Introduction
This document presents the analysis framework which was constructed using thematic lines of enquiry from Health Professional interviews (consultants and nurses).

Health Professional Interviews
A total of 23 semi-structured interviews were carried out with consultants (15 Principal Investigators from high (n=8) and low recruiting sites (n=7)) and nurses responsible for administrating and monitoring infliximab and ciclosporin (n=8 from high recruiting sites) from across the 52 CONSTRUCT sites. Interviews addressed the ease of handling a range of drugs for Ulcerative Colitis, aspects of provision which might influence professional preference for one drug over another, and impressions about other groups' contribution to treatment and care.

Data Analysis
Transcripts underwent rigorous analysis by standard thematic analysis based on the health professional interview schedule. Thematic analysis is in keeping with a structured approach to data collection, analysis focuses on examining and identifying explicit and implicit themes within the data. The method emphasises organisation and rich description of the data using a coding process which recognises important moments in the data. Three researchers individually coded transcripts from the health professional interviews as they were completed. Following coding of four of the interviews with consultants, the three researchers worked together to agree a coding structure and developed an analysis framework. This analysis framework then guided coding of the remaining consultant interview transcripts and data were entered as interviews were completed. Following analysis of the nurse interview transcripts, the three researchers convened again to asses and amend, if necessary, the framework in light of any differences between nurse and consultant data. No amendments were made to the framework at this point and data from nurse interviews were entered into the existing framework.

The following framework presents the outcomes of analysis. Each section contains quotes from participants which are labelled by participant code name and the line number in the transcript that the quote has been taken from. Data presented within this framework is a representation of the full dataset collected. Comments specific to ciclosporin appear in the left column and to infliximab in the right column, with more general comments across the two columns at the bottom of each section.

Key - Colour of typeface

	Level of recruitment by site	**Interview ID**
	Poor overall recruitment	HP2, HP5, HP6
	High cohort, low or no RCT	HP1, HP3, HP4, HP7
	High RCT recruitment (PIs)	HP9, HP10, HP11, HP12, HP13, HP14, HP16
	High RCT recruitment (N)	HPN18, HPN19, HPN20, HPN21, HPN22, HPN23a, HPN24, HPN25a, HPN25b

Drug administration and management

Lead up to treatment

Ciclosporin	Infliximab
+ve	**+ve**
HP7 less attentive to making patients aware of adverse events in long terms, work up to treatment is less than Inflix, less of an issue (45 / 46)	HPN24 it's very easy because it's more common... there's no problem giving.. there's no problem even with the calculation and with preparation for the drug.pharmacy it's always readily available too (68, 70)
-ve	**-ve**
HP3 a lot of work for pharmacy, bringing it, solution, make it up (102) HPN5a To prepare intravenous drugs so that's two nurses off the ward you know mixing and preparing the drugs and taking it to the patient (182). HP13 it required more input from nurses in terms of making up the infusions (20) HP11 the patient needs to be counselled about the risks (cicl) (67)	HP11 there is a problem at weekends and out of hours...logistical problems with Pharmacy (34) HP12 preparation is challenging in some instances HP12 the pre-screening is the issue (39) HPN18 the patient has to have a chest x ray, they have to preferably have been seen all that kind of stuff done, they have to have the TB testing and all that. So they would normally have a period before they would start patients on infliximab (102) HPN19 it's quite a lengthy drawing up process, you can't aggravate the vials when your mixing them...slightly more time consuming because you have to wait for it to dissolve...and because they are in 100ml vials that tends to make it a longer process as well because you're drawing up 3-5 of those.... but it's not too complicated once you know how to do it (53,56,57, 62) HPN24 we have to discuss it first, we have to go through it first with the patient (225) HPN19 the whole process involves talking to the patient and educating them as to why you are giving it (inflix) (94)
General comments about criteria used to assess UC	
HP5 we follow the Oxford 5-day rule (steroids then decide) depends also on patients' age, co-morbidity, colon's state, likely benefits of medications, there are always both options open (115) HP1 If patient fit for surgery (life-saving) and have not improved by 5 days would rather have it (92) HP2 Oxford criteria for monitoring patients daily and promptly (believe in strongly) (117) HP10 the burden of administration , is in making it up, setting it up, rather than monitoring during the infusion (both drugs) (56) HP16 there's a question around TB screening though really it shouldn't be much different for ciclosporin... but in practice because of the area we live in we have got a very low endemic TB, so it's not really much of an issue (180) HPN18 in a general setting these nurses would be making the cicl themselves... as a clinical trial it comes up in an infusion bag already, they don't cannulate the patients, their cannualted by one of the doctors (time of nurses on cicl due to trial context reduced 15-20.) (419, 424)	

Drug administration

Ciclosporin	Infliximab
+ve	**+ve**
HP2 Longer administration time doesn't impact on choice of drug. Not a problem as proper administration of both in inpatients is important (53)	HP2 Inflix used frequently for Crohn's now and acute UC (40)
HP5 comfortable with administering Cicl as long as you take all precautions and watch lipids (5)	HP2 I'm more familiar with it (47)
HP5 patients are not going anywhere and are severely ill so practicalities-wise no problem (12)	HP2 Inflix [nurses] more used to it, advantages over Cicl no monitoring needed compared to level for Cicl (42)
HP5 I have had problems with sepsis of pelvis when we don't look carefully enough (39)	HP5 with severe colitis administering Inflix is not a problem (12)
HP6 comfortable with administering Cicl (13)	HP5 Inflix is easier than Cicl as you don't have to worry about electrolytes and reactions (18)
HP6 last used it when I was a registrar (10 yrs ago) bridge therapy, good experience (84)	HP5 Inflix is more straightforward than administering Cicl (19)
HP4 no problem with administration of the drug on the ward, (7)	HP5 Out of personal choice, Inflix and with younger people using it as first line of treatment as less toxic [than ciclosporin] (26/32)
HP7 no concerns about administering, well established, well used (15)	HP5 In in-patients it is nicer for something 'in and out' like Inflix over and above Cicl (84)
HP7 adverse sides to it, but equally well accepted and well established (19)	HP6 Happy to administer Inflix personally, better guidelines around administering it (37)
HP9 we've got quite well organised so it doesn't cause us any problems (16)	HP6 Always prescribed Inflix in his hospital, consultants are more comfortable with it (26,35)
HP10 I still use it and believe it is a safe approach (11)	HP1 Fully functional infrastructure in place and a lot of experience of Inflix administering (29)
HP10 rather more relaxed about it, paradoxically, simply because I know when the IV infusion is stopped, the drug disappears (75)	HP1 Inflix deserves a chance in selected patients (35) HP3 administering is time consuming but not as time consuming as Cicl (16)
HP11 We have no problem it (13)	HP3 administering is only repeated every 8 weeks (17)
HP11 we have always used Ciclo (18)	HP3 sensible and good experience of this drug 'when it works it is fantastic' (23-25)
HP 11 we're comfortable with it (21)	HP3 would go for Inflix if no contraindication. If contraindicated would have to go for Cicl (40)
HP13 its more complicated than inflix but when people get used to it, its fine (15)	HP4 no problem with administering Inflix (11)
HP14 the nice thing about cicl is you can stop it (144)	HP4 no barriers on the ward to administering (34)
HP14 I think these patients are equally likely to need surgery and I think being able to get them off their treatment is really good so in many cases I think cicl is preferable from that point of view (147)	HP7 newer than Cicl (only 15 years) more used to using it with Crohns than UC (24)
	HP7 data suggests it is effective, easier to administer, simpler regime, less palava (28)
	HP9 it's really straightforward, we have a good system for doing it (23)

HP14 I think it's a good drug as a rescue drug (65)

HP14 I think it can be used reasonably safely and I think it's quite a nice drug (65)

HP16 we're pretty happy and confident giving ciclosporin....we've a reasonable amount of experience with it (23, 28)

HP16 rather than changing the bags we run a bag over 24 hours...much as they do in oxford...makes it a little bit easier (51, 56, 61)

HP15 it's easier time wise and nursing hours it's easier to do than the infliximab (217)

HPN21 to actually mix it up and give it to the individual is quite easy to do (54)

HPN25b To be honest it does feels like you know it's just part of what we do so it's not like a thing you would think about really. (252)

HP19 I suppose you could argue on the other side, infliximab... maybe just the inconvenience of coming in to have infusions once you've gone home (136)

HP9 we all feel pretty comfortable using infliximab because we use it a lot for Crohns (39)

HP9 deep down have a sort of comfort with it that is slightly not there with ciclosporin (44)

HP10 very short infusion (22)

HP12 administration ease wise, it is much easier (23)

HP12 it's about convenience and it's certainly more convenient, if you take cost out of the equation to give inflix (78)

HP13 its pretty straightforward and I think inflix has an advantage because of its frequency in use in Chrons disease (63)

HP13 it has an advantage, a familiarity advantage (70)

HP14 infliximab has an advantage in that it's just a 2 hour infusion and then it's done (26)
HP14 there's no problem with infliximab. I think it's a good drug to administer, I think it's an easy drug to administer (30)

HP14 I like inflix because once you've done it, you've done it for 2 weeks (33)

HP14 if the 2 were equally efficacious and equally cost effective, I would choose infliximab because of that reason (practicality of administration) (138)

HP14 and yet for ease of administration, the inflix is easier (168)

HP14 it's quite easy to give (290)

HP16 staff are completely au fait with giving inflix (165)

HP16 it's straightforward, it's easy and I think from my point of view the most important thing is about an hour later it's in and you know the full dose is in (169)

HP15 compared to a continuous infusion of cicl it's a lot easier (42)

HPN18 I prefer it when they have inflix... I think it's easier for the patient... because it's just one infusion... it's a couple of hours instead of being hooked.... I mean keep in mind they have got proffusive diarrhoea... I think it's easier to administer as a nurse and it is easier for the patient to receive it as a patient (165, 169, 173, 178, 189)

HPN19 we do huge amounts of inflix and it's not an issue at all... one infusion over 2 hours and that's it (48, 58)

HPN23a I find it an easy drug to administer (28)

