Hawke's Bay Clinical Council Meeting

Date: **Wednesday, 12 October 2016**

Meeting: **3.00 pm to 5.30 pm**

Venue: **Te Waiora Meeting Room, District Health Board Corporate Office, Cnr Omahu Road & McLeod Street, Hastings**

Council Members:

Chris McKenna
Dr Mark Peterson
Dr John Gommans
David Warrington
Billy Allan
Dr Andy Phillips
Dr Robin Whyman
Dr Caroline McElnay
Robyn O'Dwyer
Jules Arthur
Dr Kiri Bird
Dr Tae Richardson
Dr David Rodgers
Dr Russell Wills
Debs Higgins
Anne McLeod

Apologies: Jules Arthur

In Attendance:

Ken Foote, Company Secretary
Tracy Fricker, Council Administrator and EA to Director QIPS
Graeme Norton, Chair HB Health Consumer Council
Kerri Nuku, Māori Relationship Board Representative

PUBLIC MEETING

Item	Section 1 – Routine	Time (pm)
1.	Apologies / Welcome	**3.00**
2.	Interests Register	
3.	Minutes of Previous Meeting	
4.	Matters Arising – Review Actions	
5.	Clinical Council Workplan	
	Section 2 – For Discussion	
6.	Quality Dashboard – John Gommans	**3.10**
7.	HB Clinical Council Annual Plan 2016/17 – Chris McKenna and Mark Peterson	**3.30**
	Section 3 – Reporting Committees / Monitoring	
8.	Infection Prevention Control Committee – Chris McKenna	**3.45**
9.	HB Nursing Midwifery Leadership Council Update – Chris McKenna	**3.55**
10.	Urgent Care Project Update – Graeme Norton (UCA Chair)	**4.05**
11.	Radiology Services Committee – Mark Peterson	**4.15**
12.	Laboratory Committee Recommendation Pregnancy Testing – Kiri Bird	**4.25**
13.	**Section 4 – Recommendation to Exclude the Public**	

PUBLIC EXCLUDED

Item	Section 5 – Routine	
14.	Minutes of Previous Meeting	**4.35**
15.	Matters Arising - Review Actions	
	Section 6 – For Information / Discussion	
16.	Letter received from CAG on Governance Matters (not discussed Sept)	**4.40**
	Section 7 – General	
17.	Topics of Interest – Member Issues / Updates	**4.50**

NEXT MEETING - QUARTERLY MEETING : Wednesday, 9 November 2016

Commencing at 12.30pm with lunch
Meeting starts at 1.00pm

Venue: Education Centre, near ED, Canning Road, Hastings

Tauwhiro Rāranga te tira He kauanuanu Ākina

Interests Register
Oct-16

Hawke's Bay Clinical Council

Name Clinical Council Member	Interest eg Organisation / Close Family Member	Nature of Interest eg Role / Relationship	Core Business Key Activity of Interest	Conflict of Interest Yes / No	If Yes, Nature of Conflict: - Real, potential, perceived - Pecuniary / Personal - Describe relationship of Interest to
Chris McKenna (Director of Nursing)	Hawke's Bay DHB - Susan Brown	Sister	Registered Nurse	Yes	Low - Personal - family member
	Hawke's Bay DHB - Lauren McKenna	Daughter	Registered Nurse	Yes	Low - Personal - family member
	Health Hawke's Bay (PHO)	Board member	HHB ensures the provision of essential primary health care services, mostly through general practices, to the population of HB	Yes	Low
Dr Mark Peterson (Chief Medical Officer - Primary Care)	Taradale Medical Centre	Shareholder and Director	General Practice - now 20% owned by Southern Cross Primary Care (a subsidiary	Yes	Low
	Royal New Zealand College of General Practitioners	Board member	GP training and standards	Yes	Low
	City Medical Napier	Shareholder	Accident and Medical Clinic	Yes	Contract with HBDHB
	Daughter employed by HBDHB from November 2015	Post Graduate Year One	Will not participate in discussions regarding Post Graduates in Community Care	Yes	Low
	PHO Services Agreement Amendment Protocol (PSAAP)	"Contracted Provider" representative	The PHO services Agreement is the contract between the DHB and PHO. PSAAP is the negotiating group that	Yes	Representative on the negotiating group
	Health Hawke's Bay Limited (PHO)	Board member	HHB ensures the provision of essential primary health care services, mostly through general practices, to the population of HB.	Yes	Low
	Council of Medical Colleges	Royal New Zealand College of General Practitioners representative and Council of Medical Colleges Executive	May impact on some discussions around medical training and workforce, at such times interest would be declared.	Yes	Low
Dr John Gommans (Chief Medical Officer - Hospital)	Stroke Foundation Ltd	Chairman of the Board of Directors	Provides information and support to people with a stroke. Has some contracts to the MOH	Yes	Low
	Internal Medicine Society of Australia and New Zealand (IMSANZ)	Immediate Past President and a current Director of IMSANZ	The IMSANZ represents the interests of specialist General Internal Medicine physicians throughout Australia and New Zealand	Yes	Low
	Royal Australasian College of Physicians (RACP), Adult Medicine Division Committee (AMDC)	Member and Chair elect of NZ Committee	RACP represents Physicians in all Adult Medicine specialties across Australasia; the NZ AMD representing those based in NZ	Yes	Low
Dr Caroline McElnay (Director Population Health & Health Equity Champion)	NZ College of Public Health Medicine	President until October 2017	NZCPHM represents the interests of Public Health Medicine specialsits in NZ, provides training of registrars, ongoing accrediation of specialists and advocacy on public health matters.	No	
	RNZ Plunket Society	National Board member	Provision of heath and social services to children under 5 years, advocacy for children	No	
William Allan (Chief Pharmacist)	Pharmaceutical Society of New Zealand	Executive member	Pharmacy advocacy, professional standards and training	Yes	Low
	Pharmaceutical Management Agency (PHARMAC)	Member, Tender Medical Subcommittee of PTAC (Pharmacology & Therapeutics Advisory Committee)	Provide advice to PHARMAC on the clinical suitability of tenders for subsidised medicines for inclusion in the Pharmaceutical Schedule and Hospital Medicines List (HML)	Yes	Low. Influences the cost of subsidised medicines to the DHB's combined pharmaceutical budget
	Executive User Group for eMedicines programme (ITHB/HQSC)	Member (Central Region's representative)	Provide leadership and guidance to the HITB and HQSC on the eMedicines (Hospital) programme (electronic prescribing & administration; eMedicines	Yes	Low
	Pharmacy Steering Group (MoH)	Member	Provide advice to the Ministry on the utilisation of pharmacists within the health workforce	Yes	Low
Jules Arthur (Midwifery Director)	National Midwifery Leaders group	Member	Forum for national midwifery and maternity issues	No	
	Central Region Midwifery Leaders report to TAS	Member	Regional approach to services	No	
	National Maternal Wellbeing and Child Protection group	Co Chair	To strengthen families by facilitating a seamless transition between primary and secondary providers of support and care; working collaboratively to engage support agencies to work with the mother and her whanau in a culturally safe manner.	No	
	NZ College of Midwives	Member	A professional body for the midwifery workforce	No	
	Central Region Quality and Safety Alliance	Member	A network of professionals overseeing clinical governance of the central region for patient quality and safety.	No	
Dr Kiri Bird (General Practitioner)	Te Timatanga Ararau Trust (Iron Maori)	Partner (Lee Grace) is a Trustee	Health and Wellbeing	Yes	Low - Contract with HBDHB
	Gascoigne Medical Raureka	General Practitioner	General Practice	Yes	Low
	Royal NZ College of General Practitioners	Member	Health and Wellbeing	No	
	Royal NZ College of General Practitioners	Lead Medical Educator in HB	Health and Wellbeing	No	
	Te Ora Board (Maori Doctors)	Deputy Chair	Health and Wellbeing	No	
	Te Akoranga a Maui (Maori chapter for RNZCGP)	Member	Health and Wellbeing	No	

Name **Clinical Council Member**	**Interest** **eg Organisation / Close Family Member**	Nature of Interest **eg Role / Relationship**	Core Business **Key Activity of Interest**	**Conflict of Interest** **Yes / No**	**If Yes, Nature of Conflict:** **- Real, potential, perceived** **- Pecuniary / Personal** **- Describe relationship of Interest to**
Robyn O'Dwyer (Nurse Practioner Whanau Ora)	Wairoa Health Care Center	Nurse Practitioner	General Practice	No	
	The College of Primary Care Nurses	Member	National submissions/member of nursing leadership	No	
	The College of Maori Nurses	Member		No	
	New Zealand Scientific Society of Diabetes	Member		No	
David Warrington (Nurse Director - Older Persons)	Havelock North Chiropractic	Wife is Practitioner and Co-owner	Chriopractic care and treatment, primary and preventative	Yes	Low
	Pilates Works	Wife is CE and Co-owner	Rehabilitation, Primary and preventative.	Yes	Low
	National Directors of Mental Health Nursing	Member		No	Low
Dr Tae Richardson (GP and Chair of Clinical Quality Advisory Committee)	Loco Ltd	Shareholding Director	Private business	No	
	Dr Bryn Jones employee of MoH	Husband	Role with Ministry of Health as Chief Advisor in Sector Capability and	Yes	Low
	Clinical Quality Advisory Committee (CQAC) for Health HB	Member	Report on CQAC meetings to Council	No	
	HQSC / Ministry of Health's Patient Experience Survey Governance Group	Member as GP representative		No	
	Life Education Trust Hawke's Bay	Trustee		No	
	Dr Bryn Jones employee of MoH	Husband	Deputy Chief Strategy & Policy Officer (Acting)	No	
	Pacific Chapter of Royal NZ College of GPs	Secretary		No	
Andrew Phillips (Director Allied Health HBDHB)	Nil	Not Applicable	Not Applicable	No	Nil
Dr David Rodgers (GP)	Tamatea Medical Centre	General Practitioner	Private business	Yes	Low. Provides services in primary care
	Tamatea Medical Centre	Wife Beth McElrea, also a GP (we job share)	Private business	Yes	Low. Provides services in primary care
	Directions Youth Health	Wife Beth involved	Assisting youth in HB	No	
	City Medical	Director and Shareholder	Medical Centre	Yes	Low. Provides services in primary care
	NZ Police	Medical Officer for Hawke's Bay	Provider of services for the NZ Police	No	
	Health Hawke's Bay (PHO) initially - from 1 July 2015 under HB District Health Board	Collaborative Clinical Pathways development	Was the Champion for the initial work, however on 1 July this moved under the HBDHB umbrella (with a community focus).	No	
	Advanced Care Planning	Steering Group member	Health and Wellbeing	No	
	Urgent Care Alliance	Group member	Health and Wellbeing	Yes	Low. Ensure position declared when discussing issues around the development of urgent care services.
	National Advisory Committee of the RNZCGPs	Member	Health and Wellbeing	No	
	Health Hawke's Bay (PHO)	Medical Advisor - Sector Development	Health and Wellbeing	Yes	Low. Ensure position declared when discussing issues in this area relating to the PHO.
Debs Higgins (Senior Nurse)	The Hastings Heatlh Centre	Practice Nurse Family Violence Intervention Coordinator	Delivery of primary health care - General Practice and training of Clinicians in family violence intervention.	No	
	The NZ Nurses Society	Member of the Society	Provision of indemnity insurance and professional support.	No	
	LIVE (Local Initiative for Violence Elimination)	Member of management Committee	Network of agencies that provide family violence intervention services.	No	
	Eastern Institute of Technology (EIT)	Lecturer - Nursing	Education.	No	
Anne McLeod (Senior Allied Health Professional)	Aeotearoa NZ Association of Social Workers	Member		Yes	Low
	HB DHB Employee Heather Charteris	Sister-in-law	Registered Nurse Diabetic Educator	Yes	Low
	Directions Coaching	Coach and Trainer	Private Business	Yes	Low: Contracts in the past with HBDHB and Hauora Tairawhiti.
Dr Robin Whyman (Clinical Director Oral Health)	NZ Institute of Directors	Member	Continuing professional development for company directors	No	
	Australian - NZ Society of Paediatric Dentists	Member	Continuing professional development for dentists providing care to children and advocacy for child oral health.	No	
Dr Russell Wills	HBDHB Community, Women and Children and Quality Improvement & Patient Safety Directorates	Employee	Employee	Yes	Potential, pecuniary
	HBDHB employee Mary Wills	Spouse	Employee	Yes	Potential, pecuniary
	Paediatric Society of New Zealand	Member	Professional network	No	
	Association of Salaried Medical Specialists	Member	Trade Union	Yes	Potential, pecuniary
	New Zealand Medical Association	Member	Professional network	No	
	Royal Australasian College of Physicians	Fellow	Continuing Medical Education	No	
	Neurodevelopmental and Behavioural Society of Australia and New Zealand	Member	Professional network	No	
	NZ Institute of Directors	Member	Professional network	No	

MINUTES OF MEETING FOR THE HAWKE'S BAY CLINICAL COUNCIL HELD IN THE TE WAIORA MEETING ROOM, HAWKE'S BAY DISTRICT HEALTH BOARD CORPORATE OFFICE ON WEDNESDAY, 14 SEPTEMBER 2016 AT 3.00 PM

PUBLIC

Present:
Chris McKenna (Co-Chair)
Dr Mark Peterson (Co-Chair)
Dr Tae Richardson
Dr Kiri Bird
Dr Russell Wills
Debs Higgins
William Allan
David Warrington
Jules Arthur
Anne McLeod

In Attendance:
Ken Foote, Company Secretary
Kaye Lafferty, Patient Safety & Clinical Compliance Manager *(on behalf of Kate Coley, Director Quality Improvement & Patient Safety)*
Graeme Norton, Chair HB Health Consumer Council
Kerri Nuku, Māori Relationship Board Member
Tracy Fricker, Council Administrator and EA to DQIPS

Apologies:
Drs Robin Whyman, John Gommans, David Rodgers, Caroline McElnay and Andy Phillips

SECTION 1: ROUTINE

1. WELCOME AND APOLOGIES

Chris McKenna (Chair) welcomed members to the meeting including newly appointed Dr Russell Wills (who replaces Dr Malcolm Arnold).

Apologies were noted as above.

2. INTERESTS REGISTER

No conflicts of interests for agenda items.

Dr Russell Wills has provided his interests which have now been updated on the register.

Dr Mark Peterson advised he has a new interest to register. He is the RNZCGP Representative on the Council of Medical Colleges and on the CMC Executive.

Action: New interest to be added to the register.

3. CONFIRMATION OF PREVIOUS MINUTES

The minutes of the meeting held on 10 August 2016, were confirmed as a correct record of the meeting.

The minutes of the Annual General Meeting which followed the 10 August meeting were also confirmed as a true and correct record of that meeting.

Moved and carried.

4. MATTERS ARISING, ACTIONS AND PROGRESS

Item 1: Clinical Council Member Portfolios
Work in progress. A meeting is to be held regarding refreshing the clinical committees and getting Clinical Council members involved so that we truly have an overview of the sector clinically. The Annual Plan will come back to Clinical Council next month for discussion.

