

DOES "POST-CODE" PRESCRIBING VARIATION STILL EXIST BETWEEN DISTRICT HEALTH BOARDS IN NEW ZEALAND?

SURVEYING ACCESS TO BIOLOGICAL THERAPY FOR INFLAMMATORY BOWEL DISEASE.

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SPONSOR PHARMAC

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ABSTRACT

Infliximab has proven efficacy in managing inflammatory bowel disease (IBD). Surveys in 2007 and 2009 revealed infliximab access and approval processes for IBD varied significantly within New Zealand according to District Health Board (DHB). The Hospital Medicines List (HML), implemented on July 1 2013, was intended to encourage nationally consistent prescribing and equitable access to medicines between DHBs. This project aimed to assess whether HML introduction has led to equitable access and use of infliximab for IBD between DHBs. Surveys to Gastroenterology Departments as well as individual prescribers were administered, and investigated use of infliximab before and after July 1, 2013. Responses showed that all DHBs had access to infliximab for IBD patients both before (1.9 to 11.0 per 100000) and after (4.7 to 13.0 per 100000) HML introduction. Use of infliximab, per capita, increased following HML implementation for the majority of responding DHBs, with no decrease in use recorded overall. Previously identified low prescribing DHBs reported increased use. Approval of infliximab prescriptions was reported to be less managerial following HML implementation, and IBD nurses were available in nearly all responding DHBs. Response rate did not allow a complete pattern of infliximab use between DHBs to be obtained, and unknown rates of IBD within each DHB makes it difficult to solely attribute increased infliximab access to HML introduction. However, these surveys suggest there has been increased and more equitable access to infliximab for IBD patients following HML implementation, and thus "post-code" prescribing appears to be reducing.

INTRODUCTION

A biological therapy, the TNF- α inhibitor infliximab (Remicade®), has well-established efficacy for induction and maintenance treatment of both Crohns disease(1, 2) and ulcerative colitis.(3)

In 2007, a survey presented at the New Zealand Society of Gastroenterology (NZSG) Annual Scientific Meeting highlighted access to and use of biological therapy for inflammatory bowel disease (IBD) varied significantly between District Health Boards (DHBs).

It is important to monitor access to and use of biological therapy for IBD patients to see if equity between DHBs is being achieved.

Consequently, in 2009 another survey was administered to further assess the use of biological therapy for IBD in each DHB between 2007 and 2009.

The 2009 survey revealed inequitable access to infliximab between DHBs, and this inequity was attributed to the absence of national guidelines for access to and use of biological therapy for IBD.(4)

Two measures were taken to address the "post-code" prescribing of infliximab identified by the 2009 survey. Firstly, "The New Zealand Society of Gastroenterology statement on the use of biological therapy in IBD" was published in 2010. This paper reviewed recently published consensus guidelines from other societies and adapted them to the special funding situation and availability issues in New Zealand. Secondly, on 1 July 2013 PHARMAC implemented the Hospital Medicines List (HML). The HML is a national medicines list to be used by all DHB prescribers to treat patients, and thus encourages nationally consistent prescribing and equitable access to medicines between DHBs.

This project aimed to assess whether equitable access to and use of infliximab for IBD between DHBs has being achieved following the introduction of the HML. Two national surveys were administered, one to prescribers of infliximab for IBD, and one to each Head of Gastroenterology Department. The surveys examined use of infliximab in 2013, both before and after the HML was implemented.

MATERIALS AND METHODS

To assess access to and use of infliximab between DHBs, two surveys, the Prescriber survey and the Heads of Department survey, were written and then distributed.

The Prescriber survey was available at tinyurl.com/infliximabsurvey2013 via laptop at the PHARMAC display table during the NZSG annual conference (20 – 22 November 2013), and then via email; the link to the survey was emailed to all 120 NZSG members on 16 December 2013. 23 responses to this survey were received.

Appendix 1 contains the Prescriber survey.

