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Papilledema Summit:

Summary Report

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March 2010

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I. INTRODUCTION

Background and Problem Definition

The Space Medicine Division at NASA Johnson Space Center is charged with maintaining the health of the astronaut corps during all phases of training, space flight, and rehabilitation. Additionally, it has an ongoing interest in understanding the effects of long-duration space flight on the crew in preparation for exploration missions. Health maintenance for space flight is re-examined periodically, and when new information becomes available from flight experience and ground studies. In accordance with this philosophy and due to recent documented changes in visual acuity in association with physical findings in crewmembers (e.g., optic disc edema, choroidal folds, and cotton wool spots) following long-duration space flight, the Advanced Projects Section of Wyle Integrated Science & Engineering organized a 2-day summit to examine the new data. The summit brought together experts in ophthalmology and related fields and sought to elicit evidence-based expert opinion on screening, diagnosis, and treatment options, identify gaps in knowledge and medical capability, and propose relevant research initiatives.

Summit Meeting Objectives

The Papilledema Summit was held on July 27-28, 2009 in Houston, Texas. Five panel members, a panel chair, and 35 participants were presented with background and clinical information regarding the findings seen in crewmembers. Questions were then posed to the panel members and discussion held on each subtopic. The primary objectives of these discussions were:

- To understand NASA's current capabilities for preflight screening, in-flight diagnosis and treatment, and postflight testing
- To review recent relevant findings from ground and microgravity studies and develop concepts for future studies
- To formulate recommendations for prevention, preflight screening, in-flight diagnosis and treatment, and postflight testing
- To understand anatomic and physiologic changes that may predispose an individual to these anomalies
- To formulate clearly defined recommendations as a deliverable to the program.

II. SUMMIT ATTENDEES

The following is a list of the summit's panel members and participants.

Summit Panel Members

James Michael Duncan, M.D. (Panel Chair)

Dr. Duncan is the Deputy Chief Medical Officer at Johnson Space Center in Houston, Texas. Dr. Duncan is board certified by the American Board of Internal Medicine in Internal Medicine and Pulmonary Disease. He served 8 years in the U.S. Navy and joined NASA as a flight surgeon in 2000. At NASA, he has served as Chief of the Space Medicine Division, Manager of Medical Operations, NASA Lead ISS flight surgeon, and supported both shuttle and ISS missions as a crew surgeon. In his current position, Dr. Duncan supports the Health and Medical Technical Authority and serves on the NASA ISS Advisory Committee. He is actively involved in ISS activities that include the Multilateral Medical Policy Board, the Multilateral Medical Operations Panel, and the Multilateral Space Medicine Board. He is a member of the STS and ISS Mission Management Teams representing the Space Life Science Directorate at Johnson Space Center.

Bruce L. Ehni, M.D.

Dr. Ehni is Associate Professor and the Chief of Neurosurgical Services, Michael E. DeBakey Veterans Affairs Medical Center, and also serves on the faculty of Baylor College of Medicine as an Associate Professor in the Department of Neurosurgery. Dr. Ehni is board certified by the American Board of Medical Specialties in Neurological Surgery. His prior hospital staff appointments were with The Methodist Hospital, St. Luke's Episcopal Hospital, Diagnostic Center Hospital, and Shriner's Hospital, all in the Houston area.

Andrew L. Lee, M.D.

Dr. Lee is Chairman of Ophthalmology at The Methodist Hospital in Houston, Texas and is a Professor of Ophthalmology at Weill Cornell Medical College. He is board certified in Ophthalmology, and has completed a clinical fellowship in Neuro-Ophthalmology with Neil R. Miller, M.D. at the Wilmer Eye Institute. His past positions include Associate Professor at Baylor College of Medicine, Adjunct Associate Professor at the M.D. Anderson Cancer Center in Houston, and Professor of Ophthalmology, Neurology, and Neurosurgery in the H. Stanley Thompson Neuro-Ophthalmology Clinic at the University of Iowa Hospitals and Clinics.

Adrian O'Malley, M.D.

Dr. O'Malley currently serves as Associate Chief of Ophthalmology at St Luke's Episcopal Hospital and is on the executive committee of the Houston Ophthalmological Society. He is board certified in Ophthalmology and completed a vitreoretinal fellowship at the Casey Eye Institute, Oregon Health Sciences University.

