

**Proposed changes to the provision of specialist
inpatient haematology services at the
County Hospital**

Communications and Engagement Plan

1. Overview

In October 2014, the Mid Staffordshire NHS Foundation Trust was formally dissolved and services were transferred to University Hospitals of North Midlands NHS Trust and The Royal Wolverhampton NHS Trust. As part of this dissolution, the Trust Special Administrators (TSA) detailed a number of service moves that needed to take place in order to ensure clinical and financial sustainability. All of the proposed changes were validated by local clinical groups and a number of national clinical bodies including the relevant Royal Colleges. As these were major changes to service provision, the proposals were subject to extensive consultation with the public, GPs and other stakeholders in summer 2013 and a report was produced (see TSA Final Report Appendix 1). The proposals were signed off by the Secretary of State in February 2014.

The majority of the proposed service changes were mentioned explicitly, but some specialist services, including services for patients suffering from haematological conditions, such as myeloma, lymphoma and leukaemia, were not mentioned individually. However, the report did state that there was a need to transfer specialist services out of what is now County Hospital, because there is clear clinical evidence that some patients would benefit from specialist treatment at a specialist centre.

With the projected patient flow changes due to the new chemotherapy unit at Cannock Chase Hospital and additional inpatient facilities at The Royal Wolverhampton NHS Trust, a consultation is being undertaken to consider the proposal of the movement of haematology inpatient services from County Hospital. The current inpatient haematology service at County Hospital does not meet the required standards for the British Society for Haematology's Level 2 standard of care and this is likely to become more difficult to achieve as it is proving increasingly difficult to recruit and retain clinical staff.

To ensure that commissioners and providers can evidence that a full debate has taken place about the proposed moves relating to these services and any decisions can stand up to scrutiny, a six-week consultation is being held on the specific move of inpatient haematology services from the County Hospital, building on the previous consultation and engagement work carried out by the TSA.

The consultation is being led by Stafford and Surrounds Clinical Commissioning Group, supported by the Midlands and Lancashire Commissioning Support Unit (CSU) and Healthwatch Staffordshire.

2. Aims and objectives

The aim of this plan is to establish the way in which we communicate and engage with staff, patients, stakeholders and the local population about the proposed move of services, clearly communicating reasons and benefits.

The communications and engagement plan will:-

- Provide a clear and transparent rationale for the proposed service moves;
- Aim to reassure the patients about the services that will not be affected by the proposal;
- Encourage patient and staff feedback on the proposals;
- Encourage public feedback from the wider communities of Cannock Chase and Stafford and Surrounds;
- Ensure the public and key service users and carers are informed about how to access new services temporarily or in the future.

More specifically, the purpose of this plan is to:-

- Define outcomes in terms of communications and stakeholder engagement for the formal consultation programme;
- Define key high-level messages;
- Identify any communications risks and seek to address them;
- Identify key audiences and appropriate level of engagement;
- Identify the appropriate methods of delivery for communication and engagement, including timescales;
- Incorporate mechanisms for monitoring and evaluating the effectiveness of communications and feeding this intelligence back to the Task and Finish Group.

3. The Legislation

The Health and Social Care Act 2012 introduced significant amendments to the NHS Act 2006, especially with regard to how NHS commissioners will function. These amendments include two complementary duties for clinical commissioning groups with respect to patient and public participation.

Section 242 states “Each relevant English body must make arrangements, as respects health services for which it is responsible, which secure that users of those services are, whether directly or through representatives, involved (whether by being consulted or provided with information, or in other ways) in:-

- a) The planning of the provision of those services
- b) The development and consideration of proposals for changes in the way those services are provided, and
- c) Decisions to be made by that body affecting the operation of those services.”

The duty applies if implementation of the proposal, or a decision (if made), would have impact on:-

- a) The manner in which the services are delivered to users of those services, or
- b) The range of health services available to those users.

A person is a “user” of any health services if the person is someone to whom those services are being, or may be provided.

4. Communications and Engagement: Approach and Delivery

This consultation intends to build upon the extensive work carried out by the Trust Special Administration (TSA) in the summer and autumn of 2013. It will identify what further actions are proposed to ensure that Commissioners and Providers can evidence that a full debate has taken place about the proposed moves related to these services and that any decisions stand up to scrutiny.

