GRADE tables: Comparison of 3 doses of purified Vero cell rabies vaccine (PVRV; Verorab) to 3 doses of human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) in people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

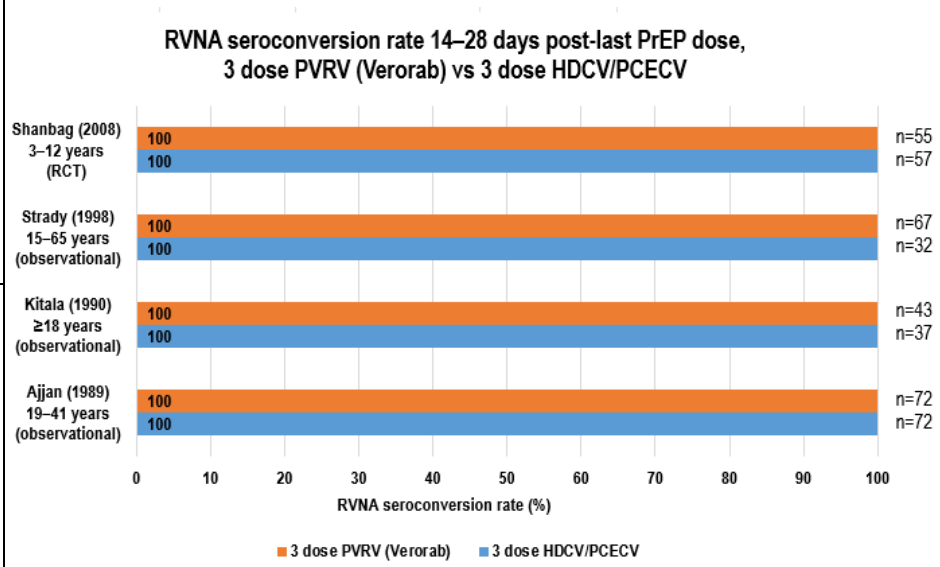
NCIRS is conducting GRADE assessments in support of the Australian Technical Advisory Group on Immunisation (ATAGI) and making pilot results available on the Centre's website. Please read this material as a supplement to the Australian Immunisation Handbook rabies and other lyssaviruses chapter.

3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination				
Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination **Intervention:** 3 doses PVRV (Verorab) **Comparison:** 3 doses HDCV or PCECV				
Outcomes	**Impact**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Interpretation**
CRITICAL OUTCOMES				
Vaccine-related serious adverse events (SAEs) [RCT] Assessed with: any vaccine-related adverse event/adverse reaction that resulted in death, was life-threatening, required hospitalisation or prolongation of existing hospitalisation, or resulted in persistent or significant disability or incapacity Follow-up: 49 days	In both studies, no unexpected or SAEs were reported during the study period. No vaccine-related SAEs occurred with either vaccine arm.	116 (1 RCT)[1]	⊕⊕⊕◯ Moderate[a,b]	3 doses PVRV (Verorab) PrEP likely results in little to no difference in vaccine-related SAEs compared to 3 doses HDCV/PCECV PrEP.

3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination				
Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination **Intervention:** 3 doses PVRV (Verorab) **Comparison:** 3 doses HDCV or PCECV				
Outcomes	**Impact**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Interpretation**
Vaccine-related SAEs [observational] Assessed with: any vaccine-related adverse event/adverse reaction that resulted in death, was life-threatening, required hospitalisation or prolongation of existing hospitalisation, or resulted in persistent or significant disability or incapacity Follow-up: 4.5 months	In both studies, no unexpected or serious adverse events (SAE) were reported during the study period. No vaccine-related SAEs occurred with either vaccine arm.	144 (1 observational study)[2]	⨁⨁◯◯ Low[a,b,c]	3 doses PVRV (Verorab) PrEP may result in little to no difference in vaccine-related SAEs compared to 3 doses HDCV/PCECV PrEP.