Howard D. Pomeranz, M.D., Ph.D.

Dr. Pomeranz is the Clinical Associate Professor of Ophthalmology and Assistant Attending at North Shore University Hospital and Long Island Jewish Hospital, New York. He is board certified in Ophthalmology, and completed a Neuro-Ophthalmology fellowship at the Massachusetts Eye and Ear Infirmary/Harvard Medical School. Before joining the medical staff at North Shore University Hospital and Long Island Jewish Hospital, Dr. Pomeranz was a member of the medical faculties at the University of Maryland and the University of Minnesota.

Rosa Tang, M.D., M.P.H., M.B.A.

Dr. Tang is currently a retired Professor from the University of Texas System and in private practice as Medical Director of Neuro-Ophthalmology of Texas, PLLC and Co-Director of MS Eye CARE at the University Eye Institute. Her past positions include Clinical Professor, Department of Neurology at the University of Texas Medical School in Houston, Research Professor at the University of Houston, and Visiting Professor at the Universidad Peruana Cayetano Heredia, Lima, Perú. Dr. Tang is board certified in Ophthalmology and completed a fellowship in Neuro-Ophthalmology at Baylor College of Medicine in Houston. Her subspecialties are Neuro-Ophthalmology and Ocular Oncology.

Summit Participants

David Baumann, B.S. – Exploration Medical Capability Element Manager, NASA/JSC
Mike Caputo, M.S. - Washington University in St. Louis
Steve Chalfin, M.D. - UT Health Science Center at San Antonio
John Charles, Ph.D. – Human Research Program - Program Scientist, NASA/JSC
Jonathan Clark, M.D., M.P.H. - NSBRI
Rick Cole, M.D., M.P.H. – UTMB/Wyle flight surgeon
Joseph P. Dervay, M.D., M.P.H. – NASA/JSC flight surgeon
Jennifer A. Fogarty, Ph.D. – Health & Medical Technical Authority Coordinator, NASA/JSC
Kathleen Garcia, R.D.C.S., R.V.T. - Advanced Projects, Wyle Integrated Science & Engineering
C. Robert Gibson, O.D. – NASA/Coastal Eye Associates
Robert Haddon, M.D. – UTMB/Wyle flight surgeon
Steven F. Hart, M.D. – NASA/JSC flight surgeon
Eric Kerstman, M.D., M.P.H. - Advanced Projects Physician, UTMB/Wyle Integrated Science & Engineering
Keith Killu, M.D. – Critical Care, Henry Ford Hospital Clinics
James P. Locke, M.D., M.S. – NASA/JSC flight surgeon
Thomas H. Mader, M.D. (by teleconference) – Alaska Native Medical Center
Keith Manuel, O.D. – Space Center Eye Associates
Christian Otto, M.D. - University of Ottawa
Anastas F. Pass, O.D., M.S., J.D. - University of Houston
Richard Rubin, M.D. – USAF
Derick Sager, M.D. – USAF/NASA flight surgeon
Ashot Sargsyan, M.D. - Advanced Projects Physician, Wyle Integrated Science & Engineering
Victor Schneider, M.D. - NASA HQ
Edward Semones, Radiation scientist, NASA/JSC
Kazuhito Shimada, M.D. – JAXA flight surgeon
Duc H. Tran, D.O. – Coastal Eye Associates
Mary Van Baalen – Radiation scientist, NASA/JSC
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Holly Williams - Wyle Integrated Science & Engineering
Kae Parker - Wyle Integrated Science & Engineering
Yvette Schulz - Wyle Integrated Science & Engineering

III. SUMMIT AGENDA

Monday, July 27, 2009

Time	Topic	Presenter(s)
8:00	**Welcome and Introductions**	**Mike Duncan, M.D.**
8:20	**Space Physiology**	**Jim Locke, M.D.**
9:30	*Break*	
9:45	**Ocular Space Physiology**	**Bob Gibson, O.D.**
10:30	**Preflight screening, In-Flight Capabilities, & Postflight Testing**	**Bob Gibson, O.D.**
11:15	**Optical Coherence Tomography**	**Anastas Pass, O.D., J.D.**
12:00	*Lunch*	
1:00	**Case Presentation #1**	**Richard Rubin, M.D.**
1:45	**Case Presentation #2**	**Bob Gibson, O.D.**
2:30	*Break*	
2:45	**Related Cases**	**Bob Gibson, O.D.**
3:30	**Etiology/Pathophysiologic Mechanisms**	**Richard Rubin, M.D.**
4:30	**Summary of Recent Research Efforts**	**Ashot Sargsyan, M.D.**
5:00	*Adjourn to Optional Group Dinner at Perry's Steakhouse*	

