



Medical Technology
Association of Australia



Patient Safety in Primary Healthcare
Australian Commission on Safety and Quality in Healthcare
Discussion Paper
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Medical Technology Association of Australia Limited
Level 12, 54 Miller Street
North Sydney NSW 2066 Australia
P: (02) 9900 0650
E: reception@mtaa.org.au
www.mtaa.org.au

MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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Contents

Contents	3
1. Executive Summary	4
2. About the Medical Technology Association of Australia and the medical technology industry	4
3. Guidelines for electronic and remote consultations.....	4
4. Safety Engineered Medical Devices (SEMDs), preventing Needlestick and Scalpel injuries in Primary Healthcare.....	9
Annex A.....	12

1. Executive Summary

This submission is in response to the August 2010 release of a discussion paper, *Patient Safety in Primary Healthcare* by the Australian Commission on Safety and Quality in Healthcare. The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the discussion paper and make specific recommendations in response to three questions posed on Page 28:

2. What are the gaps in knowledge that need to be addressed?
3. What are the key patient safety risks/ considerations within primary health care?
4. What solutions could be put in place to address these risks?

MTAA recommends:

- The implementation of guidelines to determine principles of best practice for remote consultations (online or via videoconference)
- The use of safety engineered medical devices (SEMDs) be adopted in all primary health care facilities to prevent needlestick injuries to both patients and practitioners.

2. About the Medical Technology Association of Australia and the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as bandages and syringes, to high technology items such as cochlear implants and cardiac defibrillators and diagnostic imaging equipment.

The medical technology industry manufactures many medical products that contribute to the health of Australians. These include a range of devices that can be used by primary healthcare workers to monitor patient health remotely (e.g. implantable cardiac devices, personal alarms, sensors, heart rate and other vital signs monitors, pressure sensors, enuresis sensors, scales, glucose monitors, blood pressure monitors etc). Among the range of medical products are many which contribute to the management of patient and healthcare worker safety. Examples include safety-engineered hypodermic needles, safety syringes, safety lancets and scalpels, infection control solutions and surveillance, needle-free systems and other safety engineered devices. The medical technology industry had sales in Australia of more than \$7 billion in 2008/2009 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit.

3. Guidelines for electronic and remote consultations

What are the gaps in knowledge that need to be addressed?

The discussion paper (page 21) makes reference to e-health and outlines the 2010-11 Budget provisions for personally controlled electronic health records. An additional consideration is the Labor Governments pledge of \$392.3 million to fund specialists and General Practitioners (GPs) to provide remote consultations to rural, regional

and outer metropolitan patients via video-conference or online. These changes will revolutionise the way that primary health care services are provided to rural and remote Australians; however there are large gaps in knowledge regarding best-practice in the implementation and structure of these services.

There are a number of medical technologies that meet the challenges associated with providing healthcare to ageing and remote populations. Older people wish to remain in their homes for as long as possible and there are a number of assistive technologies that can delay or stop transition into residential care. Remote monitoring, in particular consultations via video conferencing, provide a way of providing services to people in rural and remote regions.

The benefits of remote consultations include:

- Reducing barriers of access to healthcare due to geography
- Providing access to specialists in areas where there is a shortage of staff
- Reducing the pressure on an over-extended healthcare workforce
- Shifting responsibility for healthcare onto the consumer
- Provision of a viable alternative to outpatient or doctor visits
- Increasing quality of life
- Encouraging adherence to treatment regimes
- Reducing the burden on care givers
- Early detection of abnormalities/symptom exacerbations
- Reducing the number of unnecessary hospital admissions.

The investment by the Labor Government will provide:

- \$250.5 million for Medicare rebates for online consultations across a range of specialties, providing approximately 495,000 services over four years to rural, remote and outer metropolitan areas
- \$56.8 million for financial incentives for GPs and specialists to participate in delivering online services
- \$50 million to expand the GP after hours helpline and include the capacity for the helpline to provide online triage and basic medical advice via videoconference
- \$35 million to support training and supervision for health professionals using online technologies (beginning January 2011).