The Heads of Department survey was available at tinyurl.com/infliximabsurvey2013HoD via email sent to personal email addresses on 2 December 2013 or via hard copy mailed with prepaid return envelopes to each Gastroenterology department (or to the Medical Director of the DHBs without a Gastroenterology department) on the same day. The email invitation to complete this survey was re-emailed on 10 December 2013, and then again on 9 January 2013. 12 responses to this survey were received.

Appendix 2 contains the Heads of Department survey.

The tinyurl links lead to formstacker, the online form builder used to create and host the Prescriber and Heads of Department surveys. When an online survey form was completed, the data was automatically entered into an Excel spreadsheet. Any surveys returned via post were entered into an online survey form.

The main outcome measures for the Head of Department surveys were:

- 1. number of patients treated with infliximab for IBD before and after HML introduction
- 2. indications for infliximab treatment
- 3. type of approval required for prescription

The main outcome measures for the Prescriber surveys were:

- 1. indications for infliximab treatment before and after HML introduction
- 2. type of approval required for prescription before and after HML introduction

RESULTS

Heads of Department survey:

12 from 20 DHBs responded to the Heads of Department survey. 1 survey contained incomplete data (no patient numbers were provided) so data from this survey was not included in all analyses. Only paediatric use of infliximab was available for Canterbury DHB at the time this report was written.

The Heads of Department survey revealed that biological therapy was available in all 12 responding DHBs. While Heads of Departments from Counties Manakau, Waikato, and Nelson Marlborough DHBs did not respond to the survey, clinicians working in these DHBs responded to the Prescriber survey stating that they had access to DHB-funded infliximab for IBD both before and after HML introduction in 2013. A paediatrician from Canterbury filled in the Heads of Department survey using paediatric IBD data; IBD patients within this DHB do have access to infliximab although accurate per capita usage rates are currently unavailable.

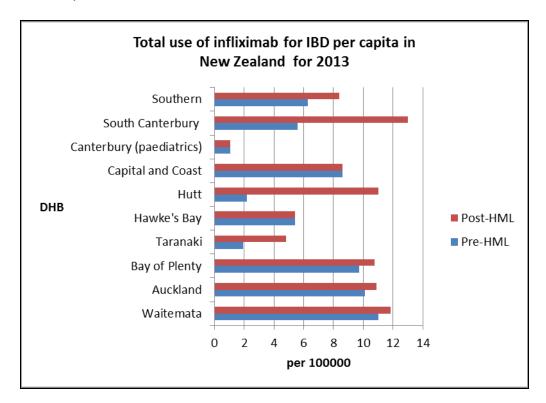


Figure 1: Total use of infliximab for IBD per capita in New Zealand, before and after HML implementation.

All 10 DHBs who supplied patient numbers used infliximab to treat IBD, both before and after HML introduction. Per capita use ranged between 1.9 and 11.0 per 100000 pre-HML introduction, and between 4.7 and 13.0 per 100000 post-HML introduction (Figure 1).

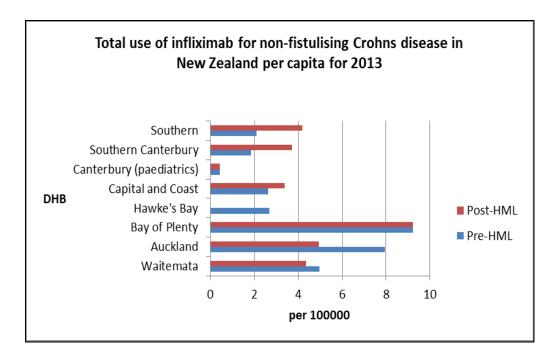


Figure 2: Total use of infliximab for non-fistulising Crohns disease per capita in New Zealand, before and after HML implementation.

8 of the 11 responding DHBs used infliximab for non-fistulising Crohns disease prior to HML, 7 after the HML was introduced. Per capita use ranged from between 0.4 and 9.2 per 100000 pre-HML introduction, and between 0 and 9.2 per 100000 post-HML introduction (Figure 2).

