Quality of life, or the baby and the bathwater

Quality-of-life has become a buzz word, enough to bring tears to most clinicians’ eyes. This is a shame because we really do need ways to measure the ways in which interventions can “make patients feel better”.

The efficacy bandwagon - purchase the effective, discard the ineffective - is long overdue, although Bandolier likes the phrase “stop unnecessary interventions” best. The cautionary note is that if we try to measure the efficacy on one dimension alone, however well validated those measurements may be, we may miss subtleties from other dimensions - the things which make the patient feel better. An example of this may be the use of counsellors in primary care - one of the DEC reports featured in Netwatch in this issue (page 6).

A crude example would be functional disability measurement. This may well categorise end-of-life disability but be useless for more minor degrees of disability such as inability to raise an arm to comb hair. The danger is that we discard interventions because of their failure to ‘score’ on one outcome and miss the subtlety, the excuse to get better, in our haste. Physiotherapy in primary care has by and large scored poorly in many of the reviews, but few of the trials have looked for these subtleties. Those seeking relief of symptoms in a self-limited disorder may appreciate those subtleties.

The one report reflex

Clinicians on the leading edge have a problem. A new trial is published showing marvellous results in a previously intracetable condition. The trial meets all the critical appraisal quality standards. Surely the next ten patients coming to the surgery with that problem should get the treatment (and the others without the condition too)?

A wise professor of medicine challenged Bandolier when confronted with the evidence that the profession was very slow to change its ways - the specific example was the use of thrombolitics after myocardial infarction - and the more than ten years it took to filter through to practice [1]. The professor’s point was that this delay might serve a purpose, to make sure that the findings were right before they were applied widely. The point was well taken, as recent flawed reviews on magnesium in myocardial infarction and low dose aspirin in high-risk pregnancy have shown.

Perhaps this is even more of a problem when safety rather than efficacy is the issue. A trial reports that drug X causes problems. Everyone stops taking drug X. The spate of pregnancies after the DVT and oral contraceptive publicity is a glaring example (Bandolier 21). For personal reasons Bandolier is worried that stopping selegiline in Parkinson’s may extend quantity of life for 1 in 10 patients but reduce quality of life for the nine (Bandolier 23).

All this shows that life isn’t easy. You have to assess the evidence and act. At least doctors have an advantage over most all other areas of professional life in that they have evidence on which to base their decisions.

Reference:

How good is that test II

Bandolier 26 reported on quality standards that should be met by reports of diagnostic procedures, and how few of those standards were met by reports in our top medical journals. Users of tests will want to know not only that tests work, but how well they work - just like NNTs for treatments.

This issue of Bandolier investigates diagnostic test qualities a little further. The problem of spectrum bias means focusing on sensitivity and specificity of tests. These, however, are not the most user-friendly of measures, so Bandolier, ever seeking simplicity, has invented a new measure - the NND, or number-needed-to-diagnose. Comments are invited.

Spectrum bias

An unrecognised (but probably very real) problem is that of spectrum bias [1]. This is the phenomenon of the sensitivity and/or specificity of a test varying with different populations tested - populations which might vary in sex ratios, age, or severity of disease as three simple examples.

Spectrum bias at its simplest means that the sensitivity and specificity of the test have to be known in a range of different patient populations.

This was tested in the paper by looking at men and women tested for urinary tract infections with urine dipsticks [1].

Overall the sensitivity was 0.83 (95%CI 0.73 - 0.91) and specificity 0.71 (0.66 - 0.77).

When the clinical prior probability of UTI being present was high the sensitivity of the test was high - 0.92 (0.82 - 0.98).

When clinical prior probability was low the test performed less well - sensitivity 0.56 (0.31 - 0.79).
For any chosen clinical endpoint the NNT is the reciprocal of the fractional improvement in a treated group minus the fractional improvement in an untreated group.

\[ \text{NNT} = \frac{1}{\text{fraction improved with active} - \text{fraction improved with control}} \]

For a diagnostic test the analogous calculation of a NND would be the reciprocal of the fraction of positive tests in the group with the disease minus the fraction of positive tests in the group without the disease.