	HPN24 it's very easy because it's more common... there's no problem giving…there's no problem even with the calculation and with preparation for the drug..pharmacy it's always readily available too (68, 70) HPN25a I've done that for quite a number of years now and that's really straightforward. (58) HPN25a It's easy to make, it's easy to give and just give the first, here we give the first three infusions over two hours and then subsequent infusions over an hour so it's really quite simple (64)
-ve	**-ve**
HP2 More troublesome than Inflix (perhaps because used less frequently, less general confidence in it, or higher dose when first introduced than now makes level monitoring more important) (32) HP6 Ciclosporin not used much in this hospital (14) HP6 not the length of administering that is the problem, rather there are more safety aspects, it is a more dangerous drug (44) HP1 No experience of Cicl IV in UC before (23) HP1 only administered to one patient so far and that was 10 years ago, before becoming consultant, and that was a failed medical therapy experience (negative experience) (12/17) HP3 administering [infliximab] is time consuming but not as time consuming as Cicl (16) HP3 administering is time consuming for staff (11) HP3 they [nurses] think it's quite labouring and need extra work (78) HP3 'is a bit debateable although I use it' (29) - Worry about toxicity and the liver, use it half-heartedly, when no choice (that or colectomy) (32/33) HP3 hassle to administer and takes a long period of time (7/11/33) HP3 lot of work for pharmacy (102) HP4 slight worries about availability of Cicl levels (12) makes people perceive it's a more difficult drug to use (18, 25) HP7 disadvantage is slight – continual infusion over long period of time, have to check levels (17) HP9 I guess there is a slight disadvantage to ciclosporin, because it's the infusion, it's continuous thing rather than infliximab which is sort of give it and then done (30)	HP3 'labouring work' but works well (25) HP7 treating people with Inflix go through risk counselling, unknown risks, no data re cancer or 10-15 years hence, potentially greater adverse effects need to make patients aware of that (35) HP10 have greater anxiety in administering infliximab in acute severe UC than ciclosporin.....concerned about duration that infliximab stays in the circulation (24) HP10 if they have had an infective complication then infliximab still around....potential for exacerbating it (should be administered in a "timely manner" if surgery is needed)(27) HP11 we often find there is a problems at weekends ad out of hours if we are going to prescribe it... logistical problems with pharmacy (33) HP14 after inflix they're going to have it for 19 weeks they're going to be immunosuppressed, you know for a long while (issues with surgery) (164) HP16 the only concern we have is if you give it and it doesn't work, if it's still in the system (249) HPN18 we needed to inform the IBD Clinical Nurse Specialist because they need to ensure that the patient was given the blood form to have blood taken a week later at a GP surgery, so when they came in for their second infusion which would have been done in a completely different setting because it would have been as an inpatient, that the bloods were in keeping with what's standard for giving inflix, so there were issues with that (74) HP13 there are differences in recommendations north and south of the border so we just can't use it (inflix) unless we go through a process called the Individual Patient Treatment Panel (SMC restrictions) (229) HP19 it's not just as if you've has the dose over, you know cos you go onto tablets and therefore don't have to come back into hospital as such other than monitoring... I think there are pros and cons to both (134)

HP10 the 6 hr infusion makes it slightly more labour intensive than the 2hr infusion of infliximab (16) HP12 difficult (9) HP12 fairly cumbersome both for the staff and equally important for patients because once you are tied to the drip and associated dript stand, it sort of restricts patients moving around (10) HP12 the staff find it fairly challenging (12) HP12 changing it every 6hrs, the bags etc, would be and will be challenging (16) HP13 it goes on over a longer period of time obviously, so the need to continue to make up bags and things over a longer time rather than just a one off infusion (25) HP13 there is a learning curve with cicl …. Because you're not familiar with it (123, 126) HP14 its quite difficult to the IV as a continuous infusion (13) HP14 you have to get the right dose and you have to get the patient connected up to a continuous drip and it tend to get behind, the nurses tend to find that it takes 8 hours instead of 6 to give each bag (14) HP14 it requires the patient to be on the ward and not go anywhere and um I think it's a bit cumbersome (19) HP14 it's more cumbersome to give (289) HP16 knowing that we're giving the right drug at the right level and first of all that the infusions are continuous, that they're put up, what are the gaps, how long is it before the next infusion is put up, all that sort of thing can sometimes cause problems (72) HP16 you can end up with having periods of delay where patients don't get their drug... I think that's potentially a significant problem... and it's difficult to get around that (87,92,96) HP16 we don't have ciclosporin levels on site so we send them off... in practice that generally means that though you can get a level back, you probably can't get a level back and act on it (levels of cicl in blood) (115) HP16 it's certainly more of a faff for the nursing staff and you've got that more prolonged period of time to wait and try and keep the patient in (285) HP16 I think they (nurses) find it far more difficult, more complex, more time consuming,	

there's maybe a little bit of a familiarity issue (398)

HP15 its time consuming and slightly messy. You know it's complicated and err it's work for the nursing staff (19)

HP15 They have to change the infusion every six hours because the issue about not being stable in the containers and it's a nuisance for the patients in that they have to be connected up to a drip all of the time (28)

HP15 more fiddly (97)

HPN18 you had to be mindful that the continuous infusion had to be prescribed to cover the weekend until Monday (27)

HPN18 once the patient has been on cicl for 24 hours they have to have bloods and if the cicl are too high then they tended to stop it . Now the issue we have is because they are having continuous cicl they have got cic going through their veins, so their levels would always be too high. So they tended to sort of mess about and putting them on oral earlier than they needed to and things so I think from that point of view it was difficult (32)

HPN18 12-20 min (bag change) (464)

HPN19 time consuming (17)

HPN19 having to make it up every six hours was time consuming, changing lines, always having to have two nurses to check it, because the way the GI Unit is split here is there's a corridor up between the two wards so obviously bed cover etc etc but only have one trained each side so this a bit at times, a bit difficult....geography of the wards...we've no one else to check the drug (21, 28, 29)

HPN19 you prime your line with your medication as well, was run the bag for 4 hours then put a flush up to get the last 2 hrs of the ciclosporin that was in the line, so you're going back to the patient quite a lot (37)

HPN20 you need two registered nurses cos our student nurses aren't allowed to check anything like that....Probably 10 – 15 mins. Make up the bags, go to the patient, check the patient, change the bag four times a day, probably an hour anyway.... over a 24 hour period probably about ¾ - 1hr would be spent dealing only with ciclosporin. (263...270)

HPN21 because the patient is on an infusion for longer they can be a little bit frustrated...longer period of time than...inflix (98)

HPN22 they (nurses) are a little bit uncomfortable with it, but only because they are not familiar with it (27)

HPN22 any new drug that you're not familiar with, its time consuming, and of course with time pressures on the ward, they can find that quite difficult (29)

HPN24 It's difficult with the cicl because we were told we are not supposed to stop it we have to continue, not supposed if patient goes off ward and needs to be continued..... there will be side effects if we stop it (24, 39)

HPN24 it was a bit difficult and also we have to work out about how many mls, because we didn't work it out ourselves it was the DR who gave use the prescription so no-one has actually taught us how to do it...even the pharmacy they also had difficulty (46)

HPN25a my experience is from years and years and years ago when I worked on a ward and it was a bit of a nuisance....it was just a nuisance for me as the nurse looking after ten other patients. (29, 38)

HPN25b patients don't particularly like being hooked up to it for such a long period....its restrictive (52, 57)

HPN25b it's intensive in that first period...it's a fairly significant drug to be administering (208, 211)

HP14 if you get rid of the IV then you get rid of the question of the difficulty we have with cicl which is the administration because it then leap frogs over inflix and becomes the easier drug to administer rather than the more difficult to administer (263)

HPN19 I suppose there are a few downsides with cicl, not that there aren't with inflix...within the trial, they went onto cicl tablets and had to be monitored more frequently that say inflix so that's slightly more logistics for the patient so that kind of scenario (134)

General comments about the administration of ciclosporin & infliximab

HP3 nurses need training up (to administer both drugs) (72)

HP4 Administering is a challenge for this particular unit, actually that is not entirely true...(6)

HP4 The concern is the availability of ciclosporin levels and people's perception is it's a more difficult drug but not true. No different administering either drug not difficult to do, we should be clear about that (13)

HP4 there is a perception that Cicl is difficult drug to use but reality is there is equal access to both drugs and equal availability of both (18)

HP9 we basically order it and the nurses are very experienced in giving both, so it doesn't really cause us problems (34)

HP9 at one stage I felt ciclosporin might be the slightly more effective of the two drugs but that infliximab was a bit easier to manage, so the two were reasonable offset by each other (47)

HP10 the burden of administration, is in making it up, setting it up, rather than monitoring during the infusion (both drugs) (56) (we make it up on the ward (136))

HP12 cicl we know because there is so much data out there. Inflix the answer is yet to be resolved and so some people might take that as a negative aspect in relation to inflix (51)

HP14 so on the one hand you've got the convenience of doing infliximab and on the other hand you've got the convenience of being able to stop cicl (151)

HP14 if I think they are really heading home but they need a bit more then I'd give them inflix and if they are really heading for surgery but they want last roll of the dice I'd give them cicl (174)

HP15 I would stress that the differences are not massive (455)

HPN18 I don't really have any views on administering it (cicl) it's a drug, we administer it (14, 18)

HPN19 it's (cicl) more involved because it's a longer period but it's slightly less involved because it's a longer period, if you know what I mean, so once you set it going, as long as you don't completely ignore them, you know, it's sort of done for 24 hours so it's kind of up and down as to whether it's helpful to have a longer infusion or a shorter one (30)

HPN21 I can't say I've seen any sort of difference between the two regarding administration (95)

HPN22 I don't see there's much difference to be honest with you in the practicalities of it (inflix vs cicl) (67)

Effectiveness

Ciclosporin	Infliximab
HP4 tend to use ciclosporin as acting more quickly (171)	HP3 sensible and good experience of this drug 'when it works it is fantastic' (23-25)
HP7 had good benefits with good effects from ciclosporin pts in past (92)	HP3 'labouring work' but works well (25)
HP9 felt ciclosporin may be the slightly more effective of the two drugs (47)	HP7 data suggests it is effective, easier to administer, simpler regime, less palava (28)
HP9 we've always been very cautious with it and as I say I've always offset that by thinking it was an effective drug (63)	HP11 this is the one thing I don't like about inflix because there is no data to give us a clear timescale or timeline for decision making (94)
HP11 one of the things I like about it (cicl) is the response or non response is very clear and clear cut and has a very short time scale (81)	HP12 the other slight issue with inflix is the speed of response (39)
HP16 I think cicl is effective (272)	HP12 the response is slightly sort of slower (45)
HP16 I don't see it being any more effective than inflix but I'd accept that it probably does work and it probably works well (276)	HP12 sometimes it is a bit challenging that you have given the inflix if they are going to take a sort of week to 10 days time, would you hold the nerve (47)
HPN24 it takes a while to settle down. As far as I can remember it took a while for that patient to settle down with his bowels ...day 3 they still feel bas they still feel worse (102,105)	HP12 it's at least as effective as ciclosporin with the additional benefit of convenience and potentially less toxic (222)
HPN25b the patients that have been using it seem to have responded really well I've not seen anybody that's had to go onto you know to anything else having had ciclosporin everyone that I've seen using it have responded well. (74)	HP16 it's very clear to me it's a very effective treatment for a proportion of patients with really severe colitis and there's no doubt that we've had some patients with toxic dialation, who've really been at the far end of the spectrum who have responded perfectly immediately (215)
	HP16 I think that the efficacy is best...at worst is broadly similar (409)

