Vancouver CoastalHealth	**Standard Operating Procedure** **Bridging Clinical Decisions with the PARIS Immunization Planning Engine-General Issues -Draft**	**Doc. No.**	SOP.XXXX
		Rev.:	00
		Rev. Date:	N/A

SITE APPLICABILITY:

All VCH Public Health Sites

PURPOSE:

The PARIS immunization rules plan accurately to reflect the standard immunization schedules located in Section IIA of the BCCDC Immunization Manual and will apply to the majority of clients immunized by VCH providers. However, PARIS cannot plan accurately for all unique client situations and nor can the BCCDC Immunization Manual.

The purpose of this document is to provide information on some of the general issues with PARIS and the associated actions:

- Forced Status
- Planning Mismatch
- Product Choice
- Grace Period
- Solid Organ Transplant
- Vaccine Evaluation Centre (VEC) clients

SCOPE:

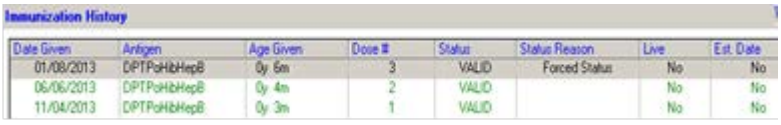
Public Health Nurses (PHNs), Educators, Practice Leads and Program Assistants

RESPONSIBILITIES:

- PHNs, Public Health Educators, Practice Leads are required to know the key resources to manually assess the client's immunization history and verify with the PARIS immunization plan.
- PHNs/Practice Leads use clinical judgment to amend records. If a record cannot be amended prior to seeing a client, act clinically and the record can be amended following the visit.
- PHNs, Educators and Leads follow the Standard Operating Procedure about how to adjust an immunization record. Follow the record adjustment process for your Community of Care (COC): **Coastal Rural:** Karen Peel, **Coastal Urban:** Nicole Roy, **Richmond:** Kim Bourhill, **Vancouver:** Practice Lead/Educator.
- PHN consults with Practice Lead or Educator via email and includes the PARIS ID# and antigen(s) in the email subject header as well as specifies whether urgent/not urgent and when the change is required.

GENERAL ISSUE and ACTION #1: FORCED STATUS

ISSUE: In general, if the status of a dose reads "FORCED" that line entry should not be changed.
However, there may be times when a "forced status" line needs to be changed when new information becomes available and the current information is incorrect. At this time, once a line is "forced" the line can no longer be changed.



Immunization History

Date Given	Antigen	Age Given	Dose #	Status	Status Reason	Live	Est. Date
01/08/2013	DPTPolHibHepB	0y 6m	3	VALID	Forced Status	No	No
06/06/2013	DPTPolHibHepB	0y 4m	2	VALID		No	No
11/04/2013	DPTPolHibHepB	0y 3m	1	VALID		No	No

ACTION: If the entry requires a change, the entire entry needs to be deleted and re-entered with correct information.

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GENERAL ISSUE and ACTION #2: VALIDATION STATUS ISSUE

ISSUE: PARIS plans for the majority of clients but a manual record adjustment may be required by a designated adjuster if deemed necessary following clinical review for unique client situations.

ACTION: Manual record adjustments involve either a change in validation status following immunization history entry into PARIS or an antigen suspension from a client's plan. There are no options to manually add antigens to a client's plan.

Types of Validation Language and Examples:

Changing Status	Example	Comments
VALID to read INVALID	Dose was expired vaccine	PARIS will re-plan dose
INVALID to read VALID	Dose falls within grace period of ≤ 4 days	
QUERIED	The Hep B antigen provided with INFANRIX hexa™ is invalid due to min age but DPTPOPHIB antigens are valid.	Antigens tied together in a grouping can't be adjusted separately. If one of the doses in the grouping is invalid, the grouping will read QUERIED. Double click on the QUERIED dose to see the status and reason for each of the components.
Forced Status	Script validation, rules update and older histories were protected as VALID with rules change.	Line can no longer be changed when 'Forced Status' validation. For more details, click on the 'Show Additional Info' icon. If a script was responsible for the 'Forced Status', the details will show in the comments box.
Suspension	Complete for Men Conj C, next dose due at age 10 years, 7 months.	Dose will be removed from the plan until the suspension end-date. E.g. Men C is next due at 10 years, 7 months. The dose will be put back on plan at that time. If no end-date the dose is suspended indefinitely

GENERAL ISSUE and ACTION #3: PLANNING MISMATCH

ISSUE: A client may become a "unique" client (off routine schedule) within the PARIS system for a variety of reasons.

Three types of general issues exist:

1. **Plan/timing is not correct for client:** in rare situations, variations in planning could be encountered and extra doses planned that are not needed. E.g. based on unusual history of a 7 year-old, PARIS planned for TdPPO due in 3 months and another Td, 3 months after.
2. **Antigen grouping does not match product choice:** PARIS rules are based on operational groupings of antigens (not products) and in most cases when PARIS groups antigens together the grouping will match the appropriate product choice for a client. However, in some cases the grouping of antigens may not match the correct product choice and clinical judgment is required.