Item 2: Alternative Health Provider - Complementary Therapies Policy
The latest version of the policy is on the agenda today, item #6.

5. CLINICAL COUNCIL WORK PLAN

The work plan was included in the meeting papers for information.

We may not have the final paper for HB integrated Palliative Care in October as there are still some processes happening externally before coming to Clinical Council. This item will be moved to the November meeting.

SECTION 2: FOR DECISION

6. COMPLEMENTARY THERAPIES POLICY

The Chair advised the policy has been to Clinical Council before, as well as the Consumer Council and Maori Relationship Board. It was acknowledged and this has been a complex piece of work and Dr Andy Phillips has done well to get it to this stage.

Feedback:

- Remove list under the scope
- Policy is still quite directive
- Opportunity for co-design, need to involve complementary therapists
- The list includes people who are regulated under the Health Practitioners Competency Assurance Act
- Register of complementary therapists, don't agree with the column on the form "review meeting" - what are we asking them for, we are not governing their practice
- We need to ask some complementary therapists what does access to your consumers on DHB premises look like for you; and also what are our consumers thinking and wanting.

We need to revisit the original intent of the policy which was the valid concern to protect people from quackery on DHB property. We are not trying to tell people that they don't have personal choice we are saying that we don't necessarily endorse it, and that we expect some safety measures put in place.

Following discussion, decision made to manage the development of this policy outside of Clinical Council in between meetings. The policy is not approved in its current form.

Action: Co-Chairs to discuss changes to policy with Andy Phillips.

7. QUALITY ACCOUNTS

The Chair welcomed Jeanette Rendle (Consumer Engagement Manager) to the meeting. Jeanette advised that feedback on the draft document previously received from Clinical Council, Consumer Council, Maori Relationship Board (MRB), Health Services and clinical teams across the sector has been incorporated into the latest update.

MRB feedback was that they had a part to play in quality in the community and wanted to know where in the document they fit. This has been rectified by adding the page "working in partnership for quality". Information on the Executive Management Team and Quality Improvement and Patient Safety Service will also been added. MRB wanted to add a pledge from the CEOs (DHB and PHO) that says were are committed to this, and requested that at the front of the document there be an opening address from the CEOs.

Any final feedback needs to be sent to Jeanette.rendle@hbdhb.govt.nz by close of business 19 September.

The Quality Accounts will go to the Board for sign off on 28 September.

The Chair thanked Jeanette Rendle and the working group for the work involved in putting the Quality Accounts together.

Recommendations approved the Quality Accounts and Communication Plan endorsed by Clinical Council.

8. MANAGE MY HEALTH

The Chair welcomed Gina McEwen (Information Services Manager) to the meeting. Gina provided an update on the pilot currently underway with The Doctors Napier and Carlyle Medical Centre. They are working alongside the DHB looking at the product to see that it meets their needs and the DHB's from a District Nursing point of view as a starting point, to introduce shared clinical access to notes. It is a simple tool which the GP practices permission access to the information they hold, or District Nurses can request access from a practice. Both practices in the pilot have feedback that the system is very easy to use and not onerous. From the District Nurses perspective they are enjoying using the tool, as it has alleviated the frustration for them of having to log on at multiple practices. Some of the benefits found already is the potential to minimise the referral process, and it is also speeding up communication.

The terms of reference have been agreed and signed off for the first stage. The pilot is due to finish at the end of this month. The pilot will then be evaluated and then we will work through the next steps. The plan is to get more of the practices in Napier on board, and then look to transition to the Hastings practices into this new model.

Questions / Feedback:

- The information the health professional access, it is the same as what the patients can access themselves? There are separate patient and health care provider portals.

- It is going to work well for district nursing. Cannot see this is going to provide any further assistance further than what care insight does e.g. to clinicians in ED? At the moment as it is currently structured we have gone with a group of people being able to access a set of information that relates to a condition. This can be flipped around and opened up to the entire patient information no matter what the condition is. There would need to be an advanced service agreement on the level of information that a group can access. At the moment DNs have read and write access. For a viewing perspective it may be just a generalised view of a set of information for the enrolled population.

- Is this a pathway to a shared care record and has that pathway been decided that it will be via MedTech/Manage My Health? No. It is a pathway to support the Ministry direction to a shared electronic health record. It pulls a set of information together which if allowed can be transported into whatever system will be the national shared electronic health record construct. We don't know what that is yet.

- We had a presentation on HealthOne last year where there was a comprehensive shared record in the south island and this was offered to other DHBs, all the protocols were already sorted, St John Ambulance, private hospitals and a whole range of partners, are we reinventing the wheel? We are not building that construct and assume they will be having that discussion at the Ministry where they see HealthOne aligning with the national shared electronic health record.

- Are other DHBs using Manage My Health across the sector? Yes, predominately in the central region. It is the endorsed model for the central region. It is only being used by GPs and District Nurses at the moment? Practice Nurses can also be permissioned to access the system. MedTech is the GP practice software, Manage My Health even though it is assigned to MedTech is a separate entity. It pulls information from MedTech and you log into it.

- Who is going to evaluate it? KPIs have been set and there will be an internal evaluation on where we are at, what we have come up against and what we need to do to move forward.

- Other than DHBs, what other clinicians in the community are using Manage My Health? The provider portal, not many at all. We have shown it to MidCentral, they like the concept. We want to get all health professionals involved in the patient record and all be able to see and share it as simply as possible instead of having to log on to multiple systems. The MedTech and My Practice environments all sit in separate silos, they don't talk to each other.

- The National Shared Health Record is about taking all the isolated silos and the important information from all these systems and bringing them to a point where they can be a shared record. That is what HealthOne does, rather than demanding that everybody get on the same system, you keep your own system but the backend of it communicates to a central point and you keep a virtual shared record together.

- Before we invest too much in this, we need to be clear is it going to be a superior alternative. We need to be certain it will give us benefits when the shared record comes.

- The original District Nursing project suffered due to multiple logins and duplication, there were issues in some practices allowing or enabling other health professionals to access patient data to do good clinical assessments and we need to make sure through this process that we are working in an inter-professional way. It is better for our patients to work this way, sharing health information through shared health records.

The Chair thanked Gina McEwan for the update and noted that the evaluation and progress with the roll out will come back to Clinical Council in the future.

9. DESIGNATED PRESCRIBER – REGISTERED NURSES

The Chair welcomed Sally Houliston (Nurse Consultant) to the meeting. The paper has been to Executive Management Team (EMT) and the Clinical Advisory Group (CAG). This is important for nursing practice and more importantly for the patient population that nurses and other health professionals provide services to with the view to freeing up access.

Sally Houliston went through the key points:

- The legislation will come into force from 20 September.

- It will enable nurses to facilitate improved, quicker health access to our vulnerable health population
- Registered Nurse Prescribers will only be able to prescribe from a limited range of medicines relating to the area in which they work in; nurse practitioners will be able to prescribe any medicines.
- The educational requirement will be a post graduate diploma in prescribing, made up of four papers, 120 credits in total.
- There is ongoing requirements for supervision 12 months after being a prescriber and ongoing annual requirements as part of the practising certificate.
- It will also bring into line the Diabetes Nurse Specialists who had prescribing through the diabetes prescribing pilot.
- From a DHB perspective there is huge scope around the areas of population health, rheumatic fever, throat infections, skin infections, teenage pregnancy and wound care. There are potential areas with nurse prescribing that can make difference in the Rural Oral and Community Service.
- Looking at the linkages with nurse prescribing, with the Pharmacy & Therapeutics Committee and the PHO Quality Group.
- The pathway is that a nurse identifies themselves as a potential prescriber. There will need to be approvals through the Service and the Senior Leadership Team to ensure that this is the right direction of travel for the service and patient population.

Questions / Feedback:

- Does the Nurse Practitioner need to be working in the area already? Yes, the Nursing Council is clear that the nurse prescriber will need to have a minimum of 3-years' experience in the area they are going to prescribe, and they need to have ongoing employment to ensure the ongoing prescribing requirements from the Nursing Council are met.

- There are two pathways, the RN Prescriber at the Postgraduate level that you need do to a maximum of four years, but can be done in two; or you have the Nurse Practitioner pathway which is at master level which you need to do academically within 5 years. The big difference is that the RN Prescriber will only be looking at a defined list of medications within the area that they work, whereas the Nurse Practitioner can prescribe any prescription medicine.

- There will be some grandparenting, we do have some nurses who have done all these papers and practicums previously. That will need assessment by an academic institution against Nursing Council competencies for prescribing. If they have a service or speciality team, then they can apply directly to the Nursing Council for endorsement.

- Has there been much enquiry about this yet? Yes from Public Health Nurses, a couple of Practice Nurses and Clinical Nurse Specialists in the hospital as well.

- There are some good advantages for patients here with our clinical nurse specialists, consult liaison nurses, saving a lot of time.

- How ready, willing are services? The Senior Nursing Leadership Team in Oral Rural and Community can identify one or two who they can see potential in the next 6 months and others on a clear pathways towards this. A lot of nurses are currently working under standing orders which are cumbersome not only for the nurse but also the medical prescriber sign-off. That will evolve and some of the current standing orders will not be needed in the future.

- There are two parts to success, having a group of nurses willing to do it and having support from Nurse Practitioners and Medical colleagues to support the mentoring. We need to monitor who are becoming mentors because we don't want to be over burdening our prescribing mentors whether they are medical or nursing.

- EIT have a visit from the Nursing Council in November for endorsement. They are looking at running the paper in both semesters next year subject to sufficient number of enrolments. Locally we will have the programme available to support our staff across the sector.

- Supportive of this. We have already seen the impact of nurse prescribing with standing orders on teenage pregnancy, skin infections and acute rheumatic fever. It is a fantastic step forward.

It has been a long journey, there have been issues out in the public forum around safety. Hence the Nursing Council as the regulator have come back with the process. The Nursing Council have put out a guide for employers which is available on their website, link below:

http://www.nursingcouncil.org.nz/Nurses/Registered-Nurse-Prescribing/Preparing-to-prescribe-information-for-employers

The next step will be to secure medical support to be prescribing mentors. How can we secure that? The clinical council needs to say clearly that we endorse and fully support it and we look forward to medical practitioners supporting nurses through this process and strongly encourage our medical colleagues to do so.

Recommendation endorsed by the Clinical Council and we encourage our medical practitioners to support their nursing colleagues through this process.

10. HEALTH & SOCIAL CARE NETWORKS UPDATE

The Chair welcomed Belinda Sleight (Project Manager) to the meeting. Belinda provided a quarterly report on the progress to date with the Health & Social Care Networks.

Key points:

- The new sponsor for the project is Tracee Te Huia (General Manager Maori Health)
- Developing a position paper on what is network
- Way forward is a steering group for support
- Building relationships with other networks, communicating with other providers and funders to get partnerships working. Sharing information and starting to work together
- Ensuring at an organisation level that we are moving in the same direction and making sure relationships are strong on the ground in Wairoa and Central Hawke's Bay
- The DHBs approach is a top down approach, but it is not prescriptive. Something like the PHO minimum standards when they were originally developed. We want a community setting up a network being able to demonstrate a certain level of behaviours and involvement of community members at governance and decision making and with co-design.
- Would it be helpful to see some local networks that are working well? Dr Russell Wills will provide names of groups and contact persons to connect with.
- We need to build on the local successes.
- We need an enabling environment which allows the networks to grow organically.
- You can learn a lot of lessons from Children's Team, what works, what doesn't, what a good enablement process look like.
- We can't make assumptions on what we need as opposed to what the community needs. Are the right people at the table, how are the community being consulted on the development.

SECTION 4: REPORTING COMMITTEES / MONITORING

11. FALLS MINIMISATION COMMITTEE UPDATE

The Chair provided an update on the last six months. A number of initiatives to reduce falls are occurring around the hospital. The Trauma Committee has been set up and the initial data shows that major trauma from falls is significant in our community.

Sports Hawke's Bay have been very proactive coming to the table, but are limited by funding streams.

We continue to work with ACC and Strategic Services are continuing those conversations as ACC are stating publicly they have funding to support falls prevention.

Nationally as a DHB we are doing reasonably well. On the annual Serious Adverse Event report this year there are three falls, patients who have fallen while in hospital and sustained fractures (there were four reported last year).

12. MATERNITY CLINICAL GOVERNANCE GROUP

The Chair asked Julie Arthur (Midwifery Director) to provide an update.

Julie Arthur advised that since the last report, there had been two significant events in Maternity Services being the opening of the Waioha Primary Birthing Centre and the publication of the Hawke's Bay Maternity Services Annual Report 2015. The report includes amazing consumer stories and quotes on what the service means to our community. Julie commended Emma Mumford (Maternity Governance Co-ordinator) on pulling the information together for the report.

The Chair congratulated Julie Arthur and the maternity team for a fantastic report, it is a lot of work, well done.

13. URGENT CARE PROJECT UPDATE

Graeme Norton provided a verbal update on the project. A key part of the urgent care process was the work to establish a model of care in Hastings, but it also need to relate to what was taking place in Napier. The requests for proposals process was suspended at the request of the parties who had registered for the RFP as they expressed that they wished to collaborate to find a model of care in conjunction with the DHB. The parties concerned have been meeting, looking for common ground and have moved to the next stage, which was to present to the DHB CEO. They met with the CEO last week and the RFP process will continue to be suspended for a further period of time. The next step in the process is to co-design with acute Services, ED in particular a model of care.

The principles that were established in the Urgent Care Alliance of what the community wants are driving the process, what is the model of care, what does it look like and how will it work, what are the resources and how will it be funded and the outcome. The timeframe they are working to is to have this work completed by April 2017.

It has been an interesting process getting the parties to collaborate. Dr Colin Hutchinson, Medical Director for Acute and Medical has been great. He has given confidence to the GPs in the room that secondary services are ready for this change.

The appropriate governance and reporting structures are in place. A progress report goes to the Finance Risk and Audit Committee (FRAC) each month.

14. CLINICAL ADVISORY & GOVERNANCE (CAG) COMMITTEE

Dr Tae Richardson advised that there are two reports available the one for July was included in the meeting papers and the September report was emailed out prior to the meeting.

The July report is taken as read. The meeting held on 6 September was a full agenda and included updates on:

- District Nursing
- engAGE
- Clinical Pharmacist Facilitators in General Practice
- Mental Health
- B4SC
- Diabetes
- Long Term Conditions

Brief discussion held regarding prioritisation of services in mental health. This topic needs appropriate time allocated to it. Suggestion made that this be included on the agenda for the quarterly meeting, combined section with the Consumer Council as this is also an interest they have already identified.

Action: Item on Mental Health to be added to the agenda for discussion at the combined Clinical and Consumer Council meeting in November.

15. LABORATORY SERVICES COMMITTEE REPORT

Dr Kiri Bird advised that the report discussed at the August meeting regarding the Easy Check Pregnancy Tests was not available for the meeting papers. It will be provided in the papers for next month.

SECTION 5: FOR INFORMATION ONLY

16. TE ARA WHAKAWAIORIA / HEALTHY WEIGHT STRATEGY

Report tabled for information. No issues discussed.