	HP16 though anecdotally I would probably feel that my infliximab response rate ...the inflix works better (414) HP15 the good thing about infliximab is that you know fairly rapidly whether it is going to work and once it's worked and patients have a dramatic benefit (106) HP15 It's quite difficult to stop it and that's actually one of the biggest issues, the clinical decision is about when to stop the drug (108) HP16 you probably get patients out of hospital quicker with inflix (287) HPN18 I felt that when they were randomised to infliximab they has a greater chance of not going to surgery ... but that's my personal gut feeling (219, 224) HPN20 the patients that were on the trial, the vast majority of the inflix ones seemed to do better (179) HPN20 very beneficial (81) HPN23a I think those that are sensitive to it, it works very very well (57) HPN23a I think we definitely see much more progress with people on inflix (122) HPN24 it worked really well on that patient (33) HPN24 there's a quicker response with inflix...patients pass comments and they always tell me I feel much better after this one (118) HPN25a it seems like a very good drug because I've seen so many successful outcomes... but that's mainly with Chron's disease and my views about ulcerative colitis are slightly mixed because the outcomes haven't been as successful but I think perhaps they've been treated a little bit later (87, 92, 95)
General comments about the effectiveness of ciclosporin & infliximab	
HP6 in terms of efficacy – sort of good similar experiences with both drugs (87) HP9 infliximab as safer and easier to manage but maybe not quite so effective and ciclosporin as a bit more sort of a fiddle, little bit more risky for the patient but perhaps a little bit more effective (91) HPN19 inflix was the new boy on the block as such and cicl was maybe seen as bit older, you know maybe less effective drug (26) HPN21 they all seem to do quite well on it (inflix) the same with cicl (84)	

Adverse events

Ciclosporin	Infliximab
HP5 I have had problems with sepsis of pelvis when we don't look carefully enough (39) HP5 Inflix is easier than Cicl as you don't have to worry about electrolytes and reactions (18) HP5 Out of personal choice, Inflix and with younger people using it as first line of treatment as less toxic [than ciclosporin] (26/32) HP6 safety aspects – thought ciclosporin was more of a dangerous drug to give (44/49), Used inf because of safety aspect (72) HP6 don't really want to continue long term because of side effects (99) HP3 worry about toxicity & liver, use it half-heartedly, when no choice (that or colectomy) (32/33) HP7 adverse sides to it, but equally well accepted and well established (19) HP9 potentially quite significant side effects that can happen… slightly uncomfortable feeling about it (60) HP9 there's the hassle of the levels and a lot of patients in my experience, end up with toxicity, tremor particularly (153) HP11 I think that in the long term the risks of renal failure are significant (125) HP11 The patient needs to be counselled on the risks (11) HP11 patients are most worried about are surprisingly seizures,,,, renal toxicity (68) HP11 renal toxicity is what worries me most of all if I don't have a reliable system to make sure that these patients are monitored (72) HP12 comorbidities in relation to toxicity and hypertension etc, renal toxicity and hypertension again in the same group elderly (76) HP16 I'm always a little bit more nervous with it.. and I think that's from the side effects, of renal impairment...I think the side effect profile of cicl although it's maybe not come out in studies still concerns us more (278, 281) HP15 Risk benefit ratio compared to inflix is slightly worse (82) HP15 we've treated lots and lots of patients with ciclosporin over many years and most	HP6 can watch out for any infusion side effects easily, with regular obs every ½ hr or so (78) HP5 Inflix is easier than Cicl as you don't have to worry about electrolytes and reactions (18) HP4 patients tend to tolerate infliximab better than ciclo (184) HP7 treating peo with Inflix go through risk counselling, unknown risks, no data re cancer or 10-15 years hence, potentially greater adverse effects need to make patients aware of that (35) HP11 It certainly has a risk of side effects profile which is no less worrying than cicl (58) HP11 anaphylactic reaction (149) HP12 hold off on inflix for older individuals (68) HP16 you don't have this concern of canullas tissuing (171) HP16 anecdotally we don't see a significant increase in complications or infections post-operatively in those patients (inflix remains in system) (259) HP15 there are less risks (69) HPN19 most of the time it goes without incident (83) HPN21 have only ever seen minor reactions to the inflix, patients don't seem too worried by it (82) HPN24 there were no side effects (99) HPN25a I've had very few problems with infusion reactions. (59) HP11 Every bad reaction I have seen with infliximab has been in older patients (220)

of them are OK, but they are more likely to get hypertension, ...slight parathesia, most...very subtle change in renal function... some of get other neurological side effects, slight tremor (87) HPN20 it's more the potential for reaction to these drugs and the increased observations really that pose a problem for a busy unit (56) HPN25b in the early stages we would monitor them for the first few hours to make sure they weren't having any reactions (182) HPN24 we have to monitor this patient closely for any side effects ... it takes 3 hrs because you've got to do obs for a couple of hours, but then sometimes we tend to forget because we get busy with other patients... so ideally it should be one to one..because we handle 9 patients (249, 255)	

Monitoring

Ciclosporin	Infliximab
HP2 Inflix [nurses] more used to it, advantages over Cicl no monitoring needed compared to level for Cicl (42) HP4 concerns re availability of ciclo levels (54), sent to another hospital, take approx 3 days for result (61) HP7 disadvantage is slight – continual infusion over long period of time, have to check levels (17) HP12 monitoring is sort of more labour intensive for nursing staff point of view (139) HP12 they have more monitoring after they leave hospital (276) HP15 you have to monitor the levels which don't currently do for inflix (92) HPN18 once the patient has been on cicl for 24 hours they have to have bloods and if the cicl are too high then they tended to stop it . Now the issue we have is because they are having continous cicl they have got cic going through their veins, so their levels would always be too high. So they tended to sort of mess about and putting them on oral earlier than they needed to and things so I think from that point of view it was difficult (32) HPN18 most research staff are only around Monday to Friday 9-5 it is very difficult to monitor what is going on with the patient (44) HPN18 they don't monitor the patient, the patient doesn't need any monitoring (12 hour	HPN20 we kind of treat both as the same, we make sure the individual is monitored every 30 mins for a period of time.. The only difference with inflix is that the infusion only last 2 hours but you're observing that patient for 4 hours, so really when you put the two together they are very similar (66)

infusion site) (442) HPN21 time consuming with regards to observation, particularly on a busy ward when you've got one nurse to 10 patients, it can take quite a huge part of your workload (16) HPN20 we're doing observations very, very frequently within a 30 minutes period over maybe 4-6 hours just to make sure that the individual is fine and comfortable (36) HPN20 your with that individual for up to 4 hours when you've got demands of other patients, that's when it becomes difficult, but that's more a time management issue and sort of staffing issue (51) HPN20 we kind of treat both as the same, we make sure the individual is monitored every 30 mins for a period of time.. The only difference with inflix is that the infusion only last 2 hours but you're observing that patient for 4 hours, so really when you put the two together they are very similar (66) HPN24 we have to monitor this patient closely for any side effects ... it takes 3 hrs because you've got to do obs for a couple of hours, but then sometimes we tend to forget because we get busy with other patients... so ideally it should be one to one..because we handle 9 patients (249, 255) HPN24 care assistants can also monitor blood pressure (269) HPN25b from a nursing point of view there are obviously monitoring issues. (41) HPN25b in the early stages we would monitor them for the first few hours to make sure they weren't having any reactions (182) HPN25b we would probably monitor them more closely over the first six hours over the first bag (232)	

Longer term maintenance

Ciclosporin	Infliximab
HP5 mostly the effect is useful acutely but after that no much use in terms of maintaining remission (60) HP5 Cicl is not good in longer-term, for maintenance (62) HP6 don't want to use in long-term because of side effects, switch to Azathioprine soon as poss (99)	HP5 Published studies show longer-term benefit of Inflix, similar to Crohns (50) HP5 issue of not being able to continue with infliximab - would you want to start with something you can't continue? (69-71) HP6 Can only give 3 Inflix infusions, not allowed to continue on maintenance basis, unlike for Crohn's (94)

HP6 if pt already on Azathioprine no point in starting ciclosporin as nowhere to go (101)	HP1 Longer term giving of Inflix, not sure, twitchy of long-term treatment (with Crohn's perspective) tell patients to come off or I take them off if they are in very deep remission (49)
HP1 Little experience of longer-term treatment for patients on Cicl 6 months to a year would be OK then I would get worried would then look to Azathiorpine (66)	HP3 personally prefer to give Inflix and over the longer-term, as maintenance too (52)
HP3 long-term renal failure wouldn't give Cicl over three months (57)	HP4 Have to argue for infliximab on named pt basis for those we need 2nd or 3rd induction and maintenance agents because have life events meaning don't want to consider surgery (199-204)
HP7 don't use Cicl long-term either switch to oral after 3 months no-one is on it long-term (74)	HP4 do have 1 or 2 pts using outside NICE guidance (206)
HP9 there's the hassle of the levels and a lot of patients in my experience, end up with toxicity, tremor particularly (153)	HP7 use Inflix for max of 12 months then stop unless they absolutely need it afterwards, maybe azathioprine is then adequate (wait and see policy) (60)
HP9 isn't particularly effective ....so would see that again as a bridge to getting them on Azathioprine (157)	HP9 there are funding concerns (121)
HP10 the real risks there are risk of infection because the deaths related to ciclosporin have generally been associated with extended use (119)	HP9 I wasn't all that impressed with it as a drug, I didn't really get the feeling it was making a huge difference for patients (125)
HP10 I give it for a limited period (ciclo) but simply because the evidence for giving cicl on a long term basis and retaining remission is ....well there is none (124)	HP9 as a maintenance option I still have some concerns about it (127)
HP11 I don't (treat patient in longer term with cicl) (116)	HP9 concern about its long term effect based on fairly limited use in UC (133)
HP11 I think that in the long term the risks of renal failure are significant (125)	HP10 first attack I would usually use infliximab as a bridge to immunomodulators with Azathioprine. If patient has relapsed..... there's a much stronger case for using infliximab as maintenance therapy (85)
HP12 absolutely no, no longer term, not at all (118)	HP10 all the infliximab in every other clinical chronic inflammatory condition shows that continued use provides continued benefit (100)
HP12 we don't have any patients pre-trial and post-trial who have continued ciclosporin more than 3mth period (122)	HP11 problems come up with NICE, we are getting increasing pressure in our area, to show that we are following NICE guidance so that becomes a problems (100)
HP12 no evidence for long term use of cic in UC setting anywhere (132)	HP11 I tend not to (101)
HP13 I don't think there is any evidence for that. (162)	HP11 There are cost implications, there are immunosuppressant implications so if it is possible for a disease which is essentially curable with surgery then I'm not sure that it's the right thing (108)
HP13 I would often stop it before that (12 weeks) or sometimes I would stop it before that if they run into complications of therapy and I have to say it really is a bridge to using azathioprine or mercaptopurine for immunosuppression (166)	HP12 we clearly individualise patients (longer term care, inflix) (95)
HP13 if somebody comes in on Azathioprine you could argue there's not much point in giving the ciclosporin because there's not a get out strategy (173)	HP12 longer term after 12 months it is clearly individualised and based on sort of consensus at the MDT (97)
HP14 I think it's limited to the bridging effect so I think on the other hand although I have access to use it long term. I don't use it long term (60)	HP12 we don't have any patient in xxxx at the moment with UC who have gone past 13mth period, that just puts it into perspective (103)