3. **Duplicate/extra doses being planned:** clients may be planned for duplicate/extra doses of antigens when that antigen is part of a combined antigen vaccine e.g. extra Rubella in MMR when only booster of measles or mumps required OR extra Tetanus or Diphtheria when only needs Pertussis. These show as purple in the immunization plan instead of black, e.g. MMR – the "R" is a duplicate dose. This allows for more validation flexibility in PARIS.

Example of a "unique" history:

Most common antigens for unique histories are Diphtheria (D/d), tetanus, pertussis (P/p), polio, HIB, hepatitis B, Rubella.

ACTION: Clinically assess client's history and determine antigen(s), appropriate timing, and best product choice. The clinical plan will override the PARIS plan. Clinical decisions are determined by a number of variables: client's history and health status, antigens needed, age of client at presentation, available product, primary series or booster.

Utilize immunization alerts and immunization case notes to communicate alternate plans to the next clinician as necessary.

Manual adjustment: Usually, once the next results are entered planning will often correct itself. Otherwise, the record may require a manual adjustment based on clinical assessment.

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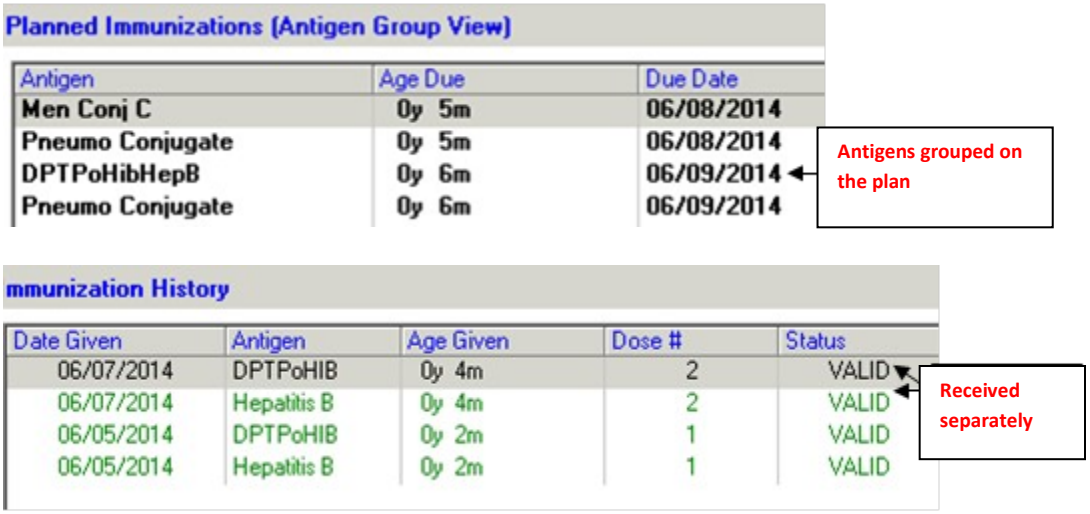
GENERAL ISSUE and ACTION #4: PRODUCT CHOICE, OPERATIONAL PLANNING & PERTUSSIS-CONTAINING VACCINE

ISSUE: Antigen groups in PARIS plan may differ from the correct product choice.



Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
Men Conj C	0y 5m	06/08/2014
Pneumo Conjugate	0y 5m	06/08/2014
DPTPoHibHepB	0y 6m	06/09/2014
Pneumo Conjugate	0y 6m	06/09/2014

Antigens grouped on the plan

mmunization History

Date Given	Antigen	Age Given	Dose #	Status
06/07/2014	DPTPoHIB	0y 4m	2	VALID
06/07/2014	Hepatitis B	0y 4m	2	VALID
06/05/2014	DPTPoHIB	0y 2m	1	VALID
06/05/2014	Hepatitis B	0y 2m	1	VALID

Received separately

Products involved are as follows:

GSK family: Infanrix Hexa™[6] (DPTPO-HIB-HB); Infanrix IPV+Hib™[5] (DPTPO-HIB); Infanrix IPV™[4](DPTPO); Boostrix®-POLIO (Tdap-IPV); Boostrix® (Tdap)

Sanofi family: Pediacel®(DPTPOHIB); QUADRACEL®(DPTPO); ADACEL®-POLIO(Tdap-IPV); ADACEL®(Tdap)

Hepatitis B: Engerix®-B or RecombivaxHB® (Hep B). Clinically assess client's history and determine antigen(s), appropriate timing, and best product choice. Clinical plan overrides PARIS plan.

ACTION: Clinically assess client's history and determine antigen(s), appropriate timing, and best product choice. The clinical plan overrides the PARIS plan. Clinical decisions are determined by a number of variables: client's history and health status, antigens needed, age of client at presentation, available product, primary series or booster.