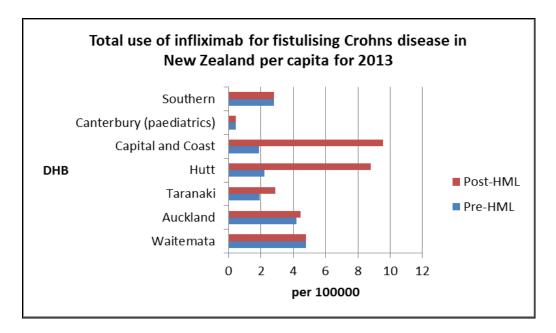


Figure 3: Total use of infliximab for fistulising Crohns disease per capita in New Zealand, before and after HML implementation.

7 of the 11 responding DHBs used infliximab for fistulising Crohns disease, both before and after HML introduction. Per capita use ranged between 0.4 and 4.8 per 100000 pre-HML introduction, and between 0.4 and 9.6 per 100000 post-HML introduction (Figure 3).

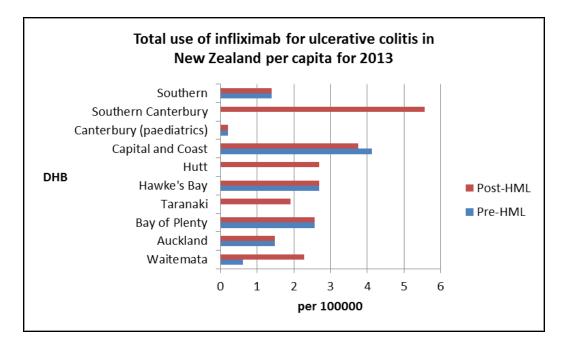


Figure 4: Total use of infliximab for ulcerative colitis per capita in New Zealand, before and after HML implementation.

7 from 11 responding DHBs used infliximab for ulcerative colitis prior to HML introduction, and 10 of the 11 responding DHBs used infliximab for ulcerative colitis after HML introduction. Per capita use ranged between 0 and 4.1 per 100000 pre-HML, 0.2 and 5.6 per 100000 post-HML (Figure 4).

Indications for prescription: the Prescriber survey helped to reveal prescription patterns in non-responding DHBs. Clinicians who work in Waikato could prescribe infliximab for all IBD indications except ulcerative colitis maintenance both before and after HML introduction; clinicians working in Nelson Marlborough and Counties Manakau DHBs stated they were only prescribing infliximab for fistulising Crohns disease pre- and post-HML.

Funding approval: prior to HML introduction, funding approval was prescriber only in 3 DHBs, and required 1 or more colleagues in agreement for 4 DHBs, multidisciplinary team consultation for 3 DHBs, hospital management approval for 3 DHBs, and Drug and Therapeutic Committee review for 1 DHB. After HML introduction, funding approval was prescriber only in 4 DHBs, and required 1 or more colleagues in agreement for 4 DHBs, multidisciplinary team consultation for 3 DHBs, hospital management approval for 1 DHB, and Chief Pharmacist sign-off for 2 DHBs.

Prescriber survey

Information regarding the ability to prescribe infliximab generally matched Heads of Department survey responses.

The 23 respondents spanned Waitemata, Auckland, Counties Manakau, Waikato, Hutt Valley, Capital and Coast, Wairarapa, Nelson Marlborough, Canterbury, and South Canterbury DHBs. 4 clinicians saw < 5 IBD patients on average per month, 4 saw between 5 and 10 IBD patients on average per month, and 15 saw > 10 IBD patients on average per month. All clinicians responding to the Prescriber survey had access to an IBD nurse specialist except for those practicing in Waikato, Nelson Marlborough, and South Canterbury DHBs.

DISCUSSION

This studentship aimed to assess whether access to and use of infliximab is more equitable between DHBs following the introduction of the HML.