SECTION 6: GENERAL

17. GASTRO OUTBREAK HAVELOCK NORTH

Presentation provided by Ken Foote (Company Secretary) and Anna Kirk (Communications Manager). This is the same presentation which was given by the CEO at the Public Meetings.

Key points:

- How events unfolded from notification on Friday, 12 August
- What we saw – ESR estimates 5198 people affected (one-third of the population of Havelock North). Only 22 people admitted to hospital
- Community Response - phenomenal response from the community, GPs and Pharmacies also Public Health and District Nursing
- Where to from here – internal investigation on health response and Government Inquiry on the outbreak to take place, the terms of reference for this are out.

Concerns still around communication and getting the messages out there. We need to have a multi-faceted approach, not everyone listens to the radio, reads the paper or is on social media. We especially need to look at how we communicate with the elderly members of our community.

We need to lead on environmental health issues.

Overall the health response was phenomenal. Feedback from the PHO was that GP practices and the community felt very supported by the DHB. In this time of crisis the relationships and strategies on integration we have built up over the years worked. The level of integration we were

able to achieve through the Emergency Operations Centre (EOC), engagement with the PHO and the use of the District Nurses allowed us deal with the issue in the community and the hospital was able to carry on, no elective surgery had to be cancelled. That is a major achievement.

Anna Kirk advised that flyers will be coming out updating the community on what is happening and the health messages they still need to be aware of.

Action: Letter of thanks to be sent to our colleagues in primary care for the exemplary work done through the crisis from the Co-Chairs on behalf of the Clinical Council.

18. RECOMMENDATION TO EXCLUDE THE PUBLIC

The Chair moved that the public be excluded from the following parts of the meeting:

19. Minutes of Previous Meeting (Public Excluded)
20. Matters Arising – Review of Actions (Public Excluded)
21. Health Awards
22. Serious Adverse Events
23. Letter received from CAG on Governance Matters
24. Member Topics of Interest

Moved and Carried.

Meeting closed at: 5.20 pm

Confirmed: _____
Chair

Date: _____

HAWKE'S BAY CLINICAL COUNCIL
Matters Arising – Review of Actions
(PUBLIC)

Action No	Date issue raised	Action to be Taken	By Whom	By When	Status
1	10/2/16	***Clinical Council Member Portfolios within the 2015/16 Council's Annual Plan review*** To be finalised for approval		Oct	On agenda
2	14/09/16	***Interests Register*** New interest for Dr Mark Peterson to be added.	Admin	Oct	Completed.
3	14/09/16	***Complementary Therapies Policy*** Discuss with Andy Phillips policy development outside of Clinical Council Meeting	Co-Chairs	Oct	
4	14/09/16	***Mental Health Topic*** Item for discussion to be included in the joint meeting with Consumer Council in November.			
5	14//09/16	***Gastro Outbreak*** Letter of thanks to be sent to primary colleagues	Co-Chairs	Oct	

OURHEALTH HAWKE'S BAY Whakawateatia

HB CLINICAL COUNCIL WORKPLAN 2016-2017

Meetings 2016	Papers and Topics	Lead(s)
9 Nov **Joint Mtg**	Mental Health topic for joint Clinical/Consumer Meeting in Nov Venue to be confirmed	
	Allied Health Professions Forum	Andy Phillips
	Orthopaedic Review – closure phase 1	Andy Phillips
	ICU Learings Action Plan update Qtly	Kate Coley
	Endocsopy / Gastro Project Build Approval / Outcomes Tender	Sharon Mason
	Draft - Event / Complaint / Hazard / Risk Management System	Kate Coley
	Travel Plan – verbal	Sharon Mason
	Tobacco – Annual Update against the Plan (for noting) **	Caroline McElnay
	Final – Reducing Alcohol-Related Harm	Caroline McElnay
	Family Violence – Strategy Effectiveness	Caroline McElnay
	HB Integerated Palliative Care (draft)	Mary Wills
	Bariatric Surgery Investigations paper	Mary Wills
	Long Term Conditions	Tim / Leigh White
	13-17 Year Old Primary Care Zero Rated Subsidy Project	Tim / Patrick LeGeyte
	Transform & Sustain Refresh	Tracee TeHuia
	System Level Measures	Carina Burgess
	Monitoring	
	Te Ara Whakawaiora / Smoking (national indicator) **	Caroline McElnay
	HB Clinical Research Committee Update	John Gommans
	Urgent Care Update	TBC
	Laboratory Services Committee Update	Kiri Bird
	CAG report update	Tae Richardson
	Annual Maori Plan Q1	Tracee TeHuia
24 Nov	**HB Health Awards presentation evening**	**Venue to be confirmed**
7 Dec	Draft - Orthopaedic Review – Phase 2	Andy Phillips
	Discussion - HB Workforce Plan	Kate Coley
	Quality Imprmovement Programme	Kate Coley
	Monitoring	
	Health and Social Care Networks Update	Tracee / Belinda Sleight
	Urgent Care Update	Mark Peterson
	Clinical Pathways Committee	Leigh White
	CAG Report	Tae Richardson

Meetings 2017	Papers and Topics	Lead(s)
8 Feb 17	Orthopaedic Review – phase 3 Draft	Andy Phillips
	ICU Learnings – Action Plan update (quarterly)	Kate Coley
	MRI Target Achievement (board request Sept 2016)	Sharon / Mark
	HB Integerated Palliative Care (Final)	Mary Wills
	Monitoring	
	Infection Control Committee (quarterly)	Chris McKenna
	Urgent Care Update	Mark Peterson
	Te Ara Whakawaiora / Access	Mark Peterson
	Annual Maori Plan Q2	Tracee TeHuia
8 Mar 17	Orthopaedic Review – phase 3 Draft	Andy Phillips
	ICU Learnings – Action Plan update (quarterly)	Kate Koley
	MRI Target Achievement (board request Sept 2016)	Sharon / Mark
	Monitoring	
	Maternity Clinical Governance Group Update (6 monthly)	Chris McKenna
	Falls Minimisation Committee	Chris McKenna
	Te Ara Whakawaiora / Breastfeeding (national indicator)	Caroline McElnay
	Laboratory Services Committee	Kiri Bird
	Urgent Care Update	Mark Peterson
	Radiology Servcies Committee	Mark Peterson
	Health & Social Care Networks (quarterly)	Tracee / Belinda Sleight
12 Apr 17	Draft Health Equity Update	Caroline McElnay
	Draft Youth Health Strategy	Caroline McElnay
	Draft Suicide Prevention Postevetion Update against 2016 plan	Caroline McElnay
	ICU Learnings Report – Action Plan update (Quarterly)	Kate Coley
	Monitoring	
	Collaborative Clinical Pathways	Mark / Leigh White
	Urgent Care Update monthly	Mark Peterson
	Te Ara Whakawaiora / Cardiology (national indicator)	John Gommans

HAWKE'S BAY District Health Board Whakawāteatia	**Quality Dashboard**
	For the attention of: **HB Clinical Council and HB Health Consumer Council**
Document Owner: Document Author(s):	Kate Coley, Director – Quality Improvement and Patient Safety Kate Coley, Director – Quality Improvement and Patient Safety
Reviewed by:	Executive Management Team
Month:	October 2016
Consideration:	For Discussion

RECOMMENDATION

That Clinical and Consumer Council:

- Endorse the establishment of a Quality Dashboard.
- Note that feedback is sought from EMT, Clinical Council and Consumer Council before being presented to FRAC.
- Note that over time this dashboard will evolve once the cross sector event reporting system is rolled out.
- Note that the dashboard will be reported on a quarterly basis and shared across the sector

OVERVIEW

The governance of clinical quality and patient safety occurs within the context of the broader governance roles of boards, which includes financial governance, health & safety, managing risk, setting strategic direction and ensuring compliance with statutory requirements. Governance of an organisation occurs at all levels and requires a program of review and improvement of internal processes and outcomes at every level.

Clinical Governance is defined as

"*the system by which the governing body, managers, clinicians and staff share responsibility and accountability for the quality of care, continuously improving, minimizing risks and fostering an environment of excellence in care for consumers, patients, community*"

An effective system of clinical governance at all levels of the health system is essential to ensure continuous improvement in the safety and quality of care, Good clinical governance makes certain that there is accountability and creates a 'just' culture that is able to embrace reporting and support improvement.

The DHB has both a stated commitment to quality and safety and a well-established patient safety and quality management system in place. With the establishment of the new Quality Improvement & Patient Safety Service however, there is now an opportunity to give more prominence to this commitment and refresh this system by aligning it more to the objectives of the Working in Partnership for Quality Framework, the national and regional priorities, and the priorities identified in Transform & Sustain. It also provides an opportunity to review and enhance the effectiveness of the governance structures with responsibilities for clinical quality and patient safety. This refinement and

evolvement has been underway for the past year and will continue over the coming year, with the implementation of the Quality Annual Plan.

The key challenge as an organisation is to continue to maintain and embed the quality framework so as to ensure that patient safety and quality of clinical care is part of everyone's business and is embedded in the culture of the organisation. The focus going forward is on continuous improvement and further development of the quality framework.

The purpose of this report is to seek approval for the establishment of a quality dashboard to provide assurance to the Board, EMT, Clinical and Consumer Councils in regards to the core dimensions of quality – centred around patient safety, clinical effectiveness and patient experience. In addition to providing this assurance it also gives greater transparency and visibility to trends, evolving issues and provides the opportunity for greater sharing of learnings across the organisation. Prior to being approved by Board, feedback will besought from Clinical Council and Consumer Council around the indicators presented.

This dashboard reinforces the endorsed new clinical governance committee structure which is currently being implemented, and will be better supported in the future with the rollout of a new cross sector event management reporting system.

OVERVIEW OF THE DASHBOARD

Currently there are a variety of mechanisms that are provided in various governance meetings which provide information around key performance indicators e.g. Clinical Council Indicators, Performance Framework. These reports have been in place for a period of time and whilst they provide measures of performance they are limited in regards to better transparency and visibility of quality improvement activities and actions that are in place to improve performance.

This new dashboard will report against the three pillars of quality – safety, clinical effectiveness and experience. This aligns with the newly defined clinical governance committee structure which is currently being implemented and is cross sector wide.

The dashboard, which is attached identifies a number of indicators and measures. Each of the indicators will have an agreed definition and target (which align to either MOH, HB Health sector or HQSC requirements) and commentary will be provided on an exceptions basis.

It is proposed that we utilise a simple RAG analysis approach so that this provides a very visual and simple tool so that drilling down into areas of non-performance can be easily done by the relevant governance groups.

The RAG analysis will be defined as follows:

- Green – Current period exceed, meets or is within 0.5% of the agreed target/baseline
- Amber – Current period is below by 0.5% to 5%
- Red – Current period is below by more than 5%

The dashboard will also show the trend direction from the previous quarter. Commentary will be focused on the reasons for below target performance and identify mitigation and quality improvement activities to get the indicator back on track.

This is a first draft of the dashboard and it will evolve over time with the establishment of a new cross sector event reporting system, which will take a period of time to implement, however it is hoped that in the long term this dashboard will be a cross sector reporting and monitoring tool.

Appendix 1 provides an overview of the dashboard visual.

Quality Improvement and Patient Safety Dashboard

OURHEALTH HAWKE'S BAY Whakawateatia

Clinical Effectiveness

		Baseline	Previous	Current	Target	Trend
Patient Movements	Number of ward movements during an episode of care	31%	31%	28%	≥ tbc	
Outliers	Medical Specialty in Surgical ward and vice versa	7%	6%	6%	≤ tbc	
Length of Stay	Averager length of stay for entire hospital (admission to discharge)	2.9	2.57	2.78	≤ tbc	
Long Stay Patients	Patients with a length of stay greater than 10 days					
Hand Hygiene						
Reduced readmissions	Readmission Rate	8%	8%	8%	≤ tbc	
Cornerstone	Practices achieving cornerstone acreditation	64%	86%	86%	≥ 80%	
Enrolments	Patients enrolled with a GP practice	95%	95%	96%	≤ 97%	
Hospital Demand	Average Hospital Status for the quarter					
Cancelled Surgeries	Surgeries cancelled on the day of surgery for non-clinical reasons					

Patient Safety

		Baseline	Previous	Current	Target	Trend
Patient ID Errors	Number of errors due to miss patient ID e.g. labs, radiology, pharmacy					
Patient Events	Number of patient events/incidents per 1,000 admissions	105.5	90.9	99.5	≤ tbc	
Deteriorating Patients	Rapid response patients success rate					
SAC1 and SAC2 Evetns	Days since last event					
Outstanding Risks	Significant number of risks outstanding	26	16	13	≥ tbc	
Standardised Hospital Mortality Rate		108	108	103	≤ 100	
Infection Rates	CLAB and SSI from HQSC					
Pressure Ulcers						
Falls Resulting in Harm						
Family Violence Intervention Training	Attendance and completion of Family Violence Intervention Training					

Patient Experience

		Baseline	Previous	Current	Target	Trend
National Patient Experience	Communication	8.7	8.6	8.7	≥ 8.4	
	Partnership	8.9	8.8	9	≥ 8.4	
	Co-ordination	8.7	8.8	8.8	≥ 8.4	
	Physical and Emotional Needs	8.9	8.8	9	≥ 8.4	
Number of Complaints		136	147	138	≤ tbc	
Number of Compliments		232	164	126	≤ tbc	
Patients Presenting to ED enorlled with GP Practise with	Enrolled with a GP Practice with an A&M clinic	0.35	0.35	0.35	≥ tbc	
Number of Privacy Breaches						
Relationship Centred Practice Training	Attendance and Completion of relationship centred practice training					

