

World leaders across science and medicine call for improved organ preservation and cryobanking to transform transplantation - citing impact on par with curing cancer

NASA RESEARCH PARK, MOFFETT FIELD, Calif., June 7, 2017/ -- [Today in Nature Biotechnology](#), 40+ world leaders across science and medicine outline the need for a modern-day “Apollo Program” to “control biological time” for organs and tissues.

Organ preservation is one of the key challenges facing biomedicine today, affecting millions of people each year worldwide by constraining the ability to treat patients for heart disease, cancer, diabetes, liver failure, and other leading causes of death. The implications for global health, the success of scientific research and drug discovery, healthcare expenditures, and national defense are profound.

In the US, for every patient on the heart transplant wait list who does not receive an organ in time, 10 hearts from organ donors go unused despite the amazing work of organ procurement organizations. Short heart preservation windows (only 3-5 hours) are a major driver of this phenomenon. Said Massachusetts General Hospital Chief of Transplantation and Harvard Professor James Markmann, “Organ preservation is a field ripe for game-changing innovation, with entirely new possibilities for organ transplantation opened up by cryopreserving organs.”

Authors of the *Nature Biotechnology* paper include Nobel Prize and Breakthrough Prize winners, leaders of transplant societies, pioneers of tissue engineering, xenotransplantation, and other fields, and scientists and/or heads of transplantation from Harvard, MIT, Stanford, Johns Hopkins, and other leading research institutions.

Many of these leaders will gather at the upcoming global [Organ Banking Summit at Harvard Medical School](#). “This is the kickoff for a modern day ‘Apollo Program in Organ Banking’. Like going to moon was audacious, but something we knew we could accomplish, so is solving organ cryobanking”, said co-lead author and chairman of the Organ Preservation Alliance, Dr. Sebastian Giwa.

As announced last year by the Obama White House, in partnership with the Organ Preservation Alliance, the [American Society of Transplantation \(AST\) just launched a new branch](#). “Organ preservation is a field long overdue for large-scale, focused attention from the surrounding scientific and medical communities. For organ cryopreservation in particular, implications for global health are enormous,” said coauthor, past president of AST and Harvard Professor, Anil Chandraker,

Examples of the scientific renaissance are developments in [nanotechnology-based cryo-warming](#) (March 2017); and cryobanking and transplantation of [whole animal limbs](#) (April 2017).

Momentum also includes government support spanning from an *NSF-funded technology roadmap* and White House roundtable to a DARPA workshop and the DoD launching six funding pipelines (see [Scientific American](#), [The Economist](#)).



A: Device that enables perfusion of organs - enabling preservation, reconditioning, assessment and even treatment and repair of organs. **B:** Breakthrough rat liver preservation at high subzero temperature for 4 days as published in *Nature Medicine*. **C:** One of least 45 species in Nature that enters suspended animation below freezing with every single organ “banked” without injury. **D:** Two kidneys at deep cryogenic temperatures, one simply frozen and severely damaged and the other safely “glassified” without ice using an advanced cryoprotectant cocktail.

See below for full press packet

Full article on Nature’s website: <http://www.nature.com/nbt/journal/v35/n6/full/nbt.3889.html>

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Press Packet: World leaders in science and medicine call to improve organ preservation

Below, you'll find. . .

1. Examples of eye-opening facts and points made in the publication
2. Further citable quotes from leaders across many field who co-authored the paper (e.g. Nobel Prize winner, Breakthrough Prize winner, many from Harvard, MIT, Stanford, Johns Hopkins, etc.)
3. Examples of the public health and economic impact of the research effort called for in the publication
4. Summary events leading up to and surrounding the publication, from roundtables on the White House and Capitol Hill, to DARPA interest, to the upcoming summit at Harvard

Dr. Sebastian Giwa (contact information above) **can provide more context & facts and/or connect you with the co-authors**