Tuesday, July 28, 2009

Time	Topic	Presenter(s)
8:00	**Welcome**	**Mike Duncan, M.D.**
8:05	**Directed Questions and Formulation of Recommendations**	
9:30	*Break*	**Panel**
9:45	**Directed Questions and Formulation of Recommendations**	
11:45	**Summary and Conclusion**	**Panel**
12:00	*Adjourn*	

IV. SUMMARY OF RECOMMENDATIONS

Likely mechanisms of space flight-related increased intraocular pressure, optic disc edema, choroidal folds, and cotton wool spots

The panel's opinion was that optic disc edema and intraocular hypertension are likely two separate processes. The panel's opinion was based on ground studies and anecdotal in-flight measurements that revealed elevated intraocular pressures during the first days of flight with normalization of the intraocular pressures thereafter. The disc edema and choroidal folds, however, appeared later in the mission timeline and remained present after landing when the corresponding intraocular pressures were normal or low. On the other hand, the panel noted that, in terrestrial experience, an initial insult caused by venous congestion (such as that seen in patients with retinal vein thrombosis or dural venous sinus thrombosis) can cause prolonged venous hypertension and disc edema even after the initial insult has resolved and the intraocular pressure has normalized.

The panel's opinion was that both the disc edema and the choroidal folds appear to share a common mechanism, which is likely that of an outflow obstruction caused by pressure elevation in the eye, in the orbit, in the intracranial space, or in a combination of those.

The panel noted that if increased intracranial pressure is the underlying mechanism, no cognitive deficits are expected, as none are noted with terrestrial pseudotumor cerebri, but headaches and visual obscurations would be expected to occur. With flown astronauts, the data seem to point to an eye/orbit-centered problem, and intracranial hypertension as the mechanism seems less likely, although it cannot be completely ruled out at this point in time.

The panel also noted that the cotton wool spots most probably represent a separate phenomenon since they appear at a different location on the retina, separate from the choroidal folds or optic disc. The panel listed possible mechanisms for the cotton wool spots, including vasoconstriction (perhaps secondary to 100% oxygen exposure), inflammation, ischemia secondary to a retinal artery embolus, such as an air bubble, or venous congestion. Of the above-mentioned mechanisms, the panel concluded that venous congestion appears to be the most likely to occur in space flight, as facial fullness and nasal congestion are commonly seen in flight and are due to cephalad fluid shifts. In addition, the venous congestion is transient, explaining the improvement seen once a crewmember returns to Earth. An ischemic process would be expected to cause permanent changes that would not show reversibility or improvement.

Risks thought to be associated with space flight induced acute/chronic optic disc edema and ocular hypertension

The panel noted that the risks of prolonged disc edema during a long-duration mission include vision loss up to complete blindness in the affected eye, while intraocular hypertension is a condition that a normal eye should be able to tolerate for several months. The panel also noted that preflight conditions such as optic nerve head drusen and small disk diameter (crowded disk anatomy) may predispose a crewmember to a higher risk for complications from increased intracranial and intraocular pressure, with less tolerability compared to a normal eye.

Parameters or risk factors that might indicate susceptibility to developing increased intraocular pressure, optic disc edema, choroidal folds, and cotton wool spots

The panel members commented that there are many unknowns at this point in our understanding of these newly described ocular phenomena. They remarked that it is unclear if the findings are new or have always been present, yet have been under recognized. They also noted that it is not known whether this is an issue specific to long-duration flight or if short-duration missions evoke these same changes.