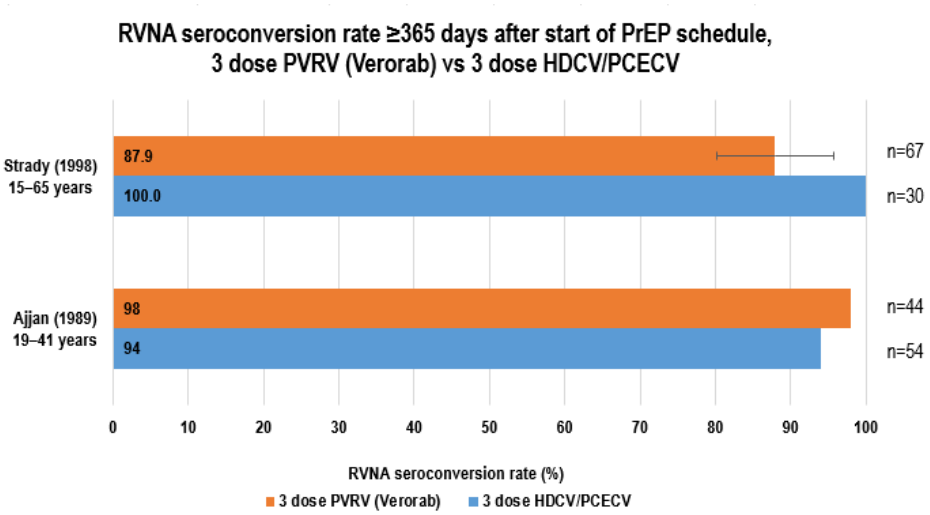
3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination
Intervention: 3 doses PVRV (Verorab)
Comparison: 3 doses HDCV or PCECV

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)	Interpretation
IMPORTANT OUTCOMES				
Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR) (%) [RCT] Assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL Follow-up: range 14–28 days		112 (1 RCT)[1]	⊕⊕⊕⊕ High[a]	3 doses PVRV (Verorab) PrEP results in little to no difference in RVNA seroconversion rate 14–28 days post-last PrEP dose compared to 3 doses HDCV/PCECV PrEP.
RVNA SCR (%) [observational] Assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL Follow-up: range 14–28 days		323 (3 observational studies)[2-4]	⊕⊕⊕◯ Moderate[d]	3 doses PVRV (Verorab) PrEP likely results in little to no difference in RVNA seroconversion rate 14–28 days post-last PrEP dose compared to 3 doses HDCV/PCECV PrEP.

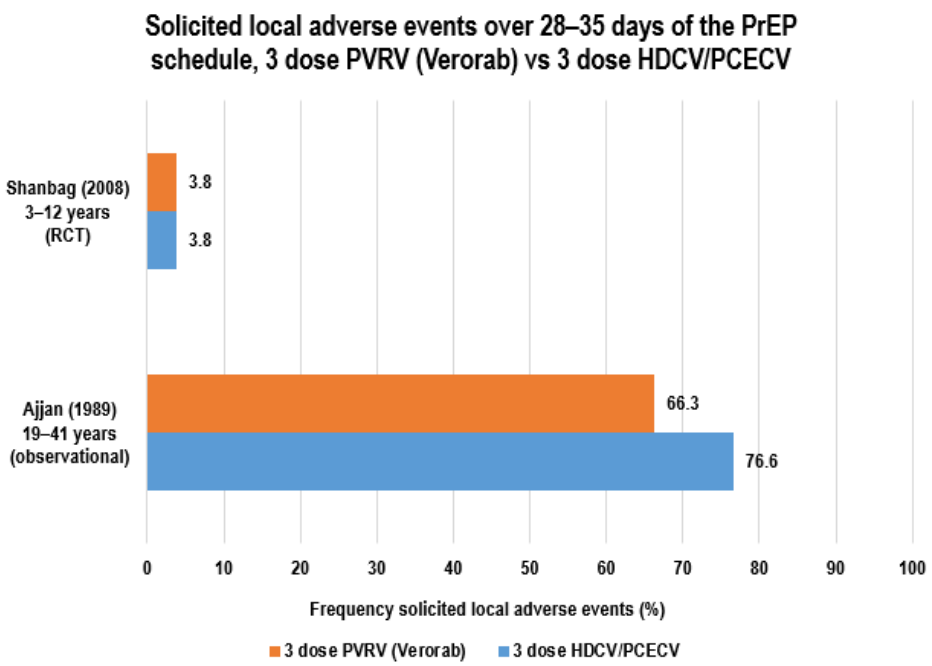
3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination
Intervention: 3 doses PVRV (Verorab)
Comparison: 3 doses HDCV or PCECV

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)	Interpretation
RVNA SCR (%) Assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL Follow-up: ≥365 days		195 (2 observational studies)[2,4]	⨁◯◯◯ Very low[b,e,f]	The evidence is very uncertain about the effect of 3 doses PVRV (Verorab) PrEP on RVNA seroconversion rate ≥365 days after the start of PrEP schedule compared to 3 doses HDCV/PCECV PrEP.