Eye-opening facts and points from the publication

- The ability to replace organs and tissues on demand could save or improve millions of lives each year globally and **create public health benefits on par with curing cancer**
- World Health Organization (WHO) estimates that **only 10% of the worldwide need for organ transplantation is being met**
- The data suggest that the organ shortage is **among the greatest crises facing biomedicine** today
- With all supply constraints removed, organ **replacement could potentially prevent up to 30% of all deaths in the US or more** doubling the average person's likelihood of living to 80 years of age
- In part because of technological limitations **only 0.3% of those who die in the United States become organ donors**
- **While an organ donor can provide 8 lifesaving organs, on average only 3-4 are transplanted**
- Each year thousands of abdominal organs are discarded, and **the majority of thoracic organs from donors (~70% of heart and 80% of lung offers) go untransplanted**
 - If just 10% of the hearts currently left unused in the US were transplanted, it would equal the number of waiting-list patients who currently die or become too sick to receiving one
- **Half of organs fail within 10 years of being transplanted**, including as many as 75% of intestines and lungs
- **The toll on the economy of the unmet need for transplantation is immense**; e.g., the cost of treating **end-stage renal disease totals over \$1 trillion in the course of a decade**
- Maximum clinical organ preservation times are measured in hours, depending on the organ transplanted, requiring transplantation almost immediately after an organ is recovered
- Organs are rushed to their destinations, often by jet or by helicopter flight straight to a landing pad on the transplant center rooftop
- **Breakthroughs in organ preservation research will help with all of above**
 - **making more organs available**
 - **improving transplant outcomes and mitigating risks**
 - **decreasing healthcare costs**
- **Preservation breakthroughs will also complement and accelerate the development of other biomedical**

technologies that can alter the landscape of transplantation

Citable quotes from world leaders who co-authored the publication

We include quotes from the broad range of leading coauthors and their organizations.

The quotes are grouped as follows

1. Transplant surgeons and stakeholder organizations
2. Scientists from surrounding and converging fields
3. Cryobiology and low temperature biology scientists

1. Leading transplantation surgeons and stakeholder organizations

Organ preservation is a field ripe for game-changing innovation, with entirely new possibilities for organ transplantation opened up by cryopreserving organs.

**Chief of Transplantation, Massachusetts General Hospital
Professor at Harvard Medical School, Dr. James Markmann**

Organ cryopreservation would be one of the biggest breakthroughs – and perhaps THE biggest breakthrough – in transplantation in the last 50 years.

**Chief of Heart Transplantation, Baptist Integris Medical Center
Dr. David Nelson**

Preserving organs and tissues outside the body is one of the great scientific challenges of this era. It's hard to find an area of medicine and biomedical that's not affected somehow by this fundamental constraint. And as regenerative medicine and replacement of diseased or failing parts becomes a larger and larger part of medicine, this constraint has to be addressed – in a big way.

President and CEO, Organ Preservation Alliance, Jedediah Lewis, J.D.

As we lay out in the paper, the organ shortage is among the greatest crises facing biomedicine today leading to a potential impact that that is truly mind-blowing:

- *Without constraints, organ replacement could prevent >30% of deaths - doubling likelihood of living to 80 years of age*
- *The ability to replace organs on demand could globally save or improve millions of lives per year and create public health benefits on par with curing cancer*

**Cofounder and Chairman, Organ Preservation Alliance, Sylvatica Biotech
and Ossium Health, Dr. Sebastian Giwa**

Organ preservation is a cross-cutting issue affecting almost all other aspects of transplantation. The American Society of Transplantation is proud to join other leaders in calling for a large-scale effort to advance the science organ preservation and increase the application of organ and tissue banking. Today we have a profound opportunity to advance organ preservation capabilities and the enormous unmet need that can be met by acting on this opportunity.

**President, American Society of Transplantation
Dr. Ronald Gill**

Each year organ and tissue donors in the U.S. give tens of thousands of patients a second chance at life and healing. We must continue our pursuit of advanced organ and tissue preservation technologies to better honor those precious gifts, to provide more opportunities for transplantation and thus to save and heal more lives.

President, Association of Organ Procurement Organizations, Gordon Bowen

Organ preservation is a field long overdue for large-scale, focused attention from the surrounding scientific and medical communities. For organ cryopreservation in particular, implications for global health are enormous.

**Past President, American Society of Transplantation
Medical Director, Kidney & Pancreas Transplantation, Brigham Women's Hospital, Harvard Medical School
Dr. Anil Chandraker**

Ex vivo organ preservation and organ banking open up a world of new possibilities for organ reengineering. We hope that the advances we describe in the manuscript will make transplantable organs and tissues available to many more patients, while making the organs we have last longer and work better.