HAWKE'S BAY CLINICAL COUNCIL - ANNUAL PLAN 2016/17 - 4 October 2016

FUNCTIONS	Provide Clinical advice and assurance to the Hawke's Bay health system senior management and governance structures	Work in partnership with the Hawke's Bay Health Consmer Council to ensure that Hawke's Bay health services are organised around the needs of people.	Provide oversight of clinical quality and patient safety	Provide clinical leadership to Hawke's Bay health system workforce
ROLES	Provide advice and/or assurance on: • Clinical implications of proposed services changes. • Prioritisation of health resources. • Measures that will address health inequities. • Integration of health care provision across the sector. • The effective and efficient clinical use of resources.	• Develop and promote a "Person and Whanau Centred Care" approach to health care delivery. • Facilitate service integrations across / within the sector. • Ensure systems support the effective transition of consumers between/within services. • Promote and facilitate effective consumer engagement and patient feedback at all levels. • Ensure consumers are readily able to access and navigate through the health system.	• Focus strongly on reducing preventable errors or harm. • Monitor effectiveness of current practice. • Ensure effective clinical risk management processes are in place and systems are developed that minimise risk • Provide information, analysis and advice to clinical, management and consumer groups as appropriate. • Ensure everyone in the HB health sector are aware of their responsibility for quality improvement and patient safety.	• Communicate and engage with clinicians and other stakeholders within HB Health Sector, providing clinical leadership when/where appropriate. • Oversee clinical education, training and research. • Ensure clinical accountability is in place at all levels.
STRATEGIES	• Review and comment on all reports, papers, initiatives prior to completion and submission to the Board. • Proactively develop, promote and recommend changes to improve health outcomes, patient experience and value from health resources. • Develop, promote and advise on strategies and actions that could assist with the reduction in health inequities. • Develop and promote initiatives and communications that will enhance clinical integration of services. • Provide input through representation on EMT, Alliance Leadership Team and through attendance at HB Health Sector Leadership Forum.	• Work collaboratively with the Consumer Council to design and implement a Person and Whanau Centred Care approach. • Understand what consumers need. • Understand what constitutes effective consumer engagement. • Promote clinical workforce education and training and role model desired culture. • Promote and implement effective health literacy practice. • Promote the development and implementation of appropriate systems and shared clinical records to facilitate a 'smooth patient experience' through the health system.	• Develop and maintain relevant and effective Clinical Indicator reporting and performance management processes. • Establish and maintain effective clinical governance structures and reporting processes. • Ensure safety and quality risks are proactively identified and managed through effective systems, delegation of accountabilities and properly trained and credentialed staff. • Ensure the "quality and safety" message and culture is spread and applied in all areas of HB health sector. • Promote "value-based decision-making" at all levels. This involves improving the processes by which decisions are made, so they take into consideration all three Triple Aim objectives: o Enhanced patient experience o Improved health outcomes o Better value for money • Ensure attendance at appropriate meetings/forums to provide appropriate assurance and confidence.	• Ensure all HB clinicians and other stakeholders are aware of the role, membership and activities of the Clinical Council. • Oversee the development, maintenance and implementation of a HB Clinical Workforce Sustainability Plan. • Promote clinical governance at all levels within the HB heatlh system. • Ensure appropriate attendance/input into National/Regional/ Local meetings/events to reflect HB clinical perspective. • Promote ongoing clinical professional development including leadership and "business" training for clinical leaders. • Facilitate co-ordination of clinical education, training and research. • Role model and promote clinical accountability at all levels.
OBJECTIVES 2016/17	• Prioritise meeting time to focus on papers with significant clinical issues. • Encourage proactive presentations / discussions on innovative issues / ideas. • Ensure risk management processes provide for early Clinical Council visibility (and input) of all significant clinical issues. • Align portfolio areas of responsibility to clinical governance structure memberships (once confirmed).	• Work in partnership with Consumer Council to develop an appropriate "Person & Whanau Centred Care" approach and culture. • Monitor "Quality Dashboard" and support performance improvement initiatives as appropriate. • Promote and support ongoing enhancements to information systems relating to clinical process and consumer records. • Support a review of the "Primary Heatlh Care" model of care. • Support and champion the development of a health literacy framework, policies, procedures, practices and action plan.	• Implement and progressively develop the proposed new Clinical Governance Committee / Advisory Group structures. • Monitor and report on the implementation of the action plan for "Governing for Quality. • Oversee and monitor the achievement of objectives within the QIPS Annual Plan.	• Enhance the profile and perceived value of Clinical Council within the sector, through improved effective two way communications. • Facilitate the development of a HB Clinical Workforce Sustainability Plan • Promote Strategies to enable the HB Clinical Workforce to adapt to meet the challenges of the future. • Support and promote the ongoing implementation of clinical leadership training and developments.

HAWKE'S BAY District Health Board Whakawāteatia	**Infection Prevention Control Committee Update**
	For the attention of: **HB Clinical Council**
Document Owner:	Chris McKenna, Chief Nursing Officer
Reviewed by:	N/a
Month:	Sepember 2016
Consideration:	For Information

8

RECOMMENDATION

That Clinical Council:

Note the contents of this report.

HAND HYGIENE

HBDHB celebrated World Hand Hygiene Day on May 5 with displays in all DHB areas and information provided in the foyer of the hospital.

HBDHB has continued to lead other DHBs in New Zealand with their compliance to the Five Moments of Hand Hygiene. Several Gold Auditors have completed training to assist in capturing more moments to continue the momentum. The next audit is due to finish by end of October 2016 with the total target being 1750 moments.

HBDHB

- Barbara McPherson, Infection Prevention & Control Advisor (IPC) retired in June 2016.
- Racquel MacDonald was appointed as an IPC Advisor and commenced the position in August 2016.
- HQSC Surgical Site Infection Improvement Programme continues (Hip and Knee Arthroplasties). The next report is due now. We continue to have 100% compliance with skin preparation and timing of antibiotic prophylaxis. The skin preparation component has now been retired by HQSC.
- IPC was involved with the recent 'Campylobacter' outbreak and worked closely with Aged Cared Facilities in Havelock North.

PROJECTS

- IPC has been part of the project team for the building of Waioha, the new primary birthing centre, the endoscopy unit and also the refurbishment of the renal unit.

Note: Due to staff absence and the campylobacter outbreak, this committee has not had a formal meetings since June 16. The next meeting is scheduled for 13 October.

OURHEALTH HAWKE'S BAY Whakawateatia	**Hawke's Bay Nursing & Midwifery Leadership Council Update**
	For the attention of: **Hawke's Bay Clinical Council**
Document Owner:	Chris McKenna, Chief Nursing Officer
Reviewed by:	
Month:	October 2016
Consideration:	For Information

RECOMMENDATION

That Clinical Council:

Note the contents of this report.

OVERVIEW

The purpose of the Nursing & Midwifery Leadership Council is to provide a consultative forum for nursing and midwifery leaders (representing their respective areas) to participate in discussion, decision-making and/or referral of professional matters that impact on clinical practice and patient care. A transparent and effective shared communication and decision-making process will ensure an intentional and responsive approach to advancing nursing and midwifery practice, to better meet the needs of the community we serve.

NURSING AND MIDWIFERY DASHBOARD

The HBNMLC dashboard is working well

- Increased focus on both midwifery and nursing: reducing average age and its relevance to succession planning while protecting the current workforce. Barriers to employing our younger workforce and increasing length of service.
- Ongoing focus on recruitment of Maori in the Nursing and Midwifery Workforce.
- Some issues with capturing mandatory training in a meaning full way i.e Anniversary date vs Calendar year. Drug Calculation modules need further investigation as course does not open until October, some new staff are showing as completed through part of their orientation.
- The dashboard will be made available on a shared drive for all DHB members and accessible through HBNMLC outside of the DHB.

The need for robust communication planning and sharing of the dashboard information was discussed. Information travels upwards to Clinical Council and disseminates down to CNM level and the information needs to be clear and succinct. Council agreement to present this data to the CNMs quarterly.

RN PRESCRIBING

Legislation came into effect on the 20th September 2016. Priority areas will initially involve exploring benefits to Primary Health and Community teams.

Key information to be aware of:

- Nurse will need to hold a Post Grad Diploma in Prescribing.
- A SMO or Nurse Practitioner will be required as a mentor. (Mentor Support is likely to be the biggest barrier as it becomes additional work for these people).
- This is not a one off qualification the nurse will need to meet ongoing requirements as part of their APC.

CNS's are ideally placed to do this but it needs to be driven by their service and managers.

EIT are looking to be approved by Nursing Council as one of five academic institutions for the pathway.

Nurse Prescribing will be a funding priority for 2017 if the DHB gets HWNZ funding – HWNZ funding is still unconfirmed and our contract ends in 2016. Post Grad applications are open and close 31st October – we are currently proceeding as if we will receive the funding.

INMD 2017

Discussion and planning for International Nurses and Midwives day is starting, the nursing theme for 2017 ""A Voice to Lead: achieving the Sustainable Development Goals (SDGs)." The Midwifery theme for 2017 is Midwives making a difference in the world.

Based on the success of the previous year format will remain similar with an evening event and speaker/s that cover both professions. Currently reviewing all award categories with the potential idea to include a Nursing & Midwifery Leadership category award.

URGENT CARE PROJECT UPDATE

Verbal

OURHEALTH HAWKE'S BAY Whakawateatia	**HB Radiology Services Committee**
	For the attention of: **HB Clinical Council**
Document Owner: Document Author(s):	Mark Peterson Angela Fuller, Radiology Manager
Reviewed by:	n/a
Month:	October 2016
Consideration:	For Information and/or discussion

RECOMMENDATION

That Clinical Council:

- Note the contents of this report.

HBDHB RADIOLOGY DEPARTMENT – Review

Full IANZ Technical Review – postponed until March/ April 2017
Surveillance visit 24/25th November
External Review Radiology – October 25th/Oct 26th – Being undertaken by team from Canterbury
Dr S Mcdonald – HOD and radiologist
Ms F Woodham – radiology Operation manager
Mr R Graham – Production Engineer

TERMS OF REFERENCE

- Tabled for discussion – to be updated

IMAGING GUIDELINES

- Tabled and accepted – to progress to clinical council

OURHEALTH HAWKE'S BAY Whakawateatia	**Laboratory Committee Recommendation around "EasyCheck Pregnancy Tests"**
	For the attention of: **HB Clinical Council**
Document Owner: Document Author(s):	Mark Peterson and Kiri Bird (as Chair of the Lab Committee) Christine Hickton, Point of Care Quality Manager
Reviewed by:	Laboratory Services Committee
Month:	October 2016
Consideration:	For Discussion

RECOMMENDATION

That the Clinical Council endorse the recommendation of the laboratory Committee that:

- Where the pregnancy is considered high risk, ie potential maternal or fetal health at risk, patients be referred for a laboratory based βHCG blood test.
- All other pregnancy tests continue to be conducted in primary care using Easy Check until such time as further advice received from Pharmac.

Find documents attached in support of the above recommendation:

"An Overview and Background"

Appendix 1: Report on EasyCheck Pregnancy Test Kit Issues

Appendix 2: Letter to Dr Anne Kolbe, Chairperson, National Health Committee, MoH from NZ Society of Pathologists

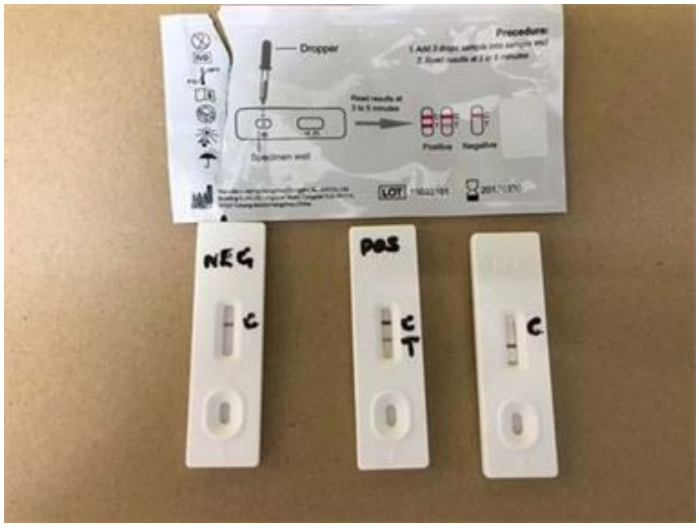
Appendix 3: Letter to Mr Derek Fitzgerald, MoH from NZ Society of Pathologists

EasyCheck Pregnancy Tests - Overview and Background

Background and Timeline

In September 2015 Pharmac changed the brand of pregnancy test kits from Innovacon to EasyCheck. There was no consultation with any interested party and no laboratory evaluation of the new kits to establish that they were fit for purpose. Some members of the New Zealand Point of Care Advisory Group (NZPOCTAG) performed a short evaluation before the kits were released into their sites. This very limited evaluation identified no real issues. The national roll-out of the new brand took place over the next few months depending on the remaining stores of the Innovocan brand. Hawkes Bay Hospital changed in January 2016 and currently issue just over 6000 tests per year in the Secondary Care setting.

In December 2015 the first issues with these kits were being reported within NZPOCTAG by Northland DHB.



Initially it identified that the diagram of expected results on the package was inaccurate, and the manufacturer corrected that by placing a sticky label over the incorrect information, this has subsequently been corrected on the packaging.

Other issues included mechanical failure of the cartridge with the absorbent pad slipping as shown in the photo, and they reported two cases of negative results using Easycheck where pregnancy was confirmed using Innovocan kit and clinical examination.

The moving of the absorbent test pad has been reported as a random finding by others in the group, and although unconfirmed, this may be the basis of other reported issues such as no line in the control space, or if it moves upwards, some of the “false negative” results.

In March 2016 Northland notified the group of further instances of possible false negative results but comments from other members of the group were that in their experience the kits were performing according to specifications on quality control testing, and they had no reported issues from clinical areas.
Northland prepared a full report in April 2016, which was updated in early June, and was circulated to Health Alliance, MedSafe and Pharmac.

REFER TO APPENDIX 1

The issue was discussed at the NZPOCTAG meeting in May, and as a result of that discussion, a letter was sent to Pharmac expressing the groups concern about the kits performance, particularly:

- The initial packaging concerns
- The test was not performing as per the claims on the package insert as below.

> There has been limited validation work performed by diagnostic laboratories to date, however, during some workup, a small sample of five specimens was included with a level around 50 mIU/mL (which is twice the value of 25 mIU/mL that the product claims it detects), only one demonstrated a positive result (with one clear negative and three equivocal). The clinical implications of this is somewhat of a grey area, however, analytically, the product is not meeting the claims of its package insert. This raises further concerns as to how it performs at other concentrations and the potential impact of missing a pregnancy prior to a contraindicated procedure. More concerning is that these inadequacies have been detected in experienced laboratory environments, indicating that the problem could be even more widespread in the community.

Medsafe issued a monitoring alert 17th May 2016 which was revised on 9th June, which is included below.

EasyCheck hCG Urine Pregnancy Test Cassette –Invalid (Negative) and Inconclusive Results

17 May 2016
Monitoring finishes 26 November 2016
Medsafe has received several reports from Clinicians, DHB's, Clinics and community providers, describing a series of problems relating to false negative test results and technical faults.
Products Affected
EasyCheck Pregnancy Test Cassette
Additional Information
This test is funded for the use in rapid, one step testing for the qualitative detection of hCG in urine as an early detection of pregnancy from 10 days after conception. It is intended to be used as a first line check and followed up with a blood test to confirm pregnancy if there is any doubt.
Regulator Actions
Medsafe is continuing to monitor reports relating to this device.
Reporting
Consumers and healthcare professionals are encouraged to report problems with this product to Medsafe
Medsafe cannot give advice about an individual's medical condition. If you have any concerns about a medicine you are taking Medsafe encourages you to talk to your healthcare professional.

On 9th June 2016 a letter from the New Zealand Society of Pathologists was sent to Ministry of Health detailing their clinical concerns with the EasyCheck pregnancy kit and the lack of formal local clinical evaluation before its introduction, and also highlighting issues and challenges with point of care testing generally in New Zealand.

REFER TO APPENDIX 2

REFER TO APPENDIX 3

The issue was reported in the New Zealand Herald 9th June 2016, the reported responses from Medsafe and the Phoenix MedCare, the supplier, are below.