HP14 we tend not to, I think we've had a couple of patients over the years who've had longer term cicl, you've got to watch their blood pressure and their renal function. I think it's probably not an acceptable long term treatment after 3 months, I'd be cautious about doing that (86) HP14 I don't think there is the trial evidence to support it (96) HP16 I would treat someone with cicl for between 3 and 6 months... then stop it (357, 362) HP16 I can use cicl as a bridge to getting them into another effective therapy (364) HP16 I see it as a short term treatment (384) HP15 we don't generally, I've got only one or two patients, most of them only have it for three months (179) HP15 long term toxicity (189) HP15 I think that in young people where there is a significant risk of renal damage long term then I'm very very wary about using it long term (189) HP15 in some ways it's easier to make that decision for cicl because the risks are greater for long term therapy (195) HPN18 As long as it's tolerated there's no issues with continuing ciclosporin in the long term (207) HPN19 (discussing longer term cicl) again if it works for the patient, sometimes it comes down to an individual decision then I would be happy to do that (202) HPN22 if it works for them, then yes, absolutely (115)	HP13 I think the published data is not great (134) HP13 I would like to have it available for a few selected people who I don't think are quite ready for colectomy (135) HP13 I don't have anybody left on it and I've tried but for one reason or another people have failed treatment and come off it (141) HP13 if you rescued somebody like that with inflix then they should continue on the drug (179) HP14 I think the current NICE guidelines are um, a bit tricky because I think if you are going to give a patient infliximab you need to give them…., and then they respond to it, if they do respond to it you want to be able to continue the treatment and I think it may have more of a long term use than the NICE guidelines that we're currently using (38) HP14 if a patient is responding well to infliximab I think there's a case for them continuing it (54) HP14 It's what we do in Crohn's disease, we're familiar with doing it, it feels comfortable, patients do well and I don't have any problem with it (71) HP16 if you get someone who responds very well then we will give them three doses and we will try and assess them at the end of this and if they are better we'll stop it but if they relapse then we will continue (332) HP15 it works fantastic (102) HP15 it is generally well tolerated in young people (long term) ... and actually when they are on it and have has a really dramatic response it's much more difficult then to withdraw it (200,205) HPN18 the patients seem to do quite well on it generally (201) HPN19 we now have to request the funding for patients with UC on long term inflix...so that's a bit of a challenge and it means that decisions are made differently to whether a patient is going on to maintenance inflix (154, 156) HPN19 (discussing longer term inflix) it sometimes comes down to a very individualised decision because it depends on how the patients are, how they feel you know.(183) HPN22 It's already an issue because we can't really treat as maintenance with inflix so obviously if a patient responds well we've had to get exceptional funding and thing like that and so there is a case for it I think (103) HPN23a Some (patients) prefer it longer but some go onto Humira, the Adalimumab, the

	injections that they have but some are happy to just have the inflix and it works for them ... I think they are quite happy to have that done because they feel great benefit from it (71, 78) HPN23a We've got some who have been having it in excess of 5 years (86) HPN25a Most of the patients we treat have have been on it long term or do continue to have it long term....over a year... And many of our patients have been on it for much longer than that... a lot of the patients that we try to withdraw treatment end up going back on it because they relapse. (122, 126, 130, 133)
General comments about the use of ciclosporin & infliximab as longer term maintenance	
HP5 In an acute situation you tailor your support according to your gut feeling (76) HP1 Depends what is best for the patient (54/56)	

Personal preference and involvement in the trial

Consultants' personal preferences

Ciclosporin	Infliximab
HP5 I have more experience of Cicl and am more cautious, looking for infection foci (38) HP5 I have a lot of good experience with this drug but I am more wary than I am with Inflix (42) HP6 last time I really used a lot of ciclo was 10-11 yrs ago but only about 3 or 4 pts (84) HP4 Only tend to use Cicl as acting more quickly (171) HP9 a sort of slightly uneasy feeling about ciclosporin that I think I do have (56) HP10 rather more relaxed about it, paradoxically, simply because I know when the IV infusion is stopped, the drug disappears (75) HP11 I might reach a preference with cicl a the moment (155) HP11 I've used it for a long time and I'm comfortable with it (160) HP13 if I was looking at the data and assuming efficacy is equal I would favour cicl (270) HP13 unless you've got a bloody good reason you should be using cicl (444)	HP2 I'm more familiar with it (47) HP5 My own personal preference would be Inflix (103) HP5 Out of personal choice, Inflix and with younger people using it as first line of treatment as less toxic (26/32) HP6 personally prefer Inflix see results more quickly can watch out for side effects, seen good outcomes, I would choose it if I had the choice (77) HP1 treatment preference based on familiarity for nurses and me (from Crohns treatment) (86) HP3 sensible and good experience of this drug 'when it works it is fantastic' (23-25) HP3 Inflix personal preference, 'absolutely' but follows NICE guidelines (unfortunately) (116) HP3 would go for Inflix if no contraindication. If contraindicated would have to go for Cicl (40) HP4 I suspect my prejudice is towards infliximab, if I had to have one. Probably because of lack of availability of Cicl and not having the ability to monitor it closely as I would like (164) HP7 newer than Cicl (only 15 years) more used to using it with Crohns than UC (24)

HP14 i don't much like it (9) HP14 I would be more likely to use oral cicl than I would IV cicl ... I don't think IV ciclosporin is what I would use in the future but we've used it for the trial (259, 262) HP16 I'm a little bit relunctant to treat with cicl anybody who's already on azathioprine (313)	HP9 probably slightly in favour of infliximab just due to ease and sort of slight feeling that it's a bit more predictable and the side effects are easier to manage (190) HP11 I personally am yet to be convinced that it has anything to offer in terms of advantage over and above cicl (36) HP11 I don't feel comfortable using it (60) HP11 (on inflix) if there is data to suggest that it significantly better in terms of avoiding surgery in terms of success of treatment then I'm willing to change my mind (62) HP12 that is a difficult one but I would say yes at the moment if I had to choose between the two I would go for infliximab because there is, although not good quality RCT data... but there is clinical experience data (85) HP12 I mean personal preference would be for offering infliximab and then colectomy (159) HP14 if the 2 were equally efficacious and equally cost effective, I would choose infliximab because of that reason (practicality of administration) (138) HP16 my treatment preference is inflix...my reasoning for that is that I think that the efficacy is best.....at worst broadly similar (405, 409) HP15 My personal view is that they probably have equal efficacy, I think inflix have overall my clinical impression is that it has less side effects so if I was given a free choice, if it was asking it for me or if my loved ones, I would opt for infliximab (65) HP15 my treatment preference is slightly in the direction of inflix (222) HP15 when a patient was given inflix I was rather please and when they were given cicl I was less enthusiastic...we wondered about the tolerance for the patient and the convenience for the patients (380, 394
General comments on PI personal preference	
HP4 the subtleties of which sub-group of people respond to a certain drug, you will always be slightly biased by personal preference (183) HP4 find that patients tend to tolerate Inflix better than Cicl, but that is general impression, not data-based, but I am more in favour of ensuring appropriate medical rescue is provided rather than giving preference to one drug (185) HP7 I don't have a treatment preference happy to administer either (90) HP14 I want the one that's more effective (141) HP14 some patients I'd choose and some other patients I'd choose the other (170)	

Consultants' views on nurses' preferences

Ciclosporin	Infliximab
HP6 I often find that nursing staff aren't as comfortable with it (13)	HP2 Inflix more used to it, advantages over Cicl no monitoring needed compared to level for Cicl (42)
HP6 Clinicians don't like using ciclo (21) and attitude has infiltrated down through the nursing staff, so they weren't happy using it either (30)	HP2 most nurses more familiar with Inflix (41/91)
HP6 the only thing is with unfamiliarity with using it (108)	HP2 specialist IBD nurses more comfortable with Inflix (92)
HP3 they [nurses] think it's quite labouring and need extra work (78)	HP5 nurses think that Inflix is easier to handle (81)
HP11 nurses on the ward are very familiar with it (44)	HP5 nurses think Inflix is less problematic (82)
HP14 the problem they have with cicl is keeping up with the drips (115)	HP5 nurses think Inflix is quicker (85)
HP16 I think that they would wish that we didn't prescribe cicl again (389)	HP5 nurses prefer to give Inflix (82)
HP16 I think they find it far more difficult, more complex, more time consuming, there's maybe a little bit of a familiarity issue (398)	HP6 Attitude of gastro consultants has filtered down to nurses to prefer Inflix (30)
	HP6 nurses are happier administering Inflix, (36/37)
	HP6 nurses unfamiliar with Cicl, used to Inflix, happier with it, fear of the unknown 112)
	HP6 preference for infliximab (116-8)
	HP6 would like to use for grumbling colitic pts who aren't severe enough to require admission but not that well on drugs in the community (124)
	HP1 nurses prefer Inflix from the experience and numbers they have treated so far (79)
	HP1 one patient with Cicl compared to 30-40 Inflix means more familiarity with Inflix, more comfort (80)
	HP1 treatment preference based on familiarity for nurses and me (from Crohns treatment) (86)
	HP3 one specialist nurse gives Inflix only (70)
	HP3 nurses are used to giving Inflix (108)
	HP7 prefer Inflix, more familiar, used more generally, simpler, easier to prepare and administer (83)