Due to the nature of the services included in the proposals and the relatively small number of patients who would be affected (83 recorded instances over a year period commencing April 2014), the main focus of the consultation will be targeted at those patients, their carers and their families. It will also target any staff within the haematology departments at both Trusts,

to seek their views on the proposals and seek independent guidance from specialists in these fields.

The NHS, however, has an obligation to inform and engage the wider public about any proposed changes; in particular those who may not be engaged through traditional methods. The consultation will therefore seek to communicate and engage with the wider populations of Cannock Chase and Stafford and Surrounds. The consultation with the wider public will be supported by Healthwatch Staffordshire.

Midlands and Lancashire CSU will lead all Communications and Engagement to ensure the public voice is heard, and information gathered is fed back to the Task and Finish Group.

All communications and engagement activities will be delivered over the course of six weeks, as recommended by the Healthy Staffordshire Select Committee. The consultation will be launched on Monday 14th September 2015 and run till Tuesday 26th October 2015.

5. Health Equality Impact Assessment (HEIA)

Stafford and Surrounds CCG will undertake additional HEIA work in August 2015 as part of its formal consultation process in line with the Equality Act 2010. To ensure that the consultation is fully informed and complementary to the Quality Impact Assessment the HEIA will inform the following areas:

- Provide an understanding of the impact on the health of the local population of the proposed move of haematology inpatient beds from County Hospital
- Assess the impact of the proposal on specific groups within the local population and staff
- Assess the impact of the proposal on patient travel times
- Quantify where possible the impact of the proposal and recommendations and gather additional evidence where required
- Make recommendations to the CCG on actions to potentially mitigate negative impacts and help develop positive impacts

The assessment process itself will have two strands of enquiry, one which focuses on Health and the second that will focus on Equity:

- Health - consideration of the health consequence of the changes and identification of its impact for the local population, with particular attention to those at increased risk of a negative impact
- Equity - consideration of the potential impact for those groups covered by the public sector equality duty, with a primary focus on age, disability, sex, and race (these are the prioritised "protected characteristics")

The Impact Assessment Process can be found in Appendix 1 of this document.

6. Risks

- Timelines – relatively tight turnaround time and some of the processes required are not within the control of the CCGs i.e. regional and national sign off
- Previous consultation on service moves raised concerns about transport which has and will not change from current arrangements
- Proposals are likely to be perceived as further downgrading of County Hospital
- The proposals are not supported by the existing consultants, who will be in direct contact with patients during the consultation process

- Questions over patient choice need to be addressed versus the patient desire for continuity of care
- Possible perception of interim move (on grounds of safety) to be a fait accompli; public consultation is deemed to be tokenistic

7. Key messages

It is important that our messages are consistent to give the review a clear voice, and ensure that we are credible with all of our audiences. Wherever possible the key messages need to be backed up with specific detail, in particular on the numbers and types of patients who would be affected, or not.

Media coverage has created some confusion about what the proposals relate to and mixed messages for patients and the public. The key messages for the public about what will not be changing are:

- There would not be any change to the clinical haematology outpatient service, with the exception of the change in referral pathway, which is not subject to public consultation
- There would not be any change to the chemotherapy treatment unit, which provides day case services

There are also a number of communicable benefits associated with the proposed move of inpatient beds that need to be shared with patients.

- New patient referrals from Cannock Chase CCG will be given the choice to receive treatment, including access to services, at the Royal Wolverhampton NHS Trust or University Hospitals of North Midlands
- Haematology patients from Cannock Chase would have access to a more locally provided service
- Patients receiving outpatient treatment in Stafford would be given the choice of remaining at County Hospital or transferring to a newly developed haematology service at Cannock Chase Hospital. Any moves would be supported to provide continuity of care
- A considerable investment is being made to provide a new chemotherapy unit at County Hospital, which is due to open in summer 2016
- Only a small number of patients, carers and families would be directly affected by the proposals (approximately 83 patients per annum)
- Centralising a small number of inpatient services would ensure access to state-of-the-art facilities and to a more specialist level 3 service at the Royal Stoke Hospital; as recommended under the British Haematological Society's classification guide
- All patients would have access to specialist support services, which enables greater patient safety as well as leading to continued improvements in patient outcomes and satisfaction. The safety issues relate to the support for patients with bone marrow suppression, specifically neutropenia and potential for sepsis and deterioration.
- Patients would have access to a wider range of professionals such as advanced nurse practitioners, dietetics and therapies, as well as the services provided by a large acute hospital, such as critical care

- Significant consultation took place with the public and other stakeholders as part of the Trust Special Administrator process and this information is still valid and has been used to inform these proposals
- There are financial implications of the 'do nothing' option
- There is a future risk to clinical sustainability and patient safety due to the difficulty in maintaining the required staffing levels together with the lack of appropriate facilities.