Results from both the Prescriber and Heads of Department surveys indicate that "post-code" prescribing has decreased in 2013; all responding DHBs had access to infliximab for IBD patients both before (1.9 to 11.0 per 100000) and after (4.7 and 13.0 per 100000) the HML was implemented. This is in comparison to the 2009 survey, where per capita use ranged between 0-13 per 100000, a wider range than recorded in either half of 2013, and where some DHBs were unable to access infliximab for IBD patients. Furthermore, all DHBs responding to the survey demonstrated increased per capita use of infliximab for IBD post-HML introduction except for Canterbury (paediatrics), Capital and Coast, and Hawkes Bay DHBs which demonstrated consistent total per capita use before and after the HML was implemented.

DHBs that responded to this survey and were previously recognised as low prescribers in the 2009 survey(4) (Otago (now part of Southern), Hutt Valley, and Taranaki) all reported use of infliximab for IBD comparable to other responding DHBs before the HML was introduced, and documented increased per capita use post HML-introduction, suggesting improved access to infliximab for IBD patients in these regions.

As the prevalence of IBD is not known for each DHB, it is hard to determine whether the increased per capita use of infliximab seen in the responding DHBs is due to increased access to the biologic for a stable IBD population, an increased incidence of IBD, the introduction of the HML, or a combination of these factors. However, as monthly infliximab usage was consistently increasing nationally and within each DHB prior to HML introduction (unpublished PHARMAC data) we cannot state with certainty that the increased per capita use seen for most responding DHBs post-HML introduction is entirely due to the HML. Furthermore, infliximab maintenance therapy is long-term, so over time as new patients begin infliximab induction and then move to maintenance treatment use will increase irrespective of other factors. However, we believe the increased use recorded by survey respondents is partially due to HML introduction; patients who meet the clinical criteria are now eligible for infliximab treatment irrespective of how DHBs distribute their funds.

One limitation to Heads of Department survey is the response rate: information of per capita use of infliximab for IBD was not provided for 9 DHBs. 4 of these non-responding DHBs do not have a Gastroenterology department, and this may be limiting access to infliximab for IBD patients in these regions. While it is likely these DHBs are linked to Gastroenterology departments in larger centres, accessing infliximab infusions may be complicated by travel and access to specialist knowledge. However, we know from the 2009 survey that all non-responding DHBs had access to biologics for IBD treatment except for the Wairarapa. Although we cannot be certain, it is tempting to assume that these DHBs would have followed the trend of DHBs who did reply to the 2013 survey by reporting increased total use for IBD per capita post-HML implementation. We know that Wairarapa IBD patients had access to infliximab both prior to and following the implementation of the HML from information provided by a clinician working within that DHB who responded to the Prescriber survey.

8 responding DHBs used infliximab for non-fistulising Crohns prior to HML-introduction, and 7 post-HML introduction. Southern, Southern Canterbury, and Capital and Coast DHBs showed increased use of infliximab per capita post-HML, Canterbury (paediatrics) and Bay of Plenty DHBs showed no change in use post-HML, and Waitemata, Auckland, and Hawke's Bay DHBs showed decreased use post-HML. While decreased use of infliximab post-HML implementation might suggest that the HML has decreased access to this pharmaceutical in some DHB regions, in 2009 adalimumab (Humira®) became available in the

community for severe Crohns disease so this may be decreasing per capita use of infliximab in some DHBs.

7 responding DHBs used infliximab for fistulising Crohns disease pre-HML introduction, and all reported increased per capita use post-HML introduction except for Waitemata, Canterbury (paediatrics), and Southern DHBs who reported no change in per capita use during that time. Overall, DHB trends suggest increased access to infliximab for this indication following the introduction of the HML.

Auckland and Waitemata DHBs documented increased infliximab use for ulcerative colitis per capita post HML-introduction, suggesting increased access to the biologic for patients in these regions. No change in per capita use of infliximab for ulcerative colitis was observed for Bay of Plenty, Hawkes Bay, and Southern DHBs following HML introduction. Taranaki, Hutt Valley, and South Canterbury DHBs all documented no infliximab use for ulcerative colitis prior to HML introduction, but use comparable to other responding DHBs post-HML introduction. This more-equitable access to infliximab is likely attributable to the HML. Capital and Coast DHB was the only DHB to report decreased use per capita post-HML introduction; while patients in this region may be experiencing decreased access, infliximab prescriptions nationwide appear to becoming more equitable.