Medsafe says the cassette test is intended to be used as a first-line pregnancy check from 10 days after conception and followed up with a blood test to confirm pregnancy if there is any doubt.
Family Planning staff make frequent use of the cassette test, which is the only Pharmac-funded urine test for pregnancy, said the group's national medical adviser Dr Christine Roke. She was aware of a handful of cases in which the cassette test had not worked properly, including some false negatives.
"Mostly it's that they have been inconclusive so we've [retested]."
Phoenix managing director Brad Rodger said there was "one alleged report of a false negative" in December and one unconfirmed report of another in January. The company, which began supplying the cassette test kits last July, had supplied more than 500,000 since then.
"During this period there has been some minor feedback with tests showing incomplete control lines from isolated sites in a minor number. This is likely due to incorrect procedural or storage techniques. We have not been able to replicate this issue unless we purposely follow an incorrect testing method.
"In the 12 months to December 2015 there were [around] 2.94 million of this test type supplied worldwide, with no reportable adverse events.
"We do not know the cause of the two alleged false negatives. We were not supplied with this information when it was requested."
Medsafe compliance manager Derek Fitzgerald said: "When investigating claims of problems with medical devices, [options] may include fault with the product, user error or the need for user education. Recall of the product ... could be considered after further investigation."

Phoenix MedCare, then posted the following information on their website:

You may have seen an article in the NZ Herald on the 9th June regarding the efficacy of the EasyCheck Pregnancy Test Cassettes.

Following these reports of the efficacy of the product we have had 150 packaged cassettes tested by Labtec Scientific &Technical Services. These tests were selected randomly from four cartons to be tested at two variants of human chorionic gonadotropin (hCG). Of the 150 cassettes tested (at 25 and 100 mIU hCG /mL concentrations) all resulted in a visible 'T' line (and 'C' line) and were therefore correct. Our conclusion is that any false negative result is likely due to incorrect procedural or storage techniques. We have only been able to replicate this issue by purposely following an incorrect testing method such as shaking the product after the test has been taken.

> There are number of variants that can cause a false negative in a pregnancy test, these include but are not limited to testing too early in the pregnancy while hCG levels are low, unknown medical conditions and dilution of urine caused by excessive fluid intake. We provide full instructions to the health care professionals that administer these tests but understand sometimes these instructions are not adhered to.
>
> Phoenix MedCare works closely and with full transparency, honesty and integrity with the regulators and funders of medical devices in New Zealand and our focus is product quality and patient wellbeing. The notification to the Medsafe website is a positive step to encourage robust and thorough reporting to the regulators so if there is any product concern it can be fully investigated and the appropriate facts are available to both Medsafe and Phoenix MedCare.

In a follow up meeting of the chair of NZPOCTAG with the New Zealand manager of Phoenix MedCare, it was established that the evaluation mentioned above was performed on reference materials, which are not necessarily representative of the sample matrix presented by human samples. At that meeting it was requested that the company provide a number of kits to allow members of NZPOCTAG to perform a laboratory based evaluation. Phoenix MedCare have readily agreed to this and an evaluation is being organised, involving a number of laboratories around the country but to date there are no timeframes on when the evaluation will begin or be completed.

DHB Responses

The responses around the country have been varied.
Waitemata DHB laboratory clinical director sent the following memo recommending moving to laboratory testing:

> "We have made the decision with Ross Boswell and Andrew Brant to encourage the discontinuation of use of these kits as an interim measure until further investigations are complete, and switch to blood testing for B-hCG where this is not already in place. This is the gold standard testing modality anyway. As our Biochemist Ross Boswell stated:
>
> - The laboratory provides blood testing for B-hCG which is well-controlled and reliable.
> - The results are reported to Éclair and so are documented in the patient's record.

Waitemata report that some areas have continued to use urine testing against their recommendations, and have bought Innovocan for that purpose.
Auckland DHB issued a recall and sourced the Innocavon kits following two laboratory confirmed issues with the EasyCheck kit – one false negative result in a patient with a serum βHCG level of 1900u/L and one mechanical cassette problem. The POCT coordinator noted that since the recall other anecdotal incidents have been reported to him.
Counties Manukau have quarantined the EasyCheck kits and replaced with Innovacon kits.
Northland DHB have recalled the EasyCheck kits and replaced them with Innovocan, and also recommend where practical, that a βHCG is performed.
Canterbury DHB have recommended plasma βHCG rather than use an alternative kit.
Waikato DHB do not use EasyCheck, they use a urine meter to read the results on a kit relevant to that meter.
Capital Coast have issued an alert suggesting that if there are any doubts of the results using a pregnancy test kit it should be followed up with a serum βHCG.

All members of NZPOCTAG are aware that the same brand of kits are available In Primary Care, but the responses have all been based in Secondary Care.

Issues with Point of Care Testing

The difficulty with establishing real problems with any point of care testing is that it is performed outside the laboratory walls by people who are not laboratory staff, which makes follow up of possible issues difficult as they are often not reported immediately and processes and record keeping are often not ideal. There have been more possible issues reported since alerts were issued, but they are historical and anecdotal. There are only a handful of examples that have clearly been repeatable in the laboratory environment, considering that over 500,000 kits have been supplied, that number is very small.

All point of care testing is subject to influences not normally seen with laboratory testing and urine pregnancy tests are no different. The influence with the most impact on the result is the sample itself. Package inserts recommend that urine pregnancy tests are performed on an early morning urine sample to minimise any effect of sample dilution which will obviously affect the sensitivity of the test. However in the clinical settings where

this test is performed, it is more likely that a random urine sample will be used and so there is always the potential influence of sample dilution. Any dilution of the sample, particularly in early pregnancy when the levels are low, will make negative or equivocal results more likely.
While Innovocan is the test that most of the DHBs are reverting to, as it has been used for many years, it has never been subject to a full laboratory evaluation either. This lack of laboratory evaluation is part of the rational for those laboratories who have recommended moving to laboratory βHCG testing.

The lack of sensitivity of urine testing in early pregnancy is an issue. Many clinical staff are unaware of the limitations of point of care testing in this situation particularly when the sample provided is less than ideal.

> From the 1st August 2016, to avoid radiation exposure to a foetus, all female patients between the ages of 12-60 are required to have their pregnancy status determined on admission on the day of their surgery. If a patient indicates that they are unsure of their pregnancy status the admitting nurse will be required to test for pregnancy using the Easycheck Urine Kit. Once again they will need to send a blood sample to the laboratory which will delay the entire theatre list as described above.

The DHB needs to consider whether any urine pregnancy test is sensitive enough to detect early pregnancy in patients presenting to hospital, or if serum βHCG should be the test of choice.

A move to solely laboratory based testing will have implications for clinical areas as the current turn around time for laboratory based testing of an urgent sample is one hour. If this recommendation is followed, clinical areas will need to re-evaluate their processes to accommodate this increased turn around time.

Options for Consideration

The Laboratory Committee considered the following options

Option 1 – Continue with EasyCheck until there is a definitive evaluation.
This is the approach used at Capital Coast and is the approach suggested by MedSafe.

The benefits of adopting this approach are :

- The number of reported issues are small and mainly anecdotal
- The EasyCheck kits are the Pharmac provided kits and there is only 1% variance allowable in the contract, so there is a financial risk to going over the 1% allowable.
- All POCT testing is affected by sample variations and any results of concern, regardless of kit used, should be followed up by laboratory testing
- No pregnancy test kits have been laboratory evaluated for reliability and sensitivity in New Zealand.

The risks of this approach are :

- An unknown number of false positives and negatives leading to patient harm.
- Once the clinical areas were informed the kits were on the MedSafe watch list, a number of clinical staff expressed concern about the validity of the results and the continued use of these kits.

Option 2 – Continue using current stocks of EasyCheck until these run out and then replace with Innovocan.

The benefits of this approach are the same as stated above :

- The number of reported issues are small and mainly anecdotal
- The EasyCheck kits are the Pharmac provided kits and there is only 1% variance allowable in the contract, so there is a financial risk to going over the 1% allowable.
- All POCT testing is affected by sample variations and any results of concern, regardless of kit used, should be followed up by laboratory testing
- No pregnancy test kits have been laboratory evaluated for reliability and sensitivity in New Zealand.

The risks of this approach are :

- An unknown number of false positives and negatives leading to patient harm.
- Once the clinical areas were informed the kits were on the MedSafe watch list, a number of clinical staff expressed concern about the validity of the results and the continued use of these kits.
- Difficulties in managing the situation if there are different brands of kits being used in different areas.

Option 3 – Move away from POCT testing of pregnancy in the hospital to blood testing by laboratory

This is the approach of Canterbury Health Laboratory and the recommended approach at Waitemata, on the basis the laboratory test is the gold standard. This is a long term approach that is recommended by the Laboratory Committee for Secondary Care patients and high risk Primary Care patients.

The benefits in moving to laboratory testing are :

- All pregnancy test kits recommend early morning urine samples to minimise sample dilution issues however The clinical setting in which this testing is performed means that this recommendation is rarely followed
- No urine pregnancy test kits are as sensitive as laboratory testing in early pregnancy, which is where many of the critical decisions are being made.

The disadvantages would be

- The cost of laboratory testing is higher than the cost of the urine test kits
- There is turn around time of one hour in obtaining a laboratory result for urgent requests.

Option 4 –Withdraw Easycheck and replace with Innovocan until there is a definitive evaluation

The benefits of this approach are

- Clinical staff are more confident with the Innovocan brand
- Patient safety in the light of the reported issues with EasyCheck

The disadvantages are

- Possible penalty to the HBDHB because of the Pharmac contract
- There may still be the same sample dilution issues with Innovocan in early pregnancy

Recommendation – Hospital Services consider moving to Option 3, and Primary Care proceed with Option 1 until an evaluation is complete, but revert to a blood test in high risk situations.

Currently Secondary Care is following Option 4 in the short term, but the recommendation of the Laboratory Committee is that the DHB consider that all patients presenting to Secondary Care should be considered high risk for either maternal or (potential) foetal health, and that Option 3 should be followed, with urine pregnancy tests not offered at all in Secondary Care, and the laboratory based βHCG blood test be the only test available.

Currently the approach in Primary Care is that they should follow Option 1 until a definitive answer to an evaluation is obtained. In a situation where maternal or (potential) foetal health is at risk, a laboratory βHCG which is the “Gold Standard” should be performed. If the evaluation shows that there are demonstrated inadequacies with EasyCheck kits then the Pharmac response to that event should be followed.

Christine Hickton
Point of Care Quality Manager

29th July 2016

NORTHLAND DISTRICT HEALTH BOARD
Te Poari Hauora Ā Rohe O Te Tai Tokerau

Appendix 1

Report on EasyCheck Pregnancy Test Kit Issues

Report Commissioned by:	Dr Michael Roberts, Chief Medical Officer
Author:	Geoff Herd, Point-of-Care Testing Coordinator
Version 1	19 April 2016
Version 2	3 June 2016
Distribution:	Dr David Hammer, HOD Laboratory Services Vivien Goldsmith, Laboratory Services Manager Andrew Potts, General Manager Joanne West, Service Manager Margaret Broodkoorn, Director of Nursing Jeanette Wedding, General Manager Penny Mitchell, Clinical Product Coordinator, healthAlliance Dr Trish Mahoney, Contract Manager, PHARMAC Bronwyn Hale, Therapeutic Group Manager, PHARMAC Julie Lagan, Advisor – Medical Devices, Medsafe Vanessa Buchan and Mark Burnett, Convenors, NZPOCTAG Dr Samarina Musaad, Chemical Pathologist, NZSP

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Executive Summary

The PHARMAC funded EasyCheck urine pregnancy test kits became available for use by Northland providers in September 2015. At the time of writing, these point-of-care testing (POCT) devices are in use in NDHB hospitals and clinics and also in the community. This report describes a series of problems related to these devices including misleading packaging information (now rectified), false negative test results and technical faults.

In response to these issues, NDHB distributed a Patient Safety Alert to its hospitals and clinics and the two Northland Primary Health Organisations on 15 December 2015. Other organisations including healthAlliance, Phoenix MedCare (the local supplier), PHARMAC and Medsafe have also been advised.

To date NDHB has not received any reports of physical patient harm as a result of the issues with the EasyCheck kit but clinicians, medical management and laboratory staff remain concerned about its performance and clinical reliability. Therefore this report also includes the following list of recommendations.

Following notification of further incidents from Auckland DHB and Northland DHB, additional material (Appendix 6) was added to this report on 3 June 2016.

Recommendations

- NDHB will investigate the feasibility of changing to an alternative urine pregnancy test kit such as the Innovacon kit;
- PHARMAC should consult with the New Zealand Point-of-Care Testing Advisory Group and the New Zealand Society of Pathologists with regard to the selection and validation of devices prior to funding;
- PHARMAC should ensure that New Zealand accredited laboratories carry out validation of test kits prior to funding decisions;
- PHARMAC should ensure that suppliers carry sufficient stocks of more than one batch number of devices at all times in the case of problems with a single lot number;
- PHARMAC should consider the feasibility of more than one supplier of devices, so that if a fault is found, then an alternative device is available for use until the problem is rectified.

Introduction

This report presents the timeline and investigation into the issues and problems related to the PHARMAC funded, EasyCheck urine pregnancy test kit which was received by the Northland District Health Board (NDHB) in September 2015. The types of problems recorded to date have been of concern to clinicians, medical management and laboratory teams. This has cast doubt on its ongoing performance and clinical reliability, in particular for those settings where a blood test for B-hCG may not be practical or feasible. Patient welfare is paramount and patients have the right to appropriate standards of care[1] in this case, accurate pregnancy test results.

Methodology and Time Line

This report comprises a synopsis of telephone and email discussions with the New Zealand Point-of-Care Testing Advisory Group (NZPOCTAG), DHB clinical settings, community providers and healthAlliance staff who reported the problems along with a series of photographic images of the devices.

The report also includes correspondence with the other organisations involved in the supply and use of these kits, the NDHB responses to the issues as they occurred and the descriptions of the quality assurance activities undertaken. Copies of the relevant correspondence and the NDHB Patient Safety Alert are included in the appendices. A list of recommendations in included in the discussion and the executive summary.

Results

The timeline of events related to the EasyCheck kits is compiled below.

- ***1 July 2015 EasyCheck Package Insert and Packaging Errors***

  Southern DHB staff and the NZPOCTAG noted that the package insert and cassette package showed contradictory test result information (this correspondence is included in Appendix 1). The information leaflet contains the correct pregnancy test interpretative information as depicted in Figure 1. The cassette package shows an error with the interpretation whereby the image on the packaging depicts a valid result (control line only result) as an *invalid* result as shown in Figure 2.