	HP12 they prefer, clearly infliximab, primarily because it (cicl) is challenging reconstituting is messy as well as changing bags every 6 hrs, monitoring is sort of more labour intensive for nursing staff point of view (137) HP13 we find umm, infliximab easier (189) HP12 you could sometimes get from the nurses reaction after we got the randomisation, immediately you can see they are relieved if it is infliximab as opposed to ciclosporin (17)
General consultant comments about nurses preferences about ciclosporin & infliximab	
HP3 nurses are not happy giving any of them (72) HP3 nurses agree with me that it is all time consuming (77) HP3 nurses don't have experience of both drugs (68) HP4 nurses don't have a problem with either drug, fully conversant with both (150, 154) HP9 I think they're OK with both 1(171) HP9 historically they probably have more experience of using ciclosporin on the wards than infliximab but now it's pretty equal. I don't think that's a barrier to the use of it really (172) HP11 I've never heard any complaints about either drug (135) HP14 they don't have big problems with either of them. They are more familiar with inflix than they are with cicl and the problem they have with cic is keeping up with the drips (114)	

Consultants' views on colleagues' preferences

Ciclosporin	Infliximab
HP2 most specialists are confident with Inflix and more familiar, level monitoring of Cicl is problematic (81) HP5 My unit is more likely to use Cicl (107) HP6 some gastro colleagues less used to using ciclo (20) HP6 Gastroenterologists who have worked there a long time don't like Cicl. They didn't like it from the word go (21) HP4 perception that Cicl is more cumbersome (25) HP4 outside the trial (where there is no choice because of randomisation) people's perception is that Cicl is more difficult (lack of availability, Cicl levels more	HP2 most specialists are confident with Inflix and more familiar, level monitoring of Cicl is problematic (81) HP2 (pro Inflix) most specialists feel 'well if I'm given a choice why don't I go down the path of least resistance which is human nature' (83) HP2 my colleagues are more familiar with Infliximab, they favour Inflix given the choice (47) HP6 Always prescribed Inflix in this hospital, consultants are more comfortable with it (26,35) HP6 colleagues prefer prescribing biological (26) HP9 there might be a preference towards infliximab just in terms of sort of ease and comfort (66)

unpredictable, more cumbersome) (54, 66) HP9 it's a drug we don't use very often (referring to unease with cicl) (58) HP12 cicl is the devil who you know because we have used it for many years (40)	HP9 something that is there in all of us in a way (referring to preference for infliximab) HP12 I would suspect that other colleagues mostly favour infliximab (252) HP16 think if they were given the option they would tend to favour inflix simply, I think it's done and its done and it's a much more well trodden pathway (612) HP15 I think most of them would be very keen to use the infliximab if they got the chance (340)
General comments on consultant views of colleague preferences	
HP2 Not all colleagues are happy to use either drug equally (73) HP4 personal view we pre-decide what happens in drug use for each individual patient according to what drugs they were on before, long term sensible goals, what is acceptable, pre-defined outcome (95) HP4 the subtleties of which sub-group of people respond to a certain drug, you will always be slightly biased by personal preference (183) HP7 I don't have a treatment preference happy to administer either (90) HP9 some colleagues were strict ciclorsporin users because of what the HTA [think he means NICE] had said and then there were others who were coming down on the infliximab side (300) HP14 I run it as a dictatorship so it's the same as (laughs) my views about, I'm in charge (laughs) so yea I think we appreciate they are equally effective (252) HP14 equally effective and there isn't a scientific preference between the two (255)	

Nurses' personal preferences

Ciclosporin	Infliximab
HPN19 I think their view is that they're not so keen on it but that's not necessarily based in any facts or knowledge it's just their opinion (20) HPN25a I don't have anything to do with ciclosporin so I probably if I was on a ward though I would prefer to use infliximab because it's easier to mix.... It's (cicl) much more high maintenance for the nurse so if I was on the ward and had the choice I probably would still go for infliximab (174)	HPN18 I prefer it when they have inflix... I think it's easier for the patient... because it's just one infusion... it's a couple of hours instead of being hooked.... I mean keep in mind they have got profusive diarrhoea... I think it's easier to administer as a nurse and it is easier for the patient to receive it as a patient (165, 169, 173, 178, 189) HPN18 Myself it would be infliximab but basically my reason for that..my background it haematology/oncology as we used a lot of the group of MAB therapies... we have has some really good, you know reactions with them (264) HPN19 I'm happy to treat patients with it (93) HPN19 I think there are pros and cons to both to be quite honest..... I don't rule out cicl as a treatment, but I think it's still, patient wise and other nurses and I think the general feeling it

	that infliximab is seen as better rightly or wrongly (144, 146) HPN19 probably still say it is inflix... and I probably fall into the same category or it's a recent drug and its...maybe again it's personal experience because I've probably seen the effects of inflix more... I speak to patients and find out their experiences and I don't see cicl (232, 236) HPN21 it's quite a good drug to be honest with you (119) HPN21 Personally I feel that the inflix is better but that's only because of the experiences we've had with the inflix rather than the cicl ... seen patients do very well on it, particularly when before there perhaps wouldn't have been any other outcome than surgery for them (209...217) HPN22 I've always considered infliximab is a good drug (77) HPN22 I kind of lean towards inflix but obviously, you know if the evidence tell us something different....just because I'm more familiar with it, that I see more patients have a good effect from it, but that's probably just because we've used it more (145, 150) HPN23a for most of the patients it a wonder drug, so I'm definitely all for it (28) HPN23a my own experience with inflix is a positive one, you know for patients so I can only think that it's a great thing to have (190) HPN23a I just think it's a great treatment, I think it's very good it's very effective and it's nice to see that it's actually being used widely with it being such an expensive one (254) HPN25a I don't have anything to do with ciclosporin so I probably if I was on a ward though I would prefer to use infliximab because it's easier to mix.... It's (cicl) much more high maintenance for the nurse so if I was on the ward and had the choice I probably would still go for infliximab (174)
General comments on nurses personal preferences	
HPN20 I can't say I do, I can't say I don't (179)	

Nurses' views on consultants' preferences

Ciclosporin	Infliximab
	HPN18 My feeling , that the doctors think that there is more value in giving someone infliximab than perhaps continuing with standard care (cicl) (237) HPN19 I think there is still the perception that there is still the perception that inflix is better....because it is the new one...not necessarily the consultants but maybe the doctors who aren't as experienced or a new rotation or new into it as such that maybe they don't

	necessarily know cic (211,214) HPN25a I don't know that that's what they would choose but I think now if they could use infliximab they probably would. And if they can use it they do (155, 160)

General comments on nurses views of consultant preferences

HPN19 I think they're happy to do both (211)

HPN20 (doctors considering practicalities for nurses) No they give no consideration whatsoever I would say (laughs) (168)

HPN20 I don't think they know enough about it, if I'm being honest with you, because we have a 3 month changeover for our medical team on the ward that they simply don't have enough confidence with the drug, they rely heavily on the nurses to tell them what it is and how they must prescribe it and again if there's a reaction, what they need to do about it, they don't seem to have the knowledge base as perhaps they should... they seem to be quite unconfident with it, purely from a lack of education, I feel (164...176)

HPN22 (doctors views on administering drugs) I don't think they actually probably consider it to be honest with you...no I don't think they think about the actual administration at all (121)

HPN23a They're just of the opinion that if it suits the patient and they get relief from it then they're quite happy for them to have it....it's an expensive drug (inflix) to have but it's just very effective so I don't think they mind at all (97)

HPN25a don't think they have much opinion on the practicalities of it because it's not for them to worry about.... Yeh I don't think they give any consideration to that to be honest I think they you know they're more interested in the outcomes for the patient. (160, 165)

Equipoise and views on trial

HP2 Efficacy of both drugs is equal, so not choosing one over the other on those terms (65)

HP2 Both drugs are equally available in the Trust (103)

HP2 Not all colleagues are happy to use either drug equally (73)

HP5 we haven't been successful in the Trial, we don't have nurses who can support it (169/173)

HP5 support for recruitment has not been there, only one single-handed nurse specialist (179)

HP5 'I'm fighting my corner again [for research support], as usual, story of my life' (180)

HP5 Trial nurses support the Trials Unit but they won't cover the wards where patients are both treated and recruited (189)

HP5 the Trial is good, very useful, very important. (197)

HP5 'I would like to make a thing about the Trial' (196) paperwork is hard for us to get, too much of it, too much for different departments to handle (R&D, pharm), much more than usual, top-heavy (197) (207)

HP5 the drug we choose ultimately depends on the patient (75)

HP5 you can always find reasons why Cicl is contraindicated! So you can say that Inflix is indicated for patients with acute colitis because, for example, they were at risk of infection (142)

HP1 I would give both Inflix and Cicl info to patients in an open setting if they want (41)

HP3 did not have any admissions severe enough to recruit to the RCT (191)

HP3 we had lots of people in the cohort but all responded to steroids (191)

HP3 luckily for the patients no one was eligible up to now for the RCT (192)

HP3 no patients have gone to to Cicl or have had colectomies for UC so no one ready yet (200)

HP4 quite well equipoised for this, so there would not have been a cost issue colouring our thinking, we do use both drugs (74)

HP4 There is a big difference in cost but it wouldn't drive our decision making outside this trial (80)

HP4 if choice has already been made about drugs, for those patients obviously don't want to be randomised to the trial – would obviously be a great number of patients in that situation (129)

HP4 I am aware that our numbers who have gone to randomisation are small but our cohort is reasonably big, trying to think why this might be (136)

HP4 we are not actively not getting them randomised into the trial, we have a research nurse and do 11 o'clock ward round to pick patients up (146)

HP4 you can use Inflix for acute rescue in the context of the trial, which is good and appropriate for the trial (204)

HP4 "I feel increadibly embarrassed that we have only had 1 randomisation and I know I am very proactive when I am on the ward and I know some patients will have been missed because inevitably no system is perfect…" (245)

HP4 "It is going to prompt me to look back at the cohort… because I do want to understand why so few people needed to go on….is proactively driven by my colleague… it either means all our patients are going into remission or we are failing to recognise that they need to be offered medical therapy and then not being randomised in the context of the trial… don't quite know what all the variables are to explain our very low recruitment" (252)