Follow this criteria:

- Stick to same manufacturer's family of products for the 3-dose primary series, if trade name is known.
- It is acceptable to interchange combination products for booster doses.
- If the best product choice is unavailable it is acceptable to look to other options including a different manufacturer or a dose that may provide extra antigens such as HIB or polio or lower concentrations of little "d" or "p". This is preferable to deferring the immunization.
- Extra HIB or polio may be provided to reduce the number of injections. For example, a 6 year-old needs Hep B and DPTPO 3-dose primary series, but not Hib. InfanrixHexa™[6] is an acceptable product choice.

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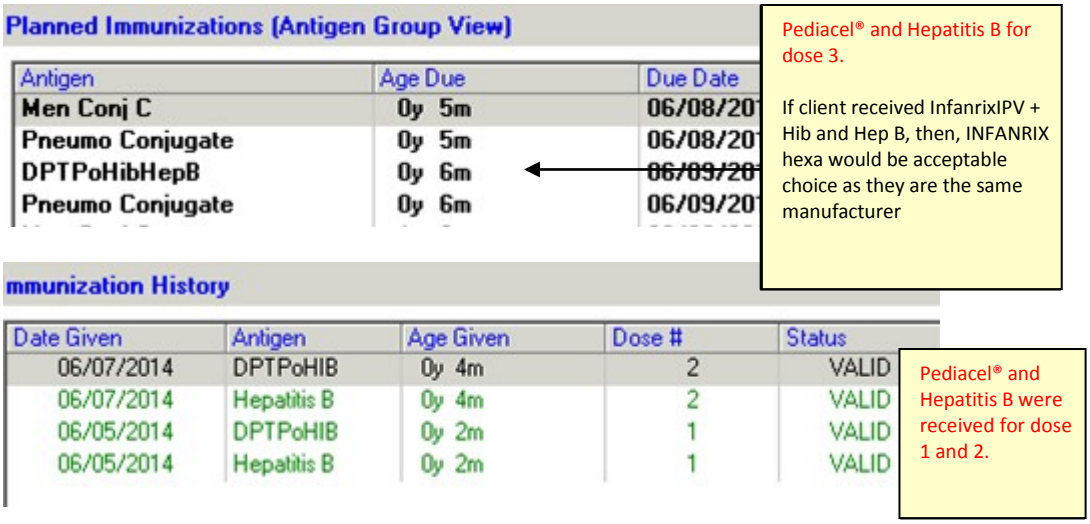
Case scenario



GENERAL ISSUE and ACTION#5: Grace Period ≤ 4 days

This is a variance to provincial practice as per the BCCDC Immunization Program Manual

ISSUE: If a dose has been received ≤ 4 days before minimum due date or age, the dose can be considered valid. This applies to all antigens. This allowance is not to be used for booking clients (except exceptional circumstance) but rather to validate histories by external providers. Read the full details in the grace period bulletin.

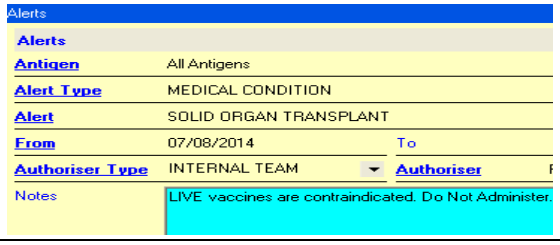
At this time PARIS only accommodates automatic validation of MMR, varicella, and Hep B dose 3 24 weeks minus 4 days variances.

ACTION: All other antigens that qualify for valid status based on grace period need to be sent for a manual validation and suspension of further planning where necessary. See #23 for more information about pneumococcal validation.

GENERAL ISSUE and ACTION #5: SOLID ORGAN TRANSPLANT

ISSUE: Live vaccines (MMR, V, VZ) are contraindicated for solid organ transplant recipients. There is no immunization alert in PARIS to suspend live vaccines in this situation.

ACTION: Enter a medical/solid organ transplant alert and write an immunization case note to identify contraindication and send the record to an immunization lead for an indefinite suspension of MMR, V, & VZ.



GENERAL ISSUE and ACTION #6: VACCINE EVALUATION CENTRE (VEC) CLIENTS

ISSUE: Vaccine Evaluation Centre (VEC) clients are involved in research studies that can be testing alternative schedules. When these histories are entered into PARIS some doses may be invalidated but they are VALID as per the research study. See FAQ bulletin for complete data entry guidelines.

ACTION: Any doses that are included in the study and are being invalidated by PARIS may require a manual change in status to VALID. If the client is complete for age as per the study (generally verified by serology), and PARIS is still planning further doses, the planning may also require a suspension (Not Required - VEC study participant). When the VEC study information is no longer relevant the VEC alert can be end-dated by clinician.

REFERENCES/ASSOCIATED DOCUMENTS:

- BCCDC Immunization Manual for the most up-to-date provincial schedules, products and dosing guidelines.
- VCH intranet for the VCH program reviews by antigen and other program resources to support learning and clinical judgment.

APPROVALS		
(Operations Director)	*Cindy Masaro*	*Date March 24th,2017*
(Manager)		*Date*
(Practice Director)		*Date*

REVISION HISTORY			
Revision#	Description of Changes	Prepared by	Effective Date
OO			