The Importance of Value Initiative’s Advocacy Domain to the Advancement of Nuclear Medicine and Molecular Imaging

Satoshi Minoshima, MD, PhD, FSNMMI – Chair and Founder, SNMMI Value Initiative

Advancing Nuclear Medicine’s Advocacy work with Federal and State Legislatures and Regulators stands as a pivotal domain within the Value Initiative. The tireless efforts of SNMMI ensure our field is well represented amidst the introduction of bills and regulations, whether favorable or unfavorable.

On April 5th, 2024, SNMMI hosted our Annual Hill Day, a cornerstone event in our advocacy efforts. Sixty-Two dedicated individuals, spanning SNMMI leadership, physicians, scientists, technologists, industry colleagues, and patients, converged from across the nation to participate. This annual Hill Fly-In Day event serves as a crucial opportunity for education and advocacy on Capitol Hill.

Attendees engage our federal leaders, imparting essential knowledge about nuclear medicine’s fundamentals, its promise in diagnosing and treating various diseases, and advocating for SNMMI’s policy priorities. Participants, including SNMMI members, patients, and corporate partners, unite with one objective – to enhance patients’ access to nuclear medicine.

Hill Day commences with a unifying breakfast briefing at the Hyatt near Capitol Hill. Here, attendees gain insights into the composition of the House and Senate, familiarize themselves with SNMMI’s Hill Day priority issues, and hone their advocacy skills for effective meetings.

Participants are organized into teams comprising SNMMI members, medical experts, staff, patients, and company representatives, strategically focusing on key geographic locations nationwide. This year, our record-breaking cohort engaged with 62 congressional staff, comprising 35 House offices and 27 Senate offices.

Advocacy efforts centered on three legislative priorities: urging Members of Congress to co-sponsor the FIND Act, supporting the inclusion of neuroendocrine tumors (NETs) in FY25 DoD funding legislation, and opposing legislation detrimental to patients and the field of nuclear medicine.

I extend my gratitude to everyone who contributed to the success of Hill Day, a testament to the ongoing commitment of the Value Initiative. Your efforts significantly bolster our advocacy endeavors, serving clinicians, researchers, and most importantly, our patients.

We were pleased to learn, on April 23, 2024, the Food and Drug Administration granted approval for lutetium Lu 177 dotatate for pediatric patients aged 12 and above with...

Continued on page 2. See The importance of Value Initiative’s.
Nuclear Medicine and Early and Accurate Diagnosis of Alzheimer’s Disease

Neena Patel, PhD, Kristen Cardinal, PhD and Susan De Santi, PhD – Eisai Inc.
An article by Eisai Inc., an SNMMI Value Initiative Industry Alliance Leadership Circle Partner

There are an estimated 6.9 million Americans, ages 65 and older, who are living with Alzheimer’s dementia (AD) in 2024. This prevalence has an immense cost to society with an estimated economic value of nearly $350 billion in 2023 for unpaid care provided by care partners in the United States. A patient’s journey from initial clinical presentation to dementia specialist and treatment plan can take 18.6 months. Depending on the patient’s disease staging, differential treatments are prescribed. As such, it is more important than ever for the healthcare system to be prepared for efficient patient evaluations to ultimately provide an early and accurate diagnosis and initiate the most appropriate treatment as soon as possible for the greatest impact.

AD is characterized by the hallmark pathological presentation of beta amyloid (Aβ) plaques and tau neurofibrillary tangles in the brain. It is a neurodegenerative disease which progresses over time due to the continuous buildup of Aβ plaques and neurofibrillary tangles. Nuclear medicine physicians and neuroradiologists can identify these pathologies in vivo through Positron Emission Tomography (PET) imaging with amyloid or tau radiopharmaceuticals. FDA approved ligands include Neuraceq, Vizamyl, and Amyvid for Aβ plaques and Tauvid for neurofibrillary tangles indicated for patients with cognitive impairment who are being evaluated for AD and other causes of cognitive impairment (see Figure 1 for examples of negative and positive Aβ PET images).

