

Time for change: Proposed safety improvements to the labelling and packaging of Neuromuscular Blocking Agents in Australia

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SUMMARY OF RECOMMENDATIONS

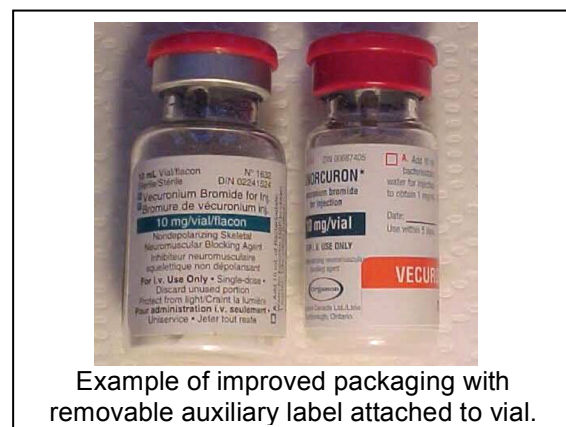
Proposed NMBA manufacture packaging and labelling improvements in Australia:

The VicTAG QUM group¹ strongly support the recommendations from the Australian Commission on Safety and Quality in Health Care (ACSQH)² that were submitted to the TGA in August 2012; for Australia to align with international NMBA packaging and labelling standards that exist in Canada and the US. In addition, the Quality and Safety Committee of Australian and New Zealand College of Anaesthetists (ANZCA) have indicated their willingness to prepare a submission, if invited, to comment on this matter.

The proposed improvements to Australian NMBA packaging and labelling that arise from US/Canada recommendations^{3,4,5} (figure 1) are included in Table 1, below.

Table 1. Proposed improvements to Australian NMBA packaging and labelling	
Improvement	Advantage
1. Packaged in vial, as opposed to ampoule.	To standardise shape & provide enough space for warning labels to be included on vial cap, ferrule and label.
2. Red vial cap with white lettering: "Warning: Paralyzing agent" or "Paralyzing Agent"	To differentiate from other drug classes significantly decreasing the risk of look-alike and sound alike drug selection errors.
3. Red ferrule with white lettering: "Warning: Paralyzing agent" or "Paralyzing Agent"	
4. Red lettering on the product label: "Paralyzing agent" or "Warning: Paralyzing Agent."	
5. Peel-off label, using the colour scheme and content information recognized by ISO26825 ⁶ and other Australian label recommendations ⁷ .	To improve efficiency with labelling of syringe.
6. Prominence of the NMBA generic name on product label, strength expressed over total ampoule volume. (Consideration to use of TALL-man lettering for generic names of neuromuscular blocking agents.)	To prevent inter-class drug selection errors
7. Space on the product label for bar code application.	To enhance correct product selection from pharmacy.

Figure 1. Examples of improvements to NMBA labelling and packaging in US/Canada (Reprinted with permission from ISMP Canada)



PURPOSE

In this report the Victorian Therapeutic Advisory Group Quality Use of Medicines (Vic TAG QUM) group have addressed concerns regarding the unsafe labelling and packaging of Neuromuscular Blocking Agents (NMBA's) and proposed improvements to them. This report is for submission to the Council of Australian Therapeutic Advisory Groups (CATAG) with the intent that recommendations be made to the Therapeutic Goods Administration (TGA) to standardise packaging of this high risk drug class in Australia.

BACKGROUND

NMBA's are high risk drugs^{3, 8-21}, often administered in high risk settings. They are indicated to produce skeletal (including respiratory) muscle relaxation to facilitate endotracheal intubation, and control of the airway, to allow mechanical ventilation¹⁸. The unintentional administration of a NMBA to a non-intubated, non-ventilated patient can result in severe permanent injury or death of a patient¹³. Although the frequency of incidents involving NMBA's may not be greater compared with other drugs, without adequate safeguards the outcome of an incident involving these high risk medications can be catastrophic. The severe consequences are well documented globally^{3, 8-20,22-30}.