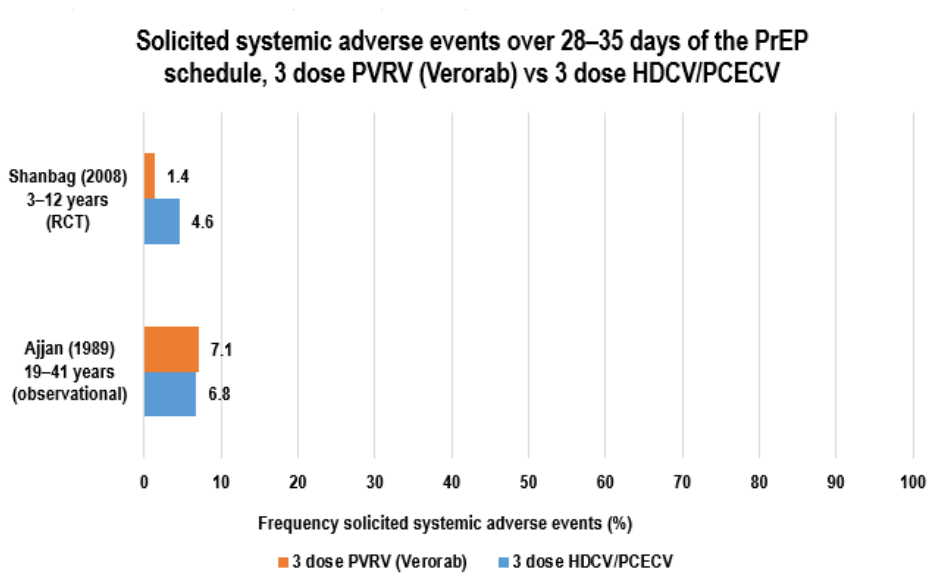
3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination
Intervention: 3 doses PVRV (Verorab)
Comparison: 3 doses HDCV or PCECV

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)	Interpretation
Solicited local adverse events (AEs) [RCT] Assessed with: frequency of solicited pain at the injection site (30 minutes and 24 hours post-dose), erythema, induration and swelling recorded by an assessor Follow-up: 35 days		116 (1 RCT)[1]	⨁⨁⨁◯ Moderate[a,b]	3 doses PVRV (Verorab) PrEP likely results in little to no difference in solicited local AEs compared to 3 doses HDCV/PCECV PrEP.
Solicited local AEs [observational] Assessed with: frequency of solicited redness, induration, local pain and itching recorded by questionnaire Follow-up: 28 days		144 (1 observational study)[2]	⨁⨁◯◯ Low[a,b,c]	3 doses PVRV (Verorab) PrEP may result in a slight reduction in solicited local AEs compared to 3 doses HDCV/PCECV PrEP.

3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

Patient or population: People who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination
Intervention: 3 doses PVRV (Verorab)
Comparison: 3 doses HDCV or PCECV

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)	Interpretation
Solicited systemic adverse events (AEs) [RCT] Assessed with: frequency of solicited irritability, malaise, headache, fever (axillary temperature ≥38.0°C), myalgia and allergic reactions recorded by an assessor Follow-up: 35 days		116 (1 RCT)[1]	⨁⨁⨁◯ Moderate[a,b]	3 doses PVRV (Verorab) PrEP likely results in little to no difference in solicited systemic AEs compared to 3 doses HDCV/PCECV PrEP.
Solicited systemic AEs [observational] Assessed with: frequency of solicited fever, rash, hives, anaphylaxis, fatigue, lymphadenopathy and headaches recorded by questionnaire Follow-up: 28 days		144 (1 observational study)[2]	⨁⨁◯◯ Low[a,b,c]	3 doses PVRV (Verorab) PrEP may result in little to no difference in solicited systemic AEs compared to 3 doses HDCV/PCECV PrEP.

Explanations
a. Only one study of this study design assessed this outcome
b. Small sample size (<400); study may not be powered to detect a difference between groups
c. Study had serious risk of bias overall due to serious risk of bias in the cofounding domain
d. Two of three studies had serious risk of bias overall due to serious risk of bias in the cofounding domain (one also had moderate risk of bias in the missing data domain). One study had moderate risk of bias overall due to moderate risk of bias in the confounding domain
e. Both studies had serious risk of bias overall due to serious risk of bias in the cofounding domain, and moderate risk of bias in the missing data domain
f. Difference in size and direction of results between two observational studies

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

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.