Nuclear Medicine physicians play an essential role in the early and accurate diagnosis of AD. Specifically, they can provide the interpretation of an Aβ and tau PET scans to frontline physicians (i.e., primary care physicians, neurologists, or gerontologists) to be used in combination with cognitive and clinical assessments and ensure an accurate differential diagnosis. Examples of the important role that PET imaging plays in diagnosis of AD were shown in several studies including the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) Study where a 35.6% change in etiological diagnosis and 60% change in patient management ensued due to Aβ PET scans results in cases where there was diagnostic uncertainty. Further, de Wilde and colleagues implemented amyloid PET in routine daily clinical practice in a memory clinic showing changes in etiological diagnosis (25%), diagnostic confidence (10%) and treatment (24%) in patients with and without dementia. CSF assays and blood-based biomarker assays of Aβ and tau are gaining wide interest for use in research and clinical settings to aid in AD diagnosis. Many of these assays use PET as their standard of truth.

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The importance of Value Initiative’s. Continued from page 1.

SSTR-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This milestone marks the first FDA approval of a radioactive drug for pediatric patients in this indication.

Concurrently, the FDA has postponed its decision on the Alzheimer’s disease drug donanemab, signaling the importance of ongoing educational efforts and dialogues with regulators and legislators to advance our field.

As our field progresses, it is imperative that our advocacy efforts remain steadfast. On May 6-7, SNMMI convened a highly successful Dose Optimization workshop, engaging FDA officials and over 400 participants both virtually and in-person. These initiatives foster crucial dialogue and awareness, ultimately serving the interests of our patients.

For those interested in participating in future Hill Days or other advocacy initiatives, please reach out to Julia Bellinger, Director of Health Policy and Regulatory Affairs at SNMMI (jbellinger@snmmi.org).

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Figure 1: Examples of Negative (left) Aβ PET images and Positive (right) Aβ PET images for Florbetaben (Neuraceq), Florbetapir (Amyvid), and Flutemetamol (Vizamyl; modified from).
Advancing Pediatric Molecular Imaging With Biograph Vision Quadra

By Claudette Lew | Data courtesy of Rigshospitalet, Copenhagen, Denmark
An article by Siemens Healthineers, an SNMMI Value Initiative Industry Alliance Leadership Circle Partner

When it comes to molecular imaging in pediatrics, one must remember that children are not simply small adults. Their unique needs and vulnerabilities necessitate a tailored approach. At Rigshospitalet in Denmark, Dr. Lise Borgwardt and the team have been at the forefront of the evolving journey of molecular imaging in pediatrics since its introduction in 2000.1 As chief physician in the Department of Clinical Physiology and Nuclear Medicine, subspecialized in pediatric nuclear medicine and PET, Dr. Borgwardt’s dedicated efforts have been pivotal in advancing patient care and diagnostics at this facility.

The Role of PET/CT in Pediatric Patient Care

Clinicians in the pediatric team at the Department of Clinical Physiology and Nuclear Medicine at Rigshospitalet, led by chief physician and team leader of Pediatric PET Kim Francis Andersen, MD, together with Dr. Borgwardt, encounter many oncology cases ranging from malignant lymphomas, soft tissue, and bone sarcomas to neuroblastomas and brain tumors.

To serve these patients, Rigshospitalet has implemented advanced technology to optimize PET/CT scanning for pediatric patients. The majority of all pediatric patients are now scanned with Siemens Healthineers Biograph Vision Quadra™ PET/CT scanner. Recognized for its long axial field of view that allows ultra-fast scan times and the ability to realize low-dose accommodations for young patients, it was the right scanner for pediatric patients.2,3 Together with Dr. Flemming L. Andersen and Professor Malene Fischer, MD, the team has developed dedicated protocols tailored to the specific challenges associated with pediatric PET/CT imaging.

“With 106-cm axial field of view,” said Dr. Borgwardt, “we can see all the patient’s organs in the same field of view. Biograph Vision Quadra gives us the ability to customize scans for each individual child. We can turn the scan time up and down, adjust injected tracer activity, and improve image quality to get an optimized scan for each child. And the short acquisition time of only a few minutes helps us to get young patients through scans without general anesthesia or sedation.”

Prioritizing Scheduling and Comfort

Younger pediatric patients, often restless and unable to remain still for extended periods, have traditionally required general anesthesia or sedation during PET/CT scans.4 This practice not only poses potential risks but can also extend the duration of the procedure.