**Representative for the American Society of Transplant Surgeons a
Assistant Professor of Surgery, Northwestern University,
Dr. Jason Wertheim**

The rapid convergence of complementary technologies in organ and tissue preservation will transform how we respond to mass casualty events and how we rebuild our wounded warriors. This is a game-changing area that will alter the practice of medicine.

**Co-founder and former Deputy Director, Dept. of Defense Tissue Injury & Regenerative Medicine Program
Director of the Molecular Biology Laboratory and Academy Professor, West Point Military Academy
Lt. Col. Luis Alvarez, PhD**

Progress in cryobanking would be game-changing and would enable our ever-improving transplantation abilities to help maimed American servicemen, as well as firefighters, factory workers, or civilians and children around the world who have lost their hands or arms.

**Director of the Department of Plastic & Reconstructive Surgery and Professor, Johns Hopkins,
Dr. Andrew Lee**

In addition to scarce availability of vital organs like heart and kidneys, there is a tremendous lack of vascularized composite tissues for reconstructive surgery and regenerative medicine needs. Over 1,600 service members have suffered amputations from injuries in Iraq and Afghanistan and over 4,000 Service members have sustained severe craniomaxillofacial injuries. Being able to bank complex vascularized tissues would revolutionize the way we can restore these brave young men and women who serve our country.

**Director, Plastic Surgery Transplantation, Brigham and Women's Hospital
Harvard Medical School Professor, Bohdan Pomahac**

People seem to underestimate what could be coming. This is a big step towards a future in which we routinely replace damaged organs and tissues to restore both form and function, in a way that only transplantation allows – replacing 'like with like'. The ability to build real organ and tissue banks could transform the entire field of transplantation.

**Scientific Director, Reconstructive Transplant Program, Johns Hopkins School of Medicine
Associate Professor of Plastic and Reconstructive Surgery, Johns Hopkins School of Medicine,
Dr. Gerald Brandacher**

For the first-time ever, stopping biological time and enabling banking of human hearts, livers and kidneys is within reach. We see this consensus paper and the upcoming summit at Harvard as the kickoff for a modern day 'Apollo Program in Organ Banking'. Like going to moon was audacious, but something we knew we could accomplish, so is solving organ banking.

**Co-founder and Chairman, Organ Preservation Alliance
Co-founder and Chairman, Sylvatica Biotech
Co-founder and Chairman, Ossium Health
Dr. Sebastian Giwa**

The response to the DoD organ and tissue preservation innovation grant solicitations has been unprecedented. Over 70 groups including top universities and hospital centers put forward novel approaches to preservation and three new companies were started with SBIR funding. The response has been overwhelming.

**Co-founder and former Deputy Director, Dept. of Defense Tissue Injury & Regenerative Medicine Program
Director of the Molecular Biology Laboratory and Academy Professor, West Point Military Academy
Lt. Col. Luis Alvarez, PhD**

2. Leading scientists from surrounding and converging fields

Millions of people each year worldwide could benefit from organ replacement. The public health implications of these technologies are nothing short of staggering.

**Professor of Genetics, Harvard and MIT,
Dr. George Church**

Tissue engineering progress could be dramatically accelerated by cryopreservation, which could overcome one of the main bottlenecks in the field. It's not enough to make the tissue; you have to get it to the clinic and the patient. We now have the blueprint and are working on the technologies to address this problem.

Institute Professor and Professor of Bioengineering, MIT, Dr. Robert Langer

Organ banking would open up many new possibilities for live kidney donation, including paired exchanges that are no longer bounded by time or space. We may well see many more international exchanges as this technology develops, increasing access to kidney transplantation for hard-to-match populations and allowing more donation worldwide.

**Nobel Laureate, Professor of Economics, Stanford and Harvard,
Dr. Alvin Roth**

*My book **Your Life or Mine** explains why it is impossible for real-time human organ donations to ever save more than a small percentage of people dying from end-stage organ disease. The only solution to this dilemma is to use advanced technology such as extended organ preservation and assessment to convert our current paradigm of organ scarcity into a new paradigm of organ abundance.*

**Chairman & CEO, United Therapeutics and President & CEO, Lung Biotechnology
Dr. Martine Rothblatt**

The possibilities created by organ cryopreservation for the future of transplantation would be game-changing. Until now, the induction of immune tolerance (which enables transplants to survive without immunosuppressive drugs), often called the "holy grail" of transplantation, has only been achieved for kidneys, using living donors. Organ banking could permit the use of deceased donors and thereby extend this technology to other organs, not available from living donors.

