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Water quality parameters in relation to Chronic Kidney Disease in Sri Lanka

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Abstract

In Sri Lanka, high concentrations of certain water quality parameters in drinking water are assumed to be causing Chronic Kidney Disease (CKD). North Central Province (NCP) in Sri Lanka reports the highest number of CKD patients and mortality rates. The reported research herein concentrates on re-examining diverse causative factors identified by previous researchers on CKD and analysis of water quality in samples from shallow wells supplying drinking water to CKD patients and non-patients in NCP. The samples were tested for a number of parameters such as anions, cations, and heavy metals. These include Cadmium (Cd), Sodium (Na), Calcium (Ca), Fluoride (F) and Chloride (Cl) which previous researchers have suggested as causative factors for CKD. The preliminary analyses of data indicated majority of water quality parameters collected from the study area did not exceed the WHO drinking water quality standards. The critical water quality parameters that could cause the CKD were investigated using Factor Analysis techniques. From the water samples collected from the CKD patients drinking water wells, the parameters of Na, Cl, (Magnesium) Mg, F and Ca could be grouped into one Factor and considered as hydro-geologically originating. Another Factor which could be due to nutrients from fertilizer was identified consisting of (Nitrate) N and Phosphate (P) whereas Cd was grouped into a single Factor. In contrast, the water quality parameters in water samples collected from CKD non-patients drinking water wells were different and could not be clearly grouped into any special category except F was grouped into a single Factor. It could be considered that Fluoride by itself may not be the contributing factor for CDK. However, Fluoride combined together with other variables as identified in Patients samples could be contributing to CKD.

Keywords: Chronic Kidney Disease (CKD), North Central Province (NCP) in Sri Lanka, CKD Patients, Water Quality Analysis, Statistical Analysis, Factor Analysis

1. Introduction

Chronic Kidney Disease (CKD) has become a serious medical concern in Sri Lanka. North Central Province (NCP) in Sri Lanka reports the highest number of CKD patients and mortality rates due to CKD. NCP consists of two administrative divisions namely Polonnaruwa and Anuradhapura districts. Anuradhapura District reports the highest number and Polonnaruwa District reports the second highest number of CKD patients (Poulter and Mendis, 2009). It is estimated approximately 3000 had died between the years of 2003 to 2008 (Edirisuriya, 2010) by CKD and the present number of patients estimated to be around 15,000 (Johnson et al. 2012).

More than 65% of the people in NCP depend on basic farming for living (Lasantha, 2008). Anuradhapura and Polonnaruwa districts fall under dry agro-ecological zone of Sri Lanka with an average annual precipitation of 960mm. Most of the precipitation is brought by the North-East monsoonal rains which fall in the months from October to March. During the dry period lasting approximately for eight months, farmers depend on surface water which includes more than 3000 medium and large scale irrigation tanks in NCP (Karunaratne, 1983). NCP has hard rock or crystalline basement complex of rocks which are well known for their very limited shallow groundwater aquifers (Panabokke, 2003). Groundwater is the main drinking water resource and more than 85% of the drinking water requirements for the rural communities which are obtained from shallow and deep wells (Lasantha, 2008). The shallow groundwater sources are known to benefit by seepage from small tank cascade systems located upstream (Panabokke, 2003).

One of the suspected chemical contaminants to cause CKD in Sri Lanka is Fluoride (F). High Fluoride levels (above 1.5mg/L) in well water in the NCP had been observed as far back as 1976 and subsequent studies have shown that 40% of wells in NCP were rich in Fluoride and a number of 456 deep tube wells in Anuradhapura district has also been found with Fluoride contents ranging from 0.78 to 2.68 mg/L (Lasantha, 2008). Previous studies have shown even in low doses (of 7.5mg) of F over long periods of time (example 100 days) can make morphological changes in kidneys (Manocha et al., 1975) and also chronic exposure to F leading to inflammatory response in kidneys in mice (Greenberg, 1986).

Another cause of CKD explained by Chandrajith et al. (2011) is Sodium/Calcium (Na/Ca) ratio in drinking water with high levels of Fluoride. Accordingly, with high Na in the presence of F in water is said to form Sodium Fluoride ($NaFl_2$) which is soluble in water which does not cause Kidney Tubular Damage. On the other hand with high Ca in the presence of F, Calcium Fluoride ($CaFl_2$) is said to form which is insoluble in water causing Kidney Tubular Damage (Chandrajith et al. 2011). Thus high Ca concentrations compared to Na concentrations in drinking water are said to be influencing CKD. They have further shown a Na/Ca ratio in a range of 1.6 to 6.6 in the CKD endemic areas and a range between 35 and 469 in the non-endemic regions.

This is supported by the fact that in Anuradhapura District, 34% of the wells exceed the maximum desirable level of 100mg/L of Ca in drinking water and also 8% of the wells exceeding the maximum permissible level of 240mg/L (Lasantha, 2008), leading to high Ca concentrations in water.

Heavy metal pollution is a recent concern for CKD in Sri Lanka and Arsenic and Cadmium (Cd) are mainly suspected as heavy metal pollutants (Johnson et al. 2012) suspected to be originating from agrochemicals (Wijewardena, 2012). A research by Bandara et al. (2008) had shown that Cd concentrations between 0.03 to 0.06 mg/L in dissolved form in certain irrigation tanks of NCP. Since then Chandrajith et al. (2011) have shown that there is hardly any Cd in drinking water sources in NCP.

A relationship between Fluoride and Aluminum utensil usage have also been established by Herath et al. (2005) concluding Aluminum and Fluoride in combination could be a another factor to cause CKD in areas with high Fluoride in groundwater. They have concluded that Aluminum leaching is higher when the Aluminum pots are used for cooking using acidic ingredients.

Research objectives of the current study included identifying main sources of contaminants of drinking water which are suspected to cause CKD. The paper reveals in its introduction, the background into the problem. The materials and methods applied for chemical and statistical analyses are also described. Descriptive statistical results are shown in graphical form comparing the chemical parameters with WHO recommended levels. The Factor results showed the chemical parameters of water which are correlated to each other in water samples collected from patients and non-patients drinking water wells. Conclusions were based on the Factor and the descriptive statistical results.