This funding is closely aligned to the National Broadband Plan which will provide broadband to rural Australians¹ and will be rolled out from July 2011. Fast internet speeds will reduce download times for medical data such as X-rays and enable case-conferencing with multiple medical specialists. The largest beneficiaries will be patients in remote communities who will no longer have to travel large distances to receive specialist care and patients of consultants, endocrinologists, dermatologists, ophthalmologists, psychiatrists and surgeons providing post operative follow-up.

There is a drive to move healthcare from hospital settings into the community. The discussion paper aligns the scope of 'primary care' and 'primary health care', with the National Primary Health Care Strategy, with the definition including services provided by GPs, Aboriginal Health practitioners, nurses and allied health providers, within both public and private sectors. Australia has an ageing population and a rising prevalence of chronic disease. The need to reduce hospitalization and provide care

¹ <http://www.nbnco.com.au/>

in home and community settings provides a unique set of challenges for safety and quality in primary care settings.

Consistent reimbursement procedures have enabled remote monitoring in the US, where providers pay for services delivered via telemedicine using the same code and at the same rate as if the service was delivered in the traditional manner. A number of lessons can be taken from the US experience and applied to the Australian context. In 1997, the Balanced Budget Act mandated that Medicare reimburse for telemedicine services. However a range of constraints made the practical provision of services difficult. These included: limiting reimbursement to rural areas; excluding nurses as eligible services providers; limiting reimbursement to specific current procedural terminology (CPT) codes; excluding store-and-forward telemedicine, and implementing a fee split between the teleconsulting physician and the referring practitioner.

In 2000 Congress passed the Benefits Improvement Act (BIPA), which: abolished fee splitting and set a fee per visit to cover facility costs at the site where patient examination occurs; increased the number of eligible CPT codes; expanded eligible sites to include any rural area with professional shortages; expanded the definition of site to include hospitals, rural health clinics and practitioners offices and eliminated the requirement for a Medicare participating telepresenter to be present. Perhaps of most relevance to the Australian context, other healthcare providers such as advanced nurse practitioners, certified nurse midwives and rural health clinics are able to bill (Federal Labor's policy provides rebates for GPs or practice nurses where the service is accessed and for specialists conducting consultations). Flexible reimbursement procedures incentivize health professionals and have encouraged the use of remote consultations in the United States. The use of remote consultations is increasing and most providers bill as usual and do not use modifiers or specialized CPT codes. Service providers generally consider telemedicine services in the same way they would face-to-face medical practices and consider 'special coding' systems as generally being counter productive. In most cases reimbursement is on the same fee-for-service basis as a face-to-face consultation and made at both ends.

What are the key patient safety risks/ considerations within primary health care?

Section 3.4 *Other possible patient safety risk areas* (page 8) asks for consideration of potential risks associated with:

- Access to services and the safety of alternative models of care such as telephone triage services
- Provision of primary health care services in the home environment.

The Medicare rebate for electronic consultations will be three times the regular rate, and will drive up rate of uptake of these services. There is a risk to patient safety if there are not clear guidelines outlining how these services should be structured and delivered, as well as vigorous monitoring and evaluation during the implementation phases.

Some of the safety risks/considerations include:

- Lack of evidence-based guidelines/standards for online consultations
- Concerns about data privacy and security, ensuring confidentiality
- Intraoperability between medical devices

- Identification of errors that may occur during transmission and execution during online consultations (e.g. connection disruptions)
- Release of information and informed consent
- Licensing, liability and malpractice issues
- Training of health professionals in the use of equipment
- Changes in physician-patient relationship – in the absence of a direct relationship (a patient and physician may never meet), a remote physician may interpret an x-ray or diagnostic tool which impacts a treatment decision made by another physician
- Services involving remote prescribing or medication dispensing
- Potential fraud and abuse.

What solutions could be put in place to address these risks?

Australia is already a world leader in the provision of unique medical care to remote communities. The Royal Flying Doctor Service² provides over 85,000 remote consultations a year via telephone, radio, or video conference. A number of Australian States, in particular Western Australia and Queensland, have already trialled a number of pilot projects delivering healthcare to remote regions. The Government has pledged to develop protocols on those conditions appropriate for doctors and nurses to diagnose over the internet.