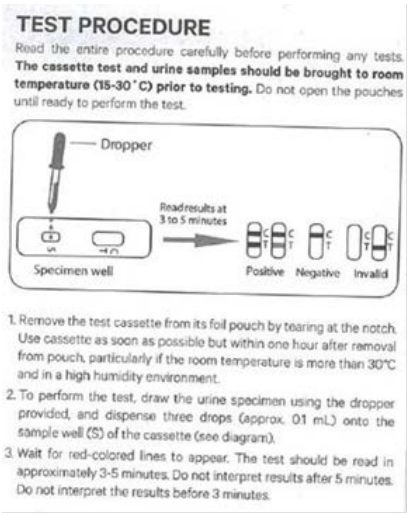


Figure 1 - EasyCheck package insert showing correct “Invalid” result interpretation

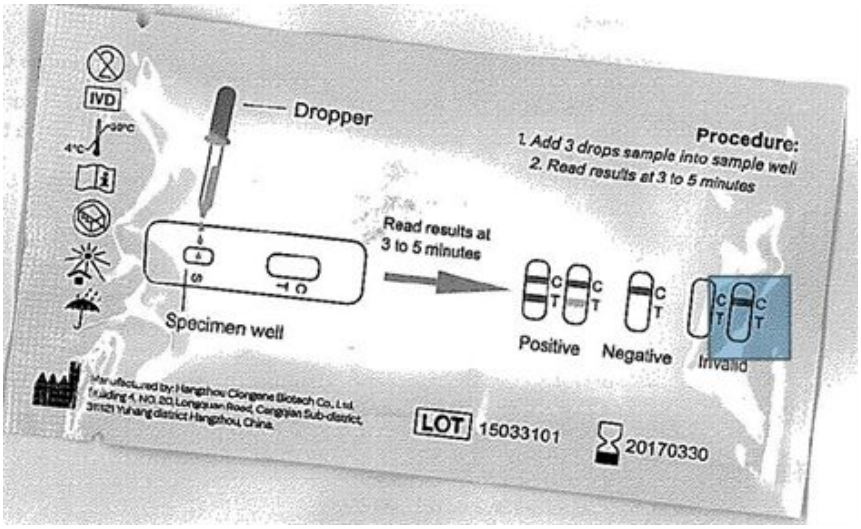


Figure 2 - EasyCheck packaging showing incorrect "Invalid" result interpretation

The instructions on the cassette packages are confusing, incorrect and misleading to clinical staff. The central interpretative diagram correctly states that a dark pink line in the Control zone next to the letter C in the absence of a line in the Test zone is a Negative result.

However, the diagram on right hand side of the package shows the same valid Negative pregnancy test result (i.e. only a Control line visible) as Invalid.

The local supplier, Phoenix MedCare and PHARMAC were notified about the interpretation error by Southern DHB on 1 July 2015. The packaging was relabelled with a white sticky label in order conceal the misleading information as shown in Figure 3 below. However, in doing so, all reference to Invalid results was obscured on the packaging. At the time of writing, the correct Invalid diagrams have been correctly printed on the packaging.

12.1

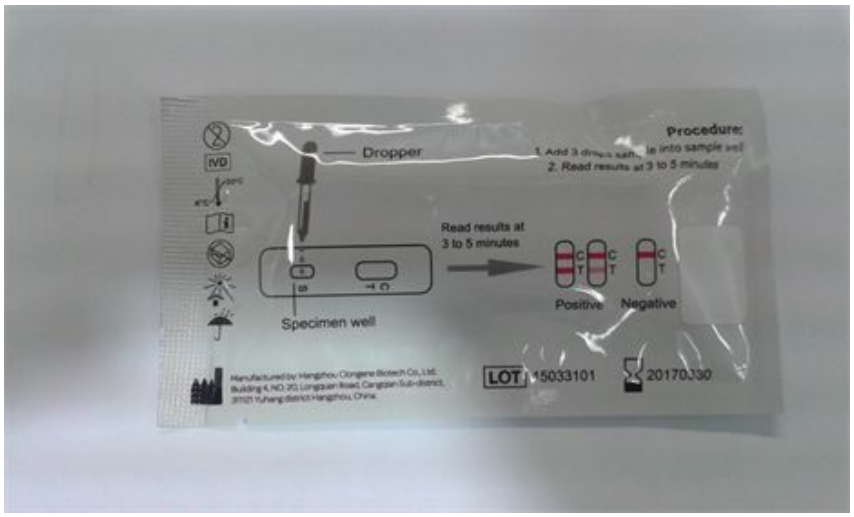


Figure 3 - EasyCheck packaging showing sticky label covering "Invalid" result interpretation error

- ***17 November 2015 Problems with EasyCheck Pregnancy Tests***

  The NDHB 123 Sexual Health Clinic staff reported some anomalous results. These included:
  - reports of false negative results in a pregnant patient;
  - reports of indistinct lines in the test zone;
  - two reports of the immune-absorbent pad not absorbing the urine sample correctly;
  - one report where the control line was not visible.

  These are experienced staff, so operator error is unlikely. No photographs were taken of these anomalous results but Quality Control (QC) checks on some cassettes of the same lot number 15033101, expiry date 30/3/2017 showed expected results. The staff were advised to continue using the device and to report any further incidents.

- ***10 December 2015 Problems with EasyCheck Pregnancy Tests***

  The NDHB 123 Sexual Health Clinic staff reported a more serious problem where the Control Line appeared to have slipped down to the Test Line zone because the immuno-chromatographic pad had moved inside the cassette. This sample was taken from a patient who was pregnant and the test was performed with a kit from the same lot number as previously reported. This cassette was photographed and the image is displayed below:

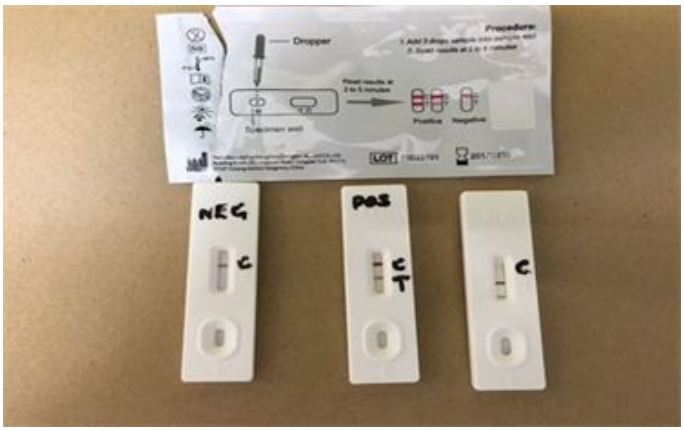


Figure 4 - The immuno-chromatographic pad appears to have moved inside the cassette

- ***11 December 2015 NDHB Response***

  In light of this December incident and the other incidents in November 2015, the Acting Chief Medical Officer and the Chief Medical Officer were advised and hospital staff were notified on 11/12/2015. healthAlliance procurement teams were advised and a Patient Safety Alert was distributed to DHB and Primary Health Organisation (PHO) personnel on 15/12/2015. A copy of the Patient Safety Alert is included in the Appendix 2.

  At that time NDHB had insufficient information to assess the scale of the problem. It was not known, for example, if other batch numbers were available or affected and if any other batch numbers had been subjected to laboratory validation. Therefore a batch recall at that time was not feasible. Clinical staff were advised to continue to use the EasyCheck kit and requested to report any anomalous results. Clinical staff using the EasyCheck kits were also advised to carry out plasma B-hCG testing, in addition to the urine pregnancy tests, where possible. It was realised that some departments, notably the Sexual Health Clinic and the Rawene Hospital in the Hokianga, did not have access to a plasma B-hCG assay. Therefore, all available stock of an alternative, urine based pregnancy test kit (the Innovacon kit) was secured so that parallel testing could be performed.

  healthAlliance staff notified Phoenix MedCare, PHARMAC and Medsafe about the problems. healthAlliance was asked to determine if the alternative Innovacon urine pregnancy test kit could be obtained as quickly as possible. On 21/12/15, NDHB received 18 boxes of the Innovacon kit. Quality control checks were completed and the Innovacon kits were delivered to the Sexual Health Clinic and Rawene Hospital. Staff were advised to test patient urine samples with both the EasyCheck and the Innovacon kit and to report any anomalous results.

- ***22 December 2015 Report of an Invalid EasyCheck Result from a GP***

  An invalid (? negative) result and correct positive result were reported by a GP from the Paramount Medical Practice in Whangarei. This sample was from a patient considered to be about six weeks pregnant. The photographs below show one cassette with a faint line in the control zone but no visible line in the test zone. The second cassette shows a positive test (i.e. correct result)

Figure 5 - Invalid result and (below)

Figure 6 - Positive test result from the same patient sample

- ***27 January 2016 Counties Manukau DHB Report via healthAlliance about EasyCheck Pregnancy test kits***

  This email report noted that staff at Counties Manukau DHB had reported issues related to "Phoenix EasyCheck Pregnancy Tests – Lot #15033101 … false negative readings if the test is read after 3 minutes". This email is included in Appendix 3. More detail was requested and a follow-up email dated 5/4/2016 stated that there had been no further issues.

- ***16 March 2016 Discussion with Dr Trish Mahoney and Bronwyn Hale from PHARMAC***

  The author outlined the issues with TM and BH from PHARMAC who confirmed that it had received an email from healthAlliance about the faulty EasyCheck product on 15/12/2015. TM and BH also had discussions with healthAlliance staff on 17/12/2015 about the issues raised by NDHB and also that NDHB had issued a Patient Safety Alert. PHARMAC also confirmed that healthAlliance had advised Medsafe on 16/12/2015. A copy of this email correspondence is included in Appendix 4.

- ***21 March 2016 Report received from PHO Clinical Director***

  This clinician described a false negative test, photographed below and also mentioned two other false negative tests in two young women who had attended the Youth Scape facility in Whangarei. The photograph below is significant because the quoted sensitivity of the EasyCheck kit and Innovacon kit are same i.e. 25 mIU/mL. [2,3] The three Innovacon cassettes on the left hand side of the image show clear positive results but the EasyCheck shows a clear negative result on this patient.

Figure 7 - Positive test result from the same patient sample using the Innovacon kit and a negative result using the EasyCheck kit

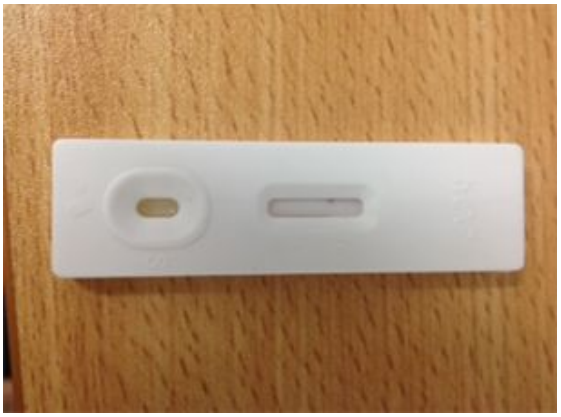
- ***23 March 2016 Meeting with Dr Michael Roberts, NDHB CMO and Dr David Hammer, NDHB Laboratory Head of Department and the author***

  The ongoing and recent problems with the EasyCheck kits are very concerning. It was resolved that NDHB would explore the feasibility of obtaining an alternative test such as the Innovacon kit and consider the change management process which would be required for Northland. An email to that effect was sent to healthAlliance personnel on 23/03/2016. Dr Roberts also requested the present report on the background and issues surrounding the EasyCheck kits at that meeting. The author collated the information to hand and also requested updates from the NZPOCTAG and healthAlliance. To date no further reports of anomalous results or problems have been received from NZPOCTAG or other DHBs.

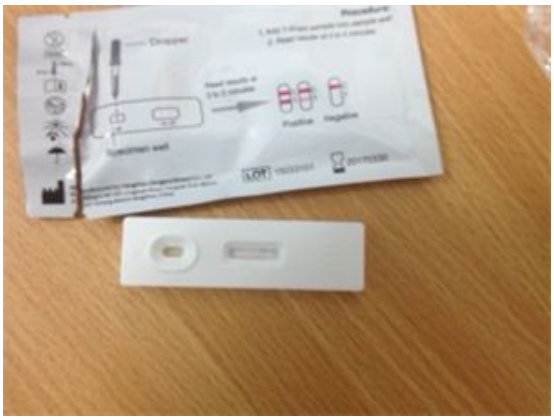
- ***15 April 2016 Email correspondence regarding false negative tests***

  This report, with photographs as depicted below, describes problems with false negative results and also cassettes with absent control lines. This report also mentions that, " … providers have no faith in these preg tests now, abdo pain becomes an ectopic until proven otherwise, so may increase ed referrals," which in turn increases uncertainty and anxiety for patients.

  Figure 8 (following page) depicts the photographs showing the faulty cassettes.



12.1



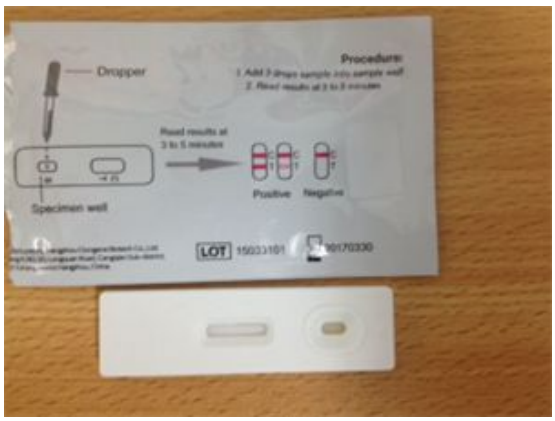


Figure 8 - EasyCheck cassettes showing invalid results

- ***2-3 June 2016 Email correspondence regarding false negative tests from Auckland DHB***

  This report, with photograph as depicted below, describes a faulty control line on a sample from a patient who was pregnant. Follow up tests on this sample showed three false negative results and a plasma β-hCG of 1900 IU/L.

  Figure 9 (below) depicts the photograph showing the faulty cassettes.

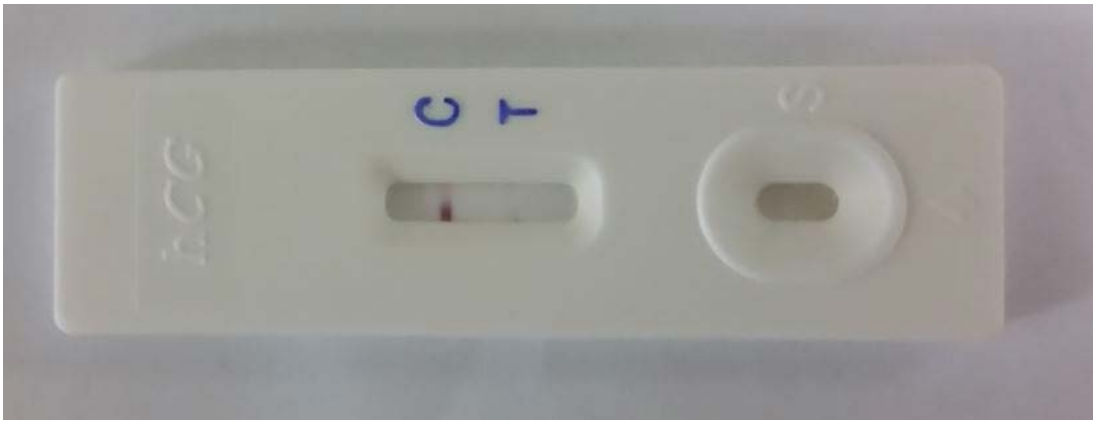


Figure 9 - EasyCheck cassette showing invalid result

In addition to the above, Northland DHB has become aware of two additional incidents whereby :

- A pregnancy test from an under-aged assault victim where the urine sample failed to absorb correctly on to the pad, and therefore the control line was not visible;
- A false positive urine test was reported on another patient and a follow up plasma β-hCG assay on this patient was negative.

