

Coversheet on evidence assessment by ATAGI using the GRADE framework for PVRV (Verorab) rabies vaccine and updates to pre-exposure prophylaxis (PrEP) rabies vaccination

A summary of the use of the GRADE approach in the development of ATAGI and Australian Immunisation Handbook recommendations on the use of PVRV (Verorab) and the use of a 2-dose (2-visit) schedule of currently approved vaccines for rabies PrEP

Background

- There had previously been a provision by the Therapeutic Goods Administration (TGA) under Section 19A for the supply and use of PVRV (Verorab) in place of other registered rabies vaccines that were unavailable or in short supply.
- PVRV (Verorab) was [TGA approved and registered](#) on the Australian Register of Therapeutic Goods (ARTG) in October 2022 for use in children and adults indicated to receive rabies vaccination (both PrEP and post-exposure prophylaxis [PEP] schedules).
- The US Advisory Committee on Immunization Practices (ACIP) moved from a 3-dose rabies PrEP schedule to a 2-dose rabies PrEP schedule in May 2022.
- In February 2023, following the full registration of PVRV (Verorab) and updates to the PrEP rabies immunisation schedules of several overseas immunisation advisory groups, the Australian Technical Advisory Group on Immunisation (ATAGI) undertook GRADE assessment of PVRV (Verorab) and 2-dose (2-visit) rabies PrEP vaccination schedules to allow for informed recommendations regarding rabies vaccination.
- The [Australian Immunisation Handbook](#) has been updated to reflect the ATAGI recommendations on the use of PVRV (Verorab) and on the use of 2-dose (2-visit) PrEP schedules for Australian people indicated to receive rabies vaccination.

Research questions

1. Should people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination receive 3 doses of PVRV (Verorab) for PrEP against rabies?

Table 1: Population, Intervention, Comparator, Outcomes (PICO) – 3 doses PVRV (Verorab) PrEP vs 3 doses HDCV or PCECV PrEP, people indicated to receive rabies PrEP vaccination

Population	People indicated to receive rabies PrEP vaccination
Intervention	3 doses PVRV (Verorab) PrEP [IM]*
Comparator	3 doses human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) PrEP [IM]*
Outcomes	<p><i>Critical</i></p> <ul style="list-style-type: none"> • Vaccine-related serious adverse events (SAE) <p><i>Important</i></p> <ul style="list-style-type: none"> • Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR)** 14–28 days after final PrEP dose • RVNA SCRs (%) persistence at ≥ 365 days after first dose of PrEP vaccination • Solicited local adverse events (AE) • Solicited systemic AE

*Intramuscular (IM) administration only

**Defined by WHO-recommended RVNA titre of ≥ 0.5 IU per mL

2. Should people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination receive 2 doses PVRV (Verorab) for PrEP against rabies?

Table 2: PICO – 2 doses PVRV (Verorab) PrEP vs 3 doses HDCV or PCECV PrEP, people indicated to receive rabies PrEP vaccination

Population	People indicated to receive rabies PrEP vaccination
Intervention	2 doses PVRV (Verorab) PrEP [IM]*
Comparator	3 doses HDCV or PCECV PrEP [IM]*
Outcomes	<p><i>Critical</i></p> <ul style="list-style-type: none"> Vaccine-related SAE up to 180 days after vaccination <p><i>Important</i></p> <ul style="list-style-type: none"> RVNA seroconversion rate (SCR)** ≥ 14 days after final PrEP dose RVNA SCRs (%) persistence at 180 days after first dose of PrEP vaccination RVNA SCRs (%) persistence at ≥ 365 days after first dose of PrEP vaccination Solicited local AE up to day 7 Solicited systemic AE up to day 7

*IM administration only

**Defined by WHO-recommended RVNA titre of ≥ 0.5 IU per mL

3. Should people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination receive 2 doses of HDCV or PCECV (instead of 3 doses) for PrEP against rabies?

Table 3: PICO – 2 doses of HDCV or PCECV PrEP vs 3 doses of HDCV or PCECV PrEP, people indicated to receive rabies PrEP vaccination

Population	People indicated to receive rabies PrEP vaccination
Intervention	2 doses HDCV or PCECV PrEP [IM and ID]*
Comparator	3 doses HDCV or PCECV PrEP [IM and ID]*
Outcomes	<p><i>Critical</i></p> <ul style="list-style-type: none"> Vaccine-related SAE <p><i>Important</i></p> <ul style="list-style-type: none"> RVNA seroconversion rate (SCR)** ≥ 7 days after final PrEP dose RVNA SCRs (%) persistence at 180 days after first dose of PrEP vaccination RVNA SCRs (%) persistence at ≥ 365 days after first dose of PrEP vaccination Solicited local AE Solicited systemic AE