It is important to recognize that internet consultations will provide challenges to safety and quality. To date telemonitoring services (with the exception of telepsychiatry) have not been funded under the Medicare Benefits Schedule (MBS). The provision of Government funding for remote consultations will revolutionise healthcare in Australia. However standards, including general guidelines and patient safety, need to be developed. These could include incorporating the rules for telepsychiatry or modifying international guidelines that are most relevant.

Telepsychiatry services have specific MBS item numbers and are available for patients in regional, rural or remote areas. The rules applicable to Category 1 telepsychiatry services could be applied to remote consultations. For example, the psychiatrist is responsible for keeping a record of episodes of care provided; there are limits to the number of consultations per year; and the consultant must use an outcome tool where clinically appropriate. The consult may include a mental state examination, a psychiatric diagnosis and the provision of a management plan.

Core Standards for remote consultations have been developed by the American Telemedicine Association³. The standards provide a comprehensive list of requirements that must be met by medical professionals who provide remote medical services and electronic consultations (including videoconferencing, transmission of still images and remote monitoring of vital signs). Specific clinical practices are addressed by separate work groups. The Home Telehealth Clinical Guidelines outline:

- Universal principles for home telehealth deployment
- Definition of terminology

² <http://www.flyingdoctor.org.au/>

³ The American Telemedicine Association Core Standards for Telemedicine Operations, November, 2007.

- Universal principles guiding the development and deployment of home telehealth in the future
- Patient criteria – inclusion/exclusion criteria, set up procedures, patient informed consent, privacy and confidentiality, patient/caregiver/home assessment, use of telehealth based on specific needs, education (storage, operation, electrical connections for equipment), written instructions regarding peripherals, safety instructions
- Technology criteria - organizational policies and procedures, equipment maintenance (per health and safety codes and infection control standards), installation kits, patient privacy and confidentiality (e.g. patients should not be heard or viewed without prior consent, patient photographs not to be used without written consent, patient data may not be viewed at a remote location without consent), frequency order and each encounter should be documented, changes in frequency should be approved by the physician, any changes must be charted
- Health provider criteria – licensing of providers, provider education/training, evidence of Health Insurance Portability and Accountability Act (HIPAA) compliance, organizational policies and procedures must reference monitoring procedures; frequency of monitoring, method of data capture, procedures to review and respond to monitored data, definition of acceptable values and actions in response to outliers, expected timeliness of response to patient data, policy re inclusion of data in patients electronic medical record, and procedures for handling ‘unwanted events’.

The American Telemedicine Association has developed practice guidelines for videoconferencing-based telehealth⁴. The guidelines provide detail on two-way interactive videoconferencing for the delivery of remote consultations and include:

- Standard operating procedures/protocols – staff, licensing, credentialing, training, authentication
- Clinical specifications – remote care must be equivalent to standard care
- General practice issues - exam inclusion criteria/scope, contraindications to remote assessment, consult request data, procedures for information sharing
- Videoteleconferencing (VTC) - identification of all persons at both sites prior to consultation, patient permission for additional persons, legal and regulatory requirements for sharing of clinical history/results, access to relevant clinical data, use of electronic prescribing, traceable record keeping, recommended language for consult (e.g. “based on the video images” ...), secure methods of transfer for reports, outline of consultant reports, guidelines for medication management
- Guidelines for special groups (children, elderly, rural populations)
- Sensitivity regarding impact of disclosures made during emergency management in small communities
- Ethical considerations
- Technical considerations – equipment and standards-based software, features of videoconferencing systems, audio, remote camera control, visual feedback cue, user messages, image viewing, capacity for upgrades, satellite communications, specifications for microphones/speakers, room specifications
- Transmission speed and bandwidth

⁴ American Telemedicine Association. Telemental Health Standards and Guidelines Working Group. Practice guidelines for videoconferencing-based telemental health, October, 2009.