The first term, the fraction of positive tests in the group with disease is the sensitivity (true positive/true positive plus false positive). Specificity is defined as the proportion of people without the disease who have a negative test. So the second term, the fraction of positive tests in the group without the disease, is 1 - specificity.

\[ \text{NND} = \frac{1}{\text{sensitivity} - (1 - \text{specificity})} \]

Problem

The problem is handling tables of sensitivity and specificity - two sets of numbers that can go up or down independently in different populations. It is just too much for simple or busy brains. It is hard enough remembering just how sensitivity and specificity are defined. If the evidence is too complicated to be used, then we have a problem.

Simplify

Is it possible to simplify these measures? Well, a whole raft of calculations can be done knowing the true and false positive and negative rates, none of which condenses the information down to a single useful figure. Using positive and negative predictive values (as one example) still means carrying too much baggage.

Given Bandolier’s predilection for the number-needed-to-treat, we wondered whether it was possible to generate an analogous “number-needed-to-diagnose”. The arguments go something like this (and forgive a little jargon):

For any chosen clinical endpoint the NNT is the reciprocal of the fractional improvement in a treated group minus the fractional improvement in an untreated group.

\[ \text{NNT} = \frac{1}{\text{fraction improved with active} - \text{fraction improved with control}} \]

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Number-needed-to-diagnose

The number-needed-to-diagnose is therefore:

\[ \text{NND} = \frac{1}{\text{sensitivity} - (1 - \text{specificity})} \]

How does this work in practice?

Take Helicobacter pylori infections as an example. Serology tests for the presence of anti-H pylori immunoglobulins and urea

<table>
<thead>
<tr>
<th>Test</th>
<th>Subgroup</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine dipstick for UTI</td>
<td>overall</td>
<td>0.83</td>
<td>0.71</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>high prior probability</td>
<td>0.92</td>
<td>0.42</td>
<td>2.9</td>
</tr>
<tr>
<td></td>
<td>low prior probability</td>
<td>0.56</td>
<td>0.78</td>
<td>2.9</td>
</tr>
<tr>
<td>Serology for H pylori infection</td>
<td>all patients</td>
<td>0.95</td>
<td>0.95</td>
<td>1.1</td>
</tr>
<tr>
<td>CEA screening for colon cancer</td>
<td>Duke stage A or B</td>
<td>0.36</td>
<td>0.87</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>Duke stage C or D</td>
<td>0.74</td>
<td>0.83</td>
<td>1.8</td>
</tr>
<tr>
<td>Exercise ECG for coronary ischaemia</td>
<td>Men</td>
<td>0.73</td>
<td>0.83</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>0.57</td>
<td>0.86</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>Age &lt;40 years</td>
<td>0.56</td>
<td>0.84</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>Age &gt; 60 years</td>
<td>0.84</td>
<td>0.70</td>
<td>1.9</td>
</tr>
<tr>
<td>Biochemical tests of smoking status</td>
<td>Breath carbon monoxide</td>
<td>0.98</td>
<td>0.92</td>
<td>1.12</td>
</tr>
<tr>
<td></td>
<td>Serum thiocyanate</td>
<td>0.82</td>
<td>0.91</td>
<td>1.37</td>
</tr>
<tr>
<td></td>
<td>Urine nicotine metabolite</td>
<td>0.98</td>
<td>0.94</td>
<td>1.09</td>
</tr>
</tbody>
</table>
breath tests have sensitivities and specificities each of about 95%. So the NND calculation using fractions would be:

\[ \text{NND} = \frac{1}{0.95 - (1 - 0.95)} = \frac{1}{0.95 - 0.05} = \frac{1}{0.9} = 1.1 \]

Using examples from the paper on spectrum bias gives a series of results with NND values up to about 4. Thus using CEA as a diagnostic screening test for colon cancer in patients with the disease would yield a NND of 4.4 in early cancers, but as low as 1.6 in late cancers - a clear case of spectrum bias. Similar differences exist for other examples.

Interesting is the effect of NND calculations on the authors’ own data on urine testing. Because sensitivity goes down but specificity increases in patients with few symptoms of UTI, the NND of 2.9 remains the same whether the clinical suspicion is high or low. Their best result was the overall NND of 1.8, because of a combination of relatively high sensitivity and specificity. Perhaps this emphasises the need to consider sensitivity and specificity combined in a single term.