2. Description of Sample Collection

A list of CKD patients was obtained from the Health Registry of CKD endemic area. Out of them random patient households were visited and water samples obtained directly from their drinking sources. They were named as 'Patient' samples. From the same area, random households with members not having CKD were selected and drinking water samples were obtained from their water sources. They were named as 'Non-Patient' samples. Those Patient and Non-Patient drinking water sources were shallow wells but two Patient samples were drawn from tube wells. Those sample locations were Medawachchiya Village Division in Anuradhapura District and Medirigiriya Village Division in Polonnaruwa District. Another set of samples were obtained from a CKD free area namely Gampaha District from shallow wells used for drinking. When choosing sampling water sources, those which have been used for more than 10 years for drinking by CKD patients or non-patients were selected. Sample collection was carried out between December 2010 and August 2011. The patient and non-patient water samples were grouped as: Polonnaruwa Patients (P-POL) and Non- Patients (NP-POL); Anuradhapura Patients (P-ANU) and Non- Patients (NP-ANU) making four total groups

from CKD endemic area and Control group from CKD free area of Gampaha (C-GAM). Those five groups were considered in statistical analysis (Figure 1).
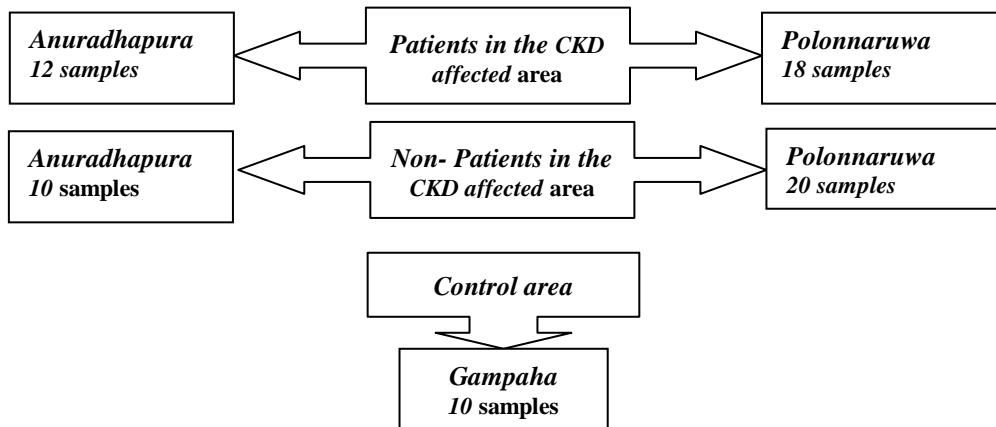
| Anuradhapura 12 samples | ◁— | Patients in the CKD affected area | —▷ | Polonnaruwa 18 samples |

| Anuradhapura 10 samples | ◁— | Non- Patients in the CKD affected area | —▷ | Polonnaruwa 20 samples |

Control area

Gampaha 10 samples

Figure 1: Water Sample Collection Locations

3. Chemical Analysis

Chemical parameters of water samples were tested in a commercial laboratory namely SGS Laboratories Pvt. Ltd in Colombo. Preservatives of HNO_3 and H_2SO_4 were added to the samples before transporting them to the lab for chemical analysis. Chemical parameters analyzed were Chloride (Cl), Fluoride (F), Nitrate (N), Phosphate (P), Calcium (Ca), Magnesium (Mg), Sodium (Na) and Cadmium (Cd). Other Chemical parameters were not analyzed due to resource constrains. Test Protocols used by the lab include: 3120 APHA 21st ED for Cadmium, Sodium, Magnesium and Calcium; 4500 APHA 21st ED for Fluoride, Chloride and Total Phosphorus; 4500 APHA 21st ED for Nitrate.

After chemical analysis, the levels of parameters in each sample category were compared with World Health Organization (WHO) standards. WHO standards were used for comparison of chemical variables as those values are the basis for regulation and guidelines for drinking water in developing and developed countries.

4. Factor Analysis

Factor Analysis was carried out to find whether any of the water quality parameters can be grouped into factors depending on their interdependency as it is used to identify factors that statistically explain the variation and co-variation among variables (Green and Salkind, 2005). This technique is applied by many researchers to characterize and evaluate groundwater and surface water quality data (Kumar and Singh, 2010; Guan et al. 2005; Yidana, 2008). Factor Analysis identifies a group of parameters correlated to each other and combines them into factors which are independent of variables in another factor. Factor Analysis was carried out

for all Patient and Non-Patient data from the CKD endemic area of Anuradhapura and Polonnaruwa. Factor Analysis was not carried out for data from the Control area (Gampaha).

5. Results and Discussion

5.1 Descriptive statistics

Descriptive statistical results included average, median, maximum and minimum. The maximum and average values of each chemical parameter in each sampling group were compared with WHO recommended water quality standards (Figure 2).

Although the literature suggests that F concentrations are high in the NCP of Sri Lanka, only one sample (out of 60 samples collected for the CKD endemic area) of P-ANU exceeded the WHO standard of 1.5ml/L. The samples from the Control area (Gampaha) had the lowest levels of F.

In Cl levels, five out of twelve Patient samples and one out of ten Non-Patient samples exceeded the WHO standard (250ml/L) in Anuradhapura. However, none of the samples in Polonnaruwa have exceeded the WHO standard. Furthermore, the concentration levels of Cl in Gampaha Control area was almost the same as in samples collected from the Polonnaruwa District. With regard to Na, two P-ANU samples exceeded the recommended WHO standard of 200mg/L but NP-ANU samples did not exceed this limit. None of the samples from Polonnaruwa exceeded the WHO limits for Na and they were almost equal to maximum and minimum levels of Na in C-GAM.

Ca, Mg and P levels in drinking water samples showed similar results compared to WHO standards where the average or maximum levels of all sample groups did not exceed the WHO standards of 200mg/L for Ca, 150 mg/L for Mg and 5mg/L for P.

In contrast to all other variables, N concentrations of some P-ANU and NP-ANU samples as well as P-POL samples in some locations have exceeded the WHO standard (10mg/L), but none of the NP-POL samples have exceeded this limit. In the control area of Gampaha N levels in two out of the ten samples have exceeded the WHO standard. Gampaha is mainly an urbanized residential area which could be the reason for this.

None of the drinking water samples in Anuradhapura District had Cd. However both P-POL and NP-POL samples contained Cd, but they did not exceed the WHO permissible level of 0.005mg/L in both the maximum and averages values. In the Control area in Gampaha Cd was not detectable in any of the water samples.