Following HML introduction, infliximab prescriptions require less managerial input, and are based more on clinical assessment: 3 DHBs required managerial approval prior to HML-introduction, and only 1 DHB required this after. 2 DHBs currently require Chief Pharmacist sign-off for infliximab prescriptions which implies the HML is actively being adhered to in these regions, even though it is not currently enforced.

All DHBs responding to the survey had access to an IBD nurse for their patients except for Waikato, Nelson-Marlborough, and South Canterbury DHBs; South Canterbury does not have a Gastroenterology department. Thus, increased and more equitable access to infliximab post-HML introduction appears to be matched by the ability to offer better patient support.

Some comments from the Prescriber survey suggest that it is difficult for full-time private specialists to gain access to public system funding, that access has decreased for some DHBs following HML-implementation due to IBD patients now not meeting the clinical criteria, and that while infliximab is available for ulcerative colitis it is rarely prescribed for this indication.

Feedback from the Heads of Department survey suggests that access has improved post-HML implementation; previously, some DHBs were capped and could only start a patient on the treatment once another had stopped. One DHB reports that the national system allows their patients to receive earlier maintenance; a different DHB disagrees with increased access and states that the new criteria are too restrictive and that some of their patients have not qualified under the new system. A DHB reports that access has improved but management have expressed concerns about burgeoning costs. Concerns were also raised that the HML has made the prescription of infliximab easier for clinicians but not necessarily the pharmacist.

CONCLUSION

The results from this survey suggest there has been increased and more equitable access to infliximab for IBD patients following HML implementation. All responding DHBs had access to infliximab prior to HML introduction, and all documented increased or consistent per capita use of infliximab after the HML was implemented. Thus, "post-code" prescribing appears to be reducing, in line with the goal of the HML. Further surveys to monitor patterns of infliximab use within and between DHBs would be beneficial to ensure more equitable access continues to be achieved, as would IBD incidence and prevalence data for each DHB to ensure that increased use of infliximab per capita is resulting from increased access to the biologic.

Thank you to PHARMAC for funding and facilitating this summer studentship.

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APPENDIX 1: Prescriber survey

Does "post-code" prescribing variation still exist between District Health Boards (DHBs) in New Zealand?

In 2009, a survey revealed that patient access to infliximab (Remicade®) for treatment of inflammatory bowel disease (IBD) varied significantly between DHBs.

On 1 July 2013, the Hospital Medicines List was established with the goal of encouraging nationally consistent prescribing.

This survey will assess use of infliximab (Remicade®) for treatment of IBD, before and after the introduction of the Hospital Medicines List.

If you have any questions regarding this survey, please email us at infliximabsurvey2013@gmail.com.

1. What is your role? (please tick the appropriate circle(s))

- o I'm a specialist
- o I'm a registrar

2. What is your specialty?

- Surgeon
- o Physician

3. Where do you practice?

- Public hospital
- o Private
- University

4. In which DHB(s) did you work or to which DHB(s) did you refer patients this year?

- Auckland
- Bay of Plenty
- Canterbury
- Capital Coast
- o Counties Manukau
- Hawkes Bay
- Hutt Valley
- o Lakes
- Midcentral
- Nelson Marlborough

- Northland South Canterbury Southern o Tairawhiti o Taranaki Waikato Wairarapa o Waitemata West Coast Whangerei 5. On average, how many IBD patients do you see per month? o none 0 < 5 ○ 5 **- 10** o > 10 6. From 1 January to 30 June 2013, were you able to prescribe DHB-funded infliximab (Remicade®) for **IBD** patients? Yes (please proceed to question 7) Why not? (please proceed to question 10) No IBD patients
 - IBD patients seen did not require infliximab (Remicade®)
 - Prescribed adalimumab (Humira®)
 - Departmental policy did not allow use of infliximab (Remicade®)
 - Which hospital? ________
 - DHB policy did not allow use of infliximab (Remicade®)
 - Other
 - Please specify:
- 7. In which DHB site(s) were you able to prescribe DHB-funded infliximab (Remicade®)?
 - o Auckland
 - o Bay of Plenty
 - Canterbury
 - Capital Coast
 - Counties Manukau
 - o Hawkes Bay
 - Hutt Valley
 - o Lakes
 - Midcentral
 - Nelson Marlborough
 - Northland
 - South Canterbury