Choosing which test

There are occasions where different tests can be used to make the same diagnosis. NNDs may help to choose between them when faced with an array of sensitivity and specificity figures.

The table opposite shows three tests of smoking status from a Northern Ireland study [2] measured against self-reporting. They are all good, but urine nicotine metabolite or breath carbon monoxide are much better than serum thiocyanate. Even small improvements are important if considering routine or screening use of such tests.

Implications

1. No implications until verification should be the rule here. Bandolier would welcome comments from statisticians and those performing and using diagnostic tests that these NND calculations are valid.

2. Remember the confidence interval issue. It is not immediately clear just how confidence intervals should be calculated for NND, and even a cursory glance at the calculations show that NNDs would in some circumstances be quite sensitive to small changes in sensitivity or specificity.

3. Interpretation of any test, and its quality, cannot be made without looking at what the consequences of a positive or negative test might be. Where the consequences are significant we need the best tests, but can use tests with higher NNDs where the consequences are minimal.

References:


SCREENING FOR ABDOMINAL AORTIC ANEURYSM

Bandolier has been asked by a GP whether there is enough evidence about the effectiveness of screening for abdominal aortic aneurysm (AAA) for it to be introduced into his practice. To try and answer this we searched MEDLINE from 1993 to the present to see if there were any new reports which helped. There was no single source of information which brought this subject together, but we did find some interesting papers.

RCT for AAA

A recently published English randomised trial in Chichester [1] has tried to examine the incidence of rupture following AAA screening. It was the most useful report and worth examining in some detail.

The setting was 15,775 men and women aged 65-80 years identified from GP registers and FHSA lists. These people were then randomised by computer to control and screening groups. Those randomised to screening were invited for abdominal ultrasonographic scanning by letter from their family practice; one reminder was sent if there was no reply.

Aneurysm was defined as maximum aortic diameter of 3 cm or more. Annual re-scanning took place if the diameter was 3 - 4.4 cm, and at three-monthly intervals if it was 4.5 - 5.9 cm. This protocol was continued until February 1994 or until the patient died, underwent surgery or declined further follow-up. Aortic diameters of 6 cm or more, and increase of diameter of 1 cm or more in a year, or developments of symptoms attributable to the aneurysm all constituted criteria for considering surgery.

Screening and acceptance

The population screened was:

Of those invited for screening, 5394 (68%) accepted. The acceptance rate declined with increasing age in both men and women, but refusal was always higher in women. About 30% of men and 38% of women in their eighth decade refused.

Prevalence of aneurysm

The prevalence of aneurysm in the screened population was higher in men than women, and highest (at about 9%) in men in their eighth decade.

The distribution of aortic diameter was about the same in men and women: about 68% were below 4 cm, 88% below 5 cm and about 8% were 6 cm in diameter or greater.

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened</td>
<td>3205</td>
<td>4682</td>
</tr>
<tr>
<td>Control</td>
<td>3228</td>
<td>4660</td>
</tr>
</tbody>
</table>
Outcome in controls

The 5-year mortality in the control population was 12.5%. Twenty men in the control group presented with aortic rupture, of whom 17 died within one year. Two women had rupture, and died within one year.

Seven patients (five men) had an AAA that was detected clinically and treated routinely by operation; none died within one year of the operation.

Death from ruptured aortic aneurysm according to registrar returns over five years in the same health authority are shown by age and sex in the figure below. They occur predominantly in men and women over 70 years of age.

Outcome in screened population

The 5-year mortality in the screened population was 13.1%. There were four ruptures in people who refused scanning, all of whom died without surgery. In the screened population there were 4 ruptures who died without surgery and 31 people had surgery (3 emergency); 29 survived to one year.

Ruptured aortic aneurysm

The incidence of ruptured aortic aneurysm in men over the follow-up period of five years showed a fall of more than 50% (9 of 3205 in scanned plus refused scan versus 20 of 3228 in control). In women there was no difference (3 of 4682 in scanned plus refused scan versus 2 of 4660 in control).