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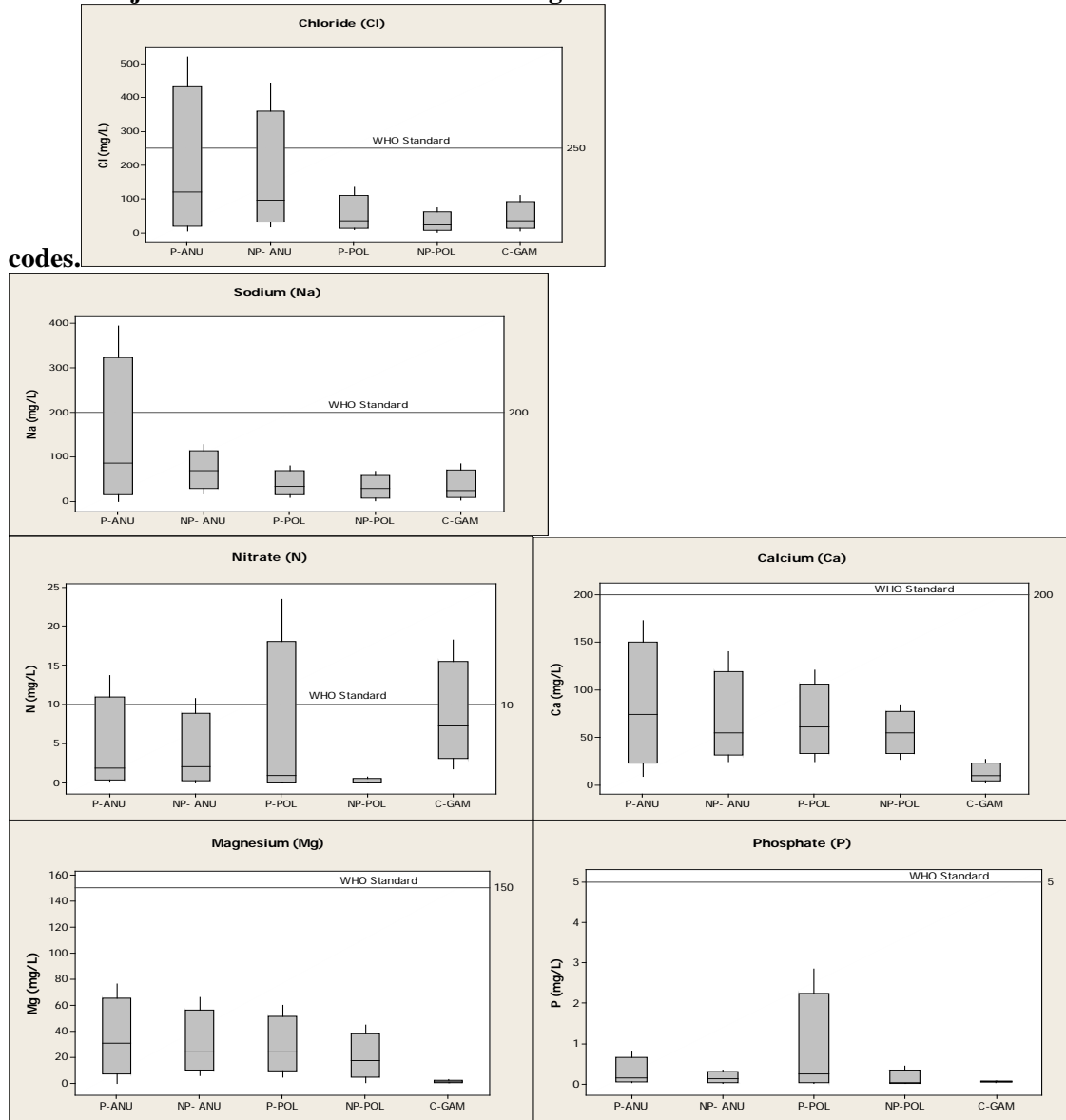
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Figure 2: The average, maximum and minimum values of variables F, Cl, Na, Mg, Ca, N, P and Cd in the five sampling groups compared to WHO recommended limits

5.2 Cross-correlation matrix

Initially a cross-correlation analysis was carried out to determine whether the Factor Analysis could be carried out with the obtained data. According to Kaiser (1974) there has to be cross-correlation coefficients of above 0.3 to proceed with the Factor Analysis. The correlation matrices given in Table 1 (Patient) and 2 (Non-Patient) in CKD endemic area (Anuradhapura and Polonnaruwa) depict a number of cross-correlation coefficients above 0.3 which indicated Factor Analysis could proceed.

Table 1: The correlation matrix between variables in Patient data

Parameter	Cross-correlation coefficient							
	Cl	*F*	*N*	*P*	*Ca*	*Mg*	*Na*	*Cd*
Cl	*1.00*							
F	*0.60*	*1.00*						
N	*0.08*	*0.02*	*1.00*					
P	*-0.13*	*-0.04*	*0.74*	*1.00*				
Ca	*0.83*	*0.45*	*0.21*	*-0.04*	*1.00*			
Mg	*0.73*	*0.72*	*0.26*	*-0.01*	*0.74*	*1.00*		
Na	*0.87*	*0.75*	*0.02*	*-0.12*	*0.66*	*0.70*	*1.00*	
Cd	*-0.17*	*0.02*	*-0.08*	*0.21*	*-0.23*	*-0.02*	*-0.14*	*1.00*

Table 2: The correlation matrix between variables in Non-Patient data

Parameter	Cross- correlation coefficient							
	Cl	*F*	*N*	*P*	*Ca*	*Mg*	*Na*	*Cd*
Cl	*1.00*							
F	*0.08*	*1.00*						
N	*0.69*	*-0.12*	*1.00*					
P	*0.07*	*-0.06*	*0.01*	*1.00*				
Ca	*0.66*	*0.45*	*0.55*	*-0.18*	*1.00*			
Mg	*0.76*	*0.46*	*0.43*	*0.02*	*0.72*	*1.00*		
Na	*0.49*	*0.22*	*0.12*	*0.31*	*0.13*	*0.60*	*1.00*	
Cd	*-0.03*	*0.04*	*-0.06*	*-0.06*	*-0.12*	*-0.07*	*-0.07*	*1.00*

5.3 Factor extraction

In Factor Analysis it is important to identify the number of significant Factors that could be extracted from the data set in hand. The Eigen Value and the Percentage Variance are good indicators in deciding on how many factors to further analyse. Factors having an Eigen Value above 1 and a Percentage Variance above 10% are considered for further analysis as Factors (Green and Salkind, 2005). The Eigen values are given by the Scree Plots depicted in Figure 3 for data obtained from Patient and Non-Patient data sets respectively from CKD endemic area. Accordingly three Factors were extracted from each data set.
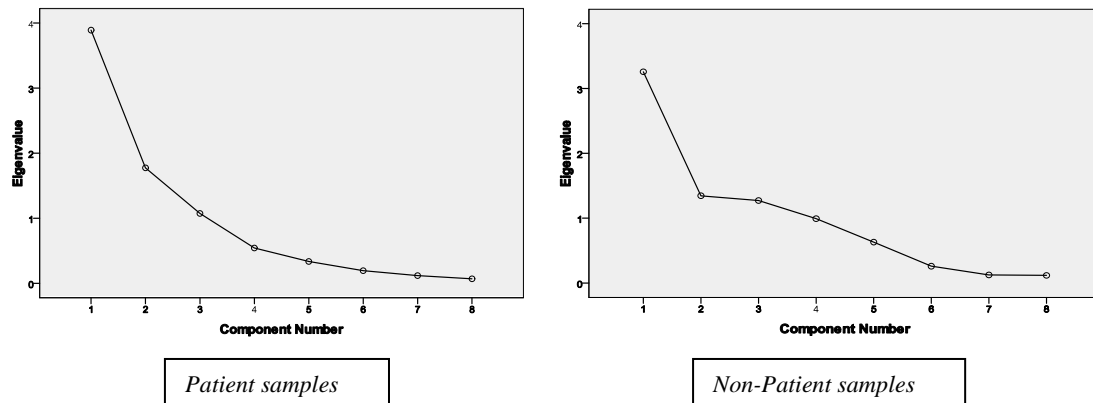
| Patient samples | Non-Patient samples |

Figure 3: The Scree plots for Patient and Non-Patient samples showing the relationship between the Factors to be extracted and Eigen Values

The Principal Component Analysis was used as the Factor Extraction method. For the Patient data, the results showed that variables of Na, Cl, Mg, F and Ca fall into one Factor showing a strong interdependency between these parameters. This was followed up by N and P falling into the second Factor and Cd falling into the third Factor (Table 3 and Figure 4).