CURRENT ISSUES

Incidents

Review and analysis of voluntary incident reports from Victorian healthcare networks involving NMBA's (Appendix 1) indicate that severe/life threatening patient harm is occurring. In NSW, NMBA incidents involving death, lead to the NSW Coroner recommending release of the 'NMBA – Minimising Risk Alert' in November 2011¹⁷. The true incidence of injuries from accidental administration of NMBA's is likely much higher than reflected by incident reports¹⁵.

Of the twelve Victorian incident reports, 11 (92%) were attributed to look-alike packaging and one (9%) to sound-alike drug names. In 9 (75%) of these reports the wrong drug reached the patient, with the remaining 3 (27%) being 'near miss' incidents. In NSW, as in Victoria, the top contributing factors to NMBA incidents also include look-alike packaging and sound-alike drug names¹⁷. Clinical incidents from these causes are well documented nationally^{18, 21,28-30} and internationally^{3,8-16}. Of the 11 look-alike incidents, ten involved administration of the NMBA instead of a drug from a different pharmacological class of the drug. This scenario is considered a much higher risk, in terms of patient harm, than giving an incorrect drug from the same class³⁰.

An Australian review of 896 drug error reports in anaesthesia by Abeysekera et al²⁸ reported 20.8% of drug errors involved selection of the wrong ampoule, in this study NMBA's were identified as the drug most commonly involved in anaesthesia drug incidents.

Victorian figures show the main drug pairs involved in these high risk look-alike incidents include:

- Atracurium instead of midazolam (33%).
- Cisatracurium instead of midazolam(25%).
- Suxamethonium instead of atropine (16%).

Figures 2, 3 & 4 are examples of the similar packaging involved in the Victorian incidents. The packaging and labelling features that led to these selection errors include similar:

- Shape and size of ampoule.
- Ampoule material (e.g. polyamp).
- Label colour &/or small unclear print.

Figure 2: Look-alike packaging, Cisatracurium 10mg/5mL & Midazolam 5mg/5mL



Figure 3: Look alike packaging, Atracurium 50mg/5mL & Midazolam 5mg/5mL



Figure 4: Look-alike packaging, Suxamethonium 100mg/2mL & Pancuronium 4mg/2mL 5mg/5mL



Current labeling and packaging

A review of labelling and packaging for all commonly used NMBA brands in Australia (Appendix 2) indicates that of the 13 products, 11 (85%) are high risk as no distinctive packaging or labelling features are present to differentiate them as NMBA's. Two (15%) are considered medium risk as they feature either the international red colour coding or 'paralysing agent' on the vial cap.

International packaging standards and classification of high risk drugs

Both national^{2,17,18,31,32} and United States (US)/Canada^{3,8,10,11,13-16,25} NMBA safety alerts and guidelines include recommendations to health networks on methods to improve the safe handling of NMBA's, to prevent look-alike and sound-alike selection errors, These include:

- Safe product storage,
- Limit or control of access,
- Use of alert labelling,
- Safe prescribing and administration practices,
- Focused education and practitioner credentialing.

One standard currently in the US/Canada that does not exist in Australia focuses on industry responsibility that 'Manufacturers must use packaging, labelling and nomenclature to clearly and readily differentiate from other medications'³.

Since 1998, deaths in Canada and the US reported to the Institute of Safe Medication Practice (ISMP) led to increased awareness of the risk involved with look-alike NMBA packaging to other drugs^{3, 8, 20, 22}. Once identified, collaborative work was undertaken from ISMP & the United States Pharmacopeia (USP) to advocate manufacturer labelling and packaging standards for NMBAs with the aim that an FDA standard requirement for all NMBAs could reduce fatalities and serious injuries due to unintended administration. Practitioner input through a survey of five hundred pharmacists, physicians, and nurses⁸ plus feedback from manufacturers, was included in this process. As of October 2005, in US/Canada the FDA mandated the requirement that all manufacturers update their labeling and packaging of NMBA's (figure 4)^{3,23,33}. This has been shown to be an effective strategy to reduce incidents involving NMBA's^{34,35}.

NMBA's are also recognised on ISMP's list of high-alert-medications, this list identifies medications that bear a heightened risk of causing significant patient harm²⁰. In Australia, national safety bodies classify high risk medications via the acronym 'APINCH'³⁶, NMBA's are not included within this taxonomy.