- Image storage, retrieval, transmission and security (United States Health Insurance Portability & Accountability Act (HIPAA)), privacy requirements, conformance with privacy requirements in both location, network and security protocols, safeguards against corruption
- Encryption – security of video sessions
- Resolution – matching of display monitor and acquired image resolution
- Interoperability – equipment to be based on standards (e.g. International Telecommunications Union (ITU)), which allow successful conferencing regardless of platform or manufacturer
- Physical location/room requirements – considerations for room set up in both locations, audio and visual privacy, room lighting, back drop, ergonomic considerations, gaze angle
- Administrative issues – technical readiness of equipment, support, maintenance, safety and effectiveness of equipment, redundant systems, availability of network for critical connectivity, compliance with all relevant safety laws, regulations, and codes for safety, infection control policies and procedures for equipment and patient peripherals
- Existing digital imaging standards - Health Level-7 Data Communications Protocol (HL-7) (the communication standard which guides the transmission of health-related information).

The US Federation of State Medical Boards has published, '*Model Guidelines for the appropriate use of the Internet in Medical Practice*' (FSMB, 2002)⁵. Additional guidelines have been developed by the American Medical Association regarding the prescribing of medication via the internet. The guidelines include patient examination, reliable medical history, dialogue regarding treatment options, risk/benefits and follow up. While the National e-Health Transition Authority (NEHTA)⁶ will develop the guidelines for e-health infrastructure, there is a gap in terms of how e-health will impact safety and quality in primary health care. NEHTA has developed some e-health standards and detailed hierarchical data specifications. NEHTA does **not** provide guidelines for clinicians but rather the specifications for the data that enter the system. This includes the way that clinicians should input data for – demographics, clinical intervention, imaging, insurance details, services, medication dispensing, adverse reactions etc. Data specifications have been designed to suit the Australian model for a shared electronic health record.

4. Safety Engineered Medical Devices (SEMDs), preventing Needlestick and Scalpel injuries in Primary Healthcare

What are the key patient safety risks/ considerations within primary health care?

Australia does not mandate the use of safety engineered medical devices (SEMDs). Compelling evidence to show the scale of the problem of risk arising from the use of non-SEMD in Australia is outlined below:

- In Australia at least 18,500 nurses and other healthcare employees suffer needlestick and sharp object injuries every year (this number is likely to be higher given that needlestick injuries tend to be underreported)⁷

⁵ http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/internet_use_guidelines.htm

⁶ <http://www.nehta.gov.au/>

⁷ Murphy, C. (2008). Improved surveillance and mandated use of sharps with engineered sharp injury protections: a national call to action. *Healthcare Infection*, 13, 33–1107.

- Needlesticks and other sharps are identified as high risk occupational hazards by 43.5% of nurses⁸
- The Needlestick Safety and Prevention Act was implemented in the USA in 2001 and safety-engineered sharps must be used where feasible⁹
- Since mid 2000, occupational health & safety legislation/regulations have mandated the use of safety engineered medical devices in the majority of Canadian provinces¹⁰
- Guidelines incorporating the use of safety-engineered sharps as a standard were incorporated into EU health and safety legislation in March 2010. The three directives (89/391/EC, 89/655/EC and 2000/54/EC) mandate the use of safety engineered devices and ban the practice of recapping¹¹
- The introduction of the Needlestick Safety and Prevention Act (USA, 2000) was associated with a 36% decrease in the rate of injury from hollow-bore needles¹².

Requirements differ between Australian states and there is no centralized system for monitoring and reporting sharps injuries. Chapter 23 of the Infection Control Guidelines outlines safety measures for Needlestick and other blood or body fluid incidents. Additionally, the Australian National Council for AIDS, Hepatitis C and Related Diseases (ANCAHRD) has published a comprehensive bulletin which outlines the management of exposure to blood and body fluids contaminated with blood, including needlestick/sharp injuries¹³.

What solutions could be put in place to address these risks?

MTAA would like to see the use of safety sharps mandated in Australia. Australia is behind the majority of international healthcare systems that have introduced safety sharps. The USA introduced safe needles into health care settings in 2000 and the use of devices with safety engineered features is thought to have reduced the rates of needlestick injuries¹⁴. MTAA does not promote the use of any specific SEMD. There is a wide variety of products available in the market. Retractable technology is only one example of the broad range of SEMDs which have been designed and produced with built-in safety features to assist in reducing the risk of occupational exposure to bloodborne pathogens in healthcare. These devices include: syringes with guards or sliding sheaths that shield the attached needles after use; needles that retract into a syringe after use; shielded, blunting or retracting needles used for intravenous cannulation; shielded needles used for phlebotomy procedures, blunt suture needles, surgical blades with protective covers etc.