Dr. Borgwardt and the team have published research showcasing their ability to refrain from sedating young patients for PET/CT scans, a significant departure from common practice.3 Their success in this endeavor has been attributed to the ultra-fast scan times, long axial field of view, and high sensitivity on the Biograph Vision Quadra system, coupled with a comprehensive protocol for scheduling pediatric patients. By working closely with families to schedule scans around nap times and feedings, the team can minimize patient radiation, avoid the need for anesthesia, and improve comfort and cooperation, all while maintaining image quality.

Attention to Details

“We try to maximize the schedule for our Biograph Vision Quadra, but if you want to scan children without sedation or general anesthesia in this very fragile group of youngsters, we book half an hour in advance on the scanner because the parents need to have time in the scanner room to help prepare their child. We schedule the scanner so the child can be fed in the scanner room. After feeding, the child is then wrapped, and the light is dimmed so the child can fall asleep.”

Striving for Safety

A paramount concern for pediatric patients undergoing multiple scans over time is the cumulative radiation exposure since the survival of children with cancer has increased over the last two decades.

Continued on page 5. See Advancing Pediatric.
How Point-of-Care Imaging is Changing Radiology Departments

Marty Shirley, CNMT, Digirad

Most hospitals utilize portable x-ray and portable ultrasound daily. The ability to provide point-of-care diagnostic imaging is an invaluable way to reduce costs, help patients, and increase the overall quality of care.

Advancements in technology have made delivering portable nuclear imaging as easy as ultrasound or X-Ray. Which begs the question: **Why in the world are hospitals and technologists not leveraging portable nuclear imaging in the same way?**

Point-of-care nuclear imaging is safer for patients, improves care, and helps to protect the hospital from costs associated with HAIs (healthcare-associated infections) and readmittance.

Additionally, the Coronavirus pandemic has caused many hospitals to take a fresh look at their processes, procedures, staffing, and equipment needs. We’ve seen firsthand how easily “department-centric” imaging can grind to a halt.

How Point-of-Care Testing Is Shaping Radiology

There are obvious benefits in implementing portable radiology technology in hospital settings. By harnessing its potential, you can improve patient satisfaction, quality of care, and even hospital revenue.

**Impacting Studies**

Adding point-of-care (POC) testing to your departments can significantly increase the number of studies you can perform.

Without portable imaging, there are certain settings where studies are too risky or complicated to perform. In contrast, POC tests allow you to bring imaging to the patient, which can allow for successful and transformative clinical research that can’t be performed outside of the hospital.

This unique opportunity is coupled with increased efficiency, as POC technology can be completed quickly and requires no patient transport. This can significantly boost not only the potential for studies but the amount you can perform in a given time period.

Many nuclear medicine departments are using Digirad’s Ergo camera to perform POC imaging and have reported an increased number of studies in:

- Brain Viability
- Intraoperative Imaging
- Lymphoscintigraphy
- GI Bleed
- Lung Perfusion
- HIDA
- MUGA
- Bone Flow/Blood Pool

Reducing Risk Factors Associated with Patient Transport

Patient transport is a significant risk factor in hospital settings. According to one review, some risks associated with patient transport are:

- Potential for infectious exposure
- Ventilator-acquired pneumonia
- Hypoxemia
- Pulmonary complications
- Tachycardia
- Cardiac arrest
- Arrhythmia
- Equipment dislodgement
- Interruption of therapy or care

Critically ill patients are at the highest risk in these cases and transporting them can be extremely risky. Often, the risk of transporting the patient may even outweigh the benefits. This presents a dilemma for clinicians in the hospital.

But, at times, transportation of patients for imaging is desperately needed. In these cases, patients often require devices like oxygen and a significant labor requirement for transit. Therapists, nurses, transporters, and, sometimes, even more staff must be present for successful intrahospital patient transport.

To truly improve patient care, reducing risks associated with transport is critical. Portable imaging can significantly reduce this risk. Many Digirad Ergo owners have reported great success in both risk reduction and improvements in infection control.

In contrast to labor-laden patient transport, portable imaging only requires one employee: a Nuclear Medicine...