Current Australian Guidelines

In Australia, important guidelines^{32,33} lay the foundation for safe administration of injectable drugs in anaesthesia. These guidelines cover checking and administration practices to prevent incidents. While system improvements, including NMBA administration via a red plunger syringe, are paramount to preventing many NMBA inter-class drug administration errors, incidents continue to occur - often due to mis-selection of a NMBA ampoule or vial. Webster et al³⁰ concluded drug administration error during anaesthesia is considerably more frequent than previously reported, and is estimated to occur once every 133 anaesthetics. Abeysekera et al²⁸ also highlighted 'The task of administering an intravenous drug to a patient during anaesthesia is a highly complex procedure, often taking place under conditions of stress, haste and fatigue and can be associated with up to 40 component steps; therefore it is not surprising that errors can and do occur'.

In these situations of cognitive overload, Paparella et al¹⁶ identified one cause to be the human factor issue known as 'confirmation bias', where staff 'can read drug product labels and "see" what in their minds they expect to see, rather than what is actually on the label.' Paparella et al then concluded 'Compounding this human factor problem is the issue of look-alike packaging.'

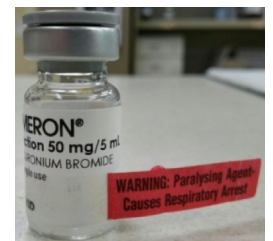
For high risk medications where the occurrence of an incident may be infrequent but the outcome catastrophic, a paper by ISMP¹¹ highlighted 'experts in human error and human perception have recommended the use of "multi-sensory warnings" to further reduce the probability of substitution errors with dangerous products.

Currently, to reduce this risk, Australian NMBA safety alerts^{17,18} include the recommendation that a warning label ('WARNING: Paralyzing Agent-Causes Respiratory Arrest') should be applied directly to all individual NMBA products that leave pharmacy (figure 5). The aim is to differentiate NMBA's from other drugs therefore preventing look-alike packaging incidents. Evidence shows this to be an effective strategy³⁷ and arguably as effective as improvements to manufacturer packaging. However this initiative relies entirely on pharmacy resources to implement, sustain and monitor. A detailed resource and cost analysis from one Victorian health network estimated the initiative to cost \$16K (Appendix 3) to introduce, sustain and importantly monitor (to reduce human error). This assumes a department that has approximately 15,000 NMB issue events from pharmacy annually. This initiative introduces two new issues:

- Due to its impact on pharmacy resources many Australian hospitals do not have the capability to effectively sustain the initiative.
- The human factor issue is not removed with this initiative. Instead it is transferred to a different area (pharmacy) as it relies on pharmacy to manually and consistently label every individual NMBA. If a single NMBA is not labelled post implementation the likelihood of a look-alike packaging selection incident is greatly increased.

With more generic brands entering the market, packaging risk is increasing. The fact that NMBA's are not recognised through the Australian high risk medication acronym 'APINCH' means their risk may not be fully recognised by Australian hospitals. Therefore it is timely that NMBA labelling and packaging be updated in accordance with the following recommendations.

Figure 5. Example of warning label recommended for pharmacy to apply.



RECOMMENDATIONS

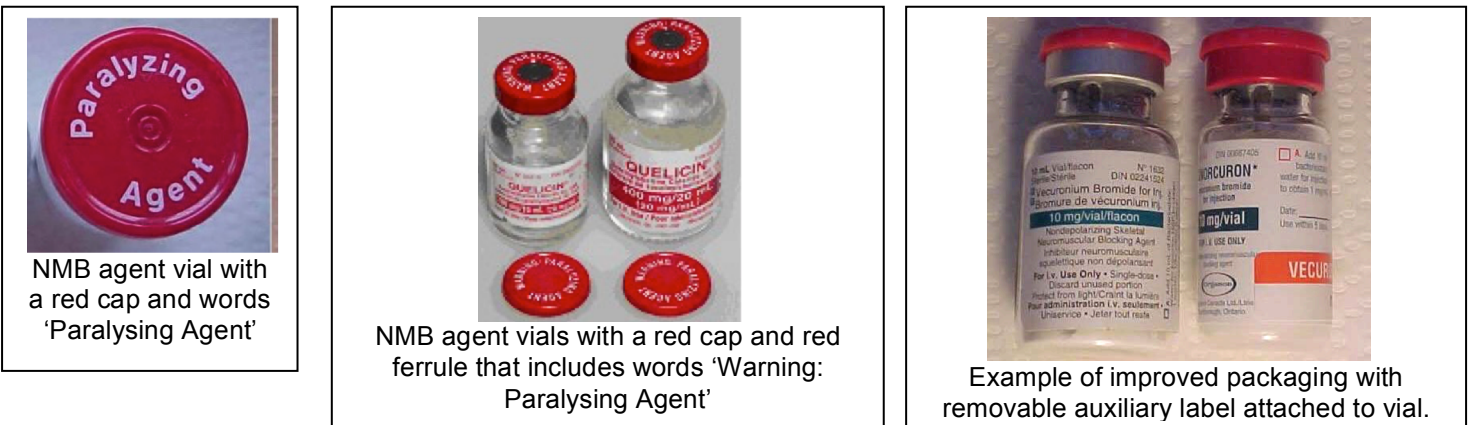
Proposed NMBA manufacture packaging and labelling improvements in Australia:

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The proposed improvements to Australian NMBA packaging and labelling that arise from US/Canada recommendations^{3,4,5} (figure 6) are included in Table 2, below.

Table 2. Proposed improvements to Australian NMBA packaging and labelling	
Improvement	Advantage
8. Packaged in vial, as opposed to ampoule.	To standardise shape & provide enough space for warning labels to be included on vial cap, ferrule and label.
9. Red vial cap with white lettering: "Warning: Paralyzing agent" or "Paralyzing Agent" 10. Red ferrule with white lettering: "Warning: Paralyzing agent" or "Paralyzing Agent" 11. Red lettering on the product label: "Paralyzing agent" or "Warning: Paralyzing Agent."	To differentiate from other drug classes significantly decreasing the risk of look-alike and sound alike drug selection errors.
12. Peel-off label, using the colour scheme and content information recognized by ISO26825 ⁶ and other Australian label recommendations ⁷ .	To improve efficiency with labelling of syringe.
13. Prominence of the NMBA generic name on product label, strength expressed over total ampoule volume. (Consideration to use of TALL-man lettering for generic names of neuromuscular blocking agents.)	To prevent inter-class drug selection errors
14. Space on the product label for bar code application.	To enhance correct product selection from pharmacy.

Figure 6. Examples of improvements to NMBA labelling and packaging in US/Canada (Reprinted with permission from ISMP Canada)



CONCLUSION

- Look-alike packaging selection errors are identified as the primary cause of clinical NMBA incidents in Australia. Without further intervention it is likely these incidents will continue to cause serious outcomes for hospitalised patients.
- The current recommendation for pharmacy to label all NMBA is unachievable for most hospitals.
- VicTAG QUM recommends that the TGA introduce mandatory NMBA packaging and labelling requirements to align Australian NMBA packaging with US/ Canada standards.
- ANZCA have indicated their willingness to prepare a submission if invited to comment on this matter.
- NMBA's need to be formally recognised in national initiatives that define high risk medications.

ACKNOWLEDGEMENTS

The reports development has been undertaken with extensive involvement from:

Dr David Bramley, Deputy Director, Department of Anaesthesia and Pain Medicine, Western Health.

Dr Claire McKie, Consultant Geriatrician, Chair Medication Safety Committee, Western Health.

Dr Raymond Tam, Anaesthetist, Western Health.

Mr Kent MacMillan, Director of Pharmacy, Western Health.














In addition, the report's author has received extensive input from members of the VicTAG QUM group. The recommendations of this report have been endorsed by the VicTAG QUM group.