One possibility that the panel raised is that all crewmembers are equally susceptible and all develop these phenomena to a certain degree, with only a minority becoming symptomatic. The panel recommended evaluating all crewmembers, both symptomatic and asymptomatic. Aging of the astronaut corps is one theory that the panel proposed to explain the recent surge in cases – a more mature astronaut cohort means lenses that are less pliable and less able to accommodate and compensate for any changes in acuity, and may be exacerbated by potential changes such as choroidal edema or retinal elevation.

Another possibility that the panel raised is that afflicted crewmembers may have an underlying venous drainage problem even before flight and, if this is the case, perhaps pretreatment could prevent development of these phenomena, although they noted that the methods for diagnosing and pretreating such individuals are not clearly defined at present.

One of the summit participants explained that individual susceptibility does play a role in terrestrial altitude sickness, with older individuals being less susceptible to symptoms because the normal age-related mild brain atrophy allows for cerebral edema to occur with minimal symptoms. Younger people, on the other hand, are thought to have less free intracranial volume to allow for brain edema and therefore manifest symptoms sooner. Drawing on this, the panel noted that, in the same way, perhaps all crewmembers get some degree of venous congestion leading to intraocular hypertension but some are less tolerant of the changes due to anatomic variability.

The panel cautioned that crewmembers who developed disc edema and choroidal folds during a mission might be at higher risk of developing ocular changes on subsequent missions. They noted that a 2-week shuttle mission might not pose much risk, as evidenced by one of the presented cases who flew a short-duration shuttle mission with no adverse effects after developing optic disc edema on a prior long-duration flight, but the panel felt that a 6-month mission might involve a more substantial risk. The panel did note that there might be a scientific benefit in allowing a crewmember with a prior history of optic disc edema or choroidal folds to fly a long-duration mission as a way to elucidate the underlying mechanism of the changes seen.

Recommended research methods for establishing root cause

1. Gonioscopy - The panel members speculated that venous congestion was the most likely underlying mechanism for the ocular findings, and recommended gonioscopy to examine the iridocorneal angle for anatomical narrowing which may be associated with venous congestion.
2. Current on-board ultrasound system – The panel recommended using the current on-board ultrasound system to obtain axial photos of crewmembers' eyes with good resolution.
3. Acoustic impedance devices – The panel suggested using acoustic impedance devices for tympanic ICP measurements (although they noted that this technology has not yet been validated).
4. Choroidal flow measurement devices – The panel suggested using this technology, although they noted that it has not yet been validated.
5. Retrospective data mining – The panel recommended data mining of retrospective data, current databases, and any available photographs (one of the summit participants noted that there are Apollo-era retinal photos stored at Brooks City Base in San Antonio). The panel noted that important data points to search for include refractive error, age, number of EVAs, mission duration, and anatomic variations.
6. Postlanding examinations – The panel recommended that crewmembers be examined on R+0/1/3, to include fundus camera photography, optical coherence tomography (OCT), optic nerve sheath ultrasonography (as an ICP surrogate), full ophthalmologic exam by a specialist, acuity and refractive changes, and optic MRI. A lumbar puncture is recommended for crewmembers with confirmed optic disc edema. The panel noted that examinations of crewmembers in Houston on R+23 (as has occurred in the past) are less helpful, as many important findings may have already diminished by that time.

Available and appropriate terrestrial analogues for testing

The panel suggested the following possible analogue study populations:

1. Patients undergoing spinal surgery in a prone position (especially head-down) – this patient population tends to get cephalad fluid shifts with resultant optic disc edema.

2. 10 degree head-down tilt-test subjects
3. Bed rest subjects

Tests that the panel recommended for the above analogue populations include:

1. Ultrasonography of the posterior eye for disc edema and optic nerve sheath diameter, with B-Mode and doppler.
2. OCT
3. Fundus photography
4. IOP measurements
5. Lumbar puncture for CSF pressure
6. Red-free photography
7. A-Scan ultrasound biometry

Consideration of ocular signs and symptoms during selection or mission assignment

The panel members recommended considering the following during crew initial selection or mission assignment:

- Elevated intraocular pressures in the range of 24-25 mmHg would be a concern
- Optic nerve head drusen – it is speculated that 3 to 4% of the astronaut corps have optic nerve head drusen, and about 80% of optic nerve head drusen cases can progress with impact to the visual fields, even without the stresses of space flight.
- Crowded optic nerve head anatomy

Recommended changes to the NASA MRID/MED Volume B for preflight, in-flight, and postflight testing for long-duration crewmembers

The panel members commented on the comprehensiveness of the current ocular testing conducted by NASA for crewmember selection, retention, and pre- and postflight screening.