Comment

This is a commendable study, and there is much more information than can be summarised here. The authors comment that the number of cases of ruptured AAA presenting for surgery fell from 15 cases in 1992/3 to 5 cases in 1994/5. They conclude (rightly) that although their study seems positive, a much larger multi-centre study would be needed to demonstrate unequivocal benefits or cost-effectiveness.

Natural history.

In any screening programme proposal, the natural history of the disorder is a necessary background. The Chichester RCT provides that for controls. A Swedish study [2] followed 88 patients with AAA found on screening and followed prospectively by repeated ultrasonography.
An aneurysm here was defined as aortic diameter of >1.5 cm, though in 19 patients it exceeded 3.9 cm. In a follow-up period of up to five years, 38 of the 88 patients died: no patient died from ruptured AAA. Mortality in patients with AAA was higher than that in a control population.

### Cost effectiveness of screening

Never an easy calculation, especially without good data on effectiveness. A group from Rochester and McMaster [3] did try and perform such an analysis using a computer model to simulate the costs and effectiveness of various screening protocols in men, covering a period of 20 years.

Using a protocol involving abdominal palpation as a “screen” with ultrasound confirmation was estimated to gain 20 life-years in a 10,000 man cohort (60-79 years) at a cost of US$28,700 per life-year. A single ultrasound screen gained 57 life-years at a cost of $41,500 per life-year (1993 estimates).

### Comment

Screening for AAA would seem to fall clearly into the ‘not proven’ category.

### References:


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**SCREENWATCH 2**

### Cholesterol screening - or snails and problem evangelists

The main terminal at Dulles International in Washington DC is a remarkable building with a roof that is curved like the wing of a soaring gull. High in this magnificent building is a very large sign exhorting American males to attend for prostate cancer screening. Are the Americans right or is UK policy correct? In the case of prostate cancer screening Bandolier firmly believes that the Americans are wrong and that there is no evidence to justify prostatic cancer screening. However, it is wise to pause and think a moment about right and wrong when interpreting evidence, and recent articles on cholesterol screening in the United States clearly demonstrate how attitudes influence the interpretation of the same body of evidence.

### ACP Guidelines

The American College of Physicians has come out with a new set of guidelines [1], and although these are complex and not as clear as they could be, they do not recommend whole population screening for primary prevention. The guidelines, which are based on good quality research which clearly emphasises the lack of evidence about screening for primary prevention, led to a fascinating Editorial by the former Editor of Annals, Frank Davidoff [2].

This Editorial reminds us of one of the central articles on screening, that by Sackett and Holland, which emphasises the need to think of people who discussed screening as either snails or evangelists, with the snails interpreting the evidence to indicate no progress and the evangelists preaching progress on the same evidence [3].

An article in the same edition of Annals gives the evangelical author the opportunity to disagree completely with the American College of Physicians’ policy; the author argues that cholesterol lowering agents are under-used in the US, whereas most people in this country would be of the opinion that they were over-used.

### Snails & evangelists

Differences of opinion within America are similar to the differences of opinion between the United States and the UK. In general we are snails and they are evangelists.

America is the “can-do” society where disease is to be tackled, fought and overcome and where the mere existence of technology is often sufficient justification for its use. It is easy to equate this approach with commercialism but there is a strong idealistic streak that drives the pioneering spirit that still exists in America.

Bandolier still believes firmly that there is no place for whole population screening for cholesterol and none of its Editors know their cholesterol levels. We are snails and proud of it. We also believe that we are right to keep total population cholesterol screening and screening for prostate cancer on our screening blacklist.

### References:

NETWATCH

The technophiles among Bandolier readers will have noticed for some time that Bandolier has an address on the Internet. There is quite a lot there - full texts of all articles of all the first 26 editions of Bandolier together with longer articles on Helicobacter pylori, latex allergy and notes on the first Bandolier conference.

There is now also a list of Bandolier’s medical links (for which many thanks to Andrew Booth at SCHAAR) - pages where more information can be garnered.

Some of these are terrific. Barry Marshall’s Helicobacter Foundation has up-to-the minute information on Helicobacter pylori diagnosis and treatment, the Journal Club on the Web keeps thoughtful reader on their toes, and JAMA allow surfers to search through recent issues of about 10 journals - mostly with abstracts.