GRADE evidence profile

Evidence profile: 3 doses PVRV (Verorab) compared to 3 doses HDCV or PCECV for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Vaccine-related serious adverse events (SAEs) [RCT] (follow-up: 49 days; assessed with: any vaccine-related adverse event/adverse reaction that resulted in death, was life-threatening, required hospitalisation or prolongation of existing hospitalisation, or resulted in persistent or significant disability or incapacity)									
1	Randomised trials	Not serious	N/A[a]	Not serious	Serious[b]	None	There were no vaccine-related SAEs in either 3-dose PVRV (Verorab) or 3-dose HDCV/PCECV arms.[1]	⊕⊕⊕◯ Moderate	CRITICAL
Vaccine-related serious adverse events (SAEs) [observational] (follow-up: 4.5 months; assessed with: any vaccine-related adverse event/adverse reaction that resulted in death, was life-threatening, required hospitalisation or prolongation of existing hospitalisation, or resulted in persistent or significant disability or incapacity)									
1	Observational studies	Serious[c]	N/A[a]	Not serious	Serious[b]	None	There were no vaccine-related SAEs in either 3-dose PVRV (Verorab) or 3-dose HDCV/PCECV arms.[2]	⊕⊕◯◯ Low	CRITICAL
Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR) (%) [RCT] (follow-up: range 14 days to 28 days; assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL)									
1	Randomised trials	Not serious	N/A[a]	Not serious	Not serious	None	The RVNA SCR 14–28 days following final dose of PrEP vaccination was 100% (95% CI: NR) after both 3 doses of PVRV (Verorab) and 3 doses of HDCV/PCECV.[1]	⊕⊕⊕⊕ High	IMPORTANT
Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR) (%) [observational] (follow-up: range 14 days to 28 days; assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL)									
3	Observational studies	Serious[d]	Not serious	Not serious	Not serious	None	The RVNA SCR 14–28 days following final dose of PrEP vaccination was 100% (95% CI: NR) after both 3 doses of PVRV (Verorab) and 3 doses of HDCV/PCECV.[2-4]	⊕⊕⊕◯ Moderate	IMPORTANT

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR) (%) (follow-up: ≥365 days; assessed with: WHO-recommended RVNA titre of ≥0.5 IU/mL)									
2	Observational studies	Serious[e]	Serious[f]	Not serious	Serious[b]	None	The RVNA SCR 365 days following vaccination ranged from 88–98% for 3 doses of PVRV (Verorab) and 94–100% for 3 doses of HDCV/ PCECV.[2,4]	⨁◯◯◯ Very low	IMPORTANT
Solicited local adverse events (AEs) [RCT] (follow-up: 35 days; assessed with: frequency of solicited pain at the injection site (30 min and 24h post-dose), erythema, induration, and swelling recorded by an assessor)									
1	Randomised trials	Not serious	N/A[a]	Not serious	Serious[b]	None	The rate of solicited local AEs was 3.8% for both 3 doses of PVRV (Verorab) and 3 doses of HDCV/PCECV.[1]	⨁⨁⨁◯ Moderate	IMPORTANT
Solicited local adverse events (AEs) [observational] (follow-up: 28 days; assessed with: frequency of solicited redness, induration, local pain, and itching recorded by questionnaire)									
1	Observational studies	Serious[c]	N/A[a]	Not serious	Serious[b]	None	The rate of solicited local AEs was 66.3% for 3 doses of PVRV (Verorab) and 76.6% for 3 doses of HDCV/PCECV (p= 0.019).[2]	⨁⨁◯◯ Low	IMPORTANT
Solicited systemic adverse events (AEs) [RCT] (follow-up: 35 days; assessed with: frequency of solicited irritability, malaise, headache, fever (axillary temperature ≥38.0°C), myalgia and allergic reactions recorded by an assessor)									
1	Randomised trials	Not serious	N/A[a]	Not serious	Serious[b]	None	The rate of solicited systemic site AEs was 1.4% for 3 doses of PVRV (Verorab) and 4.6% for 3 doses of HDCV/PCECV, but the difference was not statistically significant.[1]	⨁⨁⨁◯ Moderate	IMPORTANT
Solicited systemic adverse events (AEs) [observational] (follow-up: 28 days; assessed with: frequency of solicited fever, rash, hives, anaphylaxis, fatigue, lymphadenopathy and headaches recorded by questionnaire)									