8. Key stakeholders

The focus of the consultation will be with those who would be directly affected by the proposed changes, whether patients or staff, and also those who will be involved in the decision making process at the end of the consultation. These include:

- Patients (service users), carers and families
- Provider staff including consultants and nursing staff in Haematology
- Cannock Chase and Stafford & Surrounds CCGs' Membership Boards
- Cannock Chase and Stafford & Surrounds CCGs' Governing Bodies
- Clinical Oversight Group
- Healthy Staffordshire Select Committee (OSC)
- Local/MPs Councillors
- NHSE Regional/National
- Healthwatch
- General Public - including District and Network Patient Participation Groups
- Support Stafford Hospital and Champion Stafford Hospital Community
- Third Sector

9. 360 degrees Communications and Engagement

Central Midlands CSU Communications and Engagement Team offer end-to-end communications of service.

For the purpose of this consultation, we estimate that the **Engagement, Media and Digital and Design** teams will be most involved alongside the CCG Engagement Leads and our Account Managers, who are embedded within the two CCGs.

CSU Engagement Leads are familiar with, and have helped set up, the internal and external communications channels and will work with CCG leads to identify local key stakeholders.

Media: management of press, media and other non-paid communications channels.

Stakeholder relations: having a structured approach to stakeholder communications, ensuring that our activities cover all of our audiences. This includes an audit with the aim of understanding key concerns of major stakeholders and engaging with partner organisations.

Digital: digital media will be a major channel for delivering information, for both internal and external audiences. This will include social media and web presence including general information about the proposed move, news and updates.

Engagement: Local engagement will also be carried out via CCG and with partner organisations through existing Patient and Public Involvement channels, as well as through the provider Trust.

Communications and engagement actions

Delivery	Formal consultation	Timeline	Lead
Insight	Review and reconfirm CCG stakeholder map	15 th July	AE
	Liaise with UHNM and RWT to identify individual patients and staff who would be affected by the proposals and appropriate ways in which to engage with them.	15 th July	GA/DB/AE
	Identify key internal and external meetings to be targeted during the consultation (including CCG, Trust, OSC) and identify relevant people to attend	15 th July	AE/JB
	Reconfirmation of engagement/distribution channels across CCGs and the Provider Trusts	15 th July	AE/LL
	Draft and approval of consultation questionnaire for approval	15 th July	JS/AE
	Create and upload online version of questionnaire	w/c 31 st Aug	CSU - DP
	Engage with Healthwatch Staffordshire to support the consultation with the wider population – identify any gaps in stakeholder engagement	15 th July	AE/JB
	Evaluation of feedback	26 th Oct – 9 th Nov	CSU/JS
Engagement	Detail engagement activities on a week by week basis throughout the six week consultation	15 th July	AE
	Arrange and book appropriate venues for wider public events	15 th July	AE
	Identify engagement opportunities, working with CCG Engagement/PPI leads to promote the consultation	15 th July	AE
	Undertake Health Equality Impact Assessment	August	JB
	Facilitate patients and public engagement event	14 th Sept – 26 th Oct	AE/JS
	Facilitate engagement with staff employed in the service areas which would be directly affected by these changes	14 th Sept – 26 th Oct	GA/DB

Delivery	Formal consultation	Timeline	Lead
Media management Proactive and reactive media management, to include the following:	Development of communications message to all key stakeholders	15 th July	DB/AE
	Update and promotion of revised FAQ s to complement communications message	15 th July	BM/AE
	Liaise with UHNM to draft case studies of existing patients – to include impact of transport on carers and their families	15 th July	DB/AE
	Identify reputational risks, advise on media handling and prepare responses	25 th Aug	JC
	Briefing and preparation for OSC presentations	21 st Sept	JB
	Provide a first point of contact and lead for the management of all media enquiries	14 th Sept – 26 th Oct	JT/RS
	Draft news release and issue to key media	14 th Sept – 26 th Oct	JT/RS
	Draft responses to media enquiries and secure sign-off	14 th Sept – 26 th Oct	JT/RS
Design and digital	Management of all online/web based communications	14 th Sept – 26 th Oct	AE/LL
	Management and delivery of updates via social media, where applicable (Twitter)	14 th Sept – 26 th Oct	AE/LL/RR
	Design and print of consultation document	14 th Sept – 26 th Oct	CSU
Communications Lead	Overall day-to-day management of all regular internal and external communication channels to create awareness and understanding of the engagement		

