NSW Therapeutic Advisory Group Inc.
Promoting the quality use of medicines in public hospitals

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NSW TAG RESPONSE TO THE CONSULTATION: DRAFT CLINICAL EVIDENCE GUIDELINES- MEDICAL DEVICES Version 1.0, March 2016

These Clinical Evidence Guidelines fail to adequately describe the necessary information for the critical evaluation of devices or equipment that are associated with medicines use or that contain medicines. These include but are not limited to administration equipment e.g. elastomeric devices such as Pain Buster™, insulin pumps, intravenous infusion lines; drug-eluting or-impregnated technology such as stents and dressings; dose administration aids and automated dispensing cabinets. The lack of critical evaluation by health care professionals with appropriate expertise in the assessment of safety and efficacy of medicines and medicines regulation regarding such devices and equipment may place patients at harm. The post-marketing safety monitoring of these devices should also incorporate a pharmacovigilance perspective. This is particularly pertinent to devices that contain medicines that are scheduled, particularly when the medicine is not registered or is being used in an off-label manner (e.g. topical antimicrobials). Currently such items can be ordered within the hospital system in NSW by any employee. Furthermore, they may not be comprehensively reviewed within the hospital system prior to use as there is confusion amongst some clinicians about the evaluation and governance role of Drug and Therapeutics Committees for devices/equipment and their local use may not be appropriately monitored for effectiveness and safety.

Drug administration equipment

This equipment forms an integral part of the administration of the correct dose of medications over an appropriate timeframe. The potential for patient harm can be illustrated by elastomeric devices e.g. Pain Buster™ which are used to provide post-operative analgesia. These devices provide continuous infusion of a local anaesthetic into an intra-operative site for 24 to 48 hours. It is inserted intra-operatively and is not easily visible. There are reports of these devices being reloaded in outpatient clinics. These devices have the potential to cause anaesthetic toxicity from mild symptoms of restlessness and confusion to more serious adverse effects such as cardiac arrhythmias and respiratory and cardiac arrest. However the drug and dose that is being administered to the patient may not be documented because these interventions are seen as ‘devices’ rather than medicines and, if documented, the information is likely to be found on intra-operative records with relevant information transfer to areas such as outpatient clinics unlikely. As these interventions are classed as devices they do not undergo the critical evaluation that a Drug and Therapeutic Committee (DTC) would provide when a local anaesthetic is administered by other means e.g. a

regional block using local anaesthetic would be written on a medication chart and have a local protocol with oversight by the DTC. Although it could be said that a hospital has the ability to have policies that would mean medication-associated devices should also be evaluated by DTCs, this is less likely and liable to meet barriers when the TGA, as the Australian regulator, does not evaluate these devices from the medicines perspective as well as the device perspective. Additionally, there is the potential for devices that administer medicines to have drug interactions that will not be easily identified if they are not documented in an appropriate place.

Drug-eluting or impregnated technology

This technology has the potential for both individual patient and environmental harm, and increased financial burden to the healthcare system if it remains unchecked. In particular devices which elute antimicrobial agents should be required to undertake stringent studies into efficacy and harm for individual patients, and into the impact of indiscriminate low dose antimicrobials on the resistance of microorganisms in the environment, particularly in hospitals.

We recommend that these devices be approved through the Therapeutic Goods Authority not as therapeutic devices but as therapeutic drugs, according to the drug they are eluting. Alternately there could be a separate classification in the therapeutic goods register for devices which elute therapeutic drugs. The level of evidence for efficacy and safety required for these products should be in line with that required for therapeutic goods.

Dosage administration aids and automated dispensing cabinets

These devices have the potential to cause patient harm if not fit for purpose. Whilst market forces would potentially limit inappropriate products, evaluation by health care professionals with the relevant expertise prior to registration should be undertaken

Technology e.g. software programs

Technology such as software programs that provide e.g. dosing nomograms of scheduled medicines should also be considered for national regulation. Although this would be challenging, parameters could be provided to identify the technology that has the potential to lead to serious patient harm and require initial and ongoing oversight and evaluation. Again, market forces may not limit the uptake of these products by end-users prior to serious harm occurring.

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