HP4 "it is high on the agenda and our nurse comes to a daily ward round" (279)

HP4 "exceptionally well run and organised trial" (288)

HP4 "I think you should be congratulated" (293)

HP4 "I'm just sorry we haven't got more patients actually in the randomised cohort" (294)

HP9 I think it was a good trial for use because we were slightly divided and reasonably neutral going into it (303)

HP9 we did go into it sort of excepting that it was a good clinical question that we didn't know the answer to nd we needed to move on with that (329)

HP11 (on inflix) if there is data to suggest that it significantly better in terms of avoiding surgery in terms of success of treatment then I'm willing to change my mind (62)

HP11 we have both been very keen to give every patient with colitis who was, fits the inclusion criteria be considered for the trial (257)

HP11 we have has a lot of patients who just did not want to go to the trial because you know patients come with their own pre-conceived ideas of what's better (261)

HP12 all of them were given the same (balanced view) even the colleagues who had been using cicl for a number of years gave the same view that we know this devil but we don't that much about the other devil but these are the pros and cons so the feeling from them all was that they were comfortable (259)

HP12 we were completely open (293)

HP13 you sort of has this feeling that infliximab was going to be better but actually as the trial progressed I don't think that was true (99)

HP13 my attitude changed over the course of the trial (110)

HP13 we couldn't give people infliximab without CONSTRUCT so we tried to enter everybody. I don't think you can anticipate any selection bias from our point of view (376)

HP13 there's a big down time when people think about it and then you start to persuade people and then they enter one and it just runs from that (411)

HP13 and by the end of the study you know it was just sort of taken as red within the unit that if someone came in with acute severe colitis they would have been consent for CONSRUCT and there's just the time taken for that change in mindset (417)

HP14 In terms of the outcome of the trial yeh, we were happy to use either of them, I didn't feel "oh no it's they've got this one or oh no I've got that one when I randomised them I was quite happy (241)

HP14 equally effective and there isn't a scientific preference between the two (255)

HP14 we were happy that it was a genuine equipoise decision (320)

HP14 but there were sites, I mean the site up the road North Tyneside up the road said we don't do that trial cos we believe the infliximab is better ad we're going to give inflix (324)

HP14 I think believing that the question is real and that there is equipoise is fundamentally important to the recruitment (327)

HP16 most of my colleagues is that the efficacy is probably broadly similar between the two but that for ease and convenience and side effect profile and familiarity of use within a hospital setting a biological would edge it, but we're quite happy giving cicl to the appropriate patients (560)

HP16 if the result was that cicl was a lot better we'd use it and it the results were that inflix was a lot better, we'd use it (622)

HP16 from the point of view from patient selection, it would have been difficult for us to introduce an enormous amount of bias (662)

HP16 most patients when they read about it probably intended to favour.. they were hoping they would get inflix, from reading the literature (673)

HP15 I would say that there probably isn't equipoise here, that we're slightly on the side of infliximab.... but of course at the beginning of the trial that view would have been different because of course they was less data available...more data equivalence of efficacy, but I still think people favour inflix cos it's better tolerated.... put all patients in, we were absolutely fair about it (345, 350, 360, 368, 372)

HP15 the difference (between drugs) is not sufficiently dramatic that I would say it was unethical to put them into a randomised study (460)

HPN18 pretty much from a personal point of view, every patient that I approached came into the trial. I mean they didn't all randomise, they didn't all go into the RCT, sometimes that was clinician's decision, sometime it was because they had read the little bit in the inflix leaflet that suggests that they could end up with some type of cancer (382)

HPN19 sometimes it depended on the individual clinician particularly in the beginning I always got the impression that there was… people had specific opinions but I think once they worked within the trial, working with the two drugs I think they were a lot more open to it as it developed (318)

HPN22 I can think of a couple of occasions a least over the last few years, where a consultant decided that no they wanted one particular one over another (191)

HP15 I would say that there probably isn't equipoise here, that we're slightly on the side of infliximab.... but of course at the beginning of the trial that view would have been different because of course they was less data available...more data equivalence of efficacy, but I still think people favour inflix cos it's better tolerated.... put all patients in, we were absolutely fair about it (345, 350, 360, 368, 372)

HP15 the difference (between drugs) is not sufficiently dramatic that I would say it was unethical to put them into a randomised study (460)

HPN18 pretty much from a personal point of view, every patient that I approached came into the trial. I mean they didn't all randomise, they didn't all go into the RCT, sometimes that was clinician's decision, sometime it was because they had read the little bit in the inflix leaflet that suggests that they could end up with some type of cancer (382)

HPN19 sometimes it depended on the individual clinician particularly in the beginning I always got the impression that there was… people had specific opinions but I think once they worked within the trial, working with the two drugs I think they were a lot more open to it as it developed (318)

HPN22 I can think of a couple of occasions a least over the last few years, where a consultant decided that no they wanted one particular one over another (191)

HP13 from a pragmatic point of view because if someone comes in now and they're not in construct then they get cicl because the SMC (Scottish Medicines Consortium) say we can't use inflix (218)

Consultants' and nurses' views on surgery (colectomy)

HP2 cannot generalise on whether to go for surgery or not, go by patient's experience (120)

HP2 no preference (surgery or keep on drugs) rely on clinical judgement re individual patient (121)

HP6 some patients should go for colectomy others worth trying to salvage their colons with drugs (146)

HP6 case by case decision, surgery for some is not a failure – it is what is needed for them at the time (147)

HP6 patient shouldn't regard colectomy as failure as such (148, 155)

HP1 If patient fit for surgery (life saving) and have not improved by 5 days would rather have it (92)

HP1 preference for colectomy but would go with what patient wants (cannot put colon back) (116-117)

HP3 anti-surgery and most patients agree with me they want to keep colon (126)

HP4 Colectomy still an important option often delayed by poor decision-making (213)

HP4 conservation of the colon is important but need to look at whole picture (disease history, risk benefit, surgical salvage, level of disease, previous rescue with other drugs) (225)

HP4 patients sometimes delay coming in or have delayed contact once they are in or go to another team for a while effectively delaying the inevitable and poor decision making leads to the inappropriate delay of surgery (224)

HP7 patient views as important as anything else, combined with weighing up risks and benefits, involve them hugely (103-109)

HP7 depends on patient view of taking drugs long-term, view of surgery, views on bag (young women don't want it) (110-116)

HP7 colectomy = cure, there is long term risk of using infliximab & ciclosporin or azathioprine, all powerful drugs (105)

HP9 nice to have an option for patients that isn't colectomy (204)

HP9 I think colectomy still has a role (209)

HP9 feels a little bit disappointing having to go for colectomy because it means obviously the treatments haven' worked (for patient and doctor) (210)

HP10 lifesaving (156)

HP10 timely colectomy has reduced the mortality of patients with acute sever UC, it's about saving lives, it's not about saving colons (156)

HP10 colectomy is one of the other treatment options..... contingency planning (162, 165)

HP11 It's something we do because we have to (176)

HP11 most patients would rather keep their colon, I don't think colectomy is a cure as many surgeons put it (178)

HP11 I think we need to give medical therapy a good try because that is what patients want us to do (184)

HP12 I wouldn't say to anybody that surgery is the next step and the only step without offering them the option of inflix (69)

HP12 we do offer patients colectomy probably more than a lot of other centres, I would presume (141)

HP12 I mean personal preference would be for offering infliximab and then colectomy (159)

HP12 there is some variability but we are not adverse to offering somebody colectomy because we have excellent surgical backup (161)

HP12 you have to individualised the patient, their circumstances (181)

HP13 I think in the right circumstances absolutely the right thing to do (308)

HP13 you just talk to the patients, you know, the number of people I've met who've sort of said "you know I had that operation x number of years ago and I feel fantastic I wish I'd done it years before" (311)

HP13 I'm not saying that operations get rid of every problem, you know there are clearly problems with pouches and stomas and things like that (315)

HP13 from a quality of life point of view and from a data point of view and from a personal point of view, that surgery is right in many circumstances, not for everybody by any means (319)

HP13 but equally the ones who haven't had it are very nervous about having anything like that, it's a last ditch, it's a very difficult decision (330)

HP13 I guess if there's one truth in life when it comes out you can't put it back (338)

HP14 I think it's good but um it really does depend on the patient....it usually depends on the psychology and situation of the patient ..... they almost all say "I wish I'd had it earlier"(179, 189, 194)

HP14 we've rarely regretted sending anyone for surgery (203)

HP16 colectomies clearly can be life saving and necessary in the right patient (431)

HP16 I'd be uncomfortable with a young patient who's not been exposed to a second line agent having a colectomy unless it's because of an emergency deterioration in their symptoms (426)

HP15 it's a brilliant treatment, it's just that ileostomy and or potentially pouch procedure that you need afterwards that's the problem (232)

HP15 I think in this day and age it's actually a very safe treatment for severe UC, it just the consequences which are disabling for patients (237)

HP15 some of our patients just will not have a colectomy unless they are at death's door (243)

HP15 it's always a difficult discussion with families about when to have surgery (253)

HP15 nowadays the more medical treatments that are available the more we try to delay the surgery and then of course it becomes a little bit more difficult to make that decision (263)

HP15 (referring to acute cases, recently diagnosed) it's very much more difficult for them... they haven't lived with it (277, 281)

HPN18 with UC generally speaking if they have the surgery it generally goes away and it doesn't come back (297)

HPN18 you need to do everything you can to preserve you bowel. So my gut feeling is that we shouldn't just go straight to colectomy, we should try all possible therapies out there (309)

HPN19 I've got patients who are happy to be on medication and they want to put off colectomy as long as possible because they see it as this big bad evil and I have other patients who are more willing to accept surgery and colectomy because they want to get over the symptoms and they've such poor quality of life that they want more, better and sometimes there's that middle row as well who aren't not sure about surgery but have it and actually are really quite satisfied because it's an end to all the symptoms and the loss of quality of life and things. Though it does depend on an individual decision as well so it's very difficult (183)

HPN19 I think it comes down to personal decision, I think it's very important to have lots of discussions about all the options, medical or surgical... it's very difficult if they're newly diagnosed and they come in with their first presentation ... some people come with obvious preconceived ideas about things anyway and I think it's important to explore those feeling and how they feel and then kind of gets you to a decision because I think there are some patients who are adamant they want to try everything they possibly can medically before they go down the surgical route .. there are patients who actually get to a point where they want their life back and this is pretty ultimate... the surgery being the ultimate solution (254,267)