**Professor of Surgery, Columbia University Medical Center
Professor Emeritus, Harvard Medical School,
Dr. David Sachs**

Xenotransplantation, offering a potentially unlimited organ supply, could be years, not decades away. Organ cryopreservation is a "missing piece" of this equation; these two technologies could bring organ transplantation to thousands, if not millions, of new patients worldwide.

**Professor of Genetics, Harvard and MIT,
Dr. George Church**

With rapid progress in the last decade in new technologies, such as new imaging and bioinformatic tools, organ banking is a big idea whose time has come. This is the type of problem ideally suited to highly exploratory research on a large scale, since we increasingly have the tools to tackle it.

**Breakthrough Prize Recipient and Professor of Biological Engineering, MIT,
Dr. Ed Boyden**

Banking tissues like bone marrow, skin, and blood vessels can allow us to better bring transplantation and regenerative medicine into the emergency preparedness space. This could save lives of in the event of a terrorist attack, nuclear accident, nuclear attack, or other public health crisis.

**Associate Professor of Medicine, Harvard Medical School,
Attending Physician, Dana-Farber Cancer Institute
Associate Member, Broad Institute of MIT and Harvard,
Dr. David Weinstock**

One application of this technology is to help young patients who have treatable cancer but for whom that same life preserving treatment is can compromise fertility. In these cases, cryobanking enables doctors to protect ovaries for women and testis for men by removing them prior to treatment, banking them and then transplanting back into the patient after the gonadotoxic therapy is completed.

**Director, Women's Health Research Institute
Chief of Reproductive Biology Research, Feinberg School of Medicine, Northwestern University
Dr. Teresa Woodruff**

3. Leading cryobiology / low temperature biology scientists

The power of cryopreservation stems from the universality of breakthroughs in one complex tissue system to others. What we learn in preserving liver tissue will help us preserve limb and the knowledge gained from the limb will lead to the preservation of heart, which will ultimately lead to bio-banking of complex tissues and organs for a myriad of clinical applications relevant to civilians and injured servicemen alike.

**Professor of Biomedical Engineering, Harvard Medical School
Fellow of the International Society of Cryobiology
Dr. Mehmet Toner**

Clues from many hibernators and freeze-tolerant species in nature have inspired us to confidently anticipate extending preservation of clinical organs by weeks at high sub-zero temperatures. This approach would help circumvent many of the current problems associated with cryo-banking of organs and will transform clinical transplantation.

**Fellow of the International Society for Cryobiology
Chief Science Officer, Sylvatica Biotech
Adjunct Professor, Carnegie Mellon University,
Dr. Mike Taylor**

Cryobiologists have been able to preserve individual cells and a wide variety of organized tissues for decades, and even intestinal segments, whole uteri, and to some extent whole ovaries and whole rodent limbs at cryogenic temperatures. And exciting progress, including my group's ability to cryopreserve and successfully transplant a rabbit kidney, with subsequent life support, by avoiding ice formation entirely, suggests that much more extensive successes may be possible in the future

**Fellow of the International Society for Cryobiology
Chief Science Officer, 21st Century Medicine,
Dr. Greg Fahy**

Today we are pushing the limits of organ preservation below freezing temperatures, extending the time organs can be stored and transported from hours to days. Among many other benefits this could revolutionize donor-recipient matching, allowing us to bring the best organs to the patients most in need.

**Director, Organ Reengineering Lab, Center for Engineering in Medicine at MGH/Harvard/MIT Deputy Director of
Research, Shriners Hospitals for Children
Assistant Professor in Surgery (Bioengineering), Harvard Medical School,
Dr. Korkut Uygun**

The scientific and technical challenges that face tissue and organ preservation can be overcome through collaborative, multi-disciplinary research and development. The cryobiology community is actively engaged in establishing the scientific groundwork that will lead to innovation solutions for many of the scale-up challenges facing tissue and organ preservation

**President, Society for Cryobiology
Professor of Medicine and Dentistry, University of Alberta
Professor of Laboratory Medicine and Pathology, University of Alberta
Dr. Jason Acker**

A number of leading edge technologies can now be brought to bear on the challenge of banking organs and large tissues for transplantation. Using recent advances in nanotechnology combined with low-frequency radiowave transmission, we can deliver large amounts of heat rapidly, evenly, and safely to rewarm cryogenically stored tissues and organs.