According to the Factor Analysis results summery of Non-Patient data it was observed that N, Cl, Mg and Ca were falling into one Factor, P and Na were falling into the second Factor, and F was falling into the third Factor (Table 3 and Figure 4).

In Factor Extraction the reliability of the variables in a Factor is measured by an indicator namely Cronbach's Alpha value which measures the correlation between the variables in each Factor. High Cronbach's Alpha value indicates a high reliability of the parameters in the Factor. Cronbach's Alpha value of above 0.7 is known to be acceptable indicating the reliability of the variables in the Factor (Kaiser, 1974). The Cronbach's Alpha values obtained for each Factor in both data sets are given in Table 3. According to research results the Factor 1 in Patient samples had a Cronbach's Alpha value of 0.74 indicating all the variables in Factor 1 are highly correlated.

The Eigen Value and the Percentage Variance are given in Table 3. For the Factor 2 in Patient data with variables N and P the Cronbach's Alpha was only 0.30 indicating comparatively less correlation of the variables to its Factor. However Percentage Variance for this Factor was 22.2% and the Eigen value was 1.78 which showed that it is a significant Factor to be considered in Patient data.

It is said to be not preferable to define factors by a single variable (Green and Salkind, 2005). Conversely for the Patient data, in Factor results, Cd itself could be extracted as a Factor because it had an Eigen Value of 1.07 and a Percentage Variance of 13.42.Thus Cd itself could be extracted as a Factor in Patient data.

Table 3: Factor extraction results of drinking water samples of CKD Patient and Non-Patient data

Group Category	Factors extracted	Variables in each Factor	Cronbach's Alpha value	Initial Eigen Value	Percentage Variance (%)
Patient data	*Factor 1*	*Na, Cl, Mg, F, Ca*	*0.74*	*3.89*	*48.64*
	Factor 2	*N, P*	*0.30*	*1.78*	*22.18*
	Factor 3	*Cd*	*-*	*1.07*	*13.43*
Non-Patient data	*Factor 1*	*Mg, Ca, Cl, N*	*0.55*	*3.26*	*40.72*
	Factor 2	*P, Na*	*0.004*	*1.35*	*16.82*
	Factor 3	*F*	*-*	*1.27*	*15.91*

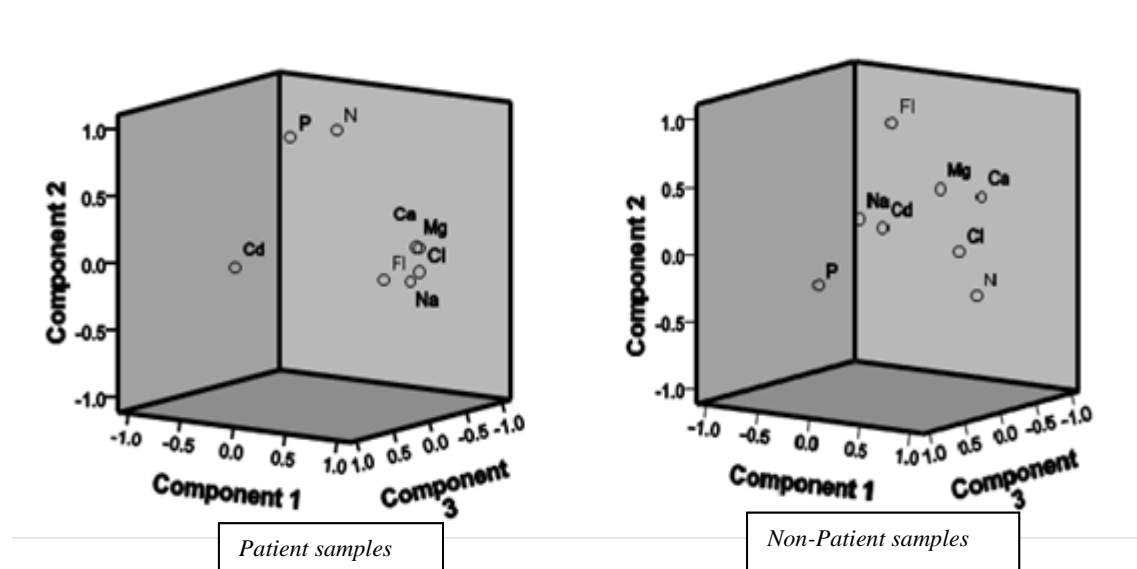Patient samples   Non-Patient samples

Figure 4: Factor Extraction Results of Patient and Non-Patient data

With regard to Patient samples, the variables of Na, Cl, Mg, F and Ca having high correlations are clearly identifiable in Factor results where they go together in one Factor. All these chemical parameters could be naturally occurring in water. The parameters of N and P in the second Factor of Patient samples could be originating from fertilizer leaching into water. Those Factors were evident in correlation analysis with Cross- correlation Coefficients above 0.60. In contrast the Factor variables of Mg, Ca, Cl and N in the Non-Patient samples were different to those variables extracted from the Patient samples. This can be explained by the smaller Cross-correlation Coefficients in the Cross-correlation matrix (Table 2). Furthermore, Cd was a dominant variable in Patient samples. On the other hand F as a single variable was a significant Factor in Non-Patient samples. As reported earlier Chandrajith et al (2011) have shown that Na/Ca ratio in F rich areas could influence CKD. Similarly Bandara et al (2008) also have shown Cd could be a causative factor of CKD. The findings from the current study are

consistent with the findings by Chadrajith et al (2011) and Bandara et al. (2008) and therefore further research is important to identify the exact causes of CKD.

6. Conclusion

Results from the descriptive statistical analysis show none of the average concentration values of water parameters exceeded WHO recommended values for drinking water for all five sample pools. Although literature suggests that the Fluoride (F) concentrations are high in North Central Province of Sri Lanka, only one sample out of 60 samples from the CKD endemic area had F concentration above the WHO recommended value for Drinking water. None of the variables analysed showed concentration levels above WHO standards in the Gampaha Control area except for Nitrate in two out of ten samples.