HPN20 I think sometimes they can carry on with the medical treatment too long, that's my opinion. (192)

HPN20 (doctors don't get to see the outcomes for patients) they probably don't see them that often after colectomy.(211)

HPN21 I think it has to be very individual... I'm sort of on neutral ground with it... from a medical background, feel that they should be given the chance for a medical intervention before we go straight to surgery (236, 238)

HPN21 sometime they may be looking for a very quick fix (241)

HPN21 it's always a last resort, it's not something I'm particularly comfortable sending them off to have (247)

HPN22 I think it's an option and I think it's different for each patient and I think that they need to be given the choice and have all the information because for some patients it can be a very good treatment and give them back their quality of life (157)

HPN23a I think it has its place, you know if the medical intervention is just not working...I think it's a very hard thing to come to terms with, patients need counselling...I think they (patients) all prefer to try the medical treatment first (140, 147)

HPN24 that would be their last resort, their last option.... I think I would rather treat it conservatively first and then see what happens (190, 193)

HPN25a well I suppose it depends on patient by patient basis I mean I have seen lots of patients who've struggled for many years with different medicine..... And had all the you know all that's available to them and still struggled and eventually gone for a colectomy and wished they'd done it years ago.... on the other hand I've seen lots of patients then have problems post surgery I mean anyway..... I think I've got mixed views about it but I'm a medical nurse so I'd probably would always plum for the medical option (189, 194, 198, 208)

HPN25b my personal thoughts are that you know that that's a last resort and I think the majority of patients feel the same that they would rather try any form of medical management.... be fair the majority of them that do end up having surgical intervention are just just relieved to be at the end of all the, you know, of the symptoms really... at the right when time it's the right thing to do but it think it you know it should always be a last resort (137, 144, 149)

Negotiated care and shared decision making

HP2 (pro Inflix) most specialists feel 'well if I'm given a choice why don't I go down the path of least resistance which is human nature' (83)

HP5 our surgeons are very active [in decision making], and Multi Disciplinary Team meetings twice a week (121)

HP5 the drug we choose ultimately depends on the patient (75)

HP1 I would give both Inflix and Cicl info to patients in an open setting if they want Cicl (41) 'I don't have experience do I' (42) 'I have never given it personally' (43-4)

HP1 preference for colectomy but would go with what patient wants (cannot put colon back) (116-117)

HP3 anti-surgery and most patients agree with me they want to keep colon (126)

HP4 Care is negotiated with the patient, patient input is important, but pre-defined pathways according to previous discussions (113)

HP4 [surgery] patients come and say I have got to that point in my career where colectomy might be acceptable then we often try to operate (127)

HP4 if we are in a situation where we are just buying time, there will already have been a choice made (129)

HP4 patients sometimes delay coming in or have delayed contact once they are in or go to another team for a while (delaying the inevitable) (224)

HP4 surgery tailored to pt's previous history, patient's wishes (239)

HP7 patient views [re surgery] as important as anything else, combined with weighing up risks and benefits, involve them hugely (103-109)

HP7 [surgery] depends on patient view of taking drugs long-term, view of surgery, views on bag (young women don't want it) (110-116)

HP10 I like to tailor the treatment to the individual patient (144)

HP11 we don't choose it lightly we of course counsel the patients about the risks etc, but they face surgery at that point (Cicl) (28)

HP11 the patient needs to be counselled about the risks (cicl) (67)

HP11 I think we need to give medical therapy a good try because that is what patients want us to do (184)

HP11 I think the majority of people are quite fond of their colon and don't want a stoma or a big operation (196)

HP12 I wouldn't say to anybody that surgery is the next step and the only step without offering them the option of inflix (69)

HP12 we clearly individualise patients (longer term care, inflix) (95)

HP12 longer term after 12 months it is clearly individualised and based on sort of consensus at the MDT (97)

HP12 you have to individualised the patient, their circumstances (181)

HP12 we actually see the patients and talk to them together (colectomy) (196)

HP12 surgeons disagree amongst themselves across the country, whether it is wise to do or not but we have no qualms (204)

HP14 some patients I'd choose on and some other patients I'd choose the other (170)

HP15 it's always a difficult discussion with families about when to have surgery (253)

HPN19 more of the time they're on their last option so patients are quite happy to have the drug and therefore it makes it easier to give it or treat a patient with it because they are more accepting...they have limited options left (87, 91)

HPN19 the whole process involves talking to the patient and educating them as to why you are giving it (inflix) (94)

HPN19 (discussing longer term inflix) it sometimes comes down to a very individualised decision because it depends on how the patients are, how they feel you know.(183)

HPN19 (discussing longer term cicl) again if it works for the patient, sometimes it comes down to an individual decision then I would be happy to do that (202)

HPN19 I think it comes down to personal decision, I think it's very important to have lots of discussions about all the options, medical or surgical... it's very difficult if they're newly diagnosed and they come in with their first presentation ... some people come with obvious preconceived ideas about things anyway and I think it's important to explore those feeling and how they feel and then kind of gets you to a decision because I think there are some patients who are adamant they want to try everything they possibly can medically before they go down the surgical route .. there are patients who actually get to a point where they want their life back and this is pretty ultimate... the surgery being the ultimate solution (254,267)

HPN22 it's whatever is best for the patient (139)

HPN22 I think it's an option and I think it's different for each patient and I think that they need to be given the choice and have all the information because for some patients it can be a very good treatment and give them back their quality of life (157)

HPN19 more of the time they're on their last option so patients are quite happy to have the drug and therefore it makes it easier to give it or treat a patient with it because they are more accepting...they have limited options left (87, 91)

Costs

Costs of the two drugs and comparative costs

Ciclosporin	Infliximab
HP6 Cost of Cicl is cheaper than Inflix so in this hospital they have to complete a form saying when they wish to start using biological drugs, patient must try Cicl (unless already tried and had adverse reaction first time around) (64) HP6 Hospital policy favouring Cicl is all based on cost whereas for consultants want Inflix because of safety aspects (70) HP3 cheaper - that is the reason that change is impeded to move to favouring Inflix (160) HP3 cost will add up though. It is more than just cost of drugs, especially if patients have complications (argument against just favouring Cicl because it is cheaper) (172)	HP9 there are funding concerns (referring to long term maintenance use) (121) HP11 it's very very expensive so I bare that in mind (54) HP11 There are cost implications (long term maintenance) 108) HP11 25% complete remission for a cost of what we pay for infliximab is probably no justifiable really (236) HP12 it's about convenience and it's certainly more convenient, if you take cost out of the equation to give inflix (78) HP12 the only counteracting point is the cost (225) HP13 that's not an excuse to use it (inflix) given the huge cost differential, that's assuming that efficacy is relatively equal (37) HP13 if CONSTRUCT shows that cicl and inflix are equivalent on terms of efficacy…. I don't think there's any good excuse then to continue using a vastly more expensive drug (inflix) (48) HP14 it's expensive its £10,000 per year (73) HP14 but if you limit it to patients who've had a good response then its £10,000 per successful treatment (75) HP14 I mean the problem is that the expense of it, they've (NICE) got to come to terms with the cost of the drug, that's the problem (219)

	HP15 there is an issue of cost of course, we're pushed all the time to stop it for cost reasons (120) HP15 (referring to NICE guideline restrictions on inflix) it's done for financial reasons.... it's cheaper to take someone's colon out and that's the bottom line (292,297) HPN19 we now have to request the funding for patients with UC on long term inflix...so that's a bit of a challenge and it means that decisions are made differently to whether a patient is going on to maintenance inflix (154, 156) HPN22 It's already an issue because we can't really treat as maintenance with inflix so obviously if a patient responds well we've had to get exceptional funding and thing like that and so there is a case for it I think (103) HPN22 It's a costly drug so there has to be some kind of guidance doesn't there (NICE)(178) HPN23a They're just of the opinion that if it suits the patient and they get relief from it then they're quite happy for them to have it....it's an expensive drug (inflix) to have but it's just very effective so I don't think they mind at all (97) HPN23a more of an expensive treatment (169) HPN23a I just think it's a great treatment, I think it's very good it's very effective and it's nice to see that it's actually being used widely with it being such an expensive one (254) HP13 it is quite closely policed here (254)
General comments about cost of ciclosporin & infliximab	
HP2 Cost does not come into clinician's mind when it comes to drug choice as a rule (60) HP5 Should use either drug when the situation is acute and not consider the money (67) HP3 where are the calculations about which is the cheaper drug in the long run? (164) HP4 although there is a big difference in cost it wouldn't be a driver in our decision making outside of the trial (80) HP13 sent us how much we'd spent on the 2 drugs during the study and there was a massive difference. That if there's not a substantial differences in efficacy I just don't think there's any way that you can justify, you know, giving 2 drugs but picking the vastly cheaper one just because it's a bit easier (276) HP13 I think total healthcare costs are vital (298) HP15 cost is a huge issue here (490)	

Evidence and guidelines

Evidence (not related to National Institute for Clinical Evidence (NICE) guidelines)

Ciclosporin	Infliximab
HP5 evidence-base for Cicl is pretty good for it now (6) HP4 use of drugs is influenced by the European trial but I think there may well be equivalence with the 2 drugs (90) HP9 going with ciclosporin because it was perhaps had a bit more evidence base (87) HP10 I give it for a limited period (ciclo) but simply because the evidence for giving cicl on a long term basis and retaining remission is ....well there is none (124) HP12 no evidence for long term use of cic in UC setting anywhere (132) HP13 I don't think there is any evidence for that (use of cicl longer term) (162) HP14 I don't think there is the trial evidence to support it actually (long term use) (96)	HP5 Published studies show longer-term benefit of Inflix, similar to Crohns (50) HP5 there is evidence (e.g. CYSIF) follow-up data on patients acutely treated with Inflix, now time for pragmatic approach (151) HP6 better delivering something with use of a protocol (37) HP6 better guidelines around administering Inflix (37) HP1 Should be rolled out from research to practice, if you want to give a good try with med therapy (115) HP7 as we have data Inflix should be used in clinical practice HP7 data suggests it is effective, easier to administer, simpler regime, less palava (28) HP10 a recent article in APT suggesting that infliximab should always be used in acute severe UC and not ciclosporin (45) HP10 it's clear that continued use is effective in reducing colectomy rates (based on published literature, ACT 1 & 2 studies) (99) HP12 Inflix in the acute setting, there is not a great deal of trial data because most of the trials in the 2 licensing trials were moderate severe ones rather than acute sever ones (41) HP13 I think that the published data is not great (long term use inflix) (134) HP16 I don't think there is much evidence that really that this is, that we're switching off the disease so I think we're just a little bit behind where we were with chrohn's (345)