**Fellow of the International Society for Cryobiology
Professor of Mechanical Engineering, University of Minnesota
Dr. John Bischof**

Organ cryopreservation is the next frontier of the cryobiology, biobanking, and organ transplantation fields. We're starting to see the cryopreservation technology, historically used to store cells, embryos, and small tissues, successfully scaled up to ever larger systems such as animal limbs, ovaries, and even vital organs. Who knows what the limits are for this technology? It seems we haven't come close to approaching them yet.

**President-Elect, Society for Cryobiology
Professor, University of Washington
Dr. Dayong Gao**

With all the possibilities that organ banking research has opened up, there is now a lot of room for scientists in other fields to come in and apply their knowledge. As a result, we may be on the path to better cryoprotectants, better rewarming techniques, better tools in almost every respect

**Past President, Society for Cryobiology
Chief Science Officer, Ossium Health
Dr. Erik Woods**

At first look, the challenge of reversible banking of human organs seems daunting, but it can be broken down into a set of tractable sub-problems, each with many potential solutions.

**Professor of Mechanical Engineering, University of California Berkeley,
Dr. Boris Rubinsky**

Canada has long been a leader in cryobiology and cryopreservation. Nowhere else in medicine is there such an opportunity for fundamental physical and biological science to have a far-reaching impact on human health as with cryobiology. With the impetus provided by the Organ Preservation Alliance and the increasing recognition of the tremendous need for tissue and organ banking in transplantation and other fields, we are now looking at new ways to combine a vast array of research disciplines to meet this grand challenge

**Canada Research Chair in Thermodynamics
Professor, University of Alberta
Dr. Janet Elliott**

Even in the applications where cryopreservation is already clinically available — the banking of some cell types and simple tissues — progress in organ preservation will lead to better techniques for all cells and tissues including difficult to preserve cells, more complex tissues as well as organs. The market value of these areas is large, and progress in them will in turn lead to further cryopreservation investment. Because of this, targeting organ preservation pushes the overall field of regenerative medicine forward

CEO and Chief Science Officer , Tissue Testing Technologies, Dr Kelvin Brockbank

Many species in Nature can initiate programmed changes that precondition their tissues to undergo suspended animation in extreme cold, tolerating freezing at body temperatures even below the freezing point with no tissue damage despite every organ being "banked:". With the help of advanced in OMICS we now have the tools to recapitulating preservation solutions already provided by Nature as a promising way to improve preservation for clinical applications.

**Fellow of the International Society for Cryobiology
Canada Research Chair in Molecular Physiology
Professor in Biochemistry at Carleton University**

Dr. Ken Storey

While the ability to store living systems for a few years is probably all we need for organ banks to transform transplantation medicine, vitrification should actually enable storage of biological material for literally as long as anyone would ever want. Cryopreservation virtually stops biological time for decades from our current knowledge, and probably much longer.

**Fellow of the International Society for Cryobiology
Professor, University College London
Dr. Barry Fuller**

We're now seeing a trend toward convergence of technologies and research that can help eliminate the organ shortage altogether. Organized research initiatives, like Charlotte Banks at the University of North Carolina Charlotte, are answering this call to action to meet one of the most important scientific challenges of this era.

**Director, Charlotte Banks (Organ Banking) Research Initiative
Professor of Mechanical Engineering, University of North Carolina Charlotte
Dr. Gloria Elliott**

Engineers are needed to help foster the emergence of organ banking through work in areas beyond cryopreservation. It will take engineers to design ways to better protect biological material between recovery and transplantation. It will be engineers who develop the hardware needed at every step of the road between the donor and the recipient.