From the Factor Analysis results, three Factors were identified in the 'Patient' samples which were distinctively different from the 'Non-Patient' samples. Accordingly in Patient samples, parameters of Sodium (Na), Chloride (Cl), Magnesium (Mg), Fluoride (F) and Calcium (Ca) were grouped into one Factor and could be considered as hydro-geologically originating. The second Factor consisting of Nitrate (N) and Phosphate (P) could be due to nutrients from fertilizer applied to the agricultural lands leaching into surface and ground water sources. The third Factor made up of Cadmium (Cd) was detected only in the samples from Polonnaruwa District due to elevated Cd levels although they were below the WHO threshold levels for drinking water.

In contrast, the factor variables from Non-Patient samples could not be identified as generating from a specific source although Fluoride was clustered into a separate Factor.

It could be considered that Fluoride by itself may not be the contributing factor for CDK. However, Fluoride combined together with other variables as identified in Patients samples could be contributing to CKD. Also repeated and persistent exposure to Cadmium would be a variable contributing to renal disease. Those Factors in the CKD Patient area require further study.

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Integrated care facilitation model reduces use of hospital resources by patients with paediatric asthma

Integrated care facilitation model reduces use of hospital resources by patients with paediatric asthma

Abstract

This evaluation assessed a model of care for Paediatric Asthma patients that aimed to promote health and reduce their preventable and/or avoidable use of acute hospital services. Paediatric asthma patients (n=223) were allocated Care Facilitators who provided assistance in the promotion of carer/self-management, education and linkage to an integrated the healthcare system, comprising of acute and community based healthcare providers. Patients' use of acute hospital services (Emergency Department presentations, Admissions and Bed-days) pre- and post-recruitment were compared using Wilcoxon signed rank tests. The Paediatric Asthma Care Givers Quality of Life Questionnaire' was used to assess changes in health and quality of life. The patients displayed a 57% reduction in Emergency Department Presentations, 74% in Admissions and a 71% reduction in bed-days. Whereas a comparator group displayed 27%, 32% and 14% increases respectively. Patients also reported significant improvements in quality of life domains of: Activity Limitation (+5.6, $p<0.001$) and Emotional function (+9.1, $p<0.001$). The reduction in the use of Hospital Services was attributed to the aversion of preventable presentations and admissions, via the enhancement of carer/self-management and access to community health services. These outcomes were supported by indicators of improved patient health and quality of life, and comments by the participant's carers.

Key words: Paediatric Asthma, Care facilitation, Model of care, Emergency department presentations

Background

In recognition of the growing demand on its hospital services, between 2001 and 2005

the Victorian State Government (Australia) invested $582 million into the

implementation of a 'Hospital Demand Management' strategy. Of this, $150 million

were for projects aimed at reducing the demand on hospital services and improving

patient health through new approaches to patient management (Department of Human

Services, 2006). These projects were collectively known as the Hospital Admissions

Risk Programme (HARP) and in the 4 years immediately following its establishment,

further funding ($53 million) was provided in 2005-06 to enable the successful models of

care to be implemented and delivered more broadly across the state (Department of

Human Services, 2006). This paper describes the patient and hospital demand outcomes

of a project that was established by a consortium (Table 1) of acute and community

health care providers, based in the western suburbs of Melbourne, for patients with

Paediatric Asthma and their carers.

Project description and model of care

Paediatric Asthma patients were identified as a group who frequently presented to

hospital Emergency Departments (ED), and for whom it was perceived that their use of

hospital services could be reduced and general health improved via the implementation of

a new model of care. The rationale for targeting this group was a perception that some of

their presentations and subsequent hospital admissions could be prevented by the

patients' carers, and for the older children the patients themselves, improving their

understanding of their condition, better carer or self-management of their condition (Clark *et al*., 2009, Spiegel *et al*., 2006), effective use of care and action plans, and facilitated access to community based health services (Department of Human Services 2003; Department of Health and Ageing 2005). These perceptions concurred with the findings of Reeves *et al*. (2006) who in a US study found that it was common for the carers of asthmatic children to not possess a spacer or written action plan, not to attend follow-up appointments after an Emergency Department (ED) visit, and to go directly to ED when needing asthma care.

Other factors liable to be contributing to this overuse of the acute sector services in the region include its socio-economic demographic, with areas characterised with mild socio-economic disadvantage (Department of Human Services, 2005; Australian Bureau of Statistics, 2001). Consequently, many of the presenting patients were from low income families who viewed the hospital as a free or low cost service. This phenomenon of over-using the hospital emergency departments was likely to have been accentuated by the relatively low number of General Practitioners and other health providers in the region (Australian Institute of Health and Welfare, 2003) and a decreasing number of General Practitioners in the region who 'bulk bill', since it has been reported that low-income clients, who did not wish to pay for services, are disinclined to visit their GP and are more likely to present to the hospital, even if they would have been reimbursed eventually (Hopkins and Speed, 2005). (The policy of bulk billing provides free GP services for the patient at the point of delivery and time of service, the alternative is to charge the patient who then seeks a rebate). Furthermore, the region is the most culturally

diverse area in Victoria (Department of Human Services, 2002; Australian Bureau of Statistics, 2001) with over one third of the region's population having been born overseas, or speaking a language other than English at home. Consequently many people from the area experience difficulties in understanding the health care system, the options available to them, and how to access these services. Inevitably therefore, the local acute hospitals, being very visible institutions, are seen by them as the primary locations for seeking all health advice and intervention.

Hence a key objective of the model of care was to breakdown the 'silo' structure of the existing healthcare system, whereby each organisation had separate funding and commonly operated with only limited linkages to other health organisations within the region. In particular, effective referral between acute and community healthy providers was deemed essential for this patient group as it would generate coordinated access to all services, and should produce a 'joined-up' and coherent health service. This was achieved through project specific funding and the involvement of senior staff from each organisation on the 'Governance Committee'. This thereby ensured that decisions concerning funding and resources could be made by the committee, and would then be implemented by their respective organisations. The importance of such "Leadership Support" and dedicated funding have been highlighted by Parrish *et al.* (2009) for the sustainability of such interventions. Additionally, the employment of staff (Care Facilitators) at both acute and community based health organisations, actively ensured linkage between health service organisations, and the Care Facilitators were able to link

patients directly to these services as well as ensuring that their carers were aware of how to continue accessing them as required in the future.

Hence many of the elements of the model concurred with the requirements for effective 'Care Transition' ("*…the movement of patients from one healthcare practitioner or setting to another…",* Parrish *et al.,* 2009), which has been identified as an important factor with the potential to reduce preventable events and readmissions. In particular previous work has highlighted the risks of poor Care Transition through discontinuity between the different components of the health-care system (Kripalani *et al.* 2007) and has emphasised the importance of collaborative hospital-community partnerships (Parrish *et al.* 2009). Other identified key elements for effective Care Transition include: communication (Kripalani *et al.* 2007), consideration of the needs of diverse communities (Parrish *et al.* 2009), engagement with social support systems (Kripalani *et al.* 2007), and a means to address patient difficulties with complex discharge instructions, medication management and self-care responsibilities (Kripalani *et al.* 2007), all of which received attention in the model of care evaluated here.