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
1	Observational studies	Serious[c]	N/A[a]	Not serious	Serious[b]	None	The rate of solicited systemic site AEs was 7.1% for 3 doses of PVRV (Verorab) and 6.8% for 3 doses of HDCV/PCECV (p>0.5).[2]	⊕⊕◯◯ Low	IMPORTANT

Explanations

a. Only one study of this study design assessed this outcome
b. Small sample size (<400); study may not be powered to detect a difference between groups
c. Study had serious risk of bias overall due to serious risk of bias in the cofounding domain
d. Two of 3 studies had serious risk of bias overall due to serious risk of bias in the cofounding domain (one also had moderate risk of bias in the missing data domain). One study had moderate risk of bias overall due to moderate risk of bias in the confounding domain
e. Both studies had serious risk of bias overall due to serious risk of bias in the cofounding domain, and moderate risk of bias in the missing data domain
f. Difference in size and direction of results between two observational studies

Abbreviations: AE=adverse events; HDCV=human diploid cell vaccine; ID=intradermal; IM=intramuscular; NR=not reported; 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

Evidence to Decision (EtD) framework: 3 doses purified Vero cell rabies vaccine (PVRV) (Verorab) compared to 3 doses human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) for people who are indicated to receive rabies pre-exposure prophylaxis (PrEP) vaccination

SHOULD PEOPLE WHO ARE INDICATED TO RECEIVE RABIES PRE-EXPOSURE PROPHYLAXIS (PrEP) VACCINATION RECEIVE 3 DOSES PVRV (VERORAB) FOR PrEP AGAINST RABIES?	
Population	People indicated to receive rabies PrEP vaccination
Intervention	3 doses PVRV (Verorab) PrEP [IM]*
Comparison	3 doses human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) PrEP [IM]
Main outcomes	• Vaccine-related serious adverse events (SAE) • Rabies virus neutralising antibody (RVNA) seroconversion rate (SCR)** 14–28 days after final PrEP dose • RVNA SCRs (%) persistence at ≥365 days • Solicited local adverse events (AE) • Solicited systemic AE *Intramuscular (IM) administration only. **Seroconversion defined as the WHO-recommended antibody titre threshold of ≥0.5 IU/mL.
Setting	France, India and Kenya
Perspective	Individual

ASSESSMENT

Problem

Is the problem a priority?

Don't know	Varies	No	Probably no	Probably yes	Yes

- Australia is not a rabies-enzootic country.[5] However, bats are a potential source of lyssaviruses and a potential risk for acquiring rabies, and exposure to classical rabies virus can occur from terrestrial animals and other mammals in rabies-enzootic countries. Rabies is nearly always fatal once symptoms begin.
- People who work with bats, laboratory workers who work with live lyssaviruses and some people who travel to rabies-enzootic areas are recommended to receive rabies vaccine as PrEP.
- People with ongoing occupational exposure to lyssaviruses are recommended to receive booster doses of rabies vaccine.
- There are two currently available rabies vaccines (Mérieux [inactivated, HDCV] and Rabipur [inactivated, PCECV]) as options for rabies PrEP in Australia.

Desirable effects

How substantial are the desirable anticipated effects? (*Note:* Compared to 3 doses HDCV/PCECV)

Don't know	Varies	Trivial	Small	Moderate	Large

- RVNA seroconversion rates at 14–28 days post-last PrEP dose were 100% for both 3 doses PVRV (Verorab) and 3 doses HDCV/PCECV across all the studies.[1-4] There is little to no difference in seroconversion rates at 14–28 days post-last PrEP dose for 3 doses PVRV (Verorab) compared to 3 doses HDCV/PCECV.
- The evidence is very uncertain about the effect of 3 doses of PVRV (Verorab) PrEP compared to 3 doses HDCV/PCECV on RVNA seroconversion rates ≥365 days after the start of the PrEP schedule.[2,4] RVNA seroconversion rate ≥365 days following vaccination ranged from 88–98% after 3 doses of PVRV (Verorab) and 94–100% after 3 doses of HDCV/ PCECV.