Appendix 1 – Victorian Neuromuscular Blocking Agent Incidents

NMB agent	Incident Detail	Other drug involved	Incident category	Actual Outcome	Potential Outcome	Prevented by safety improvements to NMB packaging? Yes/No
Atracurium	Atracurium 50mg/5mL (glass ampoule) was administered instead of midazolam 5mg/5mL (glass ampoule) in theatres. Selection error occurred when both products were placed on top of the theatre drug trolley prior to surgery. Contributing factor was both products were packaged in similar size glass ampoule. ⁷⁵	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Atracurium	Anaesthetic nurse went to select a midazolam ampoule from the Theatre S11 cupboard, handed this to the Anaesthetist who read the ampoule to in fact be Atracurium. The look-alike selection error originally occurred when re-stocking Theatre drug storage from the central Theatre drug imprest. ¹⁹	Midazolam	Look alike packaging selection error	Near miss	Severe/Life Threatening	YES
Atracurium	Inadvertent administration of Atracurium 50mg/5mL to a patient instead of Midazolam 5mg/5mL when patient was on the table in the operating room but prior to induction. The swap was immediately recognized and the patient received an IV induction for anaesthesia without incident. ¹⁹	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Atracurium	Anaesthetic nurse noticed an atracurium ampoule was due to expire at the end of the day. The atracurium was placed on top of the anaesthetic trolley, as thought the anaesthetist could use for one of the cases that afternoon. The anaesthetist mistook the atracurium ampoule on top of the trolley for midazolam and the atracurium was given in error. Patient saturation dropped and resp state deteriorated requiring bag and mask support. Saturation levels improved, but patient unable to talk due to effect of atracurium.	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Cisatracurium	A muscle relaxant (cisatracurium) was mistaken for a sedative (midazolam) and administered to the patient in Operating Theatre. The resident drew up an ampoule of cisatracurium in the belief it was an ampoule of midazolam, labelled it as midazolam, and then administered to the patient. The patient had episodes of hypertension and tachycardia during the procedure, especially associated with dilation. In recovery it was noticed that although the patient was conscious and breathing spontaneously, she appeared unusually weak, unable to lift her head with jerky uncoordinated muscle movement. The clinical picture was consistent with the effect of partially reversed muscle relaxant. Neostigmine and glycopyrrolate was used to reverse the effects of the presumed muscle relaxant. ¹⁹	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Cisatracurium	A patient in trauma was intubated and the doctor requested cisatracurium, for restless movement. Midazolam was inadvertently administered instead of cisatracurium. The patient required further anaesthetic agents, but was not harmed. The incident was a result of not checking the label and similar looking ampoules. Both products were kept out of normal storage in the ED setting. ¹⁹	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES

Cisatracurium	An intubated patient, being managed with propofol, was transported for CT scanning. The registrar requested and administered what he thought was midazolam for ongoing restlessness. The patient subsequently noted to have decreased blood gases. When checked, it was noted that cisatracurium had been selected and given in error. ¹⁹	Midazolam	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Pancuronium & Suxamethonium	A patient in ED resus was administered pancuronium (plastic polyamp, red writing) instead of suxamethonium (plastic polyamp, pink writing). Nursing staff had pre-drawn syringes of propofol, midazolam, fentanyl and suxamethonium. The anaesthetist performed the intubation while the nursing staff administered drugs on his instruction. 100 microgram fentanyl, 100mg propofol and what was intended to be 100 mg suxamethonium were administered but the patient was coughing and displayed no muscle twitches (fasciculations) which are often associated with administration of suxamethonium. This prompted a check of the drugs administered and revealed a syringe with a sticker marked suxamethonium and an empty ampoule of pancuronium 4 mg. ¹⁹	N/A	Look-alike packaging selection error.	Recovered	Severe/Life Threatening	YES
Suxamethonium	An anaesthetist asked a nurse to fetch an ampoule of suxamethonium. She was given a polyamp, drew it up and thought it was strange that it was only 1mL (suxamethonium is a 2mL polyamp). She was about to administer it to the patient when she thought she'd better double check. She then found she'd been handed a polyamp of atropine instead. ¹⁹	Atropine	Look alike packaging selection error	Near miss	Severe/Life Threatening	YES
Suxamethonium	A patient admitted to Recovery was noted to be bradycardic. An anaesthetist reviewed the patient and ordered IV atropine 600 micrograms. The nurse inadvertently handed the anaesthetist a polyamp of suxamethonium. The anaesthetist noticed the error and did not administer to the patient. The incorrect suxamethonium polyamp had been selected from the emergency drug box because it was a similar shape to the atropine polyamp. ¹⁹	Atropine	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
suxamethonium	A doctor requested an ampoule of sucrose oral solution to administer to a baby, prior to a potentially painful procedure. The nurse inadvertently selected an ampoule of suxamethonium and checked it with the doctor, who went on to administer it orally to the baby. Fortunately, no adverse effect was suffered, as suxamethonium has no pharmacological action when administered orally. ¹⁹	Sucrose oral solution	Look alike packaging selection error	Recovered	Severe/Life Threatening	YES
Vecuronium	Near miss sound alike drug section error. Vecuronium was selected instead of Vancomycin from ICU drug room shelf, picked up upon double checking prior to administration. ⁷⁶	Vancomycin	Sound alike drug selection error	Near miss	Severe/Life Threatening	YES