Recruitment to the model of care

Recruitment was through the identification of frequent presenters (two or more presentations in the previous 12 months) to the hospitals' ED departments, or in a few cases patients identified as being at risk of future frequent presentations. A flagging system in the hospital records was used for patients fulfilling these criteria, and Care Facilitators were notified upon their next presentation to ED. A Care Facilitator then

contacted the patient's carer in the hospital, or if already discharged, by telephone. The

Care Facilitator invited them to participate in the new model of care, and if they/their

carer agreed to participate, written informed consent was provided.

Model of Care

The project team for the model of care included multi-skilled Care Facilitators with

professional expertise in nursing and asthma education. The details of related projects

have been described elsewhere (Smith *et al.,* 2003), but in summary comprised of:

1. *A 'Gateway System'*. Recruitment (as described above)

2. *Disease specific streams*. Patients were allocated to the Paediatric Asthma project

   stream, which was managed by specialist medical practitioners and nurses.

   Decisions concerning strategies for the stream were discussed and reported at the

   stream steering committee, which comprised of the medical practitioners, GPs,

   school nurses, care facilitators, community health staff, project managers and

   evaluators.

3. *Assessment of needs*. A Care Facilitator performed a comprehensive assessment

   either in the hospital or in the patient's home. This included the Paediatric

   Asthma Care Givers Quality of Life Questionnaire' (PACQLQ) and/or the

   Paediatric Asthma Quality of Life Questionnaire' (PAQLQ) for the older children

   (Juniper *et al*., 1996a, 1996b).

4. *Care coordination and facilitation*. The results of each patient's assessment were

   used to identify issues for the patient, barriers to the effective management of

   their health, and factors putting the participant at risk of preventable events and

avoidable presentations to the hospital. The assessment results were taken to a

multidisciplinary case conference and this information was then used as a basis

for the individual care plan.

5. *Education and action plans.* Care Facilitators provided asthma education for

carers and patients, including the correct use of preventer medicines, spacers, and

the provision of written asthma action plans. They also arranged follow up

sessions with the carer and patient, which through being proactive were intended

to overcome some of the barriers associated with a low Primary Care follow-up

(Zorc *et al.,* 2005), and the risk of preventable events in this patient group.

6. *Facilitated access to a suite of services*. The Care Facilitators then facilitated the

patient's and carer's access to the health services they required. Examples of

services arranged included primary health care assessments, psychology services,

occasional child care for siblings whilst follow up appointments were arranged,

housing assistance and financial assistance for medical equipment.

In the process of achieving the desired level of facilitation and self/carer-management,

the Care Facilitators would arrange between 4 and 7 appointments with the patient/carer,

with most of these occurring in the patients' home, although some could take place in the

GP surgery or outpatient clinic if considered more appropriate. Patients were discharged

from the project when it was deemed that optimal self/carer-management had been

achieved

Methods of evaluation

Assessment of usage of acute hospital services

The patients' rates of Emergency Department (ED) presentations, Inpatient Admissions and Inpatient Bed-Days before and after their recruitment were calculated from the Hospitals' patient activity records. A 'Comparator Group' was generated from patients who had presented with the same characteristics in the 3 years prior to the inception of the new model of care (comparator group; n = 72). For the Comparator Group a 'dummy recruitment' date was allocated to each patient using the date of separation from their second presentation in 12-months, which under the new model of care would be the event to have initiated contact by a Care Facilitator. The Comparator Group was composed of 45 male and 27 female patients, aged 5.1 ± 4.3 years (range 1 to 18 years). They had an average of 3.6 ± 2.0 ED presentations within the period of 12 months prior to their dummy recruitment and by comparison, the HARP-Asthma group (n = 223), had an average of 3.0 ± 1.7 ED Presentations prior to recruitment. Kruskal-Wallis tests did not find any significant differences between the HARP intervention and Comparator groups with regard to standardised PRE-recruitment/dummy recruitment rates of ED Presentations (p = 0.098), Inpatient Admissions (p = 0.936), and Inpatient Bed-Days (p = 0.980) (Table 2). And there was no significant difference between the groups with regard to average age at recruitment (p = 0.097).

Assessment of Patient outcomes

The Paediatric Asthma Care Givers Quality of Life Questionnaire' (PACQLQ) was completed by the patient's parent/carer if Aged <7 yrs, or the PAQLQ completed in consultation with the patient if older. An initial assessment was conducted at recruitment

(Ax1), and repeated at intervals until discharge from the project (AxF). The PACQLQ and PAQLQ are designed to measure the limitations and anxieties faced by caregivers of children with asthma and in the case of the later, the child's perceptions of these issues. They are comprised of 13 items in 2 domains & categories: (i) Activity limitations (4 items), (ii) Emotional function (9 items). Scoring uses a 7-point Likert scales, with 1 indicating severe impairment and 7 indicating no impairment. The publishers of the questionnaire state that a change of 3.5 is considered to be of clinical importance (Juniper *et al.*, 1996a, 1996b, 1997; Guyatt, 1997). In addition to the quantitative data, carers and some of the older patients were interviewed to ascertain their perceptions of the model of care and its efficacy.

Data analysis

The general design of the evaluation and analysis of the outcome measures of the project were similar to those used in the coordinated care trials (Smith *et al.*, 2002) and other HARP projects (Bird *et al.*, 2005, 2007, 2010). Hospital demand data were analysed for patients who were offered participation in the project between February 2004 and 1st October 2007 and, who had been recruited to the project for a minimum of 90-days. The criterion of ninety days was selected subjectively, as it was deemed a suitable minimum duration for the interventions of the project to have an observable impact. The same 90-day criterion and average length of participation were applied to the 'dummy recruitment' dates of the Comparator Group. The baseline characteristics of the HARP intervention and comparator groups were compared using Kruskal-Wallis tests. Patient outcomes data

were analysed for patients who had completed a discharge assessment prior to October 2009.

Patient pre-recruitment use of Hospital services, such as the number of Emergency Department presentations, Inpatient Admissions and Bed-days, were determined from Hospital records for the 12 months prior to their recruitment. For the purposes of comparison with post-recruitment data, these data were scaled to rates of service use per day for each patient. Post recruitment rates of Emergency Department presentations, admissions and hospital bed-days were scaled by dividing the number of occurrences by the number of days since the patient had been recruited onto the project. Since data were not normally distributed, pre and post recruitment values were compared using non-parametric Wilcoxon signed rank tests with $\alpha = 0.01$, to adjust for multiple comparisons.