(Continued on page 9. See How Point-of-Care.)
With new emerging therapies being introduced targeting Aβ plaques, nuclear medicine physicians are essential in the healthcare system to provide vital neuropathological information for confirming diagnosis. Supporting the healthcare community through a coordinated effort among multidisciplinary healthcare professionals specifically between first line physicians and nuclear medicine physicians along the patient diagnosis journey could help eliminate mis- or late diagnoses and increase accurate diagnosis by 120,000 annually⁴.

REFERENCES

ADVANCING PEDIATRIC. CONTINUED FROM PAGE 3.

“Today, the majority of pediatric patients with cancer are surviving,” Borgwardt explained, “but the radiation used to diagnose and cure a child can also cause secondary malignancies—cancers developed due to the radiation exposure—so minimizing the radiation for all our examinations is therefore very important in order to give the children with cancer the best opportunity to become long-term survivors.”

“Patients who have experienced both are very excited for the Biograph Vision Quadra,” added Andersen. “They’ve gone from a two-and-a-half hour scan to a five-minute scan, where it’s only one hour between radiotracer injection and scan.” As molecular imaging continues to evolve, the role of precision medicine in pediatric patient care becomes increasingly prominent. The optimization of these imaging methods, as demonstrated by Rigshospitalet’s pioneering efforts, ensures each young patient receives tailored, safe, and effective care.

REFERENCES

DISCLAIMERS:
Biograph Vision Quadra is not commercially available in all countries. Future availability cannot be guaranteed.

The statements by Siemens Healthineers customers described herein are based on results that were achieved in the customer’s unique setting. Since there is no “typical” hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption), there can be no guarantee that other customers will achieve the same results.

Kim Francis Andersen, MD
Photo credit: Sophie Kalkear
Lise Borgwardt, MD, PhD
Photo credit: Joakim Rohde

VALUEINITIATIVE.SNMMI.ORG • 1850 SAMUEL MORSE DRIVE RESTON, VA 20190 5
At this year’s SNMMI annual meeting, Voximetry will launch groundbreaking clinical dosimetry services, designed to maximize access to sophisticated patient-specific dosimetry, minimize financial and technical risks and empower Nuclear Medicine centers to focus on what truly matters: delivering exceptional patient care.

The incorporation of Radiopharmaceutical Therapy (RPT) dosimetry into routine clinical practice has been hindered by various obstacles. Despite its acknowledged importance in optimizing treatments and established reimbursement fee codes, many centers have hesitated to embrace it.

The reasons are manifold, ranging from the labyrinth of IT approvals necessary for in-house deployment and the daunting task of hiring and training qualified staff, to concerns over lengthy capital budget cycles. However, with the introduction of innovative service models from Voximetry, a new era of streamlined and efficient dosimetry management is dawning.

To participate is elegantly simple yet profoundly impactful. Instead of navigating the maze of software acquisition and implementation, centers need only acquire quantitative SPECT-CT images post-RPT administration and upload them to a secure cloud repository. From there, Voximetry’s team of expert physicists takes over, leveraging Torch® advanced algorithms and data analytics, to perform extremely accurate dosimetry calculations.

The benefits of Voximetry’s dosimetry services extend far beyond mere operational efficiency. By harnessing the power of cloud-based technology and specialized expertise, centers are assured consistent quality and accuracy of their dosimetry assessments. With reports generated within days, physicians will have timely insights into treatment efficacy and potential side effects, enabling them to make informed decisions quickly and with confidence.

Moreover, by centralizing dosimetry management through Voximetry’s platform, centers may tap into a wealth of knowledge and best practices gleaned from across the industry. This collaborative approach will foster continuous improvement and innovation for all, driving advancements in patient care and treatment outcomes.

For clinics, this shift in approach represents a paradigmatic departure from the traditional model of dosimetry management. By outsourcing the nuts and bolts of this critical function to a centralized team of experts, centers can not only bypass the logistical headaches and resource-intensive processes associated with in-house dosimetry but also attain consistency of results, reducing variability across different assessments. Freed from the shackles of software procurement and IT complexities, clinicians can devote their energies to delivering personalized and effective treatments.