*IM and/or intradermal (ID) administration

**Defined by WHO-recommended RVNA titre of ≥ 0.5 IU per mL

Literature search

The literature search was completed on 17/02/2023 to identify all trials on PVRV (Verorab) PrEP for PICO 1 and 2. The literature search was completed on 28/02/2023 to identify all trials on 2-dose HDCV or PCECV PrEP for PICO 3. The citations were included for review if they met the following criteria:

- *Study design:* Randomised controlled trial (RCT), observational study, meta-analysis
- *Population:* People indicated to receive rabies PrEP vaccination
- *Intervention:* Rabies PrEP: (i) 3 doses PVRV (Verorab); (ii) 2 doses PVRV (Verorab); (iii) 2 doses HDCV or PCECV
- *Comparator:* 3 doses HDCV or PCECV PrEP
- *Outcomes:* Efficacy, immunogenicity, safety

PICO 1 and 2

The published literature search retrieved a total of 21 unique citations, of which 4 and 2 citations met the pre-defined inclusion criteria for the comparison of 3 doses PVRV (Verorab) PrEP vs 3 doses HDCV or PCECV PrEP or 2 doses PVRV (Verorab) PrEP vs 3 doses HDCV or PCECV PrEP, respectively. The study characteristics and RoB of each individual study are presented in appendix A Table A1 and Table A2. For detailed search strategy refer to appendix B.

PICO 3

The published literature search retrieved a total of 67 unique citations, of which 5 citations met the pre-defined inclusion criteria for the comparison of 2 doses HDCV or PCECV PrEP vs 3 doses HDCV or PCECV PrEP. The study characteristics and RoB of each individual study are presented in appendix A Table A1 and Table A2. For detailed search strategy refer to appendix B.

Inclusion criteria and rationale

Table 4: Rationale for PICO and inclusion criteria

PICO	Rationale
Study type RCT, observational study, meta-analysis	Vaccine effectiveness studies are not widely available for the PICO questions. There are also limited efficacy studies; therefore, studies investigating immunogenicity outcomes that correspond to validated measures of protection against rabies were included.
Population People indicated to receive rabies PrEP vaccination	Population of interest for this vaccine.
Intervention 1. 3-dose PVRV (Verorab) PrEP 2. 2-dose PVRV (Verorab) PrEP 3. 2-dose HDCV or PCECV PrEP	PVRV (Verorab) is a newly registered vaccine. For PVRV (Verorab), both the 3-dose and 2-dose PrEP schedules were included as the 3-dose schedule is currently approved and the 2-dose schedule is being investigated as an option for rabies PrEP vaccination. Note: Only studies investigating IM administration were included, as none of the studies investigating ID administration followed the currently approved ID PrEP schedule in the Australian Immunisation Handbook. For PICO 3, 2-dose HDCV or PCECV vs 3-dose HDCV or PCECV studies were included, as these are the current rabies vaccine platforms in use in Australia. The different dosing schedules were to investigate the possibility of a schedule change from the current 3-dose rabies PrEP schedule to a 2-dose PrEP schedule. Studies investigating IM and/or ID administration were included, if they followed the currently recommended PrEP schedule in the Australian Immunisation Handbook, or a WHO-approved PrEP schedule.
Comparator 3 doses HDCV or PCECV PrEP	Studies using non-3 dose HDCV or PCECV PrEP comparators were not included, as that does not fit the PICO. For PICO 3 only, studies investigating ID administration were included (PICO 1 and 2 only included IM).
Outcomes	Included outcomes as stated above in Table 1, Table 2 and Table 3. Included iteratively according to outcomes found in the studies.
	Ranking of importance discussed in many iterations with portfolio leads and/ ATAGI full panel.
	General framework (depending on outcomes measured in studies available): <i>Critical</i> <ul style="list-style-type: none"> Vaccine-related SAE <i>Important</i> <ul style="list-style-type: none"> RVNA SCRs (defined by WHO-recommended RVNA titre of ≥ 0.5 IU per mL) (%) RVNA SCR (%) longer-term persistence of response Solicited local AE Solicited systemic AE Note: some outcomes may be missing in GRADE projects due to no data from available studies. Extra outcomes added due to relevance.