The Discussion Paper: *Patient Safety in Primary Health Care* has a primary focus on patient safety. The MTAA is a founding partner of the Alliance for Sharps Safety and Needlestick Prevention in Healthcare, which has called on the Australian

⁸ Australian Safety and Compensation Council (ASCC). Occupational Exposures in Australian Nurses. Canberra: ASCC; 2008

⁹ United States Department of Labor. Occupational Safety and Health Administration. Needlestick Safety and Prevention Act (H.R. 5178), November, 2000

¹⁰ Canadian Occupational Health and Safety Regulations. Sharps Safety Regulations (BC, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia)

¹¹ Framework Agreement on sharps safety, signed by HOSPEEM and EPSU July 17, 2009.

¹² Jagger, J. (2007). Caring for Healthcare Workers: A Global Perspective. *Infection Control and Hospital Epidemiology*, 28, 1-4

¹³ Australian National Council for AIDS, Hepatitis C and Related Diseases (ANCAHRD). Bulletin No 29: Needlestick and Blood Accidents

¹⁴ Jagger, J., Perry, J., Gooma, A., & Phillips, E.K. (2008). The impact of U.S. policies to protect healthcare workers from bloodborne pathogens: the critical role of safety engineered devices. *Journal of Infection and Public Health*, 1(2), 52-71.

Government, States and Territories to introduce nationally consistent policy and/or legislation aimed at preventing needlestick injuries in healthcare. The aim of policy and/or legislation aimed at preventing needlestick and sharps injuries in healthcare is to create a safer working environment for both patients and all healthcare employees in Australia. The Alliance partners and objectives are set out in the Consensus Statement at Annex A. The Alliance has three objectives:

- To improve education and training of healthcare workers in the prevention of needlestick injuries
- To improve the reporting of needlestick injuries to ensure that incidents are accurately captured and followed
- To mandate the use of safety engineered medical devices in healthcare settings.

The MTAA made a detailed response to the January 2010 consultation paper: *Australian Guidelines for the Prevention and Control of Infection in Healthcare*. Specific recommendations included:

- Inclusion of guidelines mandating the use of SEMDs to prevent needlestick and other sharps injuries to healthcare workers
- Inclusion of guidelines recommending safety procedures to prevent infection from scalpel injuries.

The safety of both patients and healthcare employees can be improved by mandating the use of SEMDs to prevent needlestick injuries. The objective is the prevention of needlestick or sharps injuries (and associated infection) in patients, healthcare workers, pharmacists, waste handlers and laboratory/housekeeping personnel. MTAA would like to see a national standard mandating the use of SEMDs in accordance with US, Canadian and European laws.

MTAA provided additional detail on sharps safety for scalpels in the March 2010 submission. Given that this information is more applicable to acute care settings it will not be dealt with in this submission. In general MTAA recommends educating healthcare professionals about best safety practices around scalpels. The 'scalpel safety' technique involves using a single-handed scalpel blade remover and a hands-free passing technique (HFPT) (the scalpel is passed on to a tray or into a neutral zone before being picked up again)¹⁵. Single-handed scalpel blade removers in combination with the hands-free passing technique can potentially prevent 5 times as many injuries as safety scalpels¹⁶.

¹⁵ Sinnott, M. & Shaban, R. (2010). 'Scalpel Safety', not 'Safety Scalpel': A new paradigm in staff safety. *Perioperative Nursing Clinics*, 5, 59-67.

¹⁶ Fuentes, H., Collier, J., Sinnott, M. & Whitby, M. (2008). Scalpel Safety: Modelling the effectiveness of different safety devices' ability to reduce scalpel blade injuries. *The International Journal of Risk and Safety in Medicine*, 20(1-2), 83-89.