Appendix 2. Packaging Analysis of commonly used Neuromuscular Blocking Agent brands available in Australia

Atracurium 50mg/5mL	Cisatracurium 10mg/5mL	Mivacurium 20mg/10mL	Pancuronium 4mg/2mL	Rocuronium 50mg/5mL	Suxamethonium 100mg/2mL	Vecuronium 10mg inj
<p align="center">Hospira DBL</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Pfizer</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Aspen</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Astra Zeneca</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Sandoz</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Astra Zeneca</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Merck Sharp & Dohme</p>  <p align="center">Packaging Risk: Medium</p>
<p align="center">Aspen</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Aspen</p>  <p align="center">Packaging Risk: High</p>			<p align="center">Hospira DBL</p>  <p align="center">(Vial cap blank) Packaging Risk: High</p>		<p align="center">Aspen</p>  <p align="center">Packaging Risk: Medium</p>
	<p align="center">Hospira DBL</p>  <p align="center">Packaging Risk: High</p>			<p align="center">Merck Sharp & Dohme</p>  <p align="center">Packaging Risk: High</p>	<p align="center">Packaging Risk Assesment</p> <p>High – No warning label or red colour coding.</p> <p>Medium – Red colour vial cap or alert present ‘Warning- Paralysing Agent’ (at minimum ‘Paralysing Agent’ present).</p> <p>Low – Vial form with red colour coding & ‘Warning- Paralysing Agent’ (at minimum ‘Paralysing Agent’ present). Complies with US & Canada packaging standards.</p>	

Appendix 3 – WH Costs Analysis

Western Health (WH) Resource/Cost Analysis to Label all NMB agents that leave pharmacy											
	Implementation		Weekly Resource			Monthly Resource			Annual Resource		
	Resource	Cost	Resource (NMB units)	Qty	Cost	Resource (NMB units)	Qty	Cost	Resource (NMB units)	Qty	Cost
Initial set-up											
Completing pharmacy procedure & signage. Educating nursing, medical & pharmacy staff across four WH sites (QUM Pharmacist, Grd 3 yr4 \$56.87/hr). Labelling all NMB agents on current imprest & sourcing all NMB agents in emergency trolleys across four sites of WH sites (Senior Technician, \$31.51/hr).	120 hrs (3 wks)	\$6,824.4							120 hrs (3 wks)		\$6,824.4
	80 hrs (2 wks)	\$2,520.8							80 hrs (2 wks)		\$2,520.8
Ongoing											
Pharmacy technician (\$29.86/hr) to label all NMB agents (est 25 sec per vial) for issue to all imprest areas across the four WH sites.			2.3 hrs	314	\$68.7	8.5 hrs	1,254	\$254.1	105 hrs (2.6 wks)	15,053	\$3,135.3
Quarterly compliance audit to check all NMB agents are labelled in all imprest areas and emergency trolleys across four WH sites (Senior Technician, \$31.51/hr).			2.5 hrs	314 (approx)	\$78.8	10 hrs	1,254 (approx)	\$315.1	120 hrs (3 wks)	15,053 (approx)	\$3,781.2
NMB agent labelling											
Label for application directly to NMB agent 'WARNING: Paralyzing Agent - Causes Respiratory Arrest' Baypac label (\$16/roll, 1000 stickers per roll)			N/A	314	\$5.0	N/A	1,254	\$20.0	N/A	15,053	\$241.0
Grand total	160 hrs (5 wks)	\$9,345.2	5 hrs	314	\$152.4	18.5 hrs	1,254	\$589.2	420 hrs (10.5 wks)	15,053	\$16,502.7

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