Abbreviations: AE=adverse events; HDCV=human diploid cell vaccine; ID=intradermal; IM=intramuscular; PCECV=purified chick embryo cell vaccine; PrEP=pre-exposure prophylaxis; PVCV=purified Vero cell vaccine; PVRV=purified Vero cell rabies vaccine (Verorab); RCT=randomised controlled trial; RVNA=rabies virus neutralising antibody; SAE=serious adverse events; SCR=seroconversion rate; WHO=World Health Organization

Risk of Bias (RoB) assessment

Risk of Bias (RoB) assessment was carried out on all included studies by two assessors using ROB 2.0 and ROBINS-I for RCT and comparative observational studies, respectively. Refer to Appendix A for RoB and ROBINS-I rating of included studies.

Appendix A: Risk of Bias

Table A1: Risk of Bias assessment for comparative, observational studies using ROBINS-I

Study	Comparison	Outcome	Confounding	Selection	Intervention classification	Deviations from intervention	Missing data	Measurement of outcomes	Selection of the reported results	Overall bias
PICO 1: 3 doses PVRV (Verorab) vs 3 doses HDCV or PCECV										
Strady (1998) ¹	3-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	Serious	Low	Low	Low	Moderate	Low	Low	Serious
Ajjan (1989) ²	3-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	Serious	Low	Low	Low	Moderate	Low	Low	Serious
		Safety	Serious	Low	Low	Low	Low	Low	Low	Serious
Kitala (1990) ³	3-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	Moderate	Low	Low	Low	Low	Low	Low	Moderate
PICO 2: 2 doses PVRV (Verorab) vs 3 doses HDCV or PCECV										
Strady (1998) ¹	2-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	Serious	Low	Low	Low	Moderate	Low	Low	Serious
PICO 3: 2 doses HDCV or PCECV vs 3 doses HDCV or PCECV										
Strady (1998) ¹	2-dose HDCV PrEP vs 3-dose HDCV PrEP	Immunogenicity	Serious	Low	Low	Low	Moderate	Low	Low	Serious

Abbreviations: HDCV=human diploid cell vaccine; ID=intradermal; IM=intramuscular; PCECV=purified chick embryo cell vaccine; PrEP=pre-exposure prophylaxis; PVCV=purified Vero cell vaccine; PVRV=purified Vero cell rabies vaccine (Verorab); ROBINS-I=Risk of Bias in Non-randomised Studies – of Interventions

Table A2: Risk of bias assessment for randomised controlled trials using RoB 2.0

Study	Comparison	Outcome	Is the review team's aim for this result...?	Domain 1: Risk of bias arising from the randomisation process	Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Domain 3: Missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall risk of bias
PICO 1: 3 doses PVRV (Verorab) vs 3 doses HDCV or PCECV									
Shanbag (2008) ⁴	3-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Low	Low	Low	Low	Low
		Safety		Low	Low	Low	Low	Low	Low
PICO 2: 2 doses PVRV (Verorab) vs 3 doses HDCV or PCECV									
Quiambao (2022) ⁵	2-dose PVRV (Verorab) PrEP vs 3-dose HDCV PrEP	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Some concerns	Low	Low	Some concerns	Some concerns
		Safety		Low	Low	Low	Low	Low	Low
PICO 3: 2 doses HDCV or PCECV vs 3 doses HDCV or PCECV									
Quiambao (2022) ⁵	2-dose HDCV PrEP vs 3-dose HDCV PrEP [IM]	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Low	Low	Low	Low	Low
		Safety		Low	Low	Low	Low	Low	Low

Endy (2020) ⁶	2-dose PCECV PrEP vs 3-dose PCECV PrEP [IM and ID]	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Some concerns	Low	Low	Low	Some concerns
		Safety		Low	Low	Low	Low	Low	Low
Kamoltham (2007) ⁷	2-dose PCECV PreP vs 3-dose PCECV PreP [ID]	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Some concerns	Low	Low	Low	Some concerns
		Safety		Low	Low	Low	Low	Low	Low
Soentjens (2019) ⁸	2-visit PrEP vs 3-visit HDCV PrEP [ID]	Immunogenicity	To assess the effect of assignment to intervention (the 'intention-to-treat' effect)	Low	Low	Low	Low	Low	Low
		Safety		Low	Low	Low	Low	Low	Low

Abbreviations: HDCV=human diploid cell vaccine; ID=intradermal; IM=intramuscular; PCECV=purified chick embryo cell vaccine; PrEP=pre-exposure prophylaxis; PVCV=purified Vero cell vaccine; PVRV=purified Vero cell rabies vaccine (Verorab); RCT=randomised controlled trial