For the PAQOL and PACQOL data the group was divided into the age groups (< 5 years, 5 – 12 years, and >12 years), and their pre-intervention data (Ax1) compared using ANOVA to determine whether any pre-intervention differences were evident. The pre- and post intervention scores were then compared using a split-plot ANOVA with pre/post comparisons as a within subject factor, and age group as a between subjects factor No PAQOL or PACQOL data were available for the non-HARP comparator group.

The financial implications of the project and potential savings resulting from changes in the use of hospital and community health services were calculated from the budget expenditure reports and the cost of hospital services data derived from Weighted

Equivalent Inlier Separations (WEIS) reports provided by the hospital performance unit. Estimated savings were calculated for the current size of the HARP cohort and adjusted for the percentage change seen in the non-HARP comparator group.

Results

Hospital demand data (Tables 2 and 3)

Data were analysed for 223 patients who had agreed to participate in the HARP project. This comprised of 90 female and 133 male patients, with an average age at recruitment of 5.3 ± 3.5 years (female 5.4 ± 3.8 years and male 5.3 ± 3.3 years), and ranged from 1 to 17 years. Pre-recruitment they had an average of 3.0 ± 1.7 ED Presentations per patient per year, and 184 participants (82.5%) had a history of 2 or more ED Presentations in the year prior to recruitment. At the time of this evaluation; 67 patients (30%) were still actively recruited to the project, 146 had been discharged to GPs and/or other services (65.5%), 5 withdrawn (2.2%) and 5 were no longer contactable. Patients initially declining recruitment when contacted by a Care Facilitator, but consenting to recruitment following a later presentation to ED and contact with a Care Facilitator are included in the HARP group, with their date of recruitment being the date of discharged from the event at which recruitment was successful. Consequently, the HARP group includes some patients with pre- recruitment rates of presentation that are greater than 3 in the previous 12 months.

Overall, the HARP patients had been recruited to the project for an average of 252.6 ±

122.7 days. The main reason for discharge from the project was the intervention

resolving the patients' health care issues, usually through the project facilitating the

attainment of the required level of support from community based healthcare services

and/or improved self-management.

The Comparator group consisted of 72 patients aged 5.1 ± 4.3 years (range 1 - 18 years).

It was comprised of 45 male (4.6 ± 4.2 years) and 27 female (5.9 ± 4.4 years) patients.

The patients from the Comparator group had an average of 3.6 ± 2.0 ED presentations per

patient per year within the period of 12 months prior to their dummy recruitment. All

had a history of 2 or more ED presentations in the year prior to their dummy pre-

recruitment.

When comparing the pre-recruitment data on use of hospital services (Table 2), no

significant differences were identified between the HARP intervention and the

Comparator group for: rates of ED Presentations (p = 0.098), Inpatient Admissions (p =

0.936), and Inpatient Bed-Days (p = 0.980). Additionally, there was no significant

difference between the groups with regard to average age at recruitment (p = 0.097).

Hence, at the time of recruitment/dummy recruitment, the HARP intervention and

Comparator groups were not found to differ in their use of hospital services.

The HARP participants (n = 223) accounted for 688 ED presentations at the Hospitals

within 12 months prior to recruitment and 206 ED presentations post- recruitment. When

these data were scaled to the patients' length of time on the project, this revealed a

statistically significant, 57% reduction in ED presentation rates per day post recruitment

(Wilcoxon's Z = -9.7, p<0.001) (Table 3), with 115 having no ED presentations post-

recruitment. This was in contrast with the data for the comparator group, which displayed

a 26.5% increase in ED presentations. Likewise, similar changes and differences were

detected in inpatient admissions and hospital bed-days, with the HARP group recording

220 admissions and 342 bed-days in the 12-months pre-recruitment, and declines of 74%

and 71% respectively, post-recruitment. This was in contrast to the comparator group

which, post dummy-recruitment, showed 32% and 14% increases respectively. And as a

consequence of these diverging rates, the post-intervention rates of ED presentations,

Inpatient Admissions and Inpatient Bed-Days of the HARP and Comparator groups were

statistically significantly different (p < 0.001) (Table 2).

Patient outcome data (Table 4)

Data were analysed for four hundred and twenty four participants who had been recruited

to the HARP project between October 2004 and September 2008 (155 female and 269

male; aged 4.45 ± 3.09 years, range 0.11 – 17.21 years), of whom 331 (4.69 ± 3.19 years,

range 0.85 – 17.22 years) had completed a final assessment (AxF). These were

completed a mean of 186 ± 101 (range 29 – 919) days after their first assessment.

ANOVAs comparing the Ax1 data for the three age groups detected no statistically significant differences in their pre-intervention scores for Activity limitation (P > 0.9) or Emotional Function (P >0.6). Nor were there statistically significant differences for the length of time between Ax1 and AxF (< 5 years = 188 days; 5 – 12 years =174 days, and >12 years = 196 days; p = 0.704).

The split-plot ANOVAs showed a statistically significant and clinically important (>5 points) improvement (pre vs post-intervention) in both Activity Limitation (p < 0.001) and Emotional Function (p < 0.001). And the analyses did not detect any age group by time interaction for either domain (p = 0.841 and p = 0.795 respectively), which indicates that whilst the entire group displayed improvements in both domains, the three age groups were not found to differ in the magnitude of change. However, it is acknowledged by the authors that in the absence of a control group and/or data from the Comparator group these changes cannot be attributed to the model of care and may have occurred naturally over time and/or be related to the timing of patient recruitment into the project, i.e. recently following an ED presentation.

When the cost of the project ($400k - $600k) and additional services were compared alongside the estimated savings ($597k) attributed to fewer ED presentations, Admissions and Bed-Days, the financial outcome was found to be between cost neutral and an annual saving of $200k. This broad range spans the worst to best case scenarios, since in this evaluation it was not possible to calculate a more precise figure due to a

number of the resources and management staff being shared across parallel projects for

patients with Chronic Obstructive Pulmonary Disease, Chronic Heart Failure, and Frail

Aged (Bird *et al.,* 2007, 2010).

Discussion

The overall results indicate that carers/patients who participated in this model of care

displayed a reduced demand for acute hospital services post-recruitment compared to a

similar group who had presented to the hospital in the 3-years prior to the new model of

care. Whilst the study design cannot provide irrefutable proof that it was the model of

care that caused these improvements there are strong indicators to support a claim that it

made a substantive contribution. The reasons for these declines in demands were

attributed to carers being better informed of their child's condition, and better prepared to

prevent an episode and/or deal with one, as illustrated by the comment by one parent in

an interview:

"I feel much more in control of my child's asthma"

These findings concur with those of Sockrider *et al.* (2006), who reported that following

a family tailored self-management intervention, there were significant improvements in

carer's self-confidence to deal with an episode, and a reduction in ED visits in the twelve

months follow-up. These outcomes are also similar to those described by Khan *et al*.

(2004) who reported increased use of asthma action plans and improved parental asthma

knowledge scores to be associated with improved asthma outcomes.