- JB** - Jonathan Bletcher
- AE** - Adele Edmondson
- GA** - Gill Adamson
- DB** - Dani Baker
- LL** - Liz Limbert
- JS** - Jan Sensier
- CSU** - Commissioning Support Unit
- JT** - James Turner
- RS** - Robin Scott

Stakeholder	Engagement Activity	Date	Required Attendance/Action
Patients, carers and families	Liase with RWT/UHNM/Healthwatch to arrange patient engagement events	15 th July	Dani Baker
	Letter to all County Haematology patients explaining proposed changes and invite to patient pre-engagement events (for purposes of pathway changes) plus engagement events as part of consultation	w/c 3 rd Aug	Dani Baker/Brian Mellon
	Patient Pre-Engagement events	w/c 17 th Aug	Healthwatch
	Open evenings at RWT and UHNM	31 st Aug	Dani Baker/ G Hill
	Patient Engagement events (combined with public events) Cannock – Aquarius Ballroom, Hednesford	16 th Sept 6pm – 8pm	Andrew Donald/ Jonathan Bletcher/ Mo Huda/ Ian Chamberlain/ Healthwatch
	Stafford – Gatehouse Theatre	29 th Sept – 6pm till 8pm	Andrew Donald/ Jonathan Bletcher/ Paddy Hannigan/ Ian Chamberlain's equivalent at RWT/ Healthwatch
	Discharge summaries for inpatient transfer/post treatment period	1 month prior to move	Ian Chamberlain/S Leah
Feedback discussions with all patients moved to highlight any lessons learned	1 month post move	Ian Chamberlain/S Leah	
Provider staff consultants/nursing staff –	Staff engagement has been undertaken over the last six months and as part of the Trust's Management of		

Appendix 4

	Change process for clinical haematology at County, both group and 1:1 meetings have been offered to all staff and held with those who have attended		
NHS England – Region	All consultation documents to be submitted to NHS England	20 th July	Andrew Donald
	NHS England panel convened to consider and sign off consultation documents	7 th Aug	
	Regional sign off by NHS England	25 th August	
Stafford & Surrounds Membership Board	Initial briefing about the proposal to be presented to Members	7 th July	Dr Paddy Hannigan
	Consultation document to be shared with members once approved by NHS England Regional Team	w/c 24 th Aug	Dr Paddy Hannigan/ Adele Edmondson
	Formal consultation with members	6 th Oct	Dr Paddy Hannigan
	Update on the outcome of the consultation to be presented	3 rd Nov	Dr Paddy Hannigan
Cannock Chase Membership Board	Initial briefing about the proposal to be presented to Members	8 th July	Dr Mo Huda
	Consultation document to be shared with members once approved by NHS England Regional Team	w/c 24 th Aug	Dr Mo Huda/ Adele Edmondson
	Formal consultation with members	13 th Oct	Dr Mo Huda
	Update on the outcome of the consultation to be presented	11 th Nov	Dr Mo Huda
GPs – wider engagement	Consultation document to be shared with all GP	14 th Sept	Adele Edmondson