Appendix B: Literature Search Strategy

PICO 1 and 2

<p>MEDLINE: Rabies – Verorab vs other rabies vaccines (Human diploid cell vaccines or Purified chick embryo cell vaccines) as pre-exposure prophylaxis – FINAL (as at 17.02.23)</p> <p>Database: MEDLINE(R) All including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946-current></p> <p>Search Strategy:</p> <p>-----</p> <ol style="list-style-type: none"> 1 exp Immunization/ (205518) 2 exp Immunization Programs/ (15944) 3 (immuni\$ or vaccin\$).tw. (648177) 4 1 or 2 or 3 (708603) 5 exp Rabies/ (10832) 6 exp Rabies virus/ (5313) 7 rabies.tw. (15108) 8 5 or 6 or 7 (16606) 9 4 and 8 (7169) 10 exp Rabies Vaccines/ (6446) 11 9 or 10 (9114) 12 ((vero adj2 cell\$) or verocell\$).tw. (10613) 13 PVCV\$.tw. (21) 14 PVRV\$.tw. (123) 	<p>EMBASE: Rabies – Verorab vs other rabies vaccines (Human diploid cell vaccines or Purified chick embryo cell vaccines) as pre-exposure prophylaxis – FINAL (as at 17.02.23)</p> <p>Database: Embase <1974 to 2023 February 15></p> <p>Search Strategy:</p> <p>-----</p> <ol style="list-style-type: none"> 1 exp immunization/ (354368) 2 (immuni\$ or vaccin\$).tw. (768016) 3 1 or 2 (839698) 4 exp rabies/ (11551) 5 exp Rabies virus/ (6761) 6 rabies.tw. (14466) 7 4 or 5 or 6 (17405) 8 3 and 7 (8434) 9 exp rabies vaccine/ (7165) 10 8 or 9 (10390) 11 ((vero adj2 cell\$) or verocell\$).tw. (12340) 12 PVCV\$.tw. (23) 13 PVRV\$.tw. (154) 14 11 or 12 or 13 (12425)
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15	12 or 13 or 14 (10673)	15	10 and 14 (278)
16	11 and 15 (194)	16	(Verorab\$ or Rabivax\$ or Speeda\$ or Abhayrab\$ or Indirab\$.tw. (230)
17	(Verorab\$ or Rabivax\$ or Speeda\$ or Abhayrab\$ or Indirab\$.tw. (57)	17	15 or 16 (438)
18	16 or 17 (217)	18	(purif\$ adj2 chick\$ adj2 embryo\$ adj2 cell\$.tw. (137)
19	(purif\$ adj2 chick\$ adj2 embryo\$ adj2 cell\$.tw. (124)	19	PCECV\$.tw. (58)
20	PCECV\$.tw. (55)	20	18 or 19 (141)
21	19 or 20 (127)	21	10 and 20 (140)
22	11 and 21 (124)	22	(Rabipur\$ or RabAvert\$ or Vaxirab\$.tw. (309)
23	(Rabipur\$ or RabAvert\$ or Vaxirab\$.tw. (51)	23	21 or 22 (387)
24	22 or 23 (148)	24	(human\$ adj2 diploid\$ adj2 cell\$.tw. (1383)
25	(human\$ adj2 diploid\$ adj2 cell\$.tw. (1407)	25	HDCV\$.tw. (127)
26	HDCV\$.tw. (118)	26	24 or 25 (1413)
27	25 or 26 (1434)	27	10 and 26 (328)
28	11 and 27 (295)	28	((Merieux\$ adj2 inactivate\$) or Imovax\$ or (Kanghua\$ adj2 rabies)).tw. (260)
29	((Merieux\$ adj2 inactivate\$) or Imovax\$ or (Kanghua\$ adj2 rabies)).tw. (32)	29	27 or 28 (557)
30	28 or 29 (321)	30	27 or 29 (557)
31	24 or 30 (441)	31	17 and 30 (58)
32	18 and 31 (62)	32	exp pre-exposure prophylaxis/ (8609)
33	exp Pre-Exposure Prophylaxis/ (4488)	33	((pre adj2 exposure\$) or pre-exposure\$ or preexposure\$.tw. (17832)
34	((pre adj2 exposure\$) or pre-exposure\$ or preexposure\$.tw. (13960)	34	PrEP\$.tw. (1396267)
35	PrEP\$.tw. (1162105)	35	32 or 33 or 34 (1409199)
36	33 or 34 or 35 (1172251)	36	31 and 35 (17)