Evidence (related to NICE guidelines)

HP3 Inflix not licensed according to NICE you only give 3 doses, no maintenance (48)

HP3 Inflix personal preference, 'absolutely' but follows NICE guidelines (unfortunately) (116)

HP3 should be using more Inflix (132), not only in research (140), need guidance to change (134)

HP3 [NICE} should be using more Inflix, sooner the better (144)

HP4 NICE is constraining us re use of Inflix (197)

HP4 NICE is awkward, but we do have some patients using drugs outside of NICE guidance on specific argument of special cases (response rates, outcomes, reduction in colectomy rates, continuation of drugs (206)

HP7 as we have data Inflix [NICE] should be used in clinical practice (123/130)

HP7 NICE guidance not now appropriate now we have data, slightly outdated (123)

HP7 NICE will wait for x amount of studies before they will happily use Inflix in practice and 'Cicl is cheaper so driving a little bit the lack of impetus' (133)

HP2 Very frustrated by NICE guidelines they are one or 2 years behind what is available. They have a vast number of things that they need to do, so cannot keep up with guidance (129)

HP2 Use research setting or database setting, there is nothing else, but Inflix should be used more widely as the evidence is there just NICE haven't approved it yet (138)

HP5 NICE will recommend Inflix in time (56)

HP5 the drug we choose ultimately depends on the patient (75)

HP5 you can always find reasons why Cicl is contraindicated! So you can say that Inflix is indicated for patients with acute colitis because, for example, they were at risk of infection (142)

HP5 we are past the point where there is a question, you [NICE] should be able to use Inflix acutely (154)

HP6 NICE guidelines can only give 3 Inflix infusions cannot continue on as maintenance (94)

HP6 professionally would like to use Infix, but my hands are tied, bound by NICE (127, 131)

HP6 NICE very restricting why can't we be allowed to use Inflix (otherwise talking about surgery for patients who have severe enough symptoms to warrant a trial of Inflix) (13)

HP6 would be good if NICE guidelines were changed (161)

HP9 you can usually find a reason why ciclosporin would not be indicated and give the option (232)

HP9 I don't think it's a particularly sensible NICE guidance based on the lack of evidence that they have to make the decision on and therefore, in all honesty, because we can, we slightly ignore it (236)

HP9 I sort of treat it with a bit of contempt (239)

HP9 I think NICE promoting research when there is a question to answer is a good thing (266)

HP10 (referring to Infliximab as maintenance therapy) I know NICE don't approve but I think that NICE are behind the times and not for the first time (89)

HP10 it's a no-brainer to find a way of getting him on to infliximab again (113)

HP10 I think it's outdated, its manifestly inappropriate (196)

HP10 I think that they've got an effective drug which clearly works and I think should be allowed to use accordingly to license (217)

HP11 problems come up with NICE, we are getting increasing pressure in our area, to show that we are following NICE guidance so that becomes a problems (100)

HP11 I think it is difficult because up to recently there hasn't been convincing data to support it to be honest (207)

HP11 I think that NICE at the end of the day is also about health economics (211)

HP11 but I would support NICE at this point until there is better data (225)

HP12 statement made at a time based on the two licensing trials which did not include acute severe patients and there wasn't enough clinical practice data in the literature. So at the time probably that was a right statement, but now, you know, it is sort of unreasonable.

HP12 (should inflix only be used in research) no, because... its at least as effective as ciclosporin with the additional benefit of convenience and potentially less toxic (222)

HP13 NICE have written that guideline and I would interpret that as people can do what they want (laughs) … But we don't have that freedom (Scotland governed by SMC) (245, 250)

HP13 I'm not a massive NICE supporter but I actually think their guidance has been pretty sensible (346)

HP13 they as a national body have to have their eye on healthcare costs and I think to favour the cheaper drug if in a situation where there is such a big difference between the 2 drugs is sensible, but also to acknowledge that it's not absolutely the right drug for everybody (429)

HP14 I think the current NICE guidelines are um, a bit tricky because I think if you are going to give a patient infliximab you need to give them…., and then they respond to it, if they do respond to it you want to be able to continue the treatment and I think it may have more of a long term use than the NICE guidelines that we're currently using (38)

HP14 I think it's unduly restrictive and I think it will eventually change. I think it's actually quite hard to adhere to actually as well. I mean you've got a patient who you want to give treatment to, you're duty bound to give them the best treatment available and in some cases that's going to be inflix (208)

HP14 I mean the problem is that the expense of it, they've got to come to terms with the cost of the drug, that's the problem (219)

HP16 I think it's completely wrong (restriction of inflix) (447)

HP16 I think it's not backed up by data..so I think NICE is probably doing itself a major dis-service with this particular guidance because I think they lose credibility... this is an algorithm based on cost effectiveness that is probably outdated. (463)

HP16 I think there's been an interpretation of the results by NICE that is out of step with received gastroenterological opinion in the UK by experts in this area (504)

HP16 It's very hard to find anyone who supports the NICE guidance in its present format (516)

HP16 I'm pleased we can get access to biological in trials and I think a lot of our patients at the moment are in trials to get access to biologicals (519)

HP16 NICE guidance is from 2008 so you know the world has moved on a lot from there (528)

HP15 we bend the rules just slightly and feel it's not in their interest to have cicl, then we could use inflix... but it's bending the rules just a little bit and I'm always quite wary about that (162)

HP15 (referring to NICE guideline restrictions on inflix) it's done for financial reasons.... it's cheaper to take someone's colon out and that's the bottom line (292,297)

HP15 I think we should be allowed to use it (inflix) for UC if we use it for Crohn's disease (308)

HPN18 I think you have to have parameters there but I think there should be some kind of you know some leeway where it is not set in stone where somebody can make a decision as long as they can back it up with some kind of rationale (327)

HPN18 I don't think it (inflix) should be specifically just for research (340)

HPN19 I don't particularly agree with the NICE guidelines....NICE guidelines are key to funding issues because they go by them and strictly by them (287, 290)

HPN19 NICE kind of has a few things to answer for such as because it make these decisions and for UC there isn't a great deal of options (291)

HPN19 very personal opinion is that a bit closed minded of NICE, they need to be more open minded and flexible (294)

HPN19 (inflix in research) from a personal point of view I think having more information, having more data about different drugs and about how they affect patients I think it brilliant and I think it should be encouraged because it's the way to make informed decisions in the future (304)

HPN20 (inflix for research only) No...It works (laughs). I mean we've been using it up here for years and years as our first line treatment for our IBD patients. (245, 249) (Scotland site, NICE guidelines not applicable)

HPN21 (inflix in research only) I think it you took that element out people would be more happy to take it on board because when we mention research I think they seem to feel that it's maybe not proven to work...there's stigma around it and a bit of fear (265)

HPN22 I think it ties our hands a little bit (167)

HPN22 It's a costly drug so there has to be some kind of guidance doesn't there (178)

HPN23a more of an expensive treatment (169)

HPN23a I'm surprised at that statement (infliximab for research only) (185)

HPN25a I didn't know was if the ciclosporin is contraindicated I thought you could use it (inflix)..... I thought that erm it would we were able to use it for acute UC if I had any views it would be that I think it should be able to be used before it was acutely severe. (221, 231)

HPN25a I don't think it should only be in research. If it's a very expensive treatment I can see why NICE say that because it's incredibly expensive they'll probably compare the cost of a colectomy I can understand that point completely but I don't think if I had UC then I would want it available to me so I would think so. (251)

Nurse time on ciclosporin (health economics)

Nurses time on ciclosporin (Health Economics additional question)
HPN20 you need two registered nurses cos our student nurses aren't allowed to check anything like that....Probably 10 – 15 mins. Make up the bags, go to the patient, check the patient, change the bag four times a day, probably an hour anyway.... over a 24 hour period probably about¾ - 1hr would be spent dealing only with ciclosporin. (263...270)
HPN21 each first administration of it is going to require at least 4-5 hours of my time, bulk of which is observations, so quite a big chunk really (laughs) but after that the impact is much reduced, it's really just the initial dose it you like, the first infusion that they have. It varies because it very much depends on how much staff I've got as well (294)
HPN22 to prepare it, talk to the patient, set the patient up, do the observations and things that can take up to an hour.. and having to go back... it's about the same...for cicl and inflix , they're both time consuming 208, 232)
HPN24 usually the first few hours we would go for 2-4 hours , for the first 24 hours...we have to monitor the patient closely for side effects...but then it takes 2-4 hours because you've got the obs for a couple of hours...care assistants can also monitor blood pressure (246, 255, 269)
HPN25a from my memory it's just because you have to change the drip a number of times per shift and then you have to take another nurse to go and check it with you, you have to do their blood pressure you know I I just think it's erm as far as I remember it was quite time consuming. (269)
HPN25b in the early stages we would monitor them for the first few hours to make sure they weren't having any reactions..... After that then as you say the bags are changed six hourly so at that six hourly point, you know the patient may be on six hourly observations anyway so we would do observationsobviously check the access site and change the bag over with the intravenous additives guidelines now it's a two registered nurse procedure.... To prepare intravenous drugs so that's two nurses off the ward you know mixing and preparing the drugs and taking it to the patient.... Which I suppose could take perhaps from start to finish with our obs observe and an access check 20 minutes perhaps every six hours.....it's intensive that first period... We would probably monitor them more closely over the first six hours over the first bag..... To be honest it does feels like you know it's just part of what we do so it's not like a thing you would think about really. (169, 174,182,188, 208,232,252)

General comments about the trial

General comments about the trial
HP13 (cicl) previously we would have just written it up and then would have made it up and given and because we were doing the trial we, you know wrote a specific sort of SOP so we were clear that we were doing the right thing and doing the same thing to everybody (209)
HP13 we just thought we actually liked taking part (429)
HP14 our pharmacy made the trial as difficult as possible because they insisted we try to use trial supplies rather than normal supplies (292)
HP16 it's a relatively straightforward trial to take part in (566)
HPN18 because it is a clinical trial, we are having to make sure that things are prescribed and stuff like that (67)
HPN18 we'd actually increased her workload (IBD specialist nurse) sort of quite significantly as a result of the trial (135)
HPN18 in a general setting these nurses would be making the cicl themselves... as a clinical trial it comes up in an infusion bag already, they don't canulate the patients, their canualted by one of the doctors (time of nurses on cicl due to trial context reduced 15-20.) (419, 424)