Perhaps most importantly, Voximetry’s dosimetry services empower clinics to fulfill their mission of providing compassionate and effective care to patients. Throughout the process, the physician remains the decision maker for each patient, integrating dosimetric information with clinical data to make precision RPT a reality. By removing the barriers to dosimetry adoption, centers can finally offer treatments tailored to individual patient needs, while simultaneously enhancing operational efficiency and cost-effectiveness.
Shaping the Future of Precision Medicine
End-to-end Solutions for Pharmaceutical Innovators
An article by Cardinal Health, an SNMMI Value Initiative Industry Alliance Leadership Circle Partner

Over 40 million nuclear medicine procedures are performed annually to help diagnose, evaluate and treat a variety of diseases across the globe, including cancers, heart disease and neurological disorders. And this number is expected to grow significantly. According to MEDraysintel, the global nuclear medicine industry is expected to more than double within the next several years, growing from $7 billion in 2022 to $19 billion by 2028. This growth is being driven by theranostics, specifically radiopharmaceutical therapies.

To support this growth, Cardinal Health Nuclear & Precision Health Solutions has made a significant investment in its Center for Theranostics Advancement in Indianapolis, Indiana. Through the Center, Cardinal Health is helping to accelerate the development of a wide range of diagnostic drugs and novel therapies, supporting both established and emerging pharmaceutical companies from innovation and development through commercial manufacturing. With customized and scalable manufacturing, analytical and commercialization solutions, Cardinal Health helps innovators reduce risk by keeping manufacturing and commercialization in lockstep with demand.

The Center for Theranostics Advancement

The Center allows Cardinal Health to support pharmaceutical innovators at every stage of the product lifecycle, from helping support early-stage research and development and feasibility studies for new drugs, to manufacturing radiopharmaceuticals on a small scale for clinical trials, or, farther along the lifecycle, establishing large-scale production and distribution for commercialization.

Three facilities make up the Center for Theranostics Advancement:
- An innovation center, where Cardinal Health researchers, chemists, and engineers support pharmaceutical innovators’ development of radiopharmaceuticals and scaling for Phases 0-2 clinical trials.
- A commercial cGMP-compliant facility that supports manufacturers as they advance their radiopharmaceuticals through pre-commercial stages, including small-scale manufacturing for use in Phase 3 clinical trials.
- A large-scale commercial cGMP-compliant manufacturing facility where commercial products are manufactured once they receive approval. Current CMO operations include the only alpha manufacturing facility in the U.S. supporting global distribution.

All three state-of-the-art facilities are designed and licensed to handle alpha-, beta- and gamma-emitting radionuclides, which support both diagnostic and therapeutic drugs and biologics. Additionally, these secure facilities include lab space, microbiology quality control testing and more than 28,000 square feet that can be customized for various kinds of radiopharmaceutical manufacturing. It’s a sophisticated operation that represents the future of nuclear medicine.

The Center is integrated with the Cardinal Health network of 130 nuclear pharmacies across the U.S. that dispense a comprehensive portfolio of radiopharmaceuticals and provide white-glove delivery to healthcare providers. Through this nationwide network, over 12 million radiopharmaceutical doses are delivered annually, with a 99.8% on-time delivery rate, helping patients receive the right drug at the right time.

The Future of Precision Medicine

Innovations are changing the nuclear medicine industry almost every day. In some cases, nuclear medicine has the ability to treat diseases that were once considered not treatable, significantly improving the quality of patients’ lives. The Cardinal Health Nuclear & Precision Health Solutions end-to-end solution is enabling the development, manufacturing and distribution of novel, life-changing radiopharmaceuticals for patients across the U.S.

To learn more, visit Theranostics | Cardinal Health.

REFERENCES
Crystal Clear: Unlocking the Ideal Imaging Length for Whole-Body PET/CT

Joshua Wiley, CNMT, PET
An article by United Imaging, an SNMMI Value Initiative Industry Alliance Leadership Circle Partner

Total-body PET/CT which covers the entire patient body in one bed position, such as the uEXPLORER®, represented a significant advancement in imaging technology, addressing many clinical and research needs while also presenting new challenges. However, the adoption of this technology is not without obstacles. The cost of these systems is higher due to the amount of crystal required for their construction. There are also practical considerations related to the physical size of the scanner which can fit in most but not all PET/CT suites. Therefore, United Imaging considered clinical needs, technical specifications, room sizing, and cost in developing a whole-body system.