37 32 and 36 (18)	
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PICO 3

<p>MEDLINE: Rabies – HDCV or PCECV as PrEP -2 dose or 3 dose – FINAL (as at 28.02.23)</p> <p>Database: MEDLINE(R) All including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946-current></p> <p>Search Strategy:</p> <p>-----</p> <ol style="list-style-type: none"> 1 exp Immunization/ (205880) 2 exp Immunization Programs/ (15953) 3 (immuni\$ or vaccin\$).tw. (649463) 4 1 or 2 or 3 (709953) 5 exp Rabies/ (10836) 6 exp Rabies virus/ (5315) 7 rabies.tw. (15113) 8 5 or 6 or 7 (16611) 9 4 and 8 (7171) 10 exp Rabies Vaccines/ (6448) 11 9 or 10 (9116) 12 (purif\$ adj2 chick\$ adj2 embryo\$).tw. (211) 	<p>EMBASE: Rabies – HDCV or PCECV as PrEP -2 dose or 3 dose – FINAL (as at 28.02.23)</p> <p>Database: Embase <1974 to 2023 February 24></p> <p>Search Strategy:</p> <p>-----</p> <ol style="list-style-type: none"> 1 exp immunization/ (360979) 2 (immuni\$ or vaccin\$).tw. (780338) 3 1 or 2 (853506) 4 exp rabies/ (11633) 5 exp Rabies virus/ (6818) 6 rabies.tw. (14579) 7 4 or 5 or 6 (17554) 8 3 and 7 (8505) 9 exp rabies vaccine/ (7213) 10 8 or 9 (10474) 11 (purif\$ adj2 chick\$ adj2 embryo\$).tw. (226) 12 PCECV\$.tw. (59) 13 11 or 12 (229)
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13	PCECV\$.tw. (55)	14	10 and 13 (152)
14	12 or 13 (214)	15	(Rabipur\$ or RabAvert\$ or Vaxirab\$.tw. (309)
15	11 and 14 (134)	16	14 or 15 (395)
16	(Rabipur\$ or RabAvert\$ or Vaxirab\$.tw. (51)	17	(human\$ adj2 diploid\$ adj2 cell\$.tw. (1386)
17	15 or 16 (157)	18	HDCV\$.tw. (127)
18	(human\$ adj2 diploid\$ adj2 cell\$.tw. (1407)	19	17 or 18 (1416)
19	HDCV\$.tw. (118)	20	10 and 19 (328)
20	18 or 19 (1434)	21	((Merieux\$ adj2 inactivate\$) or Imovax\$ or (Kanghua\$ adj2 rabies)).tw. (260)
21	11 and 20 (295)	22	20 or 21 (557)
22	((Merieux\$ adj2 inactivate\$) or Imovax\$ or (Kanghua\$ adj2 rabies)).tw. (32)	23	16 or 22 (860)
23	21 or 22 (321)	24	exp pre-exposure prophylaxis/ (8860)
24	17 or 23 (450)	25	((pre adj2 exposure\$) or pre-exposure\$ or preexposure\$.tw. (18089)
25	exp Pre-Exposure Prophylaxis/ (4506)	26	PrEP\$.tw. (1409535)
26	((pre adj2 exposure\$) or pre-exposure\$ or preexposure\$.tw. (14007)	27	24 or 25 or 26 (1422622)
27	PrEP\$.tw. (1163661)	28	23 and 27 (184)
28	25 or 26 or 27 (1173832)	29	(twodose\$ or two-dose\$ or two dose\$ or 2dose\$ or 2-dose\$ or 2 dose\$.tw. (42258)
29	24 and 28 (138)	30	((modif\$ or short\$ or new\$ or 1-week or accelerat\$ or abbreviat\$) adj3 (schedul\$ or series or course\$ or program\$)).tw. (93865)
30	(twodose\$ or two-dose\$ or two dose\$ or 2dose\$ or 2-dose\$ or 2 dose\$.tw. (24729)	31	(threedose\$ or three-dose\$ or three dose\$ or 3dose\$ or 3-dose\$ or 3 dose\$.tw. (29654)
31	((modif\$ or short\$ or new\$ or 1-week or accelerat\$ or abbreviat\$) adj3 (schedul\$ or series or course\$ or program\$)).tw. (68295)	32	2 versus 3 doses.tw. (3)
32	(threedose\$ or three-dose\$ or three dose\$ or 3dose\$ or 3-dose\$ or 3 dose\$.tw. (18219)	33	2 vs 3 dose\$.tw. (9)
33	2 versus 3 doses.tw. (3)	34	day\$ 0, 7.tw. (2721)
34	2 vs 3 dose\$.tw. (7)	35	29 or 30 or 31 or 32 or 33 or 34 (164078)

35 day\$ 0, 7.tw. (1708)	36 28 and 35 (60)
36 30 or 31 or 32 or 33 or 34 or 35 (110486)	
37 29 and 36 (55)	

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