Undesirable effects

How substantial are the undesirable anticipated effects? (compared to 3 doses HDCV/PCECV)

Don't know	Varies	Large	Moderate	Small	Trivial

- In both studies that investigated this outcome, no unexpected or serious adverse events (SAEs) were reported during the study period. No vaccine-related SAEs occurred with either 3 dose PVRV (Verorab) or 3 dose HDCV/PCECV arms.[1,2]
- 3 doses of PVRV (Verorab) likely results in little to no difference in solicited local adverse events (AE) compared to 3 doses of HDCV/PCECV. The rate of solicited local AEs was 3.8% for both 3 doses of PVRV (Verorab) and 3 doses of HDCV/PCECV.[1] Evidence from one observational study showed that solicited local AEs may be lower following 3 doses PVRV (Verorab) (66.3%) compared to 3 doses HDCV/PCECV (76.6%).[2] More weighting was put on the evidence from the RCT.
- 3 doses PVRV (Verorab) PrEP (1.4–7.1%) likely results in little to no difference in solicited systemic AEs compared to 3 doses HDCV/PCECV PrEP (4.6–6.8%).[1,2]

Certainty of evidence

What is the overall certainty of the evidence of effects?

No included studies	Very low	Low	Moderate	High

- The certainty of evidence is moderate overall. Of the nine outcomes evaluated, the certainty of evidence was moderate for four outcomes, low for three, very low for one and high for one.
- The certainty of evidence is moderate due to imprecision, as most studies had small (<400) sample sizes and may not be powered to detect a difference between 3 doses PVRV (Verorab) and 3 doses HDCV/PCECV.
- The 3 outcomes that had low certainty of evidence were downgraded due to imprecision (see previous point) and for risk of bias in the confounding and/or missing data domains.
- The outcome that had very low certainty of evidence was downgraded for imprecision and risk of bias (see previous points), and downgraded for inconsistency due to the difference in size and direction of results between the two observational studies.
- There were no data comparing the vaccine schedules in 'healthy' populations with those in immunocompromised populations.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

Important uncertainty	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

- There is unlikely to be important uncertainty in how people value protection against rabies.
- No research was identified in the search that addresses this specifically.
- Rabies PrEP vaccination is only routinely recommended for people at high occupational risk or for some travellers to rabies-enzootic regions.

Balance of effects

Favours

Don't know	Varies	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention

- RVNA seroconversion rates at 14–28 days post-last PrEP dose were 100% for both 3 doses PVRV (Verorab) and 3 doses HDCV/PCECV.[1-4] The evidence is very uncertain for RVNA seroconversion rates ≥365 days following vaccination. However, RVNA seroconversion rate ≥365 days following vaccination ranged from 88–98% after 3 doses of PVRV (Verorab) and 94–100% after 3 doses of HDCV/ PCECV.[2,4]
- No vaccine-related SAEs occurred with either 3 doses PVRV (Verorab) or 3 doses HDCV/PCECV.[1,2]
- Other undesirable effects, such as solicited local and systemic AE, are minor and 3 doses PVRV (Verorab) likely results in little to no difference in undesirable effects compared to 3 doses HDCV/PCECV.[1,2]

Acceptability

Is the intervention acceptable to key stakeholders?

Don't know	Varies	No	Probably no	Probably yes	Yes

- No direct evidence was identified for this issue.
- Employers and employees at workplaces of high occupational risk, some travellers to rabies-enzootic regions, and travel medicine providers and medical associations are likely the main stakeholders impacted. No evidence was identified on the acceptability of 3 doses PVRV (Verorab) to these stakeholders. However, the dosing schedule and populations remain the same, so there is likely to be minimal impact from incorporating 3 doses of PVRV (Verorab) into the current rabies PrEP schedule.
- PVRV (Verorab) has previously been approved by the Therapeutic Goods Administration (TGA) under Section 19A due to other rabies vaccines being in short supply.[6] Providers' familiarity with PVRV (Verorab) as a rabies PrEP vaccine may make this vaccine acceptable.

Feasibility

Is the intervention feasible to implement?

Don't know	Varies	No	Probably no	Probably yes	Yes

- No direct evidence was identified for this issue.
- Rabies PrEP vaccination is only routinely recommended for people at high occupational risk or for some travellers to rabies-enzootic regions.
- The dosing schedule and populations to receive rabies PrEP remain the same, so there is likely to be minimal impact from implementing 3 doses of PVRV (Verorab) into the current rabies PrEP schedule.
- PVRV (Verorab) was previously approved by the TGA under Section 19A due to other rabies vaccines being in short supply.[6] Vaccination providers may already be familiar with the vaccine and have stock of the vaccine, making it feasible to implement into the current rabies PrEP schedule.

References

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