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	practices including link to online survey		
	Add consultation document and survey to Intranet	14 th Sept	Adele Edmondson
	Articles included in GP Newsletter	From 14 th Sept	Adele Edmondson
Stafford & Surrounds Governing Body	Consultation document to be forwarded to members	w/c 24 th Aug	Gill Hackett
	Formal consultation with members (confidential section of development session)	/22 nd Sep	Andrew Donald/Paddy Hannigan/ Jonathan Bletcher
	Joint Governing Body (GB) Meeting to make a decision based on feedback from the consultation (SaS Organisation Development GB Session)	Nov	Andrew Donald/Mo Huda/ Jonathan Bletcher/ Paddy Hannigan
Cannock Chase Governing Body	Consultation document to be forwarded to members	w/c 24 th Aug	Gill Hackett
	Formal consultation with members (confidential section)	/1 st Oct	Andrew Donald/Mo Huda/ Jonathan Bletcher
	Joint Governing Body (GB) Meeting to make a decision based on feedback from the consultation (SaS Organisation Development GB Session)	Nov	Andrew Donald/Mo Huda/ Jonathan Bletcher/ Paddy Hannigan
CCG Staff	Consultation document to be shared with all CCG staff including link to online survey	14 th Sept	Adele Edmondson
	Add consultation document and survey to Intranet	14 th Sept	Adele Edmondson
	Articles included in CCG News in Brief	From 14 th Sept	Adele Edmondson
Clinical Oversight Group	Kay Fradley to arrange and advise		Kay Fradley
Healthy Staffordshire Select	Consultation document to be forwarded to HSSC	w/c 24 th Aug	Adele Edmondson

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Committee (HSSC)	following sign off Presentation to HSSC	21 st Sept	Andrew Donald/Jonathan Bletcher
Stafford MP – Jeremy Lefroy	Face to face briefing	TBA	Andrew Donald/
Cannock MP – Amanda Milling	Face to face briefing	TBA	Andrew Donald/
Local Councillors	Consultation document to be forwarded to councillors following sign off	14 th Sept	Adele Edmondson
Healthwatch Staffordshire			
Cannock Network PEGs	Members to be invited to public engagement event Consultation with members of the Network PEGs: <i>Rugeley – briefing at the meeting with document to follow after 14th Sept)</i> <i>Great Wyrley, Cheslyn Hay, Norton Canes & Essington briefing at the meeting with document to follow after 14th Sept)</i> <i>Cannock Town</i> Update on the outcome of the consultation to be presented <i>Rugeley</i> <i>Great Wyrley, Cheslyn Hay, Norton Canes & Essington</i> <i>Cannock Town</i>	After 14 th Sep 2 nd Sept 10 th Sept 24 th Sept 2 nd Dec 10 th Dec 17 th Dec	Adele Edmondson Jonathan Bletcher/Shirley Goodchild Jonathan Bletcher/Shirley Goodchild
Stafford District PPG	Members to be invited to public engagement event Consultation with members at the District PPG Meeting <i>briefing at the meeting with document to follow after 14th Sept)</i>	After 14 th Sep 9 th Sept	Adele Edmondson Jonathan Bletcher/Shirley Goodchild

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	Update on the outcome of the consultation to be presented	9 th Dec	
Support Stafford Hospital	Healthwatch to facilitate meeting with Support Stafford Hospital group		Andrew Donald/ Jonathan Bletcher/Jan Sensier
Champion Stafford Hospital Community	Face to face meeting with the Champion Stafford Hospital Community Group	9 th Sept	Andrew Donald
	Information included on the group's Facebook Page	14 th Sept	Adele Edmondson
General Public	Consultation information to be added to the two CCG Websites including FAQs, Consultation Document and on-line survey	14 th Sept	Adele Edmondson
	Consultation document to be circulated to CCG Databases – including invitation to public engagement events	14 th Sept	Adele Edmondson
	Patient and Public Engagement events Cannock – Aquarius Ballroom, Hednesford	16 Sep 6pm till 8pm	Andrew Donald/ Jonathan Bletcher/ Mo Huda/ Ian Chamberlain/ Healthwatch
	Stafford – Stafford Gatehouse Theatre	29 th Sep – 6pm till 8pm	Andrew Donald/ Jonathan Bletcher/ Paddy Hannigan/ Ian Chamberlain's equivalent at RWT/ Healthwatch
3 rd Sector groups		After 14 th Sep	

APPENDIX 1

The Impact Assessment Process

The impact assessment being undertaken will be based on DH's guidance; this guidance proposes a five-stage process as summarised below in Table 1.

