond De Vries; Emily Dibble; Janice Firn; Len Fleck; Susan Goold; Julie Harris-Wai; Zach Landis-Lewis; David Magnus; Dorene Markel; Beza Merid; Paige Nong; Kirsten Ostherr ; Tricia Piechowski; Chithra Perumalswami; Jody Platt; Anya Prince; Mina Raj; Joshua Rubin; Kayte Spector-Bagdady; Cooper Stansbury; Matthew Sullivan; Daniel Thiel, and Gracie Trinidad.

*We will issue a call for papers to participate in the 2019 ELSI-LHS Writing Sprint. Sharpen your pencils!*

# [planning committee]

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**QUESTIONS? Visit the registration table or email elsi.4.lhs@umich.edu**

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# [sponsors]

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# [stay connected]

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> **MOBILE and ONLINE:** www.elsilhs.org

> **SOCIAL MEDIA:** Join & continue the conversation: #elsilhs
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## #elsilhs

# [notes]