0	Southern					
0	Tairawhiti					
0	Taranaki					
0	Waikato					
0	Wairarapa					
0	Waitemata					
0	West Coast					
0	Whangerei					
	m 1 January 2013 to 30 June 2013, for which of the following indications were you able to be DHB-funded infliximab (Remicade®) for IBD patients?					
	 Non-fistulising Crohn's disease induction treatment 					
	 Non-fistulising Crohn's disease maintenance treatment 					
	 Fistulising Crohn's disease induction treatment 					
	 Fistulising Crohn's disease maintenance treatment 					
	 Ulcerative Colitis induction treatment 					
	 Ulcerative Colitis maintenance treatment 					
	o Other					
	Please specify:					
	Cannot determine indication					
approv	n 1 January 2013 to 30 June 2013, how was a prescription for DHB-funded infliximab (Remicade®) ved? Prescriber only One or more colleagues A multi-disciplinary team Hospital management Other Please specify: 1 July 2013 until now, were you able to prescribe DHB-funded infliximab (Remicade®) for IBD					
patien	ts?					
	Yes (please proceed to question 11)					
0	No (please proceed to question 14) O Why not?					
	■ No IBD patients					
	 IBD patients IBD patients seen did not require infliximab (Remicade®) 					
	 Prescribed adalimumab (Humira®) 					
	 Departmental policy did not allow use of infliximab (Remicade®) 					
	Which hospital?					
	■ DHB policy did not allow use of infliximab (Remicade®)					
	Other					
	Please specify:					
	1 lease specify.					
	15 Page					

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	Bay of Plenty						
0 (Canterbury						
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	aranaki						
	Vaikato						
	Vairarapa						
	Vaitemata Vest Coast						
	vest coast Vhangerei						
	n 1 July 2013 until now, for which of the following indications were you able to prescribe DHB nfliximab (Remicade®) for IBD patients?						
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funded (nfliximab (Remicade®) for IBD patients? Non-fistulising Crohn's disease induction treatment Non-fistulising Crohn's disease maintenance treatment						
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funded	Non-fistulising Crohn's disease induction treatment Non-fistulising Crohn's disease maintenance treatment Fistulising Crohn's disease induction treatment Fistulising Crohn's disease induction treatment Ulcerative Colitis induction treatment Ulcerative Colitis maintenance treatment						

14. Do you have any further comments regarding access to DHB-funded infliximab (Remicade®) for IBD patients?

If you would like to receive a copy of any publication that reports results from this survey, please enter your email address:
If you don't mind us contacting you should we wish to clarify any of your answers to this survey, please enter your email address:

Thank you for taking the time to complete this survey. Your effort will help us to determine whether equitable access to infliximab (Remicade®) for IBD patients is being achieved following the introduction of the Hospital Medicines List.

APPENDIX 2: Heads of Department survey

Does "post-code" prescribing variation still exist between District Health Boards (DHBs) in New Zealand?

In 2009, a survey revealed that patient access to infliximab (Remicade®) for treatment of inflammatory bowel disease (IBD) varied significantly between DHBs.

On 1 July 2013, the Hospital Medicines List was established with the goal of encouraging nationally consistent prescribing.

This survey will assess use of infliximab (Remicade®) for treatment of IBD, before and after the introduction of the Hospital Medicines List.

If you have any questions regarding this survey, please email us at infliximabsurvey2013@gmail.com.