The NHS R&D programme has also put up many pages of pertinent information. One of the best is the Development and Evaluation Committee report series edited by Andrew Stevens, and maintained in the S&W.

Counsellors in primary care

This article by Glenn Roberts opens up new horizons with a useful broad brush overview in an area with only one RCT.

To pick out some points from the article:-

- 31% of practices were using counsellors in 1993.
- The task of counsellors is to “give the client an opportunity to explore, discover and clarify ways of living more resourcefully and towards greater well-being”.
- Counsellors most often work with people with depression, anxiety or panic attacks, with other mental health problems, or with relationship problems. There is scope for them to work with other people with diseases like diabetes, asthma and coronary heart disease.
- It has been suggested that a minimum of 30 hours of counselling per week per 10,000 population would realise cost savings - though it is unlikely that a single counsellor would meet a full range of needs.
- There is evidence of benefit from counselling, but perhaps the key sentence is that the “presence of a counsellor seems to be greatly appreciated by patients and their doctors”, mirroring some thoughts in the earlier editorial (page 1). There is some evidence that inadequate counselling can be a problem.
- Decreased surgery attendance, use of psychotropic drugs and reductions in referrals may result in savings to practices.

This report doesn’t have all the answers. For any practice considering the use of counsellors, or wishing to ensure the maximum benefit from their use, this report is a good place to start.

Web address - through Bandolier links, or at:

http://wwwbris.ac.uk/rd/publicat/dec/index.htm

CATARACTS

Effective Health Care Bulletins from the Centre for Reviews and Dissemination have been featured in Bandolier before. Several have been published this year, on prevention and treatment of pressure sores, on benign prostatic hyperplasia, on management of cataracts and (imminently) on performing systematic reviews. These are all terrific reviews which should be immediately available to most of us.

Cataract NNT

The bulletin on management of cataracts has clear messages for primary and secondary health care and for patients. It tells us these things:-

- Cataract surgery is highly effective - with improved levels of visual acuity in some 95% of patients. Since experience is that cataracts don’t get better without treatment, this equates to a NNT of about 1.05 - a very effective treatment.
- Cataract surgery is cost effective - but perhaps 20% of patients need laser treatment within two years of surgery for opacification of the posterior capsule.
- Other adverse events are rare.
- Day case surgery is as effective as inpatient surgery, is about 30% cheaper and acceptable to patients. Around 80% of cataract operations could be done as day cases - four times as many as now.

Effective Health Care bulletins published in 1996 include:-

Prevention and treatment of pressure sores
Benign prostatic hyperplasia
Management of cataract

They are available from Subscriptions Department, Pearson Professional, PO Box 77 Fourth Avenue, Harlow CM19 5BQ. Tel 01279 623924; Fax 01279 639609.

GI COMPLICATIONS AND NSAIDs

Bandolier 25 described a randomised controlled trial (RCT) involving nearly 9,000 patient with rheumatoid arthritis taking NSAIDs for at least a six month period [1]. The study examined GI complications associated with NSAIDs collected in a RCT. Half the patients were randomised to co-administration of misoprostol, which significantly reduced the incidence of serious and probable GI complications by 44%.

Number-needed-to-treat

These data translated into a NNT of 83 - that is, overall 83 patients had to be treated for one year with misoprostol rather than placebo to prevent one GI complication. The NNT figure used here is annualised. Though the study was of six months duration presenting the result in this standard fashion is justified because GI events occurred consistently throughout the six months, as has been shown in long-term studies [2].
Risk factors

Certain groups of people are more likely to develop GI complications while on NSAIDs. The size of the RCT enabled some of these “at risk” groups to be defined. Analysis showed that an age of 75 years or more, history of peptic ulcer, history of GI bleeding and history of cardiovascular disease were all significant indicators of increased risk. As examples, patients with GI bleeding had an odds ratio of 2.5 (95% CI 1.5 - 4.1) and with CVD 1.8 (1.1 - 3.2).

With any one risk factor the risk of a GI event was 2% in one year. Combinations of these risk factors were additive: with combinations of three of the factors the one-year risk increased to about 9% and with all four it was 18%.