**Director of The Biothermal Technology Laboratory
Professor at Carnegie Mellon University
Dr. Yoed Rabin**

Preserving human tissues for research on a broad range of diseases will facilitate and accelerate scientific advances and create impact at the clinic. It can also potentially reduce costs and decrease the need for animals in research. In a similar way, it will also aid drug screening and development reducing cost and time towards new therapies

**Professor of Radiology, Stanford University School of Medicine,
Dr. Utkan Demirci**

With the recent advances in understanding the mechanisms of cryoinjury in cells and tissues, synthetic organic chemistry is now well-positioned to facilitate the discovery and deployment of enabling technologies that prevent the cellular damage associated with ice nucleation and growth.

**Canada Research Chair in Medicinal Chemistry
Professor of Organic and Bioorganic Chemistry at the University of Ottawa
Dr. Robert Ben**

The process of vitrification, turning the entire tissue directly into a glassy state avoiding freezing and ice damage, has opened up a lot of new possibilities. It's brought us closer to addressing some of the major barriers to large tissue cryopreservation.

**Fellow of the International Society for Cryobiology
Chief Science Officer, Sylvatica Biotech
Adjunct Professor, Carnegie Mellon University,
Dr. Mike Taylor**

Examples of public health impact created by this research effort

Impact of preservation breakthroughs in other areas of biomedicine:

<u>Area of biomedicine</u>	<u>Example of public health need</u>
Cancer treatment and fertility	Ovary banking can save fertility/hormone balance in 140,000 girls and young women diagnosed with cancer and potentially exposed to chemo- and radiotherapy in the United States each year
Emergency preparedness	Banked bone marrow and cord blood could benefit >10,000 patients after a nuclear accident or attack as well as 14,000 US patients each year suffering acute injury who would benefit from a transplant
Limb recovery and transplantation	30,000 traumatic amputations per year in United States; two thirds of victims are children and young adults
Basic medical research	Human tissue would be a superior model to the 100 million mice and rats used in research each year; tissue banking advances are critically needed to aid approaches seeking to treat malignancies, neurodegenerative diseases, and other disorders
Trauma care	30,000 patients admitted to specialized US burn units each year. After a nuclear accident/attack, estimated ~3% of the skin grafts required would currently be available.
Tissue engineering and regenerative medicine	Shelf-life of regenerative medicine products, a sector with a predicted > \$500 billion market by 2025
Drug discovery	Banked human tissue would benefit pre-clinical drug testing and potentially improve low efficiency of drug development.

Impact on organ transplantation:

<u>Overall Impact</u>	<u>Value created by preservation breakthroughs</u>
Increasing pool of donor organs	Reducing organ discard Rescuing marginal organs Decreasing costs of transplantation New matching approaches in deceased donation Successive organ transplants in case of graft dysfunction
Enhancing transplant viability and function	Repairing organ injury during removal and transport Assessing organ function before transplant Enabling new immune tolerance induction strategies Transmissible disease screening for donors and organs Augmenting organs (e.g., gene therapy, immunomodulation) New donor-recipient compatibility assessment methods Preventing ischemic injury during transplant
Expanding transplantation access	Extending live kidney donation chains Enabling recipients with acute disease or trauma Flexible scheduling of transplant surgeries
Galvanizing research	Accelerating progress in cryobiology and preservation Accelerating progress in humanized xenotransplantation Accelerating progress toward lab-grown organs

Examples of surrounding momentum toward a large-scale research effort

In light of these needs and opportunities, a **growing coalition of scientists, clinicians, policymakers, advocacy groups, academic institutions, and industry is assembling to accelerate progress in organ and tissue preservation.**

- **The first global Organ Banking Summit at Stanford**, NASA Research Park, and Lawrence Berkeley National Lab
- A National Science Foundation (**NSF**)-funded **Roadmap** to Organ Banking
- A Defense Advanced Research Projects Agency (**DARPA**)-hosted **meeting** at the US Military Academy at West Point on a potential 'Organs on Demand' research program
- A **White House roundtable** on organ banking and bioengineering
- A **Capitol Hill symposium** on emerging organ preservation technologies
- The **American Society of Transplantation Launching a branch to advance organ and tissue preservation** at the American Transplant Congress, partnering with the Organ Preservation Alliance
- Summit on **Organ Banking through Converging Technologies at the Harvard** in August

Full article on Nature's website: <http://www.nature.com/nbt/journal/v35/n6/full/nbt.3889.htm>

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Interested in a **press-pass for the Organ Banking Summit at Harvard August 3-6?**

Check out: <https://obs2017.com>

Email: mark@obs2017.com