- 1. Which DHB do you represent? (please tick the appropriate circle)
 - Auckland
 - Bay of Plenty
 - Canterbury
 - o Capital Coast
 - Counties Manukau
 - Hawkes Bay
 - Hutt Valley
 - o Lakes
 - Midcentral
 - Nelson Marlborough
 - Northland
 - South Canterbury
 - o Southern
 - Tairawhiti
 - Taranaki
 - Waikato
 - Wairarapa
 - o Waitemata
 - West Coast
 - Whangerei
- 2. From 1 January 2013 to 30 June 2013, was DHB-funded infliximab (Remicade®) available for IBD patients in your service?
 - Yes (please proceed to question 3)
 - No (please proceed to question 5)
- 3. From 1 January 2013 to 30 June 2013, for which of the following IBD indications was DHB-funded infliximab (Remicade®) prescribed? (Please include new patients as well as patients receiving

mainte	nance therapy; your Chief Pharmacist may be able to help you with data collection).							
	 Non-fistulising Crohn's disease induction treatment 							
	patients							
	 Non-fistulising Crohn's disease maintenance treatment 							
	• patients							
	Fistulising Crohn's disease induction treatment							
	• patients							
	 Fistulising Crohn's disease maintenance treatment 							
	• patients							
	 Ulcerative Colitis induction treatment 							
	• patients							
	 Ulcerative Colitis maintenance treatment 							
	• patients							
	o Other							
	Please specify:							
	• patients							
	Cannot determine indication							
	• patients							
(please	 Prescriber only One or more colleagues A multi-disciplinary team Hospital management Other Please specify: proceed to question 6) 							
5. Why	not?							
J. Willy								
0	No IBD patients							
0	IBD patients seen did not require infliximab (Remicade®)							
0	Prescribed adalimumab (Humira®)							
0	Departmental policy did not allow use of infliximab (Remicade®)							
	Which hospital?							
0								
0	Other							
	Please specify:							

6. From 1 July 2013 to now, was DHB-funded infliximab (Remicade®) available for IBD patients in your service?

o Yes (please proceed to question 7)

(Remid	ade	July 2013 to now, for which of the following IBD indications was DHB-funded infliximab e) prescribed? (Please include new patients as well as patients receiving ongoing maintenance our Chief Pharmacist may be able to help you with data collection).						
	0	Non-fistulising Crohn's disease induction treatment						
		• patients						
	0	Non-fistulising Crohn's disease maintenance treatment						
		• patients						
	0	Fistulising Crohn's disease induction treatment						
	Ü	patients						
	0	Fistulising Crohn's disease maintenance treatment						
	O	patients						
	_	Ulcerative Colitis induction treatment						
	0							
	_	• patients						
	0	Ulcerative Colitis maintenance treatment						
		• patients						
	0	Other						
		Please specify:						
		patients						
	0	Cannot determine indication						
		• patients						
8. Fron	0 0 0	uly 2013 to now, how was a prescription for DHB-funded infliximab (Remicade®) approved? Prescriber only One or more colleagues A multi-disciplinary team Hospital management Other • Please specify:						
(please	-	ceed to question 10)						
-								
0		IBD patients						
0		patients seen did not require infliximab (Remicade®)						
0		scribed adalimumab (Humira®)						
0	-	partmental policy did not allow use of infliximab (Remicade®)						
		Which hospital?						
0	DHI	B policy did not allow use of infliximab (Remicade®)						
0	o Other							
		Please specify:						

o No (please proceed to question 9)

- Personal database
- Departmental database
- Multi-disciplinary team minutes (or similar)
- Pharmacy records
- o Other
 - Please specify:

11. Do you have any further	r comments re	garding access to	DHB-funded infliximal	(Remicade®)	for IBD
patients?					

If you would like to receive a copy of any publication that reports results from this survey, please enter your email address:_____

If you don't mind us contacting you should we wish to clarify any of your answers to this survey, please enter your email address:______

Thank you for taking the time to complete this survey. Your effort will help us to determine whether equitable access to infliximab (Remicade®) for IBD patients is being achieved following the introduction of the Hospital Medicines List.