12.1

Quality Assurance (QA) Programme

NDHB has carried out regular quality control (QC) checks on the current batch of EasyCheck kits, Lot Number 15033101 since their receipt on 9/9/2015 and also an alternative Lot Number 15083001, expiry 29/08/2017 since 24/12/2015. Quality control checks are also being carried out on the Innovacon kit Lot Number HCG4120030 Expiry 11/2016.

The QC checks, using commercial urine samples with known positive and negative reactivity, have been carried out at Whangarei Hospital. These tests showed that the position of the Control lines can vary slightly between cassettes but no instances were found where the pad moved to the extent that had been reported by Sexual Health Clinic staff. As part of the ongoing QA programme, staff at the 123 Sexual Health Clinic have also carried out parallel testing on urine samples from clients using both the EasyCheck and the Innovacon kits. Records of both test results for each client have been recorded and to date, 07/04/2016, no erroneous results or differences between the two kits have been found.

An additional component of the quality assurance programme is that the EasyCheck kit is continuing to be used in the Emergency Department (ED) at Whangarei Hospital along with plasma B-hCG tests. To date there have been no reports of discrepant results between the EasyCheck kit and plasma B-hCG tests on patient samples from the ED patients.

As of 3 June 2016 Northland DHB has continued to perform quality assurance tests on Lot No. 1511801 and has not to date found any anomalous results using the laboratory quality control material.

Discussion

This report documents a series of issues relating to the PHARMAC funded, EasyCheck urine pregnancy test kit. The report describes faulty interpretative information on the packaging (now rectified), false negative test results and invalid test results reported from within the NDHB and by community providers.

It is not known if the laboratory validation of the EasyCheck test kits was carried out by New Zealand accredited medical laboratories prior to the funding decisions. It would also be helpful for health providers if suppliers could carry sufficient stocks of more than one lot or batch number of devices at all times in the event of problems with an individual lot number. In addition, funding decisions should consider the feasibility of more than one supplier for devices so that if a fault is found, then an alternative device is available for use until the problem is rectified.

This report has two important limitations. Firstly, the relatively small number of anomalous test results and secondly the exact percentage of these anomalous results is unknown because of the large numbers of these tests which are performed by both DHB and community providers in Northland.

Notwithstanding with these limitations, it is fortunate that at the time of writing NDHB is not aware of physical harm to any patient as a result of the issues related to the EasyCheck product. NDHB is also concerned about clinicians' lack of confidence in the results, and that patients may need to be referred to an ED for assessment. In addition, these false negative results may cause anxiety for patients. NDHB is continuing to monitor the situation closely as part of its ongoing quality assurance programme for urine pregnancy testing and will report any further incidents to healthAlliance, PHARMAC and Medsafe.

Clinicians continue to express concerns about the problems with the kits and have requested an alternative. To that end, NDHB is currently exploring the feasibility of changing to an alternative test such as the Innovacon urine pregnancy test kit in the interests of patient safety.

Recommendations

- NDHB will investigate the feasibility of changing to an alternative urine pregnancy test kit such as the Innovacon kit;
- PHARMAC should consult with the New Zealand Point-of-Care Testing Advisory Group and the New Zealand Society of Pathologists with regard to the selection and validation of devices prior to funding;
- PHARMAC should ensure that New Zealand accredited laboratories carry out validation of test kits prior to funding decisions;
- PHARMAC should ensure that suppliers carry sufficient stocks of more than one batch number of devices at all times in the case of problems with a single lot number;

  PHARMAC should consider the feasibility of more than one supplier of devices, so that if a fault is found, then an alternative device is available for use until the problem is rectified.

References

1. The Code of Health and Disability Services Consumers' Rights 1996.
2. EasyCheck Pregnancy Test Package Information Leaflet 2015.
3. Innovacon Pregnancy Test Package Information Leaflet 2014.

Appendix 1 – 1 July 2015 EasyCheck Package Insert and Packaging Errors

From: Vanessa Buchan [mailto:Vanessa.Buchan@cdhb.health.nz]
Sent: Wednesday, 1 July 2015 2:54 p.m.
To: Vanessa Buchan; 'Geoff Herd (NDHB)'; Mark Burnett (CMDHB); Stephanie Williams (WDHB); Samarina Musaad; Andrew Meisner (ADHB); Bettina Heaton (ADHB); Steve Absalom (ADHB); Clarke,Lyn; Linley Hancock; Gloria Crossley [TDHB]; Denise Rowe [TDHB]; Clare Murphy [CCDHB]; Bernice Smith [HVDHB]; KAllan@apath.co.nz; Karen Allan; Felicity Taylor; Iona Lowrey; Roger Barton; Roger Ashton; Shelli Turner; Erin Retter; Alan Neal; Catherine Beazley; Eileen Chappell; z_Harry Major (WDHB); Don Mikkelsen (CMDHB)
Subject: FW: EasyCheck Pregnancy Test Instruction Error***PHARMAC***

Good afternoon all,

Further to the communication last week (Thanks Christine!!), please find below information from our supply department, who, along with others, have noticed inconsistencies in the packaging of the new product.

Our procurement team have arranged 40 kits for us to analyse. It would be fantastic for us to combine all of our results (realising the limitations of different testing methodologies etc) so if everyone could please indicate what validation is going on in their laboratory that would be fantastic.

Kind Regards

Vanessa Buchan
Interim Business Development Manager

Canterbury Health Laboratories
www.chl.co.nz | 0800THELAB

Check out the latest news at CHL - http://www.chl.co.nz/news

From: Karina Milnes
Sent: Wednesday, 1 July 2015 2:37 p.m.
To: Lesney Stuart; Vanessa Buchan
Subject: FW: EasyCheck Pregnancy Test Instruction Error***PHARMAC***

Hi Lesney and Vanessa
This explains the packaging issue a little more clearly then I sent through earlier. I have also attached an email from the supplier indicating they are stopping shipping of product until the packaging is sorted, however I think it is still good to ensure that it works for us.
Thanks

Regards,

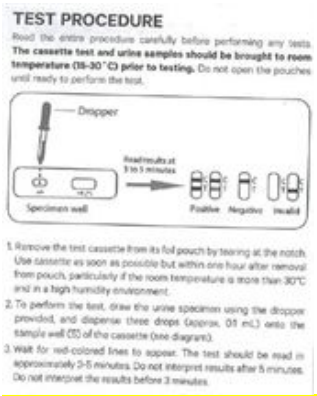
Karina Milnes, RN | Clinical Product Coordinator

Central Supply Department | Canterbury District Health Board

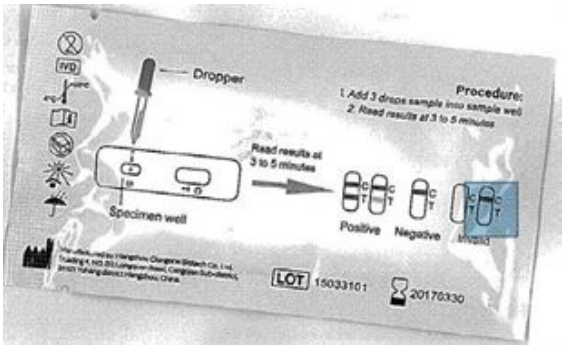
From: Liz Young [mailto:Elizabeth.Young@southerndhb.govt.nz]
Sent: Wednesday, 1 July 2015 12:20 p.m.
To: 'Brad Rodger'; 'Bronwyn Hale'
Cc: 'Julie Collins'; Karina Milnes; Chris Sutton; Jared Gray; Sandra Russell - Materials Mgmt (healthAlliance); 'Peter Barber [CCDHB]'; Maria Strachan; Carol Guise; Cathy Thomson [TDHB]; Chris Sutton; Elaine Jones [CCDHB]; Helen Cameron; Jeremy Price; Kathryn Powell; PEHNZ - Penny Mitchell; Rachael Palmer (healthAlliance); ricci.marks@schl.co.nz; steven.trotter@waikatodhb.health.nz; tina.emsden@healthalliance.co.nz
Subject: EasyCheck Pregnancy Test Instruction Error***PHARMAC***
Importance: High

Good Morning Brad

Thank you for your time on the phone regarding my concerns around the Test Procedure Instructions Error on the individual packets of Pregnancy Tests. The A4 Instruction sheet that comes in the box is correct stating the **" Invalid"** as being a dark pink line next to **"T".**



However, the instructions on the individual packets are incorrect and misleading to the clinician as it states that a**" negative" = (Dark Pink line next to C)" but also that an "Invalid" = (Dark Pink line next to C)"....** This is incorrect and should read **" Invalid = (Dark pink line next to T)"**



At a DHB level this is going to create a lot of confusion and noise from clinicians as the instruction is misleading and if they get a negative they could also believe they are getting an Invalid result, thus leading to the clinician needing to retest the patient. I am not happy to send the samples onto our clinical team until the instructions on the back of the individual packages are reading with the "Correct" instructions for use.

DHB's would order the product in Boxes of 40 from you, but once they arrive at the DHB/warehouse/3PL (depending on the individual supply chain distribution arrangements- we are all different) - - the Boxes then get broken down into individual eaches and then sent on to various departments within the organisation depending on usage. My concern is that not all areas will get the paper instructions and the correct instructions **MUST be on the individual packets too. To avoid any errors and confusion.**

I apologise for highlighting this issue and the headaches this is potentially going to cause your team, but I also wanted to let other DHB's know of the issue so they too don't end up with a disaster on their hands.

At this stage I would advise that we all put a hold on distributing the samples to clinical staff until a suitable resolution is agreed on.

We look forward to your response.

Kind regards
Liz

Liz Young | Regional Clinical Products Co-ordinator| Southern DHB
Private Bag 1921, Dunedin 9054, New Zealand | office: 03 470 9159 | mob: 027 444 0523 | elizabeth.young@southerndhb.govt.nz

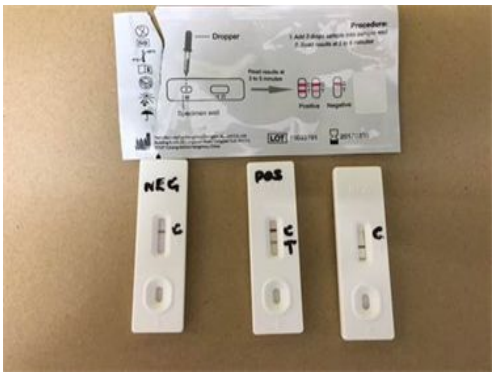
Appendix 2 – 15 December 2015 NDHB Patient Safety Alert

From: Dr Jennifer Walker, Acting Chief Medical Officer
Dr Andrew McClelland, Chairman, Laboratory and Transfusion Committee
Geoff Herd, Point of Care Testing Coordinator
Date: 15 December 2015

The purpose of this alert is to provide frontline health professionals and managers with information on high-risk actions that have the potential to cause serious or catastrophic harm to patients. The intention is to raise awareness of the potential harm and provide a strategy for local level response.

The Problems

NDHB is aware of two reports whereby the Control Line was not visible in the Control Zone of the cassette, after the three drops of urine have been added to the cassette. In one instance, this problem has occurred because the absorbent pad has slipped down inside the cassette so that the Control Line reactions appear in the Test Zone of the cassette rather than the Control Zone. As depicted in the attached image below:



In one of these cases the patient was pregnant which was confirmed by using an Innovacon kit and clinical examination.
In another report, a patient who was pregnant showed false negative results using three EasyCheck cassettes but showed a positive result using an Innovacon cassette.

Immediate Actions

Please ensure that all relevant clinical staff in your area are aware of the potential for anomalous results using the Easy Check Urine Pregnancy Test kit.
Where practicable, please ensure that all negative urine pregnancy tests are checked by sending a blood sample to the laboratory for plasma B-hCG testing.
Please notify Geoff Herd, Point-of-Care Testing Coordinator if you have any reports of anomalous results with the Easy Check test Kit; mobile 021 973 441 or #9152

Appendix 3 – 27 January 2016 Email report from Counties Manukau DHB with regard to EasyCheck pregnancy test kits

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From: Penny Mitchell (healthAlliance)
Sent: Wednesday, 27 January 2016 2:31 p.m.
To: Lisa Purcell (CMDHB)
Cc: Mark Burnett (CMDHB); Geoff Herd (NDHB)
Subject: Phoenix EasyCheck Pregnancy Test

Hi Lisa

Thank you for bring to my attention the issues that you are having with the Phoenix EasyCheck Pregnancy Tests – Lot #15033101
From my understanding you are getting false negative readings if the test is read after 3minutes.

Towards the end of last year NDHB also experienced some issues with these tests (Lot #15033101) which is currently being investigated. It was believed that the test strip had actually slipped down within the cassette obscuring the control line. This meant that when only line was showing, this was being mistaken as the control and not a positive reading.

I have been in contact with the supplier and they have asked me if you could provide some more information:

1. Please could you provide a bit more detail around the test and the issue that you are experiencing?
2. Have you filled in any incident reports reporting the false negative readings?
3. These tests are designed to read hCG in the urine when it is greater than 25mu
    a. Are you restesting the patients who are getting negatives and what test method are you using
    b. What is the patients hCG reading when you are retesting if they are pregnant

Kind regards

Penny Mitchell - Clinical Product Coordinator
Procurement and Supply Chain

Mobile 021 894 179
Fax 09 579 1426
For New Product Requests, please forward to: clinicalproduct.coordinators@healthalliance.co.nz

Appendix 4 – 18 March 2016 Email correspondence: Dr Trish Mahoney & Bronwyn Hale PHARMAC

From: Geoff Herd (NDHB)
Sent: Wednesday, 16 March 2016 4:29 p.m.
To: 'Trish Mahoney'; 'Bronwyn Hale'
Cc: Michael Roberts (NDHB); David Hammer (NDHB); Vivien Goldsmith (NDHB)
Subject: RE: 2016-03-16 EasyCheck pregnancy tests - to Geoff Herd (NDHB)

Dear Trish and Bronwyn,

Thank you for the opportunity to discuss the issues related to the Easy Check test kits and also for the time line of events.
There is one point in your email I would like to clarify. "HA said that it would be purchasing an alternative pregnancy test kit at the request of NDHB due to the funded EasyCheck being a faulty product and NDHB would not be using the EasyCheck pregnancy tests".
At the time NDHB issued the Patient Safety Alert, we were very concerned about the technical problems and the potential clinical risks. In addition, we had very limited information about the cause(s) and the extent of the problems. We had no information about the availability of alternative batches of EasyCheck kits, or laboratory validation data on the performance of other batches, or if other batch numbers were affected. So a Northland wide recall at that time was not practical.