Based on the interview data, an essential component of the success of the model in this evaluation was the development of the professional and trusting relationship between the Care Facilitator and patient/carer. Carers reported feeling that the Care Facilitator understood their circumstances and likewise through the pre-arranged repeat visits the Care Facilitator developed a strong appreciation of the patient's situation and needs for optimal quality health care. This ensured the most appropriate referral to community health services occurred and enabled the carer(s)/parent(s) to attain the level of understanding of their child's asthma, care plan, and action plan that were needed to optimise their health and a planned, coherent delivery of health services. The importance of the planned repeated contact with the Care facilitator is an interesting issue for many reasons, not least being its potential contribution towards improving carer understanding and subsequent compliance with discharge instructions, in light of the well-established phenomenon of patients with a wide variety of health issues failing to recall much of the discharge instruction provided at ED (Sanderson *et al.* 2009). It was also likely to facilitate ongoing accessing of the required services, as carers' fostered their own understanding and appreciation of those available to them. Such empowerment is likely to promote a higher quality 'Transition of Care', as identified by Coleman and colleagues (Kripalani *et al.,* 2007; Parrish *et al.,* 2009) and greatly enhancing the overall effectiveness of health service provision. This it should be noted, did not require substantive changes at the point of delivery by GPs or other specialists, but ensured optimisation of their existing services for the benefit of the patient, and through enhanced use of existing relevant health care reduced the need for acute services.

The magnitude of the reductions in ED presentations, admissions (hospitalizations) and Bed-days (total days in hospital) are similar to that reported in other studies (Cree *et al.,* 2006; Newcomb, 2006; Shelledy *et al.,* 2005) and consequently the model described here provides additional support for such preventative models of care, which can pro-actively reduce hospital demand through an enhanced continuity of care, self-management, and overcoming the barriers to follow-up primary care (Zorc *et al.,* 2005).

Furthermore, whilst it is likely that the study failed to capture all of the patients' use of services pre-recruitment, when for example they may have presented to another hospital, the researchers believe that during the post-recruitment phase, the regular contact between patient and Care Facilitator, which included regular phone monitoring, would result in minimal data loss. Consequently it is possible that any bias in data loss may result in an underestimate of the beneficial impact of the project.

Based on the size of the current group the calculated reductions in hospital demand of the HARP group compared with the recorded increases by the comparator group, estimated annual savings were approximately: 550 ED presentations, 220 hospital admissions, and 300 Bed-days. And despite the aforementioned lack of precision concerning the financial implications of the project, the financial indications appear encouraging, and since this will be an important consideration for healthcare organisations when assessing the potential of new healthcare interventions (Parrish *et al.*, 2009), a more detailed economic evaluation has been proposed. Based upon these and other findings, this project and

similar ones for other patient groups have subsequently been mainstreamed into the region's healthcare system.

Limitations

When reporting the results of this project it is appreciated that the findings could be criticized due to the lack of a randomised control group, particularly in the context of changes over time due to maturation. In generating the Comparator Group the authors acknowledge that there are issues relating to the different timeframe of the HARP intervention and non-participant (Comparator) groups, yet the 'real-world' nature of the project prohibited a randomized control design. This was also an issue faced by those evaluating the coordinated care trials (Esterman and Ben-Tovim, 2002) and the Sharing Health Care Initiative Demonstration Projects (Department of Health and Ageing, 2005).

Conclusion

Compared with the previous delivery of 'all usual care', patients recruited to the HARP project demonstrated substantial reductions in their demand for hospital services and clinically important improvements in their Activity Limitation and Emotional Function scores of the PACQOL and/or PAQLQ. These improvements were attributed to improved carer and/or self-management, linkages to community services, and improved Transition of Care, the combination of which resulted in an overall improved quality of health care.

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Table 1: Member organizations of the HARP Western Consortium

Organisation	Healthcare role
Western Health	Acute sector with 3 hospitals
ISIS Primary Care	Primary Care
Shire of Melton Council	Local Government
Djerriwarrh Health Services	Health Service, inc. Primary Care
Westgate Division of General Practice	GP Practices
Western Melbourne Division of General Practice	GP Practices
Westgate Health Co-op	GP Practice and Primary Care
Royal District Nursing service	Primary Care Nursing
Western Region Health Centre	Primary Care
Westbay Alliance PCP	Primary Care Partnership
Post Acute Facilitation Unit (PACFU)	Sub-acute services

Table 2. Hospital demand data. Standardised Ratios of ED presentations, Inpatient

Admissions and Bed-days per patient per day for HARP Intervention group vs

Comparator Group, for Pre- and Post- recruitment/dummy recruitment.

	Event	**HARP**	**Comparator**	**Difference**	*P*
Pre-intervention	ED Presentations	0.0084	0.0098	17%	0.098
	Admissions	0.0027	0.0028	4%	0.936
	Bed-days	0.0042	0.0049	17%	0.980
Post-intervention	ED Presentations	0.0036	0.0124	244%	< 0.001
	Admissions	0.0007	0.0037	429%	< 0.001
	Bed-days	0.0012	0.0056	367%	< 0.001

Table 3. Hospital demand data. Standardised Ratios of ED presentations, Inpatient
Admissions and Bed-days per patient per day Pre- versus Post- recruitment/dummy
recruitment: Wilcoxon's Signed Ranks Tests, and pre-intervention rates (HARP v
Comparator)

Group	Event	Pre	Post	Difference	*P*
HARP (N = 223)	ED Presentations	0.0084	0.0036	-57.0%	<0.001
	Admissions	0.0027	0.0007	-74.0 %	<0.001
	Bed-days	0.0042	0.0012	-71.4%	<0.001
Comparator Group (N = 72)	ED Presentations	0.0098	0.0124	+26.5%	0.312
	Admissions	0.0028	0.0037	+32.1%	0.241
	Bed-days	0.0049	0.0056	+14.3%	0.246

Table 4. Changes in PACQOL/PAQOL for the domains of Activity Limitation and

Emotional Function for the whole group and subdivided in age groups.

	Age Group	N	Ax1	AxF	Mean Difference	P
Activity Limitation	< 5 yrs	230	20.0 ± 7.0	25.5 ± 4.9	5.5	
	5 – 12 yrs	89	19.1 ± 7.2	25.0 ± 5.2	5.9	
	> 12 yrs	12	20.8 ± 8.5	25.6 ± 3.8	4.8	
	Total	331	19.8 ± 7.1	25.4± 5.0	5.6	<0.001
Emotional Function	< 5 yrs	230	48.9 ± 11.9	58.0 ± 9.1	9.1	
	5 – 12 yrs	89	47.5 ±12.7	56.9 ±9.6	9.4	
	> 12 yrs	12	46.3 ±14.6	53.1 ±11.4	6.8	
	Total	331	48.4 ±12.3	57.5 ±9.4	9.1	<0.001