Table 1 : Summary of the DH's HEIA process

Stage 1:	Stage 2:	Stage 3:	Stage 4:	Stage 5:
Screening	Identify health impacts	Identify impacts with important health outcomes	Quantify or describe important Health Impacts	Recommendations to achieve most health gains
Screening questions are used to decide whether to proceed to further stages.	<p>A long list of all the potential impacts on the health of the population is identified</p> <p>These impacts could be major or less serious, direct or indirect and occurring at any stage of the implementation of the policy</p>	<p>The most important health impacts</p> <p>These impacts may impact on the whole population or on specific groups (defined by age, ethnicity/race, religious belief, etc.)</p> <p>The impacts may be difficult to remedy or have an irreversible impact and/or cause a great deal of public concern</p> <p>The impacts may be medium to long term</p>	<p>A qualitative or quantitative judgement is made about the important health impacts</p> <p>This could cover the potential costs and benefits, how health varies in different circumstances and why</p>	<p>Recommendations are given on how to amend the policy to deliver the greatest possible health gain for the population in relation to the overall costs of the policy</p>

To support the completion of the HEIA a local Task and Finish group has been formed. Members include the Chief Officer, Chair and Director of Strategy of Stafford & Surrounds CCG; Director of Quality and Nursing at NHS England, Head of Performance and Delivery at the Trust Development Authority, Deputy Director of Finance at UHNM, Hospital Director of County Hospital, Director of Operations at County Hospital and Chief Executive of Healthwatch. It also includes representatives from the communications and engagement workstream.

It is the considered view of the Group that where appropriate, this assessment should draw on the work undertaken as part of the Mid Staffordshire Foundation Hospital Trust Special Administrator (TSA's) process. Therefore stages one and two of the HEIA will draw on the work of the Mid Staffordshire Foundation Hospital Trust HEIA Steering Group and the published report (2013) (reference) updated as appropriate, this will include:

- An initial analysis of the local population and its health needs;
- Further analysis of the local population based on a variety of datasets to provide descriptions of this population by protected and other characteristics;
- Analysis of the available evidence to prioritise the protected and other characteristics for further analysis.

Summary of Stages 3 to 5

A summary of stages three to five and the analysis that will be undertaken is set out below; details of the approach to patient, staff and public engagement can be found in the Communications and Engagement Plan.

Stage 3: Identify impacts with important health outcomes:

- Analysis and engagement with patients, staff and stakeholders to understand the implications on the identified impact areas arising from the proposal to move services
- Further analysis and engagement with patients, staff and stakeholders to understand the implications of the proposal for people with protected and other characteristics

Stage 4: Quantify or describe important health impacts:

- Further analysis to understand the impacts of the proposed changes to access to healthcare, including travel times
- Analysis of potential impact for existing staff of at the County Hospital who fall within the scope of the protected and other groups

Stage 5: Recommendations to achieve most health gains:

- Synthesising the above to identify and clarify mitigating actions for negative impacts and developments to strengthen positive impacts

To ensure that the impact of any proposed changes are identified and described in both qualitative and quantitative terms (including the impact on health outcomes and access respectively) and to be able to provide objective recommendations on how the negative impacts can be minimised and the positive impacts enhanced, the CCG will adopt Maxwell's Dimensions of Quality as its framework for assessment of the health impacts. (Ref) Maxwell (*RJ Maxwell 'Dimensions of Quality Re-visited' in Quality in Health Care 1992 1:171-177*)

Framework for assessing health impacts

This framework is based on the assertion that quality in health care is multidimensional and covers six areas: effectiveness, acceptability, efficiency, access, equity and relevance. These are summarised below:

Effectiveness

Is the treatment given the best available in a technical sense, according to those best equipped to judge? What is their evidence? What is the overall result of the treatment?

Acceptability

How humanely and considerately is the treatment/service delivered? What does the patient think of it? What would/does an observant third party think of it ("How would I feel if it were my nearest and dearest?")? What is the setting like? Are privacy and confidentiality safeguarded?

Efficiency

Is the output maximised for a given input or (conversely) is the input minimised for a given level of output? How does the unit cost compare with the unit cost elsewhere for the same treatment/service?

Access

Can people get this treatment/service when they need it? Are there any identifiable barriers to services – for example distance, waiting times, opening times or straightforward breakdowns in supply?

Equity

Is this patient or group of patients being fairly treated relative to others? Are there any identifiable failings in equity – for example, are some people under-represented in service usages?

Relevance

Is the overall pattern and balance of services the best that could be achieved, taking account of the needs and wants of the population as a whole?

Source: RJ Maxwell 'Dimensions of Quality Re-visited' in Quality in Health Care 1992 1:171-177.