The following pre- and postflight tests were recommended by the panel (some of these are already included in the updated current testing protocols, and are noted with an asterisk):

1. Optic nerve sheath diameter with ultrasound
2. OCT/RNFL scan *
3. Pre- and post-gadolinium MRI/MRV of the brain and orbit, with diffusion weighted imaging
4. Cycloplegic refraction *
5. Corneal topography/keratometry
6. A-Scan *
7. Retinal photography *
8. Macular volume (OCT)

On-orbit assessment capability that would be useful for in-flight diagnosis

The panel members recommended considering the following tests for in-flight diagnosis:

1. Assessment of hyperopic shifts with acuity, depth perception, color vision, and refraction - The panel noted that hyperopic shifts can be inferred from the above tests. Summit participants commented that there are handheld devices, some developed by the Army, that can be utilized and that the Army has also developed computer software that is a cone-contrast sensitivity test.
2. Keratometry - The panel noted that corneal changes are not very likely but may change the axial length of the eye and affect acuity.
3. Lenticular measurements – The panel noted that changes in lens thickness could change the refractive power of the eye and effect acuity.
4. Retinamax-like device – The panel noted the value of obtaining keratometry readings of the cornea as well as refraction.
5. Intraocular pressure measurement device – The summit participants noted that this can be utilized together with the Braslet and Lower-Body Negative Pressure (LBNP) devices to evaluate intraocular pressure changes in response to systemic fluid shifting.
6. Optic nerve imaging with real-time transmission to Earth
7. Spontaneous venous pulsation testing
8. Retinal photography (store and forward)
9. Questionnaires – The panel noted that a questionnaire is used for pseudotumor cerebri patients and could be easily modified for space flight.
10. Posterior eye ultrasound - The panel commented that it would be helpful to train crewmembers in the needed ultrasound techniques ahead of time, including having them learn what a normal eye should look like and what various pathologies look like so that they can identify changes if any are occurring. A few of the panel members noted that their institution can provide a training environment and patients with representative pathologies for crewmember training.
11. Comprehensive Wavefront Aberrometry - In a written postsummit communication, a summit participant emphasized the need for development of accurate and efficient acuity assessment on orbit and suggested the use of comprehensive wavefront aberrometry.

Emerging technologies that may be useful for in-flight assessment of the eye

The panel members recommended considering the following tests for in-flight diagnosis:

1. Camera for nondilated retinal photos - The panel noted that dilation can be done if needed with phenylephrine drops, which have a relatively short half-life of several hours. The panel also noted that NASA can acquire the images in flight, transmit the data to Earth, and do the data conversion and image processing on Earth.
2. Video
3. Ophthalmodynamometry (ODM) - Ocular blood flow device
4. Panoptic – A small lightweight viewing-only device that can be coupled to a camera
5. Tonometry – A summit participant mentioned a new version of the Tono-Pen (Avia) that is not calibration dependent. Another summit participant stated that the Avia has been researched by the JSC Ophthalmology group and that gravity dependent calibration is still required in certain scenarios, therefore utility for space flight is still debated.

Treatment for crewmembers with symptomatic/asymptomatic disc edema

The panel cautioned that treatment should not be given to an asymptomatic crewmember found to have ocular changes. Without knowing the underlying mechanism, the treatment might exacerbate the crewmember's condition.

However, the panel's consensus was that treatment should be offered once a crewmember is symptomatic. A summit participant noted that the number of transient visual obscurations (TVO) per hour can give a rough estimate of how quickly visual field defects can be expected to develop, with five TVOs per hour indicating a need for treatment.