Therefore, it was decided that NDHB hospitals and departments which had access to a laboratory based, plasma B-hCG test would continue to use the urine based EasyCheck tests along with follow-up plasma B-hCG tests to confirm the EasyCheck results as required. This is an important element of the ongoing quality control programme.
The Innovacon kit was purchased as a back-up kit for the EasyCheck tests for two providers, the Sexual Health Clinic and Rawene Hospital because these providers do not have access to on-site, laboratory based plasma B-hCG testing. Both providers are continuing to carry out duplicate testing using both kits until further notice.

As I explained, we are continuing to monitor the performance of the EasyCheck kit and we will keep you informed about progress and decision making.
Thanks again for your update and for affirming that NDHB can contact you at any time about PHARMAC funded products.

Kind regards,
Geoff

Geoff Herd
Point-of-Care Testing Coordinator
Phone +64 21 973 441

From: Trish Mahoney [mailto:trish.mahoney@pharmac.govt.nz]
Sent: Wednesday, 16 March 2016 9:19 a.m.
To: Geoff Herd (NDHB)
Cc: Bronwyn Hale
Subject: 2016-03-16 EasyCheck pregnancy tests - to Geoff Herd (NDHB)

Dear Geoff
I appreciate your time today to speak with us around the EasyCheck pregnancy tests.

I am happy to be contacted about any issue that relates to a PHARMAC funded product at any time, and apologise that we did not connect at an earlier date around the Easy Check issues. I look forward to an update regarding Northland DHB (NDHB) evaluation of the EasyCheck pregnancy tests, at a time when you are able.

I can confirm that on 15 December 2015, PHARMAC staff received an email from Health Alliance (HA) relating to a faulty product report from Northland DHB regarding the EasyCheck pregnancy test kits.

On 17 December 2015, Bronwyn Hale and Trish Mahoney had a discussion with a representative from Health Alliance (HA) and we were advised that NDH) had identified issues with the EasyCheck pregnancy tests, and that NDHB had issued a *safety alert* for the EasyCheck pregnancy kit. HA advised that it would be dealing with the issue as it was a faulty product issue and that NDHB wanted HA to be the contact for Medsafe and PHARMAC.

HA said that it would be purchasing an alternative pregnancy test kit at the request of NDHB due to the funded EasyCheck being a faulty product and NDHB would not be using the EasyCheck pregnancy tests. HA confirmed that the supplier Phoenix Healthcare had not been contacted. PHARMAC staff advised HA to contact the supplier to discuss the issue. HA also advised that it had conveyed information to Medsafe about the issue on 16/12/2015.

Kind regards
Trish
Trish Mahoney PhD | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: +64 4 916 7542 | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

[SEEMa

Appendix 5 – 15 April 2016, Faulty tests all from the same batch number, 15033101 exp 30 March 2017

From: Aniva Lawrence [mailto:AnivaL@manaiapho.co.nz]
Sent: Friday, 15 April 2016 5:07 p.m.
To: Geoff Herd (NDHB)
Subject: Fwd: Faulty preg tests

Hi Geoff,
See below more faulty tests all from the same batch number these are no
15033101 exp 30/03/2017. These are not even showing a control line and as u can see several were done..

The same GP said that she had a case that changes how u manage a pt due to it being Friday she wouldn't get an hcg back via blood and because our providers have no faith in these preg tests now abdo pain becomes an ectopic until proven otherwise so may increase ed referrals.

[Sentence omitted for confidentiality reasons]

Appendix 6 – 3 June 2016, Faulty tests reported by Auckland DHB from batch number, 15011801 exp 17 November 2017

Hi Andrew,
Thank you for this comprehensive report on the false negative test results obtained on this pregnant patient. I will add this to the Report I compiled in April.

It is very concerning that a second DHB in this region has well documented evidence of false negative test results in a pregnant patient. In addition, these false negative test results were obtained on lot number 15011801. The original lot number which caused problems in Northland was 15033101.

As discussed, I will send this information to our Chief Medical Officer, the Chair of the Clinical Product Committee and the health/Alliance team.

A few minutes ago this morning, I received a verbal report from our Sexual Health Clinic another faulty cassette. I have requested that the cassette and urine sample is traced and to be sent to me for follow-up.

Mike, perhaps we should consider sending a Patient Safety Alert to the Northern Region clinicians, now that we have a second lot number involved?

NDHB has decided to change to the Innovacon kit and hopefully this will be implemented shortly. I will update you on developments.

Thanks again for your advice on this.

Kind regards,
Geoff

Geoff Herd
Point-of-Care Testing Coordinator
Northland District Health Board
Phone +64 21 973 441

From: Andrew Meisner (ADHB)
Sent: Thursday, 02 June 2016 3:38 p.m.
To: Geoff Herd (NDHB)
Cc: Erin Retter (ADHB); Roxane Benney (ADHB); Chris Finlay (ADHB)
Subject: Pregnancy test issue

Hi Geoff,

As discussed, please see below and find attached an image of a urine pregnancy test performed on a POCT urine pregnancy test (lot 1511801, expiry 20171117) which the users found to be in error.

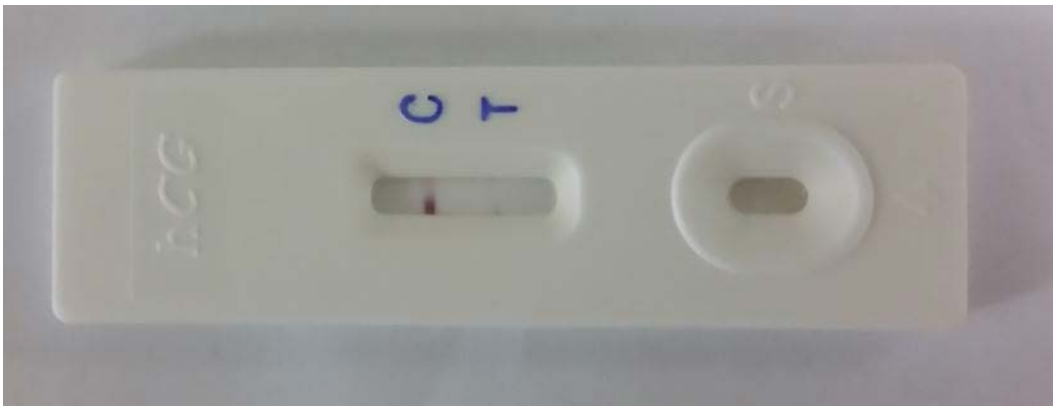
The situation occurred in Adult Emergency Department (AED) in Auckland City Hospital. I was made aware of this on 02/06/2016.

The facts as they have been verbally relayed to me are:

- A urine pregnancy test was performed on a 3rd trimester pregnant female in the AED department
- The result appeared negative
- A blood sample sent to the laboratory returned a positive result (I don't know at this stage which test was performed first)
- 3 subsequent urine pregnancy tests on the same sample appeared negative
- A urine pregnancy test using a device from another box (the same manufacturer) showed strongly positive

- The remaining box of the test kits that gave the negative result was withdrawn from use and the Point of Care Testing (POCT) service was contacted at this stage.

- This event will be recorded via a Risk Monitor Pro event which presumably will include POCT and LabPLUS Quality.



- The image above and attached is the actual pregnancy test cassette that gave the apparent negative result (on the patient whose laboratory blood result was positive). I have highlighted the control (C) and test (T) areas of the test for clarity. I note only a partial colour band for the control and perhaps a tiny amount of colour in the test area.

The POCT service will investigate further (I have the remains of the box of pregnancy test kits) when the Risk Monitor Pro comes through.

I understand you have seen a few issues with the kits from this particular manufacturer and you are welcome to add any details to your 'list'.

Thanks Geoff,

Andrew Meisner
Clinical Chemistry Technical Specialist
Point of Care Testing
LabPLUS
(09)307-4949 ext 22004
021-442-406

12.1

NZSP
NEW ZEALAND SOCIETY OF PATHOLOGISTS
PO Box 9115
HAMILTON 3240

Appendix 2

9 March 2016

Dr Anne Kolbe
Chairperson
National Health Committee
Ministry of Health,
PO Box 5013
WELLINGTON

Dear Anne

Thank you for engaging and for a constructive meeting in Queenstown on 17 September 2015. The NZSP recognises that the practice of point-of-care testing (POCT) is not regulated in New Zealand which poses risks to patients' wellbeing.

This correspondence is meant to be concise so please refer to the articles listed below for further clarification and details on the challenges and proposed solutions for POCT in New Zealand.

Definition: POCT is diagnostic testing performed outside the laboratory *and near* the patient, e.g. emergency department, intensive care unit, general practice, ambulance, home….etc. Modern medicine both in hospital and in the community is impossible without POCT.

Needs: Faster results provided by POCT can enable earlier management decisions facilitating better operational outcomes, e.g. turn-around-time, better fiscal outcomes e.g. reduced rate of hospital admissions/re-admissions, improved patient engagement and better clinical outcomes, e.g. longer time in therapeutic range for patients on warfarin. It also improves access to health services for "hard-to-reach" populations. Patient's expectations of the health system and the recognition that care needs to be centres around patients rather than institutions also drive the need for POCT.

Challenges: The advantages of POCT dictate challenges which are different from traditional laboratory testing. These include:

1. The diversity of users who may not have laboratory training or may have low health literacy;
2. IVD representatives – literally "knocking on practitioners' doors". Clinicians are experts in their fields and would want reliable and accurate devices but they are not trained to evaluate/validate/verify the clinical reliability of devices. POCT can appear to be deceptively simple to use, *"as long as they perform quality control (QC) should give them correct results"* but is not without risk;
3. Assumptions and limitations of POCT which are based on ignorance about basic laboratory techniques and risk management processes.

Status Quo: The NZPOCTAG has created a small database of POCT devices which have been evaluated and most of which are in use throughout New Zealand. There is no formal registry of diagnostic devices because registration is not compulsory.

Practices can be notoriously different, e.g. clinical and scientific oversight, quality management, risk management, needs assessment and alignment of POCT results with those for an accredited laboratory for the same analytes.

Gaps and areas that need to be addressed:

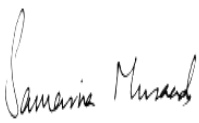
1. A national model for funding, regulation and registration of POCT devices and their intended use (tests) in New Zealand[1].
2. Where practicable, accreditation for POCT in hospitals, pharmacies, primary care etc[2]. Ideally all/any POCT practices should be accredited.
3. A model for training and accreditation for services which provide devices and tests used by patients in the home environment and an easily accessible support system for patients.
4. A national service for the evaluation of devices[2].
5. A national adverse event management system for POCT[3]
6. Continue engagement with NZSP and the NZPOCTAG with regard to POCT.

Examples (non-exhaustive) POCT schemes in New Zealand include the Community Pharmacist-led Anticoagulation Management System (CPAMS)[4], the implementation of POCT at Rawene Hospital[5,6] and the Chatham Islands.

References

1. Point-of-care testing governance in New Zealand: a national framework. Samarina M A Mussad, Geoff Herd, *NZMJ 27 September 2013, Vol 126, No 1383, ISSN 1175, 8716*
2. Point-of-care testing: High time for a dedicated Adverse Event Monitoring System: Commentary. Samarina M A Mussad, Shoukat Ali Khan, Geoff Herd, *Clin Biochem Rev 36 (1) 2015*
3. Clinical governance and point-of-care testing at health provider level: Viewpoint. Geoffrey Herd, Samarina Musaad, *NZMIJ 3 July 2015, Vol 128, No 1417, ISSN 1175-8716*
4. Shaw J, Harrison J, Harrison J, (2011). Community pharmacist-led coagulation management service: final report: School of Pharmacy, Faculty of Medical and Health Sciences, University of Auckland, Auckland.
5. Blattner K, et al. Changes in clinical practice and patient disposition following the introduction of point-of-care testing in a rural hospital. *Health Policy 2010A:96:7-12.*
6. Blattner K, et al. Introducing point-of-care testing into a rural hospital setting: thematic analysis of interviews with providers. *J Primary Health Care* 2010b;2(1):54-60.

Yours sincerely



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NZSP
NEW ZEALAND SOCIETY OF PATHOLOGISTS

Appendix 3

9 June 2016

Mr Derek Fitzgerald
MINISTRY OF HEALTH

Dear Derek

It came to the NZ society of Pathologists (NZSP) attention that a urine pregnancy test kit EasyCheck® has demonstrated significant technical and analytical errors. Although most results it produced were acceptable, the number and nature of the errors is such that patient care may be compromised. This kit has been rolled out to DHBs and the community last year (2015) as a funded urine-testing kit for the diagnosis and screening of pregnancy.

To our knowledge there has not been any formal local evaluation for this kit to date and there was no consultation with stakeholders before implementation of funding. Point-of-care testing is an indispensable form of laboratory testing. Due to its nature it entails tailored processes and often more rigorous measures than conventional laboratory testing to ensure safe and effective testing.

False results can lead to adverse incidents e.g. administration of chemotherapy or exposure to radiation during radiological procedures, or administration of drugs contraindicated in pregnancy…etc. Accordingly, due to the type of errors and their frequency it is our view that this kit is not safe for utilization by the NZ community at this point in time.

We attach a report issued by NDHB that highlights some of the problems encountered with the kit. We also attach a letter the NZSP has sent to Medsafe and PHARMAC recently highlighting challenges faced by POCT generally in New Zealand. The Royal College of Pathologists of Australasia (RCPA) has a firm stance with regards to POCT and its quality requirements as underscored in the RCPA position statement attached. Best practice guidelines written by the NZ Point of Care Testing Advisory Group and adapted to local needs are also attached.

The NZSP is keen to promote safe POCT practices which include regulatory processes and local validation of tests/devices/kits that are considered for the NZ market.

Thank you for your consideration

Ian Beer	**Michael Dray**	**Samarina Musaad**
President	**Vice President**	**POCT spokesperson**

12.1

New Zealand Society of Pathologists
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OURHEALTH
HAWKE'S BAY
Whakawateatia

Recommendation to Exclude the Public

Clause 32, New Zealand Public Health and Disability Act 2000

13

That the public now be excluded from the following parts of the meeting, namely:

14. Minutes of Previous Meeting (Public Excluded)

15. Matters Arising – Review of Actions (Public Excluded)

16. Letter received from CAG on Governance Matters (not discussed Sept)

17. Member Topics of Interest

The general subject of the matter to be considered while the public is excluded, the reason for passing this resolution in relation to the matter and the specific grounds under Clause 32(a) of the New Zealand Public Health and Disability Act 2000 for the passing of this resolution are as follows:

- Official Information Act 1982 9(2)(ba) to protect information which is subject to an obligation of confidence.
- Official Information Act 1982 9(g)(i) to maintain the effective conduct of public affairs through the free and frank expression of opinions between the organisation, board and officers of the Minister of the Crown.
- NZPHD Act 2000, schedule 3, clause 32(a), that the public conduct of the whole or relevant part of the meeting would be likely to result in the disclosure of information for which good reason for withholding would exist under any of sections 6, 7 or 9 (except section 9(2)(g)(i) of the Official Information Act 1982).