Annex A

CONSENSUS STATEMENT (December 2009)

Preventing needlestick injuries in the healthcare workplace

This Consensus Statement reflects the position of the Australian Infection Control Association, Medical Technology Association of Australia, the Australian Nursing Federation, the Royal College of Nursing Australia, the Royal College of Pathologists Australasia and independent experts in relation to a national call to action for the prevention of needlestick injuries in the healthcare workplace.

The provision of a safe and healthy working environment is a fundamental right of every employee in Australia. The duty of care provisions within occupational health and safety legislation aim to protect persons from all types of hazards and risks arising from work activities. Therefore it is reasonable to expect that healthcare employees in Australia should be protected from the hazard of occupational exposure to bloodborne pathogens from needlestick and sharp object injuries and the subsequent risk of acquiring a potentially life threatening bloodborne disease such as hepatitis B, hepatitis C or HIV/AIDS.

In Australia, it has been estimated that at least 18,000 nurses and other healthcare employees suffer needlestick and sharp object injuries every year¹. Numerous studies have shown that approximately 50% of needlestick injuries are not reported, with rates of underreporting ranging from 40% to 80%². *Therefore the actual number of injuries to healthcare professionals is likely to be in excess of 30,000 per year.*

A recent report published by the Office of the Australian Safety and Compensation Council found that needlesticks and other sharps are identified as high risk occupational hazards by 43.5% of nurses. The report shows that 1 in 9 nurses had at least one needlestick or other sharps injury in the past 12 months³.

Needlestick and other sharp object injuries generate significant cost for the Australian healthcare system and can result in great stress for the injured healthcare workers and their families.⁴

Independent studies show that the majority of needlestick injuries are preventable through the implementation and use of safety engineered medical devices (SEMD) combined with relevant education and training programs for healthcare employees.⁵⁻⁹

Unlike many countries, Australia has yet to adopt a nationally consistent approach to the use of SEMD in healthcare settings either through prescriptive legislation or policy. Guidelines, awareness and education campaigns and other non-legislative initiatives alone have generally proven ineffective in preventing needlestick injuries to healthcare employees.⁹

Today, many international jurisdictions have taken steps to amend Occupational Health and Safety Legislation and include provision for mandatory use of safety engineered needles and sharps in medical workplaces.¹⁰⁻¹³

Why should healthcare employees in Australia not be afforded the same legislative protection?

The elimination of workplace hazard and risk is a fundamental principle of occupational health and safety legislation in Australia. Every needlestick or sharp object injury at work is a foreseeable hazard faced by healthcare employees in Australia.

All employees in the Australian healthcare sector have the right to work without concern of experiencing a needlestick or sharps injury. The risk of occupational exposure to bloodborne pathogens from such injuries can be and must be eliminated.

The undersigned organisations support the introduction of nationally consistent policy and/or legislation aimed at preventing needlestick injuries in healthcare. Prevention measures must include the implementation and use of safety engineered medical devices combined with relevant training and education.

Safety and quality is central to healthcare in Australia. The safety of all healthcare employees must be viewed as paramount and is everyone's responsibility. Safety for healthcare employees is as important as patient safety.

Claire Boardman

President

Australian Infection Control Association

Associate Professor Cathryn Murphy

Managing Director

Infection Control Plus Pty Ltd

Debra Cerasa

Chief Executive Officer

Royal College of Nursing Australia

Ged Kearney

Federal Secretary

Australian Nursing Federation

Anne Trimmer

Chief Executive Officer

Medical Technology Association of Australia

Dr Debra Graves

Chief Executive Officer

Royal College of Pathologists of Australasia

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- ¹¹ Selecting Needle safe Devices, *The Occupational Health and Safety Act, 1993*, Saskatchewan, Canada Go to Section 474.1, 474.2 <http://www.qp.gov.sk.ca/documents/English/Regulations/Regulations/OI-1R1.pdf> (Accessed 28 July 2009)
- ¹² Needle Safety, Ontario Regulation 474/07, *The Occupational Health and Safety Act, 1990*, Ontario, Canada <http://canlii.org/en/on/laws/regu/o-reg-474-07/latest/o-reg-474-07.html> (Accessed 28 July 2009)
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