Recommended treatment options

For symptomatic crewmembers, the panel commented that acetazolamide (Diamox) be used. A test dose should be given before flight to rule out allergic or other adverse reactions. The usual starting dose is 500 mg twice daily (although this is for an obese terrestrial patient with pseudotumor cerebri), titrated to symptoms. The panel noted that a thin and fit crewmember could be started on 250 mg twice daily and titrated. The medication would be continued until return to Earth. Acetazolamide is contraindicated in patients with sulfa allergies. Another potential risk that the panel discussed is that the diuretic properties of acetazolamide can lead to relative dehydration and exacerbate the risk for kidney stone formation. Other possible side effects outlined by the panel include paresthesias (a common side effect that occurs even with low doses), interaction with food with resultant nausea and vomiting (should be tested before flight with the same type of food flown on board), and an alteration of taste. The panel noted that symptoms might initially get worse when treatment is started.

Concerning the question of whether silicone-filled glasses that were presented to the panel by one of the flight surgeons could be used as a treatment option for the changing spherical eye-wear prescription in space - The panel thought this would not be a useful solution because the visual acuity would be suboptimal with this type of spectacle, and they would not correct a cylindrical prescription. It would be preferable to continue sending different spectacles with a variety of prescriptions or fly extra lenses to be used as a "clip-on" to existing spectacles.

V. SUMMIT OUTCOME

The Papilledema Summit brought together experts from nationally and internationally recognized institutions as well as various NASA Centers, with expertise in ophthalmology, neuro-ophthalmology, neurosurgery, neurophysiology, and space medicine. Anatomic and physiological changes that may predispose crewmembers to the described ocular anomalies were reviewed, and NASA's current capabilities for preflight screening, in-flight diagnosis and treatment, and postflight testing were discussed. Recent findings from ground and microgravity studies were reviewed, and concepts for possible future studies were suggested. Finally, recommendations for prevention, preflight screening, in-flight diagnosis and treatment, and postflight testing were formulated.

The panel's recommendations lend support to the recent changes that were implemented in pre- and postflight ocular testing and suggest additions to the pre- and postflight protocols that will be evaluated by NASA's Space Medicine Division for future incorporation into its standards of testing.

Research efforts to help elucidate the root cause of the phenomena observed will be undertaken based on panel member comments and suggestions. Training for crewmembers on ultrasound techniques will be implemented using panel member suggestions and with the aid of panel members' institutions.

Additional operational impacts of the summit include development of real-time in-flight crewmember support with appropriate hardware, diagnostic protocols, and on-board treatments, and development of ground support for early crewmember testing postlanding.

This summit demonstrated the value of collaboration among NASA, the NASA supporting contractors, industry, and academia to promote astronaut health and support human existence in space.

LIST OF ACRONYMS

ARC	Ames Research Center
CSF	Cerebrospinal Fluid
EVA	Extravehicular Activity
HQ	Headquarters
ICP	Intracranial Pressure
IOP	Intraocular Pressure
ISS	International Space Station
JSC	Johnson Space Center
LBNP	Lower Body Negative Pressure
MED	Medical Evaluation Document
MRI	Magnetic Resonance Imaging
MRID	Medical Requirements Integration Document
MRV	Magnetic Resonance Venogram
NASA	National Aeronautics and Space Administration
NSBRI	National Space Biomedical Research Institute
OCT	Optical Coherence Tomography
ODM	Ophthalmodynamanometry
RDCS	Registered Diagnostic Cardiac Sonographer
RNFL	Retinal Nerve Fiber Layer
RVT	Registered Vascular Sonographer
STS	Space Transportation System (Shuttle)
TVO	Transient Visual Obscuration
USAF	United States Air Force
UTMB	University of Texas Medical Branch

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13. ABSTRACT *(Maximum 200 words)*

The Space Medicine Division at NASA Johnson Space Center is charged with maintaining the health of the astronaut corps during all phases of training, space flight, and rehabilitation. Additionally, it has an ongoing interest in understanding the effects of long-duration space flight on the crew in preparation for exploration missions. Health maintenance for space flight is re-examined periodically, and when new information becomes available from flight experience and ground studies. In accordance with this philosophy and due to recent documented changes in visual acuity in association with physical findings in crewmembers (e.g., optic disc edema, choroidal folds, and cotton wool spots) following long-duration space flight, the Advanced Projects Section of Wyle Integrated Science & Engineering organized a 2-day summit to examine the new data. The summit brought together experts in ophthalmology and related fields and sought to elicit evidence-based expert opinion on screening, diagnosis, and treatment options, identify gaps in knowledge and medical capability, and propose relevant research initiatives.

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