Risk factors and NNT

Misoprostol reduced the risk significantly within each of these groups, but, as Bandolier 25 pointed out, the information in the paper did not allow calculations of NNTs for high risk groups. The NNTs are now available for individual risk factors, and are shown in the Table. NNTs for the prophylactic action of misoprostol against GI complications (all events 1-11 in the original paper) with NSAIDs can be as low as 7 for patients over 75 years with prior GI bleed. NNT values below 20 were obtained for younger patients who had prior history of peptic ulcer disease or GI bleed. NNTs for other classifications (1-8) are to be found in a BMJ letter [3].

Clinical implications

As the earlier Bandolier article suggested, and as this now shows, patients taking NSAIDs at high risk of GI complications can be identified, and low NNT ascribed to misoprostol treatment. This is useful as one step in determining whether there is a bias towards prophylaxis. Groups where prophylactic misoprostol should be considered for preventing NSAID-associated GI complications are:-

- Increasing age (especially over 75 years)
- Cardiovascular disease
- Peptic ulcer history
- GI bleed history

References:

Evidence-based drinking

The new DoH suggested limits on healthy drinking can pose a challenge. Bandolier tries hard, but just can’t get its alcohol consumption up to them - still, practice makes perfect!

It is, however, possible to try and work out the NNT for beneficial effects of alcohol consumption. A Danish study in the BMJ [1] examined the relationships between alcohol consumption and high and low density lipoprotein at the start of observations, with ischaemic heart disease incidence over the following six years as the outcome measure. The study population was 2,826 men aged 53-74 years.

There are many interesting results, especially the high protective effect of alcohol in men with high LDL cholesterol drinking more than 22 drinks a week.

The most important result was the overall conclusion that drinking alcohol prevents ischaemic heart disease. In these men, whatever number of alcoholic drinks they consumed each week, or the serum levels of lipoprotein cholesterol, the NNT to prevent one ischaemic heart disease event over six years was 24 (95% CI 13 - 169).

Reference:
Since the 1970s studies have shown malnutrition to be commonplace among patients in hospital, yet it is often unrecognised and worsens during hospital stay [1]. This delays recovery, increases the incidence of serious complications and significantly increases treatment costs [2]. It is therefore commendable that nutritional screening tools have been developed to detect those who are malnourished or at risk of malnutrition.

These tools vary in quality from those published in full in peer-reviewed journals to those which appear to be little more than promotional material.

**Some assessment tools reviewed**

*Scanlan et al* [3] discuss the development of a tool and action plan by three British nurses. Assessment criteria avoided anthropometric and biochemical data not often available to nurses. While it uses criteria largely accepted as nutritional risk factors, scoring seems to be arbitrary.

The tool has not yet been subjected to reliability or validity testing; an as yet unpublished study has shown that a non-validated nutritional scoring system may fail to detect almost 50% of patients at risk of malnutrition.

*Reilly et al* [4] developed a simple Nutritional Risk Score (NRS). A team of dieticians applied the tool to 20 patients - each assessed by two dieticians. The performance of the new tool was validated by comparing NRS with dieticians’ clinical impressions and with another published risk score. Not the clearest gold standards for validity but at least there was good inter-observer reliability.

Twelve dieticians then applied the tool to 153 patients within five days of admission to hospital. Though there was a reported high correlation between dietician and nurse, only 19 patients (12%) were assessed by a nurse and only three nurses took part. A claim that this tool has been validated for use by nurses looks a little premature.

**BAPEN**

A British Association for Parenteral and Enteral Nutrition (BAPEN) working party has published recommendations for the nutritional screening of every patient admitted to hospital [5]. This tool has been developed from consensus opinion from acknowledged experts. It has yet to be subjected to validity testing. It does have the benefit (see box) of being simple - a great strength.

**Evidence-based nutritional screening**

Nurses wishing to use a nutritional screening tool must ensure that the tool is based on evidence rather than rhetoric. If nurses are to spend valuable time applying a nutritional risk tool then the demonstration of improved patient outcome is a must.

Hazel Rolling
Nutrition Nurse Specialist, Luton & Dunstable Hospital