When considering the necessary specifications for whole-body PET/CT systems, capable of scanning from head to mid-thigh in a single bed position, it is necessary to have a look at the average heights of the adult population. The median heights—178.4 cm for males and 164.7 cm for females—indicate that a significant portion of the patient population may not be fully covered in a single scan with a scan range of half a total-body system (100 cm). (Figure 1) This is especially true as you consider that sensitivity drops off at the edge of the field of view over the head and pelvic regions. This limitation can lead to the need for multiple scanning passes, which introduces potential for registration errors and increases overall scan time. The uMI Panorama™ GS addresses this issue effectively with its long axial field of view of 148 cm, allowing for coverage from the vertex to the mid-thigh in most individuals.

For total-body and whole-body PET systems, technical challenges need to be overcome to address parallax, scatter, randoms to have detector efficiency across a larger axial field of view (AFOV) and manage the substantial data they generate. Additionally, utilizing high angle line of responses which would degrade the PET image; at the same time, we need to collect as many events as possible to increase the sensitivity of the system. For the 194 cm system uEXPLORER this was managed utilizing the line of response from every 5 inter-unit coincidences of detectors. For the 148 cm uMI Panorama GS we utilize a new uExcel Digital PET detector, specifically designed for long axial field of view systems utilizing 3 inter-unit coincidences of detectors. The new detector increases the amount of readout bandwidth and optimizes position data with 100% crystal to SiPM coverage. (Figure 2) The uMI Panorama GS was also designed to fit in a standard PET/CT room which increases access to more facilities.

A long axial field of view significantly impacts clinical workflows and patient comfort. By enabling most of the body to be scanned in a single position, it reduces the need for patient repositioning, which not only minimizes discomfort and stress for patients but also reduces the risk of motion artifacts that can compromise scan quality. This aspect is particularly beneficial for patients who may experience pain or have difficulty remaining still for long periods. Additionally, new clinical and research opportunities are possible with the ability to visualize tracer movement in real time over the body. (Figure 3)

From an economic and operational perspective, digital whole-body PET/CT systems offer benefits with shorter scan times which improve the throughput of medical imaging facilities. This allows more patients to be scanned each day, thus improving access to critical diagnostic procedures. The increase

Continued on page 10. See Crystal Clear.
Technologist (NMT). Best of all, there is absolutely no patient transport necessary. This not only removes the risks associated with patient transport but cuts down on the need for expensive labor that is essential to the process.

### Why point-of-care imaging Matters
Now more than ever, portable nuclear imaging is vital for hospitals and imaging centers. Here’s why:

- **It Will Keep Your Department Running**
  Portable imaging gives your department flexibility. The COVID-19 crisis has taught us all how the ability to adapt is a critical requirement for hospitals. Being stuck in a single location within the facility limits radiology, and the ability to image throughout the hospital can keep your department running.

- **It’s Better for Patients and Families**
  The benefits of portable nuclear imaging to a patient are similar to portable ultrasound and x-ray. Namely, for specific individuals, the process of getting a nuclear medicine scan can be arduous, and the ability to obtain bedside imaging results in far less stress.

### The Bottom Line
Does your hospital or imaging facility offer portable nuclear imaging? If not, why? This technology exists and is being used throughout the country. Cameras such as the Digirad Ergo are available and in use throughout the country. Just like ultrasound or x-ray, hospitals with this nuclear camera can take it where it’s needed. As we come out of this crisis and look for better ways to serve our patients, you owe it to yourself to explore how portable nuclear imaging could work at your facility.

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### In the News:
Along with the Governor of Indiana, Alan Packard, PhD, Associate Professor of Radiology at Harvard Medical School; and Past-President, SNMMI, spoke at the opening of Novartis’ new radioligand therapy (RLT) manufacturing facility. He addressed the importance of the accessible supply of radioisotopes domestically.

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**REFERENCES**

2. Image courtesy of Sun Yat-sen University Cancer Center, GD, CHN
3. Images courtesy of The First People’s Hospital of Kunshan, CHN
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